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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	03/29/2016	9299467	56782.1.7.15	1068

22859 7590 03/09/2016

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 0 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;
Bracco Diagnostics Inc., Monroe Township, NJ;
Aaron M. Fontaine, Fridley, MN;
Janet L. Gelbach, New Albany, IN;
Patrick M. McDonald, Omaha, NE;
Kathryn M. Hunter, Knoxville, TN;
Rolf E. Swenson, Silver Spring, MD;
Julius P. Zodda, Mercerville, NJ;

Receipt date: 08/08/2014	Application Number	14455623 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	
	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	23	20090312635	A1	2009-12-17	Shimchuk	
	24	20070080223	A1	2007-04-12	Japuntich	
	25	20100030009	A1	2010-02-04	Lemer	
	26	20070140958	A1	2007-06-21	deKemp	
	27	20080191148	A1	2008-08-14	Gibson	
	28	20100312039	A1	2010-12-09	Quirico	
	29	20110071392	A1	2011-03-24	Quirico	
	30	20110172524	A1	2011-07-14	Hidem	
	31	20110209764	A1	2011-09-01	Uber	
Change(s) applied to document, /S.X.R./ 12/2/2015	32	20120098671 ~~20120098761~~	A1	2012-04-26	Wieczorek	
	33	20120312980	A1	2012-12-13	Whitehouse	

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

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
	14/455,623

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 _____ — 2016-02-16 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.

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:	14455623
Filing Date:	08-Aug-2014
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.15

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:	24920871
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
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:	56782.1.7.15
Receipt Date:	16-FEB-2016
Filing Date:	08-AUG-2014
Time Stamp:	14:52:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$960
RAM confirmation Number	1257
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	Issue Fee Payment (PTO-85B)	56782_1_7_15_Transmittal.pdf	1600391 62720ea6b919fb46e220a3b089e2e7ca1d29a028	no	1
Warnings:					
Information:					
2	Maintenance Fee Address Change	56782_1_7_15_Fee_Address_Change.pdf	204142 d81049cdb22229554fb5785cef09f957546e565f	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30662 7c095f78bafef45c9aab26a0fead0fec4c6bb3a6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1835195		

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.

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 11/16/2015
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.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

TITLE OF INVENTION: INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

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	02/16/2016

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): 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.
☐ 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 February 16, 2016
Typed or printed name Paul J. LaVanway, Jr. Registration No. 64,610

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 11/16/2015

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	

DATE MAILED: 11/16/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

TITLE OF INVENTION: INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

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	02/16/2016

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 11/16/2015
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.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

TITLE OF INVENTION: INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

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	02/16/2016

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
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 11/16/2015

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	

DATE MAILED: 11/16/2015

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. 14/455,623	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 remarks filed 27 October 2015*.
   ☐ 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 *1-5,7-19 and 21-24*. 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.

Response to Arguments

2. Applicant's arguments, see pages 2 and 3, filed 27 October 2015, with respect to the double patenting rejections of claims 1-5, 7, 8, 10-19, 21, 22, and 24 have been fully considered and are persuasive in light of the proper terminal disclaimer filed in Application No. 14/455,631. The rejections of 28 July 2015 have been withdrawn.

Allowable Subject Matter

3. **Claims 1-5, 7-19, and 21-24** 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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	("20110178359").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/22 09:12
S3	272	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/06/29 10:51
S4	187	(bracco near2 diagnostics).as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/06/29 11:01
S5	7	("20060074381" | "20070041498" | "20080150754" | "5068820" | "6061757" | "7680880" | "7978062").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/29 11:08
S6	103	("20030004463" | "20030139640" | "20040104160" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20090318745" | "20100125243" | "20100270226" | "20100312039" | "20110071392" | "20110172524" | "20120098671" | "20120312980" | "3483867" | "3710118" | "3714429" | "3774036" | "3991960" | "3997784" | "4096859" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4679142" | "4755679" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" | "6267717" | "6347711" | "6442418" | "6450936" | "6454460" | "6558125" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" | "7608831" | "7612999" | "7712491" | "7734331" | "7737415" | "7780352" | "7825372" | "7862534" | "7996068" | "8198599" | "8431909" | "8439815" | "8442803").PN. OR ("8708352").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/06/29 11:13
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S9	24	("3953567" | "3957945" | "4276267" | "4406877" | "4562829" | "4585009" | "4597951" | "5167938" | "5190735" | "5296203" | "5330731" | "5885925" | "5966583" | "5989434" | "6106799").PN. OR ("6908598").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/06/29 11:21
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S11	112	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 11:52
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S15	1804	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 15:26
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S24	93	(S21 or S22 or S23 or S20) break$4through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
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S27	442	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
S28	112	A61N2005/1021.cpc.	US-	AND	ON	2015/07/15

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S30	39	(S27 or S28 or S29 or S26) (break$4through with (test$4 or measur$3 or measurement or detect$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
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S32	3076	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 11:03
S33	3076	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 12:33
S34	49	S33 break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:34
S35	135	S33 elut$4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:35
S36	42	S33 elut$4 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) (threshold or limit$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:36
S37	668	S33 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) (threshold or limit$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:51
S38	15	S33 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or	US-PGPUB; USPAT;	AND	ON	2015/07/16 13:53

		inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	USOCR; EPO; JPO; DERWENT			
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S41	0	S40 break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:40
S42	769	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:43
S43	0	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:43
S44	30	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (treat$3 or treatment or therap$ or infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:44
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S48	20	S47 breakthrough	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:10
S49	13	("4585009" | "4585941" | "4975583" | "6049026" | "6641783" | "6713765" | "6731971" | "6733477" | "6733478" | "6901283" | "6928338" | "7169135" | "7174240").PN. OR ("7813841").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:30
S50	0	S49 breakthrough	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:31

S51	1	wo-2014041319-$.did.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/17 11:24
S52	0	("2010312039").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/17 11:25
S53	1	("20100312039").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/17 11:25
S54	30	(US-20110178359-$ or US-20100312039-$ or US-20090312630-$ or US-20070140958-$ or US-20070213848-$ or US-20090312635-$ or US-20090318745-$ or US-20090309466-$ or US-20080035542-$ or US-20090309465-$ or US-20110182808-$ or US-20060127311-$ or US-20110071392-$ or US-20140084187-$ or US-20130048883-$).did. or (US-8708352-$ or US-4562829-$ or US-6908598-$ or US-7476377-$ or US-7737415-$ or US-3953567-$ or US-4585009-$ or US-5966583-$ or US-7862534-$ or US-8071959-$ or US-8317674-$ or US-3774036-$ or US-7813841-$).did. or (JP-2012158600-$).did. or (FR-2995536-$).did.	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:39
S55	1	S54 (activity with (mci$1s or (millicurie near2 sec$4)))	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:40
S56	3080	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:40
S57	1300	A61N5/1048,1071,1075.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:40
S58	0	(S56 or S57) (activity with (mci$1s or (millicurie near2 sec$4)))	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:40
S59	1825	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S60	439	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41

S61	113	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S62	846	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S63	2	(S60 or S61 or S62 or S59) (activity with (mci$1s or (millicurie near2 (sec or second))))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S64	2	(S60 or S61 or S62 or S59) (activity with (mci$1s or (millicurie near2 (sec or second))))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S65	2	(S60 or S61 or S62 or S59) (mci$1s or (millicurie near2 (sec or second)))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S67	4	(S56 or S57) (mci$1s or (millicurie near2 (sec or second)))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:43
S69	3201	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 07:51
S70	120	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 07:55
S71	441	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 07:55
S72	1961	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 07:56

S73	866	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 07:59
S74	2	("3543752" | "3861380").PN.	US-PGPUB; USPAT	AND	ON	2015/11/04 08:00
S83	15	(S69 or S70) ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 08:16
S84	26	(S71 or S72 or S73) ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/11/04 08:17

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S46	3	(break$1through ((threshold or limit$4) with (treat$3 or treatment or therap$ or infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))).clm.	US-PGPUB; USPAT	AND	ON	2015/07/17 09:03
S68	2	"Term Removed"	US-PGPUB	AND	ON	2015/07/21 10:39
S85	3	(break$1through ((threshold or limit$4) with (treat$3 or treatment or therap$ or infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))).clm.	US-PGPUB; USPAT	AND	ON	2015/11/04 08:19

11/4/2015 10:15:16 AM
C:\Users\cdorna\Documents\EAST\Workspaces\14455623 and 14455631.wsp

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	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
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
A61B		19	/	54		I	2013-01-01
A61B		2019	/	542		A	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

CPC Combination Sets

Symbol						Type	Set	Ranking	Version
			/						
			/						

/CARRIE R DORNA/ Examiner.Art Unit 3735	11/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/09/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	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	11/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/09/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	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

/CARRIE R DORNA/ Examiner.Art Unit 3735	11/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/CHARLES A MARMOR II/ Supervisory Patent Examiner.Art Unit 3735	11/09/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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	A	1970-12-01	Hesse et al.	
	2	3861380	A	1975-01-21	Chassagne et al.	

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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
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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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11/04/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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. 14/657,598, filed March 13, 2015, entitled, "REAL TIME NUCLEAR ISOTOPE DETECTION," 48 pages. Attorney docket number 56782.1.13.3.	☐

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	11/04/2015

*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.

11/04/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CD/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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)	2015-10-27
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.**

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.

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. /CD/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	HIDEM ET AL.
	Examiner	**Art Unit**
	Carrie R. Dorna	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N 2005/1021, 1022	10/2/14	EF
A61N 5/10, 1007	10/2/14	EF
A61N 5/1001, 1002, 1007, 1014, 1015, 1016, 1017, 1027, 1048, 1071, 1075	7/2015	CD
A61N 2005/1021	7/2015	CD
A61K 51/1282	7/2015	CD
A61M 5/007	7/2015	CD
G21G 4/04, 06, 08	7/2015	CD
A61N 5/1001, 1002, 1007, 1014, 1015, 1016, 1017, 1027, 1048, 1071, 1075 updated	11/2015	CD
A61N 2005/1021 updated	11/2015	CD
A61K 51/1282 updated	11/2015	CD
A61M 5/007 updated	11/2015	CD
G21G 4/04, 06, 08 updated	11/2015	CD

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	4, 5	10/2/14	EF
378	65	10/2/14	EF

SEARCH NOTES

Search Notes	Date	Examiner
Inventor name search in EAST	10/15/14	EF
Limited class/subclass searches with text	10/2; 10/3; 10/15/14	EF

SEARCH NOTES

Search Notes	Date	Examiner
Updated class/subclass searches and additional text searching in EAST	1/14/15; 1/30/15; 2/3/15; 2/24/15	EF
see EAST search report	7/2015	CD
EAST: inventor name search, assignee search	6/2015	CD
STIC NPL search, see search report	6/2015	CD
see updated EAST search report	11/2015	CD

INTERFERENCE SEARCH

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	see EAST search report	7/2015	CD
	see updated EAST search report	11/2015	CD

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	14/455,623	Group Art Unit:	3735
Filed:	August 8, 2014	Examiner:	Carrie R. Dorna
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

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

RESPONSE

Dear Commissioner:

In response to the Office Action mailed July 28, 2015, the period of response for which runs through October 28, 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 July 28, 2015. Claims 1–5, 7–19, and 21–24 remain pending. Reconsideration of the application is respectfully requested.

Allowable Subject Matter

Applicant thanks the Examiner for the indication of allowability with respect to claims 1–5, 7–19, and 21–24 and agrees that the claims present patentable subject matter. In view of the foregoing remarks, Applicant submits that all of the pending claims are in condition for allowance and respectfully requests reconsideration and allowance of all claims.

Interview Summary

Applicant thanks the Examiner for her time and the courtesies extended during the telephonic interview conducted on August 25, 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 the provisional obviousness-type double patenting rejection lodged against the pending claims based on co-pending US Patent Application No. 14/455,631.

During the discussions, the parties discussed guidance on handling conflicting provisional obviousness-type double patenting rejections provided in MPEP § 804(I)(B)(1), which states the following:

> If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

After discussion, the Examiner indicated that entry of a terminal disclaimer in co-pending US Patent Application No. 14/455,631 would obviate the provisional obviousness-type double patenting rejections lodged in both applications. Accordingly, agreement was reached that Applicant would enter a terminal disclaimer in co-pending US Patent Application No.

14/455,631 and the Examiner would withdraw the provisional obviousness-type double patenting rejection against the present application.

Double Patenting Rejections

In the Office Action, claims 1–5, 7, 8, 10–19, 21, 22 and 24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–4, 6, 8, 10–15, 25 and 31 of copending Application No. 14/455,631 in view of Hirschman et al. (US 2011/0178359, hereinafter "Hirschman").

While Applicant does not agree with the propriety of the rejections, in view of the agreement on allowability reached during the telephone interview with the Examiner, Applicant reserves further comment regarding the features of the claims.

Comments on Statement of Reasons for Allowance

In the Office Action, the Examiner provided a statement of reasons for the indication of allowable subject matter. While Applicant agrees with the Examiner that the claims are allowable over the prior art, Applicant does not acquiesce in the characterizations of the claims, the prior art of record, or the stated reasons for allowance. Applicant respectfully submits that the claims require various limitations not taught or suggested by the prior art.

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: October 27, 2015

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.

56629807_1.doc

Electronic Patent Application Fee Transmittal

Application Number:	14455623
Filing Date:	08-Aug-2014
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.15

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:	23904056
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.15
Receipt Date:	27-OCT-2015
Filing Date:	08-AUG-2014
Time Stamp:	18:15:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	4956
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)	56782-1-7-15_IDS.pdf	1035337 c26058a89b7ece9946c0457bccccbc63c311e870	no	4
Warnings:					
Information:					
2	Non Patent Literature	NPL_56782_1_13_3.pdf	2372350 d61eff598b64e09ac947d462fc2cd057b5d85e7c	no	48
Warnings:					
Information:					
3		56782_1_7_15_Response.pdf	123265 e3ac25c55066b0bcef3fd0a6a7e26cbb6e77db86	yes	4

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Applicant Arguments/Remarks Made in an Amendment	2	4

Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30749 efcaaf147e54f313aee081bdc825858a9c367020	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	3561701	

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 (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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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	A	1970-12-01	Hesse et al.	
	2	3861380	A	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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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. 14/657,598, filed March 13, 2015, entitled, "REAL TIME NUCLEAR ISOTOPE DETECTION," 48 pages. Attorney docket number 56782.1.13.3.	☐

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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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)	2015-10-27
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.**

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.

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.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 09/11/2015

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
09/11/2015	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.** 14/455,623	**Applicant(s)** HIDEM ET AL.	
	Examiner CARRIE R. DORNA	**Art Unit** 3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Carrie R. Dorna*. (3)_____.

(2) *Paul LaVanway*. (4)_____.

Date of Interview: *25 August 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: *N/A*.

Identification of prior art discussed: *N/A*.

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 proposed filing a terminal disclaimer in related application no. 14/455,631 to overcome the obviousness-type double patenting rejections pursuant to MPEP 804 (I)(B)(1). Agreement was reached that a proper terminal disclaimer filed in the related application would overcome these rejections, placing the case in condition for allowance.

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
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.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 07/28/2015

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INTELLECTUAL PROPERTY GROUP
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MINNEAPOLIS, MN 55402

EXAMINER	
DORNA, CARRIE R	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
07/28/2015	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. 14/455,623	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 *12 June 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) *1-5,7-19 and 21-24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,7,8,10-19,21,22 and 24* is/are rejected.

8)☒ Claim(s) *9 and 23* 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 *8 August 2014* 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

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Notice of Pre-AIA or AIA Status

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

Response to Arguments

3. Applicant's arguments, see pages 2-6, filed 12 June 2015, with respect to the rejections of claims 1-5, 7-19, and 21-24 under 35 U.S.C. 103 (pre-AIA) citing at least Hirschman et al. and Alvarez-Diez et al. have been fully considered and are persuasive. The rejections of 12 March 2015 have been withdrawn.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

5. **Claims 1-5, 7, 8, 10-19, 21, 22, and 24** are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6, 8, 10-15, 25, and 31 of copending Application No. 14/455,631 in view of U.S. Patent Application Publication No. 2011/0178359 (Hirschman et al.).

Regarding **claim 1** of the instant application, claim 1 of the ‘631 application recites all the limitations found in instant claim 1. The difference between instant claim 1 and claim 1 of the '631 application lies in that instant claim 1 includes the limitation "a

computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input", which is not found in claim 1 of the '631 application.

However, Hirschman et al. teaches a system (abstract; [0120]) comprising: a shielding assembly (*Figure 4B, shielding assembly,* 280) configured to contain a radioisotope generator (*Figures 3 and 4B, radionuclide generator,* 220) that generates radioactive eluate via elution ([0120]; [0122]; [0126]); a computer (*Figures 3 and 4B, control computer,* 210) carried by the shielding assembly (280) ([0122]-[0124]; see *Figures 3 and 4B*), wherein the computer (210) is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator (220) to generate a sample of eluate via elution during quality control testing ([0122]-[0124]; [0126]-[0127]; [0130]; [0143]); and a dose calibrator (*Figures 3 and 4B, radiopharmaceutical processing module,* 230) electronically coupled to the computer (210) and configured to measure an activity of the sample of the eluate generated during quality control testing, wherein the computer (210) carried by the shielding assembly (280) is configured to receive the activity data from the dose calibrator (210) and calculate quality control test results ([0122]; [0123]; [0130]; [0134]; [0135]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of claim 1 of the '631 application such that the computer is carried by a shielding assembly, and the computer is configured to receive user input to control the radioisotope generator as taught by Hirschman et al., because such a configuration permits a practitioner to input “relevant control data and parameters” to generate the

desired sample of radioactive eluate via a stand-alone, mobile system for eluate production and patient injection (Hirschman et al., [0120]; [0122]-[0124]).

Regarding **claims 2-5, 7, 8, and 10-13** of the instant application, claims 2-4, 6, 8, and 10-15 (which encompass claim 1) of the ‘631 application in view of Hirschman et al. recite all the limitations found in instant claims 2-5, 7, 8, and 10-13.

Regarding **claim 14** of the instant application, claim 31 (which encompasses claim 25) of the '631 application recites all the limitations found in instant claim 14. The difference between claim 14 of the instant application and claim 31 of the '631 application lies in that instant claim 31 includes the limitations "a radioisotope generator contained within a shielding assembly", “a dose calibrator electronically coupled to a computer”, and “determining, with the computer, an activity”, which is not found in claim 31 of the ‘631 application.

However, Hirschman et al. teaches a method comprising: generating, with a radioisotope generator (*Figure 4B, radionuclide generator,* 220) contained within a shielding assembly (*Figure 4B, shielding assembly,* 280), a radioactive eluate via elution of an eluent ([0120]; [0122]; [0126]); measuring, with a dose calibrator (*Figures 3 and 4B, radiopharmaceutical processing module,* 230) electronically coupled to a computer (*Figures 3 and 4B, control computer,* 210) carried by the shielding assembly (280), an activity of the radioactive eluate ([0130]; [0134]; [0135]); and determining, with the computer (210), an activity of a radionuclide within the radioactive eluate ([0130]; [0134]; [0135]; [0143]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of claim 31 of the '631 application such

that the radioisotope generator is contained within a shielding assembly, and dose calibrator is electronically coupled to a computer to determine activity of a radionuclide within the eluate as taught by Hirschman et al., because such a configuration prevents unwanted radiation exposure to the practitioner, and permits automated dose calibration (Hirschman et al., [0120]; [0122]; [0130]; [0143]).

Regarding **claims 15-19, 21, 22, and 24** of the instant application, claim 6 and 31 (which encompasses claim 25) of the '631 application in view of Hirschman et al. teaches all the limitations of instant claims 15-19, 21, 22, and 24.

This is a provisional nonstatutory double patenting rejection.

Allowable Subject Matter

6. **Claims 1-5, 7, 8, 10-19, 21, 22, and 24** would be allowable if rewritten or amended to overcome the double patenting rejections set forth in this Office action.

7. **Claims 9 and 23** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: No prior art of record teach and/or fairly suggest the system of claim 1 or the method of claim 14, wherein the computer prevents a patient infusion procedure if a breakthrough test result exceeds an allowable limit, within the context of the remainder of claim 1 and 14, respectively.

The closest prior art of record, Hirschman et al. in view of Alvarez-Diez et al., cited in the previous Office action, teaches all the limitations of claim 1 and 14,

respectively, except that the computer is configured to prevent, or prevents, a patient infusion procedure if the breakthrough test result exceeds an allowable threshold. Hirschman et al. teaches that "[a] monitor which can alert or alarm may be associated with or part of dosimeter control 1026 to alert the operator if there is any change from the steady half-life decay that could indicate a leakage of liquid or a failure of some other system component" ([0184]). Alvarez-Diez et al. details the performance of an initial quality control calculation for determining the amount of breakthrough in a strontium/rubidium generator prior to administering ^{82}Rb doses to patients via an automated delivery system (pg. 1018-1020). However, neither reference specifies a patient infusion procedure is prevented by the computer that performs the breakthrough testing if the breakthrough testing result exceeds an allowable limit.

Conclusion

9. 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 (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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.D./ (07/21/2015)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Attorney Docket Number	56782.1.7.15

	1							☐

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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	/Carrie Dorna/ (07/21/2015)	Date Considered	07/21/2015

*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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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.

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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	HIDEM ET AL.
	Examiner	Art Unit
	Carrie R. Dorna	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N2005/1021, 1022	10/2/14	EF
A61N5/10, 1007	10/2/14	EF
A61N 5/1001, 1002, 1007, 1014, 1015, 1016, 1017, 1027, 1048, 1071, 1075	7/2015	CD
A61N 2005/1021	7/2015	CD
A61K 51/1282	7/2015	CD
A61M 5/007	7/2015	CD
G21G 4/04, 06, 08	7/2015	CD

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	4, 5	10/2/14	EF
378	65	10/2/14	EF

SEARCH NOTES

Search Notes	Date	Examiner
Inventor name search in EAST	10/15/14	EF
Limited class/subclass searches with text	10/2; 10/3; 10/15/14	EF
Updated class/subclass searches and additional text searching in EAST	1/14/15; 1/30/15; 2/3/15; 2/24/15	EF
see EAST search report	7/2015	CD
EAST: inventor name search, assignee search	6/2015	CD
STIC NPL search, see search report	6/2015	CD

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
	see EAST search report	7/2015	CD

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	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	10/15/2014	02/24/2015	07/21/2015						
	1	✓	✓	✓						
	2	✓	✓	✓						
	3	✓	✓	✓						
	4	✓	✓	✓						
	5	✓	✓	✓						
	6	✓	-	-						
	7	✓	✓	✓						
	8	✓	✓	✓						
	9	✓	✓	O						
	10	✓	✓	✓						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	✓	✓	✓						
	18	✓	✓	✓						
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	20	✓	-							
	21	✓	✓	✓						
	22	✓	✓	✓						
	23	✓	✓	O						
	24	✓	✓	✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	("20110178359").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/22 09:12
S3	272	((stephen near2 hidem) (aaron near2 fontaine) (janet near2 gelbach) (patrick near2 mcdonald) (kathryn near2 hunter) (rolf near2 swenson) (julius near2 zodda)).in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/06/29 10:51
S4	187	(bracco near2 diagnostics).as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2015/06/29 11:01
S5	7	("20060074381" | "20070041498" | "20080150754" | "5068820" | "6061757" | "7680880" | "7978062").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/29 11:08
S6	103	("20030004463" | "20030139640" | "20040104160" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20090318745" | "20100125243" | "20100270226" | "20100312039" | "20110071392" | "20110172524" | "20120098671" | "20120312980" | "3483867" | "3710118" | "3714429" | "3774036" | "3991960" | "3997784" | "4096859" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4679142" | "4755679" | "4769008" | "4853546" | "4994056" | "5039863" | "5254328" | "5258906" | "5274239" | "5395320" | "5475232" | "5485831" | "5590648" | "5702115" | "5739508" | "5765842" | "5827429" | "5840026" | "5885216" | "6157036" | "6267717" | "6347711" | "6442418" | "6450936" | "6454460" | "6558125" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" | "7608831" | "7612999" | "7712491" | "7734331" | "7737415" | "7780352" | "7825372" | "7862534" | "7996068" | "8198599" | "8431909" | "8439815" | "8442803").PN. OR ("8708352").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/06/29 11:13
S7	21	("3953567" | "3957945" | "4276267" | "4406877" | "4562829" | "4585009" | "4597951" | "5167938" | "5190735" | "5296203" | "5330731" | "5885925" |	US-PGPUB; USPAT;	AND	ON	2015/06/29 11:17

		"5966583" | "5989434" | "6106799").PN. OR ("7476377").URPN.	USOCR			
S8	10	S7 break$1through	US-PGPUB; USPAT; USOCR	AND	ON	2015/06/29 11:18
S9	24	("3953567" | "3957945" | "4276267" | "4406877" | "4562829" | "4585009" | "4597951" | "5167938" | "5190735" | "5296203" | "5330731" | "5885925" | "5966583" | "5989434" | "6106799").PN. OR ("6908598").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/06/29 11:21
S10	442	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 11:25
S11	112	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 11:52
S12	838	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 11:56
S13	838	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 13:10
S14	1804	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 13:25
S15	1804	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 15:26
S16	442	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 15:45
S17	112	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 15:45
S18	838	G21G4/04,06,08.cpc.	US-	AND	ON	2015/06/29

			PGPUB; USPAT; USOCR; EPO; JPO; DERWENT			15:45
S19	93	(S16 or S17 or S18 or S15) break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/06/29 15:45
S20	1822	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
S21	442	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
S22	112	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
S23	842	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
S24	93	(S21 or S22 or S23 or S20) break$4through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:19
S25	39	(S21 or S22 or S23 or S20) (break$4through with (test$4 or measur$3 or measurement or detect$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 10:22
S26	1822	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
S27	442	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
S28	112	A61N2005/1021.cpc.	US-	AND	ON	2015/07/15

			PGPUB; USPAT; USOCR; EPO; JPO; DERWENT			15:14
S29	842	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
S30	39	(S27 or S28 or S29 or S26) (break$4through with (test$4 or measur$3 or measurement or detect$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/15 15:14
S31	5	(("3535085") or ("4160910") or ("4759345") or ("6639237")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/15 16:07
S32	3076	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 11:03
S33	3076	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 12:33
S34	49	S33 break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:34
S35	135	S33 elut$4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:35
S36	42	S33 elut$4 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) (threshold or limit$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:36
S37	668	S33 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) (threshold or limit$4)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:51
S38	15	S33 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or	US-PGPUB; USPAT;	AND	ON	2015/07/16 13:53

		inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	USOCR; EPO; JPO; DERWENT			
S39	127	break$1through ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 13:54
S40	1295	A61N5/1048,1071,1075.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:01
S41	0	S40 break$1through	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:40
S42	769	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:43
S43	0	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:43
S44	30	S40 ((dos$3 or activity or radio$1activit$3 or dosimetr$3) with (measur$3 or measurement or detect$4)) ((threshold or limit$4) with (treat$3 or treatment or therap$ or infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/16 14:44
S45	132	("20070213848" | "4679142" | "5475232" | "5827429" | "6626862" | "6901283" | "6908598" | "7605384" | "7780352" | "3847138" | "20080071219" | "20080166292" | "20090312630" | "20110209764" | "3565376" | "3714429" | "5739508" | "7204797" | "7504646" | "7608831" | "7737415" | "7862534" | "8198599" | "20110178359" | "4674403" | "20030139640" | "20070140958" | "20070232980" | "20090312635" | "20100030009" | "4096859" | "4562829" | "4625118" | "4656697" | "4769008" | "5258906" | "5395320" | "5840026" | "6157036" | "6870175" | "7522952" | "7712491" | "8216181" | "8439815" | "20040054319" | "20080177126" | "20020129471" | "20050187515" | "20050277833" | "20120305730" | "20120310031" | "3997784" | "4585941" | "5885216" | "6267717" | "8295916" | "8317674" | "8431909" | "8708352" | "20070080223" | "20080093564" | "20080191148" | "20100312039" | "20140084187" | "3483867" | "3710118" | "3774036" | "4286169" | "4336036" | "5039863" | "5765842" | "6220554" | "6767319" | "7169135" | "7256888" | "20070260213" | "20030004463" | "20060015056" | "20070282263" | "20080177126" | "20130300109" |	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 09:07

		"4212303" | "4585009" | "4853546" | "4994056" | "5254328" | "5485831" | "6347711" | "6454460" | "6558125" | "7091494" | "7586102" | "7734331" | "8058632" | "8071959" | "20040104160" | "20040260143" | "20060173419" | "20080237502" | "20110071392" | "20120312980" | "20140175959" | "3991960" | "4755679" | "5274239" | "6450936" | "7476377" | "8216184" | "8442803" | "3535085" | "4160910" | "6639237" | "20050278066" | "20060151048" | "20080242915" | "20110172524" | "20120098761" | "4466888" | "4623102" | "5590648" | "5702115" | "6442418" | "7163031" | "7286867" | "7413123" | "7612999" | "7813841" | "7825372" | "7996068" | "4759345").PN.				
S47	132	("20070213848" | "4679142" | "5475232" | "5827429" | "6626862" | "6901283" | "6908598" | "7605384" | "7780352" | "3847138" | "20080071219" | "20080166292" | "20090312630" | "20110209764" | "3565376" | "3714429" | "5739508" | "7204797" | "7504646" | "7608831" | "7737415" | "7862534" | "8198599" | "20110178359" | "4674403" | "20030139640" | "20070140958" | "20070232980" | "20090312635" | "20100030009" | "4096859" | "4562829" | "4625118" | "4656697" | "4769008" | "5258906" | "5395320" | "5840026" | "6157036" | "6870175" | "7522952" | "7712491" | "8216181" | "8439815" | "20040054319" | "20080177126" | "20020129471" | "20050187515" | "20050277833" | "20120305730" | "20120310031" | "3997784" | "4585941" | "5885216" | "6267717" | "8295916" | "8317674" | "8431909" | "8708352" | "20070080223" | "20080093564" | "20080191148" | "20100312039" | "20140084187" | "3483867" | "3710118" | "3774036" | "4286169" | "4336036" | "5039863" | "5765842" | "6220554" | "6767319" | "7169135" | "7256888" | "20070260213" | "20030004463" | "20060015056" | "20070282263" | "20080177126" | "20130300109" | "4212303" | "4585009" | "4853546" | "4994056" | "5254328" | "5485831" | "6347711" | "6454460" | "6558125" | "7091494" | "7586102" | "7734331" | "8058632" | "8071959" | "20040104160" | "20040260143" | "20060173419" | "20080237502" | "20110071392" | "20120312980" | "20140175959" | "3991960" | "4755679" | "5274239" | "6450936" | "7476377" | "8216184" | "8442803" | "3535085" | "4160910" | "6639237" | "20050278066" | "20060151048" | "20080242915" | "20110172524" | "20120098761" | "4466888" | "4623102" | "5590648" | "5702115" | "6442418" | "7163031" | "7286867" | "7413123" | "7612999" | "7813841" | "7825372" | "7996068" | "4759345").PN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:09
S48	20	S47 breakthrough	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:10
S49	13	("4585009" | "4585941" | "4975583" | "6049026" | "6641783" | "6713765" | "6731971" | "6733477" | "6733478" | "6901283" | "6928338" | "7169135" | "7174240").PN. OR ("7813841").URPN.	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:30
S50	0	S49 breakthrough	US-PGPUB; USPAT; USOCR	AND	ON	2015/07/17 10:31

S51	1	wo-2014041319-$.did.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/17 11:24
S52	0	("2010312039").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/17 11:25
S53	1	("20100312039").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/17 11:25
S54	30	(US-20110178359-$ or US-20100312039-$ or US-20090312630-$ or US-20070140958-$ or US-20070213848-$ or US-20090312635-$ or US-20090318745-$ or US-20090309466-$ or US-20080035542-$ or US-20090309465-$ or US-20110182808-$ or US-20060127311-$ or US-20110071392-$ or US-20140084187-$ or US-20130048883-$).did. or (US-8708352-$ or US-4562829-$ or US-6908598-$ or US-7476377-$ or US-7737415-$ or US-3953567-$ or US-4585009-$ or US-5966583-$ or US-7862534-$ or US-8071959-$ or US-8317674-$ or US-3774036-$ or US-7813841-$).did. or (JP-2012158600-$).did. or (FR-2995536-$).did.	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:39
S55	1	S54 (activity with (mci$1s or (millicurie near2 sec$4)))	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:40
S56	3080	A61N5/1001,1002,1007,1014,1015,1016,1017,1027.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:40
S57	1300	A61N5/1048,1071,1075.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:40
S58	0	(S56 or S57) (activity with (mci$1s or (millicurie near2 sec$4)))	US-PGPUB; USPAT; JPO; DERWENT	AND	ON	2015/07/21 10:40
S59	1825	A61M5/007.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S60	439	A61K51/1282.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41

S61	113	A61N2005/1021.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S62	846	G21G4/04,06,08.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:41
S63	2	(S60 or S61 or S62 or S59) (activity with (mci$1s or (millicurie near2 (sec or second))))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S64	2	(S60 or S61 or S62 or S59) (activity with (mci$1s or (millicurie near2 (sec or second))))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S65	2	(S60 or S61 or S62 or S59) (mci$1s or (millicurie near2 (sec or second)))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:42
S67	4	(S56 or S57) (mci$1s or (millicurie near2 (sec or second)))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	AND	ON	2015/07/21 10:43

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S46	3	(break$1through ((threshold or limit$4) with (treat$3 or treatment or therap$ or infus$4 or inject$4 or administer$4 or administration) with (prevent$4 or stop$4 or halt$4))).clm.	US-PGPUB; USPAT	AND	ON	2015/07/17 09:03
S68	2	"Term Removed"	US-PGPUB	AND	ON	2015/07/21 10:39

7/21/2015 1:29:48 PM
C:\Users\cdorna\Documents\EAST\Workspaces\14455623 and 14455631.wsp

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 06/30/2015

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
06/30/2015	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)	
	14/455,623	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, Jr*. (4)_____.

Date of Interview: *24 June 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: *2011/0178359 (Hirschman) and Alvarez-Diez (cited in the previous Office Action)*.

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 described the background of the invention, current challenges in the art, and the inventive concept set forth in the present application. Following discussion of the remarks filed 12 June 2015, agreement was reached that the current rejections would be withdrawn and prosecution re-opened.

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.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	14/455,623	Group Art Unit:	3735
Filed:	August 8, 2014	Examiner:	DORNA, CARRIE
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

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

INTERVIEW SUMMARY

Applicant thanks the Examiner for her time and the courtesies extended during the telephonic interview conducted on June 24, 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 the outstanding Final Office Action mailed March 12, 2015, the art cited therein, and Applicant's After-Final Response filed June 12, 2015. No exhibits were introduced or discussed.

Applicant's representative started the discussion with a background explanation of the underlying technology. For example, Applicant's representative provided a high-level discussion of the operation of strontium-rubidium radioisotope generators and their use to generate radioactive rubidium for injection into a patient. Applicant's representative further discussed unintended strontium release from a strontium-rubidium radioisotope generator column and the undesired effects of injecting such strontium into a patient because of the comparatively long half-life of strontium as compared to rubidium.

Applicant's representative continued the discussion by providing an overview of the claimed features and the real-world benefits provided by embodiments of such features. For example, Applicant's representative discussed potential benefits associated with an integrated system that includes a radioisotope generator, an on board dose calibrator to measure breakthrough (e.g., strontium breakthrough), and computer control of such a system. Applicant's representative discussed how the combination of the dose calibrator with the underlying

radioisotope generator system can offer an integrated system where computing hardware and/or software for controlling patient infusion procedures also controls dose calibration activity determination. The computing hardware and/or software in such an integrated system can prevent a patient infusion procedure in instances where data from the on board dose calibrator indicates that a breakthrough testing result exceeds an allowable limit.

Applicant's representative and the Examiner continued the conversation by discussing the outstanding rejections lodged against the pending claims. The Examiner agreed with Applicant's remarks in the After-Final Response that the outstanding Office Action should not have been made final. The Examiner also agreed with Applicant's position in the After-Final Response that the applied references do not disclose or suggest all the features of the claims. For example, Applicant's representative and the Examiner discussed how the applied references do not disclose or suggest a system that includes a computer configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit, particularly in combination with the other claimed features.

In addition to discussing the substantive issues in the case, Applicant's representative also clarified an unintended typographical omission in the After-Final Response. Page 4 of the After-Final Response included the statement: "Alvarez-Diez does disclose or suggest preventing a patient infusion procedure if a breakthrough test result exceeds an allowable limit." In fact, the statement was intended to recite: "Alvarez-Diez does <u>not</u> disclose or suggest preventing a patient infusion procedure if a breakthrough test result exceeds an allowable limit." Applicant's representative wished to clarify the record and note that no admission was intended by the typographical omission. The Examiner indicated that Applicant's intended language was apparent from the context and remainder of the response.

The Examiner agreed to withdraw the outstanding Final Office Action and undertake further search, examination, and consideration of the application for potential allowability. Applicant's representative invited the Examiner to telephone at the below-identified number to the extent it would be helpful to advance prosecution of the application.

Dated: June 29, 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.

56226272_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	22767950
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.15
Receipt Date:	29-JUN-2015
Filing Date:	08-AUG-2014
Time Stamp:	14:23:38
Application Type:	Utility under 35 USC 111(a)

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	Applicant summary of interview with examiner	56782_1_7_15_Interview_Summary.pdf	101644 ff0f1ea2ba111b25dd91166bce1bc42b36ec9a23	no	3

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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.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	14/455,623	Group Art Unit:	3735
Filed:	August 8, 2014	Examiner:	DORNA, CARRIE
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

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

AFTER-FINAL RESPONSE

Dear Commissioner:

In response to the Office Action mailed March 12, 2015, the period of response for which runs through June 12, 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 March 12, 2015. Claims 1–5, 7–19, and 21–24 remain pending. Reconsideration of the application is respectfully requested.

Withdrawal of Finality of Office Action

Applicant respectfully requests withdrawal of the finality of the Office Action because the Examiner rejected the claims on a new ground of rejection that was not necessitated by Applicant's prior claim amendment. In the Non-Final Office Action dated October 23, 2014, independent claims 1 and 14, as well as dependent claims 6 and 20, were rejected as allegedly being unpatentable over de Kemp et al. (US 2007/0213848) in view of de Kemp (US 2007/0140958). Applicant responded to the Non-Final Office Action in an Amendment filed on January 23, 2015 in which Applicant amended independent claim 1 to incorporate the features of dependent claim 6 and independent claim 14 to incorporate the features of dependent claim 20. Accordingly, amended independent claims 1 and 14 presented the same combination of features originally presented in dependent claims 6 and 20. In the current Final Office Action, independent claims 1 and 14 have been rejected as allegedly being unpatentable over Hirschman (US 2011/0178659) in view of Alvarez-Diez et al. as evidenced by Klein et al.

MPEP 706.07(a) states that:

> Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement . . . .

Since the Final Office Action has introduced a new ground of rejection against the features of independent claims 1 and 14, and the new ground of rejection was not necessitated by Applicant's claim amendment (since the features were originally present in claims 6 and 20), the finality of the Office Action is improper and should be withdrawn.

Claim Rejections Under pre-AIA 35 U.S.C. § 103(a)

In the Office Action, claims 1–5, 7–10, 12–19 and 21– 24 were rejected under pre-AIA 35 U.S.C. § 103(a) as purportedly being unpatentable over Hirschman et al. (US 2011/0178659, hereinafter "Hirschman") in view of "Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using

positron emission tomography" by Alvarez-Diez et al. (hereinafter "Alvarez-Diez"), as evidenced by "Precision Control of Eluted Activity from a Sr/Rb Generator for Cardiac Positron Emission Technology" by Klein et al. (hereinafter "Klein"). In addition, claim 11 was rejected under pre-AIA 35 U.S.C. § 103(a) as purportedly being unpatentable over Hirschman in view of Alvarez-Diez, as evidenced by Klein, and further in view of Tate et al. (US 2008/0177126, hereinafter "Tate").

Applicant respectfully traverses the rejections. 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.

The applied references do not disclose or suggest the features of the claims including, for example, independent claim 1. Independent claim 1 is directed to a system that includes a shielding assembly, a computer, and a dose calibrator. The claim states that the shielding assembly is configured to contain a radioisotope generator that generates radioactive eluate via elution and the computer is carried by the shielding assembly. The computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing. The dose calibrator is electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing. The claim further specifies that the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results and also configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

In support of the rejection of independent claim 1, the Office Action cited Hirschman as purportedly disclosing a system that includes a shielding assembly, a computer carried by a cabinet structure, and a dose calibrator electronically coupled to the computer. The Office Action conceded that Hirschman does not teach performing breakthrough testing or preventing a patient infusion procedure if a breakthrough test result exceeds an allowable limit. The Office Action cited Alvarez-Diez in attempt to overcome these deficiencies and asserted, on this basis, that the features of independent claim 1 would have been obvious. Applicant respectfully disagrees for multiple reasons.

First, even if the system of Hirschman were modified in view of Alvarez-Diez in the manner proposed in the Office Action, the resulting combination would not yield all the features

required by independent claim 1. In particular, the resulting system would not provide a system where a computer carried by a shielding assembly is configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit, as per claim 1.

In support of the rejection of this feature, the Office Action conceded that Hirschman does not disclose a computer configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit. Alvarez-Diez similarly does not disclose such a feature. Rather, Alvarez-Diez is concerned with "a novel and simple manufacturing protocol which include the quality control procedures for the production of $^{82}Sr/^{82}Rb$ generators."[1] Alvarez-Diez does disclose or suggest preventing a patient infusion procedure if a breakthrough test result exceeds an allowable limit. Thus, even if the system of Hirschman were modified in view of Alvarez-Diez, the resulting system would not have a computer carried by a shielding assembly and configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit. This is a clear "missing element" from the cited art.

In the rejection of independent claim 1, the Office Action alleged that it would have been obvious to "modify the alarms/alerts of Hirschman to prevent infusion if a breakthrough test result exceeds an allowable limit."[2] Yet neither Hirschman nor Alvarez-Diez ever contemplate or disclose preventing a patient infusion procedure under any circumstances, much less when a test result exceeds an allowable limit. The references fail to recognize or convey to a person of ordinary skill in the art the features and advantages of having such a feature, as recognized and disclosed by the Applicant.

Second, even if the system of Hirschman were modified in view of Alvarez-Diez in the manner proposed in the Office Action, the resulting combination would not yield other features required by the claim. For example, independent claim 1 requires a computer carried by a shielding assembly and "configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing." The Office Action cited Hirschman as purportedly disclosing a computer configured to receive user input and "responsive to receiving the user input, control the radioisotope generator."[3] However, independent claim 1 does not require a computer configured to receive user input and merely "control the radioisotope generator" but rather "generate a

[1] Alvarez-Diez at page 1016.
[2] Office Action dated March 12, 2015, at page 5.
[3] *Id.* at page 3.

sample of eluate via elution during breakthrough testing." Besides the previously-mentioned citation to Hirschman, the Office Action did not place any additional evidence or arguments on the record as to how allegedly this claim feature is disclosed or rendered obvious. Applicant submits that a computer carried by a shielding assembly and "configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing" is not disclosed or suggested by the applied references.

