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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8

CONFIRMATION NO. 7402

POWER OF ATTORNEY NOTICE

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

OC000000068219661

Date Mailed: 05/06/2014

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/29/2014.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/sleutchit/

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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/137,377	06/11/2008	Charles R. Quirico	RB116 US

CONFIRMATION NO. 7402

31834
Bracco Research USA Inc.
c/o Bracco Diagnostics Inc.
259 Prospect Plains Road
Building H
Monroe Township, NJ 08831

POA ACCEPTANCE LETTER

OC000000068219669

Date Mailed: 05/06/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/29/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/sleutchit/

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

PTO/SB/81A (12-08)
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PATENT - POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Patent Number	8,708,352
Issue Date	4/29/2014
First Named Inventor	Charles R. QUIRICO
Title	Cabinet Structure Configurations For Infusion Systems
Attorney Docket Number	RB116 US

I hereby revoke all previous powers of attorney given in the above-identified patent.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 31,834

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified patent 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:

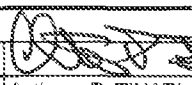
☐ Inventor, having ownership of the patent.

OR

☒ Patent owner.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Inventor or Patent Owner

Signature		Date	4/29/2014
Name	Anthony P. TINARI	Telephone	(609) 514-2303
Title and Company	Vice President & General Counsel for Bracco Diagnostics Inc.		

NOTE: Signatures of all the inventors or patent owners of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, 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.**

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

PTO/SB/96 (07-09)
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RB116 US

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Bracco Diagnostics Inc.

Application No./Patent No.: 8,708,352 Filed/Issue Date: 4/29/2014

Titled: Cabinet Structure Configurations For Infusion Systems

Bracco Diagnostics Inc. , a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. ☐ the assignee of the entire right, title, and interest in;

2. ☐ an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is _____ %); or

3. ☒ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy therefore is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: inventors: E.B., J.C., D.C., P.M., C.Q. To: Bracco Diagnostics Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 022011 , Frame 0371 , or for which a copy thereof is attached.

2. From: Janet L. GELBACH To: Bracco Diagnostics Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 024712 , Frame 0042 , or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____ , Frame _____ , or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/M. Caragh Noone, Reg. No. 37,197/ — Signature

April 29, 2014 — Date

M. Caragh Noone — Printed or Typed Name

US Chief Patent Counsel for Bracco Research USA Inc. — Title

Privacy Act Statement

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

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:
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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: 31,834

OR

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

PATENT NUMBER (if known)	APPLICATION NUMBER
8,708,352	12/137,377

Completed by (check one):

☐ Applicant/Inventor — /M. Caragh Noone, Reg. No. 37,197/ (Signature)

☑ Attorney or Agent of record 37,197 (Reg. No.) — M. Caragh Noone, Reg. No. 37,197 (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) — (609) 514-2454 (Requester's telephone number)

☐ Assignee recorded at Reel _____ Frame_____ — April 29, 2014 (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

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

Electronic Acknowledgement Receipt

EFS ID:	18888107
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Mary Caragh Noone/Pamela Gewirtz
Filer Authorized By:	Mary Caragh Noone
Attorney Docket Number:	56782.1.8
Receipt Date:	29-APR-2014
Filing Date:	11-JUN-2008
Time Stamp:	12:54:59
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	Miscellaneous Incoming Letter	4-29-14_a_transmittal_sb21_RB116-US.pdf	265680 8faed0cfdbfdb556953a2746c31aa0752b03b322	no	2

Warnings:	
Information:	

2	Power of Attorney	4-29-14_b_sb81a_Revoke-w-NewPoA_xcuted_RB116-US.pdf	147475 64966a1a6b7b7f9971d02d04e07a3daf98dc9acc	no	2
Warnings:					
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3	Assignee showing of ownership per 37 CFR 3.73.	4-29-14_c_sb96_stmnt3-73b_RB116-US.pdf	842975 101e69415347b80e7396fbf9ee1161ace040230f	no	2
Warnings:					
Information:					
4	Maintenance Fee Address Change	4-29-14_d_sb47_FeeAddressIndication_RB116-US.pdf	205152 20d38763abef4f0e782c1ef4e115f6c6806d5c7b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1461282		

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.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	8

Application Number	12/137,377, now US 8,708,352
Filing Date	6/11/2008, issued 4/29/2014
First Named Inventor	Charles R. QUIRICO
Art Unit	3618
Examiner Name	Erez GURARI
Attorney Docket Number	RB116 US

ENCLOSURES (*Check all that apply*)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☑ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Forms PTO/SB/81A and PTO/SB/96; and PTO/SB/47: Fee Address Indication form

Remarks

No fee is believed due: Revoke with New Power of Attorney; Corr & Fee Address so MF statements are mailed to Customer No. 31,834. However, if any fees are deemed necessary, the Director is hereby authorized to charge any required fees and credit any overpayments to Deposit Account No. 50-2168.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature	/M. Caragh Noone, Reg. No. 37,197/		
Printed name	M. Caragh Noone		
Date	April 29, 2014	Reg. No.	37,197

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Electronically Filed Using the EFS-WEB Electronic Filing System of the United States		
Typed or printed name	Patent and Trademark Office on:	Date	April 29, 2014

This collection of information is required by 37 CFR 1.5. 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 and1.14. This collection is estimated to 2 hours 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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	04/29/2014	8708352	56782.1.8	7402

22859 7590 04/09/2014

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 845 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):

Charles R. Quirico, Warren, NJ;
Ernest Balestracci, Iselin, NJ;
Jacob S. Childs, Minneapolis, MN;
Peter B. Madson, Shanghai, CHINA;
Daniel V. Clements, Minneapolis, MN;
Janet L. Gelbach, New Albany, IN;

CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

RELATED APPLICATIONS

[01] The present application is related to the following commonly assigned utility patent applications, all of which are filed concurrently herewith and all of which are hereby incorporated by reference in their entireties: ~~Practitioner Docket No.~~ 12/137356 56782.1.5, entitled: SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS; ~~Practitioner Docket No. 56782.1.6~~ 12/137363, entitled: INFUSION SYSTEM CONFIGURATIONS; and ~~Practitioner Docket No. 56782.1.7~~ 12/137364, entitled: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE.

Change(s) applied to document, /T.C.T./ 5/3/2012

TECHNICAL FIELD

[02] The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to cabinet structures supporting the systems.

BACKGROUND

[03] Nuclear medicine employs radioactive material for therapy and diagnostic imaging. Positron emission tomography (PET) is one type of diagnostic imaging, which utilizes doses of radiopharmaceutical, 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).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	20110209764		2011-09-01	Uber	

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	1	244513	SU		1969-12-31	Bogoudinov		☐
	2	2288755	RU		2006-12-10	Shchetinin		☐
	3	2131273	RU		1999-06-10	Sajens		☐

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Receipt date: 11/08/2013	Application Number	12137377 12137377 - GAU: 3618
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	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
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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]
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Examiner Signature	/Erez Gurari/	Date Considered	03/31/2014

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☒ See attached certification statement.

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☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-11-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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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Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Gurari, Erez
Attorney Docket Number	56782.1.8

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Receipt date: 01/02/2014	Application Number	12137377	12137377 - GAU: 3618
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	First Named Inventor	Charles R. Quirico	
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	Examiner Name	Gurari, Erez	
	Attorney Docket Number	56782.1.8	

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-01-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Gurari, Erez
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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2014-01-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 319 148 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **88310567.8**

(51) Int. Cl.[4]: **G06F 12/08**

(22) Date of filing: **10.11.88**

(30) Priority: **30.11.87 US 127000**

(43) Date of publication of application:
07.06.89 Bulletin 89/23

(84) Designated Contracting States:
DE FR GB

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(54) Method of operating a multi-processor system for the transfer of data between processor units.

(57) A method for minimising I/O mechanical assess operations on secondary storage devices in a data processing system having a plurality of processor units interconnected in a cluster configuration to permit each processor unit to request and obtain data that is resident only on a secondary storage device of one processor unit. The method involves the steps of maintaining at each processor unit information about each copy of data that has been sent from the unit to another unit to permit a second request to the unit to be serviced by transferring a copy of the data from the main memory which is storing the data to the requesting unit rather than servicing the request with a relatively slow I/O accessing operation to a secondary storage device.

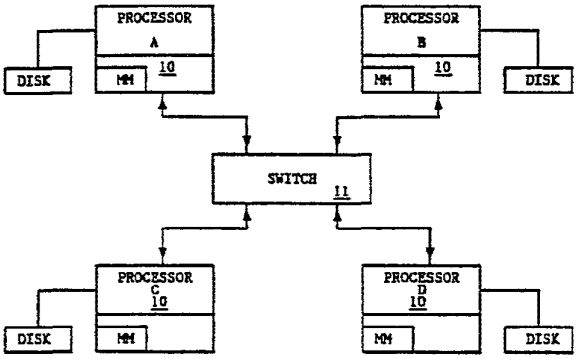

FIG. 1

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METHOD OF OPERATING A MULTI-PROCESSOR SYSTEM FOR THE TRANSFER OF DATA BETWEEN PROCESSOR UNITS

This invention relates in general to data processing systems comprising a plurality of similar interconnected data processing units which share the same virtual memory addressing space and in particular to an arrangement for reducing disk I/O access by each of the processing units.

A related application, European Published Application No. A-229691, is directed to a method for use in a multi-user page segmented virtual memory data processing system in which a mapped file data structure is selectively created to permit all I/O operations to the secondary storage devices to be executed by simple load and store instructions under the control of the page fault handler.

The prior art has disclosed a number of virtual memory data processing systems which employ a single stand alone Central Processing Unit (CPU). These systems generally employ a main memory having a plurality of individually addressable storage locations, each of which stores one byte of data and a secondary storage device such as a Disk File which includes a plurality of block addressable storage locations each of which stores a block of data. For discussions purposes it is convenient to assume that each block address of the disk file stores a page of data comprising for example 2K (2048) bytes of data. The virtual memory concept involves what is sometimes referred to as a single-level store. In a single-level store, the maximum address range of the system is generally much larger than the real capacity of the main memory. The main memory is made to appear much larger by the use of a paging mechanism and a secondary storage device which cooperate to keep the data required by the application program in main memory. The function of the paging mechanism is to transfer a page of data from the disk file to main memory whenever a page which is addressed by the application program is not in main memory. This is called a page fault. Transferring the page of data from the disk file to main memory is called page fault handling.

The performance of a virtual memory data processing system is directly related to the number of disk accesses that occur in servicing page faults since accessing a disk is a relatively slow process typically requiring several milliseconds, whereas accessing main memory typically involves less than a single microsecond. Prior art virtual memory systems therefore employ various techniques to reduce disk accesses and increase the percentage of "hits" that are made in addressing virtual memory. A hit is made in addressing virtual memory if data addressed by an application program is in main memory at the time the application program addressed the data. The hit ratio r of a virtual memory system is the number of hits h in addressing virtual memory divided by the number of hits h plus misses m, or

$$r = h / (h + m)$$

The prior art has also disclosed a number of multi-processor system configurations that are sometimes employed to obtain increased data processing power. A multi-processor system configuration may be thought of as a plurality of processing units sharing a logical communication channel. The logical communication channel may take the form of memory shared among the processing units into which messages from the processing unit to another processing unit may be placed. Additionally, the logical communication channel may take the form of a communication network through which from one processing unit to another processing unit may travel. In some prior art multi-processor system configurations referred to as tightly-coupled multi-processor configurations, the processing units in the configuration share some amount of memory which any of the processing units in the configuration may access, and each processing unit may have some amount of private memory which only it and no other processing unit may access.

Computing systems arranged in a tightly-coupled multi-processor configuration have the benefit of rapid communication via shared memory and may also exploit the shared memory as a disk cache. A page fault may occur when an application program executing on one of the processing units in a tightly-coupled multi-processor configuration addresses a page of data that is not in main memory. During page fault handling, the appropriate secondary storage device connected to the configuration is commanded to place the appropriate page of data into the shared memory. Once the page of data has been placed in the shared memory it may be addressed by any of the processing units in the configuration.

If the plurality of processing units in a multi-processor configuration are working on a common problem, it is normal for the data they access to be accessed in such a way as to experience "locality of reference". The term locality of reference is used when there is some non-zero probability that a page of data retrieved from secondary storage and placed in shared memory to satisfy a page fault resulting from an access to

virtual memory by an application program executing on one processing unit in the configuration will also be accessed by another application program executing on another processing unit in the configuration before the page frame in shared memory holding that page of data has been re-used by the configuration to hold another page of data. If such an access by another application program executing on another processing unit in the configuration occurs, the configuration may avoid a disk access by satisfying the page fault with that page of data already in shared memory.

A practical limit however is reached for tightly-coupled multi-processor configurations when the contention for access to shared memory among the processing units in the configuration exceeds the benefit provided by the shared memory when used as a disk cache. For instance, one processing unit in the configuration may attempt to change the contents of a page of data while another processing unit is attempting to examine the contents of the same page of data. Some mechanism must normally be provided by the configuration to lock out one of the processing units in favour of the other so that the two processing units see a consistent view of the data.

Various methods exist in the prior art to enforce a consistent view of data upon the processing units in a tightly-coupled multi-processor configuration. These methods involve idling one of the processing units in the configuration until the other processing unit has completed its access to shared memory. The processing unit that has been idled cannot be idle and also perform useful work; thus, contention for access to shared memory inevitably results in some loss of processing power for the configuration when considered as a whole. For these reasons, the number of processing units in a single tightly coupled multi-processor configuration rarely exceeds six. In some other prior art multi-processor system configurations referred to as closely-coupled multi-processor configurations, the plurality of processing units is connected via a communications network and each processing unit may access its own memory directly and so other processing unit has access to that memory. The processing units in a closely-coupled multi-processor configuration may share data by sending messages via the communications network to other processing units within the configuration. A variation on the closely-coupled multi-processor configuration distinguishes one of the processing units in the configuration as a shared memory processing unit. The main memory attached to the shared memory processing unit is used as a disk cache managed by the shared memory processing unit. The shared memory processing unit is assigned the function of controlling which of the other processing units can have access to what area of the shared memory at what time and under what configurations. When the shared memory is a virtual memory involving a fast main memory which is required to obtain a respectable hit ratio is directly related to the total number of instructions that are being executed by the multi-processor configuration per second. Individual processing units are sometimes rated in Millions of Instructions Per Seconds (MIPS). If two 4 MIPS processing units and a third shared memory processing unit are employed in a closely-coupled multi-processor configuration, the main memory associated with the configuration must have approximately 80 megabytes of byte addressable memory to obtain a respectable hit ratio. The rule of thumb that is used is that 10 megabytes of byte addressable main memory per MIPS is required to obtain an 85 percent hit ratio in the shared memory. Therefore, if another 4 MIPS processing unit is added to the multi-processor configuration, another 40 megabytes of the shared memory processing unit to maintain the 85 percent hit ratio. A practical limit however is reached in the number of processing units that can be added to the configuration before the cost parameters and performance reach the point of diminishing returns.

More recently stand alone personal computers or stand alone engineering work stations have been configured into local area networks. In such an arrangement, which is called a loosely-coupled multi-processor configuration or a distributed system configuration or a cluster configuration, any work station can communicate with another work station employing standard communication protocols. The motivation that exists for establishing the cluster configuration is not necessarily more data processing power, but simply one of the convenience of exchanging information electronically vs. non-electronic exchange. However, it has been found insome situations that the individual work stations are running the same operating system and at times run the same application programs. A paper entitled "Memory Coherence is Shared Virtual Storage Systems" authored by Kai Liand Paul Hudak and presented at the 5th Annual Association for Computing Machinery Symposium on Principles of Distributed Computing 1986, discloses a plurality of virtual memory data processing units interconnected in a cluster configuration. In this arrangement all units have the same operating system and address the same virtual address space. Each unit is the owner of a different set of files which is stored in that owner's memory system. A non-owner running an application program obtains access to the other unit's memory system through a suitable communication link, which causes requests to the file owner for virtual pages of data which are then returned to the requester.

Each unit of the cluster configuration therefore shares the set of files in its virtual memory system with the other units in the configuration. Page faults resulting from requests are serviced by the file owner. If the

request is local, that is from the owner, the requested page is transferred from the owner's secondary storage directly to the owner's main memory. If the request is from a remote unit, the page is transferred from the owner's secondary storage to the requester's main memory through the communication link. A system protocol is established to control what happens to pages of data after the requesting unit is finished with them. This protocol addresses such issues as, when to return a page to the owner, how to manage concurrent requests for the same page if one unit wants to write to that page while other units want to read from that page, and various other situations that are common to functions that share stored data.

The sharing by each processing unit of its virtual memory with other processing units in the cluster has some potential advantages in that the size or capacity of the secondary storage devices can be reduced since the total number of files available to the cluster is spread out among a number of secondary storage devices. This would permit the use of devices with faster access times and/or lower cost. A potential disadvantage is that concurrent requests from a number of different units to an owning unit will each result in a number of disk accesses to occur in sequence. While the requests are generally serviced in an overlapped manner, a disk access is a relatively time consuming operation for the unit and could severely impact the performance of the owning unit which is perhaps executing an unrelated application program, that is competing for the services of the secondary storage device.

The present invention is directed to an arrangement for use by a shared virtual memory, cluster configured, data processing system in which the number of page faults requiring access to the secondary storage devices is considerably reduced.

According to the invention, there is provided a method of operating a data processing system comprising at least three inter-coupled processor units, each having a main memory and a secondary data storage device, said system including a switch system for selectively interconnecting any pair of the units for the transfer of data stored in the main memory of the second of the pair in response to requests from the second unit, comprising the steps of:

maintaining at each unit a list of files stored in the system and indications of the unit storing each file and coordinating access thereto;

opening a specified file stored at a first unit of a pair in response to a request for specified data from the second unit of the pair;

transferring the specified data requested by the second unit from the secondary storage device of the first unit to the main memory of the second unit in the pair; and

if said request has been initiated by a request for said specified data from a third unit to said second unit, transferring a copy of said specified data from the main memory of the second unit of the pair to the main memory of the third unit.

In an embodiment of the invention to be detailed later, the individual processor units within a cluster of multi-processors, individually coordinate access to multiple segments of the common virtual memory address space. Each segment of virtual memory is logically composed of 128K (131,072) pages, each of which is composed of 2K (2048) bytes of memory. The processor units within the cluster share these virtual memory segments among other processor units within the cluster. A single processor unit serves as the access coordinator of a given file of data assigned to a specified virtual memory segment. Other processor units that use the virtual memory segment are individually called "using processor units". The strategy of the method to implement consistent access to cached pages of virtual memory basically comprises four important aspects.

1. The ownership of a page changes dynamically with its use; thus the right to update a page may be assigned by the access coordinator for the segment containing the page to a given using processor unit and remains with that processor unit until contention for the page requires it to be revoked by the access coordinator for the segment containing that page and assigned processor unit.

2. Ownership of one portion of page implies ownership of the entire page. If, for example, a processor unit accesses the first byte on a page and that unit is granted the capability of accessing that byte, it is also granted the capability of accessing the entire page.

3. The coordination of access to a page is assigned statically and is the processor unit coordinating the segment containing the page.

4. The access coordinator for a given page records in the Virtual Shared Memory Table (VSMT) which processor units have a copy of the page, the access rights individual processor units hold (e.g., read only vs. read/write) and a list of other processor units that are seeking access to the page. The method involves recording at a segment's access coordinator, which pages of the segment are resident in the memory of which using processor unit. The using processor unit requesting access to a page avoids disk I/O by reading the page from a processor unit that has it in its memory system, rather than reading it from disk. In this way, the private memories attached to the individual processor units within the cluster are

virtually shared among each other.

The number of entries in the VSMT table are determined at cluster IPL time or at execution time, based on performance measurements and requirements. The number of VSMT entries is always bounded by the number of page frames of real storage in the cluster. For example, if a cluster consists of 16 processor units each of which has 16 megabytes of memory directly attached to it, there is a total of 2**17 frames in the cluster. If an entry for each frame were allocated to the VSMT in each processor unit, then 11 megabytes of storage would have to be allocated in each processor unit for the VSMT table. For practical purposes, the VSMT table never needs to be that large. The VSMT table does not need to represent pages in the real memory of the access coordinator since these pages are already represented in its page table. Only those pages of those segments, both code and data that are actually shared across the cluster and are in real memory at any given time, need to be represented in the VSMT table. Thus, only a fraction of physical memory frames will contain pages of shared segments at any given time, other frames containing non-shared pages need not be represented to the VSMT table.

The strategy to determine the number of entries in the VSMT table is to create it initially with a small number of entries and to let the number of entries grow with use.

The arrangement further employs "Triangular I/O" which is a scheme for performing I/O among two or more processors. In the unit processor view of the world, I/O is performed between a master unit, the processor and a "slave unit" (a control unit). The master sends requests to the slave, which processes them and responds to them. For example, a processor might send a request for a virtual page to some control unit for a set of disks. The control unit would handle the request by locating the appropriate blocks of data on its disks and transferring them back to the requesting processor. In a cluster, the concept of master and slave units is less clear. For example, a processor unit R might send a request to some of her processor unit Q for a page P stored on a disk device connected directly to processor unit Q. Processor unit Q might handle the request in the same way the control unit would or it might try to avoid a disk I/O by forwarding the request to another processor unit T that has a copy of the requested page in physical memory attached to it. Processor unit T might send the requested page to processor unit R rather than having to send it through processor unit Q. In this sense processor units R, Q and T are involved in a "Triangular I/O" with page P. Interprocess communication is reduced and a second I/O operation to a disk device is avoided.

The embodiment will now be described in detail, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a Functional Block Diagram of a plurality of processor units interconnected in a cluster configuration, in which the method of the present invention may be advantageously employed;

Fig. 2 is a Block diagram of one of the processor units shown in Fig. 1, illustrating the various functions that are incorporated in one of the units;

Fig. 3 is a Block diagram of one of the processing units shown in Fig. 1 illustrating the various software functions that are incorporated in the unit of Figs. 2 and 3;

Fig. 4 illustrates an External Page Table (XPT) data structure employed by the Virtual Memory Manager function of the unit shown in Figs. 2 and 3;

Fig. 5 illustrates an Inverted Page Table structure employed by the Virtual Memory Manager function of the unit shown in Figs. 2 and 3;

Fig. 6 illustrates the Global and Local Segment Identifier data structures which uniquely identify virtual memory segments;

Fig. 7 illustrates the Virtual Shared Memory Table (VSMT) data structure;

Fig. 8 illustrates the VSMT hash anchor table;

Fig. 9 shows a model of a shared map file and the segments associated with it;

Fig. 10 is a block diagram of a basic cluster configuration which is one environment employed to describe some typical operations that are performed;

Fig. 11 is a flow chart illustrating the steps for creating a new file that is stored on one of the processing units in the cluster;

Figs. 12a and 12B show a flow chart illustrating how an existing file is opened by an application program running on a processing unit within the cluster.

Fig. 13 is a flow chart illustrating how an existing file is loaded into the virtual memory shared in a cluster configuration;

Fig. 14 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit wishes to page-in a copy of a page that is not in the memory of the processing units in the configuration;

Fig. 15a and 15b show a flow chart illustrating the detailed steps of how the VSMT is updated by the access coordinator when a page of data is transferred from one processing unit to another processing unit;

Fig. 16 is a flow chart illustrating the steps performed by the access coordinator when a using processor unit sends a request to cast a page of its main memory and there is a copy of the page in the memory of another processing unit;

Fig. 17 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast a page out of its main memory and there is no copy of the page in the memory of any other processing unit; and

Fig. 18 is a flow chart illustrating the steps performed by the access coordinator when it determines that a given page of data must be cached by a shared processing unit.

Fig. 1 is a block diagram of a multi-processor cluster configured data processing system in which the method of the present invention may be advantageously employed. As shown in Fig. 1, the data processing system comprises a plurality of processor units 10, a switch 11 and a plurality of communication links 12, each of which connects one processor unit 10 to switch 11. The function of switch 11 is to permit any processor unit 10 to communicate with any other processor unit. The specific details of the switch and the communication links are not considered relevant to an understanding of the present invention and hence are neither shown nor described in detail. Examples of the switching arrangement that may be employed may be found in U.S. Patents 4,635,250; 4,633,394; 4,630,015; 4,605,928.

Fig. 2 illustrates in detail one of the processor units 10 shown in Fig. 1. Processor unit 10 may be high function personal computer or an engineering work station such as the IBM PC RT running a Unix (T.M.) type operating system such as the IBM AIX (T.M.) operating system. The processor unit 10, as shown in Fig. 2, comprises a microprocessor 16, a main memory management unit 18 which controls the transfer of data between the processor 16 and memory 17, and a plurality of I/O adapters or ports 20A-20E. Ports 20A and 20B function to connect display type terminals 21 and 22 to the system. Port 20C connects a printer to the system while port 20D connects disk drive 24 to the system. The communication port 20E is employed to connect the processor unit 10 to the communication link 12. For purposes of discussion, processor unit 10 corresponds generally to the virtual memory data processing system that is described in detail in cross referenced application Serial Number 819,458. As described in that application, the processor has a 32 bit effective address that is converted into a 40 bit virtual address by employing the 4 high order bits 31-28 to select one of 16 segment registers, each of which stores a 12 bit segment address that defines one of 4096 unique segments. Each segment comprises 256 megabytes of storage (2**28). If a page includes 2K bytes of data, then a segment contains 128K pages. On the other hand, if a page includes 4K bytes of data, the segment then has 64K pages, or more precisely, 64K virtual addresses which may be used to identify pages of data that are currently assigned to that segment.

As explained in the cross referenced to application, a Unix type operating system is employed for the processor unit so that application programs and data employed by these programs are organised in accordance with the Unix file system type of organisation. Existing files are stored on the secondary storage devices of the processor unit which may be assumed to be a disk file. The unit of storage or addressability of the disk file is a disk block, which for purposes of discussion, will be assumed to store one page of data. Unix read and write system calls function to control the transfer of data between main memory and disk storage.

In a virtual memory organisation, the memory manager and a page fault handling mechanism also function to control the transfer of pages between the disk file and main memory in response to load and store type of instructions being executed by the application program. In the system disclosed in the cross referenced application, the operating system is provided with a Map Page Range Service (MPRS) which functions to map a file into an assigned segment of the virtual address space.

The MPRS employs an External Page Table (XPT) data structure in which the disk block address containing a page of a file is assigned a virtual address in the assigned segment. The memory manager also employs an Inverted Page Table (IPT) data structure for correlating real addresses in main memory where a page of data is stored to a virtual address assigned to that page. The system disclosed in the cross referenced application also employed a way to convert read and write system calls in the operating system to load and store instructions having virtual address which reflected the system call parameters and the Unix offset pointer in the file. All disk I/O operations were therefore under control of the memory manager and page fault handling mechanism in the system of the cross referenced application.

The operation of the processor unit 10 in executing an instruction for an application program is briefly as follows. The virtual address of the instruction is hashed with a suitable hashing algorithm to provide an index into a Hash Anchor Table (HAT). The indexed entry in the HAT contains a pointer to the first entry in

a list of virtual addresses that hash to the same value. If a page having a virtual address that would hash to the value that provides the pointer to the list is in real memory, then the virtual address is on the list. The page frame in real memory where the page of data is stored is obtained from the entry in the list containing the virtual address. If the virtual address is not on the list, the corresponding page is not in real memory and a page fault has occurred.

The page fault handling mechanism is then activated. By referencing the XPT entry created when the file was mapped, the page fault handling mechanism locates the disk block address where the page having the requested virtual address is stored. Since the XPT is not pinned in memory, the page fault handling mechanism may encounter a page fault when it first references in XPT. However, once the appropriate page of XPT entries is paged into memory, the original page fault can be serviced. The page is transferred to a page frame in memory that has been available and the application process is restarted.

It should be understood that the virtual memory manager operation summarised above is just one of the many prior art virtual memory management functions that can be used in the processor unit shown in Fig. 1 and on which the method of the present invention relies.

As indicated in Fig. 1, the units are interconnected by switch 10 and communication links 12 to permit one unit to be selectively interconnected in a data transferring relationship with one other unit. As stated earlier, communication port 20E is the normal interface to communication link 12 that is connected to the switch 11. A remote memory manager function is added to each unit 10 and provides an interface between port 20E and the native memory manager function 18. The function of the remote memory manager of processor unit 10A for example, is to process a request for a virtual page P of data from the remote memory manager function of processor unit 10B. The request is sent to processor unit 10A because 10A has been assigned as the access coordinator for that page and file. To process the request for page P, the remote memory manager function first determines if the requested page is in the main memory of the unit 10A. If the page P is there, a copy Pb is returned to unit 10B and a data structure referred to as the Virtual Shared Memory Table (VSMT) and shown in Fig. 7, records the fact that unit 10B has a copy of the requested page in its main memory. The remote request was initiated by unit 10B when an instruction having a virtual address was executed by unit 10B and recognised as involving a file that was stored at unit A. The manner in which the Access Coordinator of a file or a virtual page is recognised is discussed in detail later on the specification.

The above operation is a simple direct request and transfer operation involving two processor units. A slightly more involved operation occurs if it is assumed that the requested page Pa is paged out of the main memory of unit A so that the only copy in any main memory is the copy Pb that was previously sent to unit B. Assume now that C requests a copy of the same page from unit A. Unit A does have a copy of the requested page P on disk, but this would require a relatively long disk I/O operation to retrieve it and forward it to unit C. The remote memory manager of unit A in servicing the request from unit C would first check unit 10A's inverted page table and determine that it was not in the main memory of unit 10A. At this point, prior art systems would take the page fault and retrieve the page from disk. The new method, however, merely checks the SVMT data structure for the virtual address of the requested page Pb and is advised that a copy Pb is still in the main memory of unit 10B. The remote memory manager of unit 10A therefore sends a message to the remote memory manager of unit 10B, requesting that unit 10B send a copy of the page Pb to the remote memory manager of unit 10C. The initial request by unit 10C is said to have been serviced by a "triangular I/O operation." While a triangular I/O operation involves a number of messages including the transfer of a page of data, the time involved is at least 2 orders of magnitude faster with present day storage and communication technologies than would be involved in retrieving the requested page from unit 10A's disk file.

It should be noted that in the cluster shown in Fig. 1, each unit is running the same operating system and that preferably only one copy of each file exists in the cluster. Each file is assigned a processor unit which acts as the Access Coordinator for that file. The file is stored on the processor unit's secondary storage device. The file/access coordinator assignment can be established by the name given to the file similar to the convention employed by the PC-DOS operating system which uses drive and path parameters in the full name of the file. Alternately, a simple access coordinator table could be employed listing each file in the cluster along with the current access coordinator.

It should be assumed that in the following discussion, a page of data comprises 2**11 or 2K bytes (2048), that a segment consists of 2**17 or 128K pages (131,072). Since the virtual address space employed by the cluster is used by each processor unit, two new data structures and identifiers are employed. The Local Segment Identifier (LSID) shown in Fig. 6 uniquely identifies a segment with its access coordinator. The LSID comprises 12 bits.

The Global Segment Identifier (GSID) shown in Fig. 6 comprises 19 bits which uniquely identify the

processor unit within the segment. The GSID comprises an 7 bit processor ID portion and the 12 bit LSID. The VSMT data structure is shown in Fig. 7 and is similar in many respects and functions to an inverted page table used by each processor unit.

Each entry of the VSMT includes the following fields:

State Indicator	4 bits
Local Segment ID	24 bits
Page Number Within Local Segment	16 bits
Last Entry Indicator	1 bit
Processor ID	8 bits
Index of Next Entry on Hash Chain	31 bits

As discussed earlier, the inverted page table employed by each processor unit 10 functions to correlate page frame addresses in main memory with the virtual address of the page that is stored in the page frame. An inverted page table as shown in Fig. 5 has one entry for each page frame in its main memory. The data contained in each of the inverted page tables in the cluster is not per se duplicated in the VSMT that is stored by that processor unit. The function of the VSMT for a processor unit is to log entries that reflect that a virtual page which is being coordinated by that processor unit has been sent to another unit in the cluster. Stated differently, the VSMT for a processor unit is updated when a virtual page that the processor unit is coordinating is transferred to another processor unit of the cluster.

The VSMT for a processor unit 10 is a list of entries as shown in Fig. 7. Entry into the table is by an index stored in the system hash anchor table shown in Fig. 8. The index is to the first entry in the section of the table whose virtual addresses hash to the same value. These sections are referred to as hash value sections. Entries in each hash value section are sequenced in ascending order of Local Segment ID's. Within the same LSID, entries are sequenced increasingly by virtual page index. The hash value for a virtual address is obtained for example by hashing the LSID of the segment containing the page with the page's Virtual Page Index. The hash value is an index into the anchor table to provide a pointer to the head of the hash entries in the VSMT.

A shared mapped file consists of at least two virtual memory segments. At each using processing unit on which at least one application program has the file open there is one segment per open system call issued by an application program, and at the owning processing unit there is one segment. Figure 9 shows a model of a shared mapped file. The segment at using processing unit 10a is bound to the segment at owning processing unit 10b using the Bind Remote Segment Service (BRSS). All of the pages of processing unit 10a's segment are mapped read-write to the owning processing unit segment using the Map Remote Page Range Service (MRPRS).

To map a file, an application program first issues the open system call to open the file. The application program then issues the shmat system call to map the file into the application program's virtual address space. The shmat system call uses the Map Page Range Service (MPRS) to load the file into virtual memory. The application program can now directly access the file with load and/or store instructions. No other interaction with the operating system is required to access the file. When the application program is finished with the file, it can remove the file from its virtual address space by issuing the shmat system call. Alternatively, the program could just issue the close system call since the close system call will automatically perform the shmat system call as required.

Sharing of the data in a given mapped file is performed in a cluster environment by binding the using processing unit's segment associated with the open file to the owning processing unit's segment associated with the open file. Each using processing unit that has a file mapped into a virtual memory segment has one segment for each mapped file that application programs executing on it have opened. All application programs at a given using processing unit or the owning processing unit logically share the same segment. The owning processing unit's segment associated with the open file is the segment to which each using processing unit's segment associated with the open file is linked.

One of the requirements for sharing virtual memory segments across a cluster configuration is to ensure that updates to mapped files behave the same in both a stand alone configuration and a cluster configuration. This implies that each store instruction executed against mapped file must appear to be immediately applied to all copies of the mapped file shared throughout the cluster. This may be achieved by enforcing a set of consistency rules on access to mapped files.

These consistency rules are:

(1) At most one processing unit within the cluster configuration may have a copy of given page of the segment if one or more application programs executing on that processing unit is (are) writing into the page.

(2) Any number of processing units within the cluster configuration may have a copy of a given page of the segment if no application programs executing on any processing units in the cluster are writing into the page.

The virtual memory managers (VMMs) at the owning processing unit and the using processing units cooperate to enforce these consistency rules. Each VMM enforces these consistency rules by using a prior art hardware page protection mechanism. Each page in shared virtual memory has two page protection keys associated with it. The former key is the requested protection key specified using the Create Segment Service (CSS) or the Protect Page Service (PPS). This key is used to determine what type of memory access is valid for the page. The latter key is the effective protection key. This key is used to enforce the data consistency rules for shared mapped files.

Each page in a mapped file has one of three distinct consistency states at any given time. These consistency states apply to both using processing unit and owning processing unit shared mapped files. The consistency states for a given page of a mapped file that is shared across a cluster are recorded in the Virtual Shared Memory Table (VSMT) State Field (see Figure 7). A description of how the VSMT data structure is updated is described below. The consistency states are as follows:

NoAccess A copy of the page is in the main memory of the processing unit. Any access to the page by an application program will result in a page fault occurred interrupt to be signalled to the VMM. This state places no additional restrictions on the valid consistency states of a copy of the page at any other processing unit in the cluster.

ReadOnly A copy of the page is in the main memory of the processing unit and the copy of the page has not been modified since having been placed in main memory. The effective protection key for the page is read-only. A store access to the page will result in a page fault occurred interrupt to be signalled to the VMM if the requested protection key is read-write. A store access to the page will result in a protection exception occurred interrupt to be signalled to the VMM if the requested protection key is read-only. The former interrupt is used to inform the VMM that an application program attempted to access the page for writing. The latter interrupt is used to inform the VMM that an application program attempted to access the page for writing although it did not have permission to do so. This is generally considered an error condition, and appropriate error handling must be executed to handle the error in an appropriate way.

Other processing units within the cluster may access the same page for reading when the page is in the ReadOnly consistency state. No other processing units within the cluster may access the same page for writing when the page is in the ReadOnly consistency state.

ReadWrite A copy of the page is in the main memory of the processing unit and the page has been modified since it was placed in the main memory of the processing unit. The effective protection key for the page is read-write. An access to the page for either reading or writing will be allowed without causing a page fault occurred interrupt to be signalled to the VMM. An access to the page for reading may cause a protection exception interrupt to be signalled to the VM if the requested protection key does not allow read access to the page. An access to the page for writing may cause a protection exception interrupt to be signalled to the VMM if the requested protection key does not allow write access to the page. No other processing unit within the cluster may access the same page for either reading or writing when the page is in the ReadWrite consistency state.

The consistency state of a page may be effected by the occurrence of one of several different events. These events are: (1) accesses to the page by application programs executing on the same processing unit; (2) execution of the Purge Page Range (PPRS) at the same processing unit; (3) execution of the Purge Segment Service (PSS) at the same processing unit; (4) execution of the VMM page replacement mechanism at the same processing unit; and (5) changes to the consistency state of the page at another processing unit within the cluster. The VMMs executing at each of the processing units within a cluster cooperate to ensure that an occurrence of any of these events results in a valid transition of the page consistency state. The valid transitions allowed by the VMMs are:

NoAccess to ReadOnly This consistency state transition is triggered by a page fault occurred interrupt having been signalled to the using processing unit VMM resulting from a read access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for reading to the using processing unit VMM.

In some instances it may be desirable for the VMM at the using processing unit to "remember" the

previous consistency state for the page and treat this transition as if it were a write access to the page occurring when the consistency state of the page was ReadWrite instead of a read access to the page occurring when the consistency state of the page was NoAccess. This variation in protocol would prevent two consistency state changes when a write access to the page follows a read access to the page which in practice is often the case. If this variant protocol is adopted, upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for writing to the using processing unit VMM.

NoAccess to ReadWrite This consistency state transition is triggered by a page fault occurred interrupt being signalled to the using processing unit VMM resulting from a write access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send the data for the page along with permission to access the page for writing to the using processing unit VMM.

ReadOnly to ReadWrite This consistency state transition is triggered by a page fault occurred interrupt being signalled to the using processing unit VMM resulting from a write access to the page. Upon receipt of the page fault occurred interrupt, the using processing unit VMM sends a message to the owning processing unit VMM requesting that the owning processing unit VMM send permission to access the page for writing to the using processing unit VMM.

ReadOnly to NoAccess This consistency state transition is triggered when a page frame containing an unmodified page is reassigned by the using processing unit VMM to hold another page of data or when an unmodified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processing unit that has the file mapped for read-write attempts to access the page for writing.

ReadWrite to NoAccess This consistency state transition is triggered when a page frame containing a modified page is selected for replacement by the using processing unit VMM or when a modified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processing unit that has the file mapped for read-write attempts to access the page for writing. The using processing unit VMM sends the data contained in the page to the owning processing unit VMM along with notification that the using processing unit VMM has changed the consistency state for the page to NoAccess, and has purged the page from its main memory.

ReadWrite to ReadOnly This consistency state transition is triggered when a page frame containing a modified page is selected for replacement by the using processing unit VMM or when a modified page is purged using either the Purge Segment Service (PSS) or the Purge Page Range Service (PPRS), or when the owning processing unit VMM requested that the using processing unit VMM change the effective protection key for the page to NoAccess, which would occur if an application program executing at another using processor unit that has the file mapped for read-write attempts to access the page for writing. The using processing unit VMM sends the data contained in the page to the owning processing unit VMM along with notification that the using processing unit VMM has changed the consistency state for the page to ReadOnly, and has set the effective protection key to allow read-only access to the page.

The owning processing unit VMM ensures that a valid combination of consistency states exists at each of the nodes accessing the mapped file. This is achieved by having the owning processing unit VMM maintain a list of writers to each page that is managed under the owning processing unit's consistency control algorithm and by having the owning processing unit send requests to using processing units to change the consistency state of a given page of data. Any request by any using processing unit to access the page for reading will cause the owning processing unit to send a request to a using processing unit that has an application program executing on it that has written to the page to change the consistency state for the page from ReadWrite to ReadOnly. Any request by any using processing unit to send a request to a using processing unit that has an application program executing on it that has the page in the ReadWrite consistency state to change the consistency state for the page to NoAccess, or to send a request to each using processing unit that has the page in the ReadOnly consistency state to change the consistency state for the page to NoAccess.

The protocol for updating the various SVMT of each processor unit to reflect the processing of the pages that it is coordinating, by other processors units will depend to a large extent on the particular application. In some applications it may be more efficient to notify the Access Coordinator when the copy is

no longer in main memory of the requester so that the coordinator will not service another request by a triangular I/O operation involving that unit.

Likewise the protocol for protecting pages being written by more than one processor unit could take the form of many of the prior art protection schemes involving locking bits. The techniques discussed by A. Chang and M. Mergen in an article entitled "801 Storage: Architecture and Programming", presented in the Proceeding of the 1987 Conference of the ACM Special Interest Group on Operating Systems on November 26, 1987 may be employed.

Typical operations will now be described in connection with Figures 10. Figure 10 is a block diagram of a cluster configuration consistency of three processing units 10a, 10b, and 10c, a switch 11, and three communication links 12 that connect the processing units to the switch. Each of the processing units has a secondary storage device which may be thought of as a disk attached directly to it. Except for the contents of the files stored on the secondary storage devices attached to an individual processing unit, processing units 10a, 10b, and 10c should be thought of as identical. We shall use Figures 10 - 13 to illustrate typical operations in the cluster configuration. The description of these operations and the flow of messages is at a level of detail such that a person skilled in the art of implementing a software virtual memory manager component of a general purpose operating system will be able, without undue experimentation, to implement the method.

Figure 11 is a flow chart illustrating the steps for creating a new file that is stored on one of the processing units in the cluster.

In Step A of Figure 11, an application program executing on processing unit 10a uses the create (sic) system call to create the file "/u/smorgan/database se".

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system examines the "root" system directory. The system directories, individually contain lists of file names each with the name of the access coordinator for that file. We shall assume for the purpose of discussion that a UNIX file naming convention and directory structure is used, although persons skilled in the art will understand that this assumption is not necessary for the purpose of implementing the method. For example, the application program may have asked to create the file "/u/smorgan/database". The operating system examines the root system directory, called "/", and finds that it contains an entry for "u" and that u is a directory.

In Step D the operating system examines the u directory and determines that it contains an entry for "smorgan" and that smorgan is a directory.

In Step E the operating system examines the smorgan directory and finds that it does not contain an entry for "database". Steps C-E are called the directory lookup phase of the create system call.

In Step F the operating system determines which processing unit in the cluster is a good candidate to serve as the access coordinator for the file once it is created. The operating system uses some algorithm, whose exact working is unnecessary for an understanding of the method, to make a judicious choice. For example, the choice of an access coordinator might be based on a computation of which of the processing units is least heavily loaded with access coordinator duties for other existing files. By picking the least heavily loaded processing unit, the operating system might be making an assumption that the configuration will provide the best overall performance if the access coordination function is spread uniformly among the various processing units in the configuration.

After having chosen one processing unit in the configuration as the access coordinator for the to-be-created file /u/smorgan/database, which for the purpose of discussion is assumed to be processing unit 10c.

In Step G processing unit 10a sends message 1 to processing unit 10c to create the file.

In Step H, upon receipt of message 1 from processing unit 10a, processing unit 10c determines that the file does not yet exist within the configuration by examining the various shared directories in a way similar to that performed by processing unit 10a in the directory lookup phase (Steps C-E) of the create system call.

In Step I processing unit 10c creates the file and assigns it a file identifier FID. For the purpose of this discussion we shall assume that a file identifier is a 32 bit integer that uniquely identifies the file in the configuration. The file identifier may have been composed by concatenating the processing unit identifier for the access coordinator (processing unit 10c) with a number chosen by the access coordinator that uniquely identifies the file to the access coordinator. A processor identifier is a 7 bit integer that uniquely identifies a given processing unit within a cluster configuration.

In Step J processing unit 10c sends message 2 to each of the other processing units 10a and 10b in the configuration that the file identified by FID has been created. Message 2 includes the name of the file, its file identifier FID, and the processor identifier PID of the access coordinator.

In Step H, upon receipt of message 2 from processing unit 10c, each of the other processing units 10a and 10b updates its copy of the system directories to indicate the existence of the newly created file /u/smorgan/data base along with the file identifier FID and the access coordinator processor identifier PID for the file.

In Step K, upon receipt of message 2 from processing unit 10c, processing unit 10a determines that the file /u/smorgan/database has been created, and

In Step L 10A informs the application program executing on processing unit 10a that this is the case.

Figs. 12A and 12B is a flow chart illustrating how an existing file is opened by an application program running on a processing unit within the cluster.

In Step A of Figure 12, an application program executing on processing unit 10a uses the open system call to open the file "/u/smorgan/database" for read-write access.

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system examines the root system directory "/" and finds that it contains an entry for "u" and that u is a directory.

In Step D the operating system examines the u directory for "smorgan" and determines that smorgan is a directory.

In Step E the operating system examines the smorgan directory for "database" and determines: (1) that database is a file; (2) that the access coordinator for the file is processing unit 10c; and (3) that the file identifier FID is associated with the file. In step F the operating system executing at processing unit 10a sends message 1 containing file identifier by FID to processing unit 10c, requesting that the file identified by FID be opened on behalf of an application program executing on processing unit 10a.

In Step G, upon receipt of message 1 from processing unit 10a, processing unit 10c determines the location on its secondary storage device of file descriptor FD, which describes the file identified by FID. The processing unit 10c locates file descriptor FD by using file identifier FID to index into the File Descriptor Table (FDT) located at processing unit 10c. The FDT located at processing unit 10c contains a file descriptor for each existing file for which processing unit 10c serves as access coordinator. A file descriptor identifies the number and location of disk blocks on secondary storage devices attached to processing unit 10c that are part of a given file. In addition, a file descriptor contains other information about a file, such as its length, the time it was most recently accessed, the name of the its owner, etc. Persons skilled in the art will understand that the additional information contained in a file descriptor is irrelevant insofar as developing an understanding of the method is concerned; thus, it is not discussed.

In Step H processing unit 10c determines that the file identified by FID is not currently open, i.e. it does not currently have a local virtual segment associated with it.

In Step I processing unit 10c uses the Create Segment Service (CSS) to create a virtual memory segment for the file FID. In doing so, processing unit 10c specifies that the segment is to be created using file descriptor FD, and also that the requested protection key for the segment to be created is to be read-write. CSS returns a segment identifier S by which the segment it created may be identified.

In Step J processing unit 10c sends message 2 to processing unit 10a responding that processing unit 10c has successfully opened the file identified by FID on behalf of processing unit 10a. Message 2 identifies the segment identifier S as the segment associated with the file identified by FID.

In Step K processing unit 10a determines that the file identified by FID is not currently open, i.e. it does not currently have a local virtual segment associated with it.

In Step L processing unit 10a creates a local segment SA for the file identified by FID using the Create Remote Segment Service (CRSS). CRSS takes the segment identifier S and creates a "dummy" segment SA. A dummy segment is a local segment with a segment identifier and a Segment Identifier Table (SIT) entry, but without an External Page Table (XPT).

In Step M processing unit 10a uses the Bind Remote Segment Service (BRSS) to bind the local segment SA to the global segment S. BRSS takes the segment identifiers S and SA, the processor identifier PID of the access coordinator (processing unit 10c), and modifies the SIT entry associated with segment SA to indicate that segment SA relates to segment S whose access is coordinated by processing unit PID.

In Step N processing unit 10a determines that file /u/smorgan/database has been successfully opened and informs the application program that this is the case.

Fig. 13 is a flow chart illustrating how an open file is loaded into the virtual memory shared in a cluster configuration.

In Step A of Figure 13, an application program executing on processing unit 10a uses the shmat system call to map the local segment SA associated with the open file "/u/smorgan/database" into the application program's virtual address space for read-write access.

In Step B the operating system executing on processing unit 10a intercepts the system call from the application program.

In Step C the operating system determines that the local segment SA is bound to a remote segment S whose access is coordinated by processing unit 10c. Processing unit 10a makes this determination by examining the Segment Identifier Table (SIT) relating a given segment identifier for a currently open file to the appropriate remote segment for the currently open file and the processor identifier of the access coordinator associated with that segment.

In Step D processing unit 10a uses the Map Page Range Service (MPRS) to map the contents of segment SA into the virtual address space of the application program.

In Step E processing unit 10a determines that the file /u/smorgan/data base has been successfully mapped into the virtual address space of the application program and informs the application program that this is the case.

Fig. 14 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit wishes to page-in a copy of a page that is not in the memory of any of the processing units in the configuration. This description assumes for the purpose of discussion that:

(1) an application program executing on processing unit 10a has previously opened the file and had the file mapped into the application program's virtual address space; and

(2) that processing unit 10c serves as the access coordinator for the file.

In Step A of Figure 14 an application program executing on processing unit 10a attempts to access for reading page P of segment SL containing file F.

In Step B the application program page faults. In Step C the operating system executing on processing unit 10a intercepts the page fault and determines that it was caused by a read access to page P of segment SL by the application program.

In Step D processing unit 10a determines that segment SL is a remote segment whose access is coordinated by processing unit 10c.

In Step E processing unit 10a determines that segment SL is bound to remote segment SR.

In Step F processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10c send a copy of page P of segment SR to processing unit 10a.

In Step G, upon receipt of message 1, processing unit 10c examines its VSM Table looking for entries for page P of segment SR. Assume for the sake of discussion that exactly one entry exists in the VSM Table for page P of Segment SR, and that the entry indicates that processing unit 10b has a copy of the page in its memory, and that the ReadOnly consistency state is associated with that copy of the page.

In Step H processing unit 10c determines that segment SR is bound to segment ST in processing unit 10b.

In Step I processing unit 10c sends message 2 to processing unit 10b requesting that processing unit 10b send a copy of page P of segment ST to processing unit 10a and that the copy of the page have the ReadOnly consistency state associated with it. Message 2 further indicates that processing unit 10a refers to segment ST as segment SL.

Figs 15a and 15b is a flow chart illustrating the detailed steps of how the VSMT is updated by the access coordinator when a page of data is transferred from one processing unit to another processing unit. This description assumes for the purpose of discussion that: (1) an application program executing on processing unit 10a has previously opened the file and had the file mapped into the application program's virtual address space; and (2) that processing unit 10c serves as the access coordinator for the file.

In Step A of Fig. 15A an application program executing on processing unit 10a attempts to access for reading page P of segment SA containing the file F.

In Step B the application program page faults.

In Step C the operating system executing on processing unit 10a intercepts the page fault and determines that it was caused by a read access to page P of segment SA by the application program.

In Step D processing unit 10a determines that segment SA is a local segment bound to remote segment S whose access is coordinated by processing unit 10c.

In Step E processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10c send a copy of page P of segment S to processing unit 10a.

In Step F, upon receipt of message 1, processing unit 10c examines its VSM Table looking for entries for page P of segment S. We shall assume for the purpose of discussion that: (1) exactly one entry exists in the VSM Table for page P of Segment S; (2) the entry indicates that processing unit 10b has a copy of the page in its memory; (3) the ReadOnly consistency state is associated with that copy of the page.

In Step G processing unit 10c sends message 2 to processing unit 10b requesting that processing unit

10b send a copy of page P of segment S to processing unit 10a and that the copy of the page have the ReadOnly consistency state associated with it.

In Step H processing unit 10c adds an entry to its VSM Table indicating that processing unit 10a has been sent a copy of page P of segment S with the ReadOnly consistency state associated with it. In order to add an entry to the VSM Table for page P of segment S, the following steps must be performed by processing unit 10c:

(H1) Hash the segment identifier SR and the page number P together to locate the hash anchor table entry that would correspond to page P of segment SR if there were already an entry for this page in the VSM Table.

(H2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(H3) Follows the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10b. We shall refer to this below as entry E of the VSM Table.

(H4) Allocate an entry F in the VSM Table by taking an entry off the free-list of currently unused VSM Table entries. Allocating an entry in a data structure from a free list is well known, simple, and will be understood by a person skilled in the art of computer programming; therefore, it is not illustrated here.

(H5) Fill the appropriate values into entry F. Specifically, fill in:

(a) the Processor Identifier field with an integer that uniquely identifies processing unit 10a;

(b) the Page Number field with the page number P;

(c) the Local Segment Identifier field with the segment identifier S; and

(d) the State field with an integer that uniquely identifies consistency state ReadOnly.

(H6) Add entry F to the hash chain for the computed hash value. Perform this operation by:

(a) copying the Next Entry Index field of entry E into the Next Entry Index field of entry F; then

(b) copying the number F into the Next Entry Index field of entry E. After Step H6 has been completed, entry F is on the hash chain for the computed hash value.

In Step I, upon receipt of message 2 from processing unit 10c, processing unit 10b locates page P of segment S in its main memory.

In Step J processing unit 10b sends message 3 containing page P of segment S to processing unit 10a. Message 3 indicates that page P of segment S has the ReadOnly consistency state associated with it.

In Step K, upon receipt of message 3 from processing unit 10b, processing unit 10a places the copy of page P of segment S in its main memory, changes the virtual address of page P of segment S to indicate that the page is page P of segment SA, then sets the effective protection key for the page to ReadOnly.

Fig. 16 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast-out a page from its main memory.

In Step A of Fig. 16 processing unit 10a selects page P of segment SA for replacement. This would happen in the normal course of events if, for example, the virtual memory manager (VMM) component of the operating system executing on processing unit 10a determined that page P of segment SA had not been accessed by any application program for an extended period of time.

In Step B, processing unit 10a determines that page P is contained within segment SA, and that segment SA is a local segment bound to remote segment S whose access is coordinated by processing unit 10c.

In Step C processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step D, upon receipt of message 1 from processing unit 10a, processing unit 10c examines its VSM Table for all entries corresponding to page P of segment S. We shall assume for the purpose of discussion that: (1) exactly two entries exist in its VSM Table for page P of segment S; (2) the former entry indicates that processing unit 10a has a copy of page P of segment S in its memory in ReadOnly consistency state; and (3) the latter entry indicates that processing unit 10b also has a copy of page P of segment S in its memory, and that this copy is also in ReadOnly consistency state.

In Step E processing unit 10c determines that, since: (1) there are currently two copies of the page cached in the main memory of processing units within the cluster configuration; and (2) both copies of the page are in ReadOnly consistency state, then processing unit 10a may be allowed to cast page P of segment S out of its main memory without the significant degradation of performance that re-reading page

P of segment S from secondary storage might later incur.

In Step F processing unit 10c sends message 2 to processing unit 10a responding that processing unit 10a may cast page P of segment S out of its main memory.

In Step G, upon receipt of message 2 from processing unit 10c, processing unit 10a casts page P of segment S out of its main memory.

Figure 17 is a flow chart illustrating the steps performed by the access coordinator when a using processing unit sends a request to cast a page out of its main memory and there isn't a copy of the page in the memory of any other processing unit.

In Step A of Fig. 17 the VMM component of the operating system executing at processing unit 10a selects page P of segment SA as a candidate for replacement.

In Step B processing unit 10a sends message 1 to processing unit 10c requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step C, upon receipt of message 1 processing unit 10c examines its VSM Table for entries for page P of segment S. We shall assume for the purpose of discussion that no entry exist in its VSM Table for page P of segment S.

In Step D processing unit 10c determines that it has enough space in its main memory to hold page P of Segment S and allocates a frame for that purpose.

In Step E processing unit 10c sends message 2 to processing unit 10a requesting that processing unit 10a send a copy of page P of to processing unit 10c.

In Step F, upon receipt of message 2 from processing unit 10c, processing unit 10a sends message 3 containing page P of segment S to processing unit.

In Step G, upon receipt of message 3 from processing unit 10, processing unit 10c add page P of segment S to its main memory.

In Step H processing unit 10c updates its VSM Table indicating that a copy of page P with the ReadOnly consistency state associated with it, has been moved from processing unit 10a's main memory to processing unit 10c's main memory. In order to update the an entry in the VSM Table for page P of segments the following steps must be performed by processing unit 10c.

(H1) Hash the segment identifier S and the page number P together to locate the hash anchor table entry that would correspond to page P of segment S if there were already an entry for this page in the VSM Table.

(H2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(H3) Follow the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10a.

(H4) Update the processor identifier field of entry E with an integer that uniquely identifies processing unit 10c. after Step 4 has been completed Entry E has been updated.

Figure 18 is a flow chart illustrating the steps performed by the access coordinator when it determines that a given page of data must be cached by a shared memory processing unit.

In Step A of Fig. 18 the VMM component of the operating system executing at processing unit 10a selects page P of segment S as a candidate for replacement.

In Step B processing unit 10a sends message 1 to processing unit 10c, the access coordinator for segment S, requesting that processing unit 10a be allowed to cast page P of segment S out of its main memory.

In Step C, upon receipt of message 1 processing unit 10c examines its VSM Table for entries for page P of segment S. Assume for the purpose of discussion that no entry exist in its VSM Table for page P of segment S.

In Step D processing unit 10c determines that it does not have enough space in its main memory to cache page P of segment S. In Step E processing unit 10c determines that processing unit 10b is acting as a shared memory unit for the cluster configuration and sends message 2 to processing unit 10b requesting that processing unit 10b cache a copy of page P of segment S in its main memory, processing unit 10c.

In Step F processing unit 10c adds an entry to its VSM Table indicating processing unit 10b now holds a copy of page P of segment S with the ReadOnly consistency state associated with it. In order to add an entry in the VSM Table for page P of segment S the following steps must be performed by processing unit 10c.

(F1) Hash the segment identifier S and the page number P together to locate the hash anchor table entry that would correspond to page P of segment S if there were already an entry for this page in the VSM Table.

(F2) Determine whether the hash chain is empty. Perform this operation by examining the Empty bit in the hash anchor table entry for the computed hash value. In the case at hand the hash chain contains at least one entry, which is the entry for page P of segment S located at processing unit 10b; thus, the Empty bit will be clear.

(F3) Follow the hash chain for the computed hash value until it finds the entry for page P of segment S at processing unit 10a.

(F4) Update the processor Identifier field of entry E with an integer that uniquely identifies processing unit 10b. After Step 4 has been completed entry E has been updated.

(G) In Step G upon receipt of message 2 from processing unit 10c, processing unit 10b allocates a page frame in its main memory and sends message 3 to processing unit 10a requesting that processing unit 10a send page P of Segment S to processing unit 10b.

(H) In Step H upon receipt of message 3 from processing unit 10c, processing unit 10a sends page P of Segment S along with the ReadOnly consistency state associated with that page to processing unit 10b.

While the preferred embodiment has been described for use in a virtual memory environment, it will be apparent that the method is equally applicable to a cluster configuration comprising a plurality of processing units which do not employ a virtual type of memory. The underlying problem of I/O disk access for obtaining a copy of data that is currently in the main memory of another unit can be solved in the manner taught in this application, namely maintaining information on what data has been sent to the main memory by what processor unit and transferring a copy of that data to the requester from main memory having the copy rather than performing an I/O operation to disk to obtain the data.

Claims

1. A method of operating a data processing system comprising at least three inter-coupled processor units, each having a main memory and a secondary data sotrae device, said system including a switch system for selectively interconnecting any pair of the units for the transfer of data stored in the main memory of a first of the pair to the main memory of the second of the pair in response to requests from the second unit, comprising the steps of:

maintaining at each unit a list of files stored in the system and indications of the unit storing each file and coordinating access thereof;
opening a specified file stored at a first unit of a pair in response to a request for specified data from the second unit of the pair;
transferring the specified data requested by the second unit from the second storage device of the first unit to the main memory of the second unit in the pair; and
if said request has been initiated by a request for said specified data from a third unit to said second unit, transferring a copy of said specified data from the main memory of the second unit of the pair to the main memory of the third unit.

2. A method according to claim 1 including the further step of:

maintaining, in each unit, a virtual shared memory (VSM) table identifying any other unit holding a copy of data in files coordinated by the unit.

3. A method according to claim 2, including the further step of:

updating said VSM table of the first unit in a pair of transfer of data to the second unit of the pair.

4. A method according to claim 2 or claim 3, including the further step of:

updating said VSM table of the first unit in a pair on transfer of data to the third unit from the second unit in the pair.

5. A method according to any of the previous claims in whcih said main memory and secondary storage device of each unit comprise a virtual memory system, each virtual memory system having the same virtual address range, each secondary storage device includes a plurality of block addressable locations, each for storing a page of data, each main memory includes a plurality of page frames for storing a page of data, and each unit includes a page manager including a page fault handling system for revolving page faults that occur in response to requests for pages of data not in the main memory of the unit.

6. A method according to claim 5, in which each unit contains application programs unique to itself within the system, including the further steps of:

establishing, in each unit, a first data structure having a unique identifier for each application program in the unit together with a rocessor unit identifer to designate the processor controlling access to the program; and storing the first data structure in the main memory of the unit.

7. A method according to claim 6 including the further steps of:

establishing, in each unit, a second data structure having a plurality of entries indicating the virtual address of a page of data transferred from a file coordinated by a first unit and the identity of any other unit holding a copy of the transferred page; and

storing the second data structure in the main memory of the unit.

8. A method according to claim 7 including the further step of:

resolving local page faults in each unit by determining from said second data structure whether a copy of a page causing a local fault is stored in the main memory of another unit prior to resolving the page fault with the page fault handling system of the unit.

9. A method according to claim 8 including the further step of resolving a page fault at a remote unit for a page from a file coordinated by a further unit by:

determining, by reference to the first data structure, the unit controlling access to a file containing the faulting page;

requesting coupling between the unit controlling access and the remote unit through the switch system; and

sending a message to the unit controlling access requesting that a copy of the faulting page be sent to the remote unit.

