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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	03/28/2017	9607722	56782.1.7.2	3733

22859 7590 03/08/2017

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 486 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Stephen E. Hidem, Plymouth, MN;
Aaron M. Fontaine, Fridley, MN;
Janet L. Gelbach, New Albany, IN;
Patrick M. McDonald, Omaha, NE;
Kathryn M. Hunter, Knoxville, TN;
Rolf E. Swenson, Princeton, NJ;
Julius P. Zodda, Mercerville, NJ;

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22859 7590 11/23/2016
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INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

TITLE OF INVENTION: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$960	~~$960~~ $0	02/23/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
DORNA, CARRIE R	3735	600-004000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Fredrikson & Byron, P.A.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

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(A) NAME OF ASSIGNEE: Bracco Diagnostics Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Monroe Township, New Jersey

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 06-1910 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Paul J. LaVanway, Jr./ Date February 23, 2017

Typed or printed name Paul J. LaVanway, Jr. Registration No. 64,610

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Acknowledgement Receipt

EFS ID:	28439942
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	23-FEB-2017
Filing Date:	16-JUN-2010
Time Stamp:	17:27:38
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Post Allowance Communication - Incoming	56782-1-7-2-Issue-Fee-LTR.pdf	96582 a1c948ac2e91e7c2dc297bd3a7ac5d30dfcbc87d	no	2

Warnings:

Information:					
2	Issue Fee Payment (PTO-85B)	56782-1-7-2-Issue-Fee-Transmittal.pdf	1668059 3081b9f2e90744e473d2acb9ebdc445d5133d4fd	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	1764641	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 20010	Examiner:	Carrie R Dorna
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ISSUE FEE PAYMENT TRANSMITTAL

Dear Commissioner:

In response to the Notice of Allowance mailed November 23, 2016 for the above-referenced patent application, Applicant is hereby submitting the Fee Transmittal form to proceed with grant of the patent application. Applicant previously paid the Issue Fee payment due for the application on July 20, 2016 when responding to an earlier-issued Notice of Allowance. Applicant subsequently petitioned to have the application withdrawn from issuance to have additional art considered and made of record. Since the issue fee payment has already been made for the application, Applicant understands that no further issue fee payment is due. However, Commissioner is authorized to charge any deficiencies that may be due for the application to Deposit Account No. 06-1910.

The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: February 23, 20107

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

60833905_1.doc

IEW

PART B - FEE(S) TRANSMITTAL

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

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nonprovisional	UNDISCOUNTED	$960	$0	$960	~~$960~~ $0	02/23/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
DORNA, CARRIE R	3735	600-004000

02/24/2017 CCHAU2 00000022 12808467
01 FC:1501 960.00 OP

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☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
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(A) NAME OF ASSIGNEE: Bracco Diagnostics Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Monroe Township, New Jersey

Adjustment date: 02/24/2017 CCHAU2
07/21/2016 INTEFSW 00005410 12808467
01 FC:1501 -960.00 OP

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
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Authorized Signature /Paul J. LaVanway, Jr./ Date February 23, 2017
Typed or printed name Paul J. LaVanway, Jr. Registration No. 64,610

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 11/23/2016

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 11/23/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

TITLE OF INVENTION: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$960	$960	02/23/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
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EXAMINER	ART UNIT	CLASS-SUBCLASS
DORNA, CARRIE R	3735	600-004000

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Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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22859 7590 11/23/2016

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MINNEAPOLIS, MN 55402

EXAMINER	
DORNA, CARRIE R	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 11/23/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner CARRIE R. DORNA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2 August 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-5, 37-48, and 51-55*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/CARRIE R DORNA/ Examiner, Art Unit 3735	/Charles A. Marmor, II/ Supervisory Patent Examiner, Art Unit 3735

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2 August 2016 has been entered.

Allowable Subject Matter

3. **Claims 1-5, 37-48, and 51-55** are allowed for the reasons noted in the previous Office action.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARRIE R. DORNA whose telephone number is (571)270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. R. D./
Examiner, Art Unit 3735

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R Dorna
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3576998	A	1971-05-04	Deutsch et al.	
	2	5166526	A	1992-11-24	Dietzel	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060164093	A1	2006-07-27	Ooe et al.	
	2	20070226175	A1	2007-09-27	Resnic et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	317114	EP	A1	1989-05-24	OROS SYSTEMS LTD		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.R.D/ 11/17/2016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R Dorna
Attorney Docket Number	56782.1.7.2

	2	2004080523	WO	A2	2004-09-23	HAMMERSMITH IMANET LTD		

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/CARRIE R DORNA/	Date Considered	11/17/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R Dorna
Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2016-08-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.R.D/

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.R.D/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	CARRIE R. DORNA	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N5/1002, 1007	8/5/14	EF
A61N 2005/1021	8/5/14	EF
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028	9/2015	CD
A61N 2005/1021	9/2015	CD
A61M 5/007	9/2015	CD
G21G 4/08	9/2015	CD
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028 updated	4/2016	CD
A61N 2005/1021 updated	4/2016	CD
A61M 5/007 updated	4/2016	CD
G21G 4/08 updated	4/2016	CD
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028 updated	11/2016	CD
A61N 2005/1021 updated	11/2016	CD
A61M 5/007 updated	11/2016	CD
G21G 4/08 updated	11/2016	CD

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES

Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF
Updated class/subclass searches and text searching in EAST for AFCP 2.0 submission	8/5/14	EF
Updated class/subclass searches	11/17/14	EF
Updated class/subclass searches	4/16/15	EH
see EAST search report	9/2015	CD
EAST: inventor name search, assignee search	9/2015	CD
see updated EAST search report	4/2016	CD
see updated EAST search report	11/2016	CD

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
	see EAST search report	9/2015	CD
	see updated EAST search report	4/2016	CD
	see updated EAST search report	11/2016	CD

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	3597	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/11/17 14:21
L3	207	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/11/17 14:29
L4	2539	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/11/17 14:30
L5	444	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/11/17 14:35
L6	23	(2 or 3 or 4 or 5) ((display$4 with tim$3) or (tim$3 with count$3) or (tim$3 with elaps$3)) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/11/17 14:43
S2	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/08/14 10:57
S3	3	(("20070213848") or ("20080237502") or ("20070260213")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/08/14 11:17
S4	2	(time with elaps$3 with elut$4) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:51
S5	107	(time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT;	AND	ON	2015/08/14 12:52

			USOCR; EPO; JPO; DERWENT			
S6	0	(display$4 with time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S7	3	(display$4 same (time with elaps$3)) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S8	2	(display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:16
S9	2	S4 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S10	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/08/14 13:21
S11	1	S10 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S12	275	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:01
S13	191	(bracco near2 diagnostics).as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:03
S14	2	("3543752" | "3861380").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S15	4	("3535085" | "4160910" | "4759345" | "6639237").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S16	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT;	AND	ON	2015/09/28 13:21

			USOCR; EPO; JPO; DERWENT			
S17	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 15:51
S18	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 16:45
S19	1899	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 17:04
S20	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:22
S21	0	(S17 or S18 or S19 or S20) (display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:55
S22	31	(S17 or S18 or S19 or S20) (display$4 same tim$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:56
S23	7	(("20070140958") or ("7966068") or ("20060015056") or ("4585941") or ("20050187515") or ("5395320") or ("20030139640")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:33
S24	1	("7996068").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:59
S25	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S26	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S27	1899	A61M5/007.cpc.	US-	AND	ON	2015/09/28

			PGPUB; USPAT; USOCR; EPO; JPO; DERWENT			21:25
S28	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S29	32	(S25 or S26 or S27 or S28) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S30	33	("4202345").PN. OR ("4562829").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/09/28 21:26
S31	1	((display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:32
S33	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:03
S34	160	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:07
S35	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:08
S36	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:14
S37	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S38	160	A61N2005/1021.cpc.	US-PGPUB; USPAT;	AND	ON	2016/04/11 11:35

			USOCR; EPO; JPO; DERWENT			
S39	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S40	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S41	38	(S37 or S38 or S39 or S40) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S42	20	(S37 or S38 or S39 or S40) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:51
S43	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S44	160	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S45	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S46	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S47	21	(S43 or S44 or S45 or S46) ((display$4 with tim$3) or (tim$3 with count$3) or (tim$3 with elaps$3)) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S48	135	("20020129471" | "20030004463" | "20030139640" | "20040054319" |	US-PGPUB;	AND	ON	2016/04/11 13:26

		"20040104160" | "20040260143" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20060173419" | "20070080223" | "20070140958" | "20070213848" | "20070232980" | "20070260213" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080191148" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20100030009" | "20100312039" | "20110071392" | "20110172524" | "20110178359" | "20110209764" | "20120098671" | "20120305730" | "20120310031" | "20120312980" | "20130300109" | "20140084187" | "20140175959" | "3483867" | "3535085" | "3543752" | "3565376" | "3710118" | "3714429" | "3774036" | "3847138" | "3861380" | "3991960" | "3997784" | "4096859" | "4160910" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4674403" | "4679142" | "4755679" | "4759345" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" | "6220554" | "6267717" | "6347711" | "6442418" | "6450936" | "6454460" | "6558125" | "6626862" | "6639237" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" | "7608831").PN. OR ("7612999" | "7712491" | "7734331" | "7737415" | "7780352" | "7813841" | "7825372" | "7862534" | "7996068" | "8058632" | "8071959" | "8198599" | "8216181" | "8216184" | "8295916" | "8317674" | "8431909" | "8439815" | "8442803" | "8708352").PN. OR ("9299467").URPN.	USPAT; USOCR			
S57	4	("20060164093" | "20070226175" | "3576998" | "5166526").PN.	US-PGPUB; USPAT	OR	OFF	2016/11/16 15:14
S58	4	S57 and tim$3	US-PGPUB; USPAT	OR	OFF	2016/11/16 15:17

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L7	3	((((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or	US-PGPUB; USPAT	AND	ON	2016/11/17 15:03

		computer) break$1through tim$3).clm.				
S32	0	((display$4 with tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT	AND	ON	2015/09/28 21:32
S49	0	((display$4 with tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 breatk$1through).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:03
S54	5	(((((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:04
S55	3	(((((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through tim$3).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:05
S56	131	("20020129471" | "20030004463" | "20030139640" | "20040054319" | "20040104160" | "20040260143" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20060173419" | "20070080223" | "20070140958" | "20070213848" | "20070232980" | "20070260213" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080191148" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20100030009" | "20100312039" | "20110071392" | "20110172524" | "20110178359" | "20110209764" | "20120098671" | "20120305730" | "20120310031" | "20120312980" | "20130300109" | "20140084187" | "20140175959" | "3483867" | "3535085" | "3543752" | "3565376" | "3710118" | "3714429" | "3774036" | "3847138" | "3861380" | "3991960" | "3997784" | "4096859" | "4160910" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4674403" | "4679142" | "4755679" | "4759345" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" | "6220554" | "6267717" | "6347711" | "6442418" | "6450936" | "6454460" | "6558125" | "6626862" | "6639237" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" |	US-PGPUB; USPAT	AND	ON	2016/04/11 13:05

		"7608831").PN. OR ("7612999" | "7712491" | "7734331" | "7737415" | "7780352" | "7813841" | "7825372" | "7862534" | "7996068" | "8058632" | "8071959" | "8198599" | "8216181" | "8216184" | "8295916" | "8317674" | "8431909" | "8439815" | "8442803" | "8708352").PN. OR ("9299468").URPN.				

11/ 17/ 2016 3:11:03 PM
C:\ Users\ cdorna\ Documents\ EAST\ Workspaces\ 12808467.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

CPC							
Symbol						**Type**	**Version**
A61M		5	/	16881		F	2013-01-01
A61N		5	/	1001		I	2013-01-01
A61N		2005	/	1021		A	2013-01-01
A61B		90	/	39		I	2016-02-01
A61M		5	/	14		I	2013-01-01
G21F		7	/	00		I	2013-01-01
G21G		1	/	0005		I	2013-01-01
A61B		6	/	507		I	2013-01-01
A61B		6	/	107		I	2013-01-01
A61B		6	/	481		I	2013-01-01
A61M		5	/	007		I	2013-01-01
A61M		5	/	142		I	2013-01-01
G21F		3	/	00		I	2013-01-01
A61K		51	/	00		I	2013-01-01
G21G		4	/	08		I	2013-01-01
A61B		6	/	037		I	2013-01-01
A61B		2090	/	392		A	2016-02-01
A61M		5	/	16854		I	2013-01-01
A61N		5	/	1075		I	2013-01-01
A61N		2005	/	1074		A	2013-01-01
A61N		2005	/	1094		A	2013-01-01
A61M		2005	/	1403		A	2013-01-01
A61M		2205	/	505		A	2013-01-01
A61M		2209	/	084		A	2013-01-01
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A61N		2005	/	1022		A	2013-01-01
G21G		1	/	001		I	2013-01-01
G21G		2001	/	0031		A	2013-01-01

CPC Combination Sets

/CARRIE R DORNA/ Examiner.Art Unit 3735	11/17/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

Symbol	Type	Set	Ranking	Version

/CARRIE R DORNA/ Examiner.Art Unit 3735	11/17/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		G	2	1	G	4 / 08 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/CARRIE R DORNA/ Examiner.Art Unit 3735	11/17/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/17/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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-	14	-	30	16	46										
-	15	-	31	17	47										
-	16	-	32	5	48										

/CARRIE R DORNA/ Examiner.Art Unit 3735 (Assistant Examiner)	11/17/2016 (Date)	**Total Claims Allowed:** 22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735 (Primary Examiner)	11/17/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1A

UNITED STATES PATENT AND TRADEMARK OFFICE

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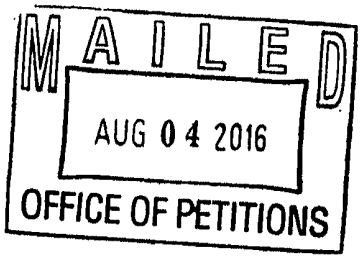
MINNEAPOLIS MN 55402



In re Application of	:	
Stephen E. Hidem, et al.	:	
Application No. 12/808,467	:	DECISION GRANTING PETITION
Filed: June 16, 2010	:	UNDER 37 CFR 1.313(c)(2)
Attorney Docket No. 56782.1.7.2	:	

This is a decision on the petition under 37 CFR 1.313(c)(2), filed, August 2, 2016 to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED**.

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). *See* 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid on July 20, 2016 cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.[1]

Telephone inquiries should be directed to Terri Johnson at (571) 272-2991.

This application is being referred to Technology Center AU 3735 for processing of the request for continued examination under 37 CFR 1.114 and for consideration of the concurrently filed information disclosure statement.

/Terri Johnson/
Terri Johnson
Paralegal Specialist
Office of Petitions

[1] *The request to apply the issue fee to the new Notice may be satisfied by completing and returning the new Part B – Fee(s) Transmittal Form (along with any balance due at the time of submission). Petitioner is advised that the Issue Fee Transmittal Form must be completed and timely submitted to avoid abandonment of the application.*

22859
Customer Number

Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Carrie R. Dorna
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

PETITION UNDER 37 CFR 1.313(c) FOR WITHDRAWAL FROM ISSUE

Mail Stop PETITIONS
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Applicant hereby petitions for withdrawal of the above-identified patent application from issue. The issue fee for this case was paid July 20, 2016.

Applicant requests that the application be withdrawn from issue in accordance with the provisions of 37 C.F.R. § 1.313(c) to enable the United States Patent and Trademark Office to consider a Request for Continued Examination (filed concurrently). The Request for Continued Examination is accompanied by an Information Disclosure Statement listing references not previously considered by the Examiner. The Information Disclosure Statement constitutes a sufficient submission.

This petition is accompanied by the $140.00 petition fee required under 37 CFR 1.17(h). The Commissioner is further authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910.

Dated: August 2, 2016

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.
59333636_1.DOC

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/808,467	Filing Date	2010-06-16	Docket Number (if applicable)	56782.1.7.2	Art Unit	3735
First Named Inventor	Stephen E. Hidem			Examiner Name	Carrie R. Dorna		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 061910

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2016-08-02
Name	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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(54) Automatic chromatography apparatus.

(57) Automatic chromatography apparatus comprises a column packed with adsorbent or attractant material;
means for supplying an elutant solution to the column;
loading means for loading controlled quantities of a material into the column, the material containing a substance to be eluted;
automatic control means which control the loading means so as to load the column with a first charge of the material and subsequently to load the column with a second charge of the material, the first charge being sufficiently small to ensure that the capacity of the column is not exceeded and the second charge being sufficiently large to ensure that the capacity of the column is exceeded;
first monitoring means for monitoring and controlling flow rate to provide accurate flow information to enable peak area integration;
second monitoring means which monitor the peaks of elution of the substance from the column resulting from the first and second charges of material;
processing means connected to the monitoring means and arranged to integrate the elution peak with respect to the first charge of material so as to derive the concentration of the substance in the material, and to determine from the peak of elution of the substance from the column resulting from the second charge of material the maximum practical capacity of the column for the said substance; and, optionally,
means for providing a controlled change in time in a chemical parameter of the elutant supplied to the column under control of the control means thereby enabling the processing means to determine from elution peaks monitored by the monitoring means the optimum value for said parameter for elution of the said substance and whether or not other similar substances are being eluted from the column.

EP 0 317 114 A1

AUTOMATIC CHROMATOGRAPHY APPARATUS

This invention relates to an automated system for chromatography, particularly adsorption chromatography, and in particular adsorption chromatography of monoclonal antibodies.

In the preparation of microbiological and cell culture derived products such as monoclonal antibodies or fragments thereof, the main problem is the separation of the required material from raw materials and by-products and also from the preparation medium. It is frequently the case that the concentration of the required product in the preparation medium is in fact very low, so that the product has to be won from large volumes of culture liquor.

A convenient method for capturing and isolating materials such as monoclonal antibodies and fragments thereof comprises chromatography, particularly affinity chromatography, in which the medium is contacted with an adsorbent or otherwise attractant material in a column so that the required product is bound, and the column is subsequently eluted with a suitable medium to cause the product to become selectively unbound.

Practical problems arise in running column chromatography of this type, especially on a preparative, as opposed to an investigative, scale. Often, the affinity of the product for the column packing is unknown, especially if the product is new. Secondly, the concentration of the desired product in the medium may not be known with any degree of accuracy, and thirdly the degree of purity of the medium may not be known. For example, the preparation of a monoclonal antibody supply may be contaminated with rogue polyclonal products. There is thus always a considerable degree of investigation and calibration to be done before routine chromatography can be carried out. Such investigative work can be time consuming and troublesome and can also lead to wastage of highly valuable product. There is thus a need for an automated system which solves these problems.

This invention provides a novel application of expert software control to a chromatography system and also to particular combinations of apparatus of use in this process.

According to a first aspect of the present invention there is provided automatic chromatography apparatus comprising:

a column packed with adsorbent or attractant material;

means for supplying an elutant solution to the column;

loading means for loading controlled quantities of a material into the column, the material containing a substance to be eluted;

automatic control means which control the loading means so as to load the column with a first charge of the material and subsequently to load the column with a second charge of the material, the first charge being sufficiently small to ensure that the capacity of the column is not exceeded and the second charge being sufficiently large to ensure that the capacity of the column is exceeded;

first monitoring means for monitoring and controlling flow rate to provide accurate flow information to enable peak area integration;

second monitoring means which monitor the peaks of elution of the substance from the column resulting from the first and second charges of material;

processing means connected to the monitoring means and arranged to integrate the elution peak with respect to the first charge of material so as to derive the concentration of the substance in the material, and to determine from the peak of elution of the substance from the column resulting from the second charge of material the maximum practical capacity of the column for the said substance; and, optionally,

means for providing a controlled change in time in a chemical parameter of the elutant supplied to the column under control of the control means thereby enabling the processing means to determine from elution peaks monitored by the monitoring means the optimum value for said parameter for elution of the said substance and whether or not other similar substances are being eluted from the column. The parameter can be, for example, the pH, the ionic strength or the chemical composition, e.g. the presence of a certain quantity of a chaotropic agent such as urea, guanidine etc.

According to a second aspect of the present invention there is provided a method of automatic chromatography characterisation comprising the steps of: automatically;

loading onto a column packed with adsorbent or attractant material a relatively small sample containing a substance to be eluted, the relatively small sample being sufficiently small so as to ensure that the adsorption capacity of the column is not exceeded;

eluting the substance from the column to obtain an elution peak;

integrating the elution peak with respect to the relatively small sample so as to derive the concentration of the substance in the sample;

loading the column with a relatively large sample containing the substance, the relatively large sample being sufficiently large to ensure that the ca-

pacity of the column is exceeded;
calculating the maximum practical capacity of the column; and, optionally
providing a controlled change in time in a chemical parameter of the elutant supplied to the column to determine the optimum value at which the substance can be eluted.

The apparatus and method are suitable for chromatographic separation generally, but are particularly suitable for affinity chromatography especially immunological affinity chromatography needed for the separation of monoclonal antibodies. Thus, the column packing can be any suitable adsorbent or otherwise attractant material, but for immunological purposes a substance which can bind to an antibody or a fraction thereof by means of specific affinity is most suitable. A particularly desirable material comprises an inert packing to which is bound an immunological material such as protein A.

The packing generally comprises a rigid or semi-rigid inert support material, either porous or nonporous, of which many are known and produced commercially, for example Sepharose and other agarose-based materials, silica and derivatives and other synthetic organic polymers and copolymers. Preferably, a 60 micron porous bead (pore size 3500nm) composed of hydroxyethylmethacrylate to which protein A (obtained either naturally or by means of genetic manipulation) is convalently attached using a chemical means of which many are known but preferably by means of divinylsulphone. The amount of protein A may be attached to the support material is, in practice, limited only by the chemical means of attachment, but preferably 2.5 to 3.5 mg of protein A is attached per ml of support material.

One of the problems of continuous chromatography of this type is that after a while the column becomes overloaded with impurities and by-products so that the capacity for the required product and the sharpness of the elution peak for that product gradually decrease. Under such circumstances, it is usually necessary for some kind of cleaning cycle to be operated before the column can be operated at its optimum efficiency. It is therefore desirable that the apparatus should be provided with means for determining when such an operation becomes necessary.

According to a further aspect of the present invention there is provided apparatus for controlling the efficiency of operation of a chromatography column, comprising:
monitoring means which monitor the shape and magnitude of the elution peak of the substance on the column;
memory means for storing at least one reference and details of one or more corrective actions which may counteract deterioration of the said efficiency of operation;
comparator means which compare output from the monitoring means with the said reference;
processing means which apply output from the comparator means to select a stored corrective action; and
control means which automatically execute the selected corrective action.

According to a still further aspect of the present invention, there is provided a method of controlling the efficiency of operation of a chromatography column, comprising the steps of:
monitoring the continuing performance of the column by automatic elution peak analysis, said peak analysis including the comparison of peak shape and magnitude with at least one prestored reference, the analysis further including identifying from a plurality of prestored options the most probable corrective action to counteract deterioration of the said efficiency of operation; and
automatic execution of the identified corrective action.

The system may select corrective actions from a choice of several but also may try choices in a sequence, moving from one to another as the benefit of the first is exhausted.

Preferably, peak shape analysis comprises determining the degree of asymmetry of the peak.

Beneficially, two references are prestored, one of the references being varied in accordance with the efficiency of the column itself and the other of the references representing the minimum acceptable efficiency of the column.

A more detailed description of the apparatus and its use follows.

A typical characterisation sequence for use with a monoclonal antibody on a protein A column is as follows:-

The objective of the characterisation cycle is to obtain certain parameters for an unknown antibody which enable the instrument to set itself up automatically to purify the antibody with maximum efficiency.

The parameters obtained are as follows:-

1. The capacity of the column for the antibody.

2. The concentration of antibody in the crude feedstock.

3. The pH at which the antibody can be eluted from the column.

4. The number of resolvable peaks in the chromatogram.

These parameters are stored by the software to be used subsequently to control the operation of the purification runs. They are needed for the following reasons:-

1. In order to load an amount of antibody onto the column which is as high as possible without losing part of that antibody in the unbound protein fraction, it is necessary to know the capacity of the column for that particular antibody. This capacity will be different for different antibodies and so the capacity must be established for each new antibody of interest.

2. Once the capacity is known, the volume of feedstock to load for each purification cycle can only be calculated from the concentration of antibody in the feedstock. This is often not known accurately beforehand.

3. Antibody is eluted from the column by lowering the pH of the solution passing through the column. Different antibodies will be eluted at different pH values. Whilst it would be possible to elute all antibodies at, say, pH 3.0, many antibodies are not stable at low pH and so it is important to elute at as high a pH as possible. This must be determined experimentally for each antibody of interest.

4. A clonal hybridoma culture should only produce a single monoclonal antibody. However sometimes by accident cell cultures are used to produce antibody that are di-, tri- or polyclonal and so more than one antibody may be found in the culture fluid. Furthermore, cells may be grown in animal serum that contains antibody from another species. or in mouse ascites which contains normal polyclonal mouse antibodies. In each of these cases it is possible that on elution of the antibody from protein A, more than one peak of antibody may be obtained. By running a pH gradient during the characterisation sequence the instrument may detect these additional components and prompt the operator to analyse each component and tell the computer which of the peaks is of interest and should be collected during the purification runs. Where the characterisation experiment gradient only achieves partial resolution of peaks, a second, shallower gradient may be run on a repeat cycle to attempt a better resolution.

These parameters may be obtained automatically by the instrument as follows:-

When a new antibody is presented to the machine, the operator causes it to perform the characterisation sequence by making an entry at the keyboard.

The machine is also told the source of the antibody (e.g. ascites, cell culture or concentrated cell culture) and the operator's estimate of the antibody concentration, if possible. From this information the software calculates approximately how much feedstock to load in order to achieve 5-15% saturation of the column. Under this condition all of the applied antibody will be retained by the column and, on elution, the peak integral may be used to calculate accurately the total antibody concentration. The elution in this automatic experiment is done at pH 3 to obtain a single eluted peak.

Next the instrument loads the column with an amount of antibody equivalent to more than an estimate of the saturation amount. The estimate is made on the basis of experience of typical saturation values for different types of antibody which have been previously determined by experiment and stored in the computer. During the loading of this material, the unbound protein stream is returned to the feedstock vessel to avoid loss of antibody in the waste stream. The volume returned in this way is recorded. Alternatively this stream may be collected in a separate vessel. The bound antibody is then eluted from the column, this time using a linear pH gradient from 8.8 down to 2.0. The integral values of the total number of peaks of eluted antibody obtained is used to determine the saturation capacity of the column. In cases where more than one peak is obtained, the operator is prompted to decide which of the peaks is/are collected. This peak is then used to determine the saturation capacity. Where the unbound protein stream was returned to the feedstock vessel, the total antibody eluted from the column is used to perform a calculation to take account of the now diluted feedstock and a revised concentration for the remaining antibody is obtained.

The chromatogram obtained is used by the software to determine the appropriate pH for elution. This is done by relating the protein concentration measurements to the pH measurements and selecting a pH which is equivalent to the point at, say, 75% of the peak width.

The characterisation sequence described above derives the antibody concentration and column capacity for each new antibody.

These values can be in error to an extent where the performance of the instrument would be compromised and so a rourine is performed during each separation which checks the actual yield (peak integral) against expected values obtained during characterization and takes appropriate action if significant deviations are detected. This routine can also spot the onset ot column fouling by detecting the reduction in yield that often accompanies fouling.

The flow sheet in Fig. 1 illustrates this rather complex routine and the variables have the following meaning:-

R35 = peak integral from last cycle

R24 = expected peak integral from characterisation cycle

C = cycle number

R27 = conversion factor to generate mass from peak integral

R5 = volume of feed to load
R42 = corrected feed concentration
R8 = column capacity

First Cycle (C = 1)

The peak integral obtained is compared with 70% and 90% of the expected peak integral. A value below 70% indicates that the original concentration estimate was too high and so on the basis that all of the antibody on this cycle was captured and eluted, the actual concentration may be estimated from this eluted mass divided by the volume of feed that was applied. Since too high a concentration estimate would have lead to the determination of a capacity that was possibly too low, the instrument then performs the characterisation cycle again using the revised concentration estimate.

A value for the peak integral above 90% of expectation indicates that the concentration was probably underestimated at the start and so the load volume for the next cycle is set to 10% of the previous value. On subsequent cycles the load volume will be increased until the obtained peak integral falls in the 70-90% range.

Second Cycle (C = 2)

The range comparison is made again this time from the second cycle peak integral. Integrals falling within the range are ignored and the next cycle is performed without adjustment. Integral values below 70% will indicate that the column has possibly become fouled since the first cycle (concentration overestimate is not possible this time since it would have been detected and corrected on the first cycle). If on the first cycle an underestimate was diagnosed then the concentration is recalculated from the eluted mass and the volume of feed applied. Using this corrected concentration, the feed volume is then adjusted and the next cycle performed. This strategy will work because if an underestimate was diagnosed on the first cycle, the feed volume will have been set to 10% of the original feed value (see above). Consequently, one would have expected to obtain a low peak integral on the second cycle in order to recalculate the feed concentration accurately.

If a concentration underestimate was not diagnosed on the first cycle, then the yield obtained is tested to determine whether it is below a preset lower limit. If it is, then the run is aborted and a column replacement is recommended. If the yield is above the preset lower limit then the software determines that a cleaning cycle should be performed before the next cycle.

If the second cycle peak integral is above 90% of the expected value then an overload is assumed and the load volume is reduced by 10%. This protects against a loss of antibody in the unbound protein fraction because the capacity was exceeded.

Subsequent Cycles (C > 2)

As before, the integral obtained is compared with the range 7090%. Integrals falling below 70% indicate column fouling and this leads to the same analysis of yield as for the second cycle case above. However, if the yield is below the preset lower limit then the run may be aborted and a column replacement is recommended. If the yield is above this preset lower limit, then the software checks to seewhether a cleaning cycle was performed before the last cycle. It it was, then another cleaning is performed before the next cycle but the loaded volume is reduced to an amount determined from the actual yield of the most recent cycle. This takes account of the gradual loss of column capacity as fouling increases cycle by cycle. If no cleaning took place, then the column is cleaned and the next cycle runs without a reduction in load volume, since the cleaning may well restore the capacity.

For peak integrals above 90%, the same load reduction sequence is triggered as for the same case for the second cycle above.

The peak analysis routines are as follows, in a preferred embodiment:-

1. Peak Shape.

The peak shape analysis is performed by the control computer after every separation run on the instrument. The objective is to detect on-line any deterioration in performance during the run and then to take action to correct it.

The first step is to perform a calculation on the peak and determine a parameter (skewness) which represents the extent to which the eluted peak diverges from a symmetric distribution. The skewness factor obtained is then compared with a preset level of acceptable skewness and if a value in excess of this acceptable level is found, then corrective action is taken. The acceptable level of skewness (P) is a variable resident in the software which is set from experimental determination of the best peak shape obtainable with the system. A new column has a P value which is set on installation of

the column. As the performance of the column detericrates, the P value is adjusted so that at any time it represents the best peak shape obtainable with the particular column in place.

There is further constant (P′) which represents an extreme value for the skewness. At the point where the determined skewness reaches P′, it is judged that the column in place is no longer servicable and should be replaced.

Once the skewness value has been determined, the software proceeds to work through a decision tree which enables it to take the appropriate corrective action.

Two basic factors can cause the eluted peak shape to deteriorate from the expected shape.

The first of these is elution pH. If the characterisation sequence determines an elution pH which in practice turns out to be too high, then antibody will not be eluted from the column with the maximum efficiency and so the peak obtained will tend to broaden and an extended tail to the peak may be obtained. The second factor is column fouling. The crude feedstocks that are used with the instrument may contain lipid and denatured protein which will tend to interact with the column in a non-specific fashion and may not be eluted during normal cycling. Eventually the build up of these materials will give rise to uneven flow through the column and consequently the shape of the eluted peak will deteriorate. This may be corrected wholely or in part by cleaning the column with appropriate solutions.

Before any production run the column will have been cleaned and so if poor peak shape is detected at the outset it most likely to be a pH problem and so initially the software adjusts the elution pH downward by 0.5. However, if during the characterization experiments the apparatus detected a second unwanted peak within 1 pH unit of the peak of interest, pH adjustment would not be attempted as this might lead to inadequate resolution of the two components. The next separation cycle is then run and the skewness factor determined. If there has been an improvement over the previous cycle but the skewness is still above the preset value 'P' then the pH is again decremented by 0.5 and another cycle is performed. If the skewness is now below P then the next cycle is performed without further adjustment.

Once the potential to improve the shape using pH has been exhausted or the shape improvement has resulted in a skewness of less than P, then a flag is set in software to indicate that no further pH adjustment should be attempted.

Where a pH adjustment is made and fails to improve the peak shape on the next production cycle, then the pH is restored by 0.5 and a cleaning sequence is performed before the next production cycle.

If a poor peak shape fails to be improved by pH adjustment or is improved up to a point but still has a skewness greater than P, then a cleaning cycle is performed before the subsequent production cycle.

The skewness obtained from the eluted peak from a cycle performed after the column has been cleaning is checked against P′, the maximum allowable skewness. If this value is exceeded then the instrument warns the operator that the column is now performing below specification and recommends replacement. Whether P′ is exceeded or not, the software resets P to the skewness determined on the cycle following a clean since this is now likely to be the best possible peak shape obtainable with the column in place.

The new value of P is retained in software for use on subsequent runs since this variable is a characteristic of the column installed on the machine. When the column is replaced, P is reset to the original value.

Determination of Skewness

Mean (x)
= (sum from i = 1 to n of xi*yi) /(sum from i = 1 to n of yi)
Variance(s^2)
= (sum from i = 1 to n of yi(xi - x)^2) /(sum from i = 1 to n of yi)
Standard Deviation = S
Third Moment (m3)
= (sum from i = 1 to n of yi(xi - x)^3) / (sum from i = 1 to n of yi)
Coefficient of Skewness = m3/S^3
where, Yi = protein concentration value at a point, Xi along the eluted volume axis of the peak; and
i = the number of the coordinate out of a total of n coordinates which define the peak.

The coefficient of skewness will be 0 for a perfectly symmetrical peak and will have increasing positive or negative values reflecting the extent to which the leading or trailing edges of the peak deviate from normality.

Under the situation described here only trailing edge deviations will be observed and hence the extent of the positive value for the skewness can be used as a measure of the extent to which the eluted peak "tails".

This mathematics is a well known statistical manipulation and is included for information only.

The sequence of steps is illustrated in Fig. 2.

In the above procedure no account is taken of the nature of the deterioration in the peak shape. Only the extent of deviation from a symmetrical

peak is considered.

By means of the following procedure it is possible to separate shape changes leading to wider but symmetrical peaks from wider but asymmetrical peaks. This is of use to the control system because wide symmetrical peaks are usually the result of column fouling whilst wide asymmetrical peaks are usually the result of too high an elution pH.

This procedure works as follows:-

After the peak has been eluted from the column, two measurements are made. Firstly the width of the peak is measured between set thresholds of protein concentration. Secondly, the position of the peak maximum is measured and the width of the leading edge of the peak is determined.

If the peak width is less than a preset value of acceptability (w') then no action is taken.

If the width exceeds this preset value then the width of the leading edge is also compared with a preset value of acceptability (l'). In this case if this leading edge width is exceeded then a cleaning cycle is performed, since this indicates that the peak is probably symmetrical but of excessive width.

If the leading edge width is within the limit of l', then the instrument decreases the elution pH by 0.5, since this indicates that, despite the excessive width of the peak overall, the leading edge is normal.

In deciding whether to adjust the pH downward, the software first checks from the characterisation data that there is not a second peak set to elute at a lower pH. If such a second peak does exist and it is within a pH unit of the peak of interest, then a reduction in elution pH would cause co-elution of the two.

It will be appreciated that these two strategies for managing changes in the shape and width of eluted peaks can be combined.

The apparatus according to the present invention may incorporate a number of optional features to aid effective use.

One such feature is an automatic arrangement for changing to an alternative filter. The inlet stream to the chromatography column should, desirably, pass through a filter to exclude undissolved residues. In the course of time such a filter becomes overloaded and ceases to be efficient. A simple arrangement for overcoming this problem is to have two filters connected in parallel, with the flow of liquid controlled by a toggle valve. Upstream of the toggle valve the pipeline is provided with a pressure sensor connected to operating means serving to actuate the toggle valve. Thus, in operation, liquid passes the pressure sensor and leaves the toggle valve to pass through one of the filters. After a certain time, the back pressure in the system builds to an undesirable level. The pressure sensor and actuating means are calibrated to operate when the pressure reaches this predetermined value and the toggle valve is switched so that the liquid flow passes the second filter. The first filter can then be removed and cleaned or replaced.

Another useful feature for the apparatus according to this invention is the provision of sensing means, for example small infra-red detectors, to monitor liquid levels in the storage vessels to which product solutions etc. are delivered. The sensing means can be arranged to detect whether the storage vessel is full or empty. In a particularly preferred embodiment, the apparatus is provided with means to signal the absence of the vessel, for example a spring-loaded interrupter arranged to interrupt the infra-red beam if the storage vessel is removed. The sensing means can be arranged to cooperate with control means serving to control filling and washing cycles etc.

In a further preferred embodiment, a device to eliminate gas bubbles from the feed stream to the column comprises 2 level sensing devices mounted one above the other in a cyclindrical chamber which is also provided with ports for the entry and exit of the liquid flow at the base and a further port at the top of the chamber above the level sensing devices which is connected to a valve. This is under the control of the computer and when opened connects the inside of the chamber to the atmosphere. Bubbles of gas entering the chamber rise up before they can be removed in the exit stream and replace the liquid which initially fills the chamber. The upper of the 2 level sensing devices detects when this collected gas exceeds a certain volume and as a consequence the control computer opens the vent valve until the gas is replaced in the chamber by liquid from the inlet stream. If a large quantity of gas enters the chamber or if the upper level sensing device fails then the second, lower level sensor will detect an abnormally large quantity of gas in the chamber and as a consequence the computer will divert the flow from passing through the column in order to protect it from damage caused by entry of gas, as well as opening the vent valve.

In another preferred embodiment, the provision of a gradually changing pH in the elutant solution over a period of time can be achieved by arranging two buffered solutions to flow in parallel to a toggle valve connected to a single conduit leading to the column. The toggle valve is arranged so that for part of the cycle one of the buffer solutions is passed to the conduit and for the remainder of the cycle the other buffer solution is passed to the conduit. Control means can be provided to adjust

the ratio between these times on a gradually changing basis, so that the pH of the emerging elutant gradually changes. Throughout the operation, the toggle valve "toggles", i.e. constantly switches from one supply to the other and back again. Typical buffer solutions for this purpose are a phosphate buffer at pH 8.8 and a citrate buffer at pH 2.0. For preferance, the conduit is connected to the column via auxiliary mixing means, such as a small reservoir, optionally fitted with baffles. To be effective, the reservoir should have a volume equal to the output of the toggle valve over a number of toggle cycles, so that the alternate streams of buffer have a chance to mix and stabilise before passing to the column. In this way an effectively linear transition of pH can be achieved very simply.

Claims

1. Automatic chromatography apparatus comprising a column packed with adsorbent or attractant material;
means for supplying an elutant solution to the column;
loading means for loading controlled quantities of a material into the column, the material containing a substance to be eluted;
automatic control means which control the loading means so as to load the column with a first charge of the material and subsequently to load the column with a second charge of the material, the first charge being sufficiently small to ensure that the capacity of the column is not exceeded and the second charge being sufficiently large to ensure that the capacity of the column is exceeded;
first monitoring means for monitoring and controlling flow rate to provide accurate flow information to enable peak area integration;
second monitoring means which monitor the peaks of elution of the substance from the column resulting from the first and second charges of material;
processing means connected to the monitoring means and arranged to integrate the elution peak with respect to the first charge of material so as to derive the concentration of the substance in the material, and to determine from the peak of elution of the substance from the column resulting from the second charge of material the maximum practical capacity of the column for the said substance; and, optionally,
means for providing a controlled change in time in a chemical parameter of the elutant supplied to the column under control of the control means thereby enabling the processing means to determine from elution peaks monitored by the monitoring means the optimum value for said parameter for elution of the said substance and whether or not other similar substances are being eluted from the column.

2. Apparatus according to claim 1 including means for providing a controlled change in time in a chemical parameter selected from the group consisting of pH, ionic strength and chemical composition.

3. Apparatus according to claim 2 further comprising supplies of two buffered solutions arranged to flow in parallel to a toggle valve arranged to alternate between the two solutions, and control means arranged to adjust the ratio between the times of the flow of each of the solutions on a gradually changing basis, whereby the pH of the emerging elutant gradually changes.

4. Apparatus according to any of claims 1 to 3, wherein the said adsorbent or attractant material comprises an inert packing to which is bound an immunological material.

5. Apparatus of according to any of claims 1 to 4, wherein the said immunological material comprises protein A.

6. Apparatus according to any of claims 1 to 5 further comprising two filters arranged in parallel, upstream of the column;
a toggle valve arranged to control the flow of liquid to the filters;
a pressure sensing means arranged upstream of the toggle valve and serving to actuate the toggle valve.

7. Apparatus according to any of claims 1 to 6, further comprising sensing means arranged to monitor liquid levels in strong vessels to which product solutions etc are delivered by the column.

8. Apparatus according to any of claims 1 to 7, including a device to eliminate gas bubbles from the feed stream to the column, comprising two level sensing devices mounted one above the other in a cylindrical chamber, said chamber being provided with ports for the entry and exit of the liquid flow at the base thereof and a further port at the top of the chamber above the level sensing devices and connected to a controllable valve for venting the chamber to the atmosphere.

9. A method of automatic chromatography characterisation comprising the steps of: automatically;
loading onto a column packed with adsorbent or attractant material a relatively small sample containing a substance to be eluted, the relatively small sample being sufficiently small so as to ensure that the adsorption capacity of the column is not exceeded;
eluting the substance from the column to obtain an elution peak;
integrating the elution peak with respect to the relatively small sample so as to derive the con-

centration of the substance in the sample;
loading the column with a relatively large sample containing the substance, the relatively large sample being sufficiently large to ensure that the capacity of the column is exceeded;
calculating the maximum practical capacity of the column; and, optionally
providing a controlled change in time in a chemical parameter of the elutant supplied to the column to determine the optimum value at which the substance can be eluted.

10. Apparatus for controlling the efficiency of operation of a chromatography column, comprising:
monitoring means which monitor the shape and magnitude of the elution peak of the substance on the column;
memory means for storing at least one reference and details of one or more corrective actions which may counteract deterioration of the said efficiency of operation;
comparator means which compare output from the monitoring means with the said reference;
processing means which apply output from the comparator means to select a stored corrective action; and
control means which automatically execute the selected corrective action.

11. A method of controlling the efficiency of operation of a chromatography column, comprising the steps of:
monitoring the continuing performance of the column by automatic elution peak analysis, said peak analysis including the comparison of peak shape and magnitude with at least one prestored reference, the analysis further including identifying from a plurality of prestored options the most probable corrective action to counteract deterioration of the said efficiency of operation; and
automatic execution of the identified corrective action.

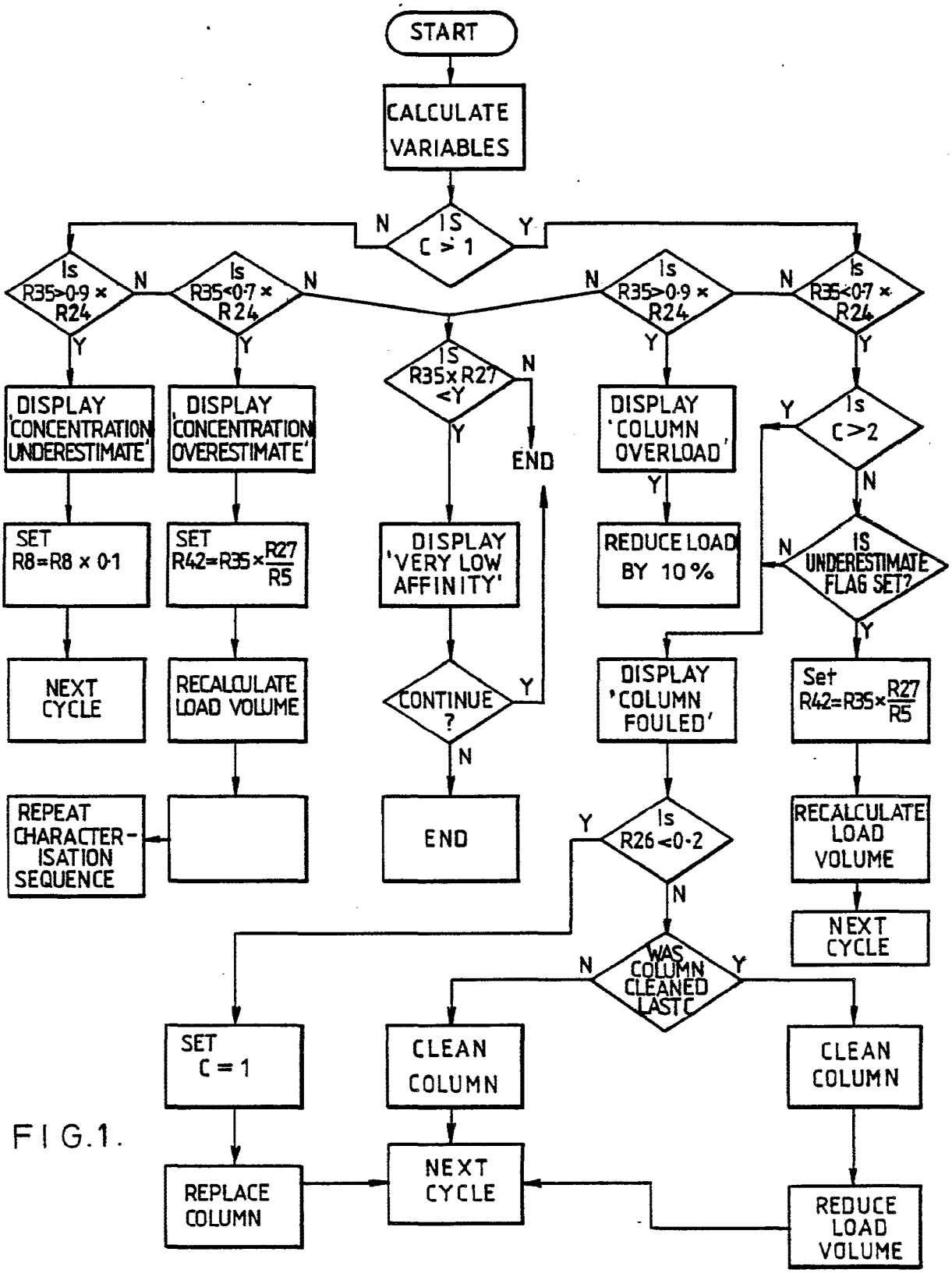
START
CALCULATE VARIABLES
IS C > 1
N
Y
Is R35>0·9 × R24
Is R35<0·7 × R24
IS R35 x R27 <Y
Is R35>0·9 × R24
Is R35<0·7 × R24
DISPLAY 'CONCENTRATION UNDERESTIMATE'
DISPLAY 'CONCENTRATION OVERESTIMATE'
END
DISPLAY 'COLUMN OVERLOAD'
Is C>2
SET R8=R8 x 0·1
SET R42=R35×R27/R5
DISPLAY 'VERY LOW AFFINITY'
REDUCE LOAD BY 10%
IS UNDERESTIMATE FLAG SET?
NEXT CYCLE
RECALCULATE LOAD VOLUME
CONTINUE ?
DISPLAY 'COLUMN FOULED'
Set R42=R35×R27/R5
REPEAT CHARACTER-ISATION SEQUENCE
END
Is R26<0·2
RECALCULATE LOAD VOLUME
NEXT CYCLE
WAS COLUMN CLEANED LAST C
SET C = 1
CLEAN COLUMN
CLEAN COLUMN
REPLACE COLUMN
NEXT CYCLE
REDUCE LOAD VOLUME

FIG.1.

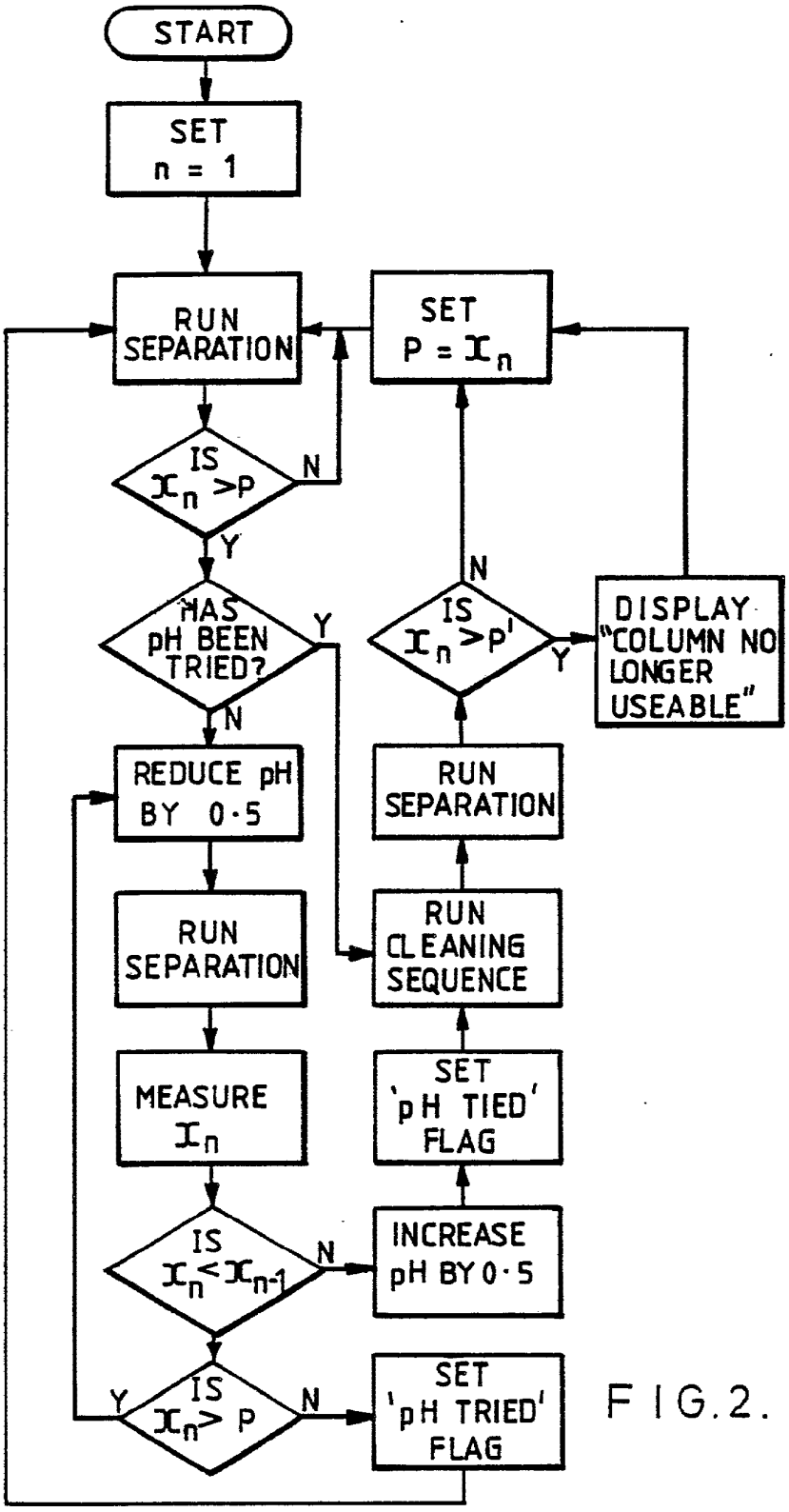
START
SET n = 1
RUN SEPARATION
IS $I_n > P$
N
Y
HAS pH BEEN TRIED?
Y
N
REDUCE pH BY 0·5
RUN SEPARATION
MEASURE I_n
IS $I_n < I_{n-1}$
N
Y
IS $I_n > P$
N
Y
SET 'pH TRIED' FLAG
INCREASE pH BY 0·5
SET 'pH TIED' FLAG
RUN CLEANING SEQUENCE
RUN SEPARATION
IS $I_n > P'$
N
Y
SET $P = I_n$
DISPLAY "COLUMN NO LONGER USEABLE"

FIG.2.

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 31 0238

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US-A-4 674 323 (RULF) * Column 11, line 1 - column 18, line 50 *	1	G 01 N 30/88 B 01 D 15/08
A	EP-A-0 103 082 (SCHÖNESHOFER) * Pages 20-28 *	1	
A	US-A-4 681 870 (BALINT) * Columns 10-12; claims *	4,5	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

G 01 N
B 01 D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	06-03-1989	WENDLING J.P.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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(54) Title: RADIOPHARMACEUTICAL GENERATION SYSTEM

(57) Abstract: The present invention relates to radiopharmaceutical generation system for use in generating a radiopharmaceutical, and is particularly concerned with improving the amount of information, relating to the process of generating the pharmaceutical, that is available. In a first aspect of the invention, the radiopharmaceutical generation system comprises a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical, the fluid processing system having a plurality of system elements and being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state; and at least one monitoring software component arranged to derive data from said output signals and to compare said derived data with one or more operating conditions in order to identify system elements not in the expected operative state. Since the expected operating state of the system elements is monitored during execution of the processes, real-time monitoring is possible. This means that fault finding and trouble shooting is easier than it is with current systems.

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RADIOPHARMACEUTICAL GENERATION SYSTEM

The present invention relates to a radiopharmaceutical generation system, and is particularly, but not exclusively, related to aspects of control thereof.

Background

Nuclear medicine involves the use of radioactive isotopes (radioisotopes) within a body. The radioisotopes are attracted to specific organs, bones or tissues, and the emissions produced by the radioisotopes are used provide information about a particular type of disease. Examples of radioisotopes commonly used in nuclear medicine include carbon-11, oxygen-15, fluorine-18 and bromine-75.

Positron emission tomography (PET) is an example of a nuclear medicine diagnostic technique whereby images of physiological function of organs are acquired by imaging the decay of radio-isotopes bound to molecules having known biological properties. Suitable radio-isotopes are synthesized into a carrier (also called a tracer) that enables the radio-isotope to be delivered to the organ being examined. Such a carrier is commonly referred to as a radiopharmaceutical.

One commonly used radio-isotope is Oxygen-15 (^{15}O), which is produced by deuteron bombardment of natural nitrogen through the $^{14}N(d,n)^{15}O$ nuclear reaction; this process is carried out by a device commonly referred to as a cyclotron. The present invention is not concerned with the way in which the radio-isotope is generated, and the cyclotron will not be described in further detail.

One radiopharmaceutical associated with the Oxygen-15 radio-isotope is ^{15}O-labelled water. Typically, ^{15}O-labelled water is produced on-line from Oxygen -15 in a radiopharmaceutical generator by mixing Oxygen-15 with hydrogen, in a stochiometric proportion, and passing the mixture over a palladium catalyst in an oven at 150°C. The resulting radioactive water vapour

diffuses across a semi-permeable membrane (cellulose acetate) into a sterile saline solution (0.9% NaCl), which is pumped continuously through the system with a medical infusion pump to generate a solution containing ^{15}O-labelled water.

One radiopharmaceutical generator suitable for generating ^{15}O-labelled water is described in an article entitled "Technical performance and operating procedure of a bedside [^{15}O] water infuser", authored by H Touchon-Danguy et al and published in the Journal of Label. Cmpds. Radiopharm., volume 37 pages 662 – 664, in 1995.

The radiopharmaceutical generator comprises several components, some of which are independent of, and others of which are interrelated with, other components. This means that, when there is a problem with the operation of the radiopharmaceutical generator, it is extremely difficult to work out where, in the radiopharmaceutical generator, the problem is. Typically, a technician has to test each and every component, which can be extremely time consuming and have a significant impact on operation of the whole PET facility. Moreover, if there is any risk of radioactivity leaks, the entire PET facility is shut down; since downtime associated with trouble-shooting is costly and inconvenient, being able to identify whether the entire facility requires shutting down becomes increasingly important.

The act of noting the progress of the fluid generation process is known from US 4,625,118, in which a photoelectric barrier is used to detect output of fluid from a syringe. In the US 4,625,118 system, once the presence of fluid has been detected, the configuration of certain valves is modified so as to adjust the fluid delivery path. Whilst providing a means of triggering a change to the flow delivery path (in this case enabling the fluid in the syringe to fill a flushing station), this does not provide any detailed information as to the operational status of the generator, and thus does not readily facilitate isolation of problems with devices therein.

It would thus be desirable to provide a means of improving identification of faults associated with the radiopharmaceutical generator.

A second problem results from the fact that radioactivity is only measured within the radiopharmaceutical generator itself. The distance between the radiopharmaceutical generator and the subject being examined can be significant, due to logistical constraints (layout, shielding and safety requirements etc.). Thus by the time that the radiopharmaceutical is delivered to the subject, the actual level of radioactivity may be substantially different to the level measured in the radiopharmaceutical generator. For a radiopharmaceutical based on Oxygen-15, which has a half-life of 2 minutes, this distance, and thus decay in radioactivity, can be appreciable.

It would thus be desirable to provide a means quantifying the level of radioactivity delivered to the subject.

Summary of the Invention

According to a first aspect of the present invention there is provided a radiopharmaceutical generation system comprising:

a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical, the fluid processing system having a plurality of system elements and being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state; and

at least one monitoring software component arranged to derive data from said output signals and to compare said derived data with one or more operating conditions in order to identify system elements not in the expected operative state.

The fluid processing system may be a radiopharmaceutical generator, which, in one embodiment is a water generator, and the one or more processes may constitute a radiopharmaceutical generation event.

Since the expected operating state of system elements is monitored during a radiopharmaceutical generation event, real-time monitoring of the generator is possible. This means that fault finding and trouble shooting is easier than it is with current systems.

Conveniently, the or each system element is arranged to receive one or more control signals that have been issued by a controller, and said one or more processes (i.e. radiopharmaceutical generation event) are performed in accordance with said control signals. Additionally the controller is arranged to output data to the monitoring software component as it issues control signals to at least one system element. In one arrangement the controller comprises at least one software component.

Preferably the controller is arranged to receive said output signals indicative of the state of the radiopharmaceutical generation system, and it tracks the state of the radiopharmaceutical generator on the basis thereof. In response to a change in the state of the radiopharmaceutical generator, the controller is arranged to output data to the monitoring software component.

Advantageously the monitoring software component includes an outputting software component in the form of, for example, a display means or an alerting means. The outputting component provides a means of communicating said real-time state information to an operator of the radiopharmaceutical generation system.

In one arrangement, the radiopharmaceutical generation system elements include: a heating device; a radiopharmaceutical delivery system comprising an output to a subject (e.g. patient); a plurality of valves arranged to control the path of the delivery system; a dialyser; a pump for pumping the radiopharmaceutical around the delivery system; and at least one radioactivity detector arranged in the path of the radiopharmaceutical delivery path. The system elements are respectively operable to output signals indicative of at least some of: temperature of heating device; energised status of the valves; flow rate through, and pressure applied by, the pump; radioactivity measured by radioactivity detector; and time elapsed since the process started. In such an arrangement the monitoring software component is arranged to identify which of the processes is currently being performed on the basis of data identifying the energised status of the valves, and the display means is arranged to display a natural language descriptor corresponding to said identified process.

Alternatively, the monitoring software component is arranged to identify which of the processes is currently being performed on the basis of radioactivity data measured by the radioactivity detector, since the radioactivity detector is located in a specific part of the delivery path of the radiopharmaceutical.

In the following description, a radiopharmaceutical generator is alternatively referred to as a radiochemistry module.

According to a further aspect of the present invention there is provided a radiopharmaceutical generation system comprising:

a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical, the fluid processing system having at least one actuator element capable of adopting a plurality of operating positions, the fluid processing system being arranged to determine a current operating position of the actuator element and to output a signal indicative of the determined operating position; and

at least one monitoring software component arranged to process data derived from said output signal during execution of said one or more processes in order to identify a state of the fluid processing system.

In this aspect of the invention, the operating positions, or states, of actual devices are determined, which enables accurate pinpointing of faults, together with a means of proactively planning for part replacement. Examples of actuator elements include flow valves, pumping mechanisms, and the like.

According to a yet further aspect of the present invention there is provided a radioactivity detection system for use in relation to a radiopharmaceutical, the detection system comprising:

a fluid processing module arranged to receive a radioisotope and to generate a radiopharmaceutical therefrom;

a radiopharmaceutical delivery system arranged to deliver the generated radiopharmaceutical to a subject, the radiopharmaceutical delivery system comprising a delivery path operable between said fluid processing module and said subject; and

a radioactivity detector arranged to measure radioactivity in the delivery path and output a signal indicative thereof.

The fluid processing module may be a radiopharmaceutical generator, which, in one embodiment is a water generator, and is enclosed within a lead shielding. In a preferred arrangement, the radioactivity detector is located as close to subject as possible thereby quantifying initial radioactivity levels as accurately as possible. More specifically the radioactivity detector is conveniently located along the delivery path at a distance of between 5% and 50% of the delivery path length from the subject, more preferably at a distance of between 7% and 12% of the delivery path length from the subject. In one arrangement, the radioactivity detector is located between 100 and 150 mm from the subject, the delivery path having a total length of approximately 1.2 metres; in a second arrangement the radioactivity detector is located between 300 and 350 mm from the subject, the delivery path having a total length of approximately 3.5 metres.

This measured data is then used in the post-processing of scanned images of the subject, thereby increasing the accuracy of quantitative measurements of biological activity of the subject.

Brief Description of Drawings

Figure 1 is a schematic diagram of the radiopharmaceutical generator with which embodiments of the invention inter-operate;

Figure 2a is a schematic diagram showing the valves of Figure 1 arranged in a first configuration;

Figure 2b is a schematic diagram showing the valves of Figure 1 arranged in a second configuration;

Figure 2c is a schematic diagram showing the valves of Figure 1 arranged in a third configuration;

Figure 2d is a schematic diagram showing the valves of Figure 1 arranged in a fourth configuration;

Figure 3 is a schematic diagram showing a controller for the radiopharmaceutical generator of Figure 1 according to an embodiment of a first aspect of the invention;

Figure 4 is a flow diagram showing steps carried out by the controller of Figure 3 according to an embodiment of a first aspect of the invention;

Figure 5 is a schematic diagram of a GUI comprising part of the controller of Figure 3;

Figure 6 is a flow diagram showing further steps carried out by the controller of Figure 3;

Figure 7 is a flow diagram showing yet further steps carried out by the controller of Figure 3;

Figure 8 is a schematic diagram of a GUI comprising part of the controller of Figure 3;

Figure 9 shows a schematic diagram of a nuclear medicine diagnosis facility according to a second aspect of the invention;

Figure 10 is a schematic diagram illustrating a holding device for a second detector according to the second aspect of the invention;

Figure 11 is a flow diagram showing steps carried out by the controller of Figure 3, which has been modified to process data in accordance with the second aspect of the invention; and

Figure 12 is a perspective representation of the radiopharmaceutical generator according to the first aspect of the invention, comprising a radiochemistry module.

Overview of Operating Environment of Embodiments of the Invention

Figure 1 is a schematic diagram of a radiopharmaceutical generator, which in this embodiment is a conventional water generator 100, showing a catalyst furnace (oven) 101 for producing radioactive water vapour ($H_2{}^{15}O$); a saline source 103; a dialyser (semi-permeable membrane) 105 for binding radioactive water vapour with saline; a pump 107 for pumping the saline into the dialyser 105 and towards subject 115; and a Geiger Muller (GM) tube 109 for measuring radioactivity in the saline radiopharmaceutical. Referring also to Figure 12, the radiopharmaceutical generator 100 is enclosed in a lead shield 1201, and includes a waste decay coil 1203 (shown schematically as waste 111 on Figure 1) that allows the radioactive water to decay before it exits the lead shield.

The radiopharmaceutical generator 100 also includes two operating valves, V1 and V2, which control movement of fluid within the radiopharmaceutical generator 100. Referring to Figures 2a – 2d, the valves V1, V2 are configured such that the radiopharmaceutical generator 100 can operate in a plurality of modes (in the Figure, the pathway through the valve is indicated by an open quadrant). In a first mode, shown in Figure 2a (buildup: $mode_1$), V1 is energised and V2 is de-energised. Thus in one direction D1, saline is held in region 113 of the dialyser 105, thereby creating the radiopharmaceutical, and in another direction D2 saline passes out to waste 111. In a second mode, shown in Figure 2b, (infusion: $mode_2$), V1 is de-energised and V2 is energised, which means that the radiopharmaceutical present in region 113 is delivered to the subject 115 via delivery path 116, passing through the GM tube 109. In a third mode, shown in Figure 2c, (flushing: $mode_3$), both V1 and V2 are energised, and pure saline (from saline source 107) flushes out any radiopharmaceutical present in the radiopharmaceutical generator, the delivery tube 116 and in the subject 115 itself. In a fourth mode, shown in Figure 2d, (waste: $mode_4$), both V1 and V2 are de-energised, so that any remaining material exits via waste output 111.

Preferably the valves include sensors (not shown), which sense whether or not the valves are energised.

Overview of Embodiments of the Invention

In the prior art, control of the radiopharmaceutical generator 100 shown in Figure 1 is either manual – by manually opening and closing valves V1, V2 – or automatic – by means of bespoke control unit. An advantage of controlling the radiopharmaceutical generator automatically is that various combinations of the modes described above (with differing intervals between successive modes) can be pre-programmed, and the timings can be accurately controlled. As a result, the valves can be controlled remotely, which, when the fluid involves radioactive material, is important from the point of view of health and safety.

However, in known automatic control arrangements, little or no information is fed back to the operator regarding the progress of generating and infusing the radiopharmaceutical into the subject. As a result, when there are problems with operation of the radiopharmaceutical generator 100, it can be extremely difficult to identify the source of the problem. Typically, a technician has to test each and every component, which can be extremely time consuming and have a significant impact on operation of the whole diagnostic facility. Moreover, if there is any risk to the patient, the entire diagnostic facility has to be shut down; since downtime associated with trouble-shooting is costly and inconvenient, being able to identify whether or not the problem will affect the patient, and thus whether the entire facility requires shutting down, becomes increasingly important.

Embodiments of the invention are thus concerned with improving speed and accuracy with which the source of the problem is identified. In one embodiment, the controller includes software components that send data to, and request data from, the various radiopharmaceutical generator components, and output, e.g. via a display, the data. Since the behaviour of these components can be well defined, the data received from the components can be compared with specified operating criteria, and/or simply displayed for inspection by an experienced operator.

Turning to Figure 3, an embodiment of the invention, for the case where the radiopharmaceutical generator is a water generator, will now be described in more detail. The controller of the radiopharmaceutical generator 100 comprises a programmable logic controller (PLC) 301 and a plurality of operational software components 311, which run locally on the PLC 301 in response to signals received from a conventional PC computer 320. The signals received from the PC 320 are generated under control of configuration software components 321. The operational software components 311 include software for controlling and retrieving data in respect of the radiopharmaceutical generator, and the configuration software 321 include software components arranged to receive operator-selected and/or operator-specified data, to send such data to the operational software 311, and to process data retrieved by the operational software 311. In one arrangement, the configuration software 321 is written using the Labview® programming language, but the skilled person will realize that any suitable computer programming language, or combinations of computer programming languages, could be used. The operational software 311 is written using the proprietary programming language associated with the PLC 301.

As shown in Figure 3, the computer 320 comprises processing unit (CPU) 323, memory 324, hard disc drive 325 and I/O device 326, which facilitates interconnection of the computer 320 with the PLC 301. Operating system programs 327 are stored on the hard disc drive 325, and control, in a known manner, low level operation of the computer 320. The computer 320 also includes a display and keyboard (not shown), which receive input from an operator and pass, via I/O device 326, the input to the O/S programs 327 in accordance with known techniques.

As also shown in Figure 3, the PLC 301 comprises: a bus 314, into which various operating modules can be plugged; a bus controller 315, which co-ordinates processing of data associated with the operating modules; and an I/O device 313, which is arranged both to receive input from external devices such as computer 320 and to output signals in accordance with operation of the

operating modules. In one arrangement, the input part of I/O device 313 comprises an RS232 interface which is arranged to receive input signals from the computer 320 (via serial link L1), and the output part of I/O device 313 has a plurality of output terminals, each being associated with a different one of the modules plugged into the bus 314 and connected to whichever component of the radiopharmaceutical generator 100 corresponds to that module. The bus controller 315 is arranged to receive data from the RS232 interface, process the received data in accordance with the operational software 311, and distribute data to an appropriate module on the bus 314. An example of a suitable PLC 301 is the Beckhoff™ PLC (model BC8100); the skilled person would realize that other types (notably those manufactured by Siemens™ or a bespoke PLC) could be used. The operating modules that plug into the bus 314 are not shown in Figure 3, but include: a module for controlling the temperature of the catalyst furnace 101; a module for controlling valves V1, V2; a module for controlling and monitoring pump 107 and receiving data therefrom; and a module for receiving data from the GM tube 109. When the valves V1, V2 include sensors indicating their energised state, the bus 314 also includes a module for receiving status data therefrom.

The functionality associated with energising and de-energising valves V1 and V2 is conventional. However, other aspects of the operational software 311 are new, as are aspects of the configuration software 321 for processing operator-selected and/or operator -specified data. In particular, the configuration software 321 includes a graphical user interface (GUI), which can be used to specify operating parameters such as time intervals between mode changes (i.e. valve energizing and de-energising, Figures 2a – 2d); details of a radiopharmaceutical generator event; details of data to be retrieved from the radiopharmaceutical generator 100; and authentication criteria. These data, once entered via the GUI, are sent to the operational software 311 (as will be described in more detail below), which is arranged to transmit corresponding control signals to the radiopharmaceutical generator 100 in order to execute a radiopharmaceutical event.

The operational software 311 is also arranged to inform the configuration software 321 of the transmission of such control signals via confirmation signals and/or to initiate requests for data from components of the radiopharmaceutical generator during execution of the radiopharmaceutical event. When the operational software 311 requests data from components of the radiopharmaceutical generator, any data received in response thereto are forwarded to the configuration software 311 for post processing thereof, alongside, or in addition to, the confirmation signals received from the operational software 321. Such post-processing facilitates monitoring of real-time performance of the radiopharmaceutical generator and validation of radiopharmaceutical generator events, as is described in more detail below.

Firstly, however, steps involved in configuring a radiopharmaceutical generator event according to an embodiment of the invention will be described, with reference to Figures 4 and 5. Figure 4 is a flow diagram illustrating these steps and Figure 5 is a schematic diagram showing an example of a graphical user interface forming part of the configuration software components 321. Turning to Figure 4, at step 401, an operator enters data relating both to the subject 115 and to the radiopharmaceutical generator event. This information includes the names of the subject 115 and of the clinician responsible for the radiopharmaceutical generator event, and authentication data. Preferably this information is entered via text entry boxes 501, 502, 503, 504, 505 of the GUI, shown in Figure 5. In addition, the operator reviews calibration values relating to components of the radiopharmaceutical generator on a separate screen, accessible via tab 511. These calibration values include background radioactivity levels and are typically read from the database DB, to which only authorized users have access. In the event that the calibration values do not represent current conditions, the operator can request such an authorized user to change the values in the database.

The operator then selects 403 one of a plurality of operating protocols, e.g. from a drop-down menu that is displayed when the cursor hovers over a particular region 506 of the GUI. Each protocol typically represents a

configuration of the afore-mentioned valve modes ($mode_1$ – $mode_4$), together with temporal data relating thereto, and corresponds to a type of radiopharmaceutical generator event. The GUI includes an "operate" button 507, which the operator presses to request the start of a radiopharmaceutical generator event. The configuration software 321 includes a verification software component (not shown), which is arranged to verify that data have been entered into particular boxes of the GUI; the start button 507 is disabled by the verification software component until certain conditions have been satisfied (e.g. data entered into certain boxes 501 ... 505 etc.).

In response to activation of the "operate" button 507, the configuration software 321 validates 405 the entered authentication data, e.g. by comparing the entered authentication data with an expected entry, which may be stored in validation database DB. Assuming the authentication data to be successfully validated, the configuration software 321 stores 407, locally, the data entered at step 401, and then formulates 409 a control string S1 for input to the PLC 301. Since in this embodiment data are transmitted via the serial port of the computer 320, the control string S1 takes the form of a comma delimited hexadecimal string. The control string S1 includes data identifying the protocol selected at step 403, together with a request for data relating to at least one of: time since commencement of the radiopharmaceutical generator event; valve status set by the operational software 311; actual status of one or both valves V1, V2 (detectable via the sensors associated with the valves); protocol applied by the operational software 311; furnace 101 temperature; and radioactivity measured by GM tube 109. The request data can be specified either via the GUI, or via data stored in the database DB, or hard-coded into the configuration software 321. At step 411, the configuration software 321 outputs the control string S1, asynchronously, via the I/O device 326. Configuration software 321 is then effectively "paused" until such time as data are received from the PLC 301.

Turning now to Figure 6, which is a flow diagram showing steps involved in processing a radiopharmaceutical generator event, aspects of the operational software 311 will now be described. The control string S1 sent at

step 411 is received by the operational software 311 and processed (step 601) to extract information therein. The extracting step 601 involves decomposing control string S1 into its constituent parts and converting to Boolean or numerical data as required. For illustrative purposes it is assumed that the protocol selected at step 403 corresponds to the following sequence: 120 seconds buildup ($mode_1$); 20 seconds infusion ($mode_2$); 120 seconds flush ($mode_3$), and that the request part includes requests for all data that can be monitored during the sequence. Accordingly, having decomposed control string S1, the operational software 311 firstly runs 603 an initialization process, which involves checking the temperature of the furnace 101 (since if the furnace temperature is not sufficiently hot, the radiopharmaceutical generator event cannot be processed), de-energising the valves V1, V2, and requesting the operating module corresponding to the valve sensors to record, via its own internal clock, the periods in which each valve is energised and de-energised.

Assuming the temperature of the furnace to be within certain specified operating limits, at step 605 the operational software 311 initiates the processes associated with $mode_1$, which involves setting a timer t1, sending a signal to the operating module associated with the valves V1, V2, causing V1 to be energised, and noting the time at which the valve is so activated. After 120 seconds have elapsed, the operational software 311 changes mode (steps 609, 610, 611, 605), sending a signal to the same operating module, which causes V1 to be de-energised and V2 to be energised (setting $mode_2$). After 20 seconds have elapsed, the operational software 311 again changes mode (steps 609, 610, 611, 605), sending a signal to the same operating module, which causes V1 to be energised (setting $mode_3$); and after a further 120 seconds have elapsed, the operational software 311 yet again changes mode (steps 609, 610, 611, 613 (since the condition at step 611 is, on this cycle, satisfied)), sending a signal to the same operating module, this time causing both valves to be de-energised (setting $mode_4$).

During these time intervals, the operational software 311 sends signals to various operating modules (plugged into the bus 314 of the PLC 301) requesting

items of data relating to their operation. Each data item corresponds to a part extracted from the control string S1 at step 601, namely value of timer t1 (time elapsed since start of radiopharmaceutical generator event); actual status of the valves retrieved from the valve sensors (energised or de-energised); temperature of the furnace 101; and number of counts recorded by the GM tube 109. Data items received in response to these signals are, under certain conditions, sent to the configuration software 321. In one arrangement, the operational software 321 monitors (step 607) the values of the requested data items, and, each time a value of a requested status data item changes, it creates a comma delimited hexadecimal return string S2 comprising the or each data item into and sends the return string S2 to the RS232 I/O port 313 for receipt by the configuration software 321 (step 608). In addition, each time the operational software 311 transmits a control signal to a component of the radiopharmaceutical generator – e.g. one of the valves – it generates a return string S2, so that, at the very least, a return string S2 is sent each time the operational software 311 attempts to instigate a mode change.

If the value of one of the data items has not changed since the last time data was sent from the PLC 301, the portion of return string S2 corresponding to that data item assumes its previous value. Thus, during the first mode (Figure 2a), when the saline passing through the GM tube 109 is not radioactive, the GM tube 109 is unlikely to register a change in level of radioactivity. Thus if one or more return strings S2 are sent to the configuration software 321 during this period (due to, e.g. a change in temperature of the furnace 101, or in the event that the actual status of the valve changes) the values relating to the GM tube 109 of successively transmitted return strings S2 are likely to be identical, or at least very similar, to one another. However, during the second mode (Figure 2b), when the radiopharmaceutical in region 113 is transported to the subject, the level of measured radioactivity (thus part of return strings S2 corresponding thereto) can be expected to vary. Since return string S2 is transmitted during a radiopharmaceutical generator event, the present

embodiment makes real-time monitoring of the radiopharmaceutical generator possible.

The configuration software 321 can alternatively or additionally send explicit data requests (via request string S3 shown in Figure 3) to the operational software 311, which causes the operational software 311 either to create return string S2 using the data items currently available, or to send requests for the data items to the various operating modules and create a return string S2 using the data sent in response thereto.

As a further alternative, the operational software 311 can create and send a return string S2 to the configuration software 321 periodically. In this arrangement the configuration software 321 is configured to poll for such a return string S2 with corresponding periodicity. In the event that the configuration software 321 cannot identify a return string S2 at an expected time, the configuration software 321 is arranged to generate an alert, which may be output, e.g. via the GUI.

Turning now to Figures 7 and 8, which are respectively a flow diagram showing steps involved in post-processing return string S2 and a schematic diagram showing output displayed by the configuration software 321, post-processing of the return string S2 will be described. When a return string S2 is received at I/O port 326 of the computer 320, the configuration software 321 firstly performs 701 an error check, and, if the error check is successful, breaks 703 the return string S2 down into constituent parts and converts 705 the constituent parts to boolean or integer/non-integer values in accordance with a specified set of conversion rules. The error check involves, for example, checking the length of return string S2 against a specified length. As described above, each of the constituent parts corresponds to a data item – status of the valves V1, V2, temperature of the furnace 101 and/or radioactivity measured at the GM tube 109 etc. – which is subsequently processed by the configuration software 321 in order to assess the operating status of the various components of the radiopharmaceutical generator. In one arrangement, the set of rules includes one or more rules corresponding to each of the data items in the return string S2,

namely valves (actual status and protocol applied), GM tube measurements, oven temperature, etc.; for clarity, the following passages will describe post-processing of individual data items in turn.

Considering firstly post-processing of data relating to valves V1, V2, step 706 includes identifying whether the return string S2 comprises one or both of actual valve data sensed by the valve sensors or/and confirmation of control signals sent by the operational software 311. In the event that both actual and confirmation data are available, the mode of operation corresponding to each type of data, together with a "natural language" description thereof, are identified (step 707) from a stored mapping (not shown) between mode and description (buildup: $mode_1$; infusion: $mode_2$, flush: $mode_3$, waste: $mode_4$). In the event that there is correspondence between the mode identified from the valve sensor data and the mode identified from the confirmation of control signal data, the natural language description identified at step 707 can be displayed 709 on the GUI of the configuration software 311 (box 531), for inspection by an operator. Monitoring actual, or real-time, status of the valves V1, V2 thus enables the operator to track the progress of a radiopharmaceutical generator event. In the event that the modes do not agree, an alert is generated.

If available, the actual times at which the valve sensors ascertained changes in valve state can also be displayed (not shown), and/or used to quantify any latency in the PLC 301 and/or operation of the valves (since the operator can compare an expected duration, specified in the protocol selected at step 403, with the actual duration (steps 611, 613), and, in the event that the actual duration fails to meet certain conditions (indicating, for example, a failed valve), generate an alert). In the event that the return string S2 only comprises confirmation of control signals sent by the operational software 311, there is no post-processing of temporal data, and the natural language description of operational mode corresponds to that identified from the confirmation data alone.

Referring also to Figure 7, and considering next the post-processing of data relating to the catalyst furnace 101, having extracted temperature data from

the return string S2, the configuration software 321 applies 721 rules to identify whether the temperature is within a specified operating range and displays 723 the temperature (box 801) on the GUI; in the event that the temperature falls outside of the specified operating range, the configuration software 321 constructs and displays an alert (steps 725, 727). Step 723 can also include storing the value of the temperature data item, which provides a means of tracking historical temperature values.

Considering next the post-processing of data from the GM tube 109, step 731 includes applying a correction to the measured radioactivity data item values in order to compensate for measurement errors and levels of background radioactivity. This step therefore involves retrieving the calibration and background values selected at step 401 and applying them to the radioactivity values extracted at step 705 in order to identify a corrected level of radioactivity. This corrected level is then displayed 733 in real-time on the graph area 521 shown in Figure 5 as a function of elapsed time t1 (itself displayed in box 533, shown in Figure 5); successively received return strings S2 thus provide a means of tracking the change in radioactivity associated with the radiopharmaceutical generator in real-time (since these values are plotted on graph area 521), as well as monitoring the magnitude of radioactivity infused into the subject 115.

Thus the above described embodiment enables the operator to monitor both the operation of components of the radiopharmaceutical generator 100 and the progress of a radiopharmaceutical generator event. This enables prompt identification of problems, which in turn facilitates evaluation of the affect of the problem on the subject and isolation of the component(s), and only that/those component(s), responsible for the problem. This reduces the possibility of a potentially dangerous event becoming an actual danger, reduces time spent investigating the source of the problem, and thus reduces the down-time of a PET facility.

As stated in the introductory section, a further problem with current radiopharmaceutical generators is that the level of radioactivity is only measured at the radiopharmaceutical generator itself. As is well known, the decay of a

radio isotope is determined by its half-life, and decays exponentially. The decay of the radio-isotope within a subject (measured by the PET facility, and which is not a concern of this invention) includes a contribution from its half-life and a contribution from any biological effect resulting from the radio-isotopes binding with molecules of the subject. In order to ascertain the biological effect, the decay resulting from the half-life of the radio-isotope has to be removed from measurements, and thus firstly requires quantifying. Referring to Figure 9, the radiopharmaceutical generator 100 and the subject 115 can be separated by a reasonable distance, so that it takes a certain amount of time for the radiopharmaceutical to travel from the radiopharmaceutical generator 100 to the subject 115. As a result, the level of radioactivity measured by the detector 109 within the radiopharmaceutical generator 100 is unlikely to be indicative of that infused into the subject.

If the level of radioactivity measured within the radiopharmaceutical generator is then used to represent the half-life, the apparent magnitude of the biological contribution is likely to be lower than its actual value, since the level of radioactivity in the radiopharmaceutical generator can be expected to be higher than it is at the subject. For a radio-isotope such as Oxygen-15 this can be significant, since the half-life of Oxygen-15 is only 2 minutes.

Referring again to Figure 9, in a second aspect of the invention, the radiopharmaceutical generator 100 includes a second radioactivity detector 901, which may be another GM tube or other suitable device, positioned in the vicinity of the scanner 903 of the PET facility. This facilitates measurement of radioactivity as close to the subject 115 as possible, thereby improving quantitative measurements of a subject's biological properties. In one arrangement, for a delivery tube 116 of length 1200 mm, the second radioactivity detector 901 could be positioned between 100 and 150 mm from the point of entry into the subject.

If the radiopharmaceutical were infused into an arm, the detector 901 could be located proximate to the delivery tube 116 at the patient's arm. A suitable holding device 1001, such as that shown in Figure 10, could be used to

secure the detector 901 in place; as can be seen, the delivery tube 116 passes through opening 1000 of the holding device 1001 and is thus exposed to the detector 901. The holding device 1001 includes a plate 1003 for securing the device 1001 to the scanner 903, via holes 1005.

A data output of the second detector 901 can be coupled to the PLC 301 via a data link and further operating module (not shown), which is configured to receive and request data from the detector 901. Alternatively, the operating module corresponding to GM tube 109 can be arranged to communicate with both the GM tube 109 and the detector 901. Either way, the return string S2 generated by the operational software 311 will be created as described above, and in this second aspect of the invention will include data from both the GM tube 109 and the detector 901. This means that the configuration software 321 has to carry out some processing steps not described in Figure 7. These steps are shown in Figure 11; those that are common to both aspects of the invention are referred to using the reference numerals introduced in Figure 7. Initially, therefore, as for the first aspect of the invention, at step 701 the configuration software 321 performs an error check, and, if the error check is successful, breaks 703 the return string S2 down into constituent parts, converting 705 the constituent parts to boolean or integer/non-integer values in accordance with a specified set of conversion rules. At steps 1101a, 1101b the radioactivity data items corresponding to the detectors 109, 901 are corrected to account for background and calibration adjustments (note that if the detectors are of different types, the background and calibration values specified at step 401 are likely to differ). Since the detector 901 is measuring the radioactivity values close to the subject 115, these corrected values are displayed (step 1102) in the graph area 521 and are output for further processing to a processing part of the PET facility (not shown).

In addition to facilitating an improved quantification of the biological contribution to any measured decay (measured by the PET facility), these additional data can be used to monitor the behaviour of the radio-isotope and verify operation of the detectors 109, 901. Accordingly, in one arrangement, the

radioactivity values measured by the GM tube 109 are adjusted to take account of the distance between the two detectors, in order to estimate an expected level of radioactivity at the second detector 901 (step 1103). This expected value is compared (step 1105) with the actual value measured by the second detector 901, and, if the difference between the expected value and the actual value measured by second detector 901 exceeds a specified threshold, an alert is generated (step 1109). Since, at this stage, it is unclear which of the detectors 109, 901 is incorrect, the alert is passed to the processing part of the PET facility as well as to the operator of the radiopharmaceutical generator 100 (e.g. via the GUI).

Whilst in the first aspect of the invention a specific protocol (radiopharmaceutical generator event) involving 120 seconds build-up/ 20 seconds infusion/ 120 seconds flush is described, other protocols are possible. These are selectable from the pop-up menu 507 and include (non-exhaustive list):

1. 120 second build-up / 20 second infusion / 120 second flush;
2. 120 second build-up / 20 second infusion / 50 second flush;
3. 120 second build-up / 20 second infusion / 20 second flush;
4. Activity test: As 1 but V2 permanently to waste to check radioactivity level;
5. Sterilise mode: step through all 4 combinations of V1 and V2 allowing all paths to be cleaned;
6. Long flush: permanently energise V2 while stepping V1 between its 2 states;
7. Take samples: energise V2 for 30 seconds, de-energise for 1 minute, energise both V1 and V2 for 30 seconds;
8. Energise V1 and V2 for 50 seconds to fill the line to subject with fresh saline;
9. Turn oven heater ON or OFF as required during maintenance;
10. Turn valves V1 and V2 ON or OFF as required during maintenance; and

11. Terminate mode: valves V1, V2 OFF.

Whilst in the above embodiments the connection between the PLC 301 and the PC is described as being a serial link, the connection could alternatively be wireless, e.g. Bluetooth or WLAN.