Third, there is no reason why a person of ordinary skill in the art would have modified the system of Hirschman in view of Alvarez-Diez as proposed in the Office Action. The system described in the cited passages of Hirschman is not a strontium-rubidium generator system. To the contrary, Hirschman describes that the system in cited FIG. 3 uses a technetium Tc-99m generator that draws saline through a column containing molybdenum Mo-99.[4] Given that Hirschman and Alvarez-Diez relate to entirely different radionuclides with different half-lives and different behaviors, a person of ordinary skill in the art would not have found the teachings in Alvarez-Diez concerning quality control procedures for a strontium-rubidium generator to be at all relevant to the system of Hirschman.

Moreover, Applicant respectfully disagrees that the Office Action presented a legally sufficient justification as to why allegedly it would have been obvious to modify the system of Hirschman in view of Alvarez-Diez. It is well established that rejections based on obviousness cannot be sustained on mere conclusory statements but must be supported with articulated reasoning grounded in rational underpinnings of fact. Yet in the Office Action, the conclusion of obviousness was based on the following rationale:

> It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer and in-line dosimeters of the integrated radiopharmaceutical patient treatment system of Hirschman to perform breakthrough testing as taught by Alvarez-Diez . . . a because elution of ^{82}Sr and ^{85}Sr isotopes (half-life 25 and 65 days respectively) to the patient is undesired, as Sr tends to accumulate in the bone marrow, which is particularly radiation sensitive (Klein, page 1396).[5]

Applicant respectfully submits that the argument advanced in the Office Action and reproduced above does not provide any legally justifiable basis for alleging that it would have been obvious

[4] *See* Hirschman at paragraph [0126].
[5] Office Action dated March 12, 2015, at page 5.

to modify the system of Hirschman in view of the teachings of Alvarez-Diez. If anything, the arguments advanced in the Office Action indicate that it would not have been obvious to modify the technetium Tc-99m generator of Hirschman with the strontium-rubidium techniques of Alvarez-Diez because, according to the Office Action, "elution of ^{82}Sr and ^{85}Sr isotopes . . . to the patient is undesired, as Sr tends to accumulate in the bone marrow, which is particularly radiation sensitive."

For at least the reasons given above, the applied references do not render independent claim 1 unpatentable. Independent claim 14, though differing in scope from independent claim 1, recites features similar to independent claim 1 and is therefore patentable for at least the reasons given above. Claims 2–5, 7–13, 15–19, and 21–24 depend from independent claims 1 or 14 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: June 12, 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.
53152756_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	22612664
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
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:	56782.1.7.15
Receipt Date:	12-JUN-2015
Filing Date:	08-AUG-2014
Time Stamp:	12:20:04
Application Type:	Utility under 35 USC 111(a)

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_15_OAR.pdf	122383 22d8345abcedd04de96f7c11b0ab46caa39fc2c5a	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
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National Stage of an International Application under 35 U.S.C. 371
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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)
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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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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	14455623
	Filing Date	2014-08-08
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Carrie R. Dorna
	Attorney Docket Number	56782.1.7.15

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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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Carrie R. Dorna
Attorney Docket Number	56782.1.7.15

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.**

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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 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.

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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.

Electronic Patent Application Fee Transmittal

Application Number:	14455623
Filing Date:	08-Aug-2014
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.15

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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**

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EFS ID:	22560801
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
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:	56782.1.7.15
Receipt Date:	08-JUN-2015
Filing Date:	08-AUG-2014
Time Stamp:	18:24:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	5077
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	Information Disclosure Statement (IDS) Form (SB08)	56782_1_7_15_SIDS.pdf	612300 7e836929e0f3d7effb8218aa96c35e3a8a847f0e	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30750 1963e8e8a819ae54e61db77a259ba588d31db97c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	643050		

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
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PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Stephen E. Hidem Date (Optional): 3/18/15

Signature: S. E. Hidem

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Aaron M. Fontaine Date (Optional): 3/3/2015

Signature: Aaron Fontaine

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Janet L. Gelbach Date (Optional): 8/27/2014

Signature: Janet Gelbach

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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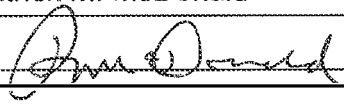
LEGAL NAME OF INVENTOR

Inventor: Patrick M. McDonald Date (Optional): 13 Aug 2014

Signature: 

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LEGAL NAME OF INVENTOR

Inventor: Kathryn M. Hunter Date (Optional) : _____

Signature: Kathryn M Hunter

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)
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LEGAL NAME OF INVENTOR

Inventor: ROLF E. SWENSON Date (Optional): 7/29/14

Signature: Rolf E Swenson

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: JULIUS P. ZODDA Date (Optional): July 29, 2014

Signature: Julius P. Zodda

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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:	22237758
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.15
Receipt Date:	04-MAY-2015
Filing Date:	08-AUG-2014
Time Stamp:	16:16:07
Application Type:	Utility under 35 USC 111(a)

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	Oath or Declaration filed	56782_1_7_15_Executed_Declarationsx.pdf	11855742 810b794d7b2b85cd421417e1f51fb3bb7e315217	no	8
Warnings:					
Information:					

Total Files Size (in bytes):	11855742

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 03/12/2015

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
03/12/2015	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. 14/455,623	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 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) *1-5,7-19 and 21-24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,7-19 and 21-24* 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 *December 23, 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.

Response to Amendment

2. The Amendment filed January 23, 2015 is acknowledged. Claims 1-5, 7-19, & 21-24 are pending, claims 6 & 20 are canceled, and claims 1 & 14 are amended.

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 1-5, 7-10, 12-19, and 21-24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Hirschman et al. (US Publication No. 2011/0178359 A1) in view of "Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using positron emission tomography" by Alvarez-Diez et al. (hereinafter "Alvarez-Diez"), as evidenced by "Precision Control of Eluted Activity from a Sr/Rb Generator for Cardiac Positron Emission Technology" by Klein et al. (hereinafter "Klein").

Regarding claim 1, Hirschman teaches an integrated radiopharmaceutical patient treatment system (Abstract). Hirschman teaches a cabinet structure with a radionuclide generation module (220) inside (paragraphs [0121]-[0122] & [0126]-[0127]; Figure 3). Hirschman teaches the radionuclide generation module (220) is desirably contained within a shielded compartment of radiation protection module (280) ("a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution") (paragraph [0126]; Figure 3). Hirschman teaches a computer is carried by the cabinet structure (see control computer (210) in Figure 3; paragraph [0122]). Hirschman teaches the computer is configured to receive user input, and responsive to receiving the user input, control the radioisotope generator (paragraphs [0123], [0125], [0131], [0142], & [0153]; see GUI (212) in Figure 4B). Hirschman teaches a dose calibrator electronically coupled to the computer and configure to measure an activity of the sample of eluate (paragraphs [0019], [0027], [0031], [0032], [0082], [0086], [0130], [0143], [0144], [0181], [0184], [0189], [0203], [0206], & [0210]; Figures 3 & 16). Hirschman teaches the computer is configured to receive the activity data from the dose calibrator (paragraphs [0130], [0131], & [0134]).

Hirschman teaches creating an isotope, which is the precursor material to the radiopharmaceutical agent (paragraphs [0080], [0115], & [0116]), but does not explicitly teach performing breakthrough testing. Hirschman teaches manual checks must be performed prior to injection (paragraph [0012]) and a quality control subsystem of module (240) is used to ensure the correct radiopharmaceutical fluid is delivered in the correct quantity to the correct patient (paragraph [0135]; Figure 3); the quality control module (240) communicates its status and any alarms to the operator through control computer (210) (paragraph [0136]); a monitor, which can alert or alarm, is associated with any part of dosimeter control (1026) to alert the operator if there is any change from the steady half-life decay that could indicate a leakage of liquid or a failure of some other system component (paragraph [0184]); but does not teach preventing a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

Alvarez-Diez teaches quality control of $^{82}Sr/^{82}Rb$ generators including radionuclide purity (^{82}Sr and ^{85}Sr breakthrough) (page 1018). Alvarez-Diez found $^{82}Sr/^{82}Rb$ ratio limit to be 0.02 μCi/mCi and ^{82}Sr and ^{85}Sr breakthrough measurements performed daily before administration to the patients using a dose calibrator (pages 1018 & 1019).

$$^{82}Sr\ breakthrough = \frac{^{82}Sr}{^{82}Rb} \quad (1)$$

;

$$^{82}Sr = \frac{\text{Radioactivity at one hour}}{1 + 0.48 \times R'}. \quad (2)$$

;

$$^{85}Sr\ breakthrough = ^{82}\ Sr\ Breakthrough \times R'. \qquad (3)$$

;

where R´ is the $^{85}Sr/^{82}Sr$ ratio on the date of the measurement (page 1019).

Alvarez-Diez teaches taking daily ^{82}Sr and ^{85}Sr breakthrough measurements in a dose calibrator using Eqs. (1) and (3), which allowed correction of the contribution of ^{85}Sr to the ^{82}Sr breakthrough reading, which could have otherwise resulted in overestimates of the ^{82}Sr breakthrough (page 1020). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer and in-line dosimeters of the integrated radiopharmaceutical patient treatment system of Hirschman to perform breakthrough testing as taught by Alvarez-Diez and modify the alarms/alerts of Hirschman to prevent infusion if a breakthrough test result exceeds an allowable limit because elution of ^{82}Sr and ^{85}Sr isotopes (half-life 25 and 65 days respectively) to the patient is undesired, as Sr tends to accumulate in the bone marrow, which is particularly radiation sensitive (Klein, page 1396).

Regarding claim 2, Hirschman teaches creating an isotope, which is the precursor material to the radiopharmaceutical agent (paragraphs [0080], [0115], & [0116]) and teaches knowledge of concentration of radioactivity in tissue and blood is important for radioisotopes with short half-lives, such as Rubidium-82 (paragraph [0115]) and teaches an isotope generator (1006) (see Figure 14A), but does not explicitly disclose the radioisotope generator comprises a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82.

Alvarez-Diez teaches a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82 (pages 1018-1020). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the generic radiopharmaceutical generation of Hirschman to be a $^{82}Sr/^{82}Rb$ generator as taught by Alvarez-Diez because it would be a simple

substitution of known ways of generating a radioisotope to yield the predictable result of a compound to be infused into a patient.

Regarding claim 3, Alvarez-Diez teaches calculating the breakthrough test results by at least calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82 (pages 1019 & 1020; Eqs. (1)-(3)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer of Hirschman to calculate the breakthrough test results as taught by Alvarez-Diez since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 4, Hirschman teaches manual checks must be performed prior to injection (paragraph [0012]) and a quality control subsystem of module (240) is used to ensure the correct radiopharmaceutical fluid is delivered in the correct quantity to the correct patient (paragraph [0135]; Figure 3); the quality control module (240) communicates its status and any alarms to the operator through control computer (210) (paragraph [0136]); a monitor, which can alert or alarm, is associated with any part of dosimeter control (1026) to alert the operator if there is any change from the steady half-life decay that could indicate a leakage of liquid or a failure of some other system component (paragraph [0184]); but does not teach the computer is further configured to indicate if the breakthrough test results are within allowable limits.

Alvarez-Diez found $^{82}Sr/^{82}Rb$ ratio limit to be 0.02 μCi/mCi and ^{82}Sr and ^{85}Sr breakthrough measurements performed daily before administration to the patients using a dose calibrator (pages 1018 & 1019). It would have been obvious to one of ordinary skill in the art at

the time of the invention to modify the alerts/alarms provided by the control computer of Hirschman to indicate if the breakthrough test results are within the allowable limits taught by Alvarez-Diez in order to notify the operator of undesired presence of Sr isotopes (*see* Klein, page 1396).

Regarding claim 5, Alvarez-Diez teaches the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie (pages 1018 & 1019).

Regarding claim 7, Hirschman teaches an activity detector (*see* dosimeters (232a) & (232b) in Figure 3; dosimeter (1014) in Figure 14A; paragraphs [0138], [0184]).

Regarding claim 8, Hirschman teaches the computer is configured to divert eluate generated via elution to a waste bottle until the activity detector detects a given level of activity (paragraphs [0025], [0082], [0122], [0127], [0156]-[0159], & [0167]-[0172]).

Regarding claim 9, Alvarez-Diez teaches measuring the activity of strontium and rubidium (pages 1018-1020), but does not teach the given level of activity is approximately 1.0 millicurie per second. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general activity levels taught by Hirschman and Alvarez-Diez, as evidenced by Klein, such that the given level of activity is approximately 1.0 millicurie per second since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272 (CCPA 1980).

Regarding claim 10, Hirschman teaches a display configured to display the test results (*see* integrated system controller (110c) in Figure 2C; GUI (212) in Figures 4A-4B; paragraphs [0094], [0123], [0131], [0135], [0143], & [0160]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the breakthrough testing of Hirschman in view of Alvarez-Diez, as evidenced by Klein, to be displayed on the display of Hirschman in order to verify the results prior to injecting the radiopharmaceutical into the patient (Hirschman, paragraph [0143]).

Regarding claim 12, Hirschman teaches a cabinet structure (paragraphs [0121]-[0122] & [0126]-[0127]; Figure 3), wherein the shielding assembly is positioned inside the cabinet structure and the computer is carried by the cabinet structure (paragraphs [0121]-[0122] & [0126]-[0127]; Figure 3).

Regarding claim 13, Hirschman teaches the dose calibrator is configured to physically receive the sample of eluate generated during breakthrough testing (paragraphs [0082], [0086], [0087], [0199], & [0203]).

Regarding claim 14, Hirschman teaches generating, with a radioisotope generator contained within a shielding assembly, a radioactive eluate via elution of an eluent (paragraphs [0080], [0115], [0116], [0122], & [0126]-[0130]; *see* radionuclide generation module (220) & radiation protection module (280) in Figure 3; *see* isotope generator (1006) in Figure 14A); measuring with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate (*see* control computer (210) in Figure 3; Figure 16; paragraphs [0019], [0027], [0031], [0032], [0082], [0086], [0122], [0130], [0143], [0144],

[0181], [0184], [0189], [0203], [0206], & [0210]); determining, with the computer, an activity of within the radioactive eluate (paragraphs [0130], [0131], & [0134]).

Hirschman does not explicitly teach determining the activity of rubidium-82. Hirschman teaches manual checks must be performed prior to injection (paragraph [0012]) and a quality control subsystem of module (240) is used to ensure the correct radiopharmaceutical fluid is delivered in the correct quantity to the correct patient (paragraph [0135]; Figure 3); the quality control module (240) communicates its status and any alarms to the operator through control computer (210) (paragraph [0136]); a monitor, which can alert or alarm, is associated with any part of dosimeter control (1026) to alert the operator if there is any change from the steady half-life decay that could indicate a leakage of liquid or a failure of some other system component (paragraph [0184]); but does not teach preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

Alvarez-Diez teaches quality control of $^{82}Sr/^{82}Rb$ generators including radionuclide purity (^{82}Sr and ^{85}Sr breakthrough) (page 1018). Alvarez-Diez found $^{82}Sr/^{82}Rb$ ratio limit to be 0.02 μCi/mCi and ^{82}Sr and ^{85}Sr breakthrough measurements performed daily before administration to the patients using a dose calibrator (pages 1018 & 1019).

$$^{82}Sr\ breakthrough = \frac{^{82}Sr}{^{82}Rb} \quad (1)$$

;

$$^{82}Sr = \frac{\text{Radioactivity at one hour}}{1 + 0.48 \times R'}. \quad (2)$$

;

$$^{85}Sr\ breakthrough = ^{82}\ Sr\ Breakthrough \times R'. \qquad (3)$$

;

where R´ is the $^{85}Sr/^{82}Sr$ ratio on the date of the measurement (page 1019).

Alvarez-Diez teaches taking daily ^{82}Sr and ^{85}Sr breakthrough measurements in a dose calibrator using Eqs. (1) and (3), which allowed correction of the contribution of ^{85}Sr to the ^{82}Sr breakthrough reading, which could have otherwise resulted in overestimates of the ^{82}Sr breakthrough (page 1020). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer and in-line dosimeters of the integrated radiopharmaceutical patient treatment system of Hirschman to perform breakthrough testing and measure the activity of rubiudium-82 as taught by Alvarez-Diez and modify the alarms/alerts of Hirschman to prevent infusion if a breakthrough test result exceeds an allowable limit because elution of ^{82}Sr and ^{85}Sr isotopes (half-life 25 and 65 days respectively) to the patient is undesired, as Sr tends to accumulate in the bone marrow, which is particularly radiation sensitive (Klein, page 1396).

Regarding claim 15, Alvarez-Diez teaches determining an activity of strontium-82 and an activity of strontium-85 in the radioactive eluate (pages 1018-1020). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer of Hirschman to measure the activity of strontium-82 and strontium-85 as taught by Alvarez-Diez since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 16, Alvarez-Diez teaches determining a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the

activity of rubidium-82 (pages 1019 & 1020; Eqs. (1)-(3)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer of Hirschman to calculate the activity ratios as taught by Alvarez-Diez since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 17, Alvarez-Diez teaches determining if the ratio of activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are within allowable limits (pages 1018 & 1019). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the control computer of Hirschman to determine when the ratio exceeded the limit taught by Alvarez-Diez since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 18, Alvarez-Diez teaches the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie (pages 1018 & 1019).

Regarding claim 19, Hirschman teaches displaying test results determined by the computer (*see* integrated system controller (110c) in Figure 2C; GUI (212) in Figures 4A-4B; paragraphs [0094], [0123], [0131], [0135], [0143], & [0160]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the breakthrough testing of Hirschman in view of Alvarez-Diez, as evidenced by Klein, to be displayed on the display of

Hirschman in order to verify the results prior to injecting the radiopharmaceutical into the patient (Hirschman, paragraph [0143]).

Regarding claim 21, Hirschman teaches measuring, with an activity detector electronically coupled to the computer, an activity of the radioactive eluate (*see* dosimeters (232a) & (232b) in Figure 3; dosimeter (1014) in Figure 14A; paragraphs [0138], [0184]).

Regarding claim 22, Hirschman teaches controlling, with the computer, a diverter valve to divert the radioactive eluate to a waste bottle until the activity detector detects a given level of activity (paragraphs [0122], [0127], [0156]-[0161], & [0207]).

Regarding claim 23, Alvarez-Diez teaches measuring the activity of strontium and rubidium (pages 1018-1020), but does not teach the given level of activity is approximately 1.0 millicurie per second. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general activity levels taught by Hirschman and Alvarez-Diez, as evidenced by Klein, such that the given level of activity is approximately 1.0 millicurie per second since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272 (CCPA 1980).

Regarding claim 24, Hirschman teaches the shielding assembly is positioned inside a cabinet structure and the computer is carried by the cabinet structure (paragraph [0126]; *see* control computer (210) in Figure 3).

6. Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Hirschman in view of Alvarez-Diez, as evidenced by Klein , and further in view of Tate et al. (US Publication No. 2008/0177126 A1).

Regarding claim 11, the combination of Hirschman and Alvarez-Diez, as evidenced by Klein, teaches the system of claim 10, but does not teach the computer is configured to control the display to provide an indication of progress of the breakthrough testing.

Tate discloses a fluid path set for a fluid delivery system (Abstract). Tate teaches a progress bar (1126a) indicates the degree of progress in a Background Check (paragraph [0199]; shown at 20% in Figure 17). Tate teaches the "Constancy/Accuracy" test display bar (1128) includes a test progress bar, similar to bar (1126a), indicating the degree of progress to the operator (paragraph [0202]). Tate teaches when the system is priming the SPDS (700) a progress bar (1213) is generated to indicate the degree of completion (shown at 17% in Figure 26A). Tate teaches the display (1000) includes a progress bar (1213a) to indicate the degree of progress made in completing the test injection procedure (shown at 45% in Figure 27A; paragraph [0220]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the computer and display of Hirschman and Alvarez-Diez, as evidenced by Klein, to include a progress bar taught by Tate in order to indicate a degree of progress in the breakthrough testing to the operator (Tate, paragraphs [0199], [0202], [0203], [0219], [0220], [0223], [0230], [0232]).

Response to Arguments

7. Applicant's arguments with respect to claims 1-5, 7-19, and 21-24 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection. Hirschman teaches a computer carried by a shielding assembly (see computer (210) and shielding (280) in Figure 3) and teaches a dose calibrator electronically coupled to the

computer (see above rejection). The combination of Hirschman and Alvarez-Diez, as evidenced by Klein, teaches all the claimed limitations because Hirschman teaches a radioisotope generator and using the control computer to gather activity information, while Alvarez-Diez teaches measuring the activity and ratios of strontium-82, strontium-85, rubidium-82, and allowable limits of breakthrough testing (see above rejection).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). 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 date of this final action.

9. 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. 14/455,623	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-2008/0177126 A1	07-2008	Tate et al.	600/5
	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	"Precision Control of Eluted Activity from a Sr/Rb Generator for Cardiac Positron Emission Technology" by R. Klein, A. Adler, R.S. Beanlands, R.A. deKemp (Proceedings of the 26th Annual International Conference of the IEEE EMBS, San Francisco, CA, USA, September 1-5, 2004, pages 1393-1396.
	V	"Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using positron emission tomography" by T.M. Alvarez-Diez, R. deKemp, R. Beanlands, J. Vincent, Applied Radiation and Isotopes 50 (1999) 1015-1023.
	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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	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	10/15/2014	02/24/2015							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	-							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
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	18	✓	✓							
	19	✓	✓							
	20	✓	-							
	21	✓	✓							
	22	✓	✓							
	23	✓	✓							
	24	✓	✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L7	16	(US-20110178359-$ or US-20080242915-$ or US-20080200747-$ or US-20140374614-$ or US-20090312635-$ or US-20090312630-$ or US-20080177126-$).did. or (US-7204797-$ or US-6767319-$ or US-4585009-$ or US-4562829-$ or US-8071959-$ or US-6267717-$ or US-7813841-$ or US-4674403-$ or US-3847138-$).did.	US-PGPUB; USPAT	OR	ON	2015/02/24 12:12
L8	6	L7 and (progress$3)	US-PGPUB; USPAT; USOCR	OR	ON	2015/02/24 12:12
S1	122	("20020129471" | "20030004463" | "20030139640" | "20040104160" | "20040260143" | "20050187515" | "20050277833" | "20050278066" | "20060015056" | "20060151048" | "20060173419" | "20070080223" | "20070140958" | "20070213848" | "20070232980" | "20070282263" | "20080071219" | "20080093564" | "20080166292" | "20080177126" | "20080191148" | "20080237502" | "20080242915" | "20090312630" | "20090312635" | "20100030009" | "20100312039" | "20110071392" | "20110172524" | "20110209764" | "20120098761" | "20120305730" | "20120310031" | "20120312980" | "20130300109" | "20140084187" | "20140175959" | "3483867" | "3565376" | "3710118" | "3714429" | "3774036" | "3991960" | "3997784" | "4096859" | "4212303" | "4286169" | "4336036" | "4466888" | "4562829" | "4585009" | "4585941" | "4623102" | "4625118" | "4656697" | "4679142" | "4755679" | "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" | "6767319" | "6870175" | "6901283" | "6908598" | "7091494" | "7163031" | "7169135" | "7204797" | "7256888" | "7286867" | "7413123" | "7476377" | "7504646" | "7522952" | "7586102" | "7605384" | "7608831" | "7612999" | "7712491" |	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/02 15:20

		"7734331" | "7737415" | "7780352" | "7813841" | "7825372" | "7862534" | "7996068" | "8058632" | "8071959" | "8198599" | "8216181" | "8216184" | "8295916" | "8317674" | "8431909" | "8439815" | "8442803" | "8708352").PN.				
S2	266	600/4,5.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/02 15:21
S3	112	A61N2005/1021,1022.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/02 15:30
S4	2014	A61N5/10,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/02 15:32
S5	1678	378/65.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/02 15:36
S6	266	600/4,5.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:54
S7	112	A61N2005/1021,1022.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:54
S8	2014	A61N5/10,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:54
S9	1678	378/65.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:54
S10	3729	S6 or S7 or S8 or S9	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:54
S11	21	S10 and (shield$3 same generator) and computer and (dose with calibrat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:55
S12	13	S11 and (rubidium or strontium)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:55
S13	42	("4401108" | "4409966" | "4472403" | "4562829" | "4585009" | "4883459" | "5383858" | "5472403" | "5514071" | "5520653" | "5918443" | "5927351" | "5947890" | "6267717" | "6450936" | "6471674" | "6520930").PN. OR ("6767319").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:57
S14	2	("4562829" | "4585009").pn.	US-PGPUB;	OR	ON	2014/10/03 08:57

			USPAT; USOCR			
S15	25	("4202345").PN. OR ("4562829").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:57
S16	266	600/4,5.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
S17	112	A61N2005/1021,1022.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
S18	2020	A61N5/10,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
S19	1682	378/65.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
S20	3738	S16 or S17 or S18 or S19	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
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S24	13	S20 and ((processor or microprocessor or computer) same shield$3) and (radioisotope near4 generat$3) and (dose with calibrat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:33
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S31	12	S28 and (breakthrough or (break adj through)) and (strontium or rubidium) and (dose with calibrat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 08:16
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S33	1	(11/312368).APP.	US-PGPUB; USOCR	OR	ON	2014/10/15 08:45
S34	0	S20 and ((breakthrough or (break adj through)) same prevent$3)	US-PGPUB; USPAT;	OR	ON	2014/10/15 09:18

			USOCR			
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S36	12	S28 and ((breakthrough or (break adj through)) same (limit or threshold))	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 09:19
S37	10	S28 and ((breakthrough or (break adj through)) same display$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 09:25
S38	1	S28 and ((breakthrough or (break adj through)) same (limit or threshold)) and (microcurie or millicurie)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 09:34
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S41	15	S20 and (shield$3 same (radioisotope near4 generat$3))	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 09:36
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S45	3	((Aaron) near2 (Fontaine)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
S46	4	((Janet) near2 (Gelbach)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
S47	53	((Patrick) near2 (McDonald)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
S48	2	((Kathryn) near2 (Hunter)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
S49	107	((Rolf) near2 (Swenson)).INV.	US-	OR	ON	2014/10/15

			PGPUB; USPAT; USOCR			10:24
S50	21	((Julius) near2 (Zodda)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
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S60	203	B01D15/362.cpc.	US-PGPUB; USOCR	OR	ON	2015/01/14 14:10
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S89	5	S86 and (millicurie with (sec or second))	US-PGPUB; USPAT; USOCR	OR	ON	2015/02/03 14:34
S90	26	S86 and (waste with (sec or second))	US-PGPUB; USPAT; USOCR	OR	ON	2015/02/03 14:34
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S94	15	S86 and (waste with activity)	US-PGPUB; USPAT; USOCR	OR	ON	2015/02/03 14:36

2/ 24/ 2015 12:31:32 PM
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.15

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							☐

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

Receipt date: 12/23/2014	Application Number	14455623	14455623 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-08-08	
	First Named Inventor	Stephen E. Hidem	
	Art Unit	3735	
	Examiner Name	Eileen Foley Hyde	
	Attorney Docket Number	56782.1.7.15	

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	01/30/2015

*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.

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N2005/1021, 1022	10/2/14	EF
A61N5/10, 1007	10/2/14	EF

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	4, 5	10/2/14	EF
378	65	10/2/14	EF

SEARCH NOTES

Search Notes	Date	Examiner
Inventor name search in EAST	10/15/14	EF
Limited class/subclass searches with text	10/2; 10/3; 10/15/14	EF
Updated class/subclass searches and additional text searching in EAST	1/14/15; 1/30/15; 2/3/15; 2/24/15	EF

INTERFERENCE SEARCH

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/E.F./ Examiner.Art Unit 3735	

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	14/455,623	Group Art Unit:	3735
Filed:	August 8, 2014	Examiner:	Eileen Foley Hyde
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

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

AMENDMENT

Dear Commissioner:

In response to the Office Action mailed October 23, 2014, the period of response for which runs through January 23, 2015, please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 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 comprising:

a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution;

a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing; and

a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing,

wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results, and

the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

2. (Original) The system of claim 1, wherein the radioisotope generator comprises a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82.

3. (Original) The system of claim 1, wherein the computer is configured to calculate the breakthrough test results by at least calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82.

4. (Original) The system of claim 3, wherein the computer is further configured to indicate if the breakthrough test results are within allowable limits.

5. (Original) The system of claim 4, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

6. (Canceled)

7. (Original) The system of claim 1, further comprising an activity detector.

8. (Original) The system of claim 7, wherein the computer is configured to divert eluate generated via elution to a waste bottle until the activity detector detects a given level of activity.

9. (Original) The system of claim 8, wherein the given level of activity is approximately 1.0 millicurie per second.

10. (Original) The system of claim 1, further comprising a display configured to display the breakthrough test results.

11. (Original) The system of claim 10, wherein the computer is configured to control the display to provide an indication of progress of the breakthrough testing.

12. (Original) The system of claim 1, further comprising a cabinet structure, wherein the shielding assembly is positioned inside the cabinet structure and the computer is carried by the cabinet structure.

13. (Original) The system of claim 1, wherein the dose calibrator is configured to physically receive the sample of eluate generated during breakthrough testing.

14. (Currently Amended) A method comprising:

generating, with a radioisotope generator contained within a shielding assembly, a radioactive eluate via elution of an eluant;

measuring, with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate; ~~and~~

determining, with the computer, an activity of rubidium-82 within the radioactive eluate, and

preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

15. (Original) The method of claim 14, further comprising determining, with the computer, an activity of strontium-82 and an activity of strontium-85 in the radioactive eluate.

16. (Original) The method of claim 15, further comprising determining, with the computer, a ratio of the activity of strontium-82 divided by the activity of rubidium-82 and a ratio of the activity of strontium-85 divided by the activity of rubidium-82.

17. (Original) The method of claim 16, further comprising determining, with the computer, if the ratio of activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are within allowable limits.

18. (Original) The method of claim 17, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

19. (Original) The method of claim 14, further comprising displaying breakthrough test results determined by the computer.

20. (Canceled)

21. (Original) The method of claim 14, further comprising measuring, with an activity detector electronically coupled to the computer, an activity of the radioactive eluate.

22. (Original) The method of claim 21, further comprising controlling, with the computer, a diverter valve to divert the radioactive eluate to a waste bottle until the activity detector detects a given level of activity.

23. (Original) The method of claim 22, wherein the given level of activity is approximately 1.0 millicurie per second.

24. (Original) The method of claim 14, wherein the shielding assembly is positioned inside a cabinet structure and the computer is carried by the cabinet structure.

REMARKS

This Amendment is responsive to the Office Action dated October 23, 2014. Applicant has amended independent claim 1 to incorporate the features of dependent claim 6 and independent claim 14 to incorporate the features of dependent claim 20. Claims 1–5, 7–19, and 21–24 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 January 14, 2015. Examiner Eileen Foley, the Examiner's Supervisor Jacqueline Cheng, 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 and dependent claim 6. The parties also discussed de Kemp et al. (US 2007/0213848, hereinafter "de Kemp '848") and de Kemp (US 2007/0140958, hereinafter "de Kemp '958"), which were previously cited by the Patent Office. No exhibits were introduced or discussed.

Applicant's representative started the discussion with a background explanation of the underlying technology. For example, Applicant's representative provided a high-level discussion of the operation of strontium-rubidium radioisotope generators and their use to generate radioactive rubidium for injection into a patient. Applicant's representative further discussed unintended strontium release from a strontium-rubidium radioisotope generator column and the undesired effects of injecting such strontium into a patient because of the comparatively long half-life of strontium as compared to rubidium.

Applicant's representative continued the discussion by providing an overview of the claimed features and the real-world benefits provided by embodiments of such features. For example, Applicant's representative discussed potential benefits associated with an integrated system that includes a radioisotope generator, an on board dose calibrator to measure breakthrough (e.g., strontium breakthrough), and computer control of such a system. For example, with particular reference to claim 6, Applicant's representative discussed how the combination of the dose calibrator with the underlying radioisotope generator system can offer an integrated system where computing hardware and/or software for controlling patient infusion

procedures also controls dose calibration activity determination. The computing hardware and/or software in such an integrated system can prevent a patient infusion procedure in instances where data from the on board dose calibrator indicates that a breakthrough testing result exceeds an allowable limit.

Applicant's representative furthered the conversation by discussing distinctions between the claims and the previously applied references. For example, Applicant's representative discussed how the combination of references does not disclose or suggest a "computer carried by a shielding assembly." Applicant's representative also discussed how the combination of references does not disclose a computer that is configured to "receive activity data from the dose calibrator and calculate breakthrough test results." The Examiner kindly noted the issues raised by Applicant's representative and the differences between the intended scope of the claims and the technology discussed in the cited references. The Examiner suggested that amendments to the claims to further highlight the technical distinctions could help advance prosecution.

Continuing discussion, Applicant's representative and the Examiner also discussed the features of dependent claim 6. Applicant's representative respectfully submitted that it did not appear that the Office Action had followed the framework of *Graham v. John Deere* or provided any motivation for modifying the de Kemp '848 reference in view of the de Kemp '958 reference with respect to the features of claim 6. In addition, Applicant's representative discussed how the features of claim 6 did not appear to be disclosed in the cited portions of the de Kemp '958 reference. The Examiner acknowledged that further consideration and additional detail on the grounds of rejection for claim 6 would have been appropriate. In light of the perceived deficiencies of the rejection of claim 6 and the importance of maintaining open dialogue on the current Track I application, Applicant's representative proposed amending the features of claim 6 into independent claim 1 and requested that if allowance was not forthcoming, any subsequent action be made Non-Final. The Examiner agreed that if a subsequent Office Action was issued, the action would be Non-Final.

While no agreement was reached regarding allowability, Applicant's representative agreed to present expanded remarks consistent with those below for further study and consideration by the Examiner.

Claim Rejections Under pre-AIA 35 U.S.C. § 103(a)

In the Office Action, claims 1–9, 13–18, and 20–23 were rejected under pre-AIA 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 de Kemp (US 2007/0140958, hereinafter "de Kemp '958"). In addition, claims 10–12, 19 and 24 were rejected under pre-AIA 35 U.S.C. § 103(a) as purportedly being unpatentable over de Kemp '848 in view of de Kemp '958 and further in view of Hirschman et al. (US 2011/0178359, hereinafter "Hirschman").

Applicant respectfully traverses the rejections. 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.

The applied references do not disclose or suggest the features of the claims including, for example, independent claim 1. Independent claim 1 is directed to a system that includes a shielding assembly, a computer, and a dose calibrator. The claim states that the shielding assembly is configured to contain a radioisotope generator that generates radioactive eluate via elution and the computer is carried by the shielding assembly. The computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing. The dose calibrator is electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing. As amended, the claim specifies that the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results and also configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

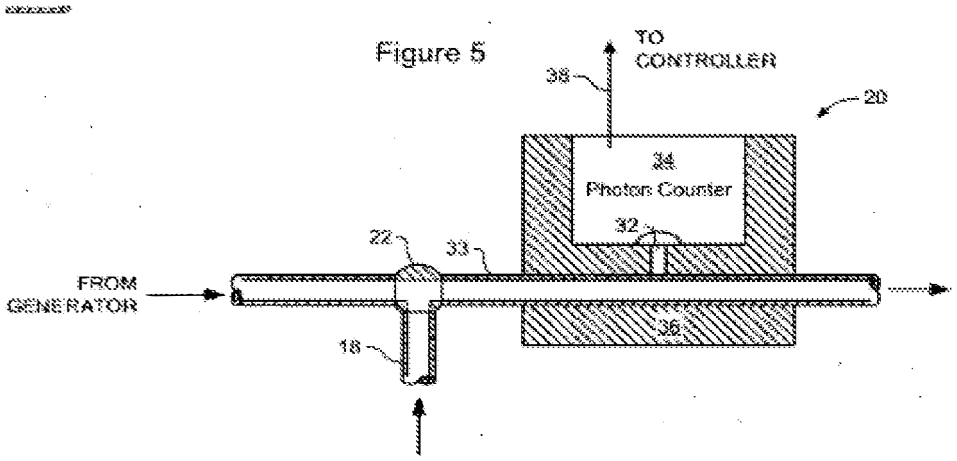
In support of the rejection of previously-presented independent claim 1, the Office Action cited de Kemp '848 as disclosing all the features of the claim except a shielding assembly configured to contain a radioisotope generator.[1] The Office Action characterized a controller 28 of de Kemp '848 as a computer carried by a shielding assembly and cited paragraphs [0047] and [0054]–[0057] of the reference as disclosing a dose calibrator electronically coupled to the computer.[2] In an attempt to overcome the acknowledged shortcomings of the de Kemp '848

[1] Office Action dated October 23, 2014, at page 3.
[2] *Id.*

reference, the Office Action cited de Kemp '958.[3] The Office Action appeared to assert that it would have been obvious to modify the radiation shield 36 of the de Kemp '848 reference to be configured to contain a radioisotope generator according to the teachings of the de Kemp '958 reference in order to provide a dense shielding material around the generator.[4] Based on the foregoing, the Office Action asserted that the features of independent claim 1 would have been obvious. Applicant respectfully disagrees for multiple reasons discussed below.

A. THE SYSTEM OF DE KEMP '848 IN VIEW OF DE KEMP '958 DOES NOT DISCLOSE OR SUGGEST "A COMPUTER CARRIED BY A SHIELDING ASSEMBLY," PER CLAIM 1.

Even if the system of de Kemp '848 were modified in view of de Kemp '958 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 system would not provide a "computer carried by a shielding assembly" as recited by the claim. In support of the rejection of this feature, the Office Action cited FIG. 5 of de Kemp '848 and asserted that controller 28 in the reference is a computer carried by a shielding assembly. FIG. 5 of de Kemp '848 is reproduced below.



As seen above and as further described in de Kemp '848, FIG. 5 of the reference schematically illustrates a positron detector usable in an elution system.[5] The only mention of controller 28 in connection with FIG. 5 above is that "the number of photons detected within a predetermined

[3] *Id.*
[4] *See id.*
[5] *See* de Kemp '848 at paragraph [0019].

period of time is counted (e.g., by the controller 28)."[6] In no way does cited FIG. 5 of de Kemp '848 or the related description disclose or suggest a computer carried by a shielding assembly, as recited by independent claim 1.

Indeed, Applicant wishes to note that the assertion in the Office Action that FIG. 5 of de Kemp '848 discloses a computer carried by a shielding assembly is inconsistent with the acknowledgement in the Office Action that de Kemp '848 fails to disclose a shielding assembly configured to contain a radioisotope generator.[7] As de Kemp '848 does not disclose a shielding assembly according to the requirements of claim 1, the reference necessarily cannot and does not disclose a computer carried by such a shielding assembly.

During the telephone interview between Applicant's representative and the Examiner, the Examiner took the position that the phrase "carried by" could be read under the broader standards of patent examination as meaning more than "physically attached to." While Applicant agrees that the Examiner is entitled to read the claim language broadly, the breadth of that reading is limited to what is reasonable in light of the specification. For example, the Federal Circuit has held that the "broadest-construction rubric coupled with the term 'comprising' does not give the PTO an unfettered license to interpret claims to embrace anything remotely related to the claimed invention. Rather, claims should always be read in light of the specification and teachings in the underlying patent."[8] Applicant respectfully submits that there is no reasonable interpretation of the phrase "carried by" upon which FIG. 5 of de Kemp '848 reads.

B. THE SYSTEM OF KEMP '848 IN VIEW OF DE KEMP '958 DOES NOT DISCLOSE OR SUGGEST A DOSE CALIBRATOR ELECTRONICALLY COUPLED TO A "COMPUTER CARRIED BY A SHIELDING ASSEMBLY," PER CLAIM 1.

Even assuming for sake of argument that the system of de Kemp '848 in view of de Kemp '958 does disclose a computer carried by a shielding assembly (which Applicant does not concede), the system does not further disclose or suggest a dose calibrator electronically coupled to the computer "carried by a shielding assembly." This is further required by independent claim 1.

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[6] *Id.* at paragraph [0028].
[7] *See* Office Action dated October 23, 2014, at page 3.
[8] *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1261 (Fed. Cir. 2010).

In the rejection of independent claim 1, the Office Action characterized controller 28 in de Kemp '848 as a computer carried by a shielding assembly.[9] The Office Action further cited paragraphs [0047] and [0054]–[0057] of de Kemp '848 as disclosing a "dose calibrator electronically coupled to the computer."[10] Yet these cited portions of de Kemp '848 do not even mention controller 28, much less disclose a dose calibrator electronically coupled to controller 28.

The de Kemp '848 reference describes controller 28 as being part of an elution system.[11] By contrast, the reference indicates that the dose calibrator described in the cited portions of the reference is not part of the elution system or coupled to controller 28. For example, the de Kemp '848 reference describes the dose calibrator as being merely a "conventional dose calibrator."[12] The de Kemp '848 reference does not mention controller 28 in connection with the dose calibrator. Nor does the de Kemp '848 reference disclose or suggest that controller 28 is electronically coupled to the dose calibrator. This is contrary to the requirements of independent claim 1.

C. A PERSON OF ORDINARY SKILL IN THE ART WOULD NOT HAVE FOUND IT OBVIOUS TO MODIFY THE SYSTEM OF KEMP '848 IN VIEW OF DE KEMP '958 IN THE MANNER PROPOSED IN THE OFFICE ACTION.

In addition to the features discussed above, Applicant respectfully submits that a person of ordinary skill in the art would not have found it obvious to modify the de Kemp '848 system in view of de Kemp '958 in the manner proposed in the Office Action. In the rejection of independent claim 1, the Office Action acknowledged that de Kemp '848 does not disclose a shielding assembly configured to contain a radioisotope generator.[13] The Office Action attempted to overcome this deficiency by citing de Kemp '958.[14] The Office Action asserted that de Kemp '848 teaches a radiation shield 36 and appeared to take the position that it would have been obvious to modify the radiation shield 36 of the de Kemp '848 reference to be configured to

[9] Office Action dated October 23, 2014, at page 3.
[10] *Id.*
[11] *See* de Kemp '848 at paragraph [0025].
[12] *See id.* at paragraph [0054].
[13] Office Action dated October 23, 2014, at page 3.
[14] *Id.*

contain a radioisotope generator according to the teachings of the de Kemp '958 reference in order to provide a dense shielding material around the generator.[15]

A person of ordinary skill in the art would have consciously avoided modifying radiation shield 36 of the de Kemp '848 reference to be configured to contain a radioisotope generator because such a modification would have rendered the system unsuitable for the purposes required by the reference. As described in greater detail in de Kemp '848, radiation shield 36 is a component of positron detector 20 positioned downstream of a strontium-rubidium generator 8.[16] The de Kemp '848 reference describes that radiation shield 36 functions to block ambient gamma and beta radiation from reaching scintillator 32 and photon counter 34.[17] This allows the positron detector to measure beta radiation generated by ^{82}Rb decay.[18]

If radiation shield 36 of the de Kemp '848 system were modified to receive a radioisotope generator, the radiation shielding would no longer provide a functional positron detector. This would prohibit the de Kemp '848 system from measuring beta radiation generated by ^{82}Rb decay. A person of ordinary skill in the art therefore would not have found it obvious to modify the radiation shield 36 of the de Kemp '848 system to be configured to contain a radioisotope generator according to the teachings of the de Kemp '958 reference, as proposed in the Office Action.