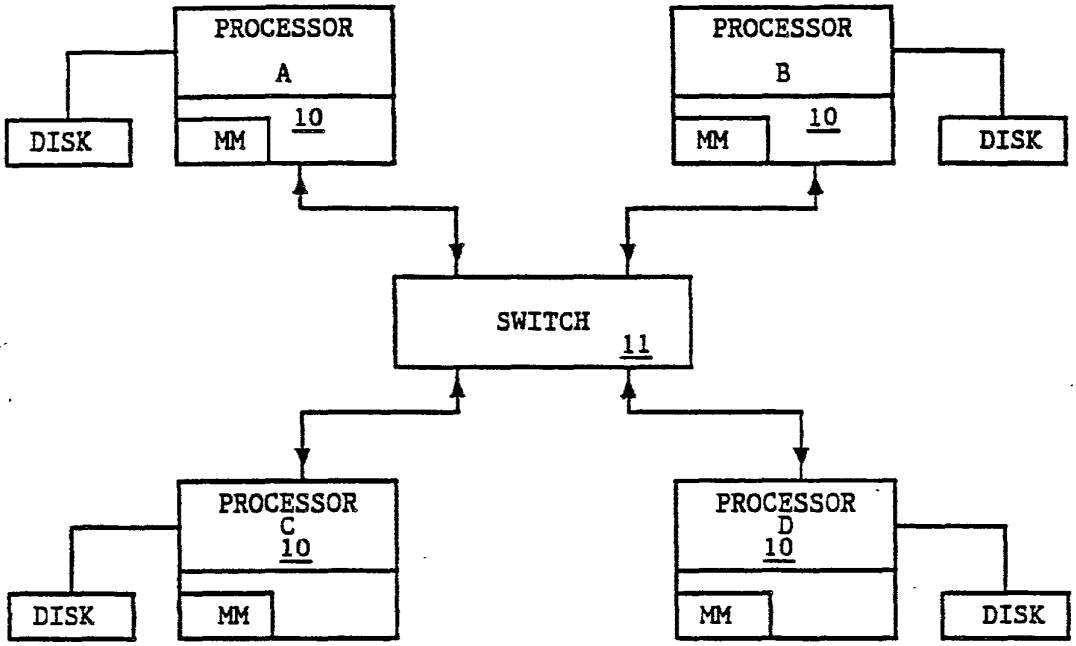
PROCESSOR
A
10
MM
DISK
PROCESSOR
B
10
MM
DISK
SWITCH
11
PROCESSOR
C
10
MM
DISK
PROCESSOR
D
10
MM
DISK

FIG. 1

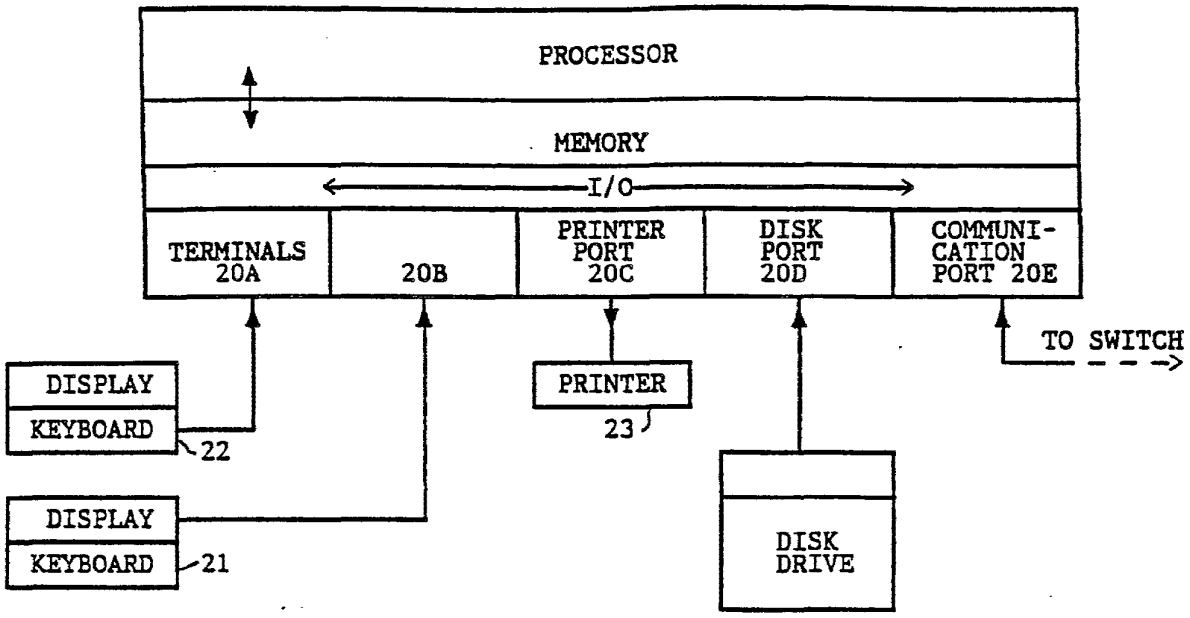
PROCESSOR
MEMORY
I/O
TERMINALS 20A
20B
PRINTER PORT 20C
DISK PORT 20D
COMMUNI-CATION PORT 20E
TO SWITCH
DISPLAY
KEYBOARD
22
PRINTER
23
DISPLAY
KEYBOARD
21
DISK DRIVE

FIG. 2

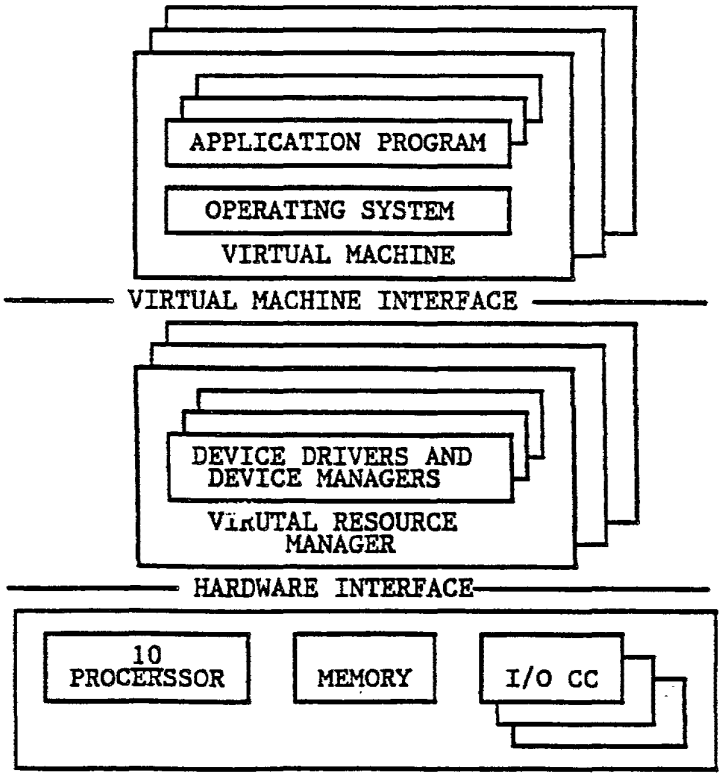
APPLICATION PROGRAM
OPERATING SYSTEM
VIRTUAL MACHINE
VIRTUAL MACHINE INTERFACE
DEVICE DRIVERS AND DEVICE MANAGERS
VIRUTAL RESOURCE MANAGER
HARDWARE INTERFACE
10 PROCERSSOR
MEMORY
I/O CC

FIG. 3

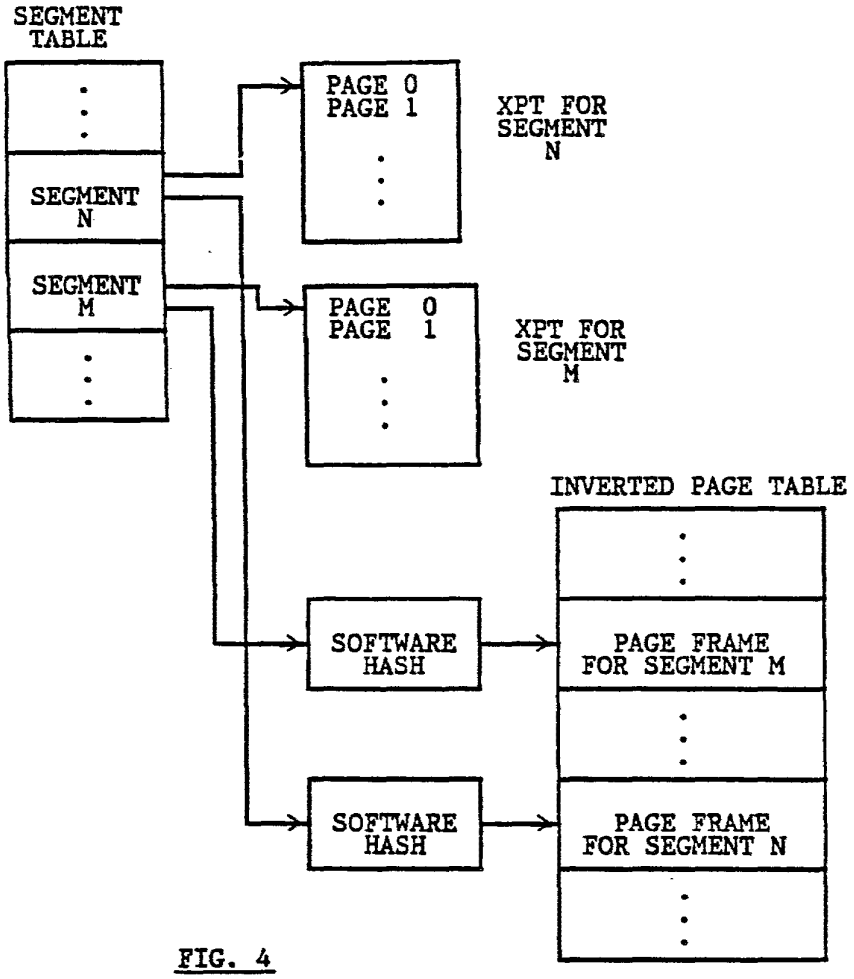
SEGMENT TABLE
SEGMENT N
SEGMENT M
PAGE 0
PAGE 1
XPT FOR SEGMENT N
PAGE 0
PAGE 1
XPT FOR SEGMENT M
INVERTED PAGE TABLE
SOFTWARE HASH
SOFTWARE HASH
PAGE FRAME FOR SEGMENT M
PAGE FRAME FOR SEGMENT N

FIG. 4

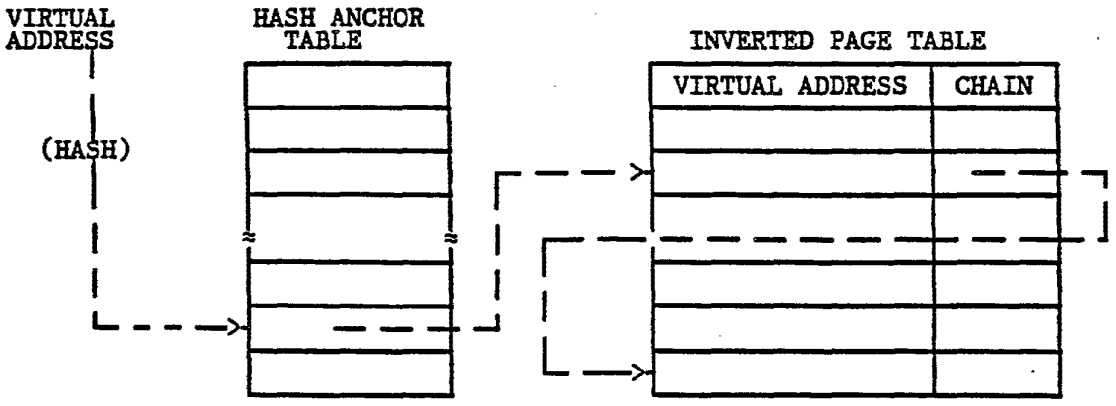
VIRTUAL ADDRESS
(HASH)
HASH ANCHOR TABLE
INVERTED PAGE TABLE
VIRTUAL ADDRESS
CHAIN

FIG. 5

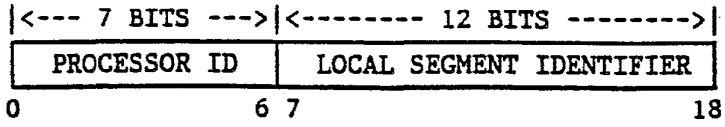

FIG. 6

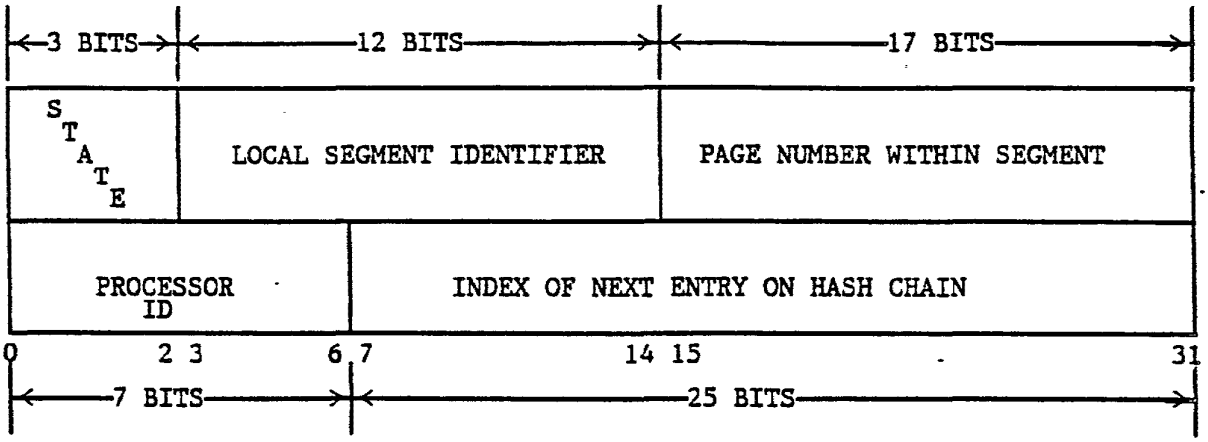

FIG. 7

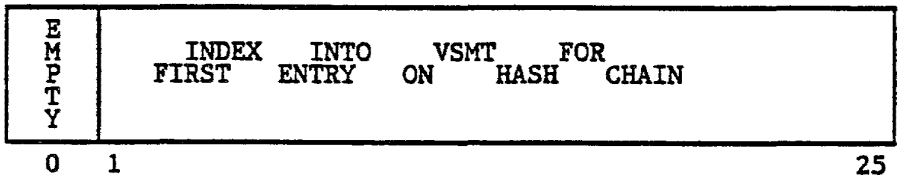

FIG. 8

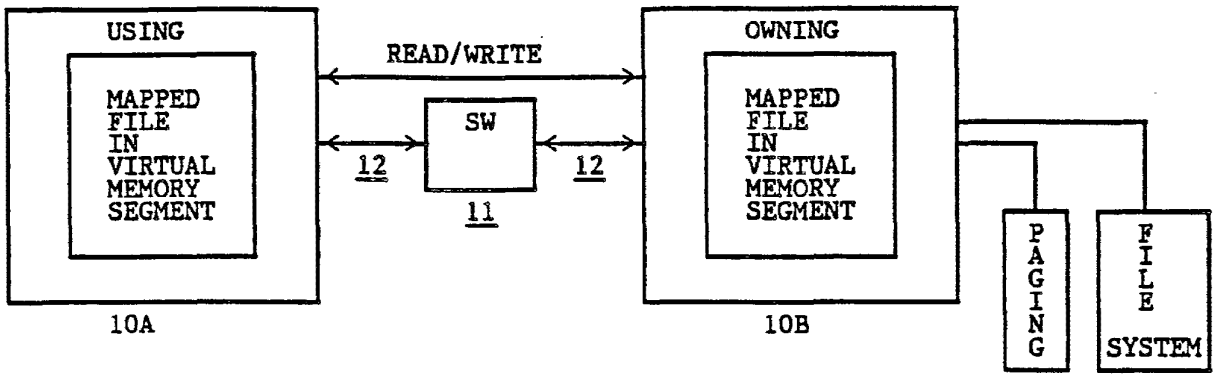
USING
MAPPED FILE IN VIRTUAL MEMORY SEGMENT
10A
READ/WRITE
SW
12
12
11
OWNING
MAPPED FILE IN VIRTUAL MEMORY SEGMENT
10B
PAGING
FILE SYSTEM

FIG. 9

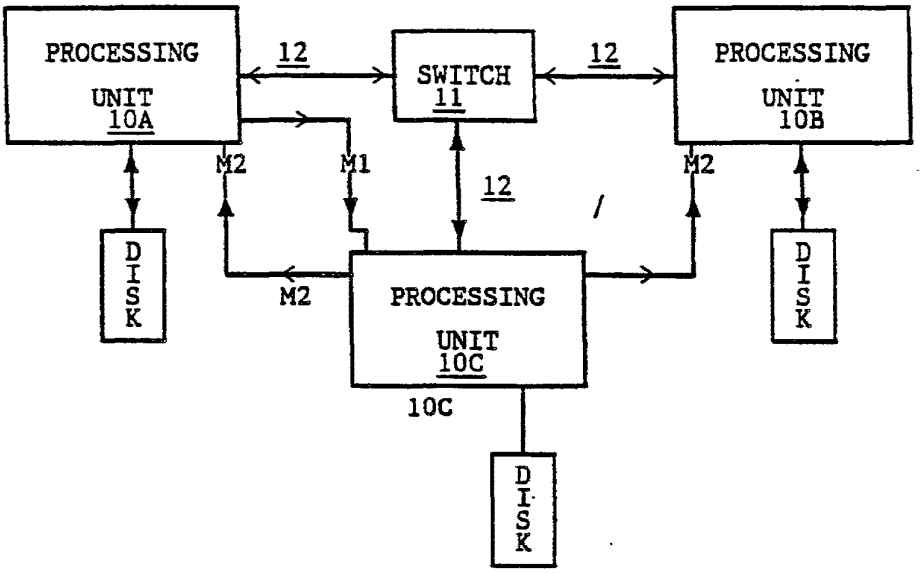
PROCESSING UNIT 10A
12
SWITCH 11
12
PROCESSING UNIT 10B
M2
M1
12
M2
DISK
M2
PROCESSING UNIT 10C
DISK
10C
DISK

FIG. 10

USER TO CREATE AND OPEN A FILE NAMED /U/SMORGAN/DATABASE ON UNIT 10A

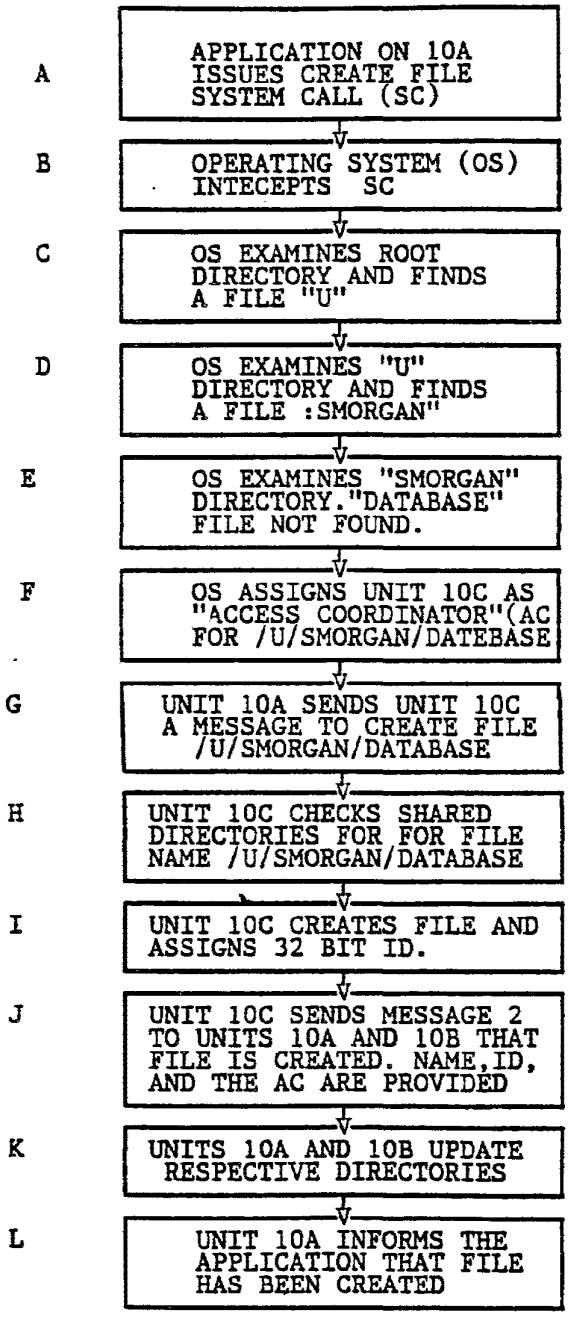

FIG. 11

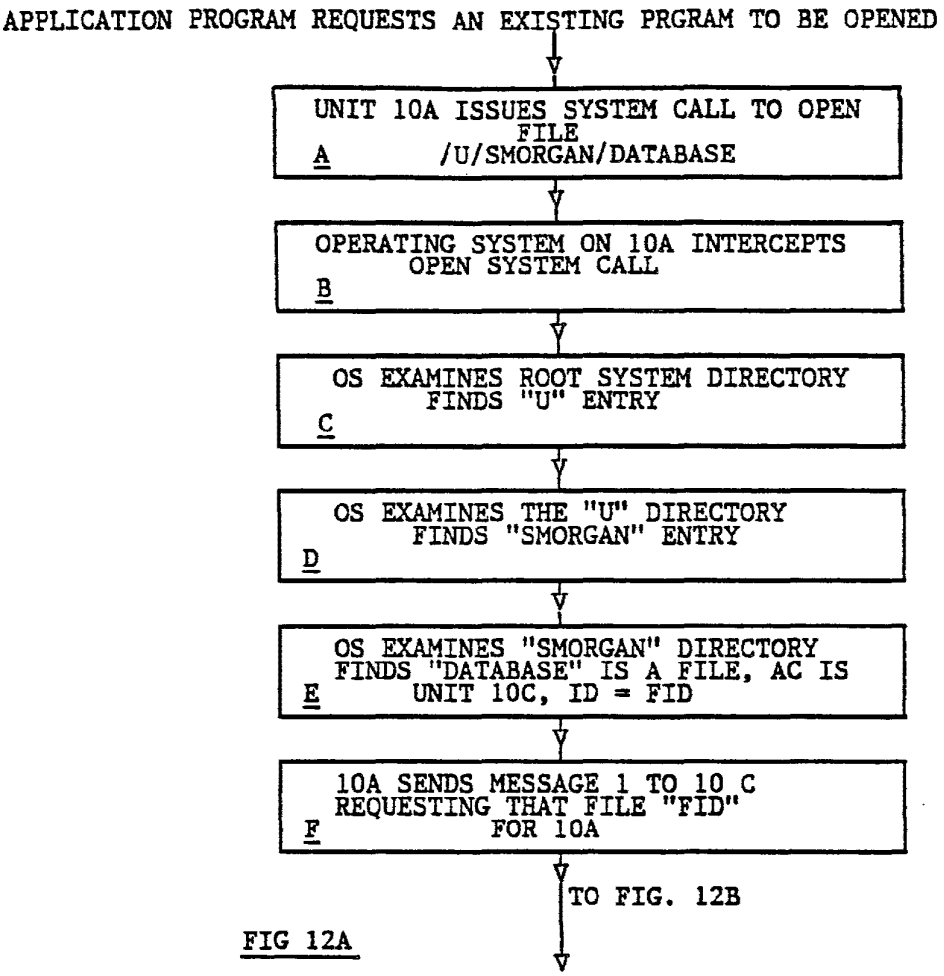
APPLICATION PROGRAM REQUESTS AN EXISTING PRGRAM TO BE OPENED
UNIT 10A ISSUES SYSTEM CALL TO OPEN FILE
A /U/SMORGAN/DATABASE
OPERATING SYSTEM ON 10A INTERCEPTS OPEN SYSTEM CALL
B
OS EXAMINES ROOT SYSTEM DIRECTORY FINDS "U" ENTRY
C
OS EXAMINES THE "U" DIRECTORY FINDS "SMORGAN" ENTRY
D
OS EXAMINES "SMORGAN" DIRECTORY FINDS "DATABASE" IS A FILE, AC IS
E UNIT 10C, ID = FID
10A SENDS MESSAGE 1 TO 10 C REQUESTING THAT FILE "FID"
F FOR 10A
TO FIG. 12B

FIG 12A

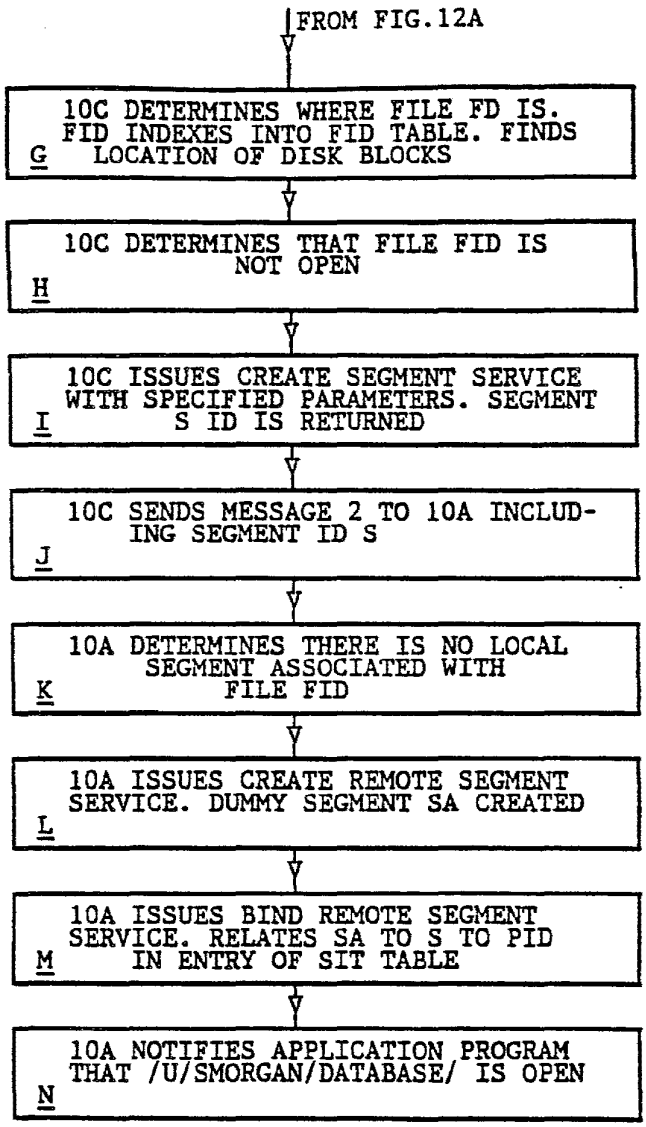
FROM FIG.12A
10C DETERMINES WHERE FILE FD IS. FID INDEXES INTO FID TABLE. FINDS LOCATION OF DISK BLOCKS
G
10C DETERMINES THAT FILE FID IS NOT OPEN
H
10C ISSUES CREATE SEGMENT SERVICE WITH SPECIFIED PARAMETERS. SEGMENT S ID IS RETURNED
I
10C SENDS MESSAGE 2 TO 10A INCLUDING SEGMENT ID S
J
10A DETERMINES THERE IS NO LOCAL SEGMENT ASSOCIATED WITH FILE FID
K
10A ISSUES CREATE REMOTE SEGMENT SERVICE. DUMMY SEGMENT SA CREATED
L
10A ISSUES BIND REMOTE SEGMENT SERVICE. RELATES SA TO S TO PID IN ENTRY OF SIT TABLE
M
10A NOTIFIES APPLICATION PROGRAM THAT /U/SMORGAN/DATABASE/ IS OPEN
N

FIG. 12B

APPLICATION PROGRAM EXECUTING ON 10 ISSUES SCHMAT CALL TO MAP SA

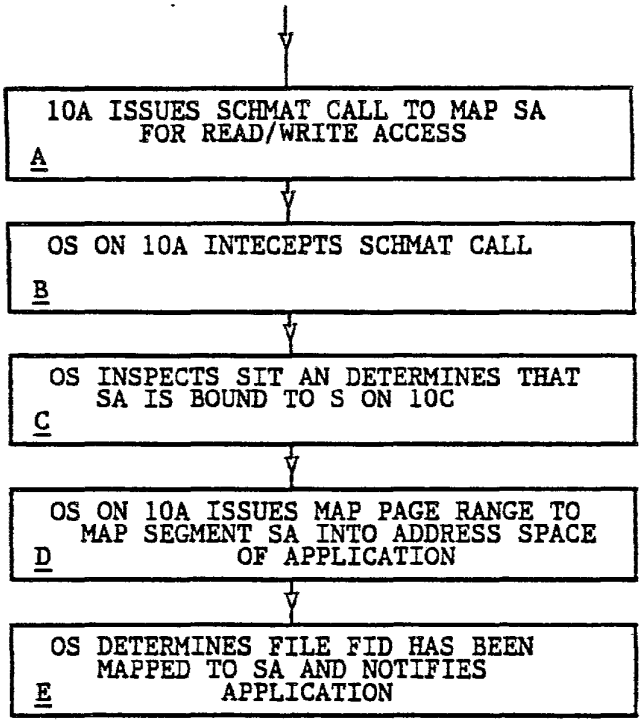

FIG. 13

APPLICATION PROGRAM EXECUTING ON 10A REQUEST PAGE P OF SEGMENT SL FOR FILE F

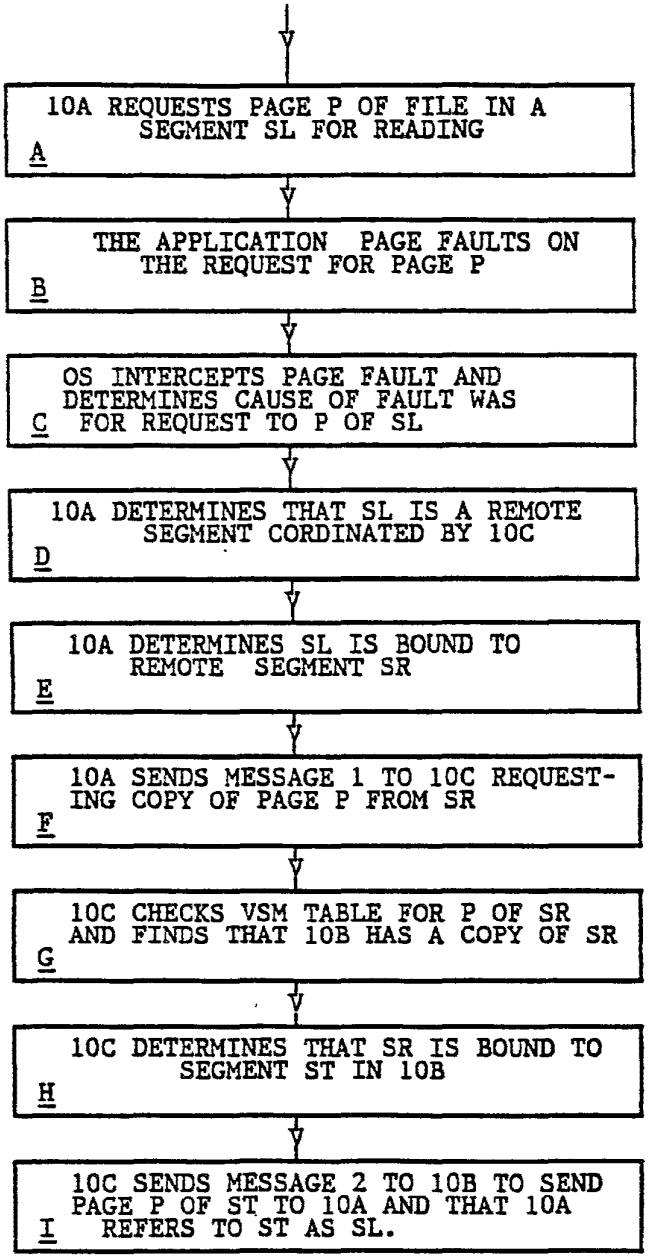

FIG. 14

UPDATE OF VSMT BY UNIT 10C AFTER 10B SENDS COPY TO 10A IN RESPONE TO APPLICATION PROGRAM EXECUTING ON 10A REQUESTING PAGE P OF SEGMENT SL FOR FILE F

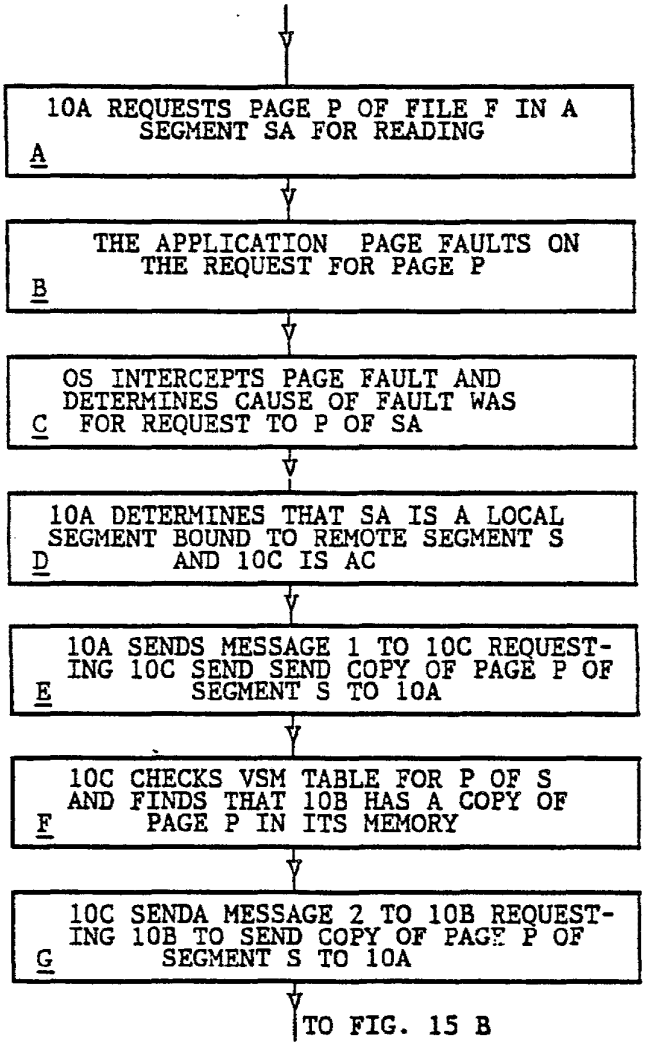

FIG. 15A

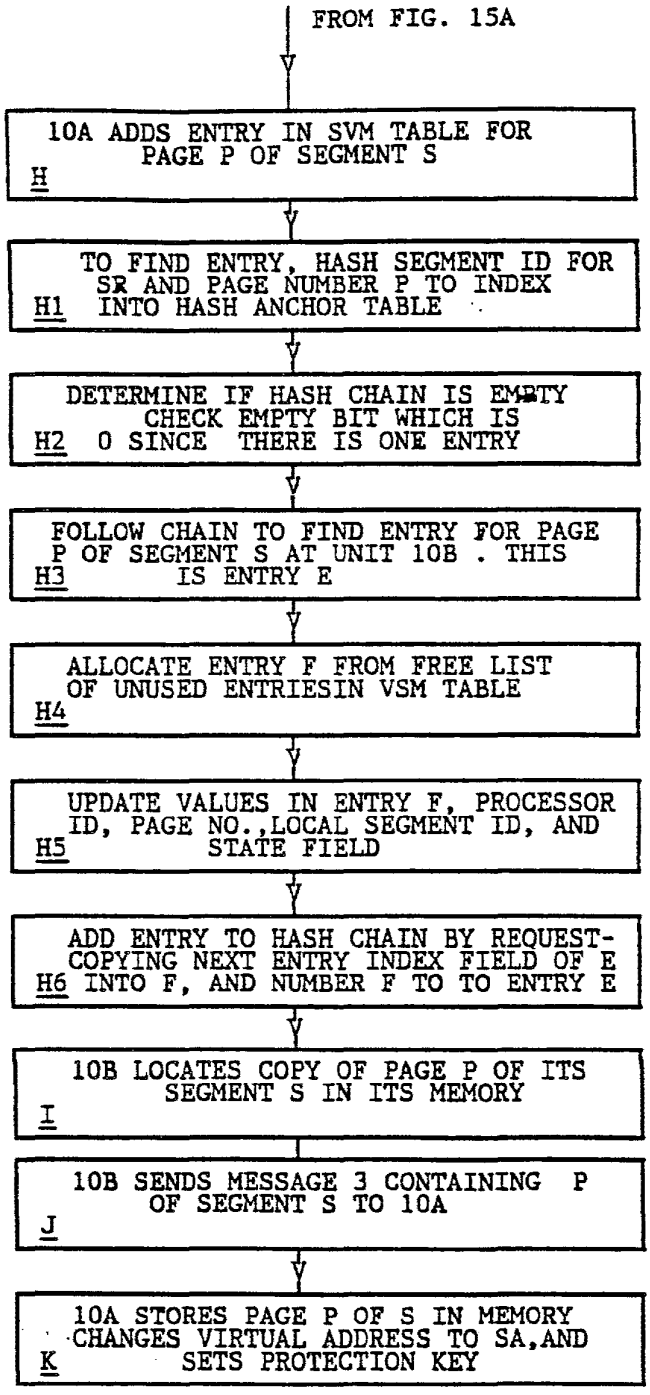
FROM FIG. 15A
10A ADDS ENTRY IN SVM TABLE FOR PAGE P OF SEGMENT S
H
TO FIND ENTRY, HASH SEGMENT ID FOR SR AND PAGE NUMBER P TO INDEX
H1 INTO HASH ANCHOR TABLE
DETERMINE IF HASH CHAIN IS EMPTY CHECK EMPTY BIT WHICH IS
H2 0 SINCE THERE IS ONE ENTRY
FOLLOW CHAIN TO FIND ENTRY FOR PAGE P OF SEGMENT S AT UNIT 10B . THIS
H3 IS ENTRY E
ALLOCATE ENTRY F FROM FREE LIST OF UNUSED ENTRIESIN VSM TABLE
H4
UPDATE VALUES IN ENTRY F, PROCESSOR ID, PAGE NO.,LOCAL SEGMENT ID, AND
H5 STATE FIELD
ADD ENTRY TO HASH CHAIN BY REQUEST-COPYING NEXT ENTRY INDEX FIELD OF E
H6 INTO F, AND NUMBER F TO TO ENTRY E
10B LOCATES COPY OF PAGE P OF ITS SEGMENT S IN ITS MEMORY
I
10B SENDS MESSAGE 3 CONTAINING P OF SEGMENT S TO 10A
J
10A STORES PAGE P OF S IN MEMORY CHANGES VIRTUAL ADDRESS TO SA,AND
K SETS PROTECTION KEY

FIG. 15B

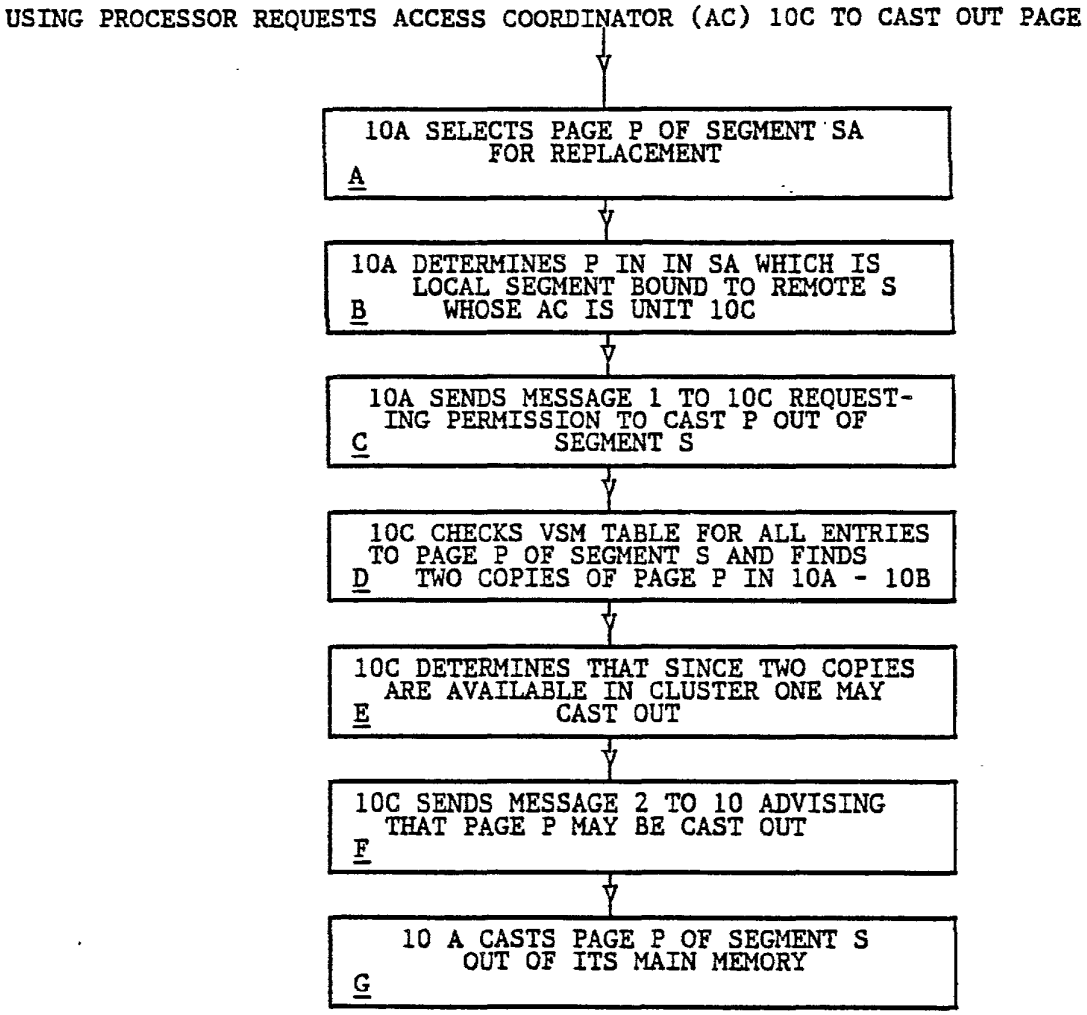
USING PROCESSOR REQUESTS ACCESS COORDINATOR (AC) 10C TO CAST OUT PAGE
10A SELECTS PAGE P OF SEGMENT SA FOR REPLACEMENT
A
10A DETERMINES P IN IN SA WHICH IS LOCAL SEGMENT BOUND TO REMOTE S WHOSE AC IS UNIT 10C
B
10A SENDS MESSAGE 1 TO 10C REQUESTING PERMISSION TO CAST P OUT OF SEGMENT S
C
10C CHECKS VSM TABLE FOR ALL ENTRIES TO PAGE P OF SEGMENT S AND FINDS TWO COPIES OF PAGE P IN 10A - 10B
D
10C DETERMINES THAT SINCE TWO COPIES ARE AVAILABLE IN CLUSTER ONE MAY CAST OUT
E
10C SENDS MESSAGE 2 TO 10 ADVISING THAT PAGE P MAY BE CAST OUT
F
10 A CASTS PAGE P OF SEGMENT S OUT OF ITS MAIN MEMORY
G

FIG. 16

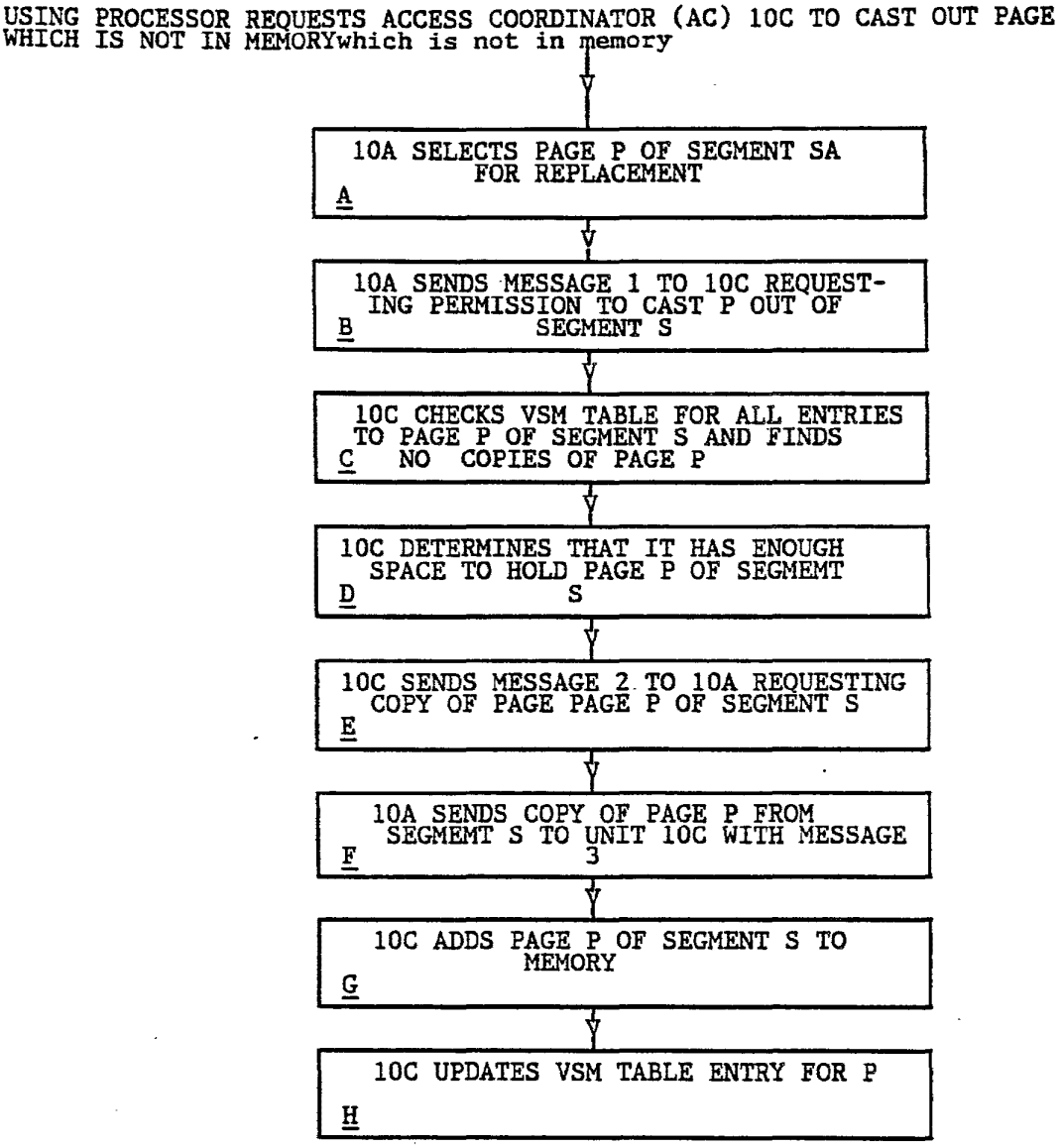
USING PROCESSOR REQUESTS ACCESS COORDINATOR (AC) 10C TO CAST OUT PAGE WHICH IS NOT IN MEMORYwhich is not in memory
10A SELECTS PAGE P OF SEGMENT SA FOR REPLACEMENT
A
10A SENDS MESSAGE 1 TO 10C REQUESTING PERMISSION TO CAST P OUT OF SEGMENT S
B
10C CHECKS VSM TABLE FOR ALL ENTRIES TO PAGE P OF SEGMENT S AND FINDS NO COPIES OF PAGE P
C
10C DETERMINES THAT IT HAS ENOUGH SPACE TO HOLD PAGE P OF SEGMEMT S
D
10C SENDS MESSAGE 2 TO 10A REQUESTING COPY OF PAGE PAGE P OF SEGMENT S
E
10A SENDS COPY OF PAGE P FROM SEGMEMT S TO UNIT 10C WITH MESSAGE 3
F
10C ADDS PAGE P OF SEGMENT S TO MEMORY
G
10C UPDATES VSM TABLE ENTRY FOR P
H

FIG. 17

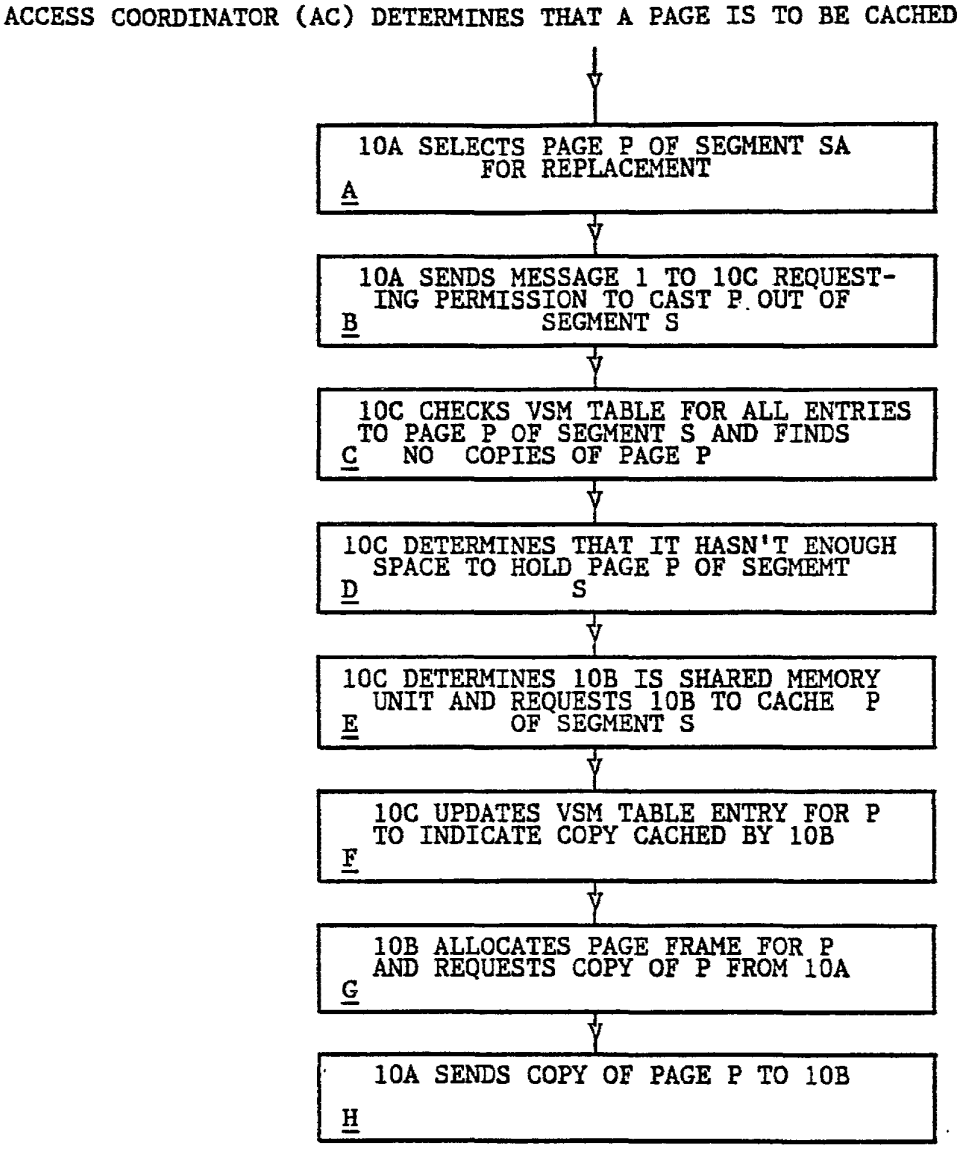
ACCESS COORDINATOR (AC) DETERMINES THAT A PAGE IS TO BE CACHED
10A SELECTS PAGE P OF SEGMENT SA FOR REPLACEMENT
A
10A SENDS MESSAGE 1 TO 10C REQUESTING PERMISSION TO CAST P OUT OF SEGMENT S
B
10C CHECKS VSM TABLE FOR ALL ENTRIES TO PAGE P OF SEGMENT S AND FINDS NO COPIES OF PAGE P
C
10C DETERMINES THAT IT HASN'T ENOUGH SPACE TO HOLD PAGE P OF SEGMEMT S
D
10C DETERMINES 10B IS SHARED MEMORY UNIT AND REQUESTS 10B TO CACHE P OF SEGMENT S
E
10C UPDATES VSM TABLE ENTRY FOR P TO INDICATE COPY CACHED BY 10B
F
10B ALLOCATES PAGE FRAME FOR P AND REQUESTS COPY OF P FROM 10A
G
10A SENDS COPY OF PAGE P TO 10B
H

FIG. 18

Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr./Barb Avery
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	17794654
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	02-JAN-2014
Filing Date:	11-JUN-2008
Time Stamp:	12:06:25
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	12389
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_8_SIDS.pdf	612414 b07d7de86c58751a50f830b90aede5286120235a	no	4
Warnings:					
Information:					
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2	Foreign Reference	EP0319148A2.pdf	1861514 2b5a8d6b4a960dec602b31d868ba8c2bb2e1bac8	no	32
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30590 87a94597de24eb5612588354a4657ee154bbd9aa	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2504518	

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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.

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 10/01/2013
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	~~$1780~~ $960	~~$300~~ $0	$0	~~$2080~~ $960	01/02/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
GURARI, EREZ	3618	280-047350

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, NJ 08831

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 credit 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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Paul J. LaVanway, Jr./ Date January 2, 2014

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

This collection of information 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.

Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr./Barb Avery
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

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

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

Electronic Acknowledgement Receipt

EFS ID:	17799158
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	02-JAN-2014
Filing Date:	11-JUN-2008
Time Stamp:	16:14:50
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	3455
Deposit Account	
Authorized User	

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_8_Issue_Fee.pdf	162554 86265638d8c4ea0aba4cf739293eb3e284ea9f92	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30640 0df08903cbb5b5c594a3ab689044d7e187824f7b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	193194	

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

22859 7590 11/20/2013

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

EXAMINER
GURARI, EREZ

ART UNIT	PAPER NUMBER
3618	

NOTIFICATION DATE	DELIVERY MODE
11/20/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
12/137,377	11 June, 2008	QUIRICO ET AL.	56782.1.8

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

EXAMINER	
RICHARD ELLIS	
ART UNIT	PAPER
OPIM	A-19365

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The attached addendum forms part of the previously mailed PTOL-85 (Notice of Allowance and Fees Due). This addendum does NOT change the time period set in the PTOL-85 for payment of the issue fee.

ANY QUESTIONS REGARDING THIS COMMUNICATION SHOULD BE DIRECTED TO THE OFFICE OF PATENT LEGAL ADMINISTRATION AT (571) 272-7701.

PTO-90C (Rev.04-03)

Notices of Allowance and Fee(s) Due mailed between October 1, 2013 and December 31, 2013

(Addendum to PTOL-85)

If the "Notice of Allowance and Fee(s) Due" has a mailing date on or after October 1, 2013 and before January 1, 2014, the following information is applicable to this application.

If the issue fee is being timely paid on or after January 1, 2014, the amount due is the issue fee and publication fee in effect January 1, 2014. On January 1, 2014, the issue fees set forth in 37 CFR 1.18 decrease significantly and the publication fee set forth in 37 CFR 1.18(d)(1) decreases to $0.

If an issue fee or publication fee has been previously paid in this application, applicant is not entitled to a refund of the difference between the amount paid and the amount in effect on January 1, 2014.

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	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20110209764		2011-09-01	Uber	

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	244513	SU		1969-12-31	Bogoudinov		☐
	2	2288755	RU		2006-12-10	Shchetinin		☐
	3	2131273	RU		1999-06-10	Sajens		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

If you wish to add additional Foreign Patent Document citation information please click the Add button			Add
NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐
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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

CERTIFICATION STATEMENT

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

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

OR

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

☒ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-11-08
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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.

Espacenet

Bibliographic data: RU2131273 (C1) — 1999-06-10

LIQUID DELIVERY DEVICE

No documents available for this priority number.

Inventor(s): MARSHALL S KRIESEL [US] ± (MARSHALL S.KRIESEL)

Applicant(s): SAJENS INKORPOREJTED [US] ± (SAJENS INKORPOREJTED)

Classification: **- international:** ***A61M37/00; A61M5/152;*** *A61M5/14; A61M5/142;* (IPC1-7): A61M37/00
- cooperative: **A61M5/152**; A61M2205/197; A61M5/1407; A61M5/1409; A61M5/14248

Application number: RU19950122716 19940515

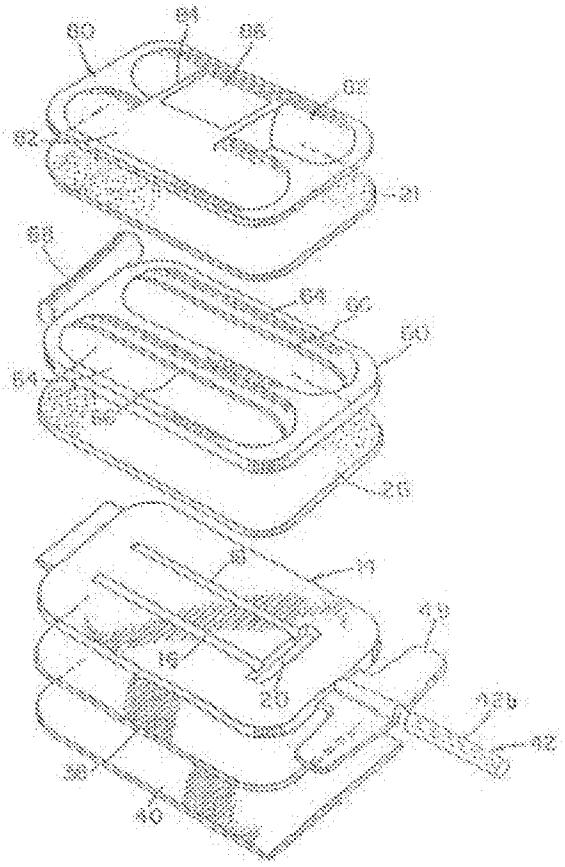
Priority number (s): WO1994US05389 19940516 ; US19930046438 19930413

Also published as: WO9426348 (A1) JPH08510658 (A) EP0700308 (A1) EP0700308 (A4) CN1126950 (A) CA2163242 (A1) BR9406808 (A) AU6949394 (A) AU697117 (B2) less

Abstract of RU2131273 (C1)

FIELD: medical engineering. SUBSTANCE: device is intended for accurate infusion of medicinal substances into ambulatory patient at definite speed within long periods of time. Device represents compact, low-profile laminated construction. It has flexible stretchable membrane which in combination with thin flat base outlines boundaries for liquid provided with outlet. This membrane permeable for liquid controls accurately rate of liquid flow through liquid outlet. It is positioned inside liquid chamber which allows convenient fixing to parts of patient's body. EFFECT: higher efficiency of infusion. 12 cl, 94 dwg

Last updated: 09.10.2013 Worldwide Database 5.8.11.5; 93p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(19) RU (11) 2 131 273 (13) C1

(51) МПК[6] A 61 M 37/00

РОССИЙСКОЕ АГЕНТСТВО
ПО ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ

(12) ОПИСАНИЕ ИЗОБРЕТЕНИЯ К ПАТЕНТУ РОССИЙСКОЙ ФЕДЕРАЦИИ

(21), (22) Заявка: 95122716/14, 15.05.1994

(30) Приоритет: 18.05.1993 US 08/046438

(46) Дата публикации: 10.06.1999

(56) Ссылки: 1. US 5154697, 13.10.92. 2. SU 1404080 A1, 23.06.88. 3. US 5176641, 05.01.93.

(85) Дата перевода заявки PCT на национальную фазу: 18.12.95

(86) Заявка PCT:
US 94/05389 (15.05.94)

(87) Публикация PCT:
WO 94/26348 (24.11.94)

(98) Адрес для переписки:
103735, Москва, ул.Ильинка 5/2 Союзпатент
Дудушкину С.В.

(71) Заявитель:
Сайенс Инкорпорейтед (US)

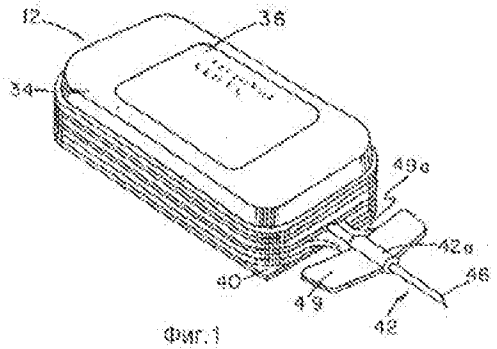
(72) Изобретатель: Маршалл С.Криесел (US)

(73) Патентообладатель:
Сайенс Инкорпорейтед (US)

(54) УСТРОЙСТВО ДОСТАВКИ ЖИДКОСТИ

(57) Реферат:

Устройство предназначено для точной инфузии лекарственных средств амбулаторно пациенту с определенными скоростями на протяжении длительных периодов времени. Устройство представляет компактную низкопрофильную слоистую конструкцию и включает эластичную растягиваемую мембрану, которая в сочетании с тонким плоским основанием очерчивает границы для жидкости, имеющей жидкостный выход. Тонкая проницаемая для жидкости мембрана, которая точно контролирует скорость течения жидкости через жидкостный выход, расположена внутри жидкостной камеры, что позволяет удобно фиксироваться к частям тела пациента и использоваться им с минимальными профессиональными знаниями. 2 с. и 10 з.п. ф-лы, 94 ил.



Фиг.1

RU 2131273 C1

RU 2131273 C1

(19) RU (11) 2 131 273 (13) C1

(51) Int. Cl.[6] A 61 M 37/00

RUSSIAN AGENCY
FOR PATENTS AND TRADEMARKS

(12) ABSTRACT OF INVENTION

(21), (22) Application: 95122716/14, 15.05.1994

(30) Priority: 18.05.1993 US 08/046438

(46) Date of publication: 10.06.1999

(85) Commencement of national phase: 18.12.95

(86) PCT application:
US 94/05389 (15.05.94)

(87) PCT publication:
WO 94/26348 (24.11.94)

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(72) Inventor: Marshall S.Kriesel (US)

(73) Proprietor:
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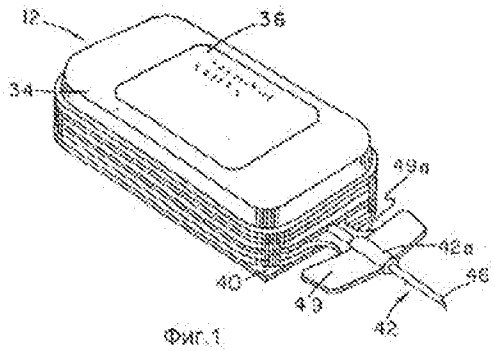
(54) LIQUID DELIVERY DEVICE

(57) Abstract:

FIELD: medical engineering. SUBSTANCE: device is intended for accurate infusion of medicinal substances into ambulatory patient at definite speed within long periods of time. Device represents compact, low-profile laminated construction. It has flexible stretchable membrane which in combination with thin flat base outlines boundaries for liquid provided with outlet. This membrane permeable for liquid controls accurately rate of liquid flow through liquid outlet. It is positioned inside liquid chamber which allows convenient fixing to parts of patient's body. EFFECT: higher efficiency of infusion. 12 cl, 94 dwg



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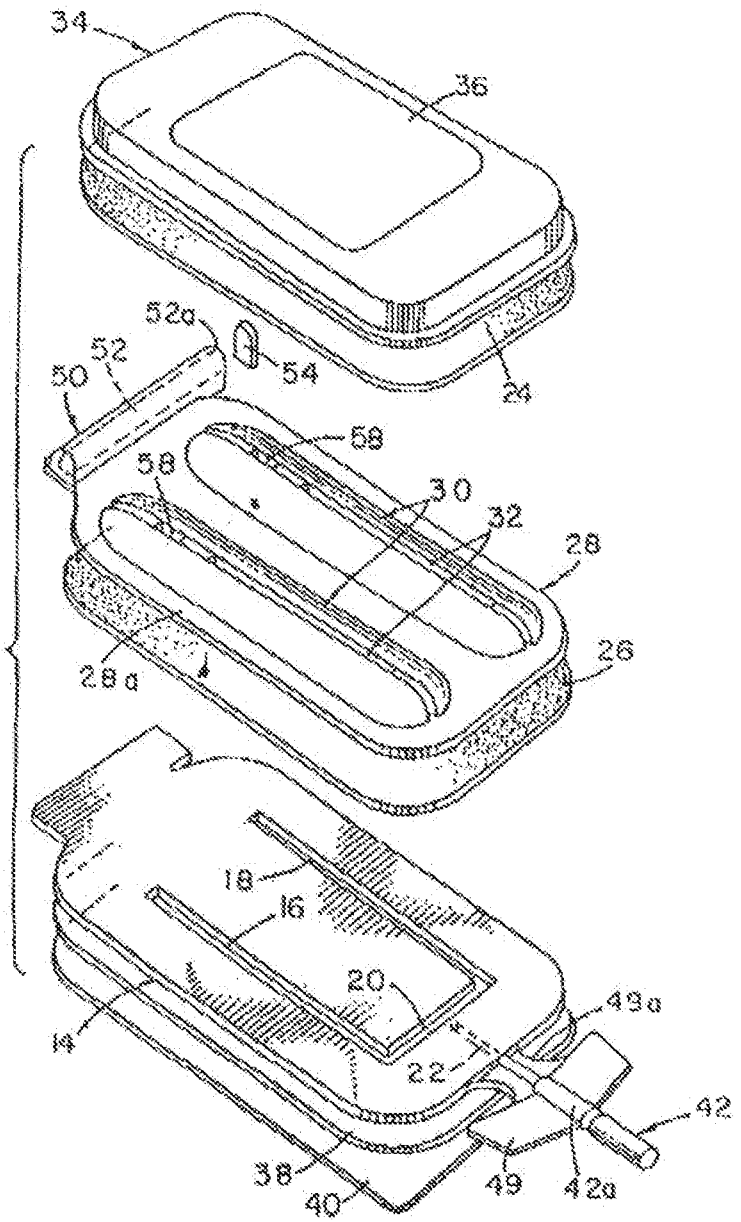

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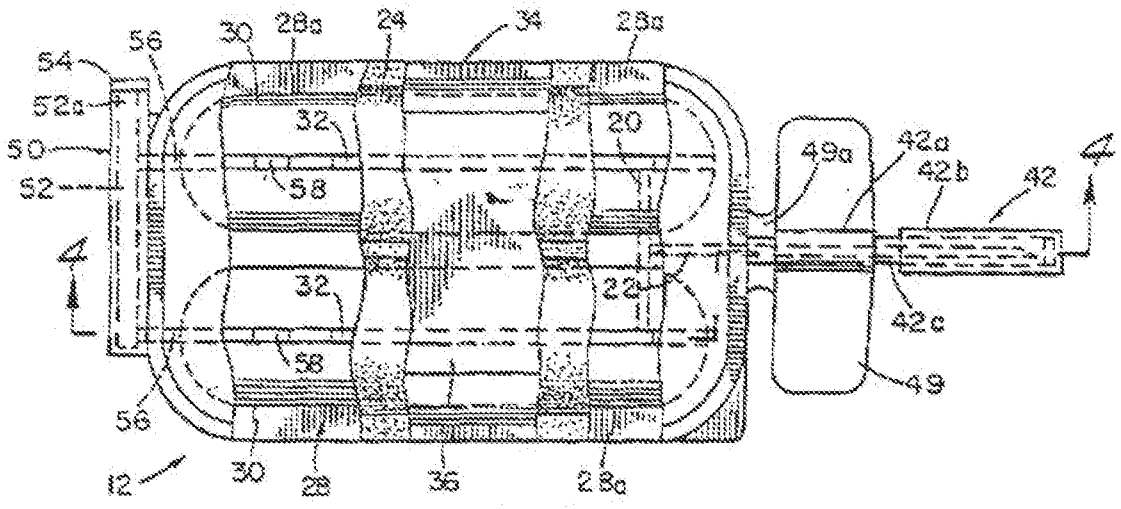

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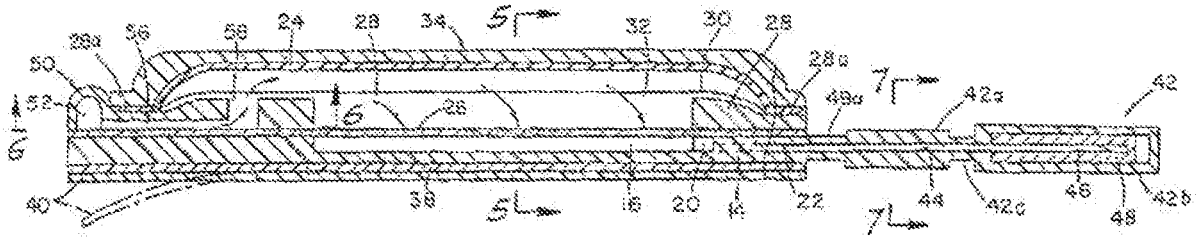

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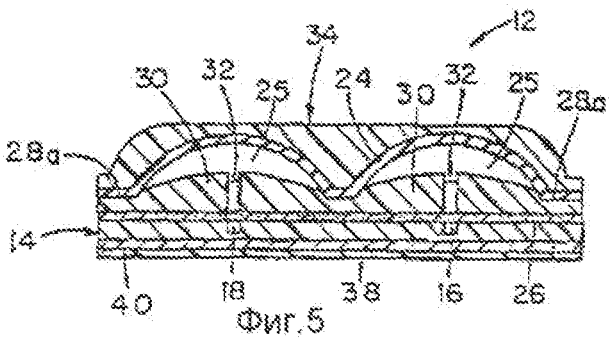

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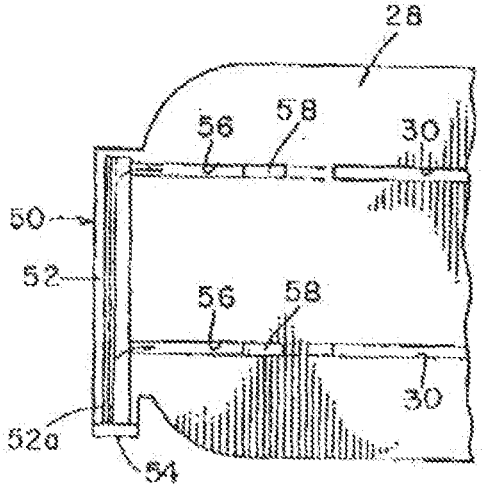

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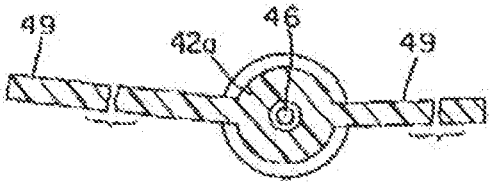

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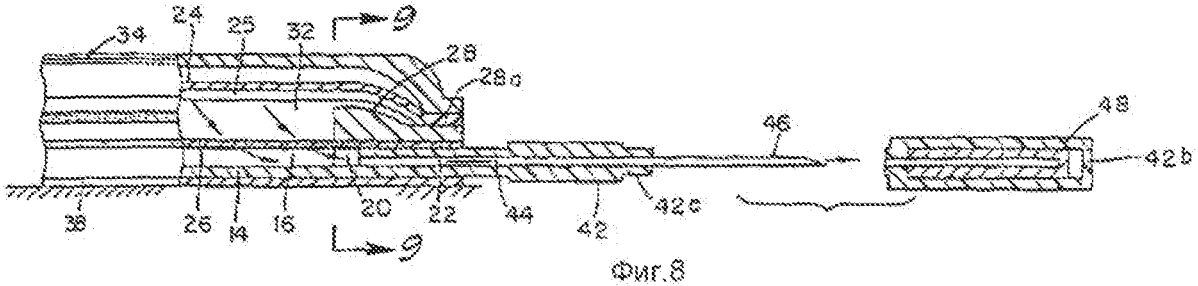

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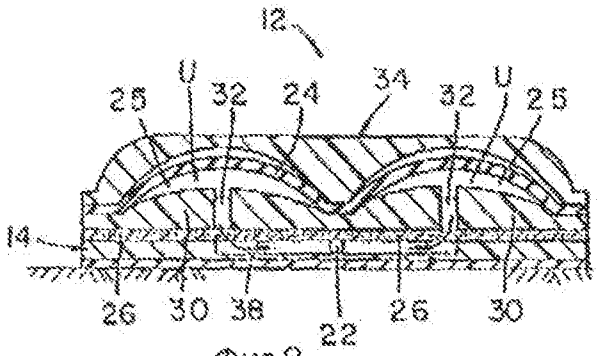

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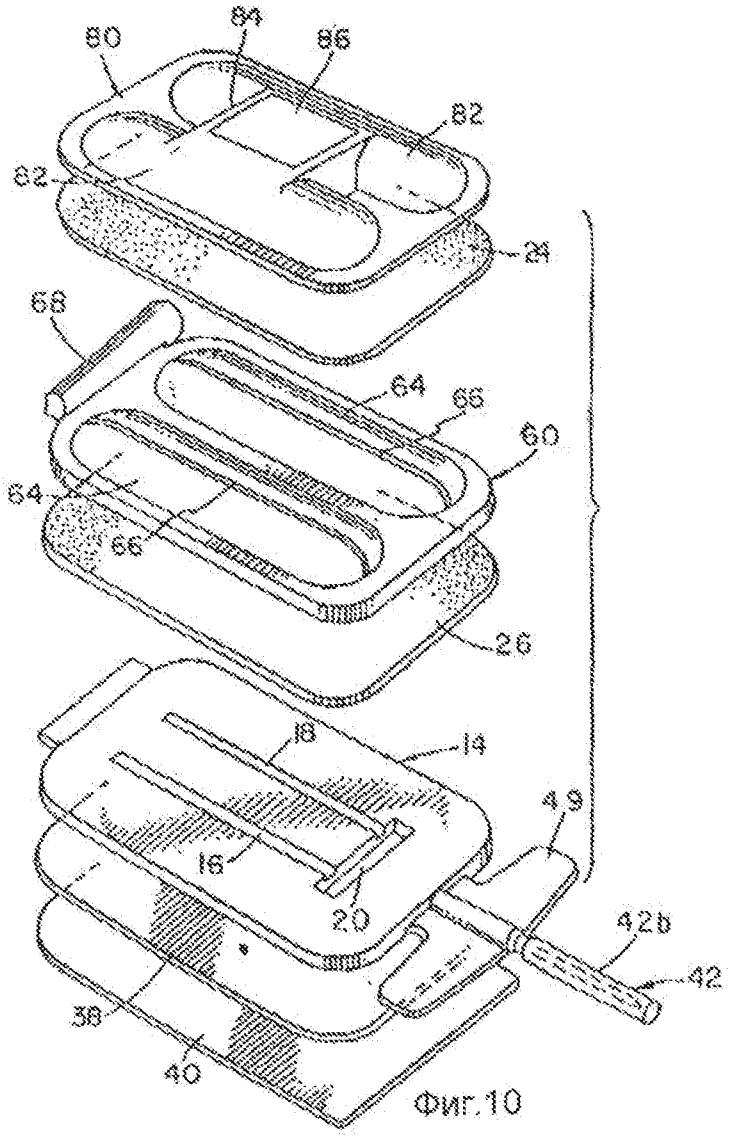

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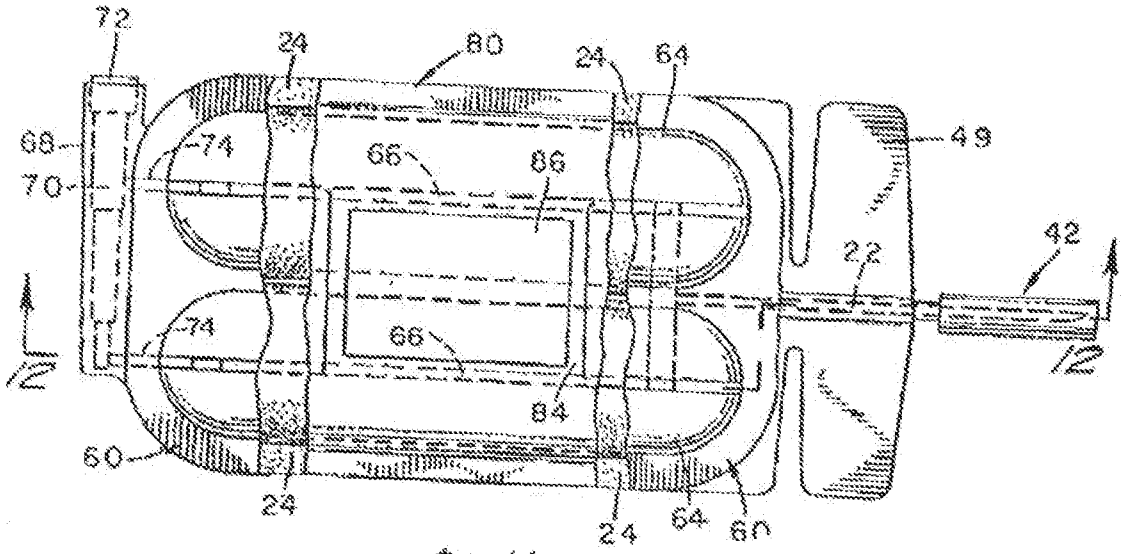

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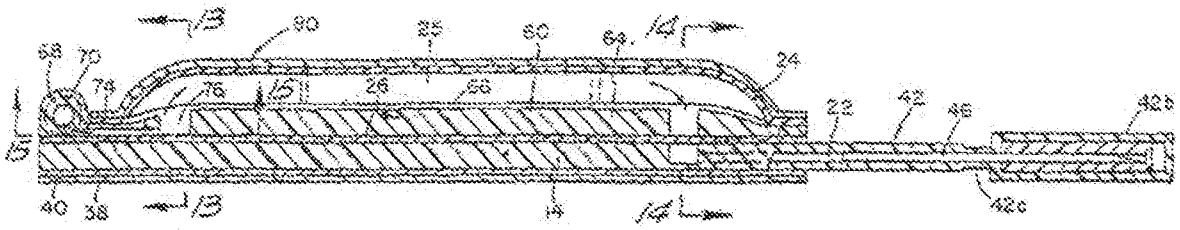

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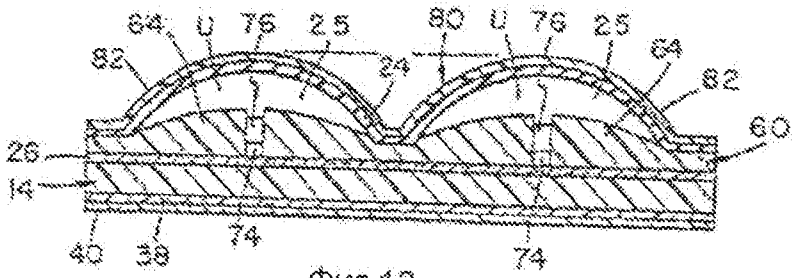

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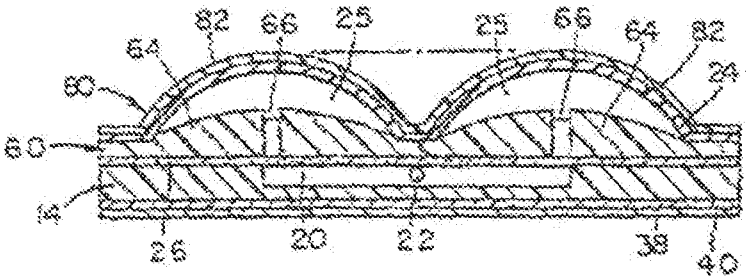

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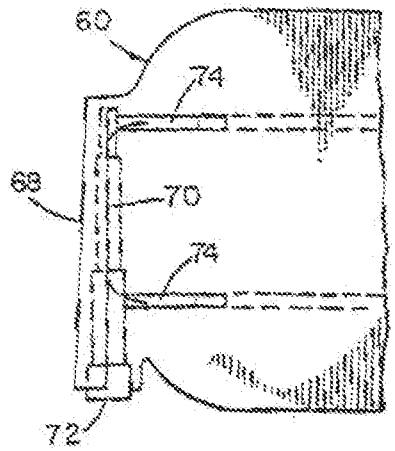