Whilst step 401 involves manually entering data into the GUI, identification data could instead be stored in a log file, or similar, and read therefrom when the GUI is invoked.

Whilst in the embodiment relating to the first aspect of the invention described above, the operating software 311 requests data from the valves V1, V2, GM tube 109 and the furnace 101, the operating software 311 may also request data items in respect of the pump 107. Specifically, in the event that the pump 107 is equipped with means for measuring pressure and mass flow rate of the saline pumped therethrough, the operating software 311 may receive the flow rate and pump pressure data (e.g. via another module on bus 314) and include these data in the return string S2. Processing of a return string S2 comprising the pump data would then involve monitoring a change in flow rate over time, and, if the change satisfied certain conditions, the configuration software 321 would create an alert message that includes the option of generating a "stop" radiopharmaceutical generator event. In addition, the pump pressure would be monitored over time, and, if a specified rise in pump pressure were accompanied by a specified drop in flow rate, the operator would similarly be sent an alert message (and possibility of halting the radiopharmaceutical generator). This is particularly useful since a drop in mass flow rate accompanied by a rise in pump pressure may signify either a blocked pipe (harmless) or some reaction by the subject 115 as saline is infused therein (potentially harmful). This feature of the invention thus enables the operator a) to know that a problem exists that may affect the subject 115; b) to shut down the radiopharmaceutical generator 100; c) pinpoint the source of the problem accurately and d) investigate the source of the problem far earlier than is currently possible.

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

5

CLAIMS

1. A radiopharmaceutical generation system comprising:

a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical, the fluid processing system having a plurality of system elements and being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state; and

at least one monitoring software component arranged to derive data from said output signals and to compare said derived data with one or more operating conditions in order to identify system elements not in the expected operative state.

2. A system according to claim 1, wherein the or each system element is arranged to receive one or more control signals, the system including a controller arranged to generate said control signals, wherein said one or more processes are performed in accordance with said control signals.

3. A system according to claim 2, wherein the controller is arranged to receive said output signals indicative of state of the radiopharmaceutical generation system.

4. A system according to claim 3, wherein the controller is arranged to track the state of the radiopharmaceutical generation system on the basis of said received output signals, and transmit data indicative of a state of the fluid processing system to the monitoring software component in response to a change in the state of the radiopharmaceutical generation system.

5. A system according to claim any one of claim 2 to claim 4, wherein the signals indicative of a state of the fluid processing system correspond to transmission of control signals to at least one system element.

6. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to trigger a termination control signal in response to the derived data satisfying a specified condition, the termination control signal, when received by a system element, causing a currently executing process to terminate.

7. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to trigger a termination control signal to each of said system elements identified as not being in the expected operative state, the termination control signal, when received by said system element, causing a currently executing process to terminate.

8. A system according to any one of the preceding claims, including alerting means arranged to generate an alert in response to the monitoring software component identifying that one of said system elements is not in the expected operative state.

9. A system according to any one of the preceding claims, wherein the monitoring software component is arranged to process said data derived from said output signals in order to identify a state of the fluid processing system.

10. A system according to claim 9, including an outputting software component arranged to output data indicative of the identified state.

11. A system according to claim 10, wherein the outputting software component includes display means arranged to display the data indicative of the identified state.

12. A system according to claim 11, wherein the display means is arranged to display a natural language descriptor corresponding to said identified state.

13. A system according to any one of the preceding claims, wherein the fluid processing system includes: a heating device; a radiopharmaceutical delivery system comprising an output to a subject; a plurality of valves arranged to control the path of the delivery system; a dialyser; a pump for pumping the radiopharmaceutical around the delivery system; and at least one radioactivity detector arranged in the path of the radiopharmaceutical delivery path.

14. A system according to claim 13, wherein the fluid processing system is operable to output signals indicative of at least some of: temperature of heating device; energised status of the valves; flow rate through, and pressure applied by, the pump; radioactivity measured by radioactivity detector; and time elapsed since the process started.

15. A system according to claim 14, wherein the monitoring software component is arranged to identify which of the processes is currently being performed on the basis of data identifying the energised status of the valves.

16. A system according to any one of claim 13 to claim 15, wherein the monitoring software is arranged to compare data derived in respect of the pump pressure and data derived in respect of the flow rate with specified operating limits, and, in the event that one or both of the pressure and/or flow rate fall outside of the operating limits, to generate an alert.

17. A system according to any one of the preceding claims, wherein the radiopharmaceutical comprises ^{15}O-labelled water.

18. A computer program product arranged to perform at least some of the steps of:

generating a plurality of control signals for use in control of a fluid processing system;

transmitting said generated control signals to a plurality of system elements in the fluid processing system;

communicating data indicative of at least some of said generated control signals to a monitoring system;

processing the communicated data so as to identify expected operating states of said system elements;

receiving data indicative of operating states of said system elements;

comparing the received data against one or more predetermined conditions based on the expected operating states, and, in response to the received data indicating that one or more of the system elements is not in the expected state, transmitting data indicative thereof to the monitoring system.

19. A computer program product arranged to perform at least some of the steps of:

transmitting specified operating conditions to a controller for use in formulating control signals for controlling a fluid processing system;

receiving data indicative of a state of the fluid processing system;

evaluating said received data in accordance with specified conditions; and

generating user-perceptible output indicative of the evaluated data.

20. A radiopharmaceutical generation system comprising:

a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical, the fluid processing system having at least one actuator element capable of adopting a plurality of operating positions, the fluid processing system being arranged to determine a current operating position of

the actuator element and to output a signal indicative of the determined operating position; and

at least one monitoring software component arranged to process data derived from said output signal during execution of said one or more processes in order to identify a state of the fluid processing system.

21. A system according to claim 20, wherein said actuator elements include valve elements.

22. A radiopharmaceutical generation system comprising:

a fluid processing system arranged to perform one or more processes in relation to a radiopharmaceutical in accordance with a plurality of control signals, the fluid processing system having a plurality of system elements and being arranged to output signals indicative of a state of the fluid processing system, each of said system elements having an expected operative state;

a controller arranged to control the fluid processing system, the controller having at least one control software component arranged to generate at least some of said control signals;

a monitoring software component arranged to receive data in relation to the state of the radiopharmaceutical generation system,

wherein the controller is arranged to track the state of the radiopharmaceutical generation system during execution of said one or more processes and output data indicative of the same to the monitoring software component, the monitoring software component being arranged to compare said output data with one or more operating conditions in order to identify system elements not in the expected operative state.

23. A radioactivity detection system for use in relation to a radiopharmaceutical, the detection system comprising:

a fluid processing module arranged to receive a radioisotope and to generate a radiopharmaceutical therefrom;

a radiopharmaceutical delivery system arranged to deliver the generated radiopharmaceutical to a subject, the radiopharmaceutical delivery system comprising a delivery path operable between said fluid processing module and said subject; and

a radioactivity detector arranged to measure radioactivity in the delivery path and output a signal indicative thereof.

24. A radioactivity detection system according to claim 23, wherein the radioactivity detector is located along the delivery path at a distance of between 5% and 50% of the delivery path length from the subject, more preferably at a distance of between 7% and 12% of the delivery path length from the subject.

25. A radioactivity detection system according to claim 23 or claim 24, wherein the radioactivity detection system includes a processing system arranged to process said output signal.

26. A radioactivity detection system according to any one of claims 23 to 25, wherein the fluid processing module includes a module radioactivity detector therein, said module radioactivity detector being arranged to measure radioactivity in the fluid processing module and output a signal indicative thereof, wherein the processing system is arranged to process said output signal.

27. A radioactivity detection system according to claim 26, wherein the processing system is arranged to compare signals received from the radioactivity detector and said module radioactivity detector.

28. A radioactivity detection system according to claim 27, wherein an output signal comprises a plurality of signal components, and, for at least one such signal component received from the module radioactivity detector, the

processing system is arranged to identify a corresponding component in the signal received from the radioactivity detector.

29. A radioactivity detection system according to claim 27 or claim 28, wherein, for at least one such signal component received from the module radioactivity detector, the processing system is arranged to identify the temporal delay between detection thereof and detection of a corresponding component in the signal received from the radioactivity detector.

30. A radioactivity detection system according to any one of claim 26 to claim 29, wherein the processing system is arranged to receive data indicative of distance between the radioactivity detector and said module radioactivity detector.

31. A radioactivity detection system according to claim 30 when dependent on any one of claim 27 to claim 29, wherein, for any signal component of the signal received from the radioactivity detector, the processing system is arranged to estimate an expected delay in occurrence thereof in relation to a corresponding component of the signal received from the module radioactivity detector, based on the distance data, and to compare the identified temporal delay corresponding to the signal component with the estimated delay.

32. A radioactivity detection system according to claim 30 or claim 31 when claim 30 is dependent on any one of claim 27 to claim 29, wherein, for any signal component of the signal received from the module radioactivity detector, the processing system is arranged to estimate an expected radioactivity value, based on the half-life of the radioisotope and the distance data, and to compare the signal component with the estimated radioactivity value.

33. A radioactivity detection system according to any one of claim 23 to claim 32, wherein the fluid processing module includes: a heating device;

a plurality of valves arranged to control the path of the delivery system; a dialyser; and a pump for pumping the radiopharmaceutical around the delivery system.

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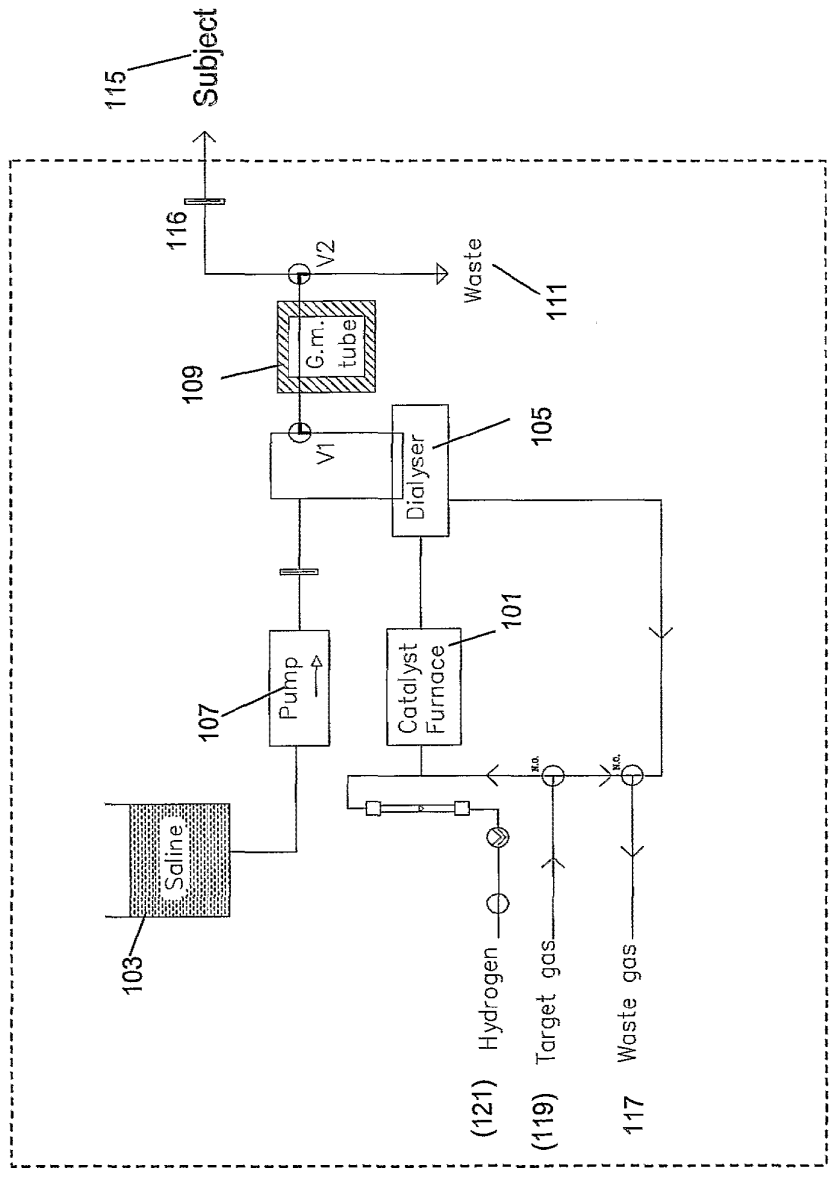

Figure 1

PRIOR ART

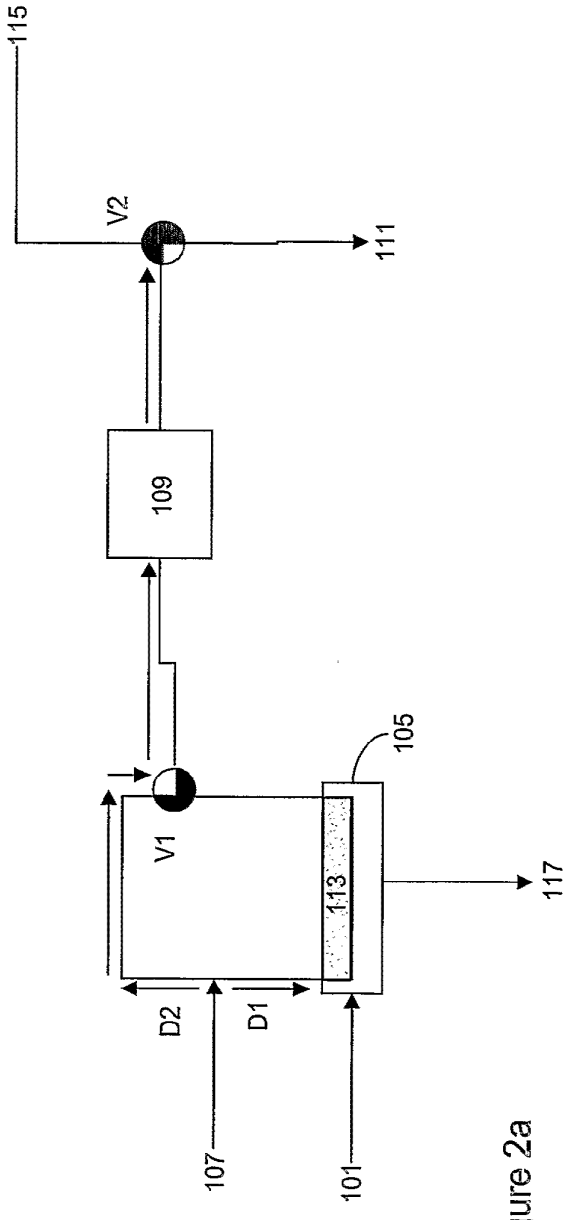

Figure 2a

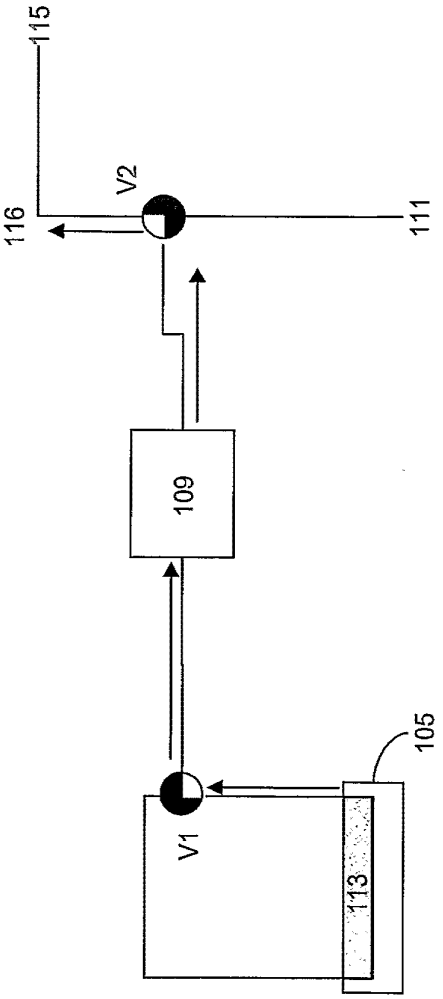

Figure 2b

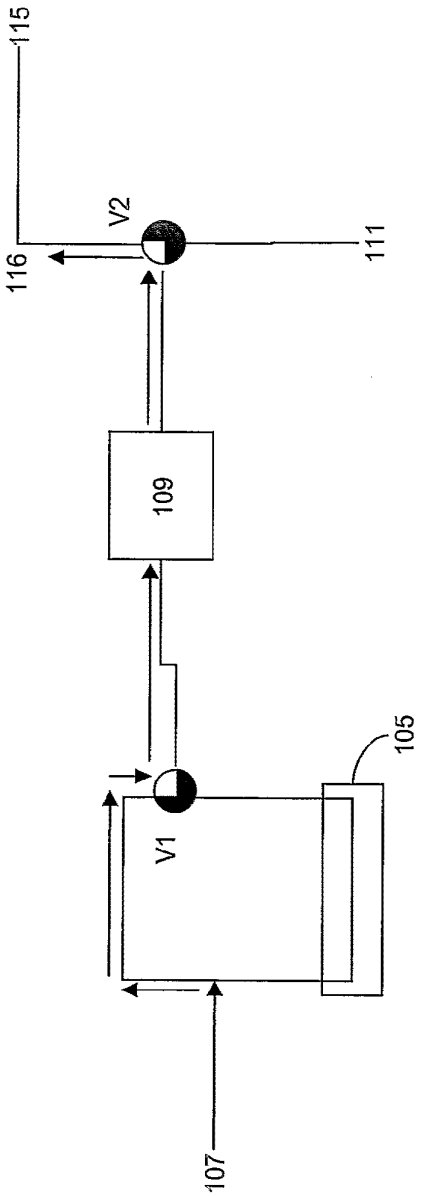

Figure 2c

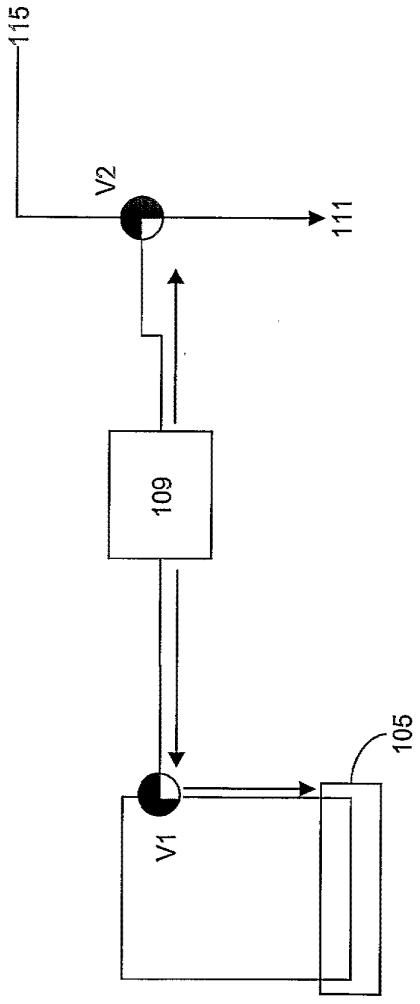

Figure 2d

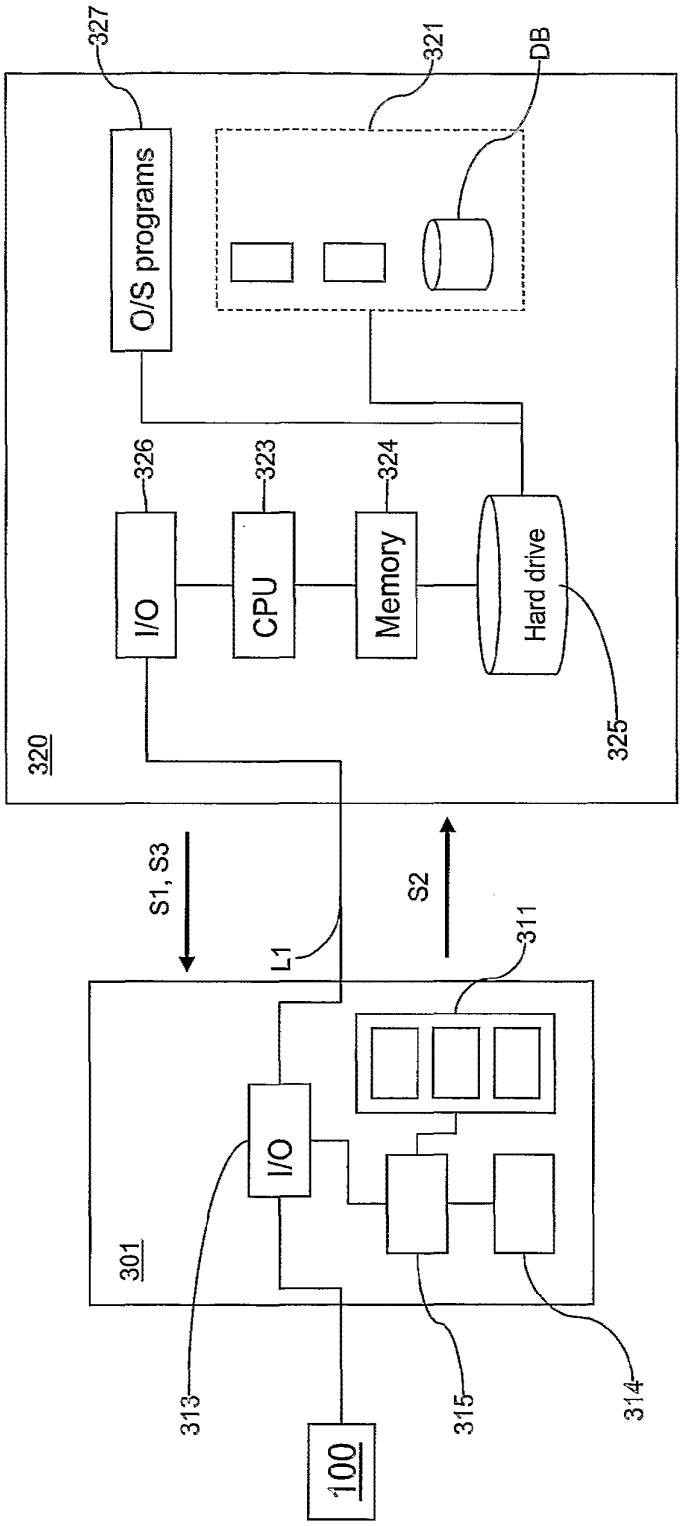
327
321
DB
O/S programs
326
323
324
I/O
CPU
Memory
Hard drive
325
320
S1, S3
S2
L1
311
I/O
301
313
315
314
100

Figure 3

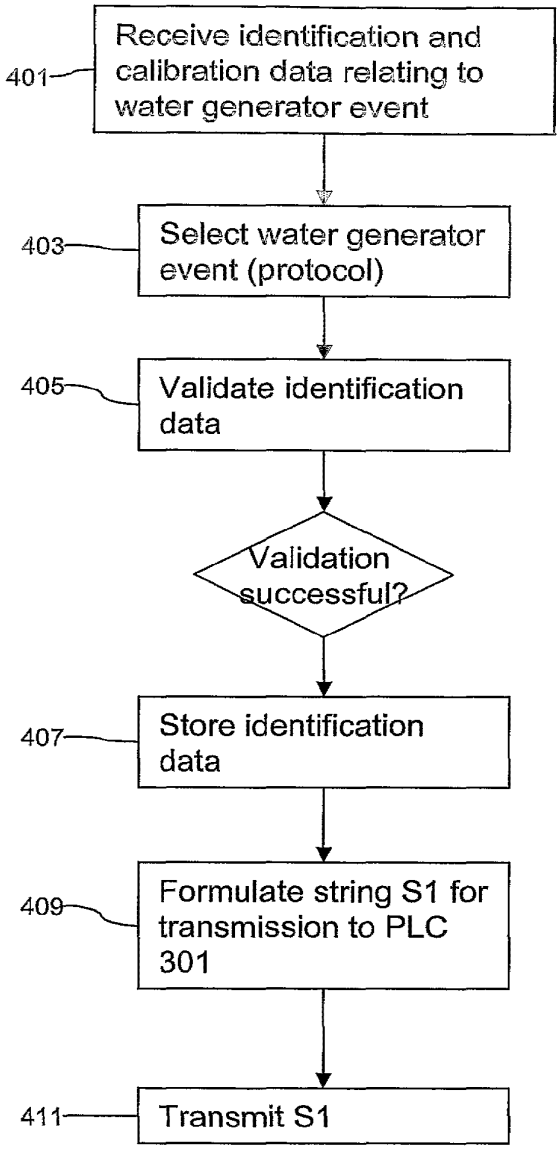
Receive identification and calibration data relating to water generator event
401
Select water generator event (protocol)
403
Validate identification data
405
Validation successful?
Store identification data
407
Formulate string S1 for transmission to PLC 301
409
Transmit S1
411

Figure 4

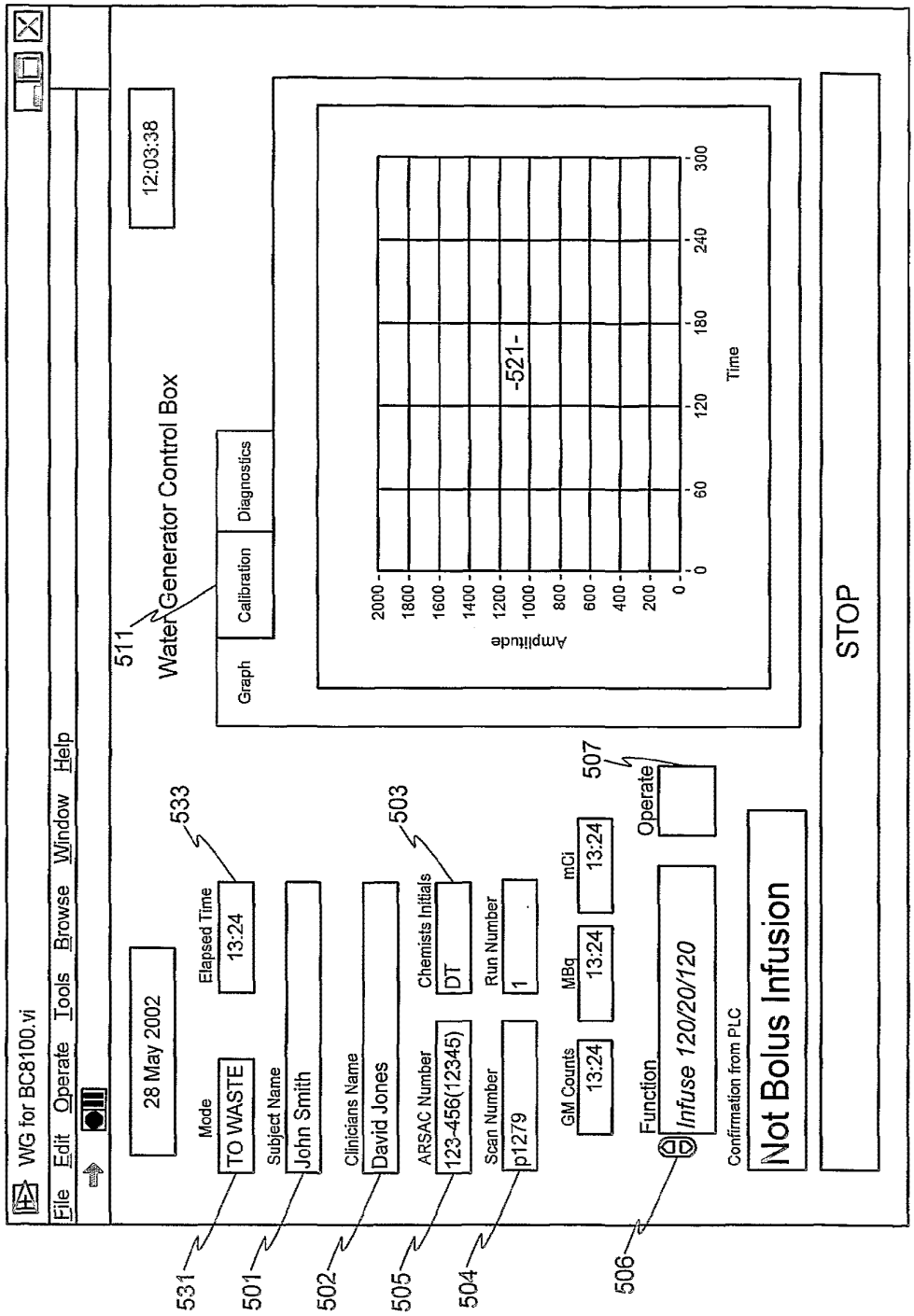
WG for BC8100.vi
File Edit Operate Tools Browse Window Help
28 May 2002
12:03:38
Water Generator Control Box
511
Graph
Calibration
Diagnostics
Amplitude
Time
-521-
STOP
Mode
TO WASTE
Elapsed Time
13:24
533
Subject Name
John Smith
Clinicians Name
David Jones
ARSAC Number
123-456(12345)
Chemists Initials
DT
503
Scan Number
p1279
Run Number
1
GM Counts
13:24
MBq
13:24
mCi
13:24
507
Operate
Function
Infuse 120/20/120
Confirmation from PLC
Not Bolus Infusion
531
501
502
505
504
506

Fig. 5

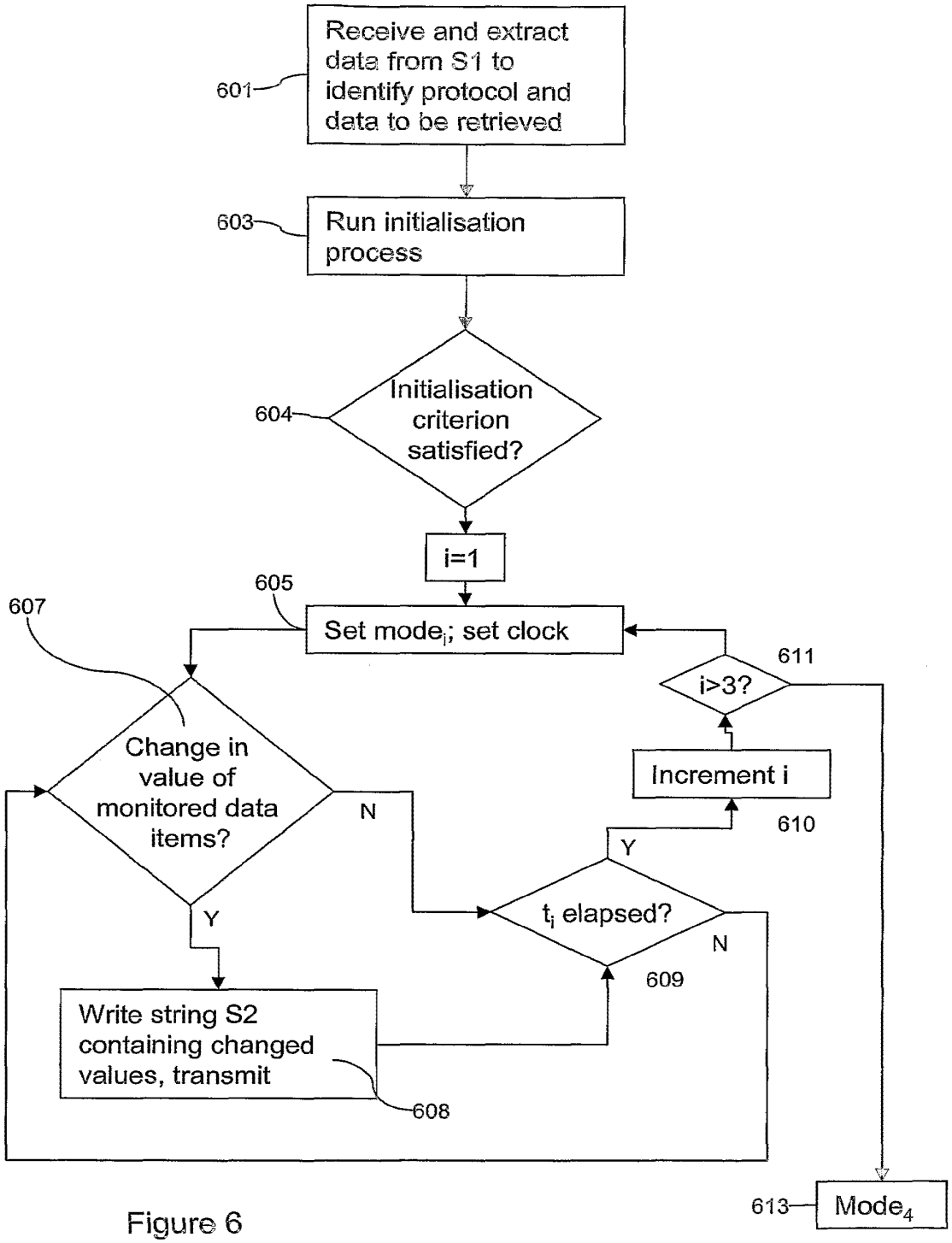
Receive and extract data from S1 to identify protocol and data to be retrieved
601
Run initialisation process
603
Initialisation criterion satisfied?
604
i=1
Set mode$_i$; set clock
605
607
Change in value of monitored data items?
N
Y
t_i elapsed?
N
Y
609
Increment i
610
i>3?
611
Write string S2 containing changed values, transmit
608
Mode$_4$
613

Figure 6

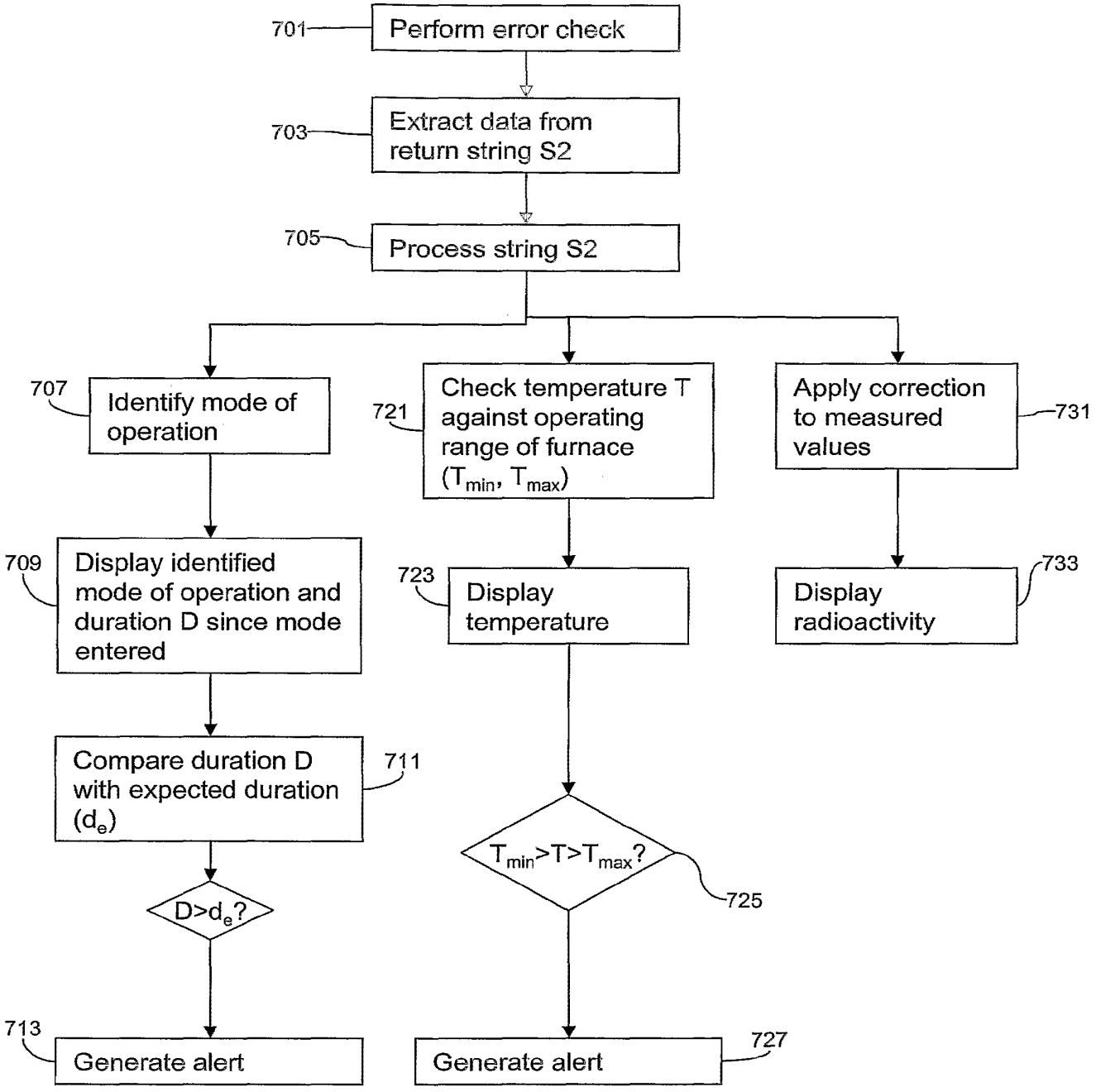
701
Perform error check
703
Extract data from return string S2
705
Process string S2
707
Identify mode of operation
721
Check temperature T against operating range of furnace (T_{min}, T_{max})
731
Apply correction to measured values
709
Display identified mode of operation and duration D since mode entered
723
Display temperature
733
Display radioactivity
Compare duration D with expected duration (d_e)
711
$D>d_e$?
$T_{min}>T>T_{max}$?
725
713
Generate alert
727
Generate alert

Figure 7

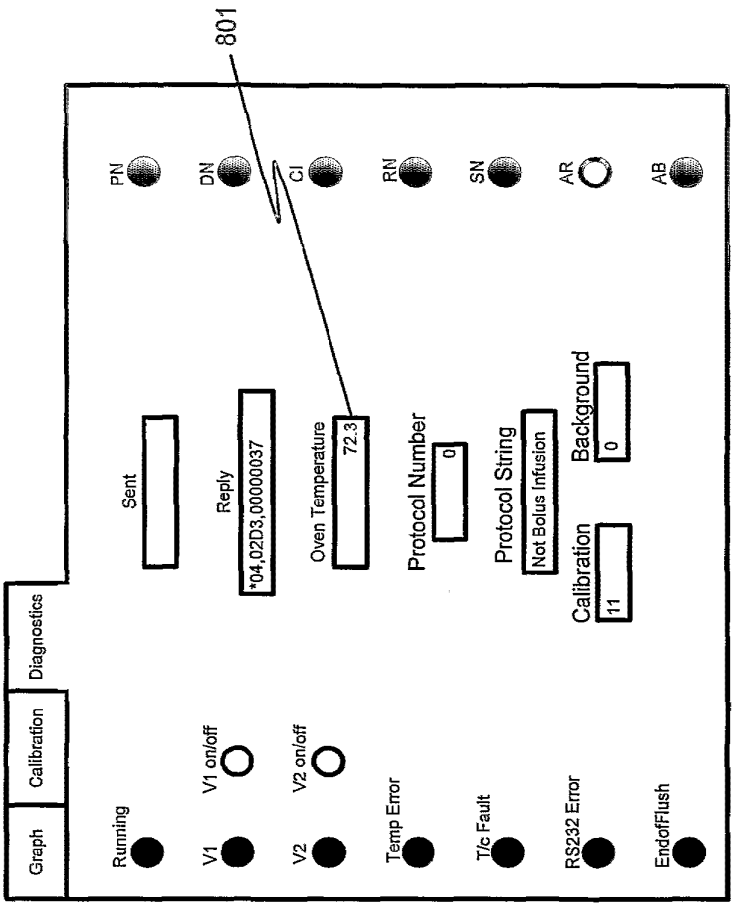
801
Graph
Calibration
Diagnostics
Running
V1
V1 on/off
V2
V2 on/off
Temp Error
T/c Fault
RS232 Error
EndofFlush
Sent
Reply
*04,02D3,00000037
Oven Temperature
72.3
Protocol Number
0
Protocol String
Not Bolus Infusion
Calibration
11
Background
0
PN
DN
CI
RN
SN
AR
AB

Fig. 8

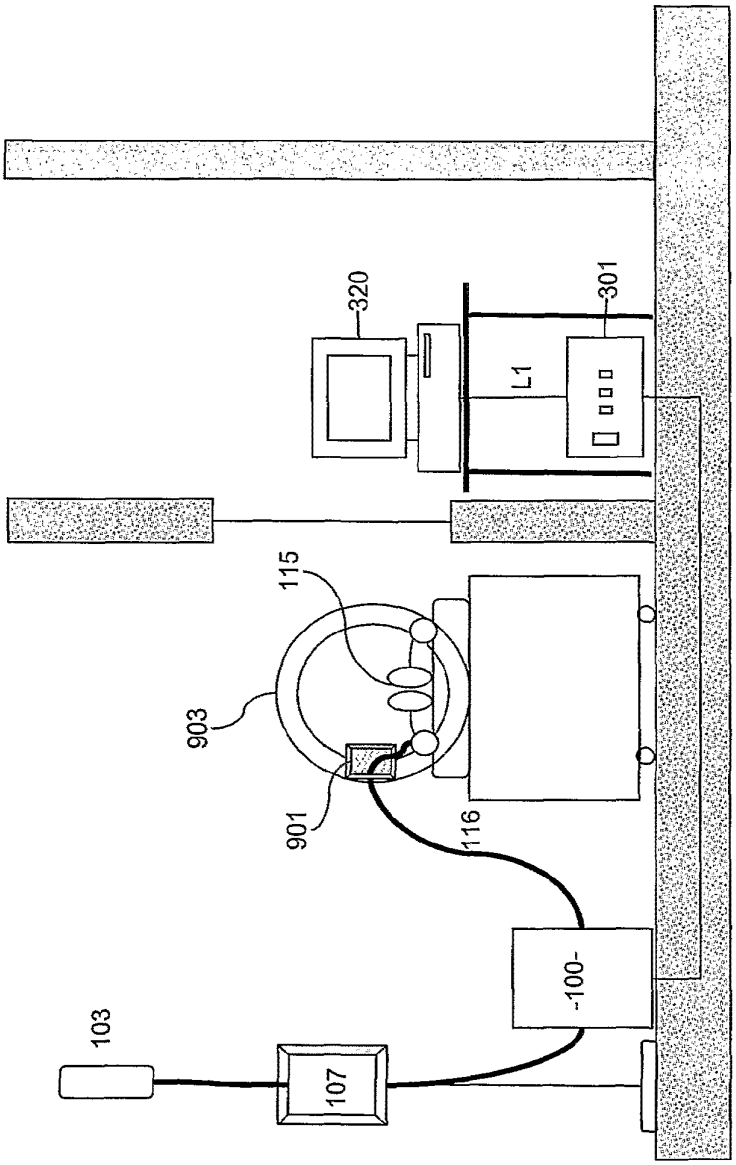

Figure 9

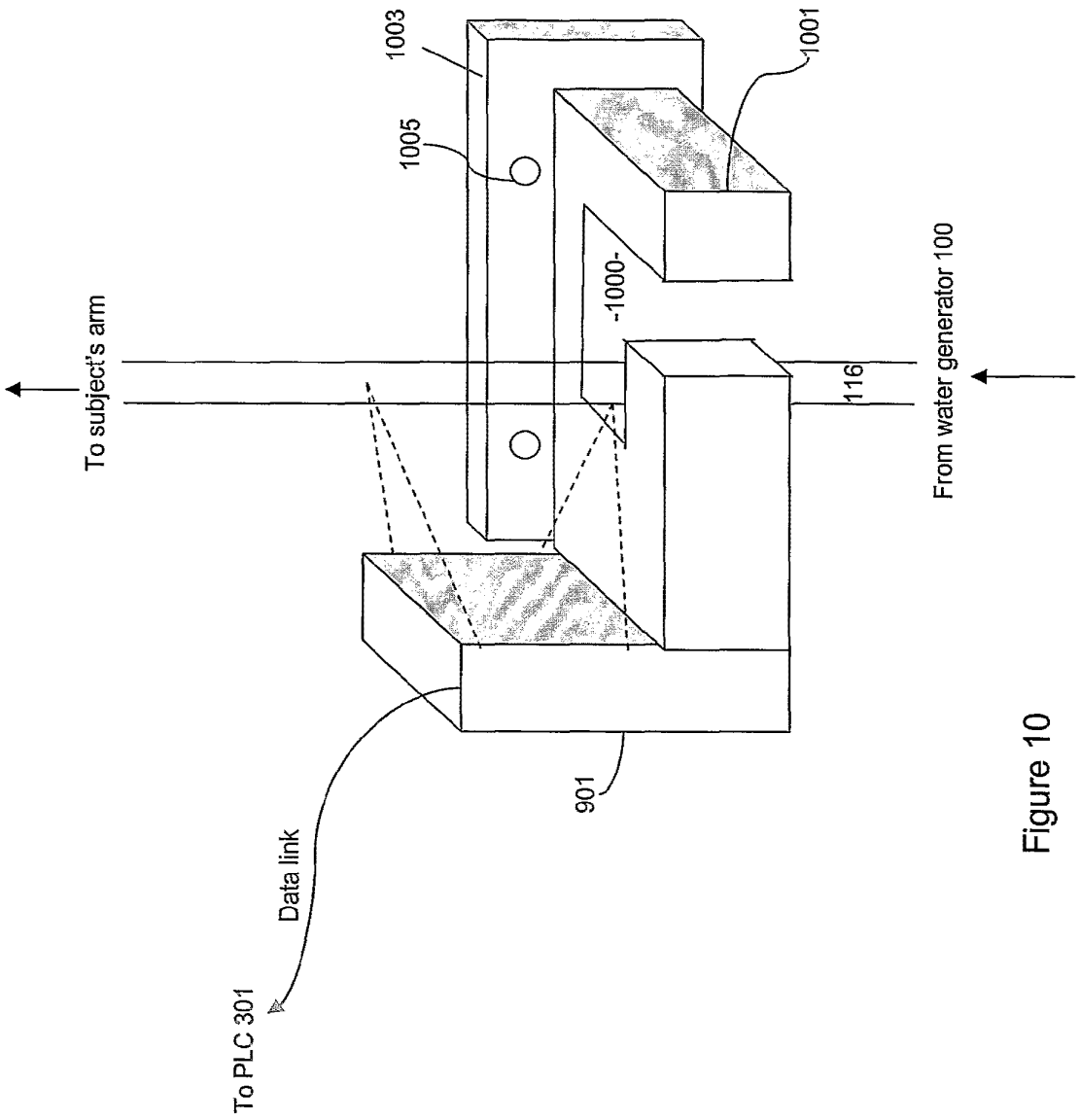
1003
1001
1005
-1000-
To subject's arm
From water generator 100
116
901
Data link
To PLC 301

Figure 10

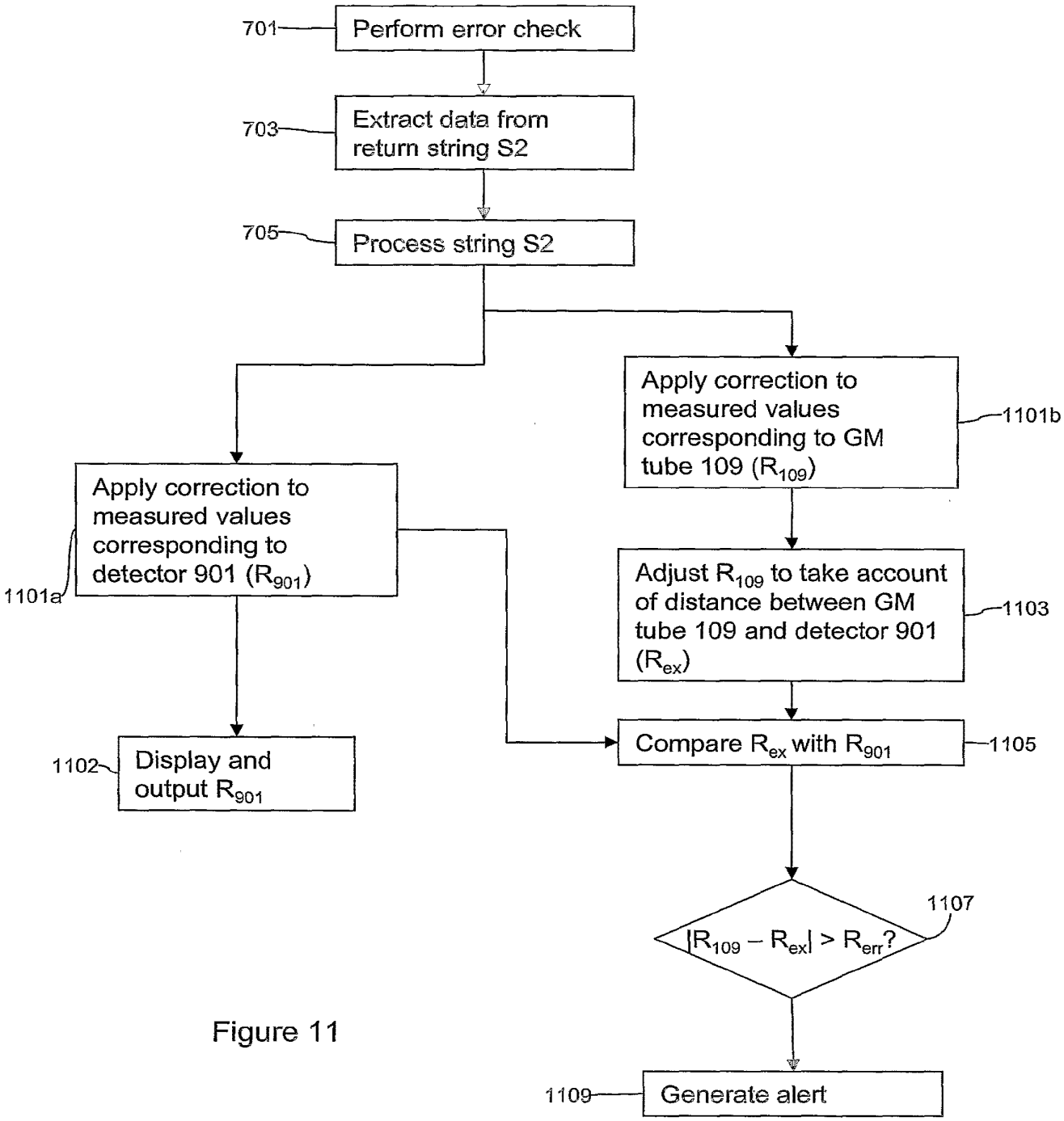
701
Perform error check
703
Extract data from return string S2
705
Process string S2
Apply correction to measured values corresponding to GM tube 109 (R_{109})
1101b
Apply correction to measured values corresponding to detector 901 (R_{901})
1101a
Adjust R_{109} to take account of distance between GM tube 109 and detector 901 (R_{ex})
1103
1102
Display and output R_{901}
Compare R_{ex} with R_{901}
1105
1107
$|R_{109} - R_{ex}| > R_{err}$?
1109
Generate alert

Figure 11

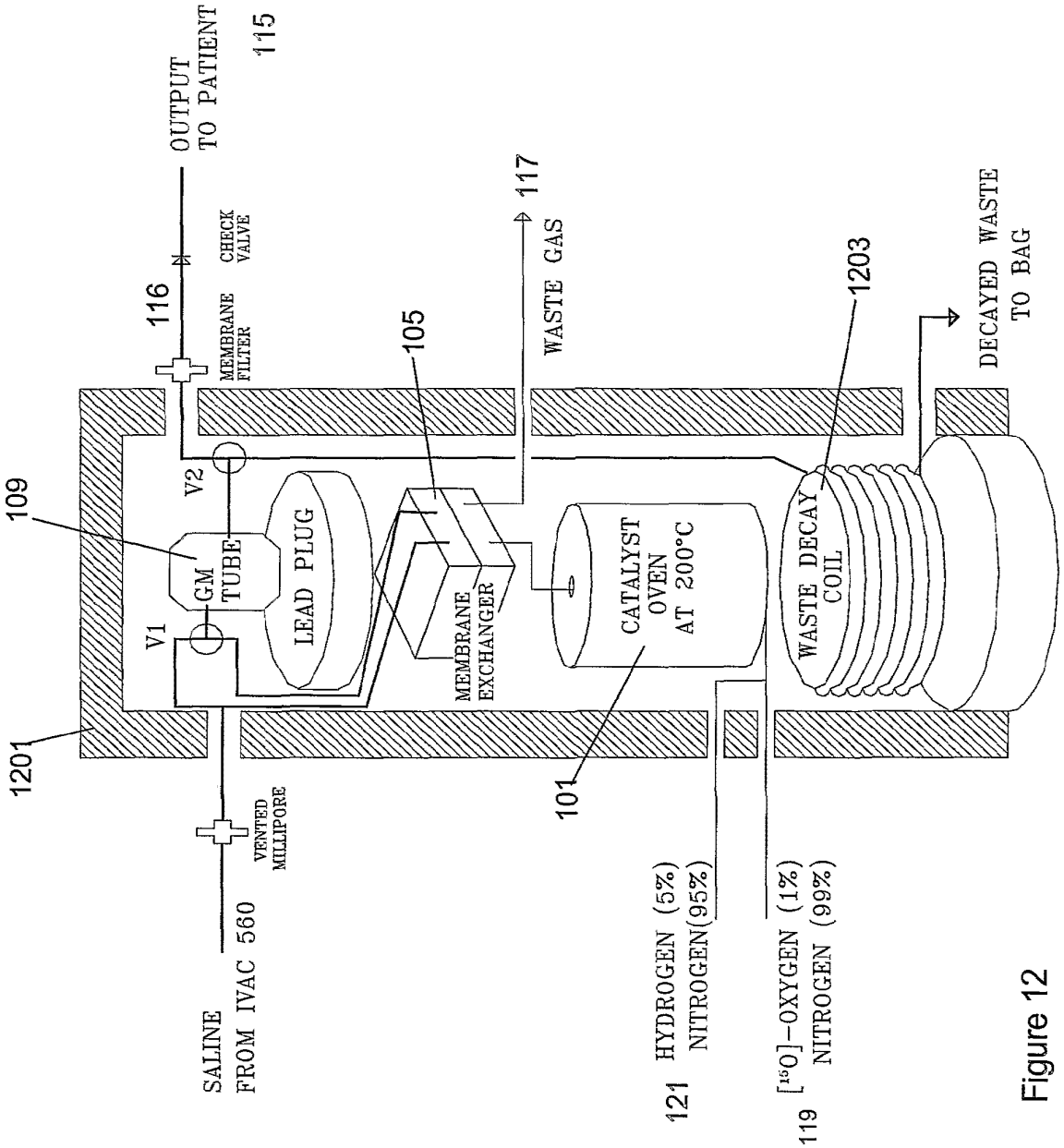
OUTPUT
TO PATIENT
115
CHECK
VALVE
116
MEMBRANE
FILTER
117
WASTE GAS
105
1203
DECAYED WASTE
TO BAG
109
V2
GM
TUBE
LEAD PLUG
V1
MEMBRANE
EXCHANGER
CATALYST
OVEN
AT 200°C
WASTE DECAY
COIL
1201
101
VENTED
MILLIPORE
SALINE
FROM IVAC 560
121
HYDROGEN (5%)
NITROGEN(95%)
119
[15O]-OXYGEN (1%)
NITROGEN (99%)

Figure 12

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition fee- 37 CFR 1.17(h) (Group III)	1464	1	140	140
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1840**

Electronic Acknowledgement Receipt

EFS ID:	26522160
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Sarah Munson
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	02-AUG-2016
Filing Date:	16-JUN-2010
Time Stamp:	16:12:24
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1840
RAM confirmation Number	080316INTEFSW16124700
Deposit Account	9797
Authorized User	Paul LaVanway
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition to Withdraw from Issue	56782_1_7_2_Petition_Withdraw.pdf	87659 9f3bbe5c19616cd303e91429e1f3cdf4cb3cdf35	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_SIDS.pdf	1007237 e482ccabe10b613625cc2b775167f680579e2b2c	no	4
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	56782_1_7_2_RCE.pdf	1363979 7c4b2afc041d098b127df2b562f5ba35e2e62daf	no	3
Warnings:					
Information:					
4	Foreign Reference	FR_EP0317114A1.PDF	839941 82fe4990403049125796a073a4f13b81ab155433	no	12
Warnings:					
Information:					
5	Foreign Reference	FR_WO2004080523A2.PDF	1927387 7fe344a0144daf92b13f8ecdf4cefdcf0a038bef	no	45
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	32684 96997ebe0ad617e9df0ad996b551a19c220597f2	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	5258887

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R Dorna
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3576998	A	1971-05-04	Deutsch et al.	
	2	5166526	A	1992-11-24	Dietzel	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060164093	A1	2006-07-27	Ooe et al.	
	2	20070226175	A1	2007-09-27	Resnic et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	317114	EP	A1	1989-05-24	OROS SYSTEMS LTD		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Carrie R Dorna
	Attorney Docket Number	56782.1.7.2

	2	2004080523	WO	A2	2004-09-23	HAMMERSMITH IMANET LTD		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Carrie R Dorna
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2016-08-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Receipt date: 12/16/2011	Application Number	12808467	12808467 - GAU: 4157
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2010-06-16	
(Not for submission under 37 CFR 1.99)	First Named Inventor	STEPHEN E. HIDEM	
	Art Unit	3768	
	Examiner Name	CATTUNGAL, SANJAY	
	Attorney Docket Number	56782.1.7.2	

	4	20090312630		2009-12-17	Hidem		
	5	20090318745		2009-12-24	Quirico		
	6	20100125243		2010-05-20	Balestracci		
	7	20100270226		2010-10-28	Balestracci		
	8	20100312039		2010-12-09	Quirico		
	9	20110071392		2011-03-24	Quirico		
	10	20060151048		~~2005-12-27~~ 07/2006	Tochon-Danguy		

Change(s) applied to document, /M.P.F./ 7/8/2016

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0919249	EP		1999-06-02	NISSHO KK		☐
	2	1421960	EP		2004-05-26	GVS S P A		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22859 7590 04/20/2016
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

TITLE OF INVENTION: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/20/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
DORNA, CARRIE R	3735	600-004000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Fredrikson & Byron, P.A.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: BRACCO DIAGNOSTICS INC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): PRINCETON, NEW JERSEY

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
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☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 06-1910 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Paul J. LaVanway, Jr./ Date July 20, 2016
Typed or printed name Paul J. LaVanway, Jr. Registration No. 64,610

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	26404039
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	20-JUL-2016
Filing Date:	16-JUN-2010
Time Stamp:	19:04:11
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$960
RAM confirmation Number	072116INTEFSW19050101
Deposit Account	9797
Authorized User	Paul LaVanway
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Post Allowance Communication - Incoming	56782_1_7_2_Bracco_ReasonsforAllowance.pdf	85274 e9180a6bcfde4d7c6590363a0a91273bcb12d543	no	1
Warnings:					
Information:					
2	Change of Address	56782_1_7_2_Bracco_FeeAddressForm.pdf	203796 38481a79302fe60e039558d3520e7875f0f2a659	no	2
Warnings:					
Information:					
3	Issue Fee Payment (PTO-85B)	Bracco_IssueFeeTransmittal.pdf	205965 e2bff610bd15f6da6bb5bf2098d8b44d74f54a21	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30699 31157e1184c14e06adfdda5f8d0f235eb0d799c7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	525734		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

22859
Customer Number

Patent
Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Carrie R. Dorna
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mailstop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Dear Commissioner:

Applicant has reviewed the Examiner's Statement of Reasons for Allowance accompanying the Notice of Allowance mailed April 20, 2016. Applicant does not acquiesce in the stated reasons for allowance.

Applicant agrees with the Examiner that the claims are allowable over the prior art. Applicant points out, however, that the claims require multiple limitations not taught or suggested by the prior art and that the claims are allowable for at least the reasons set forth in Applicant's previous communications.

Applicant respectfully requests that the Examiner place the preceding comments into the prosecution record prior to issuance of the above-identified application. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Dated: July 20, 2016

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

59027420_1.docx

PTO/SB/47 (03-09)
Approved for use through 05/31/2015. OMB 0651-0016
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below**: If you have a Customer Number to represent the fee address. **When to check the second box below**: If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☑ Customer Number: 31834

OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
	12/808,467

Completed by (check one):

☐ Applicant/Inventor — /Paul J. LaVanway, Jr./ (Signature)

☑ Attorney or Agent of record 64610 (Reg. No.) — Paul J. LaVanway, Jr. (Typed or printed name)

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) — 612-492-7387 (Requester's telephone number)

☐ Assignee recorded at Reel _____ Frame_____ — _____ (Date)

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more that one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.363. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1. 11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313- 1450. DO NOT SEND COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Mail Stop M Correspondence, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/808,467	06/16/2010	3735	2356	56782.1.7.2	38	5

CONFIRMATION NO. 3733

CORRECTED FILING RECEIPT

22859
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

OC000000084181823

Date Mailed: 07/07/2016

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Stephen E. Hidem, Plymouth, MN;
Aaron M. Fontaine, Fridley, MN;
Janet L. Gelbach, New Albany, IN;
Patrick M. McDonald, Omaha, NE;
Kathryn M. Hunter, Knoxville, TN;
Rolf E. Swenson, Princeton, NJ;
Julius P. Zodda, Mercerville, NJ;

Applicant(s)

Stephen E. Hidem, Plymouth, MN;
Aaron M. Fontaine, Fridley, MN;
Janet L. Gelbach, New Albany, IN;
Patrick M. McDonald, Omaha, NE;
Kathryn M. Hunter, Knoxville, TN;
Rolf E. Swenson, Princeton, NJ;
Julius P. Zodda, Mercerville, NJ;

Assignment For Published Patent Application

BRACCO DIAGNOSTICS INC., Princeton, NJ

Power of Attorney: The patent practitioners associated with Customer Number 22859

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US09/47031 06/11/2009
which is a CON of 12/137,356 06/11/2008 PAT 8317674
and is a CON of 12/137,363 06/11/2008 PAT 7862534
and is a CON of 12/137,364 06/11/2008
and is a CON of 12/137,377 06/11/2008 PAT 8708352

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: No

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 04/01/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/808,467**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/808,467	06/16/2010		2356	56782.1.7.2	38	5

CONFIRMATION NO. 3733

CORRECTED FILING RECEIPT

22859
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

OC00000047345354

Date Mailed: 04/26/2011

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

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Rolf E. Swenson, Princeton, NJ;
Julius P. Zodda, Mercerville, NJ;

Assignment For Published Patent Application

BRACCO DIAGNOSTICS INC., Princeton, NJ

Power of Attorney: The patent practitioners associated with Customer Number 22859

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US09/47031 06/11/2009

~~**Foreign Applications** (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)~~

~~UNITED STATES OF AMERICA 12/137364 06/11/2008~~
~~UNITED STATES OF AMERICA 12/137377 06/11/2008~~
~~UNITED STATES OF AMERICA 12/137363 06/11/2008~~
~~UNITED STATES OF AMERICA 12/137356 06/11/2008~~

(Domestic Priority data as claimed by applicant cont.)
which is a CON of 12/137,356 06/11/2008 PAT 8317674
and is a CON of 12/137,363 06/11/2008 PAT 7862534
and is a CON of 12/137,364 06/11/2008
and is a CON of 12/137,377 06/11/2008 PAT 8708352

If Required, Foreign Filing License Granted: 04/01/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/808,467**

Projected Publication Date: 07/14/2011

Non-Publication Request: No

Early Publication Request: No
Title

INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO/SB/14 (11-08)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Stephen	E.	Hidem	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Plymouth	State/Province	MN	Country of Residence	US

Citizenship under 37 CFR 1.41(b)	US

Mailing Address of Applicant:

Address 1	4710 Juneau Lane North
Address 2	

City	Plymouth	State/Province	MN
Postal Code	55446	Country	US

Applicant 2

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Aaron	M.	Fontaine	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Fridley	State/Province	MN	Country of Residence	US

Citizenship under 37 CFR 1.41(b)	US

Mailing Address of Applicant:

Address 1	5663 West Bavarian Pass
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City	Fridley	State/Province	MN
Postal Code	55432	Country	US

Applicant 3

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Janet	L.	Gelbach	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	New Albany	State/Province	IN	Country of Residence	US

Supplemental

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Citizenship under 37 CFR 1.41(b)	US		
Mailing Address of Applicant:			
Address 1	4204 Shetland Court		
Address 2			
City	New Albany	**State/Province**	IN
Postal Code	47150	**Country**	US

Applicant 4

Applicant Authority (●) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Patrick	M.	McDonald	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Omaha	**State/Province**	NE	**Country of Residence**	US
Citizenship under 37 CFR 1.41(b)	US				

Mailing Address of Applicant:			
Address 1	15395 Nicholas Street		
Address 2			
City	Omaha	**State/Province**	NE
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Applicant 5

Applicant Authority (●) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kathryn	M.	Hunter	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Knoxville	**State/Province**	TN	**Country of Residence**	US
Citizenship under 37 CFR 1.41(b)	US				

Mailing Address of Applicant:			
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Address 2			
City	Knoxville	**State/Province**	TN
Postal Code	37931	**Country**	US

Applicant 6

Applicant Authority (●) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Rolf	E.	Swenson	

Residence Information (Select One) (●) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Princeton	**State/Province**	NJ	**Country of Residence**	US
Citizenship under 37 CFR 1.41(b)	US				

PTO/SB/14 (11-08)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Mailing Address of Applicant:			
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Postal Code	08540	Country	US

Applicant 7

Applicant Authority	(●) Inventor	( ) Legal Representative under 35 U.S.C. 117	( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Julius	P.	Zodda	

Residence Information (Select One)	(●) US Residency	( ) Non US Residency	( ) Active US Military Service		
City	Mercerville	State/Province	NJ	Country of Residence	US
Citizenship under 37 CFR 1.41(b)	US				

Mailing Address of Applicant:			
Address 1	3 Tigers Court		
Address 2			
City	Mercerville	State/Province	NJ
Postal Code	08619	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	22859		
Email Address	IP@fredlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		
Attorney Docket Number	56782.1.7.2	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	27	Suggested Figure for Publication (if any)	

Supplemental

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	22859		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12808467	a 371 of international	PCT/US2009/047031	2009-06-11

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCT/US2009/047031	Continuation of	12137356	2008-06-11	8317674	2012-11-27

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCT/US2009/047031	Continuation of	12137363	2008-06-11	7862534	2011-01-04

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2009/047031	Continuation of	12137364	2008-06-11

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCT/US2009/047031	Continuation of	12137377	2008-06-11	8708352	2014-04-29

Supplemental

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country[i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			○ Yes ◉ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

If the Assignee is an Organization check here. ☒

Organization Name	Bracco Diagnostics Inc.		
Mailing Address Information:			
Address 1	107 College Road East		
Address 2			
City	Princeton	**State/Province**	NJ
Country[i]	US	Postal Code	08540
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button.

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Elisabeth Lacy Belden/			Date (YYYY-MM-DD)	2010-06-16
First Name	Elisabeth Lacy	Last Name	Belden	Registration Number	50751

Supplemental

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.2
	Application Number	12/808,467
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 December 2009 (17.12.2009)

PCT

(10) International Publication Number
WO 2009/152323 A2

(51) International Patent Classification:
A61M 5/00 (2006.01) *A61M 5/14* (2006.01)

(21) International Application Number:
PCT/US2009/047031

(22) International Filing Date:
11 June 2009 (11.06.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

12/137,364	11 June 2008 (11.06.2008)	US
12/137,377	11 June 2008 (11.06.2008)	US
12/137,363	11 June 2008 (11.06.2008)	US
12/137,356	11 June 2008 (11.06.2008)	US

(71) Applicant *(for all designated States except US)*: **BRACCO DIAGNOSTICS INC.** [US/US]; 107 College Road East, Princeton, NJ 08540 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ZODDA, Julius, P.** [US/US]; 3 Tigers Court, Mercerville, NJ 08619 (US). **HUNTER, Kathryn, M.** [US/US]; 1312 Judy Reagan Lane, Knoxville, TN 37931 (US). **SWENSON, Rolf, E.** [US/US]; 35 Fieldston Road, Princeton, NJ 08540 (US). **FONTAINE, Aaron, M.** [US/US]; 5663 West Bavarian Pass, Fridley, MN 55432 (US). **HIDEM, Stephen, E.** [US/US]; 4710 Juneau Lane North, Plymouth, MN 55446 (US). **MCDONALD, Patrick, M.** [US/US]; 15395 Nicholas Street, Omaha, NE 68154 (US). **GELBACH, Janet, L.** [US/US]; 4204 Shetland Court, New Albany, IN 47150 (US).

(74) Agents: **BELDEN, Elisabeth, L.** et al.; Fredrikson & Byron, P.A., 200 South Sixth Street, Suite 4000, Minneapolis, MN 55402-1425 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

(57) **Abstract**: Methods for setting up, maintaining and operating a radiopharmaceutical infusion system, that includes a radioisotope generator, are facilitated by a computer of the system. The computer includes pre-programmed instructions and a computer interface, for interaction with a user of the system, for example, in order to track contained volumes of eluant and/or eluate, and/or to track time from completion of an elution performed by the system, and/or to calculate one or more system and/or injection parameters for quality control, and/or to perform purges of the system, and/or to facilitate diagnostic imaging.

WO 2009/152323 A2

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/US09/47031

International Application No.

11 JUNE 2009 (11/06/09)

International Filing Date

PCT INTERNATIONAL APPLICATION RO/US

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 56782.1.7.1

Box No. I TITLE OF INVENTION

INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Box No. II APPLICANT ☐ This person is also inventor

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BRACCO DIAGNOSTICS, INC.
107 College Road East
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US

Telephone No.
(609) 514-2252

Facsimile No.
(609) 514-2429

Applicant's registration No. with the Office

☐ **E-mail authorization**: Marking this check-box authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, if the Office or Authority so wishes, advance copies of notifications in respect of this international application. *(See also the Notes to Boxes Nos. II and III.)*

E-mail address

State *(that is, country)* of nationality:
US

State *(that is, country)* of residence:
US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

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Agent's registration No. with the Office
50,751

☒ **E-mail authorization**: Marking this check-box authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, if the Office or Authority so wishes, advance copies of notifications in respect of this international application. *(See also the Notes to Boxes Nos. II and III.)*

E-mail address
IP@fredlaw.com

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HIDEM, Stephen E.
4710 Juneau Lane North
Plymouth, Minnesota 55446
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

FONTAINE, Aaron M.
5663 West Bavarian Pass
Fridley, Minnesota 55432
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

GELBACH, Janet L.
4204 Shetland Court
New Albany, Indiana 47150
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

McDONALD, Patrick M.
15395 Nicholas Street
Omaha, Nebraska 68154
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HUNTER, Kathryn M.
1312 Judy Reagan Lane
Knoxville, Tennessee 37931
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SWENSON, Rolf E.
35 Fieldston Road
Princeton, New Jersey 08540
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

ZODDA, Julius P.
3 Tigers Court
Mercerville, New Jersey 08619
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1. *If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided,* ***the space is insufficient*** *to furnish all the information: in such case, write "Continuation of Box No...." (indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*

   (i) ***if more than one person is to be indicated as applicant and/or inventor*** *and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;*

   (ii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the indication* ***"the States indicated in the Supplemental Box"*** *is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*

   (iii) *if, in Box No. II or in any of the sub-boxes of Box No. III,* ***the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America****: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*

   (iv) *if, in addition to the agent(s) indicated in Box No. IV, there are* ***further agents****: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*

   (v) *if, in Box No. VI, there are* ***more than four earlier applications whose priority is claimed****: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*

2. *If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication "****patent of addition,****" "****certificate of addition,****" "****inventor's certificate of addition****" or "****utility certificate of addition,****" the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other parent grant or the date of filing of the parent application (Rules 4.11(a)(i) and 49bis.1(a) or (b)).*

3. *If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication "****continuation****" or "****continuation-in-part****" and the number and the filing date of the parent application (Rules 4.11(a)(ii) and 49bis.1(d)).*

Continuation of Box No. IV:

BELDEN, Elisabeth L., Reg. No. 50,751
CHICOINE, Caroline G., Reg. No. 38,198
DOLAN, John F., Reg. No. 45,382;
FAIRBAIRN, Kara K., Reg. No. 49,079;
FELLER, Michael J., Reg. No. 59,296;
GOLDMAN, Philip M., Reg. No. 31,162
GRAHAM, Matthew J.S., Reg. No. 54,647
HALLER, James R., Reg. No. 24,906;
HIPKINS, Thomas R., Reg. No. 57,659
KADIEVITCH, Natalie D., Reg. No. 34,196;
KLEPINSKI, Robert, Reg. No. 30,187
McMASTERS, Thomas L. Reg. No. 45,593;
MENDOZA, Mia E., Reg. No. 56,688
NEBLETT, Adonis A., Reg. No. 32,358;
PARZYCH, John S., Reg. No. 52,097;
SEGELBAUM, Charles D., Reg. No. 42,138;
SNUSTAD, Eric J., Reg. No. 45,120;
WEST, David C., Reg. No. 35,735

all of:

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, Minnesota 55402-1425
US

Box No. V DESIGNATIONS

The filing of this request **constitutes under Rule 4.9(a) the designation** of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.

However,

☐ DE Germany **is not designated** for any kind of national protection

☐ JP Japan **is not designated** for any kind of national protection

☐ KR Republic of Korea **is not designated** for any kind of national protection

☐ RU Russian Federation **is not designated** for any kind of national protection

(The check-boxes above may only be used to exclude (irrevocably) the designations concerned if, at the time of filing or subsequently under Rule 26bis.1, the international application contains in Box No. VI a priority claim to an earlier national application filed in the particular State concerned, in order to avoid the ceasing of the effect, under the national law, of this earlier national application.)

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application: regional Office	international application: receiving Office
item (1) (11.06.2008) 11 June 2008	12/137,356	US		
item (2) (11.06.2008) 11 June 2008	12/137,363	US		
item (3) (11.06.2008) 11 June 2008	12/137,364	US		
item (4) (11.06.2008) 11 June 2008	12/137,377	US		

☐ Further priority claims are indicated in the Supplemental Box.

Transmit certified copy: the receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ other, see Supplemental Box

Restore the right of priority: the receiving Office is requested to restore the right of priority for the earlier application(s) identified above or in the Supplemental Box as item(s) (_____). *(See also the Notes to Box No. VI; further information **must** be provided to support a request to restore the right of priority.)*

Incorporation by reference: where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if more than one International Searching Authority is competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA/ EP

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains**:

(a) **on paper,** the following number of sheets:

request (including declaration and supplemental sheets)	:	6
description (excluding sequence listing and/or tables related thereto)	:	34
claims	:	11
abstract	:	1
drawings	:	27
Sub-total number of sheets	:	79
sequence listing	:	
tables related thereto	:	
(for both, actual number of sheets if filed on paper, whether or not also filed in electronic form; see (c) below)		
Total number of sheets	:	79

(b) ☐ **only in electronic form** (Section 801(a)(i))
- (i) ☐ sequence listing
- (ii) ☐ tables related thereto

(c) ☐ **also in electronic form** (Section 801(a)(ii))
- (i) ☐ sequence listing
- (ii) ☐ tables related thereto

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the
- ☐ sequence listing: . . . . . .
- ☐ tables related thereto: . . . . . .

(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)

This international application is **accompanied by** the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item):*

		Number of items
1. ☒ fee calculation sheet	:	1
2. ☐ original separate power of attorney	:	
3. ☐ original general power of attorney	:	
4. ☐ copy of general power of attorney; reference number, if any:	:	
5. ☐ statement explaining lack of signature	:	
6. ☐ priority document(s) identified in Box No. VI as item(s):	:	
7. ☐ translation of international application into *(language)*:	:	
8. ☐ separate indications concerning deposited microorganism or other biological material	:	
9. ☐ sequence listing in electronic form *(indicate type and number of carriers)*		
(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(i) or (c)(i) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing mentioned in left column	:	
10. ☐ tables in electronic form related to sequence listing *(indicate type and number of carriers)*		
(i) ☐ copy submitted for the purposes of international search under Section 802(b-*quater*) only (and not as part of the international application)	:	
(ii) ☐ *(only where check-box (b)(ii) or (c)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-*quater*)	:	
(iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column	:	
11. ☐ copy of results of earlier search(es) (Rule 12*bis*.1(a))	:	
12. ☐ other *(specify)*:	:	

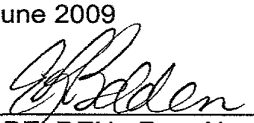
Figure of the drawings which should accompany the abstract:

Language of filing of the international application: English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Dated: 11 June 2009



Elisabeth L. BELDEN, Reg. No. 50,751

For receiving Office use only

1. Date of actual receipt of the purported international application: 11 JUNE 2009 (11/06/09)

2. Drawings:
- ☐ received:
- ☐ not received:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority (if two or more are competent): ISA /

6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Carrie R. Dorna
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS, REQUEST FOR SUPPLEMENTAL ADS, AND REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This Transmittal is in response to the Notice to File Corrected Application Papers mailed May 4, 2016, the period of response for which runs through July 5, 2016 (July 4th falling on a federal holiday). This Transmittal is accompanied by a Supplemental Application Data Sheet and a Request for a Corrected Filing Receipt.

Response to Notice to File Corrected Application Papers

In the Notice to File Corrected Application Papers mailed May 4, 2016 (the "Notice"), the Office objected to the pending application for purportedly claiming priority to four US Non-Provisional applications—US 12/137,364; US12/137,377; US12/137,363; and US12/137,356—with foreign priority claims. The Notice indicated that a 35 U.S.C. § 119(a)-(d) foreign priority claim cannot be based on a US application.

Upon review, Applicant respectfully submits that the priority claim to the four US Non-Provisional applications was properly made as a domestic priority claim in the application and that the filing receipt incorrectly listed the priority claims as being foreign priority claims. Accordingly, Applicant is enclosing a request for a corrected filing receipt and supplemental application data sheet to correct and clarify the prosecution history. Applicant's position that the priority claims to the four US Non-Provisional applications was correctly made is supported by multiple pieces of evidence in the record.

First, the standards for making a priority claim to a prior application are set out at MPEP § 211.02. Since the present application was filed prior to September 16, 2012, the relevant language is as follows:

> For applications filed prior to September 16, 2012, the specific reference to the prior application must be in an application data sheet (37 CFR 1.76(a)) and/or in the first sentence(s) of the specification following the title, although the Office prefers the use of an application data sheet. If applicant is claiming the benefit of multiple prior applications, and the reference to the prior applications is in the specification, the reference may be in a continuous string of multiple sentences at the beginning of the specification. The multiple sentences must begin as the first sentence after the title, and any additional sentence(s) including a benefit claim must follow the first sentence and not be separated from the first sentence by any other sentence not making a benefit claim. If the specific reference is only contained in the application data sheet, then the benefit claim information will be included on the front page of any patent or patent application publication, but will not be included in the first sentence(s) of the specification.

In the present case, Applicant properly claimed priority to the four US Non-Provisional applications through a priority claim made in the first sentence of the specification. In particular, in a preliminary amendment accompanying the national stage filing, Applicant amended the application specification to include the following first paragraph:

> The present application claims priority to International Application No. PCT/US2009/047031 filed 11 June 2009, which in turn claims priority to the following U.S. patent applications: U.S. patent application serial No. 12/137,356, filed June 11, 2008; U.S. patent application serial No. 12/137,363, filed June 11, 2008; U.S. patent application serial No. 12/137,364, filed June 11, 2008; and U.S. patent application serial No. 12/137,377, filed June 11, 2008, the teaching of all of which are incorporated herein by reference.

As seen above, the priority claim made in the first paragraph of the specification referenced the four US Non-Provisional applications as being US patent applications, not foreign applications. Accordingly, the Office should have assigned a domestic priority claim, not a foreign priority claim to the four applications on the filing receipt.

Second, MPEP § 1893.03(c) and 37 C.F.R. § 1.76(g) set out standards for claiming the benefit of an earlier filed application in US national stage applications. The provisions state, in relevant part:

> In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 119(e) of a prior U.S. provisional application, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a). 37 CFR 1.78(a)(2) requires that the prior provisional application must be entitled

> to a filing date as set forth in 37 CFR 1.53(c), and the basic filing fee set forth in 37 CFR 1.16(d) must be paid on the provisional application within the time period set forth in 37 CFR 1.53(g). Additionally, the provisional application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112. The national stage application must contain a reference to the provisional application identifying it as a provisional application, and including the provisional application number (series code and serial number). If the national stage application has an international filing date prior to September 16, 2012, then the reference must be in either an application data sheet (37 CFR 1.76) or in the first sentence(s) of the specification. See pre-AIA 37 CFR 1.78(a)(5)(iii). If the national stage application has an international filing date that is on or after September 16, 2012, then the reference must be in an application data sheet (37 CFR 1.76). See 37 CFR 1.78(a)(3). However, **the requirement for inclusion of the benefit claim in an application data sheet will be satisfied in a U.S. national stage application by the presentation of such benefit claim in the PCT request form contained in the international application or the presence of such benefit claim on the front page of the published international application**. See 37 CFR 1.76(g).[1]

and

> The requirement in § 1.78 for the presentation of a benefit claim under 35 U.S.C. 119 , 120 , 121 , or 365 in an application data sheet **will be satisfied in a national stage application under 35 U.S.C. 371 by the presentation of such benefit claim in the Patent Cooperation Treaty Request Form contained in the international application or the presence of such benefit claim on the front page of the publication of the international application under PCT Article 21(2)**. The requirement in § 1.55 or § 1.78 for the presentation of a priority or benefit claim under 35 U.S.C. 119 , 120 , 121 , or 365 in an application data sheet and the requirement in § 1.46 for the presentation of the name of the applicant under 35 U.S.C. 118 in an application data sheet will be satisfied in an application under 35 U.S.C. 111 by the presentation of such priority or benefit claim and presentation of the name of the applicant in a Patent Cooperation Treaty Request Form. If a Patent Cooperation Treaty Request Form is submitted in an application under 35 U.S.C. 111 , the Patent Cooperation Treaty Request Form must be accompanied by a clear indication that treatment of the application as an application under 35 U.S.C. 111 is desired.[2]

In the present case, the current application is a 371 national stage application of PCT/US09/47031. The four US Non-Provisional applications were properly claimed on the Patent Cooperation Treaty Request Form contained in that international application. Further, the priority claims for the four US Non-Provisional applications were published on the front page of

[1] MPEP § 1893.03(c)(II) (emphasis added).

[2] 37 CFR § 1.76(g) (emphasis added).

the international application: WO2009/152323. A copy of the Patent Cooperation Treaty Request Form for PCT/US09/47031 and the front page of WO2009/152323 are attached as exhibits to this Transmittal. Accordingly, the benefit claim of the four US Non-Provisional applications under 35 USC § 120 was properly made pursuant to MPEP § 1893.03(c) and 37 C.F.R. § 1.76(g). For this additional reason, the priority claim to the four US Non-Provisional applications is proper and should be recognized in the application.

Request for Supplemental ADS and Corrected Filing Receipt

In view of the above, Applicant respectfully submits that the priority to the four US Non-Provisional applications referenced in the Notice—US 12/137,364; US12/137,377; US12/137,363; and US12/137,356—was properly made. To clarify and correct the prosecution record, Applicant is enclosing a request for a corrected filing receipt and supplemental application data sheet with the present Transmittal.

The Filing Receipt mailed April 26, 2011, as well as the Application Data Sheet, have been amended by way of the annotated corrected Filing Receipt and Supplemental ADS to reflect that the present application is a 371 national stage filing of PCT/US2009/047031, filed June 11, 2009, which is a Continuation of 12/137,356, filed June 11, 2008, issued as 8,317,674 on November 27, 2012, and is a Continuation of 12/137,363, filed June 11, 2008, issued as 7,862,534 on January 4, 2011, and is a Continuation of 12/137,364, filed June 11, 2008, and is a Continuation of 12/137,377, filed June 11, 2008, issued as 8,708,352 on April 29, 2014. Applicant respectfully requests entry of the Supplemental ADS and issuance of a corrected filing receipt reflecting the proper priority claim for the application.

Conclusion

In view of the foregoing, Applicant believes that all requirements set forth in the Notice have been complied with. The Commissioner is authorized to charge any fees due and credit any overpayments to Deposit Account No. 06-1910. The Office is invited to telephone the undersigned if there are any questions or the Office believes it would be useful.

Dated: July 5, 2016

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000

Paul J. LaVanway, Jr.

Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Registration No. 64,610

59131785_1.docx

Electronic Acknowledgement Receipt

EFS ID:	26260974
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	05-JUL-2016
Filing Date:	16-JUN-2010
Time Stamp:	19:42:41
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Corrected Filing Receipt	56782_1_7_2_Corrected_Filing_Receipt-Final.pdf	3603635 66da20a40a24dd4d7b9af701e131a7b59e9164d5	no	3

Warnings:

Information:					
2	Application Data Sheet	56782_1_7_2_Supp_ADS_markups-Final.pdf	139465 c45313fed34edf70b543352828d388a26e93110a	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Miscellaneous Incoming Letter	WO2009152323_Publication_Page1.pdf	70600 297dd5c94f51b1aa1258295314f73aca70f5b30	no	1
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	WO2009152323_Request.pdf	517867 8080a8558568e0ad60d78d3a6f580fb258318b92	no	6
Warnings:					
Information:					
5	Miscellaneous Incoming Letter	Transmittal_to_Notice.pdf	67671 37bd195cffc5c01fa4b907266e6df67aff0c0651	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	4399238		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 05/04/2016

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
05/04/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 12808467
Applicant : Hidem
Filing Date : 06/16/2010
Date Mailed : 05/04/2016

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

Even if the Office has recognized a benefit claim and has entered it into the Office's database and included it on applicant's filing receipt, the benefit claim is not a proper benefit claim unless the reference in compliance with 37 CFR 1.78 is included, depending upon the application's filing date and as indicated in the attachment, in an application data sheet or in the first sentence(s) of the specification and all other requirements are met.

See attachment.

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Nran Hem/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 12808467

APPLICATION FILED PRIOR TO SEPTEMBER 16, 2012, NOT IN COMPLIANCE WITH 37 CFR 1.78

☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification does not indicate the relationship (continuation, division, continuation-in-part) to the prior U.S. nonprovisional application or international application designating the U.S. See document coded dated , listing application number(s) .

☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title does not provide the U.S. nonprovisional application number (series code and serial number) or, with respect to an international PCT application designating the U.S., it provides the international application number or international filing date but not both. See document coded dated , in which the following is missing: .

☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. nonprovisional application number, international PCT application number, or international PCT filing date. See document coded dated , in which the following error was made: .

☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title, thus removing the validating link under 35 U.S.C. 119(a)-(d) to a prior foreign application or under 35 U.S.C. 119(e) to a prior U.S. provisional application.

☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title.

☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application is not present on an application data sheet or in first sentence(s) of the specification following the title.

☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title does not provide the provisional application number (series code and serial number). See document coded dated , in which the following is missing: .

☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. provisional application number. See document coded dated , in which the following error was made: .

☒ Other: SPEC 6/16/10 incorrectly claims non-provisional applications 12/137364, 12/137377, 12/137363, 12/137356 as a foreign priority claim. A 35 U.S.C. 119(a)-(d) foreign priority claim cannot be based on a US application..

HOW TO RESPOND

A proper response to this notice would include any one of: (1) a supplemental Application Data Sheet (ADS) pursuant to 37 CFR 1.76(c) which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); (2) an amendment to the first sentence(s) of the specification which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); or (3) a petition filed pursuant to the provisions of 37 CFR 1.78(a)(3) or 37 CFR 1.78(a)(6) if the benefit information from the document identified above by code and date does not accurately reflect the benefits under 35 U.S.C. 119(e), 120, 121 or 365(c) as claimed by applicant (a grantable petition would include either a supplemental ADS or an amendment to the first sentence(s) of the specification as required by 37 CFR 1.78(a)(3)(i) or 37 CFR 1.78(a)(6)(i)). Such amendments to the specification or supplemental ADS submission may be filed after payment of the issue fee if limited to informalities noted herein. See Waiver of 37 CFR 1.312 for Document Required by Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004).

WARNING: If Applicant fails to timely submit a proper response, the benefit information will be deleted and the patent will be printed without the benefit information present.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 04/20/2016

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 04/20/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

TITLE OF INVENTION: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/20/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22859 7590 04/20/2016
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

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APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/20/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
DORNA, CARRIE R	3735	600-004000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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22859 7590 04/20/2016

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MINNEAPOLIS, MN 55402

EXAMINER	
DORNA, CARRIE R	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 04/20/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner CARRIE R. DORNA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendments filed 6 April 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-5,37-48 and 51-55*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/CARRIE R DORNA/ Examiner, Art Unit 3735	/Charles A. Marmor, II/ Supervisory Patent Examiner, Art Unit 3735

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 April 2016 has been entered.

Response to Arguments

3. Applicant's arguments, see pages 13-15, filed 6 April 2016, with respect to the rejections of claim 1 and its dependents under 35 U.S.C. 103 (pre-AIA) citing at least de Kemp, Fago, and Williams et al. have been fully considered and are persuasive in light of the amendments to the claims. The rejections of 6 October 2015 have been withdrawn.

Allowable Subject Matter

4. **Claims 1-5, 37-48, and 51-55** are allowed.

5. The following is an examiner's statement of reasons for allowance:

No prior art of record teach and/or fairly suggest a system for generating and infusing radiopharmaceuticals required by claim 1, comprising: a computer configured to

execute a breakthrough test by controlling the system to activate the pump to fill a test vial with an eluate sample, display a time lapse indicating the time passed since cessation of the pump, receiving a first activity measurement of the sample and the time elapsed since completion of the elution and the first activity measurement, receiving a second activity measurement at a later time, and determining a result of the breakthrough test using the received activity measurements and time lapsed, within the context of the remainder of claim 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARRIE R. DORNA whose telephone number is (571)270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. R. D./
Examiner, Art Unit 3735

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/08/14 10:57
S3	3	(("20070213848") or ("20080237502") or ("20070260213")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/08/14 11:17
S4	2	(time with elaps$3 with elut$4) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:51
S5	107	(time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:52
S6	0	(display$4 with time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S7	3	(display$4 same (time with elaps$3)) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S8	2	(display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:16
S9	2	S4 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S10	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2	US-PGPUB; USPAT; USOCR;	OR	ON	2015/08/14 13:21

		zodda)).in.	EPO; JPO; DERWENT			
S11	1	S10 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S12	275	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:01
S13	191	(bracco near2 diagnostics).as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:03
S14	2	("3543752" | "3861380").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S15	4	("3535085" | "4160910" | "4759345" | "6639237").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S16	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 13:21
S17	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 15:51
S18	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 16:45
S19	1899	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 17:04
S20	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:22
S21	0	(S17 or S18 or S19 or S20) (display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR;	AND	ON	2015/09/28 18:55

			EPO; JPO; DERWENT			
S22	31	(S17 or S18 or S19 or S20) (display$4 same tim$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:56
S23	7	(("20070140958") or ("7966068") or ("20060015056") or ("4585941") or ("20050187515") or ("5395320") or ("20030139640")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:33
S24	1	("7996068").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:59
S25	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S26	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S27	1899	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S28	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S29	32	(S25 or S26 or S27 or S28) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
S30	33	("4202345").PN. OR ("4562829").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/09/28 21:26
S31	1	((display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:32
S33	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR;	AND	ON	2016/04/11 10:03

			EPO; JPO; DERWENT			
S34	160	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:07
S35	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:08
S36	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 10:14
S37	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S38	160	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S39	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S40	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S41	38	(S37 or S38 or S39 or S40) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:35
S42	20	(S37 or S38 or S39 or S40) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 11:51
S43	3371	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR;	AND	ON	2016/04/11 13:09

			EPO; JPO; DERWENT			
S44	160	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S45	2221	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S46	427	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S47	21	(S43 or S44 or S45 or S46) ((display$4 with tim$3) or (tim$3 with count$3) or (tim$3 with elaps$3)) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2016/04/11 13:09
S48	135	("20020129471" | "20030004463" | "20030139640" | "20040054319" | "20040104160" | "20040260143" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20060173419" | "20070080223" | "20070140958" | "20070213848" | "20070232980" | "20070260213" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080191148" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20100030009" | "20100312039" | "20110071392" | "20110172524" | "20110178359" | "20110209764" | "20120098671" | "20120305730" | "20120310031" | "20120312980" | "20130300109" | "20140084187" | "20140175959" | "3483867" | "3535085" | "3543752" | "3565376" | "3710118" | "3714429" | "3774036" | "3847138" | "3861380" | "3991960" | "3997784" | "4096859" | "4160910" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4674403" | "4679142" | "4755679" | "4759345" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" |	US-PGPUB; USPAT; USOCR	AND	ON	2016/04/11 13:26

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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S32	0	((display$4 with tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT	AND	ON	2015/09/28 21:32
S49	0	((display$4 with tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 breatk$1through).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:03
S54	5	((((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:04
S55	3	((((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) break$1through tim$3).clm.	US-PGPUB; USPAT	AND	ON	2016/04/11 13:05
S56	131	("20020129471" | "20030004463" | "20030139640" | "20040054319" | "20040104160" | "20040260143" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20060173419" | "20070080223" | "20070140958" | "20070213848" | "20070232980" | "20070260213" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080191148" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20100030009" | "20100312039" | "20110071392" | "20110172524" | "20110178359" | "20110209764" | "20120098671" | "20120305730" | "20120310031" | "20120312980" | "20130300109" | "20140084187" | "20140175959" | "3483867" | "3535085" | "3543752" | "3565376" | "3710118" | "3714429" | "3774036" |	US-PGPUB; USPAT	AND	ON	2016/04/11 13:05

		"3847138" | "3861380" | "3991960" | "3997784" | "4096859" | "4160910" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4674403" | "4679142" | "4755679" | "4759345" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" | "6220554" | "6267717" | "6347711" | "6442418" | "6450936" | "6454460" | "6558125" | "6626862" | "6639237" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" | "7608831").PN. OR ("7612999" | "7712491" | "7734331" | "7737415" | "7780352" | "7813841" | "7825372" | "7862534" | "7996068" | "8058632" | "8071959" | "8198599" | "8216181" | "8216184" | "8295916" | "8317674" | "8431909" | "8439815" | "8442803" | "8708352").PN. OR ("9299468").URPN.				

4/ 11/ 2016 3:09:33 PM
C:\ Users\ cdorna\ Documents\ EAST\ Workspaces\ 12808467.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

CPC						
Symbol					**Type**	**Version**
G21G		4	/	08	F	2013-01-01
A61N		5	/	1001	I	2013-01-01
A61N		2005	/	1021	A	2013-01-01
A61B		90	/	39	I	2016-02-01
A61M		5	/	14	I	2013-01-01
G21F		7	/	00	I	2013-01-01
G21G		1	/	0005	I	2013-01-01
A61B		6	/	507	A	2013-01-01
A61B		6	/	107	I	2013-01-01
A61B		6	/	481	I	2013-01-01
A61M		5	/	007	I	2013-01-01
A61M		5	/	142	I	2013-01-01
G21F		3	/	00	I	2013-01-01
A61K		51	/	00	I	2013-01-01
A61B		6	/	037	A	2013-01-01
A61B		2090	/	392	A	2016-02-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/CARRIE R DORNA/ Examiner.Art Unit 3735	04/11/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	04/15/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		G	2	1	G	4 / 08 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/CARRIE R DORNA/ Examiner.Art Unit 3735	04/11/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	04/15/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R DORNA	3735

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	-	17	-	33	-	49								
2	2	-	18	-	34	-	50								
3	3	-	19	-	35	18	51								
4	4	-	20	-	36	19	52								
6	5	-	21	7	37	20	53								
-	6	-	22	8	38	21	54								
-	7	-	23	9	39	22	55								
-	8	-	24	10	40										
-	9	-	25	11	41										
-	10	-	26	12	42										
-	11	-	27	13	43										
-	12	-	28	14	44										
-	13	-	29	15	45										
-	14	-	30	16	46										
-	15	-	31	17	47										
-	16	-	32	5	48										

/CARRIE R DORNA/ Examiner.Art Unit 3735 (Assistant Examiner)	04/11/2016 (Date)	**Total Claims Allowed:** 22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735 (Primary Examiner)	04/15/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1A

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	CARRIE R. DORNA	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N5/1002, 1007	8/5/14	EF
A61N 2005/1021	8/5/14	EF
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028	9/2015	CD
A61N 2005/1021	9/2015	CD
A61M 5/007	9/2015	CD
G21G 4/08	9/2015	CD
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028 updated	4/2016	CD
A61N 2005/1021 updated	4/2016	CD
A61M 5/007 updated	4/2016	CD
G21G 4/08 updated	4/2016	CD

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES

Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF
Updated class/subclass searches and text searching in EAST for AFCP 2.0 submission	8/5/14	EF
Updated class/subclass searches	11/17/14	EF
Updated class/subclass searches	4/16/15	EH
see EAST search report	9/2015	CD
EAST: inventor name search, assignee search	9/2015	CD
see updated EAST search report	4/2016	CD

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
	see EAST search report	9/2015	CD
	see updated EAST search report	4/2016	CD

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/808,467	Filing Date	2010-06-16	Docket Number (if applicable)	56782.1.7.2	Art Unit	3735
First Named Inventor	Stephen E. Hidem			Examiner Name	Carrie R. Dorna		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 061910

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (07-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2016-04-06
Name	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Carrie R. Dorna
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND REQEUST FOR CONTINUED EXAMINATION

Dear Commissioner:

In response to the outstanding Final Office Action, please amend the application as follows. This Amendment is accompanied by a Request for Continued Examination under 37 C.F.R. § 1.114 and constitutes a sufficient submission.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A system that generates and infuses radiopharmaceuticals comprising: an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle, a computer, and a computer interface;

wherein the infusion tubing circuit includes ~~including~~ an eluant line coupled to the pump and to the generator, and an eluate line coupled to the generator~~, to the activity detector~~ and to the waste bottle, the eluate line being positioned to pass over the activity detector; ~~and~~

the computer is communicatively ~~being~~ coupled to the computer interface, to the pump, and to the activity detector, ~~and~~

the computer is configured to receive a command via the computer interface to deliver eluate during a patient infusion procedure and, in response to receiving the command, control the pump to pump eluant through the generator, thereby generating eluate that is infused into a patient; and

the computer is further configured to receive a command via the computer interface to execute a breakthrough test and, in response to receiving the command, control the system by at least: ~~being pre-programmed to execute a method the method comprising~~:

activating the pump to pump a volume of eluant from the reservoir, through the eluant line and through the generator, thereby providing a sample of ~~in order to generate a sample~~ eluate sized to fill a test vial for breakthrough testing ~~or a dose of eluate in the eluate line, via elution within the generator, each sample being intended for a quality control measurement, and each dose being intended for diagnostic imaging~~;

~~providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator; and~~

upon stopping the pump and thereby completing elution, displaying, via the computer interface, a time lapse indicating an amount of time passed since ~~each~~ elution was completed,

receiving, via the computer interface, a first activity measurement of the sample and the time lapse corresponding to the amount of time passed since elution was completed and the first activity was measured,

receiving, via the computer interface, a second activity measurement of the sample, where the second activity measurement is taken at a time later than the first activity measurement, and

determining a breakthrough test result using the first activity measurement, the time lapse received via the computer interface, and the second activity measurement.

2. (Currently Amended) The system of claim 1, wherein the computer is further configured to execute the breakthrough test by ~~pre-programmed method further comprises~~:

counting elutions per unit time;

categorizing each counted elution as having been generated as a sample or a dose; and

maintaining a record of the counted and categorized elutions.

3. (Currently Amended) The system of claim 2, wherein the computer is further configured to execute the breakthrough test by ~~pre-programmed method of the computer further comprises~~ receiving a detected activity level of the eluate for the ~~each dose and~~ sample, from the activity detector, and entering the detected activity level for each elution into the record.

4. (Currently Amended) The system of claim 3, wherein the computer is further configured to execute the breakthrough test by ~~pre-programmed method of the computer further comprises~~ compiling a report that contains the record, the report being formatted for printing and/or for electronic transfer to another system.

5. (Currently Amended) The system of claim 1, wherein the computer is further configured to ~~pre-programmed method further comprises~~:

~~maintaining~~ maintain a record of elutions that categorizes each elution of the generator as having been generated for the patient infusion procedure or the breakthrough test ~~a sample or a dose~~;

~~receiving~~ receive a detected activity level of the eluate for each elution ~~dose and sample~~, from the activity detector, and enter ~~entering~~ the detected activity level for each elution into the record;

~~calculating and tracking~~ calculate and track an amount of activity left in the generator after each elution, over a life of the generator; and

~~compiling~~ compile a report that includes an amount of activity left in the generator after a final elution at an end of the life of the generator.

6–36. (Canceled)

37. (Currently Amended) The system of claim 1, wherein the computer is further configured to execute the breakthrough test by ~~further characterized in that the pre-programmed method of the computer further comprises the steps of~~:

providing, via the computer interface, a first set of breakthrough test data entry fields for a user of the system to enter the first activity measurement and the ~~a first activity measure of a sample of eluate and~~ the corresponding time lapse since ~~the elution was completed to a time of the first activity measure, when the activated pumping generates the sample of eluate for collection in a shielded test vial~~; and

providing, via the computer interface, a second set of breakthrough test data entry fields for a user of the system to enter the second activity measurement ~~a second activity measure of the sample after a predetermined time lapse since the elution was completed to the time of a second activity measure; and~~

~~calculating a breakthrough of the generator using the first and second activity measures and the time lapse entered by the user~~.

38. (Currently Amended) The system of claim 1, wherein the computer is further configured to execute a calibration test by at least ~~further characterized in that the pre-programmed method of the computer further comprises the steps of~~:

providing, via the computer interface, calibration data entry fields for a user of the system to enter an activity measure of a sample of eluate and the corresponding time lapse since the

elution was completed to a time of the activity measure~~, when the activated pumping generates the sample of eluate for collection in a shielded test vial~~; and

calculating a calibration coefficient of the infusion system using a detected activity, received from the activity detector, ~~and~~ the activity measure received via the computer interface, and the time lapse entered by the user.

39. (Currently Amended) The system of claim 1, wherein the computer is further configured to ~~pre-programmed method of the computer further comprises the steps of~~:

~~providing~~ provide, via the computer interface, a patient identification entry field for a user to enter a patient identification number;

~~receiving~~ receive a detected activity level of a dose of eluate from the activity detector, during the patient infusion procedure~~ when the activated pumping generates the dose for diagnostic imaging~~; and

~~compiling~~ compile a report that includes an identification number for the generated dose and the detected activity level.

40. (Currently Amended) The system of claim 1, wherein: ~~further characterized in that:~~

the system further comprises a light projector communicatively coupled to the computer; and

the ~~pre-programmed method of the~~ computer is further configured to control the light projector to emit ~~comprises the step of providing~~ a light signal ~~from the light projector~~ when the pump is activated to pump ~~each volume of~~ eluant through the generator.

41. (Currently Amended) The system of claim 1, wherein: ~~further characterized in that:~~

the system further comprises a light projector communicatively coupled to the computer; and

the ~~pre-programmed method of the~~ computer is further configured to ~~comprises the steps of~~:

~~diverting~~ divert an initial volume of eluate to the waste bottle, based upon input from the activity detector, before activating the pump during ~~the activated pumping generates the sample or the dose~~ the patient infusion procedure and the breakthrough test; and

~~providing~~ provide a first light signal from the light projector, when the initial volume of eluate is being diverted; and

~~providing~~ provide a second light signal from the light projector, after activating the pump to generate ~~when the activated pumping is generating the sample or the dose of~~ eluate, the second light signal being different from the first light signal.

42. (Currently Amended) The system of claim 1, wherein ~~further characterized in that~~:

the system further comprises a light projector communicatively coupled to the computer; and

the computer is further configured to control the light projector to provide ~~pre-programmed method further comprises providing~~ a light signal when the activity detector detects a peak bolus of radioactivity in the eluate line.

43. (Currently Amended) The system of claim 1, wherein the computer is further configured to ~~pre-programmed method of the computer further comprises the steps of~~:

~~diverting~~ divert an initial volume of eluate to the waste bottle, based upon input from the activity detector, during the patient infusion and breakthrough test ~~before the activated pumping generates the sample or the dose~~;

~~tracking~~ track the initial volume of eluate diverted to the waste bottle; and

~~providing~~ provide an indication when the waste bottle needs to be emptied based upon the tracking.

44. (Previously Presented) The system of claim 1, wherein the computer interface comprises a touch-activated display screen.

45. (Currently Amended) The system of claim 1, further comprising at least one sensor for detecting a leak in the tubing circuit, the computer being coupled to the at least one sensor; and

wherein the ~~pre-programmed method of the~~ computer is further configured to ~~comprises the step of providing~~ provide an indication, via the computer interface, when ~~that~~ a leak in the tubing circuit is detected.

46. (Currently Amended) The system of claim 1, wherein the computer is further configured, during the patient infusion procedure, to ~~further characterized in that the pre-programmed method of the computer further comprises the steps of~~:

~~calculating~~ calculate a flow rate profile, that corresponds to a desired activity profile, using a baseline activity profile, the baseline activity profile being comprised of a plurality of detected activity levels, received from the activity detector, of a sample of eluate, the sample of eluate being generated by the activated pump pumping the volume of eluant through the generator at a constant flow rate; and

~~controlling~~ control a speed of the pump, according to the calculated flow rate profile, when pumping another volume of eluant through the generator, in order to generate a dose of eluate in the eluate line, the speed being controlled according to the calculated flow rate profile in order to achieve a desired activity profile of the dose of eluate for diagnostic imaging.

47. (Currently Amended) The system of claim 1, wherein the computer is further configured to transfer ~~pre-programmed method further comprises transferring~~ to another system, for analysis, a plurality of detected activity levels, received from the activity detector~~, over time, for each dose of eluate~~.

48. (Currently Amended) The system of claim 2, wherein the computer is further configured to compile ~~pre-programmed method of the computer further comprises compiling~~ a report that contains the record, the report being formatted for printing and/or for electronic transfer to another system.

49–50. (Canceled)

51. (Previously Presented) The system of claim 1, wherein displaying the time lapse since each elution was completed comprises displaying a timer counting up or down since each elution was completed.

52. (New) The system of claim 1, wherein receiving the first activity measurement comprises receiving the first activity measurement from a dose calibrator, and receiving the second activity measurement comprises receiving the second activity measurement from the dose calibrator.

53. (New) The system of claim 52, wherein the dose calibrator is electronically coupled to the computer.

54. (New) The system of claim 1, wherein the time later than the first activity measurement is a predetermined time.

55. (New) The system of claim 1, wherein the predetermined time is 60 minutes.

REMARKS

This Amendment is responsive to the outstanding Final Office Action. Applicant has amended claims 1–5, 37–43, and 45–58, canceled claims 6, 7, 36, 49, and 50, and added new claims 52–55. No new matter has been added by way of the amendments, and support for the amendments can be found throughout Applicant's original disclosure including, e.g., at paragraphs [0062] and [0071]–[0075], FIGS. 7A–7C, and original claim 37. Claims 1–5, 37–48, and 51–55 will be pending upon entry of this Amendment. Reconsideration of the application is respectfully requested.

Interview Summary

Applicant thanks the Examiner for her time and the courtesies extended during the telephonic interview conducted on December 2, 2015. Examiner Carrie Dorna and Applicant's representative Paul J. LaVanway, Jr. (Reg. No. 64,610) were involved in the telephonic interview. The parties discussed rejected independent claim 1. The parties also discussed deKemp et al. (US 2007/0213848, hereinafter "deKemp '848"), Fago (US 2008/0237502), and Williams et al. (US 2007/0260213, hereinafter "Williams"), which were previously cited by the Patent Office. No exhibits were introduced or discussed.

Applicant's representative began the discussion by providing a background overview of the underlying technology and shared example real-world applications and benefits achievable with the claimed technology. For example, Applicant's representative discussed how the claimed technology may be used to enhance the accuracy and reliability of quality control measurements made prior to conducting patient infusion procedures. Applicant's representative continued the discussion by noting distinctions between independent claim 1 and the applied references.

For example, Applicant's representative discussed how the applied references do not disclose or suggest a system that includes a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." Applicant's representative noted how this feature, which was acknowledged to be missing from the deKemp '848 reference, could not be taught or suggested by Fago and Williams. In

particular, Applicant's representative noted how the portions of Fago relied upon to support the rejection do not even have a pump, much less provide any indication related to a pump.

In addition, Applicant's representative explained why Williams cannot be characterized as teaching a "display of time lapse since each elution." Applicant's representative pointed out how Williams does not even describe a radioisotope generator that generates eluate via elution, much less a "display of time lapse since each elution."

Although the Examiner indicated that she appreciated the background information Applicant's representative provided and also understood the substantive comments shared, the Examiner stated that she felt the Final Office Action adequately supported the rejection of the claims. The Examiner commented that, in her opinion, the claim feature of displaying a time lapse since elution was completed could be read broadly. In this regard, the Examiner indicated she thought the applied references could be read broader than Applicant was reading the references and this breadth of interpretation was leading to the discrepancy between the Applicant's reading of the references and the Examiner's interpretation of the references.

While no specific claim amendments were discussed, the Examiner suggested that Applicant amend the independent claim to tighten up the structure and function described by Applicant's representative during the background discussion on embodiments of the technology. Applicant's representative agreed to take the Examiner's suggestion under consideration. Despite productive discussion, no agreement on allowability was reached during the telephone interview.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Office Action, previously-presented claims 1, 43 and 51 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over deKemp et al. (US 2007/0213848, hereinafter "deKemp '848") in view of Fago (US 2008/0237502) and Williams et al. (US 2007/0260213, hereinafter "Williams"). In addition, previously-presented claims 2–5, 37–42 and 44–48 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over deKemp '848 in view of Fago and Williams and further in view of additional cited references.

Applicant respectfully traverses the rejections, particularly to the extent the rejections can be considered applicable to the claims as amended. The applied references do not disclose or suggest the features of the claims, and there would have been no apparent reason for

modification to arrive at the claimed features. For example, the applied references do not disclose or suggest the features of amended independent claim 1.

In support of the rejection of previously-presented independent claim 1, the Office Action cited paragraphs [0025] through [0032] of the de Kemp '848 reference as allegedly disclosing a system that includes an eluant reservoir, a pump, an infusion tubing circuit, a radioisotope generator, a computer, and a user interface. Although the Office Action conceded that the de Kemp '848 reference does not disclose "the use of a computer to control the modes of operation of the system, providing an indication that the elution is complete, or displaying, via the computer interface, a time lapse since each elution was completed," the Office Action cited Fago and Williams in an attempt to overcome these deficiencies. In particular, the Office Action cited paragraph [0034] of Fago as teaching that the volume and/or time associated with each elution process may be tracked and displayed to enable a user to estimate when the generator will be ready for another elution process. The Office Action alleged then that it would have been obvious to modify the method of controlling the elution system in the de Kemp '848 reference to include the displayed volume and time calculations of Fago. In addition, the Office Action cited paragraphs [0025] and [0045] of Williams as disclosing displaying elapsed time information related to the dispensing of media. The Office Action took the position that it would have been obvious to further modify the technique of the de Kemp '848 reference in view of Fago to display a time lapse since each elution according to Williams.

As discussed in Applicant's prior remarks, Applicant respectfully disagrees that deKemp '848 in view of Fago and Williams renders the features of previously-presented independent claim 1 obvious. For example, the combination of references does not provide a method that involves "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator," as recited by the previously-presented claim. The Office Action acknowledged that deKemp '848 does not disclose the feature but cited Fago in an attempt to overcome the acknowledged deficiency. In particular, the Office Action cited FIGS. 6 and 7 of Fago and related description in the reference as disclosing an electronic drop counter that counts drops passing through a drip chamber and is communicatively coupled to a display "for displaying metrics relating to the elution process." The Office Action alleged that this disclosure of Fago overcomes the acknowledged deficiencies of deKemp '848.

However, the embodiments of cited FIGS. 6 and 7 of Fago do not even have a pump, much less provide an indication related to a pump. Instead, Fago describes that the systems in cited FIGS. 6 and 7 utilize an eluate collection bottle that "begin[s] in an evacuated condition."[1] The reference continues to describe that the evacuated collection bottle causes "eluate residing in the generator 22 to begin filling the bottle," which correspondingly causes eluate from the eluate supply container 4 to "begin flowing into the generator 22."[2] In other words, the systems in cited FIGS. 6 and 7 of Fago do not have a pump but instead utilize a pressure differential to drive eluant flow.

Because Fago does not have a pump, Fago necessarily does not provide any indication "when a pump has completed pumping," as per claim 1. Since the Office Action relied on Fago to teach this feature of independent claim 1 and overcome the acknowledged deficiencies of deKemp '848, and since Fago does not in fact disclose the feature, the combination of deKemp '848 in view of Fago does not render the claim feature *prima facie* obvious.

As another example, Applicant respectfully disagrees that deKemp '848 in view of Fago and Williams renders the features of previously-presented independent claim 1 obvious because the combination of references does not disclose or suggest a system that execute a method that includes "displaying, via the computer interface, a time lapse since each elution was completed," as further recited by the claim. In support of the rejection of this claim feature, the Office Action conceded that neither deKemp '848 nor Fago disclose a computer pre-programmed to execute a method that includes "displaying, via the computer interface, a time lapse since each elution was completed." However, the Office Action cited Williams in an attempt to overcome this deficiency. Specifically, the Office Action rejected independent claim 1 based on the legal conclusion that it would have been obvious to modify the elution process of deKemp '848 and Fago "to display a time lapse since each elution as taught by Williams." Williams, though, does not even describe a radioisotope generator that generates eluate via elution, much less a "display of time lapse since each elution."

Williams is directed to an injection device for dispensing contrast media as part of a dispensing procedure.[3] For example, Williams describes that the injection device includes syringes that can be filled with contrast media, flushing media, or combinations thereof for

[1] Fago at paragraph [0031].
[2] *See id.*
[3] *See* Williams at Abstract.

injection into a patient.[4] Nowhere, however, does Williams describe a radioisotope generator system or generating eluate via elution. Williams makes no mention of such a feature. Therefore, Williams necessarily cannot and does not teach displaying "a time lapse since each elution," as asserted in the Office Action.

While Applicant does not agree with the propriety of rejection of previously-presented independent claim 1, for at least the reasons discussed above, Applicant has amended the claim to advance prosecution and grant of the application. In particular, Applicant has amended the claim to specify that the claimed system includes a computer that is configured to both (1) "receive a command via the computer interface to deliver eluate during a patient infusion procedure and, in response to receiving the command, control the pump to pump eluant through the generator, thereby generating eluate that is infused into a patient" and (2) "receive a command via the computer interface to execute a breakthrough test and, in response to receiving the command, control the system." The amended claim further specifies that the computer is configured to execute the breakthrough test by, among other elements, (a) activating the pump to provide a sample of eluate sized to fill a test vial for breakthrough testing, (b) displaying a time lapse indicating an amount of time passes since elution was completed, (c) receiving a first activity measurement and time lapse corresponding to the amount of time passed since elution was completed and the first activity was measured, (d) receiving a second activity measurement taken at a time later than the first activity measurement, and (e) determining a breakthrough test result using the first activity measurement, the time lapse received via the computer interface, and the second activity measurement. Nothing in the applied references discloses or suggests the combination of features recited by amended independent claim 1.

For example, neither deKemp '848, Fago, nor Williams disclose or suggest an infusion system having a computer configured to both execute a patient infusion procedure and execute a breakthrough test, where the breakthrough test involves determining a breakthrough test result using a first activity measurement, a time lapse received via a computer interface, and a second activity measurement, as per amended independent claim 1. In deKemp '848, the only discussion of breakthrough is in paragraph [0055] of the reference. As described in that paragraph, however, the deKemp '848 system is not configured to receive a first activity measurement, a time lapse corresponding to an amount of time since elution was completed and

[4] *See id.* at paragraph [0021].

the first activity was measured, and a second activity measurement taken at a time later than the first activity measurement, in each case via a computer interface. Nor is the deKemp '848 system configured to determine a breakthrough test result using this received data.

Rather, deKemp '848 proposes an entirely different solution that involves collecting generator performance data using a different system than the generator system to provide "stored generator performance data."[5] That is, deKemp '848 does not disclose an integrated infusion system that both executes patient infusion procedures and performs breakthrough testing, as per amended independent claim 1.

Moreover, the breakthrough analysis process described by deKemp '848 does not disclose or suggest the requirements of a breakthrough test according to amended independent claim 1. deKemp '848 does not describe a breakthrough test that involves receiving, via a computer interface, a first activity measurement and corresponding time lapse since completion of elution along with a second activity measurement taken at a later time than the first activity measurement. Rather, deKemp '848 describes a graphical analysis technique to detect ^{82}Sr breakthrough. According to deKemp '848, the technique involves curve comparison between a predicted ^{82}Rb decay curve and a curve formed through calibration data. As a result, deKemp '848 describes detecting breakthrough through curve deviation, not using a first activity measurement received via a computer interface, a corresponding time lapse received via the computer interface, and a second activity measurement as received via the computer interface. None of the cited portions of Fago or Williams provide any disclosure concerning breakthrough. Accordingly, deKemp '848 in view of Fago and Williams does not render the features of amended independent claim 1 unpatentable.

It bears noting that the Office Action rejected the features of previously-presented claim 37 based on the assertion that it would have been obvious to modify the system of deKemp '848 in view of Fago and Williams in further view of deKemp '958 to include first and second breakthrough test data entry fields. The Office Action asserted that such a modification would have been obvious "in order to determine if breakthrough is less than a threshold for permissible levels." To the extent the characterization and application of the deKemp '958 reference can be considered applicable to the claims as amended, Applicant respectfully disagrees.

[5] deKemp '848 at paragraph [0054].

Applicant respectfully submits that a person of ordinary skill in the art would not have been motivated to modify the system of deKemp '848 in view of Fago and Williams in further view of deKemp '958 to include breakthrough data entry fields via a computer interface of a computer that controls the infusion system. Neither deKemp '848 nor deKemp '958 (nor Fago or Williams) disclose or suggest configuring a computer that executes a patient infusion procedure to also execute a breakthrough test, including receiving data associated with such a test. Rather, as discussed above, deKemp '848 indicates using a different system than the infusion system to generate data that then is imported and stored as "stored generator performance data."

Moreover, a person of ordinary skill in the art would not have been motivated to modify the system deKemp '848 in view of Fago and Williams in further view of deKemp '958 to include breakthrough data entry fields because such a modification would having undermined a fundamental principal by which the deKemp '848 system operates. As discussed above, deKemp '848 describe a technique that utilizes graphical analysis of a predicted decay curve to predict breakthrough. Modifying the deKemp '848 system to provide breakthrough data entry fields, as proposed in the Office Action, would have no benefit or purpose given the divergent technique used by the system.

Additionally, Applicant wishes to point out that the cited portions of deKemp '958 do not, in fact, disclose or suggest any type of computer-implemented breakthrough testing, a computer that receives data related to breakthrough testing, or any type of data entry fields. Rather, the cited portions of deKemp '958 merely describe general background information on breakthrough that deKemp '958 alleges would be "understood by those skilled in the art." There is no disclosure or suggestion in deKemp '958 of an infusion system that can both execute a patient infusion procedure and perform breakthrough testing, much breakthrough testing according to the requirements of amended independent claim 1.

For at least the reasons given above, Applicant respectfully submits that the applied references do not disclose or suggest the features of amended independent claim 1. Claims 2–5, 37–48, and 51–55 depend from independent claim 1 and are therefore patentable at least by virtue of their dependency from the independent claim, as well as in their own right.

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the fundamental differences identified above, Applicant reserves further comment concerning the additional features set forth in the claims. However, Applicant does not acquiesce in the propriety of the Office Action's application or interpretation of the references with respect to the claims, and reserves the right to present additional arguments in any further prosecution of this application.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: April 6, 2016

Respectfully submitted,

/Paul J. LaVanway, Jr./

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Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

57712073_1.DOC

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Keisha Forsman
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**3100**

Electronic Acknowledgement Receipt

EFS ID:	25398136
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Keisha Forsman
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	06-APR-2016
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Payment Type	Credit Card
Payment was successfully received in RAM	$3100
RAM confirmation Number	1926
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	56782172_Bracco_ExtensionofTime.pdf	163657 ab8fcfcda2c61d9c85cab6734fd45e344be889e1	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	56782172_Bracco_RCE.pdf	1350064 ecf80cb2e9dcfbe8a6518a16f64385bb897a21fb	no	3
Warnings:					
Information:					
3		56782172_Bracco_ResponsetoFOA.pdf	147644 f53fd6652f0703bf4c97b9ab10ca27ad725228a1	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment Submitted/Entered with Filing of CPA/RCE	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	16

Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32575 4580a16cfe2dc96d97828f451a97a15f95ad422b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1693940	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 56782.1.7.2

Application Number: 12/808,467

Filed: June 16, 2010

For: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Art Unit: 3735

Examiner: Carrie R. Dorna

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 1,400
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 06-1910.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 64,610.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Paul J. LaVanway, Jr./ — Signature

April 6, 2016 — Date

Paul J. LaVanway, Jr. — Typed or printed name

612-492-7387 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/808,467	Filing Date 06/16/2010	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **04/06/2016**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 22	Minus	** 38	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***5	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/LASHAWN MORGAN/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 12/10/2015

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
12/10/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/808,467	HIDEM ET AL.	
	Examiner	Art Unit	
	CARRIE R. DORNA	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Carrie R. Dorna*. (3)_____.

(2) *Paul LaVanway*. (4)_____.

Date of Interview: *02 December 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *US 2007/0213848 (deKemp); US 2008/0237502 (Fago); US 2007/0260213 (Williams)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant's representative presented the arguments with respect to the combination of deKemp, Fago, and Williams that were filed 23 July 2015. The examiner stated these arguments were not persuasive for the reasons noted in the Advisory Action of 19 August 2015 and maintained in the final Office action of 6 October 2015. The examiner suggested amending the language of claim 1 in a manner that requires the computer is programmed to perform functions that the programming of the cited prior art would not be capable of performing, and/or further defining the structural elements of claim 1 over that of the prior art may overcome the present rejections. A formal agreement was not reached. An updated search will be performed upon submission of formal claim amendments.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CARRIE R DORNA/ Examiner, Art Unit 3735	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 10/06/2015

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
10/06/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Office Action Summary	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner CARRIE R. DORNA	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-7 and 36-51* is/are pending in the application.

5a) Of the above claim(s) *6,7,36,49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,37-48 and 51* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *16 June 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 September 2015 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1, 43, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.).

Regarding **claim 1**, deKemp et al. US '848 teaches a system that generates and infuses radiopharmaceuticals comprising: an eluent reservoir (*Figure 3, reservoir,* 4), a pump coupled to the reservoir (*Figure 3, pump,* 6), an infusion tubing circuit (*Figure 3, generator valve,* 16*, bypass line* 18*, patient valve* 24*, elution system,* 14, and *Figures 3 and 5, feed-line,* 33), a radioisotope generator (*Figure 3, strontium-rubidium (^{82}Sr/^{82}Rb) generator,* 8), an activity detector (*Figure 3, positron detector,* 20), a waste bottle (*Figure 3, waste reservoir,* 26), a computer (*Figure 3, controller,* 28) and a computer interface (*Figure 3, user interface,* 44) ([0025]; [0028]); the infusion tubing circuit including an eluant line coupled to the pump and to the generator (pump 6 for drawing saline from reservoir 4, [0025]), and an eluate line coupled to the generator, to the activity detector (20) and to the waste bottle (26) (Generator valve 16 proportions saline flow between the generator 8 and a bypass line 18 which meet at merge point 22, a positron detector 20 downstream of merge point 22, a patient valve 24 to control supply of saline to patient outlet 10 and waste reservoir 26, [0025]). deKemp et al. US '848 further teaches the controller (28) is connected to the pump (6), activity detector (20), valves (16) and (24), and the user interface (44) ([0025]; see *Figure 3*), wherein the pump (6) and valves (16, 24) are controlled via the controller (28) to route saline through the system (14) to generate a sample or a dose of eluate in accordance with various modes of operation ([0029]-[0032]; *Figures 6a-6d*). deKemp et al. US '848 teaches the pump (6) is controlled to draw saline from the reservoir (4) at a desired flow rate ([0025]). During an "elution" mode, deKemp et al. US '848 discloses generator valve (16) is actively controlled by a control loop (42) from the activity detector (20) to

proportion saline flow through both the generator (8) and bypass line (18) (paragraph [0032]). The limitation “each sample being intended for a quality control measurement, and each dose being intended for diagnostic imaging” is intended use, thus has not been given patentable weight. The samples generated as disclosed by deKemp et al. US ‘848 are capable of use in either quality control measurement or diagnostic imaging ([0003]-[0004]; [0054]). deKemp et al. US ‘848 does not explicitly teach providing an indication that the elution is complete, or displaying, via the computer interface, a time lapse since each elution was completed.

However, Fago teaches a system that generates and infuses radiopharmaceuticals (abstract). Fago teaches visualization of the eluate collection bottle (34) facilitates determining when the elution process is complete, e.g. the eluate collection bottle (34) is full ([0031]). Fago additionally teaches a syringe pump (40) is adapted to inject the eluent (18) into the generator (22) via tubing (10) ([0032]). Fago teaches a drip chamber (44) is incorporated in the tubing (10) to facilitate tracking or identification of an amount of eluent flowing into a generator (22) ([0033]; *Figure 6*), wherein an electronic drop counter (46) may be used to count the drops passing through the drip chamber (44) to provide metrics relating to the amount of eluant being passed from the eluant passing from the eluent supply container (4) into the generator (22) ([0033]; *Figure 7*). Fago teaches the drop counter (46) is “coupled to an electronic device and/or computer (54) to store data, facilitate communication with other devices, and/or perform calculations relating to the elution process” ([0034]), and is additionally “communicatively coupled to a display (52) for displaying metrics relating to the elution

process", wherein "the display (52) may be incorporated into the computer (54)" ([0034]). The broadest reasonable interpretation of the limitation "the computer…being pre-programmed to execute a method, the method comprising:…providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator" requires a computer programmed in a manner that it is capable of performing the recited function of providing an indication of when the pump has completed dispensation. Since Fago discloses a computer that is programmed to display a volume of dispensed eluant as discussed above ([0034]), Fago discloses a computer programmed in a manner that is capable of providing an indication via computer interface of when dispensation of an elution is complete. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of controlling an $^{82}Sr/^{82}Rb$ elution system of deKemp et al. US '848 to include the displayed volume and time calculations taught by Fago, because such a display provides a practitioner with an indication of when the proper desired amount of eluant has been dispensed (Fago: [0004]; [0034]). Accordingly, the system of de Kemp modified in view of this teaching of Fago would result in a computer providing an indication via its interface of when the pump has completed pumping the desired volume of eluant. Fago teaches the volume and/or time associated with each elution process may be tracked and displayed to enable the user to estimate when the generator will be ready for another elution process paragraph [0034]), but the combination of de Kemp et al. US '848 and Fago does not disclose displaying, via the computer interface, a time lapse since each elution was completed.

However, Williams teaches a system that generates and infuses media (abstract), and methods for displaying elapsed time information related to the dispensing of media by a dispensing device in relation to a medical procedure ([0001]). Williams teaches a user may view data corresponding to a dispensing operation, such as flow rate and elapsed time from injection of media via a display device in a user interface (230) ([0025]; [0027]). Williams teaches a computer program product comprises executable portions for directing the dispensing medical device (115) to perform at least one dispensing function, to manipulate and/or adjust the display parameters of the user interface (230), and to display a status text graphic (470) indicating the status of a given dispensing operation, such as its completion, and an elapsed time counter graphic (410) to monitor the elapsed time since the introduction of contrast media into a patient ([0045]). The broadest reasonable interpretation of the limitation "the computer…being pre-programmed to execute a method, the method comprising:…displaying, via the computer interface, a time lapse since each elution was completed" requires a computer programmed in a manner that is capable of performing the recited function of displaying via an interface a time lapse since the completion of an elution. Since Williams discloses a system including a computer programmed to display via a time counter the time elapsed following a "dispensation function" ([0044]-[0045]), Williams discloses a computer programmed in a manner that is capable of displaying a time counter that indicates the elapsed time following completion of an elution, providing the benefit of enabling a practitioner to efficiently monitor dispensation in a single interface ([0006]; [0045]). It would have been obvious to one of ordinary skill in the art at

the time of the invention to use the data associated with each elution process in the method of de Kemp et al. US '848 and Fago to display a time lapse since each elution as taught by Williams, because such a configuration enables a practitioner to efficiently monitor dispensation in a single interface (Williams, [0045]).

Regarding **claim 43**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848 teaches the pre-programmed method of the computer (28) further comprises the steps of: diverting an initial volume of eluate to the waste bottle (90), based upon input from the activity detector (20), before the activated pumping generates the sample or dose ([0029]). deKemp et al. US '848 does not teach tracking the initial volume or eluate or providing an indication when the waste bottle needs to be emptied.

However, Fago further teaches an eluate collection bottle (34) may have a standard or predefined volume, wherein a user can observe remotely via the computer the eluent levels in the eluant supply container (4) go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle (34) (This observation is construed as "tracking the initial volume of the eluate", [0005], [0024], [0026], and [0031]). Fago teaches this visualization facilitates determining when the elution process is complete, e.g. the eluate collection bottle is full, thus indicates when the collection bottle should be emptied ([0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the pre-programmed method of deKemp et al. US '848, Fago, and Williams to include tracking the initial

volume or eluate and providing an indication when the waste bottle needs to be emptied taught by Fago in order to track the amount of fluid in the bottle (Fago, [0031]).

Regarding **claim 51**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. Williams discloses a displayed "elapsed time counter graphic 410" in *Figure 4* that is described in paragraph [0045] as updated "in real time" ([0045]), thus is a "timer counting up or down".

5. **Claims 2-4, 38, 39, 44, and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2008/0177126 (Tate et al.).

Regarding **claims 2-4 and 48**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848 teaches the pre-programmed method further comprises: categorizing each counted elution as having been generated as a sample or a dose (A control algorithm regulates a flow rate and volume of the sterile saline solution 100 pumped through the generator column 10 controls valve 108, which directs the eluate through a delivery line 112 for a calibration elution or a patient elution 110, [0025]). Fago teaches the pre-programmed method further comprises: counting elutions per unit time (Computer 54 may be coupled to each of a plurality of drop counters 46 and/or displays 52 that provide data relating to elution processes in each of the generators 22, such as time associated with each counted

drop or a volume associated with the number of counted drops, [0034] and [0036]). The modified system of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions.

However, Tate teaches a system that generates and infuses radiopharmaceuticals (abstract), comprising a computer coupled to a computer interface, pre-programmed to execute a method comprising a step of maintaining a record of prior elutions (abstract; Records or Injection History button 1022, [0172], [0181]; [0238]-[0245]). Tate further teaches receiving a detected activity level of the eluate for each dose and sample, from the activity detector, and entering the detected activity level for each elution into the record ([0235]); and compiling a report that contains the record, the report being formatted printing ([0075]; [0235]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the pre-programmed method of the system of deKemp et al. US '848, Fago, and Williams to maintaining a record of prior the elutions as taught by Tate, because maintaining such a record permits a practitioner to access prior injection and elution records as needed for compiling and printing injection records (Tate, [0181]; [0235]; [0238]-[0245]).

Regarding **claim 38**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848 teaches sampling the activity level in the dose calibrator at regular intervals throughout the duration of the elution run ([0055]). deKemp et al. US '848 also teaches calibration data collected during the elution can be used to calculate the proportionality constant K between the activity parameter (C_{det}) and the ^{82}Rb activity concentration ([0056]-[0057]). The combination of

deKemp et al. US '848, Fago, and Williams does not teach providing via the computer interface, calibration data entry fields for a user.

However, Tate further teaches user-friendly data entry mechanisms for the system (10) ([0170]), such that calibration data may be entered by the user ([0269]-[0271]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of deKemp et al. US '848, Fago, and Williams such that calibration and activity data of may be input by a user through the user-friendly data entry mechanisms taught by Tate in order to clearly and unambiguously communicate the current status of the system to an operator (Tate, [0170]; [0269]-[0271]).

Regarding **claim 39**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848, Fago, and Williams do not teach providing a patient identification entry field for a user to enter a patient identification number, receiving a detected activity level of a dose of eluate from the activity detector, or compiling a report that includes an identification number for the generated dose and detected activity level.

However, Tate further teaches the touch screen arrangement (1000) can be used for four categories of tasks, including Patient Treatment ([0172]). Tate discloses the "Patient Treatment" category includes a number of tasks including inputting patient and/or case identification information into the system (10) and measuring the activity level of the radiopharmaceutical dose ([0207]). Tate teaches that the pharmaceuticals are used in imaging procedures ([0069]). Tate teaches that the printer (24) may be used to generate records of the injection and/or imaging procedures performed for inclusion

in their medical records ([0075]). Tate discloses a "Case Information" pop-up display (1217) including an "Identification" field (1217a) and a keypad (1217j) for inputting a patient or other identification number ([0216]). Lastly, Tate discloses a detailed injection history display (1360), which includes activity level of the injection and the patient identification number, and can be printed using "Print" button (1363) ([0245]; *Figure 34B*). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the identification information taught by Tate in order to generate records of the injection and/or imaging procedures performed for inclusion in patient's medical records (Tate, [0075]).

Regarding **claim 44**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848, Fago, and Williams do not teach the computer interface comprises a touch-activated display screen.

However, Tate further teaches that the fluid delivery system (10) includes a display or graphical user interface display (15) for programming and operating the system (10) and may incorporate touch-screen capability ([0071]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the touch-screen capability taught by Tate to improve ease of use of the system (Tate, [0071]).

6. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago)

and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2008/0177126 (Tate et al.) and U.S. Patent Application Publication No. 2007/0140958 (deKemp, hereinafter “deKemp US ‘958").

Regarding **claim 5**, deKemp et al. US ‘848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US ‘848 teaches the pre-programmed method comprises categorizing each counted elution as having been generated as a sample or a dose (A control algorithm regulates a flow rate and volume of the sterile saline solution 100 pumped through the generator column 10 and controls valve 108, which directs the eluate through a delivery line 112 for a calibration elution or a patient elution 110, [0025]). deKemp et al. US ‘848 does not specify the pre-programmed method comprises receiving a detected activity level and entering the detected activity level for each elution into the record and calculating and tracking the amount of activity left in the generator after each elution.

However, Fago further teaches receiving a detected activity level and entering the detected activity level for each elution into the record (An actual radioactivity level of the eluate can be determined at a given time, programmed into the computer 54, [0034]; [0036]); and calculating and tracking the amount of activity left in the generator after each elution (The radioactivity level can be incorporated with other data to determine an expected radioactivity level at a specified future time and thus estimate when the generator will be ready for another elution process, [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of

deKemp et al. US '848 to include the radioactivity information and estimations taught by Fago in order to estimate when a generator will be ready to perform another elution process (Fago, [0034]). The combination of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions or compiling a report that includes an amount of activity left in the generator.

However, Tate teaches a system that generates and infuses radiopharmaceuticals (abstract), comprising a computer coupled to a computer interface, pre-programmed to execute a method comprising a step of maintaining a record of prior elutions (abstract; Records or Injection History button 1022, [0172], [0181]; [0238]-[0245]). Tate further teaches receiving a detected activity level of the eluate for each dose and sample, from the activity detector, and entering the detected activity level for each elution into the record ([0235]); and compiling a report that contains the record ([0075]; [0235]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the pre-programmed method of the system of deKemp et al. US '848, Fago, and Williams to maintaining a record of prior the elutions as taught by Tate, because maintaining such a record permits a practitioner to access prior injection and elution records as needed for compiling and printing injection records (Tate, [0181]; [0235]; [0238]-[0245]). The combination of deKemp et al. US '848, Fago, Williams, and Tate does not teach compiling a report that includes an amount of activity left in the generator.

However, deKemp US '958 teaches a system that generates and infuses radiopharmaceuticals (abstract), comprising a computer coupled to a computer

interface, pre-programmed to execute a method wherein a valve (108) directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ([0025]). The calibration eluate is tested for 82Rb yield and 82Sr breakthrough to determine if the yield is above a predetermined radioactivity limit ([0029]; *Figure 5*). deKemp US '958 teaches the pre-programmed method comprises controlling a volume of fluid during generator column (10) flushes and elutions, and accepts the cumulative volume and stores it ([0031]). Lastly, deKemp US '958 teaches that the cumulative volume is recomputed after each elution and disposing of the generator column if the volume limit is exceeded ([0032]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yield and volume determinations of deKemp US '958 in the records of the computer controlled elution system of deKemp et al. US '848, Fago, Williams, and Tate in order to determine if the generator column can safely continue to be used for patient elutions (deKemp US '958, [0028]).

7. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2007/0140958 (deKemp, hereinafter "deKemp US '958").

Regarding **claim 37**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848, Fago, and Williams do not teach providing a first and second set of breakthrough test data entry fields.

However, deKemp US '958 teaches a system that generates and infuses radiopharmaceuticals (abstract), wherein a generator column (10) is flushed with 50 ml of sterile saline solution in order to remove any strontium breakthrough, and then the operator waits for a predetermined period of time of at least 10 minutes before performing the calibration elution ([0029]). deKemp US '958 teaches that the calibration eluate subsequently tested for ^{82}Rb yield and ^{82}Sr breakthrough ([0029]). deKemp US '958 discloses that those skilled in the art would know to test the radioactivity of the elution after about 26 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and will not distort the test results ([0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the breakthrough measurements taught by deKemp US '958 in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to determine if breakthrough is less than a threshold for permissible levels ([0030]).

8. **Claim 40** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent No. 7,996,068 (Telischak et al.).

Regarding **claim 40**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. The cited prior art does not teach a light projector or providing a light signal when the pump is activated.

However, Telischak teaches a detection system wherein a visible light is projected at all times when the device is activated (col. 8, lines 18-26). It would have been obvious to one of ordinary skill in the art to include the light projecting when the device is activated as disclosed by Telischak in the pump of the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to confirm to a practitioner that the device is operational (Telischak, col. 8, lines 24-25).

9. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2006/0015056 (Ellingboe et al.).

Regarding **claim 41**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. deKemp et al. US '848 teaches a "waiting for threshold" mode of system (14), in which the saline flow is routed through the generator (8) and into the waste reservoir (26) ([0031]), and an "elution" mode where the active saline solution is directed to the patient outlet ([0032]). The combination of deKemp et al. US '848, Fago, and Williams does not teach a light projector or providing a first light signal when an initial volume of eluate is being diverted or providing a second light signal when the pumping is generating the sample or the dose of eluate.

However, Ellingboe teaches a system for fluid delivery, wherein an animated light indicator may be provided to indicate when cardioplegia is being delivered (e.g. via

green illumination) and when delivery is stopped (e.g. via red illumination) ([0243]; *Figure 301*). It would have been obvious to one of ordinary skill in the art to include the different illumination signals disclosed by Ellingboe in the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to provide indicators to the operator regarding which stage of the infusion is occurring.

10. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent No. 4,585,941 (Bergner).

Regarding **claim 42**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. The cited prior art does not teach a light projector or providing a light signal when the activity detector detects a peak bolus of radioactivity.

However, Bergner teaches a system that generates and infuses radiopharmaceuticals (abstract), wherein an LED display (100) is immediately about the total dose thumbwheel switches (98) and displays the total dose which has been infused in the patient (56) (col. 5, lines 8-25). Bergner teaches the actual dose rate present in the eluate within the tube (30) in front of the dosimetry probe (58) is displayed on LED display (104) (col. 5, lines 8-25). It would have been obvious to one of ordinary skill in the art to include the LED signals emitted based on actual dose as disclosed by Bergner in the computer controlled infusion system of deKemp et al. US '848, Fago, and

Williams in order to provide a description of the dose present in the eluate (Bergner, col. 5, lines 19-22).

11. **Claim 45** is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2005/0187515 (Varrichio et al.).

Regarding **claim 45** deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. The cited prior art does not teach at least one sensor for detecting a leak in the tubing and providing an indication that a leak has been detected.

However, Varrichio et al. teaches an infusion system comprising: a sensor (251) that may be utilized to detect a leak in the valve system (241) ([0027]). Varrichio et al. teaches that if one of the flow valves leaks, a midpoint pressure will drift higher if primary flow valve (343) is leaking and lower if redundant flow valve (344) is leaking, thus providing an indication that a leak has been detected ([0036]). Varrichio et al. discloses a user interface for external program controller (260), which provides real-time status information with respect to infusate pump (200), and may provide audible alarms upon detection of particular conditions and may report conditions to the doctor using information from sensor (251) ([0027]; [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the leak detecting sensor of Varrichio et al. in the computer controlled elution system of deKemp et al. US '848,

Fago, and Williams in order to provide feedback to the doctor to indicate presence of a leak (Varrichio et al., [0027]).

12. **Claim 46** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of (U.S. Patent No. 5,395,320) (Padda et al.).

Regarding **claim 46**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. The cited prior art does not teach calculating a flow rate profile or controlling a speed of the pump according to the calculated flow rate profile.

However, Padda teaches an infusion pump which can be programmed to deliver any of a variety of selected profiles of fluid medicine volume over time (abstract). Padda discloses examples of delivery profiles including fixed rate of flow, ramp up, ramp down, fixed rate with increased rate spikes at specified intervals, and no flow with an infusion bolus at specified intervals (col. 2, lines 42-50). Padda teaches a pumping mechanism (24) provides accurate delivery of medicine (col.4, lines 9-10). Padda teaches a piggyback delivery profile function which allows for the use of a second profile applied before, during an interrupt, or after the first profile, and a different medicine and different fluid to be infused through the infusion pump (col. 4, line 59- col. 5, line 6). Padda discloses a CPU that sends a motor control drive (14) a code containing information on the desired motor speed and a motor speed control (15) (col. 6, line 66- col. 7, line 16).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flow control and profile mechanisms of Padda in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to provide a variety of different fluid delivery profiles to a patient (Padda, col. 2, lines 31-34).

13. **Claim 47** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2007/0213848 deKemp et al. (hereinafter "deKemp et al. US '848") in view of U.S. Patent Application Publication No. 2008/0237502 (Fago) and U.S. Patent Application Publication No. 2007/0260213 (Williams et al.), as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2003/0139640 (Whittacre et al.).

Regarding **claim 47**, deKemp et al. US '848 in view of Fago and Williams teaches the limitations of claim 1. The cited prior art does not teach transferring a plurality of detect activity levels to another system.

However, Whittacre teaches a system for infusing radiopharmaceuticals (abstract), comprising: a display of the amount of isotope which is generating the radioactivity and transferring those values to a database if accepted by the operator ([0195]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the data transfer of Whittacre in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to allow one or more physicians to access the displayed information (Whittacre, [0202]).

Response to Arguments

14. Applicant's arguments filed 23 July 2015 have been fully considered but they are not persuasive for the reasons given in the Advisory Action mailed 19 August 2015.

Conclusion

15. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARRIE R. DORNA whose telephone number is

(571)270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
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Art Unit 3735

/C. R. D./
Examiner, Art Unit 3735

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7	(("20070140958") or ("7966068") or ("20060015056") or ("4585941") or ("20050187515") or ("5395320") or ("20030139640")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:33
L2	1	("7996068").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/28 20:59
L3	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
L4	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
L5	1899	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
L6	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
L7	32	(L3 or L4 or L5 or L6) (display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:25
L8	33	("4202345").PN. OR ("4562829").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/09/28 21:26
L9	1	((display$4 same tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 21:32
S2	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/08/14 10:57
S3	3	(("20070213848") or ("20080237502") or ("20070260213")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/08/14 11:17

S4	2	(time with elaps$3 with elut$4) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:51
S5	107	(time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:52
S6	0	(display$4 with time with elaps$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S7	3	(display$4 same (time with elaps$3)) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 12:53
S8	2	(display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:16
S9	2	S4 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S10	273	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/08/14 13:21
S11	1	S10 (time with elaps$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/08/14 13:21
S12	275	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) or (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:01
S13	191	(bracco near2 diagnostics).as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/09/28 13:03
S14	2	("3543752" | "3861380").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S15	4	("3535085" | "4160910" | "4759345" | "6639237").PN.	US-PGPUB; USPAT	AND	ON	2015/09/28 13:16
S16	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 13:21

S17	3184	A61N5/1001,1002,1007,1014-1017,1027,1028.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 15:51
S18	118	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 16:45
S19	1899	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 17:04
S20	407	G21G4/08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:22
S21	0	(S17 or S18 or S19 or S20) (display$4 same (time with (idl$3 or compet$))) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:55
S22	31	(S17 or S18 or S19 or S20) (display$4 same tim$3) (radio$1pharmaceutical$1 with generat$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/09/28 18:56

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	0	((display$4 with tim$3) (((radioactiv$3 with (inject$4 or infus$4 or fluid)) or radio$1pharmaceutical$1) with generat$4) (control$4 or process$4 or computer) pump$4 detect$4).clm.	US-PGPUB; USPAT	AND	ON	2015/09/28 21:32

9/28/2015 9:34:57 PM
C:\Users\cdorna\Documents\EAST\Workspaces\12808467.wsp

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Jacqueline Cheng
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3535085	A	1970-10-20	Shumate	
	2	4160910	A	1979-07-10	Thornton et al.	
	3	4759345	A	1988-07-26	Mistry	
	4	6639237	B2	2003-10-28	Pedersen et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

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	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/CARRIE DORNA/	Date Considered	09/28/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

09/28/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

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Art Unit	3735
Examiner Name	Jacqueline Cheng
Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-06-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application Number	12808467
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First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3543752		1970-12-01	Hesse et al.	
	2	3861380		1975-01-21	Chassagne et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

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	1							☐

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Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.2

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/CARRIE DORNA/	Date Considered	09/28/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-09-24
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R. DORNA	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014	04/16/2015	09/28/2015		
	1	✓	✓	✓	✓	✓	✓	✓		
	2	✓	✓	✓	✓	✓	✓	✓		
	3	✓	✓	✓	✓	✓	✓	✓		
	4	✓	✓	✓	✓	✓	✓	✓		
	5	✓	✓	✓	✓	✓	✓	✓		
	6	N	N	N	N	N	N	N		
	7	N	N	N	N	N	N	N		
	8	-	-	-	-	-	-	-		
	9	-	-	-	-	-	-	-		
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	21	-	-	-	-	-	-	-		
	22	-	-	-	-	-	-	-		
	23	-	-	-	-	-	-	-		
	24	-	-	-	-	-	-	-		
	25	-	-	-	-	-	-	-		
	26	-	-	-	-	-	-	-		
	27	-	-	-	-	-	-	-		
	28	-	-	-	-	-	-	-		
	29	-	-	-	-	-	-	-		
	30	-	-	-	-	-	-	-		
	31	-	-	-	-	-	-	-		
	32	-	-	-	-	-	-	-		
	33	-	-	-	-	-	-	-		
	34	-	-	-	-	-	-	-		
	35	-	-	-	-	-	-	-		
	36	N	N	N	N	N	N	N		

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	CARRIE R. DORNA	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014	04/16/2015	09/28/2015		
	37	✓	✓	✓	✓	✓	✓	✓		
	38	✓	✓	✓	✓	✓	✓	✓		
	39	✓	✓	✓	✓	✓	✓	✓		
	40	✓	✓	✓	✓	✓	✓	✓		
	41	✓	✓	✓	✓	✓	✓	✓		
	42	✓	✓	✓	✓	✓	✓	✓		
	43	✓	✓	✓	✓	✓	✓	✓		
	44	✓	✓	✓	✓	✓	✓	✓		
	45	✓	✓	✓	✓	✓	✓	✓		
	46	✓	✓	✓	✓	✓	✓	✓		
	47	✓	✓	✓	✓	✓	✓	✓		
	48	✓	✓	✓	✓	✓	✓	✓		
	49	N	N	N	N	N	N	N		
	50	N	N	N	N	N	N	N		
	51					✓	✓	✓		

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	CARRIE R. DORNA	3735

CPC- SEARCHED		
Symbol	Date	Examiner
A61N5/1002, 1007	8/5/14	EF
A61N 2005/1021	8/5/14	EF
A61N 5/1001, 1002, 1007, 1014-1017, 1027, 1028	9/2015	CD
A61N 2005/1021	9/2015	CD
A61M 5/007	9/2015	CD
G21G 4/08	9/2015	CD

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF
Updated class/subclass searches and text searching in EAST for AFCP 2.0 submission	8/5/14	EF

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Updated class/subclass searches	11/17/14	EF
Updated class/subclass searches	4/16/15	EH
see EAST search report	9/2015	CD
EAST: inventor name search, assignee search	9/2015	CD

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
	see EAST search report	9/2015	CD

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12808467	Filing Date	2010-06-16	Docket Number (if applicable)	56782.1.7.2	Art Unit	3735
First Named Inventor	Stephen E. Hidem			Examiner Name	Carrie R. Dorna		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 061910

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-09-24
Name	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3543752		1970-12-01	Hesse et al.	
	2	3861380		1975-01-21	Chassagne et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Carrie R. Dorna
	Attorney Docket Number	56782.1.7.2

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Carrie R. Dorna
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-09-24
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	600	600
Miscellaneous:				
RCE- 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**2300**

Electronic Acknowledgement Receipt

EFS ID:	23596969
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	24-SEP-2015
Filing Date:	16-JUN-2010
Time Stamp:	17:37:15
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2300
RAM confirmation Number	5794
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	56782_1_7_2_EOT.pdf	187413 46fc0c8da437cc04e039e470a5aa7c92354c1f7c	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	56782_1_7_2_RCE_sb0030e_fill.pdf	697800 1dcfbfe7172b8e7aa445f57c2207c35919972c5c	no	3
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_SIDS09240215.pdf	612235 af3dcc1d761bd3b2c0a35a63686c69cf29644d0e	no	4
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32494 92374316ae4bf97a0be4c56ea1e5ad03469dced0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1529942		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/22 (03-13)
Approved for use through 3/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional)
56782.1.7.2

Application Number	Filed
12/808,467	June 16, 2010

For INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Art Unit	Examiner
3735	Carrie R. Dorna

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☑ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$ 600.00
☐ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 06-1910.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration number 64,610.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Paul J. LaVanway, Jr./	September 24, 2015
Signature	Date
Paul J. LaVanway, Jr.	612-492-7387
Typed or printed name	Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 08/19/2015

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EXAMINER
DORNA, CARRIE R

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
08/19/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 12/808,467	**Applicant(s)** HIDEM ET AL.	
	Examiner CARRIE R. DORNA	**Art Unit** 3735	**AIA (First Inventor to File) Status** No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 July 2015 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): (a) ☐ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1-5,37-48 and 51.
    Claim(s) withdrawn from consideration: 6,7,36,49 and 50.

/Charles A. Marmor, II/ Supervisory Patent Examiner, Art Unit 3735	/CARRIE R DORNA/ Examiner, Art Unit 3735

Continuation of 12. Applicant's arguments filed 23 July 2015 have been fully considered but they are not persuasive.

Applicant contends that the combination of de Kemp, Fago, and Williams fails to meet the invention of claim 1 in part because Fago does not disclose a computer providing an indication that each elution is completed (arguments, page 3-5). Applicant alleges that since Fago discloses separate, unrelated embodiments wherein a syringe pump is employed to dispense eluant and wherein the volume dispensed is displayed via a drip counter, respectively, Fago fails to disclose providing an indication via a computer when a pump has competed dispensation (arguments, pages 3-5). The examiner does not find these arguments to be persuasive. The broadest reasonable interpretation of the limitation "the computer…being pre-programmed to execute a method, the method comprising:…providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator" requires a computer programmed in a manner that it is capable of performing the recited function of providing an indication of when the pump has completed dispensation. The deficiency of de Kemp with respect to this limitation is that de Kemp lacks a teaching of a computer programmed to be capable of providing an indication that the pump has completed pumping a volume of eluant. Since Fago discloses a computer that is programmed to display a volume of dispensed eluant ([0034]), Fago discloses a computer programmed in a manner that is capable of providing an indication via computer interface of when dispensation of an elution is complete. Fago teaches the benefit of providing such a display is to provide a practitioner with an indication of when the proper desired amount of eluant has been dispensed ([0004]; [0034]). Accordingly, the system of de Kemp modified in view of this teaching of Fago would result in a computer providing an indication via its interface of when the pump has competed pumping the desired volume of eluant.

Applicant additionally contends the cited combination of de Kemp, Fago, and Williams further fails to meet the invention of claim 1 as Williams does not disclose displaying the time elapsed since completion of an elution (arguments, pages 5-6). Applicant alleges that Williams is not directed to a radioisotope generator, and further teaches displaying the time elapsed since the "beginning" of a procedure (the introduction of contrast media into a patient) instead of the time elapsed since the completion of a procedure (elution) (arguments, page 7). The examiner does not find these arguments to be persuasive. The broadest reasonable interpretation of the limitation "the computer…being pre-programmed to execute a method, the method comprising:…displaying, via the computer interface, a time lapse sinse each elution was completed" requires a computer programmed in a manner that is capable of performing the recited function of displaying via an interface a time lapse since the completion of an elution. While Fago describes time data related to dispensation of an elution may be used to determine "a certain time when an elution should be performed" based on a calculated "expected radioactivity level at a specified future time" ([0034]), de Kemp and Fago fail to disclose a computer programmed to be capable of displaying a time lapse since the elution was completed. Since Williams discloses a system including a computer programmed to display via a time counter the time elapsed following a "dispensation function" ([0044]-[0045]), Williams discloses a computer programmed in a manner that is capable of displaying a time counter that indicates the elapsed time following completion of an elution, providing the benefit of enabling a practitioner to efficiently monitor dispensation in a single interface ([0006]; [0045]).

Applicant contends that the Office has not properly supported a prima facie conclusion of obviousness with respect to the limitations of claim 51 (arguments, pages 8-9). The examiner does not find this argument to be persuasive. The limitations of claim 51 further define the limitations of claim 1 directed to displaying a time lapse for which Williams is applied, and is maintained for the reasons noted above. Williams discloses a displayed "elapsed time counter graphic 410" in Figure 4 that is described in paragraph [0045] as updated "in real time" ([0045]), thus is a "timer counting up or down". The limitaitons of claim 51 are met by the combination of de Kemp, Fago, and Williams, and would have been obvious to one of ordinary skill in the art at the time of the invention for the reasons noted above and in the previous Office action.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Jacqueline CHENG
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFTER-FINAL RESPONSE

Dear Commissioner:

In response to the Office Action mailed April 24, 2015, the period of response for which runs through July 24, 2015, reconsideration of the application is respectfully requested in view of the following remarks.

Remarks begin on page 2 of this paper.

REMARKS

These Remarks are responsive to the Office Action dated April 24, 2015. Claims 1–7 and 36–51 remain pending, with claims 6, 7, 36, 49, and 50 withdrawn from consideration. Reconsideration of the application is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Final Office Action, the Examiner maintained the rejections set out in the Non-Final Office Action dated November 25, 2014. In particular, the Final Office Action rejected claims 1, 43 and 51 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over deKemp et al. (US 2007/0213848, hereinafter "deKemp '848") in view of Fago (US 2008/0237502) and Williams et al. (US 2007/0260213, hereinafter "Williams"). In addition, claims 2–5, 37–42, and 44–48 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over de Kemp '848 in view of Fago and Williams and in further view of additional cited references. Applicant respectfully traverses the rejections. The applied references fail to disclose or suggest the features defined by the claims, and there would have been no apparent reason for modification to arrive at the claim features.

In response to Applicant's previous arguments discussing the deficiencies of deKemp '848 in view of Fago and Williams, the Final Office Action indicated that the remarks were considered by the Examiner but that the Examiner deemed the rejections to still be proper.[1] Accordingly, the current Office Action rejected the claims on the same grounds of rejection presented in the Office Action dated November 25, 2014.[2] Applicant respectfully disagrees.

As an initial matter, Applicant reiterates and incorporates by reference the arguments presented in the Office Action response dated February 23, 2015 as to why the applied references do not render the pending claims unpatentable. Those remarks focused on two primary points traversing the grounds of rejection lodged against the pending claims. First, Applicant submitted that the applied references do not disclose or suggest a system that includes a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of

[1] *See* Final Office Action dated April 24, 2015, at page 18.
[2] *See id.* at page 3.

eluant through the generator."[3] Second, Applicant took the position that the Office Action had improperly characterized Williams as teaching a "display of time lapse since each elution."[4] The "Response to Arguments" section of the present Office Action responded to those earlier arguments of Applicant.

While Applicant appreciates the additional insight into the grounds of rejection provided by the Examiner in the "Response to Arguments" section, Applicant still respectfully disagrees with the rejections. For sake of clarity, the following remarks focus on why Applicant still respectfully disagrees with the rejection of the claims, as those rejections were developed in the "Response to Arguments" portion of the Office Action.

Issue 1

In Applicant's remarks responding to the Non-Final Office Action dated November 25, 2014, Applicant explained why, even if the system of deKemp '848 were modified in view of Fago and Williams as proposed in the Office Action, the resulting combination would not yield a method that involves "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." Specifically, the Office Action acknowledged that deKemp '848 does not disclose the feature but cited Fago in an attempt to overcome the acknowledged deficiency.[5] In particular, the Office Action cited FIGS. 6 and 7 of Fago and related description in the reference as disclosing an electronic drop counter that counts drops passing through a drip chamber and is communicatively coupled to a display "for displaying metrics relating to the elution process."[6] The Office Action appeared to allege that this disclosure of Fago overcomes the acknowledged deficiencies of deKemp '848.[7]

However, the embodiments of cited FIGS. 6 and 7 of Fago do not even have a pump, much less provide an indication related to a pump. Instead, Fago describes that the systems in cited FIGS. 6 and 7 utilize an eluate collection bottle that "begin[s] in an evacuated condition."[8] The reference continues to describe that the evacuated collection bottle causes "eluate residing in

[3] *See* Office Action response dated February 23, 2015, at page 3.
[4] *See id.* at page 7.
[5] *See* Office Action dated April 24, 2015, at page 4.
[6] *See id.* at page 4-5.
[7] *See id.*
[8] Fago at paragraph [0031].

the generator 22 to begin filling the bottle," which correspondingly causes eluate from the eluate supply container 4 to "begin flowing into the generator 22."[9] In other words, the systems in cited FIGS. 6 and 7 of Fago do not have a pump but instead utilize a pressure differential to drive eluant flow.

Because Fago does not have a pump, Fago necessarily does not provide any indication "when a pump has completed pumping," as per claim 1. Since the Office Action relied on Fago to teach this feature of independent claim 1 and overcome the acknowledged deficiencies of deKemp '848, and since Fago does not in fact disclose the feature, the combination of deKemp '848 in view of Fago does not render the claim feature *prima facie* obvious.

The current Final Office Action responded to Applicant's prior arguments concerning the failure of the applied references to disclose or suggest a method that involves "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." In particular, the current Final Office Action responded by alleging that "Fago does teach provid[ing] an indication when a pump has completed pumping" because "Fago teaches a syringe pump [that] is adapted to inject eluent into a generator and teaches an electronic drop counter [to] count the drops passing through the drip chamber."[10] The Final Office Action further stated that Fago "would provide an indication that the pump has completed pumping when the display shows no volume of fluid is passing through the drip chamber."[11]

Applicant respectfully disagrees. Contrary to the position taken in the "Response to Arguments" section of the present Final Office Action, Fago does not disclose or suggest the use of a syringe pump in combination with a drip chamber. Rather, Fago describes two different and unrelated embodiments: one embodiment utilizes a syringe pump but not a drip chamber while the second embodiment utilizes a drip chamber but not a syringe pump. For example, in connection with FIG. 5, Fago describes a generator that has a syringe pump but does not have a drip counter.[12] In this embodiment, Fago describes that graduations or volumetric marks on the syringe enable the user to measure and/or observe the amount of eluant injected into the

[9] *See id.*
[10] Final Office Action dated April 24, 2015, at page 18.
[11] *Id.*
[12] *See, e.g.*, Fago at FIG. 5; paragraph [0032].

generator.[13] For embodiments where there is no pump to directly measure the amount of eluant injected, an alternative measuring arrangement is needed. Accordingly, in connection with the embodiments of FIGS. 6 and 7, which do not have a pump but instead utilize a pressure differential to drive eluant flow, Fago describes using a drip chamber to measure eluant flow.[14]

Nowhere, however, does Fago disclose or suggest using a syringe pump in combination with a drip counter. Indeed, such a combination would not appear to be technically feasible because the pressurized stream of eluant discharging from the pump would not form the slow stream of drips needed for counting and tracking by a drip counter. Accordingly, the factual grounds relied upon in the Final Office Action to assert that Fago discloses providing an indication when a pump has completed pumping is not supported by substantial evidence. Fago does not disclose or suggest providing "an indication that the [syringe] pump has completed pumping when the display shows no volume of fluid is passing through the drip chamber"[15] because Fago does not disclose or suggest using a syringe pump in combination with a drip counter.

Issue 2

In Applicant's remarks responding to the Non-Final Office Action dated November 25, 2014, Applicant also took the position that the rejection of independent claim 1 based on deKemp '848 in view of Fago and Williams is improper because the Office Action improperly characterized the teachings of Williams.[16] In support of the rejection of independent claim 1, the Office Action conceded that neither deKemp '848 nor Fago disclose a computer pre-programmed to execute a method that includes "displaying, via the computer interface, a time lapse since each elution was completed."[17] However, the Office Action cited Williams in an attempt to overcome this deficiency.[18] Specifically, the Office Action rejected independent claim 1 based on the legal conclusion that it would have been obvious to modify the elution process of deKemp '848 and Fago "to display a time lapse since each elution as taught by

[13] *See id.* at paragraph [0032].
[14] *See id.* at paragraph [0033].
[15] *See* Final Office Action dated April 24, 2015, at page 18.
[16] *See* Office Action response dated February 23, 2015, at page 6–7.
[17] *See* Final Office Action dated April 24, 2015, at page 5.
[18] *See id.*

Williams."[19] Williams, though, does not even describe a radioisotope generator that generates eluate via elution, much less a "display of time lapse since each elution."

Williams is directed to an injection device for dispensing contrast media as part of a dispensing procedure.[20] For example, Williams describes that the injection device includes syringes that can be filled with contrast media, flushing media, or combinations thereof for injection into a patient.[21] Nowhere, however, does Williams describe a radioisotope generator system or generating eluate via elution. Williams makes no mention of such a feature. Therefore, Williams necessarily cannot and does not teach displaying "a time lapse since each elution," as asserted in the Office Action.

The current Final Office Action responded to Applicant's prior arguments concerning the failure of Williams to disclose or suggest displaying "a time lapse since each elution." In particular, the current Final Office Action responded by stating that "Williams teaches an elution of contrast media via a dispensing device that is injected into a patient for use in a medical imaging procedure."[22] The Final Office Action further stated that "Williams teaches an elapsed time counter graphic (410) to monitor the elapsed time since the introduction of contrast media into a patient."[23] Applicant again respectfully disagrees.

First, Applicant wishes to reiterate that, contrary to the assertion in the "Response to Arguments" section, Williams does not disclose or suggest elution or generating eluate via elution. While the cited passages of Williams mention contrast media, the passages do not expressly or inherently disclose elution of contrast media. Indeed, the passages make no mention of elution. It is unclear to Applicant how the Office Action is characterizing Williams as purportedly teaching elution, particularly since the Office Action states that Williams teaches "an elution of contrast media via a dispensing device." The dispensing device described in the cited passages of Williams is an injection syringe. On the other hand, Applicant's independent claim 1 requires a radioisotope generator that generates eluate via elution within the generator. Accordingly, Williams does not disclose elution as required by claim 1 and therefore cannot and does not teach displaying "a time lapse since each elution," as further recited by the claim.

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[19] *Id.* at page 6.
[20] *See* Williams at Abstract.
[21] *See id.* at paragraph [0021].
[22] Final Office Action dated April 24, 2015, at page 19.
[23] *Id.*

Second, the characterization of Williams advanced in the "Response to Arguments" section supports—rather than refutes—Applicant's arguments that deKemp '848 in view of Fago and Williams fails to disclose or suggest all the elements required by the claims. As discussed above, Applicant took the position that Williams does not describe a radioisotope generator that generates eluate via elution and therefore cannot disclose a "display of time lapse since each elution." The Office Action responded by stating that "Williams teaches an elapsed time counter graphic (410) to monitor the elapsed time since the introduction of contrast media into a patient."[24] However, Applicant's independent claim 1 does not recite monitoring elapsed time "since the introduction of contrast media into a patient." Rather, the claim recites "displaying, via the computer interface, a time lapse since each elution was completed." An elapsed time since the introduction of contrast media into a patient (as the Office Action alleged Williams teaches) is different than a time lapse since each elution is completed (as per claim 1).

The Office Action based the rejection of independent claim 1 on the legal conclusion that it would have been obvious to modify the elution process of deKemp '848 and Fago "to display a time lapse since each elution as taught by Williams."[25] Since Williams does not teach displaying a time lapse since each elution, as acknowledged in the "Response to Arguments" section of the Office Action, the Office Action did not support the rejection of the claim features by substantial evidence.

Summary

For at least the reasons given above, Applicant respectfully submits that the rejection of independent claim 1 is unfounded and should be reversed. Contrary to the position taken in the Office Action, the combination of the de Kemp '848 reference in view of Fago does not disclose or suggest a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." Further, the Office Action improperly characterized the teachings of Williams in a way that is not supported by the reference.

[24] *Id.*
[25] *Id.* at page 6.

Claims 2–5, 37–48, and 51 depend from independent claim 1 and are therefore patentable for at least the reasons given above with respect to the independent claim, as well as upon additional patentable features and elements claimed in the dependent claims but not explicitly discussed herein. None of the other references overcome the fundamental deficiencies of the de Kemp '848 reference, Fago, and Williams set forth above.

For example, with respect to claim 51, the applied references do not disclose or suggest a computer pre-programmed to execute a method where displaying the time lapse since each elution was completed comprises displaying a timer counting up or down since each elution was completed. In support of the rejection of this feature, the Office Action cited paragraph [0038] and FIG. 4 of Williams. Applicant respectfully disagrees.

Applicant reiterates that Williams does not disclose any type of elution and therefore cannot disclose a "time lapse since each elution was completed." Moreover, in connection with claim 51, the passages of Williams cited in the Office Action do not disclose a timer counting up or down since any type of medical procedure is completed, much less "each elution was completed." Williams describes initiation of the "time counter graphic 410" in cited paragraph [0045] of the reference as follows:

> [T]he elapsed time counter graphic 410 may be automatically initiated concurrently with a dispensing function, such as the dispensing of contrast media by the extension of the injector ram 215, 216 into a syringe 211, 213 filled with contrast media. Thus, a user of the dispensing medical device 115 may, using this embodiment of the computer program product of the present invention, monitor the elapsed time since the introduction of contrast media into a patient . . . .[26]

As seen above, Williams describes monitoring a time "since the introduction of contrast media into a patient." Such time would be the beginning of the medical procedure, not when the medical procedure is "completed."

Applicant notes that the Final Office Action did not address Applicant's prior remarks concerning the insufficiency of the Williams reference to disclose or suggest the features of claim 51. The Final Office Action did not respond to the remarks or provide Applicant with any additional guidance on how allegedly the applied references render the features of claim 51 obvious. Applicant respectfully submits that the prior remarks responding to the rejection of claim 51 in the Non-Final Office Action dated November 25, 2014 overcame any *prima facie* case of obviousness. Accordingly, the burden shifted back to the Patent Office to provide

[26] *Id.* at paragraph [0045].

reasons and evidence to substantiate a *prima facie* case of obviousness. Since the Office Action did not provide any further discussion of claim 51 in the Final Office Action, Applicant respectfully submits that a *prima facie* case of obviousness has not been established.

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the fundamental differences identified above, Applicant reserves further comment concerning the additional features set forth in the claims. However, Applicant does not acquiesce in the propriety of the Office Action's application or interpretation of the references with respect to the claims, and reserves the right to present additional arguments in any further prosecution of this application.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: July 23, 2015

Respectfully submitted,

/Paul J. LaVanway, Jr./

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Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

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Electronic Acknowledgement Receipt

EFS ID:	23001197
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Sarah Munson
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	23-JUL-2015
Filing Date:	16-JUN-2010
Time Stamp:	17:14:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		56782_1_7_2_OAR.pdf	130681 60b1e7b75dfbb6bc9d2a7c7c4ec5ceae0de30cf5	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Applicant Arguments/Remarks Made in an Amendment	2	9
Warnings:			
Information:			
	Total Files Size (in bytes):	130681	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
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PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Jacqueline Cheng
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3535085	A	1970-10-20	Shumate	
	2	4160910	A	1979-07-10	Thornton et al.	
	3	4759345	A	1988-07-26	Mistry	
	4	6639237	B2	2003-10-28	Pedersen et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Jacqueline Cheng
	Attorney Docket Number	56782.1.7.2

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Jacqueline Cheng
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-06-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	22560769
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Sarah Munson
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	08-JUN-2015
Filing Date:	16-JUN-2010
Time Stamp:	18:06:38
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	4882
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_SIDS.pdf	612367 a54f103222a1d50a7442a32ce95c20c80d9c2c45	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30780 b48de05d362971fa710d5ed2b559ec3b95eda12e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	643147		

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New International Application Filed with the USPTO as a Receiving Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 04/24/2015

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
HYDE, EILEEN FOLEY

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
04/24/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Office Action Summary	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 23, 2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-7 and 36-51* is/are pending in the application.

5a) Of the above claim(s) *6,7,36,49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,37-48 and 51* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *See Continuation Sheet*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Continuation of Attachment(s) 2). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :March 27, 2015; December 23, 2014.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment

2. The Response filed on February 23, 2015 is acknowledged. Claims 1-5, 37-48, & 51 are pending and claims 6, 7, 36, 49, & 50 are withdrawn based on a prior restriction/election.

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 43, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. (US Publication No. 2007/0213848 A1) (hereinafter "deKemp et al. US '848") (cited in the Office Action dated January 4, 2013) in view of Fago (US Publication No. 2008/0237502 A1) (cited in the Office Action dated October 2, 2013) and Williams et al. (US Publication No. 2007/0260213 A1) (cited in the Office Action dated November 25, 2014).

Regarding claim 1, deKemp et al. US '848 teaches an eluent reservoir (*reservoir (4)* (paragraph [0025]; Figure 3)), a pump coupled to the reservoir (*pump (6)* (paragraph [0025]; Figure 3)), an infusion tubing circuit (*generator valve (16), bypass line (18), patient valve (24), elution system (14)* (paragraph [0025]; Figure 3) *and feed-line (33)* (paragraph [0028]; Figure 5)), a radioisotope generator (*strontium-rubidium ($^{82}Sr/^{82}Rb$) generator (8)* (paragraph [0025]; Figure 3)), an activity detector (*positron detector (20)* (paragraph [0025]; Figure 3)), a waste bottle (*waste reservoir (26)* (paragraph [0025]; Figure 3)), a computer (*controller (28)* (paragraph [0025]; Figure 3)) and a computer interface (*user interface (44)* (Figure 3)). deKemp et al. US '848 also teaches the infusion tubing circuit including an eluant line coupled to the pump and to the generator (*pump (6) for drawing saline from reservoir (4)* (paragraph [0025])) and an eluate line coupled to the generator, to the activity detector and to the waste bottle (*generator valve (16) to proportion saline flow between the generator (8) and a bypass line (18) which meet at merge point (22), a positron detector (20) downstream of merge point (22), a patient valve (24) to control supply of saline to patient outlet (10) and waste reservoir (26)* (paragraph [0025])).

deKemp et al. US '848 further teaches a controller (28) is connected to pump (6), positron detector (20), valves (16) and (24), and user interface (44) (paragraph [0025]; Figure 3)

that pump (6) and valves (16, 24) are controlled to route saline through the system (14) in accordance with various modes of operation (paragraphs [0029]-[0032]; Figures 6a-6d). deKemp et al. US '848 teaches a pump (6) for drawing saline from the reservoir (4) at a desired flow rate (paragraph [0025]). During an "elution" mode, deKemp et al. US '848 discloses generator valve (16) is actively controlled by a control loop (42) from the positron detector (20) to proportion saline flow through both the generator (8) and bypass line (18) (paragraph [0032]).

deKemp et al. US '848 does not explicitly teach the use of a computer to control the modes of operation of the system, providing an indication that the elution is complete, or displaying, via the computer interface, a time lapse since each elution was completed.