Moreover, given that radiation shield 36 of part of a positron detector 20 positioned downstream of a strontium-rubidium generator 8, a person of ordinary skill in the art would not have considered it obvious to configure the radiation shield to receive a radioisotope generator. The system disclosed in de Kemp '848 already provides a generator before the radiation shield 36. Configuring the radiation shield to receive a radioisotope generator would serve no apparent function and provide no identifiable benefit.

For at least these reasons, a person of ordinary skill in the art would not have found it obvious to modify the de Kemp '848 system in view of de Kemp '958 in the manner proposed in the Office Action.

[15] *See id.*
[16] *See* de Kemp '848 at paragraph [0025] and [0028].
[17] *See id.* at paragraph [0028].
[18] *See id.*

D. THE SYSTEM OF KEMP '848 IN VIEW OF DE KEMP '958 DOES NOT DISCLOSE OR SUGGEST A COMPUTER "FURTHER CONFIGURED TO PREVENT A PATIENT INFUSION PROCEDURE IF A BREAKTHROUGH TEST RESULT EXCEEDS AN ALLOWABLE LIMIT," AS PREVIOUSLY PRESENTED IN CLAIM 6 AND NOW PRESENTED IN INDEPENDENT CLAIM 1.

While Applicant does acquiesce in the propriety of the rejections of previously-presented independent 1, Applicant has amended the independent claim to incorporate the features of previously-presented claim 6. Specifically, Applicant has amended the claim to specify that the computer carried by the shielding assembly and electronically coupled to the dose calibrator is configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

In the rejection of previously-presented claim 6 (the features of which are now presented in independent claim 1), the Office Action did not discuss the primary de Kemp '848 reference or provide any explanation about how the features of the claim relate to the overall system of de Kemp '848. Instead, the Office Action stated without further explanation that "de Kemp '958 teaches the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit (paragraphs [0029]–[0031]).[19] Applicant respectfully traverses the rejection of the claim features for several reasons.

First, as discussed in greater detail during the telephonic interview, Applicant's representative respectfully submits that the Office Action did not follow the framework of *Graham v. John Deere*. The Office Action did not set out the scope and content of the cited art or identify differences between the cited art and the features of claim 6, as required. Nor did the Office Action identify any reason it allegedly would have been obvious to modify the de Kemp '848 system in view of the de Kemp '958 reference with respect to the features of claim 6. For at least these reasons, the Office Action did not establish a *prima facie* case of obviousness.

Second, even if the Office Action had set forth a *prima facie* case of obviousness, Applicant respectfully disagrees that the cited portions of de Kemp '958 support the rejection of the features of previously-presented claim 6. The Office Action cited paragraphs [0029]–[0031] of de Kemp '958 to support the rejection of the claim features. These paragraphs generally discuss steps for using a generator column. While the cited paragraphs note that "jurisdictions define a threshold for permissible levels of ^{82}Sr, ^{85}Sr breakthrough," the paragraphs provide no

[19] Office Action dated October 23, 2014, at page 4.

disclosure or suggestion that a computer carried by a shielding assembly can prevent a patient infusion procedure under any circumstances, much less instances where a breakthrough test result exceeds an allowable limit. Indeed, the cited paragraphs provide no disclosure of any computer control of the described generator operation steps.

For at least the additional reasons given above, Applicant respectfully submits that the applied references do not render the features of previously-presented claim 6 (now incorporated into independent claim 1) unpatentable.

E. SUMMARY

For at least the reasons given above, as well as those discussed with Applicant's representative during the telephonic interview, the applied references do not disclose or suggest the features of independent claim 1. A person of ordinary skill in the art would not have modified the de Kemp '848 system in view of de Kemp '958 in the manner proposed in the Office Action. Further, the resulting system would not provide each and every feature recited by independent claim 1.

Independent claim 14 is directed to a method that includes generating, with a radioisotope generator contained within a shielding assembly, a radioactive eluate via elution of an eluant, and measuring, with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate. The method further includes determining, with the computer, an activity of rubidium-82 within the radioactive eluate, and preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit. Independent claim 14 is therefore patentable for at least the reasons given above with respect to claim 1.

Claims 2–5, 7–13, 15–19, and 21–24 depend from independent claims 1 or 14 and are therefore patentable at least by virtue of 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: January 23, 2015

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.

51898070_1.DOC

Electronic Acknowledgement Receipt

EFS ID:	21245194
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.15
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Time Stamp:	17:59:14
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Arguments/Remarks Made in an Amendment	RB115A1US.pdf	115550 5da409f82d9ba55837d7aef5a7611b8795f2a4d9	no	15

Warnings:	
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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/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/455,623	Filing Date 08/08/2014	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	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

		(Column 1)		(Column 2)	(Column 3)		
	01/23/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 22	Minus	** 24	= 0	x $80 =	0
AMENDMENT	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x $420 =	0
AMENDMENT	☐ Application Size Fee (37 CFR 1.16(s))						
AMENDMENT	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)		
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	x $ =	
AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=	x $ =	
AMENDMENT	☐ Application Size Fee (37 CFR 1.16(s))						
AMENDMENT	☐ 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
/CAROL BARNES/

This collection of information is required by 37 CFR 1.16. 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, 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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 01/22/2015

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EXAMINER	
HYDE, EILEEN FOLEY	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
01/22/2015	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)	
	14/455,623	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: *14 January 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: *1,3 and 6*.

Identification of prior art discussed: *de Kemp '848 and '958*.

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 provided an overview of the invention and technology. Applicant and Examiner discussed the combination of claim 1 to modify the existing shielding of de Kemp '848 to contain a radioisotope generator as taught by de Kemp '958. Applicant and Examiner discussed the methods of breakthrough testing used in the claimed invention and the de Kemp references. Applicant discussed bringing dependent claim 6 into independent claim 1. Examiner discussed features in the claims to clarify that it is a movable cart type system, to clarify that the breakthrough testing is measuring strontium, and to clarify that the breakthrough testing is done in the context of a patient infusion proceeding, not in an isolated calibration proceeding .

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./	/JACQUELINE CHENG/
Examiner, Art Unit 3735	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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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15

CONFIRMATION NO. 1068

PUBLICATION NOTICE

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

OC000000072572195

Title:INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

Publication No.US-2014-0374614-A1
Publication Date:12/25/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.15

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.	

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					

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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							☐

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Foley Hyde
Attorney Docket Number	56782.1.7.15

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.	☐

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	14455623
	Filing Date	2014-08-08
	First Named Inventor	Stephen E. Hidem
	Art Unit	3735
	Examiner Name	Eileen Foley Hyde
	Attorney Docket Number	56782.1.7.15

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.**

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.

Electronic Patent Application Fee Transmittal

Application Number:	14455623
Filing Date:	08-Aug-2014
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.7.15

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:	21041220
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.7.15
Receipt Date:	23-DEC-2014
Filing Date:	08-AUG-2014
Time Stamp:	17:10:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	17705
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_15_IDS_12-23-14.pdf	612342 487f8c22b62aa72fa152938d77a35d3e27ac2c60	no	4
Warnings:					
Information:					
2	Non Patent Literature	NPL_CardioGen.pdf	1030665 b94d1fcc43954f4e9a1f2021068d482640b65302	no	53
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30749 c8a72967948aff8b810dd790cb29ba634bbab0eb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1673756		

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15	1068

22859 7590 10/23/2014

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
10/23/2014	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. 14/455,623	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 *August 8, 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) *1-24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-24* 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 :August 8, 2014; October 8, 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.

Claim Rejections - 35 USC § 103

2. 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.

3. 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.

4. Claims 1-9, 13-18, and 20-23 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over de Kemp (US Publication No. 2007/0213848 A1) (hereinafter "de Kemp '848") in view of de Kemp (US Publication No. 2007/0140958 A1) (hereinafter "de Kemp '958") (both cited in the IDS filed August 8, 2014).

Regarding claim 1, de Kemp ‘848 teaches a system comprising: radioisotope generator that generates radioactive eluate via elution (paragraph [0025]); a computer (*see* controller (28)) carried by the shielding assembly (see Figure 5), wherein the computer is configured to receive a user input (paragraphs [0025], [0034], [0037], & [0040]) and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing (paragraphs [0034], [0037], [0040], [0051], & [0055]); and
a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing (paragraphs [0047] & [0054]-[0057]), wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results (paragraphs [0051] & [0055]-[0057]).

de Kemp ‘848 teaches a radiation shield (36) (paragraph [0028]), but does not teach a shielding assembly configured to contain the radioisotope generator.

de Kemp ‘958 teaches a generator column is suspended in a shielding body (40) (paragraphs [0013], [0019], & [0022]; Figures 2 & 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the radioisotope generator of de Kemp ‘848 to be contained in a shielding body as taught by de Kemp ‘958 in order to provide a dense shielding material around the generator (de Kemp ‘958, paragraph [0022]).

Regarding claim 2, de Kemp ‘848 teaches the radioisotope generator comprises a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82 (Abstract; paragraphs [0006]-[0008], [0025], [0034], [0051], & [0054]-[0057]).

Regarding claim 3, de Kemp '958 teaches the computer is configured to calculate the breakthrough test results by at least calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82 (paragraph [0030]; claims 10 & 13).

Regarding claim 4, de Kemp '958 teaches the computer is further configured to indicate if the breakthrough test results are within allowable limits (paragraphs [0029]-[0031]).

Regarding claim 5, de Kemp '958 teaches defining a threshold for permissible levels of ^{82}Sr, ^{85}Sr breakthrough is understood by those skilled in the art (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general breakthrough limits taught by de Kemp '848 and de Kemp '958 such that the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are each less than 0.02 microcurie/millicurie since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272 (CCPA 1980).

Regarding claim 6, de Kemp '958 teaches the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit (paragraphs [0029]-[0031]).

Regarding claim 7, de Kemp '848 teaches an activity detector (paragraph [0028]).

Regarding claim 8, de Kemp '848 teaches the computer is configured to divert eluate generated via elution to a waste bottle until the activity detector detects a given level of activity (paragraphs [0029] & [0031]).

Regarding claim 9, de Kemp '848 teaches generating a target ^{82}Rb activity concentration which follows a desired function in time $C_M(t)$ (Figures 7b, 7c, 8b, & 8c; paragraphs [0036]-[0037], [0040], & [0042]-[0045]), but does not explicitly teach the given level of activity is approximately 1.0 millicurie per second. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general activity levels taught by de Kemp '848 and de Kemp '958 such that the given level of activity is approximately 1.0 millicurie per second since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272 (CCPA 1980).

Regarding claim 13, de Kemp '958 teaches the dose calibrator is configured to physically receive the sample of eluate generated during breakthrough testing (paragraph [0029]).

Regarding claim 14, de Kemp '848 teaches a method comprising (Abstract): generating, with a radioisotope generator, a radioactive eluate via elution of an eluent (paragraph [0025]); measuring, with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate (paragraphs [0028], [0034], & [0047]); and determining, with the computer, an activity of rubidium-82 within the radioactive eluate (paragraphs [0028], [0032], [0035]-[0038], & [0042]).

de Kemp '848 teaches a radiation shield (36) (paragraph [0028]), but does not teach the radioisotope generator is contained within a shielding assembly.

de Kemp '958 teaches a generator column is suspended in a shielding body (40) (paragraphs [0013], [0019], & [0022]; Figures 2 & 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the radioisotope generator of de

Kemp ‘848 to be contained in a shielding body as taught by de Kemp ‘958 in order to provide a dense shielding material around the generator (de Kemp ‘958, paragraph [0022]).

Regarding claim 15, de Kemp ‘958 teaches determining, with the computer, an activity of strontium-82 and an activity of strontium-85 in the radioactive eluate (paragraph [0030]; claim 13).

Regarding claim 16, de Kemp ‘958 teaches determining, with the computer, a ratio of the activity of strontium-82 divided by the activity of rubidium-82 and a ratio of the activity of strontium-85 divided by the activity of rubidium-82 (paragraph [0030]; claims 10 & 13).

Regarding claim 17, de Kemp ‘958 teaches determining, with the computer, if the ratio of activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are within allowable limits (paragraph [0030]; claims 10 & 13).

Regarding claim 18, de Kemp ‘958 teaches defining a threshold for permissible levels of ^{82}Sr, ^{85}Sr breakthrough is understood by those skilled in the art (paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general breakthrough limits taught by de Kemp ‘848 and de Kemp ‘958 such that the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are each less than 0.02 microcurie/millicurie since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272 (CCPA 1980).

Regarding claim 20, de Kemp '958 teaches preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit (paragraphs [0029]-[0031]).

Regarding claim 21, de Kemp '848 teaches measuring, with an activity detector electronically coupled to the computer, an activity of the radioactive eluate (paragraph [0028]).

Regarding claim 22, de Kemp '848 teaches controlling, with the computer, a diverter valve to divert the radioactive eluate to a waste bottle until the activity detector detects a given level of activity (paragraphs [0029] & [0031]).

Regarding claim 23, de Kemp '848 teaches generating a target ^{82}Rb activity concentration which follows a desired function in time $C_M(t)$ (Figures 7b, 7c, 8b, & 8c; paragraphs [0036]-[0037], [0040], & [0042]-[0045]), but does not explicitly teach the given level of activity is approximately 1.0 millicurie per second. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the general activity levels taught by de Kemp '848 and de Kemp '958 such that the given level of activity is approximately 1.0 millicurie per second since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272 (CCPA 1980).

5. Claims 10-12, 19, and 24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over de Kemp '848 in view of de Kemp '958, and further in view of Hirschman et al. (US Publication No. 2011/0178359 A1).

Regarding claim 10, the combination of de Kemp '848 and de Kemp '958 teaches the system of claim 1, but does not teach a display configured to display the breakthrough test results.

Hirschman teaches the signal representative of the detected radiation level is displayable on the user interface (paragraph [0032]). Hirschman teaches displaying values on integrated system controller (110) (paragraph [0094]). Hirschman teaches control computer (210) includes a GUI (212) for displaying relevant data and entering relevant control data and parameters into control computer (210) (paragraph [0123]; Figures 4A & 4B). Hirschman teaches a controller includes a display screen, which shows the amount of radioactivity measured by the dosimeter(s) (paragraphs [0143], [0184], & [0191]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the breakthrough data of de Kemp '848 and de Kemp '958 to be displayed as taught by Hirschman in order for the operator to verify the levels of the radiopharmaceutical prior to injecting into the patient (paragraph [0143]).

Regarding claim 11, Hirschman teaches the computer is configured to control the display to provide an indication of progress of the breakthrough testing (paragraph [0184]).

Regarding claim 12, the combination of de Kemp '848 and de Kemp '958 teaches the system of claim 1, but does not teach a cabinet structure, wherein the shielding assembly is positioned inside the cabinet structure and the computer is carried by the cabinet structure.

Hirschman teaches an integrated radiopharmaceutical patient treatment system (Abstract). Hirschman teaches a cabinet structure with a radionuclide generation module (220) inside (paragraphs [0121]-[0122] & [0126]-[0127]; Figure 3). Hirschman teaches the radionuclide generation module (220) is desirably contained within a shielded compartment of radiation protection module (280) (paragraph [0126]; Figure 3). Hirschman teaches a computer is carried by the cabinet structure (see control computer (210) in Figure 3; paragraph [0122]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the shielded radioisotope generator of de Kemp ‘848 and de Kemp ‘958 to be placed inside a cabinet structure as taught by Hirschman in order to provide a portable or mobile system (Hirschman, paragraph [0121]).

Regarding claim 19, the combination of de Kemp ‘848 and de Kemp ‘958 teaches the method of claim 14, but does not teach displaying breakthrough test results determined by the computer.

Hirschman teaches the signal representative of the detected radiation level is displayable on the user interface (paragraph [0032]). Hirschman teaches displaying values on integrated system controller (110) (paragraph [0094]). Hirschman teaches control computer (210) includes a GUI (212) for displaying relevant data and entering relevant control data and parameters into control computer (210) (paragraph [0123]; Figures 4A & 4B). Hirschman teaches a controller includes a display screen, which shows the amount of radioactivity measured by the dosimeter(s) (paragraphs [0143], [0184], & [0191]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the breakthrough data of de Kemp ‘848 and de Kemp ‘958 to be displayed as taught by Hirschman in order for the operator to verify the levels of the radiopharmaceutical prior to injecting into the patient (paragraph [0143]).

Regarding claim 24, the combination of de Kemp ‘848 and de Kemp ‘958 teaches the method of claim 14, but does not teach the shielding assembly is positioned inside a cabinet structure and the computer is carried by the cabinet structure.

Hirschman teaches an integrated radiopharmaceutical patient treatment system (Abstract). Hirschman teaches a cabinet structure with a radionuclide generation module (220) inside (paragraphs [0121]-[0122] & [0126]-[0127]; Figure 3). Hirschman teaches the

radionuclide generation module (220) is desirably contained within a shielded compartment of radiation protection module (280) (paragraph [0126]; Figure 3). Hirschman teaches a computer is carried by the cabinet structure (see control computer (210) in Figure 3; paragraph [0122]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shielded radioisotope generator of de Kemp '848 and de Kemp '958 to be placed inside a cabinet structure as taught by Hirschman in order to provide a portable or mobile system (Hirschman, paragraph [0121]).

Conclusion

6. 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.

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/E. F./
Examiner, Art Unit 3735

/JACQUELINE CHENG/
Supervisory Patent Examiner, Art Unit 3735

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	Examiner EILEEN FOLEY	Art Unit 3735	Page 1 of 1

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	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
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14/455,623	08/08/2014 RULE	600	3735	56782.1.7.15

APPLICANTS

Bracco Diagnostics Inc., Monroe Township, NJ, Assignee (with 37 CFR 1.172 Interest);

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Kathryn M. Hunter, Knoxville, TN;
Rolf E. Swenson, Silver Spring, MD;
Julius P. Zodda, Mercerville, NJ;

**** CONTINUING DATA **************************

This application is a CON of 12/808,467 06/16/2010
which is a 371 of PCT/US2009/047031 06/11/2009
which is a CON of 12/137,356 06/11/2008 PAT 8317674
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**** FOREIGN APPLICATIONS **************************

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08/18/2014

Foreign Priority claimed	☐ Yes ☑ No		STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☐ No	☐ Met after Allowance				
Verified and Acknowledged	/EILEEN DOROTHY FOLEY/ Examiner's Signature	Initials	MN	27	24	2

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MINNEAPOLIS, MN 55402
UNITED STATES

TITLE

INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

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Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.15

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	First Named Inventor	Stephen E. Hidem	
	Art Unit	3735	
	Examiner Name	Eileen Dorothy Foley	
	Attorney Docket Number	56782.1.7.15	

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Receipt date: 08/08/2014	Application Number	14455623 - GAU: 3735
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

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	24	20070080223	A1	2007-04-12	Japuntich	
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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

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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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	2	0102121	EP		1984-03-07	BYK Mallinckrodt		☐
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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

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	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

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	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	27	2006135374	WO		2006-12-21	Lynntech Inc.		☐
	28	2007016170	WO		2007-02-08	Mallinckrodt Inc.		☐
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	Art Unit	TBD
	Examiner Name	TBD
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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.	T5
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	Art Unit	TBD
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	Art Unit	TBD
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Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	266	600/4,5.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
L2	112	A61N2005/1021,1022.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
L3	2020	A61N5/10,1007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
L4	1682	378/65.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
L5	3738	L1 or L2 or L3 or L4	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 07:25
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L31	3	((Aaron) near2 (Fontaine)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
L32	4	((Janet) near2 (Gelbach)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
L33	53	((Patrick) near2 (McDonald)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24

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L35	107	((Rolf) near2 (Swenson)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/15 10:24
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S11	21	S10 and (shield$3 same generator) and computer and (dose with calibrat$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:55
S12	13	S11 and (rubidium or strontium)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:55
S13	42	("4401108" | "4409966" | "4472403" | "4562829" | "4585009" | "4883459" | "5383858" | "5472403" | "5514071" | "5520653" | "5918443" | "5927351" | "5947890" | "6267717" | "6450936" | "6471674" | "6520930").PN. OR ("6767319").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:57

S14	2	("4562829" | "4585009").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:57
S15	25	("4202345").PN. OR ("4562829").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/03 08:57

10/15/2014 10:27:13 AM
C:\Users\efoley\Documents\EAST\Workspaces\14455623.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14455623	HIDEM ET AL.
	Examiner	Art Unit
	EILEEN FOLEY	3735

CPC- SEARCHED

Symbol	Date	Examiner
A61N2005/1021, 1022	10/2/14	EF
A61N5/10, 1007	10/2/14	EF

CPC COMBINATION SETS - SEARCHED

Symbol	Date	Examiner

US CLASSIFICATION SEARCHED

Class	Subclass	Date	Examiner
600	4, 5	10/2/14	EF
378	65	10/2/14	EF

SEARCH NOTES

Search Notes	Date	Examiner
Inventor name search in EAST	10/15/14	EF
Limited class/subclass searches with text	10/2; 10/3; 10/15/14	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
	14455623	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	10/15/2014								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
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	21	✓								
	22	✓								
	23	✓								
	24	✓								

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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.15

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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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	20040054319	A1	2004-03-18	Langley	
	2	20070260213	A1	2007-11-08	Williams	

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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							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.15

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	14455623
Filing Date	2014-08-08
First Named Inventor	Stephen E. Hidem
Art Unit	3735
Examiner Name	Eileen Dorothy Foley
Attorney Docket Number	56782.1.7.15

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)	2014-10-08
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 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 Acknowledgement Receipt

EFS ID:	20361215
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
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:	56782.1.7.15
Receipt Date:	08-OCT-2014
Filing Date:	08-AUG-2014
Time Stamp:	18:25:03
Application Type:	Utility under 35 USC 111(a)

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_15_IDS_10-8-14.pdf	612200 7ba08fd2d637b295de0d268b31f64572758e8122	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	612200

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.

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United States Patent and Trademark Office
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FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS MN 55402

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/455,623

1. THE REQUEST FILED August 8, 2014 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[*Signature*]

Petitions Examiner, Office of Petitions
(Title)

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
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15

CONFIRMATION NO. 1068

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

NOTICE

OC000000070677047

Date Mailed: 09/15/2014

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Stephen E. Hidem
  Aaron M. Fontaine
  Janet L. Gelbach
  Patrick M. McDonald
  Kathryn M. Hunter
  Rolf E. Swenson
  Julius P. Zodda

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/455,623

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4			OR	x 80 =	320
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 420 =	0.00
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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1920

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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 found in the appropriate box in column 1.

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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
14/455,623	08/08/2014	3763	2060	56782.1.7.15	24	2

CONFIRMATION NO. 1068

UPDATED FILING RECEIPT

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

OC00000070677046

Date Mailed: 09/15/2014

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, Silver Spring, MD;
Julius P. Zodda, Mercerville, NJ;

Applicant(s)

Bracco Diagnostics Inc., Monroe Township, NJ

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

Domestic Priority data as claimed by applicant

This application is a CON of 12/808,467 06/16/2010
which is a 371 of PCT/US2009/047031 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.

If Required, Foreign Filing License Granted: 08/18/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/455,623**

Projected Publication Date: 12/25/2014

Non-Publication Request: No

Early Publication Request: No

Title

INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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NOT GRANTED

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	14/455,623	Group Art Unit:	3763
Filed:	August 8, 2014	Examiner:	Not Yet Assigned
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Dear Commissioner:

This submission is in response to the Notice to File Corrected Application Papers ("the Notice") dated August 20, 2014, the period of response for which runs through October 20, 2014. The Notice objected to the specification on the basis that the specification did not include a brief description of all the views of the drawings in compliance with 35 C.F.R. §§ 1.74 and 1.77(b)(9).

Attached as an Appendix to this paper is a substitute specification in compliance with 37 C.F.R. §§ 1.121 and 1.125. The Appendix includes a marked-up version of the substitute specification showing changes relative to the prior version of the specification of record. The Appendix also includes a clean version of the substitute specification that incorporates the changes identified in the marked-up version of the substitute specification. For sake of clarity, Applicant has not included a copy of the pending claims in either the marked-up version or clean version of the substitute specification.

By way of the substitute specification, Applicant has amended the specification to include a brief description of all the views of the drawings. In particular, Applicant has amended the specification to include a brief description of Figure 2B-1, which was not previously separately described in the brief description of the drawings. In accordance with 37 C.F.R. § 1.125(a), Applicant states that the substitute specification includes no new matter.

In addition to entry of the substitute specification, Applicant encloses herewith the surcharge fee of $140 set forth in the Notice for late filing of the declarations.

Conclusion

In view of the foregoing remarks and enclosed attachment, Applicant submits that the requirements set forth in the Notice have been satisfied. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. Further, the Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: September 8, 2014

Respectfully submitted,

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

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INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 12/808,467, filed June 16, 2010, which is a 371 National Stage of International Application No. PCT/US09/47031, filed June 11, 2009, which in turn claims priority to the following four patent applications: U.S. Patent Application No. 12/137,356, filed June 11, 2008, now U.S. Patent No. 8,317,674, issued November 27, 2012; U.S. Patent Application No. 12/137,363, filed June 11, 2008, now U.S. Patent No. 7,862,534, issued January 4, 2011; U.S. Patent Application No. 12/137,364, filed June 11, 2008; and U.S. Patent Application No. 12/137,377, filed June 11, 2008, now U.S. Patent 8,708,352, issued April 29, 2014. The entire contents of all of these applications are incorporated herein by reference.

TECHNICAL FIELD

The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to systems including computer-facilitated maintenance and/or operation.

BACKGROUND

Nuclear medicine employs radioactive material for therapy and diagnostic imaging. Positron emission tomography (PET) is one type of diagnostic imaging, which utilizes doses of radiopharmaceuticals, for example, generated by elution within a radioisotope generator, that are injected, or infused into a patient. The infused dose of radiopharmaceutical is absorbed by cells of a target organ, of the patient, and emits radiation, which is detected by a PET scanner, in order to generate an image of the organ. An example of a radioactive isotope, which may be used for PET, is Rubidium-82 (produced by the decay of Strontium-82); and an example of a radioisotope generator, which yields a saline solution of Rubidium-82, via elution, is the CardioGen-82● available from Bracco Diagnostics Inc. (Princeton, NJ). A PET scanner in combination with infused doses of radiopharmaceuticals may also be employed to quantify blood flow rate, for example, through the coronary arteries of a patient.

Set up, maintenance and operational procedures for infusion systems that both generate and inject doses of radiopharmaceuticals are relatively involved in order to assure the safety and efficacy of each injected dose for the patient. Efficiency in carrying out these procedures is highly desirable for technical personnel, who work with these systems on a routine basis and would like to avoid unnecessarily prolonged exposure to radioactive radiation. Thus there is a need for new system configurations that facilitate more efficient set up, maintenance and operation.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

Figure 1A is a first perspective view of an infusion system, according to some embodiments of the present invention.

Figure 1B is another perspective view of a portion of a cabinet structure of the system shown in Figure 1A, according to some embodiments.

Figure 1C is a second perspective view of the system shown in Figure 1A, according to some embodiments.

Figure 1D is a schematic of an infusion circuit, according to some embodiments of the present invention.

Figure 1E is a perspective view of exemplary sample vial shielding that may be employed in conjunction with the infusion system of Figure 1A.

Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A–C, according to some embodiments of the present invention.

Figure 2B is a perspective view of a framework of the system, according to some embodiments, and Figure 2B-1 is an enlarged detailed view of a component of the system, according to some embodiments.

Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.

Figure 3B is a perspective view of the infusion circuit, shown in Figure 1C, configured and routed, according to some embodiments.

Figure 3C is a perspective view of a disposable infusion circuit subassembly, according to some embodiments.

Figure 3D is a frame for the subassembly shown in Figure 3C, according to some embodiments.

Figure 4 is a main menu screen shot from an interface of a computer, which may be included in systems of the present invention, according to some embodiments.

Figure 5A is a schematic showing a first group of successive screen shots from the computer interface, according to some embodiments.

Figure 5B is a pair of screen shots from the computer interface, which provide indications related to eluant volume levels in a reservoir of the system, according to some embodiments.

Figure 5C is a schematic showing a second group of successive screen shots from the computer interface, according to some embodiments.

Figure 6 is a schematic showing a third group of successive screen shots from the computer interface, according to some embodiments.

Figures 7A–C are schematics showing a fourth group of successive screen shots from the computer interface, according to some embodiments.

Figures 8A–B are schematics showing a fifth group of successive screen shots from the computer interface, according to some embodiments.

Figures 9A–C are schematics showing a sixth group of successive screen shots from the computer interface, according to some embodiments.

Figure 10 is a schematic showing a seventh group of successive screen shots from the computer interface, according to some embodiments.

Figure 11 is an exemplary report which may be generated by the computer included in infusion systems, according to some embodiments.

Figures 12A–B are schematics of alternative infusion circuits that may be employed by embodiments of the present invention.

Figure 12C is a schematic illustrating exemplary activity profiles of injected doses of a radiopharmaceutical.

DETAILED DESCRIPTION

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.

Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surround an interior space in which a portion of infusion system 10 is contained (seen in Figure 1C). Shell 13 may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13; and, a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may be included, for example, a keyboard, a series of control buttons or levers, a bar code reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions, as well as to monitor system operation both during quality control infusions and during patient infusions. Operation of system 10,

which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one location to another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.

Figure 1B is a perspective view of a portion of system 10, on a side 111 of the cabinet structure, which is in proximity to wheels 121, 122. Figure 1B illustrates a lever or pedal 125, which is located for activation by a foot of the person, who grasps handle 14 to maneuver system 10. In a neutral position, pedal 125 allows wheels 121, 122 to rotate, and, if embodied as casters, to swivel freely. Pedal 125 may be depressed to a first position which prevents a swiveling of wheels 121, 122, according to those embodiments in which wheels 121, 122 are casters, and may be further depressed to brake wheels 121, 122 from rolling and swiveling, upon reaching a desired location. According to some embodiments, braking may be designed to slow system 10, for example, when rolling down an incline, and, according to yet further embodiments, system 10 may include a motor to power movement thereof.

Figure 1B further illustrates**:** a rear access panel 174 of shell 13, for example, providing access to circuit boards of the aforementioned controller contained within the interior space that is surrounded by shell 13; an optional lock 184, to secure panel 174; a power jack 118, for connecting system 10 to a power source; and a printer 117 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include a power strip by which auxiliary equipment may be powered, and one or more additional electrical connectors, or ports (not shown), which are supported by platform 113 and may be integrated into shell 13, for example, in proximity to jack 118 or printer 117; these electrical connectors/ports allow system 10 to communicate with, other devices used for nuclear imaging procedures, for example, a PET scanner/camera, and/or for coupling to an intranet network, and/or to the internet, for example, to link up with software programs for various types of data analysis, and/or

to link to computers of consulting clinicians/physicians, and/or to link into service providers and/or component suppliers data bases for enhanced maintenance and inventory management.

Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective view of system 10, wherein a removable access panel 132 is shown as a contoured portion of upper surface 131, which, when exposed, by lifting away a bin 18, that mates therewith, may be removed from another opening 137 formed in upper surface 131. Figure 1C also provides a better view of another panel 134 which may be lifted away from opening 139. According to the illustrated embodiment, openings 139 and 137 provide a user of system 10 with independent access to separate portions of infusion system 10, which are contained within shell 13, for example, to set up and maintain system 10; and openings 133 and 135 provide passageways for tubing lines to pass through shell 13. Figure 1C further illustrates an optional switch 102, which in case of an emergency, may be activated to abort function of system 10. With reference to Figures 1A and 1C, it may be appreciated that an arrangement of features formed in upper surface 131 of shell 13, in conjunction with bin 18, tray 16 and computer 17, provide a relatively ergonomic and organized work area for technical personnel who operate system 10.

Turning now to Figure 1D, a schematic of an infusion circuit 300, which may be incorporated by system 10, is shown. Figure 1D illustrates circuit 300 generally divided into a first part 300A, which includes components mounted outside shell 13, and a second part 300B, which includes components mounted within the interior space surrounded by shell 13. (Parts 300A and 300B are delineated by dotted lines in Figure 1D.) Figure 1D further illustrates second part 300B of circuit 300 including a portion contained within a shielding assembly 200, which is designated schematically as a dashed line. Some embodiments of shielding assembly 200 will be described in greater detail, in conjunction with Figures 2A-B and 3A-B, below.

According to the illustrated embodiment, circuit 300 includes: an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34 (or other device or sensor), for monitoring pumping

pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity detector 25, for measuring the activity of the eluate discharged from generator 21, in order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance.

Figure 1D illustrates an eluant tubing line 301 coupled to reservoir 15 and to pump 33, and, with reference to Figures 1A-B, it may be appreciated that opening 133 provides the passageway for tubing line 301 to enter the interior space surrounded by shell 13. According to some preferred embodiments, opening 133 includes a grommet-type seal that prevents leakage of eluant, which may spill from reservoir 15, into the interior space through opening 133, while allowing a user to assemble tubing line 301 through opening 133. Likewise opening 135, which provides a passageway for patient line 305p, may include a grommet-type seal. According to some embodiments, shell 13 further supports holders to safely hold, for example, during transport of system 10, portions of tubing lines that extend outward therefrom, for example, line 301 and/or line 305p.

Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which

controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from the generator into waste bottle 23, until activity detector 25 detects the desired activity of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21. According to some preferred methods of operation, in certain situations, which will be described in greater detail below, eluant is pumped through by-pass line 303 immediately following the flow of the prescribed volume of eluate into patient line 305p, at a higher speed, in order to push the eluate in patient line 305, thereby increasing a flow rate of the injection of eluate out from patient line 305p and into the patient. For example, once the prescribed volume of eluate has flowed into patient line 305p, and once divergence valve 35BG is set to divert flow through by-pass line 303, the speed of pump 33 may be adjusted to increase the flow rate of eluant to between approximately 70mL/min and approximately 100mL/min. This method for increasing the injection flow rate, is desirable, if a relatively high flow rate is desired for patient injection and a flow rate through generator 21 is limited, for example, to below approximately 70mL/min, maximum (typical flow rate may be approximately 50mL/min), in order to avoid an excessive back pressure created by the column of generator 21 in upstream portions of tubing circuit 300; the excessive back pressure could damage filter 37 or otherwise impede flow through eluant tubing line 302.

Although not shown in Figure 1D, a number of sensors, for example, to measure pressure and/or flow velocity, may be incorporated into circuit 300, according to some alternate embodiments, in order to monitor for flow anomalies, for example,

related to occlusions/plugs in circuit 300 and/or leaks, and/or to provide feedback for control of an activity level of infused doses of radiopharmaceutical. Suitable sensors for any of the above purposes are known to those skilled in the art. Examples of flow meters that may be incorporated into circuit 300, include the Innova-Sonic● Model 205 Transit-Time Ultrasonic Liquid Flow Meter that employs digital signal processing (available from Sierra Instruments, Inc.) and the Flocat LA10-C differential pressure flow meter. One example of a pressure sensor that may be employed to detect infusion circuit occlusions is the PRO / Pressure-Occlusion Detector (available from INTROTEK● of Edgewood, NY, a subsidiary of Magnetrol of Downers Grove, IL), which employs pulse-type ultrasound; this sensor detects subtle changes in positive and negative air pressure and produces a corresponding passive resistive output signal, which may be routed to the system controller and/or computer 17. One or more of this type of sensor may be incorporated into infusion circuit 300 by simply fitting the sensor around any of the tubing lines of infusion circuit 300; in fact, the PRO / Pressure-Occlusion Detector may be a suitable alternative to pressure syringe 34 of circuit 300. Other types of pressure sensors, for example, similar to those known in the art for blood pressure monitoring, may be employed in infusion circuit 300.

System 10 may further include sensors to detect fluid levels in eluant reservoir 15 and waste bottle 23. Some examples of such sensors, which also employ the aforementioned pulse-type ultrasound, are the Drip Chamber Liquid Level Sensor and the CLD / Continuous Level Detector (both available from INTROTEK●); alternatively, for example, an HPQ-T pipe mounted, self-contained liquid sensor (available from Yamatake Sensing Control, Ltd.), or an SL-630 Non-Invasive Disposable/Reusable Level Switch (available from Cosense, Inc. of Hauppauge, NY) may be employed to detect the fluid levels. Alternately or in addition, system 10 can include additional radiation and/or moisture detection sensors, which can detect leaks. With reference to Figure 1D, such sensors are preferably located in proximity to fittings 311, 312, 313, 314 and 315 that join portions of circuit 300 to one another. Some examples of leak detection sensors include, without limitation, those in the HPQ-D leak detection sensor family, and the HPF-D040 fiberoptic leak detector (all available from Yamatake Sensing Control, Ltd.). System 10 may further include additional sensors to detect contaminants and/or air bubbles within the tubing lines of circuit; examples of such sensors include the Point-air Detection (PAD) Sensor, that

employs pulse-type ultrasound for air bubble detection, and the Blood Component Detector that employs optical sensing technology to perform Colorimetry-based fluid detection of unwanted elements in the tubing lines (both available from INTROTEK●).

According to those embodiments that include any of the above sensors, the sensors are linked into the controller of system 10 and/or computer 17, either of which may provide a signal to a user of system 10, when a flow anomaly is detected, and/or information to the user, via monitor 172, concerning fluid levels, pressure and/or flow through circuit 300. Computer 17 may be pre-programmed to display, for example, on monitor 172, a graphic of infusion circuit 300 wherein each zone of the circuit, where an anomaly has been detected, is highlighted, and/or to provide guidance, to the system user, for correcting the anomaly. It should be noted that the alternative infusion circuits illustrated in Figures 12A-B, which will be described below, may also include any or all of these types of sensors.

With further reference to Figure 1D, it may be appreciated that shielding assembly 200 encloses those portions of circuit 300 from which radioactive radiation may emanate, with the exception of that portion of patient line 305p, which must extend out from shielding assembly 200 in order to be coupled to the patient for injection, or in order to be coupled to shielded sample vials, as will be described below. Thus, technical personnel, who operate system 10, are protected from radiation by shielding assembly 200, except at those times when an infusion is taking place, or when quality control tests require collection of eluate into sample vials. During infusions and quality control test sample collection, all technical personnel are typically in another room, or otherwise distanced from system 10, in order to avoid exposure to radiation during the infusion, and, according to some preferred embodiments of the present invention, system 10 includes at least one means for informing technical personnel that an infusion is about to take place or is taking place. With reference back to Figures 1A and 1C, system 10 is shown including a light projector 100, mounted on post 142. According to the illustrated embodiment, projector 100, projects a light signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23,

and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system 10, including in the control room.

It should be noted that, according to alternate embodiments, system 10 includes an 'on board' dose calibrator for quality control tests, and circuit 300 is expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator. According to a first set of these alternate embodiments, a sample collection reservoir is integrated into circuit 300, downstream of divergence valve 35WP and in communication with tubing line 305P, in order to receive quality control test samples of eluate, via tubing line 305P, and both the reservoir and the dose calibrator are located in a separate shielded well. According to a second set of these alternate embodiments, waste bottle 23 is configured to receive the quality control test samples of eluate, via tubing line 305W, and a dose calibrator is integrated into shielding assembly 200. Quality control procedures will be described in greater detail below, in conjunction with Figures 6-8B.

When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a threshold to be safe. Opening 139 is preferably located at an elevation of between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is

accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional maintenance procedures, such as changing out generator 21 and/or other components of circuit 300, as will be described below.

For those embodiments of system 10 in which automated quality control tests are performed and/or when system 10 is employed for relatively high volume operation, management of waste may become burdensome, even though access to waste bottle 23 is greatly facilitated, as described above. Thus, in order to facilitate waste management, some embodiments of system 10 may employ a separation system to separate salts, including radioactive elements, from water, for example, via evaporation or reverse osmosis. In an evaporation type system, the water component of the waste is evaporated, while in a reverse osmosis type system the water is separated from the salts, and, then, once confirmed to be non-radioactive, via a radiation detector, is piped to a drain. According to some other embodiments, circuit 300 may be configured so that the waste may be used to purge air from the tubing lines thereof and/or to perform the bypass flush that was described above, preferably after the radioactivity of the waste drops below a critical threshold.

Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from the infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. An exemplary test vial shield is shown in Figure 1E. The test vial shield of Figure 1E is preferably formed from Tungsten rather than lead, for example, to reduce exposure to

lead, for improved shielding, and to reduce the weight of the shield. Figure 1E illustrates the test vial shield including a handle to simplify manipulation thereof, but alternative configurations of test vial shields have no handle – for these a sling, or strap, may be employed for handling.

Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc…, into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example, deposited therein during infusion procedures. According to some embodiments, one or more additional receptacles are formed in one or more disposal containers, for example, to contain sharps and/or radioactive waste (other than that contained in waste bottle 23), which may be integrated into bin 18, or otherwise fitted into, or attached to shell 13, separate from bin 18.

Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. It should be noted that, according to alternate embodiments, the compartment enclosed by sidewall 201 is large enough to hold more than one generator, for example, to increase system operating efficiency for relatively high volume operation. In some of these alternate embodiments, tubing lines 304 and 305 are each branched for parallel flow through the multiple generators, in which case divergence valves may be employed to alternate the flow through the generators, one at a time. In others of these alternate embodiments, the multiple generators are connected in series between tubing line 304 and tubing line 305. In addition, a reservoir for accumulating eluate may be included in circuit 300, downstream of the generators and upstream of divergence valve 35 WP, in conjunction with a second pump, in some cases. Embodiments including multiple generators and/or an eluate reservoir and second pump can be employed to better manage an

activity level of each dose, or patient injection, for example, as described below, in conjunction with Figures 12A-B.

According to the embodiment illustrated in Figure 2A, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed by a sidewall 203 of shielding assembly 200 to contain waste bottle 23, as previously described. When panel 132 is separated from shell 13, and door 221 opened, generator 21 may be lifted out from an opening 231 (Figure 3A) which mates with door 221 of sidewall 201. A weight of generator 21, which includes its own shielding, may be between approximately 23 and approximately 25 pounds, thus, according to some preferred embodiments of the present invention, the elevation of each of openings 137 and 231, with respect to the lowermost portion of the cabinet structure, is between approximately 1 foot and approximately 2 feet, in order to facilitate an ergonomic stance for technical personnel to lift generator 21 out from the compartment. According to an exemplary embodiment, when shielding assembly 200 is contained in the cabinet structure of Figure 1A , openings 137 and 231 are located at an elevation of approximately 12 inches, with respect to the lower surface of platform 113, or at an elevation of approximately 19 inches, with respect to the ground surface upon which wheels 121, 122 rest. Figure 1C further illustrates access panel 132 including a security lock 138, which mates with a framework 19 of system 10, shown in Figure 2B, in order to limit access to generator 21.