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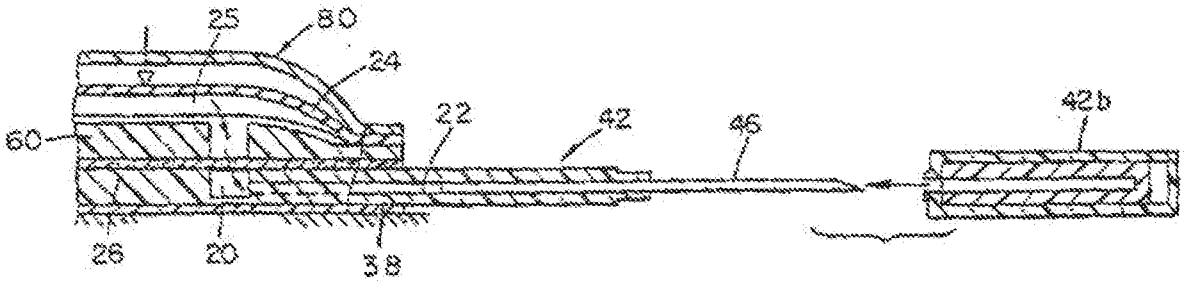

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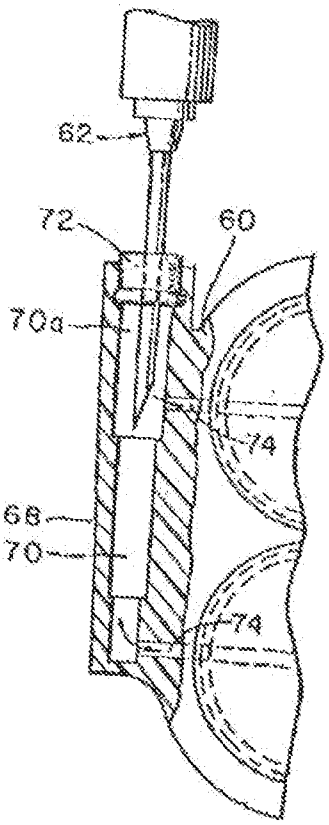

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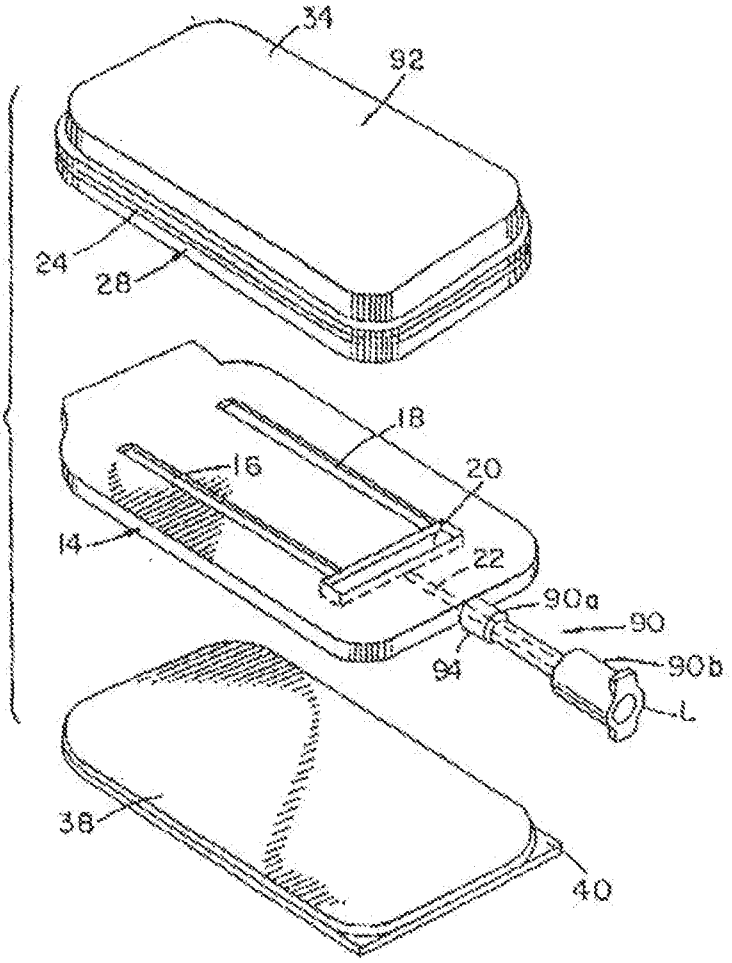

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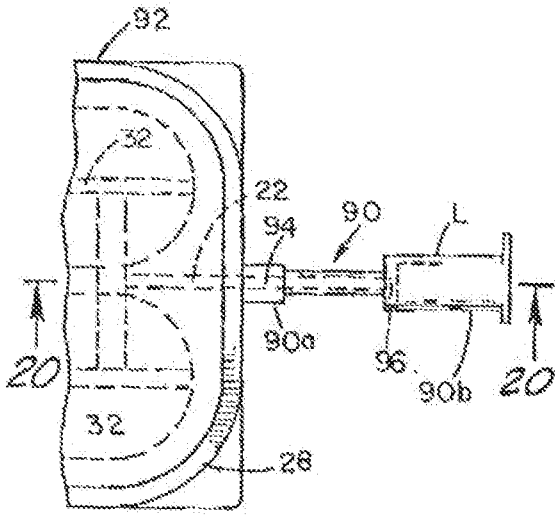

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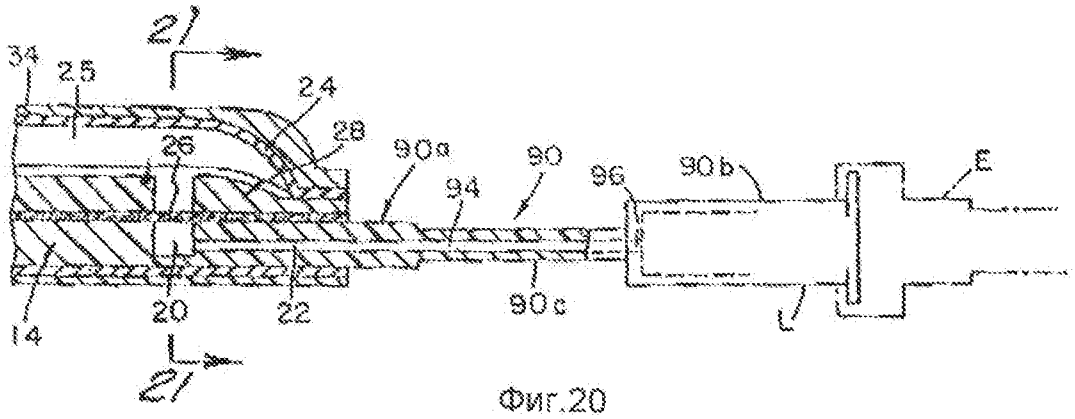

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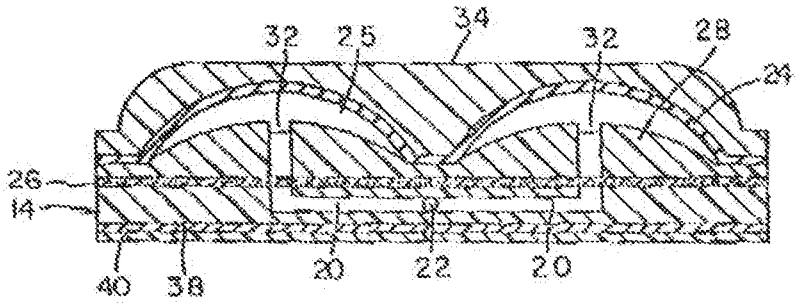

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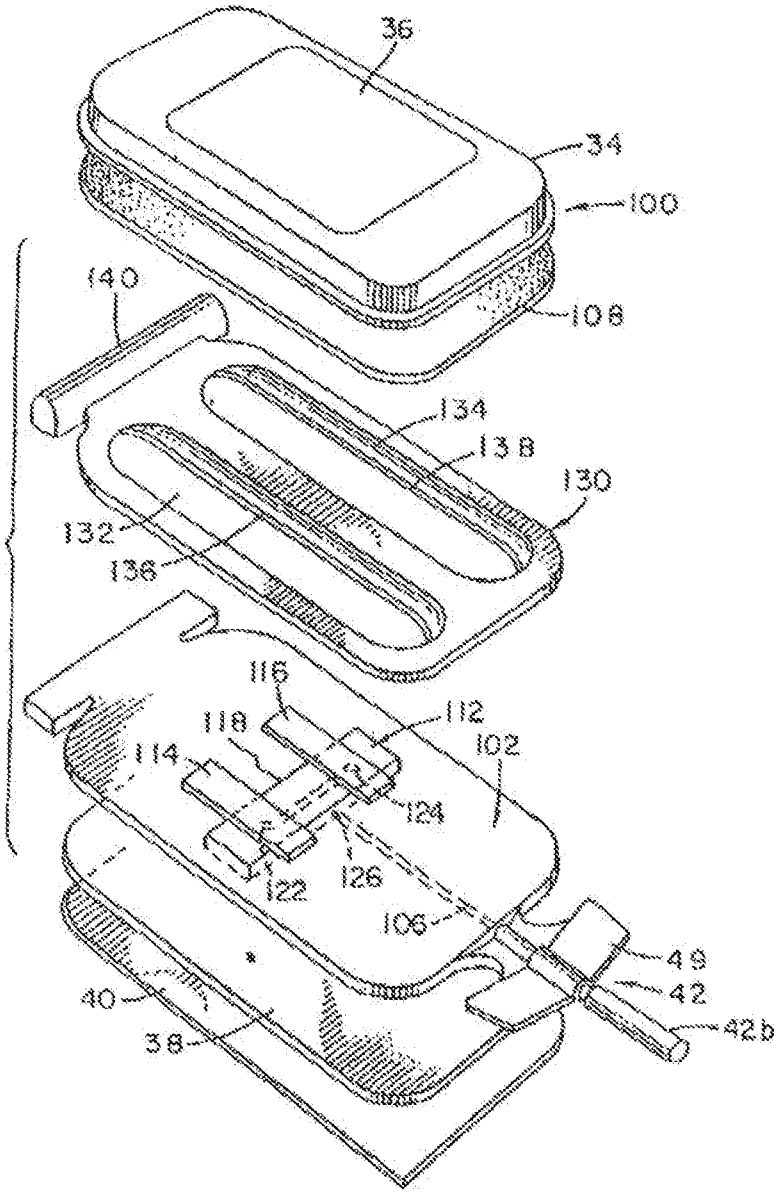

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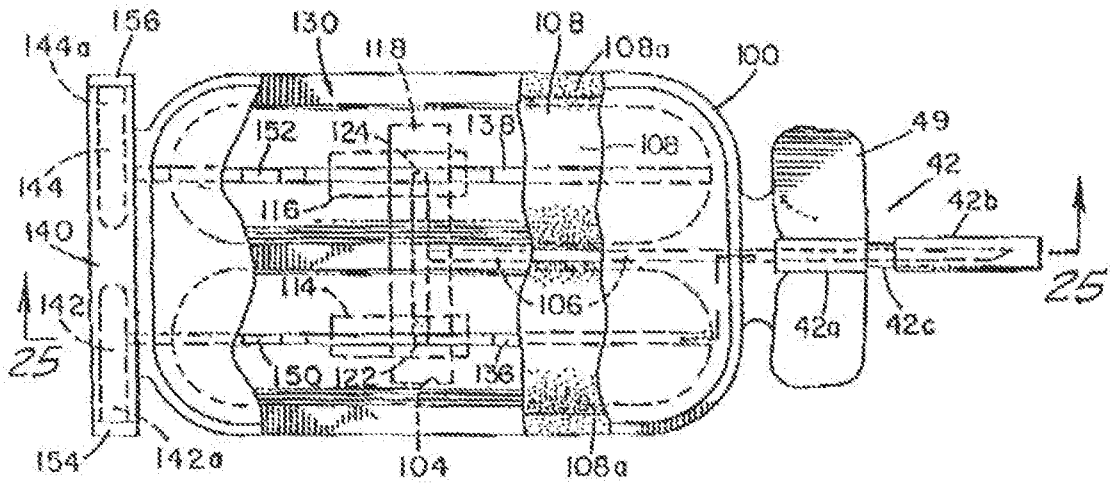

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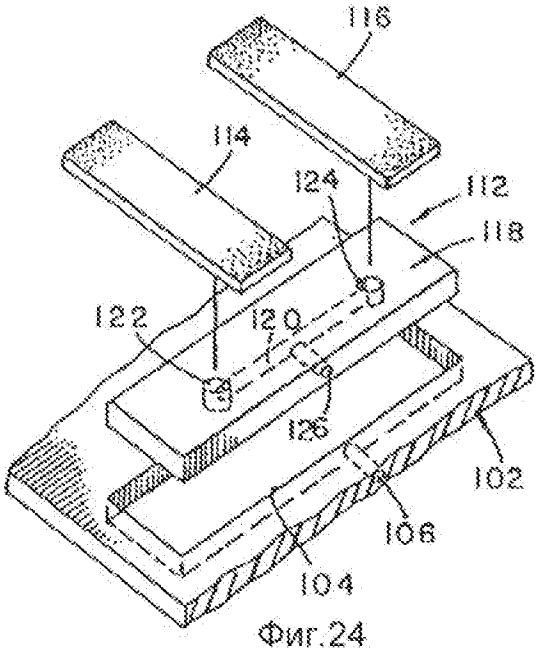

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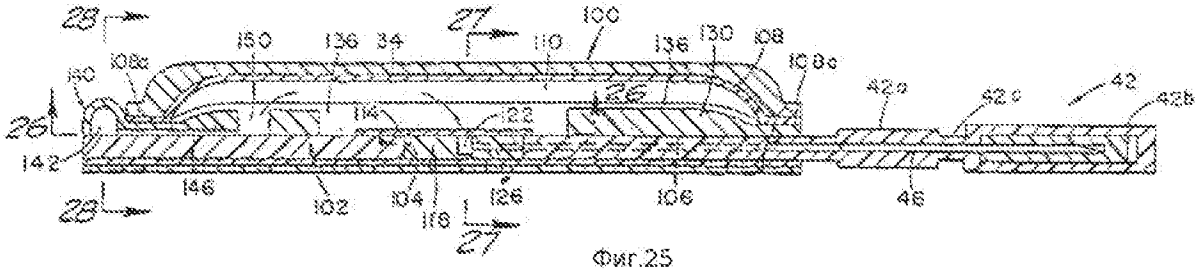

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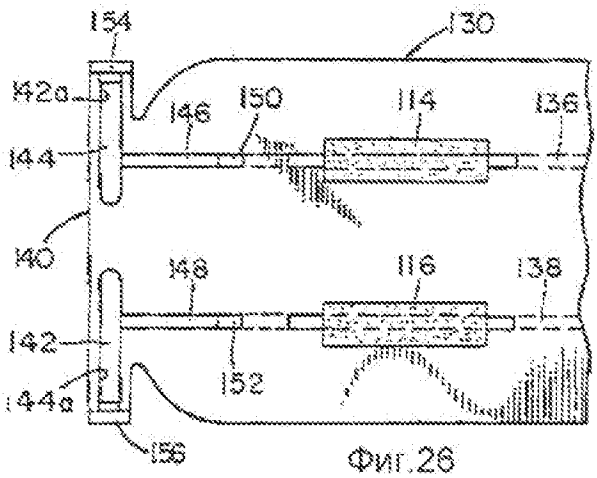

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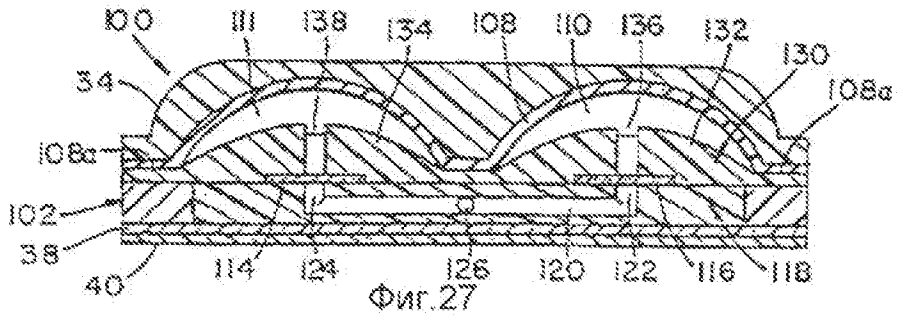

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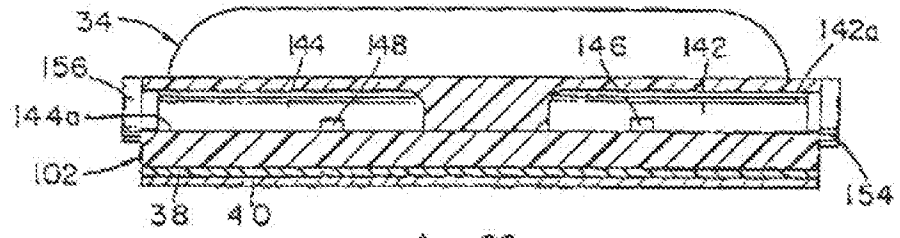

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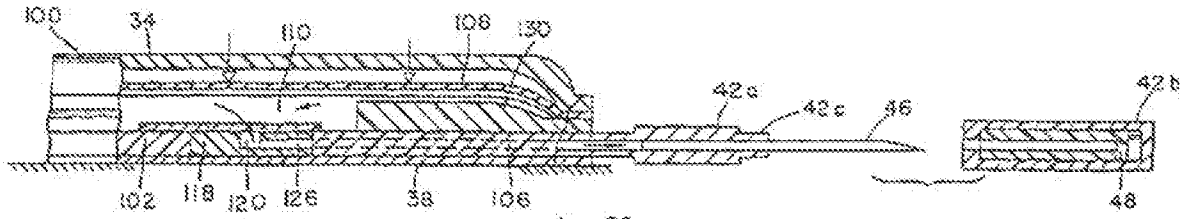

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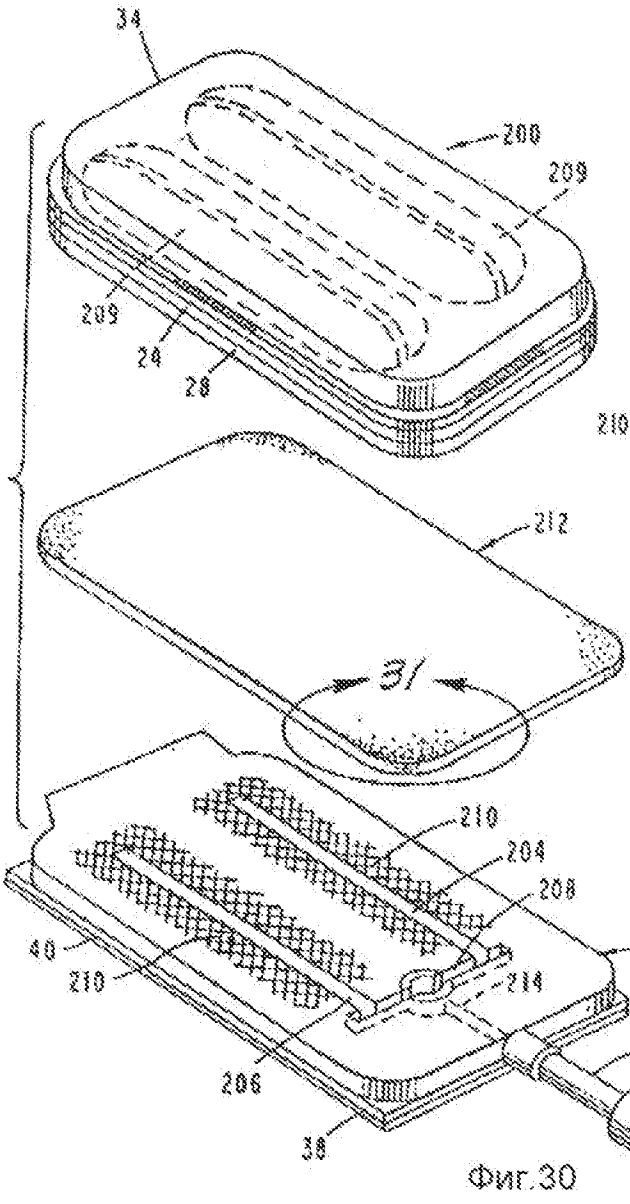

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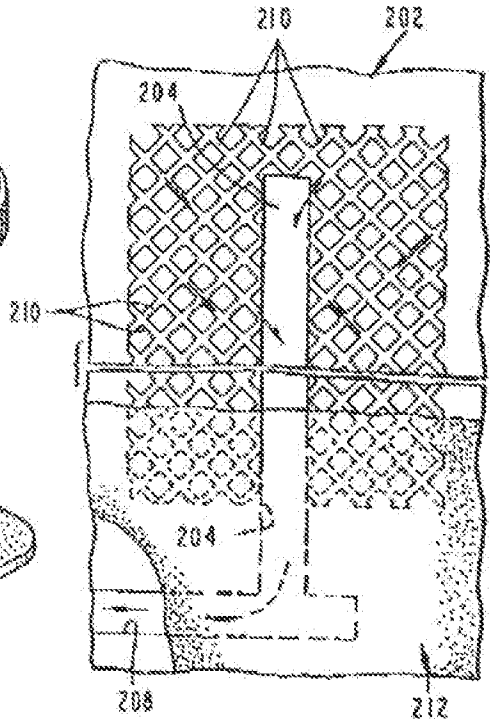

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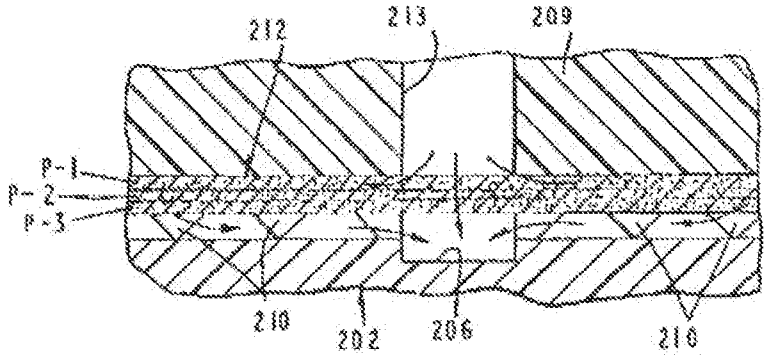

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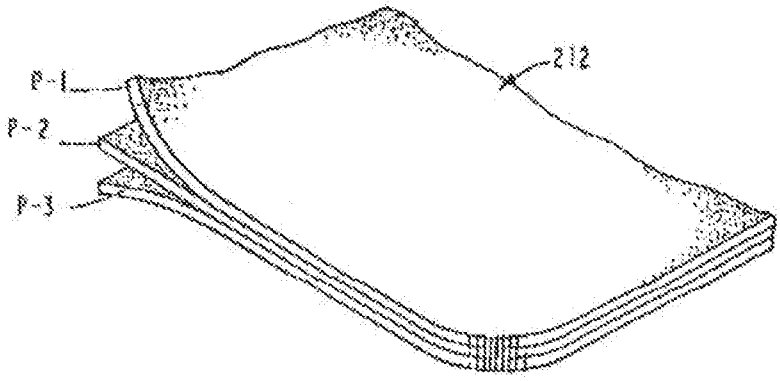

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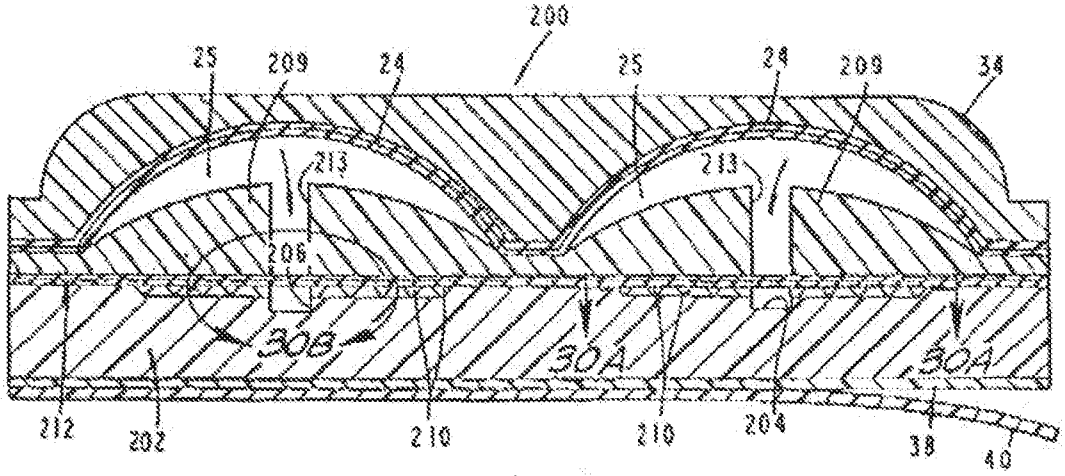

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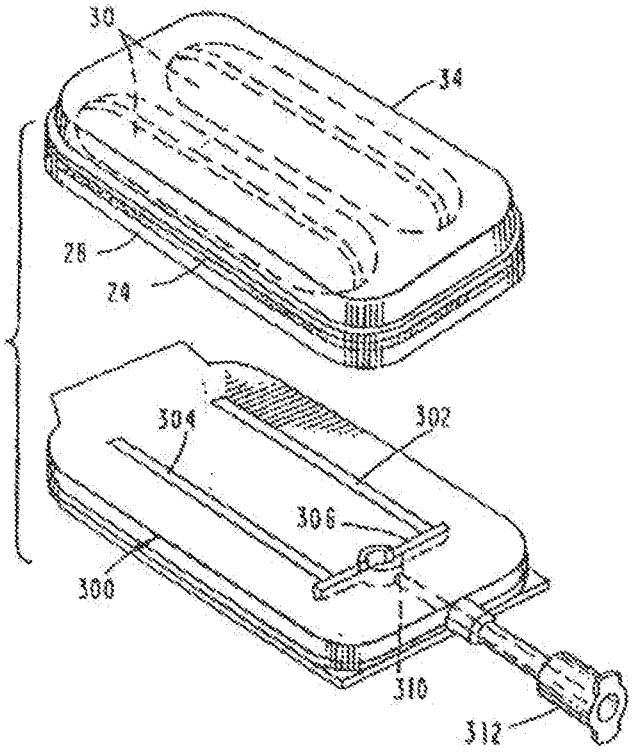

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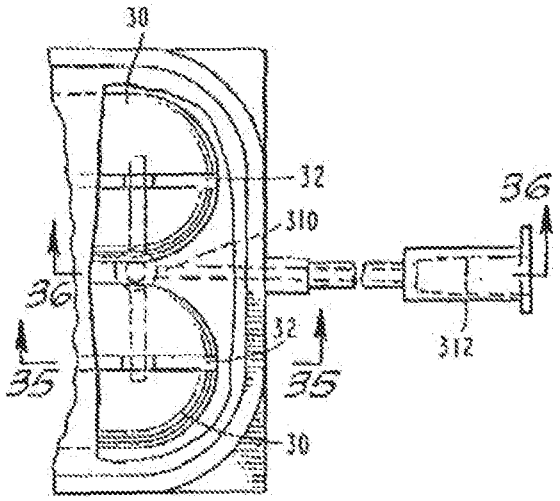

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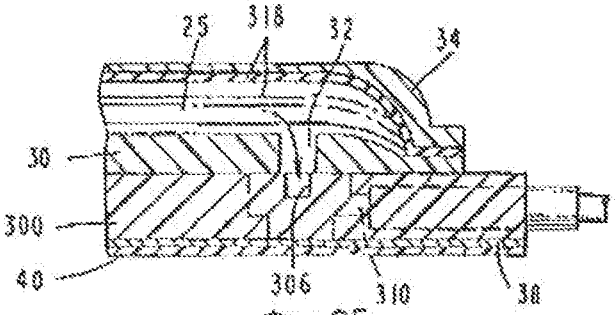

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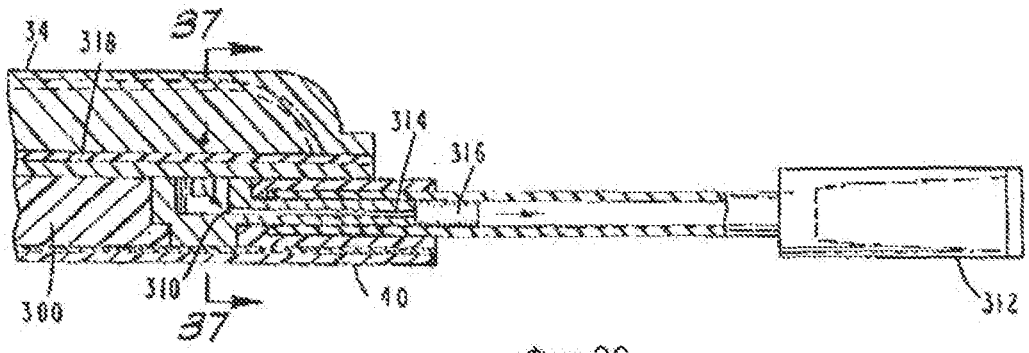

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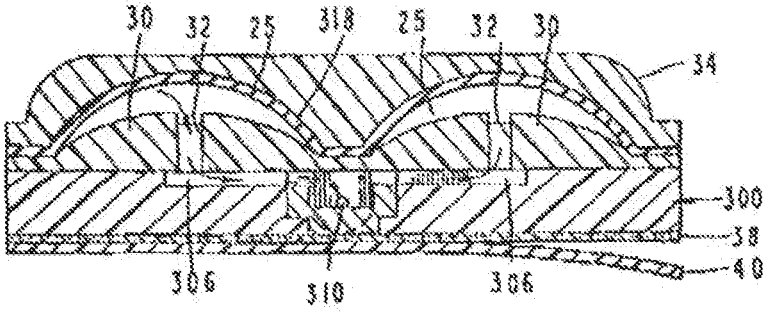

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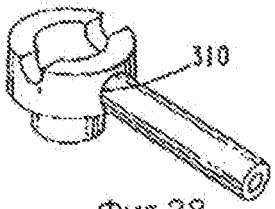

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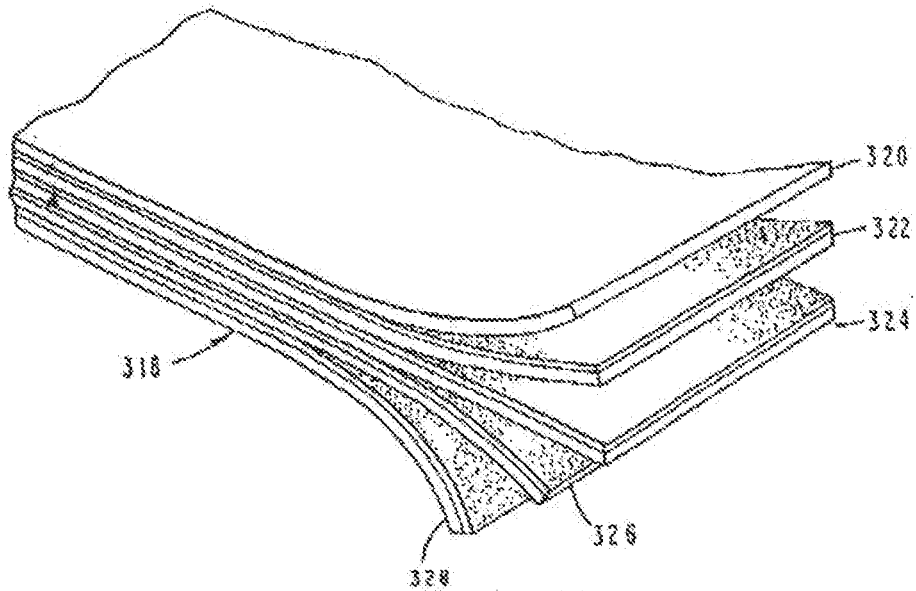

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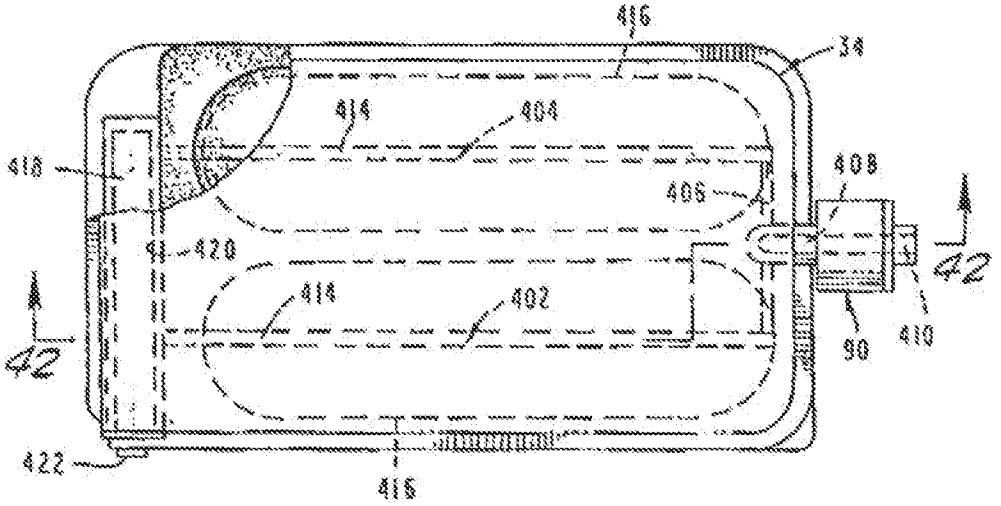

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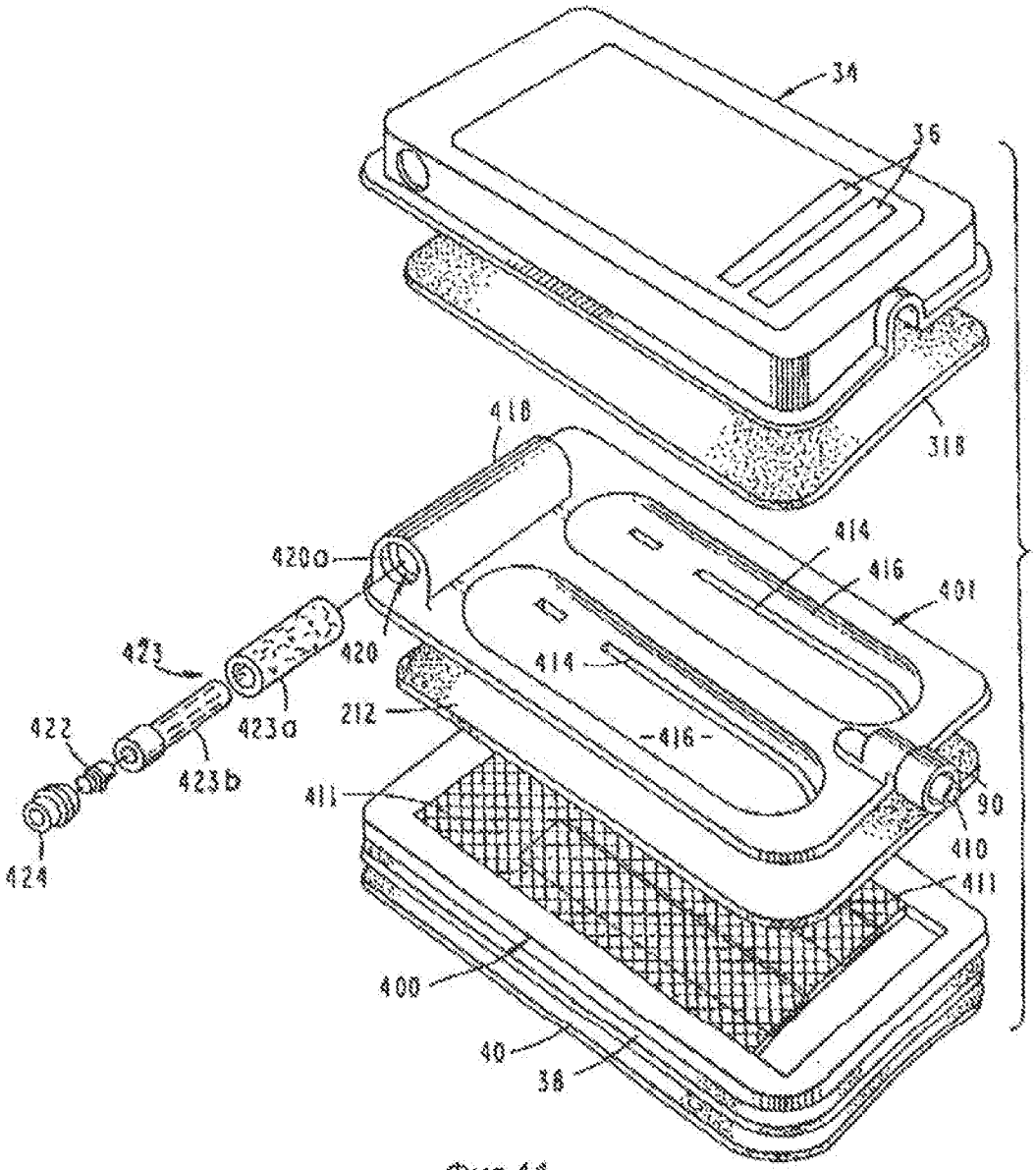

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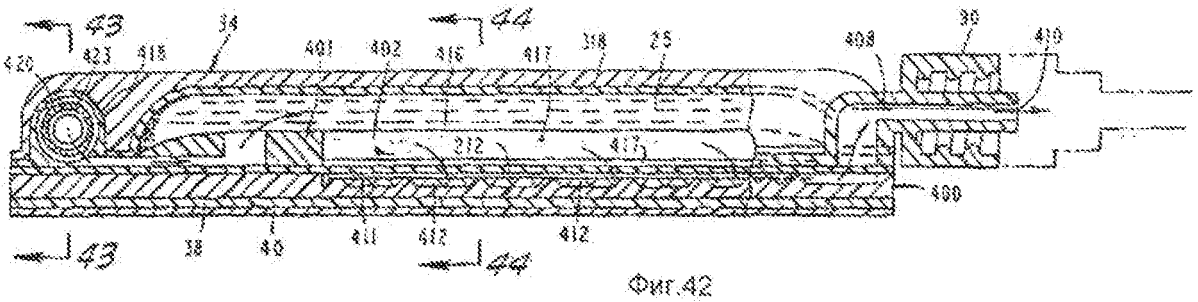

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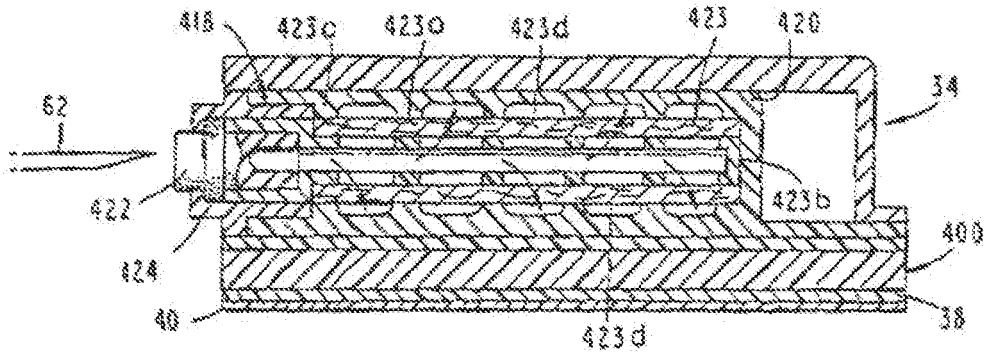

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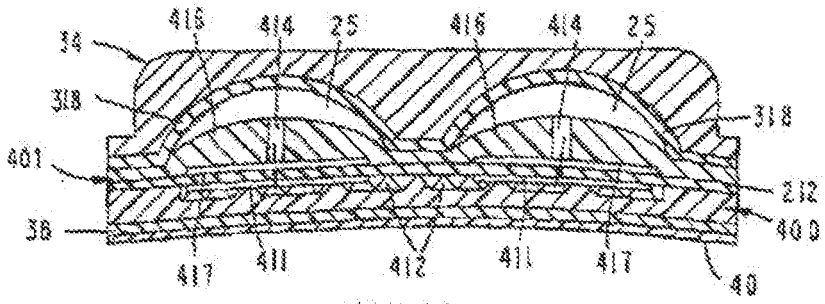
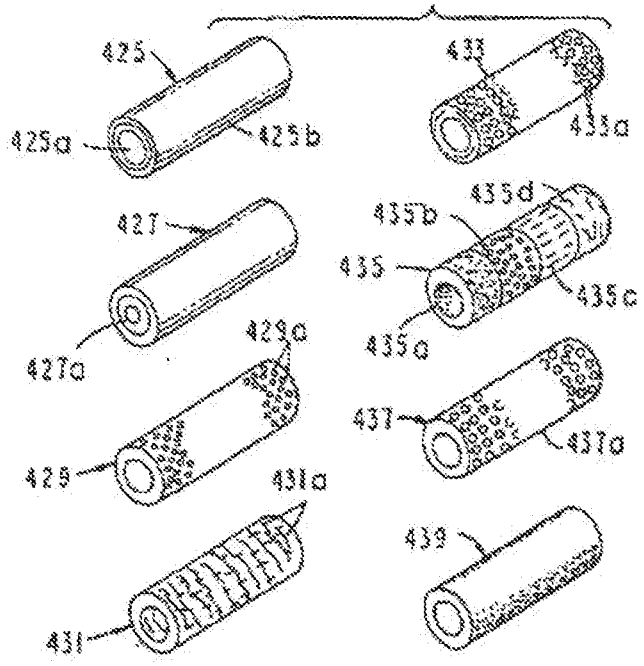
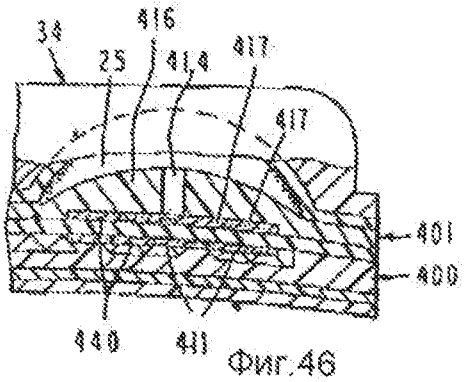


Фиг.44

RU 2131273 C1

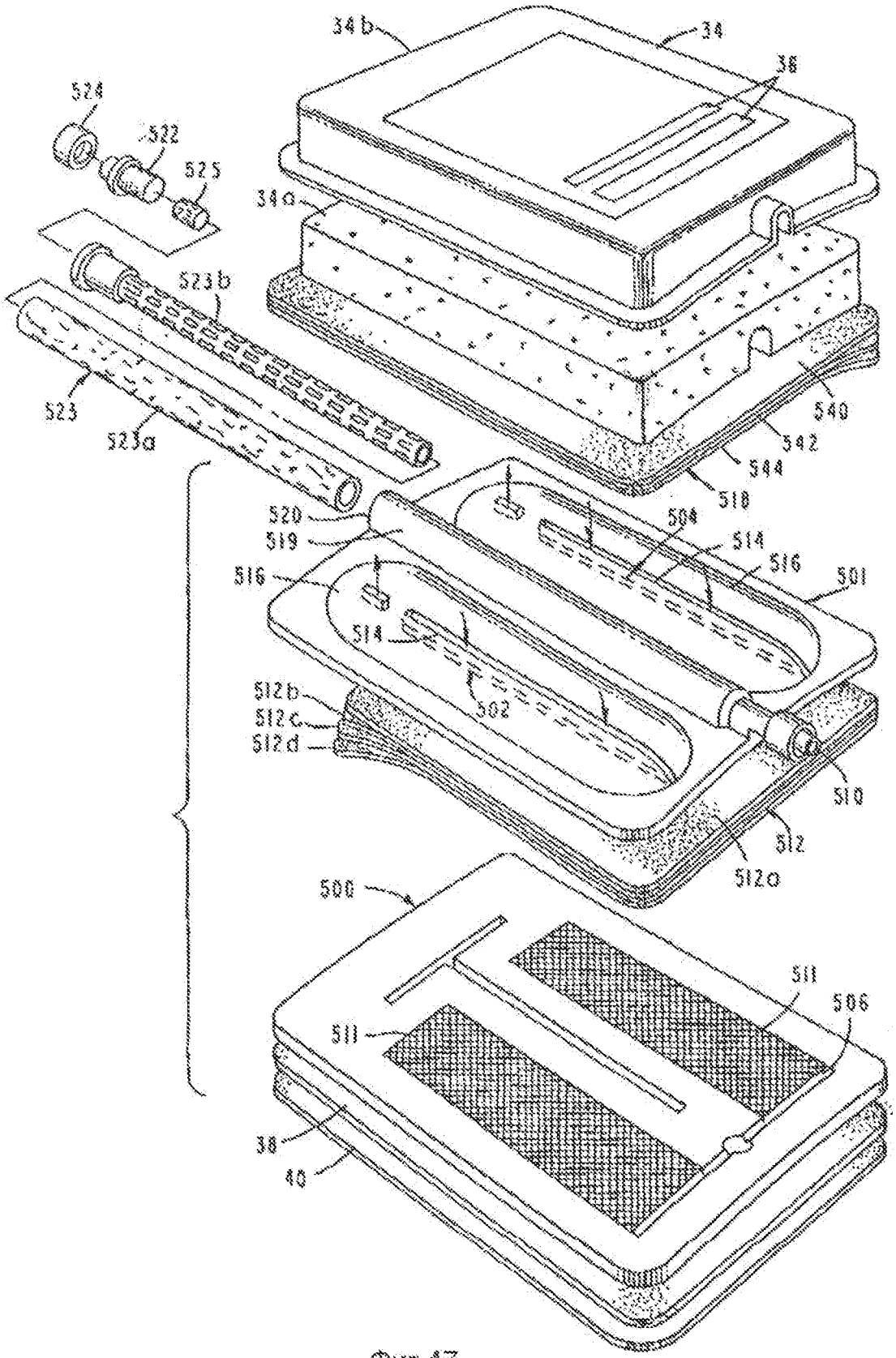


Фиг.45



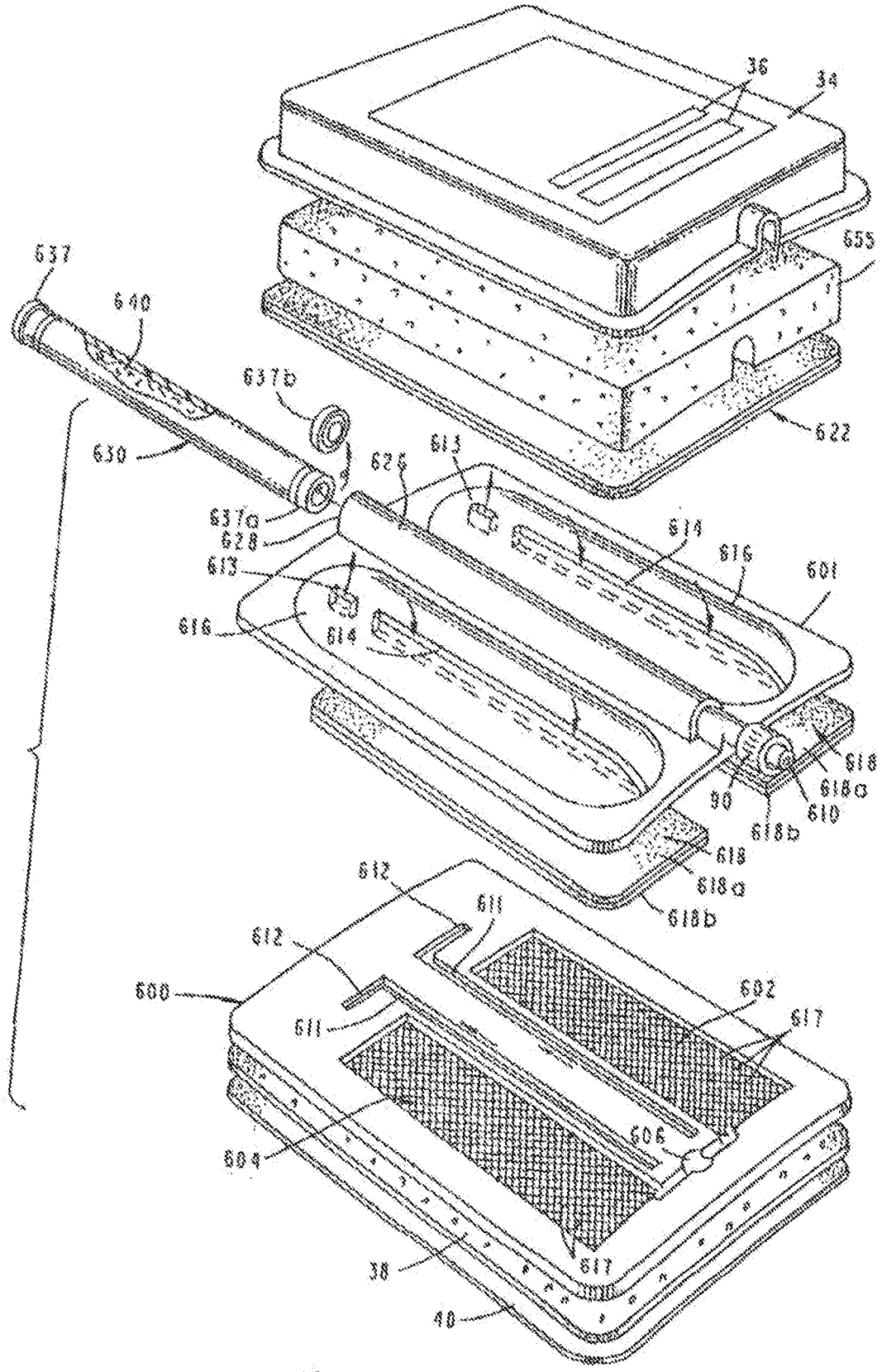
Фиг.46

RU 2131273 C1



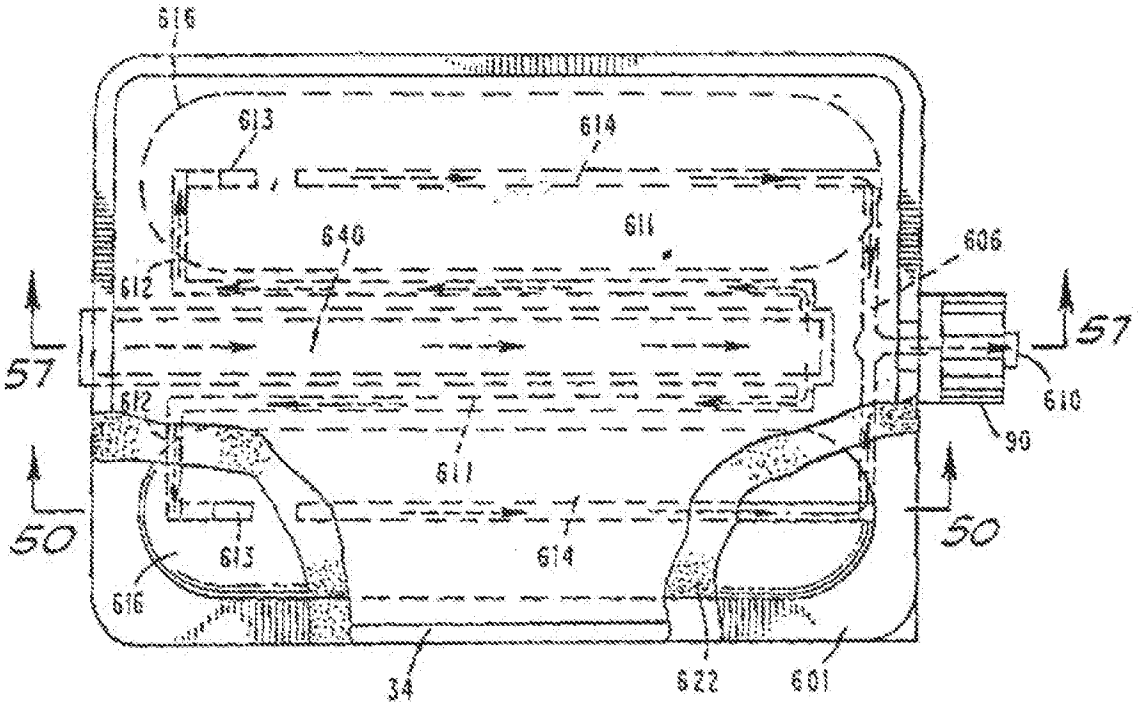
Фиг.47

RU 2131273 C1

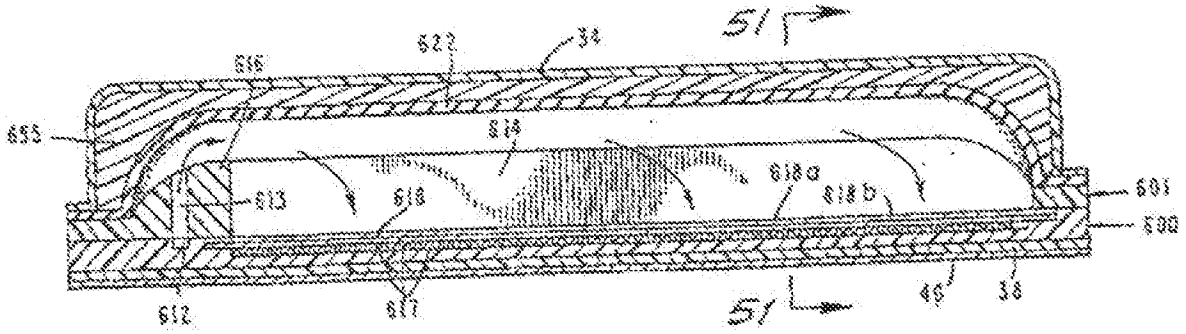


Фиг.48

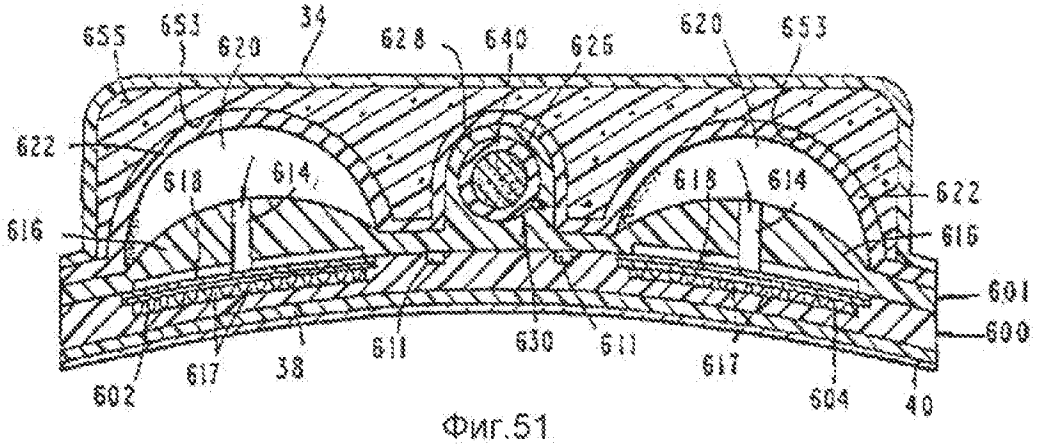
RU 2131273 C1



Фиг.49

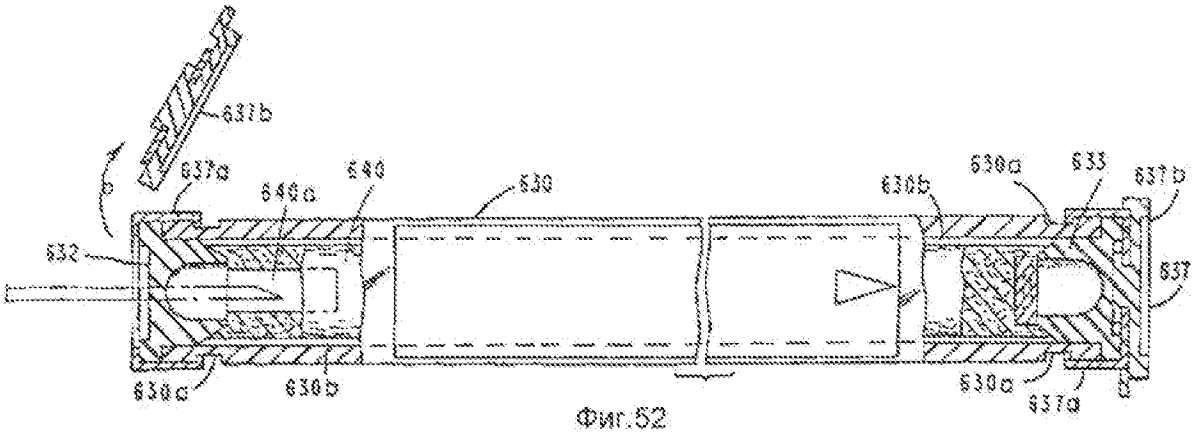


Фиг.50

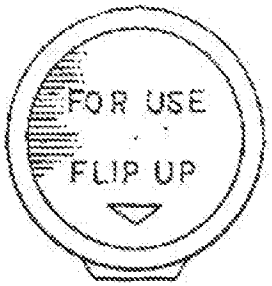


Фиг.51

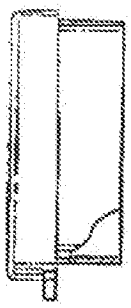
RU 2131273 C1



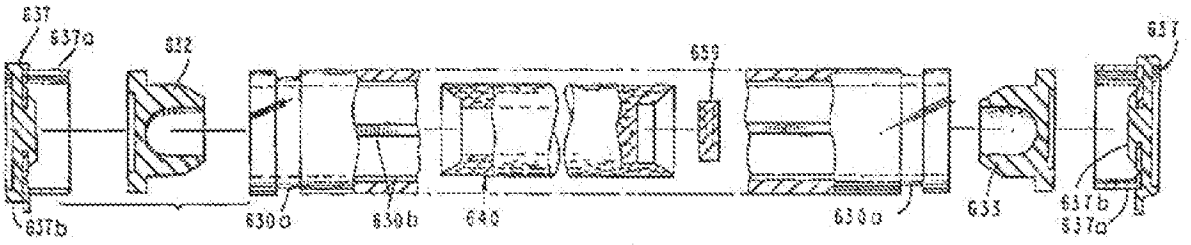
Фиг.52



Фиг.53

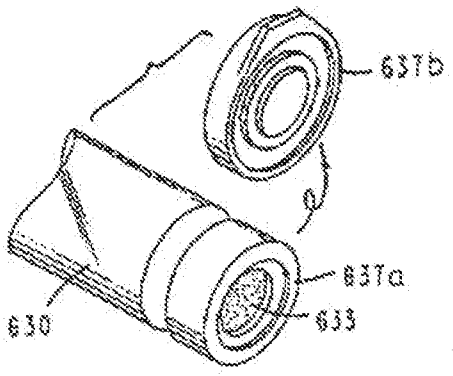


Фиг.54

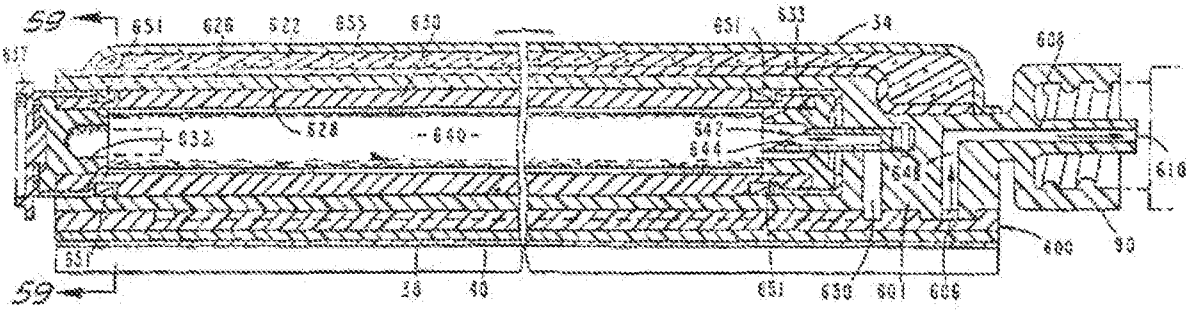


Фиг.55

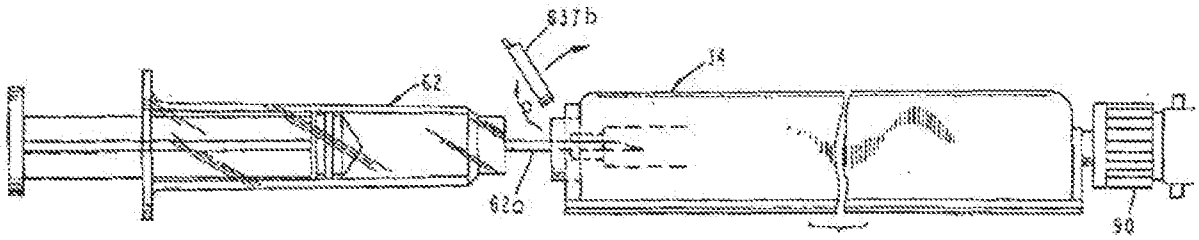
RU 2131273 C1



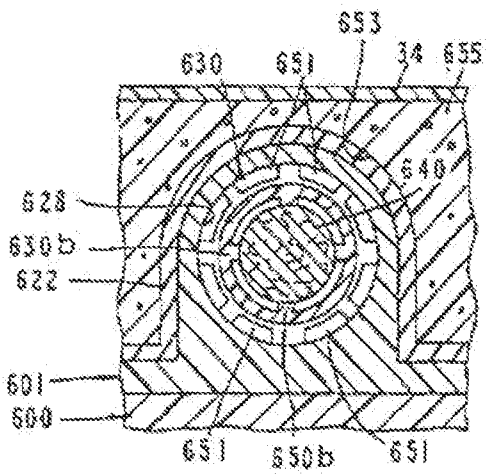
Фиг.56



Фиг.57

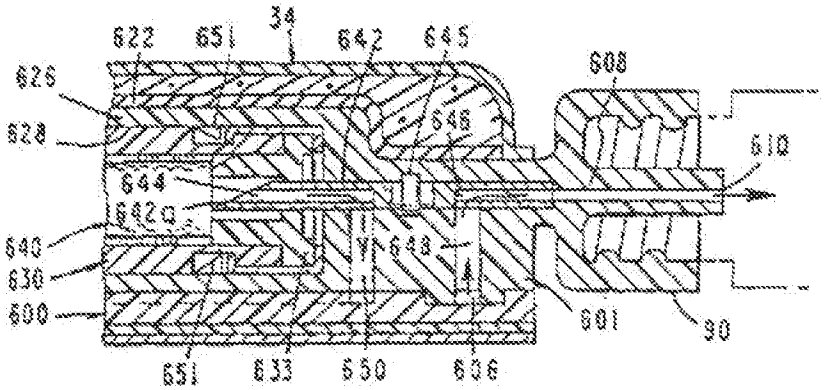


Фиг.58

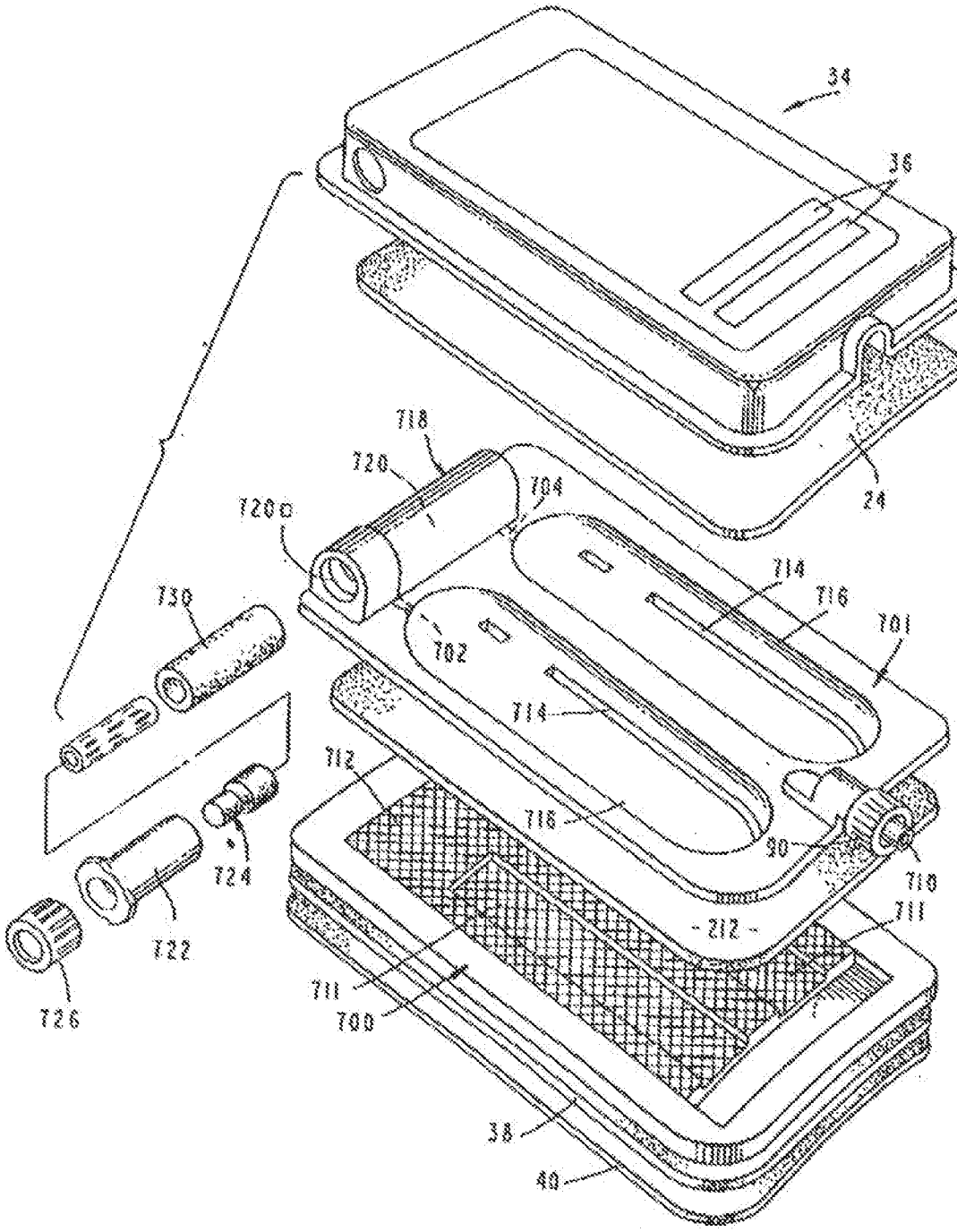


Фиг.59

RU 2131273 C1

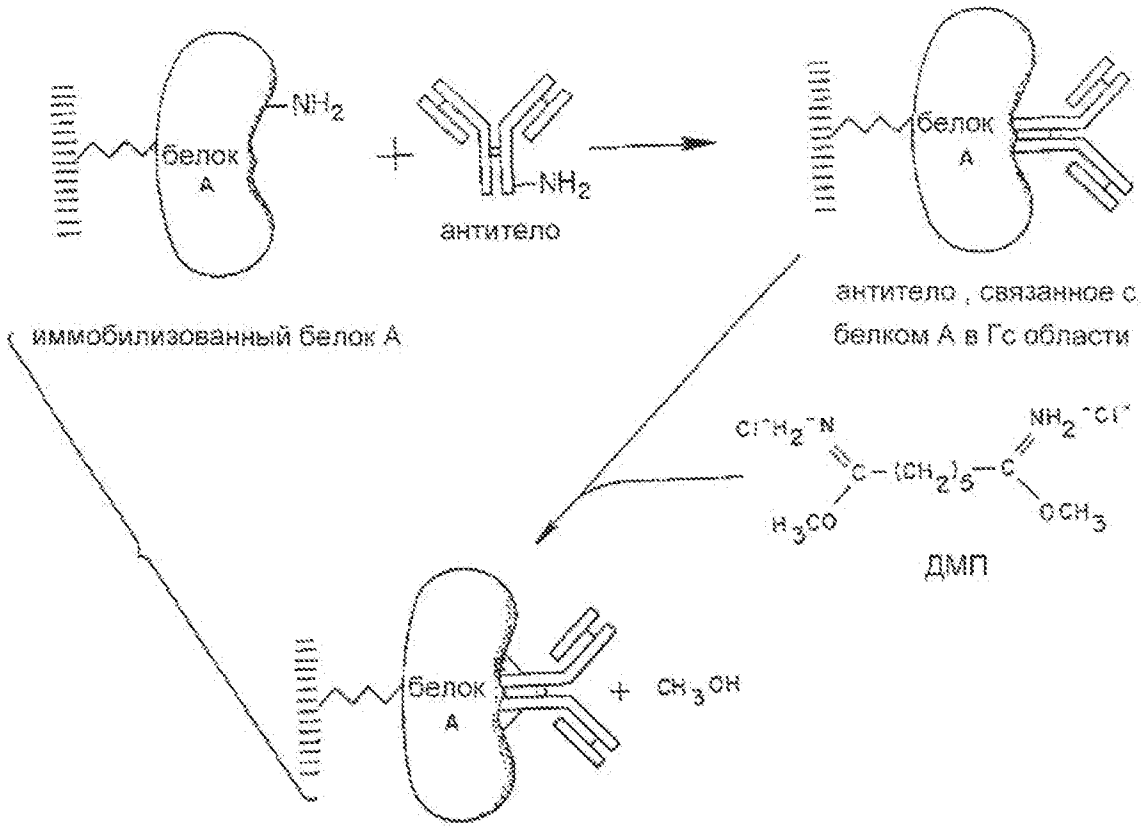


Фиг.60



Фиг.61

RU 2131273 C1



Фиг.61d

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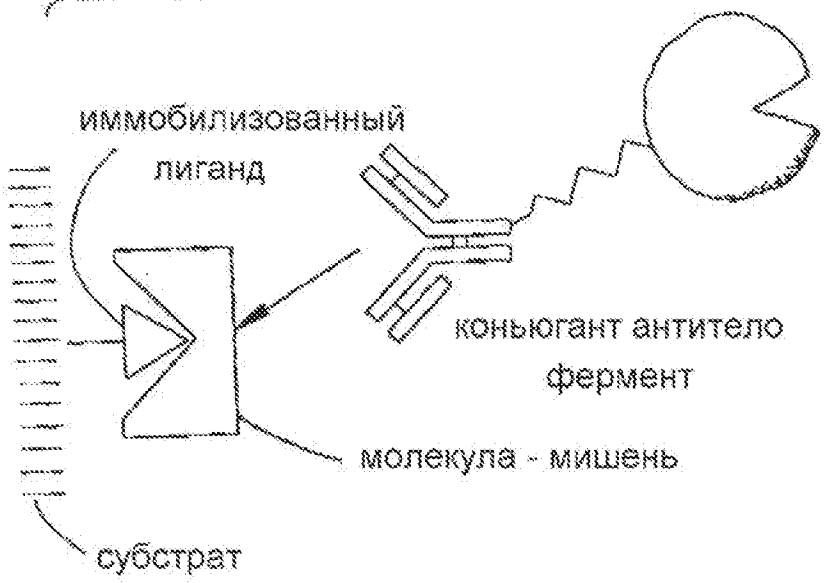
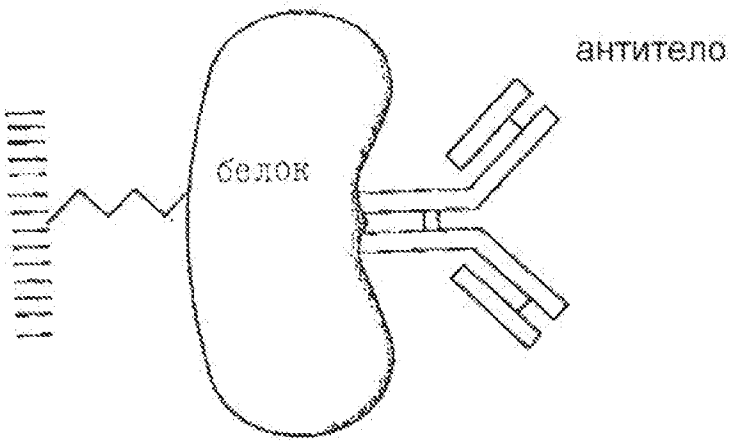
RU 2131273 C1