Fago teaches visualization of the eluate collection bottle (34) facilitates determining when the elution process is complete, e.g. the eluate collection bottle (34) is full (paragraph [0031]). Fago teaches a syringe pump (40 is adapted to inject the eluent (18) into the generator (22) via tubing (10) (paragraph [0032]). Fago teaches a drip chamber (44) is incorporated in the tubing (10) to facilitate tracking or identification of an amount of eluent flowing into a generator (22) (paragraph [0033]; Figure 6). Fago teaches an electronic drop counter (46) may be used to count the drops passing through the drip chamber (44) by using an LED (48) and a photo detector (50) to determine when a drop passes through the drip chamber (44) (paragraph [0033]; Figure 7). Fago teaches this facilitates the provision of metrics relating to the amount of eluant being passed from the eluant passing from the eluent supply container (4) into the generator (22) (paragraph [0033]). Fago teaches the drop counter (46) is coupled to an electronic device and/or computer (54) to store data, facilitate communication with other device, and/or perform calculations relating to the elution process (paragraph [0034]). Fago teaches the drop counter

(46) is communicatively coupled to a display (52) for displaying metrics relating to the elution process and that the display may be incorporated into the computer (54) (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of controlling an $^{82}Sr/^{82}Rb$ elution system of deKemp et al. US '848 to include the displayed volume and time calculations taught by Fago in order to estimate when a generator will be ready for another elution process (Fago, paragraph [0034]).

Fago teaches the volume and/or time associated with each elution process may be tracked and displayed to enable the user to estimate when the generator will be ready for another elution process paragraph [0034]), but the combination of de Kemp et al. US '848 and Fago does not teach displaying, via the computer interface, a time lapse since each elution was completed.

Williams teaches methods for displaying elapsed time information related to the dispensing of media by the dispensing device in relation to a medical procedure (paragraph [0001]). Williams teaches when the user interface (230) comprises a display device, a user may view data corresponding to the dispensing operation, such as flow rate, elapsed time from injection of media (paragraph [0025]). Williams teaches the storage device may be configured to be capable of storing a plurality of display formats and/or the displays of various dispensing tools, including an elapsed time display showing time elapsed from a given dispensing operation (paragraph [0027]). Williams teaches a computer program product comprises executable portions for directing the dispensing medical device (115) to perform at least one dispensing function, to manipulate and/or adjust the display parameters of the user interface (230) (paragraph [0045]). Williams teaches a status text graphic (470) indicating the status of a given dispensing operation, such as its completion, and an elapsed time counter graphic (410) to monitor the elapsed time

since the introduction of contrast media into a patient (paragraph [0045]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the data associated with each elution process taught by de Kemp et al. US '848 and Fago to display a time lapse since each elution as taught by Williams in order to monitor the elapsed time without a need to activate and/or monitor a timing device that is separate from the display (Williams, paragraph [0045]).

Regarding claim 43, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110), or to a shielded waste container (90) ("diverting an initial volume of eluate to the waste bottle") (paragraph [0025]). deKemp et al. US '848 does not teach tracking the initial volume or eluate or providing an indication when the waste bottle needs to be emptied.

Fago teaches an eluate collection bottle (34) may have a standard or predefined volume (paragraph [0031]). Fago teaches a user can observe, based on the visualization portal and index marks (19), the eluent levels in the eluant supply container (4) go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle (34) ("tracking the initial volume of the eluate") (paragraphs [0026] and [0031]). Fago teaches this visualization facilitates determining when the elution process is complete, e.g. the eluate collection bottle is full ("providing an indication when the waste bottle needs to be emptied") (paragraph [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the waste bottle of deKemp et al. US '848 to include the visualization portal and index marks taught by Fago in order to track the amount of fluid in the bottle (Fago, paragraph [0031]).

Regarding claim 51, Williams teaches displaying a timer counting up or down since each elution was completed (paragraph [0038]; *see* timer graphic (410) in Figure 4).

6. Claims 2-4, 38, 39, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Tate et al. (US Publication No. 2008/0177126 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 2, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]) and Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]), but the combination of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions.

Tate teaches a Records or Injection History button (1022) (paragraph [0181]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the Records or Injection

History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

Regarding claim 3, Tate teaches printing the injection information, including information about the activity and volume of the dose delivered to the patient and displaying it in pop-up (1240) (paragraph [0235]).

Regarding claim 4, Tate teaches a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]).

Regarding claim 38, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1. deKemp et al. US '848 teaches sampling the activity level in the dose calibrator at regular intervals throughout the duration of the elution run (paragraph [0055]). deKemp et al. US '848 also teaches calibration data collected during the elution can be used to calculate the proportionality constant K between the activity parameter (C_{det}) and the ^{82}Rb activity concentration (paragraphs [0056]-[0057]). The combination of deKemp et al. US '848, Fago, and Williams does not teach providing via the computer interface, calibration data entry fields for a user.

Tate teaches user-friendly data entry mechanisms for the system (10) (paragraph [0170]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the calibration and activity data of deKemp et al. US '848, Fago, and Williams to be input by a user through the user-friendly data entry mechanisms taught by Tate in order to clearly and unambiguously communicate the current status of the system to an operator (Tate, paragraph [0170]).

Regarding claim 39, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1, but does not teach providing a patient identification entry field for a user to enter a patient identification number, receiving a detected activity level of a dose of eluate from the activity detector, or compiling a report that includes an identification number for the generated dose and detected activity level.

Tate teaches the touch screen arrangement (1000) can be used for four categories of tasks, including Patient Treatment (paragraph [0172]). Tate discloses the "Patient Treatment" category includes a number of tasks including inputting patient and/or case identification information into the system (10) and measuring the activity level of the radiopharmaceutical dose (paragraph [0207]). Tate teaches that the pharmaceuticals are used in imaging procedures (paragraph [0069]). Tate teaches that the printer (24) may be used to generate records of the injection and/or imaging procedures performed for inclusion in their medical records (paragraph [0075]). Tate discloses a "Case Information" pop-up display (1217) including an "Identification" field (1217a) and a keypad (1217j) for inputting a patient or other identification number (paragraph [0216]). Tate also discloses a detailed injection history display (1360), which includes activity level of the injection and the patient identification number, and can be printed using "Print" button (1363) (paragraph [0245]; Figure 34B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the identification information taught by Tate in order to generate records of the injection and/or imaging procedures performed for inclusion in patient's medical records (Tate, paragraph [0075]).

Regarding claim 44, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1, but does not teach the computer interface comprises a touch-activated display screen.

Tate teaches that the fluid delivery system (10) includes a display or graphical user interface display (15) for programming and operating the system (10) and may incorporate touch-screen capability (paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the touch-screen capability taught by Tate for ease of use of the system (Tate, paragraph [0071]).

Regarding claim 48, Tate teaches the fluid delivery system (10) includes a printer (24) (paragraph [0074]). Tate teaches that the printer (24) may generate records of the injection and/or imaging procedures performed on patients and may be pivotally connected to the system (10) to allow an operator to load paper or labels into the printer (24) (paragraph [0075]; Figure 1B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the printer taught by Tate in order to include data in patients' medical records or for billing/inventory purposes (Tate, paragraph [0075]).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Tate and deKemp (US Publication No. 2007/0140958 A1) (hereinafter "deKemp US '958") (cited in the Office Action dated January 4, 2013).

Regarding claim 5, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]).

Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]). Fago teaches an actual radioactivity level of the eluate can be determined at a given time, programmed into the computer (54) ("receiving a detected activity level and entering the detected activity level for each elution into the record") (paragraph [0034]). Fago teaches the radioactivity level can be incorporated with other data to determine an expected radioactivity level at a specified future time and thus estimate when the generator will be ready for another elution process ("calculating and tracking the amount of activity left in the generator after each elution") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of deKemp et al. US '848 to include the radioactivity information and estimations taught by Fago in order to estimate when a generator will be ready to perform another elution process (Fago, paragraph [0034]).

The combination of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions or compiling a report that includes an amount of activity left in the generator.

Tate discloses user-friendly data entry mechanisms for the system (10) (paragraph [0170]). Tate teaches a Records or Injection History button (1022) (paragraph [0181]) and a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

The combination of deKemp et al. US '848, Fago, Williams, and Tate does not teach compiling a report that includes an amount of activity left in the generator.

deKemp US '958 teaches a control algorithm and a valve (108) direct the eluate through a delivery line (112) for a calibration elution or a patient elution (110) (paragraph [0025]). deKemp US '958 teaches that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough to determine if the yield is above a predetermined radioactivity limit (paragraph [0029]; Figure 5). deKemp US '958 teaches control software controls a volume of fluid during generator column (10) flushes and elutions, and accepts the cumulative volume and stores it (paragraph [0031]). deKemp US '958 further teaches that the cumulative volume is recomputed after each elution and disposing of the generator column if the volume limit is exceeded (paragraph [0032]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yield and volume determinations of deKemp US '958 in the records of the

computer controlled elution system of deKemp et al. US '848, Fago, Williams, and Tate in order to determine if the generator column can continue to be used for patient elutions (deKemp US '958, paragraph [0028]).

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of deKemp US '958.

Regarding claim 37, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach providing a first and second set of breakthrough test data entry fields.

deKemp US '958 teaches generator column (10) is flushed with 50 ml of sterile saline solution in order to remove any strontium breakthrough, then the operator waits for a predetermined period of time (at least 10 minutes) before performing the calibration elution (paragraph [0029]). Then, deKemp US '958 discloses that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough (paragraph [0029]). deKemp US '958 discloses that those skilled in the art would know to test the radioactivity of the elution after about 26 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and will no distort the test results (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the breakthrough measurements taught by deKemp US '958 in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to determine if breakthrough is less than a threshold for permissible levels (paragraph [0030]).

9. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Telischak et al. (US Patent No. 7,996,068 B2) (cited in the Office Action dated January 4, 2013).

Regarding claim 40, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the pump is activated.

Telischak teaches a visible light is projected at all times when the device is activated (column 8, lines 18-26). It would have been obvious to one of ordinary skill in the art to include the light projecting when the device is activated disclosed by Telischak in the pump of the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to confirm that the device is operational (Telischak, column 8, lines 24-25).

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Ellingboe et al. (US Publication No. 2006/0015056 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 41, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 also teaches a "waiting for threshold" mode of system (14), in which the saline flow is routed through the generator (8) and into the waste reservoir (26) (paragraph [0031]) and an "elution" mode where the active saline solution is directed to the patient outlet (paragraph [0032]). The combination of deKemp et al. US '848, Fago, and Williams does not teach a light projector or providing a first light signal when an initial volume of eluate is being diverted or providing a second light signal when the pumping is generating the sample or the dose of eluate.

Ellingboe teaches an animated light indicator may be provided to indicate when cardioplegia is being delivered (e.g. via green illumination) and when delivery is stopped (e.g. via red illumination) (paragraph [0243]; Figure 301). It would have been obvious to one of ordinary skill in the art to include the different illumination signals disclosed by Ellingboe in the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to provide indicators to the operator regarding which stage of the infusion is occurring.

11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Bergner (US Patent No. 4,585,941) (cited in the Office Action dated January 4, 2013).

Regarding claim 42, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the activity detector detects a peak bolus of radioactivity.

Bergner teaches an LED display (100) is immediately about the total dose thumbwheel switches (98) and displays the total dose which has been infused in the patient (56) (column 5, lines 8-25). Bergner teaches the actual dose rate which is present in the eluate within the tube (30) in front of the dosimetry probe (58) is displayed on LED display (104) (column 5, lines 8-25). It would have been obvious to one of ordinary skill in the art to include the LED signals based on actual dose disclosed by Bergner in the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to provide a description of the dose present in the eluate (Bergner, column 5, lines 19-22).

12. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Varrichio et al. (US Publication No. 2005/0187515 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 45, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach at least one sensor for detecting a leak in the tubing and providing an indication that a leak has been detected.

Varrichio et al. teaches a sensor (251) that may be utilized to detect a leak in the valve system (241) (paragraph [0027]). Varrichio et al. teaches that if one of the flow valves leaks, a midpoint pressure will drift higher if primary flow valve (343) is leaking and lower if redundant flow valve (344) is leaking, thus providing an indication that a leak has been detected (paragraph [0036]). Varrichio et al. discloses a user interface for external program controller (260), which provides real-time status information with respect to infusate pump (200) and may provide audible alarms upon detection of particular conditions and may report conditions to the doctor using information from sensor (251) (paragraphs [0027] and [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the leak detecting sensor of Varrichio et al. in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to provide feedback to the doctor (Varrichio et al., paragraph [0027]).

13. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Padda et al. (US Patent No. 5,395,320) (cited in the Office Action dated January 4, 2013).

Regarding claim 46, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach calculating a flow rate profile or controlling a speed of the pump according to the calculated flow rate profile.

Padda teaches an infusion pump which can be programmed to deliver any of a variety of selected profiles of fluid medicine volume over time (Abstract). Padda discloses examples of delivery profiles including fixed rate of flow, ramp up, ramp down, fixed rate with increased rate spikes at specified intervals, and no flow with an infusion bolus at specified intervals (column 2, lines 42-50). Padda teaches a pumping mechanism (24) provides accurate delivery of medicine (column 4, lines 9-10). Padda teaches a piggyback delivery profile function which allows for the use of a second profile applied before, during an interrupt, or after the first profile, and a different medicine and different fluid to be infused through the infusion pump (column 4, line 59-column 5, line 6). Padda discloses a CPU that sends a motor control drive (14) a code containing information on the desired motor speed and a motor speed control (15) (column 6, line 66-column 7, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flow control and profile mechanisms of Padda in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to provide a variety of different fluid delivery profiles to a patient (Padda, column 2, lines 31-34).

14. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Whittacre et al. (US Publication No. 2003/0139640 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 47, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach transferring a plurality of detect activity levels to another system.

Whittacre teaches a display of the amount of isotope which is generating the radioactivity and transferring those values to a database if accepted by the operator (paragraph [0195]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the data transfer of Whittacre in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to allow one or more physicians to access the displayed information (Whittacre, paragraph [0202]).

Response to Arguments

15. Applicant's arguments, see pages 3-6 of the Remarks filed February 23, 2015, have been fully considered but they are not persuasive. Fago does teach provide an indication when a pump has completed pumping. Fago teaches a syringe pump is adapted to inject eluent into a generator and teaches an electronic drop counter counts the drops passing through the drip chamber and is coupled to a display for displaying metrics relating to the elution process (see Office Action dated November 25, 2014), and thus would provide an indication that the pump has completed pumping when the display shows that no volume of fluid is passing through the drip chamber. The same detection of presence or absence of fluid passing through the drip chamber would apply if the flow was pressurized or single drips.

16. Applicant's arguments, see pages 6 & 7 of the Remarks filed February 23, 2015, have been fully considered but they are not persuasive. Williams does teach displaying, via the

computer interface, a time lapse since each elution was completed. Williams teaches an elution of contrast media via a dispensing device that is injected into a patient for use in a medical imaging procedure (Abstract; paragraphs [0001], [0002], [0021] & [0022]). Williams teaches an elapsed time counter graphic (410) to monitor the elapsed time since the introduction of contrast media into a patient (paragraph [0045]), which is an important parameter to the success of a medical imaging procedure which depends on the presence of contrast media in the patient. Williams discusses how contrast media is often injected into a patient's vasculature prior to the medical imaging procedure (paragraph [0002] and the time elapsed since the introduction of contrast media into a patient would be relevant to the medical professional in determining if the contrast media had sufficiently circulated in the patient's vasculature to perform the medical imaging. Further, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Williams is combined with the teachings of de Kemp '848 and Fago, which do teach generating and infusing a radioisotope (see above rejection). Williams is combined with the elution of radioisotopes taught by de Kemp '848 and Fago to provide an indicator of the time elapsed since the elution.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EILEEN FOLEY whose telephone number is (571) 270-7248. The examiner can normally be reached Monday-Thursday, and alternate Fridays, from 7:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached at (571) 272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. F./
Examiner, Art Unit 3735

/JACQUELINE CHENG/
Supervisory Patent Examiner, Art Unit 3735

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3847138	A	1974-11-12	Gollub	
	2	4674403	A	1987-06-23	Bryant et al.	

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	1	20110178359	A1	2011-07-21	Hirschman et al.	

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Receipt date: 12/23/2014	Application Number	12808467	12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16	
	First Named Inventor	Stephen E. Hidem	
	Art Unit	3735	
	Examiner Name	Eileen Foley Hyde	
	Attorney Docket Number	56782.1.7.2	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	"CardioGen-82 Infusion System User's Guide," Medical Product Service GmbH, July 3, 2007, 53 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/Eileen Foley/	Date Considered	04/16/2015

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY HYDE	3735

CPC- SEARCHED		
Symbol	Date	Examiner
A61N5/1002, 1007	8/5/14	EF
A61N2005/1021	8/5/14	EF

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF
Updated class/subclass searches and text searching in EAST for AFCP 2.0 submission	8/5/14	EF
Updated class/subclass searches	11/17/14	EF
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INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	8905	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:23
L3	8905	L2	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:23
L4	5968	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L5	5968	L4	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L6	1072	A61N5/1002,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L7	1072	L6	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L8	101	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L9	101	L8	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:24
L10	3	("20110178359" | "3847138" | "4674403").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/04/16 17:28

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 03/27/2015	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2010-06-16
(Not for submission under 37 CFR 1.99)	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.2

	1	ALVAREZ-DIEZ et al. "Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using positron emission tomography," Applied Radiation and Isotopes, 1999, pp. 1015-1023.	☐
	2	U.S. Application No. 14/657,598, filed March 13, 2015, entitled, "REAL TIME NUCLEAR ISOTOPE DETECTION," 48 pages. Attorney docket number 56782.1.13.3.	☐

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Examiner Signature	/Eileen Foley/	Date Considered	04/16/2015

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014	04/16/2015			
	1	✓	✓	✓	✓	✓	✓			
	2	✓	✓	✓	✓	✓	✓			
	3	✓	✓	✓	✓	✓	✓			
	4	✓	✓	✓	✓	✓	✓			
	5	✓	✓	✓	✓	✓	✓			
	6	N	N	N	N	N	N			
	7	N	N	N	N	N	N			
	8	-	-	-	-	-	-			
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	34	-	-	-	-	-	-			
	35	-	-	-	-	-	-			
	36	N	N	N	N	N	N			

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CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014	04/16/2015			
	37	✓	✓	✓	✓	✓	✓			
	38	✓	✓	✓	✓	✓	✓			
	39	✓	✓	✓	✓	✓	✓			
	40	✓	✓	✓	✓	✓	✓			
	41	✓	✓	✓	✓	✓	✓			
	42	✓	✓	✓	✓	✓	✓			
	43	✓	✓	✓	✓	✓	✓			
	44	✓	✓	✓	✓	✓	✓			
	45	✓	✓	✓	✓	✓	✓			
	46	✓	✓	✓	✓	✓	✓			
	47	✓	✓	✓	✓	✓	✓			
	48	✓	✓	✓	✓	✓	✓			
	49	N	N	N	N	N	N			
	50	N	N	N	N	N	N			
	51					✓	✓			

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.2

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2015-03-27
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	21903408
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Sarah Munson
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	27-MAR-2015
Filing Date:	16-JUN-2010
Time Stamp:	17:02:17
Application Type:	U.S. National Stage under 35 USC 371

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2	Non Patent Literature	Alvarez-Diez_Manufacture_of_Strontium-82.pdf	2486151 3ae9deb26f4fccb228792d502e4d68e261e0ae16	no	9
Warnings:					
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3	Non Patent Literature	NPL_56782_1_13_3_APP.pdf	2371777 b11e9ecaeb1872b62ec2f62965f18538f7bf0d20	no	48
Warnings:					
Information:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Eileen Foley Hyde
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Dear Commissioner:

In response to the Office Action mailed November 25, 2014, the period of response for which runs through February 25, 2015, reconsideration of the application is respectfully requested in view of the following remarks.

Remarks begin on page 2 of this paper.

REMARKS

These Remarks are responsive to the Office Action dated November 25, 2014. Claims 1–7 and 36–51 remain pending, with claims 6, 7, 36, 49, and 50 withdrawn from consideration. Reconsideration of the application is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Office Action, claims 1, 43 and 51 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over de Kemp et al. (US 2007/0213848, hereinafter "de Kemp '848") in view of Fago (US 2008/0237502) and Williams et al. (US 2007/0260213, hereinafter "Williams"). In addition, claims 2–5, 37–42, and 44–48 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over de Kemp '848 in view of Fago and Williams and in further view of additional cited references.

Applicant respectfully traverses the rejections. The applied references fail to disclose or suggest the features defined by the claims, and there would have been no apparent reason for modification to arrive at the claim features.

The applied references fail to disclose or suggest all the features of the claims including, for example, independent claim 1. Independent claim 1 is directed to a system that generates and infuses radiopharmaceuticals. The system includes, among other features, an eluant reservoir, a pump, an infusion tubing circuit, a radioisotope generator, and a computer. The claim specifies that the computer is programmed to execute a method that includes activating the pump to pump a volume of eluant in order to generate eluate via elution and providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator. The claim also specifies that the computer is programmed to execute a method that includes displaying, via the computer interface, a time lapse since each elution was completed.

In support of the rejection of independent claim 1, the Office Action cited paragraphs [0025] through [0032] of the de Kemp '848 reference as allegedly disclosing a system that includes an eluant reservoir, a pump, an infusion tubing circuit, a radioisotope generator, a computer, and a user interface.[1] Although the Office Action conceded that the de Kemp '848 reference does not disclose "the use of a computer to control the modes of operation of the

[1] Office Action dated November 25, 2014, at page 3–4.

system, providing an indication that the elution is complete, or displaying, via the computer interface, a time lapse since each elution was completed, the Office Action cited Fago and Williams in an attempt to overcome these deficiencies.[2] In particular, the Office Action cited paragraph [0034] of Fago as teaching that the volume and/or time associated with each elution process may be tracked and displayed to enable a user to estimate when the generator will be ready for another elution process.[3] The Office Action alleged then that it would have been obvious to modify the method of controlling the elution system in the de Kemp '848 reference to include the displayed volume and time calculations of Fago.[4] In addition, the Office Action cited paragraphs [0025] and [0045] of Williams as disclosing displaying elapsed time information related to the dispensing of media.[5] The Office Action took the position that it would have been obvious to further modify the technique of the de Kemp '848 reference in view of Fago to display a time lapse since each elution according to Williams.[6]

For multiple reasons discussed below, Applicant respectfully disagrees that the applied combination of references renders independent claim 1 obvious.

A. THE APPLIED REFERENCES DO NOT DISCLOSE OR SUGGEST A METHOD THAT INCLUDES PROVIDING AN INDICATION, VIA THE COMPUTER INTERFACE, THAT EACH ELUTION IS COMPLETED, WHEN THE PUMP HAS COMPLETED PUMPING EACH VOLUME OF ELUANT THROUGH THE GENERATOR

Even if the system disclosed in the de Kemp '848 reference were modified in view of Fago and Williams in the manner proposed in the Office Action, the resulting combination would not yield all the features required by independent claim 1. For example, the resulting combination would not provide a system that includes a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator."

In support of the rejection of this claim feature, the Office Action acknowledged that the de Kemp '848 reference does not teach the use of a computer to provide an indication that

[2] *Id.* at page 4–5.
[3] *Id.* at page 5.
[4] *Id.*
[5] *Id.*
[6] *Id.* at page 6.

elution is completed, when the pump has completed pumping each volume of eluant through the generator.[7] However, the Office Action cited Fago in an effort to overcome this acknowledged deficiency of the de Kemp '848 reference. In particular, the Office Action characterized Fago as disclosing an electronic drop counter that counts drops passing through a drip chamber and is communicatively coupled to a display "for displaying metrics relating to the elution process."[8] Based on this interpretation of Fago, the Office Action took the position that it would have been obvious to modify the method for controlling the elution system of the de Kemp '848 reference "to include the displayed volume and time calculations taught by Fago."[9]

Fago is directed to a system for identifying an amount or flow of eluant in an elution system.[10] According to Fago, a problem with radioactive shielding containers is that the containers tend to block visualization of the state and progress of an elution process.[11] The reference proposes to overcome this problem by configuring an elution supply container with a drip chamber that can be used to visually and/or electronically measure the number of drops of eluant passing through the drip chamber.[12] An example of this system is shown in FIG. 7 of the reference, which is reproduced below.

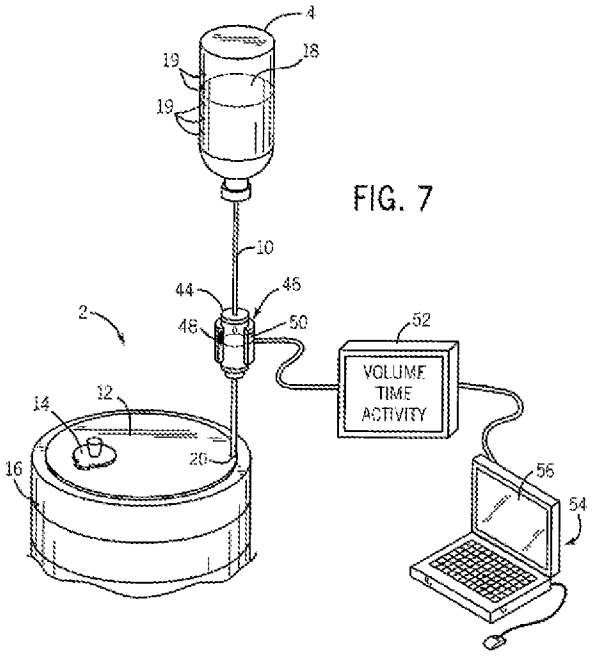

FIG. 7

[7] *See id.* at page 4.
[8] *See id.* at page 5.
[9] *Id.*
[10] Fago at paragraph [0001].
[11] *Id.* at paragraph [0004].
[12] *See id.* at paragraphs [0032]–[0033].

In connection with the figure above, Fago describes a system having a drip chamber 44, an electronic drip counter 46, and a display 52.[13] In operation, Fago states that display 52 can display metrics relating to the elution process.[14] Yet Fago provides no indication that the system of FIG. 7 above has a pump. To the contrary, Fago describes that the system above does not utilize a pump but instead relies on a pressure differential between an eluate collection bottle and the eluate supply container 4.

Fago describes the operation of the systems in cited FIGS. 6 and 7 in connection with FIG. 4 of the reference, which is the same system except that it does not have drip chamber 44. According to Fago, the system utilizes an eluate collection bottle that "begin[s] in an evacuated condition."[15] The reference continues to describe that the evacuated collection bottle causes "eluate residing in the generator 22 to begin filling the bottle," which correspondingly causes eluate from the eluate supply container 4 to "begin flowing into the generator 22."[16] In other words, the system in Fago does not have a pump but instead utilizes a pressure differential to drive eluant flow.

Since the Fago system does not have a pump, Fago necessarily cannot and does not disclose the feature of independent claim 1 acknowledged by the Office Action to be missing from the de Kemp '848 reference. In other words, because Fago does not have a pump, Fago necessarily does not provide any indication "when a pump has completed pumping," as per claim 1.

The Office Action based the conclusion of obviousness on the belief that it would have been obvious to modify the method for controlling the elution system of de Kemp '848 "to include the displayed volume and time calculations taught by Fago."[17] Yet since providing an indication when a pump has completed pumping is not something taught by Fago, and since this was acknowledged to not be disclosed in the de Kemp '848 reference, the combination of the de Kemp '848 reference in view of Fago does not render the claim feature *prima facie* obvious.

Moreover, Applicant respectfully disagrees that a person of ordinary skill in the art would have found it obvious to modify the system of the de Kemp '848 reference to include the drip counter techniques of Fago. The Office Action asserted that it would have been obvious "in

[13] *Id.* at paragraphs [0033]–[0034].
[14] *Id.* at paragraph [0034].
[15] *Id.* at paragraph [0031].
[16] *See id.*
[17] *See id.* at page 5 (emphasis added).

order to estimate when a generator will be ready for another elution process."[18] However, it is unclear how a person of ordinary skill in the art could even have modified the system of the de Kemp '848 reference to include the drop counter hardware needed to implement the volume and time calculation techniques of Fago.

As discussed above, the drop counter in Fago counts eluant drops that form when an evacuated eluate collection bottle is connected to the outlet of generator 22. If the drop counter were placed in the system of the de Kemp '848 reference, drips would not form because the pump in the de Kemp '848 reference would block flow from the eluate source. Further, during pumping, the pressurized stream of eluant discharging from the pump would not form the slow stream of drips needed by the Fago reference for counting and tracking. Since such a technical configuration would not have been feasible, a person of ordinary skill in the art would not have considered it obvious to modify the de Kemp '848 reference in view of Fago as proposed in the Office Action.

For at least the reasons given above, Applicant respectfully submits that the combination of the de Kemp '848 reference in view of Fago does not disclose or suggest a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." Further, Applicant respectfully disagrees that a person of ordinary skill in the art would have considered it obvious to modify the de Kemp '848 reference in view of Fago as suggested in the Office Action.

B. THE OFFICE ACTION HAS IMPROPERLY CHARACTERIZED THE TEACHINGS OF WILLIAMS AND, AS A RESULT, HAS NOT ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS

In addition to the features discussed above, Applicant also respectfully traverses the rejection of independent claim 1 based on the de Kemp '848 reference in view of Fago and Williams because the Office Action has improperly characterized the teachings of Williams. In support of the rejection of independent claim 1, the Office Action conceded that neither the de Kemp '848 reference nor Fago discloses a computer pre-programmed to execute a method that includes "displaying, via the computer interface, a time lapse since each elution was

[18] *Id.*

completed."[19] In an effort to overcome this deficiency, the Office Action cited Williams.[20] Specifically, the Office Action rejected independent claim 1 based on the legal conclusion that it would have been obvious to modify the elution process of the de Kemp '848 reference and Fago "to display a time lapse since each elution as taught by Williams."[21] Williams, though, does not even describe a radioisotope generator that generates eluate via elution, much less a "display of time lapse since each elution."

Williams is directed to an injection device for dispensing contrast media as part of a dispensing procedure.[22] For example, Williams describes that the injection device includes syringes that can be filled with contrast media, flushing media, or combinations thereof for injection into a patient.[23] Nowhere, however, does Williams describe a radioisotope generator system or generating eluate via elution. Williams makes no mention of such a feature. Therefore, Williams necessarily cannot and does not teach displaying "a time lapse since each elution," as asserted in the Office Action.

The Office Action based the rejection of independent claim 1 on the conclusion that it would have been obvious to modify the elution process of the de Kemp '848 reference and Fago "to display a time lapse since each elution as taught by Williams." Since Williams does not, in fact, teach displaying a time lapse since each elution, the Office Action improperly characterized the teachings of Williams. Consequently, the Office Action did not support by substantial evidence the rejection of independent claim 1 based on the de Kemp '848 reference in view of Fago and Williams.

For the additional reasons given above, Applicant respectfully submits that a *prima facie* case of obviousness was not established for independent claim 1.

C. SUMMARY

For at least the reasons given above, Applicant respectfully submits that the rejection of independent claim 1 is unfounded and should be reversed. Contrary to the position taken in the Office Action, the combination of the de Kemp '848 reference in view of Fago does not disclose or suggest a computer pre-programmed to execute a method that includes "providing an

[19] *Id.*
[20] *Id.*
[21] *Id.* at page 6.
[22] *See* Williams at Abstract.
[23] *See id.* at paragraph [0021].

indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." Further, a person of ordinary skill in the art would not have considered it obvious to modify de Kemp '848 in view of Fago as suggested in the Office Action. In addition, the Office Action improperly characterized the teachings of Williams in a way that is not supported by the reference.

Claims 2–5, 37–48, and 51 depend from independent claim 1 and are therefore patentable for at least the reasons given above with respect to the independent claim, as well as upon additional patentable features and elements claimed in the dependent claims but not explicitly discussed herein. None of the other references overcome the fundamental deficiencies of the de Kemp '848 reference, Fago, and Williams set forth above.

For example, with respect to claim 51, the applied references do not disclose or suggest a computer pre-programmed to execute a method where displaying the time lapse since each elution was completed comprises displaying a timer counting up or down since each elution was completed. In support of the rejection of this feature, the Office Action cited paragraph [0038] and FIG. 4 of Williams. Applicant respectfully disagrees.

As an initial matter, Applicant reiterates that Williams does not disclose any type of elution and therefore cannot disclose a "time lapse since each elution was completed." Moreover, in connection with claim 51, the passages of Williams cited in the Office Action do not disclose a timer counting up or down since any type of medical procedure is completed, much less "each elution was completed." Williams describes initiation of the "time counter graphic 410" in cited paragraph [0045] of the reference as follows:

> [T]he elapsed time counter graphic 410 may be automatically initiated concurrently with a dispensing function, such as the dispensing of contrast media by the extension of the injector ram 215, 216 into a syringe 211, 213 filled with contrast media. Thus, a user of the dispensing medical device 115 may, using this embodiment of the computer program product of the present invention, monitor the elapsed time since the introduction of contrast media into a patient . . . .[24]

As seen above, Williams describes monitoring a time "since the introduction of contrast media into a patient." Such time would be the beginning of the medical procedure, not when the medical procedure is "completed." For this additional reason, the applied references do not render the features of dependent claim 51 obvious.

[24] *Id.* at paragraph [0045].

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the fundamental differences identified above, Applicant reserves further comment concerning the additional features set forth in the claims. However, Applicant does not acquiesce in the propriety of the Office Action's application or interpretation of the references with respect to the claims, and reserves the right to present additional arguments in any further prosecution of this application.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: February 23, 2015

Respectfully submitted,

/Paul J. LaVanway, Jr./

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Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

52250776_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	21566177
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	23-FEB-2015
Filing Date:	16-JUN-2010
Time Stamp:	11:55:48
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		56782_1_7_2_OAR.pdf	166840 9dfbc169953489f7f8ecaf1d6d18d9d28e6e77a7	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3847138	A	1974-11-12	Gollub	
	2	4674403	A	1987-06-23	Bryant et al.	

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	1	20110178359	A1	2011-07-21	Hirschman et al.	

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	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.2

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	"CardioGen-82 Infusion System User's Guide," Medical Product Service GmbH, July 3, 2007, 53 pages.	☐

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-12-23
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	21041195
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	23-DEC-2014
Filing Date:	16-JUN-2010
Time Stamp:	17:08:22
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	17637
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Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_IDS_12-23-14.pdf	612373 53614324905e3bd3841822f74aaf6dcd35d0f599	no	4
Warnings:					
Information:					
2	Non Patent Literature	NPL_CardioGen.pdf	1030665 b94d1fcc43954f4e9a1f2021068d482640b65302	no	53
Warnings:					
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3	Fee Worksheet (SB06)	fee-info.pdf	30780 c53deec3e9256c20dddf5256c5b5756a2363dd8e	no	2
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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 11/25/2014

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
HYDE, EILEEN FOLEY

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
11/25/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Office Action Summary	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 15, 2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-7 and 36-51* is/are pending in the application.

5a) Of the above claim(s) *6,7,36,49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,37-48 and 51* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *September 15, 2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2014 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 43, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. (US Publication No. 2007/0213848 A1) (hereinafter "deKemp et al. US '848") (cited in the Office Action dated January 4, 2013) in view of Fago (US Publication No. 2008/0237502 A1) (cited in the Office Action dated October 2, 2013) and Williams et al. (US Publication No. 2007/0260213 A1).

Regarding claim 1, deKemp et al. US '848 teaches an eluent reservoir (*reservoir (4)* (paragraph [0025]; Figure 3)), a pump coupled to the reservoir (*pump (6)* (paragraph [0025]; Figure 3)), an infusion tubing circuit (*generator valve (16), bypass line (18), patient valve (24), elution system (14)* (paragraph [0025]; Figure 3) *and feed-line (33)* (paragraph [0028]; Figure 5)), a radioisotope generator (*strontium-rubidium ($^{82}Sr/^{82}Rb$) generator (8)* (paragraph [0025]; Figure 3)), an activity detector (*positron detector (20)* (paragraph [0025]; Figure 3)), a waste bottle (*waste reservoir (26)* (paragraph [0025]; Figure 3)), a computer (*controller (28)* (paragraph [0025]; Figure 3)) and a computer interface (*user interface (44)* (Figure 3)). deKemp et al. US '848 also teaches the infusion tubing circuit including an eluant line coupled to the pump and to the generator (*pump (6) for drawing saline from reservoir (4)* (paragraph [0025])) and an eluate line coupled to the generator, to the activity detector and to the waste bottle (*generator valve (16) to proportion saline flow between the generator (8) and a bypass line (18) which meet at merge point (22), a positron detector (20) downstream of merge point (22), a patient valve (24) to control supply of saline to patient outlet (10) and waste reservoir (26)* (paragraph [0025])).

deKemp et al. US '848 further teaches a controller (28) is connected to pump (6), positron detector (20), valves (16) and (24), and user interface (44) (paragraph [0025]; Figure 3) that pump (6) and valves (16, 24) are controlled to route saline through the system (14) in accordance with various modes of operation (paragraphs [0029]-[0032]; Figures 6a-6d). deKemp et al. US '848 teaches a pump (6) for drawing saline from the reservoir (4) at a desired flow rate (paragraph [0025]). During an "elution" mode, deKemp et al. US '848 discloses generator valve (16) is actively controlled by a control loop (42) from the positron detector (20) to proportion saline flow through both the generator (8) and bypass line (18) (paragraph [0032]).

deKemp et al. US '848 does not explicitly teach the use of a computer to control the modes of operation of the system, providing an indication that the elution is complete, or displaying, via the computer interface, a time lapse since each elution was completed.

Fago teaches visualization of the eluate collection bottle (34) facilitates determining when the elution process is complete, e.g. the eluate collection bottle (34) is full (paragraph [0031]). Fago teaches a syringe pump (40 is adapted to inject the eluent (18) into the generator (22) via tubing (10) (paragraph [0032]). Fago teaches a drip chamber (44) is incorporated in the tubing (10) to facilitate tracking or identification of an amount of eluent flowing into a generator (22) (paragraph [0033]; Figure 6). Fago teaches an electronic drop counter (46) may be used to count the drops passing through the drip chamber (44) by using an LED (48) and a photo detector (50) to determine when a drop passes through the drip chamber (44) (paragraph [0033]; Figure 7). Fago teaches this facilitates the provision of metrics relating to the amount of eluant being passed from the eluant passing from the eluent supply container (4) into the generator (22) (paragraph [0033]). Fago teaches the drop counter (46) is coupled to an electronic device and/or

computer (54) to store data, facilitate communication with other device, and/or perform calculations relating to the elution process (paragraph [0034]). Fago teaches the drop counter (46) is communicatively coupled to a display (52) for displaying metrics relating to the elution process and that the display may be incorporated into the computer (54) (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of controlling an $^{82}Sr/^{82}Rb$ elution system of deKemp et al. US '848 to include the displayed volume and time calculations taught by Fago in order to estimate when a generator will be ready for another elution process (Fago, paragraph [0034]).

Fago teaches the volume and/or time associated with each elution process may be tracked and displayed to enable the user to estimate when the generator will be ready for another elution process paragraph [0034]), but the combination of de Kemp et al. US '848 and Fago does not teach displaying, via the computer interface, a time lapse since each elution was completed.

Williams teaches methods for displaying elapsed time information related to the dispensing of media by the dispensing device in relation to a medical procedure (paragraph [0001]). Williams teaches when the user interface (230) comprises a display device, a user may view data corresponding to the dispensing operation, such as flow rate, elapsed time from injection of media (paragraph [0025]). Williams teaches the storage device may be configured to be capable of storing a plurality of display formats and/or the displays of various dispensing tools, including an elapsed time display showing time elapsed from a given dispensing operation (paragraph [0027]). Williams teaches a computer program product comprises executable portions for directing the dispensing medical device (115) to perform at least one dispensing function, to manipulate and/or adjust the display parameters of the user interface (230) (paragraph [0045]).

Williams teaches a status text graphic (470) indicating the status of a given dispensing operation, such as its completion, and an elapsed time counter graphic (410) to monitor the elapsed time since the introduction of contrast media into a patient (paragraph [0045]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the data associated with each elution process taught by de Kemp et al. US '848 and Fago to display a time lapse since each elution as taught by Williams in order to monitor the elapsed time without a need to activate and/or monitor a timing device that is separate from the display (Williams, paragraph [0045]).

Regarding claim 43, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110), or to a shielded waste container (90) ("diverting an initial volume of eluate to the waste bottle") (paragraph [0025]). deKemp et al. US '848 does not teach tracking the initial volume or eluate or providing an indication when the waste bottle needs to be emptied.

Fago teaches an eluate collection bottle (34) may have a standard or predefined volume (paragraph [0031]). Fago teaches a user can observe, based on the visualization portal and index marks (19), the eluent levels in the eluant supply container (4) go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle (34) ("tracking the initial volume of the eluate") (paragraphs [0026] and [0031]). Fago teaches this visualization facilitates determining when the elution process is complete, e.g. the eluate collection bottle is

full ("providing an indication when the waste bottle needs to be emptied") (paragraph [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the waste bottle of deKemp et al. US '848 to include the visualization portal and index marks taught by Fago in order to track the amount of fluid in the bottle (Fago, paragraph [0031]).

Regarding claim 51, Williams teaches displaying a timer counting up or down since each elution was completed (paragraph [0038]; *see* timer graphic (410) in Figure 4).

6. Claims 2-4, 38, 39, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Tate et al. (US Publication No. 2008/0177126 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 2, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]) and Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]), but the combination of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions.

Tate teaches a Records or Injection History button (1022) (paragraph [0181]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

Regarding claim 3, Tate teaches printing the injection information, including information about the activity and volume of the dose delivered to the patient and displaying it in pop-up (1240) (paragraph [0235]).

Regarding claim 4, Tate teaches a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]).

Regarding claim 38, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1. deKemp et al. US '848 teaches sampling the activity level in the dose calibrator at regular intervals throughout the duration of the elution run (paragraph [0055]). deKemp et al. US '848 also teaches calibration data collected during the elution can be used to calculate the proportionality constant K between the activity parameter (C_{det}) and the ^{82}Rb activity concentration (paragraphs [0056]-[0057]). The combination of deKemp et al. US '848, Fago, and Williams does not teach providing via the computer interface, calibration data entry fields for a user.

Tate teaches user-friendly data entry mechanisms for the system (10) (paragraph [0170]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the calibration and activity data of deKemp et al. US '848, Fago, and Williams to be input by a user through the user-friendly data entry mechanisms taught by Tate in order to clearly

and unambiguously communicate the current status of the system to an operator (Tate, paragraph [0170]).

Regarding claim 39, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1, but does not teach providing a patient identification entry field for a user to enter a patient identification number, receiving a detected activity level of a dose of eluate from the activity detector, or compiling a report that includes an identification number for the generated dose and detected activity level.

Tate teaches the touch screen arrangement (1000) can be used for four categories of tasks, including Patient Treatment (paragraph [0172]). Tate discloses the "Patient Treatment" category includes a number of tasks including inputting patient and/or case identification information into the system (10) and measuring the activity level of the radiopharmaceutical dose (paragraph [0207]). Tate teaches that the pharmaceuticals are used in imaging procedures (paragraph [0069]). Tate teaches that the printer (24) may be used to generate records of the injection and/or imaging procedures performed for inclusion in their medical records (paragraph [0075]). Tate discloses a "Case Information" pop-up display (1217) including an "Identification" field (1217a) and a keypad (1217j) for inputting a patient or other identification number (paragraph [0216]). Tate also discloses a detailed injection history display (1360), which includes activity level of the injection and the patient identification number, and can be printed using "Print" button (1363) (paragraph [0245]; Figure 34B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the identification information taught by Tate in order

to generate records of the injection and/or imaging procedures performed for inclusion in patient's medical records (Tate, paragraph [0075]).

Regarding claim 44, the combination of deKemp et al. US '848, Fago, and Williams teaches the system of claim 1, but does not teach the computer interface comprises a touch-activated display screen.

Tate teaches that the fluid delivery system (10) includes a display or graphical user interface display (15) for programming and operating the system (10) and may incorporate touch-screen capability (paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the touch-screen capability taught by Tate for ease of use of the system (Tate, paragraph [0071]).

Regarding claim 48, Tate teaches the fluid delivery system (10) includes a printer (24) (paragraph [0074]). Tate teaches that the printer (24) may generate records of the injection and/or imaging procedures performed on patients and may be pivotally connected to the system (10) to allow an operator to load paper or labels into the printer (24) (paragraph [0075]; Figure 1B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the printer taught by Tate in order to include data in patients' medical records or for billing/inventory purposes (Tate, paragraph [0075]).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Tate and

deKemp (US Publication No. 2007/0140958 A1) (hereinafter "deKemp US '958") (cited in the Office Action dated January 4, 2013).

Regarding claim 5, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]).

Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]). Fago teaches an actual radioactivity level of the eluate can be determined at a given time, programmed into the computer (54) ("receiving a detected activity level and entering the detected activity level for each elution into the record") (paragraph [0034]). Fago teaches the radioactivity level can be incorporated with other data to determine an expected radioactivity level at a specified future time and thus estimate when the generator will be ready for another elution process ("calculating and tracking the amount of activity left in the generator after each elution") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of deKemp et al. US '848 to include the radioactivity information and

estimations taught by Fago in order to estimate when a generator will be ready to perform another elution process (Fago, paragraph [0034]).

The combination of deKemp et al. US '848, Fago, and Williams does not teach maintaining a record of the elutions or compiling a report that includes an amount of activity left in the generator.

Tate discloses user-friendly data entry mechanisms for the system (10) (paragraph [0170]). Tate teaches a Records or Injection History button (1022) (paragraph [0181]) and a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848, Fago, and Williams to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

The combination of deKemp et al. US '848, Fago, Williams, and Tate does not teach compiling a report that includes an amount of activity left in the generator.

deKemp US '958 teaches a control algorithm and a valve (108) direct the eluate through a delivery line (112) for a calibration elution or a patient elution (110) (paragraph [0025]). deKemp US '958 teaches that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough to determine if the yield is above a predetermined radioactivity limit (paragraph [0029]; Figure 5). deKemp US '958 teaches control software controls a volume of fluid during generator column (10) flushes and elutions, and accepts the cumulative volume and stores it (paragraph [0031]). deKemp US '958 further teaches that the cumulative volume is recomputed after each elution and disposing of the generator column if the volume limit is exceeded (paragraph

[0032]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yield and volume determinations of deKemp US '958 in the records of the computer controlled elution system of deKemp et al. US '848, Fago, Williams, and Tate in order to determine if the generator column can continue to be used for patient elutions (deKemp US '958, paragraph [0028]).

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of deKemp US '958.

Regarding claim 37, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach providing a first and second set of breakthrough test data entry fields.

deKemp US '958 teaches generator column (10) is flushed with 50 ml of sterile saline solution in order to remove any strontium breakthrough, then the operator waits for a predetermined period of time (at least 10 minutes) before performing the calibration elution (paragraph [0029]). Then, deKemp US '958 discloses that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough (paragraph [0029]). deKemp US '958 discloses that those skilled in the art would know to test the radioactivity of the elution after about 26 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and will no distort the test results (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the breakthrough measurements taught by deKemp US '958 in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to determine if breakthrough is less than a threshold for permissible levels (paragraph [0030]).

9. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Telischak et al. (US Patent No. 7,996,068 B2) (cited in the Office Action dated January 4, 2013).

Regarding claim 40, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the pump is activated.

Telischak teaches a visible light is projected at all times when the device is activated (column 8, lines 18-26). It would have been obvious to one of ordinary skill in the art to include the light projecting when the device is activated disclosed by Telischak in the pump of the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to confirm that the device is operational (Telischak, column 8, lines 24-25).

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Ellingboe et al. (US Publication No. 2006/0015056 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 41, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 also teaches a "waiting for threshold" mode of system (14), in which the saline flow is routed through the generator (8) and into the waste reservoir (26) (paragraph [0031]) and an "elution" mode where the active saline solution is directed to the patient outlet (paragraph [0032]). The combination of deKemp et al. US '848, Fago, and Williams does not teach a light projector or providing a first light signal when an initial volume of eluate is being diverted or providing a second light signal when the pumping is generating the sample or the dose of eluate.

Ellingboe teaches an animated light indicator may be provided to indicate when cardioplegia is being delivered (e.g. via green illumination) and when delivery is stopped (e.g. via red illumination) (paragraph [0243]; Figure 301). It would have been obvious to one of ordinary skill in the art to include the different illumination signals disclosed by Ellingboe in the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to provide indicators to the operator regarding which stage of the infusion is occurring.

11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Bergner (US Patent No. 4,585,941) (cited in the Office Action dated January 4, 2013).

Regarding claim 42, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the activity detector detects a peak bolus of radioactivity.

Bergner teaches an LED display (100) is immediately about the total dose thumbwheel switches (98) and displays the total dose which has been infused in the patient (56) (column 5, lines 8-25). Bergner teaches the actual dose rate which is present in the eluate within the tube (30) in front of the dosimetry probe (58) is displayed on LED display (104) (column 5, lines 8-25). It would have been obvious to one of ordinary skill in the art to include the LED signals based on actual dose disclosed by Bergner in the computer controlled infusion system of deKemp et al. US '848, Fago, and Williams in order to provide a description of the dose present in the eluate (Bergner, column 5, lines 19-22).

12. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Varrichio et al. (US Publication No. 2005/0187515 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 45, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach at least one sensor for detecting a leak in the tubing and providing an indication that a leak has been detected.

Varrichio et al. teaches a sensor (251) that may be utilized to detect a leak in the valve system (241) (paragraph [0027]). Varrichio et al. teaches that if one of the flow valves leaks, a midpoint pressure will drift higher if primary flow valve (343) is leaking and lower if redundant flow valve (344) is leaking, thus providing an indication that a leak has been detected (paragraph [0036]). Varrichio et al. discloses a user interface for external program controller (260), which provides real-time status information with respect to infusate pump (200) and may provide audible alarms upon detection of particular conditions and may report conditions to the doctor using information from sensor (251) (paragraphs [0027] and [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the leak detecting sensor of Varrichio et al. in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to provide feedback to the doctor (Varrichio et al., paragraph [0027]).

13. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Padda et al. (US Patent No. 5,395,320) (cited in the Office Action dated January 4, 2013).

Regarding claim 46, the combination of deKemp et al. US '848, Fago, and Williams teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach calculating a flow rate profile or controlling a speed of the pump according to the calculated flow rate profile.

Padda teaches an infusion pump which can be programmed to deliver any of a variety of selected profiles of fluid medicine volume over time (Abstract). Padda discloses examples of delivery profiles including fixed rate of flow, ramp up, ramp down, fixed rate with increased rate spikes at specified intervals, and no flow with an infusion bolus at specified intervals (column 2, lines 42-50). Padda teaches a pumping mechanism (24) provides accurate delivery of medicine (column 4, lines 9-10). Padda teaches a piggyback delivery profile function which allows for the use of a second profile applied before, during an interrupt, or after the first profile, and a different medicine and different fluid to be infused through the infusion pump (column 4, line 59-column 5, line 6). Padda discloses a CPU that sends a motor control drive (14) a code containing information on the desired motor speed and a motor speed control (15) (column 6, line 66-column 7, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flow control and profile mechanisms of Padda in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to provide a variety of different fluid delivery profiles to a patient (Padda, column 2, lines 31-34).

14. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago and Williams, as applied to claim 1 above, and further in view of Whittacre et al. (US Publication No. 2003/0139640 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 47, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach transferring a plurality of detect activity levels to another system.

Whittacre teaches a display of the amount of isotope which is generating the radioactivity and transferring those values to a database if accepted by the operator (paragraph [0195]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the data transfer of Whittacre in the computer controlled elution system of deKemp et al. US '848, Fago, and Williams in order to allow one or more physicians to access the displayed information (Whittacre, paragraph [0202]).

Response to Arguments

15. Applicant's arguments, see pages 9-12 of the Remarks, filed July 8, 2014, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over de Kemp et al. US '848 in view of Fago and Williams, where Williams teaches the limitation "displaying, via the computer interface, a time lapse since each elution was completed" (see above rejection).

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EILEEN FOLEY whose telephone number is (571) 270-7248.

The examiner can normally be reached Monday-Thursday, and alternate Fridays, from 7:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached at (571) 272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. F./
Examiner, Art Unit 3735

/JACQUELINE CHENG/
Supervisory Patent Examiner, Art Unit 3735

Notice of References Cited	Application/Control No. 12/808,467	Applicant(s)/Patent Under Reexamination HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2007/0260213 A1	11-2007	Williams et al.	604/500
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6220554	B1	2001-04-24	Daoud	
	2	8058632		2011-11-15	Balestracci	
	3	8216181	B2	2012-07-10	Balestracci	
	4	8216184	B2	2012-07-10	Balestracci	
	5	8317674	B2	2012-11-27	Quirico	
	6	8708352	B2	2014-04-29	Quirico	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 09/15/2014	Application Number	12808467	12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16	
	First Named Inventor	Stephen E. Hidem	
	Art Unit	3735	
	Examiner Name	Eileen Dorothy Foley	
	Attorney Docket Number	56782.1.7.2	

	1	20040260143	A1	2004-12-23	Reilly	
	2	20060173419	A1	2006-08-03	Malcolm	
	3	20070080223	A1	2007-04-12	Japuntich	
	4	20070140958	A1	2007-06-21	deKemp	
	5	20120305730	A1	2012-12-06	Balestracci	
	6	20120310031	A1	2012-12-06	Quirico	
	7	20130300109	A1	2013-11-14	Balestracci	
	8	20140084187	A1	2014-03-27	Quirico	
	9	20140175959	A1	2014-06-26	Quirico	
	10	20080191148	A1	2008-08-14	Gibson	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 09/15/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467 12808467 - GAU: 3735
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	U.S. Application No. 14/290,765, filed May 29, 2014, entitled, "INFUSION SYSTEM CONFIGURATIONS," 67 pages. Attorney docket number 56782.1.6.15.	☐
	2	U.S. Application No. 61/952,270, filed March 13, 2014 entitled, "REAL TIME NUCLEAR ISOTOPE DETECTION," 30 pages. Attorney docket number 56782.1.13.2.	☐
	3	U.S. Application No. 14/455,623, filed August 8, 2014, entitled, "INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR," 64 pages. Attorney docket number 56782.1.7.15.	☐
	4	U.S. Application No. 14/455,631, filed August 8, 2014, entitled, "RADIOISOTOPE GENERATOR SYSTEM INCLUDING ACTIVITY MEASUREMENT AND DOSE CALIBRATION," 66 pages. Attorney docket number 56782.1.7.16.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Eileen Foley/	Date Considered	11/17/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	16	("20040260143" | "20060173419" | "20070080223" | "20070140958" | "20080191148" | "20120305730" | "20120310031" | "20130300109" | "20140084187" | "20140175959" | "6220554" | "8058632" | "8216181" | "8216184" | "8317674" | "8708352").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/17 09:09
L2	2	("20040054319" | "20070260213").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/17 09:10
L3	8389	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/17 09:56
L4	5802	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/17 09:56
S217	7935	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:20
S218	5640	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:20
S219	13485	S217 or S218	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:20
S220	1007	A61N5/1002,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:21
S221	93	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:22
S222	13772	S219 or S220 or S221	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:35
S223	2464	S222 and (display$3 with time)	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:35
S224	6	S222 and (display$3 with time with lapse)	US-PGPUB;	OR	ON	2014/08/05 14:35

			USPAT; USOCR			
S225	132	S222 and (display$3 with time with (elapsed or lapse))	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:37
S226	16	S222 and ((display$3 with time with (elapsed or lapse)) same (complete$1 or completion or elution))	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 14:37
S229	1	(10/433646).APP.	US-PGPUB; USOCR	OR	ON	2014/08/05 15:12
S230	1	(10/579709).APP.	US-PGPUB; USOCR	OR	ON	2014/08/05 15:27

11/17/2014 9:58:34 AM
C:\Users\efoley\Documents\EAST\Workspaces\12808467_2.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014				
	1	✓	✓	✓	✓	✓				
	2	✓	✓	✓	✓	✓				
	3	✓	✓	✓	✓	✓				
	4	✓	✓	✓	✓	✓				
	5	✓	✓	✓	✓	✓				
	6	N	N	N	N	N				
	7	N	N	N	N	N				
	8	-	-	-	-	-				
	9	-	-	-	-	-				
	10	-	-	-	-	-				
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	32	-	-	-	-	-				
	33	-	-	-	-	-				
	34	-	-	-	-	-				
	35	-	-	-	-	-				
	36	N	N	N	N	N				

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014	11/17/2014				
	37	✓	✓	✓	✓	✓				
	38	✓	✓	✓	✓	✓				
	39	✓	✓	✓	✓	✓				
	40	✓	✓	✓	✓	✓				
	41	✓	✓	✓	✓	✓				
	42	✓	✓	✓	✓	✓				
	43	✓	✓	✓	✓	✓				
	44	✓	✓	✓	✓	✓				
	45	✓	✓	✓	✓	✓				
	46	✓	✓	✓	✓	✓				
	47	✓	✓	✓	✓	✓				
	48	✓	✓	✓	✓	✓				
	49	N	N	N	N	N				
	50	N	N	N	N	N				
	51					✓				

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY	3735

CPC- SEARCHED		
Symbol	Date	Examiner
A61N5/1002, 1007	8/5/14	EF
A61N2005/1021	8/5/14	EF

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF
Updated class/subclass searches and text searching in EAST for AFCP 2.0 submission	8/5/14	EF
Updated class/subclass searches	11/17/14	EF

/E.F./ Examiner.Art Unit 3735	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/E.F./ Examiner.Art Unit 3735	

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12/808,467	Filing Date	2010-06-16	Docket Number (if applicable)	56782.1.7.2	Art Unit	3733
First Named Inventor	Stephen E. Hidem			Examiner Name	Eileen Dorothy Foley		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☐ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 061910

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-09-15
Name	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 56782.1.7.2

Application Number: 12/808,467

Filed: 2010-06-16

For: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

Art Unit: 3735

Examiner: Eileen Dorothy Foley

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$ 200
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 06-1910.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 64,688.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Paul J. LaVanway, Jr./
Signature

2014-09-15
Date

Paul J. LaVanway, Jr./
Typed or printed name

612-492-7387
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Sarah Munson
Attorney Docket Number:	56782.1.7.2

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	200	200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
		Total in USD ($)		**1400**

Electronic Acknowledgement Receipt

EFS ID:	20142028
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Sarah Munson
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	15-SEP-2014
Filing Date:	16-JUN-2010
Time Stamp:	17:42:28
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1400
RAM confirmation Number	4571
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_IDS_filed_9-15-14.pdf	613208 bded45aa0f2e2d0d34d560fb6ced4c3408302529	no	5
Warnings:					
Information:					
2	Non Patent Literature	NPL_14290765.pdf	3304416 1326a860b13a1f9864796bbf02b2cfcfe38e12a4	no	67
Warnings:					
Information:					
3	Non Patent Literature	NPL_61952270.pdf	1733174 0772c46a9a60663329be59b5734c145e45c7b85c	no	30
Warnings:					
Information:					
4	Non Patent Literature	NPL_14455623.pdf	2529716 8df06196ea0f78bac2d888390516fc7835ae1333	no	64
Warnings:					
Information:					
5	Non Patent Literature	NPL_14455631.pdf	2636860 126fabc1c59fafa6c80a50bba7f7eb05d21772a7	no	66
Warnings:					
Information:					
6	Request for Continued Examination (RCE)	56782_1_7_2_RCE.PDF	697806 8676140dfac13e1566b240a1c27cb6a8456b32c0	no	3
Warnings:					
Information:					
7	Extension of Time	56782_1_7_2_Extension_of_Time.pdf	163822 0b3085b1bd9bb332f539b0e08281da5a44104a32	no	2
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	32185 92c3216bbf41c958e546af9765f1ce77c09b5b1a	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	11711187	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6220554	B1	2001-04-24	Daoud	
	2	8058632		2011-11-15	Balestracci	
	3	8216181	B2	2012-07-10	Balestracci	
	4	8216184	B2	2012-07-10	Balestracci	
	5	8317674	B2	2012-11-27	Quirico	
	6	8708352	B2	2014-04-29	Quirico	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	1	20040260143	A1	2004-12-23	Reilly	
	2	20060173419	A1	2006-08-03	Malcolm	
	3	20070080223	A1	2007-04-12	Japuntich	
	4	20070140958	A1	2007-06-21	deKemp	
	5	20120305730	A1	2012-12-06	Balestracci	
	6	20120310031	A1	2012-12-06	Quirico	
	7	20130300109	A1	2013-11-14	Balestracci	
	8	20140084187	A1	2014-03-27	Quirico	
	9	20140175959	A1	2014-06-26	Quirico	
	10	20080191148	A1	2008-08-14	Gibson	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	U.S. Application No. 14/290,765, filed May 29, 2014, entitled, "INFUSION SYSTEM CONFIGURATIONS," 67 pages. Attorney docket number 56782.1.6.15.	☐
	2	U.S. Application No. 61/952,270, filed March 13, 2014 entitled, "REAL TIME NUCLEAR ISOTOPE DETECTION," 30 pages. Attorney docket number 56782.1.13.2.	☐
	3	U.S. Application No. 14/455,623, filed August 8, 2014, entitled, "INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR," 64 pages. Attorney docket number 56782.1.7.15.	☐
	4	U.S. Application No. 14/455,631, filed August 8, 2014, entitled, "RADIOISOTOPE GENERATOR SYSTEM INCLUDING ACTIVITY MEASUREMENT AND DOSE CALIBRATION," 66 pages. Attorney docket number 56782.1.7.16.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-09-15
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/808,467	Filing Date 06/16/2010	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **09/15/2014**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 23	Minus	** 38	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 4	Minus	***5	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/HALLEY MASSEY/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 08/14/2014

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER
FOLEY, EILEEN DOROTHY

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
08/14/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 12/808,467	**Applicant(s)** HIDEM ET AL.	
	Examiner EILEEN FOLEY	**Art Unit** 3735	**AIA (First Inventor to File) Status** No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 July 2014 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): (a) ☐ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed: .
    Claim(s) objected to: .
    Claim(s) rejected: 1-5 and 37-48.
    Claim(s) withdrawn from consideration: .

/JACQUELINE CHENG/ Supervisory Patent Examiner, Art Unit 3735	/E. F./ Examiner, Art Unit 3735

Continuation of 11. does NOT place the application in condition for allowance because: Searching was conducted pursuant to the AFCP 2.0 Pilot and references were found that, in combination with previously cited references, teach the limitation filed with the AFCP 2.0 submission, "displaying, via the computer interface, a time lapse since each elution was completed. Since additional references were found during the AFCP 2.0 search, the Examiner contacted the Applicant about conducting an interview or mailing an advisory action, pursuant to the AFCP 2.0 guidelines. Applicant asked that the advisory action be mailed. Two of the references found during the AFCP 2.0 search are Langley et al. (U.S. Publication No. 2004/0054319 A1) and Williams et al. (US Publication No. 2007/0260213 A1). Langley teaches a display panel (10) to provide alphanumeric and graphical information relating to operation of the device, including time elapsed since the previous dose was administered (see e.g. paragraphs [0036], [0057], & [0063]). Williams teaches displaying elapsed time from injection of media (see e.g. paragraphs [0001], [0006], [0025], [0027], [0038], & [0045])..

DO NOT ENTER: /E.F./

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	FOLEY, Eileen Dorothy
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFTER-FINAL AMENDMENT

Dear Commissioner:

In response to the Final Office Action mailed May 8, 2014, the period of response for which runs through August 8, 2014, please amend the application as follows. This Amendment is accompanied by a Certification and Request for Consideration Under the After Final Consideration Pilot Program 2.0.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	FOLEY, Eileen Dorothy
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A system that generates and infuses radiopharmaceuticals comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle, a computer and a computer interface; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, and an eluate line coupled to the generator, to the activity detector and to the waste bottle; and the computer being coupled to the computer interface, to the pump and to the activity detector and being pre-programmed to execute a method, the method comprising:

activating the pump to pump a volume of eluant from the reservoir, through the eluant line and through the generator, in order to generate a sample or a dose of eluate in the eluate line, via elution within the generator, each sample being intended for a quality control measurement, and each dose being intended for diagnostic imaging;

providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator; and

~~providing an indication~~ displaying, via the computer interface, [[of]] a time lapse since each elution was completed.

2. (Previously Presented) The system of claim 1, wherein the pre-programmed method further comprises:

counting elutions per unit time;

categorizing each counted elution as having been generated as a sample or a dose; and

maintaining a record of the counted and categorized elutions.

3. (Previously Presented) The system of claim 2, wherein the pre-programmed method of the computer further comprises receiving a detected activity level of the eluate for each dose and sample, from the activity detector, and entering the detected activity level for each elution into the record.

4. (Previously Presented) The system of claim 3, wherein the pre-programmed method of the computer further comprises compiling a report that contains the record, the report being formatted for printing and/or for electronic transfer to another system.

5. (Previously Presented) The system of claim 1, wherein the pre-programmed method further comprises:

maintaining a record of elutions that categorizes each elution as having been generated a sample or a dose;

receiving a detected activity level of the eluate for each dose and sample, from the activity detector, and entering the detected activity level for each elution into the record;

calculating and tracking an amount of activity left in the generator after each elution, over a life of the generator; and

compiling a report that includes an amount of activity left in the generator after a final elution at an end of the life of the generator.

6. (Withdrawn) A system that generates and infuses radiopharmaceuticals comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, a by-pass line coupled to the eluant line, via a divergence valve, and to the patient line, the by-pass line accommodating flow of eluant to the patient line, when the divergence valve is set to direct the flow to by-pass the generator; and wherein:

the patient line is coupled to the eluate line and to the by-pass line downstream of the activity detector; and

the computer is coupled to the pump, to the divergence valve and to the activity detector, and is pre-programmed to collect information, from the pump and the activity detector, and to execute a method for controlling the divergence valve and the pump according to a method, the method comprising:

activating the pump a first time, to pump a portion of a volume of eluant from the reservoir, through the eluant line and through the generator at a first flow rate, in order to generate eluate in the eluate line, via an elution within the generator;

diverting flow of the eluate into the patient line, thereby pushing a dose of the eluate into the patient line, upon receipt of feedback from the activity detector, the feedback indicating detection by the activity detector of a desired activity of the eluate in the eluate line;

setting the divergence valve to direct flow of eluant through the by-pass line, once the dose of the eluate has been pushed into the patient line; and

activating the pump a second time, to pump a second portion of the volume of eluant from the reservoir, through the eluant line, through the by-pass line and into the patient line, at a second flow rate that is higher than the first flow rate, in order to inject the dose out from the patient line.

7. (Withdrawn) The system of claim 6, wherein the first flow rate is less than approximately 70mL/minute and the second flow rate is greater than approximately 70mL/minute.

8–35. (Canceled)

36. (Withdrawn) A method for purging a tubing circuit of an infusion system with air, the system comprising a pump coupled to the tubing circuit, a radioisotope generator, a waste bottle and a computer including a computer interface, the method comprising:

receiving instructions from the computer, via the computer interface, to disconnect the pump from an eluant reservoir of the system, and to by-pass the generator by disconnecting an eluant line and an eluate line, of the tubing circuit, from the generator, and connecting the eluant line to the eluate line; and

entering, into the computer, via the computer interface, a command to perform an air purge of the tubing circuit, the air purge being automated, via the computer, to perform purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit;

wherein a first valve, of the two divergence valves, is located between a first portion of the eluate line and two downstream portions of the eluate line, a first of the two downstream portions extending to a waste bottle of the system and a second of the two downstream portions extending to a vial outside the system;

a second valve, of the two divergence valves, is located between a first portion of the eluant line, extending from the pump, and two downstream portions of the eluant line, a first of

the two downstream portions of the eluant line being connected to the first portion of the eluate line, and a second of the two downstream portions of the eluant line being connected to the second of the two downstream portions of the eluate line.

37. (Previously Presented) The system of claim 1, further characterized in that the pre-programmed method of the computer further comprises the steps of:

providing, via the computer interface, a first set of breakthrough test data entry fields for a user of the system to enter a first activity measure of a sample of eluate and the corresponding time lapse since the elution was completed to a time of the first activity measure, when the activated pumping generates the sample of eluate for collection in a shielded test vial;

providing, via the computer interface, a second set of breakthrough test data entry fields for a user of the system to enter a second activity measure of the sample after a predetermined time lapse since the elution was completed to the time of a second activity measure; and

calculating a breakthrough of the generator using the first and second activity measures and the time lapse entered by the user.

38. (Previously Presented) The system of claim 1, further characterized in that the pre-programmed method of the computer further comprises the steps of:

providing, via the computer interface, calibration data entry fields for a user of the system to enter an activity measure of a sample of eluate and the corresponding time lapse since the elution was completed to a time of the activity measure, when the activated pumping generates the sample of eluate for collection in a shielded test vial; and

calculating a calibration coefficient of the infusion system using a detected activity, received from the activity detector, and the activity measure and the time lapse entered by the user.

39. (Previously Presented) The system of claim 1, wherein the pre-programmed method of the computer further comprises the steps of:

providing, via the computer interface, a patient identification entry field for a user to enter a patient identification number;

receiving a detected activity level of a dose of eluate from the activity detector, when the activated pumping generates the dose for diagnostic imaging; and

compiling a report that includes an identification number for the generated dose and the detected activity level.

40. (Previously Presented) The system of claim 1, further characterized in that:
the system further comprises a light projector coupled to the computer; and
the pre-programmed method of the computer further comprises the step of providing a light signal from the light projector when the pump is activated to pump each volume of eluant through the generator.

41. (Previously Presented) The system of claim 1, further characterized in that:
the system further comprises a light projector coupled to the computer; and
the pre-programmed method of the computer further comprises the steps of:
diverting an initial volume of eluate to the waste bottle, based upon input from the activity detector, before the activated pumping generates the sample or the dose; and
providing a first light signal from the light projector, when the initial volume of eluate is being diverted; and
providing a second light signal from the light projector, when the activated pumping is generating the sample or the dose of eluate, the second light signal being different from the first light signal.

42. (Previously Presented) The system of claim 1, further characterized in that:
the system further comprises a light projector coupled to the computer; and
the pre-programmed method further comprises providing a light signal when the activity detector detects a peak bolus of radioactivity in the eluate line.

43. (Previously Presented) The system of claim 1, wherein the pre-programmed method of the computer further comprises the steps of:
diverting an initial volume of eluate to the waste bottle, based upon input from the activity detector, before the activated pumping generates the sample or the dose;
tracking the initial volume of eluate; and
providing an indication when the waste bottle needs to be emptied based upon the tracking.

44. (Previously Presented) The system of claim 1, wherein the computer interface comprises a touch-activated display screen.

45. (Previously Presented) The system of claim 1, further comprising at least one sensor for detecting a leak in the tubing circuit, the computer being coupled to the at least one sensor; and wherein the pre-programmed method of the computer further comprises the step of providing an indication, via the computer interface, that a leak in the tubing circuit is detected.

46. (Previously Presented) The system of claim 1, further characterized in that the pre-programmed method of the computer further comprises the steps of:

calculating a flow rate profile, that corresponds to a desired activity profile, using a baseline activity profile, the baseline activity profile being comprised of a plurality of detected activity levels, received from the activity detector, of a sample of eluate, the sample of eluate being generated by the activated pump pumping the volume of eluant through the generator at a constant flow rate; and

controlling a speed of the pump, according to the calculated flow rate profile, when pumping another volume of eluant through the generator, in order to generate a dose of eluate in the eluate line, the speed being controlled according to the calculated flow rate profile in order to achieve a desired activity profile of the dose of eluate for diagnostic imaging.

47. (Previously Presented) The system of claim 1, wherein the pre-programmed method further comprises transferring to another system, for analysis, a plurality of detected activity levels, received from the activity detector, over time, for each dose of eluate.

48. (Previously Presented) The system of claim 2, wherein the pre-programmed method of the computer further comprises compiling a report that contains the record, the report being formatted for printing and/or for electronic transfer to another system.

49. (Withdrawn) The system of claim 6, further characterized in that the pre-programmed method of the computer further comprises the steps of:

calculating a flow rate profile, that corresponds to a desired activity profile, using a baseline activity profile, the baseline activity profile being comprised of a plurality of detected

activity levels, received from the activity detector, for the eluate in the eluate line, prior to diverting the flow of eluate into the patient line; and

controlling a speed of the pump, according to the calculated flow rate profile, when activating the pump the second time.

50. (Withdrawn) A system that generates and infuses radiopharmaceuticals comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle, a computer and a computer interface; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, via a first divergence valve, a waste line coupled to the eluate line, via the first divergence valve, a by-pass line coupled to the eluant line, via a second divergence valve, and to the patient line, the by-pass line accommodating flow of eluant to the patient line, when the second divergence valve is set to direct the flow to by-pass the generator; and the system being characterized in that:

the patient line is coupled to the eluate line and to the by-pass line downstream of the activity detector; and

the computer is coupled to the pump, to the first and second divergence valves and to the computer interface, the computer being pre-programmed to execute a method for an automated air purge of the tubing circuit, the method comprising the steps of:

providing instructions to a user of the system, via the computer interface, the instructions instructing the user to disconnect the pump from the eluant reservoir and to by-pass the generator by disconnecting the eluant line and the eluate line from the generator and connecting the eluant line to the eluate line; and

performing air purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit.

51. (New) The system of claim 1, wherein displaying the time lapse since each elution was completed comprises displaying a timer counting up or down since each elution was completed.

REMARKS

This Amendment is responsive to the Office Action dated May 8, 2014. Applicant has amended independent claim 1 and added new claim 51. No new matter has been added by way of the amendments, and support for the amendments can be found throughout Applicant's original disclosure, such as at page 23, line 27–page 25, line, 10. Claims 1–7 and 36–51 will be pending upon entry of this Amendment with claims 6, 7, 36, 49, and 50 withdrawn from consideration. Reconsideration of the application is respectfully requested.

Interview Summary

Applicant thanks the Examiner and the Examiner's Supervisor for their time and the courtesies extended during the telephonic interview conducted on June 27, 2014. Examiner Eileen Foley, the Examiner's Supervisor Jacqueline Cheng, and Applicant's representative Paul LaVanway, Jr. (Reg. No. 64,610) were involved in the telephonic interview. The parties discussed rejected independent claim 1. The parties also discussed deKemp et al. (US Publication No. 2007/0213848, hereinafter "the deKemp '848 reference") and Fago (US Publication No. 2008/0237502), which were previously cited by the Patent Office. No exhibits were introduced or discussed.

Applicant's representative noted several distinctions between the independent claim and the previously applied references. First, Applicant's representative discussed how independent claim 1 requires a computer pre-programmed to execute a method that includes "providing an indication, via a computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator." The Office Action had noted that the deKemp '848 reference does not disclose this feature but did not appear to provide any additional treatment of the claim element. Thus, Applicant's representative took the position that this appears to be a "missing element" from the cited art.

The Examiners acknowledged that the Office Action did not separately discuss this claim element in the rejection of the claims but stated that the feature was intended to be addressed in connection with the "time lapse" feature of the claim and the citation to paragraph [0034] of Fago. In response, Applicant's representative pointed out that there is no pump in the Fago system but rather Fago attaches an empty bottle at vacuum pressure to the outlet of a

radioisotope generator and, upon opening the vacuum bottle to the generator, allows the vacuum pressure to draw eluant out of an eluant bottle and through the generator. Accordingly, because Fago does not have a pump, Applicant's representative submitted that the reference necessarily cannot disclose a system executing a method that includes "providing an indication, via a computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator."

Second, Applicant's representative discussed how independent claim 1 also recites "providing an indication, via the computer interface, of a time lapse since each elution was completed." The Office Action had acknowledged that the deKemp '848 reference does not disclose this feature but cited Fago in an attempt to overcome this shortcoming of the reference. Applicant's representative submitted, however, that the cited portions of Fago also do not disclose or suggest providing an indication of a time lapse since an elution was completed. Applicant's representative acknowledged that cited paragraph [0034] of Fago states that "[t]he volume and/or time associated with each elution process may be tracked and displayed to enable a user (or the computer 54) to estimate when the generator will be ready for another elution." However, Applicant's representative noted that this statement in Fago does not expressly or inherently disclose or suggest either (1) providing an indication of a time lapse or (2) providing an indication of a time lapse since each elution was completed. For example, Applicant's representative pointed out that the cited portion of Fago discusses tracking and displaying "volume and/or time associated with each elution process" whereas claim 1 calls out an indication of a time lapse since each elution was completed. Applicant's representative further asserted that the cited portion of Fago does not disclose or suggest an indication of a "time lapse." Rather, the cited portion of Fago describes that "a value corresponding to an expected radioactivity level of an elution at a certain time can be calculated and displayed on a computer screen."

The Examiners responded that the phrase "providing an indication" in claim 1 could be interpreted broadly before the USPTO and that Fago provides general guidance to a person of ordinary skill in the art to display data providing an "indication" as specified by the claim. While Applicant's representative disagreed with this application of the Fago reference, Applicant's representative proposed amending independent claim 1 as presented herein in an effort to advance prosecution. The Examiners indicated that further study and consideration of

such an amendment would be appropriate and recommended filing the amendment using the After Final Pilot program.

Finally, Applicant's representative presented concluding remarks discussing why one of ordinary skill in the art would not have been motivated to modify the system in the deKemp '848 reference in view of the teachings of Fago as proposed in the Office Action. For example, Applicant's representative explained that the eluate system described in the cited embodiment of Fago does not have a pump but rather relies on an evacuated eluate collection bottle to draw eluant from a container and through a generator.[1] Because Fago does not have a pump to actively control and monitor flow, the Fago reference incorporates an eluant electronic drop counter to track the elution process.[2] On the other hand, the system in the deKemp '848 reference has a pump that is controlled and monitored by a controller.[3] Given this technical distinction between the system in the deKemp '848 reference and the system in the Fago reference, a person of ordinary skill in the art would not have seen any benefit to be had or advantage to be gained by incorporating the electronic drop counter techniques of Fago into the system of the deKemp '848 reference. The Examiners agreed to take the argument under additional consideration in connection with the proposed amendment discussed during the interview.

Applicant's representative again thanks the Examiners for their time during the interview and the invitation to participate in the After Final Pilot program. The Examiners are invited to telephone the undersigned if it would be useful to discuss the application further.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Office Action, claims 1 and 43 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over the deKemp '848 reference in view of Fago. In addition, claims 2–5, 37–42, and 44–48 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over the deKemp '848 reference in view of Fago and in further view of additional cited references.

While Applicant does not agree with the propriety of the rejections, Applicant has amended independent claim 1 in the manner discussed during the telephone interview. For at

[1] *See* Fago at paragraph [0031].
[2] *See id.* at paragraph [0034].
[3] *See* deKemp '848 reference at paragraph [0006].

least the reasons discussed during the telephone interview, as well as those presented in Applicant's last Office Action response dated January 2, 2014, the applied references do not render the amended claims unpatentable. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: July 8, 2014

Respectfully submitted,

/Paul J. LaVanway, Jr./

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Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

50752473_1.DOC

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
56782.1.7.2	12/808,467	June 16, 2010
First Named Inventor:	**Title:**	
Stephen E. Hidem	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
    - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
    - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
        - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
        - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
            - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
            - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Paul J. LaVanway, Jr./	July 8, 2014
Name (Print/Typed) Paul J. LaVanway, Jr.	**Practitioner Registration No.** 64,610

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

[✓] * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	19515741
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	08-JUL-2014
Filing Date:	16-JUN-2010
Time Stamp:	15:47:57
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response After Final Action	56781_1_7_2_AmendAF.pdf	135160 53fe5529cdcc596eff288ee29d5981a1dc46c871	no	12

Warnings:	
Information:	

2	After Final Consideration Program Request	56782_1_7_2_Bracco_After_Final_Pilot_Program_Form.pdf	249139 84f9416d00516186a8ec6d2252db77d68c42abbb	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	384299

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/808,467	Filing Date 06/16/2010	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **07/08/2014**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 23	Minus	** 38	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 4	Minus	***5	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/TAMARA DARKO/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 07/02/2014

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER	
FOLEY, EILEEN DOROTHY	
ART UNIT	**PAPER NUMBER**
3735	

NOTIFICATION DATE	DELIVERY MODE
07/02/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	12/808,467	HIDEM ET AL.	
	Examiner	Art Unit	
	EILEEN FOLEY	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) *EILEEN FOLEY*.

(2) *JACQUELINE CHENG*.

(3) *PAUL LAVANWAY*.

(4) _____.

Date of Interview: *27 June 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *DeKemp and Fago*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant and Examiner discussed the combination of DeKemp and Fago and whether one skilled in the art would have motivation to combine the teachings. Applicant and Examiner also discussed Fago's teaching of the claim limitations 'providing an indication that each elution is completed, when the pump has completed pumping,' and 'providing an indication of a time lapse since each elution was completed.' Applicant and Examiner had different interpretations of the teaching of Fago and no agreement was reached. Examiner suggested filing a response under the After Final Consideration Pilot 2.0 with claim amendments further defining the type of indication provided for both the elution is completed and the time lapse (e.g. a display of a digital clock counting up). Further limiting the claim to quality control may also help advance prosecution. .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/E. F./ Examiner, Art Unit 3735	/JACQUELINE CHENG/ Supervisory Patent Examiner, Art Unit 3735

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/808,467	06/16/2010	Stephen E. Hidem	56782.1.7.2	3733

22859 7590 05/08/2014

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EXAMINER
FOLEY, EILEEN DOROTHY

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
05/08/2014	ELECTRONIC

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IP@FREDLAW.COM

Office Action Summary	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 2, 2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-7 and 36-50* is/are pending in the application.

5a) Of the above claim(s) *6,7,36,49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5 and 37-48* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *See Continuation Sheet*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Continuation of Attachment(s) 2). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :November 8, 2013 (2 submissions); January 21, 2014; March 28, 2014.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment

2. The Response filed January 2, 2014 is acknowledged. Claims 1-7 and 36-50 are pending, with claims 6-7, 36, and 49-50 withdrawn based on a prior restriction/election.

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. (US Publication No. 2007/0213848 A1) (hereinafter "deKemp et al. US '848") (cited in the Office Action dated January 4, 2013) in view of Fago (US Publication No. 2008/0237502 A1) (cited in the Office Action dated October 2, 2013).

Regarding claim 1, deKemp et al. US '848 teaches an eluent reservoir (*reservoir (4)* (paragraph [0025]; Figure 3)), a pump coupled to the reservoir (*pump (6)* (paragraph [0025]; Figure 3)), an infusion tubing circuit (*generator valve (16), bypass line (18), patient valve (24), elution system (14)* (paragraph [0025]; Figure 3) *and feed-line (33)* (paragraph [0028]; Figure 5)), a radioisotope generator (*strontium-rubidium ($^{82}Sr/^{82}Rb$) generator (8)* (paragraph [0025]; Figure 3)), an activity detector (*positron detector (20)* (paragraph [0025]; Figure 3)), a waste bottle (*waste reservoir (26)* (paragraph [0025]; Figure 3)), a computer (*controller (28)* (paragraph [0025]; Figure 3)) and a computer interface (*user interface (44)* (Figure 3)). deKemp et al. US '848 also teaches the infusion tubing circuit including an eluant line coupled to the pump and to the generator (*pump (6) for drawing saline from reservoir (4)* (paragraph [0025])) and an eluate line coupled to the generator, to the activity detector and to the waste bottle (*generator valve (16) to proportion saline flow between the generator (8) and a bypass line (18) which meet at merge point (22), a positron detector (20) downstream of merge point (22), a patient valve (24) to control supply of saline to patient outlet (10) and waste reservoir (26)* (paragraph [0025])).

deKemp et al. US '848 further teaches a controller (28) is connected to pump (6), positron detector (20), valves (16) and (24), and user interface (44) (paragraph [0025]; Figure 3) that pump (6) and valves (16, 24) are controlled to route saline through the system (14) in

accordance with various modes of operation (paragraphs [0029]-[0032]; Figures 6a-6d). deKemp et al. US '848 teaches a pump (6) for drawing saline from the reservoir (4) at a desired flow rate (paragraph [0025]). During an "elution" mode, deKemp et al. US '848 discloses generator valve (16) is actively controlled by a control loop (42) from the positron detector (20) to proportion saline flow through both the generator (8) and bypass line (18) (paragraph [0032]).

deKemp et al. US '848 does not explicitly teach the use of a computer to control the modes of operation of the system, providing an indication that the elution is complete, or providing an indication of a time lapse.

Fago teaches visualization of the eluate collection bottle (34) facilitates determining when the elution process is complete, e.g. the eluate collection bottle (34) is full (paragraph [0031]). Fago teaches a syringe pump (40 is adapted to inject the eluent (18) into the generator (22) via tubing (10) (paragraph [0032]). Fago teaches a drip chamber (44) is incorporated in the tubing (10) to facilitate tracking or identification of an amount of eluent flowing into a generator (22) (paragraph [0033]; Figure 6). Fago teaches an electronic drop counter (46) may be used to count the drops passing through the drip chamber (44) by using an LED (48) and a photo detector (50) to determine when a drop passes through the drip chamber (44) (paragraph [0033]; Figure 7). Fago teaches this facilitates the provision of metrics relating to the amount of eluant being passed from the eluant passing from the eluent supply container (4) into the generator (22) (paragraph [0033]). Fago teaches the drop counter (46) is coupled to an electronic device and/or computer (54) to store data, facilitate communication with other device, and/or perform calculations relating to the elution process (paragraph [0034]). Fago teaches the drop counter (46) is communicatively coupled to a display (52) for displaying metrics relating to the elution

process and that the display may be incorporated into the computer (54) (paragraph [0034]). Fago teaches the volume and/or time associated with each elution process may be tracked and displayed to enable the user to estimate when the generator will be ready for another elution process ("providing an indication via the computer interface that each elution is completed and of a time lapse since each elution was completed") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of controlling an $^{82}Sr/^{82}Rb$ elution system of deKemp et al. US '848 to include the displayed volume and time calculations taught by Fago in order to estimate when a generator will be ready for another elution process (Fago, paragraph [0034]).

Regarding claim 43, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110), or to a shielded waste container (90) ("diverting an initial volume of eluate to the waste bottle") (paragraph [0025]). deKemp et al. US '848 does not teach tracking the initial volume or eluate or providing an indication when the waste bottle needs to be emptied.

Fago teaches an eluate collection bottle (34) may have a standard or predefined volume (paragraph [0031]). Fago teaches a user can observe, based on the visualization portal and index marks (19), the eluent levels in the eluant supply container (4) go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle (34) ("tracking the initial volume of the eluate") (paragraphs [0026] and [0031]). Fago teaches this visualization

facilitates determining when the elution process is complete, e.g. the eluate collection bottle is full ("providing an indication when the waste bottle needs to be emptied") (paragraph [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the waste bottle of deKemp et al. US '848 to include the visualization portal and index marks taught by Fago in order to track the amount of fluid in the bottle (Fago, paragraph [0031]).