Figures 1C and 2A further illustrate a lid or a door 225 of another sidewall 205 (Figure 3A) of shielding assembly 200, which encloses another compartment that is accessible through opening 137 of shell 13, and which is located adjacent the compartment enclosed by sidewall 201. Each of doors 221, 225 are shown being attached by a corresponding hinge H, and another door 227 is shown attached to sidewall 203 by another hinge H. Figure 2A illustrates each of lid 223 and doors 221, 225, 227 including a handle 232, 212, 252 and 272, respectively, for moving lid 223 and doors 221, 225, 227, in order to provide access to the corresponding compartments, which can be seen in Figures 3A-B. Figure 2A further illustrates optional thumb screws 290, one securing lid 223 to sidewall 203 and another securing door 221 to sidewall 201, or other means for securing the doors, which are known to those skilled in the art, may be incorporated. Each sidewall 201, 203, 205 and the

corresponding lid/door 223, 221, 225, 227 thereof may be individually cast from 3% antimony lead, or from other known shielding materials, and then assembled together according to methods known to those skilled in the art.

According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a latch component 191 is provided to hold each of doors 221, 225 in an opened position, thereby, preventing doors 221, 225 from falling closed, which could pinch/crush fingers of technical personnel and/or tubing lines of circuit 300, when in the midst of a maintenance procedure. Figure 2B is a perspective view of framework 19 of the cabinet structure of system 10, according to some embodiments, to which latch component 191 is mounted; Figure 2B-1 is an enlarged detailed view of latch component 191, according to some embodiments. Figure 2B illustrates latch component 191 including a first pin 193, corresponding to door 225, and a second pin 195, corresponding to door 221; each pin 193, 195 includes a lever end 193A, 193B, respectively, and a holding end 193B, 195B, respectively. An edge of each door 221, 225, upon opening of doors 221, 225, may push past the holding end 195B, 193B of the corresponding pin 195, 193, in a first direction, per arrow F, and then may rest against a respective side S95 and S93 of each end 195B, 193B, until the corresponding lever end 195A, 193A is rotated in a counter-clockwise direction, per arrow cc, thereby moving the corresponding holding end 193B, 195B to make way for the closing of doors 221, 225. Doors 221, 225 being held by latch component 191 in an open position may be seen in Figure 3A.

With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225.

The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.

Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover. With further reference to Figures 3A-B, it may be appreciated that the compartment formed by sidewall 201 may have a shape matching an exterior contour of generator 21, such that generator 21 is 'keyed' to the compartment, for example, to prevent installation of an improper generator into system 10, and/or to facilitate the proper orientation of generator 21 within the compartment for the proper routing of

tubing lines. Alternately, or in addition, according to alternate embodiments, if system 10 includes a reader of encoded information in communication with computer 17, a unique identification and/or data associated with each generator may be provided, for example, in a bar code label or a radiofrequency identification (RFID) tag that is attached to each generator, so that the reader may transfer the information to computer 17, when a generator is installed, in order to either enable system operation or to provide an indication to the user that an incorrect generator has been installed. Of course a user of system 10 may, alternately, manually enter information, that is provided on a generator label or marking, into computer 17, in order to either enable system 10, or to receive feedback from computer 17 that the incorrect generator is installed.

Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305 passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.

Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together,

according to alternate embodiments, mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.

According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w, respectively, extending from second side 392 of frame 39. Although ends 406, 407 are shown extending upward from tray 39a, as they would within shielding assembly 200, it should be appreciated that the tubing lines of circuit 300 are preferably flexible and would drop down under their own weight rather than extending upward, as shown, if not supported. Referring back to Figure 1D, in conjunction with Figure 3C, it can be seen that the aforementioned fittings are provided for coupling subassembly 390 into circuit 300: first fitting 311 couples the section of eluant line 302 to filter 37; second fitting 312 couples eluant line 304 to an inlet port of generator 21; third fitting 313, which may incorporate a check valve, couples eluate line 305 to an outlet port of generator 21; fourth fitting 314 couples waste line 305w to waste bottle 23; and fifth fitting 315 couples patient line 305p to an extension thereof, which extends outside shell 13 (designated by the dotted line). Each of the fittings 311, 312, 313, 314, 315 may be of the Luer type, may be a type suitable for relatively high pressure applications, or may be any other suitable type that is known to those skilled in the art.

As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and

405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.

Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.

Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to

post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17, so that the operation of system 10 may be monitored and controlled remotely, away from radioactive radiation.

According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. Computer 17 may also be pre-programmed to interact with the controller of system 10 in order to keep a running tally or count of elutions per unit time, for a given generator employed by the system, and may further categorize each of the counted elutions, for example, as being generated either as a sample, for quality control testing, or as a dose, for patient injection. The elution count and categorization, along with measurements made on each sample or dose, for example, activity level, volume, flow rate, etc…, may be maintained in a stored record on computer 17. All or a portion of this stored information can be compiled in a report, to be printed locally, and/or to be electronically transferred to a remote location, for example, via an internet connection to technical support personnel, suppliers, service providers, etc…, as previously described. Computer 17 may further interact with the user and/or a reader of encoded information, for example, a bar code reader or a radiofrequency identification (RFID) tag reader, to store and organize product information collected from product labels/tags, thereby facilitating inventory control, and/or confirming that the proper components, for example, of the tubing circuit, and/or accessories, and/or solutions are being used in the system.

It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format. Computer 17 may also include a pre-programmed user manual, which may be viewed on monitor 172, either independent of system operation or in conjunction with system operation, for example, via pop-up help screens. Although the English language is employed in the screen shots of Figures 4-9C, it should be understood that, according to some embodiments, computer 17 is pre-programmed to provide guidance in multiple languages.

Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on. According to some multi-lingual embodiments, computer 17 presents a list of languages from which the user may select, prior to presenting main menu 470.

Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a storage medium (i.e. disk) reader, a scanner, a bar code reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc…). Although not shown, according to some embodiments, screen 570 may further include another data entry field in which the user is required to enter a license key related to the generator employed by system 10 in order to enable operation of system 10; the key may be time sensitive, related to generator contract terms. Of course any number of log in requirements may be employed, according to various embodiments, and may be presented on multiple sequentially appearing screens rather than on a single log in screen.

After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of

eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag. If system 10 includes an encoded information reader, such as a bar code or RFID tag reader, confirmation that the selected reservoir is proper, i.e., contains the proper saline solution, may be carried out by computer 17, prior to connecting the reservoir into circuit 300, by processing information read from a label/tag attached to the reservoir. Alternatively, or in addition, tubing line 301 of circuit 300 may be provided with a connector which only mates with the proper type of reservoir 15. According to some embodiments, system 10 may further include an osmolarity or charge detector, which is located just downstream of reservoir 15 and is linked to computer 17, so that an error message may be presented on monitor 172 stating that the wrong osmolarity or charge is detected in the eluant supplied by reservoir, indicating an improper solution. One example of a charge detector that may be employed by system 10 is the SciCon™ Conductivity Sensor (available from SciLog, Inc. of Middleton, WI).

Once the reservoir/saline bag is successfully replaced, computer 17 prompts the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Alternately, if system 10 includes the aforementioned reader, and the saline bag includes a tag by which volume information is provided, the reader may automatically transfer the quantity information to computer 17. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished. It should be noted that, as previously mentioned, system 10 can include a fluid level sensor coupled

to the eluant reservoir in order to detect when the level of saline drops below a certain level.

In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied. According to some alternative embodiments, a fluid level sensor may be coupled to waste bottle 23, for example, as mentioned above in conjunction with Figure 1D, in order to automatically detect when waste bottle 23 is filled to a predetermined level and to provide, via computer 17, an indication to the user that waste bottle 23 needs to be emptied and/or to automatically preclude operation of system 10 until the waste bottle is emptied.

In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate

that eluate it being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.

Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82● that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. According to some embodiments, in conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).

Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process

when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the

background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.

With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly

flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration elution process. When the user transfers the vial containing the sample of eluate into the dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 878. With further reference to Figure 8B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 879, which includes data entry fields for the activity measure and the time, with respect to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data is input by the user, as described above, the computer calculates a calibration coefficient, or ratio, and presents the ratio on a screen 880. According to Figure 8B, screen 880 further provides an indication of a desirable range for the calibration ratio and presents an option for the user to reject the calculated ratio, in which case, the user may instruct computer 17 to recalculate the ratio.

As previously mentioned, some alternate embodiments of the present invention include an on board dose calibrator so that the entire sequence of sample collection and calculation steps, which are described above, in conjunction with Figures 6-8B, for the quality control procedures, may be automated. This automated alternative preferably includes screen shots, similar to some of those described above, which provide a user of the system with information at various stages over the course of the automated procedure and that provide the user with opportunities to modify, override and/or abort one or more steps in the procedure. Regardless of the embodiment (i.e. whether system 10 employs an on board dose calibrator or not), computer 17 may further collect all quality control test parameters and results into a stored record and/or compile a report including all or some of the parameters and results for local print out and/or electronic transfer to a remote location.

With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for

example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with an option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may

be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

With further reference to Figure 9C, screen 976 shows an exemplary activity profile (activity - mCi/sec, on y-axis, versus time – sec, on x-axis) for the infusion/injected dose (designated between the two vertical lines). Those skilled in the art will appreciate that the shape of this profile depends upon the infusion flow rate, for a given volume of the dose, which flow rate is controlled, for example, by the speed at which pump 33 drives flow through the patient line, and upon the amount of Strontium-82 remaining in the generator. In the absence of flow rate control, activity profiles may change over the life of the generator. Furthermore, the peak bolus of radioactivity, particularly for injected doses from a relatively new generator, may exceed a saturation level of the imaging equipment, i.e. PET scanner. According to some preferred methods of the present invention, in order to maintain relatively consistent, and desirable/effective, activity profiles for patient injections, over the life of the generator, the operating speed of pump 33 may be varied (both over the course of a single injection and from injection to injection), according to feedback from activity detector 25. Such a method may be implemented via incorporation of another quality control test in which pump 33 is operated to drive flow through the generator at a constant rate, in order to collect, into computer, a plurality of activity measurements from activity detector 25; the plurality of measurements comprise a characteristic, or baseline activity profile from which the computer 17 may calculate an appropriate flow rate profile to control a speed of pump 33, in order to achieve the desirable/effective activity profile. In general, at the start of generator life, when Strontium-82 is plentiful, the pump is controlled to drive infusion flow at relatively lower rates, and, then, toward the end of generator life, when much of the Strontium-82 has been depleted, the pump is controlled to drive infusion flow at relatively higher rates. As was described above, in conjunction with Figure 1D, if a desired infusion/injection flow rate is relatively high, that is, high enough to create too much back pressure, via flow through the column of generator 21, by-pass line 303 may be employed by adjusting divergence valve 35BG to divert a flow of eluant therethrough after a sufficient volume has been pumped through generator at a lower flow rate.

According to this method, once a dose of eluate, from generator 21, has flowed into patient line 305p, divergence valve 35BG is set to divert the flow of eluant through by-pass line 303, and then pump speed is increased to pump eluant at a higher flow rate in order to push the dose out from patient line 305p, for injection at the higher flow rate.

Consistency of activity profiles among injected doses can greatly facilitate the use of PET scanning for the quantification of flow, for example, in coronary perfusion studies. Alternative infusion circuit configurations, operable according to alternative methods, to achieve consistency of activity profiles among injected doses, as well as a more uniform level of radioactivity across each individual dose, will be described below, in conjunction with Figures 12A-C.

Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent infusion and system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary may be downloaded onto a computer readable storage device to be electronically transferred to one or more remote computers and/or the summary may be automatically transferred to the one or more remote computers, via wireless communication or a cable connection, for example, over an intranet network and/or the internet. In order to protect private patient information, the files may be encrypted for transmission over the internet. The one or more remote computers may be included, for example, in a hospital information system, and/or a billing system, and/or in a medical imaging system. Infusion parameters, for example, corresponding to the activity profile, may also be collected and electronically transferred for analysis in conjunction with captured images, for example, in order to quantify coronary flow, via a software package that is loaded into a system that includes the PET scanner.

With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data. Additionally, certain information, which is collected by computer 17 over the course of system operation, and which defines

system operation, may be transmitted to a local or remote computerized inventory system and/or to computers of technical support personnel, maintenance/service providers and/or suppliers of infusion circuit elements/components, thereby facilitating more efficient system operation and maintenance.

Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline purge, as procedures for saline purging should be readily apparent to those skilled in the art, with reference to the schematic of infusion circuit 300 shown in Figure 1D. A saline purge of circuit 300 is desired to assure that all the air is removed from circuit 300 when a new generator and/or a new complete or partial tubing set is installed. An air purge of the tubing lines of circuit 300 may be performed after removing reservoir 15, by-passing generator 21, by connecting tubing line 304 to tubing line 305, and coupling patient line 305p to a vial, for example, as is directed by the computer interface, in screens 983 and 984 shown in Figure 10. The air purge is desirable for blowing out the tubing lines, thereby removing all remaining eluant and eluate, prior to installing a new generator and/or prior to transporting system 10 from one site to another. If generator 21 is not depleted and will be used in system 10 at the new site, it is important to by-pass the generator prior to purging the tubing lines of circuit 300 with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air

through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator. According to some embodiments, computer 17 is pre-programmed to calculate an amount of activity left in a depleted generator, for example, by tracking activity of eluate over a life of the generator. At an end of the life of the generator, computer 17 may further compile this information, along with other pertinent generator information, into a report that may accompany a declaration of dangerous goods for shipping the depleted generator out for disposal or, in some cases, back to the manufacturer for investigation. An example of such a report is shown in Figure 11. According to those embodiments of system 10 that include an encoded information reader, computer 17 may confirm that the new generator is proper by processing information that is read from an encoded label/tag attached thereto.

Figures 12A-B are schematics of alternative infusion circuits 1300A, 1300B that may be employed by system 10, in place of circuit 300 (Figure 1D), according to some additional embodiments of the present invention. Circuits 1300A, 1300B are configured to allow for alternative methods of operation, to that previously described for circuit 300, when a relatively even, or uniform level of activity over each injected dose, along with the relatively consistent level of activity from injection to injection is desired, for example, in order to facilitate a quantification of coronary artery blood flow via PET scanning. Figure 12C is a schematic illustrating activity profiles 1200A, 1200B for two injected doses, wherein profile 1200B has a more uniform level of activity than profile 1200A; profile 1200B may be achieved via the operation of circuits 1300A, 1300B as described below.

Similar to circuit 300 (Figure 1D), dashed lines are shown in each of Figures 12A-B to indicate a general boundary of a shielding assembly for portions of each circuit 1300A, 1300B. The shielding assembly for each of circuits 1300A, 1300B may be very similar, in most respects, to shielding assembly 200, which is described above for system 10, and the elements of each of circuits 1300A, 1300B may be arranged with respect to their respective shielding and with respect to shell 13 of system 10 in a similar manner to that described above for circuit 300.

Figure 12A illustrates circuit 1300A including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, through which the filtered eluant is pumped to create the radioactive eluate, activity detector 25, and waste bottle 23. Figure 12A further illustrates two filters 37 and two pressure transducers 1334 included in circuit 1300A. Circuit 1300A further includes by-pass tubing line 303, which is located downstream of divergence valve 35BG, like in circuit 300, and which accommodates the previously described eluant/saline flush. However, in contrast to circuit 300, circuit 1300A further includes a linear/proportional valve 1335 integrated into by-pass/flush line 303 so that circuit 1300A may be operated, for example, according to pre-programmed parameters of computer 17, in conjunction with feedback of information from activity detector 25, for a controlled by-pass of generator 21 in order to mix eluant with eluate and, thereby, achieve a relatively uniform level of activity over each patient injection, for example, according to profile 1200B of Figure 12C. It should be noted that, in addition to the controlled mixing, a flow rate of each injection may be varied, if necessary, in order to maintain a consistent activity level.

Figure 12B illustrates circuit 1300B including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, activity detector 25, and waste bottle 23, as well as the two filters 37 and two pressure transducers 1334, as in circuit 1300A. In contrast to circuits 300 and 1300A, circuit 1300B further includes an eluate reservoir 1350, which is shown located downstream of generator 21, in between first and second segments 305A, 305B of the eluate tubing line. It should be noted that a pump is combined with reservoir 1350, for example, similar to syringe pump 33, such that, when a divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305A, the associated pump may be operated to draw in a volume of eluate, and, then, when divergence

valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305B, the pump may be operated to push the volume of eluate out through tubing line segment 305B for a patient injection, when divergence valve 35WP is set to direct flow into patient line 305p. With reference back to Figures 3A-B, sidewall 205 of shielding assembly 200 may be enlarged to further enclose eluate reservoir 1350. For example, another shielded well, to house the eluate reservoir, may extend alongside well 255, in which activity detector 25 is described as being mounted. Furthermore, sidewall 205 may include another valve actuator receptacle for divergence valve 1335IO, similar to receptacle 253, shown in Figure 3A for divergence valve 35WP.

Collection of discrete volumes of eluate, in reservoir 1350, may help to achieve a more uniform activity level over each injection, for example, like that of profile 1200B in Figure 12C, and, according to preferred methods, feedback from activity detector 25 may be used to control the pump associated with reservoir 1350, in order to vary injection flow rate and, thereby, maintain a relatively consistent activity level across multiple injections, and, when necessary, to vary injection flow rate over an individual injection to maintain the uniform activity level. Feedback from the pressure transducer 1334, that is downstream from detector 25, and/or from a flow meter (not shown) of circuit 1300B may also be used to control the varying of injection flow rate.

With further reference to Figures 12A-B, it should be noted that alternative circuits may be configured to employ a combination of the methods described for circuits 1300A and 1300B. Furthermore, some infusion circuits of the present invention may employ multiple generators 21, as mentioned above, in conjunction with Figure 2A, to help maintain the relatively uniform level of activity over each injection and the relatively consistent level of activity from injection to injection.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 12/808,467, filed June 16, 2010, which is a 371 National Stage of International Application No. PCT/US09/47031, filed June 11, 2009, which in turn claims priority to the following four patent applications: U.S. Patent Application No. 12/137,356, filed June 11, 2008, now U.S. Patent No. 8,317,674, issued November 27, 2012; U.S. Patent Application No. 12/137,363, filed June 11, 2008, now U.S. Patent No. 7,862,534, issued January 4, 2011; U.S. Patent Application No. 12/137,364, filed June 11, 2008; and U.S. Patent Application No. 12/137,377, filed June 11, 2008, now U.S. Patent 8,708,352, issued April 29, 2014. The entire contents of all of these applications are incorporated herein by reference.

TECHNICAL FIELD

The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to systems including computer-facilitated maintenance and/or operation.

BACKGROUND

Nuclear medicine employs radioactive material for therapy and diagnostic imaging. Positron emission tomography (PET) is one type of diagnostic imaging, which utilizes doses of radiopharmaceuticals, for example, generated by elution within a radioisotope generator, that are injected, or infused into a patient. The infused dose of radiopharmaceutical is absorbed by cells of a target organ, of the patient, and emits radiation, which is detected by a PET scanner, in order to generate an image of the organ. An example of a radioactive isotope, which may be used for PET, is Rubidium-82 (produced by the decay of Strontium-82); and an example of a radioisotope generator, which yields a saline solution of Rubidium-82, via elution, is the CardioGen-82● available from Bracco Diagnostics Inc. (Princeton, NJ). A PET scanner in combination with infused doses of radiopharmaceuticals may also be employed to quantify blood flow rate, for example, through the coronary arteries of a patient.

Set up, maintenance and operational procedures for infusion systems that both generate and inject doses of radiopharmaceuticals are relatively involved in order to assure the safety and efficacy of each injected dose for the patient. Efficiency in carrying out these procedures is highly desirable for technical personnel, who work with these systems on a routine basis and would like to avoid unnecessarily prolonged exposure to radioactive radiation. Thus there is a need for new system configurations that facilitate more efficient set up, maintenance and operation.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

Figure 1A is a first perspective view of an infusion system, according to some embodiments of the present invention.

Figure 1B is another perspective view of a portion of a cabinet structure of the system shown in Figure 1A, according to some embodiments.

Figure 1C is a second perspective view of the system shown in Figure 1A, according to some embodiments.

Figure 1D is a schematic of an infusion circuit, according to some embodiments of the present invention.

Figure 1E is a perspective view of exemplary sample vial shielding that may be employed in conjunction with the infusion system of Figure 1A.

Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A–C, according to some embodiments of the present invention.

Figure 2B is a perspective view of a framework of the system, according to some embodiments, and Figure 2B-1 is ~~with~~ an enlarged detailed view of a component of the system, according to some embodiments.

Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.

Figure 3B is a perspective view of the infusion circuit, shown in Figure 1C, configured and routed, according to some embodiments.

Figure 3C is a perspective view of a disposable infusion circuit subassembly, according to some embodiments.

Figure 3D is a frame for the subassembly shown in Figure 3C, according to some embodiments.

Figure 4 is a main menu screen shot from an interface of a computer, which may be included in systems of the present invention, according to some embodiments.

Figure 5A is a schematic showing a first group of successive screen shots from the computer interface, according to some embodiments.

Figure 5B is a pair of screen shots from the computer interface, which provide indications related to eluant volume levels in a reservoir of the system, according to some embodiments.

Figure 5C is a schematic showing a second group of successive screen shots from the computer interface, according to some embodiments.

Figure 6 is a schematic showing a third group of successive screen shots from the computer interface, according to some embodiments.

Figures 7A–C are schematics showing a fourth group of successive screen shots from the computer interface, according to some embodiments.

Figures 8A–B are schematics showing a fifth group of successive screen shots from the computer interface, according to some embodiments.

Figures 9A–C are schematics showing a sixth group of successive screen shots from the computer interface, according to some embodiments.

Figure 10 is a schematic showing a seventh group of successive screen shots from the computer interface, according to some embodiments.

Figure 11 is an exemplary report which may be generated by the computer included in infusion systems, according to some embodiments.

Figures 12A–B are schematics of alternative infusion circuits that may be employed by embodiments of the present invention.

Figure 12C is a schematic illustrating exemplary activity profiles of injected doses of a radiopharmaceutical.

DETAILED DESCRIPTION

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.

Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surround an interior space in which a portion of infusion system 10 is contained (seen in Figure 1C). Shell 13 may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13; and, a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may be included, for example, a keyboard, a series of control buttons or levers, a bar code reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions, as well as to monitor system operation both during quality control infusions and during patient infusions. Operation of system 10,

which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one location to another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.

Figure 1B is a perspective view of a portion of system 10, on a side 111 of the cabinet structure, which is in proximity to wheels 121, 122. Figure 1B illustrates a lever or pedal 125, which is located for activation by a foot of the person, who grasps handle 14 to maneuver system 10. In a neutral position, pedal 125 allows wheels 121, 122 to rotate, and, if embodied as casters, to swivel freely. Pedal 125 may be depressed to a first position which prevents a swiveling of wheels 121, 122, according to those embodiments in which wheels 121, 122 are casters, and may be further depressed to brake wheels 121, 122 from rolling and swiveling, upon reaching a desired location. According to some embodiments, braking may be designed to slow system 10, for example, when rolling down an incline, and, according to yet further embodiments, system 10 may include a motor to power movement thereof.

Figure 1B further illustrates**:** a rear access panel 174 of shell 13, for example, providing access to circuit boards of the aforementioned controller contained within the interior space that is surrounded by shell 13; an optional lock 184, to secure panel 174; a power jack 118, for connecting system 10 to a power source; and a printer 117 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include a power strip by which auxiliary equipment may be powered, and one or more additional electrical connectors, or ports (not shown), which are supported by platform 113 and may be integrated into shell 13, for example, in proximity to jack 118 or printer 117; these electrical connectors/ports allow system 10 to communicate with, other devices used for nuclear imaging procedures, for example, a PET scanner/camera, and/or for coupling to an intranet network, and/or to the internet, for example, to link up with software programs for various types of data analysis, and/or

to link to computers of consulting clinicians/physicians, and/or to link into service providers and/or component suppliers data bases for enhanced maintenance and inventory management.

Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective view of system 10, wherein a removable access panel 132 is shown as a contoured portion of upper surface 131, which, when exposed, by lifting away a bin 18, that mates therewith, may be removed from another opening 137 formed in upper surface 131. Figure 1C also provides a better view of another panel 134 which may be lifted away from opening 139. According to the illustrated embodiment, openings 139 and 137 provide a user of system 10 with independent access to separate portions of infusion system 10, which are contained within shell 13, for example, to set up and maintain system 10; and openings 133 and 135 provide passageways for tubing lines to pass through shell 13. Figure 1C further illustrates an optional switch 102, which in case of an emergency, may be activated to abort function of system 10. With reference to Figures 1A and 1C, it may be appreciated that an arrangement of features formed in upper surface 131 of shell 13, in conjunction with bin 18, tray 16 and computer 17, provide a relatively ergonomic and organized work area for technical personnel who operate system 10.

Turning now to Figure 1D, a schematic of an infusion circuit 300, which may be incorporated by system 10, is shown. Figure 1D illustrates circuit 300 generally divided into a first part 300A, which includes components mounted outside shell 13, and a second part 300B, which includes components mounted within the interior space surrounded by shell 13. (Parts 300A and 300B are delineated by dotted lines in Figure 1D.) Figure 1D further illustrates second part 300B of circuit 300 including a portion contained within a shielding assembly 200, which is designated schematically as a dashed line. Some embodiments of shielding assembly 200 will be described in greater detail, in conjunction with Figures 2A-B and 3A-B, below.

According to the illustrated embodiment, circuit 300 includes**:** an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34 (or other device or sensor), for monitoring pumping

pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity detector 25, for measuring the activity of the eluate discharged from generator 21, in order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance.

Figure 1D illustrates an eluant tubing line 301 coupled to reservoir 15 and to pump 33, and, with reference to Figures 1A-B, it may be appreciated that opening 133 provides the passageway for tubing line 301 to enter the interior space surrounded by shell 13. According to some preferred embodiments, opening 133 includes a grommet-type seal that prevents leakage of eluant, which may spill from reservoir 15, into the interior space through opening 133, while allowing a user to assemble tubing line 301 through opening 133. Likewise opening 135, which provides a passageway for patient line 305p, may include a grommet-type seal. According to some embodiments, shell 13 further supports holders to safely hold, for example, during transport of system 10, portions of tubing lines that extend outward therefrom, for example, line 301 and/or line 305p.

Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which

controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from the generator into waste bottle 23, until activity detector 25 detects the desired activity of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21. According to some preferred methods of operation, in certain situations, which will be described in greater detail below, eluant is pumped through by-pass line 303 immediately following the flow of the prescribed volume of eluate into patient line 305p, at a higher speed, in order to push the eluate in patient line 305, thereby increasing a flow rate of the injection of eluate out from patient line 305p and into the patient. For example, once the prescribed volume of eluate has flowed into patient line 305p, and once divergence valve 35BG is set to divert flow through by-pass line 303, the speed of pump 33 may be adjusted to increase the flow rate of eluant to between approximately 70mL/min and approximately 100mL/min. This method for increasing the injection flow rate, is desirable, if a relatively high flow rate is desired for patient injection and a flow rate through generator 21 is limited, for example, to below approximately 70mL/min, maximum (typical flow rate may be approximately 50mL/min), in order to avoid an excessive back pressure created by the column of generator 21 in upstream portions of tubing circuit 300; the excessive back pressure could damage filter 37 or otherwise impede flow through eluant tubing line 302.

Although not shown in Figure 1D, a number of sensors, for example, to measure pressure and/or flow velocity, may be incorporated into circuit 300, according to some alternate embodiments, in order to monitor for flow anomalies, for example,

related to occlusions/plugs in circuit 300 and/or leaks, and/or to provide feedback for control of an activity level of infused doses of radiopharmaceutical. Suitable sensors for any of the above purposes are known to those skilled in the art. Examples of flow meters that may be incorporated into circuit 300, include the Innova-Sonic● Model 205 Transit-Time Ultrasonic Liquid Flow Meter that employs digital signal processing (available from Sierra Instruments, Inc.) and the Flocat LA10-C differential pressure flow meter. One example of a pressure sensor that may be employed to detect infusion circuit occlusions is the PRO / Pressure-Occlusion Detector (available from INTROTEK● of Edgewood, NY, a subsidiary of Magnetrol of Downers Grove, IL), which employs pulse-type ultrasound; this sensor detects subtle changes in positive and negative air pressure and produces a corresponding passive resistive output signal, which may be routed to the system controller and/or computer 17. One or more of this type of sensor may be incorporated into infusion circuit 300 by simply fitting the sensor around any of the tubing lines of infusion circuit 300; in fact, the PRO / Pressure-Occlusion Detector may be a suitable alternative to pressure syringe 34 of circuit 300. Other types of pressure sensors, for example, similar to those known in the art for blood pressure monitoring, may be employed in infusion circuit 300.

System 10 may further include sensors to detect fluid levels in eluant reservoir 15 and waste bottle 23. Some examples of such sensors, which also employ the aforementioned pulse-type ultrasound, are the Drip Chamber Liquid Level Sensor and the CLD / Continuous Level Detector (both available from INTROTEK●); alternatively, for example, an HPQ-T pipe mounted, self-contained liquid sensor (available from Yamatake Sensing Control, Ltd.), or an SL-630 Non-Invasive Disposable/Reusable Level Switch (available from Cosense, Inc. of Hauppauge, NY) may be employed to detect the fluid levels. Alternately or in addition, system 10 can include additional radiation and/or moisture detection sensors, which can detect leaks. With reference to Figure 1D, such sensors are preferably located in proximity to fittings 311, 312, 313, 314 and 315 that join portions of circuit 300 to one another. Some examples of leak detection sensors include, without limitation, those in the HPQ-D leak detection sensor family, and the HPF-D040 fiberoptic leak detector (all available from Yamatake Sensing Control, Ltd.). System 10 may further include additional sensors to detect contaminants and/or air bubbles within the tubing lines of circuit; examples of such sensors include the Point-air Detection (PAD) Sensor, that

employs pulse-type ultrasound for air bubble detection, and the Blood Component Detector that employs optical sensing technology to perform Colorimetry-based fluid detection of unwanted elements in the tubing lines (both available from INTROTEK●).

According to those embodiments that include any of the above sensors, the sensors are linked into the controller of system 10 and/or computer 17, either of which may provide a signal to a user of system 10, when a flow anomaly is detected, and/or information to the user, via monitor 172, concerning fluid levels, pressure and/or flow through circuit 300. Computer 17 may be pre-programmed to display, for example, on monitor 172, a graphic of infusion circuit 300 wherein each zone of the circuit, where an anomaly has been detected, is highlighted, and/or to provide guidance, to the system user, for correcting the anomaly. It should be noted that the alternative infusion circuits illustrated in Figures 12A-B, which will be described below, may also include any or all of these types of sensors.

With further reference to Figure 1D, it may be appreciated that shielding assembly 200 encloses those portions of circuit 300 from which radioactive radiation may emanate, with the exception of that portion of patient line 305p, which must extend out from shielding assembly 200 in order to be coupled to the patient for injection, or in order to be coupled to shielded sample vials, as will be described below. Thus, technical personnel, who operate system 10, are protected from radiation by shielding assembly 200, except at those times when an infusion is taking place, or when quality control tests require collection of eluate into sample vials. During infusions and quality control test sample collection, all technical personnel are typically in another room, or otherwise distanced from system 10, in order to avoid exposure to radiation during the infusion, and, according to some preferred embodiments of the present invention, system 10 includes at least one means for informing technical personnel that an infusion is about to take place or is taking place. With reference back to Figures 1A and 1C, system 10 is shown including a light projector 100, mounted on post 142. According to the illustrated embodiment, projector 100, projects a light signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23,

and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system 10, including in the control room.

It should be noted that, according to alternate embodiments, system 10 includes an 'on board' dose calibrator for quality control tests, and circuit 300 is expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator. According to a first set of these alternate embodiments, a sample collection reservoir is integrated into circuit 300, downstream of divergence valve 35WP and in communication with tubing line 305P, in order to receive quality control test samples of eluate, via tubing line 305P, and both the reservoir and the dose calibrator are located in a separate shielded well. According to a second set of these alternate embodiments, waste bottle 23 is configured to receive the quality control test samples of eluate, via tubing line 305W, and a dose calibrator is integrated into shielding assembly 200. Quality control procedures will be described in greater detail below, in conjunction with Figures 6-8B.

When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a threshold to be safe. Opening 139 is preferably located at an elevation of between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is

accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional maintenance procedures, such as changing out generator 21 and/or other components of circuit 300, as will be described below.

For those embodiments of system 10 in which automated quality control tests are performed and/or when system 10 is employed for relatively high volume operation, management of waste may become burdensome, even though access to waste bottle 23 is greatly facilitated, as described above. Thus, in order to facilitate waste management, some embodiments of system 10 may employ a separation system to separate salts, including radioactive elements, from water, for example, via evaporation or reverse osmosis. In an evaporation type system, the water component of the waste is evaporated, while in a reverse osmosis type system the water is separated from the salts, and, then, once confirmed to be non-radioactive, via a radiation detector, is piped to a drain. According to some other embodiments, circuit 300 may be configured so that the waste may be used to purge air from the tubing lines thereof and/or to perform the bypass flush that was described above, preferably after the radioactivity of the waste drops below a critical threshold.

Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from the infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. An exemplary test vial shield is shown in Figure 1E. The test vial shield of Figure 1E is preferably formed from Tungsten rather than lead, for example, to reduce exposure to

lead, for improved shielding, and to reduce the weight of the shield. Figure 1E illustrates the test vial shield including a handle to simplify manipulation thereof, but alternative configurations of test vial shields have no handle – for these a sling, or strap, may be employed for handling.

Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc…, into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example, deposited therein during infusion procedures. According to some embodiments, one or more additional receptacles are formed in one or more disposal containers, for example, to contain sharps and/or radioactive waste (other than that contained in waste bottle 23), which may be integrated into bin 18, or otherwise fitted into, or attached to shell 13, separate from bin 18.

Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. It should be noted that, according to alternate embodiments, the compartment enclosed by sidewall 201 is large enough to hold more than one generator, for example, to increase system operating efficiency for relatively high volume operation. In some of these alternate embodiments, tubing lines 304 and 305 are each branched for parallel flow through the multiple generators, in which case divergence valves may be employed to alternate the flow through the generators, one at a time. In others of these alternate embodiments, the multiple generators are connected in series between tubing line 304 and tubing line 305. In addition, a reservoir for accumulating eluate may be included in circuit 300, downstream of the generators and upstream of divergence valve 35 WP, in conjunction with a second pump, in some cases. Embodiments including multiple generators and/or an eluate reservoir and second pump can be employed to better manage an

activity level of each dose, or patient injection, for example, as described below, in conjunction with Figures 12A-B.

According to the embodiment illustrated in Figure 2A, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed by a sidewall 203 of shielding assembly 200 to contain waste bottle 23, as previously described. When panel 132 is separated from shell 13, and door 221 opened, generator 21 may be lifted out from an opening 231 (Figure 3A) which mates with door 221 of sidewall 201. A weight of generator 21, which includes its own shielding, may be between approximately 23 and approximately 25 pounds, thus, according to some preferred embodiments of the present invention, the elevation of each of openings 137 and 231, with respect to the lowermost portion of the cabinet structure, is between approximately 1 foot and approximately 2 feet, in order to facilitate an ergonomic stance for technical personnel to lift generator 21 out from the compartment. According to an exemplary embodiment, when shielding assembly 200 is contained in the cabinet structure of Figure 1A , openings 137 and 231 are located at an elevation of approximately 12 inches, with respect to the lower surface of platform 113, or at an elevation of approximately 19 inches, with respect to the ground surface upon which wheels 121, 122 rest. Figure 1C further illustrates access panel 132 including a security lock 138, which mates with a framework 19 of system 10, shown in Figure 2B, in order to limit access to generator 21.

Figures 1C and 2A further illustrate a lid or a door 225 of another sidewall 205 (Figure 3A) of shielding assembly 200, which encloses another compartment that is accessible through opening 137 of shell 13, and which is located adjacent the compartment enclosed by sidewall 201. Each of doors 221, 225 are shown being attached by a corresponding hinge H, and another door 227 is shown attached to sidewall 203 by another hinge H. Figure 2A illustrates each of lid 223 and doors 221, 225, 227 including a handle 232, 212, 252 and 272, respectively, for moving lid 223 and doors 221, 225, 227, in order to provide access to the corresponding compartments, which can be seen in Figures 3A-B. Figure 2A further illustrates optional thumb screws 290, one securing lid 223 to sidewall 203 and another securing door 221 to sidewall 201, or other means for securing the doors, which are known to those skilled in the art, may be incorporated. Each sidewall 201, 203, 205 and the

corresponding lid/door 223, 221, 225, 227 thereof may be individually cast from 3% antimony lead, or from other known shielding materials, and then assembled together according to methods known to those skilled in the art.

According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a latch component 191 is provided to hold each of doors 221, 225 in an opened position, thereby, preventing doors 221, 225 from falling closed, which could pinch/crush fingers of technical personnel and/or tubing lines of circuit 300, when in the midst of a maintenance procedure. Figure 2B is a perspective view of framework 19 of the cabinet structure of system 10, according to some embodiments, to which latch component 191 is mounted; Figure 2B-1 is ~~includes~~ an enlarged detailed view of latch component 191, according to some embodiments. Figure 2B illustrates latch component 191 including a first pin 193, corresponding to door 225, and a second pin 195, corresponding to door 221; each pin 193, 195 includes a lever end 193A, 193B, respectively, and a holding end 193B, 195B, respectively. An edge of each door 221, 225, upon opening of doors 221, 225, may push past the holding end 195B, 193B of the corresponding pin 195, 193, in a first direction, per arrow F, and then may rest against a respective side S95 and S93 of each end 195B, 193B, until the corresponding lever end 195A, 193A is rotated in a counter-clockwise direction, per arrow cc, thereby moving the corresponding holding end 193B, 195B to make way for the closing of doors 221, 225. Doors 221, 225 being held by latch component 191 in an open position may be seen in Figure 3A.

With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225.

The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.

Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover. With further reference to Figures 3A-B, it may be appreciated that the compartment formed by sidewall 201 may have a shape matching an exterior contour of generator 21, such that generator 21 is 'keyed' to the compartment, for example, to prevent installation of an improper generator into system 10, and/or to facilitate the proper orientation of generator 21 within the compartment for the proper routing of

tubing lines. Alternately, or in addition, according to alternate embodiments, if system 10 includes a reader of encoded information in communication with computer 17, a unique identification and/or data associated with each generator may be provided, for example, in a bar code label or a radiofrequency identification (RFID) tag that is attached to each generator, so that the reader may transfer the information to computer 17, when a generator is installed, in order to either enable system operation or to provide an indication to the user that an incorrect generator has been installed. Of course a user of system 10 may, alternately, manually enter information, that is provided on a generator label or marking, into computer 17, in order to either enable system 10, or to receive feedback from computer 17 that the incorrect generator is installed.

Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305 passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.

Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together,

according to alternate embodiments, mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.

According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w, respectively, extending from second side 392 of frame 39. Although ends 406, 407 are shown extending upward from tray 39a, as they would within shielding assembly 200, it should be appreciated that the tubing lines of circuit 300 are preferably flexible and would drop down under their own weight rather than extending upward, as shown, if not supported. Referring back to Figure 1D, in conjunction with Figure 3C, it can be seen that the aforementioned fittings are provided for coupling subassembly 390 into circuit 300: first fitting 311 couples the section of eluant line 302 to filter 37; second fitting 312 couples eluant line 304 to an inlet port of generator 21; third fitting 313, which may incorporate a check valve, couples eluate line 305 to an outlet port of generator 21; fourth fitting 314 couples waste line 305w to waste bottle 23; and fifth fitting 315 couples patient line 305p to an extension thereof, which extends outside shell 13 (designated by the dotted line). Each of the fittings 311, 312, 313, 314, 315 may be of the Luer type, may be a type suitable for relatively high pressure applications, or may be any other suitable type that is known to those skilled in the art.

As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and

405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.

Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.

Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to

post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17, so that the operation of system 10 may be monitored and controlled remotely, away from radioactive radiation.

According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. Computer 17 may also be pre-programmed to interact with the controller of system 10 in order to keep a running tally or count of elutions per unit time, for a given generator employed by the system, and may further categorize each of the counted elutions, for example, as being generated either as a sample, for quality control testing, or as a dose, for patient injection. The elution count and categorization, along with measurements made on each sample or dose, for example, activity level, volume, flow rate, etc…, may be maintained in a stored record on computer 17. All or a portion of this stored information can be compiled in a report, to be printed locally, and/or to be electronically transferred to a remote location, for example, via an internet connection to technical support personnel, suppliers, service providers, etc…, as previously described. Computer 17 may further interact with the user and/or a reader of encoded information, for example, a bar code reader or a radiofrequency identification (RFID) tag reader, to store and organize product information collected from product labels/tags, thereby facilitating inventory control, and/or confirming that the proper components, for example, of the tubing circuit, and/or accessories, and/or solutions are being used in the system.

It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format. Computer 17 may also include a pre-programmed user manual, which may be viewed on monitor 172, either independent of system operation or in conjunction with system operation, for example, via pop-up help screens. Although the English language is employed in the screen shots of Figures 4-9C, it should be understood that, according to some embodiments, computer 17 is pre-programmed to provide guidance in multiple languages.

Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on. According to some multi-lingual embodiments, computer 17 presents a list of languages from which the user may select, prior to presenting main menu 470.

Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a storage medium (i.e. disk) reader, a scanner, a bar code reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc…). Although not shown, according to some embodiments, screen 570 may further include another data entry field in which the user is required to enter a license key related to the generator employed by system 10 in order to enable operation of system 10; the key may be time sensitive, related to generator contract terms. Of course any number of log in requirements may be employed, according to various embodiments, and may be presented on multiple sequentially appearing screens rather than on a single log in screen.

After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of

eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag. If system 10 includes an encoded information reader, such as a bar code or RFID tag reader, confirmation that the selected reservoir is proper, i.e., contains the proper saline solution, may be carried out by computer 17, prior to connecting the reservoir into circuit 300, by processing information read from a label/tag attached to the reservoir. Alternatively, or in addition, tubing line 301 of circuit 300 may be provided with a connector which only mates with the proper type of reservoir 15. According to some embodiments, system 10 may further include an osmolarity or charge detector, which is located just downstream of reservoir 15 and is linked to computer 17, so that an error message may be presented on monitor 172 stating that the wrong osmolarity or charge is detected in the eluant supplied by reservoir, indicating an improper solution. One example of a charge detector that may be employed by system 10 is the SciCon™ Conductivity Sensor (available from SciLog, Inc. of Middleton, WI).

Once the reservoir/saline bag is successfully replaced, computer 17 prompts the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Alternately, if system 10 includes the aforementioned reader, and the saline bag includes a tag by which volume information is provided, the reader may automatically transfer the quantity information to computer 17. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished. It should be noted that, as previously mentioned, system 10 can include a fluid level sensor coupled

to the eluant reservoir in order to detect when the level of saline drops below a certain level.