Фиг.61а

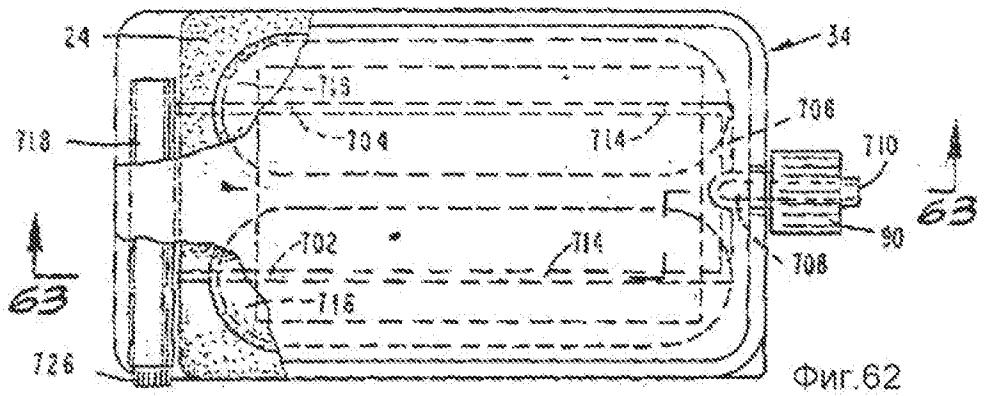
RU 2131273 C1



Фиг.61в

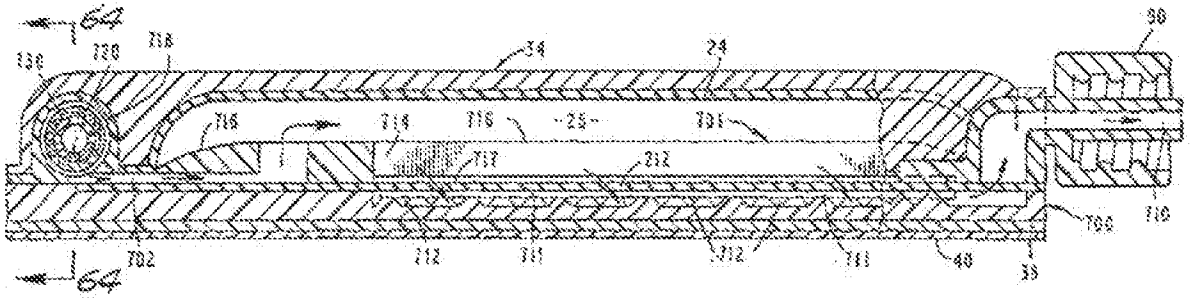


Фиг.61с

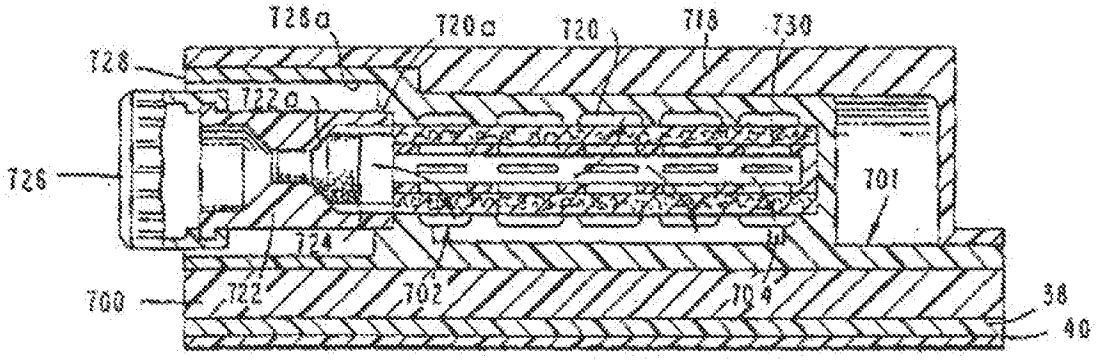


Фиг.62

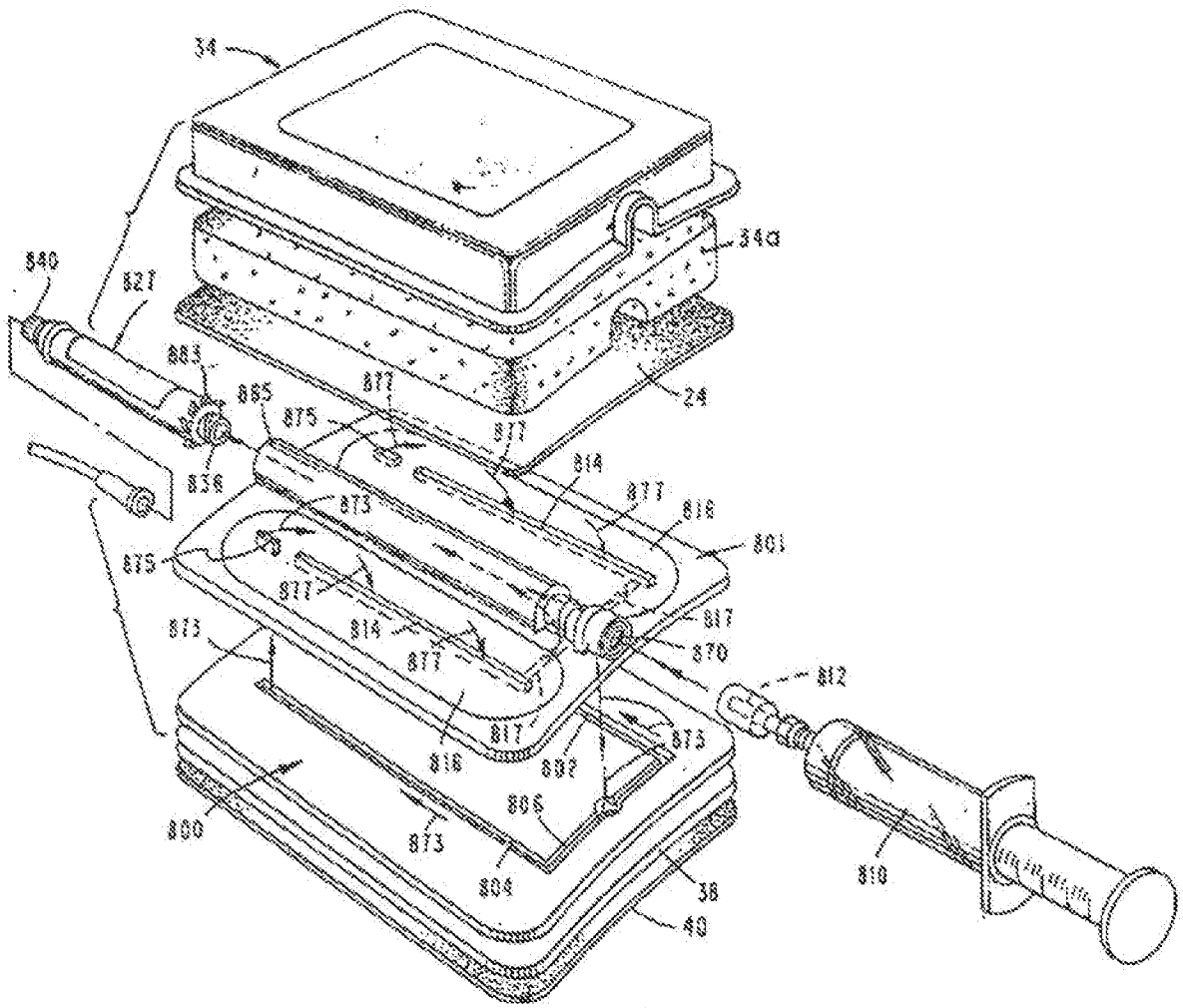
RU 2131273 C1



Фиг.63

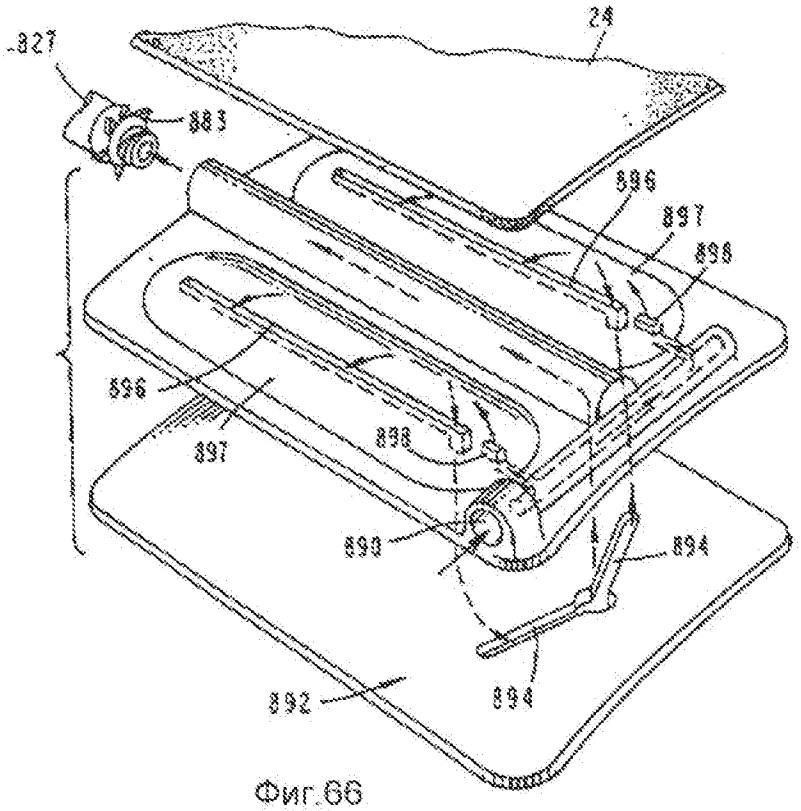


Фиг.64

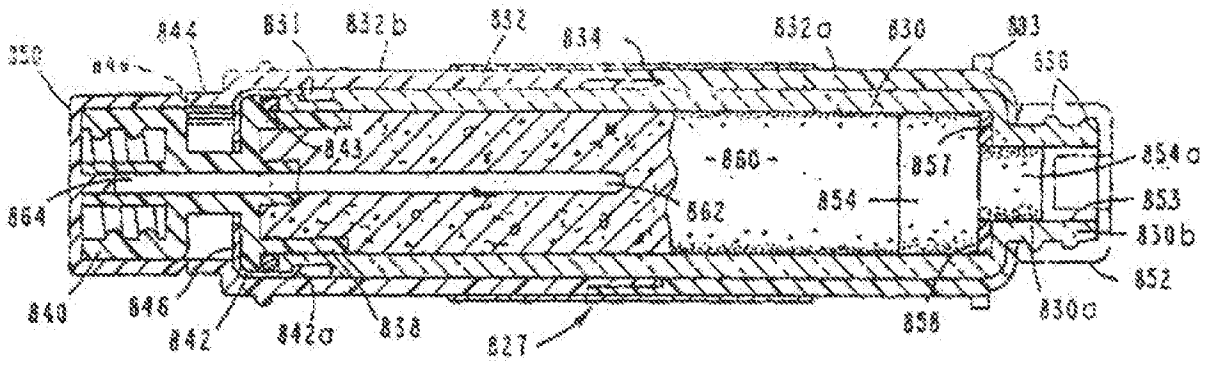


Фиг.65

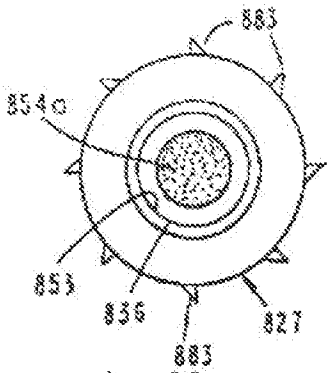
RU 2131273 C1



Фиг.66

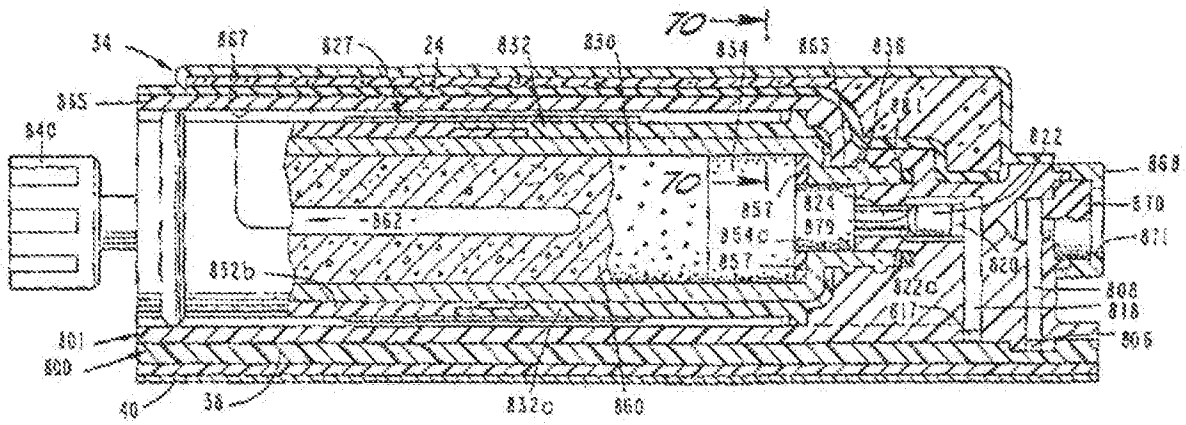


Фиг.67

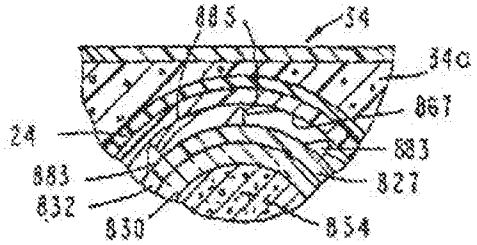


Фиг.68

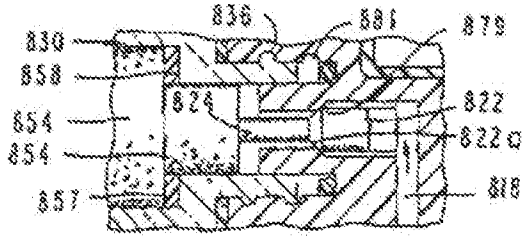
RU 2131273 C1



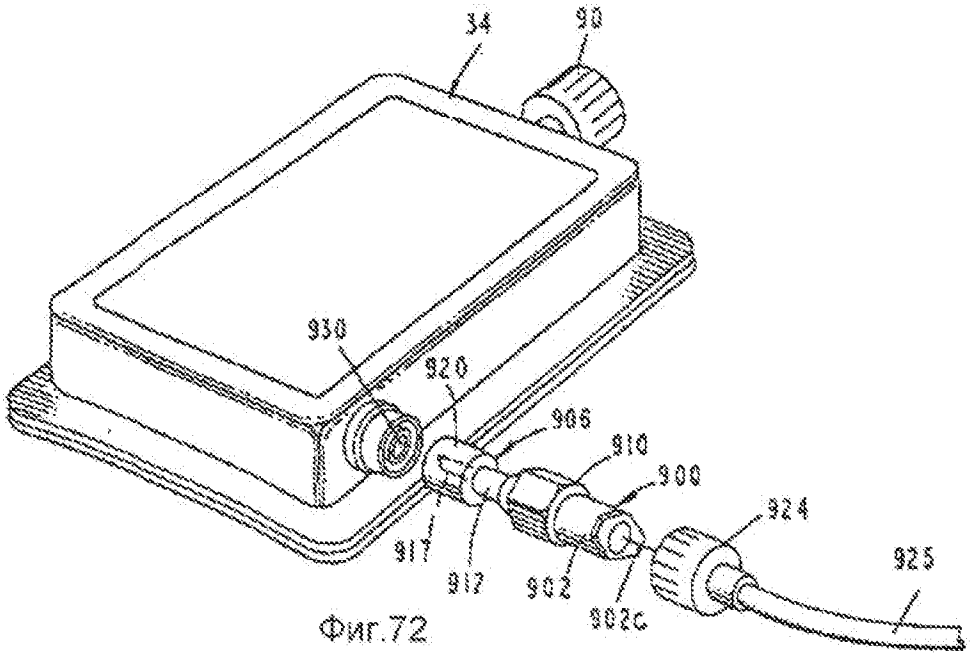
Фиг.71



Фиг.70



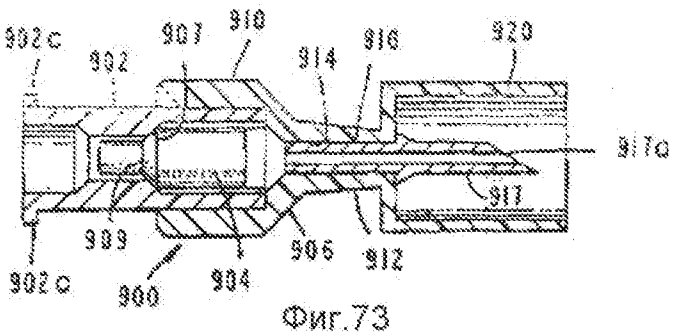
Фиг.71



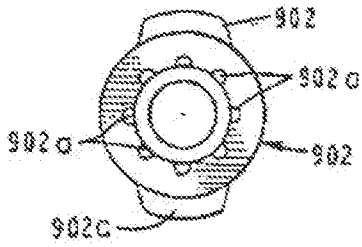
Фиг.72

RU 2131273 C1

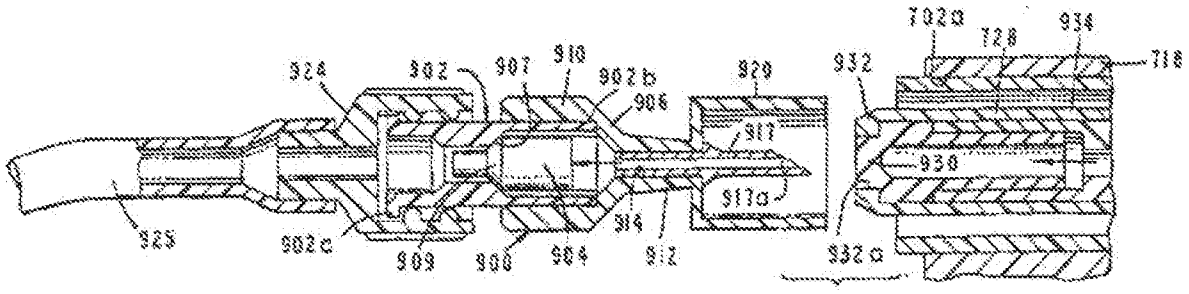
RU 2131273 C1



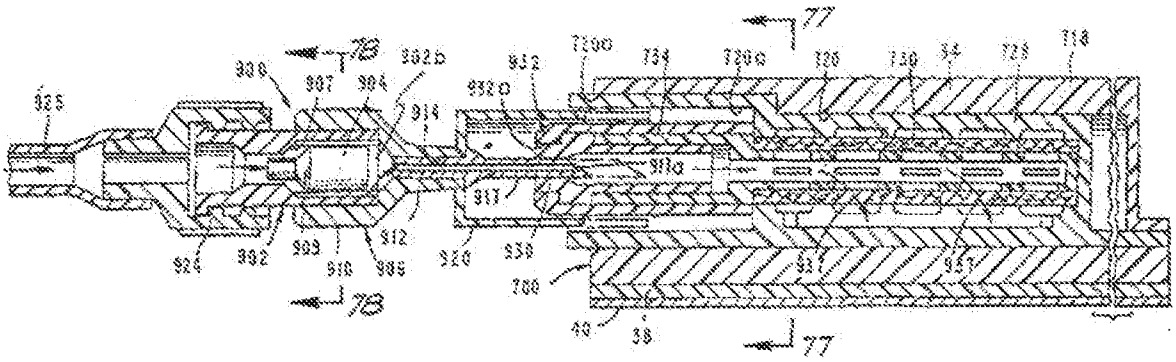
Фиг.73



Фиг.74



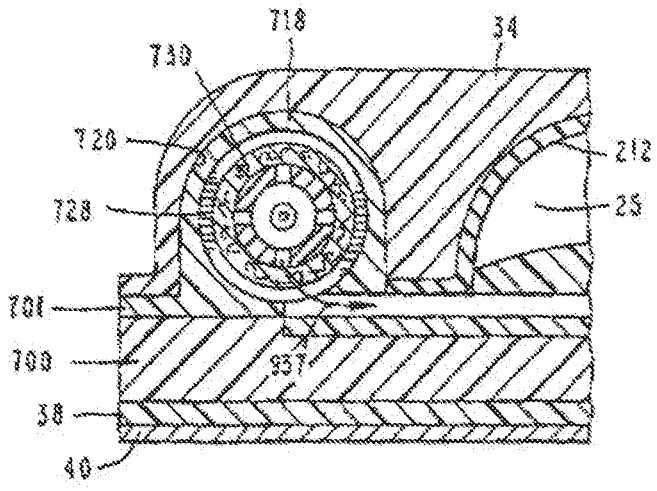
Фиг.75



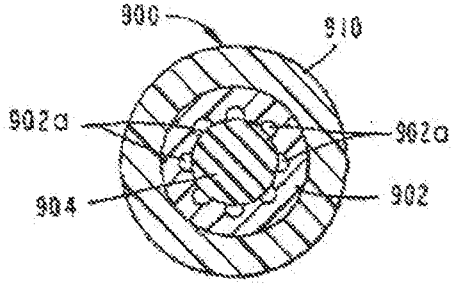
Фиг.76

RU 2131273 C1

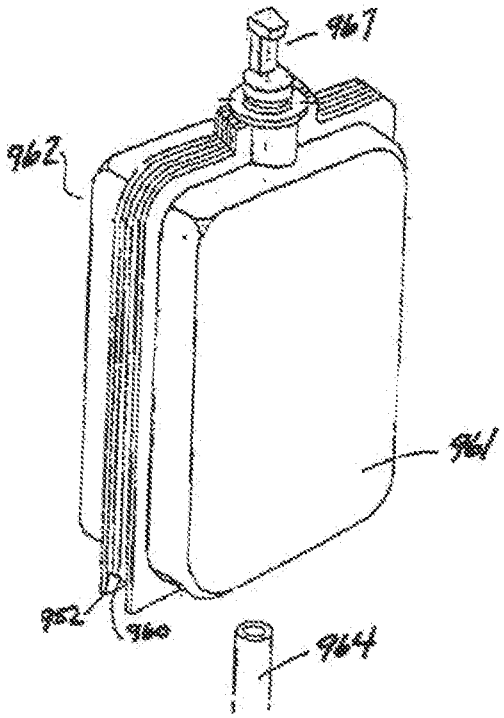
RU 2131273 C1



Фиг.77

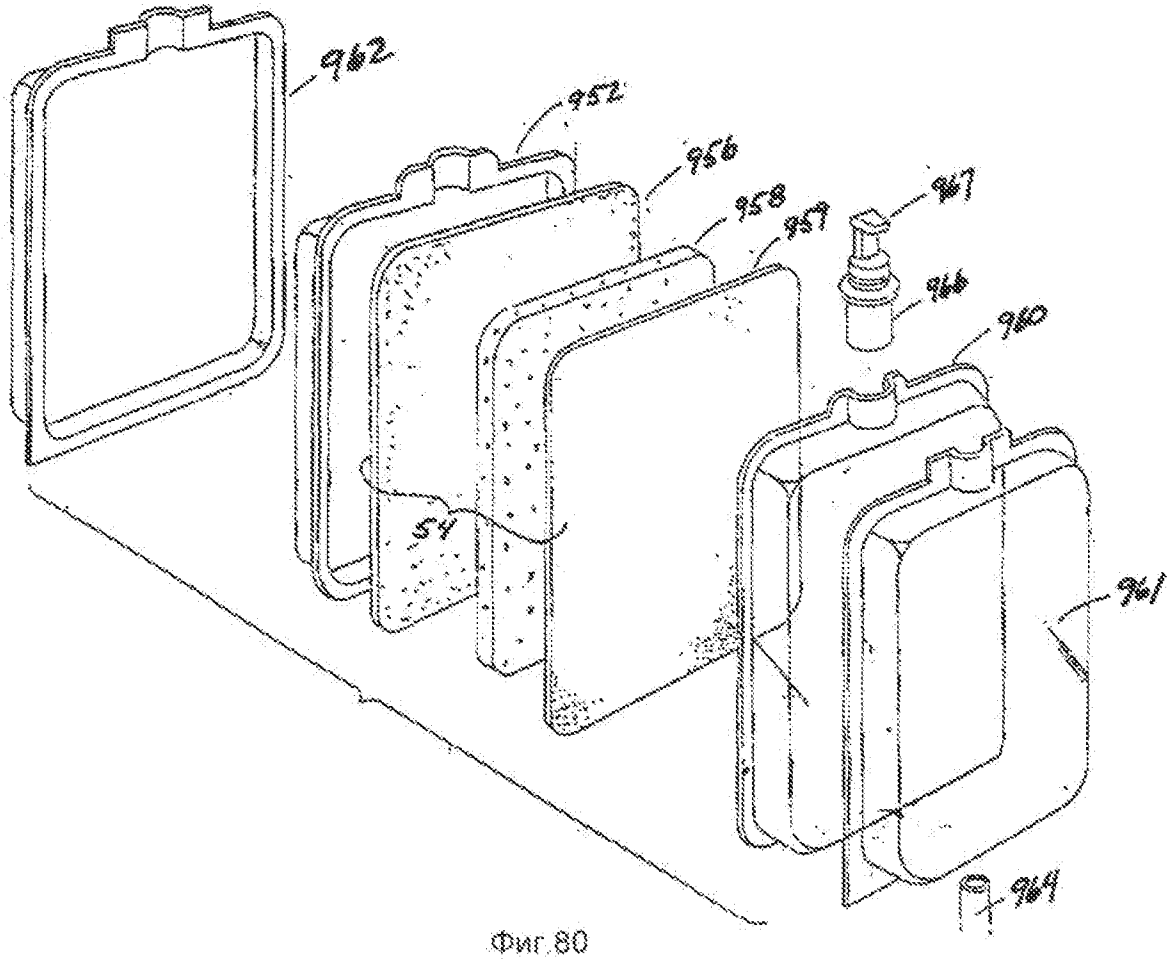


Фиг.78

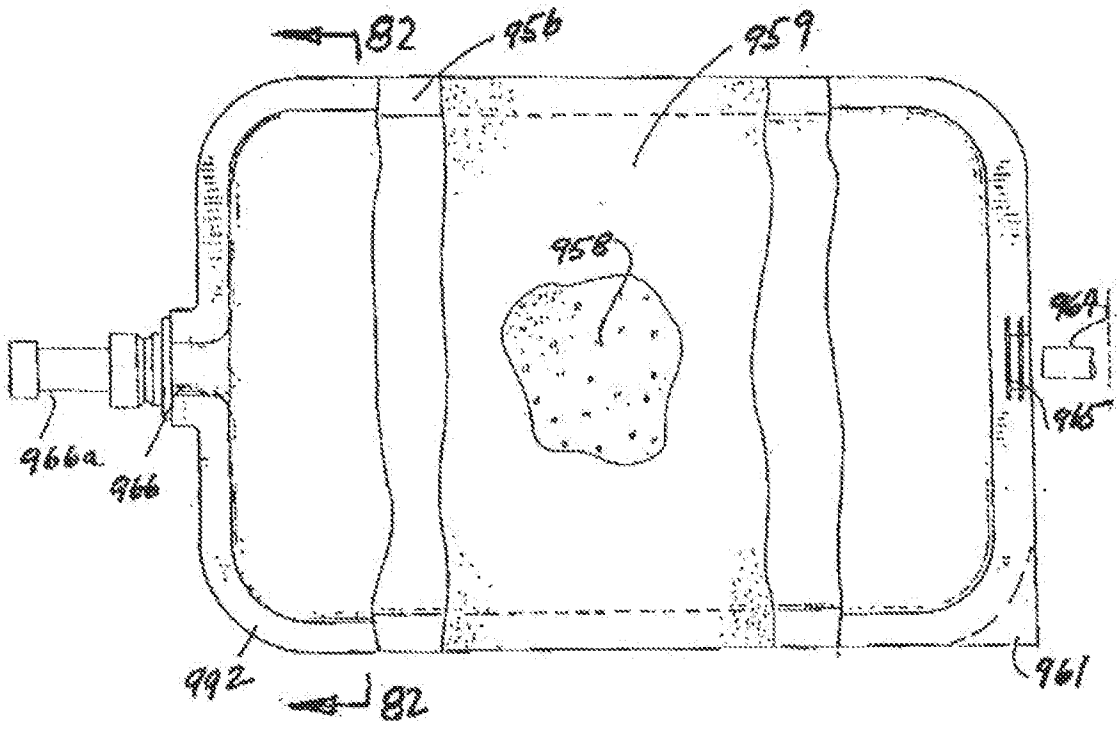


Фиг.79

RU 2131273 C1

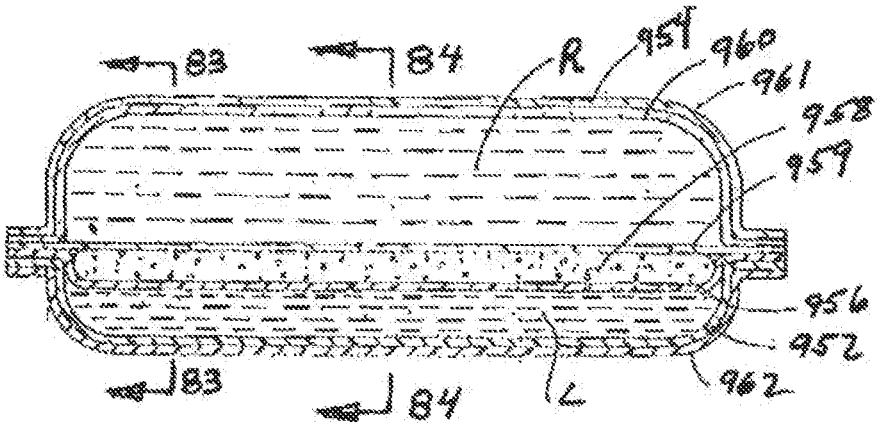


Фиг.80

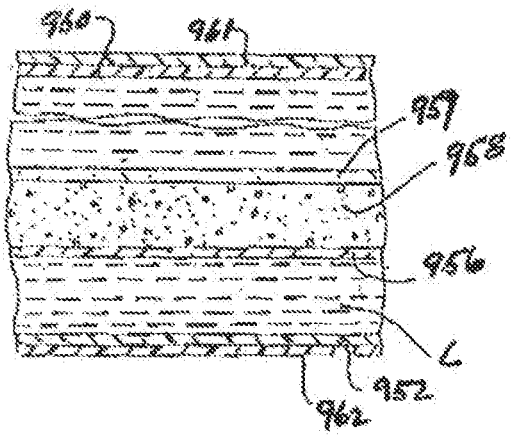


Фиг.81

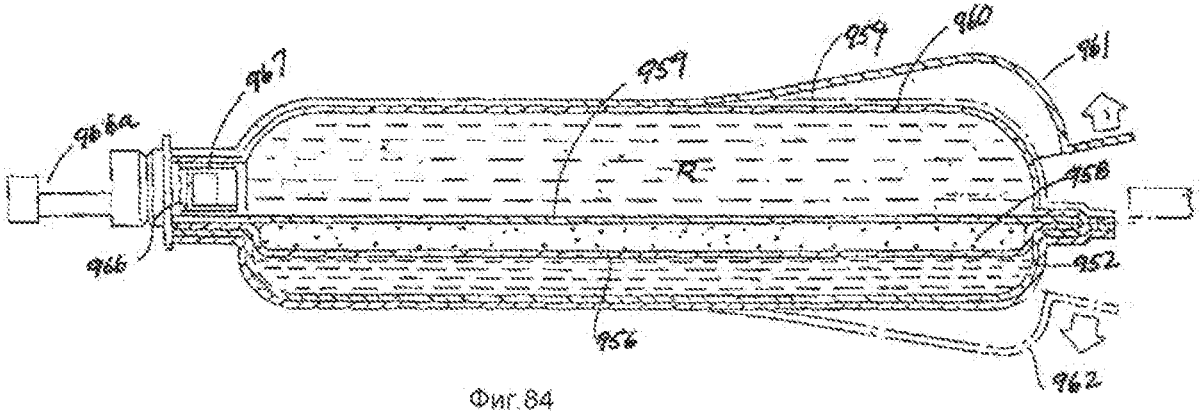
RU 2131273 C1



Фиг.82

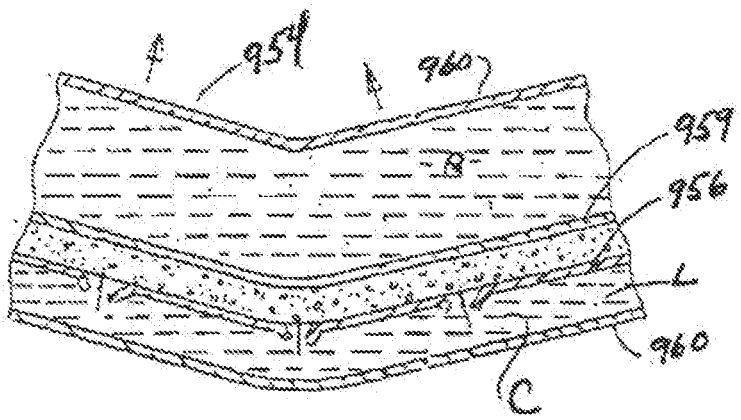


Фиг.83

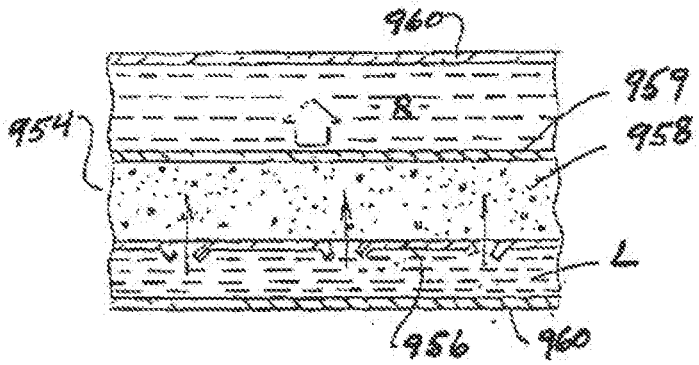


Фиг.84

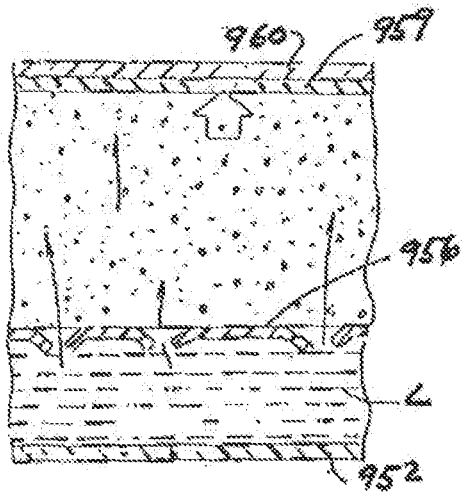
RU 2131273 C1



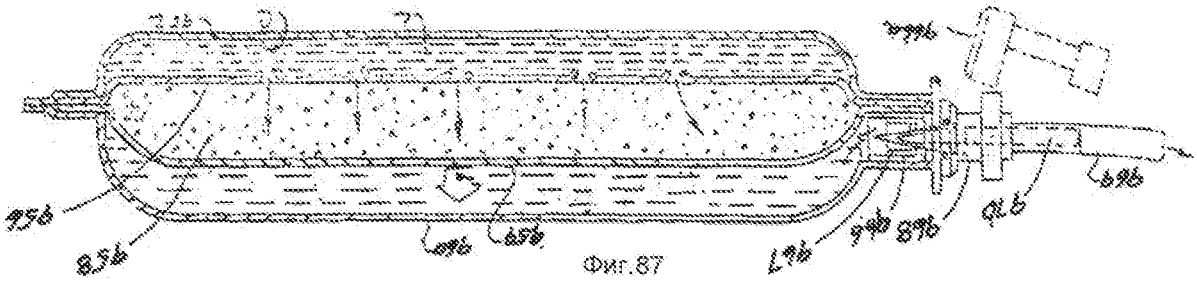
Фиг.85



Фиг.86

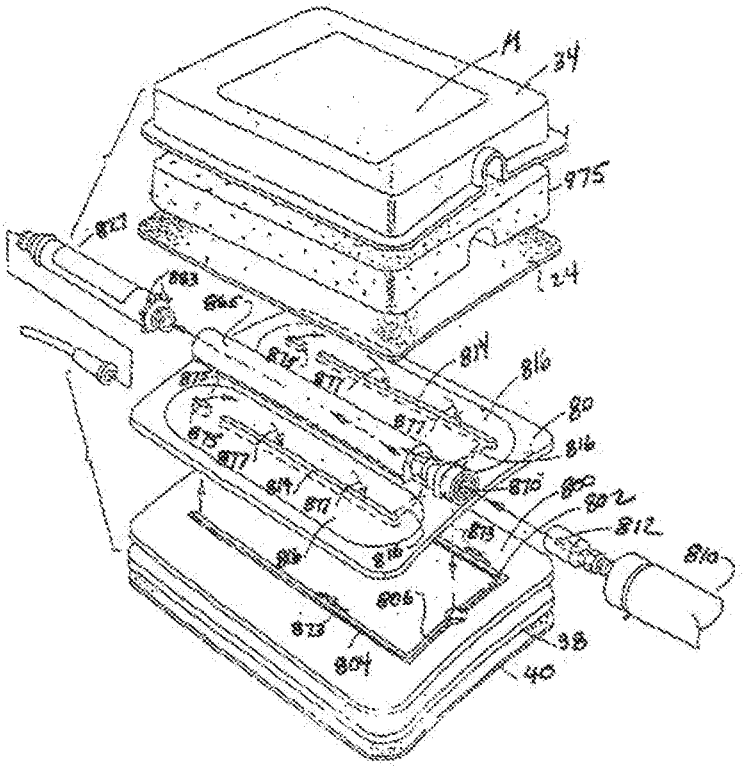


Фиг.86а

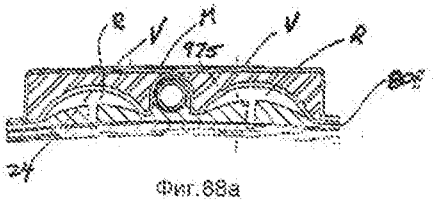


Фиг.87

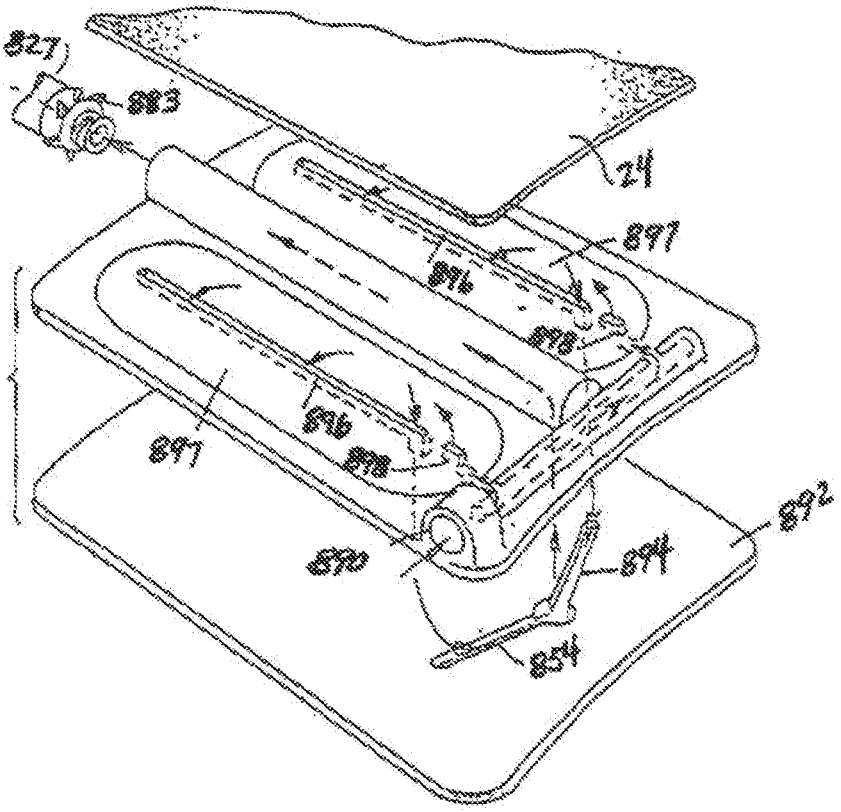
RU 2131273 C1



Фиг.88

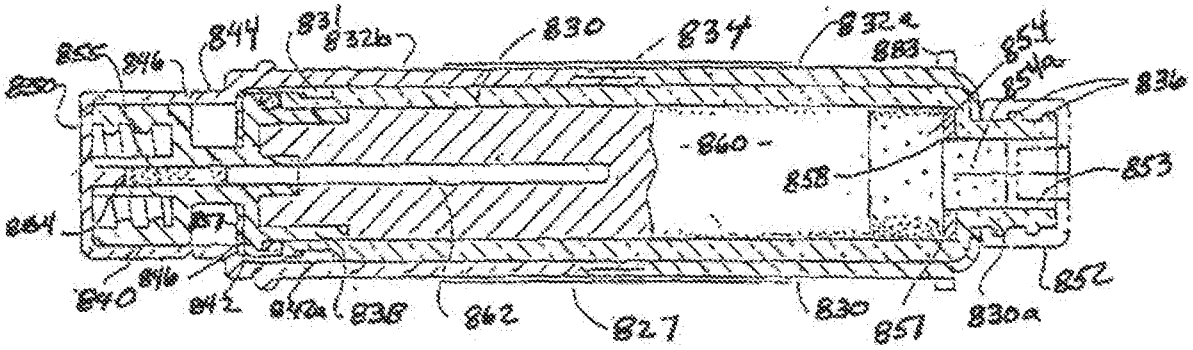


Фиг.88а

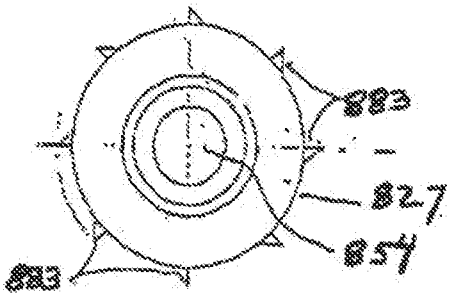


Фиг.89

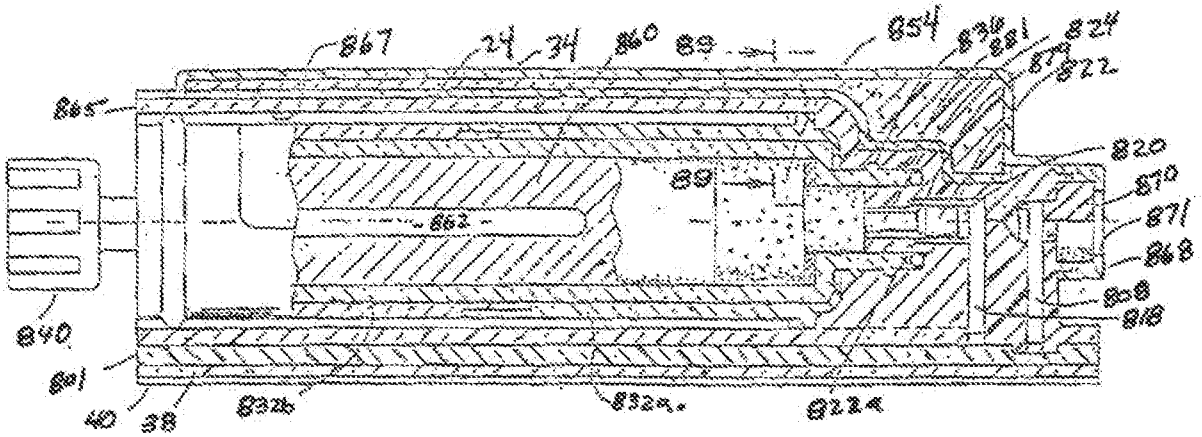
RU 2131273 C1



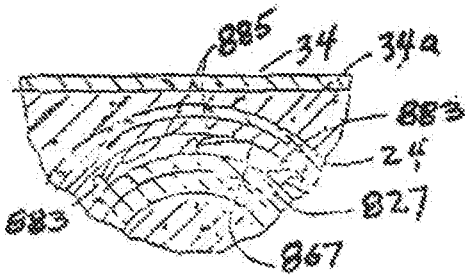
Фиг.90



Фиг.91

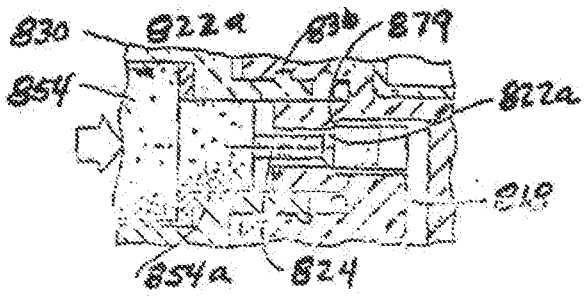


Фиг.92



Фиг.93

RU 2131273 C1



Фиг.94

RU 2131273 C1

1

SU244513A1 1969-12-31 **DEVICE of [dl] INTRODUCTIONS OF RADIOACTIVE APPLICATORS AND TRANSPORTATION OF THE [GINEKOLOGICHESKIKHBOLNYKH]** (en)

Bibliographic Data

Original Assignees: TSentralnoe konstruktorsko tekhnologicheskoe byuro mekhanizatsii Ministerstva meditsinskoj promyshlennosti SSSR Центральное конструкторско технологическое бюро механизации Министерства медицинской промышленности СССР

Inventors: R. D. Bogoudinov , YU. A. SHvedov Р. Д. Богоудинов , Ю. А. Шведов

Application Number: SU1192681

Classifications:
IPC[6]: A61M 36/00 A

Patent References Cited-Forward:

	Publication Number	Publication Date	Title	Applicant/Assignee
	RU2163100C1	2001-02-20	METHOD FOR APPLYING COMBINED TREATMENT OF ONCOLOGICAL DISEASES OF SMALL PELVIS ORGANS	Grobel' Oleg Vjacheslavovich

Description

English Description:

In essence of [at]. SV of № 171934 is described the device of [dl] of the transport of patients before the radiological department, the containing base with the wheels, three-piece panel and manual .[privody] of [dl] of [prevrashcheni] of device either beside the bed- winder or beside the gynaecological armchair.The proposed device of [dl] of [vnedreni] of radioactive applicators and [peravoaki] of gynaecological sick [otlichaets] fact that for the purpose of [povysheni] of [bystrodeystvi] and [uluchsheni] of the conditions of the work of the service personnel, before it is established hydraulic drive with the lever systems of the transfer of device from [polozheni] "roof [at]- winder beside the position "gynaecological armchair. [Dl] - [provedeni] of control X-ray photographs, [opredel] of [yushchikh] the position of radioactive preparation before the irradiated cavity, before the device of [imeets] the nest of [dl] of the insert of cassette with the x-ray film.The schematic of the described device is depicted beyond the drawing.Device consists of [osnovani] (body) 1, mobile frame 2, hydraulic drive 3 with [nolshoy] pedal 4, locking mechanism 5, levers 6 and 7, [soedin] of [yushchikh] the mobile framewith the base according to parallelogram diagram, [samoorentiruyushchikh] wheels 8 with the mechanism of 9 [dl] of forced orientation. Is mobile frame it contains three sections 10, 11 and 12 with built-in head rest 13 and mechanism of 14 [dl] of its fixation. Before nest 15 .[mogut] [ustanavlivats] detachable gynaecological [prioposobleni] 16. nest 17 it serves [dl] of the installation of cassettes.10It

[pred].[met] isoBrettnot 1.[Ustroystvo] of [dl] of [vnedreni] of radioactive applicators and transportation of the gynaecologicalsick on the author SV 171934, [otlichayushchees] fact that, for the purpose of [povysheni] of [bystrodeystvi] and [uluchsheni] of the conditions of the work of the service personnel, before it is established hydraulic drive with the lever systems of the transfer of device from [G]1[olozheni] "Bed- winder beside [pololsenie] "gynaecological armchair.2.[Ustroystvo] on p. 1, [otlichayushchees] fact that, .[tselyu] [provedeni] of control X-ray photographs, [opredel] of [yushchikh] the position

Союз Советских Социалистических Республик

Комитет по делам изобретений и открытий при Совете Министров СССР

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

К АВТОРСКОМУ СВИДЕТЕЛЬСТВУ

244513

Зависимое от авт. свидетельства № 171934

Заявлено 25.X.1967 (№ 1192681/31-16)

с присоединением заявки № —

Приоритет —

Опубликовано 28.V.1969. Бюллетень № 18

Дата опубликования описания 10.X.1969

Кл. 21g, 21/01

МПК H 05g

УДК 615.478.32:615.849.7:616-073(088.8)

Авторы изобретения Р. Д. Богоудинов и Ю. А. Шведов

Заявитель Центральное конструкторско-технологическое бюро механизации Министерства медицинской промышленности СССР

УСТРОЙСТВО ДЛЯ ВНЕДРЕНИЯ РАДИОАКТИВНЫХ АППЛИКАТОРОВ И ПЕРЕВОЗКИ ГИНЕКОЛОГИЧЕСКИХ БОЛЬНЫХ

1

В основном авт. св. № 171934 описано устройство для транспортировки больных в радиологическом отделении, содержащее основание с колесами, трехсекционную панель и ручные приводы для превращения устройства либо в кровать-каталку, либо в гинекологическое кресло.

Предлагаемое устройство для внедрения радиоактивных аппликаторов и перевозки гинекологических больных отличается тем, что с целью повышения быстродействия и улучшения условий работы обслуживающего персонала, в нем установлен гидравлический привод с рычажными системами перевода устройства из положения «кровать-каталка» в положение «гинекологическое кресло». Для проведения контрольных рентгеновских снимков, определяющих положение радиоактивного препарата в облучаемой полости, в устройстве имеется гнездо для вставки кассеты с рентгеновской пленкой.

На чертеже изображена схема описываемого устройства.

Устройство состоит из основания (каркаса) *1*, подвижной рамы *2*, гидропривода *3* с ножной педалью *4*, стопорного механизма *5*, рычагов *6* и *7*, соединяющих подвижную раму

2

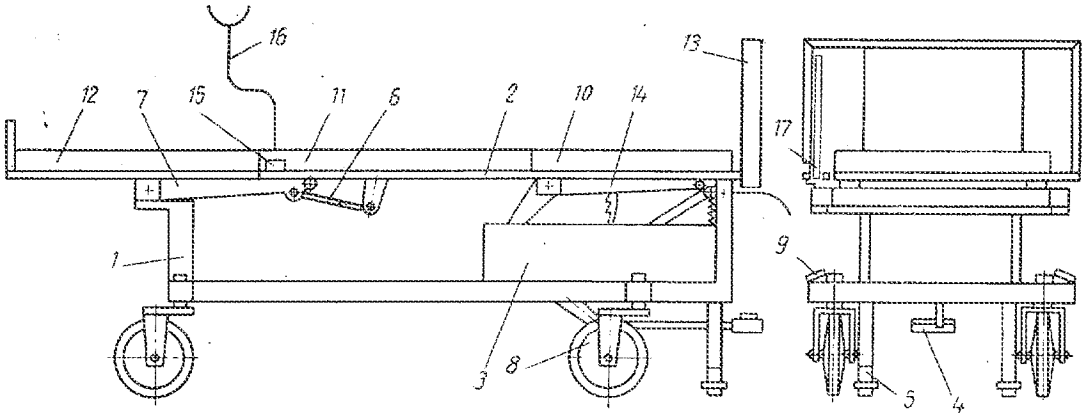
с основанием по параллелограммной схеме, самоорентирующих колес *8* с механизмом *9* для принудительной ориентации. Подвижная рама содержит три секции *10*, *11* и *12* с встроенным подголовником *13* и механизмом *14* для его фиксации. В гнезде *15* могут устанавливаться съемные гинекологические приспособления *16*.

Гнездо *17* служит для установки кассет.

Предмет изобретения

1. Устройство для внедрения радиоактивных аппликаторов и перевозки гинекологических больных по авт. св. № 171934, *отличающееся* тем, что, с целью повышения быстродействия и улучшения условий работы обслуживающего персонала, в нем установлен гидравлический привод с рычажными системами перевода устройства из положения «Кровать-каталка» в положение «гинекологическое кресло».

2. Устройство по п. 1, *отличающееся* тем, что, с целью проведения контрольных рентгеновских снимков, определяющих положение радиоактивного препарата в облучаемой полости, в нем имеется гнездо для вставки кассеты с рентгеновской пленкой.



Составитель И. Гофман

Редактор В. Сорокин Техред Л. Я. Левина Корректор Л. А. Иголкина

Заказ 2509/14 Тираж 480 Подписное
ЦНИИПИ Комитета по делам изобретений и открытий при Совете Министров СССР
Москва, Центр, пр. Серова, д. 4

Типография, пр. Сапунова, 2

Espacenet

Bibliographic data: RU2288755 (C1) — 2006-12-10

DEVICE FOR RADIONUCLIDE SURGERY

No documents available for this priority number.

Inventor(s): SHCHETININ VIKTOR VASIL EVICH [RU]; GULYJ VLADIMIR GRIGOR EVICH [RU]; CHERNIJ ALEKSANDR NIKOLAEVICH [RU] ± (SHCHETININ VIKTOR VASIL'EVICH, ; GULYJ VLADIMIR GRIGOR'EVICH, ; CHERNIJ ALEKSANDR NIKOLAEVICH)

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Classification: **- international:** ***A61B18/22; A61M36/00; A61N5/10; G01T1/161***
- cooperative:

Application number: RU20050112292 20050425

Priority number(s): RU20050112292 20050425

Abstract of RU2288755 (C1)

FIELD: medical facilities. ^ SUBSTANCE: device can be used as a tool for malignant tumors surgery. Device for radionuclide surgery has gamma radiation detector, collimator and handle. Wire of detector is connected with measuring unit. Gamma radiation detector is fixed in metal tip with sharpened side edge, which passes in plane being perpendicular to optical axis of gamma radiation detector. Detector is made in form of semiconductor crystal; two collimators adjoin opposite surfaces of crystal. Collimators have cells which pass in parallel to optical axis of gamma detector. Measuring unit has electronic circuit with sonic signal source. ^ EFFECT: ability of reaching area of lesion for removing it. ^ 4 cl, 2 dwg

РОССИЙСКАЯ ФЕДЕРАЦИЯ

(19) **RU** (11) **2 288 755** (13) **C1**

(51) МПК
A61N 5/10 (2006.01)
A61B 18/22 (2006.01)
G01T 1/161 (2006.01)
A61M 36/00 (2006.01)

ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ,
ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ

(12) ИЗВЕЩЕНИЯ К ПАТЕНТУ НА ИЗОБРЕТЕНИЕ

(21), (22) Заявка: 2005112292/14, 25.04.2005

(24) Дата начала отсчета срока действия патента:
25.04.2005

(45) Опубликовано: 10.12.2006

(56) Список документов, цитированных в отчете о поиске: FOUGERES P. et al. Sentinel node in cancer diagnosis with surgical probes. Nuclear Instruments and Methods in Physics Research, 2001, A458, p.34-40. US 6422748 A, 23.07.2002. WO 9930764 A1, 24.06.1999. RU 2112993 C1, 10.06.1998.

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(54) УСТРОЙСТВО ДЛЯ РАДИОНУКЛИДНОЙ ХИРУРГИИ

Опубликовано на CD-ROM: MIMOSA RBI 2006/34D RBI200634D

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(21) Регистрационный номер заявки: 2005112292

Дата прекращения действия патента: 26.04.2007

Извещение опубликовано: 27.07.2008 БИ: 21/2008

RU 2288755 C1

RU 2288755 C1

Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	17357166
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	08-NOV-2013
Filing Date:	11-JUN-2008
Time Stamp:	17:21:09
Application Type:	Utility under 35 USC 111(a)

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1	Transmittal Letter	SIDS-transmittal_56782-1-8.pdf	89412 d9164894ca392b5ea4fea61ee3f698c3551d1c8a	no	2
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	15th-SIDS_56782-1-8.pdf	612266 936b2075cf24604fdde978863a7596836d0b96d9	no	4
Warnings:					
Information:					
3	Foreign Reference	RU2131273.pdf	9345294 604ecbd0e6baca1572a1b17ddda29cf4d5319a87	no	40
Warnings:					
Information:					
4	Foreign Reference	SU244513.pdf	2157166 f62d49979524a24124705481b773215be480dc74	no	4
Warnings:					
Information:					
5	Foreign Reference	RU2288755.pdf	950606 daca9f67a92011c4b3fa8e15f576bf5c63b3cc21	no	2
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Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30504 60293eb3ec85e2fb9afa8fb453efc1923bf6f0ba	no	2
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National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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.: 56782.1.8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Charles R. Quirico		
Application No.:	12/137,377	Group Art Unit:	3618
Filed:	June 11, 2008	Examiner:	Gurari, Erez
Title:	CABINET STRUCTURE CONFIGURATION FOR INFUSION SYSTEMS		

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

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT AND CERTIFICATION UNDER 37 CFR 1.97(e)

This certification is being made for the accompanying Supplemental Information Disclosure Statement after receipt of a Notice of Allowance and before payment of the Issue Fee. I certify that the following reference contained in the Information Disclosure Statement was not cited in a communication from a foreign patent office in a counterpart foreign or international application, or to my knowledge, after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c), more than three months prior to the filing of this statement:

US Publication No. US2011-0209764A1 (Uber)

I also certify that the following references contained in the information disclosure statement were first cited in a 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.

RU2131273 (Sajens)
SU244513 (Bogoudinov)
RU2288755 (Shchetinin)

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission please charge any fees under 37 CFR § 1.16 1.17 1.136(a) or any additional fees to Deposit Account 06-1910

Respectfully submitted,

/ Paul J. LaVanway, Jr./

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Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
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Paul J. LaVanway, Jr.
Registration No. 64,610

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

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22859 7590 10/01/2013

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INTELLECTUAL PROPERTY GROUP
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MINNEAPOLIS, MN 55402

EXAMINER
GURARI, EREZ

ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 10/01/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	01/02/2014

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.

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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 10/01/2013
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	01/02/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
GURARI, EREZ	3618	280-047350

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 credit 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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

22859 7590 10/01/2013

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

EXAMINER	
GURARI, EREZ	

ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 10/01/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 790 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 790 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 12/137,377	Applicant(s) QUIRICO ET AL.	
	Examiner EREZ GURARI	Art Unit 3618	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 *8/26/2013*.
   ☐ 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 *1-2,5-7,10-15,17,23,25,27,33*. 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 7/2, 8/26
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 _____.

/Jeffrey J Restifo/
Primary Examiner, Art Unit 3618

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	Art Unit
	EREZ GURARI	3618

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
280	47.34,47.35,79.11,79.3,638,651,33.992,79.5,79.6	5/1-2, 9/1/2011	eg

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST	5/1-2	eg

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See EAST	9/1/2011	eg

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	
	Examiner	Art Unit
	J. ALLEN SHRIVER II	3618

✓	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	05/03/2011	09/01/2011							
	1	✓	=							
	2	✓	=							
	3	-	-							
	4	-	-							
	5	✓	=							
	6	✓	=							
	7	✓	=							
	8	-	-							
	9	-	-							
	10	✓	=							
	11	✓	=							
	12	✓	=							
	13	✓	=							
	14	✓	=							
	15	✓	=							
	16	-	-							
	17	✓	=							
	18	-	-							
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	22	-	-							
	23	✓	=							
	24	-	-							
	25	✓	=							
	26	-	-							
	27	✓	=							
	28	-	-							
	29	-	-							
	30	-	-							
	31	-	-							
	32	-	-							
	33	✓	=							

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	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

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

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

Receipt date: 07/02/2013	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1	R. KLEIN, , "Precision control of eluted Activity from a Sr/Rb generator for cardiac positron emission tomography" Proceedings of the 26th Annual International Conference of the IEEE EMBS San Francisco, CA, USA, September 1-5, 2004, 4 pages	☐

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

EXAMINER SIGNATURE

Examiner Signature	/Erez Gurari/	Date Considered	09/21/2013

*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.G./

Receipt date: 07/02/2013	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-07-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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

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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.

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

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5254328		1993-10-19	Herscheid	
	2	6267717		2001-07-31	Stoll	
	3	6454460		2002-09-24	Ramanathan	
	4	7286867		2007-10-23	Schlyer	
	5	7522952		2009-04-21	Krieg	
	6	7586102		2009-09-08	Mourtada	
	7	7605384		2009-10-20	Sonnenhol	
	8	7608831		2009-10-27	Lamb	

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

Receipt date: 08/26/2013	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

	9	7712491		2010-05-11	Tochon-Danguy	
	10	7734331		2010-06-08	Dhawale	
	11	7737415		2010-06-15	Casale	
	12	7780352		2010-08-24	Fox	
	13	7825372		2010-11-02	Allberg	
	14	8198599		2012-06-12	Bouton	
	15	8431909		2013-04-30	Horton	
	16	8439815		2013-05-14	Lemer	
	17	8442803		2013-05-14	Chen	
	18	7091494		2006-08-15	Weisner	
	19	3991960		1976-11-16	Tanaka	

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

Receipt date: 08/26/2013	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

	20	4212303		1980-07-15	Nolan	
	21	4656697		1987-04-14	Naeslund	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080237502		2008-10-02	Fago	
	2	20120098671		2012-04-26	Wieczorek	
	3	20120312980		2012-12-13	Whitehouse	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2008066586	WO	A2	2008-06-05	MALLINCKRODT INC		☐
	2	2011126522	WO	A2	2011-10-13	MEDI PHYSICS INC		☐

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	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Machine translation of abstract of RU2307378 published 2007-09-27 (Oao Sojuztsvetmetavtomatika)	☐

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Examiner Signature	/Erez Gurari/	Date Considered	09/21/2013

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	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

CERTIFICATION STATEMENT

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-08-26
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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

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

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

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

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

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

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

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	**Art Unit**
	EREZ GURARI	3618

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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	Examiner	**Art Unit**
	EREZ GURARI	3618

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
280	47.35	B	6	2	B	3 / 04						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
280	79.3	79.5			

(Assistant Examiner)	(Date)	Total Claims Allowed: 16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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	12137377	QUIRICO ET AL.
	Examiner	**Art Unit**
	EREZ GURARI	3618

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	12	17	16	33										
2	2		18												
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8	12		28												
9	13		29												
10	14		30												
11	15		31												
	16		32												

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(Assistant Examiner)	(Date)	16	
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(Primary Examiner)	(Date)	1	1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5254328		1993-10-19	Herscheid	
	2	6267717		2001-07-31	Stoll	
	3	6454460		2002-09-24	Ramanathan	
	4	7286867		2007-10-23	Schlyer	
	5	7522952		2009-04-21	Krieg	
	6	7586102		2009-09-08	Mourtada	
	7	7605384		2009-10-20	Sonnenhol	
	8	7608831		2009-10-27	Lamb	

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	Examiner Name	Erez Gurari
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	9	7712491		2010-05-11	Tochon-Danguy	
	10	7734331		2010-06-08	Dhawale	
	11	7737415		2010-06-15	Casale	
	12	7780352		2010-08-24	Fox	
	13	7825372		2010-11-02	Allberg	
	14	8198599		2012-06-12	Bouton	
	15	8431909		2013-04-30	Horton	
	16	8439815		2013-05-14	Lemer	
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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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	1	Machine translation of abstract of RU2307378 published 2007-09-27 (Oao Sojuztsvetmetavtomatika)	☐

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Electronic Acknowledgement Receipt

EFS ID:	16669479
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	26-AUG-2013
Filing Date:	11-JUN-2008
Time Stamp:	11:56:04
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	Foreign Reference	WO2008066586A2.pdf	1272548 8680ae5b7584c393f429ab1b8ea740c09894f890	no	30

Warnings:	
Information:	

2	Foreign Reference	WO2011126522A2.pdf	3863770 03b32ea73aaeb819a89b2b2e2811c298554f32c5	no	60
Warnings:					
Information:					
3	Foreign Reference	RU2307378C1_Machine-translation.pdf	155711 3145db7df125c1d6fe7f05ba87b77a67c6db9be9	no	6
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	14th-SIDS_56782-1-8.pdf	613164 b0a4b0a46136f23ca7a6df421e2bead0f0a0093c	no	6
Warnings:					
Information:					
		Total Files Size (in bytes):	5905193		

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

New International Application Filed with the USPTO as a Receiving Office
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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 June 2008 (05.06.2008)

PCT

(10) International Publication Number
WO 2008/066586 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2007/015566

(22) International Filing Date: 5 July 2007 (05.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/818,808 6 July 2006 (06.07.2006) US

(71) Applicant *(for all designated States except US)*: **MALLINCKRODT INC.** [US/US]; 675 Mcdonnell Boulevard, Hazelwood, MO 63042 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **VERBOKKEM, Arjan, Frank** [NL/NL]; Zuiderlaan 1, NL-8746NE Schraard (NL).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

WO 2008/066586 A2

(54) Title: SYSTEM AND METHOD FOR CONTROLLING ELUTION FROM A RADIOISOTOPE GENERATOR WITH ELECTRONIC PINCH VALVES

(57) Abstract: Embodiments of the present invention relate to a system and method for controlling an elution process with at least one electronic pinch valve. Specifically, embodiments of the present invention include supplying eluent to a radioisotope generator of a radioisotope elution system, and controlling elution of the radioisotope generator with at least one electronic pinch valve disposed on at least one flow line of the radioisotope elution system, wherein the electronic pinch valve is configured to either block flow through the at least one flow line or enable flow through the at least one flow line based on a state of the electronic pinch valve.

SYSTEM AND METHOD FOR CONTROLLING ELUTION FROM A RADIOISOTOPE GENERATOR WITH ELECTRONIC PINCH VALVES

[0001] This application claims the benefit of U.S. Provisional Application No. 60/818,808, filed July 6, 2006.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of nuclear medicine. Specifically, embodiments of the invention relate to a system and method for starting and stopping elution of radioisotopes from a radioisotope generator with electronic pinch valves.

BACKGROUND

[0003] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0004] Nuclear medicine is a branch of health science that utilizes radioactive material for diagnostic and therapeutic purposes by injecting a patient with a small dose of the radioactive material, which concentrates in certain organs or biological regions of the patient. Radioactive materials typically used for nuclear medicine include Technetium-99m, Indium-113m, and Strontium-87m among others. Some radioactive materials naturally concentrate toward a particular tissue; for example, iodine concentrates toward the thyroid. However, radioactive materials are often combined with a tagging or organ-seeking agent, which targets the radioactive material for a desired organ or biologic region of the patient. These radioactive materials alone or in combination with a tagging agent are typically defined as radiopharmaceuticals in the field of nuclear medicine. At relatively lower doses of the radiopharmaceutical, a radiation imaging system (e.g., a gamma camera) can provide an image of the organ or biological region that collects the radiopharmaceutical. Irregularities in the image are often indicative of a pathologic condition, such as cancer. Higher doses of the radiopharmaceutical may be used to deliver a therapeutic dose of radiation directly to the pathologic tissue, such as cancer cells.

[0005] The production of radiopharmaceuticals inherently involves radioactive material. Accordingly, it is desirable for clinicians and other individuals that work around

radioisotope elution systems to limit their exposure to the elution process and its products. Indeed, many elution systems and related devices (e.g., transportation and dispensing mechanisms) include shielding that limits the exposure of users to radiation from the elution system and its products. However, even when shielding is present, it may be desirable to further limit exposure generally involved with engaging or disengaging flow controls in the radioisotope elution system. In addition, existing systems can expose the flow controls and other mechanisms to radiation, an eluent, or other materials involved with an elution process or subsequent cleaning. These materials can adversely affect the life and operability of the flow controls.

SUMMARY

[0006] The present invention, in certain embodiments, is directed to a radioisotope elution system including electronic pinch valves disposed along flow lines of the radioisotope elution system. One or more electronic pinch valves may be positioned along the flow lines such that opening and closing the electronic pinch valves in defined combinations can stop and/or start an elution process. The electronic pinch valves may be arranged or configured to reduce the possibility of exposure of a user or operator to radiation from the elution system. For example, by preventing flow or controlling suction in components of the elution system, the electronic pinch valves may prevent or reduce the potential for spilling radioactive fluid when retrieving collected eluate from the elution system. Additionally, the electronic pinch valves may be configured for remote actuation, which may reduce the potential for exposing a user or operator to radiation from the elution system during operation. Further, the electronic pinch valves may be configured to avoid direct contamination of the valves themselves by operating to squeeze flow lines (e.g., tubing) together when closed and release the flow lines when open, thus avoiding direct contact between the valves and radioactive material and/or corrosive material in the flow lines.

[0007] Certain aspects commensurate in scope with the originally claimed invention are set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief summary of certain forms the invention might take and that these aspects are not intended to limit the scope of the invention. Indeed, the invention may encompass a variety of aspects that may not be set forth below.

[0008] In accordance with a first aspect of the present invention, there is provided a radioisotope elution system, comprising a flexible radioisotope elution line, and an electronic pinch valve disposed externally about the flexible radioisotope elution line, wherein the electronic pinch valve includes a remote electronic control connector.

[0009] In accordance with a second aspect of the present invention, there is provided a radioisotope elution system, comprising a radioisotope generator, an elution line coupled to

the radioisotope generator, wherein the elution line comprises a resilient circumferential wall disposed about a passage; and an electronic pinch valve disposed externally about the resilient circumferential wall.