6. Claims 2-4, 38, 39, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Tate et al. (US Publication No. 2008/0177126 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 2, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]) and Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]), but the combination does not teach maintaining a record of the elutions.

Tate teaches a Records or Injection History button (1022) (paragraph [0181]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

elution system of deKemp et al. US '848 and Fago to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

Regarding claim 3, Tate teaches printing the injection information, including information about the activity and volume of the dose delivered to the patient and displaying it in pop-up (1240) (paragraph [0235]).

Regarding claim 4, Tate teaches a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]).

Regarding claim 38, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches sampling the activity level in the dose calibrator at regular intervals throughout the duration of the elution run (paragraph [0055]). deKemp et al. US '848 also teaches calibration data collected during the elution can be used to calculate the proportionality constant K between the activity parameter (C_{det}) and the ^{82}Rb activity concentration (paragraphs [0056]-[0057]). The combination of deKemp et al. US '848 and Fago does not teach providing via the computer interface, calibration data entry fields for a user.

Tate teaches user-friendly data entry mechanisms for the system (10) (paragraph [0170]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the calibration and activity data of deKemp et al. US '848 and Fago to be input by a user through the user-friendly data entry mechanisms taught by Tate in order to clearly and unambiguously communicate the current status of the system to an operator (Tate, paragraph [0170]).

Regarding claim 39, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1, but does not teach providing a patient identification entry field for a user to enter a patient identification number, receiving a detected activity level of a dose of eluate from the activity detector, or compiling a report that includes an identification number for the generated dose and detected activity level.

Tate teaches the touch screen arrangement (1000) can be used for four categories of tasks, including Patient Treatment (paragraph [0172]). Tate discloses the "Patient Treatment" category includes a number of tasks including inputting patient and/or case identification information into the system (10) and measuring the activity level of the radiopharmaceutical dose (paragraph [0207]). Tate teaches that the pharmaceuticals are used in imaging procedures (paragraph [0069]). Tate teaches that the printer (24) may be used to generate records of the injection and/or imaging procedures performed for inclusion in their medical records (paragraph [0075]). Tate discloses a "Case Information" pop-up display (1217) including an "Identification" field (1217a) and a keypad (1217j) for inputting a patient or other identification number (paragraph [0216]). Tate also discloses a detailed injection history display (1360), which includes activity level of the injection and the patient identification number, and can be printed using "Print" button (1363) (paragraph [0245]; Figure 34B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the identification information taught by Tate in order to generate records of the injection and/or imaging procedures performed for inclusion in patient's medical records (Tate, paragraph [0075]).

Regarding claim 44, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1, but does not teach the computer interface comprises a touch-activated display screen.

Tate teaches that the fluid delivery system (10) includes a display or graphical user interface display (15) for programming and operating the system (10) and may incorporate touch-screen capability (paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the touch-screen capability taught by Tate for ease of use of the system (Tate, paragraph [0071]).

Regarding claim 48, Tate teaches the fluid delivery system (10) includes a printer (24) (paragraph [0074]). Tate teaches that the printer (24) may generate records of the injection and/or imaging procedures performed on patients and may be pivotally connected to the system (10) to allow an operator to load paper or labels into the printer (24) (paragraph [0075]; Figure 1B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the printer taught by Tate in order to include data in patients' medical records or for billing/inventory purposes (Tate, paragraph [0075]).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Tate and deKemp (US Publication No. 2007/0140958 A1) (hereinafter "deKemp US '958") (cited in the Office Action dated January 4, 2013).

Regarding claim 5, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]).

Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]). Fago teaches an actual radioactivity level of the eluate can be determined at a given time, programmed into the computer (54) ("receiving a detected activity level and entering the detected activity level for each elution into the record") (paragraph [0034]). Fago teaches the radioactivity level can be incorporated with other data to determine an expected radioactivity level at a specified future time and thus estimate when the generator will be ready for another elution process ("calculating and tracking the amount of activity left in the generator after each elution") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of deKemp et al. US '848 to include the radioactivity information and estimations taught by Fago in order to estimate when a generator will be ready to perform another elution process (Fago, paragraph [0034]).

The combination of deKemp et al. US '848 and Fago does not teach maintaining a record of the elutions or compiling a report that includes an amount of activity left in the generator.

Tate discloses user-friendly data entry mechanisms for the system (10) (paragraph [0170]). Tate teaches a Records or Injection History button (1022) (paragraph [0181]) and a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

The combination of deKemp et al. US '848, Fago, and Tate does not teach compiling a report that includes an amount of activity left in the generator.

deKemp US '958 teaches a control algorithm and a valve (108) direct the eluate through a delivery line (112) for a calibration elution or a patient elution (110) (paragraph [0025]). deKemp US '958 teaches that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough to determine if the yield is above a predetermined radioactivity limit (paragraph [0029]; Figure 5). deKemp US '958 teaches control software controls a volume of fluid during generator column (10) flushes and elutions, and accepts the cumulative volume and stores it (paragraph [0031]). deKemp US '958 further teaches that the cumulative volume is recomputed after each elution and disposing of the generator column if the volume limit is exceeded (paragraph [0032]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yield and volume determinations of deKemp US '958 in the records of the computer controlled elution system of deKemp et al. US '848, Fago, and Tate in order to determine if the generator column can continue to be used for patient elutions (deKemp US '958, paragraph [0028]).

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of deKemp US '958.

Regarding claim 37, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach providing a first and second set of breakthrough test data entry fields.

deKemp US '958 teaches generator column (10) is flushed with 50 ml of sterile saline solution in order to remove any strontium breakthrough, then the operator waits for a predetermined period of time (at least 10 minutes) before performing the calibration elution (paragraph [0029]). Then, deKemp US '958 discloses that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough (paragraph [0029]). deKemp US '958 discloses that those skilled in the art would know to test the radioactivity of the elution after about 26 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and will no distort the test results (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the breakthrough measurements taught by deKemp US '958 in the computer controlled elution system of deKemp et al. US '848 and Fago in order to determine if breakthrough is less than a threshold for permissible levels (paragraph [0030]).

9. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Telischak et al. (US Patent No. 7,996,068 B2) (cited in the Office Action dated January 4, 2013).

Regarding claim 40, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the pump is activated.

Telischak teaches a visible light is projected at all times when the device is activated (column 8, lines 18-26). It would have been obvious to one of ordinary skill in the art to include the light projecting when the device is activated disclosed by Telischak in the pump of the computer controlled infusion system of deKemp et al. US '848 and Fago in order to confirm that the device is operational (Telischak, column 8, lines 24-25).

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Ellingboe et al. (US Publication No. 2006/0015056 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 41, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 also teaches a "waiting for threshold" mode of system (14), in which the saline flow is routed through the generator (8) and into the waste reservoir (26) (paragraph [0031]) and an "elution" mode where the active saline solution is directed to the patient outlet (paragraph [0032]). Neither deKemp et al. US '848 nor Fago teach a light projector or providing a first light signal when an initial volume of eluate is being diverted or providing a second light signal when the pumping is generating the sample or the dose of eluate.

Ellingboe teaches an animated light indicator may be provided to indicate when cardioplegia is being delivered (e.g. via green illumination) and when delivery is stopped (e.g. via red illumination) (paragraph [0243]; Figure 301). It would have been obvious to one of ordinary skill in the art to include the different illumination signals disclosed by Ellingboe in the computer controlled infusion system of deKemp et al. US '848 and Fago in order to provide indicators to the operator regarding which stage of the infusion is occurring.

11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Bergner (US Patent No. 4,585,941) (cited in the Office Action dated January 4, 2013).

Regarding claim 42, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the activity detector detects a peak bolus of radioactivity.

Bergner teaches an LED display (100) is immediately about the total dose thumbwheel switches (98) and displays the total dose which has been infused in the patient (56) (column 5, lines 8-25). Bergner teaches the actual dose rate which is present in the eluate within the tube (30) in front of the dosimetry probe (58) is displayed on LED display (104) (column 5, lines 8-25). It would have been obvious to one of ordinary skill in the art to include the LED signals based on actual dose disclosed by Bergner in the computer controlled infusion system of deKemp et al. US '848 and Fago in order to provide a description of the dose present in the eluate (Bergner, column 5, lines 19-22).

12. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Varrichio et al. (US Publication No. 2005/0187515 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 45, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach at least one sensor for detecting a leak in the tubing and providing an indication that a leak has been detected.

Varrichio et al. teaches a sensor (251) that may be utilized to detect a leak in the valve system (241) (paragraph [0027]). Varrichio et al. teaches that if one of the flow valves leaks, a midpoint pressure will drift higher if primary flow valve (343) is leaking and lower if redundant flow valve (344) is leaking, thus providing an indication that a leak has been detected (paragraph [0036]). Varrichio et al. discloses a user interface for external program controller (260), which provides real-time status information with respect to infusate pump (200) and may provide audible alarms upon detection of particular conditions and may report conditions to the doctor using information from sensor (251) (paragraphs [0027] and [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the leak detecting sensor of Varrichio et al. in the computer controlled elution system of deKemp et al. US '848 and Fago in order to provide feedback to the doctor (Varrichio et al., paragraph [0027]).

13. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Padda et al. (US Patent No. 5,395,320) (cited in the Office Action dated January 4, 2013).

Regarding claim 46, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach calculating a flow rate profile or controlling a speed of the pump according to the calculated flow rate profile.

Padda teaches an infusion pump which can be programmed to deliver any of a variety of selected profiles of fluid medicine volume over time (Abstract). Padda discloses examples of delivery profiles including fixed rate of flow, ramp up, ramp down, fixed rate with increased rate spikes at specified intervals, and no flow with an infusion bolus at specified intervals (column 2, lines 42-50). Padda teaches a pumping mechanism (24) provides accurate delivery of medicine

(column 4, lines 9-10). Padda teaches a piggyback delivery profile function which allows for the use of a second profile applied before, during an interrupt, or after the first profile, and a different medicine and different fluid to be infused through the infusion pump (column 4, line 59-column 5, line 6). Padda discloses a CPU that sends a motor control drive (14) a code containing information on the desired motor speed and a motor speed control (15) (column 6, line 66-column 7, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flow control and profile mechanisms of Padda in the computer controlled elution system of deKemp et al. US '848 and Fago in order to provide a variety of different fluid delivery profiles to a patient (Padda, column 2, lines 31-34).

14. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Whittacre et al. (US Publication No. 2003/0139640 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 47, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach transferring a plurality of detect activity levels to another system.

Whittacre teaches a display of the amount of isotope which is generating the radioactivity and transferring those values to a database if accepted by the operator (paragraph [0195]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the data transfer of Whittacre in the computer controlled elution system of deKemp et al. US '848 and Fago in order to allow one or more physicians to access the displayed information (Whittacre, paragraph [0202]).

Response to Arguments

15. Applicant's arguments filed January 2, 2014 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, see pages 2-5 of the Remarks, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that because Fago does not have a pump, it cannot provide an indication of a time lapse since each elution was completed. However, the rejection combined Fago with the teachings of deKemp et al. US '848. deKemp et al. US '848 does teach a pump and modifying the system of deKemp et al. US '848 to include the drop counter would provide an indicated of when the pump has completed pumping, because no drops would be counted or seen once the pump stopped pumping fluid.

16. Applicant's arguments on page 5 of the Remarks that a person of ordinary skill in the art would have consciously avoided modifying the eluent counting system of Fago to utilize an eluant pump have been fully considered but they are not persuasive because the system of deKemp et al. US '848 that was modified to include the drop counter of Fago (see page 5 of the Office Action dated October 2, 2013).

17. Applicant's arguments on pages 5-6 of the Remarks that Fago does not teach an indication of a time lapse since each elution was completed have been fully considered but they are not persuasive because the volume and/or time associated with each elution process may be tracked and displayed to enable a user (or the computer 54) to estimate when the generator will be ready for another elution process (paragraph [0034]), and time displayed between the time

where no drops are sensed/counted and the time where drops are again sensed/counted would provide an indication of a time lapse since each elution was completed (Fago, paragraphs [0034]-[0036]).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EILEEN FOLEY whose telephone number is (571) 270-7248. The examiner can normally be reached Monday-Thursday, and alternate Fridays, from 7:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached at (571) 272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. F./
Examiner, Art Unit 3735

/JACQUELINE CHENG/
Supervisory Patent Examiner, Art Unit 3735

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3565376		1971-02-23	Homer J. Viers	

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	1	20020129471	A1	2002-09-19	Chin-Yang Wang	

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Receipt date: 03/28/2014	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

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	First Named Inventor	Stephen E. Hidem
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	2	2288755	RU		2006-12-10	Shchetinin		☐
	3	2131273	RU		1999-06-10	Sajens		☐

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	N	N	N	N					
	7	N	N	N	N					
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	35	-	-	-	-					
	36	N	N	N	N					

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CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013	04/25/2014					
	37	✓	✓	✓	✓					
	38	✓	✓	✓	✓					
	39	✓	✓	✓	✓					
	40	✓	✓	✓	✓					
	41	✓	✓	✓	✓					
	42	✓	✓	✓	✓					
	43	✓	✓	✓	✓					
	44	✓	✓	✓	✓					
	45	✓	✓	✓	✓					
	46	✓	✓	✓	✓					
	47	✓	✓	✓	✓					
	48	✓	✓	✓	✓					
	49	N	N	N	N					
	50	N	N	N	N					

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	FOLEY, Eileen Dorothy
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0 319 148	EP		1989-06-07	International Business Machines Corporation		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 01/21/2014	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	FOLEY, Eileen Dorothy
	Attorney Docket Number	56782.1.7.2

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Eileen Foley/	Date Considered	04/25/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7610	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:29
L2	7610	L1	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:29
L3	5508	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:29
L4	5508	L3	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:29
L5	1	"20110209764".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:30
L6	2	("3565376" | "20020129471").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/25 15:32

4/ 25/ 2014 3:51:56 PM
C:\ Users\ efoley\ Documents\ EAST\ Workspaces\ 12808467_2.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY	3735

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF
Updated class/subclass searches	4/25/14	EF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/E.F./ Examiner.Art Unit 3735	

22859
Customer Number

Patent
Case No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	Eileen Dorothy Foley
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION REGARDING
INFORMATION DISCLOSURE STATEMENT

Dear Commissioner:

Applicant wishes to notify the Commissioner that through error and in good faith, Applicant mistakenly paid the small entity fee at the time of filing the Information Disclosure Statement submitted to the U.S. Patent Office on March 28, 2014 for the above-referenced patent application. In order to rectify this error, Applicant is currently submitting an additional $90.00 payment via credit card with this communication to satisfy the $180.00 fee set forth in 37 CFR 1.17(p) for an undiscounted entity.[1]

The Commissioner is authorized to charge any surcharge or additionally required fees to Deposit Account No. 06-1910.

Respectfully submitted,

/Paul J. LaVanway, Jr./
Paul J. LaVanway, Jr.
Registration No. 64,610

Customer No. 22859

[1] The $180 fee is satisfied by the $90.00 fee paid March 28, 2014 and the $90.00 fee paid with this filing, May 2, 2014.

Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

50526716_1.DOC

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Alycia Morell
Attorney Docket Number:	56782.1.7.2

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	18931302
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Alycia Morell
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	02-MAY-2014
Filing Date:	16-JUN-2010
Time Stamp:	17:21:56
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$90
RAM confirmation Number	4121
Deposit Account	061910
Authorized User	LAVANWAY, PAUL J.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	56782_1_7_2_IDS_Comm_Underpayment_5-2-14.pdf	68627 376f94fd45c772c38280e0e84bde4f980a9fc015	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30516 43503489dc6e8c192ffa29f93e9ad41fe515cbe5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	99143		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3565376		1971-02-23	Homer J. Viers	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020129471	A1	2002-09-19	Chin-Yang Wang	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-03-28
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Alycia Morell
Attorney Docket Number:	56782.1.7.2

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	18593798
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Alycia Morell
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2
Receipt Date:	28-MAR-2014
Filing Date:	16-JUN-2010
Time Stamp:	16:01:40
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$90
RAM confirmation Number	2426
Deposit Account	061910
Authorized User	LAVANWAY, PAUL J.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_IDS_3_27_14.pdf	612226 7363dcd09b472f6088fb5fe278373ba7e7af9842	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30516 8ffd52627d1e05ec10b0e05bc672effcd7daa68e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	642742		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	FOLEY, Eileen Dorothy
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0 319 148	EP		1989-06-07	International Business Machines Corporation		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
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	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	FOLEY, Eileen Dorothy
	Attorney Docket Number	56782.1.7.2

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If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
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(54) Method of operating a multi-processor system for the transfer of data between processor units.

(57) A method for minimising I/O mechanical assess operations on secondary storage devices in a data processing system having a plurality of processor units interconnected in a cluster configuration to permit each processor unit to request and obtain data that is resident only on a secondary storage device of one processor unit. The method involves the steps of maintaining at each processor unit information about each copy of data that has been sent from the unit to another unit to permit a second request to the unit to be serviced by transferring a copy of the data from the main memory which is storing the data to the requesting unit rather than servicing the request with a relatively slow I/O accessing operation to a secondary storage device.

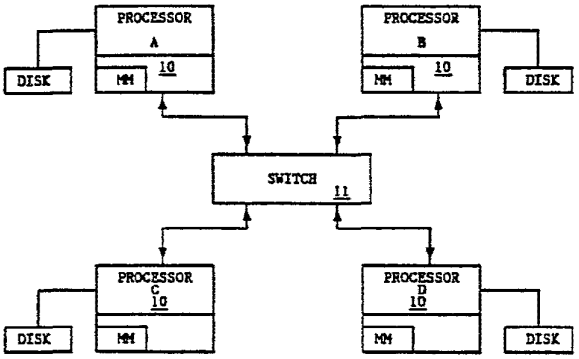

FIG. 1

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METHOD OF OPERATING A MULTI-PROCESSOR SYSTEM FOR THE TRANSFER OF DATA BETWEEN PROCESSOR UNITS

This invention relates in general to data processing systems comprising a plurality of similar interconnected data processing units which share the same virtual memory addressing space and in particular to an arrangement for reducing disk I/O access by each of the processing units.

A related application, European Published Application No. A-229691, is directed to a method for use in a multi-user page segmented virtual memory data processing system in which a mapped file data structure is selectively created to permit all I/O operations to the secondary storage devices to be executed by simple load and store instructions under the control of the page fault handler.

The prior art has disclosed a number of virtual memory data processing systems which employ a single stand alone Central Processing Unit (CPU). These systems generally employ a main memory having a plurality of individually addressable storage locations, each of which stores one byte of data and a secondary storage device such as a Disk File which includes a plurality of block addressable storage locations each of which stores a block of data. For discussions purposes it is convenient to assume that each block address of the disk file stores a page of data comprising for example 2K (2048) bytes of data. The virtual memory concept involves what is sometimes referred to as a single-level store. In a single-level store, the maximum address range of the system is generally much larger than the real capacity of the main memory. The main memory is made to appear much larger by the use of a paging mechanism and a secondary storage device which cooperate to keep the data required by the application program in main memory. The function of the paging mechanism is to transfer a page of data from the disk file to main memory whenever a page which is addressed by the application program is not in main memory. This is called a page fault. Transferring the page of data from the disk file to main memory is called page fault handling.

The performance of a virtual memory data processing system is directly related to the number of disk accesses that occur in servicing page faults since accessing a disk is a relatively slow process typically requiring several milliseconds, whereas accessing main memory typically involves less than a single microsecond. Prior art virtual memory systems therefore employ various techniques to reduce disk accesses and increase the percentage of "hits" that are made in addressing virtual memory. A hit is made in addressing virtual memory if data addressed by an application program is in main memory at the time the application program addressed the data. The hit ratio r of a virtual memory system is the number of hits h in addressing virtual memory divided by the number of hits h plus misses m, or

$$r = h / (h + m)$$

The prior art has also disclosed a number of multi-processor system configurations that are sometimes employed to obtain increased data processing power. A multi-processor system configuration may be thought of as a plurality of processing units sharing a logical communication channel. The logical communication channel may take the form of memory shared among the processing units into which messages from the processing unit to another processing unit may be placed. Additionally, the logical communication channel may take the form of a communication network through which from one processing unit to another processing unit may travel. In some prior art multi-processor system configurations referred to as tightly-coupled multi-processor configurations, the processing units in the configuration share some amount of memory which any of the processing units in the configuration may access, and each processing unit may have some amount of private memory which only it and no other processing unit may access.

Computing systems arranged in a tightly-coupled multi-processor configuration have the benefit of rapid communication via shared memory and may also exploit the shared memory as a disk cache. A page fault may occur when an application program executing on one of the processing units in a tightly-coupled multi-processor configuration addresses a page of data that is not in main memory. During page fault handling, the appropriate secondary storage device connected to the configuration is commanded to place the appropriate page of data into the shared memory. Once the page of data has been placed in the shared memory it may be addressed by any of the processing units in the configuration.

If the plurality of processing units in a multi-processor configuration are working on a common problem, it is normal for the data they access to be accessed in such a way as to experience "locality of reference". The term locality of reference is used when there is some non-zero probability that a page of data retrieved from secondary storage and placed in shared memory to satisfy a page fault resulting from an access to

virtual memory by an application program executing on one processing unit in the configuration will also be accessed by another application program executing on another processing unit in the configuration before the page frame in shared memory holding that page of data has been re-used by the configuration to hold another page of data. If such an access by another application program executing on another processing unit in the configuration occurs, the configuration may avoid a disk access by satisfying the page fault with that page of data already in shared memory.

A practical limit however is reached for tightly-coupled multi-processor configurations when the contention for access to shared memory among the processing units in the configuration exceeds the benefit provided by the shared memory when used as a disk cache. For instance, one processing unit in the configuration may attempt to change the contents of a page of data while another processing unit is attempting to examine the contents of the same page of data. Some mechanism must normally be provided by the configuration to lock out one of the processing units in favour of the other so that the two processing units see a consistent view of the data.

Various methods exist in the prior art to enforce a consistent view of data upon the processing units in a tightly-coupled multi-processor configuration. These methods involve idling one of the processing units in the configuration until the other processing unit has completed its access to shared memory. The processing unit that has been idled cannot be idle and also perform useful work; thus, contention for access to shared memory inevitably results in some loss of processing power for the configuration when considered as a whole. For these reasons, the number of processing units in a single tightly coupled multi-processor configuration rarely exceeds six. In some other prior art multi-processor system configurations referred to as closely-coupled multi-processor configurations, the plurality of processing units is connected via a communications network and each processing unit may access its own memory directly and so other processing unit has access to that memory. The processing units in a closely-coupled multi-processor configuration may share data by sending messages via the communications network to other processing units within the configuration. A variation on the closely-coupled multi-processor configuration distinguishes one of the processing units in the configuration as a shared memory processing unit. The main memory attached to the shared memory processing unit is used as a disk cache managed by the shared memory processing unit. The shared memory processing unit is assigned the function of controlling which of the other processing units can have access to what area of the shared memory at what time and under what configurations. When the shared memory is a virtual memory involving a fast main memory which is required to obtain a respectable hit ratio is directly related to the total number of instructions that are being executed by the multi-processor configuration per second. Individual processing units are sometimes rated in Millions of Instructions Per Seconds (MIPS). If two 4 MIPS processing units and a third shared memory processing unit are employed in a closely-coupled multi-processor configuration, the main memory associated with the configuration must have approximately 80 megabytes of byte addressable memory to obtain a respectable hit ratio. The rule of thumb that is used is that 10 megabytes of byte addressable main memory per MIPS is required to obtain an 85 percent hit ratio in the shared memory. Therefore, if another 4 MIPS processing unit is added to the multi-processor configuration, another 40 megabytes of the shared memory processing unit to maintain the 85 percent hit ratio. A practical limit however is reached in the number of processing units that can be added to the configuration before the cost parameters and performance reach the point of diminishing returns.

More recently stand alone personal computers or stand alone engineering work stations have been configured into local area networks. In such an arrangement, which is called a loosely-coupled multi-processor configuration or a distributed system configuration or a cluster configuration, any work station can communicate with another work station employing standard communication protocols. The motivation that exists for establishing the cluster configuration is not necessarily more data processing power, but simply one of the convenience of exchanging information electronically vs. non-electronic exchange. However, it has been found insome situations that the individual work stations are running the same operating system and at times run the same application programs. A paper entitled "Memory Coherence is Shared Virtual Storage Systems" authored by Kai Liand Paul Hudak and presented at the 5th Annual Association for Computing Machinery Symposium on Principles of Distributed Computing 1986, discloses a plurality of virtual memory data processing units interconnected in a cluster configuration. In this arrangement all units have the same operating system and address the same virtual address space. Each unit is the owner of a different set of files which is stored in that owner's memory system. A non-owner running an application program obtains access to the other unit's memory system through a suitable communication link, which causes requests to the file owner for virtual pages of data which are then returned to the requester.

Each unit of the cluster configuration therefore shares the set of files in its virtual memory system with the other units in the configuration. Page faults resulting from requests are serviced by the file owner. If the

request is local, that is from the owner, the requested page is transferred from the owner's secondary storage directly to the owner's main memory. If the request is from a remote unit, the page is transferred from the owner's secondary storage to the requester's main memory through the communication link. A system protocol is established to control what happens to pages of data after the requesting unit is finished with them. This protocol addresses such issues as, when to return a page to the owner, how to manage concurrent requests for the same page if one unit wants to write to that page while other units want to read from that page, and various other situations that are common to functions that share stored data.

The sharing by each processing unit of its virtual memory with other processing units in the cluster has some potential advantages in that the size or capacity of the secondary storage devices can be reduced since the total number of files available to the cluster is spread out among a number of secondary storage devices. This would permit the use of devices with faster access times and/or lower cost. A potential disadvantage is that concurrent requests from a number of different units to an owning unit will each result in a number of disk accesses to occur in sequence. While the requests are generally serviced in an overlapped manner, a disk access is a relatively time consuming operation for the unit and could severely impact the performance of the owning unit which is perhaps executing an unrelated application program, that is competing for the services of the secondary storage device.

The present invention is directed to an arrangement for use by a shared virtual memory, cluster configured, data processing system in which the number of page faults requiring access to the secondary storage devices is considerably reduced.

According to the invention, there is provided a method of operating a data processing system comprising at least three inter-coupled processor units, each having a main memory and a secondary data storage device, said system including a switch system for selectively interconnecting any pair of the units for the transfer of data stored in the main memory of the second of the pair in response to requests from the second unit, comprising the steps of:

maintaining at each unit a list of files stored in the system and indications of the unit storing each file and coordinating access thereto;

opening a specified file stored at a first unit of a pair in response to a request for specified data from the second unit of the pair;

transferring the specified data requested by the second unit from the secondary storage device of the first unit to the main memory of the second unit in the pair; and

if said request has been initiated by a request for said specified data from a third unit to said second unit, transferring a copy of said specified data from the main memory of the second unit of the pair to the main memory of the third unit.

In an embodiment of the invention to be detailed later, the individual processor units within a cluster of multi-processors, individually coordinate access to multiple segments of the common virtual memory address space. Each segment of virtual memory is logically composed of 128K (131,072) pages, each of which is composed of 2K (2048) bytes of memory. The processor units within the cluster share these virtual memory segments among other processor units within the cluster. A single processor unit serves as the access coordinator of a given file of data assigned to a specified virtual memory segment. Other processor units that use the virtual memory segment are individually called "using processor units". The strategy of the method to implement consistent access to cached pages of virtual memory basically comprises four important aspects.

1. The ownership of a page changes dynamically with its use; thus the right to update a page may be assigned by the access coordinator for the segment containing the page to a given using processor unit and remains with that processor unit until contention for the page requires it to be revoked by the access coordinator for the segment containing that page and assigned processor unit.

2. Ownership of one portion of page implies ownership of the entire page. If, for example, a processor unit accesses the first byte on a page and that unit is granted the capability of accessing that byte, it is also granted the capability of accessing the entire page.

3. The coordination of access to a page is assigned statically and is the processor unit coordinating the segment containing the page.

4. The access coordinator for a given page records in the Virtual Shared Memory Table (VSMT) which processor units have a copy of the page, the access rights individual processor units hold (e.g., read only vs. read/write) and a list of other processor units that are seeking access to the page. The method involves recording at a segment's access coordinator, which pages of the segment are resident in the memory of which using processor unit. The using processor unit requesting access to a page avoids disk I/O by reading the page from a processor unit that has it in its memory system, rather than reading it from disk. In this way, the private memories attached to the individual processor units within the cluster are

virtually shared among each other.

The number of entries in the VSMT table are determined at cluster IPL time or at execution time, based on performance measurements and requirements. The number of VSMT entries is always bounded by the number of page frames of real storage in the cluster. For example, if a cluster consists of 16 processor units each of which has 16 megabytes of memory directly attached to it, there is a total of 2**17 frames in the cluster. If an entry for each frame were allocated to the VSMT in each processor unit, then 11 megabytes of storage would have to be allocated in each processor unit for the VSMT table. For practical purposes, the VSMT table never needs to be that large. The VSMT table does not need to represent pages in the real memory of the access coordinator since these pages are already represented in its page table. Only those pages of those segments, both code and data that are actually shared across the cluster and are in real memory at any given time, need to be represented in the VSMT table. Thus, only a fraction of physical memory frames will contain pages of shared segments at any given time, other frames containing non-shared pages need not be represented to the VSMT table.

The strategy to determine the number of entries in the VSMT table is to create it initially with a small number of entries and to let the number of entries grow with use.

The arrangement further employs "Triangular I/O" which is a scheme for performing I/O among two or more processors. In the unit processor view of the world, I/O is performed between a master unit, the processor and a "slave unit" (a control unit). The master sends requests to the slave, which processes them and responds to them. For example, a processor might send a request for a virtual page to some control unit for a set of disks. The control unit would handle the request by locating the appropriate blocks of data on its disks and transferring them back to the requesting processor. In a cluster, the concept of master and slave units is less clear. For example, a processor unit R might send a request to some of her processor unit Q for a page P stored on a disk device connected directly to processor unit Q. Processor unit Q might handle the request in the same way the control unit would or it might try to avoid a disk I/O by forwarding the request to another processor unit T that has a copy of the requested page in physical memory attached to it. Processor unit T might send the requested page to processor unit R rather than having to send it through processor unit Q. In this sense processor units R, Q and T are involved in a "Triangular I/O" with page P. Interprocess communication is reduced and a second I/O operation to a disk device is avoided.

The embodiment will now be described in detail, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a Functional Block Diagram of a plurality of processor units interconnected in a cluster configuration, in which the method of the present invention may be advantageously employed;

Fig. 2 is a Block diagram of one of the processor units shown in Fig. 1, illustrating the various functions that are incorporated in one of the units;

Fig. 3 is a Block diagram of one of the processing units shown in Fig. 1 illustrating the various software functions that are incorporated in the unit of Figs. 2 and 3;

Fig. 4 illustrates an External Page Table (XPT) data structure employed by the Virtual Memory Manager function of the unit shown in Figs. 2 and 3;

Fig. 5 illustrates an Inverted Page Table structure employed by the Virtual Memory Manager function of the unit shown in Figs. 2 and 3;

Fig. 6 illustrates the Global and Local Segment Identifier data structures which uniquely identify virtual memory segments;

Fig. 7 illustrates the Virtual Shared Memory Table (VSMT) data structure;

Fig. 8 illustrates the VSMT hash anchor table;

Fig. 9 shows a model of a shared map file and the segments associated with it;

Fig. 10 is a block diagram of a basic cluster configuration which is one environment employed to describe some typical operations that are performed;

Fig. 11 is a flow chart illustrating the steps for creating a new file that is stored on one of the processing units in the cluster;

Figs. 12a and 12B show a flow chart illustrating how an existing file is opened by an application program running on a processing unit within the cluster.

Fig. 13 is a flow chart illustrating how an existing file is loaded into the virtual memory shared in a cluster configuration;

Fig. 14 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit wishes to page-in a copy of a page that is not in the memory of the processing units in the configuration;

Fig. 15a and 15b show a flow chart illustrating the detailed steps of how the VSMT is updated by the access coordinator when a page of data is transferred from one processing unit to another processing unit;

Fig. 16 is a flow chart illustrating the steps performed by the access coordinator when a using processor unit sends a request to cast a page of its main memory and there is a copy of the page in the memory of another processing unit;

Fig. 17 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast a page out of its main memory and there is no copy of the page in the memory of any other processing unit; and

Fig. 18 is a flow chart illustrating the steps performed by the access coordinator when it determines that a given page of data must be cached by a shared processing unit.

Fig. 1 is a block diagram of a multi-processor cluster configured data processing system in which the method of the present invention may be advantageously employed. As shown in Fig. 1, the data processing system comprises a plurality of processor units 10, a switch 11 and a plurality of communication links 12, each of which connects one processor unit 10 to switch 11. The function of switch 11 is to permit any processor unit 10 to communicate with any other processor unit. The specific details of the switch and the communication links are not considered relevant to an understanding of the present invention and hence are neither shown nor described in detail. Examples of the switching arrangement that may be employed may be found in U.S. Patents 4,635,250; 4,633,394; 4,630,015; 4,605,928.

Fig. 2 illustrates in detail one of the processor units 10 shown in Fig. 1. Processor unit 10 may be high function personal computer or an engineering work station such as the IBM PC RT running a Unix (T.M.) type operating system such as the IBM AIX (T.M.) operating system. The processor unit 10, as shown in Fig. 2, comprises a microprocessor 16, a main memory management unit 18 which controls the transfer of data between the processor 16 and memory 17, and a plurality of I/O adapters or ports 20A-20E. Ports 20A and 20B function to connect display type terminals 21 and 22 to the system. Port 20C connects a printer to the system while port 20D connects disk drive 24 to the system. The communication port 20E is employed to connect the processor unit 10 to the communication link 12. For purposes of discussion, processor unit 10 corresponds generally to the virtual memory data processing system that is described in detail in cross referenced application Serial Number 819,458. As described in that application, the processor has a 32 bit effective address that is converted into a 40 bit virtual address by employing the 4 high order bits 31-28 to select one of 16 segment registers, each of which stores a 12 bit segment address that defines one of 4096 unique segments. Each segment comprises 256 megabytes of storage (2**28). If a page includes 2K bytes of data, then a segment contains 128K pages. On the other hand, if a page includes 4K bytes of data, the segment then has 64K pages, or more precisely, 64K virtual addresses which may be used to identify pages of data that are currently assigned to that segment.

As explained in the cross referenced to application, a Unix type operating system is employed for the processor unit so that application programs and data employed by these programs are organised in accordance with the Unix file system type of organisation. Existing files are stored on the secondary storage devices of the processor unit which may be assumed to be a disk file. The unit of storage or addressability of the disk file is a disk block, which for purposes of discussion, will be assumed to store one page of data. Unix read and write system calls function to control the transfer of data between main memory and disk storage.

In a virtual memory organisation, the memory manager and a page fault handling mechanism also function to control the transfer of pages between the disk file and main memory in response to load and store type of instructions being executed by the application program. In the system disclosed in the cross referenced application, the operating system is provided with a Map Page Range Service (MPRS) which functions to map a file into an assigned segment of the virtual address space.

The MPRS employs an External Page Table (XPT) data structure in which the disk block address containing a page of a file is assigned a virtual address in the assigned segment. The memory manager also employs an Inverted Page Table (IPT) data structure for correlating real addresses in main memory where a page of data is stored to a virtual address assigned to that page. The system disclosed in the cross referenced application also employed a way to convert read and write system calls in the operating system to load and store instructions having virtual address which reflected the system call parameters and the Unix offset pointer in the file. All disk I/O operations were therefore under control of the memory manager and page fault handling mechanism in the system of the cross referenced application.

The operation of the processor unit 10 in executing an instruction for an application program is briefly as follows. The virtual address of the instruction is hashed with a suitable hashing algorithm to provide an index into a Hash Anchor Table (HAT). The indexed entry in the HAT contains a pointer to the first entry in

a list of virtual addresses that hash to the same value. If a page having a virtual address that would hash to the value that provides the pointer to the list is in real memory, then the virtual address is on the list. The page frame in real memory where the page of data is stored is obtained from the entry in the list containing the virtual address. If the virtual address is not on the list, the corresponding page is not in real memory and a page fault has occurred.

The page fault handling mechanism is then activated. By referencing the XPT entry created when the file was mapped, the page fault handling mechanism locates the disk block address where the page having the requested virtual address is stored. Since the XPT is not pinned in memory, the page fault handling mechanism may encounter a page fault when it first references in XPT. However, once the appropriate page of XPT entries is paged into memory, the original page fault can be serviced. The page is transferred to a page frame in memory that has been available and the application process is restarted.

It should be understood that the virtual memory manager operation summarised above is just one of the many prior art virtual memory management functions that can be used in the processor unit shown in Fig. 1 and on which the method of the present invention relies.

As indicated in Fig. 1, the units are interconnected by switch 10 and communication links 12 to permit one unit to be selectively interconnected in a data transferring relationship with one other unit. As stated earlier, communication port 20E is the normal interface to communication link 12 that is connected to the switch 11. A remote memory manager function is added to each unit 10 and provides an interface between port 20E and the native memory manager function 18. The function of the remote memory manager of processor unit 10A for example, is to process a request for a virtual page P of data from the remote memory manager function of processor unit 10B. The request is sent to processor unit 10A because 10A has been assigned as the access coordinator for that page and file. To process the request for page P, the remote memory manager function first determines if the requested page is in the main memory of the unit 10A. If the page P is there, a copy Pb is returned to unit 10B and a data structure referred to as the Virtual Shared Memory Table (VSMT) and shown in Fig. 7, records the fact that unit 10B has a copy of the requested page in its main memory. The remote request was initiated by unit 10B when an instruction having a virtual address was executed by unit 10B and recognised as involving a file that was stored at unit A. The manner in which the Access Coordinator of a file or a virtual page is recognised is discussed in detail later on the specification.

The above operation is a simple direct request and transfer operation involving two processor units. A slightly more involved operation occurs if it is assumed that the requested page Pa is paged out of the main memory of unit A so that the only copy in any main memory is the copy Pb that was previously sent to unit B. Assume now that C requests a copy of the same page from unit A. Unit A does have a copy of the requested page P on disk, but this would require a relatively long disk I/O operation to retrieve it and forward it to unit C. The remote memory manager of unit A in servicing the request from unit C would first check unit 10A's inverted page table and determine that it was not in the main memory of unit 10A. At this point, prior art systems would take the page fault and retrieve the page from disk. The new method, however, merely checks the SVMT data structure for the virtual address of the requested page Pb and is advised that a copy Pb is still in the main memory of unit 10B. The remote memory manager of unit 10A therefore sends a message to the remote memory manager of unit 10B, requesting that unit 10B send a copy of the page Pb to the remote memory manager of unit 10C. The initial request by unit 10C is said to have been serviced by a "triangular I/O operation." While a triangular I/O operation involves a number of messages including the transfer of a page of data, the time involved is at least 2 orders of magnitude faster with present day storage and communication technologies than would be involved in retrieving the requested page from unit 10A's disk file.

It should be noted that in the cluster shown in Fig. 1, each unit is running the same operating system and that preferably only one copy of each file exists in the cluster. Each file is assigned a processor unit which acts as the Access Coordinator for that file. The file is stored on the processor unit's secondary storage device. The file/access coordinator assignment can be established by the name given to the file similar to the convention employed by the PC-DOS operating system which uses drive and path parameters in the full name of the file. Alternately, a simple access coordinator table could be employed listing each file in the cluster along with the current access coordinator.

It should be assumed that in the following discussion, a page of data comprises 2**11 or 2K bytes (2048), that a segment consists of 2**17 or 128K pages (131,072). Since the virtual address space employed by the cluster is used by each processor unit, two new data structures and identifiers are employed. The Local Segment Identifier (LSID) shown in Fig. 6 uniquely identifies a segment with its access coordinator. The LSID comprises 12 bits.

The Global Segment Identifier (GSID) shown in Fig. 6 comprises 19 bits which uniquely identify the

processor unit within the segment. The GSID comprises an 7 bit processor ID portion and the 12 bit LSID. The VSMT data structure is shown in Fig. 7 and is similar in many respects and functions to an inverted page table used by each processor unit.

Each entry of the VSMT includes the following fields:

State Indicator	4 bits
Local Segment ID	24 bits
Page Number Within Local Segment	16 bits
Last Entry Indicator	1 bit
Processor ID	8 bits
Index of Next Entry on Hash Chain	31 bits

As discussed earlier, the inverted page table employed by each processor unit 10 functions to correlate page frame addresses in main memory with the virtual address of the page that is stored in the page frame. An inverted page table as shown in Fig. 5 has one entry for each page frame in its main memory. The data contained in each of the inverted page tables in the cluster is not per se duplicated in the VSMT that is stored by that processor unit. The function of the VSMT for a processor unit is to log entries that reflect that a virtual page which is being coordinated by that processor unit has been sent to another unit in the cluster. Stated differently, the VSMT for a processor unit is updated when a virtual page that the processor unit is coordinating is transferred to another processor unit of the cluster.

The VSMT for a processor unit 10 is a list of entries as shown in Fig. 7. Entry into the table is by an index stored in the system hash anchor table shown in Fig. 8. The index is to the first entry in the section of the table whose virtual addresses hash to the same value. These sections are referred to as hash value sections. Entries in each hash value section are sequenced in ascending order of Local Segment ID's. Within the same LSID, entries are sequenced increasingly by virtual page index. The hash value for a virtual address is obtained for example by hashing the LSID of the segment containing the page with the page's Virtual Page Index. The hash value is an index into the anchor table to provide a pointer to the head of the hash entries in the VSMT.

A shared mapped file consists of at least two virtual memory segments. At each using processing unit on which at least one application program has the file open there is one segment per open system call issued by an application program, and at the owning processing unit there is one segment. Figure 9 shows a model of a shared mapped file. The segment at using processing unit 10a is bound to the segment at owning processing unit 10b using the Bind Remote Segment Service (BRSS). All of the pages of processing unit 10a's segment are mapped read-write to the owning processing unit segment using the Map Remote Page Range Service (MRPRS).

To map a file, an application program first issues the open system call to open the file. The application program then issues the shmat system call to map the file into the application program's virtual address space. The shmat system call uses the Map Page Range Service (MPRS) to load the file into virtual memory. The application program can now directly access the file with load and/or store instructions. No other interaction with the operating system is required to access the file. When the application program is finished with the file, it can remove the file from its virtual address space by issuing the shmat system call. Alternatively, the program could just issue the close system call since the close system call will automatically perform the shmat system call as required.

Sharing of the data in a given mapped file is performed in a cluster environment by binding the using processing unit's segment associated with the open file to the owning processing unit's segment associated with the open file. Each using processing unit that has a file mapped into a virtual memory segment has one segment for each mapped file that application programs executing on it have opened. All application programs at a given using processing unit or the owning processing unit logically share the same segment. The owning processing unit's segment associated with the open file is the segment to which each using processing unit's segment associated with the open file is linked.

One of the requirements for sharing virtual memory segments across a cluster configuration is to ensure that updates to mapped files behave the same in both a stand alone configuration and a cluster configuration. This implies that each store instruction executed against mapped file must appear to be immediately applied to all copies of the mapped file shared throughout the cluster. This may be achieved by enforcing a set of consistency rules on access to mapped files.

These consistency rules are:

(1) At most one processing unit within the cluster configuration may have a copy of given page of the segment if one or more application programs executing on that processing unit is (are) writing into the page.

(2) Any number of processing units within the cluster configuration may have a copy of a given page of the segment if no application programs executing on any processing units in the cluster are writing into the page.

The virtual memory managers (VMMs) at the owning processing unit and the using processing units cooperate to enforce these consistency rules. Each VMM enforces these consistency rules by using a prior art hardware page protection mechanism. Each page in shared virtual memory has two page protection keys associated with it. The former key is the requested protection key specified using the Create Segment Service (CSS) or the Protect Page Service (PPS). This key is used to determine what type of memory access is valid for the page. The latter key is the effective protection key. This key is used to enforce the data consistency rules for shared mapped files.

Each page in a mapped file has one of three distinct consistency states at any given time. These consistency states apply to both using processing unit and owning processing unit shared mapped files. The consistency states for a given page of a mapped file that is shared across a cluster are recorded in the Virtual Shared Memory Table (VSMT) State Field (see Figure 7). A description of how the VSMT data structure is updated is described below. The consistency states are as follows:

NoAccess A copy of the page is in the main memory of the processing unit. Any access to the page by an application program will result in a page fault occurred interrupt to be signalled to the VMM. This state places no additional restrictions on the valid consistency states of a copy of the page at any other processing unit in the cluster.

ReadOnly A copy of the page is in the main memory of the processing unit and the copy of the page has not been modified since having been placed in main memory. The effective protection key for the page is read-only. A store access to the page will result in a page fault occurred interrupt to be signalled to the VMM if the requested protection key is read-write. A store access to the page will result in a protection exception occurred interrupt to be signalled to the VMM if the requested protection key is read-only. The former interrupt is used to inform the VMM that an application program attempted to access the page for writing. The latter interrupt is used to inform the VMM that an application program attempted to access the page for writing although it did not have permission to do so. This is generally considered an error condition, and appropriate error handling must be executed to handle the error in an appropriate way.

Other processing units within the cluster may access the same page for reading when the page is in the ReadOnly consistency state. No other processing units within the cluster may access the same page for writing when the page is in the ReadOnly consistency state.

ReadWrite A copy of the page is in the main memory of the processing unit and the page has been modified since it was placed in the main memory of the processing unit. The effective protection key for the page is read-write. An access to the page for either reading or writing will be allowed without causing a page fault occurred interrupt to be signalled to the VMM. An access to the page for reading may cause a protection exception interrupt to be signalled to the VM if the requested protection key does not allow read access to the page. An access to the page for writing may cause a protection exception interrupt to be signalled to the VMM if the requested protection key does not allow write access to the page. No other processing unit within the cluster may access the same page for either reading or writing when the page is in the ReadWrite consistency state.

The consistency state of a page may be effected by the occurrence of one of several different events. These events are: (1) accesses to the page by application programs executing on the same processing unit; (2) execution of the Purge Page Range (PPRS) at the same processing unit; (3) execution of the Purge Segment Service (PSS) at the same processing unit; (4) execution of the VMM page replacement mechanism at the same processing unit; and (5) changes to the consistency state of the page at another processing unit within the cluster. The VMMs executing at each of the processing units within a cluster cooperate to ensure that an occurrence of any of these events results in a valid transition of the page consistency state. The valid transitions allowed by the VMMs are:

NoAccess to ReadOnly This consistency state transition is triggered by a page fault occurred interrupt having been signalled to the using processing unit VMM resulting from a read access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for reading to the using processing unit VMM.

In some instances it may be desirable for the VMM at the using processing unit to "remember" the

previous consistency state for the page and treat this transition as if it were a write access to the page occurring when the consistency state of the page was ReadWrite instead of a read access to the page occurring when the consistency state of the page was NoAccess. This variation in protocol would prevent two consistency state changes when a write access to the page follows a read access to the page which in practice is often the case. If this variant protocol is adopted, upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for writing to the using processing unit VMM.

NoAccess to ReadWrite This consistency state transition is triggered by a page fault occurred interrupt being signalled to the using processing unit VMM resulting from a write access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for writing to the using processing unit VMM.

ReadOnly to ReadWrite This consistency state transition is triggered by a page fault occurred interrupt being signalled to the using processing unit VMM resulting from a write access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send permission to access the page for writing to the using processing unit VMM.

ReadOnly to NoAccess This consistency state transition is triggered when a page frame containing an unmodified page is reassigned by the using processing unit VMM to hold another page of data or when an unmodified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processing unit that has the file mapped for read-write attempts to access the page for writing.

ReadWrite to NoAccess This consistency state transition is triggered when a page frame containing a modified page is selected for replacement by the using processing unit VMM or when a modified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processing unit that has the file mapped for read-write attempts to access the page for writing. The using processing unit VMM sends the data contained in the page to the owning processing unit VMM along with notification that the using processing unit VMM has changed the consistency state for the page to NoAccess, and has purged the page from its main memory.

ReadWrite to ReadOnly This consistency state transition is triggered when a page frame containing a modified page is selected for replacement by the using processing unit VMM or when a modified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processor unit that has the file mapped for read-write attempts to access the page for writing. The using processing unit VMM sends the data contained in the page to the owning processing unit VMM along with notification that the using processing unit VMM has changed the consistency state for the page to ReadOnly, and has set the effective protection key to allow read-only access to the page.

The owning processing unit VMM ensures that a valid combination of consistency states exists at each of the nodes accessing the mapped file. This is achieved by having the owning processing unit VMM maintain a list of writers to each page that is managed under the owning processing unit's consistency control algorithm and by having the owning processing unit send requests to using processing units to change the consistency state of a given page of data. Any request by any using processing unit to access the page for reading will cause the owning processing unit to send a request to a using processing unit that has an application program executing on it that has written to the page to change the consistency state for the page from ReadWrite to ReadOnly. Any request by any using processing unit to send a request to a using processing unit that has an application program executing on it that has the page in the ReadWrite consistency state to change the consistency state for the page to NoAccess, or to send a request to each using processing unit that has the page in the ReadOnly consistency state to change the consistency state for the page to NoAccess.

The protocol for updating the various SVMT of each processor unit to reflect the processing of the pages that it is coordinating, by other processors units will depend to a large extent on the particular application. In some applications it may be more efficient to notify the Access Coordinator when the copy is

no longer in main memory of the requester so that the coordinator will not service another request by a triangular I/O operation involving that unit.

Likewise the protocol for protecting pages being written by more than one processor unit could take the form of many of the prior art protection schemes involving locking bits. The techniques discussed by A. Chang and M. Mergen in an article entitled "801 Storage: Architecture and Programming", presented in the Proceeding of the 1987 Conference of the ACM Special Interest Group on Operating Systems on November 26, 1987 may be employed.

Typical operations will now be described in connection with Figures 10. Figure 10 is a block diagram of a cluster configuration consistency of three processing units 10a, 10b, and 10c, a switch 11, and three communication links 12 that connect the processing units to the switch. Each of the processing units has a secondary storage device which may be thought of as a disk attached directly to it. Except for the contents of the files stored on the secondary storage devices attached to an individual processing unit, processing units 10a, 10b, and 10c should be thought of as identical. We shall use Figures 10 - 13 to illustrate typical operations in the cluster configuration. The description of these operations and the flow of messages is at a level of detail such that a person skilled in the art of implementing a software virtual memory manager component of a general purpose operating system will be able, without undue experimentation, to implement the method.

Figure 11 is a flow chart illustrating the steps for creating a new file that is stored on one of the processing units in the cluster.

In Step A of Figure 11, an application program executing on processing unit 10a uses the create (sic) system call to create the file "/u/smorgan/database se".

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system examines the "root" system directory. The system directories, individually contain lists of file names each with the name of the access coordinator for that file. We shall assume for the purpose of discussion that a UNIX file naming convention and directory structure is used, although persons skilled in the art will understand that this assumption is not necessary for the purpose of implementing the method. For example, the application program may have asked to create the file "/u/smorgan/database". The operating system examines the root system directory, called "/", and finds that it contains an entry for "u" and that u is a directory.

In Step D the operating system examines the u directory and determines that it contains an entry for "smorgan" and that smorgan is a directory.

In Step E the operating system examines the smorgan directory and finds that it does not contain an entry for "database". Steps C-E are called the directory lookup phase of the create system call.

In Step F the operating system determines which processing unit in the cluster is a good candidate to serve as the access coordinator for the file once it is created. The operating system uses some algorithm, whose exact working is unnecessary for an understanding of the method, to make a judicious choice. For example, the choice of an access coordinator might be based on a computation of which of the processing units is least heavily loaded with access coordinator duties for other existing files. By picking the least heavily loaded processing unit, the operating system might be making an assumption that the configuration will provide the best overall performance if the access coordination function is spread uniformly among the various processing units in the configuration.

After having chosen one processing unit in the configuration as the access coordinator for the to-be-created file /u/smorgan/database, which for the purpose of discussion is assumed to be processing unit 10c.

In Step G processing unit 10a sends message 1 to processing unit 10c to create the file.

In Step H, upon receipt of message 1 from processing unit 10a, processing unit 10c determines that the file does not yet exist within the configuration by examining the various shared directories in a way similar to that performed by processing unit 10a in the directory lookup phase (Steps C-E) of the create system call.

In Step I processing unit 10c creates the file and assigns it a file identifier FID. For the purpose of this discussion we shall assume that a file identifier is a 32 bit integer that uniquely identifies the file in the configuration. The file identifier may have been composed by concatenating the processing unit identifier for the access coordinator (processing unit 10c) with a number chosen by the access coordinator that uniquely identifies the file to the access coordinator. A processor identifier is a 7 bit integer that uniquely identifies a given processing unit within a cluster configuration.

In Step J processing unit 10c sends message 2 to each of the other processing units 10a and 10b in the configuration that the file identified by FID has been created. Message 2 includes the name of the file, its file identifier FID, and the processor identifier PID of the access coordinator.

In Step H, upon receipt of message 2 from processing unit 10c, each of the other processing units 10a and 10b updates its copy of the system directories to indicate the existence of the newly created file /u/smorgan/data base along with the file identifier FID and the access coordinator processor identifier PID for the file.

In Step K, upon receipt of message 2 from processing unit 10c, processing unit 10a determines that the file /u/smorgan/database has been created, and

In Step L 10A informs the application program executing on processing unit 10a that this is the case.

Figs. 12A and 12B is a flow chart illustrating how an existing file is opened by an application program running on a processing unit within the cluster.

In Step A of Figure 12, an application program executing on processing unit 10a uses the open system call to open the file "/u/smorgan/database" for read-write access.

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system examines the root system directory "/" and finds that it contains an entry for "u" and that u is a directory.

In Step D the operating system examines the u directory for "smorgan" and determines that smorgan is a directory.

In Step E the operating system examines the smorgan directory for "database" and determines: (1) that database is a file; (2) that the access coordinator for the file is processing unit 10c; and (3) that the file identifier FID is associated with the file. In step F the operating system executing at processing unit 10a sends message 1 containing file identifier by FID to processing unit 10c, requesting that the file identified by FID be opened on behalf of an application program executing on processing unit 10a.

In Step G, upon receipt of message 1 from processing unit 10a, processing unit 10c determines the location on its secondary storage device of file descriptor FD, which describes the file identified by FID. The processing unit 10c locates file descriptor FD by using file identifier FID to index into the File Descriptor Table (FDT) located at processing unit 10c. The FDT located at processing unit 10c contains a file descriptor for each existing file for which processing unit 10c serves as access coordinator. A file descriptor identifies the number and location of disk blocks on secondary storage devices attached to processing unit 10c that are part of a given file. In addition, a file descriptor contains other information about a file, such as its length, the time it was most recently accessed, the name of the its owner, etc. Persons skilled in the art will understand that the additional information contained in a file descriptor is irrelevant insofar as developing an understanding of the method is concerned; thus, it is not discussed.

In Step H processing unit 10c determines that the file identified by FID is not currently open, i.e. it does not currently have a local virtual segment associated with it.

In Step I processing unit 10c uses the Create Segment Service (CSS) to create a virtual memory segment for the file FID. In doing so, processing unit 10c specifies that the segment is to be created using file descriptor FD, and also that the requested protection key for the segment to be created is to be read-write. CSS returns a segment identifier S by which the segment it created may be identified.

In Step J processing unit 10c sends message 2 to processing unit 10a responding that processing unit 10c has successfully opened the file identified by FID on behalf of processing unit 10a. Message 2 identifies the segment identifier S as the segment associated with the file identified by FID.

In Step K processing unit 10a determines that the file identified by FID is not currently open, i.e. it does not currently have a local virtual segment associated with it.

In Step L processing unit 10a creates a local segment SA for the file identified by FID using the Create Remote Segment Service (CRSS). CRSS takes the segment identifier S and creates a "dummy" segment SA. A dummy segment is a local segment with a segment identifier and a Segment Identifier Table (SIT) entry, but without an External Page Table (XPT).

In Step M processing unit 10a uses the Bind Remote Segment Service (BRSS) to bind the local segment SA to the global segment S. BRSS takes the segment identifiers S and SA, the processor identifier PID of the access coordinator (processing unit 10c), and modifies the SIT entry associated with segment SA to indicate that segment SA relates to segment S whose access is coordinated by processing unit PID.

In Step N processing unit 10a determines that file /u/smorgan/database has been successfully opened and informs the application program that this is the case.

Fig. 13 is a flow chart illustrating how an open file is loaded into the virtual memory shared in a cluster configuration.

In Step A of Figure 13, an application program executing on processing unit 10a uses the shmat system call to map the local segment SA associated with the open file "/u/smorgan/database" into the application program's virtual address space for read-write access.

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system determines that the local segment SA is bound to a remote segment S whose access is coordinated by processing unit 10c. Processing unit 10a makes this determination by examining the Segment Identifier Table (SIT) relating a given segment identifier for a currently open file to the appropriate remote segment for the currently open file and the processor identifier of the access coordinator associated with that segment.

In Step D processing unit 10a uses the Map Page Range Service (MPRS) to map the contents of segment SA into the virtual address space of the application program.

In Step E processing unit 10a determines that the file /u/smorgan/data base has been successfully mapped into the virtual address space of the application program and informs the application program that this is the case.

Fig. 14 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit wishes to page-in a copy of a page that is not in the memory of any of the processing units in the configuration. This description assumes for the purpose of discussion that:

(1) an application program executing on processing unit 10a has previously opened the file and had the file mapped into the application program's virtual address space; and

(2) that processing unit 10c serves as the access coordinator for the file.

In Step A of Figure 14 an application program executing on processing unit 10a attempts to access for reading page P of segment SL containing file F.

In Step B the application program page faults. In Step C the operating system executing on processing unit 10a intercepts the page fault and determines that it was caused by a read access to page P of segment SL by the application program.

In Step D processing unit 10a determines that segment SL is a remote segment whose access is coordinated by processing unit 10c.

In Step E processing unit 10a determines that segment SL is bound to remote segment SR.

In Step F processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10c send a copy of page P of segment SR to processing unit 10a.

In Step G, upon receipt of message 1, processing unit 10c examines its VSM Table looking for entries for page P of segment SR. Assume for the sake of discussion that exactly one entry exists in the VSM Table for page P of Segment SR, and that the entry indicates that processing unit 10b has a copy of the page in its memory, and that the ReadOnly consistency state is associated with that copy of the page.

In Step H processing unit 10c determines that segment SR is bound to segment ST in processing unit 10b.

In Step I processing unit 10c sends message 2 to processing unit 10b requesting that processing unit 10b send a copy of page P of segment ST to processing unit 10a and that the copy of the page have the ReadOnly consistency state associated with it. Message 2 further indicates that processing unit 10a refers to segment ST as segment SL.

Figs 15a and 15b is a flow chart illustrating the detailed steps of how the VSMT is updated by the access coordinator when a page of data is transferred from one processing unit to another processing unit. This description assumes for the purpose of discussion that: (1) an application program executing on processing unit 10a has previously opened the file and had the file mapped into the application program's virtual address space; and (2) that processing unit 10c serves as the access coordinator for the file.

In Step A of Fig. 15A an application program executing on processing unit 10a attempts to access for reading page P of segment SA containing the file F.

In Step B the application program page faults.

In Step C the operating system executing on processing unit 10a intercepts the page fault and determines that it was caused by a read access to page P of segment SA by the application program.

In Step D processing unit 10a determines that segment SA is a local segment bound to remote segment S whose access is coordinated by processing unit 10c.

In Step E processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10c send a copy of page P of segment S to processing unit 10a.

In Step F, upon receipt of message 1, processing unit 10c examines its VSM Table looking for entries for page P of segment S. We shall assume for the purpose of discussion that: (1) exactly one entry exists in the VSM Table for page P of Segment S; (2) the entry indicates that processing unit 10b has a copy of the page in its memory; (3) the ReadOnly consistency state is associated with that copy of the page.

In Step G processing unit 10c sends message 2 to processing unit 10b requesting that processing unit

10b send a copy of page P of segment S to processing unit 10a and that the copy of the page have the ReadOnly consistency state associated with it.

In Step H processing unit 10c adds an entry to its VSM Table indicating that processing unit 10a has been sent a copy of page P of segment S with the ReadOnly consistency state associated with it. In order to add an entry to the VSM Table for page P of segment S, the following steps must be performed by processing unit 10c:

(H1) Hash the segment identifier SR and the page number P together to locate the hash anchor table entry that would correspond to page P of segment SR if there were already an entry for this page in the VSM Table.

(H2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(H3) Follows the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10b. We shall refer to this below as entry E of the VSM Table.

(H4) Allocate an entry F in the VSM Table by taking an entry off the free-list of currently unused VSM Table entries. Allocating an entry in a data structure from a free list is well known, simple, and will be understood by a person skilled in the art of computer programming; therefore, it is not illustrated here.

(H5) Fill the appropriate values into entry F. Specifically, fill in:

(a) the Processor Identifier field with an integer that uniquely identifies processing unit 10a;

(b) the Page Number field with the page number P;

(c) the Local Segment Identifier field with the segment identifier S; and

(d) the State field with an integer that uniquely identifies consistency state ReadOnly.

(H6) Add entry F to the hash chain for the computed hash value. Perform this operation by:

(a) copying the Next Entry Index field of entry E into the Next Entry Index field of entry F; then

(b) copying the number F into the Next Entry Index field of entry E. After Step H6 has been completed, entry F is on the hash chain for the computed hash value.

In Step I, upon receipt of message 2 from processing unit 10c, processing unit 10b locates page P of segment S in its main memory.

In Step J processing unit 10b sends message 3 containing page P of segment S to processing unit 10a. Message 3 indicates that page P of segment S has the ReadOnly consistency state associated with it.

In Step K, upon receipt of message 3 from processing unit 10b, processing unit 10a places the copy of page P of segment S in its main memory, changes the virtual address of page P of segment S to indicate that the page is page P of segment SA, then sets the effective protection key for the page to ReadOnly.

Fig. 16 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast-out a page from its main memory.

In Step A of Fig. 16 processing unit 10a selects page P of segment SA for replacement. This would happen in the normal course of events if, for example, the virtual memory manager (VMM) component of the operating system executing on processing unit 10a determined that page P of segment SA had not been accessed by any application program for an extended period of time.

In Step B, processing unit 10a determines that page P is contained within segment SA, and that segment SA is a local segment bound to remote segment S whose access is coordinated by processing unit 10c.

In Step C processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step D, upon receipt of message 1 from processing unit 10a, processing unit 10c examines its VSM Table for all entries corresponding to page P of segment S. We shall assume for the purpose of discussion that: (1) exactly two entries exist in its VSM Table for page P of segment S; (2) the former entry indicates that processing unit 10a has a copy of page P of segment S in its memory in ReadOnly consistency state; and (3) the latter entry indicates that processing unit 10b also has a copy of page P of segment S in its memory, and that this copy is also in ReadOnly consistency state.

In Step E processing unit 10c determines that, since: (1) there are currently two copies of the page cached in the main memory of processing units within the cluster configuration; and (2) both copies of the page are in ReadOnly consistency state, then processing unit 10a may be allowed to cast page P of segment S out of its main memory without the significant degradation of performance that re-reading page

P of segment S from secondary storage might later incur.

In Step F processing unit 10c sends message 2 to processing unit 10a responding that processing unit 10a may cast page P of segment S out of its main memory.

In Step G, upon receipt of message 2 from processing unit 10c, processing unit 10a casts page P of segment S out of its main memory.

Figure 17 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast a page out of its main memory and there isn't a copy of the page in the memory of any other processing unit.

In Step A of Fig. 17 the VMM component of the operating system executing at processing unit 10a selects page P of segment SA as a candidate for replacement.

In Step B processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step C, upon receipt of message 1 processing unit 10c examines its VSM Table for entries for page P of segment S. We shall assume for the purpose of discussion that no entry exist in its VSM Table for page P of segment S.

In Step D processing unit 10c determines that it has enough space in its main memory to hold page P of Segment S and allocates a frame for that purpose.

In Step E processing unit 10c sends message 2 to processing unit 10a requesting that processing unit 10a send a copy of page P of to processing unit 10c.

In Step F, upon receipt of message 2 from processing unit 10c, processing unit 10a sends message 3 containing page P of segment S to processing unit.

In Step G, upon receipt of message 3 from processing unit 10, processing unit 10c add page P of segment S to its main memory.

In Step H processing unit 10c updates its VSM Table indicating that a copy of page P with the ReadOnly consistency state associated with it, has been moved from processing unit 10a's main memory to processing unit 10c's main memory. In order to update the an entry in the VSM Table for page P of segments the following steps must be performed by processing unit 10c.

(H1) Hash the segment identifier S and the page number P together to locate the hash anchor table entry that would correspond to page P of segment S if there were already an entry for this page in the VSM Table.

(H2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(H3) Follow the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10a.

(H4) Update the processor identifier field of entry E with an integer that uniquely identifies processing unit 10c. after Step 4 has been completed Entry E has been updated.

Figure 18 is a flow chart illustrating the steps performed by the access coordinator when it determines that a given page of data must be cached by a shared memory processing unit.

In Step A of Fig. 18 the VMM component of the operating system executing at processing unit 10a selects page P of segment S as a candidate for replacement.

In Step B processing unit 10a sends message 1 to processing unit 10c, the access coordinator for segment S, requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step C, upon receipt of message 1 processing unit 10c examines its VSM Table for entries for page P of segment S. Assume for the purpose of discussion that no entry exist in its VSM Table for page P of segment S.

In Step D processing unit 10c determines that it does not have enough space in its main memory to cache page P of segment S. In Step E processing unit 10c determines that processing unit 10b is acting as a shared memory unit for the cluster configuration and sends message 2 to processing unit 10b requesting that processing unit 10b cache a copy of page P of segment S in its main memory, processing unit 10c.

In Step F processing unit 10c adds an entry to its VSM Table indicating processing unit 10b now holds a copy of page P of segment S with the ReadOnly consistency state associated with it. In order to add an entry in the VSM Table for page P of segment S the following steps must be performed by processing unit 10c.

(F1) Hash the segment identifier S and the page number P together to locate the hash anchor table entry that would correspond to page P of segment S if there were already an entry for this page in the VSM Table.

(F2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(F3) Follow the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10a.

(F4) Update the processor Identifier field of entry E with an integer that uniquely identifies processing unit 10b. After Step 4 has been completed entry E has been updated.

(G) In Step G upon receipt of message 2 from processing unit 10c, processing unit 10b allocates a page frame in its main memory and sends message 3 to processing unit 10a requesting that processing unit 10a send page P of Segment S to processing unit 10b.

(H) In Step H upon receipt of message 3 from processing unit 10c, processing unit 10a sends page P of Segment S along with the ReadOnly consistency state associated with that page to processing unit 10b.

While the preferred embodiment has been described for use in a virtual memory environment, it will be apparent that the method is equally applicable to a cluster configuration comprising a plurality of processing units which do not employ a virtual type of memory. The underlying problem of I/O disk access for obtaining a copy of data that is currently in the main memory of another unit can be solved in the manner taught in this application, namely maintaining information on what data has been sent to the main memory by what processor unit and transferring a copy of that data to the requester from main memory having the copy rather than performing an I/O operation to disk to obtain the data.

Claims

1. A method of operating a data processing system comprising at least three inter-coupled processor units, each having a main memory and a secondary data sotrae device, said system including a switch system for selectively interconnecting any pair of the units for the transfer of data stored in the main memory of a first of the pair to the main memory of the second of the pair in response to requests from the second unit, comprising the steps of:

maintaining at each unit a list of files stored in the system and indications of the unit storing each file and coordinating access thereof;
opening a specified file stored at a first unit of a pair in response to a request for specified data from the second unit of the pair;
transferring the specified data requested by the second unit from the second storage device of the first unit to the main memory of the second unit in the pair; and
if said request has been initiated by a request for said specified data from a third unit to said second unit, transferring a copy of said specified data from the main memory of the second unit of the pair to the main memory of the third unit.

2. A method according to claim 1 including the further step of:

maintaining, in each unit, a virtual shared memory (VSM) table identifying any other unit holding a copy of data in files coordinated by the unit.

3. A method according to claim 2, including the further step of:

updating said VSM table of the first unit in a pair of transfer of data to the second unit of the pair.

4. A method according to claim 2 or claim 3, including the further step of:

updating said VSM table of the first unit in a pair on transfer of data to the third unit from the second unit in the pair.

5. A method according to any of the previous claims in whcih said main memory and secondary storage device of each unit comprise a virtual memory system, each virtual memory system having the same virtual address range, each secondary storage device includes a plurality of block addressable locations, each for storing a page of data, each main memory includes a plurality of page frames for storing a page of data, and each unit includes a page manager including a page fault handling system for revolving page faults that occur in response to requests for pages of data not in the main memory of the unit.

6. A method according to claim 5, in which each unit contains application programs unique to itself within the system, including the further steps of:

establishing, in each unit, a first data structure having a unique identifier for each application program in the unit together with a rocessor unit identifer to designate the processor controlling access to the program; and storing the first data structure in the main memory of the unit.

7. A method according to claim 6 including the further steps of:

establishing, in each unit, a second data structure having a plurality of entries indicating the virtual address of a page of data transferred from a file coordinated by a first unit and the identity of any other unit holding a copy of the transferred page; and

storing the second data structure in the main memory of the unit.

8. A method according to claim 7 including the further step of:

resolving local page faults in each unit by determining from said second data structure whether a copy of a page causing a local fault is stored in the main memory of another unit prior to resolving the page fault with the page fault handling system of the unit.

9. A method according to claim 8 including the further step of resolving a page fault at a remote unit for a page from a file coordinated by a further unit by:

determining, by reference to the first data structure, the unit controlling access to a file containing the faulting page;

requesting coupling between the unit controlling access and the remote unit through the switch system; and

sending a message to the unit controlling access requesting that a copy of the faulting page be sent to the remote unit.

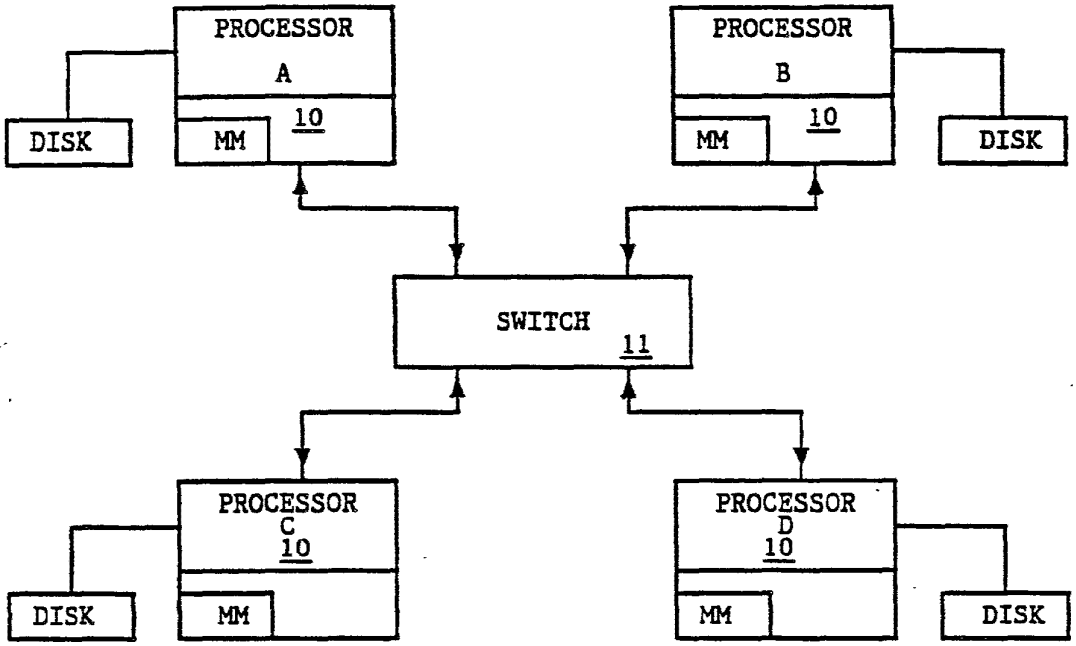
PROCESSOR
A
10
DISK
MM
PROCESSOR
B
10
MM
DISK
SWITCH
11
PROCESSOR
C
10
DISK
MM
PROCESSOR
D
10
MM
DISK

FIG. 1

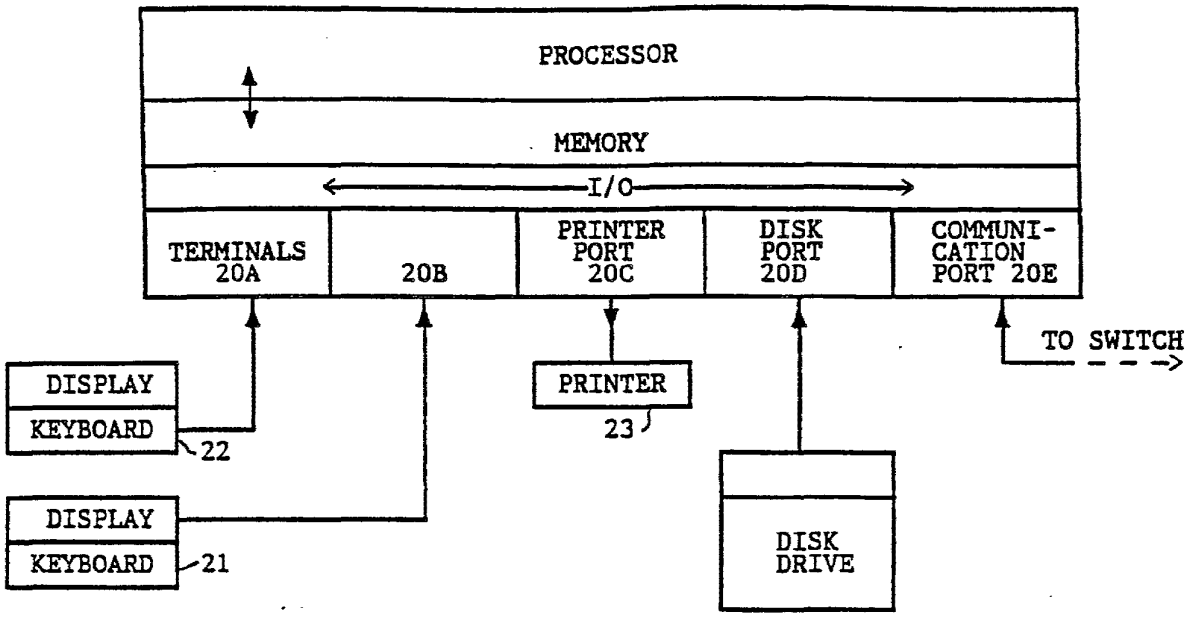
PROCESSOR
MEMORY
I/O
TERMINALS 20A
20B
PRINTER PORT 20C
DISK PORT 20D
COMMUNI-CATION PORT 20E
TO SWITCH
DISPLAY
KEYBOARD
22
PRINTER
23
DISPLAY
KEYBOARD
21
DISK DRIVE

FIG. 2

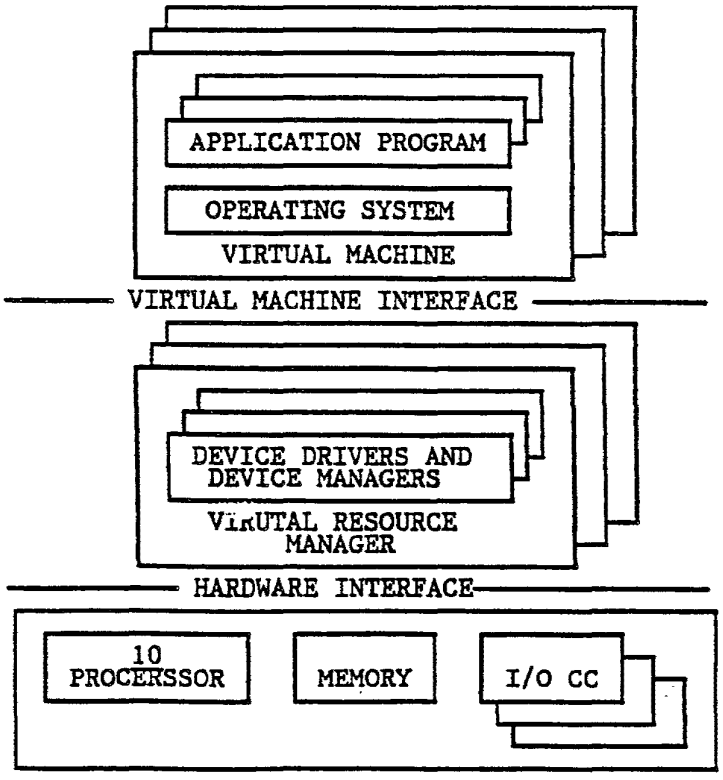
APPLICATION PROGRAM
OPERATING SYSTEM
VIRTUAL MACHINE
VIRTUAL MACHINE INTERFACE
DEVICE DRIVERS AND DEVICE MANAGERS
VIRUTAL RESOURCE MANAGER
HARDWARE INTERFACE
10 PROCERSSOR
MEMORY
I/O CC

FIG. 3

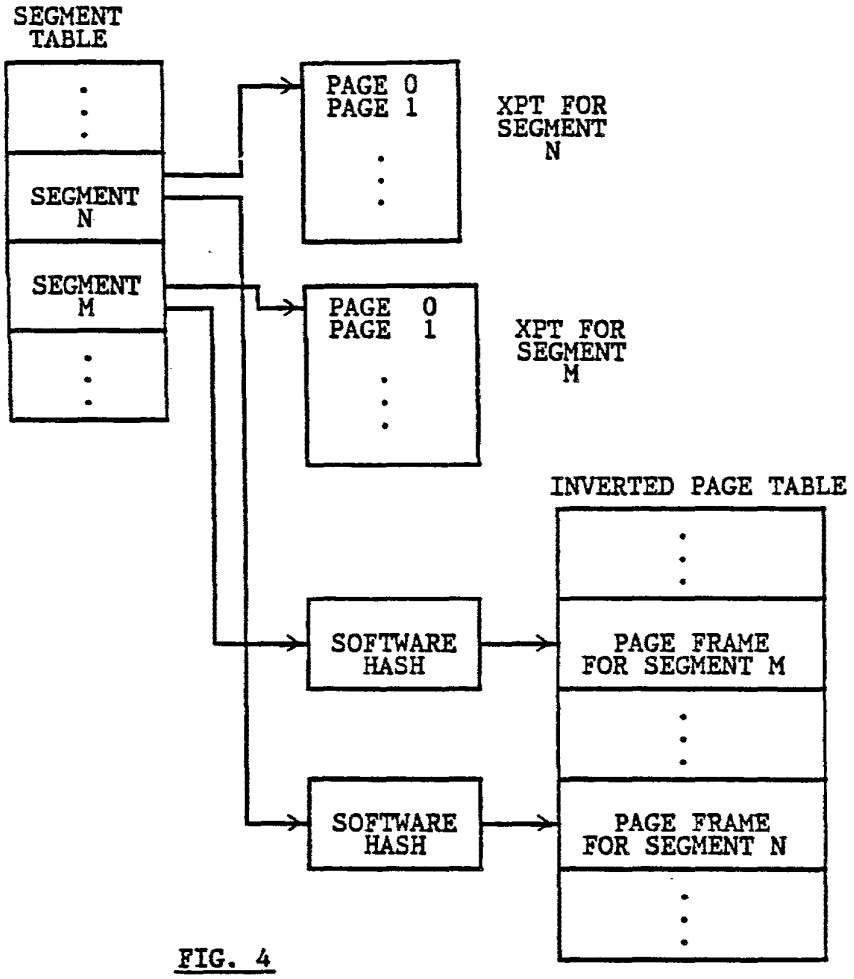
SEGMENT TABLE
SEGMENT N
SEGMENT M
PAGE 0
PAGE 1
XPT FOR SEGMENT N
PAGE 0
PAGE 1
XPT FOR SEGMENT M
INVERTED PAGE TABLE
SOFTWARE HASH
SOFTWARE HASH
PAGE FRAME FOR SEGMENT M
PAGE FRAME FOR SEGMENT N

FIG. 4

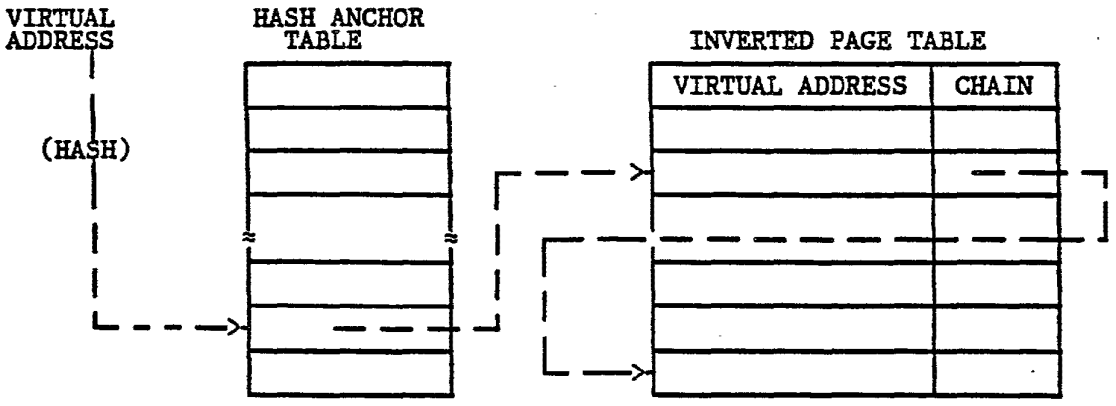
VIRTUAL ADDRESS
(HASH)
HASH ANCHOR TABLE
INVERTED PAGE TABLE
VIRTUAL ADDRESS
CHAIN

FIG. 5

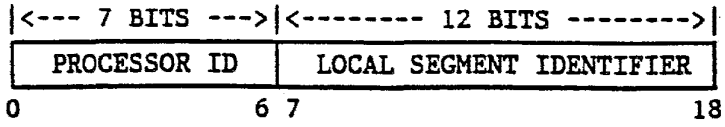

FIG. 6

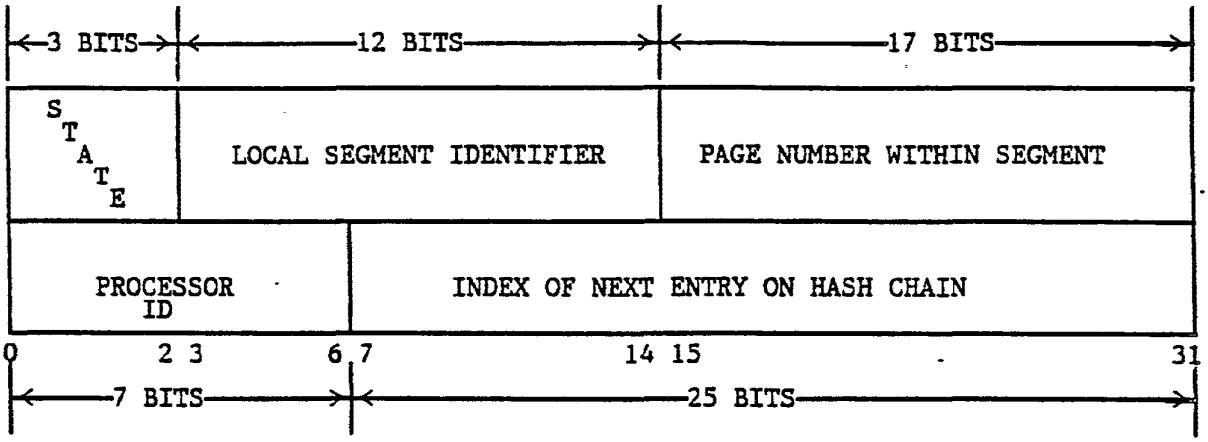

FIG. 7

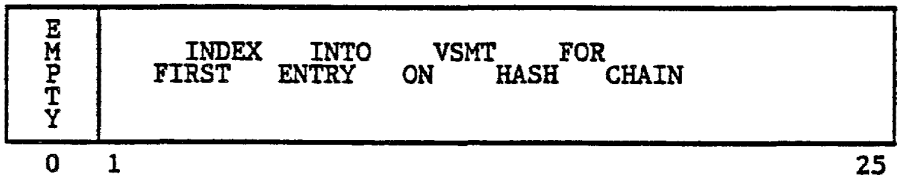

FIG. 8

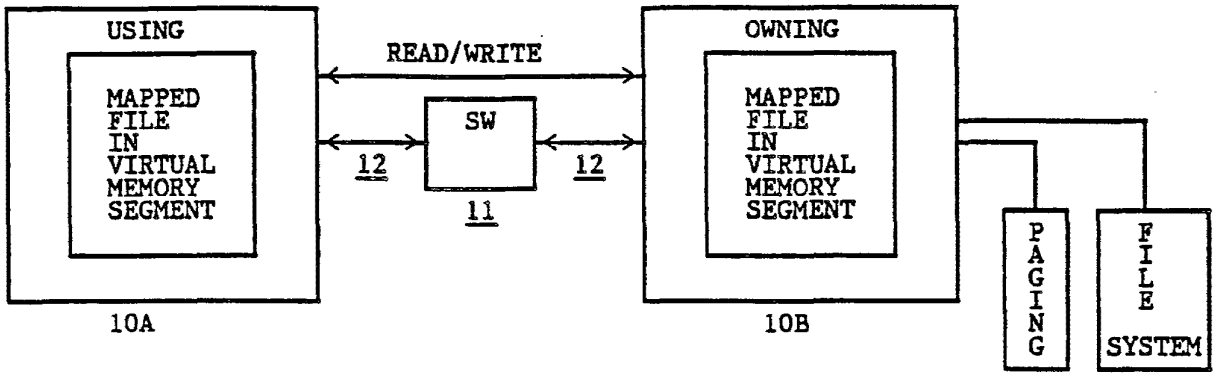
USING
MAPPED FILE IN VIRTUAL MEMORY SEGMENT
10A
READ/WRITE
SW
12
12
11
OWNING
MAPPED FILE IN VIRTUAL MEMORY SEGMENT
10B
PAGING
FILE SYSTEM