In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied. According to some alternative embodiments, a fluid level sensor may be coupled to waste bottle 23, for example, as mentioned above in conjunction with Figure 1D, in order to automatically detect when waste bottle 23 is filled to a predetermined level and to provide, via computer 17, an indication to the user that waste bottle 23 needs to be emptied and/or to automatically preclude operation of system 10 until the waste bottle is emptied.

In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate

that eluate it being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.

Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82● that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. According to some embodiments, in conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).

Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process

when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the

background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.

With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly

flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration elution process. When the user transfers the vial containing the sample of eluate into the dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 878. With further reference to Figure 8B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 879, which includes data entry fields for the activity measure and the time, with respect to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data is input by the user, as described above, the computer calculates a calibration coefficient, or ratio, and presents the ratio on a screen 880. According to Figure 8B, screen 880 further provides an indication of a desirable range for the calibration ratio and presents an option for the user to reject the calculated ratio, in which case, the user may instruct computer 17 to recalculate the ratio.

As previously mentioned, some alternate embodiments of the present invention include an on board dose calibrator so that the entire sequence of sample collection and calculation steps, which are described above, in conjunction with Figures 6-8B, for the quality control procedures, may be automated. This automated alternative preferably includes screen shots, similar to some of those described above, which provide a user of the system with information at various stages over the course of the automated procedure and that provide the user with opportunities to modify, override and/or abort one or more steps in the procedure. Regardless of the embodiment (i.e. whether system 10 employs an on board dose calibrator or not), computer 17 may further collect all quality control test parameters and results into a stored record and/or compile a report including all or some of the parameters and results for local print out and/or electronic transfer to a remote location.

With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for

example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with an option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may

be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

With further reference to Figure 9C, screen 976 shows an exemplary activity profile (activity - mCi/sec, on y-axis, versus time – sec, on x-axis) for the infusion/injected dose (designated between the two vertical lines). Those skilled in the art will appreciate that the shape of this profile depends upon the infusion flow rate, for a given volume of the dose, which flow rate is controlled, for example, by the speed at which pump 33 drives flow through the patient line, and upon the amount of Strontium-82 remaining in the generator. In the absence of flow rate control, activity profiles may change over the life of the generator. Furthermore, the peak bolus of radioactivity, particularly for injected doses from a relatively new generator, may exceed a saturation level of the imaging equipment, i.e. PET scanner. According to some preferred methods of the present invention, in order to maintain relatively consistent, and desirable/effective, activity profiles for patient injections, over the life of the generator, the operating speed of pump 33 may be varied (both over the course of a single injection and from injection to injection), according to feedback from activity detector 25. Such a method may be implemented via incorporation of another quality control test in which pump 33 is operated to drive flow through the generator at a constant rate, in order to collect, into computer, a plurality of activity measurements from activity detector 25; the plurality of measurements comprise a characteristic, or baseline activity profile from which the computer 17 may calculate an appropriate flow rate profile to control a speed of pump 33, in order to achieve the desirable/effective activity profile. In general, at the start of generator life, when Strontium-82 is plentiful, the pump is controlled to drive infusion flow at relatively lower rates, and, then, toward the end of generator life, when much of the Strontium-82 has been depleted, the pump is controlled to drive infusion flow at relatively higher rates. As was described above, in conjunction with Figure 1D, if a desired infusion/injection flow rate is relatively high, that is, high enough to create too much back pressure, via flow through the column of generator 21, by-pass line 303 may be employed by adjusting divergence valve 35BG to divert a flow of eluant therethrough after a sufficient volume has been pumped through generator at a lower flow rate.

According to this method, once a dose of eluate, from generator 21, has flowed into patient line 305p, divergence valve 35BG is set to divert the flow of eluant through by-pass line 303, and then pump speed is increased to pump eluant at a higher flow rate in order to push the dose out from patient line 305p, for injection at the higher flow rate.

Consistency of activity profiles among injected doses can greatly facilitate the use of PET scanning for the quantification of flow, for example, in coronary perfusion studies. Alternative infusion circuit configurations, operable according to alternative methods, to achieve consistency of activity profiles among injected doses, as well as a more uniform level of radioactivity across each individual dose, will be described below, in conjunction with Figures 12A-C.

Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent infusion and system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary may be downloaded onto a computer readable storage device to be electronically transferred to one or more remote computers and/or the summary may be automatically transferred to the one or more remote computers, via wireless communication or a cable connection, for example, over an intranet network and/or the internet. In order to protect private patient information, the files may be encrypted for transmission over the internet. The one or more remote computers may be included, for example, in a hospital information system, and/or a billing system, and/or in a medical imaging system. Infusion parameters, for example, corresponding to the activity profile, may also be collected and electronically transferred for analysis in conjunction with captured images, for example, in order to quantify coronary flow, via a software package that is loaded into a system that includes the PET scanner.

With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data. Additionally, certain information, which is collected by computer 17 over the course of system operation, and which defines

system operation, may be transmitted to a local or remote computerized inventory system and/or to computers of technical support personnel, maintenance/service providers and/or suppliers of infusion circuit elements/components, thereby facilitating more efficient system operation and maintenance.

Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline purge, as procedures for saline purging should be readily apparent to those skilled in the art, with reference to the schematic of infusion circuit 300 shown in Figure 1D. A saline purge of circuit 300 is desired to assure that all the air is removed from circuit 300 when a new generator and/or a new complete or partial tubing set is installed. An air purge of the tubing lines of circuit 300 may be performed after removing reservoir 15, by-passing generator 21, by connecting tubing line 304 to tubing line 305, and coupling patient line 305p to a vial, for example, as is directed by the computer interface, in screens 983 and 984 shown in Figure 10. The air purge is desirable for blowing out the tubing lines, thereby removing all remaining eluant and eluate, prior to installing a new generator and/or prior to transporting system 10 from one site to another. If generator 21 is not depleted and will be used in system 10 at the new site, it is important to by-pass the generator prior to purging the tubing lines of circuit 300 with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air

through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator. According to some embodiments, computer 17 is pre-programmed to calculate an amount of activity left in a depleted generator, for example, by tracking activity of eluate over a life of the generator. At an end of the life of the generator, computer 17 may further compile this information, along with other pertinent generator information, into a report that may accompany a declaration of dangerous goods for shipping the depleted generator out for disposal or, in some cases, back to the manufacturer for investigation. An example of such a report is shown in Figure 11. According to those embodiments of system 10 that include an encoded information reader, computer 17 may confirm that the new generator is proper by processing information that is read from an encoded label/tag attached thereto.

Figures 12A-B are schematics of alternative infusion circuits 1300A, 1300B that may be employed by system 10, in place of circuit 300 (Figure 1D), according to some additional embodiments of the present invention. Circuits 1300A, 1300B are configured to allow for alternative methods of operation, to that previously described for circuit 300, when a relatively even, or uniform level of activity over each injected dose, along with the relatively consistent level of activity from injection to injection is desired, for example, in order to facilitate a quantification of coronary artery blood flow via PET scanning. Figure 12C is a schematic illustrating activity profiles 1200A, 1200B for two injected doses, wherein profile 1200B has a more uniform level of activity than profile 1200A; profile 1200B may be achieved via the operation of circuits 1300A, 1300B as described below.

Similar to circuit 300 (Figure 1D), dashed lines are shown in each of Figures 12A-B to indicate a general boundary of a shielding assembly for portions of each circuit 1300A, 1300B. The shielding assembly for each of circuits 1300A, 1300B may be very similar, in most respects, to shielding assembly 200, which is described above for system 10, and the elements of each of circuits 1300A, 1300B may be arranged with respect to their respective shielding and with respect to shell 13 of system 10 in a similar manner to that described above for circuit 300.

Figure 12A illustrates circuit 1300A including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, through which the filtered eluant is pumped to create the radioactive eluate, activity detector 25, and waste bottle 23. Figure 12A further illustrates two filters 37 and two pressure transducers 1334 included in circuit 1300A. Circuit 1300A further includes by-pass tubing line 303, which is located downstream of divergence valve 35BG, like in circuit 300, and which accommodates the previously described eluant/saline flush. However, in contrast to circuit 300, circuit 1300A further includes a linear/proportional valve 1335 integrated into by-pass/flush line 303 so that circuit 1300A may be operated, for example, according to pre-programmed parameters of computer 17, in conjunction with feedback of information from activity detector 25, for a controlled by-pass of generator 21 in order to mix eluant with eluate and, thereby, achieve a relatively uniform level of activity over each patient injection, for example, according to profile 1200B of Figure 12C. It should be noted that, in addition to the controlled mixing, a flow rate of each injection may be varied, if necessary, in order to maintain a consistent activity level.

Figure 12B illustrates circuit 1300B including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, activity detector 25, and waste bottle 23, as well as the two filters 37 and two pressure transducers 1334, as in circuit 1300A. In contrast to circuits 300 and 1300A, circuit 1300B further includes an eluate reservoir 1350, which is shown located downstream of generator 21, in between first and second segments 305A, 305B of the eluate tubing line. It should be noted that a pump is combined with reservoir 1350, for example, similar to syringe pump 33, such that, when a divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305A, the associated pump may be operated to draw in a volume of eluate, and, then, when divergence

valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305B, the pump may be operated to push the volume of eluate out through tubing line segment 305B for a patient injection, when divergence valve 35WP is set to direct flow into patient line 305p. With reference back to Figures 3A-B, sidewall 205 of shielding assembly 200 may be enlarged to further enclose eluate reservoir 1350. For example, another shielded well, to house the eluate reservoir, may extend alongside well 255, in which activity detector 25 is described as being mounted. Furthermore, sidewall 205 may include another valve actuator receptacle for divergence valve 1335IO, similar to receptacle 253, shown in Figure 3A for divergence valve 35WP.

Collection of discrete volumes of eluate, in reservoir 1350, may help to achieve a more uniform activity level over each injection, for example, like that of profile 1200B in Figure 12C, and, according to preferred methods, feedback from activity detector 25 may be used to control the pump associated with reservoir 1350, in order to vary injection flow rate and, thereby, maintain a relatively consistent activity level across multiple injections, and, when necessary, to vary injection flow rate over an individual injection to maintain the uniform activity level. Feedback from the pressure transducer 1334, that is downstream from detector 25, and/or from a flow meter (not shown) of circuit 1300B may also be used to control the varying of injection flow rate.

With further reference to Figures 12A-B, it should be noted that alternative circuits may be configured to employ a combination of the methods described for circuits 1300A and 1300B. Furthermore, some infusion circuits of the present invention may employ multiple generators 21, as mentioned above, in conjunction with Figure 2A, to help maintain the relatively uniform level of activity over each injection and the relatively consistent level of activity from injection to injection.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

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First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Sarah Munson
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Late Filing Fee for Oath or Declaration	1051	1	140	140
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First Named Inventor/Applicant Name:	Stephen E. Hidem
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1	Applicant Response to Pre-Exam Formalities Notice	56782_1_7_15_Response_to_Notice.pdf	102460 2457bb34f68bbeb02ca67dbcba58cfefafce70eb	no	2
Warnings:					
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2	Specification	56782_1_7_15_Specification_Clean_Version.pdf	195031 a66a6bed57483bb0a85014c42a3f5843262a3cb7	no	34
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3	Applicant Arguments/Remarks Made in an Amendment	56782_1_7_15_Specification_Marked-Up_Version.pdf	195492 7a5f6f7144a0c1cc8c5b81aca2ed8a7e056bb651	no	34
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4	Fee Worksheet (SB06)	fee-info.pdf	30353 a9d43f672b1324295a1ee1e80116f01e0de36b7	no	2
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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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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.

If Required, Foreign Filing License Granted: 08/18/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/455,623**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

Title

INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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).

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/455,623

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4			OR	x 80 =	320
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 420 =	0.00
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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1920

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	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 found in the appropriate box in column 1.

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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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/455,623	08/08/2014	Stephen E. Hidem	56782.1.7.15

CONFIRMATION NO. 1068

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

FORMALITIES LETTER

OC000000070260125

Date Mailed: 08/20/2014

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The substitute specification must be submitted with markings and be accompanied by a clean version (without markings) as set forth in 37 CFR 1.125(c) and a statement that the substitute specification contains no new matter (see 37 CFR 1.125(b)). The specification, claims, and/or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
  - The application contains drawings, but the specification does not contain a brief description of the several views of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(9).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **140** surcharge.
- $(**0**) previous unapplied payment amount.
- $ **140** TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Stephen E. Hidem
  Aaron M. Fontaine
  Janet L. Gelbach
  Patrick M. McDonald
  Kathryn M. Hunter
  Rolf E. Swenson
  Julius P. Zodda

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/aabranyos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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	
Filing Date	
First Named Inventor	Stephen E. Hidem
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	56782.1.7.15

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	3483867	A	1969-12-16	Markovitz	
	2	3565376	A	1971-02-23	Viers	
	3	3710118	A	1973-01-09	Holgate	
	4	3714429	A	1973-01-30	Mozley	
	5	3774036	A	1973-11-20	Gerhart	
	6	3991960	A	1976-11-16	Tanaka	
	7	3997784	A	1976-12-14	Pecunko	
	8	4096859	A	1978-06-27	Agarwal	

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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	9	4212303	A	1980-07-15	Nolan	
	10	4286169	A	1981-08-25	Rossem	
	11	4336036	A	1982-06-22	Leeke	
	12	4466888	A	1984-08-21	Verkaart	
	13	4562829	A	1986-01-07	Bergner	
	14	4585009	A	1986-04-29	Barker	
	15	4585941	A	1986-04-29	Bergner	
	16	4623102	A	1986-11-18	Hough, Jr.	
	17	4625118	A	1986-11-25	Kriwetz	
	18	4656697	A	1987-04-14	Naeslund	
	19	4679142	A	1987-07-07	Lee	

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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	20	4755679	A	1988-07-05	Wong	
	21	4769008	A	1988-09-06	Hessel	
	22	4853546	A	1989-08-01	Abe	
	23	4994056	A	1991-02-19	Ikeda	
	24	5039863	A	1991-08-13	Matsuno	
	25	5254328	A	1993-10-19	Herscheid	
	26	5258906	A	1993-11-02	Kroll	
	27	5274239	A	1993-12-28	Lane	
	28	5395320	v	1995-03-07	Padda	
	29	5475232	A	1995-12-12	Powers	
	30	5485831	A	1996-01-23	Holdsworth	

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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	31	5590648	A	1997-01-07	Mitchell	
	32	5702115	A	1997-12-30	Pool	
	33	5739508	A	1998-04-14	Uber, III	
	34	5765842	A	1998-06-16	Phaneuf	
	35	5827429	A	1998-10-27	Ruschke	
	36	5840026	A	1998-11-24	Uber, III	
	37	5885216	A	1999-03-23	Evans, III	
	38	6157036	A	2000-12-05	Whiting	
	39	6267717	B1	2001-07-31	Stoll	
	40	6347711	B1	2002-02-19	Goebel	
	41	6442418	B1	2002-08-27	Evans, III	

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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	42	6450936	B1	2002-09-17	Smith, III	
	43	6454460	B1	2002-09-24	Ramanathan	
	44	6558125	B1	2003-05-06	Futterknecht	
	45	6626862	B1	2003-09-30	Duchon	
	46	6767319	B2	2004-07-27	Reilly	
	47	6870175	B2	2005-03-22	Dell	
	48	6901283	B2	2005-05-31	Evans, III	
	49	6908598	B2	2005-06-21	Sylvester	
	50	7091494	B2	2006-08-15	Weisner	
	51	7163031	B2	2007-01-16	Graves	
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	53	7204797	B2	2007-04-17	Reilly	
	54	7286867	B2	2007-10-23	Schlyer	
	55	7256888	B2	2007-08-14	Staehr	
	56	7413123	B2	2008-08-19	Ortenzi	
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	58	7504646	B2	2009-03-17	Balestracci	
	59	7522952	B2	2009-04-21	Krieg	
	60	7586102	B2	2009-09-08	Mourtada	
	61	7605384	B2	2009-10-20	Sonnenhol	
	62	7608831	B2	2009-10-27	Lamb	
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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	64	7712491	B2	2010-05-11	Tochon-Danguy	
	65	7734331	B2	2010-06-08	Dhawale	
	66	7737415	B2	2010-06-15	Casale	
	67	7780352	B2	2010-08-24	Fox	
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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	75	8431909	B2	2013-04-30	Horton	
	76	8439815	B2	2013-05-14	Lemer	
	77	8442803	B2	2013-05-14	Chen	
	78	6220554	B1	2001-04-24	Daoud	
	79	8058632	B2	2011-11-15	Balestracci	
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	82	8317674	B2	2012-11-27	Quirico	
	83	8708352	B2	2014-04-29	Quirico	

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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

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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	1	20020129471	A1	2002-09-19	Wang	
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	3	20030139640	A1	2003-07-24	Whittacre	
	4	20040104160	A1	2004-06-03	Scagliarini	
	5	20050187515	A1	2005-08-25	Varrichio	
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	8	20060015056	A1	2006-01-19	Ellingboe	
	9	20060151048	A1	2006-07-13	Tochon-Danguy	
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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	12	20070282263	A1	2007-12-06	Kalafut	
	13	20070140958	A1	2007-06-21	DeKemp	
	14	20080071219	A1	2008-03-20	Rhinehart	
	15	20080093564	A1	2008-04-24	Tartaglia	
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	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	23	20090312635	A1	2009-12-17	Shimchuk	
	24	20070080223	A1	2007-04-12	Japuntich	
	25	20100030009	A1	2010-02-04	Lemer	
	26	20070140958	A1	2007-06-21	deKemp	
	27	20080191148	A1	2008-08-14	Gibson	
	28	20100312039	A1	2010-12-09	Quirico	
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	30	20110172524	A1	2011-07-14	Hidem	
	31	20110209764	A1	2011-09-01	Uber	
	32	20120098761	A1	2012-04-26	Wieczorek	
	33	20120312980	A1	2012-12-13	Whitehouse	

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	Attorney Docket Number	56782.1.7.15

	34	20120305730	A1	2012-12-06	Balestracci	
	35	20120310031	A1	2012-12-06	Quirico	
	36	20130300109	A1	2013-11-14	Balestracci	
	37	20140084187	A1	2014-03-27	Quirico	
	38	20140175959	A1	2014-06-26	Quirico	

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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	1968653	CN		2007-05-03	E Z EM Inc.		☐
	2	0102121	EP		1984-03-07	BYK Mallinckrodt		☐
	3	0160303	EP		1985-11-06	E.R. Squibb		☐
	4	0310148	EP		1989-04-05	E.R. Squibb		☐

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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	5	0919249	EP		1999-06-02	Nissho KK		☐
	6	1421960	EP		2004-05-26	GVS SPA		☐
	7	2492920	EP	A2	2012-08-29	Draximage General Partnership		☐
	8	2011126	EP	B1	2012-05-23	Draximage General Partnership		☐
	9	0319148	EP	A2	1989-07-06	International Business Machines Corporation		☐
	10	2867084	FR		2005-09-09	General Electric Company		☐
	11	2006325826	JP		2006-12-07	S.D. Giken		☐
	12	2000350783	JP		2000-12-19	Sumitomjo Heavy Ind Ltd.		☐
	13	2131273	RU		1999-06-10	Sajens Inc.		☐
	14	2010020596	WO		2010-02-25	Stichting Jeroen Bosch		☐
	15	2011126522	WO	A2	2011-10-13	Medi Physics Inc		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	16	244513	SU		1969-12-31	Bogoudinov		☐
	17	2288755	RU		2006-12-10	Shchetnin		☐
	18	9615337	WO		1996-05-23	Nilsson		☐
	19	9956117	WO		1999-11-04	General Hospital Corp		☐
	20	02096335	WO		2002-12-05	Hill ROM Services		☐
	21	2004059661	WO		2004-07-15	Lynntech, Inc.		☐
	22	20050002971	WO		2005-01-13	Iphase Technologies		☐
	23	2006007750	WO		2006-01-26	Universität Zürich		☐
	24	2006026603	WO		2006-03-09	Bracco Diagnostics		☐
	25	2006074473	WO		2006-07-13	Atlas Systems		☐
	26	2006129301	WO		2006-12-07	Spec-Trum Dynamics		☐

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	Filing Date	
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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	27	2006135374	WO		2006-12-21	Lynntech Inc.		☐
	28	2007016170	WO		2007-02-08	Mallinckrodt Inc.		☐
	29	2007030249	WO		2007-03-15	Mallinckrodt Inc.		☐
	30	2007071022	WO		2007-06-28	Ottawa Heart Inst		☐
	31	2007104133	WO		2007-09-20	Ottawa Heart Inst		☐
	32	2007149108	WO		2007-12-27	Mallinckrodt Inc.		☐
	33	2008028165	WO		2008-03-06	Catholic Health		☐
	34	2008037939	WO		2008-04-03	Lemer Protection		☐
	35	2008082966	WO		2008-07-10	Medrad, Inc.		☐
	36	2008140351	WO		2008-11-20	Obshchestvo		☐
	37	2008066586	WO	A2	2008-06-05	Mallinckrodt Inc.		☐

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	Filing Date	
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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	38	2009152320	WO		2009-12-17	Bracco Diagnostics Inc.		☐

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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	Brochure, "IV and Liquid Filters: Speedflow Adult 0.2 um Positive", http://www.gvs.it/flex/FixedPages/UK/LiquidFilters.php/L/UK/ID/Speedflow%20Adjust%.... Retrieved from URL on 11/11/2008.	☐
	2	BRACCO Brochure, "Rubidium 82 Infusion System, Easy to Operate...Automated...Complete", © Bracco Diagnostics, Inc., 0605-002NA, June 2001, (2 pages).	☐
	3	BRACCO, "Cardio-Gen82® Infusion System User's Guide", July 3, 2007, pages 1-42.	☐
	4	IMAGING TECHNOLOGY NEWS, web exclusive: "FDG-PET Injector Thrusts New Life into Molecular Imaging", April 2008, 2 pages.	☐
	5	NEIL J. EPSTEIN, "A Rb82 infusion system for quantitative perfusion imaging with 3D PET" Applied Radiation and Isotopes, vol. 60, 9 February 2004, pages 921-927, XP002557544 DOI:10, 1016/j. apradiso.2004.02.002.	☐
	6	R. KLEIN, "Precision controlled elution of a Sr82/Rb82 generator for cardiac perfusion imaging with positron emission tomography" Physics in Medicine and Biology, vol. 52, 11 January 2007, pages 659-673, XP002557545 DOI:10, 1088/0031-9155/52/3/009.	☐
	7	International Search Report and Written Opinion for International Patent Application No. PCT/US2009/047027, dated 02-25-2010, 22 pages.	☐
	8	International Search Report and Written Opinion for International Patent Application No. PCT/US2009/047030, dated 02-17-2010, 17 pages.	☐

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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

	9	International Search Report and Written Opinion for International Patent Application No. PCT/US2009/047031, 20 pages.	☐
	10	International Search Report and Written Opinion for International Patent Application No. PCT/US2009/047034, dated 02-25-2010, 15 pages.	☐
	11	International Search Report and Written Opinion for International Patent Application No. PCT/US2009/063788, dated 01-04-2010, 13 pages.	☐
	12	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (copyright date May 2008).	☐
	13	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.	☐
	14	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.	☐
	15	Machine translation of abstract of RU2307378 published 2007-09-27 (Oao Sojuztsvetmetavtomatika)	☐
	16	U.S. Application No. 14/290,765, filed May 29, 2014, entitled, "INFUSION SYSTEM CONFIGURATIONS," 67 pages. Attorney docket number 56782.1.6.15.	☐
	17	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.	☐
	18	U.S. Application filed August 8, 2014, entitled, "RADIOISOTOPE GENERATOR SYSTEM INCLUDING ACTIVITY MEASUREMENT AND DOSE CALIBRATION." Attorney docket number 56782.1.7.16.	☐

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	Filing Date	
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	Filing Date	
	First Named Inventor	Stephen E. Hidem
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	56782.1.7.15

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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.

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)	2014-08-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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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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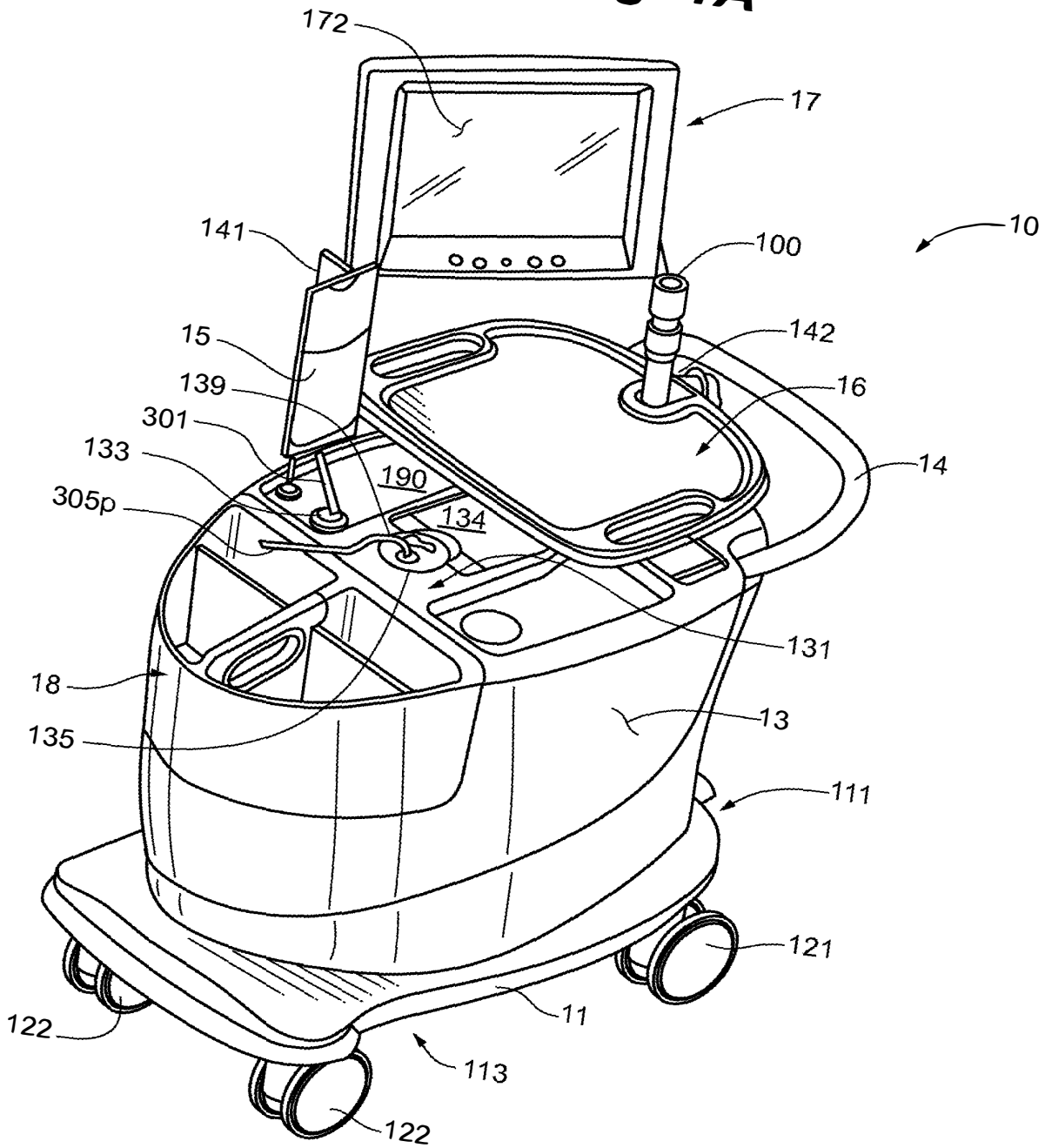
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Fig. 1B

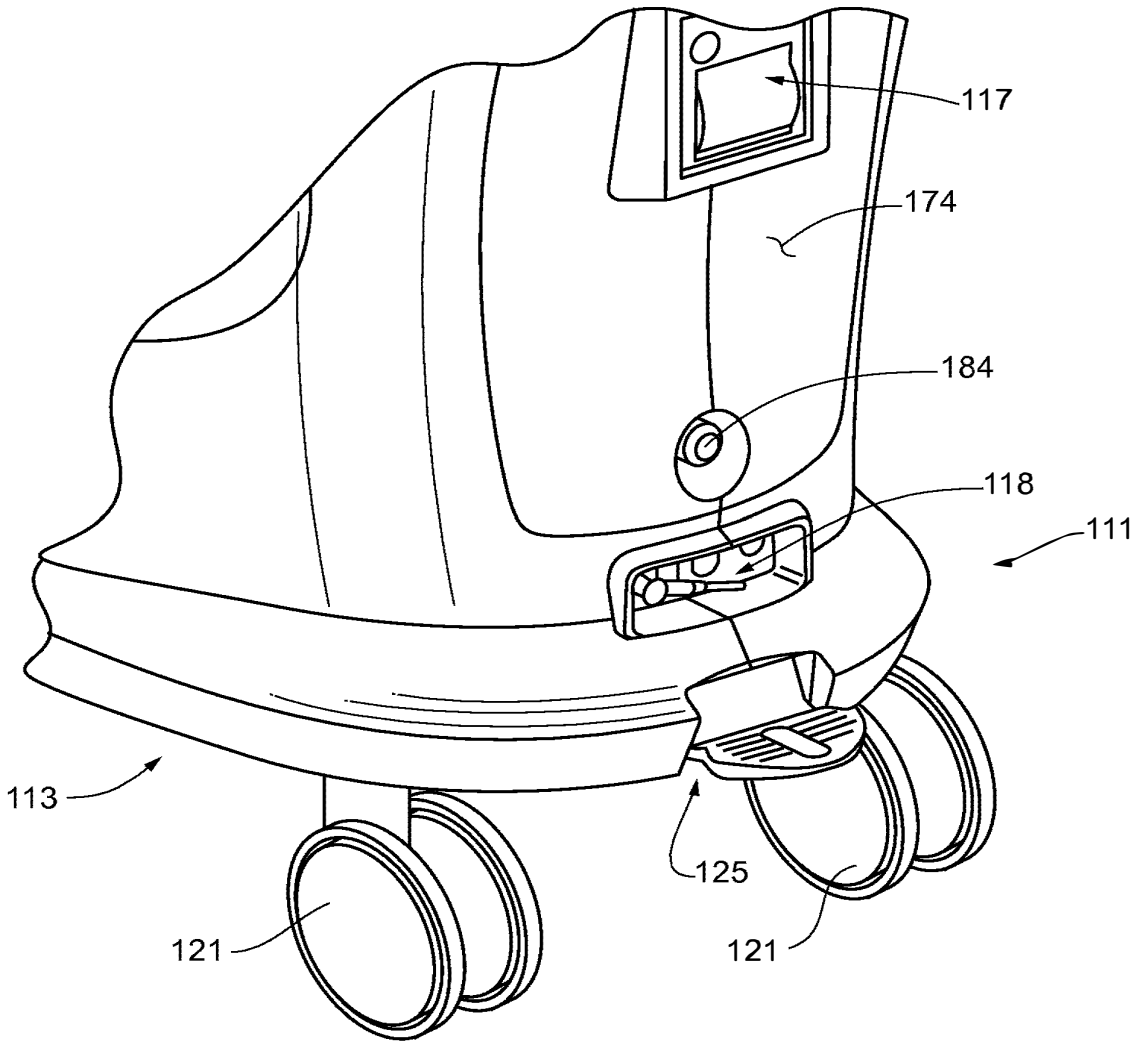
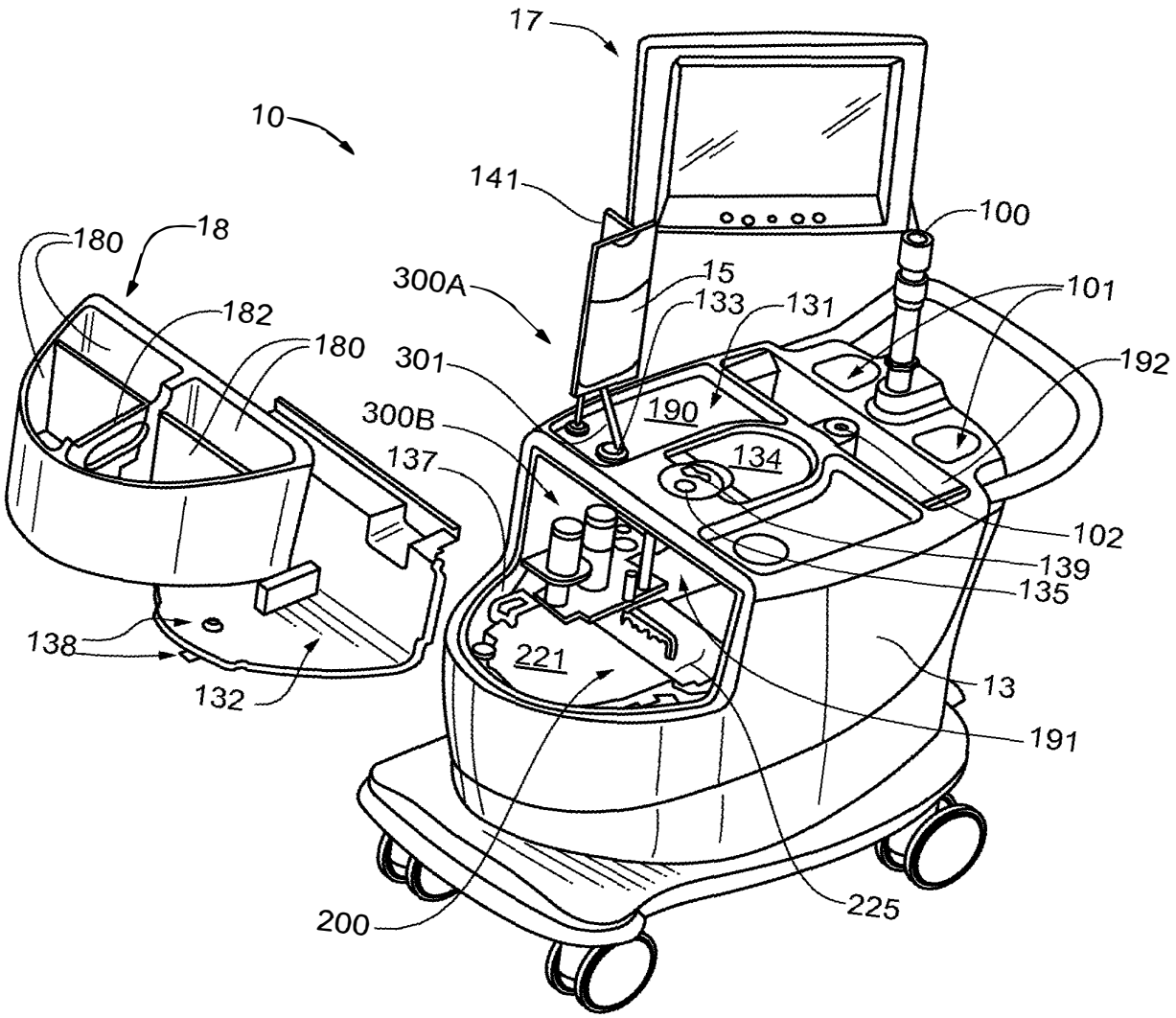


Fig. 1C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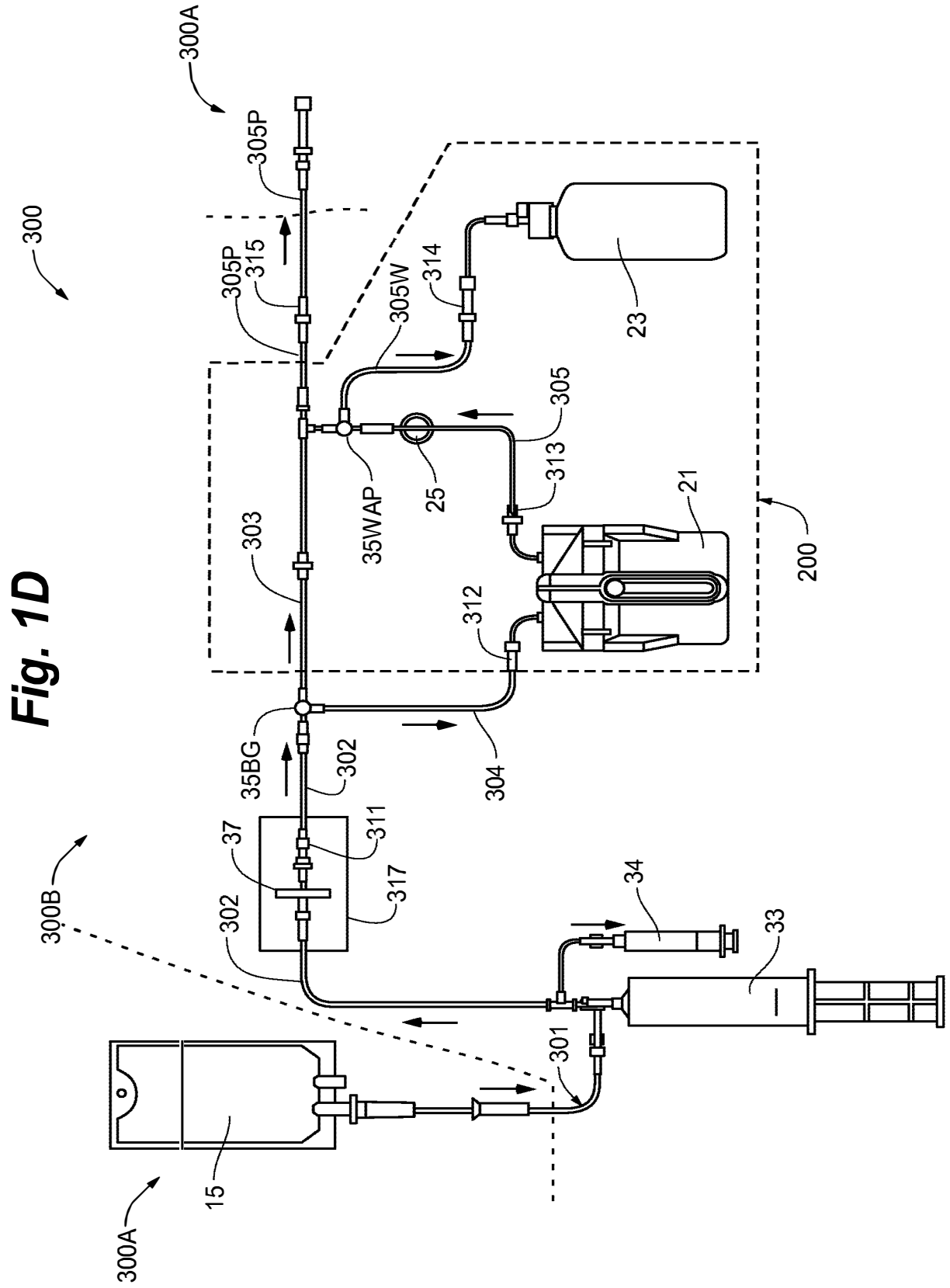
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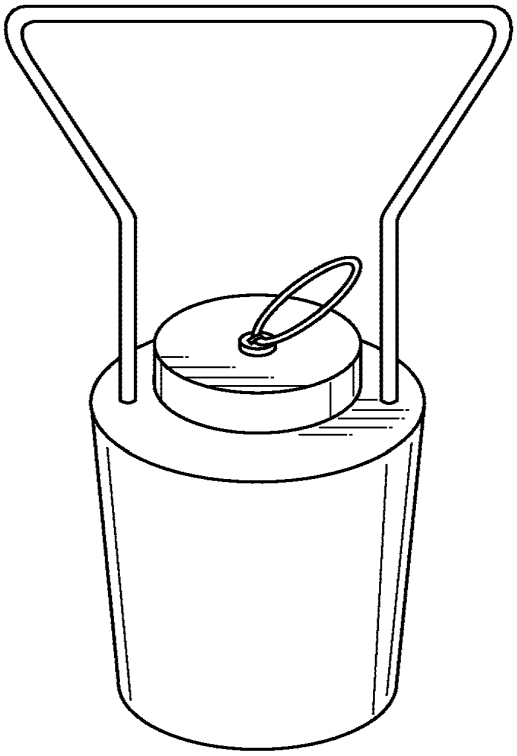
Fig. 1D

Fig. 1E



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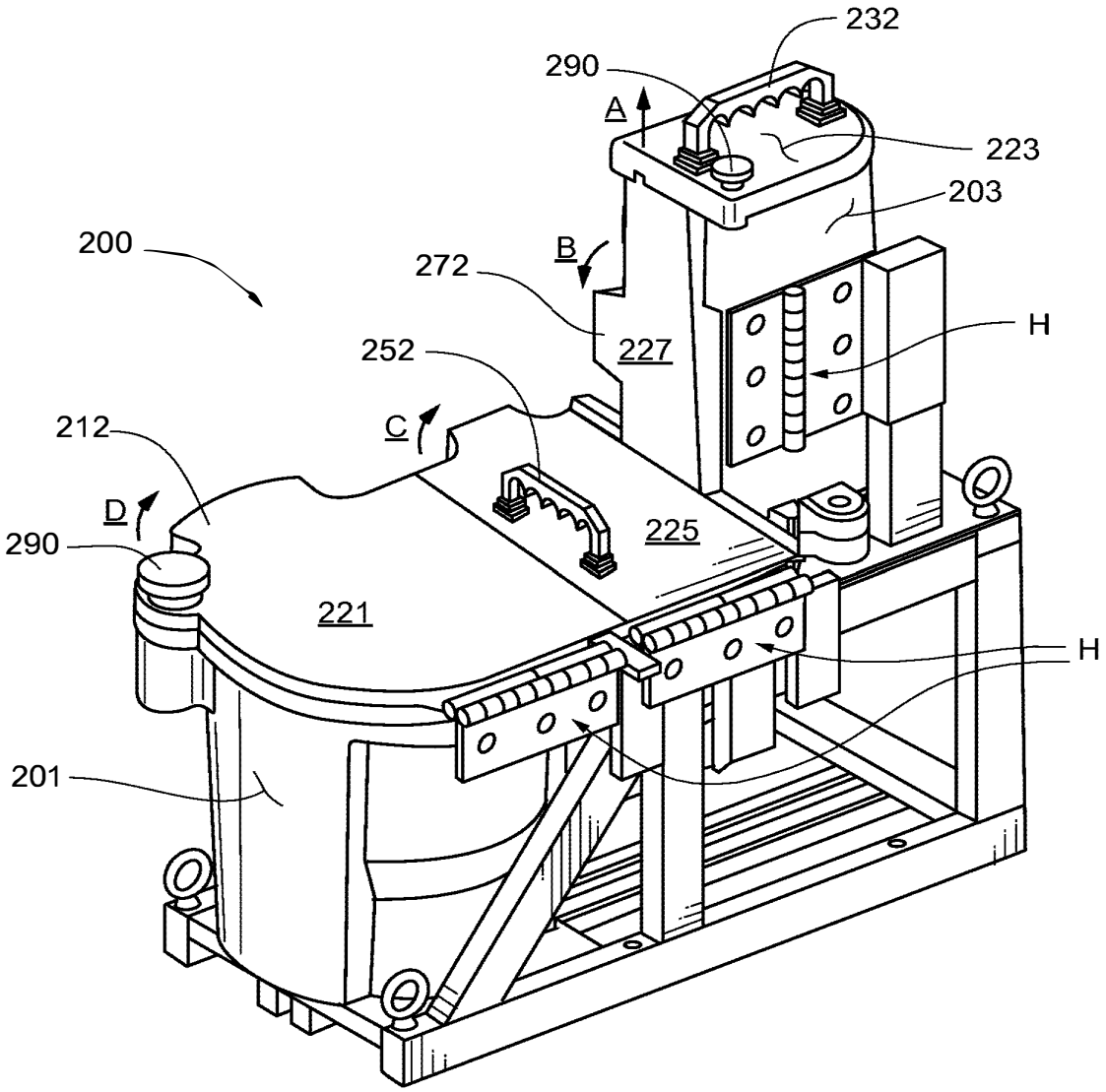