[0010] In accordance with a third aspect of the present invention, there is provided a method, comprising electronically manipulating a state of at least one electronic pinch valve disposed externally about at least one resilient flow line of a radioisotope elution system between constricting and not constricting the at least one resilient flow line to control elution of a radioisotope generator.

[0011] Various refinements exist of the features noted above in relation to the various aspects of the present invention. Further features may also be incorporated in these various aspects as well. These refinements and additional features may exist individually or in any combination. For instance, various features discussed below in relation to one or more of the illustrated embodiments may be incorporated into any of the above-described aspects of the present invention alone or in any combination. Again, the brief summary presented above is intended only to familiarize the reader with certain aspects and contexts of the present invention without limitation to the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other features, aspects, and advantages of the present invention will become better understood when the following detailed description is read with reference to the accompanying drawings in which like characters represent like parts throughout the drawings, wherein:

[0013] FIG. 1 is a cross-sectional view of an embodiment of a radioisotope elution system including electronic pinch valves;

[0014] FIGS. 2-6 are diagrams of various embodiments of a radioisotope elution systems including electronic pinch valves;

[0015] FIG. 7 is a flowchart illustrating an embodiment of a nuclear medicine process;

[0016] FIG. 8 is a diagram of an embodiment of a radiopharmaceutical preparation system; and

[0017] FIG. 9 is a diagram of an embodiment of a nuclear medicine imaging system.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0018] One or more exemplary embodiments of the present invention are described below. In an effort to provide a concise description of these embodiments, some features of an actual implementation may not be described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions may be made to achieve the developers'

specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Such a development effort would be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

[0019] FIG. 1 is a cross-sectional side view of an embodiment of a radioisotope elution system 10 including a pair of electronic pinch valves 22,24 disposed on flow lines 26. It should be noted that a line may include a single line or a system of lines. The illustrated elution system 10 also may include a radioisotope generator 12, radiation shielding 14, an elution output assembly 16, an eluent supply bottle 18, and an eluate collection bottle 20. The elution output assembly 16 may include an elution shield 16A disposed about the eluate collection bottle 20. Each of the electronic pinch valves 22, 24 is coupled to a flow line 26 (e.g., resilient tubing) of the elution system 10 to facilitate automatic and/or remote control of an elution process being performed by the elution system 10. One or both of the electronic pinch valves 22, 24 may be disposed at least partially within the radioisotope generator 12.

[0020] In certain embodiments, the flow line 26 may include one or more lengths of resilient tubing in parallel or in series, or continuous, or intermittently coupled with other elution components, or a combination thereof. For example, a first portion of the flow line 26 may be disposed upstream from the radioisotope generator 12, while a second portion of the flow line 26 may be disposed downstream of the radioisotope generator 12. Together, the first and second portions may represent the overall elution flow line 26. The electronic pinch valves 22, 24 may be disposed externally about the flow line 26 on various upstream and/or downstream portions relative to the radioisotope generator 12 or in proximity to fluid connectors on the radioisotope generator 12. In certain embodiments, a system operator may remotely coordinate activation or deactivation of the first and second electronic pinch valves 22, 24 to stop or start an elution. Indeed, using the electronic pinch valves 22, 24, an operator or controller may cause the elution system 10 to complete a full or a partial elution (e.g., an elution to partially fill an eluate output container) without any radiation exposure. In other words, the operator can control liquid flow without opening the shielding 14, thereby substantially reducing the potential for radiation exposure.

[0021] During an elution procedure performed with the elution system 10, eluent (e.g., saline) flows from the eluent supply bottle 18 through the generator 12, and is collected as eluate in the eluate collection bottle 20. In the illustrated embodiment, the eluent supply bottle 18 is coupled to the generator 12 via a vented spike 28 and the tubing 26. The vented spike 28 includes an eluent vent needle 28A and a container eluent output needle 28B. The tubing 26 coupling the eluent supply 18 and the generator 12 may be referred to as an eluent input line 29 or eluent supply line 29. The eluent input line 29 may couple to the generator 12 via a generator eluent input needle 29A. The vented spike 28 may also couple to a vent 30 via the

tubing 26 to regulate pressure and facilitate flow of eluent out of the eluent supply bottle 18. The tubing 26 between the vent 30 and the eluent supply bottle 18 may be referred to as a supply vent line, an eluent vent line, or an input vent line 31. The vent 30 may include a check valve to allow air into the eluent supply bottle 18 while generally preventing backflow from the eluent supply bottle 18 through the vent 30 and into other areas of the elution system 10. The tubing 26 between the eluent supply bottle 18 and the generator 12 (i.e., the eluent input line 29) may channel the eluent into the radioisotope generator 12 for flushing or generally eluting a daughter radioisotope from a parent radioisotope in the generator 12 and into the eluate collection bottle 20. The eluate collection bottle 20 may be coupled to the generator 12 via a hollow outlet needle 32 and the tubing 26 to facilitate such collection. The tubing 26 between the generator 12 and the eluate collection bottle 20 may be referred to as an eluate collection line 33 or eluate output line 33. The eluate output line 33 may couple to the generator 12 via a generator eluate output needle 33A.

[0022] The generator 12 may include a container or a shielded container designed to hold a parent radioisotope, such as Molybdenum-99, absorbed to alumina beads or another suitable exchange medium. Over time, the parent radioisotope may decay to produce a daughter radioisotope. For example, Molybdenum-99 may decay to form Technetium-99m as its daughter radioisotope. Molybdenum-99 has a half-life of approximately 67 hours. Thus, short-lived Technetium-99m, which has a half-life of approximately 6 hours, may continually be produced inside the generator 12 during operation. Once a certain amount of the radioisotope is present, the radioisotope elution system 10 may be ready for "milking." In other words, the radioisotope may be ready to be collected from the generator 12 via an elution process, which may begin with flowing eluent through the generator 12. The daughter radioisotope (e.g., Technetium-99m) is held chemically less tightly than the parent radioisotope, thereby enabling flow of eluent to flush the desired daughter radioisotope from the radioisotope generator 12 into the eluate collection bottle 20 as a component of the eluate. In some embodiments, a wet elution process is utilized, wherein the generator 12 generally remains charged and eluate is removed via the eluate collection bottle 20 at designated times.

[0023] The eluate collection bottle 20 may have a standard or predefined volume. Additionally, the eluate collection bottle 20 may begin in an evacuated condition. Thus, when the eluate collection bottle 20 is attached to the elution system 10, it creates a suction or pressure drop into the eluate collection bottle 20. This pressure drop may essentially drive the elution system 10. For example, the suction of the eluate collection bottle 20 may draw the eluate residing in the generator 12 into the eluate collection bottle 20 via the tubing 26 and the outlet needle 32. In turn, the vacancy in the generator 12 created by moving the eluate into the eluate collection bottle 20 may result in eluent being drawn into the generator 12 from the eluent supply bottle 18. This transfer of eluent through the generator 12 facilitates production

of more eluate containing the daughter radioisotope, which is being produced in the generator 12 from decay of the parent radioisotope. As set forth above, this process of collecting eluate may be referred to as "milking the cow," i.e., milking the generator 12.

[0024] An elution process, such as that discussed above, being performed by the radioisotope elution system 10 can be started or stopped by blocking and/or unblocking certain flow paths (e.g., the eluent input line 29, the supply vent line 31, and/or the eluate output line 33) in the elution system 10. This blocking and unblocking may be achieved using the first and second electronic pinch valves 22, 24 to block and unblock flow lines 26 in the elution system 10. For example, in the embodiment illustrated by FIG. 1, the first electronic pinch valve 22 may be disposed on the tubing 26 extending between the generator 12 and the eluate collection bottle 20 (i.e., the eluate output line 33). Accordingly, by closing (e.g., activating constriction components) the first electronic pinch valve 22, which may externally squeeze the resilient tubing 26 to a closed position, eluate may be substantially or entirely prevented from being drawn into the eluate collection bottle 20 by the suction therein. By reopening (e.g., releasing the constriction components) the first electronic pinch valve 22, which allows the resilient tubing 26 to expand, flow may be reinitiated. Additionally, the second electronic pinch valve 24 may be disposed on tubing 26 between the eluate collection bottle 20 and a collection bottle vent 34. The tubing 26 between the eluate collection bottle 20 and the collection bottle vent 34 may be referred to as the collection vent line 35, the eluate vent line 35, or the output vent line 35. This second electronic pinch valve 24 may control flow of air or gas at a standard pressure (e.g., atmospheric pressure) into the eluate collection bottle 20. Because the elution system 10 may be driven by the suction created by the vacuum in the eluate collection bottle 20, normalizing the eluate collection bottle 20 by opening the second electronic pinch valve 24 may stop the elution process. In some embodiments, as illustrated in FIG. 1, to stop the elution process, the first electronic pinch valve 22 may be closed in conjunction with opening the second electronic pinch valve 24. In other embodiments, different valve arrangements may be utilized to start and stop flow, as discussed in detail below. It should be noted that while two electronic pinch valves are represented, other embodiments may utilize a single electronic pinch valve or multiple electronic pinch valves to control elution and reduce radiation exposure. It should further be noted that in some embodiments the elution system 10 may be driven by increasing pressure (e.g., via a pump) in certain portions of the system 10 to drive the elution, rather than driving the elution with a vacuum in the collection portion of the system 10.

[0025] Various benefits arise from utilizing the electronic pinch valves 22, 24 in a radioisotope elution system in accordance with various embodiments. For example, a user can substantially avoid or reduce potential exposure to the radioactive substances utilized in the elution process by activating or deactivating (e.g., opening and closing the valves)

remotely. Indeed, the user can stand a great enough distance away from the elution system 10 to eliminate any potential effects of radiation from system 10. This may be achieved by utilizing a remote control unit 38 that communicatively couples to remote electronic control connectors 40 on one or both of the valves 22, 24 via a remote electronic control lead 42. Additionally, the fact that the electronic pinch valves 22, 24 are configured to squeeze the tubing 26 to stop flow may allow for reuse of the valves 22, 24, because the electronic pinch valves 22, 24 may avoid contamination from direct contact with radioactive material in the system 10. In other words, the eluent and eluate containing the daughter radioisotope may be generally contained within the generator 12, bottles 18, 20, and tubing 26, rather than directly passing through the valves 22, 24. Further, the arrangement of the valves in the elution system 10 may substantially reduce the potential for spillage. For example, in a typical elution system, removing the collection bottle 20 may result in a certain amount of eluate leakage from the outlet needle 32. A higher likelihood of leakage may exist when a vacuum remains in the collection bottle 20 at the time of removal. Specifically, for example, the collection bottle 20 may be utilized for a partial elution, and, when the partial elution is complete, the bottle 20 may retain a vacuum. Thus, upon removing a lid 36 or elution assembly 16, and retrieving the collection bottle 20 from the outlet needle 32, a certain amount of eluate may be pulled out of the outlet needle 32 and onto other portions of the elution system 10 or potentially elsewhere. The risk of such spillage and the related radiation exposure may be eliminated or substantially reduced by normalizing the collection bottle 20 and blocking eluate flow using the electronic pinch valves 22, 24. It should be noted that certain embodiments may incorporate automatic delays between opening and closing particular valves to facilitate flow or to generally prevent spills.

[0026] FIG. 2 is a perspective diagrammatical view of an embodiment of a radioisotope elution system 10 including electronic pinch valves 22, 24. Specifically, FIG. 2 depicts internal components of the elution system 10 that may include the generator 12, the eluent supply bottle 18, the eluate collection bottle 20, the tubing 26, the vent 30, the vent 34, the first electronic pinch valve 22, and the second electronic pinch valve 24. The illustrated embodiment also may include check valves 102 disposed along the tubing 26 and arranged to generally prevent or reduce the potential for backflow in the system 10. Further, the illustrated embodiment includes the remote control unit 38 communicatively coupled to the remote electronic control connectors 40 of the valves 22,24 via the remote electronic control lead 42. It should be noted that some embodiments do not include any check valves 102.

[0027] While other electronic valve types may be utilized, FIG. 2 depicts the electronic pinch valves 22, 24 as solenoid valves. A solenoid valve may be defined as an electromechanical valve that is controlled by running (or not running) an electrical current through a solenoid (i.e., a loop of wire which produces a magnetic field when current is

passed through it), which changes the state (i.e., open or closed) of the valve. For example, by closing circuits 104 and 106, a coil in each of the electronic pinch valves 22, 24 may be caused to produce a magnetic field, thus causing the electronic pinch valves 22, 24 to open or close depending on the configuration. This may be achieved remotely using the remote control unit 38. The electronic pinch valves 22, 24 may be biased open or closed in a fail-safe state by a spring (e.g., a resilient coil or resilient tubing). For example, the electronic pinch valves 22, 24 may be biased open by the tubing 26 itself, which is in a compressed state when the electronic pinch valves 22, 24 are closed.

[0028] As discussed above with respect to FIG. 1, the arrangement of the electronic pinch valves 22, 24 in FIG. 2 may directly stop flow of eluate to the collection bottle 20 by sealing the tubing 26 downstream from the generator 12, between the generator 12 and the collection bottle 20 (i.e., the eluate output line 33), and indirectly stop eluate flow by normalizing the collection bottle 20 with the atmosphere by controlling the collection vent line 35. In one embodiment, this may be achieved using a single valve, as illustrated in FIG. 3. Specifically, FIG. 3 illustrates a dual action electronic pinch valve 110 that includes a first adjustable receptacle 112 and a second adjustable receptacle 114. The electronic pinch valve 110 may be configured to close the first adjustable receptacle 112 in coordination with opening the second adjustable receptacle 114 and vice versa. For example, the tubing 26 between the generator 12 and the collection bottle 20 may be placed in the first adjustable receptacle 112 and the tubing 26 between the vent 34 and the collection bottle 20 may be placed in the second adjustable receptacle 114. When the electronic pinch valve 110 is actuated, it may open the first adjustable receptacle 112 and close the second adjustable receptacle 114 to facilitate flow of eluate into the collection bottle 20. Alternatively, the electronic pinch valve 110 may close the first adjustable receptacle 112 and open the second adjustable receptacle 114 to prevent eluate flow into the collection bottle 20. This actuation may be facilitated by a biasing spring that is disposed within the valve and that biases the electronic pinch valve 110 toward a fail-safe position. Further, the actuation may be controlled by opening or closing a circuit 116 that provides electrical current to an activating mechanism (e.g., a solenoid) in the electronic pinch valve 110.

[0029] FIG. 4 is a perspective diagrammatical view of another embodiment of a radioisotope elution system 10 including electronic pinch valves 22, 24. Much like FIG. 2, the embodiment of FIG. 4 depicts internal components of the elution system 10, which may include the generator 12, the eluent supply bottle 18, the eluate collection bottle 20, the tubing 26, the vent 30, the first electronic pinch valve 22, and the second electronic pinch valve 24. The embodiment illustrated in FIG. 4 may also include check valves 102 disposed along the tubing 26 that prevent backflow in the system 10. Further, the embodiment illustrated by FIG. 4 may also include the remote control unit 38. However, in contrast to the embodiment

illustrated by FIG. 2, the embodiment illustrated by FIG. 4 includes the second electronic pinch valve 24 disposed on the tubing between the vent 30 and the eluent supply bottle 18 (i.e., the supply vent line 31). By disposing the second electronic valve 24 in this location, suction can be created in the eluent supply bottle 18. For example, the second electronic pinch valve 24 can be closed as eluent flows out of the eluent supply bottle 18 to stop an elution process. By closing the second electronic valve 24 in this embodiment, flow into the eluent supply bottle 18 may be substantially blocked or restricted as liquid pressures equalize on input and output sides of the generator 12. Thus, volume lost as the eluent flows out of the eluent supply bottle 18 and into the generator 12 is not replaced. This may initially create suction or back pressure in the eluent supply bottle 18 and, thus, prevent further flow of eluent out of the eluent supply bottle 18 and into the generator 12. In other words, closing the second electronic pinch valve 24 over the tubing 26 between the vent 30 and the eluent supply bottle 18 (i.e., the supply vent line 31) may result in stopping an elution process as the elution system becomes closed upstream and the pressures equalize. Additionally, in the illustrated embodiment, the first electronic pinch valve 22 is disposed on the tubing between the generator 12 and the collection bottle 20 (i.e., the eluate output line 33). This valve 22 may also be closed, which may directly prevent or reduce the potential for the eluate to flow into the collection bottle 20 and, thus, generally stop an elution process. In accordance with present embodiments, these electronic pinch valves 22, 24 may be coordinated or utilized separately to start and stop an elution process by respectively opening and closing the electronic pinch valves 22, 24.

[0030] The embodiment illustrated by FIG. 4 utilizes two separate electronic pinch valves 22, 24 to squeeze or release the tubing 26 in the elution system to generally block or facilitate flow in the elution process. Thus, the two electronic pinch valves 22, 24 may be utilized to control the elution process (e.g., perform partial elutions) and provide added protection to a user from exposure to radioactive material in the process. In some embodiments, it is desirable to create back pressure or initial suction in the eluent supply bottle 18 upstream from the generator 12 in conjunction with blocking flow downstream between the generator 12 and the collection bottle 20 (i.e., the eluate output line 33). Thus, in the embodiment illustrated by FIG. 4, both of the electronic pinch valves 22, 24 may be used in upstream and downstream positions relative to the generator 12. However, as illustrated in FIG. 5, in some embodiments a single valve may be utilized to perform this flow control task. Specifically, FIG. 5 illustrates a dual action electronic pinch valve 202 that includes a first adjustable receptacle 204 and a second adjustable receptacle 206. The electronic pinch valve 202 may be configured to close the first adjustable receptacle 204 in coordination with closing the second adjustable receptacle 206 and vice versa. For example, the tubing 26 between the generator 12 and the collection bottle 20 may be placed in the first adjustable

receptacle 204 and the tubing 26 between the vent 30 and the eluent supply bottle 18 may be placed in the second adjustable receptacle 206. In other words, the same electronic pinch valve 202 may be coupled to tubing at both upstream and downstream positions relative to the generator 12. Thus, the same valve 202 may produce both back pressure via the receptacle 206 and downstream blocking to substantially block flow on both inlet and outlet sides of the generator 12. When the electronic pinch valve 202 is actuated, it may open the first adjustable receptacle 204 and the second adjustable receptacle 206 or close the receptacles 204, 206 to facilitate or stop flow of eluate into the collection bottle 20, respectively. This actuation may be controlled by opening or closing a circuit 208 that provides electrical current to an activating mechanism (e.g., a solenoid) in the electronic pinch valve 202.

[0031] FIG. 6 is a perspective diagrammatical view of a further embodiment of a radioisotope elution system 10 including electronic pinch valves 22, 24, 302. FIG. 6 represents an exemplary embodiment that demonstrates that various valve arrangements and multiple valves may be utilized to control elution processes in accordance with present embodiments. Much like FIGS. 2, 3, 4, and 5, the embodiment of FIG. 6 depicts internal components of the elution system 10, which may include the generator 12, the eluent supply bottle 18, the eluate collection bottle 20, the tubing 26, the vent 30, the vent 34, the first electronic pinch valve 22, and the second electronic pinch valve 24. The embodiment illustrated in FIG. 6 also may include check valves 102 disposed along the tubing 26 that generally prevent or reduce the potential for backflow in the system 10. However, the embodiment illustrated in FIG. 6 is distinct from the embodiments discussed above because it includes a third electronic pinch valve 302. The first electronic pinch valve 22 may be disposed on the tubing 26 between the collection bottle 20 and the vent 34 (i.e., the output vent line 35). The second electronic pinch valve 24 may be disposed on the tubing 26 between the generator and the collection bottle 20 (i.e., the eluate collection line 33). The third electronic pinch valve 302 may be disposed on the tubing 26 between the vent 30 and the eluent supply bottle 18 (i.e., the input vent line 31), and may be actuated by opening or closing a circuit 304. Each of these valves 22, 24, 302 may be coordinated or utilized separately to control the elution process, as discussed above.

[0032] FIG. 7 is a flowchart illustrating an exemplary nuclear medicine process 404 utilizing the radioactive isotope produced by the elution system 10 as illustrated in FIGS. 1-6. As illustrated, the process 404 begins with providing a radioactive isotope for nuclear medicine at block 406. For example, block 406 may include eluting technetium-99m from the radioisotope generator 12, which is illustrated and described in detail above. Such an elution may be started and stopped using electronic pinch valves 22, 24, as discussed above. At block 408, the process 404 proceeds by providing a tagging agent (e.g., an epitope or other appropriate biological directing moiety) adapted to target the radioisotope for a specific

portion, e.g., an organ, of a patient. At block 410, the process 404 proceeds by combining the radioactive isotope with the tagging agent to provide a radiopharmaceutical for nuclear medicine. In certain embodiments, the radioactive isotope may have natural tendencies to concentrate toward a particular organ or tissue. Thus, the radioactive isotope may be characterized as a radiopharmaceutical without adding any supplemental tagging agent. At block 412, the process 404 may proceed by extracting one or more doses of radiopharmaceutical into a syringe or another container, such as a container suitable for administering the radiopharmaceutical to a patient in a nuclear medicine facility or hospital. At block 414, the process 404 proceeds by injecting or generally administering a dose of the radiopharmaceutical into a patient. After a pre-selected time, the process 404 proceeds by detecting/imaging the radiopharmaceutical tagged to the patient's organ or tissue (block 416). For example, block 416 may include using a gamma camera or other radiographic imaging device to detect the radiopharmaceutical disposed on or in or bound to tissue of a brain, a heart, a liver, a tumor, a cancerous tissue, or various other organs or diseased tissue.

[0033] FIG. 8 is a block diagram of an exemplary system 500 for providing a syringe or container having a radiopharmaceutical produced in accordance with present embodiments disposed therein for use in a nuclear medicine application. As illustrated, the system 500 includes the radioisotope elution system 10 previously described with regard to FIGS. 1-6, wherein electronic pinch valves (e.g., 22, 24) are utilized to control system elutions. The system 500 also includes a radiopharmaceutical production system 502, which functions to combine a radioisotope 504 (e.g., technetium-99m eluate acquired through use of the radioisotope elution system 10) with a tagging agent 506. In some embodiment, this radiopharmaceutical production system 502 may refer to or include what are known in the art as "kits" (e.g., Technescan® kit for preparation of a diagnostic radiopharmaceutical). Again, the tagging agent 506 may include a variety of substances that are attracted to or targeted for a particular portion (e.g., organ, tissue, tumor, cancer, etc.) of the patient. As a result, the radiopharmaceutical production system 502 produces or may be utilized to produce a radiopharmaceutical including the radioisotope 504 and the tagging agent 506, as indicated by block 508. The illustrated system 500 may also include a radiopharmaceutical dispensing system 510, which facilitates extraction of the radiopharmaceutical into a vial or syringe 512. In certain embodiments, the various components and functions of the system 500 are disposed within a radiopharmacy, which prepares the syringe 512 of the radiopharmaceutical for use in a nuclear medicine application. For example, the syringe 512 may be prepared and delivered to a medical facility for use in diagnosis or treatment of a patient.

[0034] FIG. 9 is a block diagram of an exemplary nuclear medicine imaging system 600 utilizing the syringe 512 of radiopharmaceutical provided using the system 500 of FIG. 8. As illustrated, the nuclear medicine imagining system 600 includes a radiation detector 602

having a scintillator 604 and a photo detector 606. In response to radiation 608 emitted from a tagged organ within a patient 610, the scintillator 604 emits light that is sensed and converted to electronic signals by the photo detector 606. The imaging system 600 also can include a collimator to collimate the radiation 608 directed toward the radiation detector 602. The illustrated imaging system 600 also may include detector acquisition circuitry 612 and image processing circuitry 614. The detector acquisition circuitry 612 generally controls the acquisition of electronic signals from the radiation detector 602. The image processing circuitry 614 may be employed to process the electronic signals, execute examination protocols, and so forth. The illustrated imaging system 600 also may include a user interface 616 to facilitate user interaction with the image processing circuitry 614 and other components of the imaging system 600. As a result, the imaging system 600 produces an image 618 of the tagged organ within the patient 610. Again, the foregoing procedures and resulting image 618 directly benefit from the radiopharmaceutical produced by the elution system 10 having electronic pinch valves as illustrated and described with reference to FIGS. 1-6.

[0035] A test system including features in accordance with present embodiments was tested for 12 months review. Specifically, the test system contained two pinch valves and an adjusted generator system. The pinch valves were operated by an electronic switch device, which was setup in two consecutive circuits. A first circuit corresponded to "elution" and a second circuit corresponded to "elution break off," and off. The components of the test system included an ULTRA TECHNEKOW (UTK) elution system (TYCO part number: E6-11273), which is a Technetium generator, with inactive aluminum oxide columns (TYCO part number: E6-11271), an OMNIFIT pinch valve (BIO-CHEM VALVE INC. part number: 075P2NC12-01S), and a 12V power supply.

[0036] Several tests were performed using the test system. The materials utilized in the tests included a UTK eluent 100ml (TYCO part number: N5-70497), a technevial 11ml (TYCO part number: N6-11571) and a stopwatch. The results of these tests indicated that the test system was comparable with existing systems. The details of each of the tests are set forth below.

[0037] In a first test (Test 1), an elution was initiated by placing a UTK eluent 100ml and a technevial 11ml (e.g., vacuum vial 20) on the elution system. Upon positioning the eluent and technevial, the test system's switch was set to "elution." The time span between switching and elution was measured. That is, the amount of time between activating the switch to begin the elution and initiation of the actual elution was measured. The test was then repeated using a manually operated system with mechanical clamps. These steps were repeated and measurements were taken six times for both systems. For each elution, a new technevial was utilized. The results of these tests are set forth below in Table 1. It should be noted that in Table 1, "Elution" corresponds to a run number, "Elution (yes/no)" indicates

whether the clamp on the generator opened and eluent ran through the system, and "Time" represents the amount of time measured between activating the system switch to initiate the elution and actual initiation of the elution.

TABLE 1

Test 1		
Elution	Elution (yes/no)	Time (sec)
Elution system with electronic clamps		
1	Yes	3.19
2	Yes	2.06
3	Yes	2.35
4	Yes	1.85
5	Yes	2.25
6	Yes	1.66
Elution system with mechanical clamps		
1	Yes	2.78
2	Yes	2.63
3	Yes	2.81
4	Yes	1.72
5	Yes	1.88
6	Yes	2.54

[0038] Conventional systems often have issues with tubes sticking together due to the pinch force of mechanical clamps. The Time measurement in Table 1 was taken in relation to this issue. According to the data obtained from Test 1, the electronic clamps appear to have a comparable performance to that of their mechanical counterparts.

[0039] In a second test (Test 2), an elution was initiated by placing a UTK eluent 100ml and a technevial 11ml on the elution system. The weight of the technevial was measured in advance. Upon positioning the eluent and technevial on the system, the test system's switch was set to "elution." The time span between switching to "elution" and the complete fill of the technevial was measured. Further, the weight of the filled technevial was measured. The test was then repeated using a manually operated system with mechanical clamps. These steps were repeated and measurements were taken six times for both systems. For each elution, a new technevial was utilized. The results of these tests are set forth below in Table 2. It should be noted that in Table 2, "Elution" corresponds to a run number, "Elution (yes/no)" indicates whether the clamp on the generator opened and eluent ran through the system, "Time" represents a measurement of the amount of time required to completely fill the vacuum vial (e.g., vacuum vial 20) of the test system, "Weight empty" represents the weight of the vacuum vial before elution, "Weight full" represents the weight of the vacuum vial after elution (e.g., the vial plus the 11ml of eluent), and "Flow" represents a calculation of eluent flow. The values for "Flow" were calculated by converting the weight (g) of the eluent to volume (ml) by dividing the weight by density (1 g/ml) and, then, dividing the volume (ml) by time (min).

TABLE 2

Test 2						
Elution	Elution (yes/no)	Time (sec)	Weight empty (g)	Weight full (g)	Weight (g)	Flow (ml/min)
Elution system with electronic clamps						
1	Yes	42.50	12.5177	23.4041	10.8864	15.37
2	Yes	39.88	12.4667	23.5201	11.0534	16.63
3	Yes	39.78	12.2380	23.2348	10.9968	16.59
4	Yes	40.03	12.3931	23.5329	11.1398	16.70
5	Yes	39.90	12.3578	23.3912	11.0334	16.59
6	Yes	40.22	12.3870	23.4301	11.0431	16.47
Elution system with mechanical clamps						
1	Yes	48.28	12.4370	23.2549	10.8179	13.44
2	Yes	47.21	12.5231	23.6062	11.0831	14.09
3	Yes	46.47	12.3985	23.4418	11.0433	14.26
4	Yes	46.60	12.4887	23.5040	11.0153	14.18
5	Yes	46.16	12.4244	23.4596	11.0352	14.34
6	Yes	47.44	12.4111	23.5616	11.1505	14.10

[0040] FIG. 10 is a plot illustrating elution time and flow (ml/min) per system. The data designated as corresponding to System 1 in FIG. 10 was obtained from the system with electronic pinch valves and the data designated as corresponding to System 2 was obtained from the system with mechanical clamps.

[0041] In a third test (Test 3), an elution was initiated by placing a UTK eluent 100ml and a technevial 11ml on the elution system. The weight of the technevial was measured in advance. Upon positioning the eluent and technevial, the test system's switch was set to "elution." The time span between switching to "elution" and filling half of the technevial was measured. The elution was halted by switching the system to "elution break off." Further, the weight of the half-filled technevial was measured. The test was then repeated using a manually operated system with mechanical clamps. These steps were repeated and measurements were taken six times for both systems. For each elution, a new technevial was utilized. The results of these tests are set forth below in Table 3. It should be noted that in Table 3, "Elution" corresponds to a run number, "Elution (yes/no)" indicates whether the clamp on the generator opened and eluent ran through the system, "Elution break off (yes/no)" indicates whether the system stopped the elution when the switch was set to "elution break off," "Time" represents a measurement of the amount of time between start and break off of the elution, "Weight empty" represents the weight of the vacuum vial before elution, "Weight full" represents the weight of the vacuum vial after partial elution (e.g., the vial plus an amount of eluent), "Weight" represents the actual weight of the eluent obtained by subtracting the value for "Weight empty" form the value for "Weight full," and "Flow" represents a calculation of eluent flow. The values for "Flow" were calculated by converting the weight (g) of the eluent

to volume (ml) by dividing the weight by density (1 g/ml) and, then, dividing the volume (ml) by time (min).

TABLE 3

Test 3							
Elution	Elution (yes/no)	Elution break off (yes/no)	Time (sec)	Weight empty (g)	Weight full (g)	Weight (g)	Flow (ml/min)
Elution system with electronic clamps							
1	Yes	Yes	10.16	12.4213	15.8461	3.4248	20.23
2	Yes	Yes	20.25	12.4648	18.671	6.2062	18.39
3	Yes	Yes	30.12	12.3456	21.4335	9.0879	18.10
4	Yes	Yes	9.87	12.511	15.6264	3.1154	18.94
5	Yes	Yes	20.00	12.3681	18.5525	6.1844	18.55
6	Yes	Yes	30.00	12.442	21.4569	9.0149	18.03
Elution system with mechanical clamps							
1	Yes	Yes	10.00	12.4073	15.4437	3.0364	18.22
2	Yes	Yes	20.22	12.4679	17.625	5.1571	15.30
3	Yes	Yes	30.12	12.5013	20.1313	7.63	15.20
4	Yes	Yes	10.09	12.3862	14.9686	2.5824	15.36
5	Yes	Yes	20.28	12.5122	17.6431	5.1309	15.18
6	Yes	Yes	30.16	12.4969	20.0305	7.5336	14.99

[0042] FIG. 11 is a plot illustrating elution brake off and linearity elution time based on the data from Test 3. The data designated as corresponding to System 1 in FIG. 11 was obtained from the system with electronic pinch valves and the data designated as corresponding to System 2 was obtained from the system with mechanical clamps.

[0043] Based on the aforementioned results obtained in Tests 1, 2, and 3 for the test system in accordance with present embodiments, present embodiments are comparable in operation with a system containing mechanical clamps. However, present embodiments facilitate a slightly higher flow. The slightly higher flow obtained with the system containing electronic pinch valves may be attributed to the improved opening of the pinch valves in comparison to that of the mechanical clamps.

[0044] When introducing elements of the present invention or various embodiments thereof, the articles "a", "an", "the", and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including", and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements. Moreover, the use of "top", "bottom", "above", "below" and variations of these terms is made for convenience, but does not require any particular orientation of the components.

[0045] While embodiments of the present invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed.

Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

CLAIMS

1. A radioisotope elution system, comprising:

a flexible radioisotope elution line; and

an electronic pinch valve disposed externally about the flexible radioisotope elution line, wherein the electronic pinch valve includes a remote electronic control connector.

2. The radioisotope elution system of claim 1, wherein the radioisotope elution line comprises an eluent input line, an eluate output line, an input vent line, and an output vent line.

3. The radioisotope elution system of claim 1, wherein the electronic pinch valve comprises a single electronic pinch valve having a plurality of constriction components disposed externally about different lines of the flexible radioisotope elution line.

4. The radioisotope elution system of claim 1, comprising a plurality of electronic pinch valves, including the electronic pinch valve, disposed externally about different lines of the flexible radioisotope elution line.

5. The radioisotope elution system of claim 1, comprising an eluate collection container, an eluent supply container, a radioisotope generator, or a combination thereof coupled to the flexible radioisotope elution line.

6. The radioisotope elution system of claim 1, comprising a radiation shield having a radioisotope generator cavity, wherein the electronic pinch valve and at least part of the flexible radioisotope elution line is disposed inside the radioisotope generator cavity.

7. The radioisotope elution system of claim 1, comprising a remote electronic control coupled to the electronic control connector.

8. The radioisotope elution system of claim 1, wherein the radioisotope elution line comprises an eluent input line having a first end coupled to an inlet of a radioisotope generator and a second end coupled to an eluent supply bottle, a supply vent line having a first end coupled to the eluent supply bottle and a second end coupled to a supply vent, an eluate output line having a first end coupled to an outlet of the radioisotope generator and a

second end coupled to an eluate collection bottle, and an eluate vent line having a first end coupled to the eluate collection bottle and a second end coupled to an eluate vent.

9. The radioisotope elution system of claim 8, wherein the electronic pinch valve is disposed externally about the eluate output line.

10. The radioisotope elution system of claim 9, wherein the electronic pinch valve is disposed externally about the eluate vent line or a second electronic pinch valve is disposed externally about the eluate vent line.

11. The radioisotope elution system of claim 9, wherein the electronic pinch valve is disposed externally about the supply vent line or a second electronic pinch valve is disposed externally about the supply vent line.

12. A radioisotope elution system, comprising:

a radioisotope generator;

an elution line coupled to the radioisotope generator, wherein the elution line comprises a resilient circumferential wall disposed about a passage; and

an electronic pinch valve disposed externally about the resilient circumferential wall.

13. The radioisotope elution system of claim 12 wherein the electronic pinch valve includes a remote electronic control connector.

14. The radioisotope elution system of claim 12, comprising a remote electronic control coupled to the electronic control connector.

15. The radioisotope elution system of claim 12, wherein the electronic pinch valve is disposed at least partially inside the radioisotope generator.

16. The radioisotope elution system of claim 12, comprising an auxiliary shield disposed about the radioisotope generator.

17. The radioisotope elution system of claim 12, wherein the elution line includes an eluent supply line, an eluate output line, a vent line, or a combination thereof.

18. The radioisotope elution system of claim 12, wherein the elution line includes an eluent input line having a first end coupled to an inlet of the radioisotope generator and a second end coupled to an eluent supply bottle, a supply vent line having a first end coupled to the eluent supply bottle and a second end coupled to a supply vent, an eluate output line having a first end coupled to an outlet of the radioisotope generator and a second end coupled to an eluate collection bottle, and an eluate vent line having a first end coupled to the eluate collection bottle and a second end coupled to an eluate vent.

19. The radioisotope elution system of claim 18, wherein the electronic pinch valve is disposed externally about the resilient circumferential wall of the eluate vent line, or the supply vent line, or a combination thereof.

20. The radioisotope elution system of claim 18, wherein the electronic pinch valve is disposed externally about the resilient circumferential wall of the eluate vent line, or the eluate output line, or a combination thereof.

21. A method, comprising:

electronically manipulating a state of at least one electronic pinch valve disposed externally about at least one resilient flow line of a radioisotope elution system between constricting and not constricting the at least one resilient flow line to control elution of a radioisotope generator.

22. The method of claim 21, comprising controlling elution by generally increasing or decreasing a pressure differential between an elution container and a remaining portion of the radioisotope elution system via the at least one electronic pinch valve.

23. The method of claim 21, comprising opening or closing the at least one electronic pinch valve externally about an eluate output line of the radioisotope elution system.

24. The method of claim 21, comprising opening or closing the at least one electronic pinch valve externally about an eluent supply line of the radioisotope elution system.

25. The method of claim 21, comprising controlling elution of the radioisotope generator by eliminating suction in an eluate collection bottle that is driving elution by facilitating normalization of the eluate collection bottle by opening the at least one electronic pinch valve.

26. The method of claim 21, comprising controlling elution by creating suction in an eluent supply bottle of the radioisotope elution system by closing the at least one electronic pinch valve to block a supply vent line of the radioisotope elution system.

27. The method of claim 21, comprising remotely actuating the at least one electronic pinch valve.

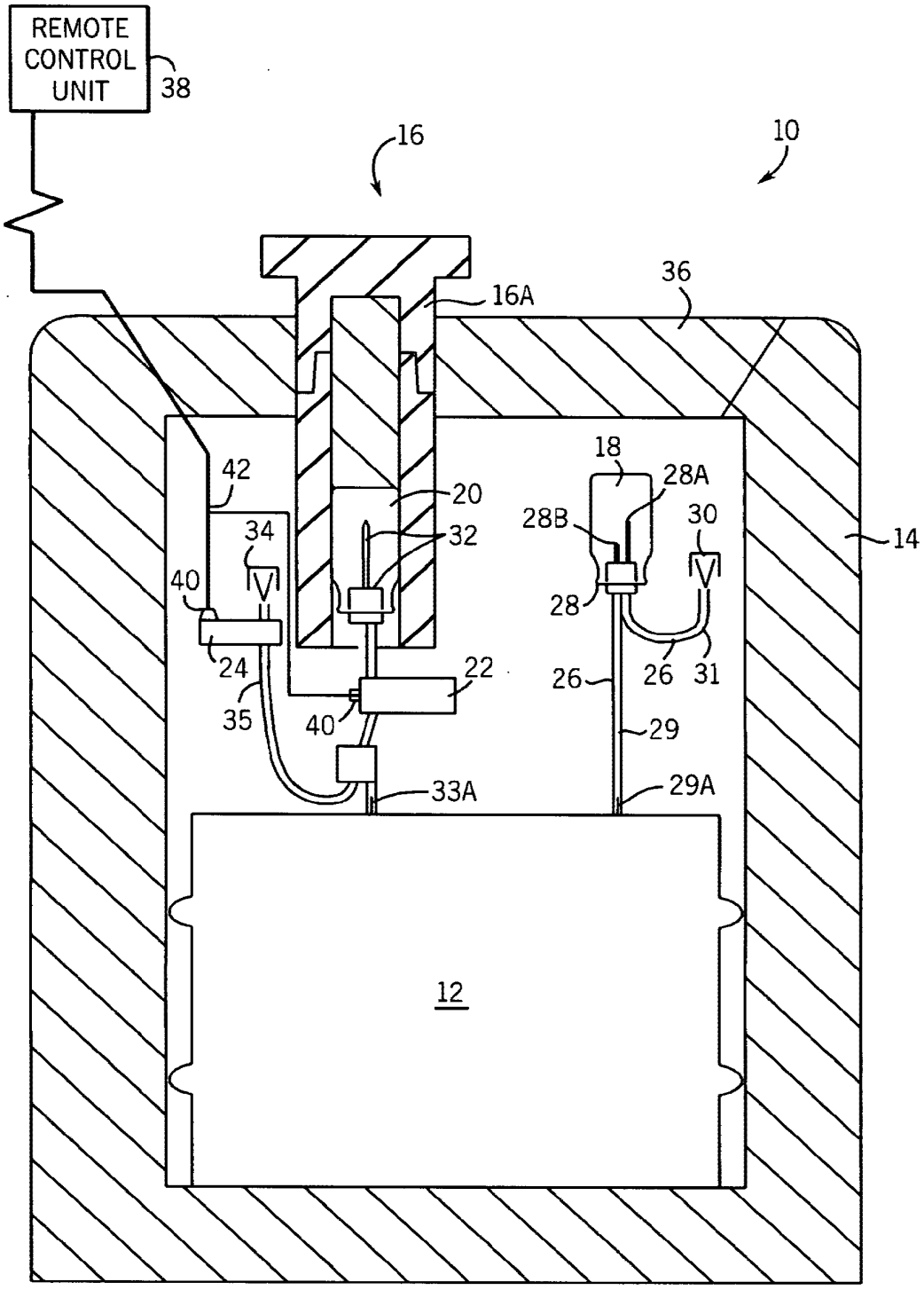
28. The method of claim 21, comprising shielding radioactivity passing through the radioisotope elution system.

29. A container of a radioisotope produce by the method of claim 21.

30. A syringe of a radioisotope produced by the method of claim 21.

31. An image acquired from a radioisotope produced by the method of claim 21.

32. A method of nuclear imaging using a radioisotope from the method of claim 21.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16A
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28B
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35
40
29
33A
29A
12

FIG. 1

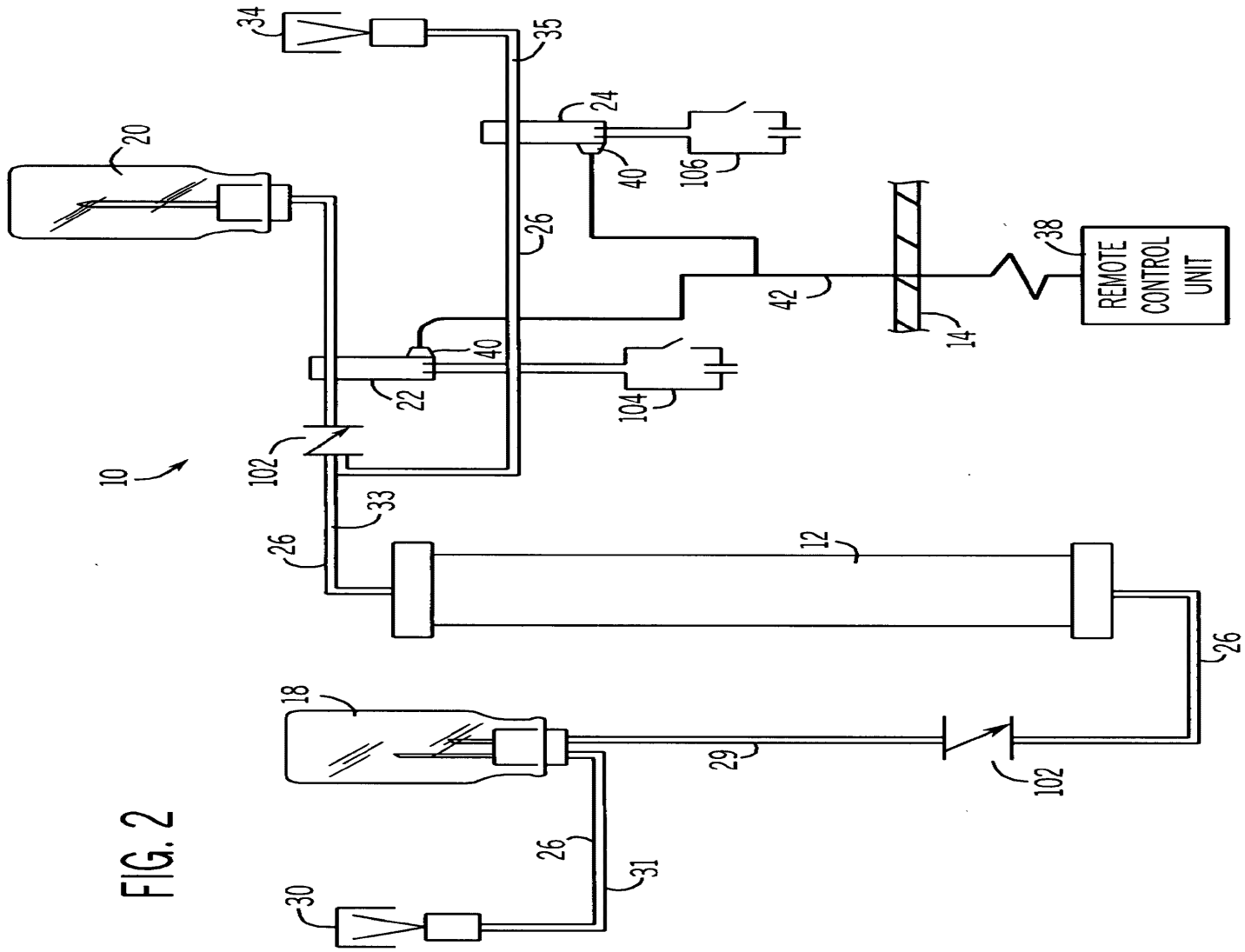
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FIG. 2

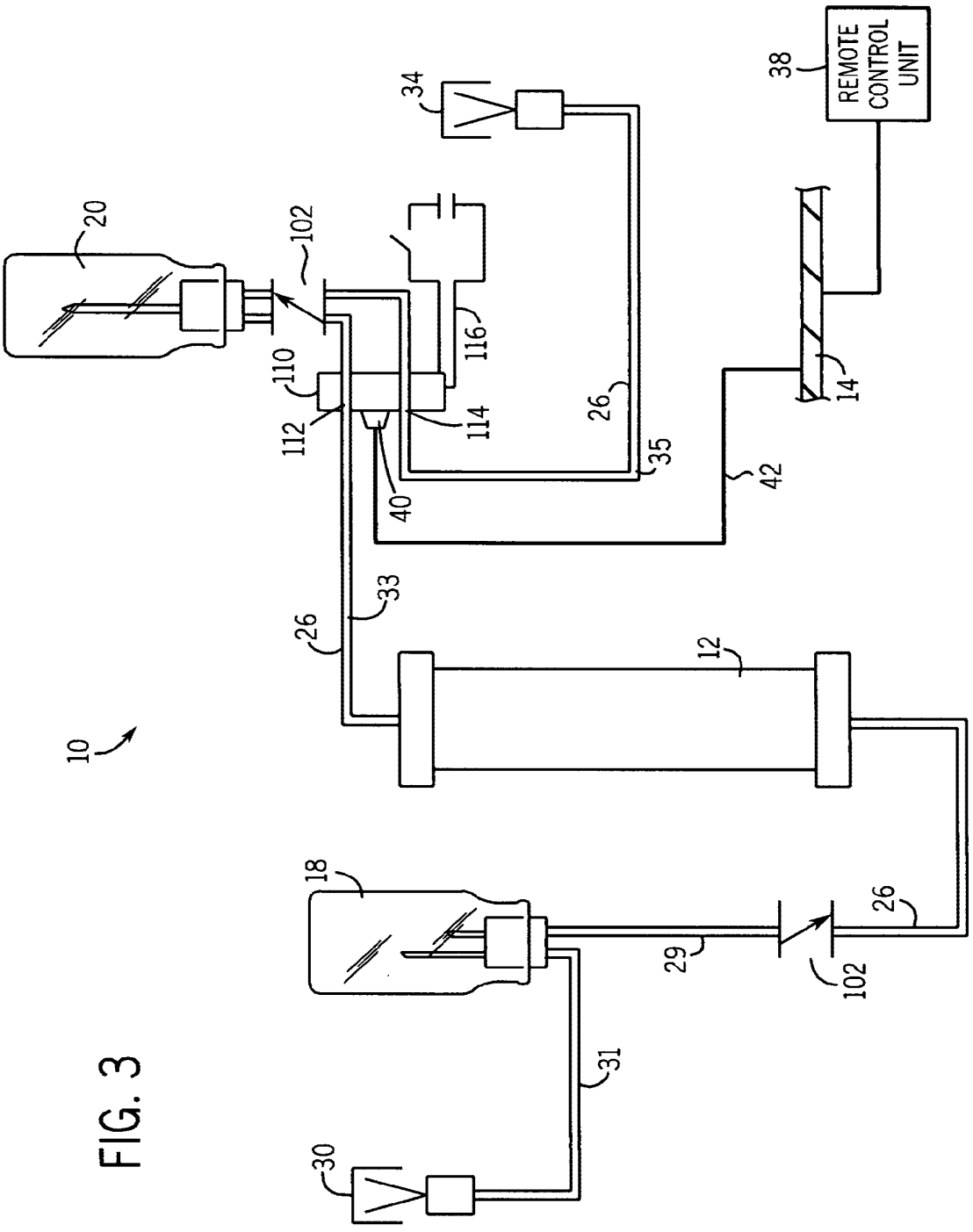
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FIG. 3

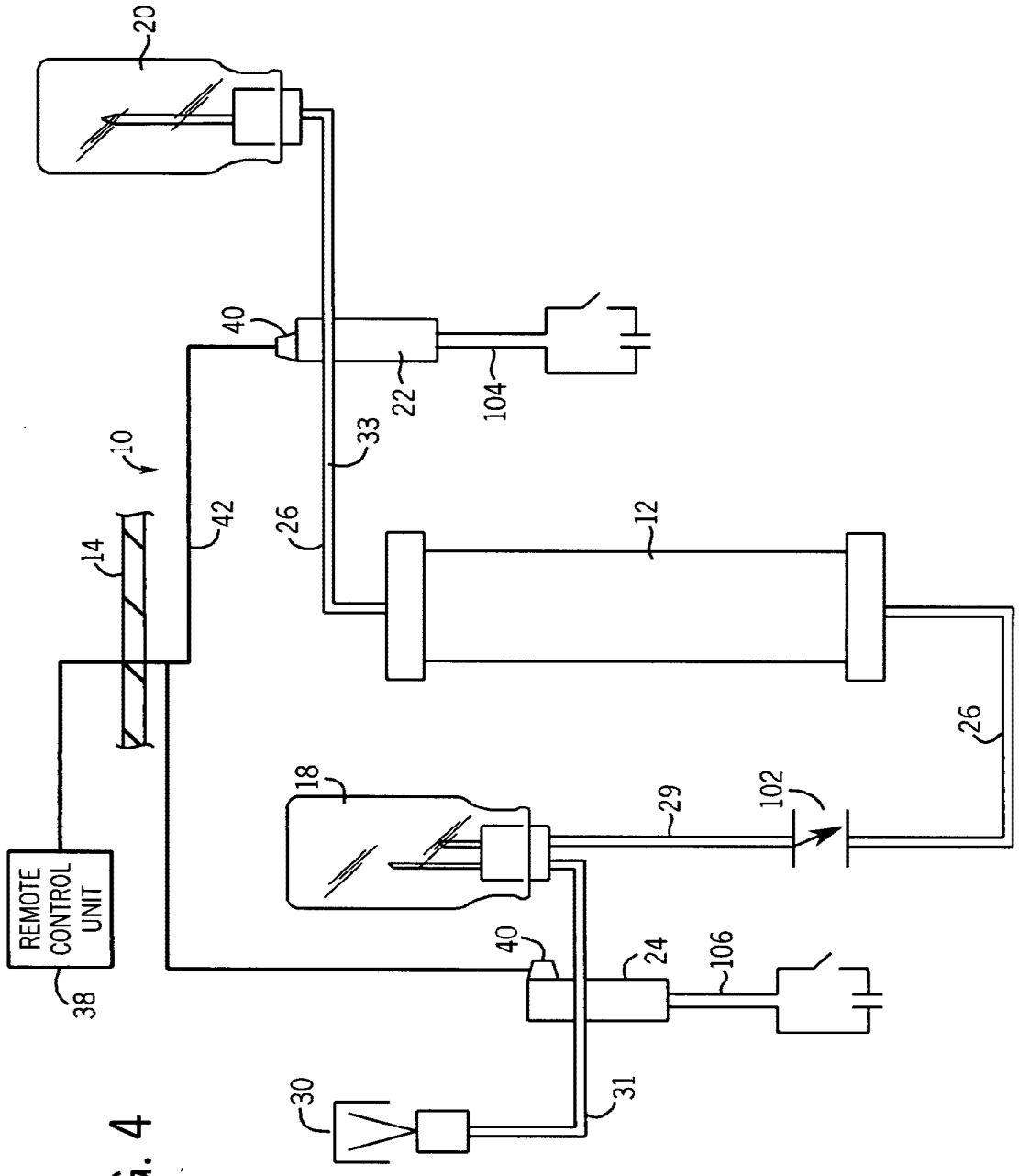
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FIG. 4

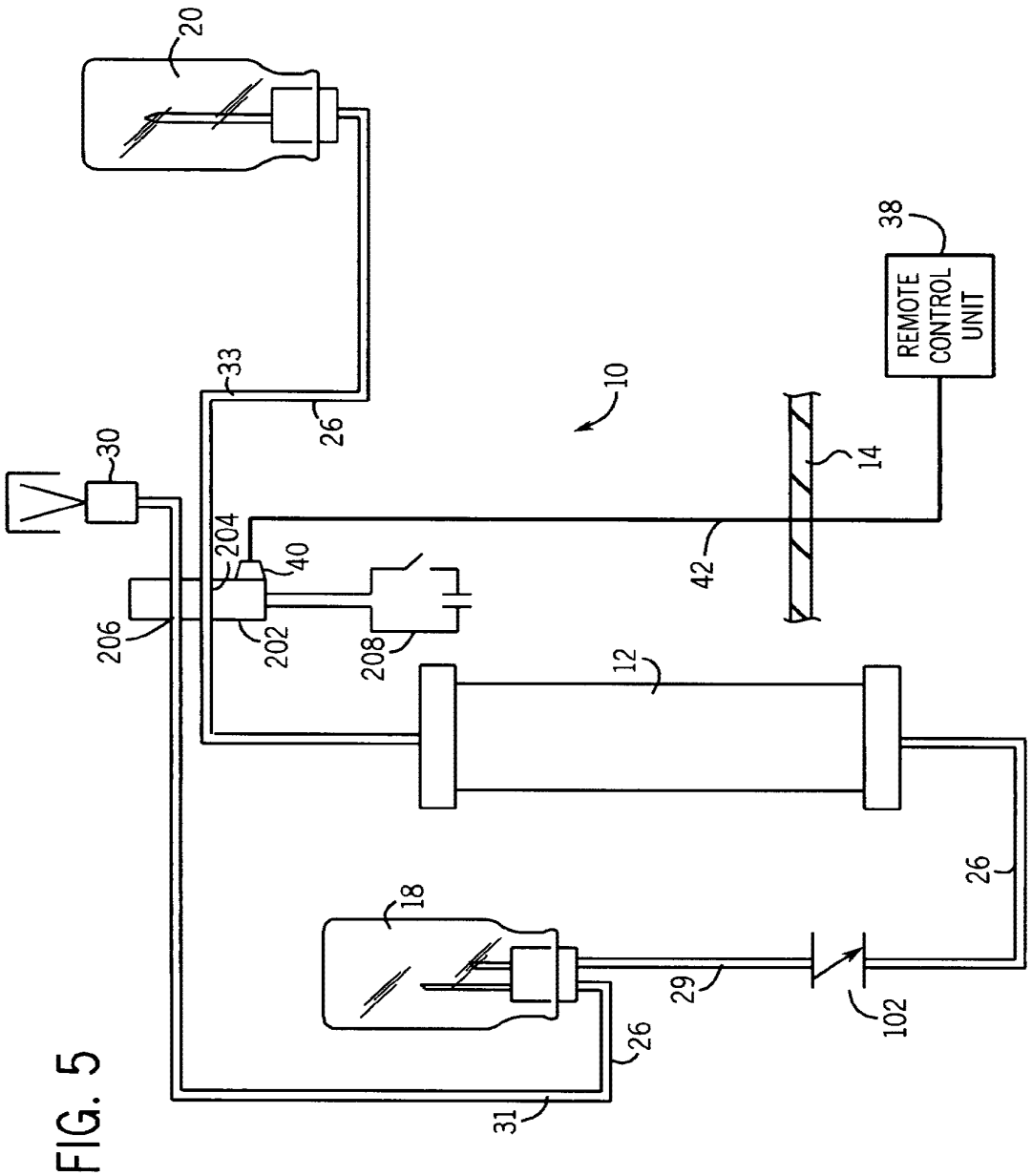
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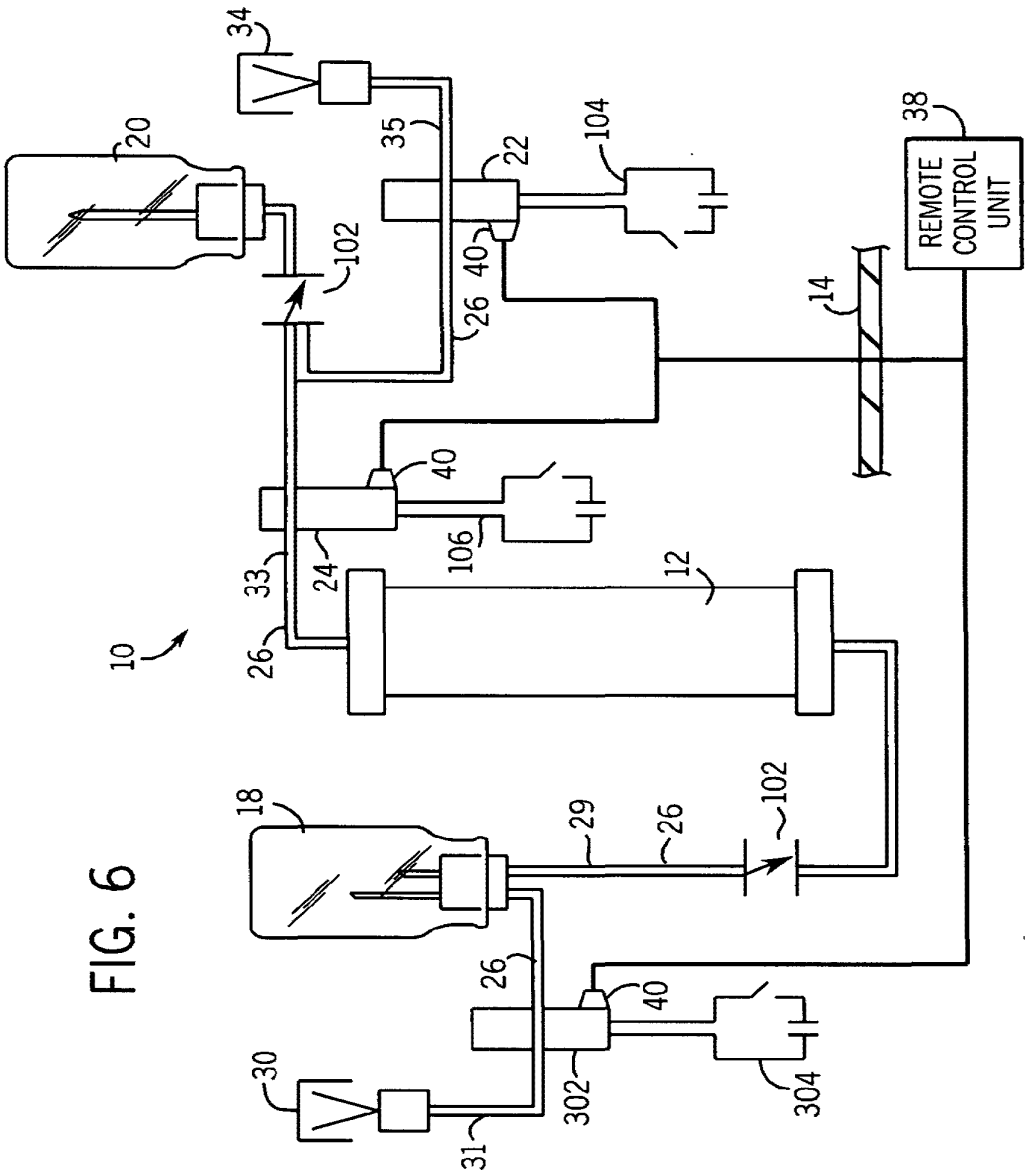
FIG. 5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302
304
31

FIG. 6

FIG. 7

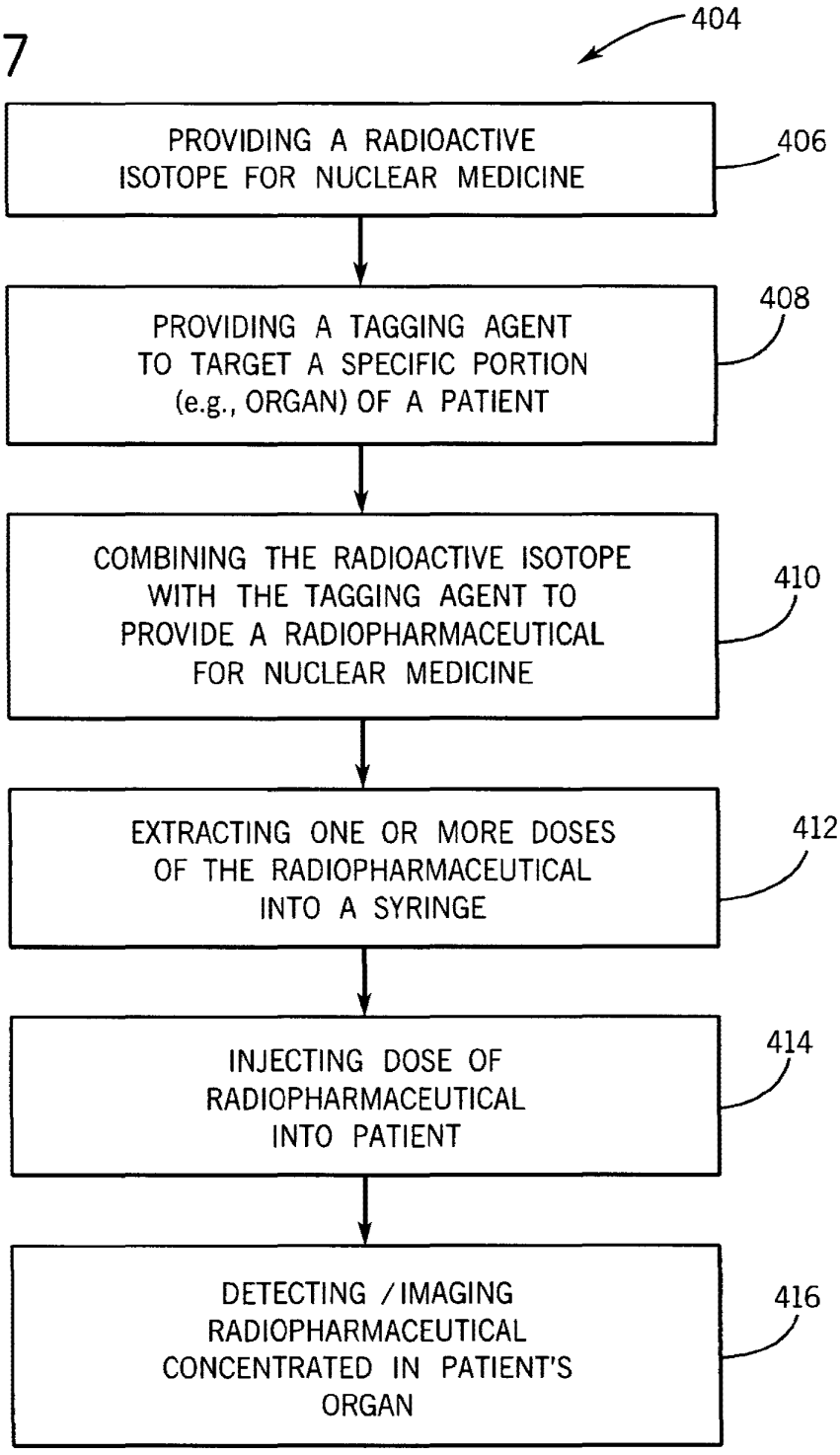
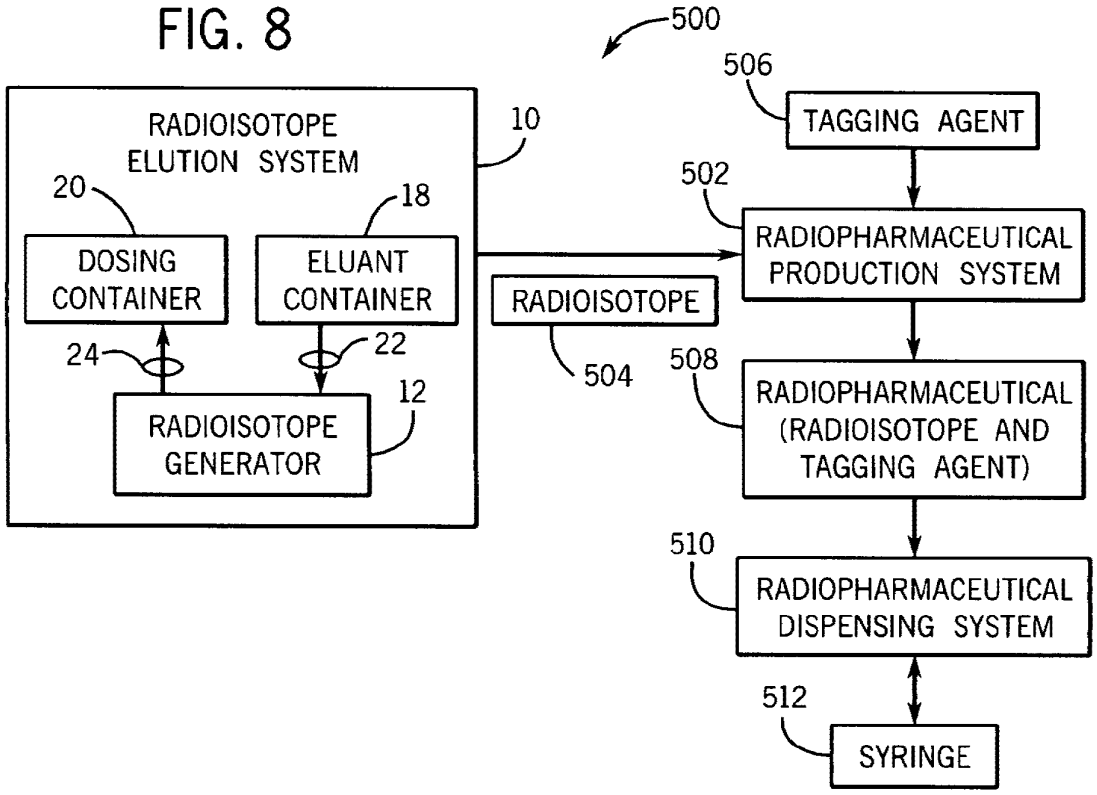

404
PROVIDING A RADIOACTIVE ISOTOPE FOR NUCLEAR MEDICINE
406
PROVIDING A TAGGING AGENT TO TARGET A SPECIFIC PORTION (e.g., ORGAN) OF A PATIENT
408
COMBINING THE RADIOACTIVE ISOTOPE WITH THE TAGGING AGENT TO PROVIDE A RADIOPHARMACEUTICAL FOR NUCLEAR MEDICINE
410
EXTRACTING ONE OR MORE DOSES OF THE RADIOPHARMACEUTICAL INTO A SYRINGE
412
INJECTING DOSE OF RADIOPHARMACEUTICAL INTO PATIENT
414
DETECTING / IMAGING RADIOPHARMACEUTICAL CONCENTRATED IN PATIENT'S ORGAN
416

FIG. 8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20
18
DOSING CONTAINER
ELUANT CONTAINER
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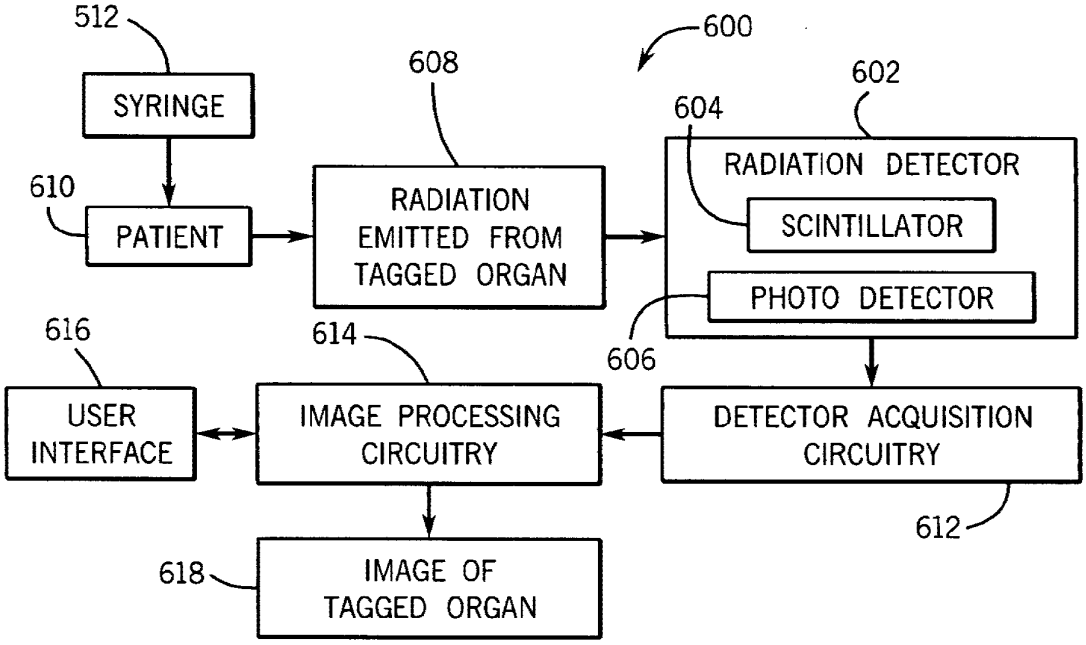
RADIOPHARMACEUTICAL PRODUCTION SYSTEM
RADIOISOTOPE
504
24
22
12
RADIOISOTOPE GENERATOR
508
RADIOPHARMACEUTICAL (RADIOISOTOPE AND TAGGING AGENT)
510
RADIOPHARMACEUTICAL DISPENSING SYSTEM
512
SYRINGE

FIG. 9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616
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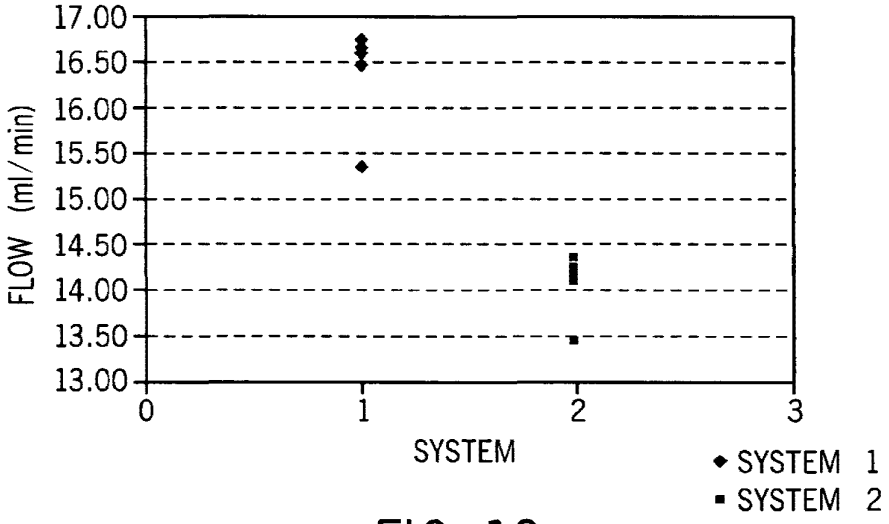
USER INTERFACE
IMAGE PROCESSING CIRCUITRY
DETECTOR ACQUISITION CIRCUITRY
612
618
IMAGE OF TAGGED ORGAN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16.00
15.50
15.00
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13.50
13.00
FLOW (ml/min)
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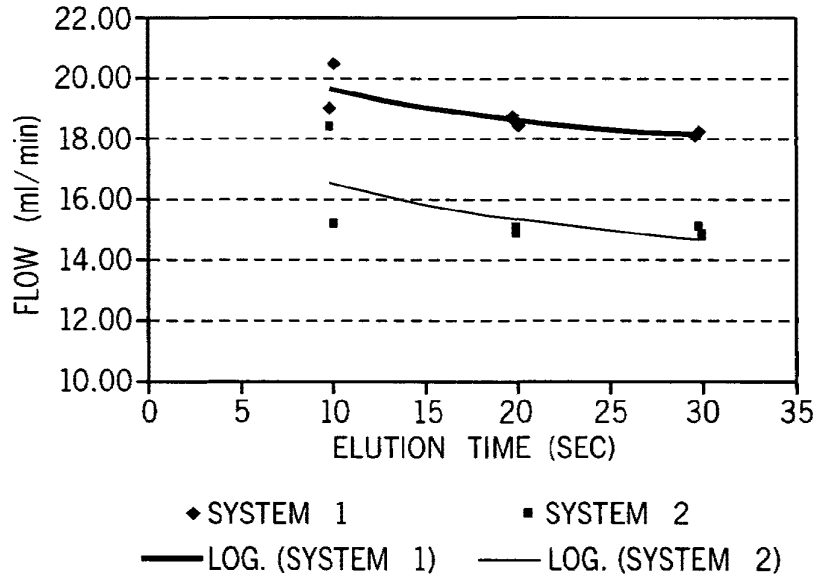
1
2
3
SYSTEM
◆ SYSTEM 1
▪ SYSTEM 2

FIG. 10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20.00
18.00
16.00
14.00
12.00
10.00
FLOW (ml/min)
0
5
10
15
20
25
30
35
ELUTION TIME (SEC)
◆ SYSTEM 1
▪ SYSTEM 2
LOG. (SYSTEM 1)
LOG. (SYSTEM 2)

FIG. 11

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 October 2011 (13.10.2011)

PCT

(10) International Publication Number
WO 2011/126522 A2

(51) International Patent Classification:
G21G 1/00 (2006.01)

(21) International Application Number:
PCT/US2010/059241

(22) International Filing Date:
7 December 2010 (07.12.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/267,295 7 December 2009 (07.12.2009) US

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(72) Inventors; and

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(74) Agents: **CHISHOLM, Robert** et al.; GE Healthcare, Inc., IP Department 101 Carnegie Center, Princeton, New Jersey 08540 (US).