FIG. 9

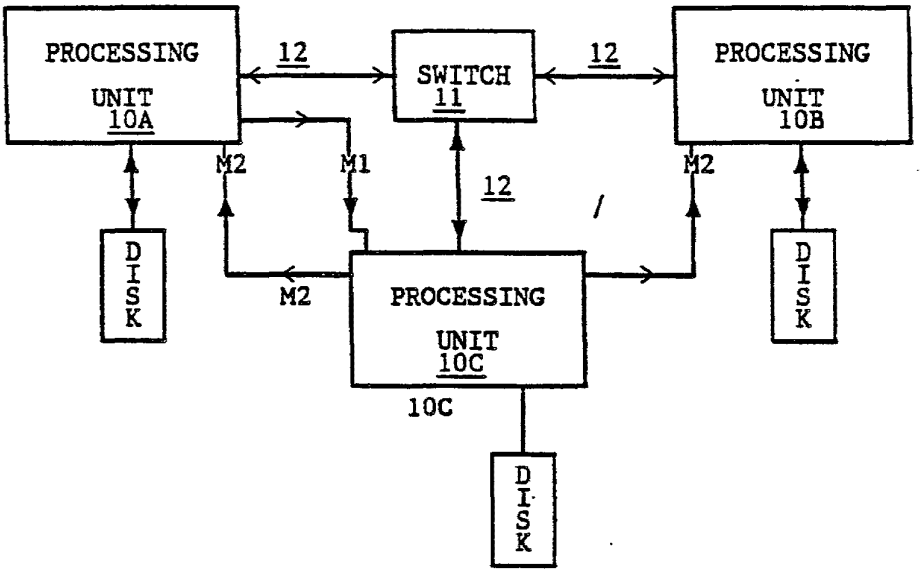
PROCESSING UNIT 10A
12
SWITCH 11
12
PROCESSING UNIT 10B
M2
M1
12
M2
DISK
M2
PROCESSING UNIT 10C
DISK
10C
DISK

FIG. 10

USER TO CREATE AND OPEN A FILE NAMED /U/SMORGAN/DATABASE ON UNIT 10A

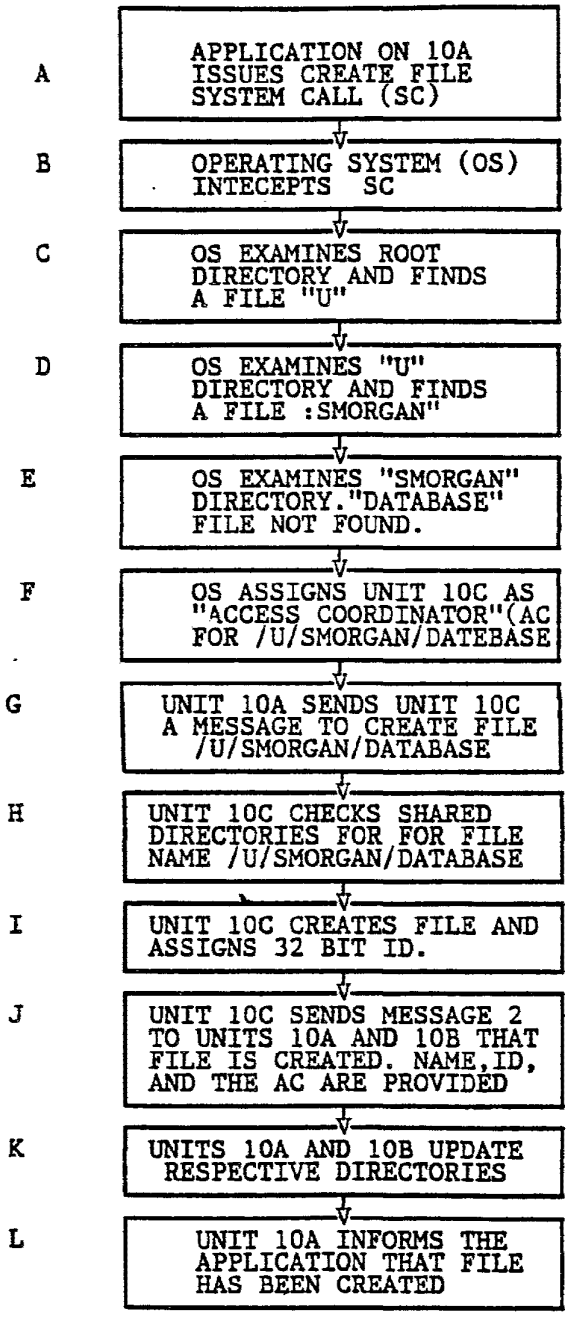

FIG. 11

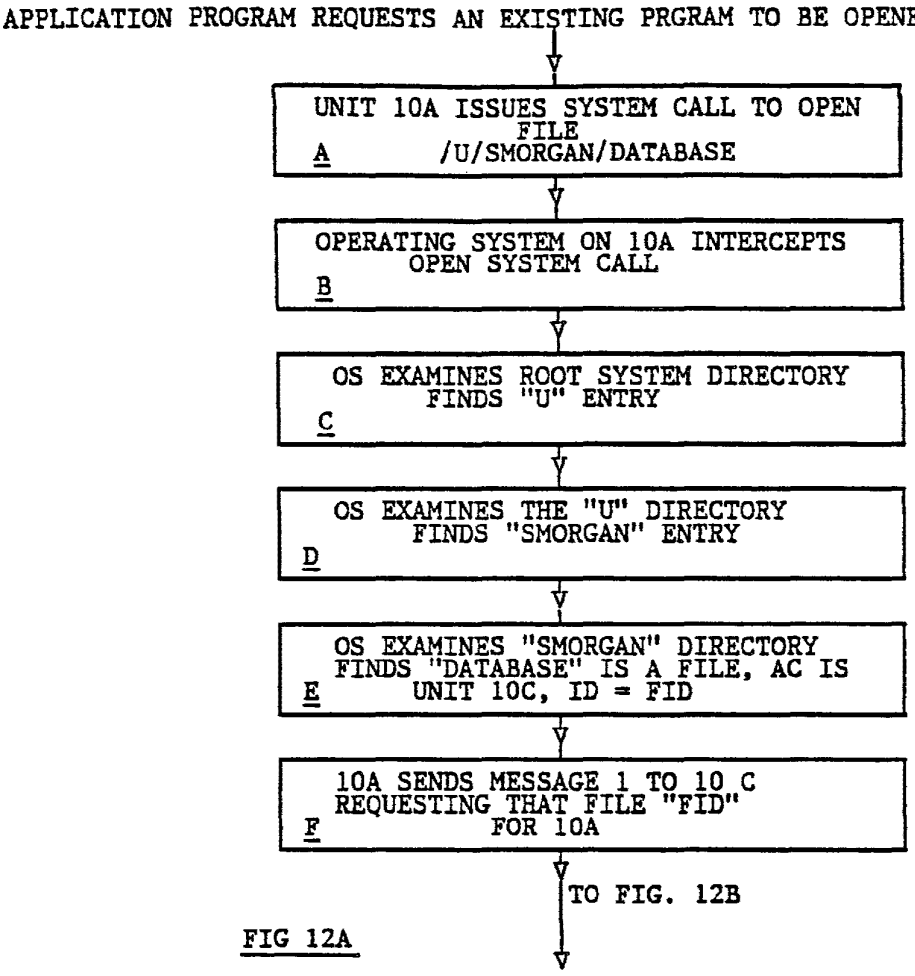
APPLICATION PROGRAM REQUESTS AN EXISTING PRGRAM TO BE OPENED
UNIT 10A ISSUES SYSTEM CALL TO OPEN FILE
A /U/SMORGAN/DATABASE
OPERATING SYSTEM ON 10A INTERCEPTS OPEN SYSTEM CALL
B
OS EXAMINES ROOT SYSTEM DIRECTORY FINDS "U" ENTRY
C
OS EXAMINES THE "U" DIRECTORY FINDS "SMORGAN" ENTRY
D
OS EXAMINES "SMORGAN" DIRECTORY FINDS "DATABASE" IS A FILE, AC IS
E UNIT 10C, ID = FID
10A SENDS MESSAGE 1 TO 10 C REQUESTING THAT FILE "FID"
F FOR 10A
TO FIG. 12B

FIG 12A

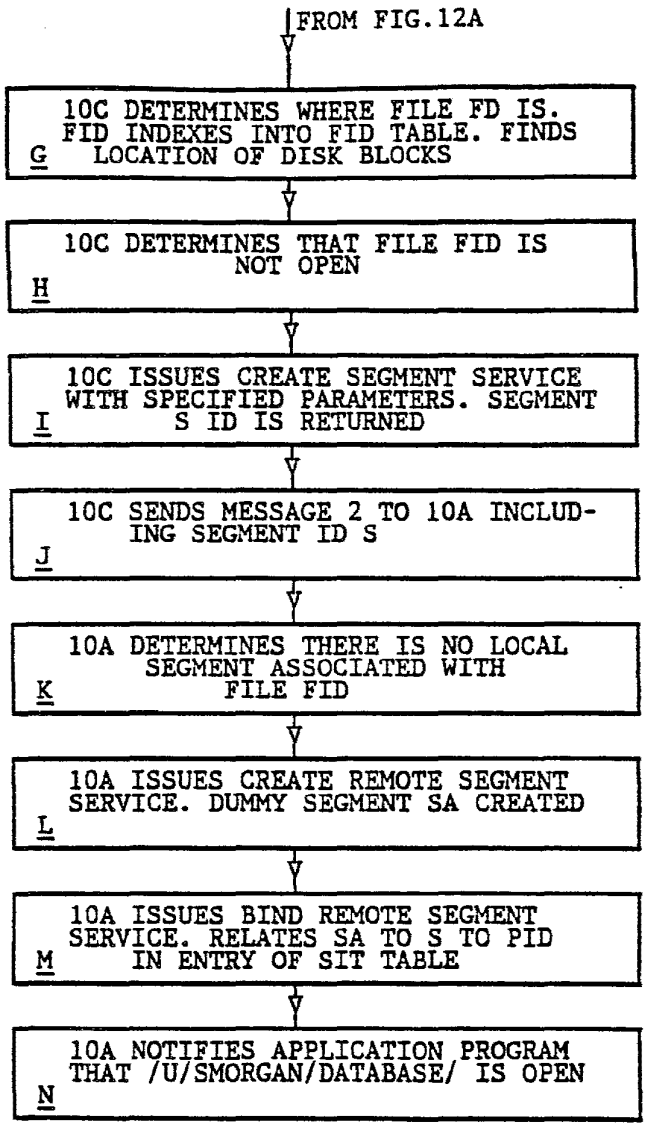
FROM FIG.12A
10C DETERMINES WHERE FILE FD IS. FID INDEXES INTO FID TABLE. FINDS LOCATION OF DISK BLOCKS
G
10C DETERMINES THAT FILE FID IS NOT OPEN
H
10C ISSUES CREATE SEGMENT SERVICE WITH SPECIFIED PARAMETERS. SEGMENT S ID IS RETURNED
I
10C SENDS MESSAGE 2 TO 10A INCLUDING SEGMENT ID S
J
10A DETERMINES THERE IS NO LOCAL SEGMENT ASSOCIATED WITH FILE FID
K
10A ISSUES CREATE REMOTE SEGMENT SERVICE. DUMMY SEGMENT SA CREATED
L
10A ISSUES BIND REMOTE SEGMENT SERVICE. RELATES SA TO S TO PID IN ENTRY OF SIT TABLE
M
10A NOTIFIES APPLICATION PROGRAM THAT /U/SMORGAN/DATABASE/ IS OPEN
N

FIG. 12B

APPLICATION PROGRAM EXECUTING ON 10 ISSUES SCHMAT CALL TO MAP SA

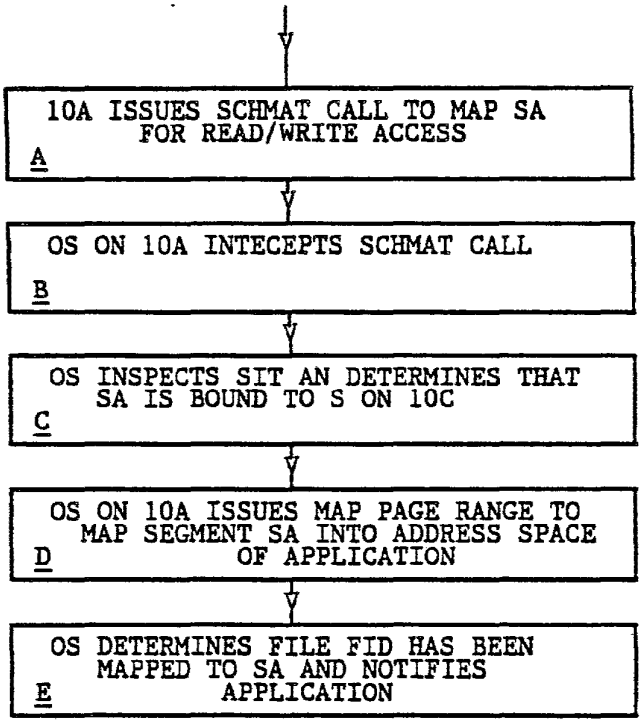

FIG. 13

APPLICATION PROGRAM EXECUTING ON 10A REQUEST PAGE P OF SEGMENT SL FOR FILE F

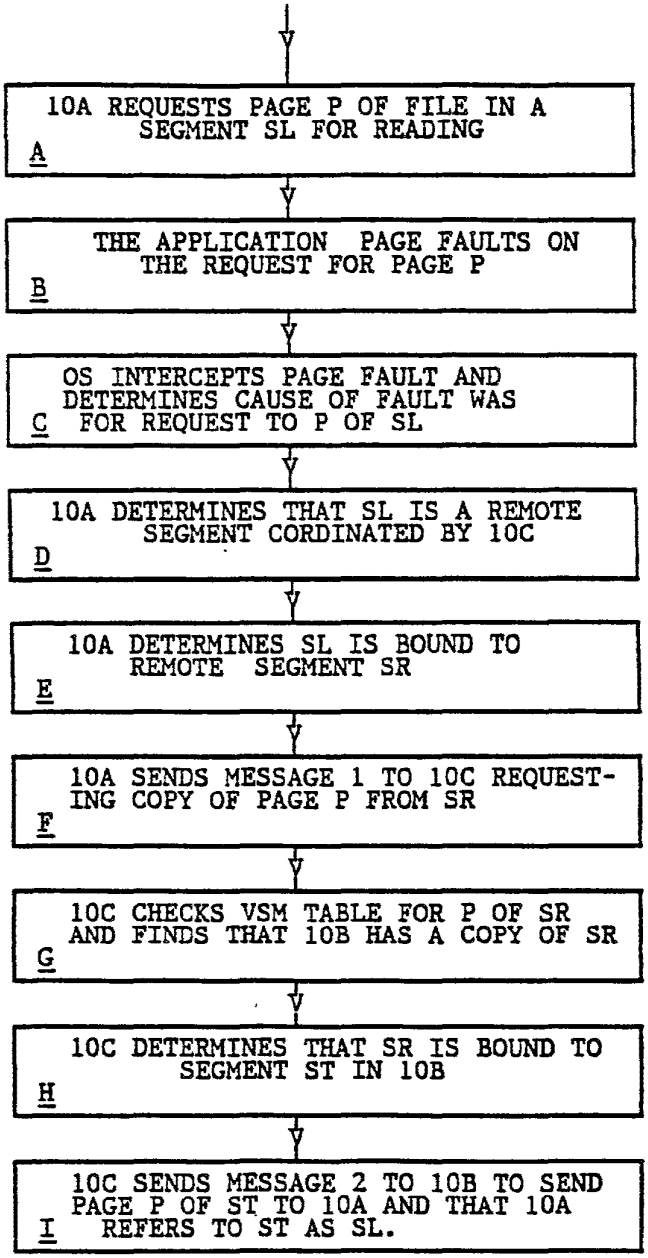

FIG. 14

UPDATE OF VSMT BY UNIT 10C AFTER 10B SENDS COPY TO 10A IN RESPONE TO APPLICATION PROGRAM EXECUTING ON 10A REQUESTING PAGE P OF SEGMENT SL FOR FILE F

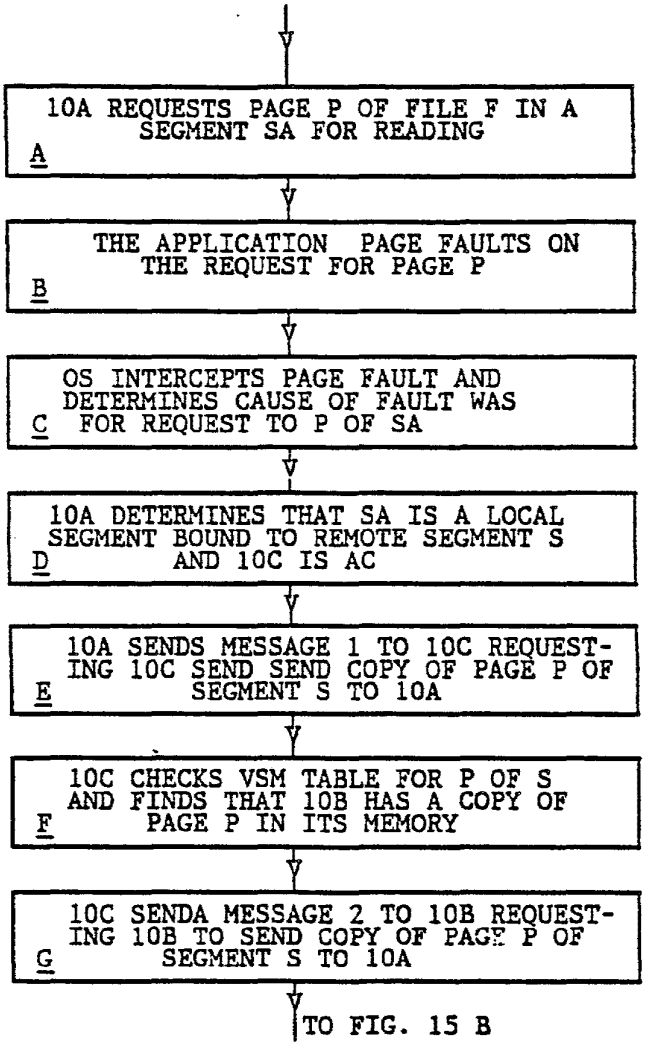

FIG. 15A

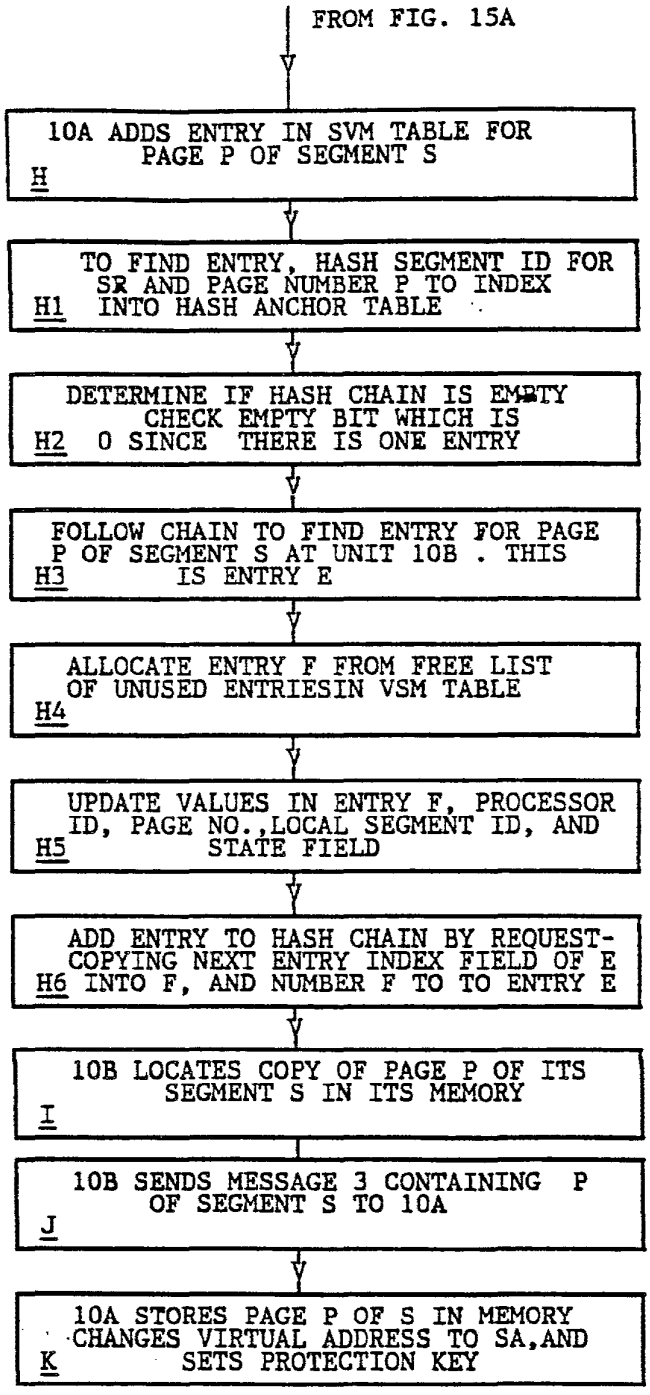
FROM FIG. 15A
10A ADDS ENTRY IN SVM TABLE FOR PAGE P OF SEGMENT S
H
TO FIND ENTRY, HASH SEGMENT ID FOR SR AND PAGE NUMBER P TO INDEX
H1 INTO HASH ANCHOR TABLE
DETERMINE IF HASH CHAIN IS EMPTY CHECK EMPTY BIT WHICH IS
H2 0 SINCE THERE IS ONE ENTRY
FOLLOW CHAIN TO FIND ENTRY FOR PAGE P OF SEGMENT S AT UNIT 10B . THIS
H3 IS ENTRY E
ALLOCATE ENTRY F FROM FREE LIST OF UNUSED ENTRIESIN VSM TABLE
H4
UPDATE VALUES IN ENTRY F, PROCESSOR ID, PAGE NO.,LOCAL SEGMENT ID, AND
H5 STATE FIELD
ADD ENTRY TO HASH CHAIN BY REQUEST-COPYING NEXT ENTRY INDEX FIELD OF E
H6 INTO F, AND NUMBER F TO TO ENTRY E
10B LOCATES COPY OF PAGE P OF ITS SEGMENT S IN ITS MEMORY
I
10B SENDS MESSAGE 3 CONTAINING P OF SEGMENT S TO 10A
J
10A STORES PAGE P OF S IN MEMORY CHANGES VIRTUAL ADDRESS TO SA,AND
K SETS PROTECTION KEY

FIG. 15B

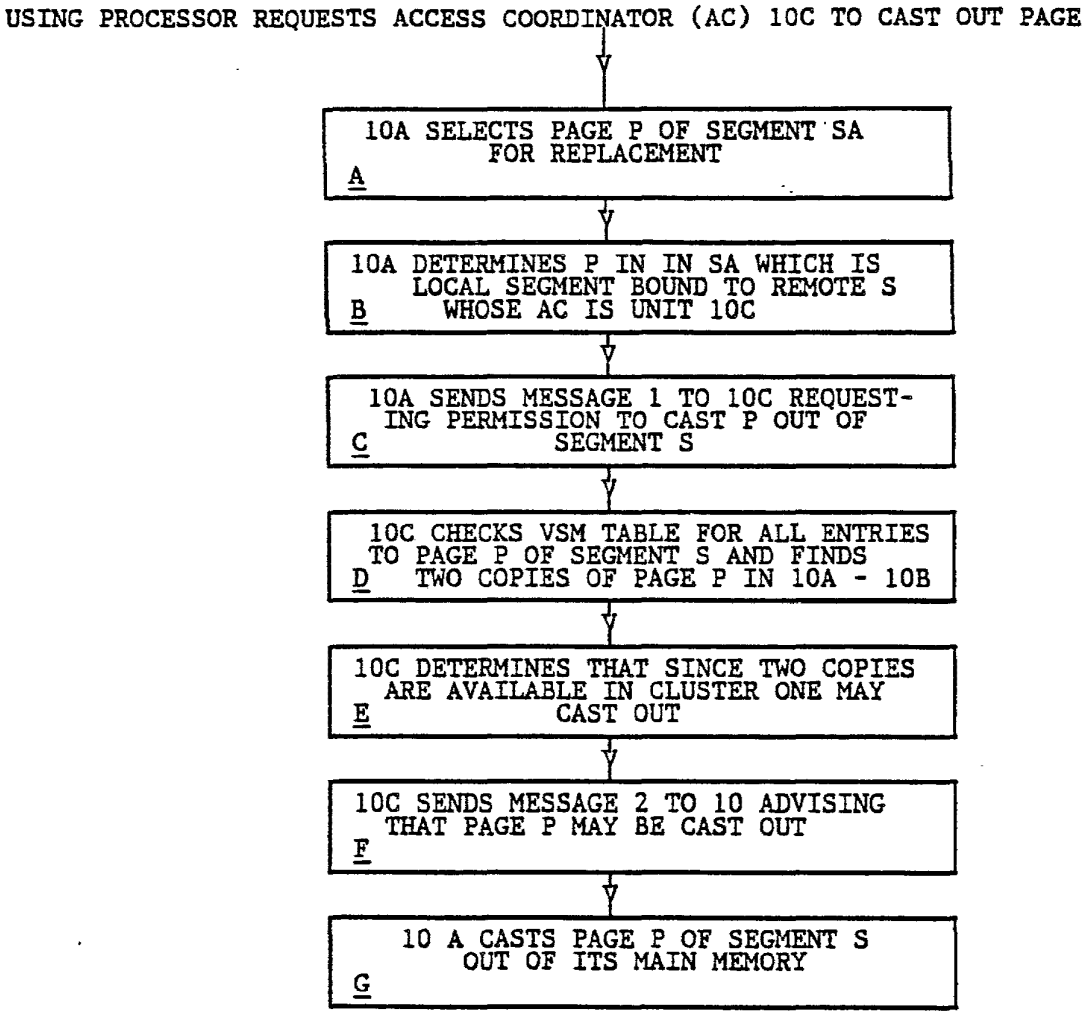
USING PROCESSOR REQUESTS ACCESS COORDINATOR (AC) 10C TO CAST OUT PAGE
10A SELECTS PAGE P OF SEGMENT SA FOR REPLACEMENT
A
10A DETERMINES P IN IN SA WHICH IS LOCAL SEGMENT BOUND TO REMOTE S WHOSE AC IS UNIT 10C
B
10A SENDS MESSAGE 1 TO 10C REQUESTING PERMISSION TO CAST P OUT OF SEGMENT S
C
10C CHECKS VSM TABLE FOR ALL ENTRIES TO PAGE P OF SEGMENT S AND FINDS TWO COPIES OF PAGE P IN 10A - 10B
D
10C DETERMINES THAT SINCE TWO COPIES ARE AVAILABLE IN CLUSTER ONE MAY CAST OUT
E
10C SENDS MESSAGE 2 TO 10 ADVISING THAT PAGE P MAY BE CAST OUT
F
10 A CASTS PAGE P OF SEGMENT S OUT OF ITS MAIN MEMORY
G

FIG. 16

USING PROCESSOR REQUESTS ACCESS COORDINATOR (AC) 10C TO CAST OUT PAGE WHICH IS NOT IN MEMORYwhich is not in memory

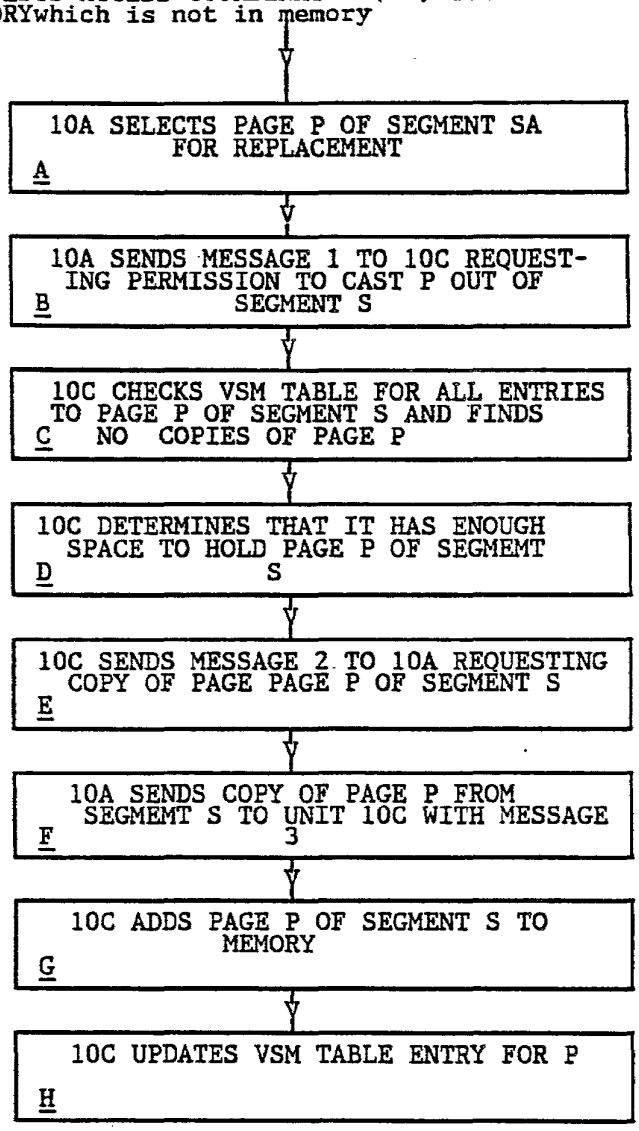

FIG. 17

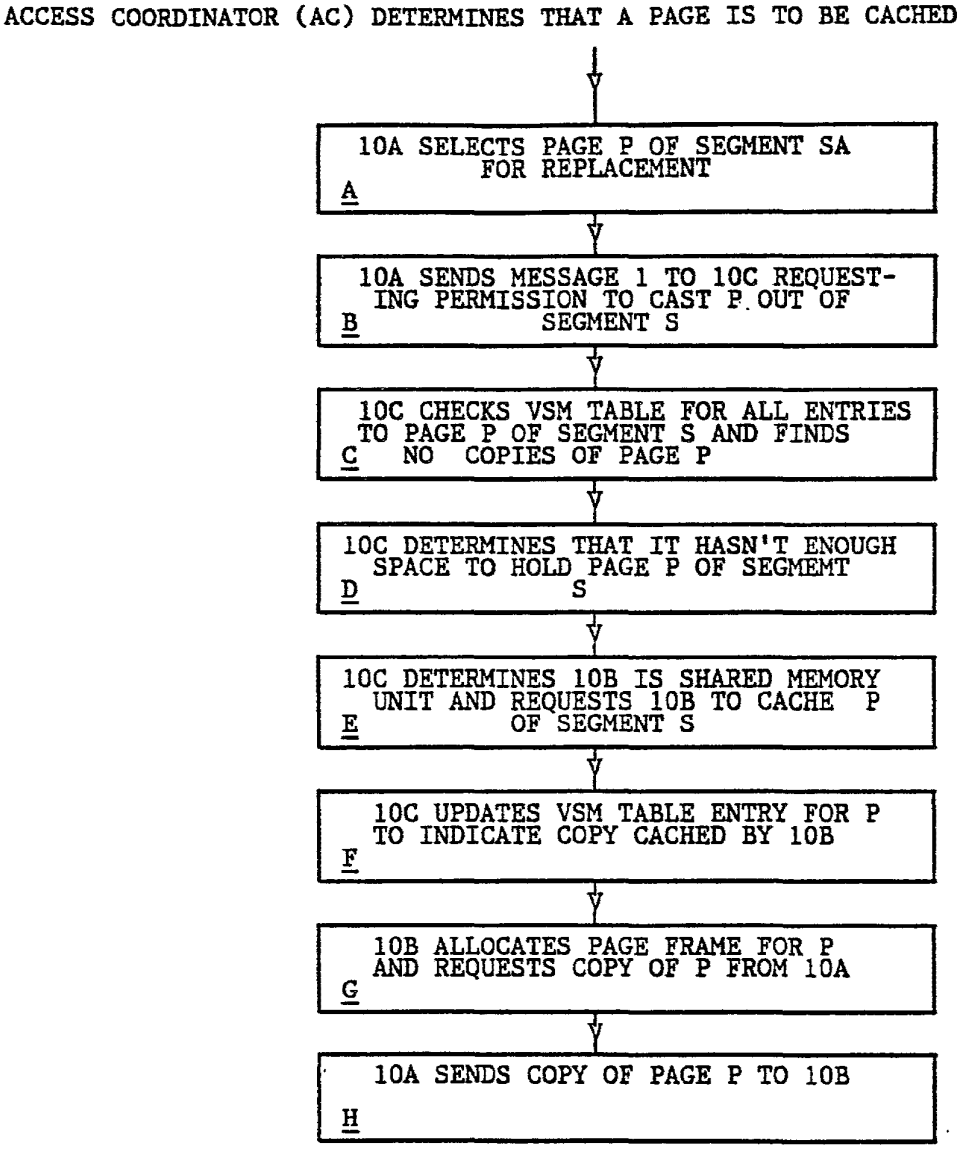
ACCESS COORDINATOR (AC) DETERMINES THAT A PAGE IS TO BE CACHED
10A SELECTS PAGE P OF SEGMENT SA FOR REPLACEMENT
A
10A SENDS MESSAGE 1 TO 10C REQUESTING PERMISSION TO CAST P OUT OF SEGMENT S
B
10C CHECKS VSM TABLE FOR ALL ENTRIES TO PAGE P OF SEGMENT S AND FINDS NO COPIES OF PAGE P
C
10C DETERMINES THAT IT HASN'T ENOUGH SPACE TO HOLD PAGE P OF SEGMEMT S
D
10C DETERMINES 10B IS SHARED MEMORY UNIT AND REQUESTS 10B TO CACHE P OF SEGMENT S
E
10C UPDATES VSM TABLE ENTRY FOR P TO INDICATE COPY CACHED BY 10B
F
10B ALLOCATES PAGE FRAME FOR P AND REQUESTS COPY OF P FROM 10A
G
10A SENDS COPY OF PAGE P TO 10B
H

FIG. 18

Electronic Acknowledgement Receipt

EFS ID:	17957176
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	21-JAN-2014
Filing Date:	16-JUN-2010
Time Stamp:	10:57:14
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_2_SIDS_14th.pdf	612251 d874e1d8e8fb40eb1e72e7bd21eac69499bade2d	no	4

Warnings:	
Information:	

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2	Foreign Reference	EP0319148A2.pdf	1861514 2b5a8d6b4a960dec602b31d868ba8c2bb2e1bac8	no	32

Warnings:

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Total Files Size (in bytes):	2473765

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/808,467	Group Art Unit:	3735
Filed:	June 16, 2010	Examiner:	FOLEY, Eileen Dorothy
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Dear Sir:

In response to the Office Action mailed October 2, 2013, the period of response for which runs through January 2, 2014, reconsideration of the application is respectfully requested in view of the following remarks.

Remarks begin on page 2 of this paper.

REMARKS

These Remarks are responsive to the Office Action dated October 2, 2013. Claims 1–7 and 36–50 remain pending, with claims 6, 7, 36, 49, and 50 withdrawn from consideration. Reconsideration of the application is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

In the Office Action, claims 1 and 43 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over deKemp et al. (US Publication No. 2007/0213848, hereinafter "the deKemp '848 reference") in view of Fago (US Publication No. 2008/0237502). In addition, claims 2–5, 37–42, and 44–48 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over the deKemp '848 reference in view of Fago and in further view of additional cited references.

Applicant respectfully traverses the rejections. The applied references fail to disclose or suggest the features defined by the claims, and there would have been no apparent reason for modification to arrive at the claim features.

The applied references fail to disclose or suggest all the features of the claims including, for example, independent claim 1. Independent claim 1 is directed to a system that generates and infuses radiopharmaceuticals. The system includes, among other features, an eluant reservoir, a pump, an infusion tubing circuit, a radioisotope generator, and a computer. The claim specifies that the computer is programmed to execute a method that includes activating the pump to pump a volume of eluant in order to generate eluate via elution and providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator. The claim also specifies that the computer is programmed to execute a method that includes providing an indication, via the computer interface, of a time lapse since each elution was completed.

In support of the rejection of independent claim 1, the Office Action cited paragraphs [0025] through [0032] of the deKemp '848 reference as allegedly disclosing a system that includes an eluant reservoir, a pump, an infusion tubing circuit, a radioisotope generator, a computer, and a user interface.[1] Although the Office Action conceded that the deKemp '848 reference does not disclose "the use of a computer to control the modes of operation of the

[1] Office Action dated October 2, 2013, at page 3–4.

system, providing an indication that the elution is complete, or providing an indication of a time lapse," the Office Action cited Fago in an attempt to overcome these deficiencies.[2] In particular, the Office Action cited paragraph [0034] of Fago as teaching that the volume and/or time associated with each elution process may be tracked and displayed to enable a user to estimate when the generator will be ready for another elution process.[3] On this basis, the Office Action alleged that the features of independent claim 1 would have been obvious. Applicant respectfully disagrees.

Even if the system disclosed in the deKemp '848 reference were modified in view of Fago, the resulting combination would not yield all the features required by independent claim 1. For example, the resulting combination would not provide a system that includes a computer pre-programmed to execute a method that includes: (1) "providing an indication, via the computer interface, that each elution is completed, when the pump has completed pumping each volume of eluant through the generator," and (2) "providing an indication, via the computer interface, of a time lapse since each elution was completed." These features are required by independent claim 1.

In the rejection of independent claim 1, the Office Action cited Fago as allegedly disclosing the claim features noted above. However, the cited embodiment of Fago does not even have a pump, much less disclose a computer programmed to execute a method that includes providing an indication that an elution is completed, when the pump has completed pumping, as per independent claim 1. The further requirement in claim 1 of providing an indication of a time lapse since each elution was completed, where each elution is completed when the pump has completed pumping, is necessarily also not disclosed by Fago.

Fago is directed to a system for identifying an amount or flow of eluant in an elution system.[4] According to Fago, a problem with radioactive shielding containers is that the containers tend to block visualization of the state and progress of an elution process.[5] With respect to cited FIGS. 6 and 7 of Fago, the reference proposes to overcome this problem by configuring an elution supply container with a drip chamber that can be used to visually and/or

[2] *Id.* at page 4.
[3] *Id.* at page 4.
[4] Fago at paragraph [0001].
[5] *Id.* at paragraph [0004].

electronically measure the number of drops of eluant passing through the drip chamber.[6] An example of this system is shown in FIG. 7 of the reference, which is reproduced below.

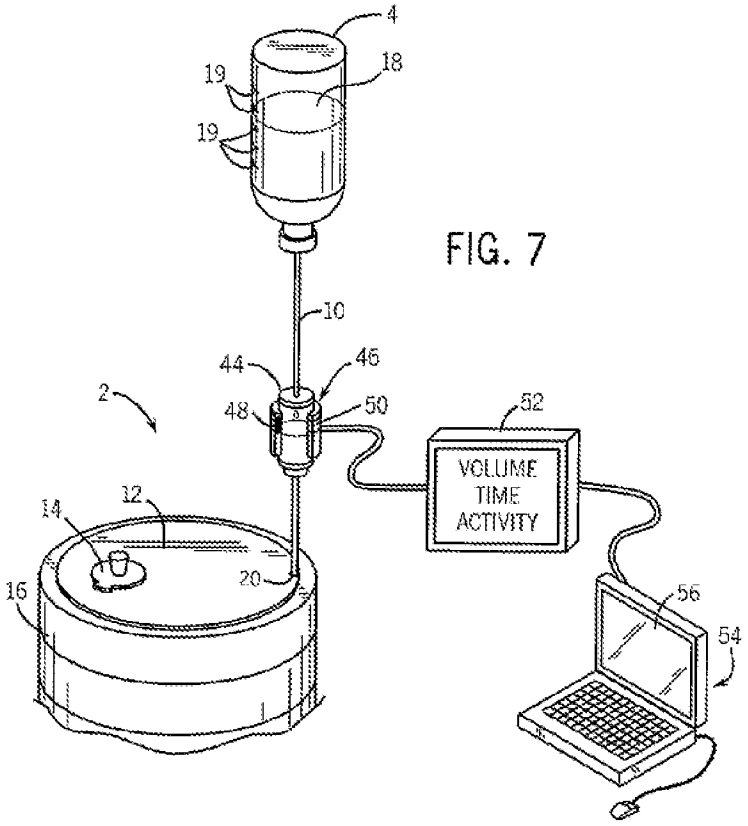

FIG. 7

In connection with the figure above, Fago describes a system having a drip chamber 44, an electronic drip counter 46, and a display 52.[7] In operation, Fago states that display 52 can display metrics relating to the elution process.[8] Yet Fago provides no indication that the system of FIG. 7 above has a pump. To the contrary, Fago describes that the system above does not utilize a pump but instead relies on a pressure differential between an eluate collection bottle and the eluate supply container 4.

Fago describes the operation of the systems in cited FIGS. 6 and 7 in connection with FIG. 4 of the reference, which is the same system except that it does not have drip chamber 44. According to Fago, the system utilizes an eluate collection bottle that "begin[s] in an evacuated condition."[9] The reference continues to describe that the evacuated collection bottle causes "eluate residing in the generator 22 to begin filling the bottle," which correspondingly causes

[6] *See id.* at paragraphs [0032]–[0033].
[7] *Id.* at paragraphs [0033]–[0034].
[8] *Id.* at paragraph [0034].
[9] *Id.* at paragraph [0031].

eluate from the eluate supply container 4 to "begin flowing into the generator 22."[10] In other words, the system in cited FIGS. 6 and 7 of Fago does not have a pump but instead utilizes a pressure differential to drive eluant flow.

Because the Fago system does not have a pump, Fago does not and cannot disclose a computer programmed to execute a method that includes providing an indication that an elution is completed, when a pump has completed pumping. Since the Office Action acknowledged that the deKemp '848 reference also does not disclose this feature, the proposed modification of the deKemp '848 reference in view of Fago does not disclose or suggest this feature of independent claim 1.

Moreover, a person of ordinary skill in the art would have consciously avoided modifying the eluant counting system of Fago to utilize an eluant pump because the Fago system requires a pumpless configuration. In the system of cited FIG. 7 of Fago, the reference tracks eluant by providing a drip counter and a motion detector that detects a number of eluant drops passing through the drip counter.[11] If the system were modified to include an eluant pump, the system would no longer provide a slow stream of drips that can be counted and tracked but instead would have a pressurized stream of eluant discharging from the pump. This would undermine a fundamental principle by which the Fago system operates and, as a result, the person of ordinary skill in the art would not have found it obvious to make such a modification.

In addition to the features discussed above, the deKemp '848 reference in view of Fago also fails to disclose or suggest a computer pre-programmed to execute a method that includes "providing an indication, via the computer interface, of a time lapse since each elution was completed," as further recited by independent claim 1. The Office Action conceded that the deKemp '848 reference does not disclose this feature of independent claim 1 but again cited Fago. Applicant respectfully disagrees for several reasons set forth below.

First, as discussed in greater detail above, the cited Fago system does not have a pump and cannot therefore provide any indication related to completion of an elution, where each elution is completed when the pump has completed pumping, as per independent claim 1. Second, independent claim 1 recites an indication of a time lapse since each elution was completed. On the other hand, as recognized by the Examiner, the cited portion of Fago only

[10] *See id.*
[11] *See id.* at paragraph [0033].

states that the "volume and/or time associated with each elution process may be tracked and displayed to enable a user (or the computer 54) to estimate when the generator will likely be ready for another elution process."[12] This statement in Fago says nothing about a time lapse since an elution was completed. Rather, the statement indicates that the Fago system tracks volume and/or time while an elution is occurring, not since an elution was completed, as per independent claim 1.

This interpretation of Fago is reinforced by the sentences in cited paragraph [0034] of the references immediately preceding the sentence stating that "volume and/or time associated with each elution process may be tracked." These preceding sentences indicate that the volume that can be tracked is "a volume associated with the number of drops counted" and the time that can be tracked is "[a] time associated with each counted drop."[13] In other words, Fago describes tracking volume and/or time associated with a flow of eluant during an elution process.

In short, there is no disclosure or suggestion in the cited portions of Fago about providing an indication, via a computer interface, of a time lapse since each elution was completed. As the Office Action conceded that the deKemp '848 reference does not disclose this feature of independent claim 1, and as Fago also fails to disclose the claim feature for the reasons outlined above, the combination of the deKemp '848 reference and Fago likewise fails to disclose the claim feature.

For at least the reasons given above, the deKemp '848 reference in view of Fago does not disclose or suggest each and every feature recited by independent claim 1. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 2–5 and 37–48 depend from independent claim 1 and are therefore patentable for at least the reasons given above with respect to the independent claim, as well as upon additional patentable features and elements claimed in the dependent claims but not explicitly discussed herein.

[12] *Id.* at paragraph [0034].
[13] *Id.*

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the fundamental differences identified above, Applicant reserves further comment concerning the additional features set forth in the claims. However, Applicant does not acquiesce in the propriety of the Office Action's application or interpretation of the references with respect to the claims, and reserves the right to present additional arguments in any further prosecution of this application.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: January 2, 2014

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

7480524_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	17794310
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	02-JAN-2014
Filing Date:	16-JUN-2010
Time Stamp:	10:48:18
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	56782_1_7_2_Response.pdf	144048 4fa199a34b0540e863f4f5f76fc1be3d9584a7c6	no	7

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-11-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	17347453
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	08-NOV-2013
Filing Date:	16-JUN-2010
Time Stamp:	16:50:23
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	SU244513.pdf	2157166 f62d49979524a24124705481b773215be480dc74	no	4

Warnings:	
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2	Foreign Reference	RU2288755.pdf	950606 daca9f67a92011c4b3fa8e15f576bf5c63b3cc21	no	2
Warnings:					
Information:					
3	Foreign Reference	RU2131273.pdf	9345294 604ecbd0e6baca1572a1b17ddda29cf4d5319a87	no	40
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	12th-SIDS_56782-1-7-2.pdf	612288 2bd0c23de0e949111fac89c13bedfc9a14ee174a	no	4
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5	Information Disclosure Statement (IDS) Form (SB08)	13th-SIDS_56782-1-7-2.pdf	612169 488efec8acc37ad6278a73e9efeafd4097f9f6e8	no	4
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		Total Files Size (in bytes):	13677523		

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New Applications Under 35 U.S.C. 111

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New International Application Filed with the USPTO as a Receiving Office

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1

SU244513A1 1969-12-31 **DEVICE of [dl] INTRODUCTIONS OF RADIOACTIVE APPLICATORS AND TRANSPORTATION OF THE [GINEKOLOGICHESKIKHBOLNYKH]** (en)

Bibliographic Data

Original Assignees: TSentralnoe konstruktorsko tekhnologicheskoe byuro mekhanizatsii Ministerstva meditsinskoj promyshlennosti SSSR Центральное конструкторско технологическое бюро механизации Министерства медицинской промышленности СССР

Inventors: R. D. Bogoudinov , YU. A. SHvedov Р. Д. Богоудинов , Ю. А. Шведов

Application Number: SU1192681

Classifications:
IPC[6]: A61M 36/00 A

Patent References Cited-Forward:

	Publication Number	Publication Date	Title	Applicant/Assignee
	RU2163100C1	2001-02-20	METHOD FOR APPLYING COMBINED TREATMENT OF ONCOLOGICAL DISEASES OF SMALL PELVIS ORGANS	Grobel' Oleg Vjacheslavovich

Description

English Description:

In essence of [at]. SV of № 171934 is described the device of [dl] of the transport of patients before the radiological department, the containing base with the wheels, three-piece panel and manual .[privody] of [dl] of [prevrashcheni] of device either beside the bed- winder or beside the gynaecological armchair.The proposed device of [dl] of [vnedreni] of radioactive applicators and [peravoaki] of gynaecological sick [otlichaets] fact that for the purpose of [povysheni] of [bystrodeystvi] and [uluchsheni] of the conditions of the work of the service personnel, before it is established hydraulic drive with the lever systems of the transfer of device from [polozheni] "roof [at]- winder beside the position "gynaecological armchair. [Dl] - [provedeni] of control X-ray photographs, [opredel] of [yushchikh] the position of radioactive preparation before the irradiated cavity, before the device of [imeets] the nest of [dl] of the insert of cassette with the x-ray film.The schematic of the described device is depicted beyond the drawing.Device consists of [osnovani] (body) 1, mobile frame 2, hydraulic drive 3 with [nolshoy] pedal 4, locking mechanism 5, levers 6 and 7, [soedin] of [yushchikh] the mobile framewith the base according to parallelogram diagram, [samoorentiruyushchikh] wheels 8 with the mechanism of 9 [dl] of forced orientation. Is mobile frame it contains three sections 10, 11 and 12 with built-in head rest 13 and mechanism of 14 [dl] of its fixation. Before nest 15 .[mogut] [ustanavlivats] detachable gynaecological [prioposobleni] 16. nest 17 it serves [dl] of the installation of cassettes.10It

[pred].[met] isoBrettnot 1.[Ustroystvo] of [dl] of [vnedreni] of radioactive applicators and transportation of the gynaecologicalsick on the author SV 171934, [otlichayushchees] fact that, for the purpose of [povysheni] of [bystrodeystvi] and [uluchsheni] of the conditions of the work of the service personnel, before it is established hydraulic drive with the lever systems of the transfer of device from [G]1[olozheni] "Bed- winder beside [pololsenie] "gynaecological armchair.2.[Ustroystvo] on p. 1, [otlichayushchees] fact that, .[tselyu] [provedeni] of control X-ray photographs, [opredel] of [yushchikh] the position

Союз Советских Социалистических Республик

Комитет по делам изобретений и открытий при Совете Министров СССР

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

К АВТОРСКОМУ СВИДЕТЕЛЬСТВУ

244513

Зависимое от авт. свидетельства № 171934

Заявлено 25.X.1967 (№ 1192681/31-16)

с присоединением заявки № —

Приоритет —

Опубликовано 28.V.1969. Бюллетень № 18

Дата опубликования описания 10.X.1969

Кл. 21g, 21/01

МПК H 05g

УДК 615.478.32:615.849.7:616-073(088.8)

Авторы изобретения Р. Д. Богоудинов и Ю. А. Шведов

Заявитель Центральное конструкторско-технологическое бюро механизации Министерства медицинской промышленности СССР

УСТРОЙСТВО ДЛЯ ВНЕДРЕНИЯ РАДИОАКТИВНЫХ АППЛИКАТОРОВ И ПЕРЕВОЗКИ ГИНЕКОЛОГИЧЕСКИХ БОЛЬНЫХ

1

В основном авт. св. № 171934 описано устройство для транспортировки больных в радиологическом отделении, содержащее основание с колесами, трехсекционную панель и ручные приводы для превращения устройства либо в кровать-каталку, либо в гинекологическое кресло.

Предлагаемое устройство для внедрения радиоактивных аппликаторов и перевозки гинекологических больных отличается тем, что с целью повышения быстродействия и улучшения условий работы обслуживающего персонала, в нем установлен гидравлический привод с рычажными системами перевода устройства из положения «кровать-каталка» в положение «гинекологическое кресло». Для проведения контрольных рентгеновских снимков, определяющих положение радиоактивного препарата в облучаемой полости, в устройстве имеется гнездо для вставки кассеты с рентгеновской пленкой.

На чертеже изображена схема описываемого устройства.

Устройство состоит из основания (каркаса) *1*, подвижной рамы *2*, гидропривода *3* с ножной педалью *4*, стопорного механизма *5*, рычагов *6* и *7*, соединяющих подвижную раму

2

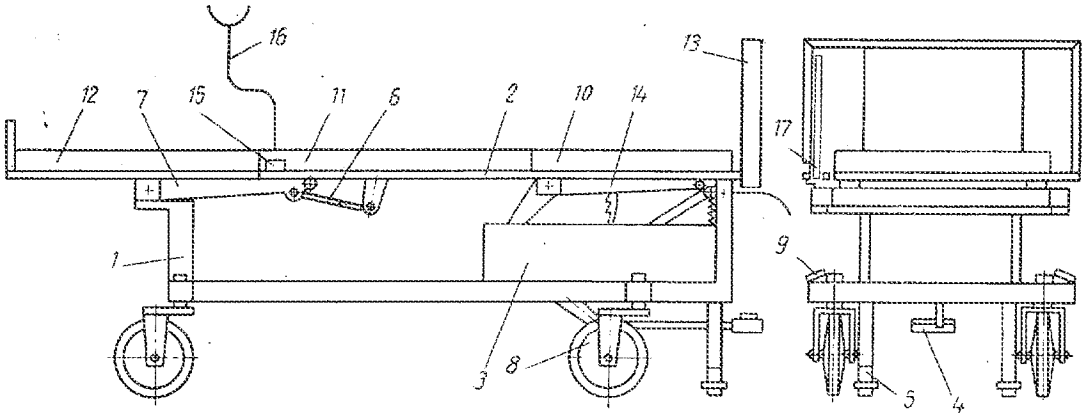
с основанием по параллелограммной схеме, самоорентирующих колес *8* с механизмом *9* для принудительной ориентации. Подвижная рама содержит три секции *10*, *11* и *12* с встроенным подголовником *13* и механизмом *14* для его фиксации. В гнезде *15* могут устанавливаться съемные гинекологические приспособления *16*.

Гнездо *17* служит для установки кассет.

Предмет изобретения

1. Устройство для внедрения радиоактивных аппликаторов и перевозки гинекологических больных по авт. св. № 171934, *отличающееся* тем, что, с целью повышения быстродействия и улучшения условий работы обслуживающего персонала, в нем установлен гидравлический привод с рычажными системами перевода устройства из положения «Кровать-каталка» в положение «гинекологическое кресло».

2. Устройство по п. 1, *отличающееся* тем, что, с целью проведения контрольных рентгеновских снимков, определяющих положение радиоактивного препарата в облучаемой полости, в нем имеется гнездо для вставки кассеты с рентгеновской пленкой.



Составитель И. Гофман

Редактор В. Сорокин Техред Л. Я. Левина Корректор Л. А. Иголкина

Заказ 2509/14 Тираж 480 Подписное
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Москва, Центр, пр. Серова, д. 4

Типография, пр. Сапунова, 2

Espacenet

Bibliographic data: RU2288755 (C1) — 2006-12-10

DEVICE FOR RADIONUCLIDE SURGERY

No documents available for this priority number.

Inventor(s): SHCHETININ VIKTOR VASIL EVICH [RU]; GULYJ VLADIMIR GRIGOR EVICH [RU]; CHERNIJ ALEKSANDR NIKOLAEVICH [RU] ± (SHCHETININ VIKTOR VASIL'EVICH, ; GULYJ VLADIMIR GRIGOR'EVICH, ; CHERNIJ ALEKSANDR NIKOLAEVICH)

Applicant(s): SHCHETININ VIKTOR VASIL EVICH [RU]; GULYJ VLADIMIR GRIGOR EVICH [RU]; CHERNIJ ALEKSANDR NIKOLAEVICH [RU] ± (SHCHETININ VIKTOR VASIL'EVICH, ; GULYJ VLADIMIR GRIGOR'EVICH, ; CHERNIJ ALEKSANDR NIKOLAEVICH)

Classification: **- international:** ***A61B18/22; A61M36/00; A61N5/10; G01T1/161***
- cooperative:

Application number: RU20050112292 20050425

Priority number(s): RU20050112292 20050425

Abstract of RU2288755 (C1)

FIELD: medical facilities. ^ SUBSTANCE: device can be used as a tool for malignant tumors surgery. Device for radionuclide surgery has gamma radiation detector, collimator and handle. Wire of detector is connected with measuring unit. Gamma radiation detector is fixed in metal tip with sharpened side edge, which passes in plane being perpendicular to optical axis of gamma radiation detector. Detector is made in form of semiconductor crystal; two collimators adjoin opposite surfaces of crystal. Collimators have cells which pass in parallel to optical axis of gamma detector. Measuring unit has electronic circuit with sonic signal source. ^ EFFECT: ability of reaching area of lesion for removing it. ^ 4 cl, 2 dwg

Last updated: 09.10.2013 Worldwide Database 5.8.11.5; 92p

РОССИЙСКАЯ ФЕДЕРАЦИЯ

(19) **RU** (11) **2 288 755** (13) **C1**

(51) МПК
A61N 5/10 (2006.01)
A61B 18/22 (2006.01)
G01T 1/161 (2006.01)
A61M 36/00 (2006.01)

ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ,
ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ

(12) ИЗВЕЩЕНИЯ К ПАТЕНТУ НА ИЗОБРЕТЕНИЕ

(21), (22) Заявка: 2005112292/14, 25.04.2005

(24) Дата начала отсчета срока действия патента:
25.04.2005

(45) Опубликовано: 10.12.2006

(56) Список документов, цитированных в отчете о поиске: FOUGERES P. et al. Sentinel node in cancer diagnosis with surgical probes. Nuclear Instruments and Methods in Physics Research, 2001, A458, p.34-40. US 6422748 A, 23.07.2002. WO 9930764 A1, 24.06.1999. RU 2112993 C1, 10.06.1998.

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Гулый Владимир Григорьевич (RU),
Черний Александр Николаевич (RU)

(54) УСТРОЙСТВО ДЛЯ РАДИОНУКЛИДНОЙ ХИРУРГИИ

Опубликовано на CD-ROM: MIMOSA RBI 2006/34D RBI200634D

MM4A - Досрочное прекращение действия патента СССР или патента Российской Федерации на изобретение из-за неуплаты в установленный срок пошлины за поддержание патента в силе

(21) Регистрационный номер заявки: 2005112292

Дата прекращения действия патента: 26.04.2007

Извещение опубликовано: 27.07.2008 БИ: 21/2008

RU 2288755 C1

RU 2288755 C1

Espacenet

Bibliographic data: RU2131273 (C1) — 1999-06-10

LIQUID DELIVERY DEVICE

No documents available for this priority number.

Inventor(s): MARSHALL S KRIESEL [US] ± (MARSHALL S.KRIESEL)

Applicant(s): SAJENS INKORPOREJTED [US] ± (SAJENS INKORPOREJTED)

Classification: **- international:** ***A61M37/00; A61M5/152;*** *A61M5/14; A61M5/142;* (IPC1-7): A61M37/00
- cooperative: **A61M5/152**; A61M2205/197; A61M5/1407; A61M5/1409; A61M5/14248

Application number: RU19950122716 19940515

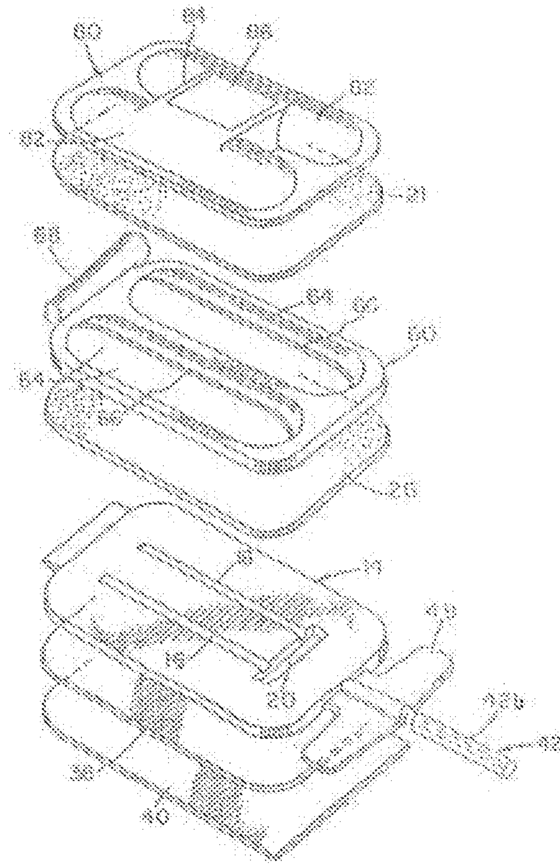
Priority number (s): WO1994US05389 19940516 ; US19930046438 19930413

Also published as: WO9426348 (A1) JPH08510658 (A) EP0700308 (A1) EP0700308 (A4) CN1126950 (A) CA2163242 (A1) BR9406808 (A) AU6949394 (A) AU697117 (B2) less

Abstract of RU2131273 (C1)

FIELD: medical engineering. SUBSTANCE: device is intended for accurate infusion of medicinal substances into ambulatory patient at definite speed within long periods of time. Device represents compact, low-profile laminated construction. It has flexible stretchable membrane which in combination with thin flat base outlines boundaries for liquid provided with outlet. This membrane permeable for liquid controls accurately rate of liquid flow through liquid outlet. It is positioned inside liquid chamber which allows convenient fixing to parts of patient's body. EFFECT: higher efficiency of infusion. 12 cl, 94 dwg

Last updated: 09.10.2013 Worldwide Database 5.8.11.5; 93p



(19) RU (11) 2 131 273 (13) C1

(51) МПК[6] A 61 M 37/00

РОССИЙСКОЕ АГЕНТСТВО
ПО ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ

(12) ОПИСАНИЕ ИЗОБРЕТЕНИЯ К ПАТЕНТУ РОССИЙСКОЙ ФЕДЕРАЦИИ

(21), (22) Заявка: 95122716/14, 15.05.1994

(30) Приоритет: 18.05.1993 US 08/046438

(46) Дата публикации: 10.06.1999

(56) Ссылки: 1. US 5154697, 13.10.92. 2. SU 1404080 A1, 23.06.88. 3. US 5176641, 05.01.93.

(85) Дата перевода заявки PCT на национальную фазу: 18.12.95

(86) Заявка PCT:
US 94/05389 (15.05.94)

(87) Публикация PCT:
WO 94/26348 (24.11.94)

(98) Адрес для переписки:
103735, Москва, ул.Ильинка 5/2 Союзпатент
Дудушкину С.В.

(71) Заявитель:
Сайенс Инкорпорейтед (US)

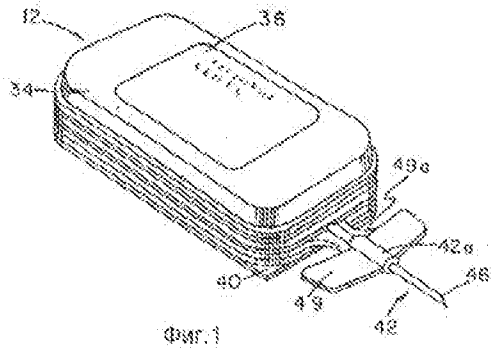
(72) Изобретатель: Маршалл С.Криесел (US)

(73) Патентообладатель:
Сайенс Инкорпорейтед (US)

(54) УСТРОЙСТВО ДОСТАВКИ ЖИДКОСТИ

(57) Реферат:

Устройство предназначено для точной инфузии лекарственных средств амбулаторно пациенту с определенными скоростями на протяжении длительных периодов времени. Устройство представляет компактную низкопрофильную слоистую конструкцию и включает эластичную растягиваемую мембрану, которая в сочетании с тонким плоским основанием очерчивает границы для жидкости, имеющей жидкостный выход. Тонкая проницаемая для жидкости мембрана, которая точно контролирует скорость течения жидкости через жидкостный выход, расположена внутри жидкостной камеры, что позволяет удобно фиксироваться к частям тела пациента и использоваться им с минимальными профессиональными знаниями. 2 с. и 10 з.п. ф-лы, 94 ил.



Фиг.1

RU 2131273 C1

RU 2131273 C1

(19) RU (11) 2 131 273 (13) C1

(51) Int. Cl.[6] A 61 M 37/00

RUSSIAN AGENCY
FOR PATENTS AND TRADEMARKS

(12) ABSTRACT OF INVENTION

(21), (22) Application: 95122716/14, 15.05.1994

(30) Priority: 18.05.1993 US 08/046438

(46) Date of publication: 10.06.1999

(85) Commencement of national phase: 18.12.95

(86) PCT application:
US 94/05389 (15.05.94)

(87) PCT publication:
WO 94/26348 (24.11.94)

(98) Mail address:
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Dudushkinu S.V.

(71) Applicant:
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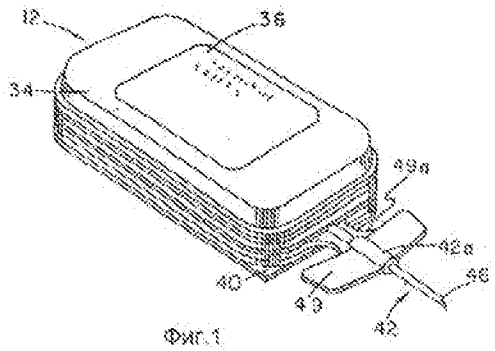
(72) Inventor: Marshall S.Kriesel (US)

(73) Proprietor:
Sajens Inkorporejted (US)

(54) LIQUID DELIVERY DEVICE

(57) Abstract:

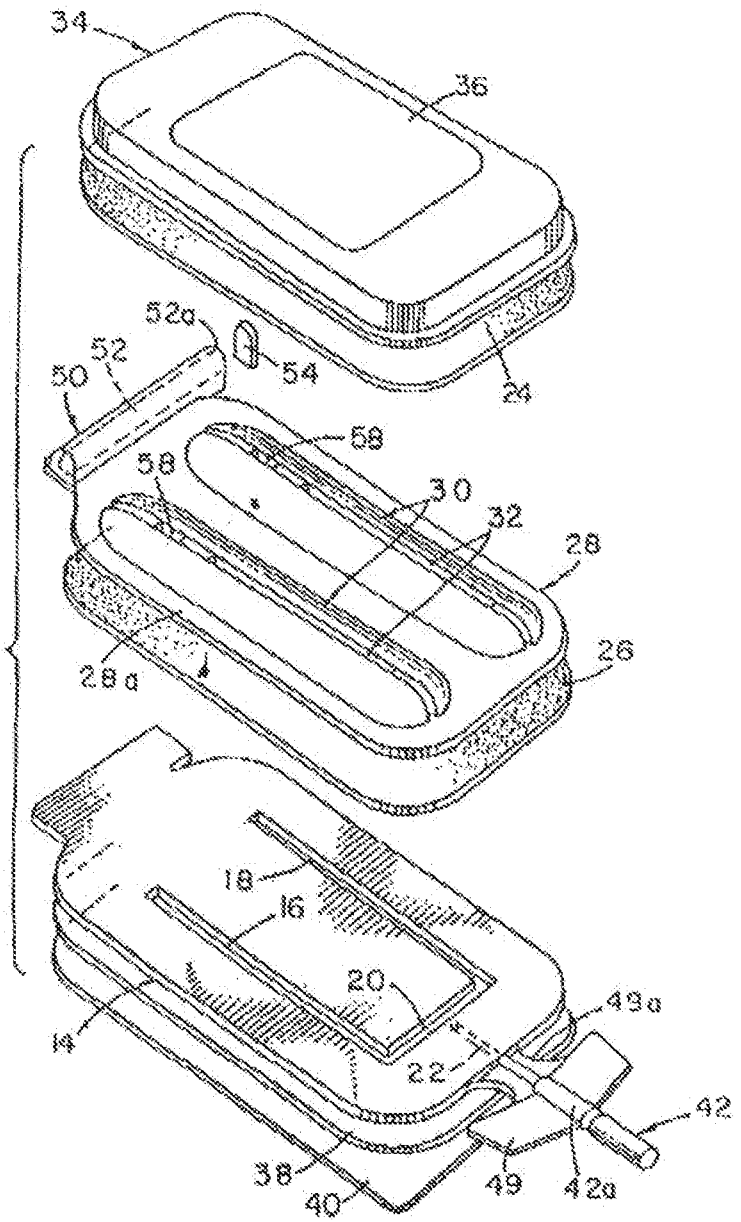
FIELD: medical engineering. SUBSTANCE: device is intended for accurate infusion of medicinal substances into ambulatory patient at definite speed within long periods of time. Device represents compact, low-profile laminated construction. It has flexible stretchable membrane which in combination with thin flat base outlines boundaries for liquid provided with outlet. This membrane permeable for liquid controls accurately rate of liquid flow through liquid outlet. It is positioned inside liquid chamber which allows convenient fixing to parts of patient's body. EFFECT: higher efficiency of infusion. 12 cl, 94 dwg



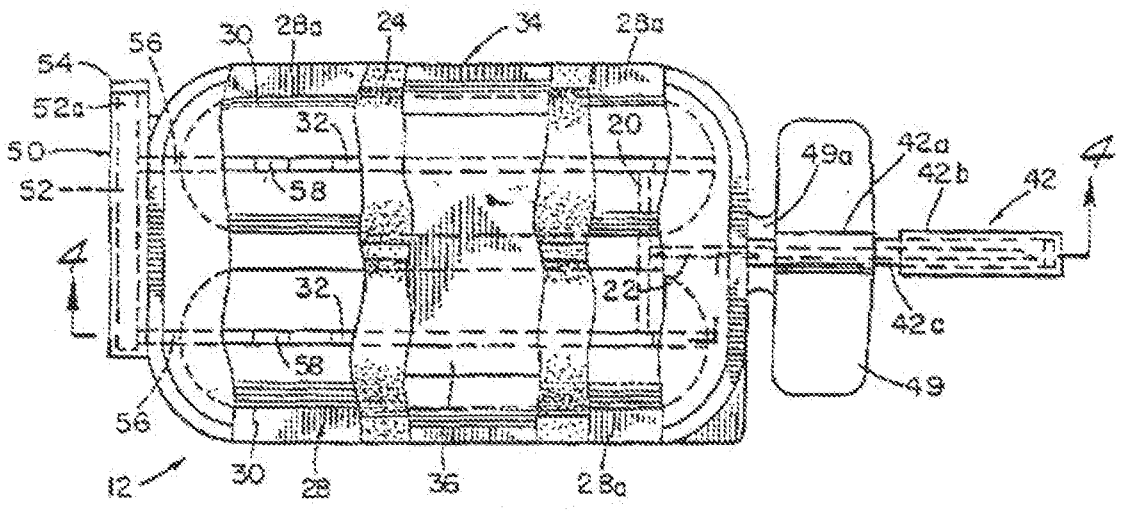
Фиг.1

RU 2131273 C1

RU 2131273 C1

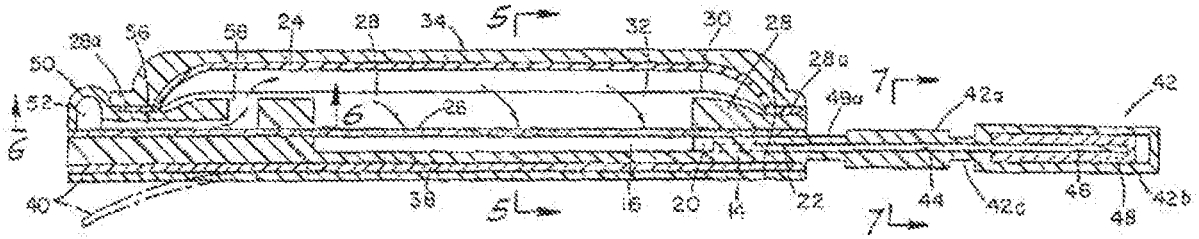


Фиг.2

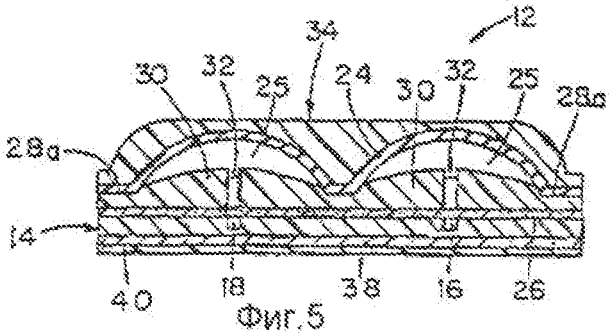


Фиг.3

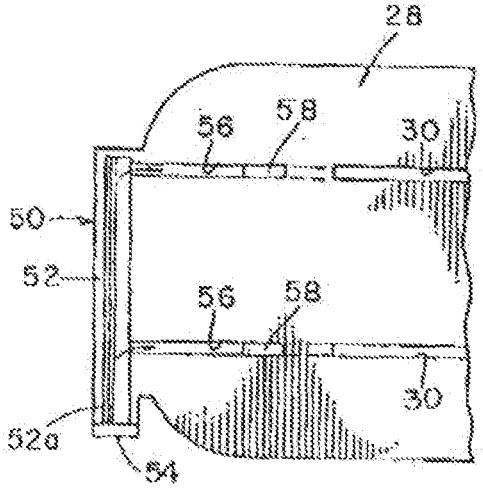
RU 2131273 C1



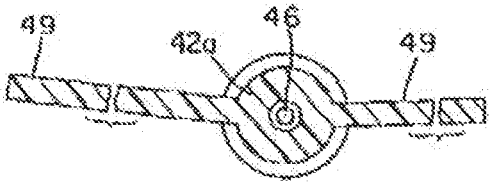
Фиг.4



Фиг.5



Фиг.6



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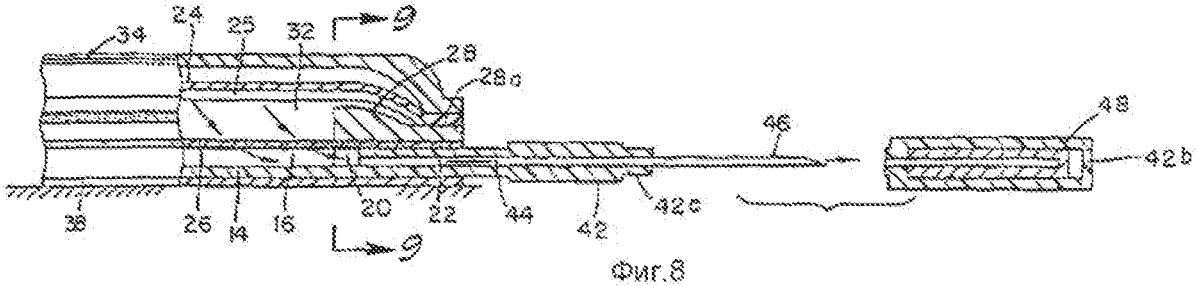
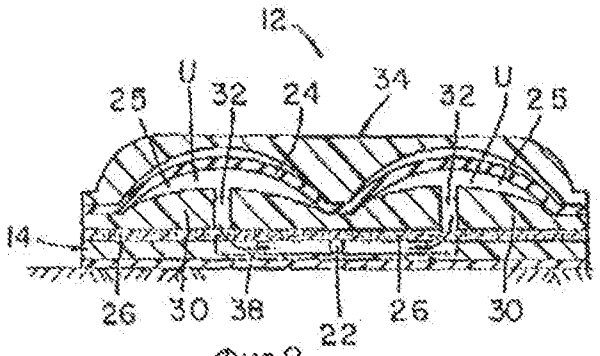
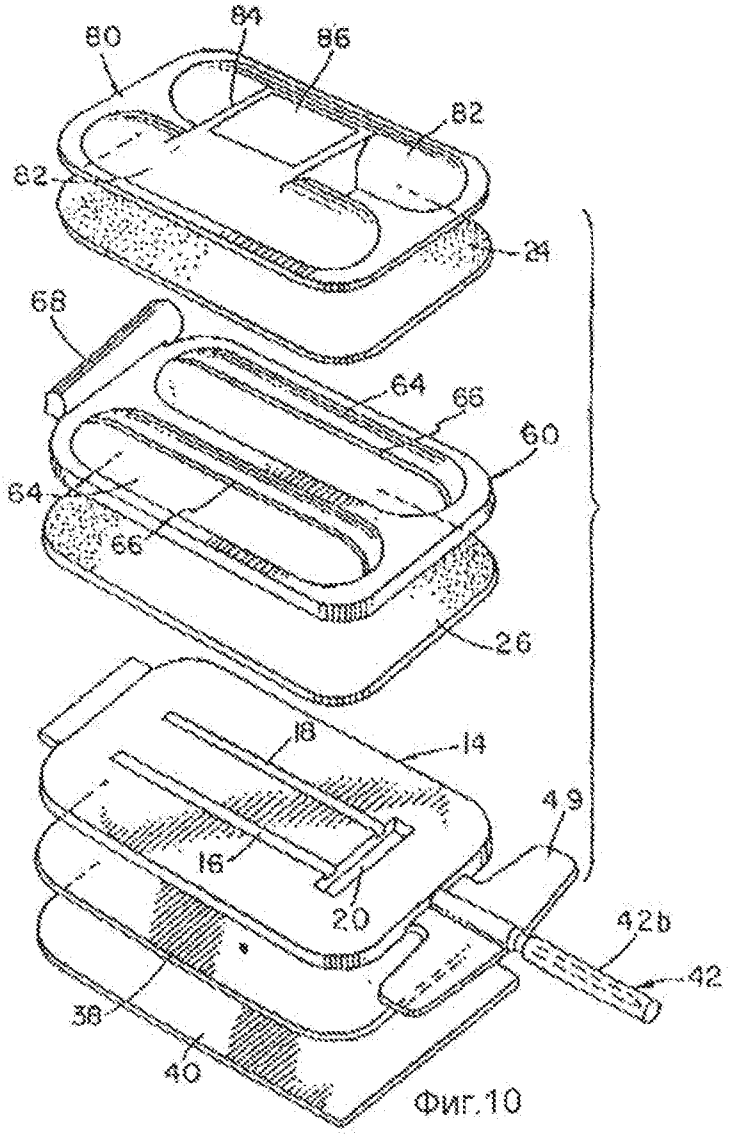