Fig. 2B

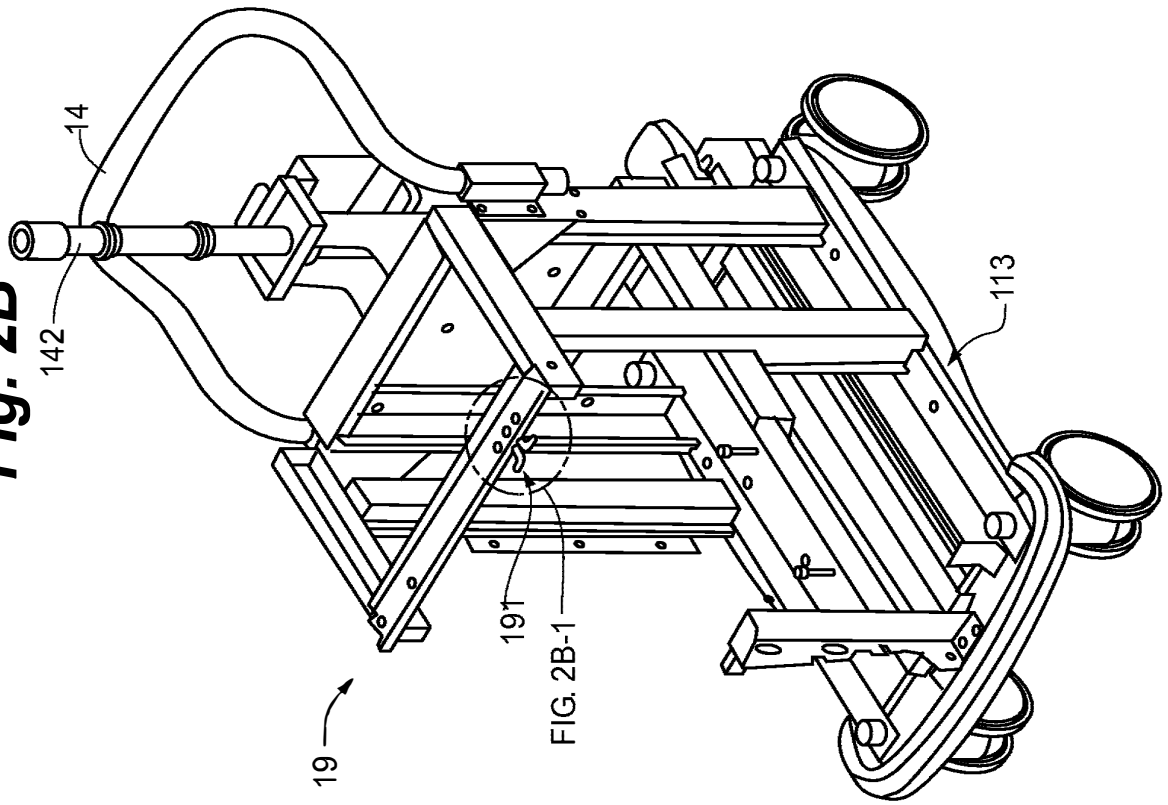


Fig. 2B-1

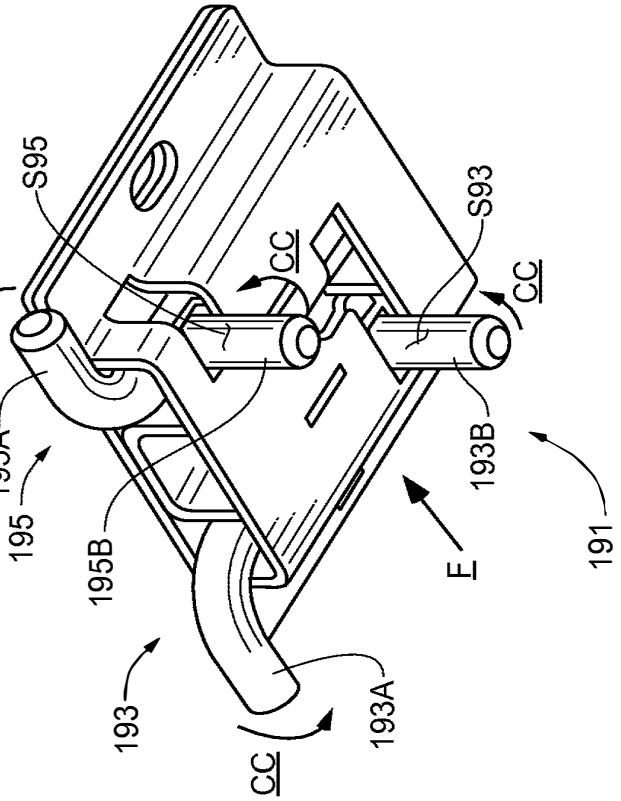
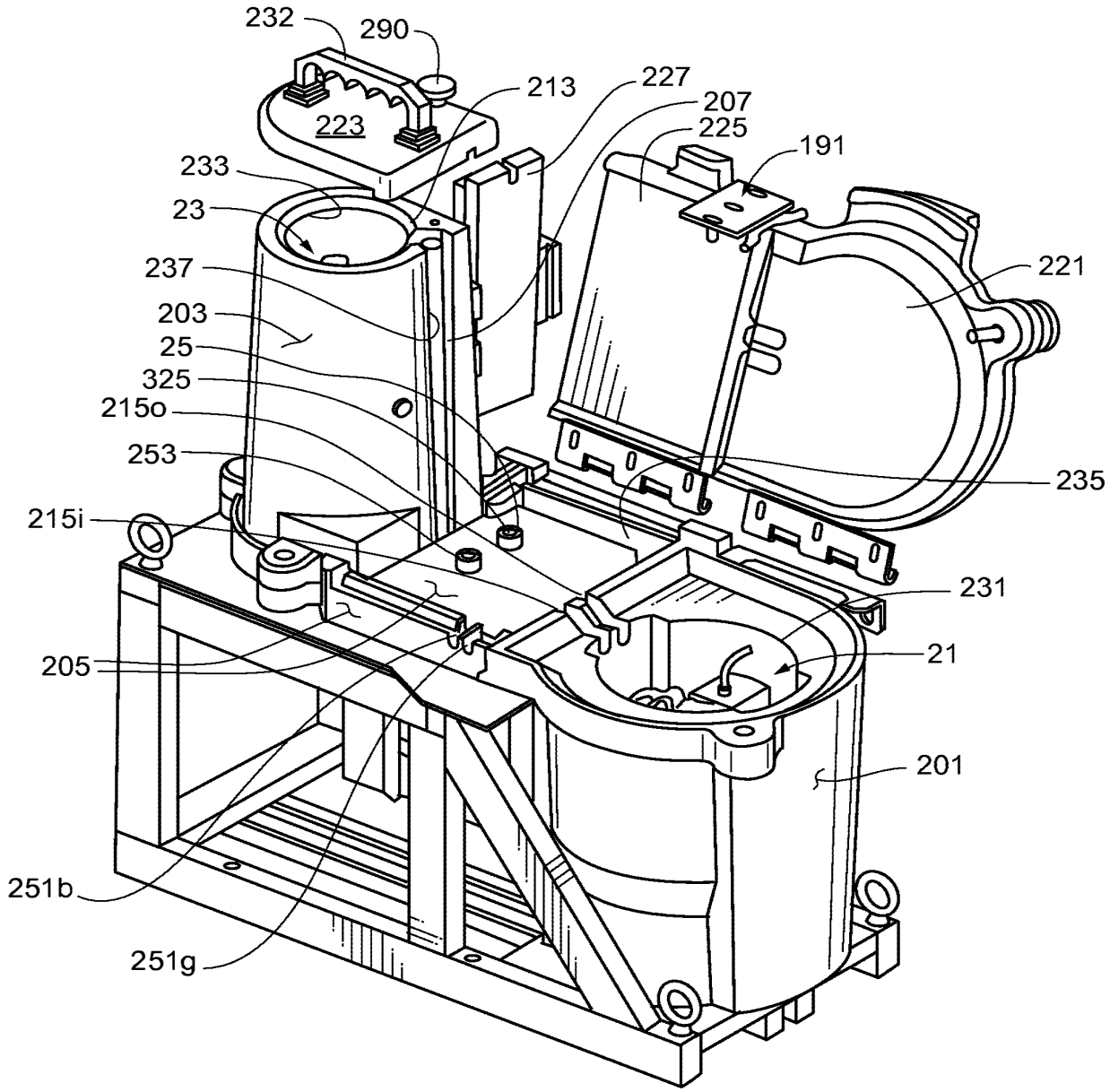


Fig. 3A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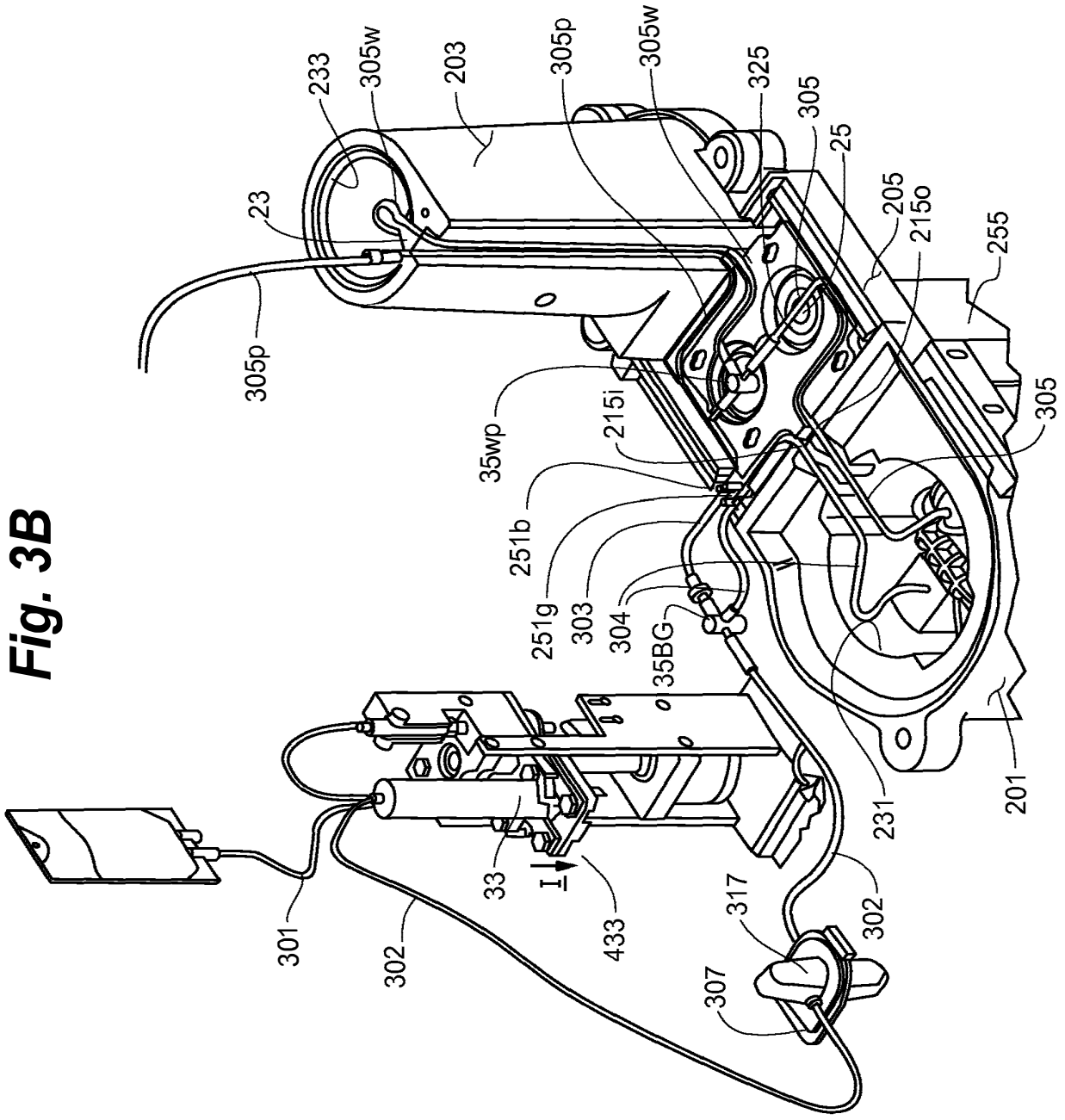
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Fig. 3B

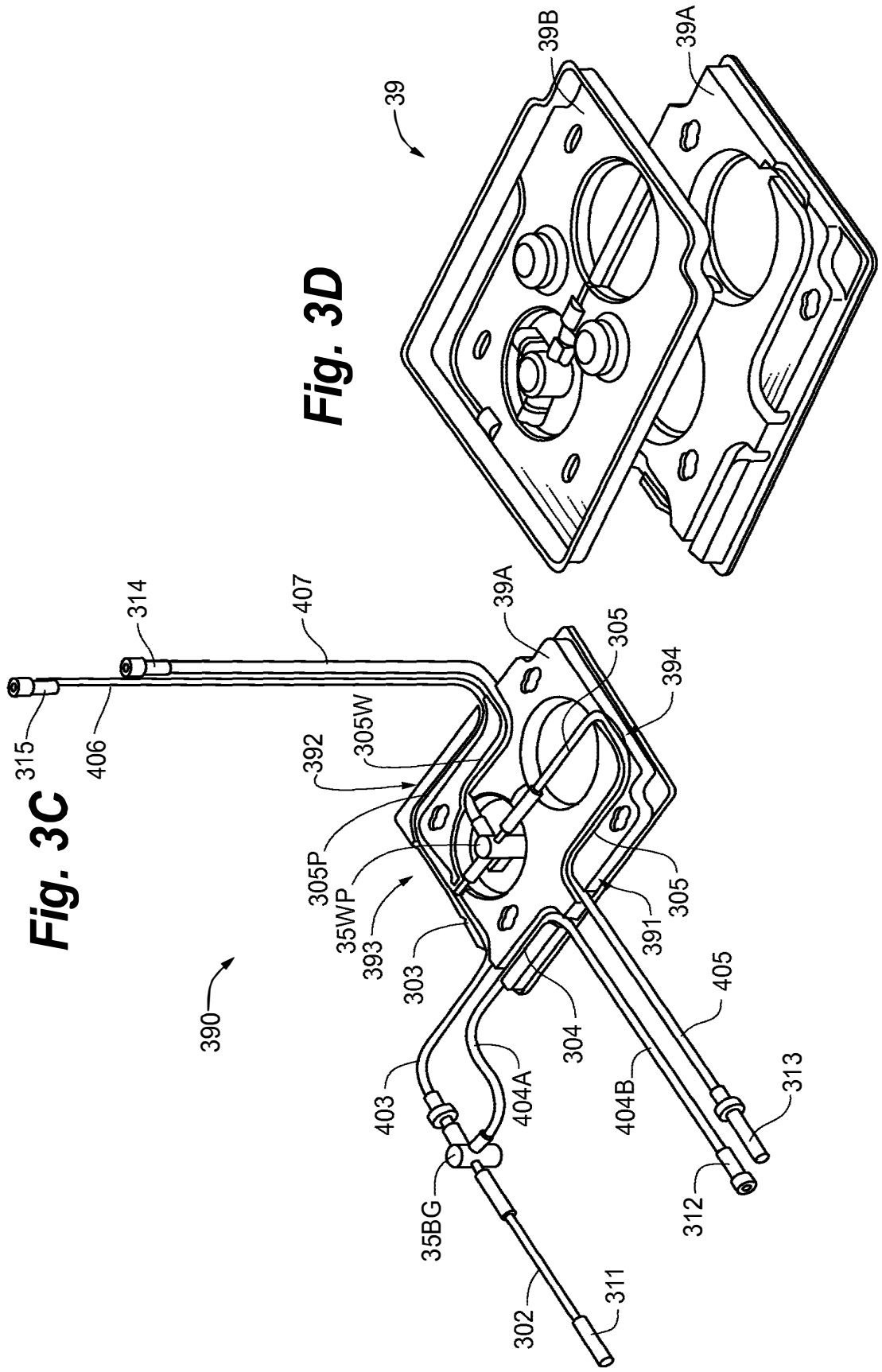
Fig. 3C
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Fig. 3D
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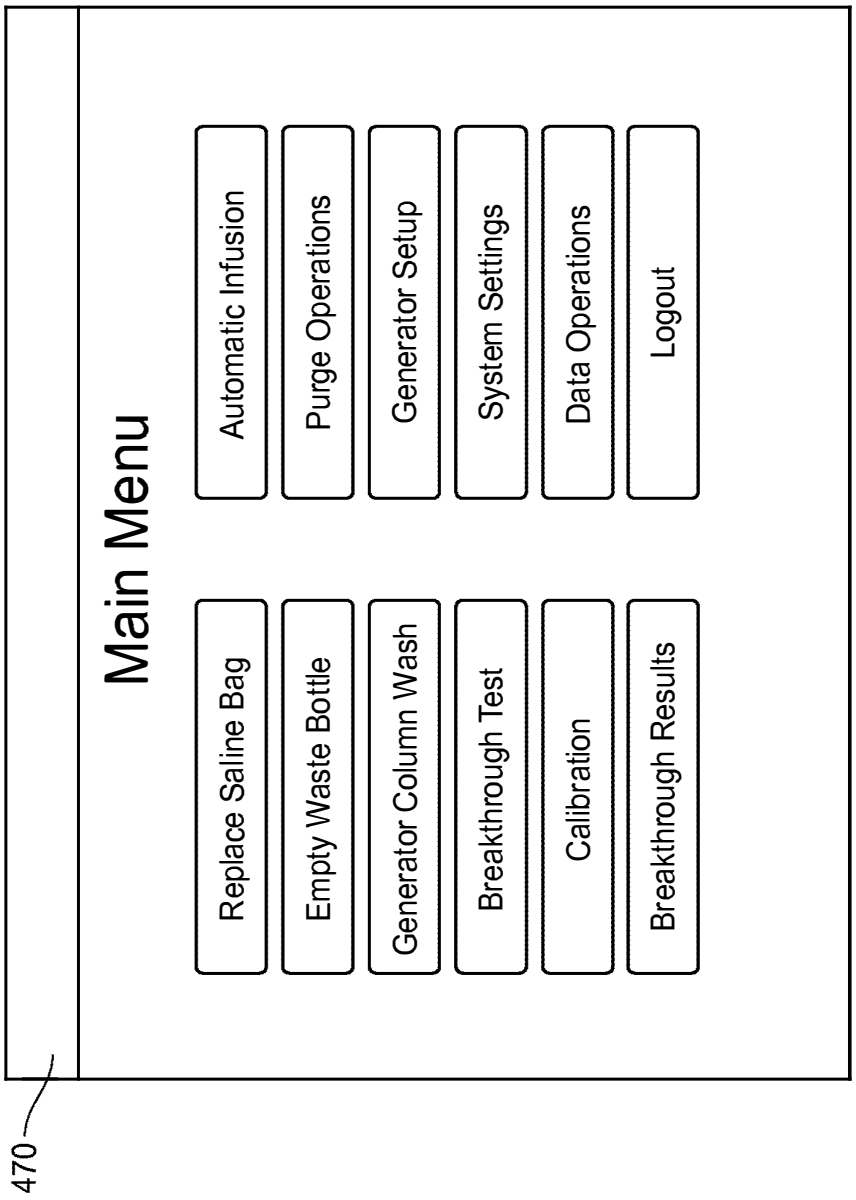
39B
39A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Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470

Fig. 4

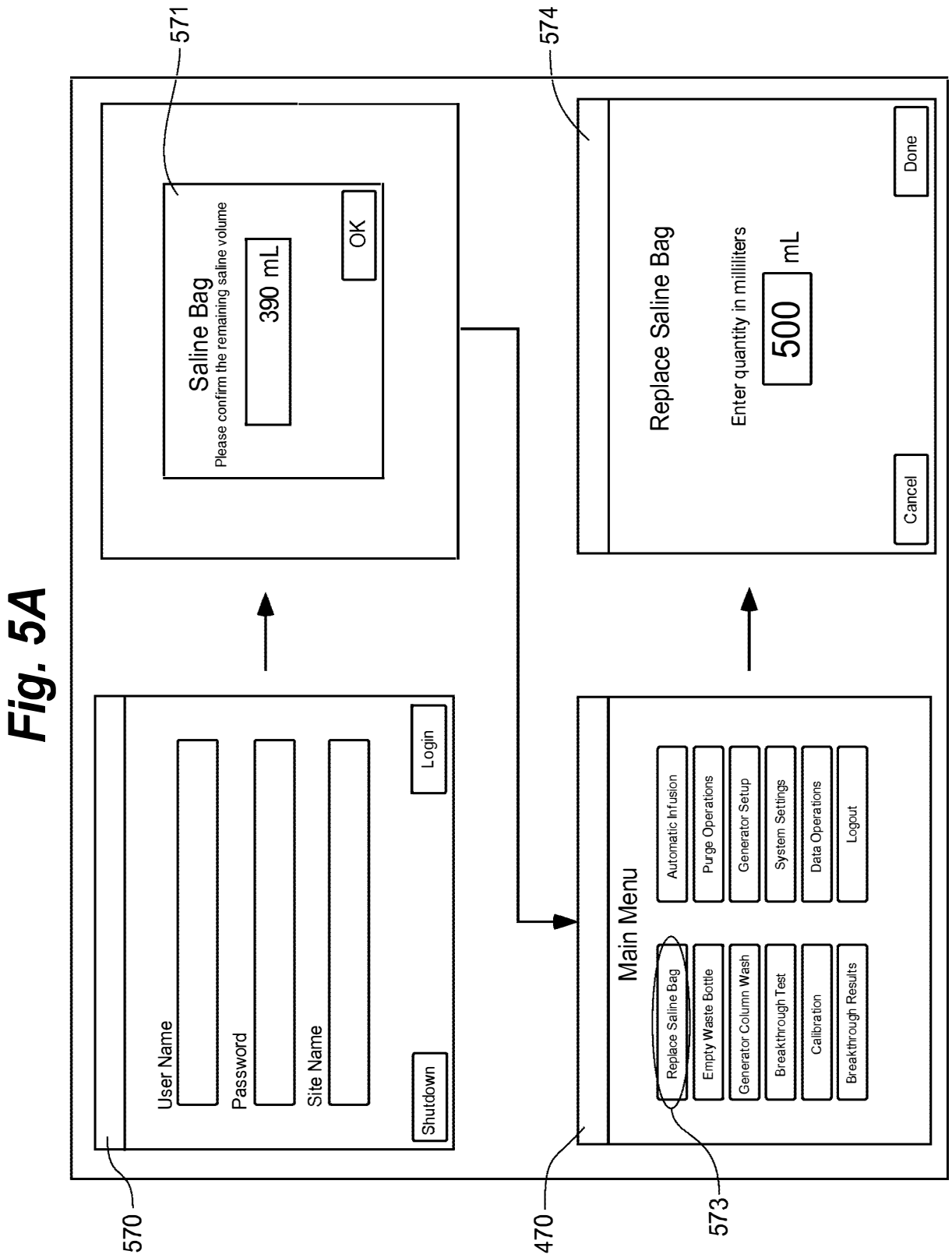
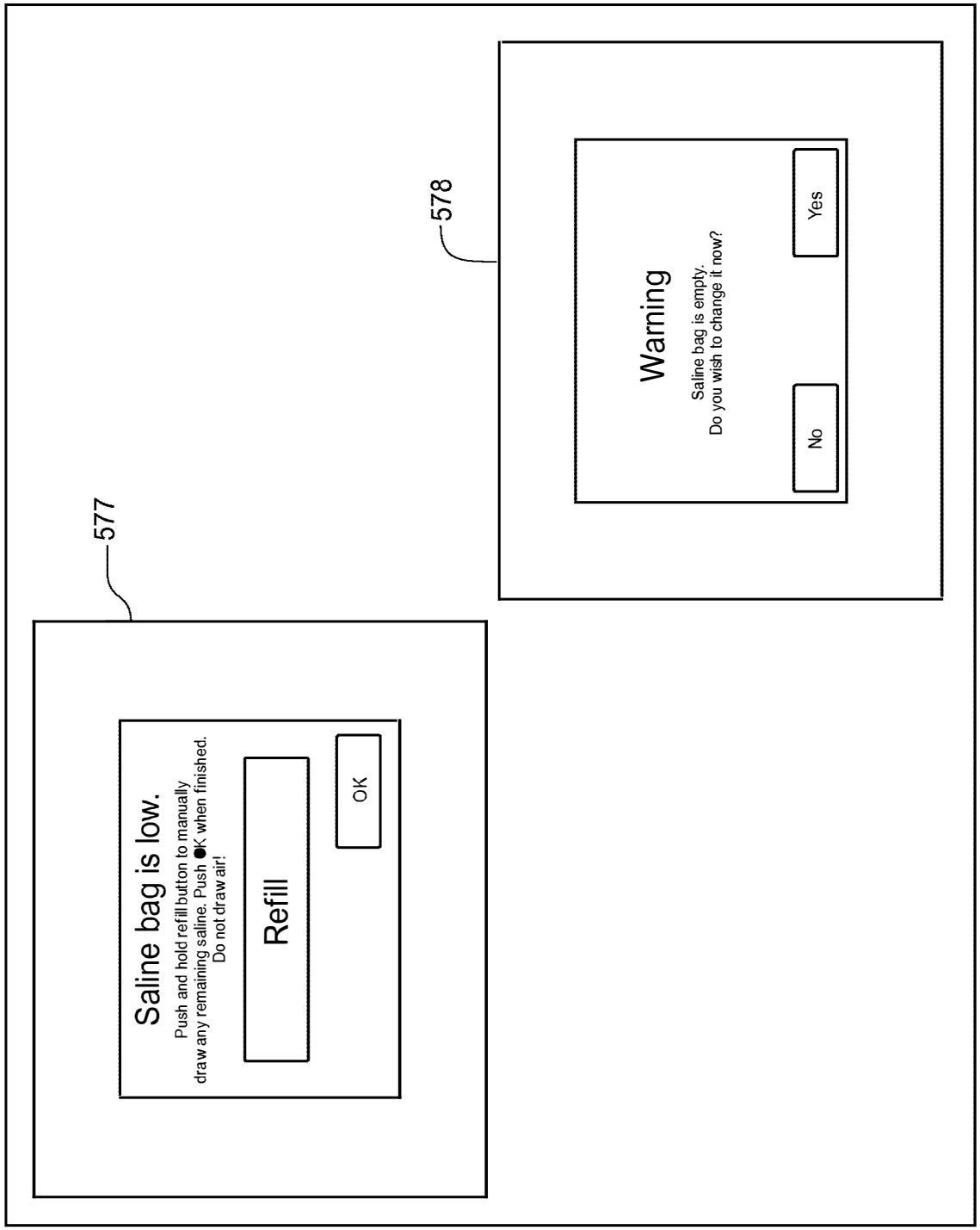

571
574
Saline Bag
Please confirm the remaining saline volume
390 mL
OK
Replace Saline Bag
Enter quantity in milliliters
500
mL
Done
Cancel
User Name
Password
Site Name
Login
Shutdown
Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
570
470
573

Fig. 5A

Fig. 5B


577
Saline bag is low.
Push and hold refill button to manually draw any remaining saline. Push OK when finished.
Do not draw air!
Refill
OK
578
Warning
Saline bag is empty.
Do you wish to change it now?
No
Yes

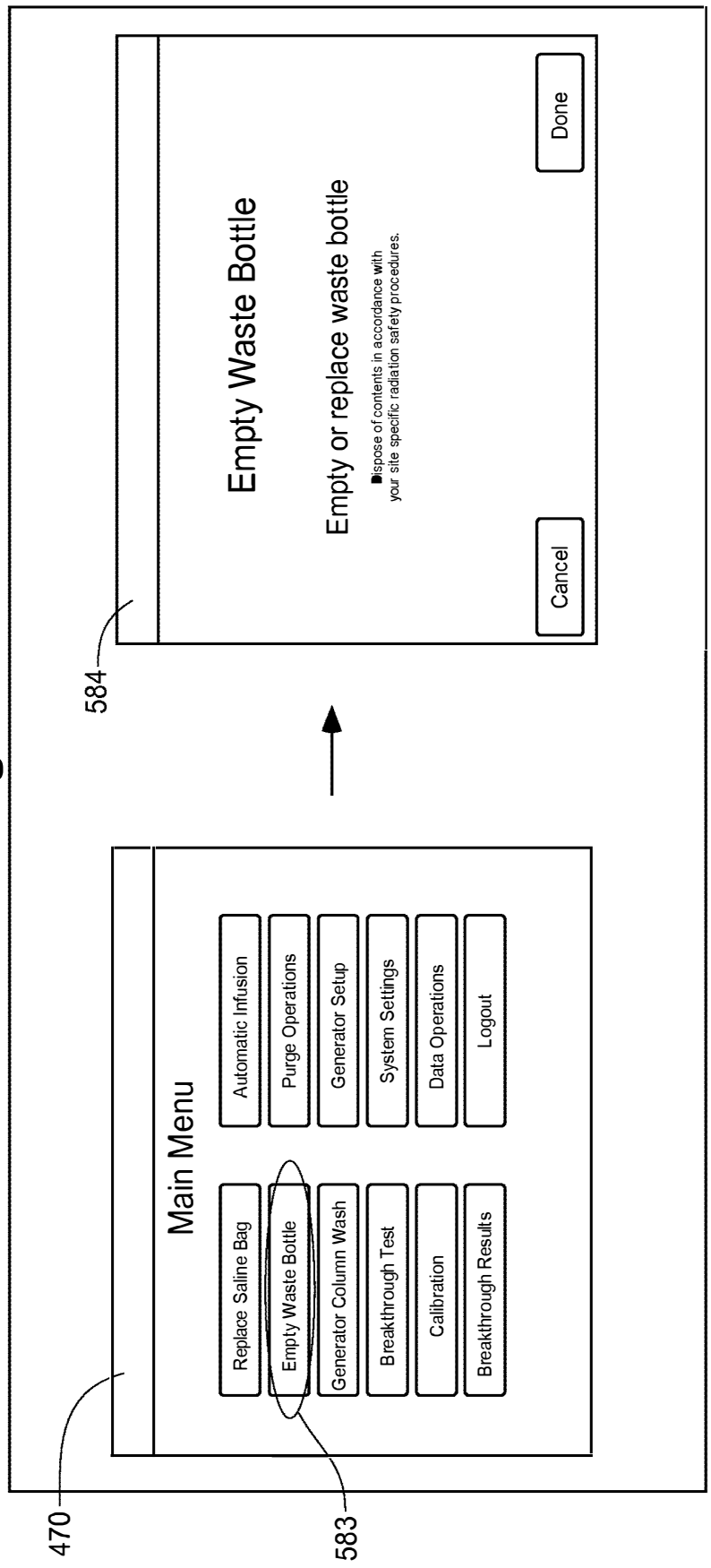

Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Empty Waste Bottle
Empty or replace waste bottle
Dispose of contents in accordance with your site specific radiation safety procedures.
Cancel
Done
470
583
584

Fig. 5C

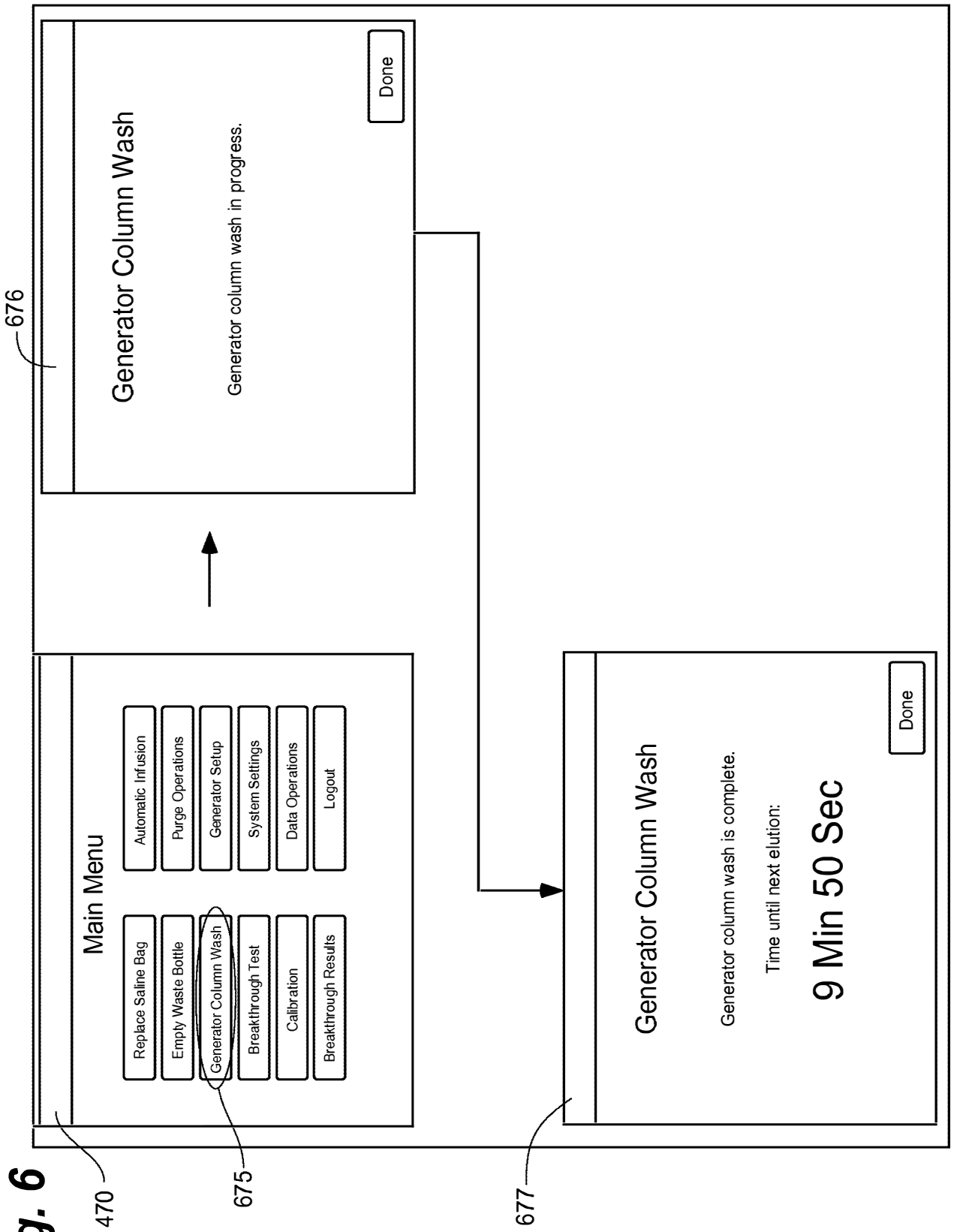
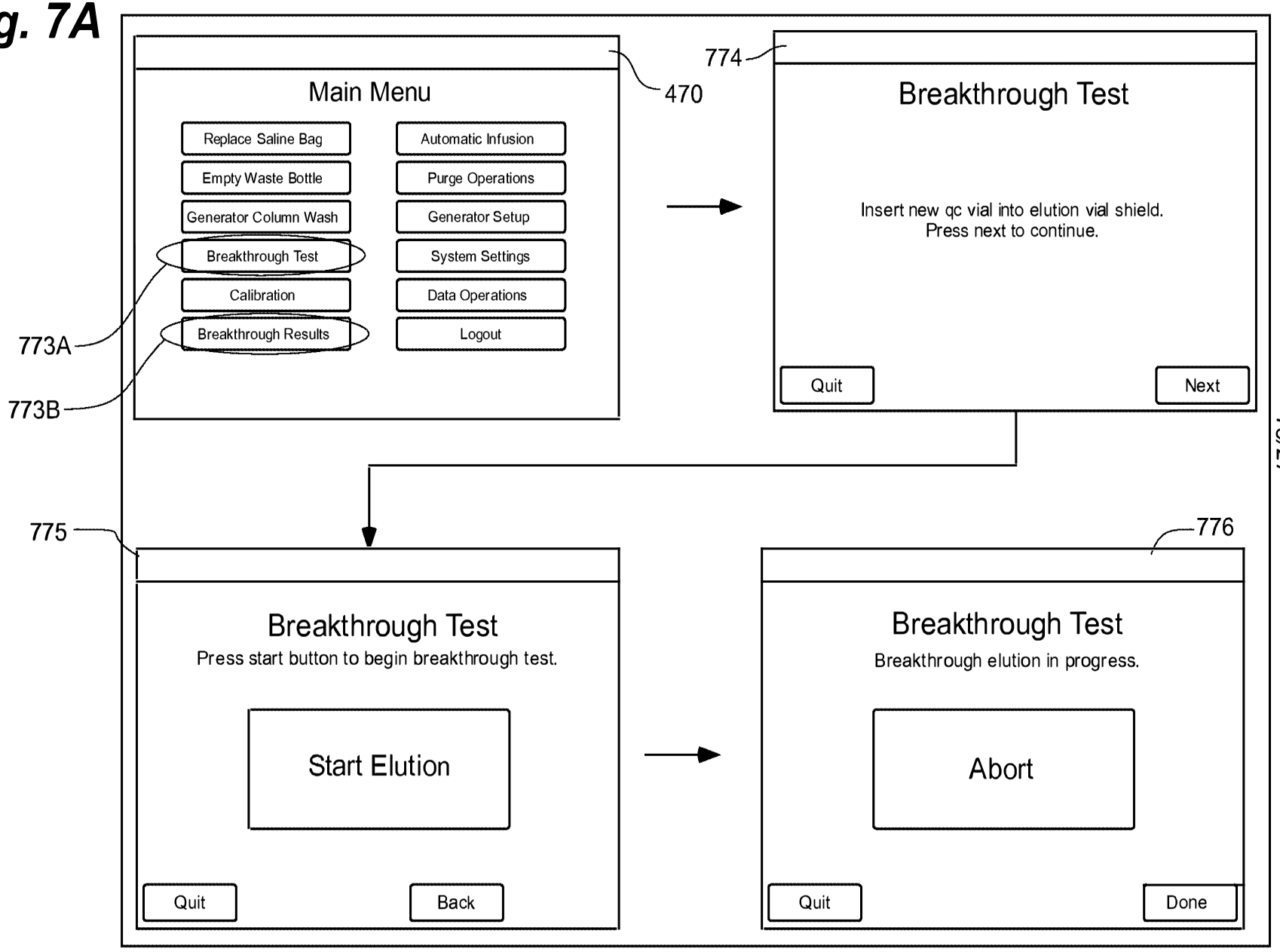

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Generator Column Wash
Generator column wash in progress.
Done
Generator Column Wash
Generator column wash is complete.
Time until next elution:
9 Min 50 Sec
Done
470
675
676
677

Fig. 6

Fig. 7A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Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
773A
773B
774
Breakthrough Test
Insert new qc vial into elution vial shield.
Press next to continue.
Quit
Next
775
Breakthrough Test
Press start button to begin breakthrough test.
Start Elution
Quit
Back
776
Breakthrough Test
Breakthrough elution in progress.
Abort
Quit
Done
16/27