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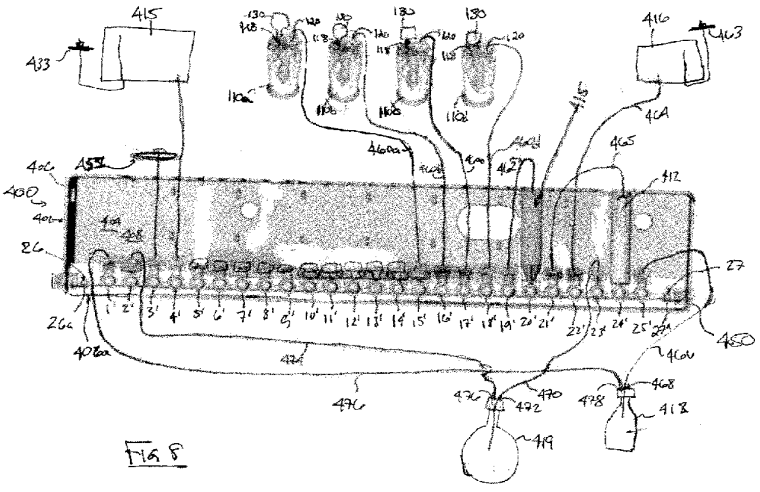
Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

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

(54) **Title**: MULTIPLE GENERATOR ELUTION SYSTEM



(57) **Abstract**: A multiple generator elution system for selectively eluting from a plurality of parent-daughter generators according to an elution schedule it calculates taking into account supply data, demand data, and available activity in each of the generators.

WO 2011/126522 A2

MULTIPLE GENERATOR ELUTION SYSTEM

Field of the Invention

The present invention relates to the field of radioisotope generators. More specifically, the present invention is directed to a multiple generator elution system.

Background of the Invention

Fission-produced Mo-99 supply is in a state of uncertainty. Only two reactors, the Canadian NRU reactor and the Petten HFR reactor, represent approximately 60-70% of the world's supply of fission produced Mo-99. When either of these reactors goes off-line, whether for scheduled maintenance or for unscheduled repairs, the result is to effectively reduce nuclear medicine procedures to only essential cases. All the reactors used to manufacture fission Mo-99 are nearing the end of their respective working lives, currently only one replacement reactor is planned, the Petten replacement called Pallas. Of additional concern is the proliferation of highly enriched uranium (HEU), the target material for fission Mo-99, falling into the hands of terrorists or rogue governments. HEU is used for manufacturing nuclear weapons.

Alternatively, a gel-based generator uses Mo-99 obtained from neutron activation (n,γ) of natural molybdenum, which can be performed in any nuclear reactor including power reactors. Unfortunately, Mo-99 produced from n,γ methods tends to be of low specific activity when compared to Mo-99 produced from fission of U-235, whether HEU or low enriched uranium (LEU). Low specific activity means the Mo-99 must be either placed on a very large alumina column to absorb all the inactive molybdenum, or turned into an insoluble gel matrix that reduces the overall volume of the elutable column (e.g. zirconium molybdate or titanium molybdate). Subsequently, large elution volumes are required to elute the column of the Tc-99m daughter nuclide, particularly if an alumina column is used. The prior art fails to address all of the issues encountered with low specific activity and or low activity generators.

Nucl.Med.Comm., 25 609-614 (2004) discusses the need to obtain high radioactive concentrations of Tc-99m from zirconium molybdate gel generators (higher concentrations are often required for "cold kit" compounding, as well as economic reasons in larger radiopharmacies).

US patent 5,729,821 discloses a method for concentration of Tc-99m from Mo-99 sorbent on an alumina based column. The system requires multiple columns to achieve concentration of the eluate. Multiple columns must be used because the Tc-99m is eluted off the primary column by means of ion exchange with the chloride ion in saline. The cation (sodium) is then removed by the secondary column (in this case a silver halide based), and the pertechnetate is concentrated in the tertiary anion column for subsequent elution with saline to form sodium pertechnetate. This method requires the use of an acid salt or weak acid to separate and elute Tc-99m from the parent nuclideMo-99 (e.g. alumina columns), as well as a cation ion column to remove the cation from the elution, so that the pertechnetate ion can be concentrated on an anion column.

Applied Radiation and Isotopes 66 (2008) 1814-1817 discloses a method which extracts Tc-99m from a solution containing Mo-99. This is a complicated procedure that requires the use of organic solvents (tetrabutylammonium bromide solution in methylene chloride) to extract and concentrate the Tc-99m.

Applied Radiation and Isotope 66 (2008) 1295-1299 discloses a method cited which is a variant of the above method where a low specific activity alumina based generator is eluted with saline to remove the Tc-99m. The eluate is concentrated on strong anion exchanger Dowex column. The Tc-99m is removed by elution with tetrabutylammonium bromide solution with methylene chloride into a collected in a vial. The organic solvent is removed by vacuum pumping to dryness and reconstituted with saline for use with cold kits. This method is impractical because of time required to prepare the concentrated Tc-99m.

U.S. Patent 6,157,036 discloses a method for low specific activity ion exchange type generators (i.e. alumina). The system uses multiple columns similar in method to U.S.

Patent No. 5,729,821. The method uses positive pressure instead of safer negative pressure to move fluids - negative pressure (vacuum) is inherently safer for transfers involving radioactive materials.

There is therefore a need for a system which manages grow-in of the daughter nuclide for efficiency purposes. There is also a need in the art for an elution system which minimizes the waste and maximizes the use of the daughter nuclide produced by a series of generators. There is further a need for an elution system which can reduce the risk of proliferation of HEU. There is also a need for a manifold kit which is operable by an automated actuation system for directing the eluate from a series of generators to a collection vial.

Summary of the Invention

In view of the needs of the art, the present invention provides a multiple generator elution system, comprising a plurality of parent-daughter nuclei generators and a control system for tracking the grow-in of the activity of each of the parent-daughter nuclei generators.

The control system receives demand data indicating requirements for activity production and is configured to elute from selected ones of the generators with a first eluate in order to provide a desired amount of a daughter nuclide. A receivingr unit receives demand data which includes at least an amount of daughter nuclide to be produced and a schedule for the production of the amount of daughter nuclide. The receiving unit is operable with the control system so that the control system will schedule the elution of the daughter nuclide from the plurality of generators to meet the demand represented by the demand data. The receiving unit will also receive supply data

The present invention also provides a concentration column for collecting the generator daughter nuclide from the selected ones of the plurality of generators. The

concentration column contains an appropriate column media. For example, when the daughter nuclide is Tc-99m, concentration column is desirably an anion column from which the daughter nuclide is eluted. Also provided is a collection container for receiving the daughter nuclide from said concentration column.

Additionally, the present invention provides a control system a multiple generator elution system which tracks the grow-in of the activity of each of the parent-daughter nuclei generators and schedules elution from among the generators to meet an inputted demand for the daughter nuclide.

The present invention may also provide a source of second eluent to elute the columns. Depending on the application, the second eluent may be different from the first eluent or both may be the same. Additionally, in embodiments where the same eluent is used to elute both the generators and the concentration column, the eluent may be drawn from a single source. Alternatively, the source of first eluent may be provided individually to each generator, rather than from a common source. The present invention also provides that when highly pure water, such as water for injection, is provided from a common reservoir for eluting the generators, this water may also be used to rinse the components of the elution system between elution runs. The present invention also contemplates that a source of highly pure water may be provided only for the purpose of rinsing components of the multiple generator elution system.

Additionally still, the present invention provides a method for operating a multiple generator elution system which coordinates inputted demand data for the daughter nuclide produced by the generators, tracks the available activity in each of the generators over time, and schedules elution from among the generators to meet the inputted demand for the daughter nuclide.

Furthermore, the present invention provides a kit for a manifold system which may be operated by a control system to direct the elutions from among a plurality of parent-daughter generators to a separations column.

The present invention solves problems for those skilled in managing and operating generators in a nuclear pharmacy. Using Tc-99m/Mo-99 generator for purposes of illustration, and not of limitation, the preset invention combines and concentrates the daughter nuclide technetium [Tc-99m] pertechnetate elutions from multiple generator units and extends the useful life of decayed or low activity generators. The present invention automatically manages the isotope "grow-in" for maximum efficiency and cost savings, in conjunction with demand data from an ERP system or manual inputs. The present invention also allows operating personnel to model "what-if" scenarios such as when modeling supply shortages and unexpected increases in demand. Additionally, the present invention may be housed behind a radiological shielding that safely stores generators, as well as all components handling radioactivity. The present invention allows a gamma gel based Mo-99 generators to be more operationally competitive with fission based generators, thus facilitating a viable alternative to Mo-99 produced by the irradiation of highly enriched uranium (HEU), and thus reducing the proliferation of nuclear bomb grade material. Moreover, the present invention provides prescription compounding data interchange for electronic medical records.

The Mo-99 isotope used in Tc-99m/Mo-99 generators typically represents 75% or more of the total cost of a generator. Generator and isotope purchases are typically the largest single expense item. Mo-99 decays into Tc-99m at a known exponential rate, Tc-99m also decays at a known exponential rate. A typical generator contains a known amount activity when delivered. When the generator is eluted the Tc-99m is removed leaving the Mo-99 behind to continue to decay into Tc-99m. The calculations required to accurately determine the amount of available Tc-99m on a generator at any given time are very complex, and not easily performed. The present invention provides a control system incorporating software for easily and quickly executes these calculations. Utilizing this software in conjunction with the multiple generator elution system allows the control system to select an efficient combination of generators for any given demand. Additionally, historical or real-time demand can be obtained by either manual operator entry, or by data link from an enterprise resource planning system.

A titanium molybdate "gel" based generator uses very low specific activity Mo-99, which leads to elutions that are less concentrated and of generally lower total radioactive content than the industry standard fission Mo-99 based generator. The multiple generator elution system of the present invention eliminates these issues allowing the gel- based generator to be more operationally competitive than the industry standard fission based generator.

Brief Description of the Drawing

Figure 1 is a cross-sectional schematic of a parent-daughter generator of the prior art.

Figure 2 depicts an activity decay curve for a Mo-99/Tc-99m generator.

Figure 3 depicts the decay curve for Tc-99m in a Mo-99/Tc-99m generator after serial elutions of the Tc99m isotope ions.

Figure 4 depicts a multiple generator elution system for gel-based Mo-99 generators.

Figure 5 depicts an alternate representation of the elution system of Figure 4.

Figure 6 depicts a multiple generator elution system for alumna-based Mo-99 generators.

Figure 7 depicts an alternate representation of the elution system of Figure 6.

Figure 8 depicts a cassette-based manifold as part of a multiple generator elution system of the present invention.

Figure 9 is a flow-chart depicting a method of the present invention.

Figure 10 depicts a screen shot of a graphical user interface (GUI) of the present invention for providing supply information for a multiple generator elution system of the present invention.

Figure 11 depicts a screen shot of a GUI for an elution management system for a multiple generator elution system.

Detailed Description of the Preferred Embodiments

The present invention concentrates eluates from large volume elutions for reconstitution with "cold kits" that require higher radioactive concentrations. In one embodiment, the present invention provides a system for concentrating Tc-99m. The present invention can concentrate eluates in larger radiopharmacies to achieve work flow efficiencies, particularly with QC testing of eluates, and eliminates time consumed eluting multiple generators individually. Additionally, the present invention allows generators nearing expiry, which tend not to be used because of low yields and thus lower radioactive concentration of eluate, to be more fully utilized to expiry, achieving cost savings. The present invention incorporates software to better match demand with supply, thus achieving cost savings and minimizing waste and loss. The present invention obviates the need for using organic solvents, thus eliminating waste and use of hazardous organic solvents.

The present invention provides a multiple generator elution system which uses multiple parent-daughter generators, tracks the in-growth relationship for the parent-daughter isotopes in each of the generators, and concentrates the output of the generators which are eluted. Bringing all three of these concepts together solves inherent issues with low specific activity generators, in both in application and efficiency of use.

The multiple generator elution system is desirably enclosed within a radiation-shielding enclosure, such as a lead-walled hot cell. While the present invention would work

for managing elution from a single generator, in the preferred embodiment, multiple generators are managed. One embodiment of the present invention utilizes a number of Mo-99 titanium/ Tc-99m titanium [Mo-99] molybdate gel generators utilizing Mo-99 obtained from neutron activation of natural molybdenum (n,γ Mo-99). While particular reference is made to managing the elutions from Mo-99/Tc-99m parent-daughter generators, the present invention contemplates that other types of generators may also be employed to elute and other daughter isotopes, or daughter nuclides.

Thus in one embodiment of the present invention, a lead-shielded enclosure contains 1 or more Mo99/Tc99m generators. The generators are connected together via a fluid path system, which enables any combination of generator to be eluted onto a concentration column or columns. In the case of Tc-99m, the concentration column is an anion column. The concentrated Tc99m is subsequently eluted off the concentration column into a collection vial at the required radioactive concentration ready for use in the radio-pharmacy. The control system selects the most efficient combination of generators based on demand, available supply and future demand.

Both the available supply of activity and the current and future demand for activity may be manually entered or electronically transferred into the receiving unit and into the control system from the generators themselves and from the radio-pharmacy Enterprise Resource Planning (ERP) system, respectively. For example, data transferred from the generators themselves could be electronically read or scanned from a label on the generator, such as a bar code. Such data regarding the generators, also called the 'supply data', can include the calibration data for the generator, providing both date and activity. Additionally the supply data is contemplated to include the time and date that the generator is available for use and the time and date of the first elution off set. Similarly, the demand data, including the required activity and the time such activity is required from the system may be either manually or electronically entered into the control system. The present invention contemplates that a data receiving unit is configured for the manual and/or electronic input of the demand data.

Using the supply data, the control system can calculate the available activity in each generator, desirably in set intervals, e.g. every thirty minutes, and displays the same to an operator. The demand data is desirably similarly displayed over the same time intervals as the supply data. The control system includes a computer to calculate the best fit elution profile, or schedule, for selecting which of the available generators will be eluted at a given time to meet the demand data in the most efficient way possible, thus maximizing the useful life of each generator and minimizing waste. The control system is desirably programmed to perform a Generalized Reduced Gradient Algorithm analysis of the demand data and the activity levels of the plurality of generators to determine the optimum elution schedule for minimizing waste. Alternatively, the present invention contemplates that the control system is programmed to run simulations of various elution schedules from the plurality of generators and selecting the elution schedule resulting in the lowest amount of waste of the daughter nuclide upon meeting the demand data. The elution schedule will also be provided to the operator.

Desirably, the display of the elution schedule is provided on a GUI which gives the operator the option of overriding the calculated optimized elution schedule by instead scheduling different generators for elution at a given time. When the operator decides to modify the elution schedule, the control system will recalculate the elution schedule and display the both the updated activity availability over time for each generator as well as the scheduled time of elution from each of the generators. If the updated elution schedule is satisfactory to the operator, the elution instructions will be followed for eluting the selected generators according the schedule. In this way, the present invention provides the option of an 'operator-in-the-loop' to oversee and manage the elution from the generators and allow the operator to override the calculated schedule. Alternatively, the present invention is able to operate without the need for operator intervention and can thus perform the scheduled elutions automatically without operator input, thereby freeing the operator to tend to other pharmacy duties.

The elution instructions will be used to electronically control the elution of the selected generators. As the generators are eluted, the control system will update the

ingrowth calculations and update the elution schedule if necessary. The present invention contemplates that either an operator or the system will perform the step of confirming that the selected generators were in fact eluted.

Calculations used in populating the elution schedule will desirably take into account known constants such as the parent nuclide half-life and decay equation, the daughter nuclide half life and decay equation, the elution yield efficiency as well as the fraction of the elution available the parent nuclide decay. Additionally the control system will consider the equilibrium equation for the parent-daughter and the expiration time for the generator. Most generators have a 2 week life – this is a pharmaceutical expiry requirement – but it could be much longer if the parent isotope has a long half life, e.g., Sr-90 / Y-90

The present invention offers numerous advantages both technically and economically. The present invention is thus able to perform as a concentrator of the activity eluted from the selected generators for each elution run. Not only does this allow the efficient utilization of the generators, but it also allows that generators nearing expiry can still be utilized in combination with each other as their activities are concentrated together. Automated operations can reduce exposure to the doses by the pharmacy staff. Labor efficiencies are realized as well. For example, if four generators are to be individually eluted, then four distinct quality control tests are required. The present invention, by concentrating the individual elutions, allows that only a single quality control test be performed on the concentrated elutions, allowing for more activity to be retained in the collection vial for clinical use.

The present invention makes the use of gel generators a commercially viable option, despite their lower comparative specific activity to fission generators. The multiple generator elution system (MGES) of the present invention is intended to eliminate the disadvantages of gel based generator systems discussed above. Additionally, the use of gel generators improves the management of isotope supply during outages or shortages by the conventional sources.

The system desirably includes a shielded area that houses two or more gel generators. These generators are connected to separate valve manifolds, which can be selected by the control system to elute the selected generator(s) at the appropriate time to meet planned demand. The Tc-99m is eluted by passing an eluent through the selected one or more generators. The Tc-99m is collected on an alumina concentration column. When the collection(s) from the generator(s) is complete, the control system elutes the concentration column with eluent into an industry standard shielded collection vial. The eluent can be drawn from a reservoir or from individual saline vials currently used to elute generators.

All the fluid paths, concentration column, and collection vial equipment are desirably shielded by a hotcell to provide radiological protection to the operators. Shielding of individual components may be alos provided within the radiation-shielding hot cell.

Various methods of concentrating Tc-99m elutions have been documented. The calculations for determining the in-growth relationship for parent daughter isotopes are widely known, but not often used because of complexity. The use of n,γ Mo-99 in gel generators systems and other generator systems is also known. The present invention brings all three of these concepts together into a single elution system that manages the supply data, the available activity, and demand data for a plurality of generators, and overcomes issues inherent with low specific activity generators, in both in application and efficiency of use.

The present invention will work with zirconium or titanium molybdate gel generator systems. With modification, the present invention (as detailed) will work with alumina based systems as well. To work with alumina based systems additional columns and fluid paths therefore will be required.

The concept of a titanium molybdate gel generator design has been proven. The gel is produced post irradiation from irradiated natural molybdenum metal. The established

method includes irradiating the pre formed gel or molybdenum trioxide. Irradiating metal offers yield, safety, and processing efficiency advantages.

Referring now to Figure 1, a parent-daughter generator 110 of the prior art and incorporated into the multiple generator elution system of the present invention includes a long-lived parent nuclide that decays to a shorter-life daughter nuclide. As the parent and daughter nucludes are not isotopes, it is possible to chemically isolate the daughter nuclide. An eluent is directed through a column containing the parent and daughter nuclides, but carries off only the daughter nuclide as eluate from the column. After the elution, the parent nuclide (remaining in the generator) will decay to provide a fresh supply of daughter nuclide. The generator is thus able to provide a fresh supply of daughter nuclide as needed until the parent activity is depleted.

Generator 110 includes a generator body 112 formed from a radiation-shielding material such as lead. Generator body 112 defines a column cavity 114 containing a column 116 holding the parent nuclide. Generator body 112 defines an elongate eluent channel 118 and an elongate eluate channel 120 extending in fluid communication between column cavity 114 and an eluent cavity 122 and a collection cavity 124, respectively. Column 116 contains a media 126 to which the parent nuclide binds but from which the daughter nuclide therein may be eluted. Eluent cavity 122 supports an eluent vial 130 and collection cavity 124 supports a collection vial 132 therein. An eluent conduit 134 extends in fluid communication between eluent vial 130 and column 116 so as to deliver the eluent from within vial 130 into column 116. At each end, eluent conduit 134 terminates in an elongate needle 125a and 125b for puncturing septums of vial 130 and column 116, respectively. An eluate conduit 136 extends from column 116 to collection vial 132 so as to deliver the eluate from column 116 into vial 132. At each end, eluate conduit 136 terminates in an elongate needle 129a and 129b for puncturing septums of vial 132 and column 116, respectively. Typically, collection vial 132 is an evacuated vial so that the low pressure within the vial draws the eluent fluid from eluent vial 130, through column 116 and thereinto. A separate air inlet conduit 140 extends in fluid communication between eluent vial 116 and an air

intake filter 142 so as to assist the evacuation of the eluent from eluent vial 130. Typically, collection vial 132 is housed within its own radiation shield 144 such that removal of shield 144 from collection cavity 124 will carry the now-filled collection vial 132 with it to where a pharmacist may withdraw the collected eluate for further processing.

In one embodiment, column 116 contains Mo-99 which decays into Tc-99m with acidic alumina as the sorbent. Column 116 would then be an acidic alumina column although other types of columns, as previously described, may also be used. The present invention contemplates incorporating multiple generators 110. As will be shown hereinbelow, the present invention further contemplates providing that the collection vials are replaced for each generator with a conduit leading to a common collection vial. Additionally, the present invention contemplates that instead of each generator having its own eluent vial 130, a common source of eluent may be provided which may be directed to any and all of the generators as required. For example, when column 116 is an acidic alumina column with Mo-99, eluent vial 130 may provide a source of saline for eluting the Tc-99m nuclide from the column. Alternatively, for example, for a gel generator, a source of water for injection may be provided as an eluent.

The present invention contemplates that the generators used by the present invention may be either a fission or n,γ generator. For example, the TechneLite® (Technetium Tc99m Generator) sold by Lantheus Medical Imaging, 331 Treble Cove Rd., N. Billerica, MA 01862, USA may be used. The TechneLite generator is what is known as a dry generator, which means that it has an external source of saline to elute the system. Most generators tend to be in this format. Similar to other fission based generators the TechnelLite generator is based on acidic alumina column to facilitate the storage of Mo-99 and subsequent separation of the daughter isotope Tc-99m. Similarly, generator 110 may comprise the Ultra-Technekow™ DTE (Technetium Tc-99m Generator sold by Coviden (Mallinckrodt Inc., 2703 Wagner Place, Maryland Heights, MO 63043, USA. The Ultra-Technekow is very similar to the TechneLite unit. Alternatively still, the DryTec® (Technetium Tc99m Generator may be used with the instant invention. The Drytec generator is sold by GE

Healthcare, The Grove Centre, White Lion Road, Little Chalfont, Buckinghamshire HP7 9LL, UK, and is similar to the other fission generators listed above.

Moreover, generator 110 may be an n,γ, or gel, generator. One gel generator is the Tc-99m – Geltech Generator sold by the Government of India Dept of Atomic Energy, BRIT/BARC Vashi Complex, Sector-20 Vashi, Navi Mumbai – 400 705, India. The Geltech generator for 99mTc is a dual column system comprising of a primary Zirconium Molybdate-99Mo gel column and a secondary purification Acidic Alumina column. These types of generators, while structurally different from the fission type generator, still operate in a similar manner to produce sodium pertechnetate using a saline eluent. While the gel generators are not truly chromatographic, the term 'eluent' will be also be used herein to describe the fluid directed into the generator and the term 'eluate' will also be used herein to describe the fluid exiting the gel generator with the daughter nuclide.

Figure 2 depicts an activity decay curve for a Mo-99/Tc-99m generator. Figure 3 shows how the available activity decays over time until reaching a point where the generator is not useful. Figure 3 also depicts the decay curve for Tc-99m in a Mo-99/Tc-99m generator after serial elutions of the Tc99m isotope ions. Whereas line A depicts the overall decay of the parent nuclide, Mo-99, lines B-D depict the grow-in of the daughter nuclide, Tc-99m, up to a near maximum at which time the daughter nuclide is eluted so that there is none left in the column of the generator. The parent nuclide will continue to decay into the daughter nuclide so the increase in the available activity of the daughter nuclide is shown over time. Equation 1 is the equilibrium equation that describes the theoretical Tc-99m activity (A_2) present in the generator at any time (t) after the previous elution when one knows the Mo-99 activity A^0_1 present at the time of the previous elution.

$$A_2 = \frac{0.86\lambda_2}{\lambda_2 - \lambda_1} A_1^0\left(e^{-\lambda_1 t} - e^{-\lambda_2 t}\right) + A_2^0 e^{-\lambda_2 t} \qquad \text{Eq. (1)}$$

Where λ_1 is the decay constant for Mo-99 and λ_2 is the decay constant for Tc-99m. The present invention links the demand for activity with the calculated availability of activity for each of the generators.

Figures 4 depicts a multiple generator elution system 200 of the present invention. Multiple generator elution system 200 incorporates a plurality of generators 110. The generators 110 are desirably connected to a manifold (not shown) that includes valves and conduits so that individual ones of the valves are in selectable fluid communication with corresponding individual ones of the generators. Desirably, the manifold is connected to a low pressure, or vacuum source, for pulling the eluents through system 300. The manifold directs the generator eluate output to a concentration column 212. An eluent is directed from a first eluent source 214 to selected ones of the generators 110 and the resulting eluate from the selected generators is all directed to column 212. Concentration column 212 traps the daughter nuclide from the generators therein. A second eluent from a second eluent source 216 is directed through concentration column 212 to elute the daughter nuclide into a collection vial 218. The generators 110, column 212, eluent sources 214 and 216 and collection vial are desirably placed within the cavity 224 of a radiation-shielding hot cell 222 so as to limit exposure of the operators.

System 200 includes a control system 226 and receiving unit 228. Receiving unit 228 and control system 226 may be provided as part of a single computer system. Receiving unit 228 receives both supply data and demand data, which control system 226 can use to generate the elution schedule for the generators 110 as will be described for Figures 9-12. The supply data allows calculation of the amount of activity available from each of generators 110, based on the calibration data, including the known starting activity and date, the time and date of when the generator was available for use, and the time and date of the first elution off set. The demand data relates to the amount of activity required and when. The demand data may be automatically inputted into the receiving unit 328 from an ERP module 231, such as SAP or Slimline, or it may be entered in manually into receiving unit 228. Control system 226 desirably calculates the elution schedule by determining which generators will be eluted and when so as to match the demand data to the available activity

so as to maximize the eluted daughter nuclide with the minimum amount of waste. Control system 226 will then desirably download instructions to an actuation system 235 located within hot cell 222 for conducting the elutions. The present invention further contemplates that control system 226 may be alternatively provided within hotcell 222 either separately from actuation system 235 or as a unitary computerized system peforming the functions for both.

By way of illustration and not of limitation, in this configuration, the generators 110 are Mo99/Tc99m generator (titanium [99Mo] molybdate) gel generators. The first eluent source 214 desirably provides a weak acid as the first eluent for eluting the daughter nuclide Tc-99m from the generators, although highly pure water, such as sterile water for injection may also be used to elute the gel generator. Concentration column 212 includes an alumina sorbent to capture the pertechnate in the eluate from generators 110. Second eluent source 216 provides saline for eluting the sodium pertechnate from column 212 and collection in collection vial 218. The sodium pertechnate may then be used with cold kits for labeling a radiotracer.

With the present invention, any combination of generators may be eluted and the activity from the eluted generators collected in column 212. The final radioactivity concentration is determined by the elution of the concentration column 212, which can be eluted in a very small volume. Additionally, because the activity can be collected from multiple generators and concentrated, the generators may be used continuously until expiry.

Referring now to Figure 5, an alternate presentation multiple generator elution system 200 is shown. In Figure 5, five gel generators 110a-e are shown connected with a valve manifold 250. Manifold 250 is desirably based on the linearly-arranged stopcock manifold used in FASTlab™ cassettes, sold by GE Healthcare, Liege, BE. Manifold 250 includes sixteen 3way/3position stopcocks valves, 1-17. Each of valves 1-17 include three open ports opening to adjacent manifold valves and to a respective luer located therebetween. Each valve includes a rotatable stopcock which puts any two of the three associated ports in fluid communication with each other while fluidically isolating the third

port. The present invention further contemplates that the stopcock could include a T-shaped internal passageway therein so as to also allow all three ports to be placed in fluid communication across the valve, but such an embodiment would provide dead spaces which could require additional rinsing so as to prevent the occurrence of contamination between successive fluid flows. Manifold 250 further includes, at opposing ends thereof, first and second socket connectors 18 and 19, each defining vacuum ports 18a and 19a, respectively. Manifold 250 and the stopcocks of valves 1-17, as well as the conduits described below, are desirably formed from a polymeric material, e.g. PP, PE, Polysulfone, Ultem, or Peek. As will be shown in Figure 8, the manifold desirably includes twenty-five 3way/3position stopcocks valves, although the actual number of valves is scaleable to meet the needs of the user. Unused valves may simply have their luer connection capped by a luer fitting and their stopcocks providing fluid communication for flow between adjacent valves.

Each of the connections at the valves described herein are made at the port defined by its luer connector. As shown in Figure 5, valve 1 supports a filtered vent 251 at its luer connection. Valve 2 is connected to first eluent source 214 by an elongate conduit 252.. First eluent source 214 provides the eluent for eluting the daughter nuclide from generators 110a-e. First eluent source 214 desirably is also connected in fluid communication with a filtered vent 233 to assist the outflow of the eluent through conduit 252 towards valve 2. Valve 3 is connected by an elongate conduit 254 to a second manifold 256 providing open connection to the eluent channels 118 of generators 110a-e. That is, the present invention desirably provides a single source of eluent for eluting each of the generators, although the present invention also contemplates that each generator may have its own source of eluent as shown in Figure 1. The eluate channels 120 of generators 110a-e are connected back to manifold 250 by elongate conduit 260a-e, respectively. Conduits 260a-e extend between the respective eluate channels 120 of generators 110a-e to valves 4-8, respectively.

Valve 9 is connected by elongate conduit 262 to an input port of concentration column 212 so that eluate from the generators may be directed to column 212. Valve 10 is connected to second eluent source 216 by an elongate conduit 264. Second eluent source 216 provides the eluent to elute the daughter nuclide from column 212. Second eluent

source 216 desirably is also connected in fluid communication to a filtered vent 263 to assist outflow of the second eluent through conduit 262 towards valve 9. Valves 11 and 12 are capped by a luer fitting and their stopcocks oriented to provide fluid flow there through between valves 10 and 13. Valve 13 is connected by elongate conduit 266 to an input port 268 of collection vial 218 so as to be able to direct a product fluid therein. Valve 14 is connected by elongate conduit 270 to an input port 272 of a waste vial 219. Valve 15 is connected to the output port of column 212, such that column 212 desirably connects directly to valve 15. Valve 16 is connected by elongate conduit 274 to an outlet port 275 of waste vial 215. Valve 17 is connected by elongate conduit 276 to an outlet port 278 of collection vial 218.

A sample elution will now be described. An elution schedule has been calculated that requires eluting the activity from generators 110a and 110c. By application of a vacuum (ie, a sufficient low pressure) at port 19a, the first eluent will be drawn from first source 214. Valves 1-17 are set so that the first eluent flows through valves 2 and 3 and conduit 254 into manifold 256. First, valves 5-8 are set to allow for eluate flow from generator 110a to flow through conduit 260a through to valve 9. Valve 9 directs the eluate flow through conduit 262 to the input port of column 212. From column 212 the eluate will be drawn through valve 15 to valve 14 and into waste vial 219. The volume of waste vial 219 will be sufficient to collect all of the liquid thus delivered from column 212. The stopcock of valve 4 is then rotated to isolate generator 110a and the stopcock of valve 6 is rotated so that the first eluent will be drawn from second manifold 256 into generator 110c. The eluate from generator 110c is then directed through valves 6-8 to valve 9. Valve 9 directs the eluate flow through conduit 262 to the input port of column 212. From column 212 the eluate will be drawn through valve 15 to valve 14 and into waste vial 219. The daughter nuclides from generator 110a and 110c have thus been collected in concentration column 212.

To elute the daughter nuclide from column 212, valve 10 will be set to direct, under suction at port 19a, the second eluent from source 264 through conduit 264 and towards valve 9. The second eluent is drawn through conduit 262 through the input port of column

212 and through column 212. Upon exiting column 212 into valve 15, the column 212 eluate will contain the daughter nuclide for dispensement into collection vial 218. This eluate will be directed to valve 13 and through conduit 266 into vial 218, the suction from port 19a being applied through valve 17 and conduit 276. Vial 218 may then be either removed or drawn from to provide the daughter nuclide for further processing by the pharmacist. Subsequent dispensements from the generators may thus be directed into the same collection vial or otherwise combined with unusued eluate from a previous dispensement, as control system 226 has included any leftover activity in its calculations for dispensing from generators 110a-e in order to meet the requirements of the demand data.

Manifold 250 is desirably formed to be attached to an actuation system 235 which engages and sets the orientation of the stopcocks of the valves and provides the low-pressure suction, or vacuum, for drawing fluids through the manifold and into the vials. Actuation system 235 includes rotatable arms which engage each of the stopcocks of valves 1-17 and can position each in a desired orientation throughout elution operations. The actuation system 235 also includes a pair of spigots, each of which engages one of ports 18a and 19a in fluid-tight connection to provide a source of low pressure, or vacuum, to manifold 250 in accordance with the present invention. Desirably, manifold 250 is attachable to a FASTLab^{TM} (sold by GE Healthcare, Liege, BE) synthesis device which has been programmed to operate the valves and apply the vacuum. As the FASTlab synthesizer is already designed to operate in a hot cell environment, it is ideally suited as the actuation device for system 200. Actuation system 235 is directed to act by control system 226 according to the calculated elution schedule.

Figures 6 and 7 depict a multiple generator elution system 300 for alumna-based Mo-99 generators 110. Multiple generator elution system 300 incorporates a plurality of generators 110. In this embodiment, the generators 110 are Mo99/Tc99m alumina generators (ie, incorporate alumina in the generator's column). The generators 110 are desirably connected to a manifold (not shown) that includes valves and conduits so that individual ones of the valves are in selectable fluid communication with corresponding

individual ones of the generators. The manifold directs the generator eluate output to a cation column 315. The generator eluate flows through the cation column 315 and then into a concentration column 312. Desirably, the manifold is connected to a vacuum source for pulling the eluents through system 300. The cation column is not used for trapping the daughter nuclide but contains an appropriate media for removing competing ions which adversely interfere with the concentration column. Thus, in system 300 an eluent is directed from a first eluent source 314 to selected ones of the generators 110 and the resulting eluate from the selected generators is all directed through column 315 and to column 312. Concentration column 312 traps the daughter nuclide from the generators therein. A second eluent from a second eluent source 316 is directed through concentration column 312 to elute the daughter nuclide into a collection vial 318. The generators 110, column 312, eluent sources 314 and 316 and collection vial are desirably placed within the cavity 324 of a radiation-shielding hot cell 322 so as to limit exposure of the operators.

System 300 includes a control system 326 and receiving unit 328. Receiving unit 328 and control system 326 may be provided as part of a single computer system. Receiving unit 328 receives both supply data and demand data, which control system 226 can use to generate the elution schedule for the generators 110 as will be described for Figures 9 and 10. The supply data allows calculation of the amount of activity available from each of generators 110, based on the calibration data, including the known starting activity and date, the time and date of when the generator was available for use, and the time and date of the first elution off set. The demand data relates to the amount of activity required and when. The demand data may be automatically inputted into the receiving unit 328 from an electronic ERP module 331, such as SAP or Slimline, or it may be entered in manually into receiving unit 328 by an operator. Control system 326 desirably calculates the elution schedule by determining which generators will be eluted and when so as to match the demand data to the available activity so as to maximize the eluted daughter nuclide with the minimum amount of waste. Control system 326 will then desirably download instructions to an actuation system 335 located within hot cell 322 for conducting the elutions. The present invention further contemplates that control system 326 may be alternatively provided within

hotcell 322 either separately from actuation system 335 or as a unitary computerized system peforming the functions for both.

In this configuration, first eluent source 314 desirably provides an acid salt or weak acid, typically saline, as the first eluent for eluting the daughter nuclide Tc-99m from the generators. As the first eluent is saline, cation column 315 is used first to remove the sodium ion so as to allow concentration on the concentration column 312. Concentration column 312 includes an alumina sorbent to capture the pertechnate in the eluate from generators 110. Second eluent source 316 provides saline for eluting the sodium pertechnate from column 312 and collection in collection vial 318. The sodium pertechnate may then be used with cold kits for labeling a radiotracer.

With the present invention, any combination of generators may be eluted and the activity from the eluted generators passed through column 315 and collected in column 312. The two column method allows generators based on fission Mo-99 and alumina technology to take advantage of the efficiencies of the concentrator system of the present invention. The final radioactivity concentration is determined by the elution of the concentration column 312, which can be eluted in a very small volume. Additionally, because the activity can be collected from multiple generators and concentrated, the generators may be used continuously until expiry.

Referring now to Figure 7, an alternate presentation of multiple generator elution system 300 is shown. In Figure 7, five gel generators 110a-e are shown connected with a valve manifold 350. Manifold 350 is desirably based on the linearly-arranged stopcock manifold used in FASTlab™ cassettes, sold by GE Healthcare, Liege, BE. Manifold 350 includes sixteen 3way/3position stopcocks valves, 1-17. Each of valves 1-17 include three open ports opening to adjacent manifold valves and to a respective luer located thereon, the luer port located between the opposed other ports. Each valve includes a rotatable stopcock which puts any two of the three associated ports in fluid communication with each other while fluidically isolating the third port. The present invention further contemplates that the stopcock could include a T-shaped internal passageway therein so as to also allow all three

ports to be placed in fluid communication across the valve, but such an embodiment would provide dead spaces which could require additional rinsing so as to prevent the occurrence of contamination between successive fluid flows. Manifold 350 further includes, at opposing ends thereof, first and second socket connectors 18 and 19, each defining vacuum ports 18a and 19a, respectively. Manifold 350 and the stopcocks of valves 1-17, as well as the conduits described below, are desirably formed from a polymeric material, e.g. PP, PE, Polysulfone, Ultem, or Peek. As will be shown in Figure 8, the manifold desirably includes twenty-five 3way/3position stopcocks valves, although the actual number of valves is scaleable to meet the needs of the user. Unused valves may simply have their luer connection capped by a luer fitting and their stopcocks providing fluid communication for flow between adjacent valves.

Each of the connections at the valves described herein are made at the luer port defined by its luer connector. As shown in Figure 8, valve 1 supports a filtered vent 351 at its luer connection. Valve 2 is connected to first eluent source 314 by an elongate conduit 352. First eluent source 314 provides the eluent for eluting the daughter nuclide from generators 110a-e. First eluent source 314 desirably is also connected in fluid communication with a filtered vent 333 to assist the outflow of the eluent through conduit 352 towards valve 2. Valve 3 is connected by an elongate conduit 354 to a second manifold 356 providing open connection to the eluent channels 118 of generators 110a-e. That is, the present invention desirably provides a single source of eluent for eluting each of the generators, although the present invention also contemplates that each generator may have its own source of eluent as shown in Figure 1. The eluate channels 120 of generators 110a-e are connected back to manifold 350 by elongate conduit 360a-e, respectively. Conduits 360a-e extend between the respective eluate channels 120 of generators 110a-e to valves 4-8, respectively.

Valve 9 is connected by elongate conduit 362 to an input port of a cation column 315. Cation column 315 serves to remove competing ions from the eluate from the generators prior to concentration. Valve 10 is connected to second eluent source 316 by an elongate conduit 364. Second eluent source 316 provides the eluent to elute the daughter

nuclide from column 312. Second eluent source 316 desirably is also connected in fluid communication to a filtered vent 363 to assist outflow of the second eluent through conduit 362 towards valve 9. Valve 11 is connected to the output port of cation column 315. Valve 12 is connected by elongate conduit 365 to an input port of concentration column 312.

Valve 13 is connected by elongate conduit 370 to an input port 372 of a waste vial 319. Valve 14 is connected by elongate conduit 366 to an input port 368 of collection vial 318 so as to be able to direct a product fluid therein. Valve 15 is connected to the output port of column 312, such that column 312 desirably connects directly to valve 15. Valve 16 is connected by elongate conduit 374 to an outlet port 375 of waste vial 315. Valve 17 is connected by elongate conduit 376 to an outlet port 378 of collection vial 318.

A sample elution will now be described. The elution schedule has been calculated that requires eluting the activity from generators 110a and 110c. By application of a vacuum (ie, a sufficient low pressure) at port 19a, the first eluent will be drawn from first source 314. Valves 1-17 are set so that the first eluent flows through valves 2 and 3 and conduit 354 into manifold 356. First, valves 5-8 are set to allow for eluate flow from generator 110a to flow through conduit 360a through to valve 9. Valve 9 directs the eluate flow through conduit 362 to the input port of cation column 315. From column 315 the eluate will be drawn through valve 12 and into elongate conduit 265 into the inlet port for concentration column 312. Waste material will continue to be drawn through column 312 through valve 15 down to valve 13 and into waste vial 319. The volume of waste vial 319 will be sufficient to collect all of the liquid thus delivered from column 315. The stopcock of valve 4 is then rotated to isolate generator 110a and the stopcock of valve 6 is rotated so that the first eluent will be drawn from second manifold 356 into generator 110c. The eluate from generator 110c is then directed through valves 6-8 to valve 9. Valve 9 directs the eluate flow through conduit 362 to the input port of column 315. From column 315 the eluate will be drawn through valve 12 and into elongate conduit 265 into the inlet port for concentration column 312. Waste material will continue to be drawn through column 312 through valve 15 down to valve 13 and into waste vial 319. The daughter nuclides from generator 110a and 110c have thus been collected in concentration column 312.

To elute the daughter nuclide from column 312, valve 10 will be set to direct, under suction at port 19a, the second eluent from source 316 through conduit 364 and towards valve 12. The second eluent is drawn through conduit 365 through the input port of column 312 and through column 312. Upon exiting column 312 into valve 115, the column 312 eluate will contain the daughter nuclide for dispensement into collection vial 318. This eluate will be directed to valve 14 and through conduit 366 into vial 318, the suction from port 19a being applied through valve 17 and conduit 376. Vial 318 may then be either removed or drawn from to provide the daughter nuclide for further processing by a pharmacist or technician. Subsequent dispensements from the generators may thus be directed into the same collection vial or otherwise combined with unusued eluate from a previous dispensement, as control system 326 has included any leftover activity in its calculations for dispensing from generators 110a-e in order to meet the requirements of the demand data.

Manifold 350 is formed to be attached to actuation system 335 which engages and sets the orientation of the stopcocks of the valves and provides the low-pressure suction, or vacuum, for drawing fluids through the manifold and into the vials. Actuation system 335 includes rotatable arms which engage each of the stopcocks of valves 1-17 and can position each in a desired orientation throughout elution operations. The actuation system 335 also includes a pair of spigots, each of which engages one of ports 18a and 19a in fluid-tight connection and to provide a source of low pressure, or vacuum, to manifold 350 in accordance with the present invention. Desirably, manifold 250 is attachable to a FASTLab™ (sold by GE Healthcare, Liege, BE) synthesis device which has been programmed to operate the valves and apply the vacuum. As the FASTlab synthesizer is already designed to operate in a hot cell environment, it is ideally suited as the actuation device for system 300. Actuation system 335 is directed to act by control system 326 according to the calculated elution schedule.

Referring now to Figure 8, an elution cassette 400 for use with a multiple generator elution system is shown. In Figure 8, four alumina generators 110a-d for producing Tc-99m

from decaying Mo-99 are shown connected with a valve manifold 450. Cassette 400 includes a case 402 with a planar front wall 404 bounded by a perimetrical wall 406 defining a case cavity 408. Cassette 400 supports an elongate manifold 450 in cavity 408 adjacent to a bottom wall 406a. Manifold 450 is desirably based on the linearly-arranged stopcock manifold used in FASTlab™ cassettes, sold by GE Healthcare, Liege, BE. Manifold 450 includes twenty five 3way/3position stopcocks valves, 1'-25'. Each of valves 1'-25' include three open ports opening to adjacent manifold valves and to a respective luer located thereon, the luer port located between the opposed other ports. Each valve includes a rotatable stopcock which puts any two of the three associated ports in fluid communication with each other while fluidically isolating the third port. The present invention further contemplates that the stopcock could include a T-shaped internal passageway therein so as to also allow all three ports to be placed in fluid communication across the valve, but such an embodiment would provide dead spaces which could require additional rinsing so as to prevent the occurrence of contamination between successive fluid flows and loss of fluid trapped in deadspaces therein. Manifold 450 further includes, at opposing ends thereof, first and second socket connectors 26 and 27, each defining vacuum ports 26a and 27a, respectively. Manifold 450 and the stopcocks of valves 1'-25', as well as the conduit connectors described below, are desirably formed from a polymeric material, e.g. PP, PE, Polysulfone, Ultem, or Peek. As shown in Figure 8, the manifold includes twenty-five 3way/3position stopcocks valves, although the actual number of valves is scaleable to meet the needs of the user. Unused valves may simply have their luer connection capped by a luer fitting and their stopcocks providing fluid communication for flow between adjacent valves.

Cassette 400 is a variant of a pre-assembled synthesis cassette designed to be adaptable for synthesizing clinical batches of different radiopharmaceuticals with minimal customer installation and connections. Cassette 400 is desirably provided in kit form with all of the conduit tubings and supported connectors and filters to be connected to the generators, vials, and eluent source or sources for eluting a nuclide according to the present invention. Desirably, cassette 400 is provided to users with each connection of the conduits to the luers of its valves already made, so that only the free ends need to be mated with the

appropriate component. The cassette so provided may be assembled and packaged in a sterile condition such that if opened in an appropriately clean environment will maintain an appropriate level of sterility for pharmaceutical operations.

Each of the connections at the valves described herein are made at the luer port defined by its luer connector. As shown in Figure 8, valve 3' supports a filtered vent 451 at its luer connection. Valve 4' is connected to rinse fluid source 415 by an elongate conduit 452. Rinse fluid source 415 provides a rinse fluid for rinsing manifold 250 between elution runs or as desired. Rinse fluid source 415 desirably is also connected in fluid communication with a filtered vent 433 to assist the outflow of the eluent through conduit 452 towards valve 4'. That is, while the present invention contemplates that cassette 400 can provide a single source of eluent for eluting each of the generators as described in Figures 5 and 8, in the embodiment of Figure 8, the present invention includes each generator having its own source of eluent, provided in an elutent vial 130, as shown in Figure 1. Providing each generator with its own eluent source 130 may be desirable so as to prevent the risk of over-dilution of the eluate volume from a common reservoir. Additionally, by providing each generator with its own attached elution source, more of the manifold valves 5'-14' will be available for connection to a generator. The air vent on the manifold is used to bleed off excess or unused vacuum. The eluate channels 120 of generators 110a-d are connected back to manifold 450 by elongate conduit 460a-d, respectively. Conduits 460a-d extend between the respective eluate channels 120 of generators 110a-d to valves 15'-18', respectively.

Valves 5'-14' are each capped by a luer fitting which seals the luer port for each valve. Valves 5'-14' are available for scaling up cassette 400 to accommodate additional generators, should a user so desire.

Valve 19' is connected by elongate conduit 462 to an input port of a cation column 415. Cation column 415 serves to remove competing ions from the eluate from the generators prior to concentration. Valve 20' is connected to the output port of cation column 415. Valve 21' is connected by elongate conduit 465 to an input port of

concentration column 412. Valve 22' is connected to second eluent source 416 by an elongate conduit 464. Second eluent source 416 provides the eluent to elute the daughter nuclide from concentration column 412. Second eluent source 416 desirably is also connected in fluid communication to a filtered vent 463 to assist outflow of the second eluent through conduit 462 towards valve 22'. Valve 24' is connected to the output port of column 412, such that column 412 desirably connects directly to valve 24'.

Now the connections to the waste and collection vials will be described. Valve 23' is connected by elongate conduit 470 to an input port 472 of a waste vial 419. Valve 25' is connected by elongate conduit 466 to an input port 468 of collection vial 418. Valve 1' is connected by elongate conduit 476 to an outlet port 478 of collection vial 418. Valve 2' is connected by elongate conduit 474 to an outlet port 475 of waste vial 415.

A sample elution will now be described. The elution schedule has been calculated that requires eluting the activity from generators 110b and 110d. By application of a vacuum (ie, a sufficient low pressure) at port 26a, the first eluent will be drawn from first source vial 130 for generator 110b. Valves 1'-25' are set so that the first eluent flows through generator 110b, through conduit 460b to valve 16' and on through to valve 19'. Valve 19' directs the eluate flow through conduit 462 to the input port of cation column 415. From column 415 the eluate will be drawn through valve 21' and into elongate conduit 465 into the inlet port for concentration column 412. Waste material will continue to be drawn through column 412 through valve 24' down to valve 23' and into waste vial 419. The volume of waste vial 419 will be sufficient to collect all of the liquid thus delivered from column 412.

The stopcock of valve 16' is then rotated to isolate generator 110b and the stopcock of valve 18' is rotated so that the first eluent will be drawn from the vial 130 connected to generator 110d. The eluate from generator 110d is then directed through conduit 460d to valve 18' and then on to valve 19'. Valve 19' directs the eluate flow through conduit 462 to the input port of column 415. From column 415 the eluate will be drawn through valve 21' and into elongate conduit 465 into the inlet port for concentration column 412. Waste

material will continue to be drawn through column 412 through valve 24' down to valve 23' and into waste vial 419. The daughter nuclides from generator 110b and 110d have thus been collected in concentration column 412.

To elute the daughter nuclide from column 412, valve 22' will be set to direct, under suction at port 26a, the second eluent from source 416 through conduit 464 and valve 22' and towards valve 21'. The second eluent is drawn through conduit 465 through the input port of column 412 and through column 412. Upon exiting column 412 into valve 24', the column 412 eluate will contain the daughter nuclide for dispensement into collection vial 418. This eluate will be directed to valve 25' and through conduit 466 into vial 418, the suction from port 26a being applied through valve 1' and conduit 476. Vial 418 may then be either removed or drawn from to provide the daughter nuclide for further processing by the pharmacist. Subsequent dispensements from the generators may thus be directed into the same collection vial or otherwise combined with unusued eluate from a previous dispensement, as the control system of the present invention has included any leftover activity in its calculations for dispensing from generators 110a-d in order to meet the requirements of the demand data.

Cassette 400 is formed to be attached to an actuation system which engages and sets the orientation of the stopcocks of the valves and provides the low-pressure suction, or vacuum, for drawing fluids through the manifold and into the vials. The actuation system includes rotatable arms which engage each of the stopcocks of valves 1'-25' and can position each in a desired orientation throughout elution operations. The actuation system also includes a pair of spigots, each of which engages one of ports 26a and 27a in fluid-tight connection and to provide a source of low pressure, or vacuum, to manifold 450 in accordance with the present invention. Desirably, manifold 450 is attachable to a FASTLab™ (sold by GE Healthcare, Liege, BE) synthesis device which has been programmed to operate the valves and apply the vacuum. As the FASTlab synthesizer is already designed to operate in a hot cell environment, it is ideally suited as the actuation device for cassette 400, receiving its actuation instructions from a control system to operate according to the calculated elution schedule.

For all embodiments of the cassette and manifold systems of the present invention, including those detailed in Figures 5, 7, and 8, the cassette or manifold is desirably attachable to a FASTlab device. All liquid transfers are performed by the applied vacuum (or low pressure). All connections to the manifold cassette are contemplated to be via standard luer locks. The conduits used to connect to the generator are desirably silicon tubing terminated with a septum to allow penetration by the needles 125a and 129a at the respective port on the generator 110. In the event an eluent vial 130 is attached to a generator, a standard connection may be used. Thus the generators do not need to be modified to work with the present invention.

Additionally for all embodiments, an external source of rinse fluid, such as water for injection (WFI), may also be connected to the manifold for cleaning and rinsing proposes. When eluting a gel generator, the WFI source may be connected to each generator to also act as a first eluent. As more particularly described for Figure 8, the present invention contemplates that first eluent can be from a reservoir or a pre measured container or "elution vial" individually connected to each generator. A pre-measured source is desirable so as to prevent over dilution of the eluate volume and to free up an additional manifold valve for connection to a generator. The air vent on the manifold is used to bleed off excess or unused vacuum.

The present invention further contemplates that for some embodiments, depending on the required elution chemistry, the first source of eluent that is connected directly to the manifold (as described for Figures 5 and 7) may be used to elute both the generators and the concentration column, thus obviating the need for a second source of eluent to be connected to the manifold. For example, if system 300 of Figure 7 employs alumina generators and an alumina concentration column, the present invention contemplates that first source of eluent may provide saline that is used both for eluting the generators and for eluting the concentration column.

The cation column is used to remove competing ions, such as chloride, from the eluate. In some embodiments, the pertechnetate ions flow through the cation column and on to the acidified alumina column where it is captured (concentrated). The liquid is allowed to flow through the column and into the waste collection vessel for future disposal. The acidified alumina column (as stated above) is used to capture and concentrate the pertechnetate (^{99m}Tc). While the pertechnetate is being captured on the alumina column, the liquid (essentially water) is removed from the bottom of the column by vacuum and collected in the waste vessel. Once the concentration step is completed the alumina column is desirably eluted with a small volume of saline to remove the pertechnetate as sodium pertechnetate [$Na^{99m}TcO_4$ -] , basically in exactly the same way as current fission generators and collected in the product collection vial.

With reference to Figure 9, the present invention uses demand data and supply data to determine and execute the most efficiency utilization of a set of parent-daughter generators in a radio-pharmacy operation. The supply data allows the automated calculation of the amount of available activity (of the daughter nuclide) at any given time. Generators are sold with known amounts of activity. The supply data can be obtained from a generator barcode or manual data entry. The demand data is the amount of activity required at specific times to meet customer orders. The data can come from either an ERP software system, for example SAP or Slimline (or equivalent) via an electronic transfer, or by manual entry. Typically, in a radio-pharmacy environment, customer orders are segregated into delivery runs, scheduled at certain times of the day.

The present invention compares the demand activity requirements with the available activity at any given time. Additionally, the system will attempt to configure the generator elution plan to deliver a best-fit solution representing the best efficiency for eluting from the given generators. Once the best fit solution has been calculated, the operator has several options: a) Execute the elution plan determined by the system, b) reconfigure the elution plan manually – letting the system calculate and display the effect to the operator, or c) model 'what-if scenarios' by inputting certain demand requirements and/or supply data and

reviewing the calculated elution schedule determined by the system under the entered constraints.

The present invention, upon confirmation from the operator the calculated elution plan is acceptable, sends the data to the actuation system to elute the selected generators according the elution schedule. The eluates from the selected generators are all passed through the cassette to concentrate, for example, Tc-99m, onto an alumina column. Once all the generator elutions are complete, the alumina column is eluted in the required volume of eluent, eg, saline, (typically 5-6mL). Once this operation is completed, the control system updates the activity data, re-calculates the grow-in and updates the elution schedule with any required changes.

Generally, an ERP system is an integrated computer-based application used to manage internal and external resources, including tangible assets, financial resources, materials, and human resources. Its purpose is to facilitate the flow of information between all business functions inside the boundaries of the organization and manage the connections to outside stakeholders. Built on a centralized database and normally utilizing a common computing platform, ERP systems consolidate all business operations into a uniform and enterprise-wide system environment. An ERP system can either reside on a centralized server or be distributed across modular hardware and software units that provide "services" and communicate on a local area network. The distributed design allows a business to assemble modules from different vendors without the need for the placement of multiple copies of complex and expensive computer systems in areas which will not use their full capacity.

The method of the present invention thus includes an inputting step 610 where the supply data for each of the generators is inputted into a receiving unit of the elution system. The method then includes a second step 620 of inputting into the receiving unit the demand data of what activity is required and when from the multiple generators. This is followed by a calculating and selecting step 630 where the optimum elution schedule for each of the multiple generators is determined according to the inputted supply data and the inputted

demand data. The calculating and selecting step 630 desirably compares current demand of activity, future demand for activity, and the available activity from the generators both presently and at subsequent demand points, or elution times, and selects which generators will be eluted and when so as to minimize the waste of daughter nuclide produced by the generators in meeting the demand data. Then, there is an eluting step 670 in which the daughter nuclide is eluted from the selected generators.

Step 610 further includes the steps of inputting calibration data for each generator, 612, typically the activity and date for each generator, inputting the time and date that the generator is available, 614, and inputting the time and date that the first elution is off-set from a reference time. Steps 612, 614, 616 may be performed manually by manually entering into the receiving unit the information from each of these steps, such information generally being provided with each generator. Alternatively, steps 612, 614, and 616 may be performed electronically, or automatically, by scanning such information from a bar code pertaining to each generator. Likewise, step 620 may be performed either manually or electronically, with the demand data generally being supplied by an ERP system. For manually performing step 620, an operator will take the demand data information and enter it into the receiving unit. Desirably, when the demand data is manually entered, the receiving unit or control system will compiling the information into the demand data set, although the operator may also perform the compilation prior to entering the aggregate demand data. Alternatively, the ERP system may be electronically communicating with the receiving unit so that the individual orders are automatically entered into the system and the elution schedule calculated.

The present invention further contemplates that step 610 can include the step of inputting known data constants, 618. Step 618 can provide for the consideration of such data constants in the step 630. The data constants desirably include the parent nuclide half-life and decay equation, the daughter nuclide half life and decay equation, the elution yield efficiency, the fraction of the elution available the parent nuclide decay, the equilibrium equation for the parent-daughter activity, and the expiration time for the generator.

Step 630 includes the step of calculating 632 and displaying 634 the available activity for each generator, desirably in fixed intervals such as thirty minutes. Desirably, the calculating step 632 employs Equation (1) and the displaying step 634 displays the activity in each generator at the calculated intervals. Moreover, step 630 may include the step of performing a Generalized Reduced Gradient Algorithm analysis of the demand data and the activity levels of the plurality of generators to determine the optimum elution schedule for minimizing waste. Alternatively, step 630 is contemplated to run simulations of various elution schedules from the plurality of generators and selecting the elution schedule resulting in the lowest amount of waste of the daughter nuclide upon meeting the demand data. Additionally, the method desirably includes the step 638 of displaying the demand data over the same intervals as the supply data. Step 630 desirably further comprises the step of calculating the best fit elution profile, or schedule, 638, for selecting which of the available generators will be eluted at a given time to meet the demand data in the most efficient way possible, thus maximizing the useful life of each generator and minimizing waste. The method may then include the step of providing the elution schedule to the operator, 640.

Desirably, the display of the elution schedule is provided on a graphic-user interface (GUI) and the method includes the steps of offering the operator the option of overriding the calculated optimized elution schedule, 642, by instead scheduling different generators for elution at a given time. If the operator declines to override the system, the method will then progress to the step of sending the elution instructions to the actuation system, 660. If the operator chooses to override the elution instructions from step 638, the method further includes the step of the operator manually entering a modification to the elution schedule, 644. Step 644 allows the operator to select a when particular generators will be eluted. The method then includes the step of recalculating the elution schedule, 646, and displaying both the updated activity availability over time for each generator as well as the scheduled time of elution from each of the generators, 648. Step 646 desirably employs the same algorithm as step 630 in determining the optimum elution schedule, given any additional operator constraints. The method then includes the step of prompting the operator to accept the updated elution schedule 650. If the operator accepts the updated elution schedule, the

elution schedule will be set and the control system will provide the appropriate instructions to the actuation system for eluting from the generators, step 660. If the operator does not accept the updated elution schedule, the method will repeat steps 644, 646, and 648 until the operator does accept the elution schedule. Once the updated elution schedule is satisfactory to the operator, the method will proceed to step 660.

After step 660, the actuation system will perform step 670 and elute the generators according to the elution schedule. Steps 642, 644, 646, 648, and 650 provide the option of an 'operator-in-the-loop' to oversee and manage the elution from the generators and allow the operator to override the calculated schedule. In any event, the present invention is able to operate without the need for operator intervention and can thus perform the scheduled elutions automatically without operator input once the schedule, thereby freeing the operator to tend to other pharmacy duties. However, it is deemed desirable to provide the operator at some point in the cycle so as to accept the elution schedule.

After the eluting step 670, the method can include the step of confirming that the selected generators were eluted, 672. Additionally, the method desirably includes the steps of re-calculating the activity in-growth 674, modifying the activity data in step 632 and, if necessary, repeating steps 638 et seq. to recalculate the best-fit elution schedule for meeting the demand data.

The present invention further provides a computer program product for managing the elution from a multiple generator elution system according to the present invention. The present invention further provides a multiple generator elution system which includes computer hardware for executing the computer program product of the present invention. The computer program product includes computer usable medium having computer-usable program code for performing the method of the present invention. The computer program code includes a computer-usable medium having computer-usable program code that manages a multiple generator elution system. The computer program product including computer-usable program code that receives inputted supply data for a number of parent-daughter generators and demand data for activity from the generators. The computer

program further includes computer-usable program code that calculates an elution schedule for the generators based on the available activity in the generators and the demand data; as well as computer program code that directs an actuation system of the elution system to elute from selected ones of the generators according to the elution schedule.

The computer program product desirably further includes computer program code for displaying at least one of the supply data, the demand data, the available activity in the generators, and the elution schedule. Additionally, the computer program code that calculates an elution schedule also includes computer program code for performing a Generalized Reduced Gradient Algorithm analysis of the demand data and the activity levels of the plurality of generators to determine the optimum elution schedule for minimizing waste. Alternatively, the computer program code for calculating an elution schedule also includes computer program code for running simulations of various elution schedules from the plurality of generators and selecting the elution schedule resulting in the lowest amount of waste of the daughter nuclide upon meeting the demand data. The computer program product desirably also includes computer program code for allowing an operator to override the calculated elution schedule by inputting new constraints to the computer program product, and computer program code for calculating a new elution schedule based on the new constraints. Moreover, the computer program product desirably includes computer program code for storing the supply data, the demand data, and the elution schedule for future retrieval and can serve for purposes of record keeping or supporting record keeping.

Figure 10 depicts a screen shot of a graphical user interface (GUI) of the present invention for providing supply data information for a multiple generator elution system of the present invention. Figure 10 shows the supply data input screen 700. Screen 700 provides a Microsoft Excel® screen showing the supply data for the six generators listed in column A, rows 6-11. Column B, rows 6-11 lists the Reference Time for each generator. Column C, rows 6-11 lists the first elution offset (in hours) for each of the listed generators. Lack of an entry will be treated as zero offset. Column D, rows 6-11 list the starting activity at the reference time for each generator. Column E, rows 6-11 lists when each generator was available for use. As an error check for the data entry, the Reference Time in Column

A must be at least twelve hours prior to the Available for use time in Column E. Column F, rows 6-11 will show any error messages for each generator. Column E, rows 2-3 provides the Net Efficiency, or elution yield efficiency, for the generators, typically about 0.83.

Figure 11 depicts a screen shot of a GUI of the present invention for providing the elution schedule calculated for the six generators of Figure 10. Figure 10 shows an elution management window 800 providing the supply data, demand data, and elution schedule for a multiple generator elution system. This is the worksheet or best fit result for balancing efficiency with future activity needs based on the demand. While Figure 11 displays a close-up of the relevant information in rows 46 to 69, representing from July 11, 2010 at 10p.m. to July 12, 2010 at 9:30am, the information of window 800 continues for the life of the generators, typically two weeks and may be scrolled to. Column A, rows 46 to 69, provides the interval times for which the calculations and dispensings occur over the shown time period. The time intervals are given in thirty minute intervals. Column D, rows 46 to 69 lists the time for when dispensing must occur according to the demand data. The listed time takes into account the further processing time required post-elution to get the nuclides to the user in the desired state. Thus, for example, Column D shows that elutions will be run on Monday July 12, 2010 at 12:00am, 2:00am, 4:00am, and 7:00am. Scrolling further down the table to unseen rows will show the demand and other information at later times. Column E provides the balance remaining from any previous elutions that were not used, and shows the decay as time goes forward. Columns F, P, Z, AJ, AT, and BD note when elutions are schedule for the generators listed in Row 1, Columns G, Q, AA, AK, AU, and BE, respectively. The number '1' is entered into columns F, P, Z, AJ, AT, and BD at the time in which the activity was eluted from the respective generator. As can be seen, for each eluted generator, the next row after elution shows much less activity, indicating that, post elution, activity grow-in is occurring.

As shown in Column D, row 50, at midnight (row 50) there is a demand for 14,350mCi of activity. The control system has calculated that, in order to best meet all of the known demand in Column D, generator 1 and generator 5 will be eluted to meet this demand, providing an unused balance of 27mCi, which may incorporated into future

elutions. Similarly, at the 2:00am elution (row 54), in order to meet the demand for 15,931 mCi of activity, 2405.5mCi of activity will be eluted from generator 2, 2405.5mCi of activity will be eluted from generator 3, and 11,120.5mCi of activity will be eluted from generator 4, providing an unused balance of 22mCi. The remaining activity from the previous elution will also be included in this elution, so in some instance the current elutions may not total the listed demand on their own.

An operator may override the provided elution schedule by deleting the '1' from the elute column and selecting another generator to elute from. The control system will re-populate the entries in window 800 to show the new elution schedule as well as the available activity in each generator at each given time, the demand at each elution time, and any balance in activity that is leftover. The modeling feature of the present invention allows, for example, that when a supply shock occurs, the present invention to be particularly useful for evaluating the impact of "what if" scenarios, and ultimately delivering the most doses for the given supply situation. In any event, when the operator is satisfied with the elution schedule, it may be left alone to run automatically as shown. With the elutions performed automatically, the operator will be free to tend to other duties. Additionally, the software provides a record of the elutions performed, simplifying record keeping purposes. Furthermore, while supply data screen 700 and elution management window 800 are tracking six genarators, the present invention scalable in that it is capable of monitoring as many generators as are included in the multiple generator elution system.

The present invention can provide cost savings to radio-pharmacies. The largest single cost for a radio-pharmacy is the Tc-99m/Mo99 generator that is used to compound the "cold kits" (the diagnostic agents). An action workout with experienced radio pharmacists, showed that the average pharmacy generator efficiency was 65-68%. Post implementation of the new tool average efficiency has steadily risen to 98-100%. Typically, an average pharmacy might consume four 18Ci generators a week. Each generator has a useful shelf life of two weeks. Thus on a weekly basis, the pharmacy would need to manage eight generators through their decay and use cycles. Currently, using four 18Ci units per week @ $7,000

each is a cost of $1.456MM annually. If the same pharmacy improves its efficiency from 65% to 100% by using the present invention, the annual cost is lowered by about $0.5MM.

While the particular embodiment of the present invention has been shown and described, it will be obvious to those skilled in the art that changes and modifications may be made without departing from the teachings of the invention. The matter set forth in the foregoing description and accompanying drawings is offered by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined in the following claims when viewed in their proper perspective based on the prior art.

What is Claimed Is:

1. A multiple generator elution system, comprising:

a plurality of generators;

a source of eluent;

a control system for tracking the activity of each of said plurality of parent-daughter nuclei generators, receiving demand data indicating requirements for activity production, said control system configured to elute from selected ones of said plurality of generators with a first eluent in order to provide a desired amount of a daughter isotope;

a receiving unit for receiving supply data and demand data, wherein said supply data comprises information allowing calculation of the available activity in the generators and said demand data further comprises at least an amount of daughter nuclide to be produced and a schedule for the production of the amount of daughter nuclide, said receiving unit operable with said control system so that control system will schedule the elution of the daughter nuclide from said plurality of generators to meet the demand represented by the demand data;

a concentration column for collecting the generator daughter nuclide from said selected ones of said plurality of generators, wherein said concentration column contains an appropriate column media; and

a collection container for receiving the daughter nuclide from said concentration column.

2. A multiple generator elution system of claim 1, further comprising a source of a second eluent to elute the daughter nuclide from the concentration column

3. A multiple generator elution system of claim 2, wherein said plurality of parent-daughter nuclei generators comprise a plurality of Mo99/Tc99m generator (titanium [99Mo] molybdate) generators.

4. A multiple generator elution system of claim 2, wherein said plurality of parent-daughter nuclei generators comprise a plurality of Mo99/Tc99m generator (titanium [99Mo] molybdate gel generators.

5. A multiple generator elution system of claim 2, wherein said first eluate comprises deionized water.

6. A multiple generator elution system of claim 2, wherein said first eluent comprises a high purity water.

7. A multiple generator elution system of claim 2, wherein said first eluent comprises water for injection.

8. A multiple generator elution system of claim 1, wherein said concentration column is an anion column and wherein said column media comprises alumina.