Фиг.8

RU 2131273 C1



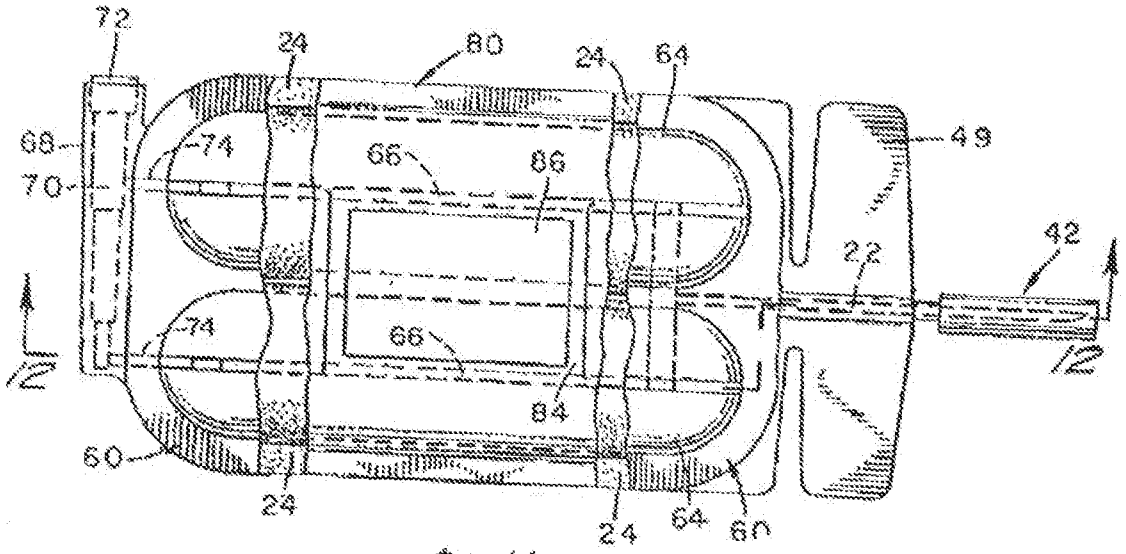
Фиг.9



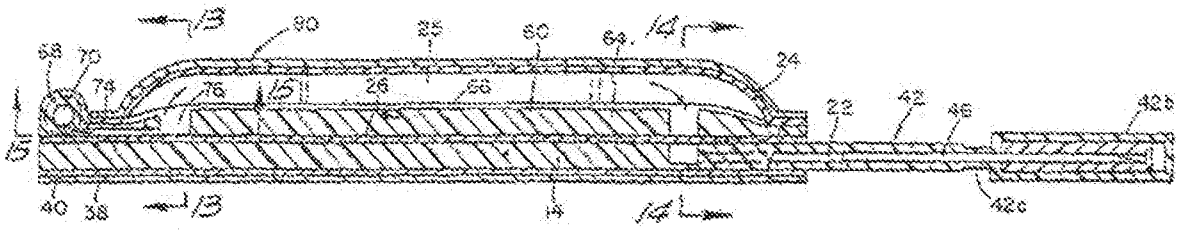
Фиг.10

RU 2131273 C1

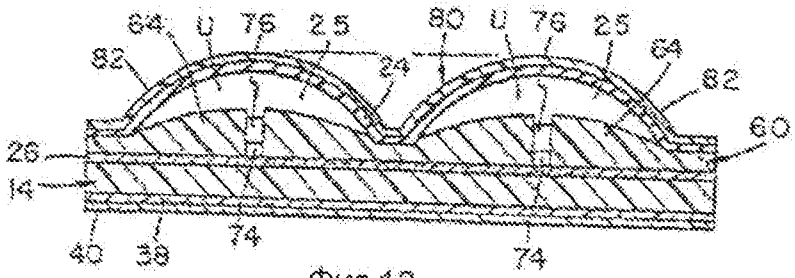
RU 2131273 C1



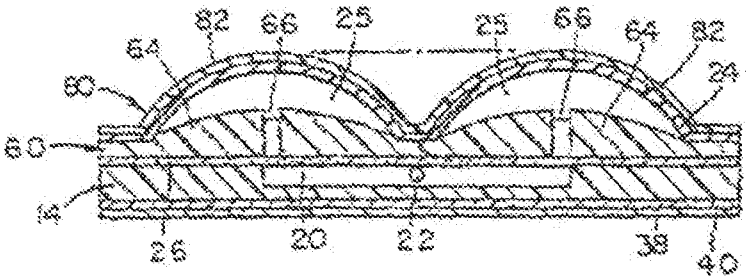
Фиг.11



Фиг.12

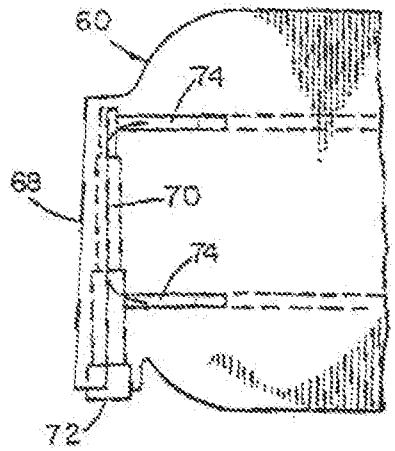


Фиг.13

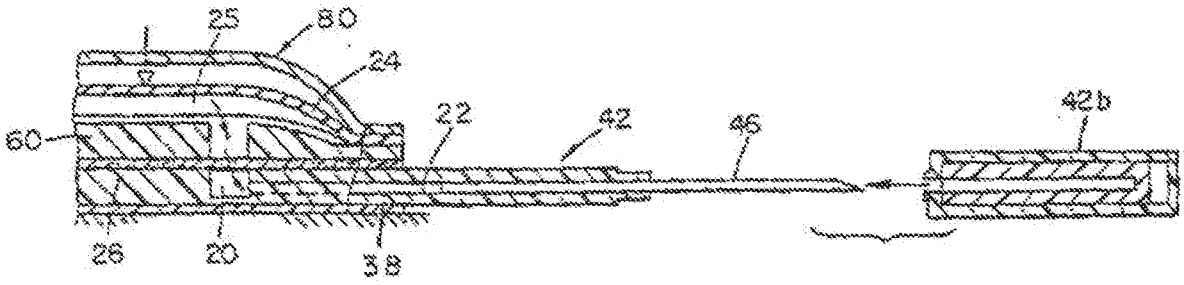


Фиг.14

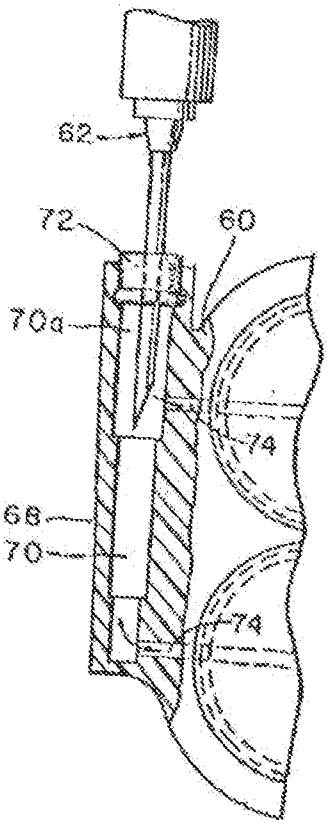
RU 2131273 C1



Фиг.15

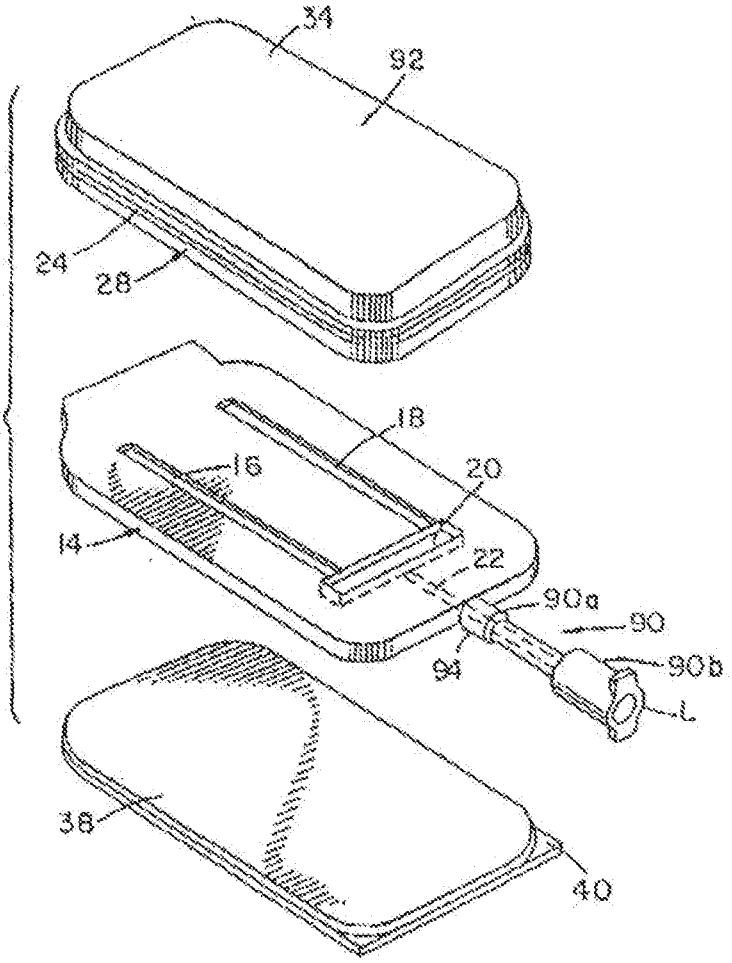


Фиг.16

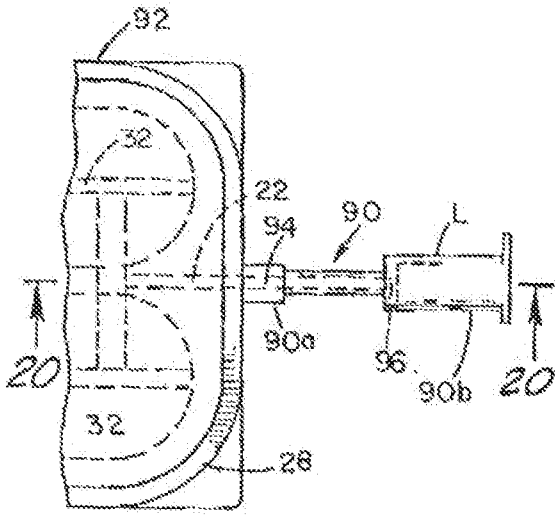


Фиг.17

RU 2131273 C1

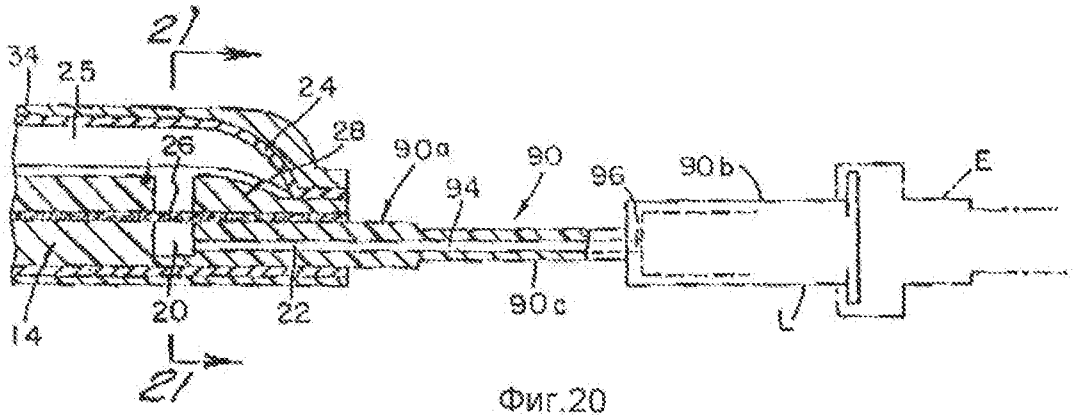


Фиг.18

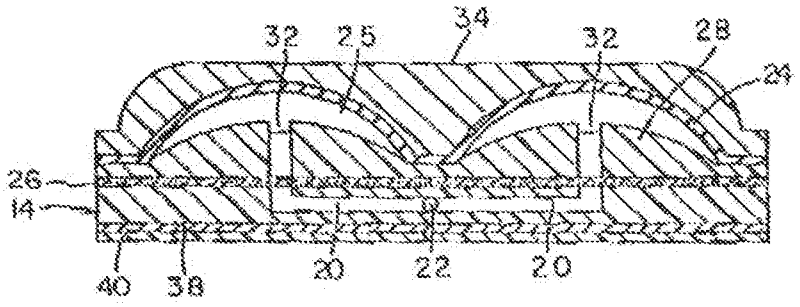


Фиг.19

RU 2131273 C1

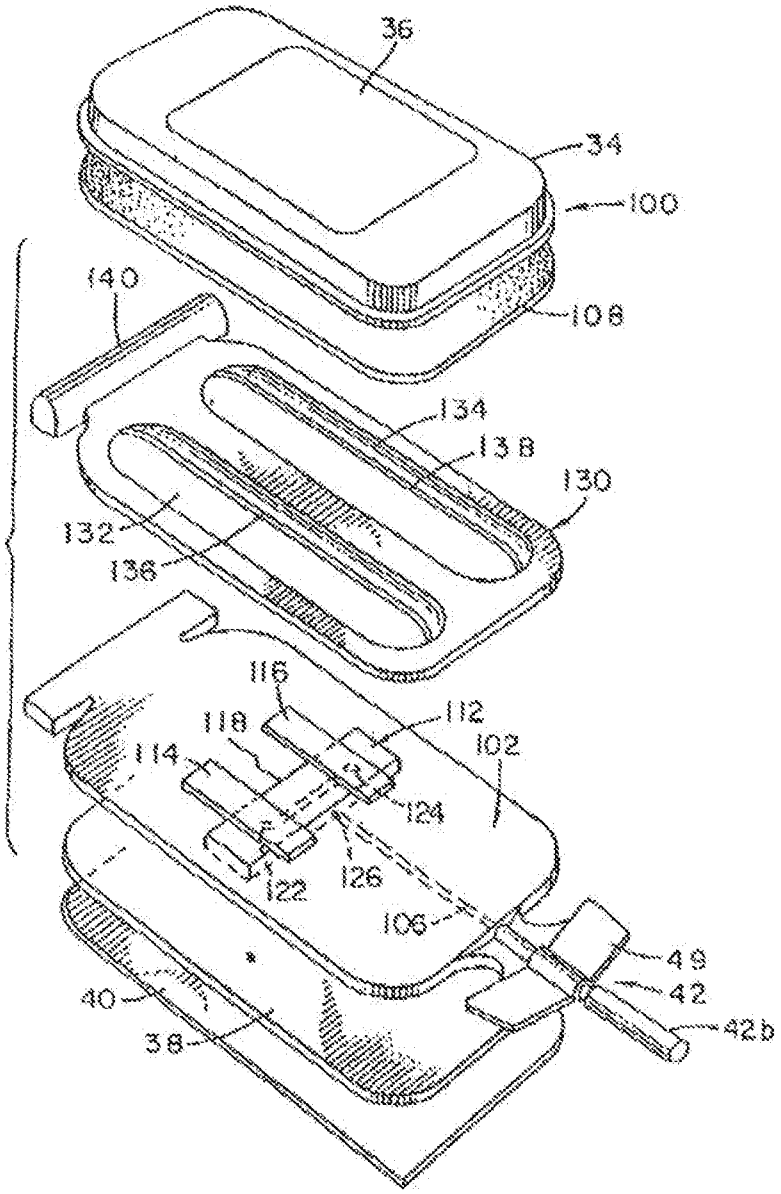


Фиг.20

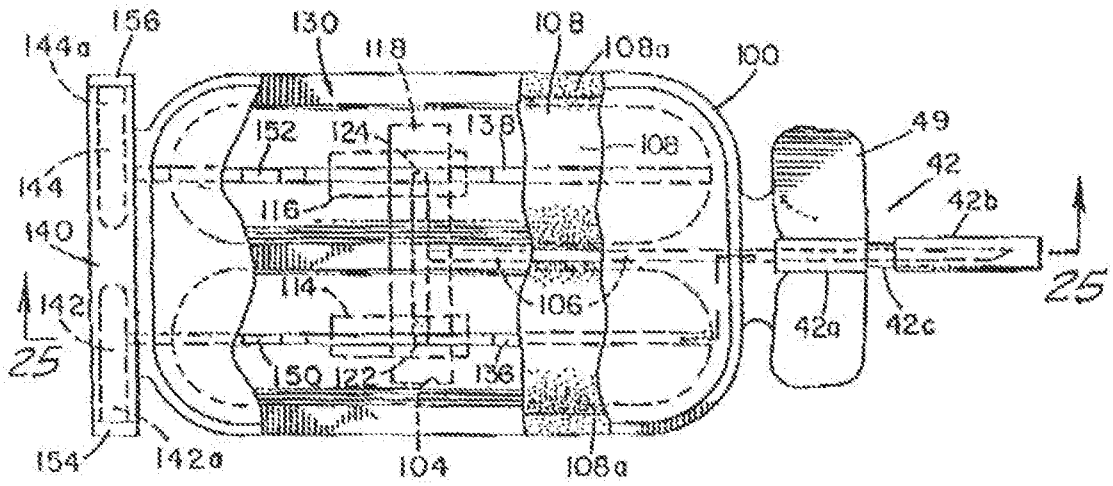


Фиг.21

RU 2131273 C1

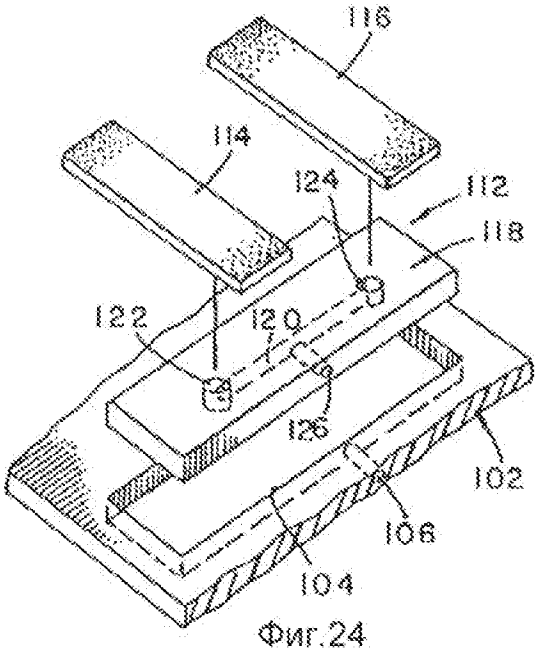


Фиг.22

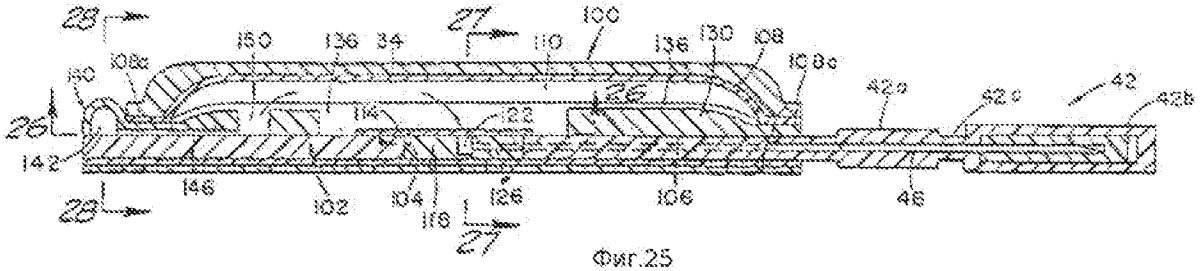


Фиг.23

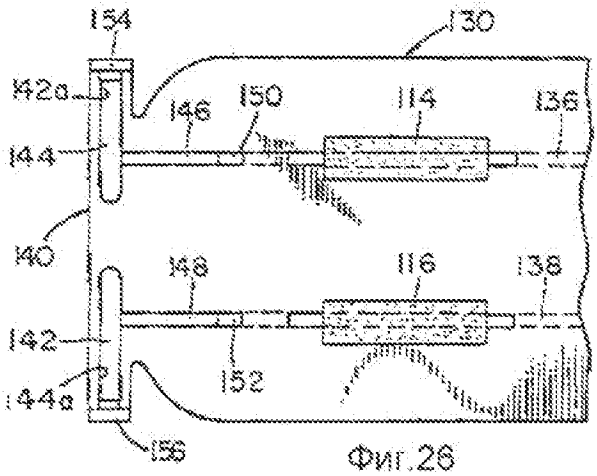
RU 2131273 C1



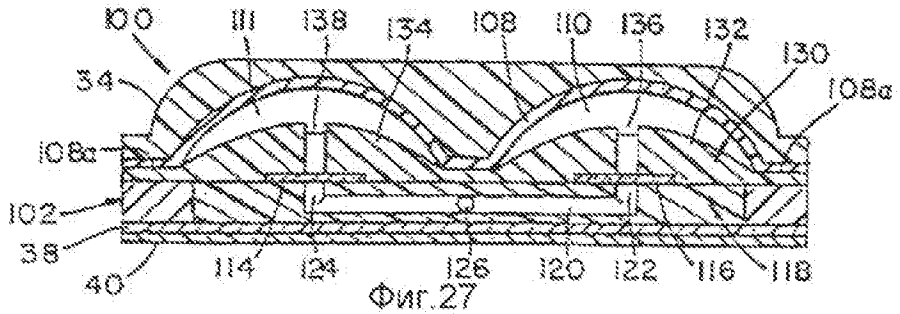
Фиг.24



Фиг.25

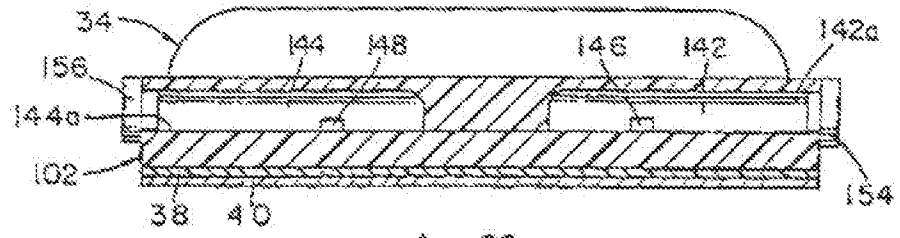


Фиг.26

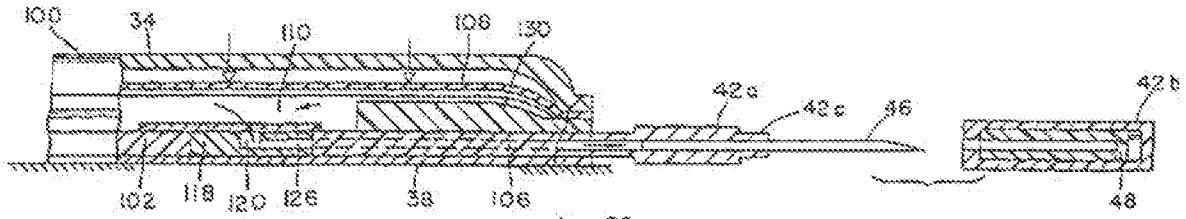


Фиг.27

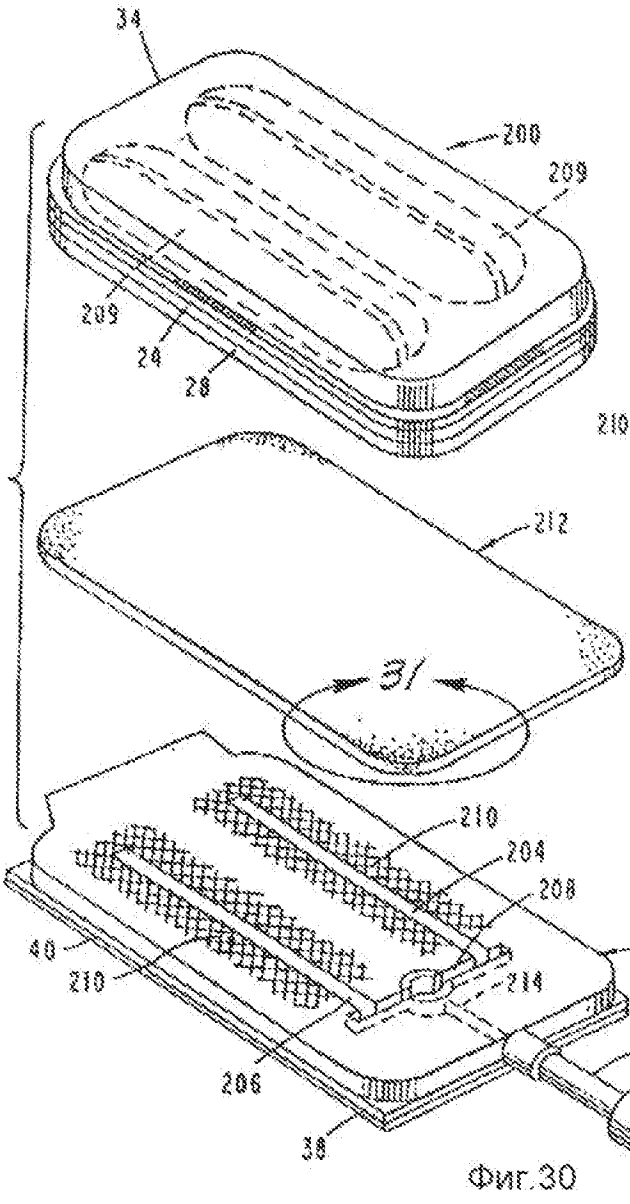
RU 2131273 C1



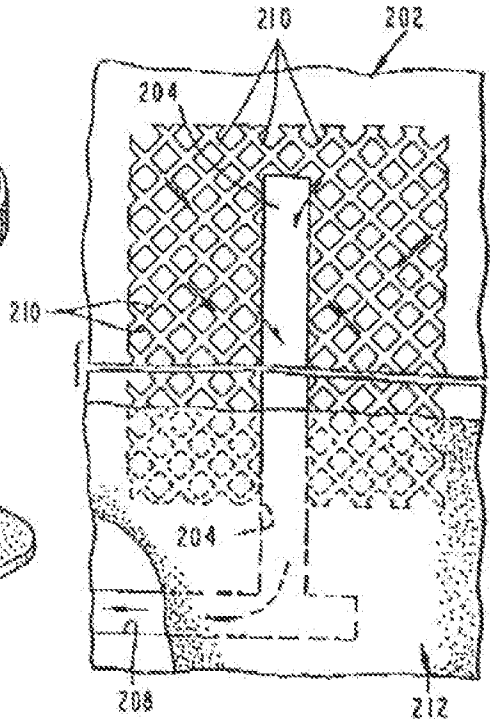
Фиг.28



Фиг.29

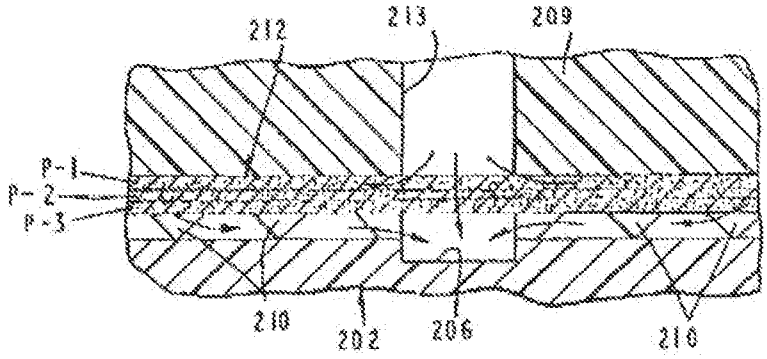


Фиг.30

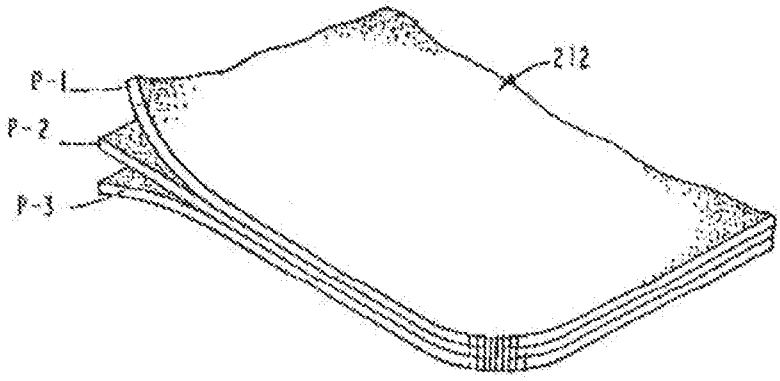


Фиг.30а

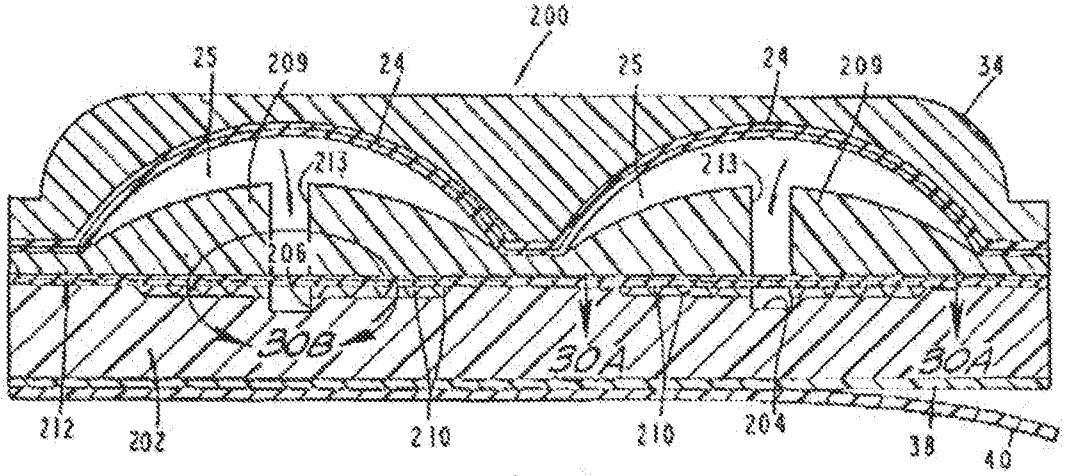
RU 2131273 C1



Фиг.30в

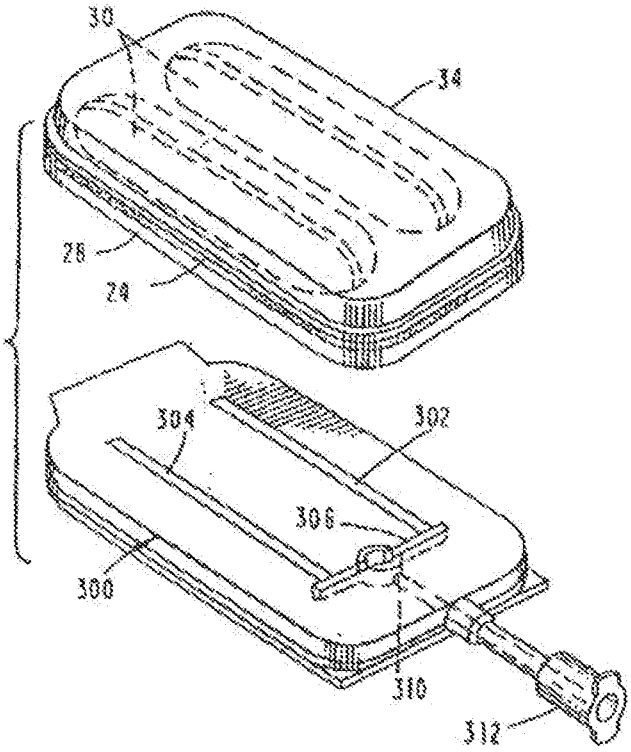


Фиг.31

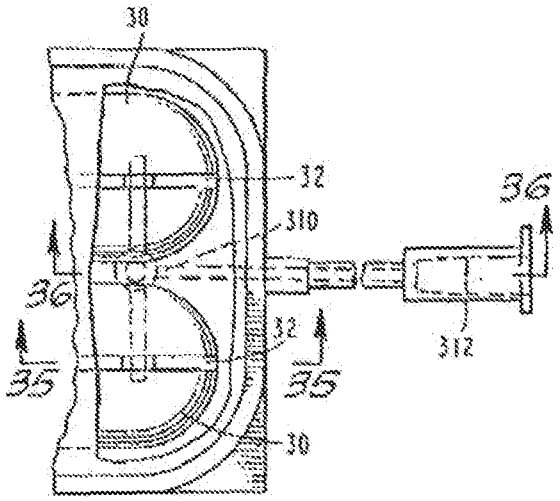


Фиг.32

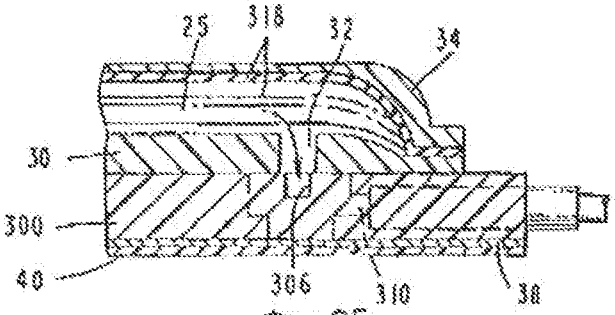
RU 2131273 C1



Фиг.33

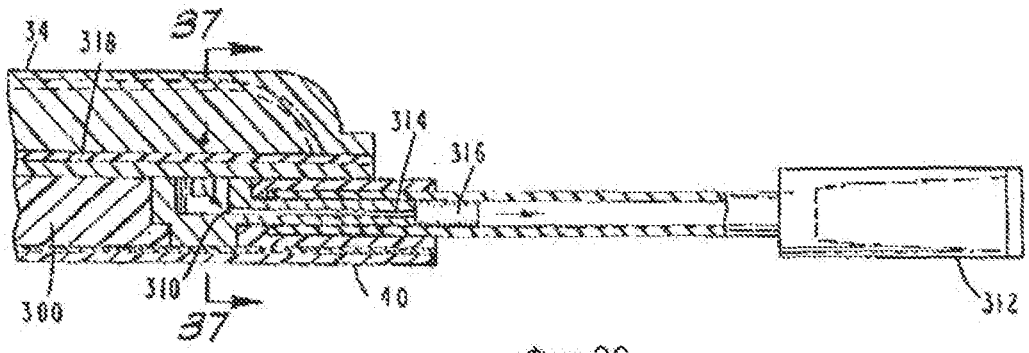


Фиг.34

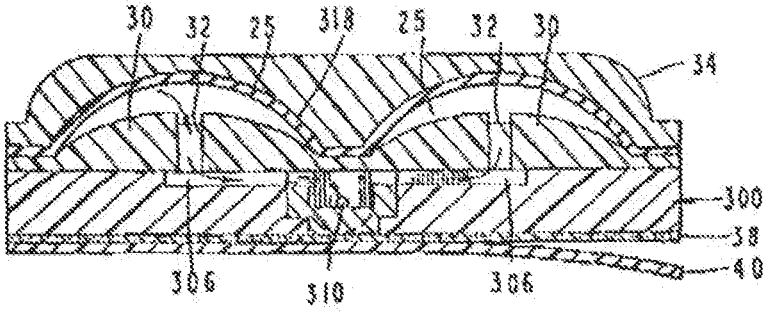


Фиг.35

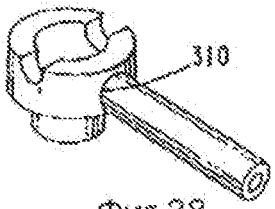
RU 2131273 C1



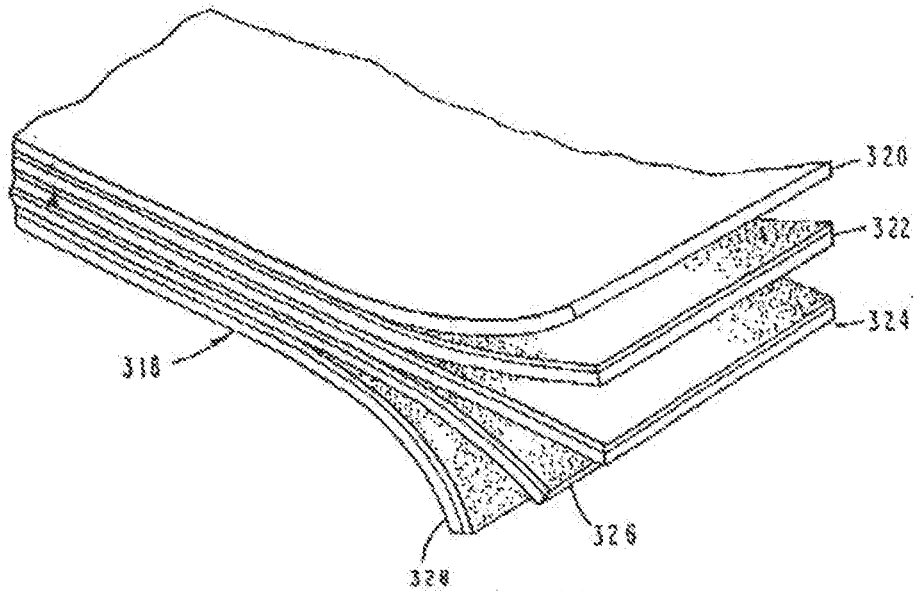
Фиг.36



Фиг.37

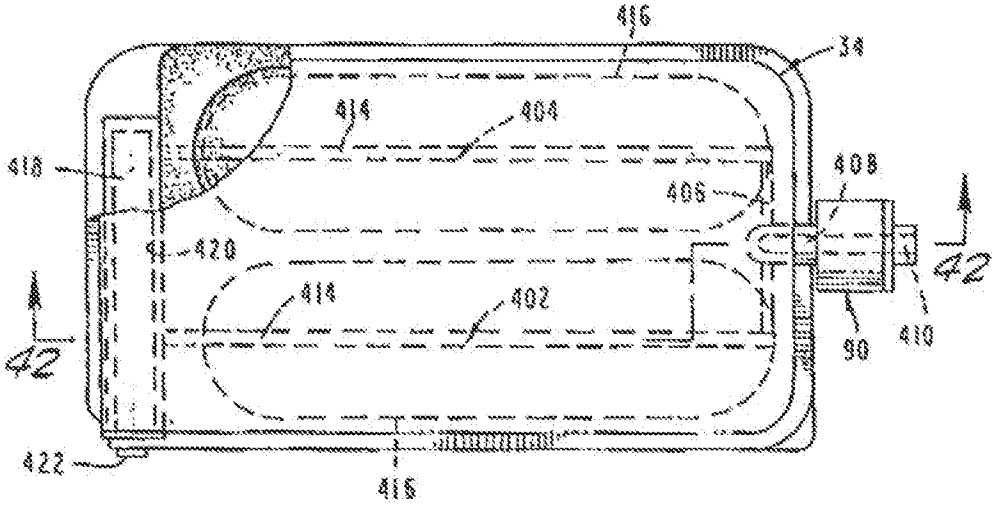


Фиг.38

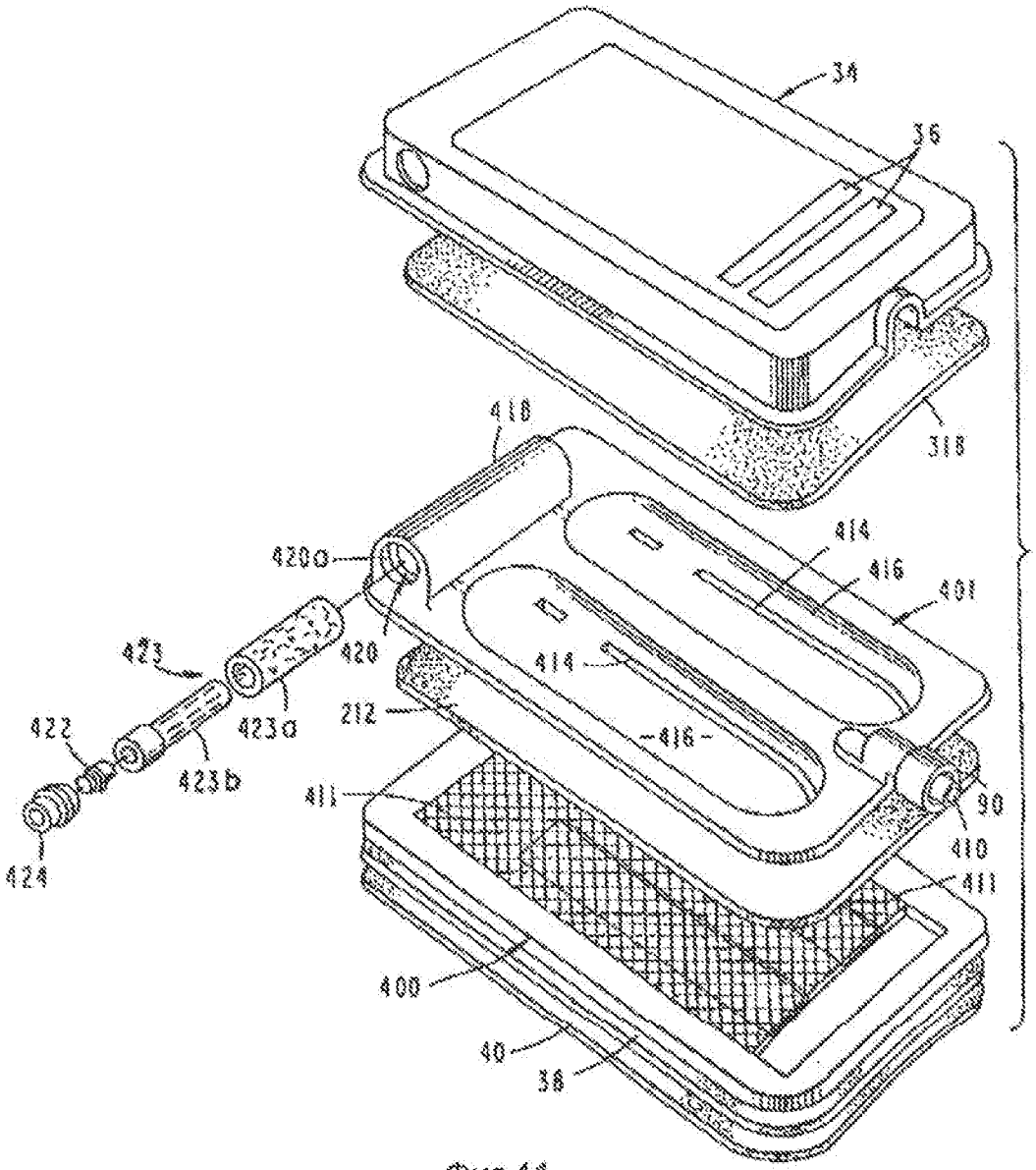


Фиг.39

RU 2131273 C1

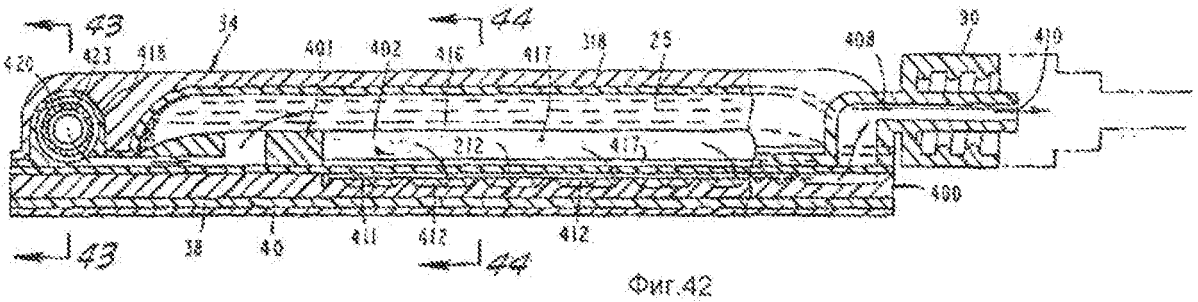


Фиг.40

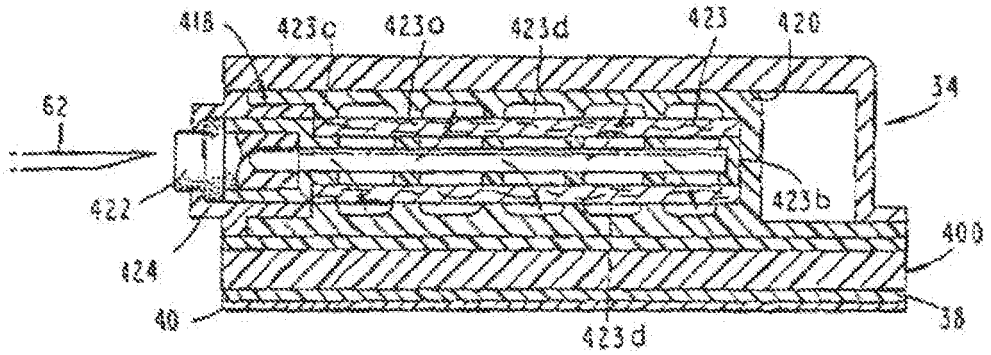


Фиг.41

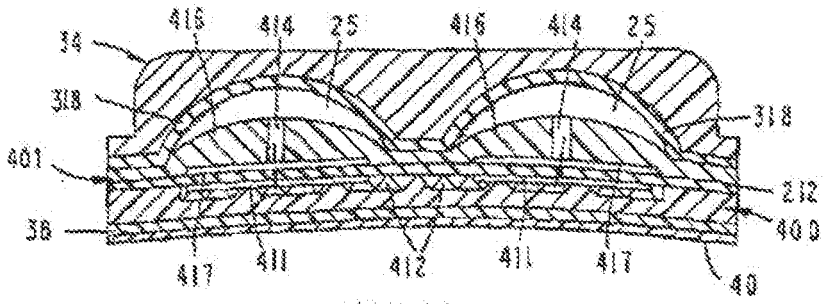
RU 2131273 C1



Фиг.42



Фиг.43



Фиг.44

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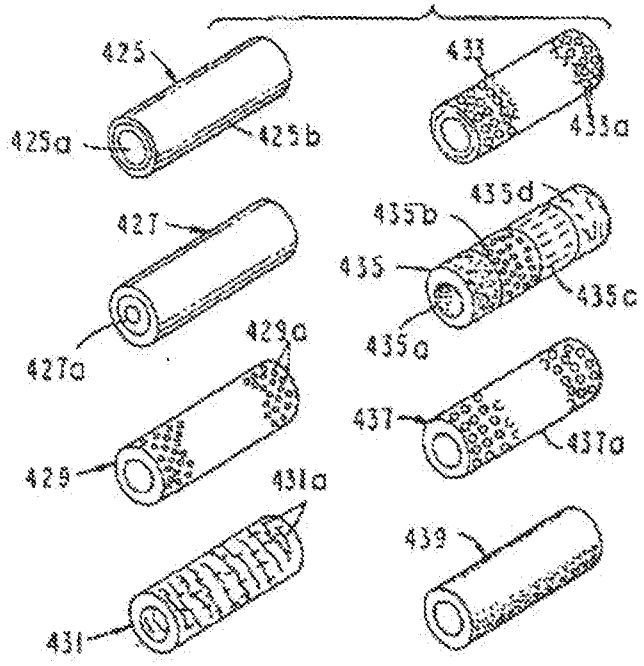
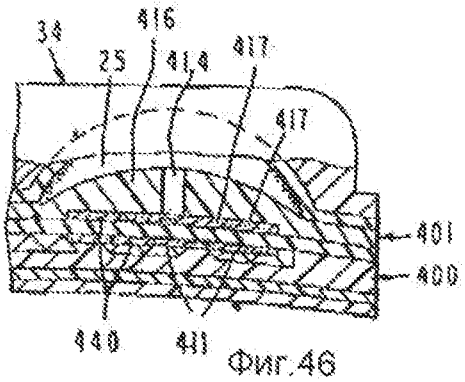
RU 2131273 C1

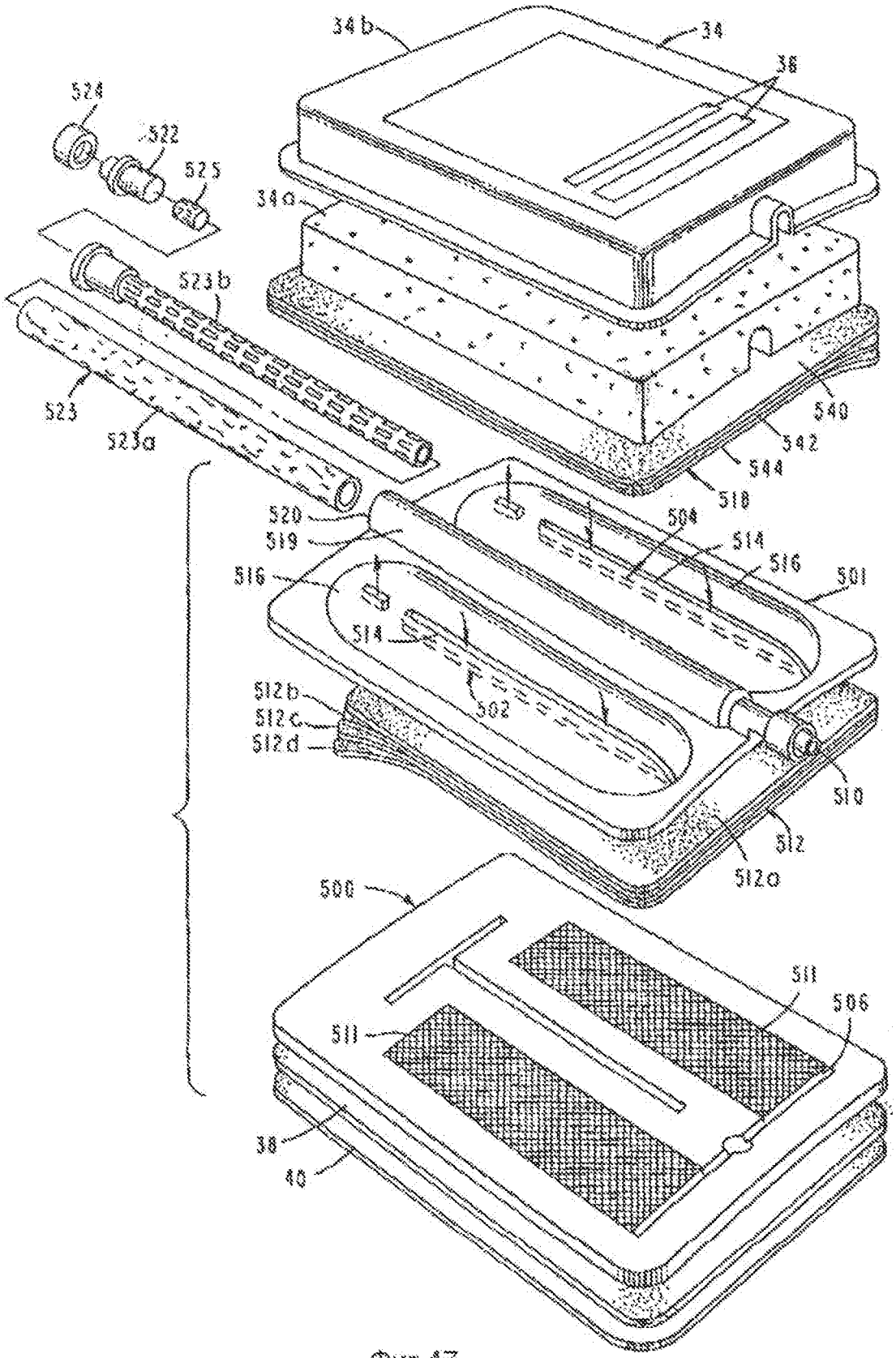


Фиг.45



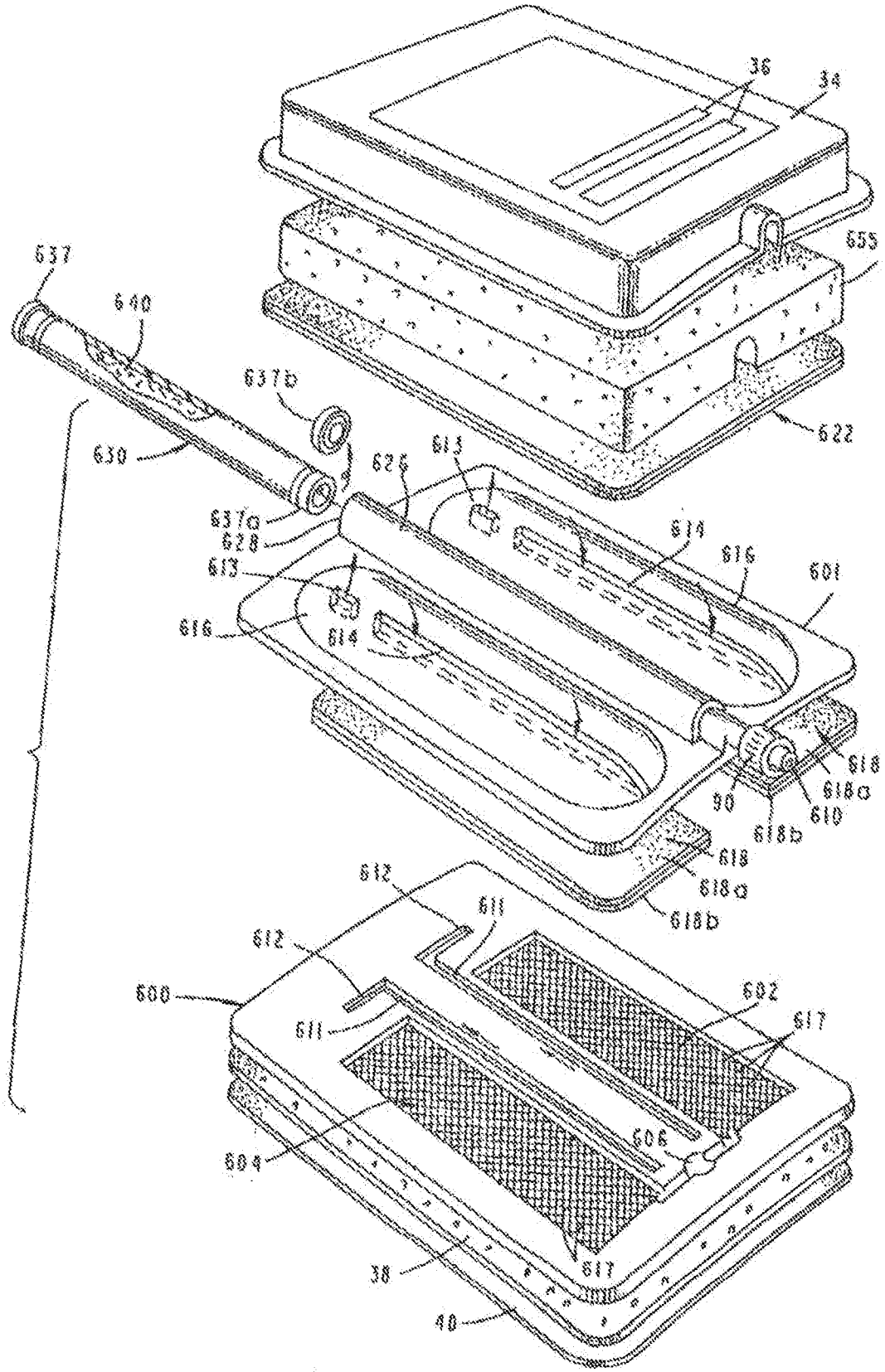
Фиг.46

RU 2131273 C1



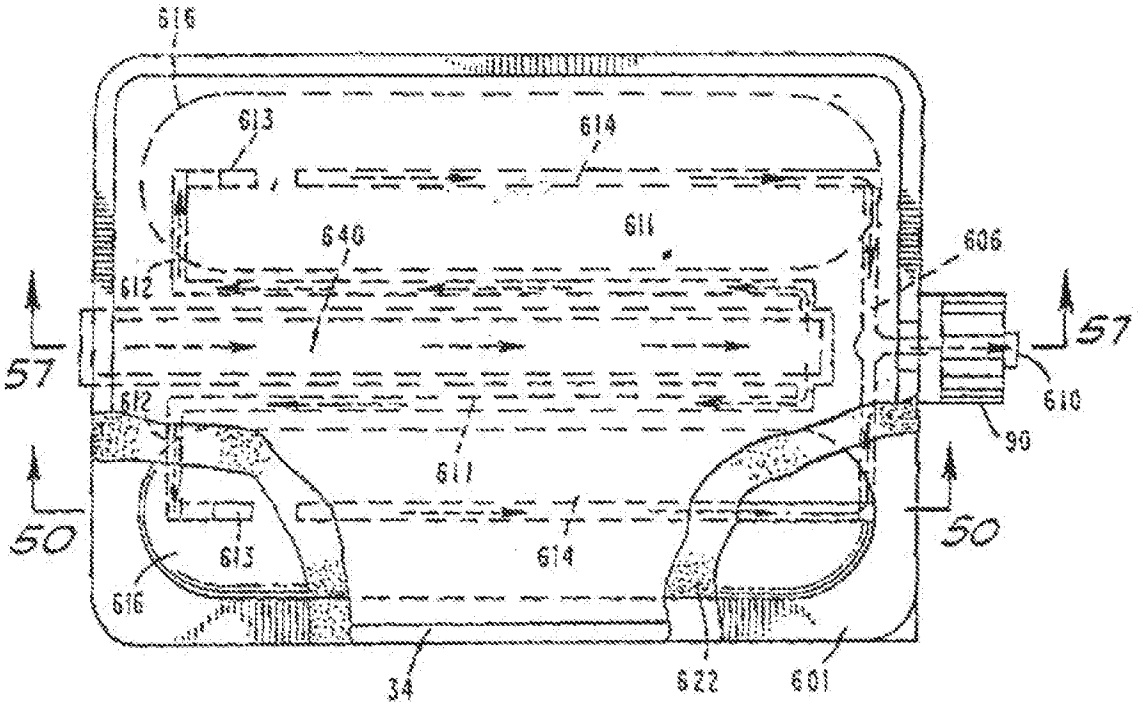
Фиг.47

RU 2131273 C1

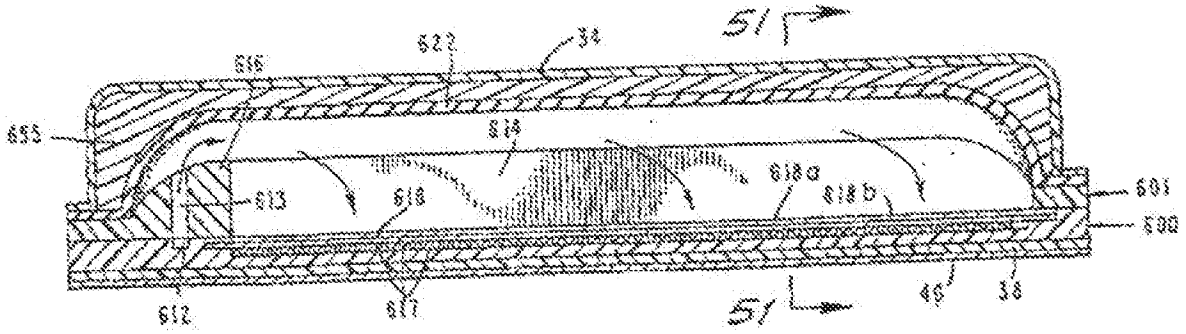


Фиг.48

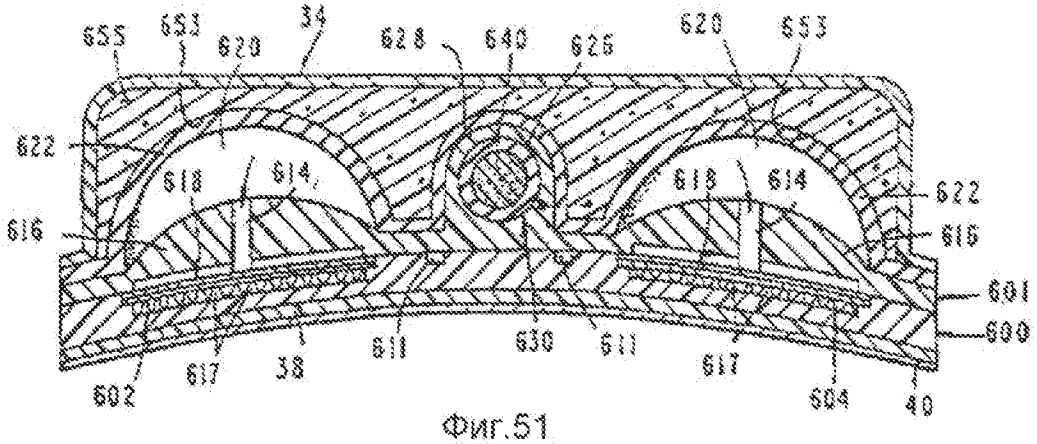
RU 2131273 C1



Фиг.49

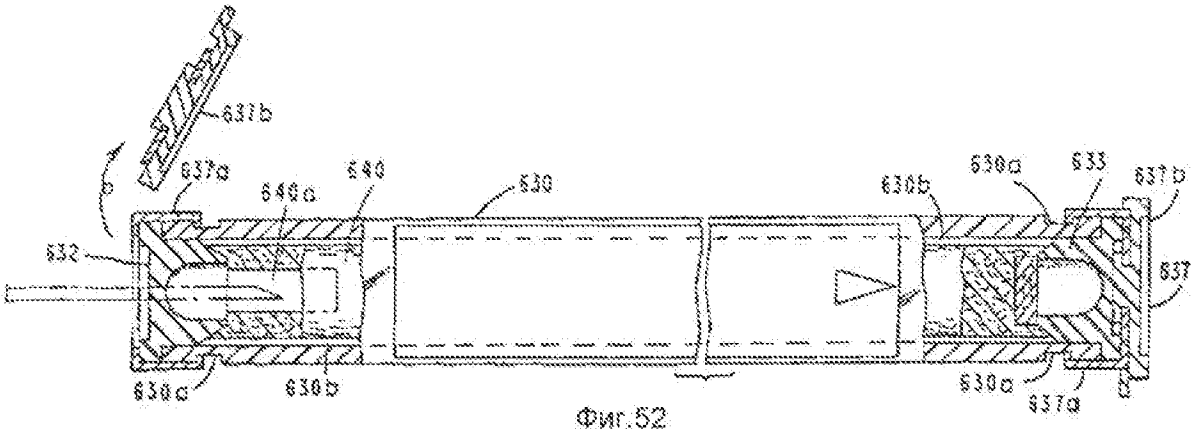


Фиг.50

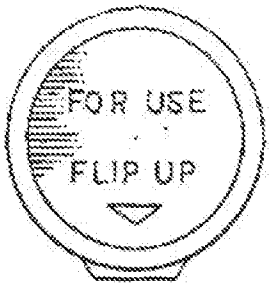


Фиг.51

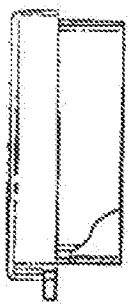
RU 2131273 C1



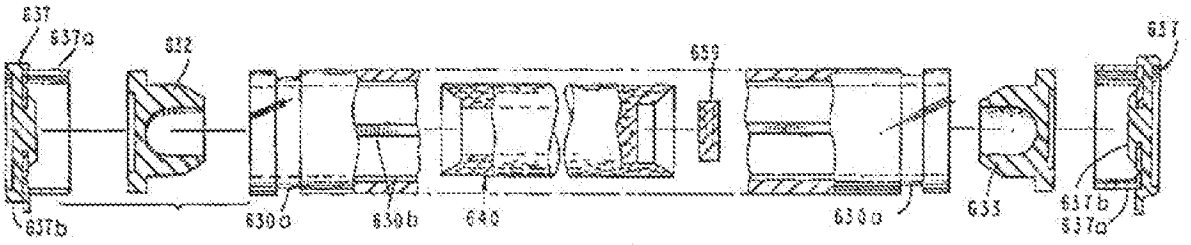
Фиг.52



Фиг.53

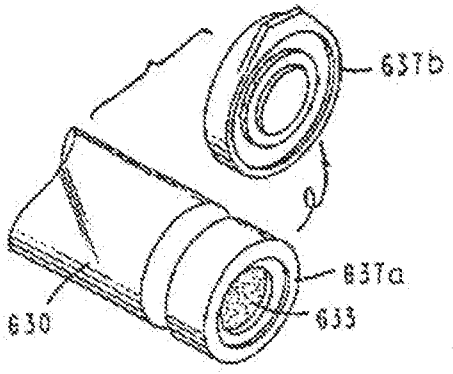


Фиг.54

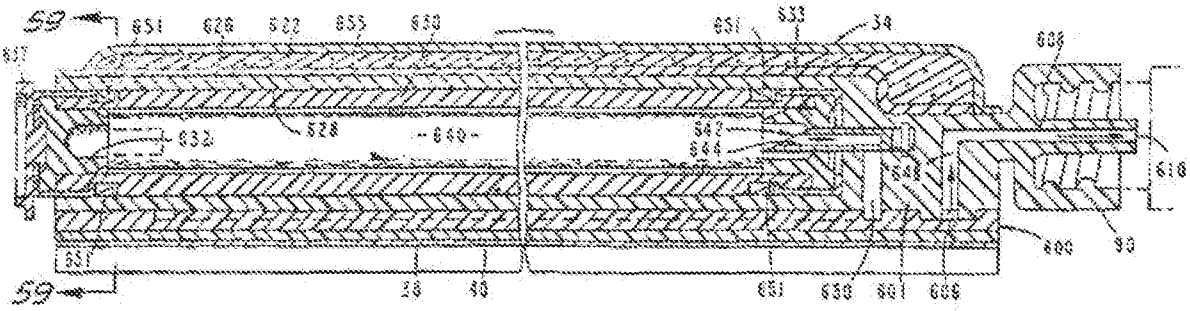


Фиг.55

RU 2131273 C1



Фиг.56



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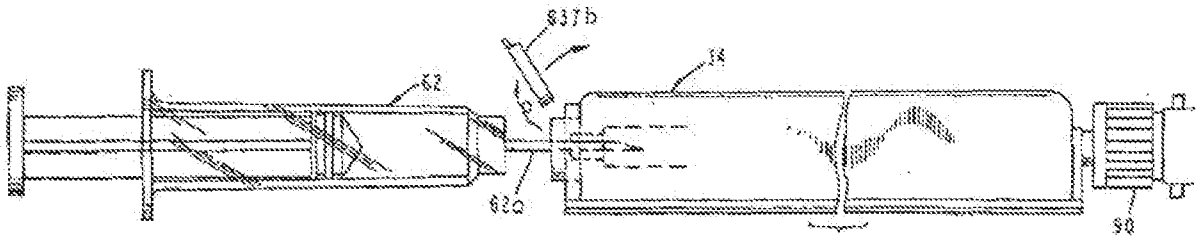

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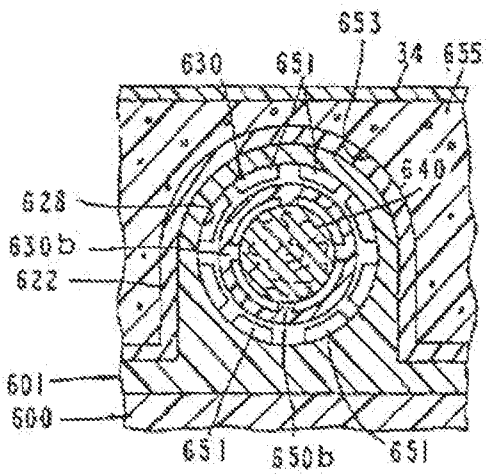

Фиг.59

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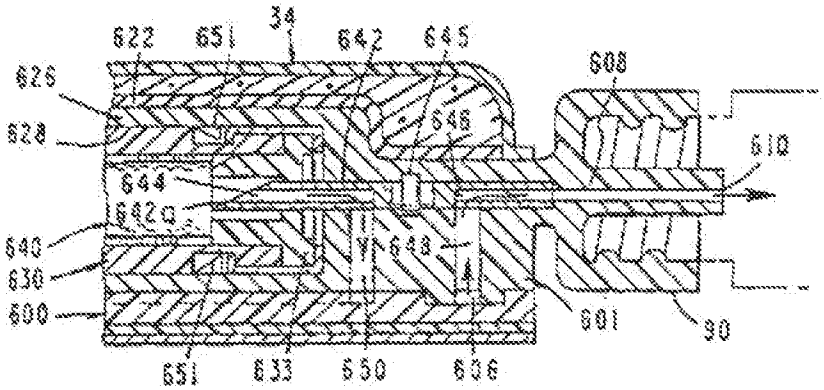

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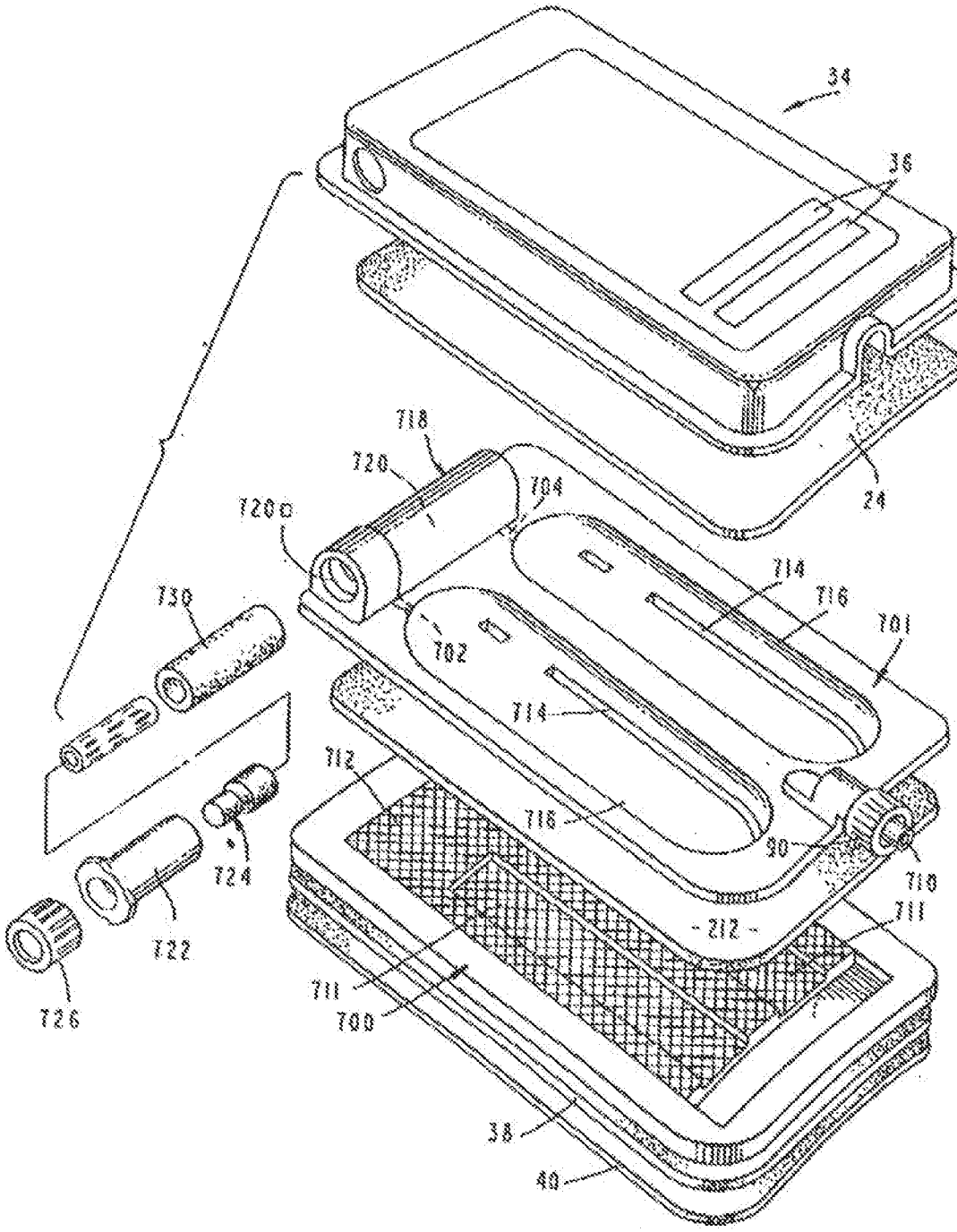

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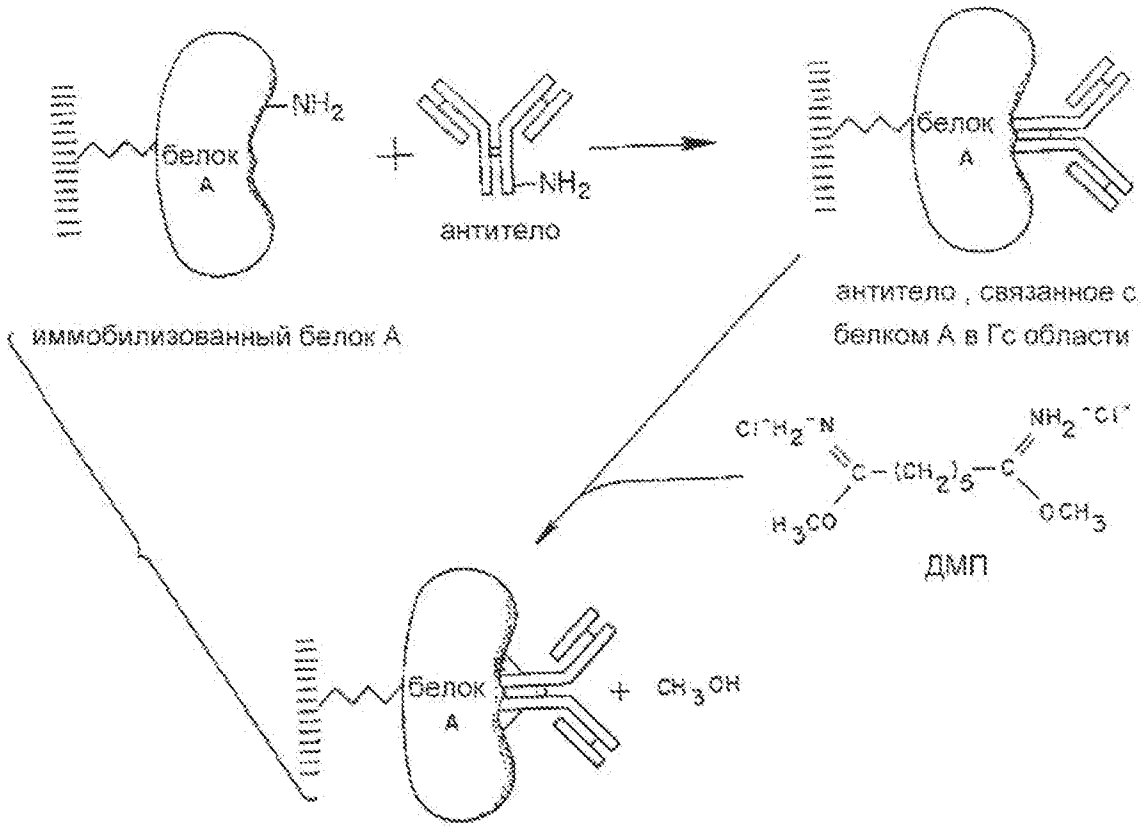

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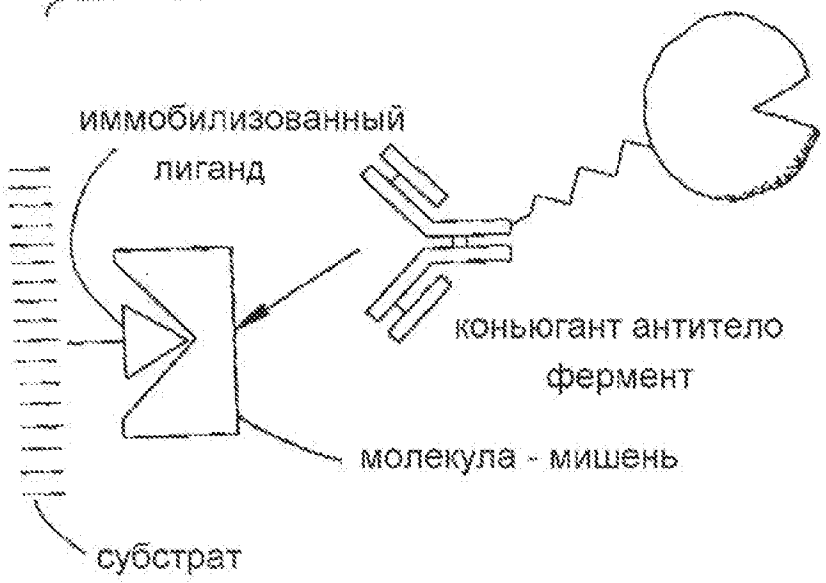
Фиг.61а

RU 2131273 C1



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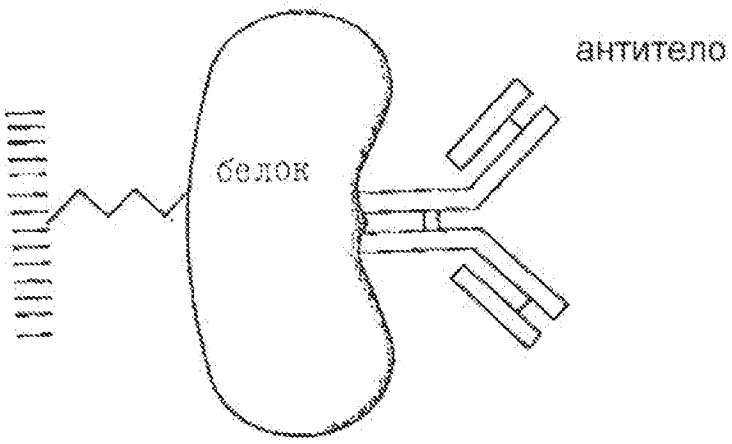

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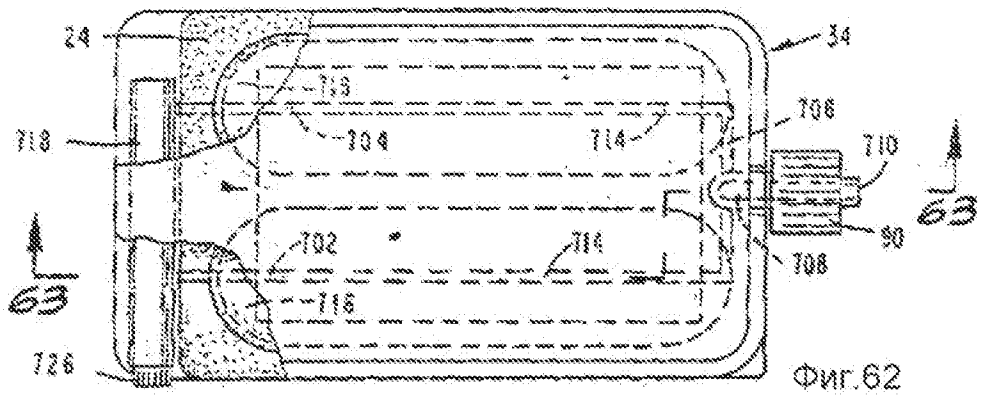

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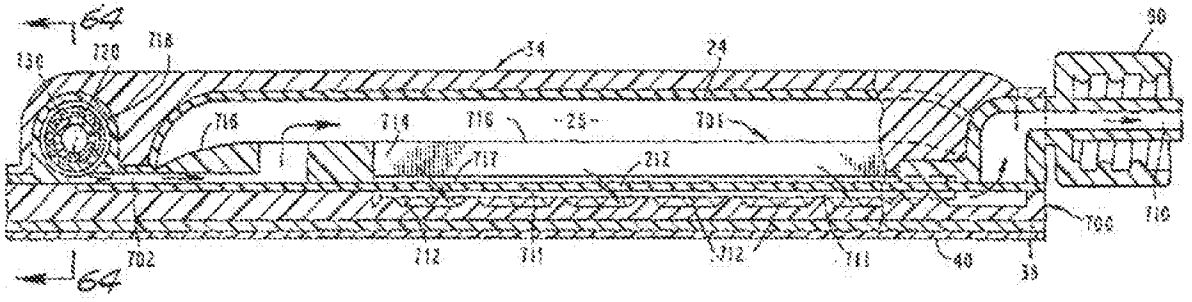
RU 2131273 C1



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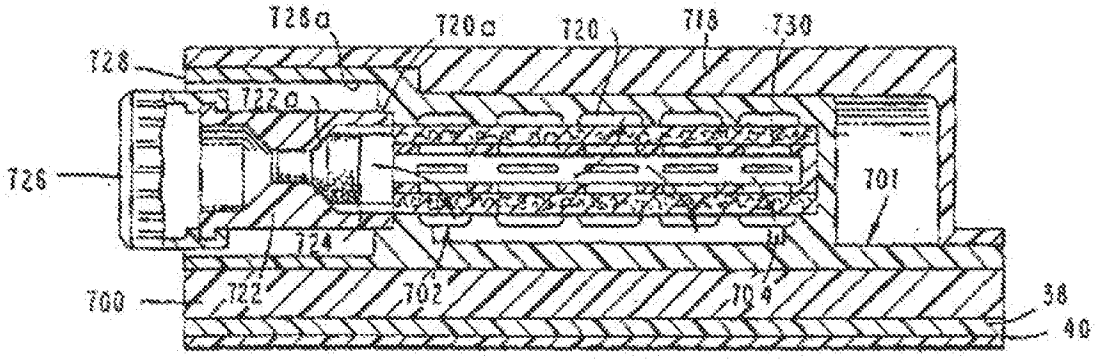

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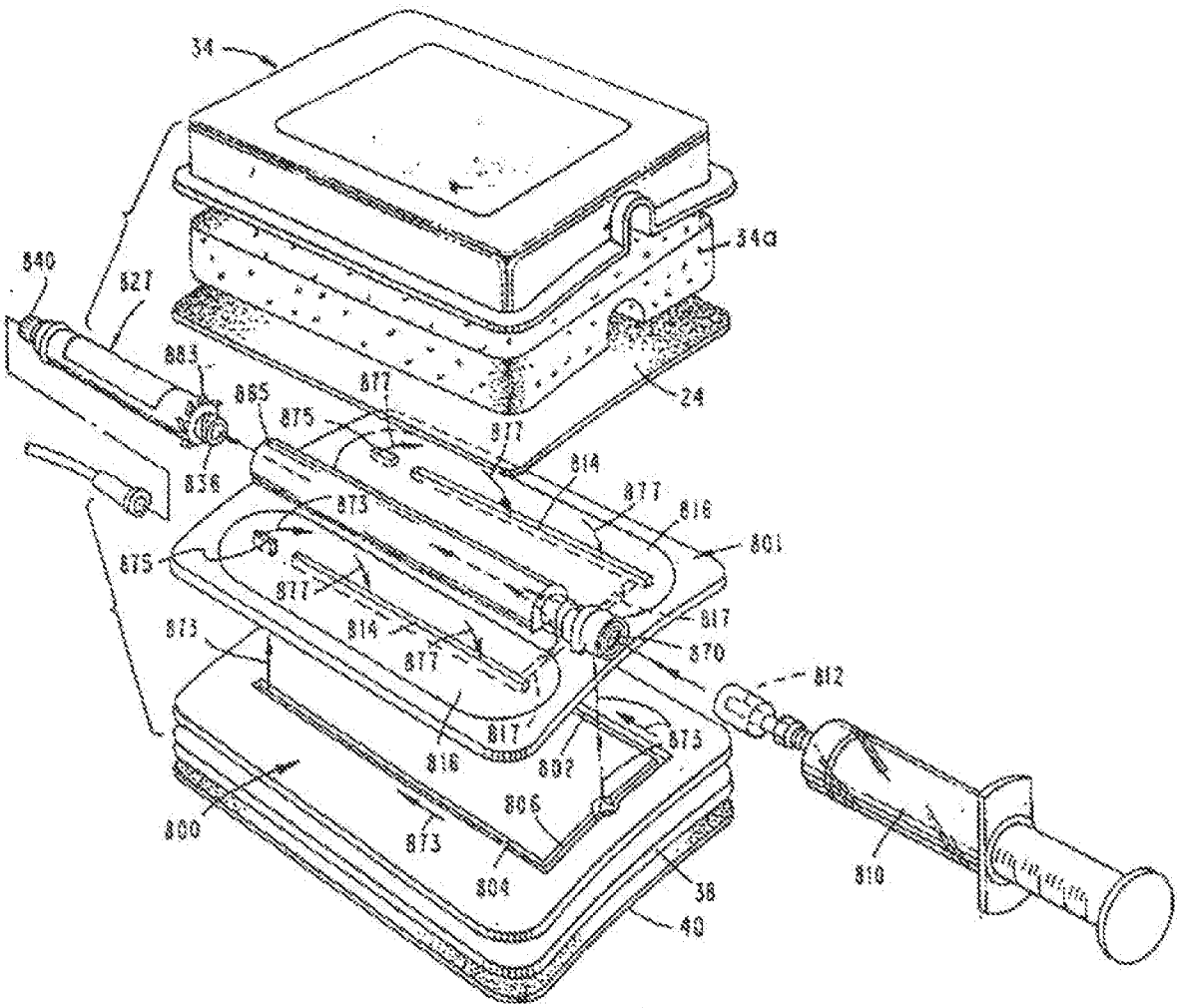

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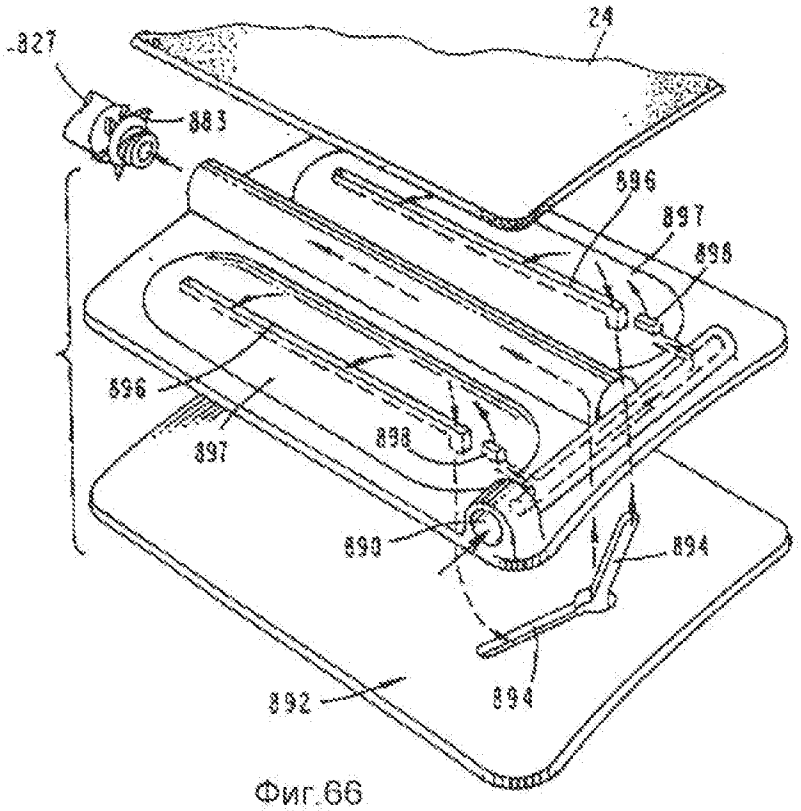
RU 2131273 C1



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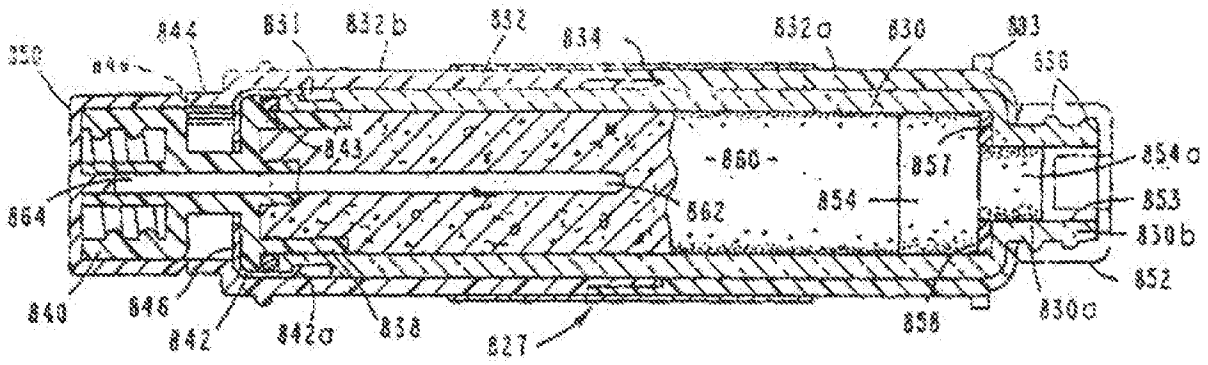

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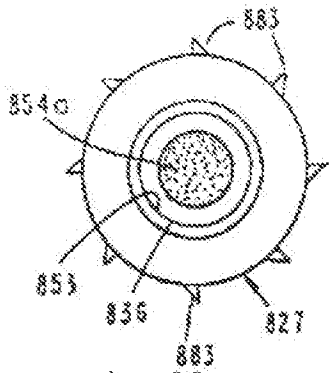

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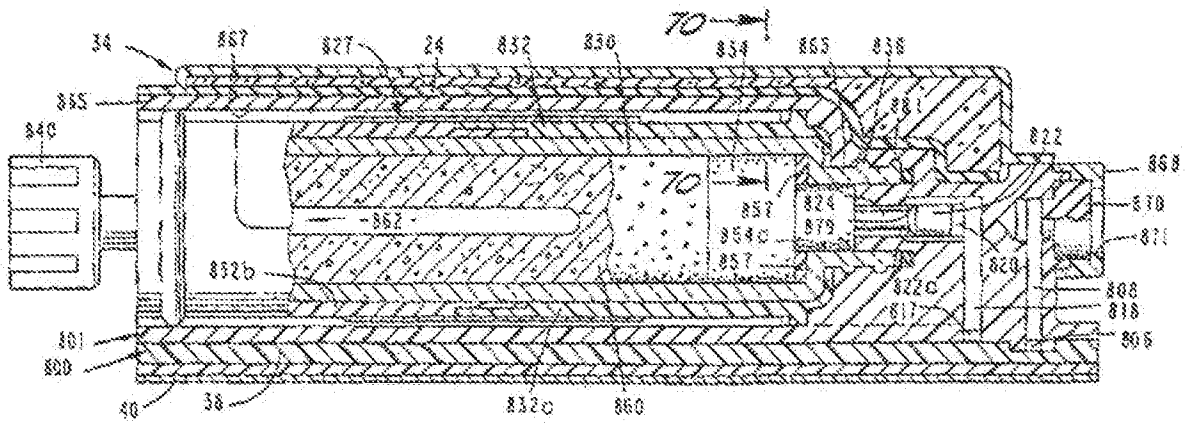

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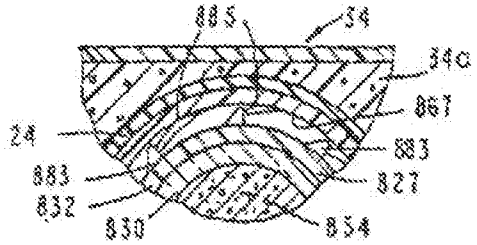

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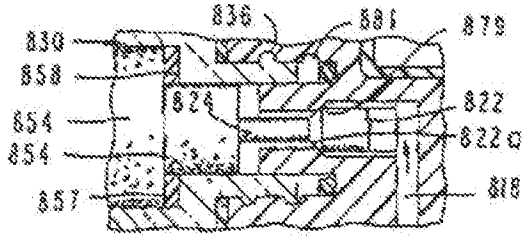

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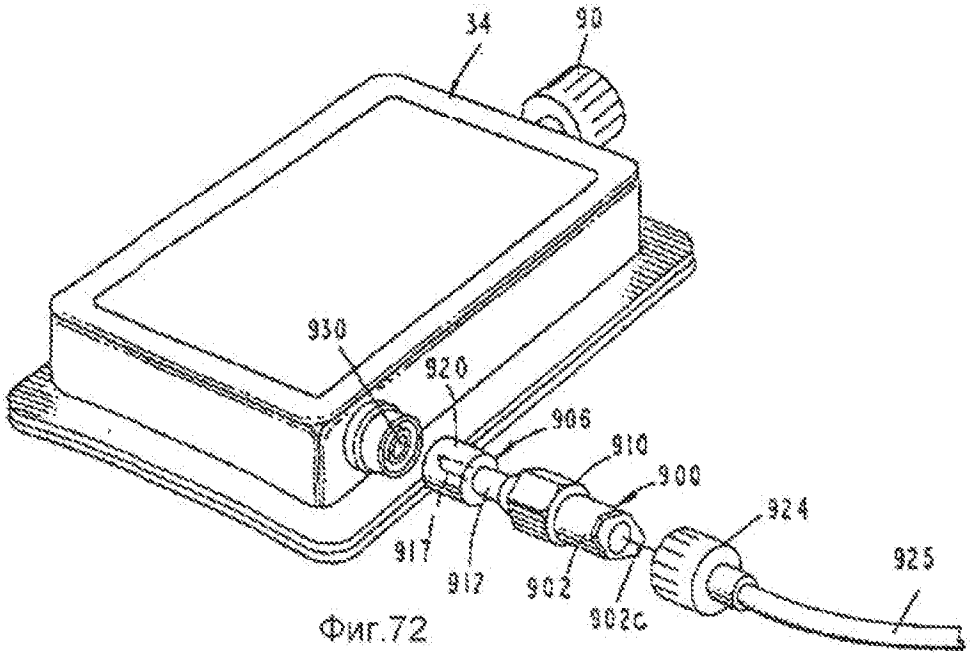

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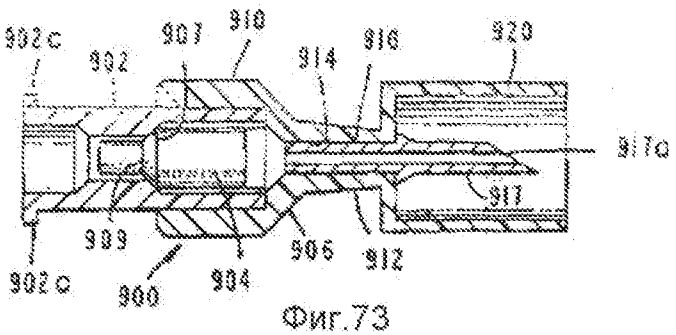

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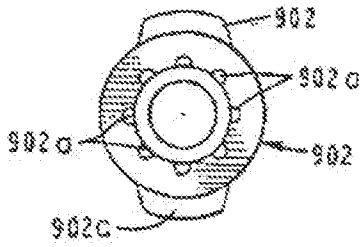

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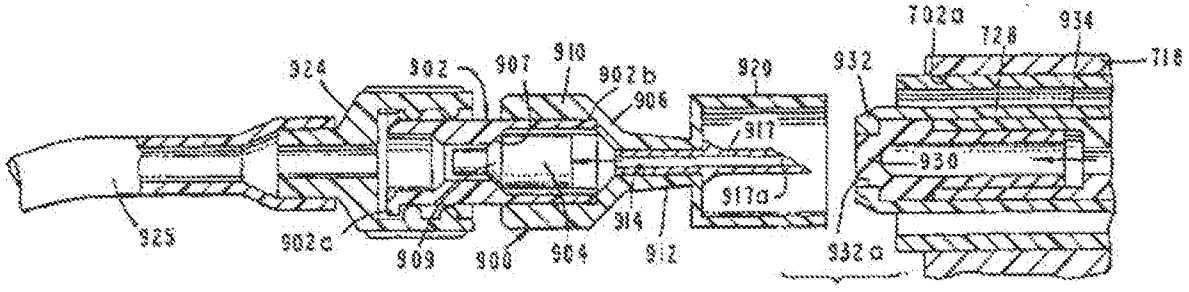