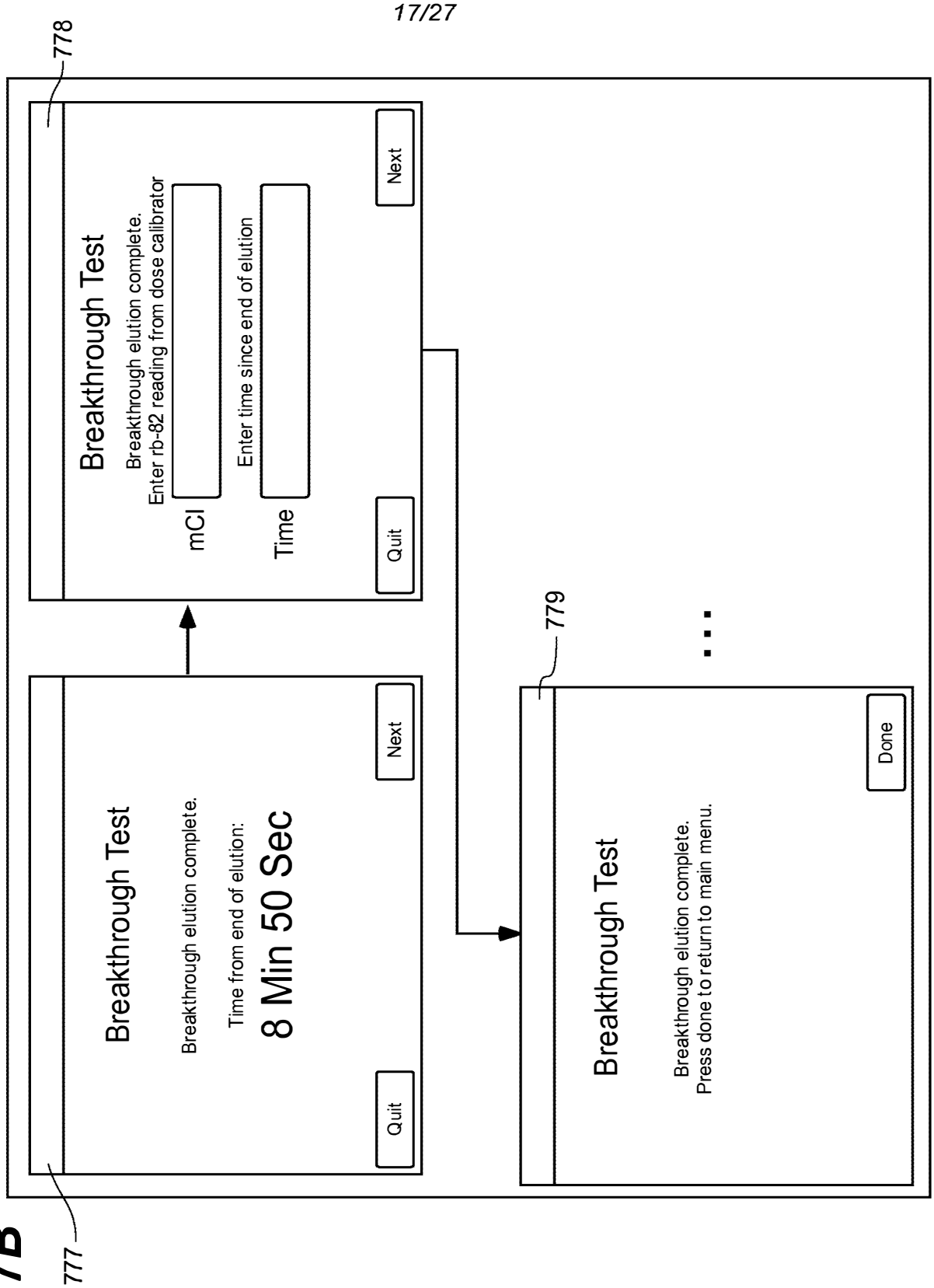
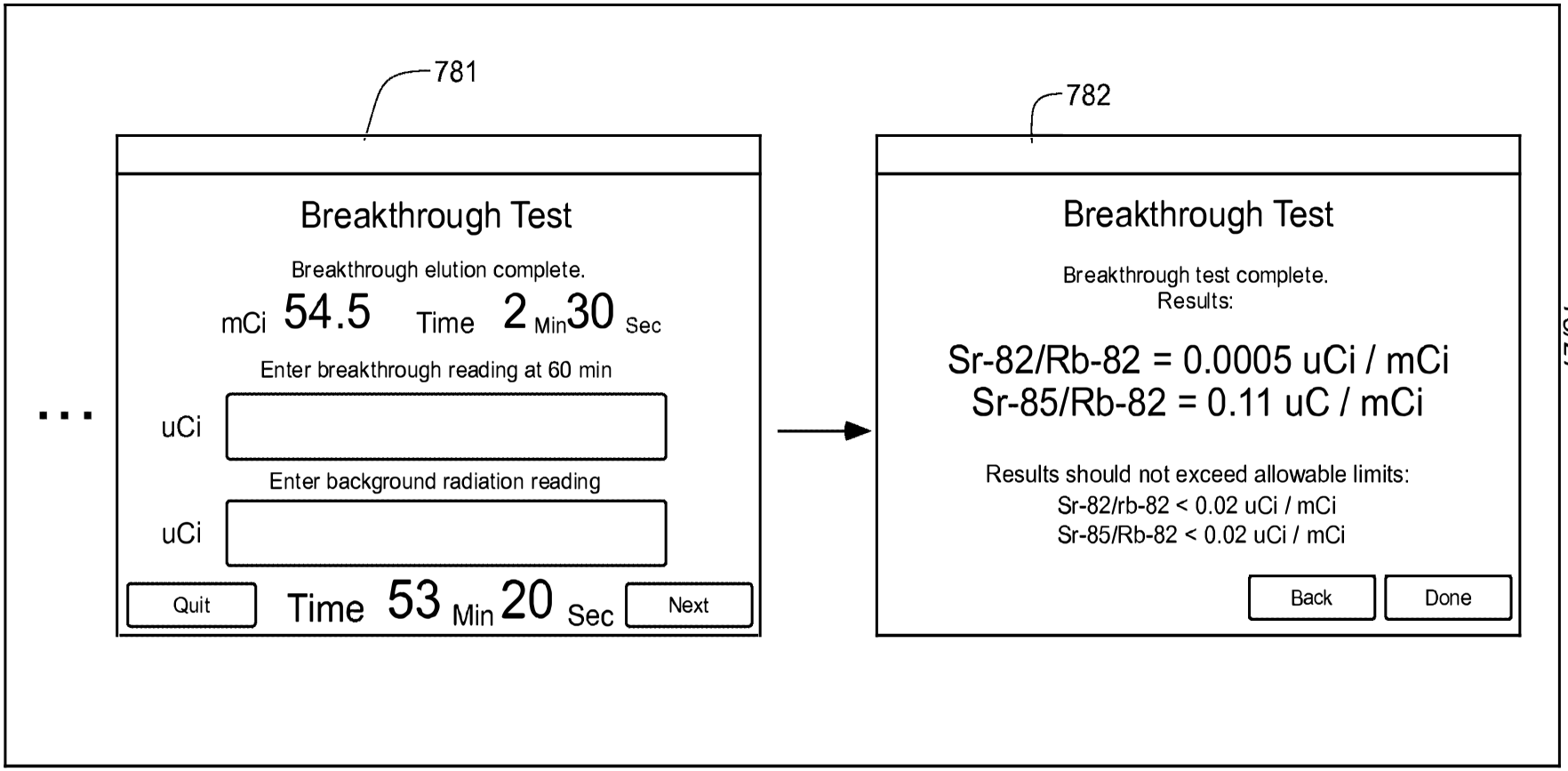

777
Breakthrough Test
Breakthrough elution complete.
Time from end of elution:
8 Min 50 Sec
Quit
Next
778
Breakthrough Test
Breakthrough elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time since end of elution
Time
Quit
Next
779
Breakthrough Test
Breakthrough elution complete.
Press done to return to main menu.
Done

Fig. 7B

Fig. 7C


781
782
Breakthrough Test
Breakthrough elution complete.
mCi 54.5 Time 2 Min 30 Sec
Enter breakthrough reading at 60 min
uCi
Enter background radiation reading
uCi
Quit
Time 53 Min 20 Sec
Next
Breakthrough Test
Breakthrough test complete.
Results:
Sr-82/Rb-82 = 0.0005 uCi / mCi
Sr-85/Rb-82 = 0.11 uC / mCi
Results should not exceed allowable limits:
Sr-82/rb-82 < 0.02 uCi / mCi
Sr-85/Rb-82 < 0.02 uCi / mCi
Back
Done
18/27

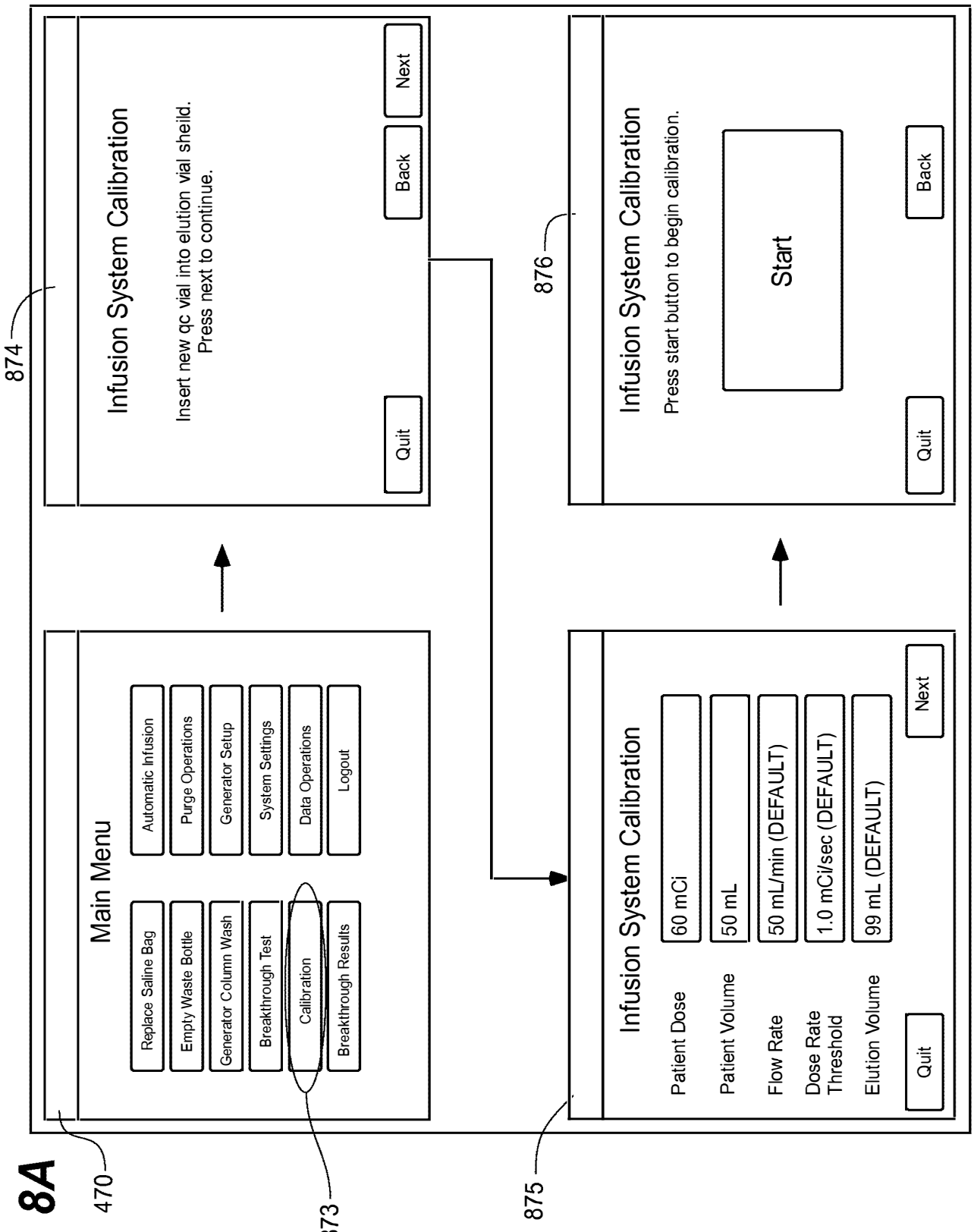

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Infusion System Calibration
Insert new qc vial into elution vial sheild.
Press next to continue.
Quit
Back
Next
Infusion System Calibration
Patient Dose
60 mCi
Patient Volume
50 mL
Flow Rate
50 mL/min (DEFAULT)
Dose Rate Threshold
1.0 mCi/sec (DEFAULT)
Elution Volume
99 mL (DEFAULT)
Quit
Next
Infusion System Calibration
Press start button to begin calibration.
Start
Quit
Back
470
873
874
875
876

Fig. 8A

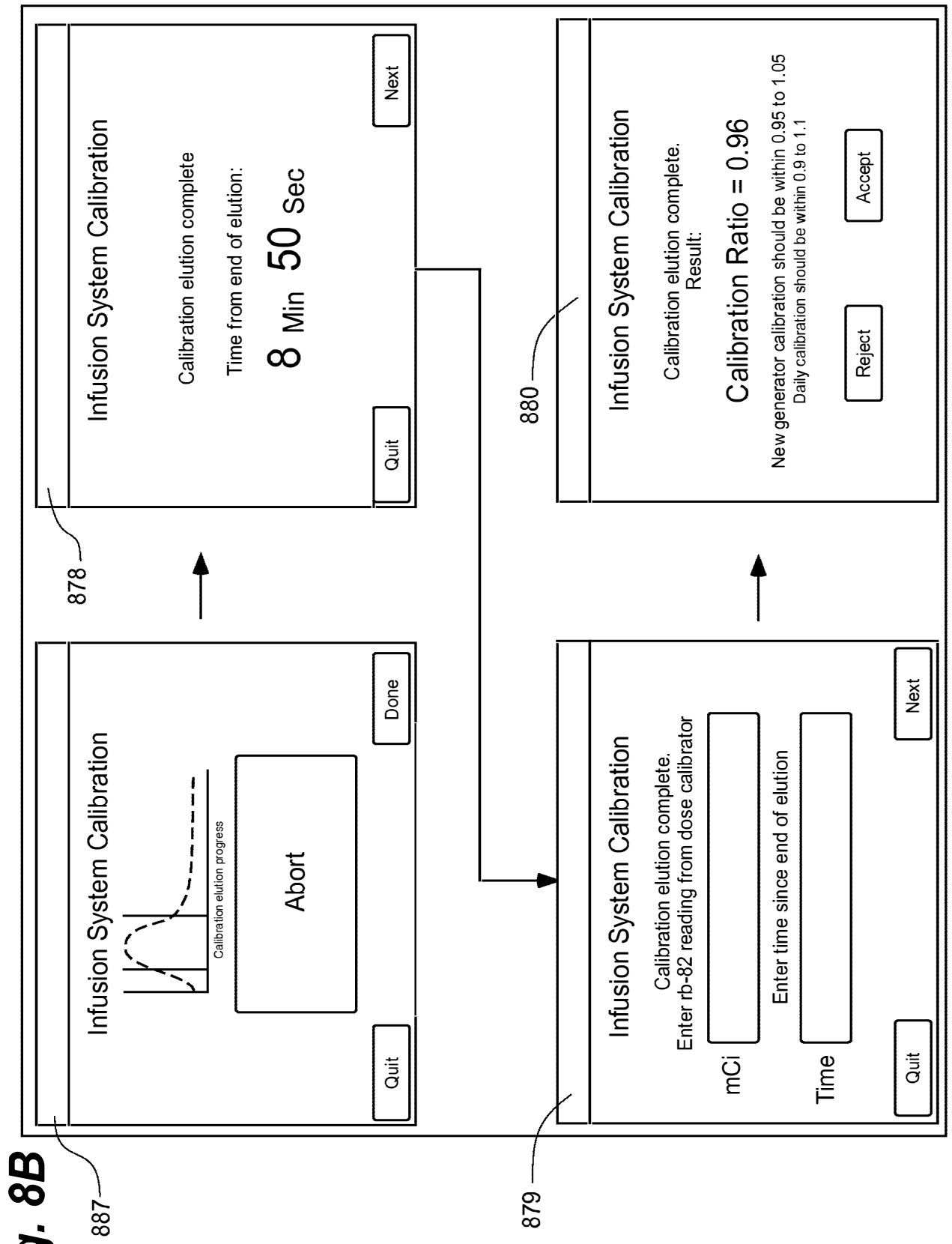

Infusion System Calibration
Calibration elution progress
Abort
Done
Quit
887
Infusion System Calibration
Calibration elution complete
Time from end of elution:
8 Min 50 Sec
Next
Quit
878
Infusion System Calibration
Calibration elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time since end of elution
Time
Next
Quit
879
Infusion System Calibration
Calibration elution complete.
Result:
Calibration Ratio = 0.96
New generator calibration should be within 0.95 to 1.05
Daily calibration should be within 0.9 to 1.1
Reject
Accept
880

Fig. 8B

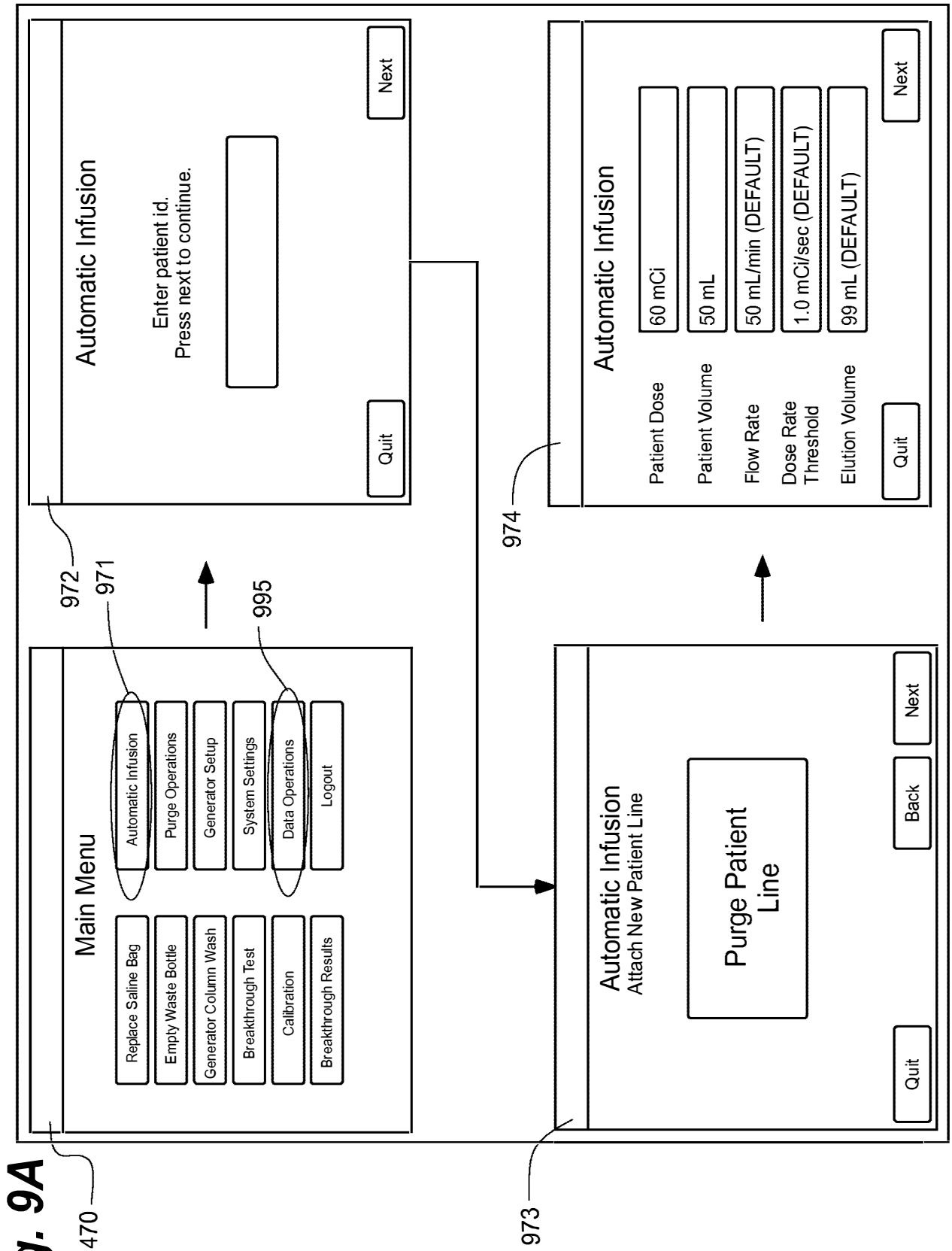

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Quit
Automatic Infusion
Enter patient id.
Press next to continue.
Next
Quit
Automatic Infusion
Attach New Patient Line
Purge Patient Line
Quit
Back
Next
Automatic Infusion
Patient Dose
60 mCi
Patient Volume
50 mL
Flow Rate
50 mL/min (DEFAULT)
Dose Rate Threshold
1.0 mCi/sec (DEFAULT)
Elution Volume
99 mL (DEFAULT)
Quit
Next
470
971
972
973
974
995

Fig. 9A

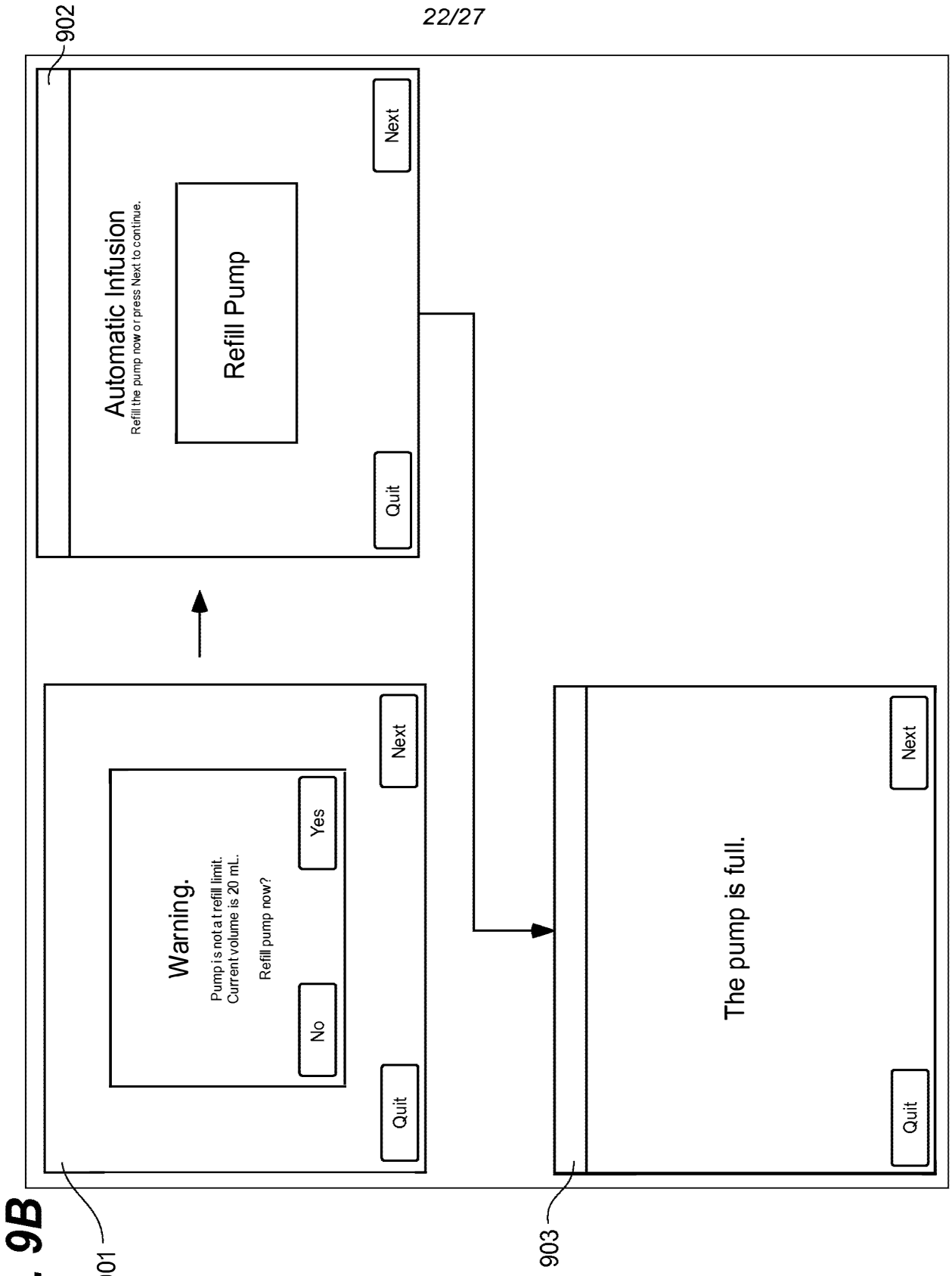
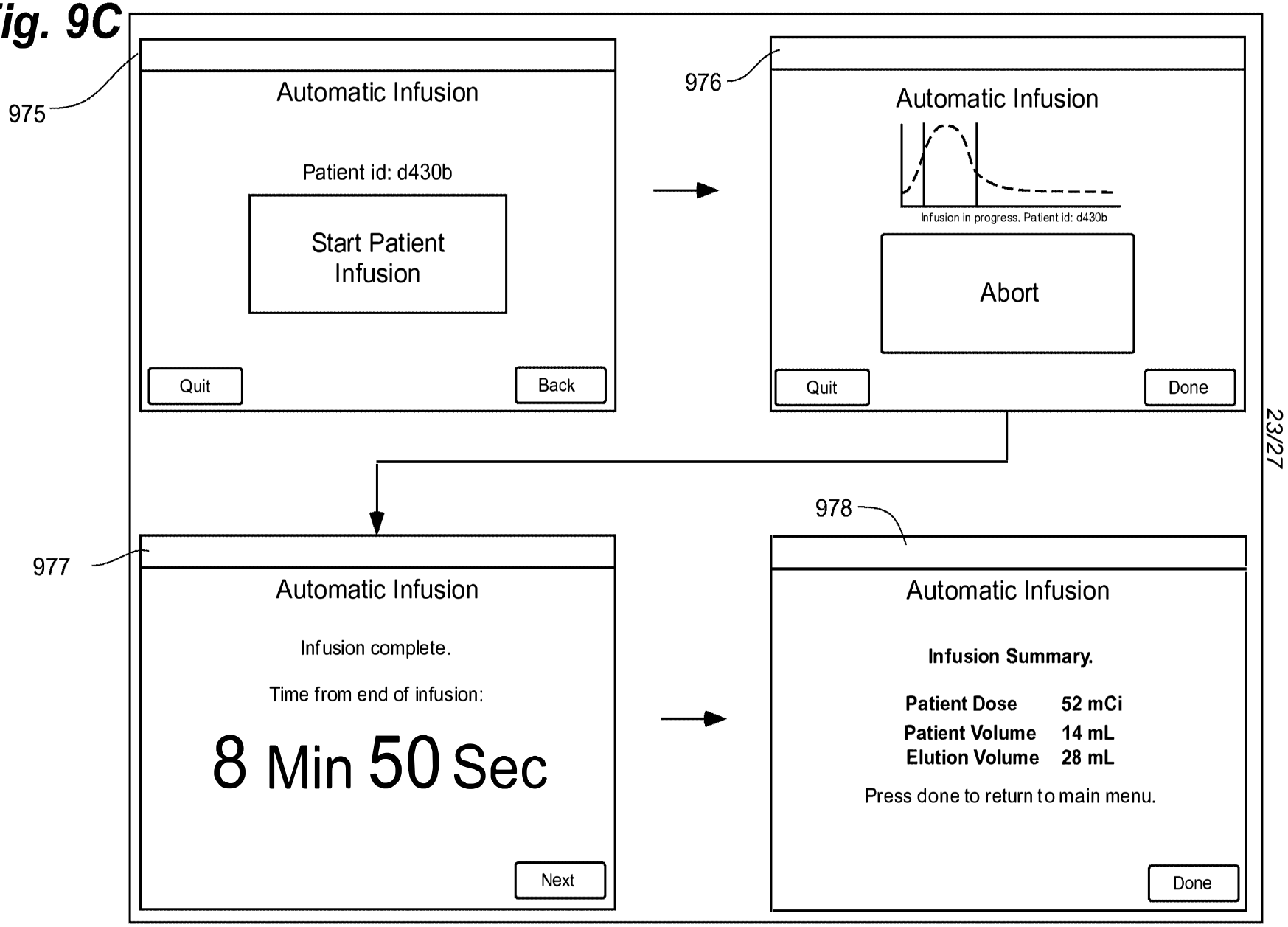

902
Automatic Infusion
Refill the pump now or press Next to continue.
Refill Pump
Next
Quit
Warning.
Pump is not at refill limit.
Current volume is 20 mL.
Refill pump now?
Yes
No
Next
Quit
The pump is full.
Next
Quit
901
903

Fig. 9B

Fig. 9C


975
Automatic Infusion
Patient id: d430b
Start Patient Infusion
Quit
Back
976
Automatic Infusion
Infusion in progress. Patient id: d430b
Abort
Quit
Done
977
Automatic Infusion
Infusion complete.
Time from end of infusion:
8 Min 50 Sec
Next
978
Automatic Infusion
Infusion Summary.
Patient Dose 52 mCi
Patient Volume 14 mL
Elution Volume 28 mL
Press done to return to main menu.
Done

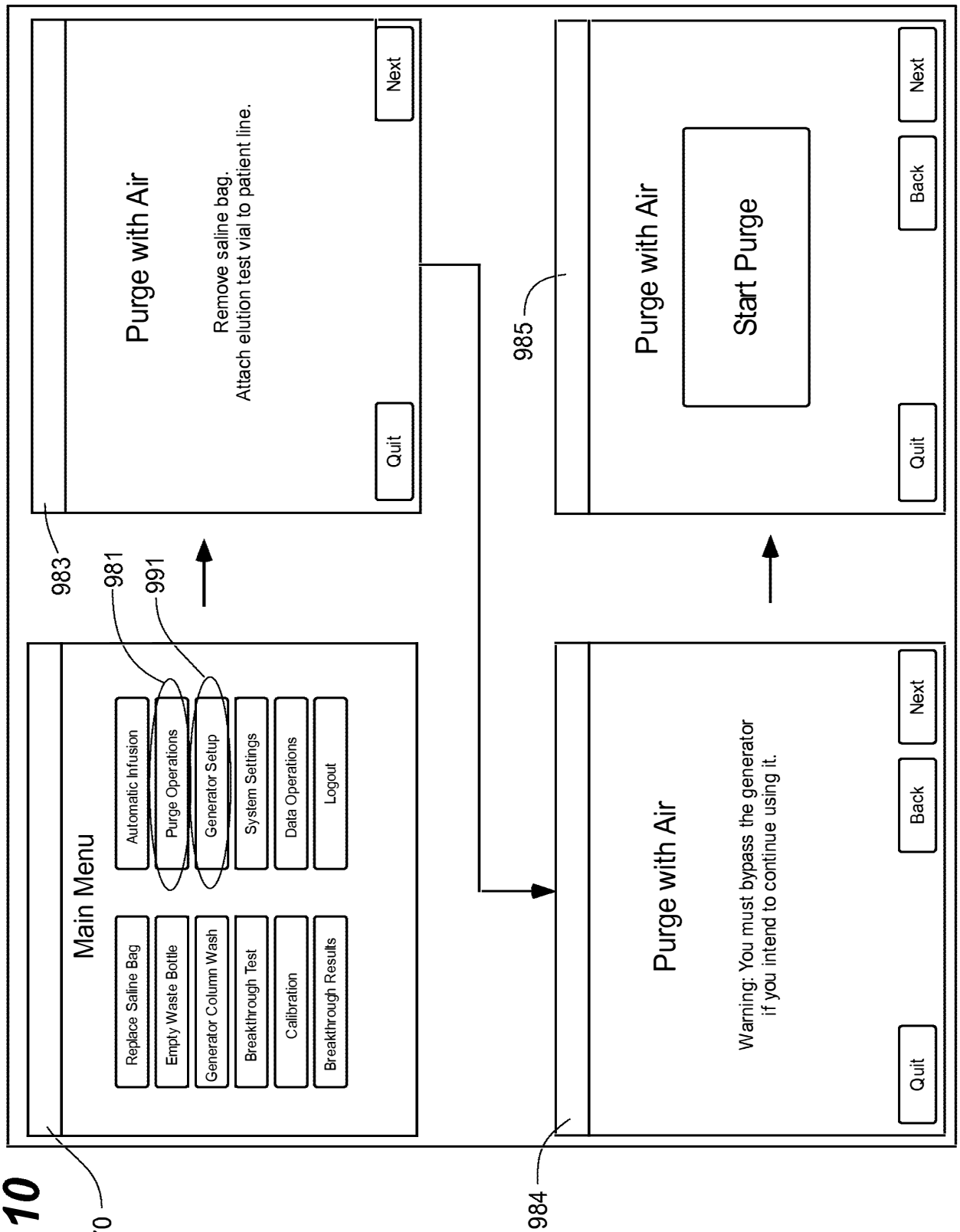

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470
981
991
983
Purge with Air
Remove saline bag.
Attach elution test vial to patient line.
Quit
Next
984
Purge with Air
Warning: You must bypass the generator
if you intend to continue using it.
Quit
Back
Next
985
Purge with Air
Start Purge
Quit
Back
Next

Fig. 10

Fig. 11

CARDIOGEN-82 GENERATOR MONTHLY RECEIPT/RETURN WORKSHEET

GENERATOR RECEIPT		
DATE OF DELIVERY:	11/9/2008	
DATE OF CALIBRATION:	11/10/2008	
LOT NUMBER:		
Sr-82 ACTIVITY:	100	mCi
TOTAL ACTIVITY:	256	mCi
Sr-85 ACTIVITY:	156	mCi

RECEIPT SURVEY		
SURFACE:	10.0	mrem/hr (MUST BE < 50 mrem/hr)
1 METER:	0.6	mrem/hr (MUST BE < 1 mrem/hr)
SURFACE WIPE:	1599	dpm (MUST BE < 2200 dpm/100 cm2)

GENERATOR RETURN	
DATE OF RETURN:	12/27/2008
DAYS SINCE CALIBRATION DATE:	47

RETURN SURVEY		
SURFACE:	5.6	mrem/hr (MUST BE < 50 mrem/hr)
1 METER:	0.2	mrem/hr (MUST BE < 1 mrem/hr)
SURFACE WIPE:	1278	dpm (MUST BE < 2200 dpm/100 cm2)

Sr-82 RETURN CALCULATIONS		
INITIAL Sr-82 ACTIVITY:	100	mCi
DECAY FACTOR:	0.2718	
REMAINING Sr-82 IN mCi:	27.18	mCi
REMAINING Sr-82 IN GBq	1.01	GBq

SUMMARY		
TOTAL Sr-82/Sr-85 ACTIVITY:	120.95	mCi
TOTAL Sr-82/Sr-85 ACTIVITY:	4.48	GBq
TRANSPORT INDEX:	0.2	

Sr-85 RETURN CALCULATIONS		
INITIAL Sr-85 ACTIVITY:	156	mCi
DECAY FACTOR:	0.6011	
REMAINING Sr-85 IN mCi:	93.77	mCi
REMAINING Sr-85 IN GBq	3.47	GBq

Fig. 12A

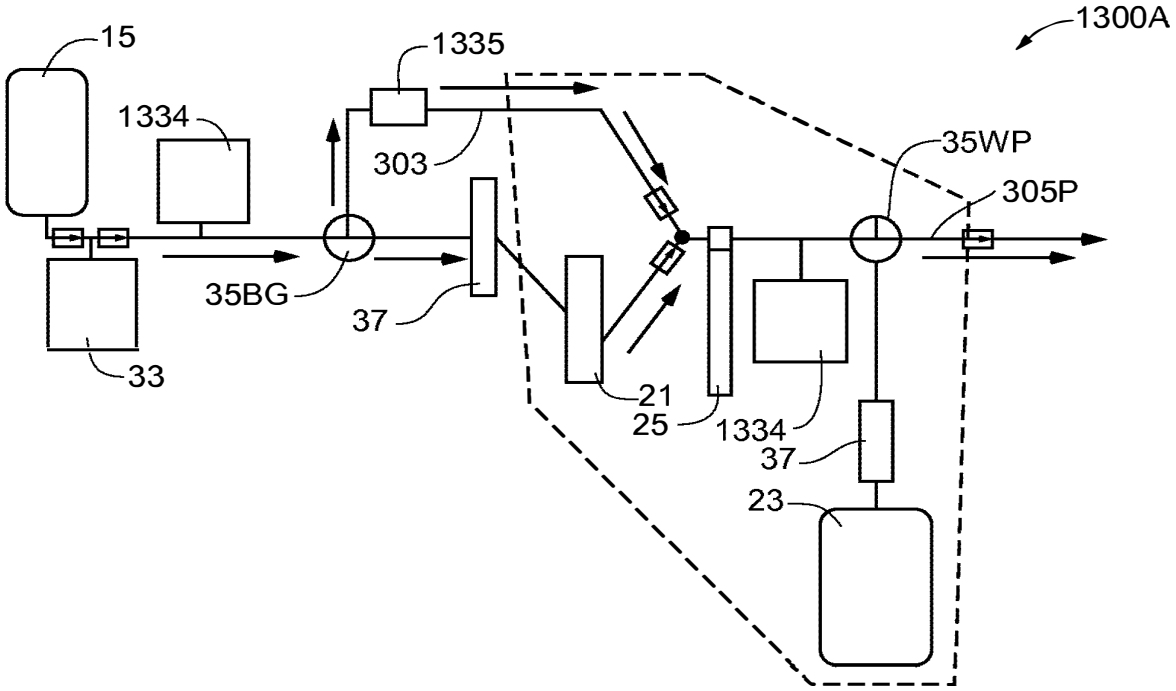


Fig. 12B

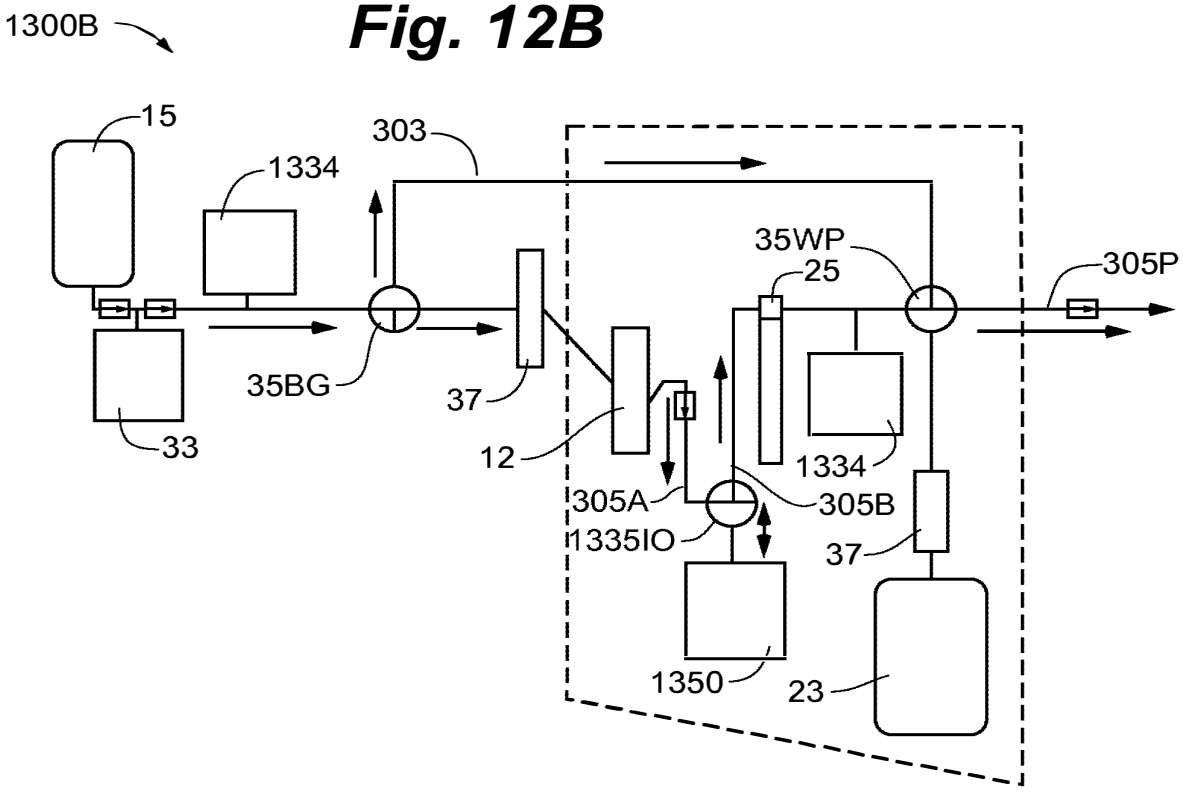
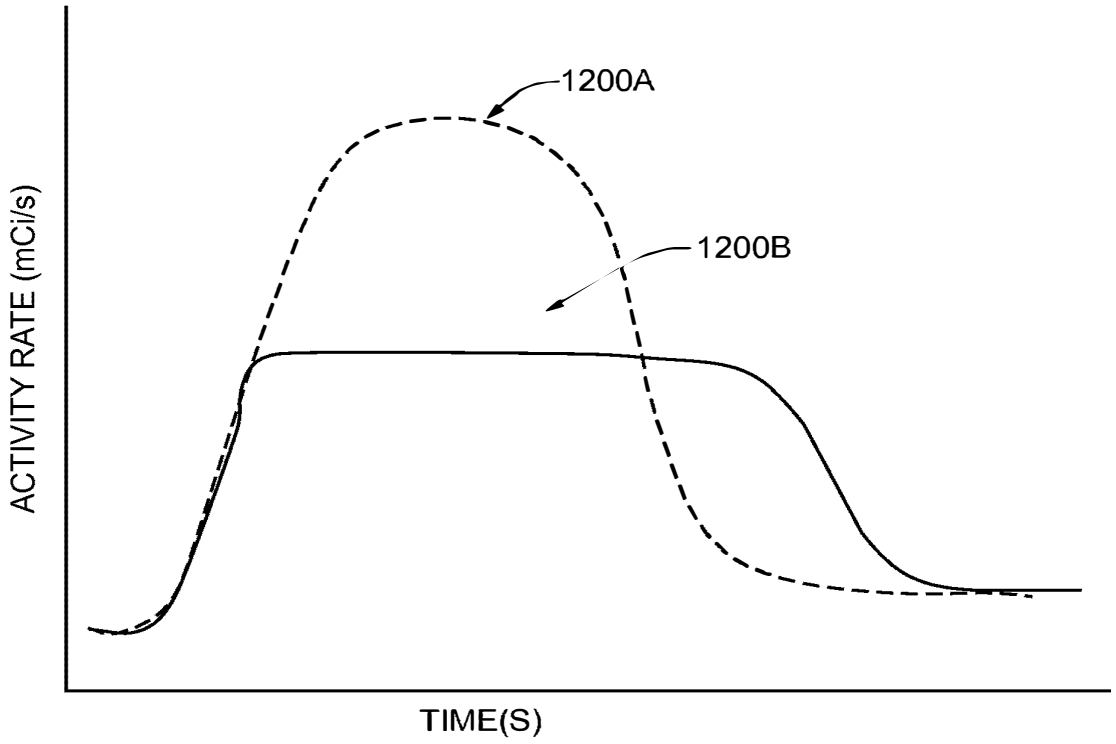


Fig. 12C



INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 12/808,467, filed June 16, 2010, which is a 371 National Stage of International Application No. PCT/US09/47031, filed June 11, 2009, which in turn claims priority to the following four patent applications: U.S. Patent Application No. 12/137,356, filed June 11, 2008, now U.S. Patent No. 8,317,674, issued November 27, 2012; U.S. Patent Application No. 12/137,363, filed June 11, 2008, now U.S. Patent No. 7,862,534, issued January 4, 2011; U.S. Patent Application No. 12/137,364, filed June 11, 2008; and U.S. Patent Application No. 12/137,377, filed June 11, 2008, now U.S. Patent 8,708,352, issued April 29, 2014. The entire contents of all of these applications are incorporated herein by reference.

TECHNICAL FIELD

The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to systems including computer-facilitated maintenance and/or operation.

BACKGROUND

Nuclear medicine employs radioactive material for therapy and diagnostic imaging. Positron emission tomography (PET) is one type of diagnostic imaging, which utilizes doses of radiopharmaceuticals, for example, generated by elution within a radioisotope generator, that are injected, or infused into a patient. The infused dose of radiopharmaceutical is absorbed by cells of a target organ, of the patient, and emits radiation, which is detected by a PET scanner, in order to generate an image of the organ. An example of a radioactive isotope, which may be used for PET, is Rubidium-82 (produced by the decay of Strontium-82); and an example of a radioisotope generator, which yields a saline solution of Rubidium-82, via elution, is the CardioGen-82● available from Bracco Diagnostics Inc. (Princeton, NJ). A PET scanner in combination with infused doses of radiopharmaceuticals may also be employed to quantify blood flow rate, for example, through the coronary arteries of a patient.

Set up, maintenance and operational procedures for infusion systems that both generate and inject doses of radiopharmaceuticals are relatively involved in order to assure the safety and efficacy of each injected dose for the patient. Efficiency in carrying out these procedures is highly desirable for technical personnel, who work with these systems on a routine basis and would like to avoid unnecessarily prolonged exposure to radioactive radiation. Thus there is a need for new system configurations that facilitate more efficient set up, maintenance and operation.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

Figure 1A is a first perspective view of an infusion system, according to some embodiments of the present invention.

Figure 1B is another perspective view of a portion of a cabinet structure of the system shown in Figure 1A, according to some embodiments.