9. A multiple generator elution system of claim 2, wherein said second eluent comprises a salt of an acid.

10. A multiple generator elution system of claim 9, wherein said salt of an acid is saline.

11. A multiple generator elution system of claim 1, further comprising:

a vacuum source for drawing eluent through said generators to direct generator eluate towards said concentration column.

12. A multiple generator elution system of claim 1, further comprising:

an elongate manifold connected to said plurality of generators, said manifold including a plurality of valves, wherein individual ones of said plurality of valves are in selectable fluid communication with corresponding individual ones of said plurality of generators.

13. A multiple generator elution system of claim 11, further comprising a cassette body, said cassette body supporting said manifold therein, said manifold being disconnectably connectable to a vacuum source, a source of said first eluent for eluting the generators, a source of a second eluent for eluting the concentration column, said collection container, and a waste container.

14. A multiple generator elution system of claim 13, wherein said cassette body and manifold are cooperatively engaged by an actuation system, said actuation system engaging said valves so as to selectively set each said valve so as to direct fluid through said manifold, said actuation system further providing said vacuum source.

15. A multiple generator elution system of claim 12, further comprising a second column containing an appropriate media to remove competing ions which adversely interfere with the concentration column connected to said manifold and wherein said collection column is connected to said manifold, each said column having a first port in fluid communication with a first valve and a second port in fluid communication with a second valve.

16. A multiple generator elution system of claim 15, wherein said second column is a cation column.

17. A multiple generator elution system of claim 16, wherein said cation column contains a column media for removing chloride from the eluate received from said selected ones of said generators.

18. A multiple generator elution system of claim 1, wherein each one of said plurality of generators are gel generators.

19. A multiple generator elution system of claim 18, wherein each one of said plurality of generators are one of a zirconium molybdate gel generator and a titanium molybdate gel generator.

20. A multiple generator elution system of claim 15, wherein each one of said plurality of generators are an alumina based generator.

21. A multiple generator elution system of claim 1, wherein said demand data requires multiple elutions from said concentration column over a period of time.

22. A multiple generator elution system of claim 1, wherein said control system selects the optimum combination(s) of generators based on current demand, future demand and the available activity both presently and at a subsequent demand point so as to minimize waste of daughter isotope produced by said plurality of generators.

23. A multiple generator elution system of claim 22, wherein said control system automatically performs each elution of said daughter nuclide from said selected ones of said plurality of generators.

24. A multiple generator elution system of claim 1, wherein said demand data is manually-entered into said receiving unit.

25. A multiple generator elution system of claim 1, wherein said demand data is automatically entered into said receiving unit.

26. A multiple generator elution system of claim 1, wherein said daughter isotope is Tc-99m, said column media of said concentration column is a silver column, and said column media of said second column is alumina.

27. A multiple generator elution system, comprising:

a plurality of generators;

a control system for tracking the activity of each of said plurality of parent-daughter nuclei generators, receiving demand data indicating requirements for activity production, said control system configured to elute from selected ones of said plurality of generators with a first eluent in order to provide a desired amount of a daughter isotope;

a receiving unit for receiving supply data and demand data, wherein said supply data comprises information allowing calculation of the available activity in the generators and said demand data comprises at least an amount of daughter nuclide to be produced and a schedule for the production of the amount of daughter nuclide, said receiving unit operable with said control system so that control system will schedule the elution of the daughter nuclide from said plurality of generators to meet the demand represented by the demand data;

a concentration/anion column for collecting the generator daughter nuclide from said selected ones of said plurality of generators, wherein said concentration column contains an appropriate column media; and

a collection container for receiving the daughter nuclide from said concentration column,

wherein said control system selects the optimum combination(s) of generators based on current demand, future demand and the available activity both presently and at a subsequent demand point so as to minimize waste of daughter isotope produced by said plurality of generators for all demand data entered.

28. A multiple generator elution system of claim 27, further comprising a source of second eluent to elute the daughter nuclide from the concentration column;

29. A multiple generator elution system of claim 27, further comprising a second column containing an appropriate media to remove competing ions which adversely interfere with the concentration column connected to said manifold and wherein said collection column is connected to said manifold, each said column having a first port in fluid communication with a first valve and a second port in fluid communication with a second valve.

30. A multiple generator elution system of claim 29, wherein said second column is a cation column and wherein said cation column contains a column media for removing chloride from said first eluate received from said selected ones of said generators.

31. A multiple generator elution system of claim 27, wherein said plurality of parent-daughter nuclei generators comprise a plurality of one of Mo99/Tc99m generator (titanium [99Mo] molybdate) generators and Mo99/Tc99m generator (titanium [99Mo] molybdate gel generators.

32. A multiple generator elution system of claim 27, further comprising:

an elongate manifold connected to said plurality of generators, said manifold including a plurality of valves, wherein individual ones of said plurality of valves are in selectable fluid communication with corresponding individual ones of said plurality of generators.

33. A multiple generator elution system of claim 32, further comprising a cassette body, said cassette body supporting said manifold therein, said manifold being disconnectably connectable to a vacuum source, a source of said first eluent, a source of a second eluent, said collection container, and a waste container, wherein said cassette body and manifold are cooperatively engageable by an actuation system, said actuation system engaging said valves so as to selectively set each said valve so as to direct fluid through said manifold, said actuation system further providing said vacuum source.

34. A method of eluting a daughter nuclide from a plurality of parent-daughter generators, comprising the steps of:

inputting the supply data comprising information allowing calculation of the available activity in the generators into an elution system;

inputting demand data into the elution system, said demand data comprising at least an amount of radioactivity of daughter nuclide to be produced and a schedule for the production of the amount of daughter nuclide;

calculating and selecting the optimum elution schedule for each of said plurality of generators based on said demand data, said calculating and selecting step comparing current demand, future demand and the available activity from said plurality of generators both presently and at a subsequent demand point so as to minimize waste of daughter isotope produced by said plurality of generators in meeting the demand data;

eluting the daughter nuclide from selected ones of said plurality of generators according to the optimum elution schedule;

collecting the daughter nuclide from each of said selected ones of said plurality of generators in a concentration column;

eluting the daughter nuclide from said concentration column into a collection container.

35. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said calculating and selecting step further comprises performing a Generalized Reduced Gradient Algorithm analysis of the demand data and the activity levels of the plurality of generators.

36. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said calculating and selecting step further comprises running simulations of various elution schedules from the plurality of generators and selecting the elution schedule resulting in the lowest amount of waste of the daughter nuclide upon meeting the demand data.

37. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said step of inputting demand data further comprises entering the demand data into a receiving unit which provides the demand data to the control system.

38. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 37, wherein said step of inputting demand data further comprises the step of manually entering the demand data into a receiving unit which provides the demand data to the control system.

39. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 37, wherein said step of inputting demand data further comprises the step of automatically entering the demand data into a receiving unit electronically.

40. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 39, wherein said step of automatically entering the demand data into a receiving unit electronically further comprises the step of receiving the demand data from a web-based order processing site.

41. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 37, wherein said calculating and selecting step is performed by a control system which receives the demand data from the receiving unit.

42. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said inputting supply data step further comprises the steps of inputting calibration data for each generators, the date and time that each generator is available for use, the time and date of the first elution off set for each generator.

43. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said calculating and selecting step considers the parent nuclide half-life, the parent nuclide decay equation, the daughter nuclide half-life, the daughter nuclide decay equation, the elution yield efficiency, the fraction of elution available from the parent nuclide decay, the equilibrium equation, and the expiration time for each generator.

44. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, further comprising the steps of:

displaying the available activity in each of the plurality of generators as calculated for a schedule of times;

displaying the demand data in a table at the schedule of times; and

displaying the selected elution schedule profile from said calculating and selecting step.

45. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 44, further comprising the steps of:

manually overriding the selected elution schedule profile;

calculating an override elution schedule profile resulting from said allowing step;

displaying the override elution schedule profile said allowing step; and

allowing an operator to one of confirm the override elution schedule profile and manually overriding the override elution schedule profile.

46. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 45, wherein said manually overriding steps further comprise the steps of selecting which of the plurality of generators will be eluted at a time of the schedule of times.

47. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said step of inputting supply data further comprises the step of calculating the in-growth activity levels of the selected ones of the plurality of generators after said eluting step.

48. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 34, wherein said calculating and selecting step and said eluting step are performed by a control system.

49. A method of eluting a daughter nuclide from a plurality of parent-daughter generators of claim 48, wherein said control system performs each said eluting step according to the selected elution profile without further operator input.

50. A kit for a multiple generator elution system, said kit comprising:

a manifold adaptable comprising a number of 3way/3position manifold valves to be operated by a control system to direct the elutions from among a plurality of parent-daughter generators to a separations column;

conduit tubings and supported connectors; and

filters,

wherein each of said conduit tubings are adaptable to be connected to the generators, as well as to vials and to an eluent source or sources for eluting a nuclide from the generators.

51. A kit of claim 50, wherein each the conduits which are connectable to the generators, vials, and eluent source or sources are made to luers of the manifold valves, so that only the free ends of such conduits need to be mated with the appropriate component.

52. A kit of claim 51, wherein said manifold and conduits are assembled and packaged in a sterile condition such that if the package is opened in an appropriately clean environment the kit will maintain an appropriate level of sterility for pharmaceutical operations.

53. A computer program product for managing the elution from a multiple generator elution system, comprising:

a computer-usable medium having computer-usable program code that manages a multiple generator elution system, computer program product including: computer-usable program code that receives inputted supply data for a number of parent-daughter generators; computer-usable program code receives demand data for activity from the generators; computer-usable program code that calculates an elution schedule for the generators based on the available activity in the generators and the demand data; and computer program code that directs an actuation system of the elution system to elute from selected ones of the generators according to the elution schedule.

54. A computer program product of claim 53, further comprising computer program code for displaying at least one of the supply data, the demand data, the available activity in the generators, and the elution schedule.

55. A computer program product of claim 53, wherein the computer program code that calculates an elution schedule further comprises computer program code for performing a

Generalized Reduced Gradient Algorithm analysis of the demand data and the activity levels of the plurality of generators to determine the optimum elution schedule for minimizing waste.

56. A computer program product of claim 53, wherein the computer program code for calculating an elution schedule further comprises computer program code for running simulations of various elution schedules from the plurality of generators and selecting the elution schedule resulting in the lowest amount of waste of the daughter nuclide upon meeting the demand data.

57. A computer program product of claim 53, further comprising computer program code for allowing an operator to override the calculated elution schedule by inputting new constraints to the computer program product, and computer program code for calculating a new elution schedule based on the new constraints.

58. A computer program product of claim 53, further comprising computer program code for storing the supply data, the demand data, and the elution schedule for future retrieval.

59. A multiple generator elution system comprising a computer for executing the computer program product of claim 53.

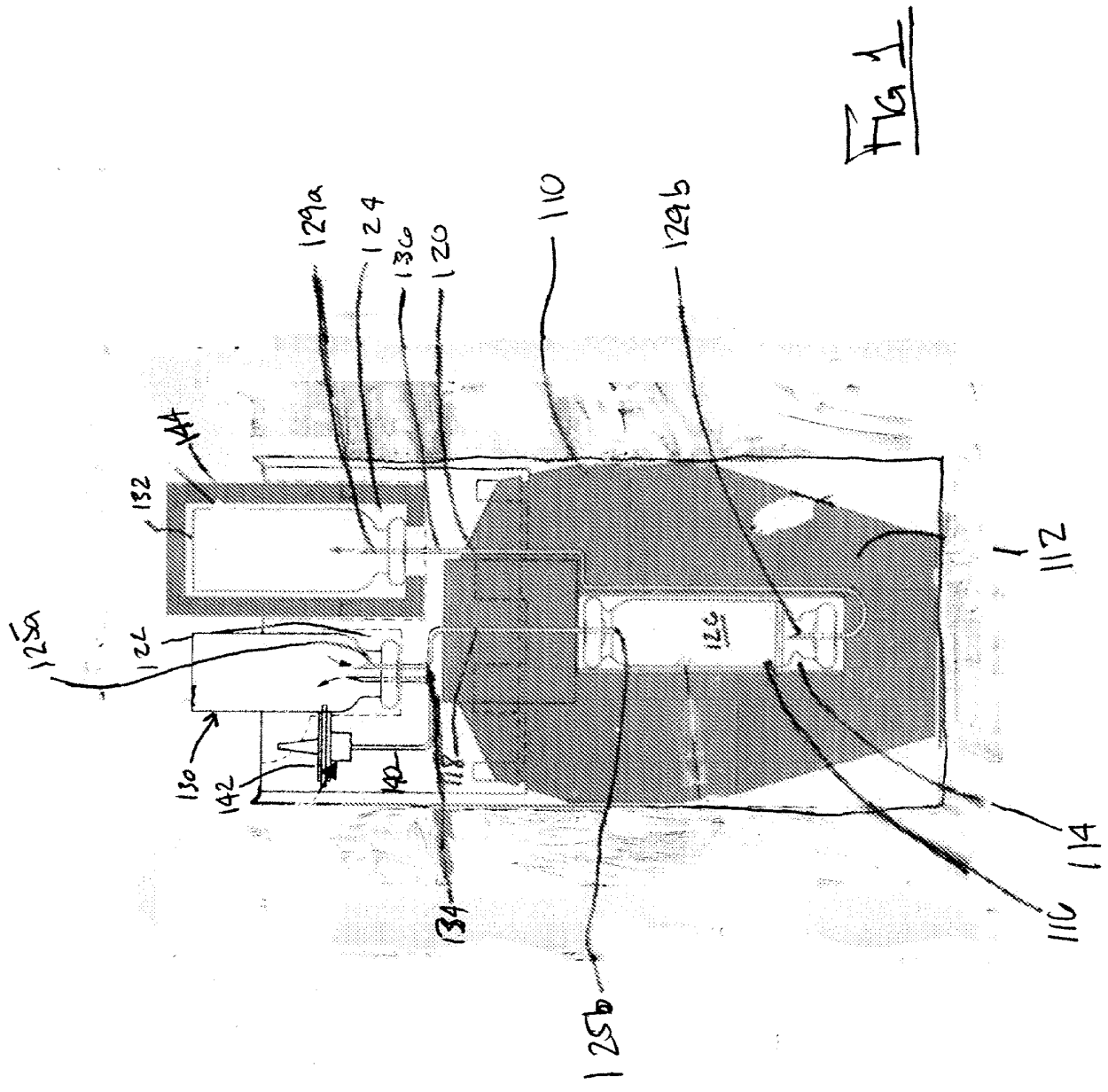

129a
124
130
120
110
129b
144
132
112
126
127
125a
130
142
140
118
134
125b
114
116

FIG 1

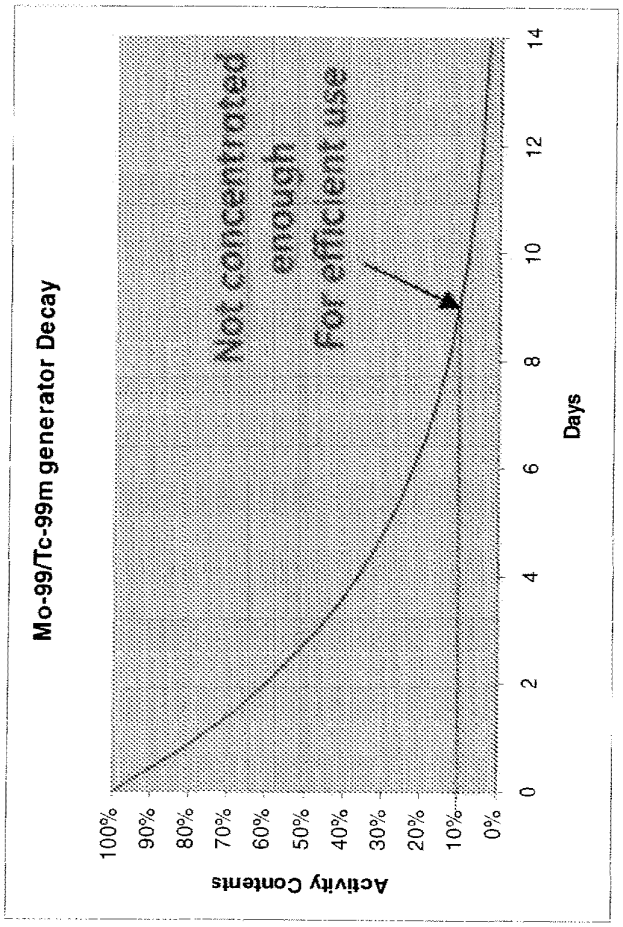

Mo-99/Tc-99m generator Decay
Not concentrated enough For efficient use
Activity Contents
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
2
4
6
8
10
12
14
Days

FIG. 1

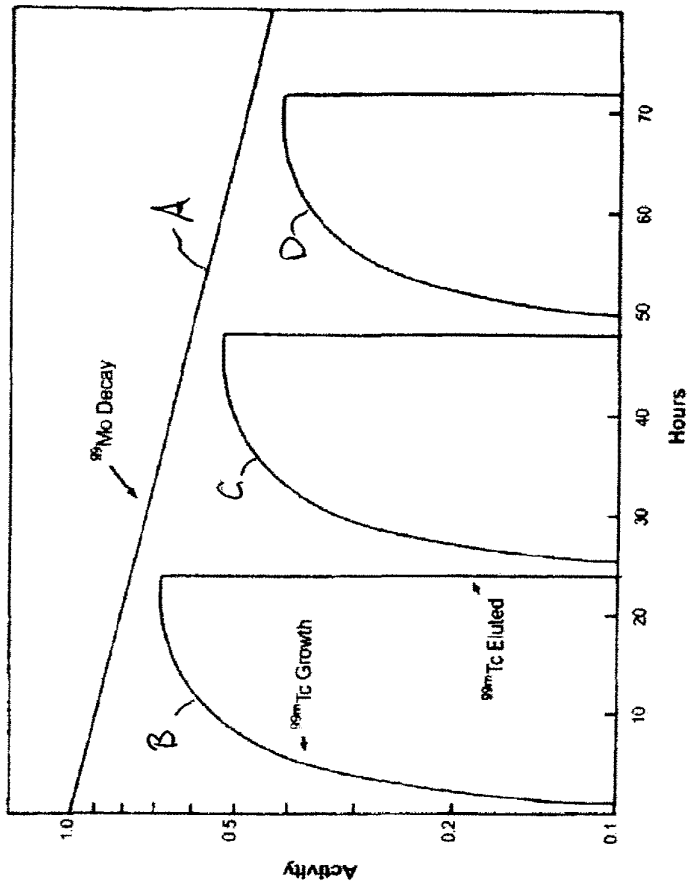

A
B
C
D
99Mo Decay
99mTc Growth
99mTc Eluted
Activity
1.0
0.5
0.2
0.1
10
20
30
40
50
60
70
Hours

FIG. 2

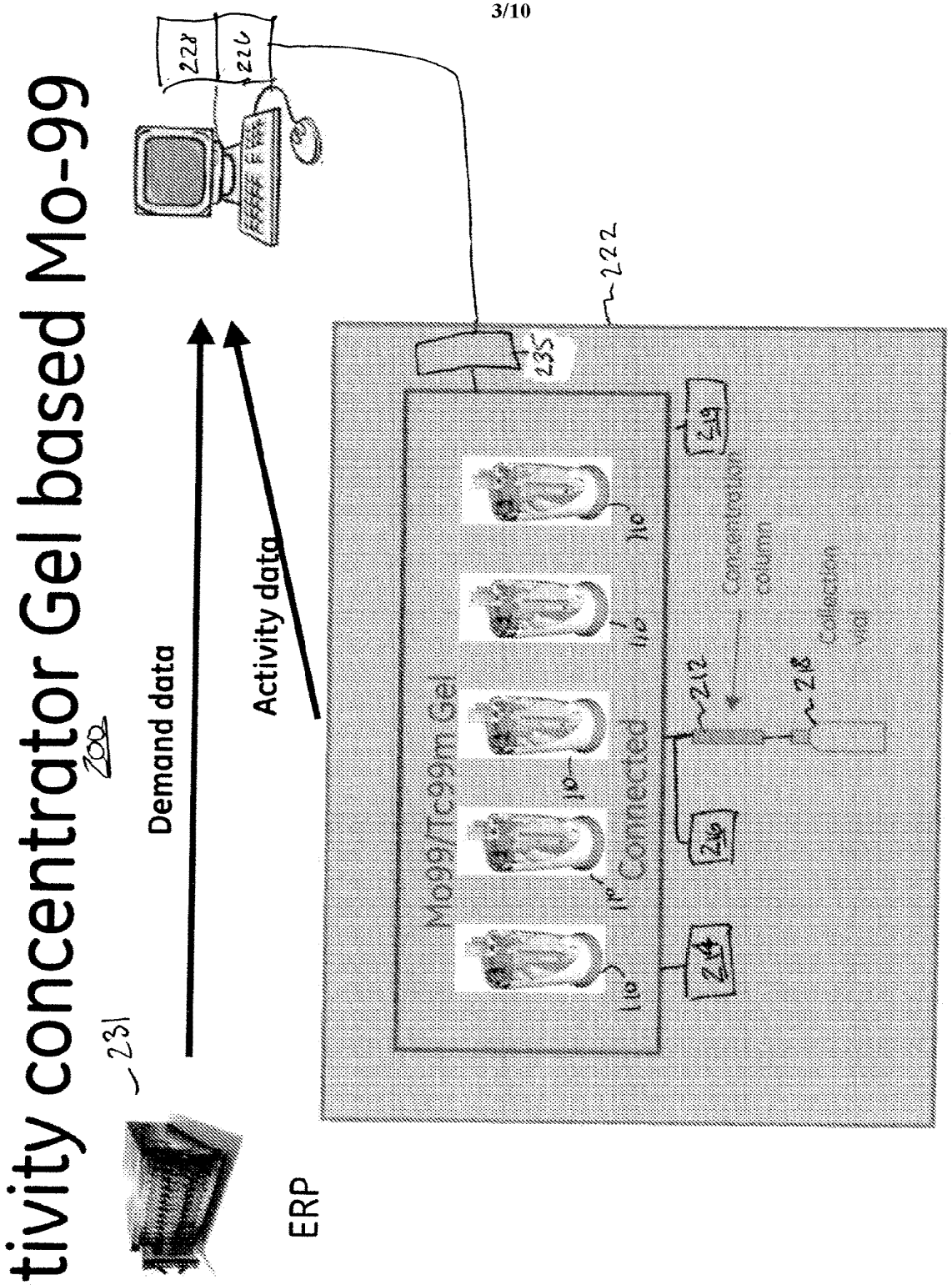

Activity concentrator Gel based Mo-99
200
Demand data
Activity data
ERP
231
222
228
226
235
Mo99/Tc99m Gel
1st Connector
210
212
214
216
218
220
240
Communication
column
Collection
vial

Fig 4

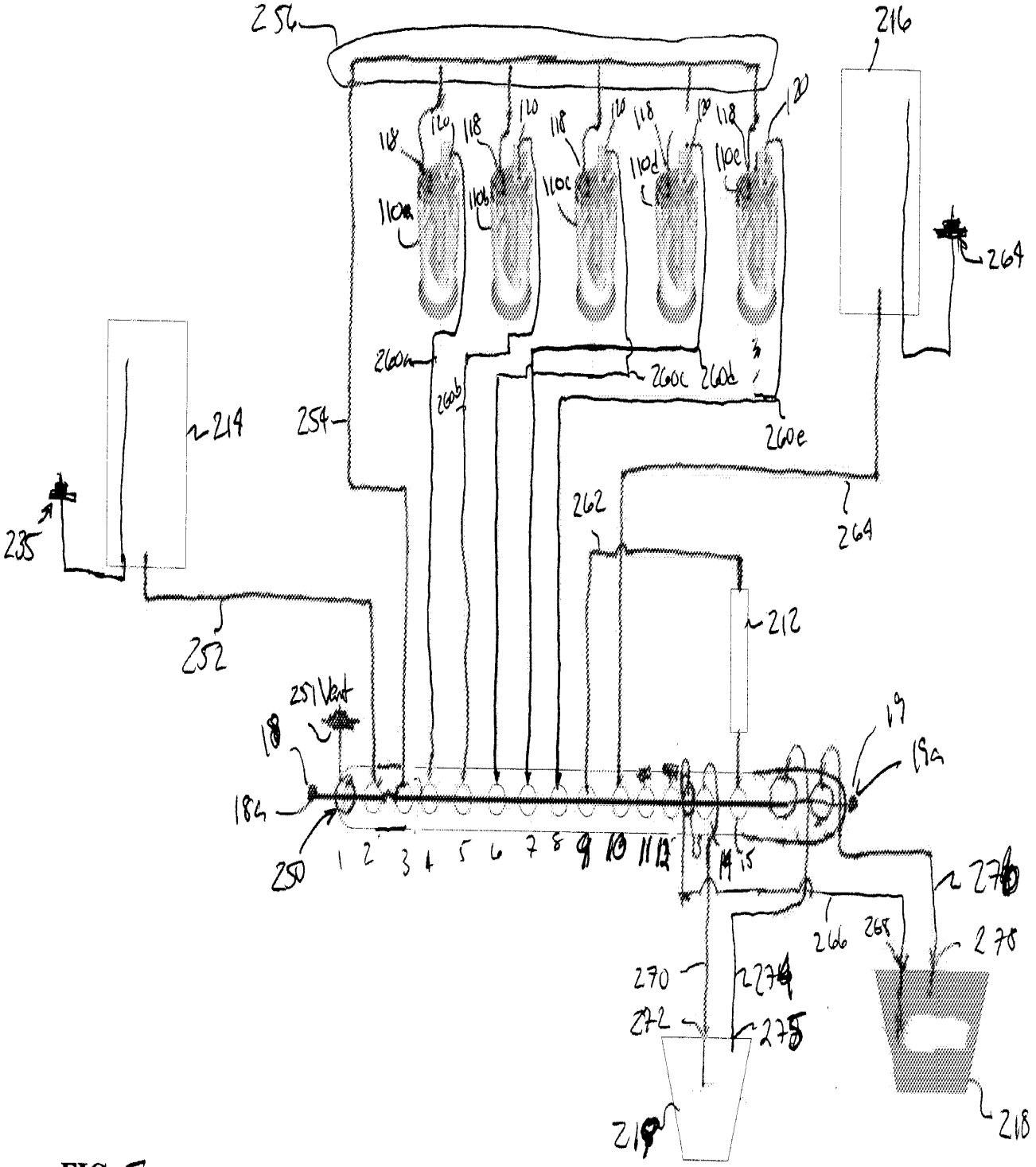
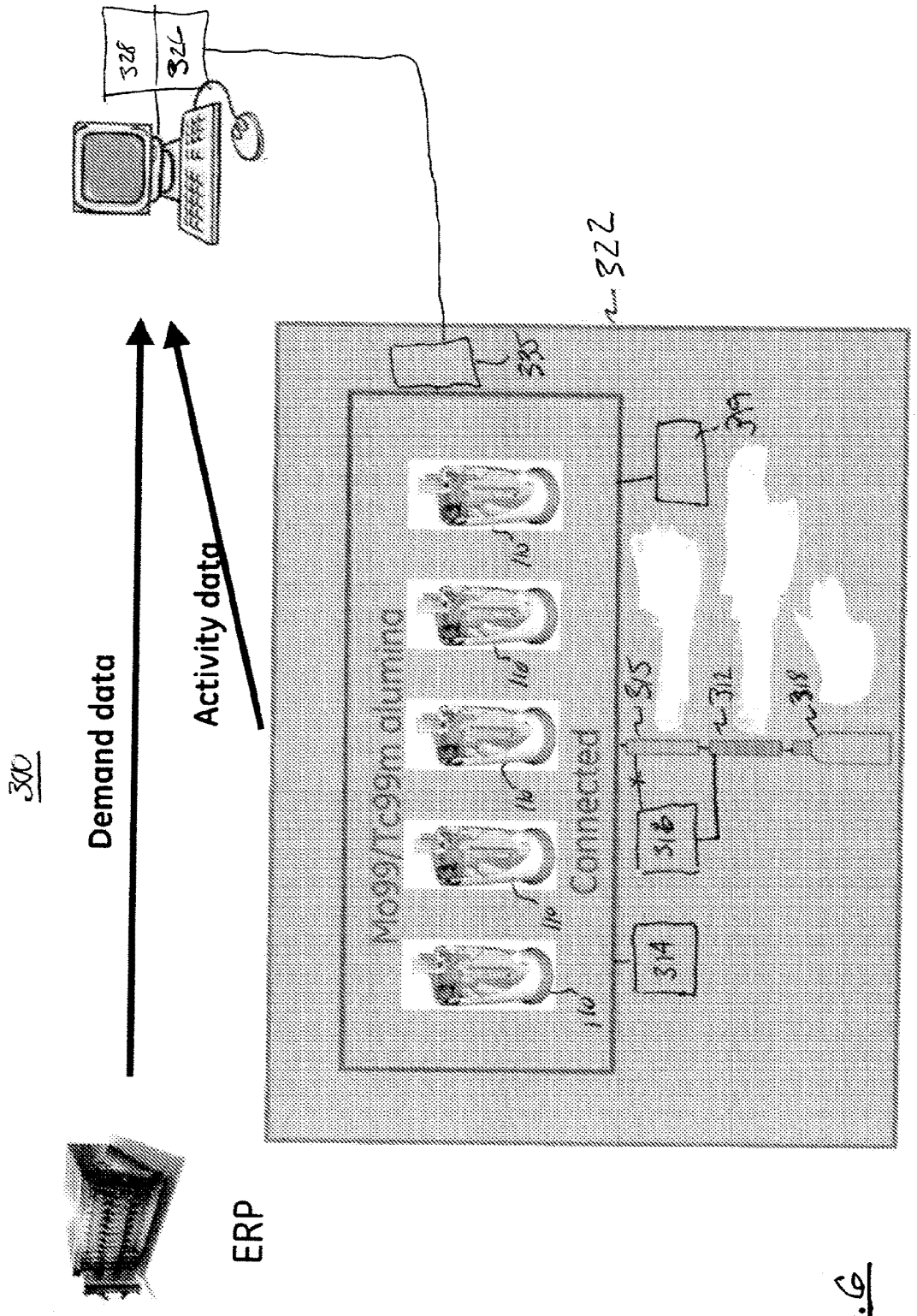

256
216
118
120
110a
110b
110c
110d
110e
264
260a
260b
260c
260d
260e
214
254
285
262
252
212
251 Vent
18
19
19a
184
250
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
276
266
268
278
270
272
274
275
218

FIG. 5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325
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Connected
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312
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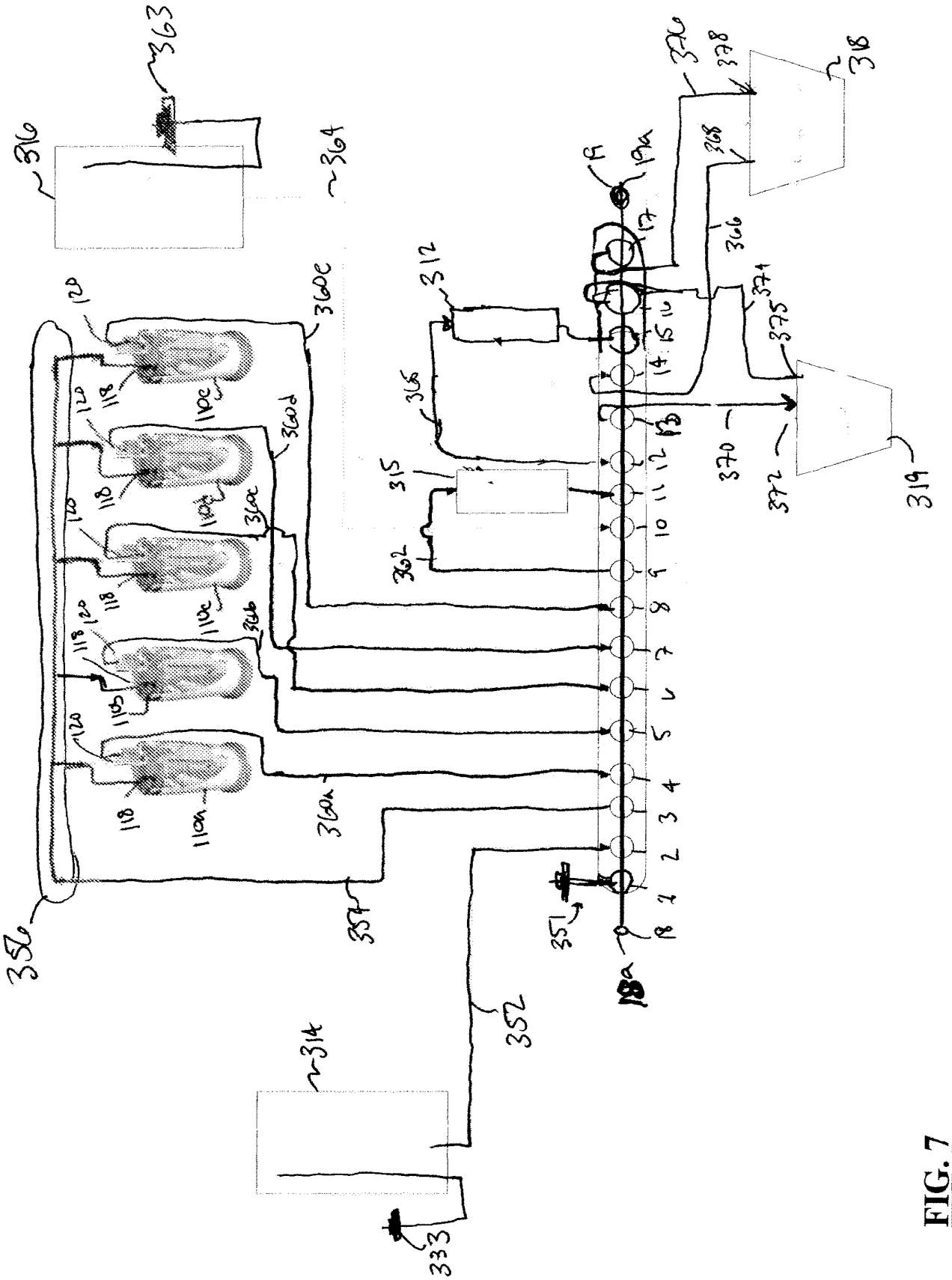
Demand data
Activity data
300
ERP

FIG. 6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319
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

FIG. 7

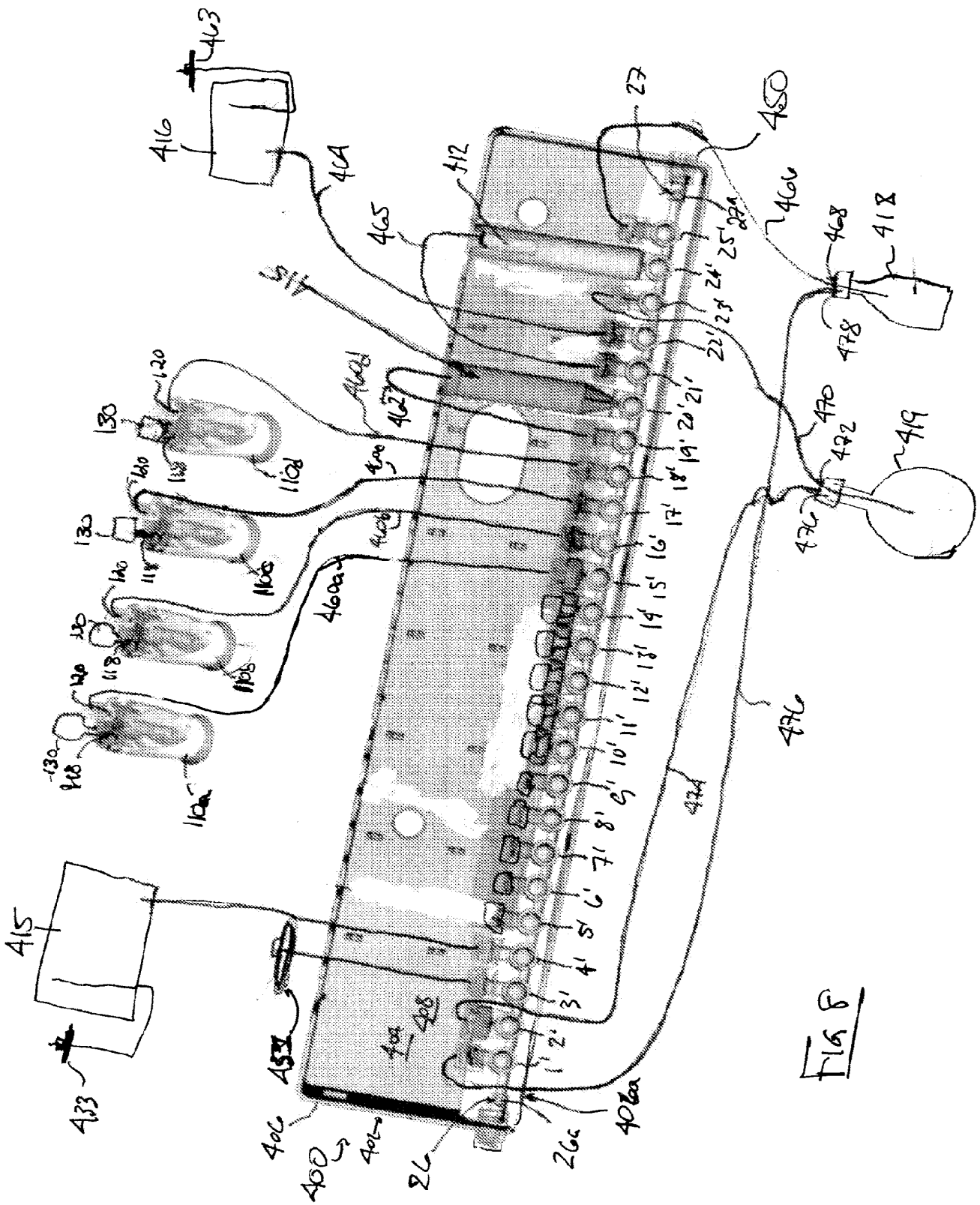
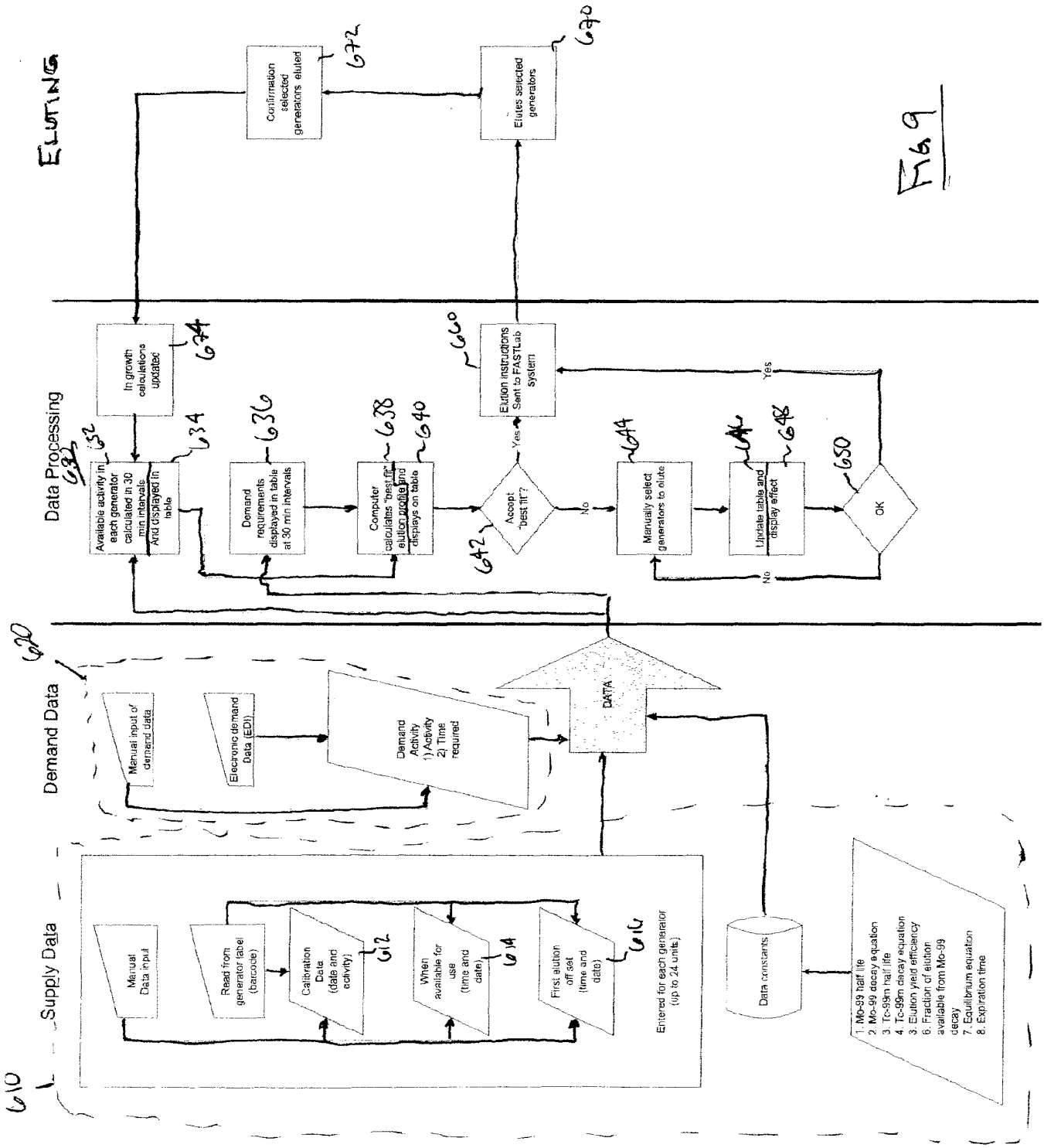


FIG 8


Elutions
Confirmation selected generators eluted
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Elutes selected generators
670
In growth calculations updated
674
Elution instructions Sent to FASTLab system
660
Data Processing
632
Available activity in each generator calculated in 30 min intervals And displayed in table
634
Demand requirements displayed in table at 30 min intervals
636
Computer calculates "best fit" elution profile and displays on table
638
640
Accept "best fit"?
642
Yes
No
Manually select generators to elute
644
Update table and display effect
646
648
OK
650
Yes
No
Demand Data
620
Manual input of demand data
Electronic demand Data (EDI)
Demand Activity 1) Activity 2) Time required
DATA
Supply Data
610
Manual Data input
Read from generator label (barcode)
Calibration Data (date and activity)
612
When available for use (time and date)
614
First elution off set (time and date)
616
Entered for each generator (up to 24 units)
Data constants
1. Mo-99 half life
2. Mo-99 decay equation
3. Tc-99m half life
4. Tc-99m decay equation
5. Elution yield efficiency
6. Fraction of elution available from Mo-99 decay
7. Equilibrium equation
8. Expiration time

Fig 9

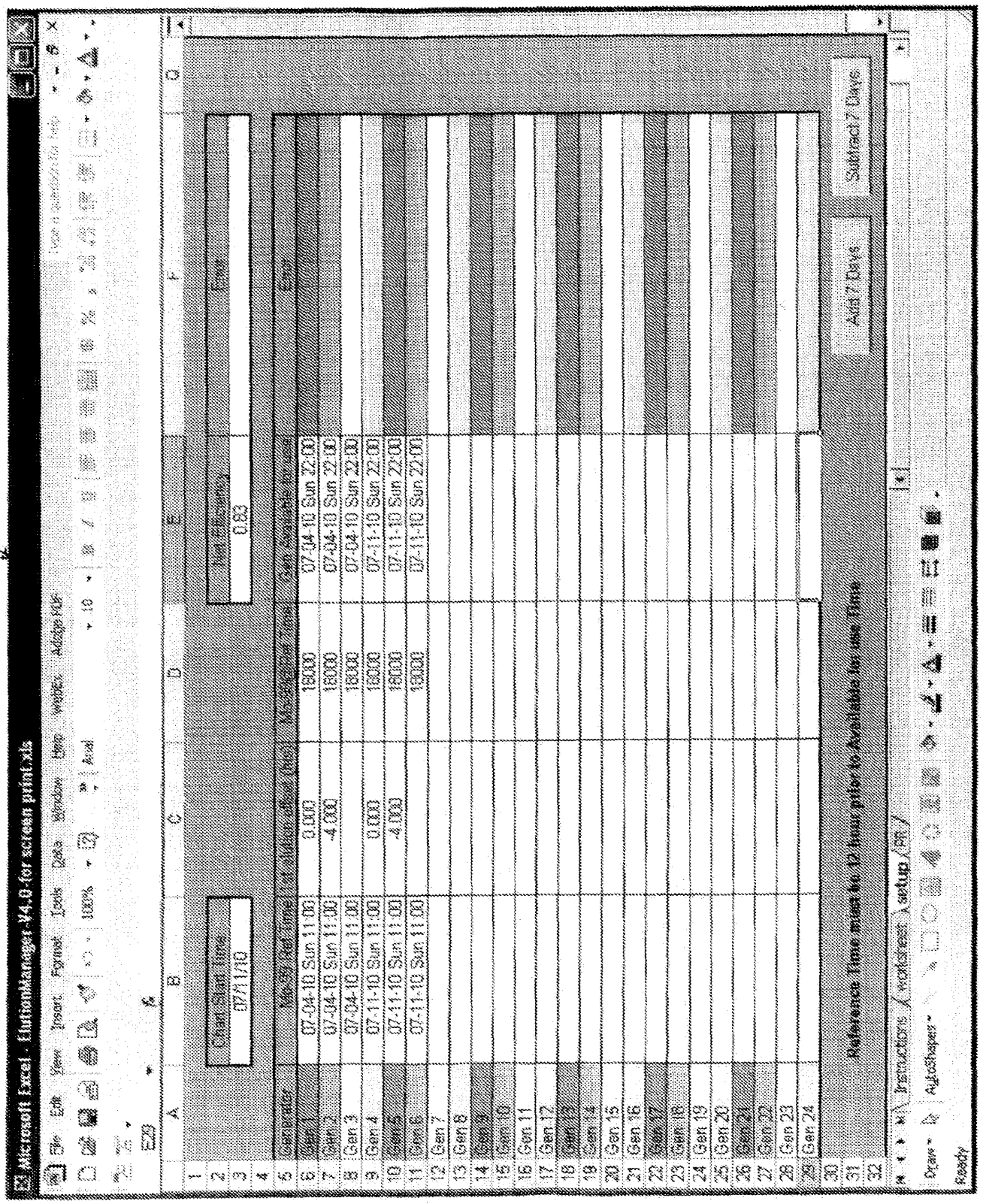
202
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Chart Start Time
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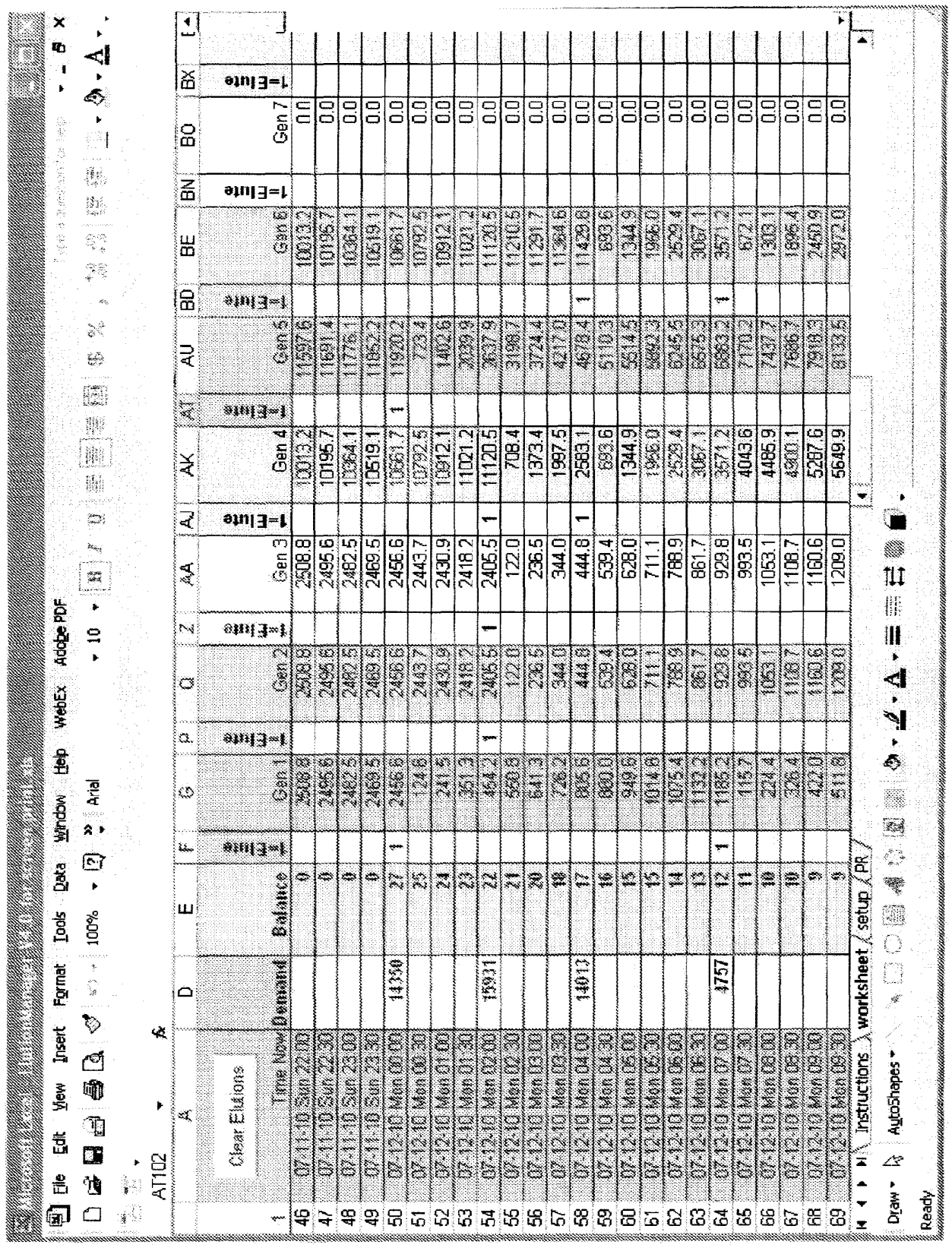
Enter
Add 7 Days
Subtract 7 Days
Reference Time must be 12 hour prior to Available for use Time
Instructions
setup
Ready

FIG 10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Arial
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Clear Elutions
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Gen 3
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Gen 5
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07-12-10 Mon 09:00
07-12-10 Mon 09:30
14350
15931
14013
4757
Instructions
worksheet
setup
PR
Draw
AutoShapes
Ready

8a

Fig 11

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Number	12/137,377	Filing Date	2008-06-11	Docket Number (if applicable)	56782.1.8	Art Unit	3618
First Named Inventor	Charles R. Quirico			Examiner Name	GURAI, Erez		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

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

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-07-02
Name	Paul J. LaVanway, Jr.	Registration Number	64610

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

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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

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

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

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

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

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

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1	R. KLEIN, , "Precision control of eluted Activity from a Sr/Rb generator for cardiac positron emission tomography" Proceedings of the 26th Annual International Conference of the IEEE EMBS San Francisco, CA, USA, September 1-5, 2004, 4 pages	☐

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EXAMINER SIGNATURE

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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-07-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	16214803
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	02-JUL-2013
Filing Date:	11-JUN-2008
Time Stamp:	18:07:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1700
RAM confirmation Number	5704
Deposit Account	
Authorized User	

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Continued Examination (RCE)	RCE_56782-1-8.pdf	697792 cba76431b2642844d9986ae17833318bb9db6c17	no	3
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	12thSIDS_56782-1-8.pdf	612268 f268c35738ac7c44bff0748fb5942634f93b79b8	no	4
Warnings:					
Information:					
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3	Non Patent Literature	Article_Klein-2004.pdf	802719 7352e689d95ccca91c0c1e377f680c13c74d52ed	no	4
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Information:					
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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.

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

New International Application Filed with the USPTO as a Receiving Office

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22859 7590 06/14/2013

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

EXAMINER	
GURARI, EREZ	
ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 06/14/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	09/16/2013

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 06/14/2013
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	09/16/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
GURARI, EREZ	3618	280-047350

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 credit 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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

22859 7590 06/14/2013

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

EXAMINER	
GURARI, EREZ	

ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 06/14/2013

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

The Patent Term Adjustment to date is 790 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 790 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 12/137,377	Applicant(s) QUIRICO ET AL.	
	Examiner EREZ GURARI	Art Unit 3618	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 *5/2/2013*.
   ☐ 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 *1-2,5-7,10-13,15,17,23,25,27,33*. 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: _____.

   Interim copies:

   a) ☐ All b) ☐ Some c) ☐ None of the: Interim copies of the priority documents have been 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 5/2/2013
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 _____.

EREZ GURARI
Examiner
Art Unit: 3618

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	
	Examiner	Art Unit
	J. ALLEN SHRIVER II	3618

✓	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	05/03/2011	09/01/2011							
	1	✓	=							
	2	✓	=							
	3	-	-							
	4	-	-							
	5	✓	=							
	6	✓	=							
	7	✓	=							
	8	-	-							
	9	-	-							
	10	✓	=							
	11	✓	=							
	12	✓	=							
	13	✓	=							
	14	✓	=							
	15	✓	=							
	16	-	-							
	17	✓	=							
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	22	-	-							
	23	✓	=							
	24	-	-							
	25	✓	=							
	26	-	-							
	27	✓	=							
	28	-	-							
	29	-	-							
	30	-	-							
	31	-	-							
	32	-	-							
	33	✓	=							

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	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	2492920	EP	A2	2012-08-29	DRAXIMAGE GEN. PARTNERSHIP		☐
	2	2011126	EP	B1	2012-05-23	DRAXIMAGE GEN. PARTNERSHIP		☐
	3	1968653	CN		2007-05-23	E Z EM INC.		☐

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

Receipt date: 05/02/2013	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

If you wish to add additional Foreign Patent Document citation information please click the Add button			Add
NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐
If you wish to add additional non-patent literature document citation information please click the Add button			Add

EXAMINER SIGNATURE			
Examiner Signature	/Erez Gurari/	Date Considered	06/02/2013

*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.G./

Receipt date: 05/02/2013	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-05-01
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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

Privacy Act Statement

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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.

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

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

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

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

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

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

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

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	Art Unit
	EREZ GURARI	3618

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
280	47.34,47.35,79.11,79.3,638,651,33.992,79.5,79.6	5/1-2, 9/1/2011	eg

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST	5/1-2	eg

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See EAST	9/1/2011	eg

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	14	("1968653" or "2011126" or "2492920").did.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2013/06/02 19:57
L2	3	("1968653" or "2011126" or "2492920").did.	USPAT	ADJ	ON	2013/06/02 19:58
S3	103	("20030004463" | "20030004463" | "20050278066" | "20070140958" | "20070213848" | "20070140958" | "20070232980" | "20070282263" | "20080093564" | "20080242915" | "20080071219" | "20080166292" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5590648" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 16:53
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S5	1642	medical with cart	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 17:48
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S10	182	(280/79.5).ccls.	US-PGPUB;	ADJ	ON	2011/05/01 18:38

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S15	6	access panel with handle and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:07
S16	3	bin with connect$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:14
S17	2	bin with mat$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:15
S18	6	basket with (mat$4 or connect$4) with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:16
S19	99	basket with (mat$4 or connect$4) with top and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:17
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EAST Search History (Interference)

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C:\ Users\ egurari\ Documents\ EAST\ Workspaces\ 12137377.wsp

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
12137377	QUIRICO ET AL.
Examiner	**Art Unit**
J. ALLEN SHRIVER IIEREZ GURARI	36183618

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
280	47.35

CROSS REFERENCE(S)					
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**				
280	79.3	79.5			

INTERNATIONAL CLASSIFICATION					
CLAIMED					**NON-CLAIMED**
B	6	2	B	3 / 04	

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office

Part of Paper No. 20130127

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
1213737712137377	QUIRICO ET AL.
Examiner	**Art Unit**
J. ALLEN SHRIVER IIEREZ GURARI	36183618

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Number	12/137,377	Filing Date	2008-06-11	Docket Number (if applicable)	56782.1.8	Art Unit	3618
First Named Inventor	Charles R. Quirico			Examiner Name	GURAI, Erez		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

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

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-05-01
Name	Paul J. LaVanway, Jr.	Registration Number	64610

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

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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
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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]
	1	2492920	EP	A2	2012-08-29	DRAXIMAGE GEN. PARTNERSHIP		☐
	2	2011126	EP	B1	2012-05-23	DRAXIMAGE GEN. PARTNERSHIP		☐
	3	1968653	CN		2007-05-23	E Z EM INC.		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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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]
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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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-05-01
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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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 492 920 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
29.08.2012 Bulletin 2012/35

(51) Int Cl.:
G21G 1/02 *(2006.01)*

(21) Application number: **12168843.6**

(22) Date of filing: **16.12.2006**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **12.01.2006 US 758419 P**
14.12.2006 US 610574

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
06851254.0 / 2 011 126

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Remarks:
This application was filed on 22-05-2012 as a divisional application to the application mentioned under INID code 62.

(54) Systems and methods for radioisotope generation

(57) Systems and methods are disclosed for producing customized, predictable, and reproducible supplies of radioisotopes using, for example, a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port, a chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port, and a changeable filter module that is disposed external to said reactor housing and in fluid communication with said exit port.

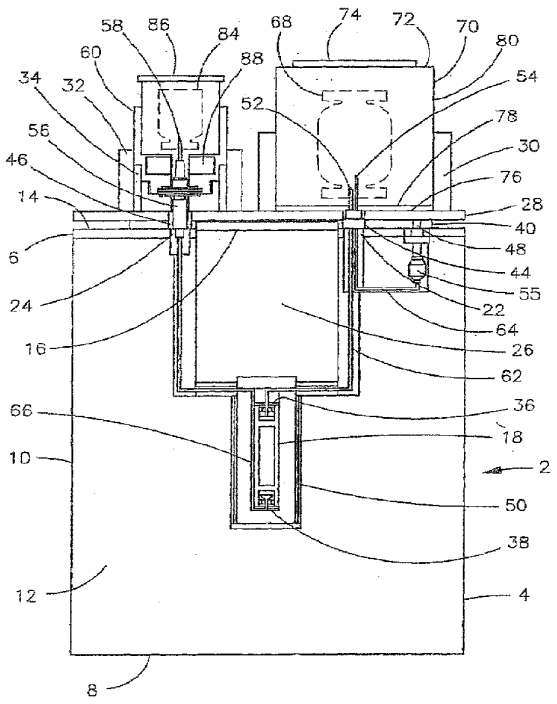

Fig. 1

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Description

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial Number 60/758,419, filed January 12, 2006, and from U.S. Patent Application Serial No. 11/610,574, filed December 14,2006, the respective contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates generally to systems and methods for radioisotope generation. In one aspect, this invention relates to systems and methods for producing customized, predictable and reproducible supplies of radioisotopes for use in nuclear medicine.

BACKGROUND OF THE INVENTION

[0003] Nuclear medicine is a branch of medicine dealing with the use of radioisotopes as radiopharmaceuticals or radioactive tracers in the diagnosis and treatment of disease. Radioisotopes are natural or artificially created isotopes (isotopes being one of two or more atoms having the same atomic number but different mass numbers) of a chemical element that have an unstable nucleus that decays, emitting alpha, beta, or gamma rays until stability is reached.

[0004] Radioisotopes, such as the meta stable Technetium-99m (Tc-99m), are used in medical tests as radioactive tracers that medical equipment can detect in the body. Other generator-derived radioisotopes that are used as tracers include yttrium-90, rhenium-188, and *gallium*-68. Tc-99m, in particular, emits readily detectable gamma rays, and it has a half-life of 6 hours. A variety of different radiopharmaceuticals based on Tc-99m are used for imaging and functional studies of the brain, myocardium, thyroid, lungs, liver, gallbladder, kidneys, skeleton, blood and tumors. Schwochau, Klaus. Technetium, Wiley-VCH (2000) (ISBN 3-527-29496-1). Scientists continue to find new uses for radioisotopes, such as Tc-99m. For example, doctors recently used Tc-99m to diagnose precisely the infected lymph nodes in breast cancer patients by injecting Tc-99m into the breast around the tumor to allow them to locate the node quickly and precisely before ever making an incision. *Brookhaven National Laboratory site on the history of the technetium cow.* (http://www.bnl.gov/bnJweb/history/Tc-99m.asp).

[0005] A Tc-99m generator, often called a technetium cow, is a device used to extract Tc-99m from decaying molybdenum-99 ("Mo-99"). Mo-99 has a half-life of 66 hours and can be transported over long distances to radiopharmacies and hospitals where its decay product Tc-99m is used for nuclear medicine diagnostic procedures. Removing the Tc-99m from the generator ("milking" the generator) is typically done every 6 hours or, at most, twice daily. Most commercial generators use column chromatography, in which Mo-99 is adsorbed onto alumina. Normal saline solution can be run through a column of immobilized Mo-99 to elute soluble Tc-99m, resulting in a saline solution containing the Tc-99m.

[0006] Today, commercial radiopharmacies typically replace their generators on a biweekly basis, since the useful life of a Tc-99m generator is about 6 half lifes or approximately two weeks. Hence, typical clinical nuclear medicine units purchase at least one such generator every two weeks or order several in a staggered fashion. The lead-lined generators are heavy and bulky and represent significant manipulation and toil for personnel to replace and to dispose of spent generators. Large quantities of lead, molded plastic containers, and packing materials are used only once and discarded after two weeks. Shipping costs and waste are real considerations for end-users. Further, conventional generator systems lack flexibility as they are limited to fixed activity denominations per unit sold, resulting in limited predictability and reproducibility. Typical generators also do not provide activity above 19 Ci.

[0007] It would be desirable therefore to provide systems and methods for producing customized, predictable and reproducible supplies of radioisotopes, including high activity levels, that do not require weekly replacement, handling and transport of heavy shielding materials associated with conventional generators.

SUMMARY OF THE INVENTION

[0008] In one aspect, the present invention provides systems comprising a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; a chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and a filter module that is disposed external to said reactor housing and in fluid communication with said exit port.

[0009] In another aspect, the present invention provides kits comprising a column, a delivery housing, and a shielded filter module.

[0010] The present invention also provides methods comprising the steps of providing a system that comprises: a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; a first chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and a first filter module that is disposed external to said reactor housing and in fluid communication with said exit port; and positioning a first delivery vessel comprising a solution of at least one radioisotope

external to said reactor housing and in fluid communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said solution.

[0011] In yet another aspect, the present invention provides methods comprising the steps of providing a system that comprises: a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; a first chromatographic column that comprises at least one radioisotope and is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and a filter module that is disposed external to said reactor housing and in fluid communication with said exit port; and removing said first chromatographic column from said reactor housing.

[0012] In still yet another aspect, the present invention provides methods comprising the steps of providing a system that comprises: a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; a first chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and a first filter module that is disposed external to said reactor housing and in fluid communication with said exit port; and removing said first filter module.

[0013] The present invention also provides methods comprising the steps of: providing a system that comprises: a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; said internal volume being substantially defined by a first end, a second end, and a wall extending between said first end and said second end; a first chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and a filter module that is disposed external to said reactor housing and in fluid communication with said exit port; positioning a collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module.

[0014] In yet another aspect, the present invention provides methods comprising the steps of: receiving customer information including a target output of a radioisotope; and adding a solution of a parent radioisotope to a delivery vessel in an amount sufficient to produce said target output upon decay of said parent radioisotope.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a cutaway side view depicting one generator system according to the invention.

[0016] **FIG. 2** is a cutaway side view depicting one shielded filter module according to the invention.

[0017] **FIG. 3** is an isometric view of one cart according to the invention.

[0018] **FIG. 4** is a cutaway side view of one generator system according to the invention.

[0019] **FIG. 5** is a perspective view of a column assembly being inserted into an internal volume of a reactor housing according to the invention.

[0020] **FIG. 6** is a perspective view of a radioactive shielding plug being inserted into an opening in a reactor housing according to the invention.

[0021] **FIG. 7** is a perspective view of an adapter disk disposed on the surface of a reactor housing according to the invention.

Further aspects of the invention are set out below in the following numbered paragraphs:-

1. A system comprising:

   a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port;
   a chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and
   a filter module that is disposed external to said reactor housing and in fluid communication with said exit port.

2. The system of paragraph 1 wherein said radioactive shielding material is lead, tungsten or depleted uranium.

3. The system of paragraph 1 wherein said reactor housing is substantially rectilinear.

4. The system of paragraph 1 wherein said reactor housing is substantially cylindrical.

5. The system of paragraph 1 wherein said reactor housing includes a first end, a second end, and a wall extending between said first end and said second end.

6. The system of paragraph 5 wherein said entry port and said exit port are positioned at said first end.

7. The system of paragraph 6 further comprising a ridge of radioactive shielding material extending around said entry port at said first end.

8. The system of paragraph 6 further comprising a ridge of radioactive shielding material extending

around said exit port at said first end.

9. The system of paragraph 1 wherein said column comprises aluminum oxide particles from about 50 to about 200 μm in size.

10. The system of paragraph 1 wherein said column comprises silica gel particles from about 20 to about 100 μm in size.

11. The system of paragraph 1 wherein said column comprises one or more layers or polypropylene filter membranes, deactivated fused silica wool, one or more glass filter membranes from about 0.2 to about 10 μm in size and made of polyether sulfone, or stainless steel tubing with needle and filter adaptors.

12. The system of paragraph 11 further comprising two acetal plastic plugs with funnel drains.

13. The system of paragraph 1 wherein said filter module comprises a sterile 13 to 25 mm filter membrane from about 0.1 to about 0.22 μm size.

14. The system of paragraph 1 wherein said filter module is attached to said reactor vessel by a tread type adaptor.

15. The system of paragraph 14 wherein a needle is attached to said filter module.

16. The system of paragraph 1 wherein a collection housing is connected to said reactor housing via said filter module.

17. The system of paragraph 1 wherein said column comprises at least one radioisotope.

18. The system of paragraph 17 wherein said at least one radioisotope is Molybdate Mo- 99.

19. The system of paragraph 17 wherein said at least one radioisotope is Pertechnetate Tc99m.

20. The system of paragraph 1 further comprising a delivery vessel that is disposed external to said reactor housing and in fluid communication with said entry port.

21. The system of paragraph 20 wherein said delivery vessel is contained within a delivery housing that is fabricated from radioactive shielding material, such as lead, tungsten or depleted uranium.

22. The system of paragraph 21 wherein said delivery housing has a first end that includes a first coupling, a second end that includes a second coupling, and a walj extending between said first end and said second end.

23. The system of paragraph 22 wherein said first coupling is threaded.

24. The system of paragraph 22 further comprising a transfer tool that comprises a pick-up and release rod having a handle at a first end thereof and a coupling at a second end thereof that is compatible with said first coupling.

25. The system of paragraph 24 wherein said transfer tool is a T-bar handle.

26. The system of paragraph 20 wherein said delivery vessel comprises a solution of at least one radioisotope.

27. The system of paragraph 26 wherein said at least one radioisotope is Molybdate Mo- 99.

28. The system of paragraph 26 wherein said solution is Sodium Molybdate Mo-99.

29. The system of paragraph 26 wherein said delivery vessel comprises about 1 to about 50 Ci.

30. The system of paragraph 20 wherein said delivery vessel comprises Normal Saline [0.9%] solution.

31. The system of paragraph 21 wherein said delivery housing abuts a ridge of material that is external to said reactor housing and extends around said entry port.

32. The system of paragraph 21 wherein said delivery housing is at least partially contained within a ridge of material that is external to said reactor housing and extends around said entry port.

33. The system of paragraph 20 wherein said delivery vessel is at least partially contained within a ridge of material that is external to said reactor housing and extends around said entry port.

34. The system of paragraph 1 further comprising a collection vessel that is disposed external to said reactor housing and in fluid communication with said exit port via said filter module.

35. The system of paragraph 34 wherein said collection vessel is evacuated.

36. The system of paragraph 34 wherein said collection vessel comprises a solution of at least one radioisotope.

37. The system of paragraph '36 wherein said at least

one radioisotope is Technetium Tc99m.

38. The system of paragraph 36 wherein said solution is Sodium Pertechnetate Tc-99m.

39. The system of paragraph 1 further comprising an adapter disk disposed on said reactor housing, comprising a ridge of material that extends around said entry port and a ridge of material that extends around said exit port.

40. The system of paragraph 39 further comprising an adapter ridge disposed circumferentially internal to said ridge of material that extends around said entry port.

41. The system of paragraph 40 further comprising a saline vessel that is disposed external to said reactor housing and in fluid communication with said entry port.

42. The system of paragraph 41 wherein said saline vessel comprises Normal Saline [0.9%] solution.

43. The system of paragraph 34 wherein said filter module abuts a ridge of radioactive shielding material that is external to said reactor housing and extends around said exit port.

44. The system of paragraph 34 wherein said filter module is at least partially contained within a ridge of radioactive shielding material that is external to said reactor housing and extends around said exit port.

45. The system of paragraph 34 wherein said collection vessel is contained within a collection housing that is fabricated from radioactive shielding material.

46. The system of paragraph 45 wherein said collection housing abuts a ridge of material that is external to said reactor housing and extends around said exit port.

47. The system of paragraph 45 wherein said collection housing is at least partially contained within a ridge of material that is external to said reactor housing and extends around said exit port.

48. The system of paragraph 1 further comprising a cart that includes a plurality of delivery vessels that each independently comprises a reactor vessel.

49. The system of paragraph 1 further comprising a cart that includes a plurality of delivery vessels that each independently comprise a solution of at least one radioisotope and are contained within a delivery housing that is fabricated from radioactive shielding material.

50. The system of paragraph 49 further comprising a conveyor belt for moving said delivery housing.

51. The system of paragraph 49 further comprising a transfer tool for moving said delivery housing.

52. The system of paragraph 49 wherein said at least one radioisotope is Molybdenum-99.

53. The system of paragraph 49 wherein said solution is Sodium Molybdate Mo-99.

54. The system of paragraph 49 wherein said delivery vessels each independently comprise about 1 to about 50 Ci.

55. The system of paragraph 1 further comprising a cart that includes a plurality of evacuated collection vessels.

56. The system of paragraph 1 further comprising a cart that includes a plurality of saline vessels.

57. A kit comprising a column, delivery housing, and a filter module comprising.a radioactive shielding material insert.

58. The kit of paragraph 57 further comprising a transfer tool.

59. The kit of paragraph 57 further comprising a plurality of evacuated collection vessels.

60. The kit of paragraph 57 further comprising a plurality of saline vessels.

61. A method comprising the steps of: providing a system that comprises:

a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port;
a first chromatographic column that is positioned within said internal volume such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port; and
a first filter module that is disposed external to said reactor housing and in fluid communication with said exit port; and either:

positioning a first delivery vessel comprising a solution of at least one radioisotope external to said reactor housing and in fluid

communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said solution; or
positioning a collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module; or removing said first chromatographic column from said reactor housing; or removing said first filter module.