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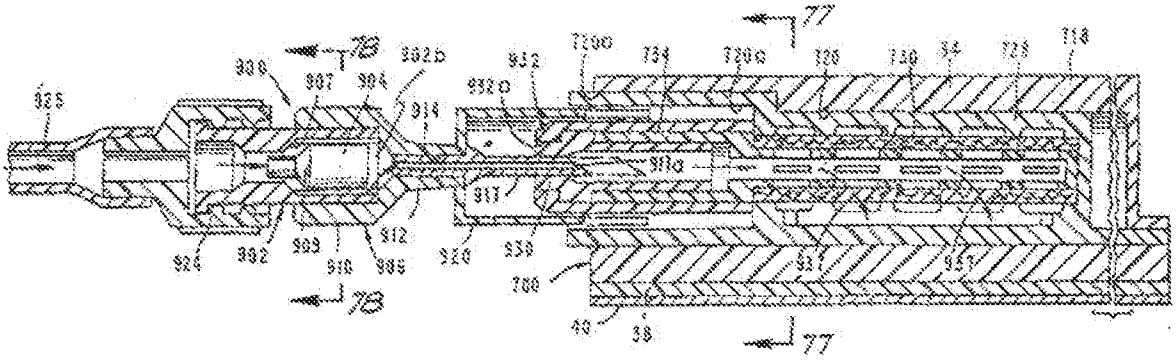

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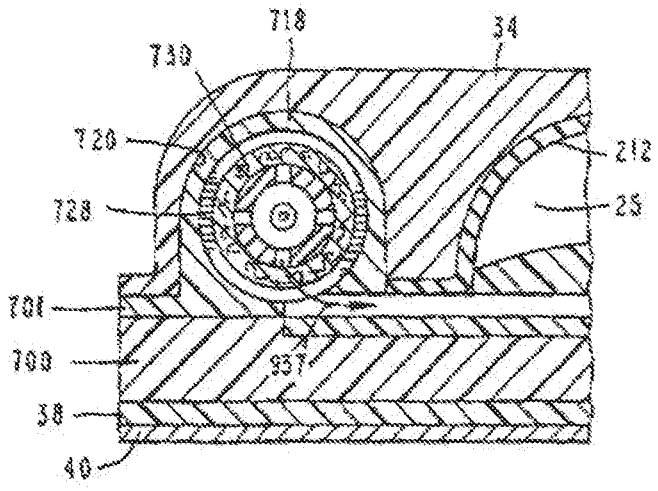

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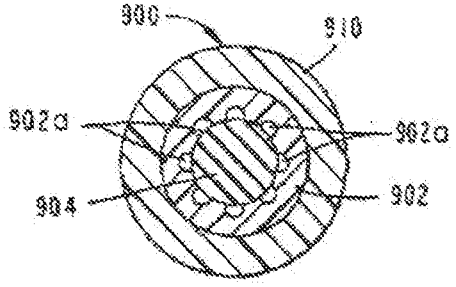

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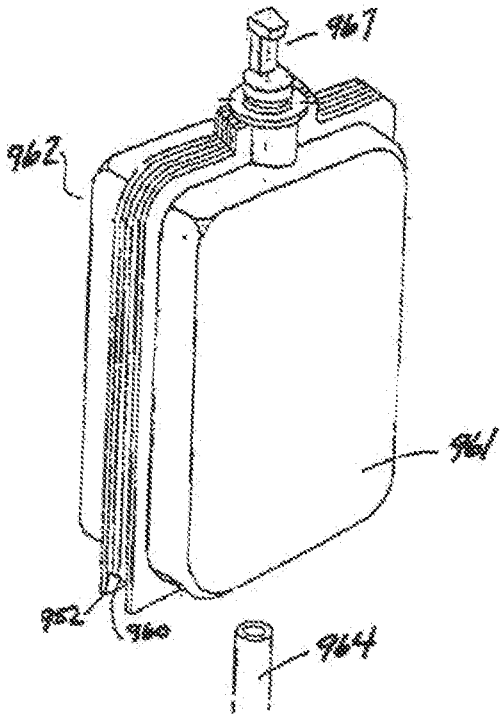

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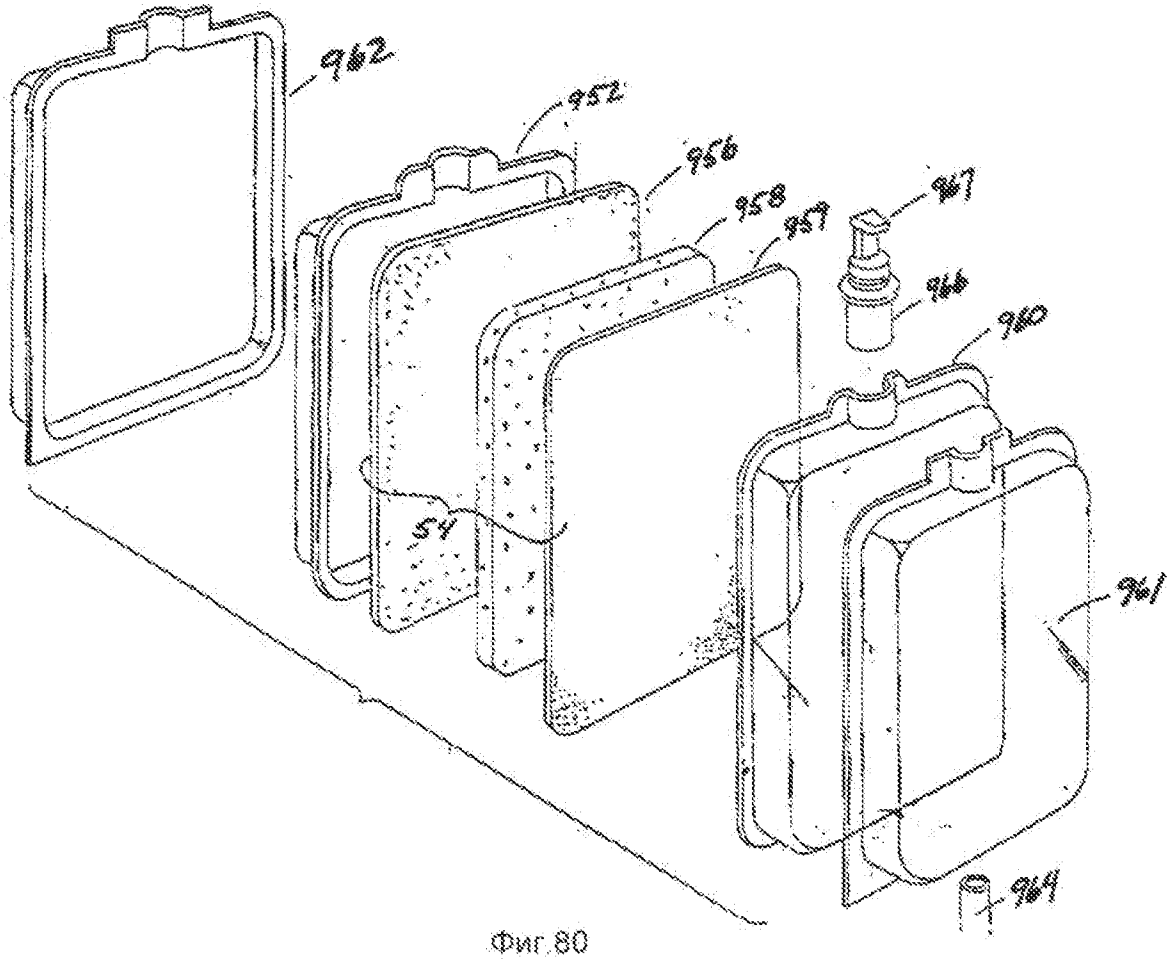

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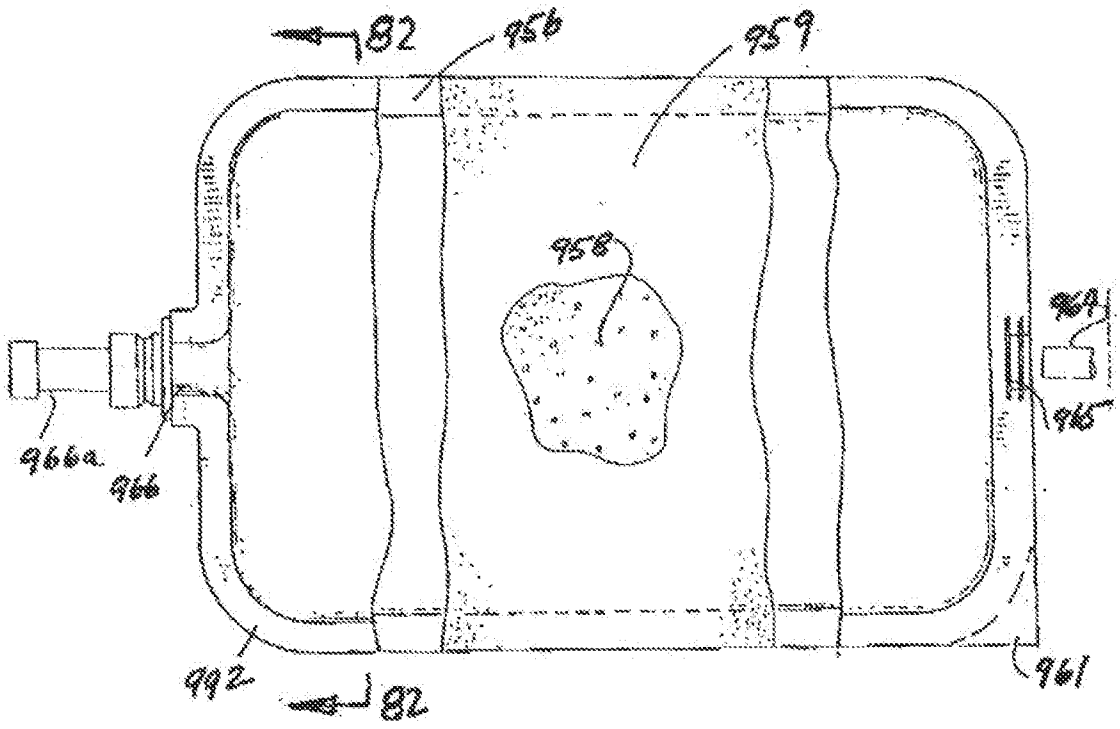

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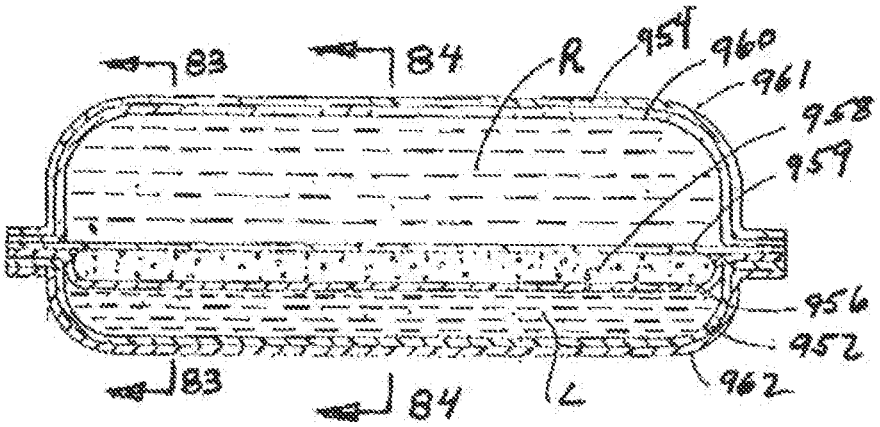

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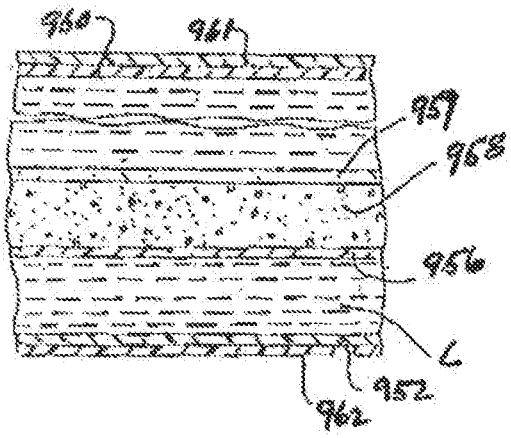

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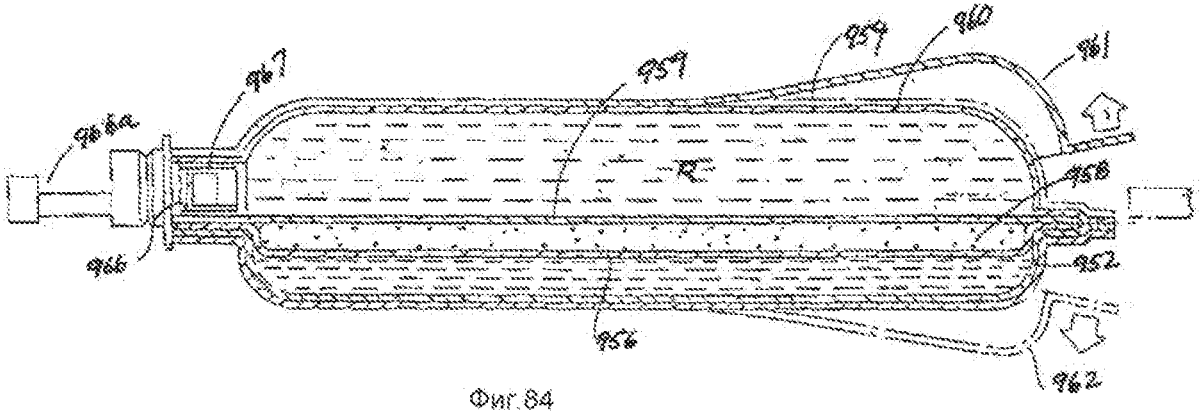

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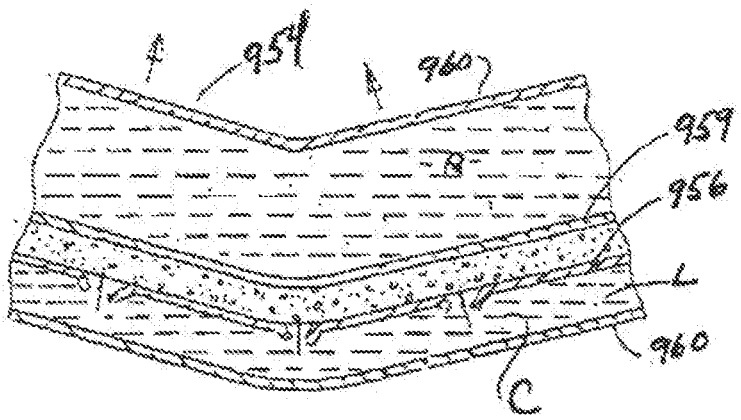

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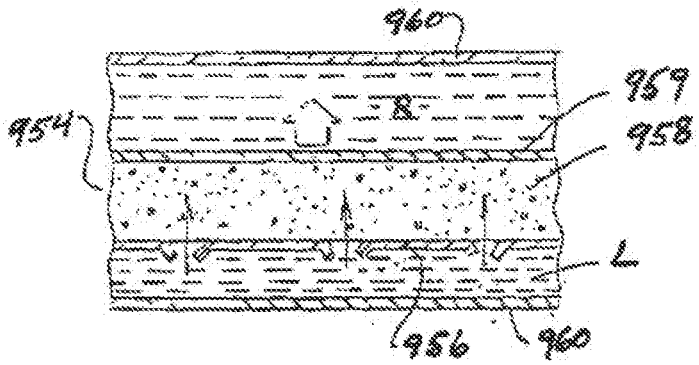

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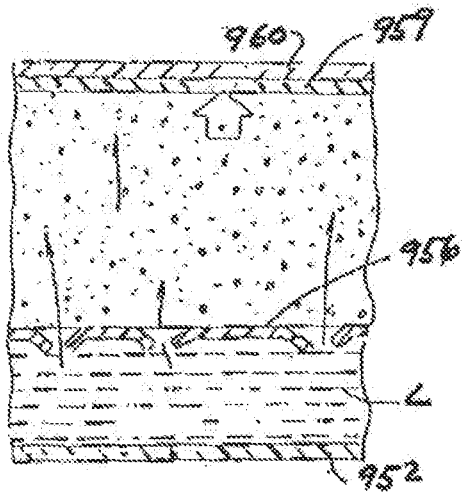

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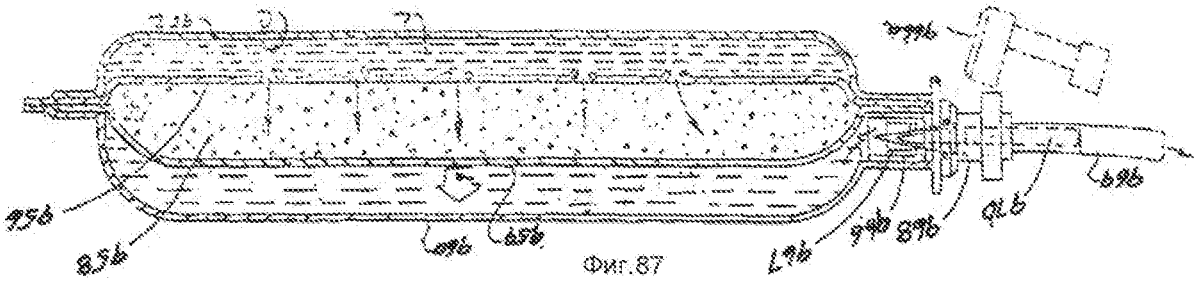

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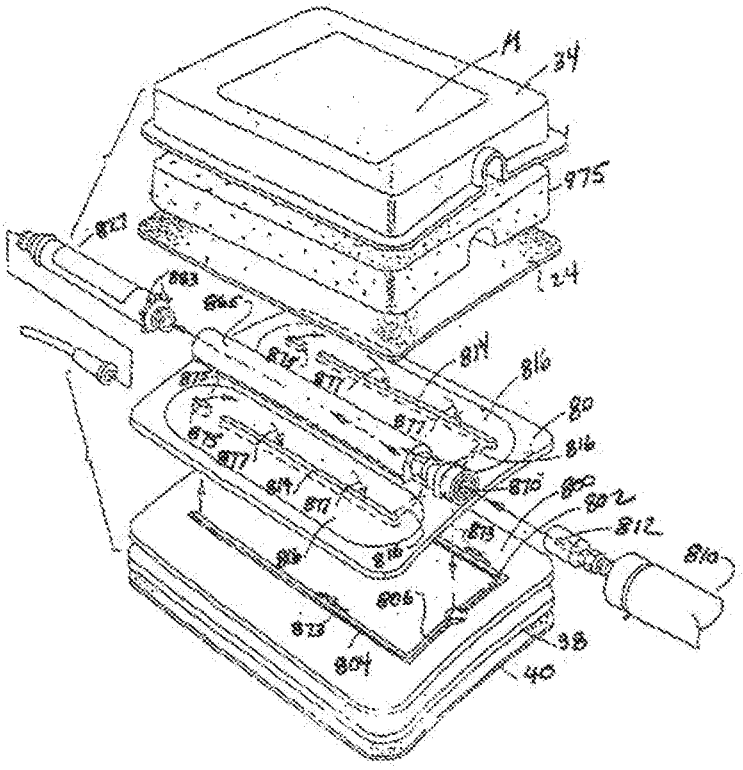

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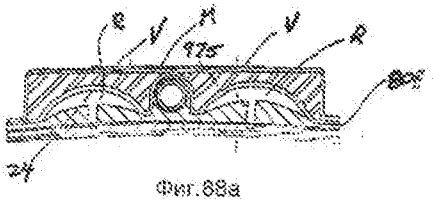

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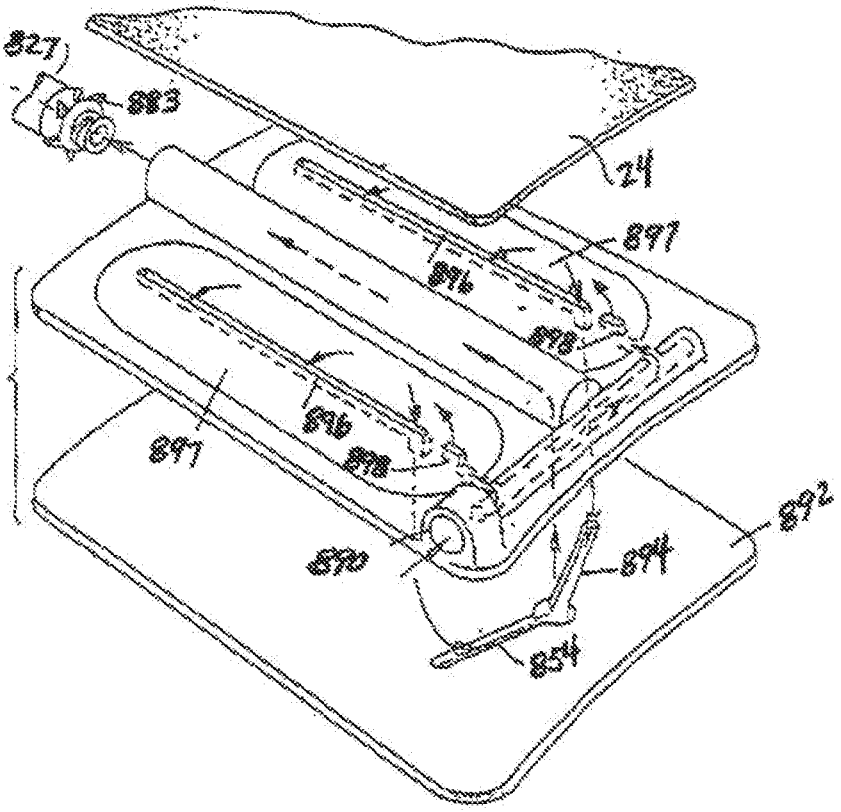

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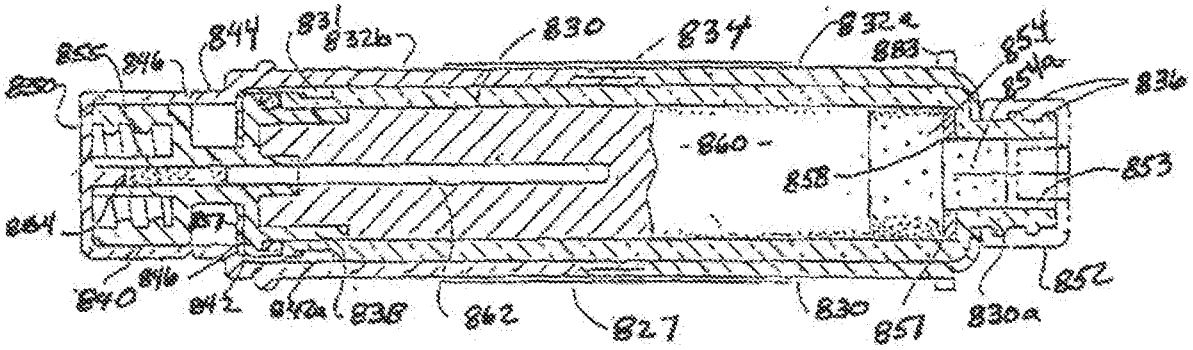

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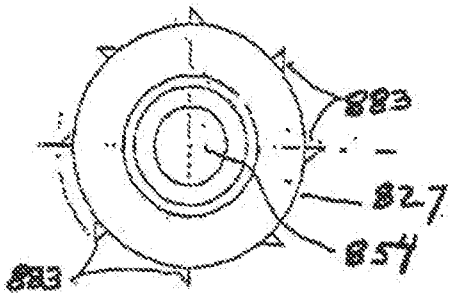

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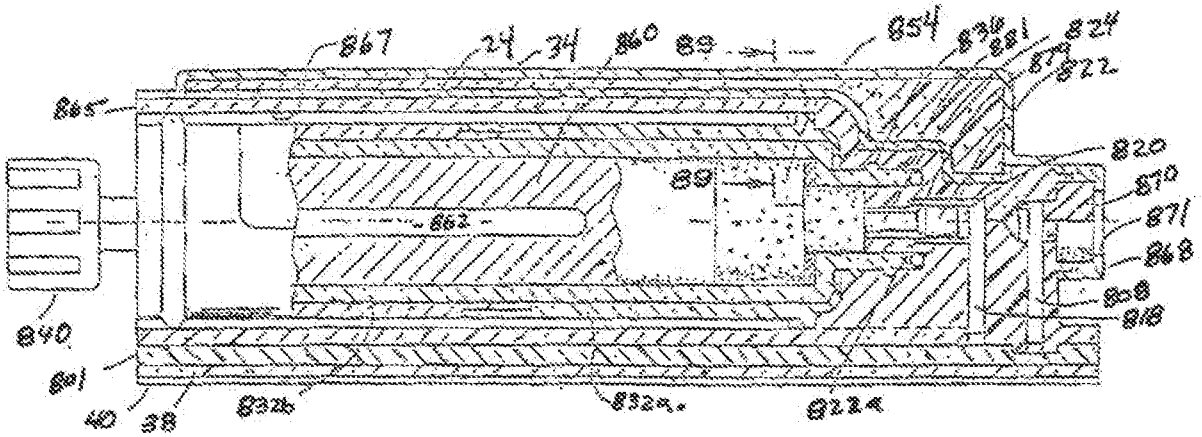

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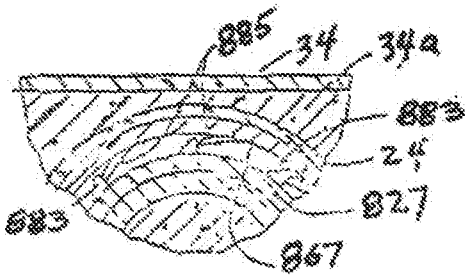

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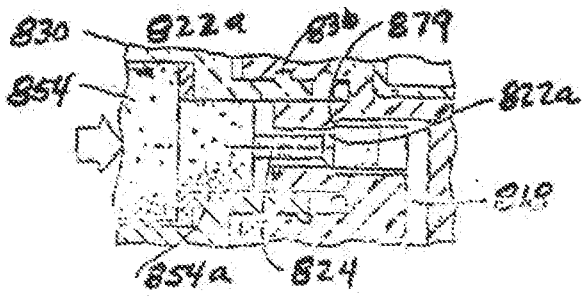

Фиг.94

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12808467
	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

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	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-11-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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EXAMINER	
FOLEY, EILEEN DOROTHY	
ART UNIT	**PAPER NUMBER**
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NOTIFICATION DATE	DELIVERY MODE
10/02/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Office Action Summary	Application No. 12/808,467	Applicant(s) HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-7 and 36-50* is/are pending in the application.

5a) Of the above claim(s) *6,7,36,49 and 50* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5 and 37-48* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Continuation of Attachment(s) 2). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :January 18, 2013; March 29, 2013; May 23, 2013; July 2, 2013; August 26, 2013.

DETAILED ACTION

Response to Amendment

1. The Response filed on March 29, 2013 is acknowledged. Claims 1-7 and 36-50 are pending with claims 6-7, 36, and 49-50 withdrawn based on a prior restriction/election requirement.

Information Disclosure Statement

2. The Supplemental information disclosure statement (IDS) submitted on January 18, 2013 has been considered by the examiner.

3. The information disclosure statements (IDS) submitted on March 29, 2013, May 23, 2013, July 2, 2013, and August 26, 2013 have been considered by the examiner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. (US Publication No. 2007/0213848 A1) (hereinafter "deKemp et al. US '848") (cited in the Office Action dated January 4, 2013) in view of Fago (US Publication No. 2008/0237502 A1).

Regarding claim 1, deKemp et al. US '848 teaches an eluent reservoir (*reservoir (4)* (paragraph [0025]; Figure 3)), a pump coupled to the reservoir (*pump (6)* (paragraph [0025]; Figure 3)), an infusion tubing circuit (*generator valve (16), bypass line (18), patient valve (24), elution system (14)* (paragraph [0025]; Figure 3) *and feed-line (33)* (paragraph [0028]; Figure 5)), a radioisotope generator (*strontium-rubidium ($^{82}Sr/^{82}Rb$) generator (8)* (paragraph [0025]; Figure 3)), an activity detector (*positron detector (20)* (paragraph [0025]; Figure 3)), a waste bottle (*waste reservoir (26)* (paragraph [0025]; Figure 3)), a computer (*controller (28)* (paragraph [0025]; Figure 3)) and a computer interface (*user interface (44)* (Figure 3)). deKemp et al. US '848 also teaches the infusion tubing circuit including an eluant line coupled to the pump and to the generator (*pump (6) for drawing saline from reservoir (4)* (paragraph [0025])) and an eluate line coupled to the generator, to the activity detector and to the waste bottle (*generator valve (16) to proportion saline flow between the generator (8) and a bypass line (18) which meet at merge point (22), a positron detector (20) downstream of merge point (22), a patient valve (24) to control supply of saline to patient outlet (10) and waste reservoir (26)* (paragraph [0025])).

deKemp et al. US '848 further teaches a controller (28) is connected to pump (6), positron detector (20), valves (16) and (24), and user interface (44) (paragraph [0025]; Figure 3) that pump (6) and valves (16, 24) are controlled to route saline through the system (14) in

accordance with various modes of operation (paragraphs [0029]-[0032]; Figures 6a-6d). deKemp et al. US '848 teaches a pump (6) for drawing saline from the reservoir (4) at a desired flow rate (paragraph [0025]). During an "elution" mode, deKemp et al. US '848 discloses generator valve (16) is actively controlled by a control loop (42) from the positron detector (20) to proportion saline flow through both the generator (8) and bypass line (18) (paragraph [0032]).

deKemp et al. US '848 does not explicitly teach the use of a computer to control the modes of operation of the system, providing an indication that the elution is complete, or providing an indication of a time lapse.

Fago teaches visualization of the eluate collection bottle (34) facilitates determining when the elution process is complete, e.g. the eluate collection bottle (34) is full (paragraph [0031]). Fago teaches a syringe pump (40 is adapted to inject the eluent (18) into the generator (22) via tubing (10) (paragraph [0032]). Fago teaches a drip chamber (44) is incorporated in the tubing (10) to facilitate tracking or identification of an amount of eluent flowing into a generator (22) (paragraph [0033]; Figure 6). Fago teaches an electronic drop counter (46) may be used to count the drops passing through the drip chamber (44) by using an LED (48) and a photo detector (50) to determine when a drop passes through the drip chamber (44) (paragraph [0033]; Figure 7). Fago teaches this facilitates the provision of metrics relating to the amount of eluant being passed from the eluant passing from the eluent supply container (4) into the generator (22) (paragraph [0033]). Fago teaches the drop counter (46) is coupled to an electronic device and/or computer (54) to store data, facilitate communication with other device, and/or perform calculations relating to the elution process (paragraph [0034]). Fago teaches the drop counter (46) is communicatively coupled to a display (52) for displaying metrics relating to the elution

process and that the display may be incorporated into the computer (54) (paragraph [0034]). Fago teaches the volume and/or time associated with each elution process may be tracked and displayed to enable the user to estimate when the generator will be ready for another elution process ("providing an indication via the computer interface that each elution is completed and of a time lapse since each elution was completed") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of controlling an $^{82}Sr/^{82}Rb$ elution system of deKemp et al. US '848 to include the displayed volume and time calculations taught by Fago in order to estimate when a generator will be ready for another elution process (Fago, paragraph [0034]).

Regarding claim 43, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110), or to a shielded waste container (90) ("diverting an initial volume of eluate to the waste bottle") (paragraph [0025]). deKemp et al. US '848 does not teach tracking the initial volume or eluate or providing an indication when the waste bottle needs to be emptied.

Fago teaches an eluate collection bottle (34) may have a standard or predefined volume (paragraph [0031]). Fago teaches a user can observe, based on the visualization portal and index marks (19), the eluent levels in the eluant supply container (4) go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle (34) ("tracking the initial volume of the eluate") (paragraphs [0026] and [0031]). Fago teaches this visualization

facilitates determining when the elution process is complete, e.g. the eluate collection bottle is full ("providing an indication when the waste bottle needs to be emptied") (paragraph [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the waste bottle of deKemp et al. US '848 to include the visualization portal and index marks taught by Fago in order to track the amount of fluid in the bottle (Fago, paragraph [0031]).

7. Claims 2-4, 38, 39, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Tate et al. (US Publication No. 2008/0177126 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 2, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]) and Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]), but the combination does not teach maintaining a record of the elutions.

Tate teaches a Records or Injection History button (1022) (paragraph [0181]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

elution system of deKemp et al. US '848 and Fago to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

Regarding claim 3, Tate teaches printing the injection information, including information about the activity and volume of the dose delivered to the patient and displaying it in pop-up (1240) (paragraph [0235]).

Regarding claim 4, Tate teaches a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]).

Regarding claim 38, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1. deKemp et al. US '848 teaches sampling the activity level in the dose calibrator at regular intervals throughout the duration of the elution run (paragraph [0055]). deKemp et al. US '848 also teaches calibration data collected during the elution can be used to calculate the proportionality constant K between the activity parameter (C_{det}) and the ^{82}Rb activity concentration (paragraphs [0056]-[0057]). The combination of deKemp et al. US '848 and Fago does not teach providing via the computer interface, calibration data entry fields for a user.

Tate teaches user-friendly data entry mechanisms for the system (10) (paragraph [0170]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the calibration and activity data of deKemp et al. US '848 and Fago to be input by a user through the user-friendly data entry mechanisms taught by Tate in order to clearly and unambiguously communicate the current status of the system to an operator (Tate, paragraph [0170]).

Regarding claim 39, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1, but does not teach providing a patient identification entry field for a user to enter a patient identification number, receiving a detected activity level of a dose of eluate from the activity detector, or compiling a report that includes an identification number for the generated dose and detected activity level.

Tate teaches the touch screen arrangement (1000) can be used for four categories of tasks, including Patient Treatment (paragraph [0172]). Tate discloses the "Patient Treatment" category includes a number of tasks including inputting patient and/or case identification information into the system (10) and measuring the activity level of the radiopharmaceutical dose (paragraph [0207]). Tate teaches that the pharmaceuticals are used in imaging procedures (paragraph [0069]). Tate teaches that the printer (24) may be used to generate records of the injection and/or imaging procedures performed for inclusion in their medical records (paragraph [0075]). Tate discloses a "Case Information" pop-up display (1217) including an "Identification" field (1217a) and a keypad (1217j) for inputting a patient or other identification number (paragraph [0216]). Tate also discloses a detailed injection history display (1360), which includes activity level of the injection and the patient identification number, and can be printed using "Print" button (1363) (paragraph [0245]; Figure 34B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the identification information taught by Tate in order to generate records of the injection and/or imaging procedures performed for inclusion in patient's medical records (Tate, paragraph [0075]).

Regarding claim 44, the combination of deKemp et al. US '848 and Fago teaches the system of claim 1, but does not teach the computer interface comprises a touch-activated display screen.

Tate teaches that the fluid delivery system (10) includes a display or graphical user interface display (15) for programming and operating the system (10) and may incorporate touch-screen capability (paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the touch-screen capability taught by Tate for ease of use of the system (Tate, paragraph [0071]).

Regarding claim 48, Tate teaches the fluid delivery system (10) includes a printer (24) (paragraph [0074]). Tate teaches that the printer (24) may generate records of the injection and/or imaging procedures performed on patients and may be pivotally connected to the system (10) to allow an operator to load paper or labels into the printer (24) (paragraph [0075]; Figure 1B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the printer taught by Tate in order to include data in patients' medical records or for billing/inventory purposes (Tate, paragraph [0075]).

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Tate and deKemp (US Publication No. 2007/0140958 A1) (hereinafter "deKemp US '958") (cited in the Office Action dated January 4, 2013).

Regarding claim 5, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 teaches a control algorithm that regulates a flow rate and volume of the sterile saline solution (100) pumped through the generator column (10) and controls valve (108), which directs the eluate through a delivery line (112) for a calibration elution or a patient elution (110) ("categorizing each counted elution as having been generated as a sample or a dose") (paragraph [0025]).

Fago teaches computer (54) may be coupled to each of a plurality of drop counters (46) and/or displays (52) that provide data relating to elution processes in each of the generators (22), such as time associated with each counted drop or a volume associated with the number of counted drops ("counting elutions per unit time") (paragraphs [0034] and [0036]). Fago teaches an actual radioactivity level of the eluate can be determined at a given time, programmed into the computer (54) ("receiving a detected activity level and entering the detected activity level for each elution into the record") (paragraph [0034]). Fago teaches the radioactivity level can be incorporated with other data to determine an expected radioactivity level at a specified future time and thus estimate when the generator will be ready for another elution process ("calculating and tracking the amount of activity left in the generator after each elution") (paragraph [0034]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of deKemp et al. US '848 to include the radioactivity information and estimations taught by Fago in order to estimate when a generator will be ready to perform another elution process (Fago, paragraph [0034]).

The combination of deKemp et al. US '848 and Fago does not teach maintaining a record of the elutions or compiling a report that includes an amount of activity left in the generator.

Tate discloses user-friendly data entry mechanisms for the system (10) (paragraph [0170]). Tate teaches a Records or Injection History button (1022) (paragraph [0181]) and a printer (24) used to generate records of the injection and/or imaging procedures performed on patients (paragraph [0075]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elution system of deKemp et al. US '848 and Fago to include the Records or Injection History function of Tate in order to access information regarding prior injection procedures (Tate, paragraph [0181]).

The combination of deKemp et al. US '848, Fago, and Tate does not teach compiling a report that includes an amount of activity left in the generator.

deKemp US '958 teaches a control algorithm and a valve (108) direct the eluate through a delivery line (112) for a calibration elution or a patient elution (110) (paragraph [0025]). deKemp US '958 teaches that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough to determine if the yield is above a predetermined radioactivity limit (paragraph [0029]; Figure 5). deKemp US '958 teaches control software controls a volume of fluid during generator column (10) flushes and elutions, and accepts the cumulative volume and stores it (paragraph [0031]). deKemp US '958 further teaches that the cumulative volume is recomputed after each elution and disposing of the generator column if the volume limit is exceeded (paragraph [0032]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yield and volume determinations of deKemp US '958 in the records of the computer controlled elution system of deKemp et al. US '848, Fago, and Tate in order to determine if the generator column can continue to be used for patient elutions (deKemp US '958, paragraph [0028]).

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of deKemp US '958.

Regarding claim 37, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach providing a first and second set of breakthrough test data entry fields.

deKemp US '958 teaches generator column (10) is flushed with 50 ml of sterile saline solution in order to remove any strontium breakthrough, then the operator waits for a predetermined period of time (at least 10 minutes) before performing the calibration elution (paragraph [0029]). Then, deKemp US '958 discloses that the calibration eluate is tested for ^{82}Rb yield and ^{82}Sr breakthrough (paragraph [0029]). deKemp US '958 discloses that those skilled in the art would know to test the radioactivity of the elution after about 26 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and will no distort the test results (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the breakthrough measurements taught by deKemp US '958 in the computer controlled elution system of deKemp et al. US '848 and Fago in order to determine if breakthrough is less than a threshold for permissible levels (paragraph [0030]).

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Telischak et al. (US Patent No. 7,996,068 B2) (cited in the Office Action dated January 4, 2013).

Regarding claim 40, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the pump is activated.

Telischak teaches a visible light is projected at all times when the device is activated (column 8, lines 18-26). It would have been obvious to one of ordinary skill in the art to include the light projecting when the device is activated disclosed by Telischak in the pump of the computer controlled infusion system of deKemp et al. US '848 and Fago in order to confirm that the device is operational (Telischak, column 8, lines 24-25).

11. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Ellingboe et al. (US Publication No. 2006/0015056 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 41, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection. deKemp et al. US '848 also teaches a "waiting for threshold" mode of system (14), in which the saline flow is routed through the generator (8) and into the waste reservoir (26) (paragraph [0031]) and an "elution" mode where the active saline solution is directed to the patient outlet (paragraph [0032]). Neither deKemp et al. US '848 nor Fago teach a light projector or providing a first light signal when an initial volume of eluate is being diverted or providing a second light signal when the pumping is generating the sample or the dose of eluate.

Ellingboe teaches an animated light indicator may be provided to indicate when cardioplegia is being delivered (e.g. via green illumination) and when delivery is stopped (e.g. via red illumination) (paragraph [0243]; Figure 301). It would have been obvious to one of ordinary skill in the art to include the different illumination signals disclosed by Ellingboe in the computer controlled infusion system of deKemp et al. US '848 and Fago in order to provide indicators to the operator regarding which stage of the infusion is occurring.

12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Bergner (US Patent No. 4,585,941) (cited in the Office Action dated January 4, 2013).

Regarding claim 42, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach a light projector or providing a light signal when the activity detector detects a peak bolus of radioactivity.

Bergner teaches an LED display (100) is immediately about the total dose thumbwheel switches (98) and displays the total dose which has been infused in the patient (56) (column 5, lines 8-25). Bergner teaches the actual dose rate which is present in the eluate within the tube (30) in front of the dosimetry probe (58) is displayed on LED display (104) (column 5, lines 8-25). It would have been obvious to one of ordinary skill in the art to include the LED signals based on actual dose disclosed by Bergner in the computer controlled infusion system of deKemp et al. US '848 and Fago in order to provide a description of the dose present in the eluate (Bergner, column 5, lines 19-22).

13. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Varrichio et al. (US Publication No. 2005/0187515 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 45, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach at least one sensor for detecting a leak in the tubing and providing an indication that a leak has been detected.

Varrichio et al. teaches a sensor (251) that may be utilized to detect a leak in the valve system (241) (paragraph [0027]). Varrichio et al. teaches that if one of the flow valves leaks, a midpoint pressure will drift higher if primary flow valve (343) is leaking and lower if redundant flow valve (344) is leaking, thus providing an indication that a leak has been detected (paragraph [0036]). Varrichio et al. discloses a user interface for external program controller (260), which provides real-time status information with respect to infusate pump (200) and may provide audible alarms upon detection of particular conditions and may report conditions to the doctor using information from sensor (251) (paragraphs [0027] and [0031]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the leak detecting sensor of Varrichio et al. in the computer controlled elution system of deKemp et al. US '848 and Fago in order to provide feedback to the doctor (Varrichio et al., paragraph [0027]).

14. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Padda et al. (US Patent No. 5,395,320) (cited in the Office Action dated January 4, 2013).

Regarding claim 46, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach calculating a flow rate profile or controlling a speed of the pump according to the calculated flow rate profile.

Padda teaches an infusion pump which can be programmed to deliver any of a variety of selected profiles of fluid medicine volume over time (Abstract). Padda discloses examples of delivery profiles including fixed rate of flow, ramp up, ramp down, fixed rate with increased rate spikes at specified intervals, and no flow with an infusion bolus at specified intervals (column 2, lines 42-50). Padda teaches a pumping mechanism (24) provides accurate delivery of medicine

(column 4, lines 9-10). Padda teaches a piggyback delivery profile function which allows for the use of a second profile applied before, during an interrupt, or after the first profile, and a different medicine and different fluid to be infused through the infusion pump (column 4, line 59-column 5, line 6). Padda discloses a CPU that sends a motor control drive (14) a code containing information on the desired motor speed and a motor speed control (15) (column 6, line 66-column 7, line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flow control and profile mechanisms of Padda in the computer controlled elution system of deKemp et al. US '848 and Fago in order to provide a variety of different fluid delivery profiles to a patient (Padda, column 2, lines 31-34).

15. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over deKemp et al. US '848 in view of Fago, as applied to claim 1 above, and further in view of Whittacre et al. (US Publication No. 2003/0139640 A1) (cited in the Office Action dated January 4, 2013).

Regarding claim 47, the combination of deKemp et al. US '848 and Fago teaches the infusion system of claim 1, as discussed in the above rejection, but does not teach transferring a plurality of detect activity levels to another system.

Whittacre teaches a display of the amount of isotope which is generating the radioactivity and transferring those values to a database if accepted by the operator (paragraph [0195]). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the data transfer of Whittacre in the computer controlled elution system of deKemp et al. US '848 and Fago in order to allow one or more physicians to access the displayed information (Whittacre, paragraph [0202]).

Response to Arguments

16. Applicant's arguments, see pages 2-8 of the Remarks, filed March 29, 2013, with respect to the rejections of claims 1-5 and 37-48 under 35 U.S.C. § 103(a) have been fully considered and are persuasive. In particular, Applicant's arguments that Tate cannot provide indications of a time lapse since each elution was completed since Tate does not teach a system that generates radiopharmaceuticals via elution is persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of deKemp et al. US '848 and Fago, which is related to elutions and radioisotope generation and provides indications of the steps of the elution process through an electronic drop counter (see above rejection).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EILEEN FOLEY whose telephone number is (571) 270-7248. The examiner can normally be reached Monday-Thursday, and alternate Fridays, from 7:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner, Art Unit 3735

/E. F./
Examiner, Art Unit 3735

Notice of References Cited	Application/Control No. 12/808,467	Applicant(s)/Patent Under Reexamination HIDEM ET AL.	
	Examiner EILEEN FOLEY	Art Unit 3735	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2008/0237502 A1	10-2008	Fago	250/506.1
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. HIDEM
Art Unit	3735
Examiner Name	FOLEY, Eileen D.
Attorney Docket Number	56782.1.7.2

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	1	1968653	CN		2007-05-23	E Z EM INC.		☐

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Receipt date: 03/29/2013	Application Number	12808467 12808467 - GAU: 3735
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	First Named Inventor	Stephen E. HIDEM
	Art Unit	3735
	Examiner Name	FOLEY, Eileen D.
	Attorney Docket Number	56782.1.7.2

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	Art Unit	3735
	Examiner Name	FOLEY, Eileen D.
	Attorney Docket Number	56782.1.7.2

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-03-29
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

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	First Named Inventor	Stephen E. Hidem
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	Examiner Name	Eileen Dorothy Foley
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Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	1	R. KLEIN, , "Precision control of eluted Activity from a Sr/Rb generator for cardiac positron emission tomography" Proceedings of the 26th Annual International Conference of the IEEE EMBS San Francisco, CA, USA, September 1-5, 2004, 4 pages	☐

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Examiner Signature	/Eileen Foley/	Date Considered	07/18/2013

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 07/02/2013	Application Number	12808467	12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16	
	First Named Inventor	Stephen E. Hidem	
	Art Unit	3735	
	Examiner Name	Eileen Dorothy Foley	
	Attorney Docket Number	56782.1.7.2	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-07-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

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(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 01/18/2013	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	1	R. Klein, "Precise 82RB infusion system for cardiac perfusion measurement using 3D positron emission tomography", Ottawa-Carleton Institute for Electrical and Computer Engineering School of Information Technology and Engineering (Electrical & Computer Engineering), February, 2005, 147 pages	☐
	2	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (copyright date May 2008)	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Eileen Foley/	Date Considered	07/18/2013

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-01-17
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	72	(US-20090318745-$ or US-20080242915-$ or US-20080177126-$ or US-20080166292-$ or US-20060151048-$ or US-20070140958-$ or US-20070213848-$ or US-20090312630-$ or US-20110172524-$ or US-20100312039-$ or US-20090312635-$ or US-20080071219-$ or US-20090131862-$ or US-20050277833-$ or US-20050085682-$ or US-20040092787-$ or US-20090292156-$ or US-20030139640-$ or US-20090309465-$ or US-20080093564-$ or US-20070282263-$ or US-20090299277-$ or US-20050187515-$ or US-20110028775-$ or US-20100286512-$ or US-20050203329-$).did. or (US-20080097170-$ or US-20070287895-$ or US-20060015056-$ or US-20090266998-$ or US-20080237502-$).did. or (US-7612999-$ or US-7204797-$ or US-7169135-$ or US-7163031-$ or US-6870175-$ or US-6157036-$ or US-4585941-$ or US-4562829-$ or US-4336036-$ or US-4096859-$ or US-3997784-$ or US-3774036-$ or US-3714429-$ or US-3710118-$ or US-7862534-$ or US-6767319-$ or US-6626862-$ or US-4585009-$ or US-6659934-$ or US-7838844-$ or US-5317506-$ or US-8137083-$ or US-8105269-$ or US-8071959-$ or US-7925330-$ or US-7813841-$).did. or (US-7734331-$ or US-5840026-$ or US-4625118-$ or US-7700926-$ or US-4406877-$ or US-5395320-$ or US-6928338-$ or US-6731971-$ or US-6901283-$ or US-6168563-$ or US-7996068-$ or US-7141795-$ or US-4018677-$ or US-5039863-$).did. or (US-3997784-$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/17 09:19
L3	65	L2 and (count$3 or tally$3 or number$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/17 09:20
L4	940	(generat$3 with (radioisotope or isotope)) same (count$3 or tally$3 or number$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/17 09:20
L5	16	L2 and ((count$3 or tally$3 or	US-	OR	ON	2013/09/17

		number$3) same elution)	PGPUB; USPAT; USOCR			09:20
L6	0	(generat$3 with (radioisotope or isotope)) same (record$3 with elution)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/17 09:26
L7	17	(generat$3 with (radioisotope or isotope)) same ((count$3 or tally$3 or number$3) with elution)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/17 09:26
S2	3	((STEPHEN) near2 (HIDEM)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:55
S3	2	((AARON) near2 (FONTAINE)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:55
S4	2	((JANET) near2 (GELBACH)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:55
S5	43	((PATRICK) near2 (MCDONALD)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:56
S6	2	((KATHRYN) near2 (HUNTER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:56
S7	86	((ROLF) near2 (SWENSON)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:56
S8	19	((JULIUS) near2 (ZODDA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 15:56
S10	73	("20070213848" | "4625118" | "4679142" | "5258906" | "6157036" | "6767319" | "20090318745" | "6908598" | "5827429" | "5485831" | "5739508" | "5885216" | "6442418" | "20090312630" | "7504646" | "7862534" | "3714429" | "20070140958" | "4562829" | "5590648" | "5840026" | "20070232980" | "20090309466" | "20090312635" | "7163031" | "4096859" | "4769008" | "20070282263" | "20080093564" | "4585941" | "5039863" | "20060151048" | "20100125243" | "20100270226" | "20080166292" | "20080242915" | "3774036" | "3997784" | "4286169" | "5274239" | "7256888" | "20090309465" | "20100312039" | "3483867" | "4336036" | "5765842" |	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 16:09

		"20080071219" | "4853546" | "6870175" | "6901283" | "7204797" | "20060015056" | "4994056" | "6347711" | "6558125" | "20080177126" | "4755679" | "5475232" | "7476377" | "20040104160" | "20110071392" | "20050278066" | "3710118" | "4585009" | "6626862" | "7169135" | "7413123" | "4466888" | "4623102" | "5702115" | "7612999").PN.				
S11	5849	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 16:26
S12	4715	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/09 16:26
S19	3	((STEPHEN) near2 (HIDEM)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S20	2	((AARON) near2 (FONTAINE)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S21	2	((JANET) near2 (GELBACH)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S22	43	((PATRICK) near2 (MCDONALD)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S23	2	((KATHRYN) near2 (HUNTER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S24	86	((ROLF) near2 (SWENSON)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S25	19	((JULIUS) near2 (ZODDA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S26	147	S19 or S20 or S21 or S22 or S23 or S24 or S25	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 09:48
S27	5852	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:00
S28	4719	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:00

S29	10502	S27 or S28	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:00
S30	2527966	(time or seconds or minutes) near3 (lapse or duration or period or span or length)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:01
S31	5288	S29 and S30	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:01
S32	130946	((strontium or Sr) with (rubidium or Rb)) or isotope or radioisotope or radio-isotope	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:02
S33	918	S31 and S32	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:02
S34	359	S33 and computer	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:02
S35	65	S33 and (computer with interface)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 10:03
S36	75299	(automated near3 dispensing near3 system) or dosimetry or (radioisotope or radio-isotope or radio adj isotope) or (radio adj pharmaceutical or radiopharmaceutical)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 12:56
S37	1429	computer with (display or screen or output) with time near3 (lapse or elapsed or duration)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 13:02
S38	12	S36 and S37	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 13:02
S39	49	("20030004463" | "20050278066" | "20060015056" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080242915" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5590648" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN. OR ("7862534").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 13:05

S41	1	"20030004463".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 15:32
S43	1	"20080093564".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 15:37
S47	146	600/4.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/11 15:50
S49	1	"20080177126".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 10:42
S50	279	604/526.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 10:45
S51	12456	(((strontium or Sr) with (rubidium or Rb)) or isotope or radioisotope or radio-isotope or radiopharmaceutical) with (administration or system or delivery or infusion)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 12:01
S52	70873	((display or screen or output) with time near3 (lapse or elapsed or duration)) or (progress near3 (bar or indicator or indication))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 12:02
S53	52	S51 and S52	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 12:02
S54	37	S53 and computer	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 12:03
S55	49	("20030004463" | "20050278066" | "20060015056" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080242915" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5590648" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN. OR ("7862534").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 12:05
S56	36	S51 and ((count$3 or tally$3 or enumerat$3 or add$3) with elution$1 with time)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:21

S57	0	"2007140958".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:31
S58	1	"20070140958".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:31
S59	228	600/4,5.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:41
S60	48	S59 and (report$3)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:42
S61	1	"20080177126".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:46
S63	1	"20080071219".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:48
S64	5865	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:50
S65	4723	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:50
S66	10518	S64 or S65	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:50
S67	10518	S66	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:50
S68	352	S67 and (report$3 with (function or process or aspect))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:51
S69	159	S68 and (injection or infusion)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:52
S70	2	S59 and (report with (generate or generation))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 14:57
S71	31	elution with sample with dose	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:20
S72	4	S59 and (breakthrough or break near2 through)	US-PGPUB; USPAT;	OR	ON	2012/07/12 15:27

			USOCR			
S73	140	S67 and (breakthrough or break near2 through)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:27
S74	347	S51 and (breakthrough or break adj through)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:36
S75	4	dekemp.inv.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:40
S76	397	S51 and ((record or save or list or track) with (elution or level or value))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:54
S77	17	S76 and S52	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:54
S78	1	"20090309465".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 15:56
S79	352	(sort or categorize or classify or identify) with (sample and dose)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 16:19
S80	1	S79 and S59	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 16:19
S81	57434	(sort or categorize or classify or identify) with (sample or dose)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 16:20
S82	7	S81 and S59	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 16:20
S83	228	S66 and S81	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/12 16:21
S84	5869	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:05
S85	4729	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:05
S86	10528	S84 or S85	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:05
S87	10528	S86	US-	OR	ON	2012/07/17

			PGPUB; USPAT; USOCR			09:05
S88	677	S86 and (light near3 (signal or project$2))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:07
S89	264	S88 and (infusion or dosimetry or elution)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:07
S90	1528	S86 and (((strontium or Sr) with (rubidium or Rb)) or isotope or radioisotope or radio-isotope or radiopharmaceutical)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:55
S91	307	S90 and count	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 09:56
S92	97	(Bracco near2 Diagnostics).as.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 11:51
S93	5869	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:52
S94	4729	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:52
S95	10528	S93 or S94	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:52
S96	10528	S95	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:52
S97	1528	S96 and (((strontium or Sr) with (rubidium or Rb)) or isotope or radioisotope or radio-isotope or radiopharmaceutical)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:52
S98	363859	(maintain$3 or keep$3 or updat$3 or provid$3) with (record or list or archive or journal or log or report)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:55
S99	47	S97 and S98	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:55
S100	5355	S96 and (infusion or injection or elution or dosimetry)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:58
S101	383	S100 and S98	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:59

S102	180	S101 and (radio)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 15:59
S103	51	("3528407" | "3827427" | "4091287").PN. OR ("4585941").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 16:44
S104	49	("20030004463" | "20050278066" | "20060015056" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080242915" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5590648" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN. OR ("7862534").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 16:46
S105	21	("20030073854" | "2845136" | "3164980" | "3935884" | "3969243" | "4175037" | "4193867" | "4379855" | "4400358" | "4406877" | "4562829" | "4585009" | "4585941" | "5545319" | "5693223" | "6157036" | "6197174" | "6908598" | "7476377").PN. OR ("8071959").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 16:48
S106	21	("20010009994" | "20040154690" | "3935883" | "4296785" | "5039863" | "5329976" | "5479969" | "5831271" | "5911252" | "7017623").PN. OR ("7163031").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 16:49
S107	48	quirico.inv.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 17:23
S108	13	S107 and light	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/17 17:24
S109	51	("3528407" | "3827427" | "4091287").PN. OR ("4585941").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:12
S110	49	("20030004463" | "20050278066" | "20060015056" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080242915" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" |	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:12

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S113	126	S109 or S110 or S111 or S112	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:12
S114	2	S113 and (breakthrough or break adj through) same (shield$3 with (vial or tube or container))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:13
S115	12	S113 and (breakthrough or break adj through)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:14
S116	118	dosimetry and light	DERWENT	OR	ON	2012/07/18 08:48
S117	49	radiopharmaceutical and (injusion or injection or administration) and light	DERWENT	OR	ON	2012/07/18 08:49
S119	67	S113 and (sensor or leak)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 08:59
S120	24	S113 and (sensor and leak)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:00
S121	5869	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:01
S122	4729	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:01
S123	10528	S121 or S122	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:01

S124	10528	S123	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:01
S125	170	S124 and (sensor same leak)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/18 09:01
S126	1	"20090312630".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/19 11:17
S127	1	"7813841".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:01
S128	13	("4585009" | "4585941" | "4975583" | "6049026" | "6641783" | "6713765" | "6731971" | "6733477" | "6733478" | "6901283" | "6928338" | "7169135" | "7174240").PN. OR ("7813841").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:02
S129	51	("3528407" | "3827427" | "4091287").PN. OR ("4585941").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:03
S130	5887	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:05
S131	4741	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:05
S132	10558	S130 or S131	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:05
S133	347	S132 and (shield$2 with (vial or tube or container))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:06
S134	8	S133 and (breakthrough)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:06
S135	109	S133 and (calibrat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:08
S136	257	S132 and (transfer$4 with analysis)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:55
S137	33	S132 and (transfer$4 same analysis same activity)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 08:55
S138	66	S132 and (transfer$4 same analysis	US-	OR	ON	2012/07/26

		same level)	PGPUB; USPAT; USOCR			08:56
S139	782	S132 and ((control or regulate) with (speed or rate) with pump)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:18
S140	265	S139 and profile	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:19
S141	99	("3685697" | "3809871" | "3901231" | "3908652" | "3985133" | "4085747" | "4155362" | "4187057" | "4221543" | "4256437" | "4276004" | "4278085" | "4443218" | "4457751" | "4493706" | "4519792" | "4529401" | "4537561" | "4617014" | "4653987" | "4657490" | "4664430" | "4668220" | "4685903" | "4689043" | "4690673" | "4692145" | "4714462" | "4725205" | "4728265" | "4731051" | "4741736" | "4744786" | "4749109" | "4752289" | "4756706" | "4758228" | "4771694" | "4781548" | "4785799" | "4808167" | "4838860" | "4840542" | "4846637" | "4850971" | "4850980" | "4856339" | "4890984" | "4898578" | "4898579" | "4919650" | "4936760" | "4950136" | "4978335" | "5006050" | "5013303" | "5018945" | "5034004" | "5061242" | "5074756" | "5098261" | "5116203" | "5211548" | "5213483").PN. OR ("5395320").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:27
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S143	21	S139 and (profile with activity)	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:31
S144	12	S139 and (profile with (baseline or base))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:33
S145	5	S132 and (activity with generator with (left or remain$3 or after))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:39
S146	663	S132 and (activity with (left or remain$3 or after))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:39
S147	11	S132 and (activity with (generator or calibrator) with (left or remain$3 or after))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 09:40
S148	46	S132 and (waste with (empty$3 or emptied))	US-PGPUB; USPAT; USOCR	OR	ON	2012/07/26 11:29
S149	65	(US-20090318745-$ or US-20080242915-$ or US-20080177126-$ or US-20080166292-$ or US-20060151048-$ or US-20070140958-$ or US-20070213848-$ or US-20090312630-$ or US-20110172524-$ or US-20100312039-$ or US-20090312635-$ or US-20080071219-$ or US-20090131862-$ or US-20050277833-$ or US-20050085682-$ or US-20040092787-$ or US-20090292156-$ or US-20030139640-$ or US-20090309465-$ or US-20080093564-$ or US-20070282263-$ or US-20090299277-$ or US-20050187515-$ or US-20110028775-$ or US-20100286512-$ or US-20050203329-$).did. or (US-20080097170-$ or US-20070287895-$).did. or (US-7612999-$ or US-7204797-$ or US-7169135-$ or US-7163031-$ or US-6870175-$ or US-6157036-$ or US-4585941-$ or US-4562829-$ or US-4336036-$ or US-4096859-$ or US-3997784-$ or US-3774036-$ or US-3714429-$ or US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:10

		3710118-$ or US-7862534-$ or US-6767319-$ or US-6626862-$ or US-4585009-$ or US-6659934-$ or US-7838844-$ or US-5317506-$ or US-8137083-$ or US-8105269-$ or US-8071959-$ or US-7925330-$ or US-7813841-$).did. or (US-7734331-$ or US-5840026-$ or US-4625118-$ or US-7700926-$ or US-4406877-$ or US-5395320-$ or US-6928338-$ or US-6731971-$ or US-6901283-$ or US-6168563-$).did. or (US-3997784-$).did.				
S150	31	S149 and (patient with (identification or identify or identifying or information))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:11
S151	33	S149 and light	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:26
S152	16	S149 and (light with (signal or project$3))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:26
S153	79	("3528407" | "3827427" | "4006736" | "4091287").PN. OR ("4585009" | "4585941").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:28
S154	10	S153 and (light with (signal or project$3))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/27 16:28
S155	6222	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:11
S156	4881	604/236,65-67,48,218.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:11
S157	11029	S155 or S156	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:11
S158	124	S157 and (light near3 project$3)	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:11
S159	7	S157 and ((light near3 project$3) with pump)	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:11
S160	3	S157 and ((light near3 project$3) with activat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:12
S161	1947	((light near3 project$3) with (pump or activat$3))	US-PGPUB; USPAT;	OR	ON	2012/11/28 10:15

			USOCR			
S162	17566	((light near3 (signal or project$3)) with (pump or activat$3 or peak))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:21
S163	4410	((light near3 (signal or project$3)) with (peak))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:21
S164	803	((light near3 (signal or project$3)) with ((detect$3) near3 peak))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:21
S165	50	("20030004463" | "20050278066" | "20060015056" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080242915" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5590648" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN. OR ("7862534").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:27
S166	24	S165 and light	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:28
S167	9	((light near3 (signal or project$3)) with (detect$3 near3 peak near3 radioactivity))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:46
S168	37	((light near3 (signal or project$3)) with (detect$3 near3 radioactivity))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 10:48
S169	37	(((light or LED) near3 (signal or project$3)) with (detect$3 near3 radioactivity))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:33
S170	1421	((light or LED) near3 (signal or project$3)) with (detect$3 near3 (peak or maximum or largest or greatest or highest))	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:35
S171	42	S170 and radioactiv$2	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:35
S172	822	((light or LED) near3 (signal or project$3)) with (detect$3 near3 threshold)	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:39

S173	9	S172 and radioactiv$2	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:39
S174	154	(light near3 project$3) same (signal with detect$3 with peak)	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:41
S175	1	("20050277833").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:58
S176	1	("6450936").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/11/28 12:58
S177	68	(US-20090318745-$ or US-20080242915-$ or US-20080177126-$ or US-20080166292-$ or US-20060151048-$ or US-20070140958-$ or US-20070213848-$ or US-20090312630-$ or US-20110172524-$ or US-20100312039-$ or US-20090312635-$ or US-20080071219-$ or US-20090131862-$ or US-20050277833-$ or US-20050085682-$ or US-20040092787-$ or US-20090292156-$ or US-20030139640-$ or US-20090309465-$ or US-20080093564-$ or US-20070282263-$ or US-20090299277-$ or US-20050187515-$ or US-20110028775-$ or US-20100286512-$ or US-20050203329-$).did. or (US-20080097170-$ or US-20070287895-$ or US-20060015056-$).did. or (US-7612999-$ or US-7204797-$ or US-7169135-$ or US-7163031-$ or US-6870175-$ or US-6157036-$ or US-4585941-$ or US-4562829-$ or US-4336036-$ or US-4096859-$ or US-3997784-$ or US-3774036-$ or US-3714429-$ or US-3710118-$ or US-7862534-$ or US-6767319-$ or US-6626862-$ or US-4585009-$ or US-6659934-$ or US-7838844-$ or US-5317506-$ or US-8137083-$ or US-8105269-$ or US-8071959-$ or US-7925330-$ or US-7813841-$).did. or (US-7734331-$ or US-5840026-$ or US-4625118-$ or US-7700926-$ or US-4406877-$ or US-5395320-$ or US-6928338-$ or US-6731971-$ or US-6901283-$ or US-6168563-$ or US-7996068-$ or US-7141795-$).did. or (US-3997784-$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:24
S178	6852	600/1-8,301,431.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:24
S179	5165	604/236,65-67,48,218.ccls.	US-PGPUB;	OR	ON	2013/08/13 15:24

			USPAT; USOCR			
S180	11938	S178 or S179	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:24
S181	15	S180 and ((indicator or indication) with lapse)	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:25
S182	1106	S180 and ((indicator or indication) with time)	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:26
S183	210	S180 and (((indicator or indication) with time) same (elution or generat$3))	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:26
S184	8	S177 and (((indicator or indication) with time) same (elution or generat$3))	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:26
S185	8	S180 and (((indicator or indication) with time) same elut$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/13 15:27
S186	47	(US-20090312630-$ or US-20110172524-$ or US-20090309465-$ or US-20090318745-$ or US-20100312039-$ or US-20110071392-$).did. or (US-4658017-$ or US-5346988-$ or US-6261606-$ or US-6502448-$ or US-3774036-$ or US-5109160-$ or US-7862534-$ or US-8317674-$ or US-5362641-$ or US-3576998-$ or US-3655981-$ or US-3774035-$ or US-3905903-$ or US-3929600-$ or US-3972918-$ or US-3979287-$ or US-3998627-$ or US-4018677-$ or US-4020351-$ or US-4028355-$ or US-4041317-$ or US-4155982-$ or US-4279869-$ or US-4280985-$ or US-4287159-$ or US-4296785-$).did. or (US-4298578-$ or US-4330507-$ or US-4403039-$ or US-4423008-$ or US-4427639-$ or US-4435437-$ or US-4465622-$ or US-RE31687-$ or US-4541952-$ or US-4612367-$ or US-4677192-$ or US-4697003-$ or US-4710474-$ or US-4727034-$ or US-4729380-$).did.	US-PGPUB; USPAT	OR	ON	2013/08/14 09:57
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S188	118	S186 or S187	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/14 10:11
S189	16	S188 and (elution with indicat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/14 10:12
S190	18	S188 and (computer with (program or programmed or execute))	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/14 10:13
S191	16	(elution with (lapse or indicator or indication)) and radiopharmaceutical	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 12:59
S192	19	("6157036").URPN.	USPAT	OR	ON	2013/09/16 12:59
S193	31	("3655981" | "4296785" | "4387303" | "4783305" | "4833329" | "4853546" | "5039863" | "5109160" | "5186913" | "5382388" | "5580541" | "5729821").PN. OR ("6157036").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:00
S194	2	S193 and (elution with (lapse or indicator or indication))	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:00
S195	6	(generat$3 with (isotope or radioisotope)) same (elution with (lapse or indicator or indication))	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:05
S196	1	(12/441919).APP.	US-PGPUB; USOCR	OR	ON	2013/09/16 13:08
S197	6781	(generat$3 with (isotope or radioisotope))	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:18

S198	3	(generat$3 with (isotope or radioisotope)) same elution same computer	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:18
S199	256	(generat$3 with (isotope or radioisotope)) same computer	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:19
S200	1	(generat$3 with (isotope or radioisotope)) same (elution with count$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:20
S201	299	(generat$3 with (isotope or radioisotope)) same (count$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:20
S202	0	(generat$3 with (isotope or radioisotope)) same (elution with categoriz$3)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:45
S203	1	(generat$3 with (isotope or radioisotope)) same (elution with sample with dose)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:45
S204	15	(generat$3 with (isotope or radioisotope)) and (elution with sample with dose)	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/16 13:45

9/17/2013 10:30:48 AM
C:\Users\efoley\Documents\EAST\Workspaces\12808467_2.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY	3735

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	1-8, 301, 431	7/9/12-7/26/12	EF
604	48, 65-67, 218, 236, 526	7/9/12-7/26/12	EF

SEARCH NOTES		
Search Notes	Date	Examiner
Limited class/subclass searches with test	7/9/12-7/26/12	EF
Text searching in EAST (see Search History)	7/9/12-7/26/12	EF
Inventor name search in EAST	7/9/12-7/26/12	EF
Assignee name search in EAST	7/9/12-7/26/12	EF
Forward/backward searches of relevant art in EAST	7/9/12-7/26/12	EF
Updated class/subclass searches	11/27/12-11/28/12	EF
Additional text searching and forward/backward searches in EAST	11/27/12-11/28/12	EF
Updated class/subclass searches and additional text searching in EAST	8/13-9/17/13	EF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/E.F./ Examiner.Art Unit 3735	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013						
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	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	N	N	N						
	7	N	N	N						
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	36	N	N	N						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12808467	HIDEM ET AL.
	Examiner	**Art Unit**
	EILEEN FOLEY	3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/26/2012	11/28/2012	09/17/2013						
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	38	✓	✓	✓						
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	41	✓	✓	✓						
	42	✓	✓	✓						
	43	✓	✓	✓						
	44	✓	✓	✓						
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	46	✓	✓	✓						
	47	✓	✓	✓						
	48	✓	✓	✓						
	49	N	N	N						
	50	N	N	N						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5254328		1993-10-19	Herscheid	
	2	6267717		2001-07-31	Stoll	
	3	6454460		2002-09-24	Ramanathan	
	4	7286867		2007-10-23	Schlyer	
	5	7522952		2009-04-21	Krieg	
	6	7586102		2009-09-08	Mourtada	
	7	7605384		2009-10-20	Sonnenhol	
	8	7608831		2009-10-27	Lamb	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 08/26/2013	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
(Not for submission under 37 CFR 1.99)	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	9	7712491		2010-05-11	Tochon-Danguy	
	10	7734331		2010-06-08	Dhawale	
	11	7737415		2010-06-15	Casale	
	12	7780352		2010-08-24	Fox	
	13	7825372		2010-11-02	Allberg	
	14	8198599		2012-06-12	Bouton	
	15	8431909		2013-04-30	Horton	
	16	8439815		2013-05-14	Lemer	
	17	8442803		2013-05-14	Chen	
	18	7091494		2006-08-15	Weisner	
	19	3991960		1976-11-16	Tanaka	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 08/26/2013	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-06-16
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	20	4212303		1980-07-15	Nolan	
	21	4656697		1987-04-14	Naeslund	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080237502		2008-10-02	Fago	
	2	20120098671		2012-04-26	Wieczorek	
	3	20120312980		2012-12-13	Whitehouse	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2008066586	WO	A2	2008-06-05	MALLINCKRODT INC		☐
	2	2011126522	WO	A2	2011-10-13	MEDI PHYSICS INC		☐

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Receipt date: 08/26/2013	Application Number	12808467 12808467 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2010-06-16
(Not for submission under 37 CFR 1.99)	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Machine translation of abstract of RU2307378 published 2007-09-27 (Oao Sojuztsvetmetavtomatika).	☐

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Examiner Signature	/Eileen Foley/	Date Considered	09/16/2013

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Receipt date: 08/26/2013

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467 12808467 - GAU: 3735
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-08-26
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12808467
Filing Date	2010-06-16
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5254328		1993-10-19	Herscheid	
	2	6267717		2001-07-31	Stoll	
	3	6454460		2002-09-24	Ramanathan	
	4	7286867		2007-10-23	Schlyer	
	5	7522952		2009-04-21	Krieg	
	6	7586102		2009-09-08	Mourtada	
	7	7605384		2009-10-20	Sonnenhol	
	8	7608831		2009-10-27	Lamb	

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	First Named Inventor	Stephen E. Hidem
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	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

	9	7712491		2010-05-11	Tochon-Danguy	
	10	7734331		2010-06-08	Dhawale	
	11	7737415		2010-06-15	Casale	
	12	7780352		2010-08-24	Fox	
	13	7825372		2010-11-02	Allberg	
	14	8198599		2012-06-12	Bouton	
	15	8431909		2013-04-30	Horton	
	16	8439815		2013-05-14	Lemer	
	17	8442803		2013-05-14	Chen	
	18	7091494		2006-08-15	Weisner	
	19	3991960		1976-11-16	Tanaka	

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	First Named Inventor	Stephen E. Hidem
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	Examiner Name	Eileen Dorothy Foley
	Attorney Docket Number	56782.1.7.2

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Machine translation of abstract of RU2307378 published 2007-09-27 (Oao Sojuztsvetmetavtomatika).	☐

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-08-26
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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Electronic Patent Application Fee Transmittal

Application Number:	12808467
Filing Date:	16-Jun-2010
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.2

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U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	16669434
Application Number:	12808467
International Application Number:	
Confirmation Number:	3733
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.2
Receipt Date:	26-AUG-2013
Filing Date:	16-JUN-2010
Time Stamp:	11:53:46
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

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RAM confirmation Number	10288
Deposit Account	
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Foreign Reference	WO2008066586A2.pdf	1272548 8680ae5b7584c393f429ab1b8ea740c09894f890	no	30
Warnings:					
Information:					
2	Foreign Reference	WO2011126522A2.pdf	3863770 03b32ea73aaeb819a89b2b2e2811c298554f32c5	no	60
Warnings:					
Information:					
3	Foreign Reference	RU2307378C1_Machine-translation.pdf	155711 3145db7df125c1d6fe7f05ba87b77a67c6db9be9	no	6
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	11th-SIDS_56782-1-7-2.pdf	613165 3b2c169077044be8b7c37b5354420e8a800b461f	no	6
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30527 c0ccce1f856e0ab39b8ec458f021836bf1d7dbf7	no	2
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		Total Files Size (in bytes):	5935721		

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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 June 2008 (05.06.2008)

PCT

(10) International Publication Number
WO 2008/066586 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2007/015566

(22) International Filing Date: 5 July 2007 (05.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/818,808 6 July 2006 (06.07.2006) US

(71) Applicant *(for all designated States except US)*: **MALLINCKRODT INC.** [US/US]; 675 Mcdonnell Boulevard, Hazelwood, MO 63042 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **VERBOKKEM, Arjan, Frank** [NL/NL]; Zuiderlaan 1, NL-8746NE Schraard (NL).

(74) Agents: **KINNEY, Anthony, R.** et al.; Mallinckrodt Inc., 675 Mcdonnell Boulevard, Hazelwood, MO 63042 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

WO 2008/066586 A2

(54) Title: SYSTEM AND METHOD FOR CONTROLLING ELUTION FROM A RADIOISOTOPE GENERATOR WITH ELECTRONIC PINCH VALVES

(57) Abstract: Embodiments of the present invention relate to a system and method for controlling an elution process with at least one electronic pinch valve. Specifically, embodiments of the present invention include supplying eluent to a radioisotope generator of a radioisotope elution system, and controlling elution of the radioisotope generator with at least one electronic pinch valve disposed on at least one flow line of the radioisotope elution system, wherein the electronic pinch valve is configured to either block flow through the at least one flow line or enable flow through the at least one flow line based on a state of the electronic pinch valve.

SYSTEM AND METHOD FOR CONTROLLING ELUTION FROM A RADIOISOTOPE GENERATOR WITH ELECTRONIC PINCH VALVES

[0001] This application claims the benefit of U.S. Provisional Application No. 60/818,808, filed July 6, 2006.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of nuclear medicine. Specifically, embodiments of the invention relate to a system and method for starting and stopping elution of radioisotopes from a radioisotope generator with electronic pinch valves.

BACKGROUND

[0003] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0004] Nuclear medicine is a branch of health science that utilizes radioactive material for diagnostic and therapeutic purposes by injecting a patient with a small dose of the radioactive material, which concentrates in certain organs or biological regions of the patient. Radioactive materials typically used for nuclear medicine include Technetium-99m, Indium-113m, and Strontium-87m among others. Some radioactive materials naturally concentrate toward a particular tissue; for example, iodine concentrates toward the thyroid. However, radioactive materials are often combined with a tagging or organ-seeking agent, which targets the radioactive material for a desired organ or biologic region of the patient. These radioactive materials alone or in combination with a tagging agent are typically defined as radiopharmaceuticals in the field of nuclear medicine. At relatively lower doses of the radiopharmaceutical, a radiation imaging system (e.g., a gamma camera) can provide an image of the organ or biological region that collects the radiopharmaceutical. Irregularities in the image are often indicative of a pathologic condition, such as cancer. Higher doses of the radiopharmaceutical may be used to deliver a therapeutic dose of radiation directly to the pathologic tissue, such as cancer cells.

[0005] The production of radiopharmaceuticals inherently involves radioactive material. Accordingly, it is desirable for clinicians and other individuals that work around

radioisotope elution systems to limit their exposure to the elution process and its products. Indeed, many elution systems and related devices (e.g., transportation and dispensing mechanisms) include shielding that limits the exposure of users to radiation from the elution system and its products. However, even when shielding is present, it may be desirable to further limit exposure generally involved with engaging or disengaging flow controls in the radioisotope elution system. In addition, existing systems can expose the flow controls and other mechanisms to radiation, an eluent, or other materials involved with an elution process or subsequent cleaning. These materials can adversely affect the life and operability of the flow controls.

SUMMARY

[0006] The present invention, in certain embodiments, is directed to a radioisotope elution system including electronic pinch valves disposed along flow lines of the radioisotope elution system. One or more electronic pinch valves may be positioned along the flow lines such that opening and closing the electronic pinch valves in defined combinations can stop and/or start an elution process. The electronic pinch valves may be arranged or configured to reduce the possibility of exposure of a user or operator to radiation from the elution system. For example, by preventing flow or controlling suction in components of the elution system, the electronic pinch valves may prevent or reduce the potential for spilling radioactive fluid when retrieving collected eluate from the elution system. Additionally, the electronic pinch valves may be configured for remote actuation, which may reduce the potential for exposing a user or operator to radiation from the elution system during operation. Further, the electronic pinch valves may be configured to avoid direct contamination of the valves themselves by operating to squeeze flow lines (e.g., tubing) together when closed and release the flow lines when open, thus avoiding direct contact between the valves and radioactive material and/or corrosive material in the flow lines.

[0007] Certain aspects commensurate in scope with the originally claimed invention are set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief summary of certain forms the invention might take and that these aspects are not intended to limit the scope of the invention. Indeed, the invention may encompass a variety of aspects that may not be set forth below.

[0008] In accordance with a first aspect of the present invention, there is provided a radioisotope elution system, comprising a flexible radioisotope elution line, and an electronic pinch valve disposed externally about the flexible radioisotope elution line, wherein the electronic pinch valve includes a remote electronic control connector.

[0009] In accordance with a second aspect of the present invention, there is provided a radioisotope elution system, comprising a radioisotope generator, an elution line coupled to

the radioisotope generator, wherein the elution line comprises a resilient circumferential wall disposed about a passage; and an electronic pinch valve disposed externally about the resilient circumferential wall.

[0010] In accordance with a third aspect of the present invention, there is provided a method, comprising electronically manipulating a state of at least one electronic pinch valve disposed externally about at least one resilient flow line of a radioisotope elution system between constricting and not constricting the at least one resilient flow line to control elution of a radioisotope generator.

[0011] Various refinements exist of the features noted above in relation to the various aspects of the present invention. Further features may also be incorporated in these various aspects as well. These refinements and additional features may exist individually or in any combination. For instance, various features discussed below in relation to one or more of the illustrated embodiments may be incorporated into any of the above-described aspects of the present invention alone or in any combination. Again, the brief summary presented above is intended only to familiarize the reader with certain aspects and contexts of the present invention without limitation to the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other features, aspects, and advantages of the present invention will become better understood when the following detailed description is read with reference to the accompanying drawings in which like characters represent like parts throughout the drawings, wherein:

[0013] FIG. 1 is a cross-sectional view of an embodiment of a radioisotope elution system including electronic pinch valves;

[0014] FIGS. 2-6 are diagrams of various embodiments of a radioisotope elution systems including electronic pinch valves;

[0015] FIG. 7 is a flowchart illustrating an embodiment of a nuclear medicine process;

[0016] FIG. 8 is a diagram of an embodiment of a radiopharmaceutical preparation system; and

[0017] FIG. 9 is a diagram of an embodiment of a nuclear medicine imaging system.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0018] One or more exemplary embodiments of the present invention are described below. In an effort to provide a concise description of these embodiments, some features of an actual implementation may not be described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions may be made to achieve the developers'

specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Such a development effort would be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

[0019] FIG. 1 is a cross-sectional side view of an embodiment of a radioisotope elution system 10 including a pair of electronic pinch valves 22,24 disposed on flow lines 26. It should be noted that a line may include a single line or a system of lines. The illustrated elution system 10 also may include a radioisotope generator 12, radiation shielding 14, an elution output assembly 16, an eluent supply bottle 18, and an eluate collection bottle 20. The elution output assembly 16 may include an elution shield 16A disposed about the eluate collection bottle 20. Each of the electronic pinch valves 22, 24 is coupled to a flow line 26 (e.g., resilient tubing) of the elution system 10 to facilitate automatic and/or remote control of an elution process being performed by the elution system 10. One or both of the electronic pinch valves 22, 24 may be disposed at least partially within the radioisotope generator 12.

[0020] In certain embodiments, the flow line 26 may include one or more lengths of resilient tubing in parallel or in series, or continuous, or intermittently coupled with other elution components, or a combination thereof. For example, a first portion of the flow line 26 may be disposed upstream from the radioisotope generator 12, while a second portion of the flow line 26 may be disposed downstream of the radioisotope generator 12. Together, the first and second portions may represent the overall elution flow line 26. The electronic pinch valves 22, 24 may be disposed externally about the flow line 26 on various upstream and/or downstream portions relative to the radioisotope generator 12 or in proximity to fluid connectors on the radioisotope generator 12. In certain embodiments, a system operator may remotely coordinate activation or deactivation of the first and second electronic pinch valves 22, 24 to stop or start an elution. Indeed, using the electronic pinch valves 22, 24, an operator or controller may cause the elution system 10 to complete a full or a partial elution (e.g., an elution to partially fill an eluate output container) without any radiation exposure. In other words, the operator can control liquid flow without opening the shielding 14, thereby substantially reducing the potential for radiation exposure.

[0021] During an elution procedure performed with the elution system 10, eluent (e.g., saline) flows from the eluent supply bottle 18 through the generator 12, and is collected as eluate in the eluate collection bottle 20. In the illustrated embodiment, the eluent supply bottle 18 is coupled to the generator 12 via a vented spike 28 and the tubing 26. The vented spike 28 includes an eluent vent needle 28A and a container eluent output needle 28B. The tubing 26 coupling the eluent supply 18 and the generator 12 may be referred to as an eluent input line 29 or eluent supply line 29. The eluent input line 29 may couple to the generator 12 via a generator eluent input needle 29A. The vented spike 28 may also couple to a vent 30 via the

tubing 26 to regulate pressure and facilitate flow of eluent out of the eluent supply bottle 18. The tubing 26 between the vent 30 and the eluent supply bottle 18 may be referred to as a supply vent line, an eluent vent line, or an input vent line 31. The vent 30 may include a check valve to allow air into the eluent supply bottle 18 while generally preventing backflow from the eluent supply bottle 18 through the vent 30 and into other areas of the elution system 10. The tubing 26 between the eluent supply bottle 18 and the generator 12 (i.e., the eluent input line 29) may channel the eluent into the radioisotope generator 12 for flushing or generally eluting a daughter radioisotope from a parent radioisotope in the generator 12 and into the eluate collection bottle 20. The eluate collection bottle 20 may be coupled to the generator 12 via a hollow outlet needle 32 and the tubing 26 to facilitate such collection. The tubing 26 between the generator 12 and the eluate collection bottle 20 may be referred to as an eluate collection line 33 or eluate output line 33. The eluate output line 33 may couple to the generator 12 via a generator eluate output needle 33A.

[0022] The generator 12 may include a container or a shielded container designed to hold a parent radioisotope, such as Molybdenum-99, absorbed to alumina beads or another suitable exchange medium. Over time, the parent radioisotope may decay to produce a daughter radioisotope. For example, Molybdenum-99 may decay to form Technetium-99m as its daughter radioisotope. Molybdenum-99 has a half-life of approximately 67 hours. Thus, short-lived Technetium-99m, which has a half-life of approximately 6 hours, may continually be produced inside the generator 12 during operation. Once a certain amount of the radioisotope is present, the radioisotope elution system 10 may be ready for "milking." In other words, the radioisotope may be ready to be collected from the generator 12 via an elution process, which may begin with flowing eluent through the generator 12. The daughter radioisotope (e.g., Technetium-99m) is held chemically less tightly than the parent radioisotope, thereby enabling flow of eluent to flush the desired daughter radioisotope from the radioisotope generator 12 into the eluate collection bottle 20 as a component of the eluate. In some embodiments, a wet elution process is utilized, wherein the generator 12 generally remains charged and eluate is removed via the eluate collection bottle 20 at designated times.

[0023] The eluate collection bottle 20 may have a standard or predefined volume. Additionally, the eluate collection bottle 20 may begin in an evacuated condition. Thus, when the eluate collection bottle 20 is attached to the elution system 10, it creates a suction or pressure drop into the eluate collection bottle 20. This pressure drop may essentially drive the elution system 10. For example, the suction of the eluate collection bottle 20 may draw the eluate residing in the generator 12 into the eluate collection bottle 20 via the tubing 26 and the outlet needle 32. In turn, the vacancy in the generator 12 created by moving the eluate into the eluate collection bottle 20 may result in eluent being drawn into the generator 12 from the eluent supply bottle 18. This transfer of eluent through the generator 12 facilitates production