Figure 1C is a second perspective view of the system shown in Figure 1A, according to some embodiments.

Figure 1D is a schematic of an infusion circuit, according to some embodiments of the present invention.

Figure 1E is a perspective view of exemplary sample vial shielding that may be employed in conjunction with the infusion system of Figure 1A.

Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A–C, according to some embodiments of the present invention.

Figure 2B is a perspective view of a framework of the system, according to some embodiments, with an enlarged detailed view of a component of the system, according to some embodiments.

Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.

Figure 3B is a perspective view of the infusion circuit, shown in Figure 1C, configured and routed, according to some embodiments.

Figure 3C is a perspective view of a disposable infusion circuit subassembly, according to some embodiments.

Figure 3D is a frame for the subassembly shown in Figure 3C, according to some embodiments.

Figure 4 is a main menu screen shot from an interface of a computer, which may be included in systems of the present invention, according to some embodiments.

Figure 5A is a schematic showing a first group of successive screen shots from the computer interface, according to some embodiments.

Figure 5B is a pair of screen shots from the computer interface, which provide indications related to eluant volume levels in a reservoir of the system, according to some embodiments.

Figure 5C is a schematic showing a second group of successive screen shots from the computer interface, according to some embodiments.

Figure 6 is a schematic showing a third group of successive screen shots from the computer interface, according to some embodiments.

Figures 7A–C are schematics showing a fourth group of successive screen shots from the computer interface, according to some embodiments.

Figures 8A–B are schematics showing a fifth group of successive screen shots from the computer interface, according to some embodiments.

Figures 9A–C are schematics showing a sixth group of successive screen shots from the computer interface, according to some embodiments.

Figure 10 is a schematic showing a seventh group of successive screen shots from the computer interface, according to some embodiments.

Figure 11 is an exemplary report which may be generated by the computer included in infusion systems, according to some embodiments.

Figures 12A–B are schematics of alternative infusion circuits that may be employed by embodiments of the present invention.

Figure 12C is a schematic illustrating exemplary activity profiles of injected doses of a radiopharmaceutical.

DETAILED DESCRIPTION

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.

Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surround an interior space in which a portion of infusion system 10 is contained (seen in Figure 1C). Shell 13 may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13; and, a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may be included, for example, a keyboard, a series of control buttons or levers, a bar code reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions, as well as to monitor system operation both during quality control infusions and during patient infusions. Operation of system 10, which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one location to another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.

Figure 1B is a perspective view of a portion of system 10, on a side 111 of the cabinet structure, which is in proximity to wheels 121, 122. Figure 1B illustrates a lever or pedal 125, which is located for activation by a foot of the person, who grasps handle 14 to maneuver system 10. In a neutral position, pedal 125 allows wheels 121, 122 to rotate, and, if embodied as casters, to swivel freely. Pedal 125 may be depressed to a first position which prevents a swiveling of wheels 121, 122, according to those embodiments in which wheels 121, 122 are casters, and may be further depressed to brake wheels 121, 122 from rolling and swiveling, upon reaching a desired location. According to some embodiments, braking may be designed to slow system 10, for example, when rolling down an incline, and, according to yet further embodiments, system 10 may include a motor to power movement thereof.

Figure 1B further illustrates**:** a rear access panel 174 of shell 13, for example, providing access to circuit boards of the aforementioned controller contained within the interior space that is surrounded by shell 13; an optional lock 184, to secure panel 174; a power jack 118, for connecting system 10 to a power source; and a printer 117 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include a power strip by which auxiliary equipment may be powered, and one or more additional electrical connectors, or ports (not shown), which are supported by platform 113 and may be integrated into shell 13, for example, in proximity to jack 118 or printer 117; these electrical connectors/ports allow system 10 to communicate with, other devices used for nuclear imaging procedures, for example, a PET scanner/camera, and/or for coupling to an intranet network, and/or to the internet, for example, to link up with software programs for various types of data analysis, and/or to link to computers of consulting clinicians/physicians, and/or to link into service providers and/or component suppliers data bases for enhanced maintenance and inventory management.

Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective view of system 10, wherein a removable access panel 132 is shown as a contoured portion of upper surface 131, which, when exposed, by lifting away a bin 18, that mates therewith, may be removed from another opening 137 formed in upper surface 131. Figure 1C also provides a better view of another panel 134 which may be lifted away from opening 139. According to the illustrated embodiment, openings 139 and 137 provide a user of system 10 with independent access to separate portions of infusion system 10, which are contained within shell 13, for example, to set up and maintain system 10; and openings 133 and 135 provide passageways for tubing lines to pass through shell 13. Figure 1C further illustrates an optional switch 102, which in case of an emergency, may be activated to abort function of system 10. With reference to Figures 1A and 1C, it may be appreciated that an arrangement of features formed in upper surface 131 of shell 13, in conjunction with bin 18, tray 16 and computer 17, provide a relatively ergonomic and organized work area for technical personnel who operate system 10.

Turning now to Figure 1D, a schematic of an infusion circuit 300, which may be incorporated by system 10, is shown. Figure 1D illustrates circuit 300 generally divided into a first part 300A, which includes components mounted outside shell 13, and a second part 300B, which includes components mounted within the interior space surrounded by shell 13. (Parts 300A and 300B are delineated by dotted lines in Figure 1D.) Figure 1D further illustrates second part 300B of circuit 300 including a portion contained within a shielding assembly 200, which is designated schematically as a dashed line. Some embodiments of shielding assembly 200 will be described in greater detail, in conjunction with Figures 2A-B and 3A-B, below.

According to the illustrated embodiment, circuit 300 includes**:** an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34 (or other device or sensor), for monitoring pumping pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity

detector 25, for measuring the activity of the eluate discharged from generator 21, in order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance.

Figure 1D illustrates an eluant tubing line 301 coupled to reservoir 15 and to pump 33, and, with reference to Figures 1A-B, it may be appreciated that opening 133 provides the passageway for tubing line 301 to enter the interior space surrounded by shell 13. According to some preferred embodiments, opening 133 includes a grommet-type seal that prevents leakage of eluant, which may spill from reservoir 15, into the interior space through opening 133, while allowing a user to assemble tubing line 301 through opening 133. Likewise opening 135, which provides a passageway for patient line 305p, may include a grommet-type seal. According to some embodiments, shell 13 further supports holders to safely hold, for example, during transport of system 10, portions of tubing lines that extend outward therefrom, for example, line 301 and/or line 305p.

Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from the generator into waste bottle 23, until activity detector 25 detects the desired activity

of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21. According to some preferred methods of operation, in certain situations, which will be described in greater detail below, eluant is pumped through by-pass line 303 immediately following the flow of the prescribed volume of eluate into patient line 305p, at a higher speed, in order to push the eluate in patient line 305, thereby increasing a flow rate of the injection of eluate out from patient line 305p and into the patient. For example, once the prescribed volume of eluate has flowed into patient line 305p, and once divergence valve 35BG is set to divert flow through by-pass line 303, the speed of pump 33 may be adjusted to increase the flow rate of eluant to between approximately 70mL/min and approximately 100mL/min. This method for increasing the injection flow rate, is desirable, if a relatively high flow rate is desired for patient injection and a flow rate through generator 21 is limited, for example, to below approximately 70mL/min, maximum (typical flow rate may be approximately 50mL/min), in order to avoid an excessive back pressure created by the column of generator 21 in upstream portions of tubing circuit 300; the excessive back pressure could damage filter 37 or otherwise impede flow through eluant tubing line 302.

Although not shown in Figure 1D, a number of sensors, for example, to measure pressure and/or flow velocity, may be incorporated into circuit 300, according to some alternate embodiments, in order to monitor for flow anomalies, for example, related to occlusions/plugs in circuit 300 and/or leaks, and/or to provide feedback for control of an activity level of infused doses of radiopharmaceutical. Suitable sensors for any of the above purposes are known to those skilled in the art. Examples of flow meters that may be incorporated into circuit 300, include the Innova-Sonic● Model 205 Transit-Time Ultrasonic Liquid Flow Meter that employs digital signal processing (available from Sierra Instruments, Inc.) and the Flocat LA10-C differential pressure

flow meter. One example of a pressure sensor that may be employed to detect infusion circuit occlusions is the PRO / Pressure-Occlusion Detector (available from INTROTEK● of Edgewood, NY, a subsidiary of Magnetrol of Downers Grove, IL), which employs pulse-type ultrasound; this sensor detects subtle changes in positive and negative air pressure and produces a corresponding passive resistive output signal, which may be routed to the system controller and/or computer 17. One or more of this type of sensor may be incorporated into infusion circuit 300 by simply fitting the sensor around any of the tubing lines of infusion circuit 300; in fact, the PRO / Pressure-Occlusion Detector may be a suitable alternative to pressure syringe 34 of circuit 300. Other types of pressure sensors, for example, similar to those known in the art for blood pressure monitoring, may be employed in infusion circuit 300.

System 10 may further include sensors to detect fluid levels in eluant reservoir 15 and waste bottle 23. Some examples of such sensors, which also employ the aforementioned pulse-type ultrasound, are the Drip Chamber Liquid Level Sensor and the CLD / Continuous Level Detector (both available from INTROTEK●); alternatively, for example, an HPQ-T pipe mounted, self-contained liquid sensor (available from Yamatake Sensing Control, Ltd.), or an SL-630 Non-Invasive Disposable/Reusable Level Switch (available from Cosense, Inc. of Hauppauge, NY) may be employed to detect the fluid levels. Alternately or in addition, system 10 can include additional radiation and/or moisture detection sensors, which can detect leaks. With reference to Figure 1D, such sensors are preferably located in proximity to fittings 311, 312, 313, 314 and 315 that join portions of circuit 300 to one another. Some examples of leak detection sensors include, without limitation, those in the HPQ-D leak detection sensor family, and the HPF-D040 fiberoptic leak detector (all available from Yamatake Sensing Control, Ltd.). System 10 may further include additional sensors to detect contaminants and/or air bubbles within the tubing lines of circuit; examples of such sensors include the Point-air Detection (PAD) Sensor, that employs pulse-type ultrasound for air bubble detection, and the Blood Component Detector that employs optical sensing technology to perform Colorimetry-based fluid detection of unwanted elements in the tubing lines (both available from INTROTEK●).

According to those embodiments that include any of the above sensors, the sensors are linked into the controller of system 10 and/or computer 17, either of which may provide a signal to a user of system 10, when a flow anomaly is detected, and/or

information to the user, via monitor 172, concerning fluid levels, pressure and/or flow through circuit 300. Computer 17 may be pre-programmed to display, for example, on monitor 172, a graphic of infusion circuit 300 wherein each zone of the circuit, where an anomaly has been detected, is highlighted, and/or to provide guidance, to the system user, for correcting the anomaly. It should be noted that the alternative infusion circuits illustrated in Figures 12A-B, which will be described below, may also include any or all of these types of sensors.

With further reference to Figure 1D, it may be appreciated that shielding assembly 200 encloses those portions of circuit 300 from which radioactive radiation may emanate, with the exception of that portion of patient line 305p, which must extend out from shielding assembly 200 in order to be coupled to the patient for injection, or in order to be coupled to shielded sample vials, as will be described below. Thus, technical personnel, who operate system 10, are protected from radiation by shielding assembly 200, except at those times when an infusion is taking place, or when quality control tests require collection of eluate into sample vials. During infusions and quality control test sample collection, all technical personnel are typically in another room, or otherwise distanced from system 10, in order to avoid exposure to radiation during the infusion, and, according to some preferred embodiments of the present invention, system 10 includes at least one means for informing technical personnel that an infusion is about to take place or is taking place. With reference back to Figures 1A and 1C, system 10 is shown including a light projector 100, mounted on post 142. According to the illustrated embodiment, projector 100, projects a light signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23, and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an

infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system 10, including in the control room.

It should be noted that, according to alternate embodiments, system 10 includes an 'on board' dose calibrator for quality control tests, and circuit 300 is expanded to include elements for an automated collection of eluate samples for activity measurements, via the on board dose calibrator. According to a first set of these alternate embodiments, a sample collection reservoir is integrated into circuit 300, downstream of divergence valve 35WP and in communication with tubing line 305P, in order to receive quality control test samples of eluate, via tubing line 305P, and both the reservoir and the dose calibrator are located in a separate shielded well. According to a second set of these alternate embodiments, waste bottle 23 is configured to receive the quality control test samples of eluate, via tubing line 305W, and a dose calibrator is integrated into shielding assembly 200. Quality control procedures will be described in greater detail below, in conjunction with Figures 6-8B.

When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a threshold to be safe. Opening 139 is preferably located at an elevation of between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional maintenance procedures, such as changing out generator 21 and/or other components of circuit 300, as will be described below.

For those embodiments of system 10 in which automated quality control tests are performed and/or when system 10 is employed for relatively high volume operation, management of waste may become burdensome, even though access to

waste bottle 23 is greatly facilitated, as described above. Thus, in order to facilitate waste management, some embodiments of system 10 may employ a separation system to separate salts, including radioactive elements, from water, for example, via evaporation or reverse osmosis. In an evaporation type system, the water component of the waste is evaporated, while in a reverse osmosis type system the water is separated from the salts, and, then, once confirmed to be non-radioactive, via a radiation detector, is piped to a drain. According to some other embodiments, circuit 300 may be configured so that the waste may be used to purge air from the tubing lines thereof and/or to perform the bypass flush that was described above, preferably after the radioactivity of the waste drops below a critical threshold.

Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from the infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. An exemplary test vial shield is shown in Figure 1E. The test vial shield of Figure 1E is preferably formed from Tungsten rather than lead, for example, to reduce exposure to lead, for improved shielding, and to reduce the weight of the shield. Figure 1E illustrates the test vial shield including a handle to simplify manipulation thereof, but alternative configurations of test vial shields have no handle – for these a sling, or strap, may be employed for handling.

Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc…, into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example,

deposited therein during infusion procedures. According to some embodiments, one or more additional receptacles are formed in one or more disposal containers, for example, to contain sharps and/or radioactive waste (other than that contained in waste bottle 23), which may be integrated into bin 18, or otherwise fitted into, or attached to shell 13, separate from bin 18.

Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. It should be noted that, according to alternate embodiments, the compartment enclosed by sidewall 201 is large enough to hold more than one generator, for example, to increase system operating efficiency for relatively high volume operation. In some of these alternate embodiments, tubing lines 304 and 305 are each branched for parallel flow through the multiple generators, in which case divergence valves may be employed to alternate the flow through the generators, one at a time. In others of these alternate embodiments, the multiple generators are connected in series between tubing line 304 and tubing line 305. In addition, a reservoir for accumulating eluate may be included in circuit 300, downstream of the generators and upstream of divergence valve 35 WP, in conjunction with a second pump, in some cases. Embodiments including multiple generators and/or an eluate reservoir and second pump can be employed to better manage an activity level of each dose, or patient injection, for example, as described below, in conjunction with Figures 12A-B.

According to the embodiment illustrated in Figure 2A, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed by a sidewall 203 of shielding assembly 200 to contain waste bottle 23, as previously described. When panel 132 is separated from shell 13, and door 221 opened, generator 21 may be lifted out from an opening 231 (Figure 3A) which mates with door 221 of sidewall 201. A weight of generator 21, which includes its own shielding, may be between approximately 23 and approximately 25 pounds, thus, according to some preferred embodiments of the present invention, the elevation of each of openings 137 and 231, with respect to the lowermost portion of the cabinet structure, is between

approximately 1 foot and approximately 2 feet, in order to facilitate an ergonomic stance for technical personnel to lift generator 21 out from the compartment. According to an exemplary embodiment, when shielding assembly 200 is contained in the cabinet structure of Figure 1A , openings 137 and 231 are located at an elevation of approximately 12 inches, with respect to the lower surface of platform 113, or at an elevation of approximately 19 inches, with respect to the ground surface upon which wheels 121, 122 rest. Figure 1C further illustrates access panel 132 including a security lock 138, which mates with a framework 19 of system 10, shown in Figure 2B, in order to limit access to generator 21.

Figures 1C and 2A further illustrate a lid or a door 225 of another sidewall 205 (Figure 3A) of shielding assembly 200, which encloses another compartment that is accessible through opening 137 of shell 13, and which is located adjacent the compartment enclosed by sidewall 201. Each of doors 221, 225 are shown being attached by a corresponding hinge H, and another door 227 is shown attached to sidewall 203 by another hinge H. Figure 2A illustrates each of lid 223 and doors 221, 225, 227 including a handle 232, 212, 252 and 272, respectively, for moving lid 223 and doors 221, 225, 227, in order to provide access to the corresponding compartments, which can be seen in Figures 3A-B. Figure 2A further illustrates optional thumb screws 290, one securing lid 223 to sidewall 203 and another securing door 221 to sidewall 201, or other means for securing the doors, which are known to those skilled in the art, may be incorporated. Each sidewall 201, 203, 205 and the corresponding lid/door 223, 221, 225, 227 thereof may be individually cast from 3% antimony lead, or from other known shielding materials, and then assembled together according to methods known to those skilled in the art.

According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a latch component 191 is provided to hold each of doors 221, 225 in an opened position, thereby, preventing doors 221, 225 from falling closed, which could pinch/crush fingers of technical personnel and/or tubing lines of circuit 300, when in the midst of a maintenance procedure. Figure 2B is a perspective view of framework 19 of the cabinet structure of system 10, according to some embodiments, to which latch component 191 is mounted; Figure 2B includes an enlarged detailed view of latch component 191, according to some embodiments. Figure 2B illustrates latch component 191 including a first pin 193, corresponding to door 225, and a second pin

195, corresponding to door 221; each pin 193, 195 includes a lever end 193A, 193B, respectively, and a holding end 193B, 195B, respectively. An edge of each door 221, 225, upon opening of doors 221, 225, may push past the holding end 195B, 193B of the corresponding pin 195, 193, in a first direction, per arrow F, and then may rest against a respective side S95 and S93 of each end 195B, 193B, until the corresponding lever end 195A, 193A is rotated in a counter-clockwise direction, per arrow cc, thereby moving the corresponding holding end 193B, 195B to make way for the closing of doors 221, 225. Doors 221, 225 being held by latch component 191 in an open position may be seen in Figure 3A.

With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225. The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300

(Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.

Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover. With further reference to Figures 3A-B, it may be appreciated that the compartment formed by sidewall 201 may have a shape matching an exterior contour of generator 21, such that generator 21 is 'keyed' to the compartment, for example, to prevent installation of an improper generator into system 10, and/or to facilitate the proper orientation of generator 21 within the compartment for the proper routing of tubing lines. Alternately, or in addition, according to alternate embodiments, if system 10 includes a reader of encoded information in communication with computer 17, a unique identification and/or data associated with each generator may be provided, for example, in a bar code label or a radiofrequency identification (RFID) tag that is attached to each generator, so that the reader may transfer the information to computer 17, when a generator is installed, in order to either enable system operation or to provide an indication to the user that an incorrect generator has been installed. Of course a user of system 10 may, alternately, manually enter information, that is provided on a generator label or marking, into computer 17, in order to either enable system 10, or to receive feedback from computer 17 that the incorrect generator is installed.

Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305

passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.

Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together, according to alternate embodiments, mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.

According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w, respectively, extending from second side 392 of frame 39. Although ends 406, 407 are shown extending upward from tray 39a, as they would within shielding assembly 200, it should be appreciated that the tubing lines of circuit 300 are preferably flexible and would drop down under their own weight rather than extending upward, as shown, if not supported. Referring back to Figure 1D, in conjunction with Figure 3C, it can be seen that the aforementioned fittings are provided for coupling subassembly 390 into circuit 300: first fitting 311 couples the section of eluant line 302 to filter 37; second fitting 312 couples eluant line 304 to an inlet port of generator 21; third fitting 313, which may incorporate a check valve, couples eluate line 305 to an outlet port of generator 21; fourth fitting 314 couples waste line 305w to waste bottle 23; and fifth fitting 315 couples patient line

305p to an extension thereof, which extends outside shell 13 (designated by the dotted line). Each of the fittings 311, 312, 313, 314, 315 may be of the Luer type, may be a type suitable for relatively high pressure applications, or may be any other suitable type that is known to those skilled in the art.

As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.

Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed

plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.

Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17, so that the operation of system 10 may be monitored and controlled remotely, away from radioactive radiation.

According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. Computer 17 may also be pre-programmed to interact with the controller of system 10 in order to keep a running tally or count of elutions per unit time, for a given generator employed by the system, and may further categorize each of the counted elutions, for example, as being generated either as a sample, for quality control testing, or as a dose, for patient injection. The elution count and categorization, along with measurements made on

each sample or dose, for example, activity level, volume, flow rate, etc…, may be maintained in a stored record on computer 17. All or a portion of this stored information can be compiled in a report, to be printed locally, and/or to be electronically transferred to a remote location, for example, via an internet connection to technical support personnel, suppliers, service providers, etc…, as previously described. Computer 17 may further interact with the user and/or a reader of encoded information, for example, a bar code reader or a radiofrequency identification (RFID) tag reader, to store and organize product information collected from product labels/tags, thereby facilitating inventory control, and/or confirming that the proper components, for example, of the tubing circuit, and/or accessories, and/or solutions are being used in the system.

It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format. Computer 17 may also include a pre-programmed user manual, which may be viewed on monitor 172, either independent of system operation or in conjunction with system operation, for example, via pop-up help screens. Although the English language is employed in the screen shots of Figures 4-9C, it should be understood that, according to some embodiments, computer 17 is pre-programmed to provide guidance in multiple languages.

Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on. According to some multi-lingual embodiments, computer 17 presents a list of languages from which the user may select, prior to presenting main menu 470.

Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a storage medium (i.e. disk) reader, a scanner, a bar code reader (or other

reader of encoded information), a hand control (i.e. mouse, joy stick, etc…). Although not shown, according to some embodiments, screen 570 may further include another data entry field in which the user is required to enter a license key related to the generator employed by system 10 in order to enable operation of system 10; the key may be time sensitive, related to generator contract terms. Of course any number of log in requirements may be employed, according to various embodiments, and may be presented on multiple sequentially appearing screens rather than on a single log in screen.

After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag. If system 10 includes an encoded information reader, such as a bar code or RFID tag reader, confirmation that the selected reservoir is proper, i.e., contains the proper saline solution, may be carried out by computer 17, prior to connecting the reservoir into circuit 300, by processing information read from a label/tag attached to the reservoir. Alternatively, or in addition, tubing line 301 of circuit 300 may be provided with a connector which only mates with the proper type of reservoir 15. According to some embodiments, system 10 may further include an osmolarity or charge detector, which is located just downstream of reservoir 15 and is linked to computer 17, so that an error message may be presented on monitor 172 stating that the wrong osmolarity or charge is detected in the eluant supplied by reservoir, indicating an improper solution. One example of a charge detector that may be employed by system 10 is the SciCon™ Conductivity Sensor (available from SciLog, Inc. of Middleton, WI).

Once the reservoir/saline bag is successfully replaced, computer 17 prompts the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Alternately, if system 10 includes the aforementioned reader, and the saline bag includes a tag by which volume information is provided, the reader may automatically transfer the quantity information to computer 17. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag

has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished. It should be noted that, as previously mentioned, system 10 can include a fluid level sensor coupled to the eluant reservoir in order to detect when the level of saline drops below a certain level.

In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied. According to some alternative embodiments, a fluid level sensor may be coupled to waste bottle 23, for example, as mentioned above in conjunction with Figure 1D, in order to automatically detect when waste bottle 23 is filled to a predetermined level and to provide, via computer 17, an indication to the user that waste bottle 23 needs to be emptied and/or to automatically preclude operation of system 10 until the waste bottle is emptied.

In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred

methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate it being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.

Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82● that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. According to some embodiments, in conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).

Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed

by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the

sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.

With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then

a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration elution process. When the user transfers the vial containing the sample of eluate into the dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 878. With further reference to Figure 8B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 879, which includes data entry fields for the activity measure and the time, with respect to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data is input by the user, as described above, the computer calculates a calibration coefficient, or ratio, and presents the ratio on a screen 880. According to Figure 8B, screen 880 further provides an indication of a desirable range for the calibration ratio and presents an option for the user to reject the calculated ratio, in which case, the user may instruct computer 17 to recalculate the ratio.

As previously mentioned, some alternate embodiments of the present invention include an on board dose calibrator so that the entire sequence of sample collection and calculation steps, which are described above, in conjunction with Figures 6-8B, for the quality control procedures, may be automated. This automated alternative preferably includes screen shots, similar to some of those described above, which provide a user of the system with information at various stages over the course of the automated procedure and that provide the user with opportunities to modify, override and/or abort one or more steps in the procedure. Regardless of the embodiment (i.e. whether system 10 employs an on board dose calibrator or not), computer 17 may further collect all quality control test parameters and results into a stored record and/or compile a report including all or some of the parameters and results for local print out and/or electronic transfer to a remote location.

With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct

system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with an option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from

generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

With further reference to Figure 9C, screen 976 shows an exemplary activity profile (activity - mCi/sec, on y-axis, versus time – sec, on x-axis) for the infusion/injected dose (designated between the two vertical lines). Those skilled in the art will appreciate that the shape of this profile depends upon the infusion flow rate, for a given volume of the dose, which flow rate is controlled, for example, by the speed at which pump 33 drives flow through the patient line, and upon the amount of Strontium-82 remaining in the generator. In the absence of flow rate control, activity profiles may change over the life of the generator. Furthermore, the peak bolus of radioactivity, particularly for injected doses from a relatively new generator, may exceed a saturation level of the imaging equipment, i.e. PET scanner. According to some preferred methods of the present invention, in order to maintain relatively consistent, and desirable/effective, activity profiles for patient injections, over the life of the generator, the operating speed of pump 33 may be varied (both over the course of a single injection and from injection to injection), according to feedback from activity detector 25. Such a method may be implemented via incorporation of another quality control test in which pump 33 is operated to drive flow through the generator at a constant rate, in order to collect, into computer, a plurality of activity measurements from activity detector 25; the plurality of measurements comprise a characteristic, or baseline activity profile from which the computer 17 may calculate an appropriate flow rate profile to control a speed of pump 33, in order to achieve the desirable/effective activity profile. In general, at the start of generator life, when Strontium-82 is plentiful, the pump is controlled to drive infusion flow at relatively lower rates, and, then, toward the end of generator life, when much of the Strontium-82 has been depleted, the pump is controlled to drive infusion flow at relatively higher rates. As was described above, in conjunction with Figure 1D, if a desired infusion/injection flow rate is relatively high, that is, high enough to create too much back pressure, via flow through the column of generator 21, by-pass line 303 may be employed by adjusting divergence valve 35BG to divert a flow of eluant therethrough

after a sufficient volume has been pumped through generator at a lower flow rate. According to this method, once a dose of eluate, from generator 21, has flowed into patient line 305p, divergence valve 35BG is set to divert the flow of eluant through by-pass line 303, and then pump speed is increased to pump eluant at a higher flow rate in order to push the dose out from patient line 305p, for injection at the higher flow rate.

Consistency of activity profiles among injected doses can greatly facilitate the use of PET scanning for the quantification of flow, for example, in coronary perfusion studies. Alternative infusion circuit configurations, operable according to alternative methods, to achieve consistency of activity profiles among injected doses, as well as a more uniform level of radioactivity across each individual dose, will be described below, in conjunction with Figures 12A-C.

Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent infusion and system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary may be downloaded onto a computer readable storage device to be electronically transferred to one or more remote computers and/or the summary may be automatically transferred to the one or more remote computers, via wireless communication or a cable connection, for example, over an intranet network and/or the internet. In order to protect private patient information, the files may be encrypted for transmission over the internet. The one or more remote computers may be included, for example, in a hospital information system, and/or a billing system, and/or in a medical imaging system. Infusion parameters, for example, corresponding to the activity profile, may also be collected and electronically transferred for analysis in conjunction with captured images, for example, in order to quantify coronary flow, via a software package that is loaded into a system that includes the PET scanner.

With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data. Additionally, certain information, which is collected by computer 17 over the course of system operation, and which defines

system operation, may be transmitted to a local or remote computerized inventory system and/or to computers of technical support personnel, maintenance/service providers and/or suppliers of infusion circuit elements/components, thereby facilitating more efficient system operation and maintenance.

Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline purge, as procedures for saline purging should be readily apparent to those skilled in the art, with reference to the schematic of infusion circuit 300 shown in Figure 1D. A saline purge of circuit 300 is desired to assure that all the air is removed from circuit 300 when a new generator and/or a new complete or partial tubing set is installed. An air purge of the tubing lines of circuit 300 may be performed after removing reservoir 15, by-passing generator 21, by connecting tubing line 304 to tubing line 305, and coupling patient line 305p to a vial, for example, as is directed by the computer interface, in screens 983 and 984 shown in Figure 10. The air purge is desirable for blowing out the tubing lines, thereby removing all remaining eluant and eluate, prior to installing a new generator and/or prior to transporting system 10 from one site to another. If generator 21 is not depleted and will be used in system 10 at the new site, it is important to by-pass the generator prior to purging the tubing lines of circuit 300 with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping

a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator. According to some embodiments, computer 17 is pre-programmed to calculate an amount of activity left in a depleted generator, for example, by tracking activity of eluate over a life of the generator. At an end of the life of the generator, computer 17 may further compile this information, along with other pertinent generator information, into a report that may accompany a declaration of dangerous goods for shipping the depleted generator out for disposal or, in some cases, back to the manufacturer for investigation. An example of such a report is shown in Figure 11. According to those embodiments of system 10 that include an encoded information reader, computer 17 may confirm that the new generator is proper by processing information that is read from an encoded label/tag attached thereto.

Figures 12A-B are schematics of alternative infusion circuits 1300A, 1300B that may be employed by system 10, in place of circuit 300 (Figure 1D), according to some additional embodiments of the present invention. Circuits 1300A, 1300B are configured to allow for alternative methods of operation, to that previously described for circuit 300, when a relatively even, or uniform level of activity over each injected dose, along with the relatively consistent level of activity from injection to injection is desired, for example, in order to facilitate a quantification of coronary artery blood flow via PET scanning. Figure 12C is a schematic illustrating activity profiles 1200A, 1200B for two injected doses, wherein profile 1200B has a more uniform level of activity than profile 1200A; profile 1200B may be achieved via the operation of circuits 1300A, 1300B as described below.

Similar to circuit 300 (Figure 1D), dashed lines are shown in each of Figures 12A-B to indicate a general boundary of a shielding assembly for portions of each circuit 1300A, 1300B. The shielding assembly for each of circuits 1300A, 1300B may

be very similar, in most respects, to shielding assembly 200, which is described above for system 10, and the elements of each of circuits 1300A, 1300B may be arranged with respect to their respective shielding and with respect to shell 13 of system 10 in a similar manner to that described above for circuit 300.

Figure 12A illustrates circuit 1300A including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, through which the filtered eluant is pumped to create the radioactive eluate, activity detector 25, and waste bottle 23. Figure 12A further illustrates two filters 37 and two pressure transducers 1334 included in circuit 1300A. Circuit 1300A further includes by-pass tubing line 303, which is located downstream of divergence valve 35BG, like in circuit 300, and which accommodates the previously described eluant/saline flush. However, in contrast to circuit 300, circuit 1300A further includes a linear/proportional valve 1335 integrated into by-pass/flush line 303 so that circuit 1300A may be operated, for example, according to pre-programmed parameters of computer 17, in conjunction with feedback of information from activity detector 25, for a controlled by-pass of generator 21 in order to mix eluant with eluate and, thereby, achieve a relatively uniform level of activity over each patient injection, for example, according to profile 1200B of Figure 12C. It should be noted that, in addition to the controlled mixing, a flow rate of each injection may be varied, if necessary, in order to maintain a consistent activity level.

Figure 12B illustrates circuit 1300B including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, activity detector 25, and waste bottle 23, as well as the two filters 37 and two pressure transducers 1334, as in circuit 1300A. In contrast to circuits 300 and 1300A, circuit 1300B further includes an eluate reservoir 1350, which is shown located downstream of generator 21, in between first and second segments 305A, 305B of the eluate tubing line. It should be noted that a pump is combined with reservoir 1350, for example, similar to syringe pump 33, such that, when a divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305A, the associated pump may be operated to draw in a volume of eluate, and, then, when divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305B, the pump may be operated to push the volume of eluate out through tubing line segment 305B for a patient injection, when divergence valve 35WP is set to direct flow into patient line 305p. With reference back to Figures 3A-B,

sidewall 205 of shielding assembly 200 may be enlarged to further enclose eluate reservoir 1350. For example, another shielded well, to house the eluate reservoir, may extend alongside well 255, in which activity detector 25 is described as being mounted. Furthermore, sidewall 205 may include another valve actuator receptacle for divergence valve 1335IO, similar to receptacle 253, shown in Figure 3A for divergence valve 35WP.

Collection of discrete volumes of eluate, in reservoir 1350, may help to achieve a more uniform activity level over each injection, for example, like that of profile 1200B in Figure 12C, and, according to preferred methods, feedback from activity detector 25 may be used to control the pump associated with reservoir 1350, in order to vary injection flow rate and, thereby, maintain a relatively consistent activity level across multiple injections, and, when necessary, to vary injection flow rate over an individual injection to maintain the uniform activity level. Feedback from the pressure transducer 1334, that is downstream from detector 25, and/or from a flow meter (not shown) of circuit 1300B may also be used to control the varying of injection flow rate.

With further reference to Figures 12A-B, it should be noted that alternative circuits may be configured to employ a combination of the methods described for circuits 1300A and 1300B. Furthermore, some infusion circuits of the present invention may employ multiple generators 21, as mentioned above, in conjunction with Figure 2A, to help maintain the relatively uniform level of activity over each injection and the relatively consistent level of activity from injection to injection.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

CLAIMS:

1. A system comprising:

a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution;

a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing; and

a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing,

wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results.

2. The system of claim 1, wherein the radioisotope generator comprises a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82.

3. The system of claim 1, wherein the computer is configured to calculate the breakthrough test results by at least calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82.

4. The system of claim 3, wherein the computer is further configured to indicate if the breakthrough test results are within allowable limits.

5. The system of claim 4, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

6. The system of claim 1, wherein the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

7. The system of claim 1, further comprising an activity detector.

8. The system of claim 7, wherein the computer is configured to divert eluate generated via elution to a waste bottle until the activity detector detects a given level of activity.

9. The system of claim 8, wherein the given level of activity is approximately 1.0 millicurie per second.

10. The system of claim 1, further comprising a display configured to display the breakthrough test results.

11. The system of claim 10, wherein the computer is configured to control the display to provide an indication of progress of the breakthrough testing.

12. The system of claim 1, further comprising a cabinet structure, wherein the shielding assembly is positioned inside the cabinet structure and the computer is carried by the cabinet structure.

13. The system of claim 1, wherein the dose calibrator is configured to physically receive the sample of eluate generated during breakthrough testing.

14. A method comprising:

generating, with a radioisotope generator contained within a shielding assembly, a radioactive eluate via elution of an eluant;

measuring, with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate; and

determining, with the computer, an activity of rubidium-82 within the radioactive eluate.

15. The method of claim 14, further comprising determining, with the computer, an activity of strontium-82 and an activity of strontium-85 in the radioactive eluate.

16. The method of claim 15, further comprising determining, with the computer, a ratio of the activity of strontium-82 divided by the activity of rubidium-82 and a ratio of the activity of strontium-85 divided by the activity of rubidium-82.

17. The method of claim 16, further comprising determining, with the computer, if the ratio of activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are within allowable limits.

18. The method of claim 17, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

19. The method of claim 14, further comprising displaying breakthrough test results determined by the computer.

20. The method of claim 14, further comprising preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

21. The method of claim 14, further comprising measuring, with an activity detector electronically coupled to the computer, an activity of the radioactive eluate.

22. The method of claim 21, further comprising controlling, with the computer, a diverter valve to divert the radioactive eluate to a waste bottle until the activity detector detects a given level of activity.

23. The method of claim 22, wherein the given level of activity is approximately 1.0 millicurie per second.

24. The method of claim 14, wherein the shielding assembly is positioned inside a cabinet structure and the computer is carried by the cabinet structure.

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.

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First Named Inventor	Stephen E. Hidem
Title	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
Art Unit	Not Yet Assigned
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Attorney Docket Number	56782.1.7.15

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

22859

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

Name	Registration Number	Name	Registration Number

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant:

☐ Inventor or Joint Inventor

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)

SIGNATURE of Applicant for Patent

Signature		Date	June 10, 2013
Name	Anthony TINARI	Telephone	(609) 514-2303
Title and Company	Vice President & General Counsel for Bracco Diagnostics Inc.		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.

☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 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 FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: 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.

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.

Doc Code: TRACK1.REQ
Document Description: **TrackOne Request**

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Stephen E. Hidem	Nonprovisional Application Number (if known):	
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ **Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ **Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Paul J. LaVanway, Jr./	Date 2014-08-08
Name (Print/Typed) Paul J. LaVanway, Jr.	Practitioner Registration Number 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.**

☐ *Total of _____ 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/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

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.)

Inventor Information:

Inventor 1 Remove

Legal Name

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 i	US

Mailing Address of Inventor:

Address 1	4710 Juneau Lane North
Address 2	

City	Plymouth	State/Province	MN
Postal Code	55446	Country i	US

Inventor 2 Remove

Legal Name

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 i	US

Mailing Address of Inventor:

Address 1	5663 West Bavarian Pass
Address 2	

City	Fridley	State/Province	MN
Postal Code	55432	Country i	US

Inventor 3 Remove

Legal Name

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

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	

Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

City	New Albany	State/Province	IN	Country of Residence i	US

Mailing Address of Inventor:

Address 1	4204 Shetland Court		
Address 2			
City	New Albany	State/Province	IN
Postal Code	47150	Country i	US

Inventor 4 Remove

Legal Name

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 i	US

Mailing Address of Inventor:

Address 1	15395 Nicholas Street		
Address 2			
City	Omaha	State/Province	NE
Postal Code	68154	Country i	US

Inventor 5 Remove

Legal Name

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 i	US

Mailing Address of Inventor:

Address 1	1312 Judy Reagan Lane		
Address 2			
City	Knoxville	State/Province	TN
Postal Code	37931	Country i	US

Inventor 6 Remove

Legal Name

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	Silver Spring	State/Province	MD	Country of Residence i	US

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	

Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR

Mailing Address of Inventor:

Address 1	1812 Pelling Ct.		
Address 2			
City	Silver Spring	State/Province	MD
Postal Code	20905	Country i	US

Inventor 7 Remove

Legal Name

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 i	US

Mailing Address of Inventor:

Address 1	3 Tigers Court		
Address 2			
City	Mercerville	State/Province	NJ
Postal Code	08619	Country i	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 SYSTEM WITH RADIOISOTOPE DETECTOR		
Attorney Docket Number	56782.1.7.15	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	27	Suggested Figure for Publication (if any)	

Filing By Reference :

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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).
Either enter 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.
When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	12808467	2010-06-16
Prior Application Status	Expired		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

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCT/US2009/047	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/US2009/047	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/US2009/047	Continuation of	12137377	2008-06-11	8708352	2014-04-29

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

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. 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(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

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

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(●) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	Bracco Diagnostics Inc.

Mailing Address Information:

Address 1	259 Prospect Plains Road, Building H		
Address 2			
City	Monroe Township	**State/Province**	NJ
Country i	US	Postal Code	08831
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. [ ]

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7.15
	Application Number	
Title of Invention	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR	

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Remove

Signature:

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

Signature	/Paul J. LaVanway, Jr./			Date (YYYY-MM-DD)	2014-08-08
First Name	Paul J.	Last Name	LaVanway, Jr.	Registration Number	64610

Additional Signature may be generated within this form by selecting the Add button. Add

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:

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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.

22859
Customer Number

PATENT
Attorney Docket No.: 56782.1.7.15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Examiner:	Unknown
Title:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR		

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

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. § 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08a. Copies of the references listed that are not enclosed herewith are of record in Application No. 12/808,467, filed June 16, 2010, from which the present application derives priority. In accordance with 37 CFR § 1.98(d), applicant is not enclosing additional copies of these references. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This information is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required.

By submitting these references, Applicant does not admit that the references are prior art to or material to this application, and reserves the right to establish that any reference is not prior art. Applicant does not represent that the references have been reviewed in detail; there may be details in the references of which Applicant is unaware.

Dated: August 8, 2014

Respectfully submitted,

/Paul J. LaVanway, Jr./

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

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Telephone: (612) 492-7387
Facsimile: (612) 492-7077

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

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
First Named Inventor/Applicant Name:	Stephen E. Hidem
Filer:	Paul J. LaVanway Jr./Sarah Munson
Attorney Docket Number:	56782.1.7.15

Filed as Large Entity

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Claims in Excess of 20	1202	4	80	320
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**6060**

Electronic Acknowledgement Receipt

EFS ID:	19819937
Application Number:	14455623
International Application Number:	
Confirmation Number:	1068
Title of Invention:	INFUSION SYSTEM WITH RADIOISOTOPE DETECTOR
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:	56782.1.7.15
Receipt Date:	08-AUG-2014
Filing Date:	
Time Stamp:	17:46:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$6060
RAM confirmation Number	4148
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_15_IDS_8-8-14.PDF	618086 b24cf435657fa0606457cc9c17057b9aaa546c42	no	20
Warnings:					
Information:					
2	Drawings-only black and white line drawings	56782_1_7_15-Bracco-FIGS.PDF	344672 2184d8929a5a2dd2f06d0cb80338f1965e853fa47	no	27
Warnings:					
Information:					
3		56782_1_7_15-APP.pdf	201756 ee61089b520ac5ade4fe285b3eac0310f251a854	yes	37

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	33
	Claims	34	36
	Abstract	37	37

Warnings:					
Information:					
4	Power of Attorney	56782_1_7_15_POA.pdf	934454 89b99cbff3bdbe6da87216e798757abf4f560d68	no	3
Warnings:					
Information:					
5	TrackOne Request	56782_1_7_15-Bracco-TrackOneRequest.PDF	130020 347a51552d31758ebfd31936774d5cfe9216720d	no	2
Warnings:					
Information:					
6	Application Data Sheet	56782_1_7_15-Bracco-ADS.PDF	1562309 7979007d54027e058584b9dcad7bd97d59df1883	no	9
Warnings:					
Information:					
7	Transmittal Letter	56782_1_7_15_IDS_COMM_filed-8-8-14.pdf	115782 3556d7659db07d2c998de92087eba09d5e98ac57	no	2
Warnings:					
Information:					

8	Non Patent Literature	NPL_56782_1_7_16_APP.pdf	542666 eb7005c37f7376c41b5b7514b94cb8c86ae2a478	no	66
Warnings:					
Information:					
9	Non Patent Literature	NPL_14290765.pdf	3304416 1326a860b13a1f9864796bbf02b2cfcfe38e12a4	no	67
Warnings:					
Information:					
10	Non Patent Literature	NPL_61952270.pdf	1733174 0772c46a9a60663329be59b5734c145e45c7b85c	no	30
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	40208 d93eef58e1ffe440ea6a452b49b8c6cb24b36c5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	9527543		

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.