62. The method of paragraph 61 wherein said first delivery vessel is contained within a delivery housing that is fabricated from radioactive shielding material and has a first end that includes a coupling, a second end that includes a coupling, and a wall extending between said first end and said second end.

63. The method of paragraph 62 wherein positioning said first delivery vessel comprises: mating said coupling at said first end of said delivery housing with a transfer tool comprising a rod having a handle at a first end thereof and a coupling at a second end thereof that is compatible with said coupling at said first end of said delivery housing; and
lifting said delivery housing.

64. The method of paragraph 63 further comprising mating said coupling at said second end of said first delivery housing with a coupling on said reactor housing that is compatible with said coupling at said second end of said first delivery housing.

65. The method of paragraph 61 further comprising removing said first delivery vessel from said position relative to said reactor housing.

66. The method of paragraph 62 wherein said first delivery vessel is contained within a delivery housing that is fabricated from radioactive shielding material and has a first end that includes a coupling, a second end that includes a coupling, and a wall extending between said first end and said second end.

67. The method of paragraph 66 wherein removing said first delivery vessel comprises:

mating said coupling at said first end of said first delivery housing with a transfer tool comprising a rod having a handle at a first end thereof and a coupling at a second end thereof that is compatible with said coupling at said first end of said first delivery housing; and
lifting said delivery housing.

68. The method of paragraph 66 further comprising positioning a second delivery vessel comprising saline external to said reactor housing and in fluid communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said saline solution.

69. The method of paragraph 68 further comprising removing said second delivery vessel from said position relative to said reactor housing.

70. The method of paragraph 69 further comprising positioning a subsequent delivery vessel comprising saline external to said reactor housing and in fluid communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said saline solution.

71. The method of paragraph 69 further comprising positioning a subsequent delivery vessel comprising a solution of at least one radioisotope external to said reactor housing and in fluid communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said solution.

72. The method of paragraph 69 further comprising removing said first chromatographic column from said reactor housing.

73. The method of paragraph 72 further comprising positioning a subsequent chromatographic column in said reactor housing such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port.

74. The method of paragraph 69 further comprising positioning a first collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module.

75. The method of paragraph 74 wherein said collection vessel is contained within a collection housing that is fabricated from radioactive shielding material.

76. The method of paragraph 74 further comprising removing said first collection vessel from said position relative to said reactor housing.

77. The method of paragraph 69 further comprising positioning a subsequent collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module.

78. The method of paragraph 61 further comprising removing said first filter module.

79. The method of paragraph 78 further comprising positioning a subsequent filter module external to

said reactor housing and in fluid communication with said exit port.

80. The method of paragraph 61 comprising the steps of:

providing said system; and
positioning a first delivery vessel comprising a solution of at least one radioisotope external to said reactor housing and in fluid communication with said entry port for a time and under conditions effective to elute said chromatographic column with at least a portion of said solution

81. The method of paragraph 61 comprising the steps of:

providing said system; and removing said first chromatographic column from said reactor housing.

82. The method of paragraph 61 further comprising positioning a subsequent chromatographic column in said reactor housing such that a first end of said column is in fluid communication with said entry port and a second end of said column is in fluid communication with said exit port.

83. The method of paragraph 61 comprising the steps of:

providing said system; and
removing said first filter module.

84. The method of paragraph 61 further comprising positioning a subsequent filter module external to said reactor housing and in fluid communication with said exit port.

85. The method of paragraph 61 comprising the steps of:

providing said system; and
positioning a collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module.

86. A method comprising the steps of;
receiving customer information including a target output of a radioisotope; and adding a solution of a parent radioisotope to a delivery vessel in an amount sufficient to produce said target output upon decay of said parent radioisotope.

87. The method of paragraph 86 wherein said radioisotope is Technetium-99m.

88. The method of paragraph 86 wherein said parent radioisotope is Molybdenum-99.

89. The method of paragraph 86 further comprising shipping said delivery vessel to said customer.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0022] With reference to the drawings, **FIG. 1** shows one type of generator system **2** according to the invention. The generator system may include a reactor housing **4** fabricated from a radioactive shielding material such as lead, tungsten, or depleted uranium. The reactor housing **4** maybe substantially cylindrical, as shown in **FIG. 1.** In another embodiment, the reactor housing may be substantially rectilinear. The reactor housing **4** may include a first end **6**, a second end **8**, and a wall **10** extending between said first end **6** and said second end **8.** The reactor housing **4** may have both an internal volume **12** and a surface **14** that comprises an opening **16** for inserting a column **18** (said column may be included in a column assembly **20,** shown in more detail in **FIG. 5),** an entry port **22**, and an exit port **24.** The opening **16**, entry port **22** and exit port **24** may be positioned at said first end **6** of said housing **4.** A radioactive shielding plug **26** may be disposed in said opening **16** in said surface **14** above said column **18.** The radioactive shielding plug **26** may be fabricated from a radioactive shield material such as lead, tungsten, or depleted uranium. The reactor housing **4** may have an adapter disk **28** disposed on the surface **14** of said reactor housing **4** that comprises a ridge of guide **material 30** that may extend around said entry port **22** and a ridge of guide material **32** that may extend around said exit port **24.** Preferably, the adapter disk **28** and ridges of guide material **30** and **32** are plastic. A ridge of radioactive shielding material **34** may extend around said exit port **24.**

[0023] A chromatographic column **18** may be positioned within said internal volume **12** such that a first end **36** of said column **18** is in fluid communication with said entry port **22** and a second end **38** of said column **18** is in fluid communication with said exit port **24.** In one embodiment, the column **18** may be included in a column assembly **20.** The column assembly **20**, in turn, may comprise a column adaptor plate **40** having a-radioactive shielding plug opening **42,** an adaptor plate entry port **44** and an adaptor plate exit port **46** corresponding to said entry port **22** and said exit port **24** of said reactor housing, respectively, an adaptor plate vent port **48** (which may include a vent filter), and a column housing **50,** preferably fabricated from radioactive shielding material such as lead, tungsten, or depleted uranium. The column assembly **20** may comprise an entry needle **52** and a vent needle **54** disposed in said adaptor plate entry port **44**, and an exit connection **56**, adapted for fluid communication with a changeable sterile needle **58** of a filter module **60.** An entry pipe **62** may extend from said entry needle **52** to said first end **36** of said column **18.** A vent pipe **64** may

extend from said vent needle **54** to a safety valve **55** (said safety valve **55** protecting said vent filter by preventing back pressure from being released onto said vent filter) and said safety valve **55** may extend to said vent port **48.** An exit pipe 66 may extend from said second end **38** of said column **18** to said exit connection **50.** The column **18** may be inserted into said internal volume **12** of said reactor housing **4** through said opening **16** in said surface **1.4** of said reactor housing **4.** Alternatively, said column assembly **20** maybe positioned such that said column **18** is disposed in said internal volume **12** of said reactor housing **4.** The column **18** may comprise at least one radioisotope, including but not limited to Mo-99, Tc-99m, Y-90, Re-188, or Ga-68. In preferred embodiments, the column **18** is fabricated from glass. The column **18** may contain alumina in the form of aluminum oxide, Al_2O_3 (mp of about 2,000°C and specific gravity of about 4.0). Preferably, the column **18** is a glass column that contains aluminum oxide. The aluminum oxide powder preferably has a particle size of from about 20 to about 200 μm. In addition to the aluminum oxide powder, the column **18** may also include silica gel having a particle size of from about 20 to about 100 μm, The column **18** may also comprise one or more layers or polypropylene filter membranes, deactivated fused silica wool, and/or one or more glass filter membranes, The filter membranes preferably measure from about 0.2 to about 10 μm and may comprise polyether sulfone, Acetal plastic plugs with funnel drains, or stainless steel tubing with needle and filter adaptors. Particularly preferred filter membranes are those fabricated from polyether sulfone at a size of 0.2 μm.

[0024] A delivery vessel **68** may be disposed external to said reactor housing **4** and in fluid communication with said entry port **22.** The delivery vessel **68** may be a 3 to 20 ml (preferably 10 ml) borosilicate glass vessel. The delivery vessel **68** may be contained within a delivery housing **70** that is fabricated from radioactive shielding material such as lead, tungsten, or depleted uranium. The delivery housing **70** preferably is fabricated from radioactive shielding material and has a first end **72** that includes a first coupling **74,** a second end **76** that includes a second coupling **78,** and a wall **80** extending between said first end **72** and said second end **76.** The first coupling **74** and second coupling **78** may be threaded or may form a lure lock. In certain embodiments, delivery vessel **68** comprises a solution of at least one radioisotope, including but not limited Mo-99 or Tc-99m in the form of sodium molybdate Mo-99 or sodium pertechnetate Tc-99m, respectively. In such embodiments, delivery vessel **68** preferably comprises from about 1 to about 50 Ci (1 curie (Ci) is 37 gigabecquerels (GBq) exactly and 1 Bq = 2.7027×10^{-11} Ci). In other embodiments, delivery vessel **68** comprises Normal Saline [0.9%] solution. The delivery housing **70** may abut a ridge of guide material **30** that may be external to said reactor housing **4** and may extend around said entry port **22.** The delivery housing **70** may be at least partially contained within a ridge of guide material **30** that may be external to said reactor housing and may extend around said entry port **22.** In certain embodiments, an adapter guide ridge **81** may be disposed on said adapter disk **28** circumferentially internal to said ridge of guide material **30.** A saline vessel **82** may be disposed external to said reactor housing 4, and in fluid communication with said entry port **22** and may abut said adapter guide ridge **81 (FIG. 4)** that extends around said entry port **22.** The saline vessel **82** may comprise Normal Saline [0.9%] solution.

[0025] The generator system **2** may comprise a collection vessel **84** that is disposed external to said reactor housing **4** and in fluid communication with said exit port **24** via a filter module **60,** discussed below with reference to **FIG. 2.** The collection vessel **84** may be evacuated, and ultimately is used to collect a solution of at least one radioisotope. The collection vessel **84** may be a 10 to 30 ml borosilicate glass vessel. Preferably, the collection vessel **84** is a 20 to 30 ml sterile, evacuated, borosilicate glass vessel. As shown in **FIG. 1,** collection vessel **84** is contained within a collection housing **86** that is fabricated from radioactive shielding material.

[0026] As shown in **FIG. 2,** a filter module **60** may be disposed external to the reactor housing **4** and may be in fluid communication with said exit port **24.** The filter module **60** may include a radioactive shielding material insert **88** that is positioned between said collection vessel **84** and said reactor housing 4. The filter module **60** preferably holds a sterile 13 to 25 mm filter membrane **90** of 0.1 to 0.22 μm size, preferably of 0.2 μm size. The filter module **60** may be attached via a tread type adaptor to join the reactor to a sterile evacuated collection vessel **84.** A changeable sterile needle **58** may be attached to the sterile filter **90** for daily sterile eluting procedures. The filter module **60** may abut a ridge of radioactive shielding material **34** and/or may abut a ridge of guide material **32** that is external to said reactor housing 4 and extends around said exit port **24.** The filter module **60** may be at least partially contained within said ridge of radioactive shielding material **34** and/or said ridge of guide material **32.** The radioactive shielding material may be lead, tungsten, or depleted uranium.

[0027] The generator system may include a cart **92,** as shown in **FIG. 3.** The cart **92** preferably is fabricated from steel and lead. The frame is preferably fabricated from steel. The walls of cart **92** are preferably lead plates or lead brick. The cart **92** may hold a plurality of reactor housings **94, 96, 98, 100, 102, 104,** and **106** that may be fabricated from radioactive shielding material The cart **92** may also comprise a plurality of delivery vessels **68** and/or a plurality of evacuated collection vessels **84** and/or a plurality of saline vessels **82.** The cart **92** may include a transfer tool **108** that comprises a pick-up and release rod **110** having a handle **112** at a first end **114** thereof and a coupling **116** at a second end **118** thereof that is compatible with the first coupling **74** of said delivery housing **70.** The transfer tool **108** preferably is a universal T-bar handle. The cart **92** may also include a conveyor

belt **120**, or other motion enhancing device, to assist a user with moving a delivery housing **70** proximate to a reactor housing (*e.g.*, **94, 96, 98, 100, 102, 104** and **106**).

[0028] Methods of radioisotope generation according to the invention may be described with reference to **FIGS. 1** and **2.** In certain embodiments, such methods involve positioning a first delivery vessel **68** comprising a solution of at least one radioisotope external to said reactor housing **4** and in fluid communication with said entry port **22** for a time and under conditions effective to elute said chromatographic column **18** with at least a portion of said solution. The first delivery vessel **68** maybe positioned by mating said first coupling **74** at said first end **72** of said delivery housing **70** with transfer tool **108** and lifting the delivery housing **70.** The coupling **78** at said second end **76** of said first delivery housing **70** may be mated with a coupling on said reactor housing **4** that is compatible with said coupling **78** at said second end **76** of said first delivery housing **70.** The delivery vessel **68** may be removed from said position relative to said reactor housing **4** by lifting said delivery housing **70.** Subsequent delivery vessels comprising saline solution or a solution of at least one radioisotope may be used to elute said column **18** with at least a portion of said solutions. A collection vessel **84** may be positioned external to said reactor housing **4** and in fluid communication with said exit port **22** via said filter module **60.** The column **18**, column assembly **20**, filter module **60,** filter membrane **90,** sterile needle **58**, delivery vessel **68,** collection vessel **84** and/or saline vessel **82** may be removed from said reactor housing **10** and may be replaced by subsequent columns, column assemblies, filter modules, filter membranes, sterile needles, delivery vessels, collection vessels and/or saline vessels, respectively, as appropriate.

[0029] In certain embodiments, methods of radioisotope generation according to the invention involve the receipt of customer information including a target output of a radioisotope, the addition of a solution of a parent radioisotope to a delivery vessel in an amount sufficient to produce said target output upon decay of said parent radioisotope, and the shipment of said delivery vessel to said customer. The customer's generator system, in turn, may be loaded and re-loaded with varying volumes of said parent radioisotope effective to collect specific target concentrations of the desired radioisotope. The generator systems may be re-loaded more than 2 times, more preferably more than 4 times, and most preferably more than 6 times. Preferably, the customer information received includes a target output of Tc-99m from 1 to 50 Ci, and the solution added to the delivery vessel includes Mo-99 in an amount sufficient to produce said target output upon decay of said Mo-99.

[0030] A kit for radioisotope generation according to the invention is also contemplated and may be described with reference to **FIGs. 1-3.** The kit may include a column **18** or a column assembly **20**, a delivery housing **70** containing a delivery vessel **68** comprising at least one radioisotope, a filter module **60** comprising a radioactive shielding material insert **88**, a transfer tool **108**, a plurality of evacuated collection vessels **84** and a plurality of saline vessels **82.** The kit can be used to replenish existing reactor housings **4** and thereby avoids shipment and disposal thereof.

In addition, exemplary steps for radioisotope generation according to the invention may be described with reference to **FIGs. 1-7.** As shown in **FIG. 5,** a column assembly **20** may be inserted into an internal volume **12** of a reactor housing **4** (said reactor housing having an entry port **22** and an exit port **24),** through an **opening 16** in the surface **14** of the reactor, housing 4. Then, as shown in **FIG. 6,** the opening **16** above the column **18** may be plugged with a radioactive shielding plug **26.** Then, as shown in **FIG. 7,** an adapter disk **28,** comprising a ridge of guide material **30** extending around the entry port **22** and a ridge of guide material **32** extending around the exit port **24,** may be disposed on the surface **14** of the reactor housing **4.** A filter module **60** may then be disposed external to the reactor housing **4** in fluid communication with the exit port **24.** A delivery **vessel 68** containing a radioisotope, contained in a delivery housing **70,** may then be disposed external to the reactor housing **4** and in fluid communication with the entry port **22.** An evacuated collection vessel **84,** contained with a collection housing 86, may then be disposed external to the reactor housing **4** in fluid communication with the exit port **24** via the filter module **60.** After waiting a suitable amount of time (*e.g.*, more than about three minutes), the collection vessel **84** and then the delivery vessel **68** may be removed. An adapter guide ridge **81** may then be disposed on the surface of the adapter disk 28 such that it extends around the entry port **22.** A saline vessel **82** may then be disposed external to the reactor **housing 4** and in fluid communication with the entry port **22.** An evacuated collection vessel 84, contained within a collection housing **86**, may then be disposed external to the reactor housing 4 and in fluid communication with the exit port **24** via the filter module 60. After again waiting a suitable amount of time, said collection housing **86** may be removed. An evacuated collection vessel **84**, contained within a collection housing **86,** may then'be disposed external to the reactor housing **4** and in fluid communication with the exit port **24** via the filter module **60.** The aforementioned exemplary steps may be repeated with subsequent delivery vessels, columns, filter modules and collection vessels as may be appropriate.

[0031] Thus, there have been described systems and methods for producing customized, predictable and reproducible supplies of radioisotopes that do not require weekly replacement, handling and transport of heavy shielding materials associated with conventional generators. It will be appreciated that numerous modifications may be made to the example embodiments described herein, and that such modifications do not depart from the scope of the invention as defined by the following claims.

Claims

1. A system comprising:

   a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port;
   a chromatographic column that bears at least one radioisotope and is positioned within said internal volume;
   a filter module that is disposed external to said reactor housing and in fluid communication with said column;
   an adapter disk disposed on said reactor housing, comprising a ridge of material that extended around said entry port and a ridge of material that extends around said exit port, and,
   an adapter ridge disposed circumferentially internal to said ridge of material that extends around said entry port.

2. A system according to claim 1, wherein said reactor house includes a first end, a second end and a wall extending between said first end and said second end.

3. A system according to claim 1, wherein said column comprises aluminum oxide particles from about 50 to 200 μm in size.

4. A system according to claim 1, wherein said column comprises silica gel particles from about 20 to 100 μm in size.

5. A system according to claim 1, wherein a collection housing is connected to said reactor housing via said filter module.

6. A system according to claim 1, including a delivery vessel that is disposed external to said reactor housing in fluid communication with said column.

7. A system according to claim 8, wherein said delivery vessel comprises a solution of about 1 to 50 Ci of at least one radioisotope.

8. A system according to claim 1, including a collection vessel that is disposed external to said reactor housing and in fluid communication with said column via said filter module.

9. A system according to claim 1, wherein said filter module abuts a ridge of radioactive shielding material that is external to said reactor housing and extends around said exit port.

10. A system according to claim 1, wherein said filter module is at least partially contained within a ridge of radioactive shielding material that is external to said reactor housing and extends around said exit port.

11. A system according to claim 1, wherein said collection vessel is contained within a collection housing that is fabricated from radioactive shielding material.

12. A system according to claim 1, including a cart that includes a plurality of delivery vessels that each independently comprises a reactor vessel.

13. A system according to claim 1, including a cart that includes a plurality of delivery vessels that each independently comprise a solution of at least one radioisotope and are contained within a delivery housing that is fabricated from radioactive shielding material.

14. A system according to claim 13, wherein said delivery vessels each independently comprise about 1 to about 50 Ci.

15. A system according to claim 1, wherein said column is configures to be reloaded with radioisotope solution at least one.

16. A system according to claim 1, including a column assembly comprising a further chromatographic column for replacing said chromatographic column after said at least some of said radioisotope has been eluted therefrom.

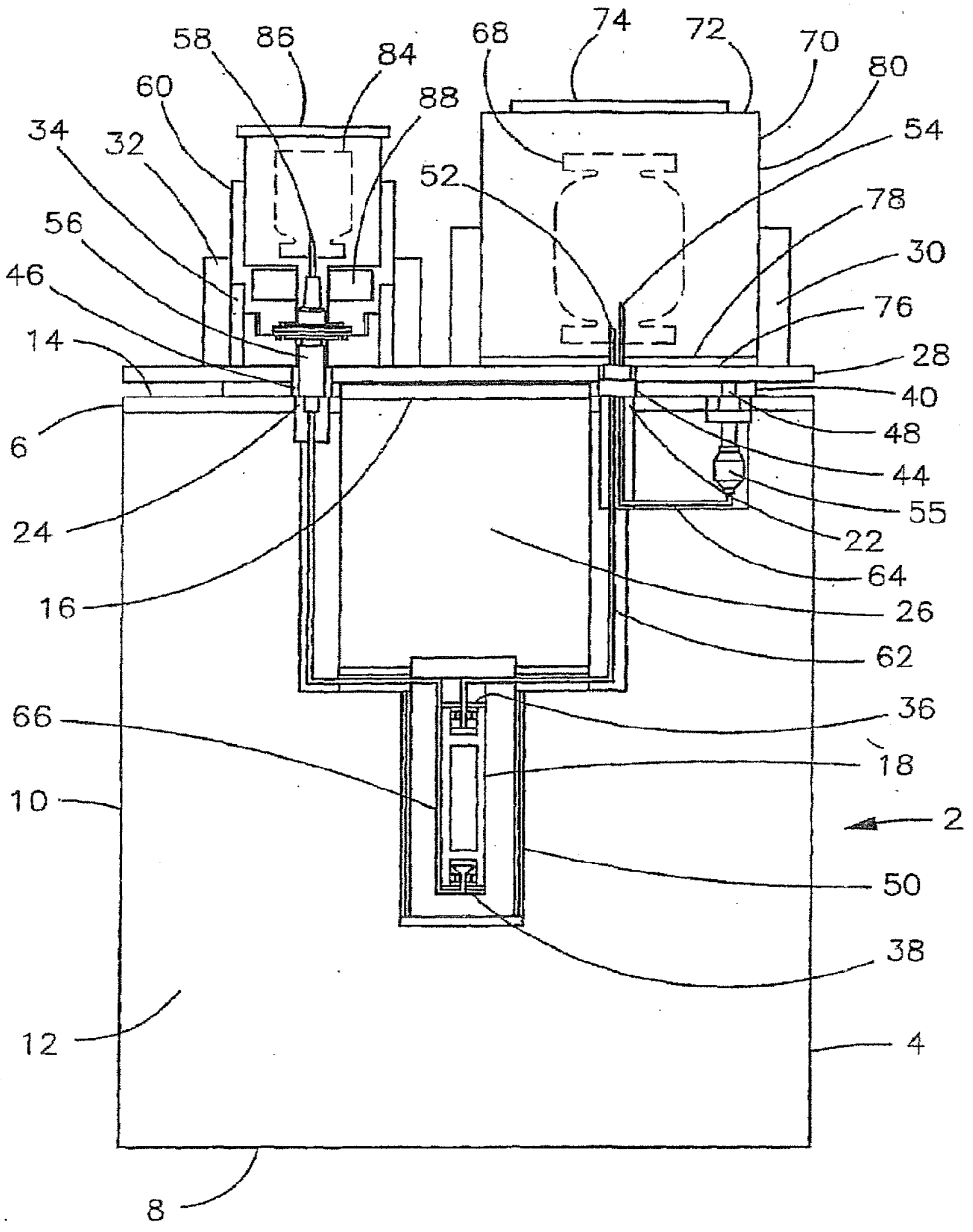
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Fig. 1

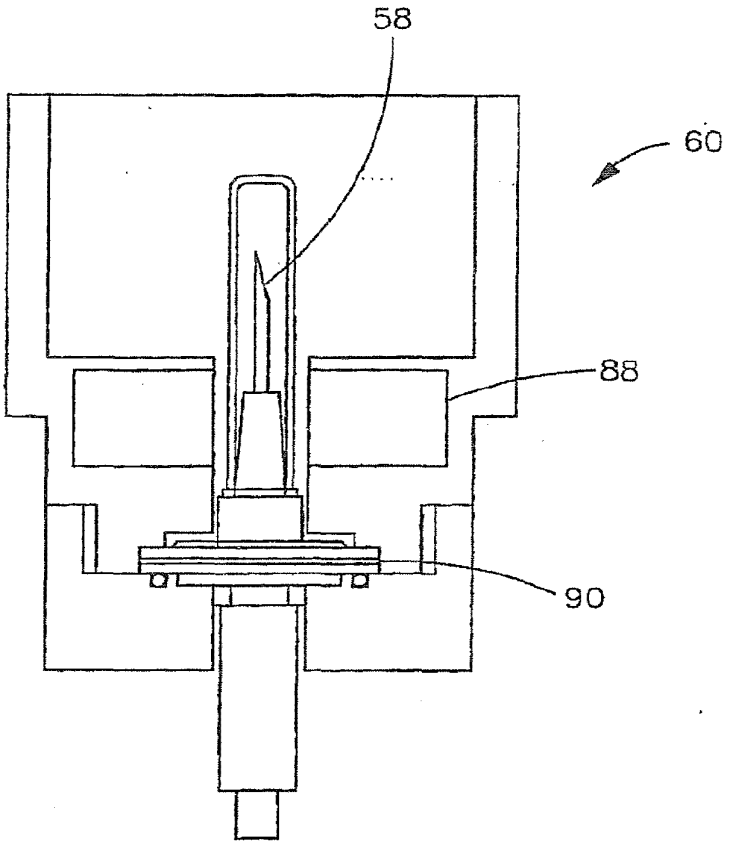

Fig. 2

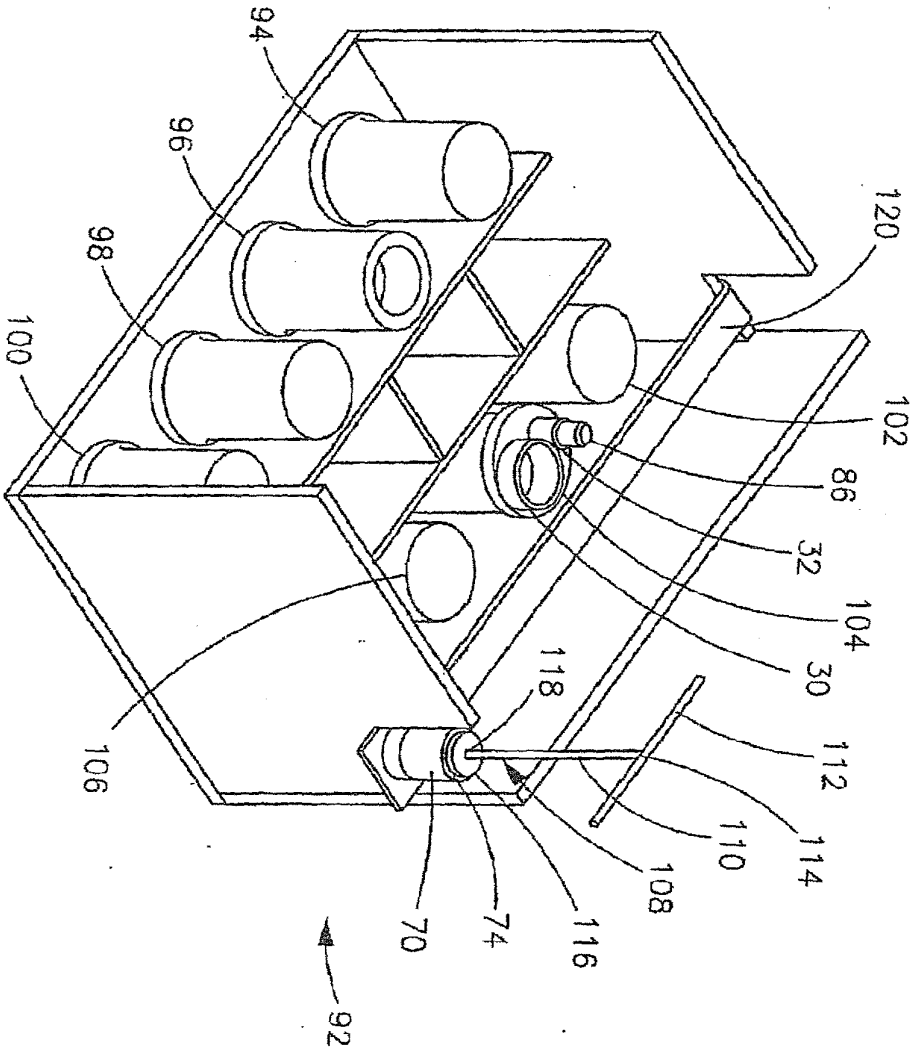
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Fig. 3

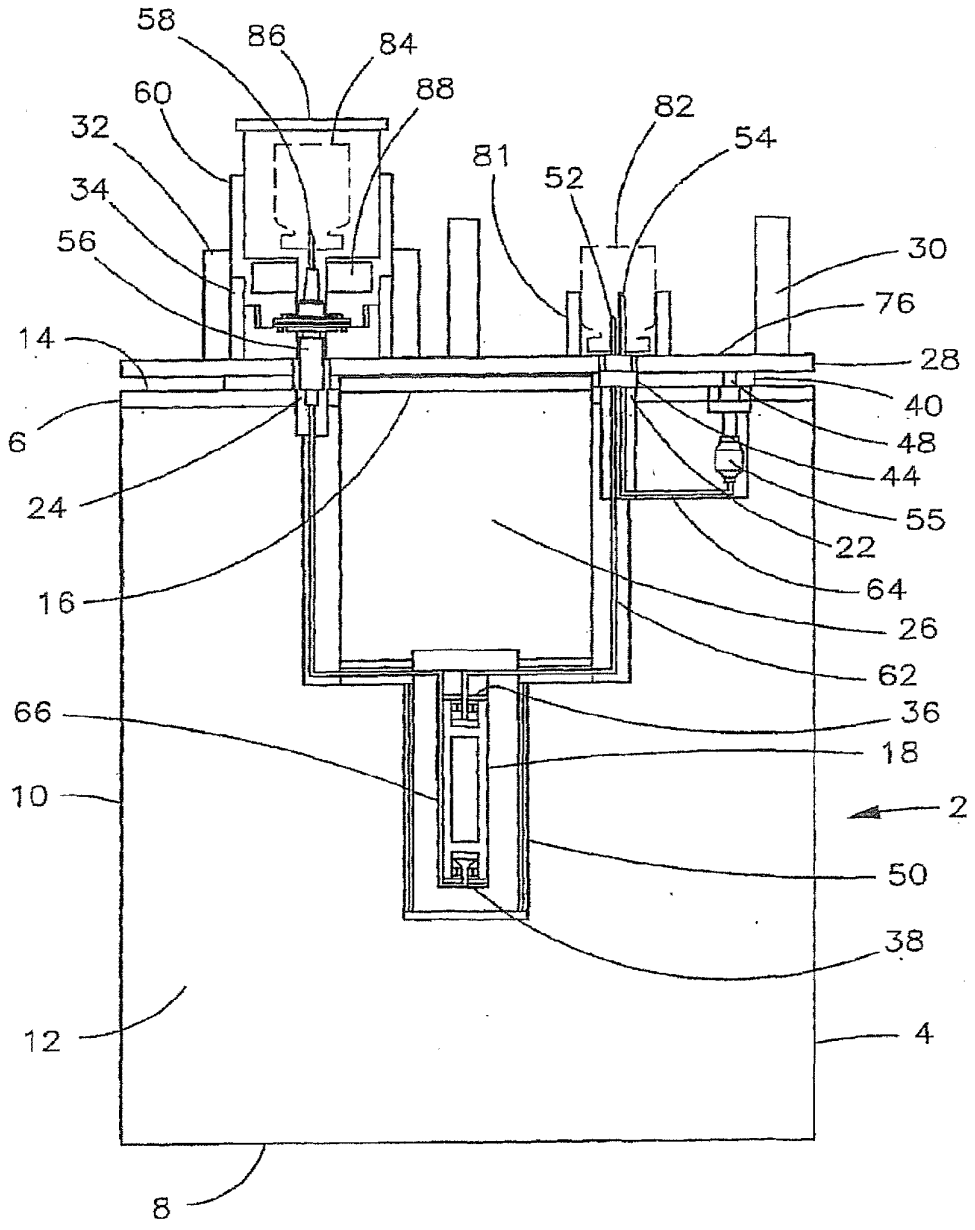
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Fig. 4

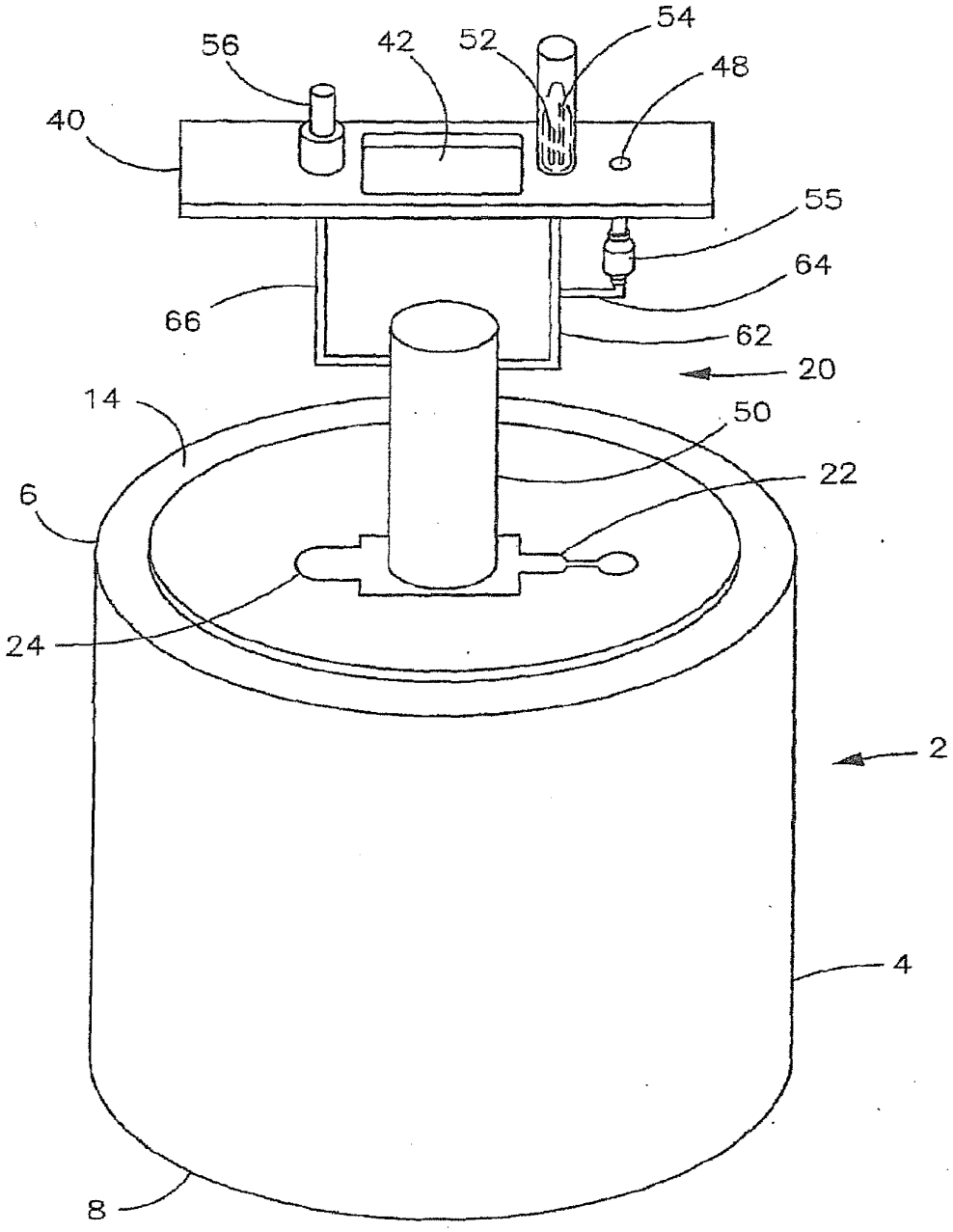

Fig. 5

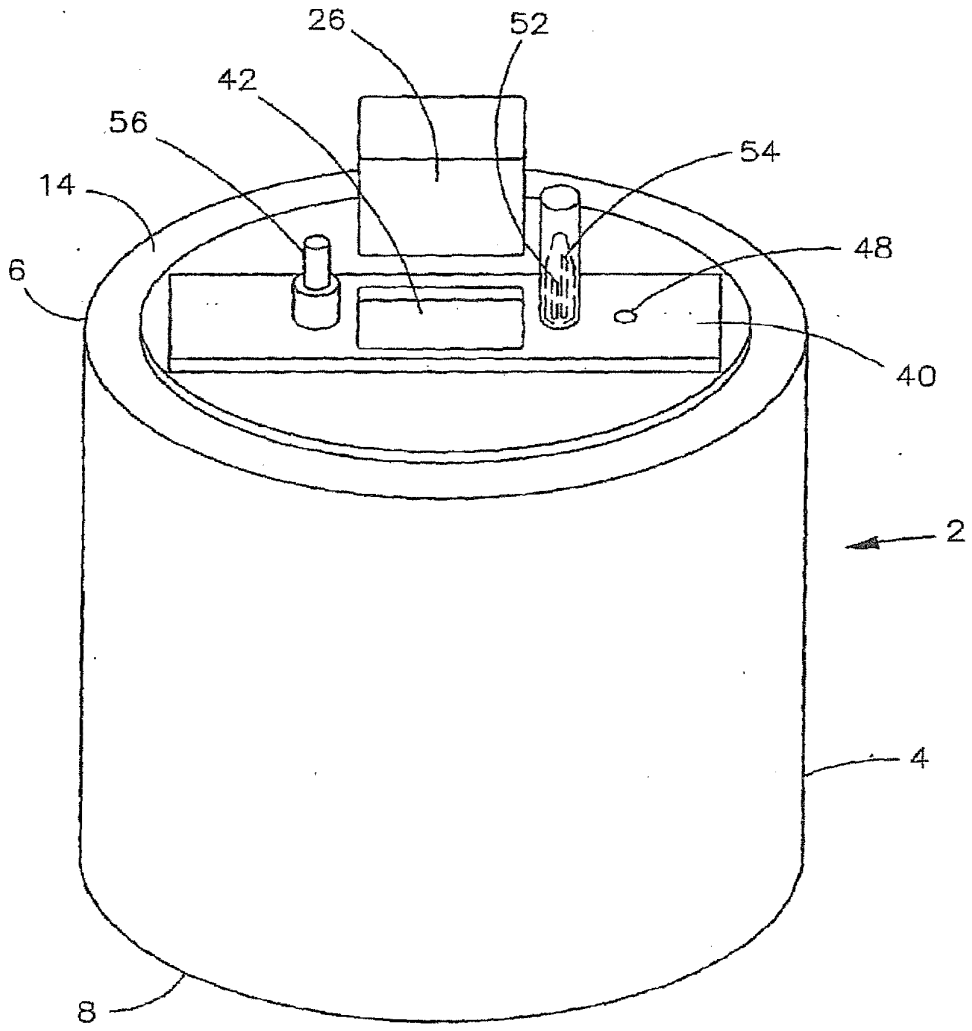

Fig. 6

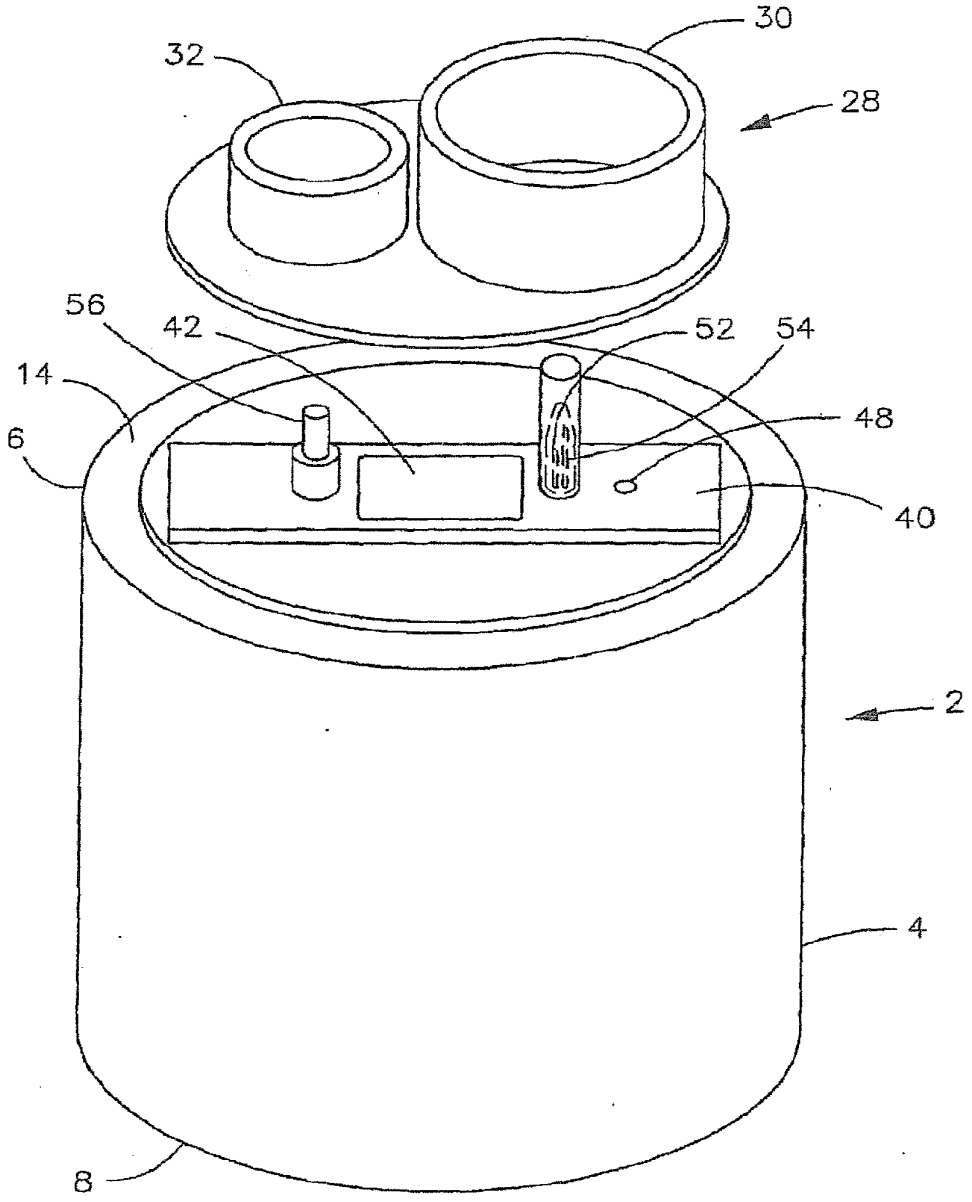

Fig. 7

REFERENCES CITED IN THE DESCRIPTION

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 011 126 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
23.05.2012 Bulletin 2012/21

(21) Application number: **06851254.0**

(22) Date of filing: **16.12.2006**

(51) Int Cl.:
G21G 1/00 *(2006.01)* ***B01D 15/10*** *(2006.01)*

(86) International application number:
PCT/IB2006/004294

(87) International publication number:
WO 2008/004028 (10.01.2008 Gazette 2008/02)

(54) **SYSTEMS AND METHODS FOR RADIOISOTOPE GENERATION**

SYSTEM UND VERFAHREN ZUR RADIOISOTOPERZEUGUNG

SYSTÈMES ET PROCÉDÉS POUR LA GÉNÉRATION DE RADIO-ISOTOPES

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **12.01.2006 US 758419 P**
14.12.2006 US 610574

(43) Date of publication of application:
07.01.2009 Bulletin 2009/02

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US-A- 6 157 036
US-B2- 6 998 052

Printed by Jouve, 75001 PARIS (FR)

EP 2 011 126 B1

Description

FIELD OF THE INVENTION

[0001] This invention relates generally to systems and methods for radioisotope generation. In one aspect, this invention relates to systems and methods for producing customized, predictable and reproducible supplies of radioisotopes for use in nuclear medicine.

BACKGROUND OF THE INVENTION

[0002] Nuclear medicine is a branch of medicine dealing with the use of radioisotopes as radiopharmaceuticals or radioactive tracers in the diagnosis and treatment of disease. Radioisotopes are natural or artificially created isotopes (isotopes being one of two or more atoms having the same atomic number but different mass numbers) of a chemical element that have an unstable nucleus that decays, emitting alpha, beta, or gamma rays until stability is reached.

[0003] Radioisotopes, such as the meta stable Technetium-99m (Tc-99m), are used in medical tests as radioactive tracers that medical equipment can detect in the body. Other generator-derived radioisotopes that are used as tracers include yttrium-90, rhenium-188, and gallium-68 . Tc-99m, in particular, emits readily detectable gamma rays, and it has a half-life of 6 hours. A variety of different radiopharmaceuticals based on Tc-99m are used for imaging and functional studies of the brain, myocardium, thyroid, lungs, liver, gallbladder, kidneys, skeleton, blood and tumors. Schwochau, Klaus. Technetium, Wiley-VCH (2000) (ISBN 3-527-29496-1). Scientists continue to find new uses for radioisotopes, such as Tc-99m. For example, doctors recently used Tc-99m to diagnose precisely the infected lymph nodes in breast cancer patients by injecting Tc-99m into the breast around the tumor to allow them to locate the node quickly and precisely before ever making an incision. *Brookhaven National Laboratory site on the history of the technetium cow.* (http://www.bnl.gov/bnlweb/history/Tc-99m.asp).

[0004] A Tc-99m generator, often called a technetium cow, is a device used to extract Tc-99m from decaying molybdenum-99 ("Mo-99"). Mo-99 has a half-life of 66 hours and can be transported over long distances to radiopharmacies and hospitals where its decay product Tc-99m is used for nuclear medicine diagnostic procedures. Removing the Tc-99m from the generator ("milking" the generator) is typically done every 6 hours or, at most, twice daily. Most commercial generators use column chromatography, in which Mo-99 is adsorbed onto alumina. Normal saline solution can be run through a column of immobilized Mo-99 to elute soluble Tc-99m, resulting in a saline solution containing the Tc-99m.

[0005] Today, commercial radiopharmacies typically replace their generators on a biweekly basis, since the useful life of a Tc-99m generator is about 6 half lifes or approximately two weeks. Hence, typical clinical nuclear medicine units purchase at least one such generator every two weeks or order several in a staggered fashion. The lead-lined generators are heavy and bulky and represent significant manipulation and toil for personnel to replace and to dispose of spent generators. Large quantities of lead, molded plastic containers, and packing materials are used only once and discarded after two weeks. Shipping costs and waste are real considerations for end-users. Further, conventional generator systems lack flexibility as they are limited to fixed activity denominations per unit sold, resulting in limited predictability and reproducibility. Typical generators also do not provide activity above 19 Ci.

[0006] It would be desirable therefore to provide systems and methods for producing customized, predictable and reproducible supplies of radioisotopes, including high activity levels, that do not require weekly replacement, handling and transport of heavy shielding materials associated with conventional generators.

SUMMARY OF THE INVENTION

[0007] In one aspect, the present invention provides a system comprising:

a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port;
a chromatographic column that is positioned within said internal volume wherein; said first chromatographic column is housed within a column assembly comprising:

a column housing defining an internal space for receiving said first chromatographic column;
a column adaptor plate;
an exit pipe in fluid communication with said first chromatographic column via said column housing and with an exit connection that is mounted on said column adaptor plate; and
an entry pipe in fluid communication with said first chromatographic column via said column housing and with an entry needle that is disposed in an adaptor plate entry port that is mounted on said column adaptor plate;

wherein said column assembly is configured for insertion as a unit into the internal volume of said reactor housing through an opening in an upper portion of said reactor housing; and;
a filter module that is disposed external to said reactor housing and in fluid communication with said column.

[0008] The present invention also provides a method comprising the steps of:

providing a system that comprises:

a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port;
a first chromatographic column that is positioned within said internal volume wherein
said first chromatographic column is housed within a column assembly comprising:
a column housing defining an internal space for receiving said first chromatographic column;
a column adaptor plate;
an exit pipe in fluid communication with said first chromatographic column via said column housing and with an exit connection that is mounted on said column adaptor plate; and
an entry pipe in fluid communication with said first chromatographic column via said column housing and with an entry needle that is disposed in an adaptor plate entry port that is mounted on said column adaptor plate;
wherein said column assembly is configured for insertion as a unit into the internal volume of said reactor housing through an opening in an upper portion of said reactor housing; and;
a first filter module that is disposed external to said reactor housing and in fluid communication with said first chromatographic column; and
positioning a first delivery vessel comprising a solution of at least one radioisotope external to said reactor housing and in fluid communication with said first chromatographic column for a time and under conditions effective to elute said first chromatographic column with at least a portion of said solution; and,
positioning a collection vessel external to said reactor housing and in fluid communication with said exit port via said filter module.

[0009] In yet another aspect, the present invention provides a method comprising the steps of:

providing a system that comprises:

a reactor housing that is fabricated from a radioactive shielding material and has both an internal volume and a surface that comprises an entry port and an exit port; and
a first chromatographic column that is positioned within said internal volume, wherein said first chromatographic column is housed within a column assembly comprising
a column housing defining an internal space for receiving said first chromatographic column;
a column adaptor plate;
an exit pipe in fluid communication with said first chromatographic column via said column housing and with an exit connection that is mounted on said column adaptor plate; and
an entry pipe in fluid communication with said first chromatographic column via said column housing and with an entry needle that is disposed in an adaptor plate entry port that is mounted on said column adaptor plate;
wherein said column assembly is configured for insertion as a unit into the internal volume of said reactor housing through an opening in an upper portion of said reactor housing;
removing said first chromatographic column from said internal volume by extracting said column assembly through an opening in an upper portion of said reactor housing;
positioning a second chromatographic column within said internal volume by inserting a second column assembly through said opening in said reactor housing;
positioning a first delivery vessel comprising a solution of at least a first radioisotope external to said reactor housing and in fluid communication with said second chromatographic column for a time and under conditions effective to elute said second chromatographic column with at least a portion of said solution; and,
positioning a first collection vessel external to said reactor housing and in fluid communication with said second chromatographic column.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a cutaway side view depicting one generator system according to the invention.

[0011] FIG. 2 is a cutaway side view depicting one shielded filter module according to the invention.

[0012] FIG. 3 is an isometric view of one cart according to the invention.

[0013] FIG. 4 is a cutaway side view of one generator system according to the invention.

[0014] FIG. 5 is a perspective view of a column assembly being inserted into an internal volume of a reactor housing according to the invention.

[0015] FIG. 6 is a perspective view of a radioactive shielding plug being inserted into an opening in a reactor housing according to the invention.

[0016] FIG. 7 is a perspective view of an adapter disk disposed on the surface of a reactor housing according to the invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0017] With reference to the drawings, **FIG. 1** shows one type of generator system **2** according to the invention. The generator system may include a reactor housing **4** fabricated from a radioactive shielding material such as lead, tungsten, or depleted uranium. The reactor hous-

ing **4** may be substantially cylindrical, as shown in **FIG. 1**. In another embodiment, the reactor housing may be substantially rectilinear. The reactor housing **4** may include a first end **6**, a second end **8**, and a wall **10** extending between said first end **6** and said second end **8**. The reactor housing **4** may have both an internal volume **12** and a surface **14** that comprises an opening **16** for inserting a column **18** (said column may be included in a column assembly **20**, shown in more detail in **FIG. 5**), an entry port **22**, and an exit port **24**. The opening **16**, entry port **22** and exit port **24** may be positioned at said first end **6** of said housing **4**. A radioactive shielding plug **26** may be disposed in said opening **16** in said surface **14** above said column **18**. The radioactive shielding plug **26** may be fabricated from a radioactive shield material such as lead, tungsten, or depleted uranium. The reactor housing **4** may have an adapter disk **28** disposed on the surface **14** of said reactor housing **4** that comprises a ridge of guide material **30** that may extend around said entry port **22** and a ridge of guide material **32** that may extend around said exit port **24**. Preferably, the adapter disk **28** and ridges of guide material **30** and **32** are plastic. A ridge of radioactive shielding material **34** may extend around said exit port **24**.

[0018] A chromatographic column **18** may be positioned within said internal volume **12** such that a first end **36** of said column **18** is in fluid communication with said entry port **22** and a second end **38** of said column **18** is in fluid communication with said exit port **24**. In one embodiment, the column **18** may be included in a column assembly **20**. The column assembly **20**, in turn, may comprise a column adaptor plate **40** having a radioactive shielding plug opening **42**, an adaptor plate entry port **44** and an adaptor plate exit port **46** corresponding to said entry port **22** and said exit port **24** of said reactor housing, respectively, an adaptor plate vent port **48** (which may include a vent filter), and a column housing **50**, preferably fabricated from radioactive shielding material such as lead, tungsten, or depleted uranium. The column assembly **20** may comprise an entry needle **52** and a vent needle **54** disposed in said adaptor plate entry port **44**, and an exit connection **56**, adapted for fluid communication with a changeable sterile needle **58** of a filter module **60**. An entry pipe **62** may extend from said entry needle **52** to said first end **36** of said column **18**. A vent pipe **64** may extend from said vent needle **54** to a safety valve 55 (said safety valve 55 protecting said vent filter by preventing back pressure from being released onto said vent filter) and said safety valve **55** may extend to said vent port **48**. An exit pipe **66** may extend from said second end **38** of said column **18** to said exit connection **50**. The column **18** may be inserted into said internal volume **12** of said reactor housing **4** through said opening **16** in said surface **14** of said reactor housing **4**. Alternatively, said, column assembly **20** may be positioned such that said column **18** is disposed in said internal volume **12** of said reactor housing **4**. The column **18** may comprise at least one radioisotope, including but not limited to Mo-99, Tc-99m, Y-90, Re-188, or Ga-68. In preferred embodiments, the column **18** is fabricated from glass. The column **18** may contain alumina in the form of aluminum oxide, Al_2O_3 (mp of about 2,000°C and specific gravity of about 4.0). Preferably, the column **18** is a glass column that contains aluminum oxide. The aluminum oxide powder preferably has a particle size of from about 20 to about 200 μm. In addition to the aluminum oxide powder, the column **18** may also include silica gel having a particle size of from about 20 to about 100 μm. The column **18** may also comprise one or more layers or polypropylene filter membranes, deactivated fused silica wool, and/or one or more glass filter membranes. The filter membranes preferably measure from about 0.2 to about 10 μm and may comprise polyether sulfone, Acetal plastic plugs with funnel drains, or stainless steel tubing with needle and filter adaptors. Particularly preferred filter membranes are those fabricated from polyether sulfone at a size of 0.2 μm.

[0019] A delivery vessel **68** may be disposed external to said reactor housing **4** and in fluid communication with said entry port **22**. The delivery vessel **68** may be a 3 to 20 ml (preferably 10 ml) borosilicate glass vessel. The delivery vessel **68** may be contained within a delivery housing **70** that is fabricated from radioactive shielding material such as lead, tungsten, or depleted uranium. The delivery housing **70** preferably is fabricated from radioactive shielding material and has a first end **72** that includes a first coupling **74**, a second end **76** that includes a second coupling **78**, and a **wall 80** extending between said first end **72** and said second end **76**. The first coupling **74** and second coupling **78** may be threaded or may form a lure lock. In certain embodiments, delivery vessel **68** comprises a solution of at least one radioisotope, including but not limited Mo-99 or Tc-99m in the form of sodium molybdate Mo-99 or sodium pertechnetate Tc-99m, respectively. In such embodiments, delivery vessel **68** preferably comprises from about 1 to about 50 Ci (1 curie (Ci) is 37 gigabecquerels (GBq) exactly and 1 Bug $=2.027\times10^{-11}$ Ci). In other embodiments, delivery vessel **68** comprises Normal Saline [0.9%] solution. The delivery housing **70** may abut a ridge of guide material **30** that may be external to said reactor housing **4** and may extend around said entry port **22**. The delivery housing **70** may be at least partially contained within a ridge of guide material **30** that may be external to said reactor housing and may extend around said entry port **22**. In certain embodiments, an adapter guide ridge **81** may be disposed on said adapter disk 28 circumferentially internal to said ridge of guide material **30**. A saline vessel **82** may be disposed external to said reactor housing **4**, and in fluid communication with said entry port **22** and may abut said adapter guide ridge **81 (FIG. 4)** that extends around said entry port **22**. The saline vessel **82** may comprise Normal Saline [0.9%] solution.

[0020] The generator system **2** may comprise a collection vessel **84** that is disposed external to said reactor housing **4** and in fluid communication with said exit port

24 via a filter module 60, discussed below with reference to FIG. 2. The collection vessel 84 may be evacuated, and ultimately is used to collect a solution of at least one radioisotope. The collection vessel 84 may be a 10 to 30 ml borosilicate glass vessel. Preferably, the collection vessel 84 is a 20 to 30 ml sterile, evacuated, borosilicate glass vessel. As shown in FIG. 1, collection vessel 84 is contained within a collection housing 86 that is fabricated from radioactive shielding material.

[0021] As shown in FIG. 2, a filter module 60 may be disposed external to the reactor housing 4 and may be in fluid communication with said exit port 24. The filter module 60 may include a radioactive shielding material insert 88 that is positioned between said collection vessel 84 and said reactor housing 4. The filter module 60 preferably holds a sterile 13 to 25 mm filter membrane 90 of 0.1 to 0.22 μm size, preferably of 0.2 μm size. The filter module 60 may be attached via a tread type adaptor to join the reactor to a sterile evacuated collection vessel 84. A changeable sterile needle 58 may be attached to the sterile filter 90 for daily sterile eluting procedures. The filter module 60 may abut a ridge of radioactive shielding material 34 and/or may abut a ridge of guide material 32 that is external to said reactor housing 4 and extends around said exit port 24. The filter module 60 may be at least partially contained within said ridge of radioactive shielding material 34 and/or said ridge of guide material 32. The radioactive shielding material may be lead, tungsten, or depleted uranium.

[0022] The generator system may include a cart 92, as shown in FIG. 3. The cart 92 preferably is fabricated from steel and lead. The frame is preferably fabricated from steel. The walls of cart 92 are preferably lead plates or lead brick. The cart 92 may hold a plurality of reactor housings 94, 96, 98, 100, 102, 104, and 106 that may be fabricated from radioactive shielding material The cart 92 may also comprise a plurality of delivery vessels 68 and/or a plurality of evacuated collection vessels 84 and/or a plurality of saline vessels 82. The cart 92 may include a transfer tool 108 that comprises a pick-up and release rod 110 having a handle 112 at a first end 114 thereof and a coupling 116 at a second end 118 thereof that is compatible with the first coupling 74 of said delivery housing 70. The transfer tool 108 preferably is a universal T-bar handle. The cart 92 may also include a conveyor belt 120, or other motion enhancing device, to assist a user with moving a delivery housing 70 proximate to a reactor housing (*e.g.*, 94, 96, 98,100, 102, 104, and 106).

[0023] Methods of radioisotope generation according to the invention may be described with reference to FIGs. 1 and 2. In certain embodiments, such methods involve positioning a first delivery vessel 68 comprising a solution of at least one radioisotope external to said reactor housing 4 and in fluid communication with said entry port 22 for a time and under conditions effective to elute said chromatographic column 18 with at least a portion of said solution. The first delivery vessel 68 may be positioned by mating said first coupling 74 at said first end 72 of said delivery housing 70 with transfer tool 108 and lifting the delivery housing 70. The coupling 78 at said second end 76 of said first delivery housing 70 may be mated with a coupling on said reactor housing 4 that is compatible with said coupling 78 at said second end 76 of said first delivery housing 70. The delivery vessel 68 may be removed from said position relative to said reactor housing 4 by lifting said delivery housing 70. Subsequent delivery vessels comprising saline solution or a solution of at least one radioisotope may be used to elute said column 18 with at least a portion of said solutions. A collection vessel 84 may be positioned external to said reactor housing 4 and in fluid communication with said exit port 22 via said filter module 60. The column 18, column assembly 20, filter module 60, filter membrane 90, sterile needle 58, delivery vessel 68, collection vessel 84 and/or saline vessel 82 may be removed from said reactor housing 10 and may be replaced by subsequent columns, column assemblies, filter modules, filter membranes, sterile needles, delivery vessels, collection vessels and/or saline vessels, respectively, as appropriate.

[0024] In certain embodiments, methods of radioisotope generation according to the invention involve the receipt of customer information including a target output of a radioisotope, the addition of a solution of a parent radioisotope to a delivery vessel in an amount sufficient to produce said target output upon decay of said parent radioisotope, and the shipment of said delivery vessel to said customer. The customer's generator system, in turn, may be loaded and re-loaded with varying volumes of said parent radioisotope effective to collect specific target concentrations of the desired radioisotope. The generator systems may be re-loaded more than 2 times, more preferably more than 4 times, and most preferably more than 6 times. Preferably, the customer information received includes a target output of Tc-99m from 1 to 50 Ci, and the solution added to the delivery vessel includes Mo-99 in an amount sufficient to produce said target output upon decay of said Mo-99.

[0025] A kit for radioisotope generation is also contemplated and may be described with reference to FIGs. 1-3. The kit may include a column 18 or a column assembly 20, a delivery housing 70 containing a delivery vessel 68 comprising at least one radioisotope, a filter module 60 comprising a radioactive shielding material insert 88, a transfer tool 108, a plurality of evacuated collection vessels 84 and a plurality of saline vessels 82. The kit can be used to replenish existing reactor housings 4 and thereby avoids shipment and disposal thereof.

In addition, exemplary steps for radioisotope generation according to the invention may be described with reference to FIGs. 1-7. As shown in FIG. 5, a column assembly 20 may be inserted into an internal volume 12 of a reactor housing 4 (said reactor housing having an entry port 22 and an exit port 24), through an opening 16 in the surface 14 of the reactor housing 4. Then, as shown in FIG. 6, the opening 16 above the column 18 may be plugged

with a radioactive shielding plug **26**. Then, as shown in **FIG. 7**, an adapter disk **28**, comprising a ridge of guide material **30** extending around the entry port **22** and a ridge of guide material **32** extending around the exit port **24**, may be disposed on the surface **14** of the reactor housing **4.** A filter module **60** may then be disposed external to the reactor housing **4** in fluid communication with the exit port **24**. A delivery vessel **68** containing a radioisotope, contained in a delivery housing **70**, may then be disposed external to the reactor housing **4** and in fluid communication with the entry port **22.** An evacuated collection vessel **84**, contained with a collection housing **86**, may then be disposed external to the reactor housing **4** in fluid communication with the exit port **24** via the filter module **60.** After waiting a suitable amount of time (*e.g.*, more than about three minutes), the collection vessel **84** and then the delivery vessel **68** may be removed. An adapter guide ridge **81** may then be disposed on the surface of the adapter disk **28** such that it extends around the entry port **22**. A saline vessel **82** may then be disposed external to the reactor housing **4** and in fluid communication with the entry port **22**. An evacuated collection vessel **84**, contained within a collection housing **86**, may then be disposed external to the reactor housing **4** and in fluid communication with the exit port **24** via the filter module **60.** After again waiting a suitable amount of time, said collection housing **86** may be removed. An evacuated collection vessel **84**, contained within a collection housing **86**, may then be disposed external to the reactor housing **4** and in fluid communication with the exit port **24** via the filter module **60**. The aforementioned exemplary steps may be repeated with subsequent delivery vessels, columns, filter modules and collection vessels as may be appropriate.

[0026] Thus, there have been described systems and methods for producing customized, predictable and reproducible supplies of radioisotopes that do not require weekly replacement, handling and transport of heavy shielding materials associated with conventional generators. It will be appreciated that numerous modifications may be made to the example embodiments described herein, and that such modifications do not depart from the scope of the invention as defined by the following claims.

Claims

1. A system comprising:

a reactor housing (4) that is fabricated from a radioactive shielding material and has both an internal volume (12) and a surface (14) that comprises an entry port (22) and an exit port (24);
a first chromatographic column (18) that is positioned within said internal volume (12) wherein;
said first chromatographic column (18) is housed within a column assembly (20) comprising:

a column housing (50) defining an internal space for receiving said first chromatographic column (18);
a column adaptor plate (40);
an exit pipe (66) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an exit connection (46) that is mounted on said column adaptor plate (40); and
an entry pipe (62) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an entry needle (52) that is disposed in an adaptor plate entry port (44) that is mounted on said column

adaptor plate (40);
wherein said column assembly (20) is configured for insertion as a unit into the internal volume (12) of said reactor housing (4) through an opening in an upper portion of said reactor housing (4); and;
a filter module (60) that is disposed external to said reactor housing (4) and in fluid communication with said column (18).

2. The system of claim 1 further comprising one or more of the following:

(i) a delivery vessel (68) that is disposed external to said reactor housing (4) and in fluid communication with said first chromatographic column (18);
(ii) a collection vessel (84) that is disposed external to said reactor housing (4) and in fluid communication with said first chromatographic column (18) via said filter module (60);
(iii) an adapter disk (28) disposed on said reactor housing (4), comprising a ridge of material (30) that extends around said entry port (22) and a ridge of material (34) that extends around said exit port (24); and
(iv) a cart (92) that includes one or more of
a plurality of delivery vessels (68) that each independently comprises a reactor vessel;
a plurality of delivery vessels that each independently comprises a solution of at least one radioisotope and is contained within a delivery housing that is fabricated from radioactive shielding material;
a plurality of evacuated collection vessels (84); and
a plurality of saline vessels (82).

3. A method comprising the steps of:

providing a system that comprises:

a reactor housing (4) that is fabricated from a radioactive shielding material and has both an internal volume (12) and a surface (14) that comprises an entry port (22) and an exit port (24);
a first chromatographic column (18) that is positioned within said internal volume (12) wherein
said first chromatographic column (18) is housed within a column assembly (20) comprising:

a column housing (50) defining an internal space for receiving said first chromatographic column (18);
a column adaptor plate (40);
an exit pipe (66) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an exit connection (46) that is mounted on said column adaptor plate (40); and
an entry pipe (62) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an entry needle (52) that is disposed in an adaptor plate entry port (44) that is mounted on said column adaptor plate (40);

wherein said column assembly (20) is configured for insertion as a unit into the internal volume (12) of said reactor housing (4) through an opening in an upper portion of said reactor housing (4); and;
a first filter module (60) that is disposed external to said reactor housing (4) and in fluid communication with said first chromatographic column (18); and
positioning a first delivery vessel (68) comprising a solution of at least one radioisotope external to said reactor housing (4) and in fluid communication with said first chromatographic column (18) for a time and under conditions effective to elute said first chromatographic column (18) with at least a portion of said solution; and,
positioning a collection vessel (84) external to said reactor housing (4) and in fluid communication with said exit port (24) via said filter module (60).

4. The method of claim 3 further comprising

(i) removing said first delivery vessel (68) from said position relative to said reactor housing (4); and/or
(ii) removing said first filter module (60).

5. The method of claim 3 comprising the steps of:

providing said system; and
positioning a first delivery vessel (68) comprising a solution of at least one radioisotope external to said reactor housing (4) and in fluid communication with said entry port (44) for a time and under conditions effective to elute said chromatographic column (18) with at least a portion of said solution.

6. The method of claim 3 comprising the steps of:

providing said system; and
removing said first chromatographic column (18) from said reactor housing (4).

7. The method of claim 3 further comprising positioning a subsequent chromatographic column in said reactor housing (4) such that a first end of said column is in fluid communication with said entry port (22) and a second end of said column is in fluid communication with said exit port (24).

8. The method of claim 3 comprising the steps of:

providing said system; and
removing said first filter module (60).

9. The method of claim 3 further comprising positioning a subsequent filter module external to said reactor housing (4) and in fluid communication with said exit port (24).

10. The method of claim 3 comprising the steps of:

providing said system; and
positioning a collection vessel (84) external to said reactor housing (4) and in fluid communication with said exit port (24) via said filter module (60).

11. The method according to claim 3 further comprising the steps of:

receiving customer information including a target output of a radioisotope; and
adding a solution of a parent radioisotope to a delivery vessel (68) in an amount sufficient to produce said target output upon decay of said parent radioisotope.

12. The method of claim 11 further comprising shipping said delivery vessel (68) to said customer.

13. A method comprising the steps of:

providing a system that comprises:
a reactor housing (4) that is fabricated from a radioactive shielding material and has both an internal volume (12) and a surface (14) that comprises an entry port (22) and an exit port (24); and
a first chromatographic column (18) that is positioned within said internal volume (12).
wherein said first chromatographic column (18) is housed within a column assembly (20) comprising
a column housing (50) defining an internal space for receiving said first chromatographic column (18);
a column adaptor plate (40);
an exit pipe (66) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an exit connection (46) that is mounted on said column adaptor plate (40); and
an entry pipe (62) in fluid communication with said first chromatographic column (18) via said column housing (50) and with an entry needle (52) that is disposed in an adaptor plate entry port (44) that is mounted on said column adaptor plate (40);
wherein said column assembly (20) is configured for insertion as a unit into the internal volume (12) of said reactor housing (4) through an opening in an upper portion of said reactor housing (4);
removing said first chromatographic column (18) from said internal volume (12) by extracting said column assembly (20) through an opening in an upper portion of said reactor housing (4);
positioning a second chromatographic column within said internal volume (12) by inserting a second column assembly through said opening in said reactor housing (4);
positioning a first delivery vessel (68) comprising a solution of at least a first radioisotope external to said reactor housing (4) and in fluid communication with said second chromatographic column for a time and under conditions effective to elute said second chromatographic column with at least a portion of said solution; and,
positioning a first collection vessel (84) external to said reactor housing (4) and in fluid communication with said second chromatographic column.

14. The method of claim 13 further comprising removing said first delivery vessel (68) from said position relative to said reactor housing (4).

15. The method of claim 13 further comprising positioning a second delivery vessel comprising saline solution external to said reactor housing (4) and in fluid communication with said second chromatographic column for a time and under conditions effective to elute said second chromatographic column with at least a portion of said saline solution.

16. The method of claim 13 further comprising communicating a target output of at least a second radioisotope to a vendor of said solution of at least a first radioisotope.

Patentansprüche

1. System, umfassend:

ein Reaktorgehäuse (4), das aus einem Radioaktivität abschirmenden Material hergestellt ist und das sowohl ein inneres Volumen (12) als auch eine Oberfläche (14) mit einer Eintrittsöffnung (22) und einer Austrittsöffnung (24) aufweist,
eine erste chromatographische Säule (18), die in dem inneren Volumen (12) angeordnet ist, wobei
die erste chromatographische Säule (18) in einer Säulenanordnung (20) angeordnet ist, die:

ein Säulengehäuse (50), das einen inneren Raum zum Aufnehmen der ersten chromatographischen Säule (18) definiert,
eine Säulenanschlussplatte (40),
ein Austrittsröhrchen (66), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Austrittsverbindung (46), die auf der Säulenanschlussplatte (40) montiert ist, und
ein Eintrittsröhrchen (62), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Eintrittsnadel (52), welche in einer Anschlussplatteneintrittsöffnung (44) angeordnet ist, die auf der Anschlussplatte (40) montiert ist, umfasst,

wobei die Säulenanordnung (20) zum Einführen als eine Einheit in das innere Volumen (12) des Reaktorgehäuses (4) durch eine Öffnung in einem oberen Abschnitt des Reaktorgehäuses (4) ausgestaltet ist, und
ein Filtermodul (60), das außerhalb des Reaktorgehäuses (4) angeordnet ist und in Fluidverbindung mit der Säule (18) steht.

2. System nach Anspruch 1, das weiter eines oder

mehrere der nachfolgenden Merkmale aufweist:

(i) ein Abgabebehälter (68), der außerhalb des Reaktorgehäuses (4) angeordnet ist und der in Fluidverbindung mit der ersten chromatographischen Säule (18) steht,
(ii) ein Sammelbehälter (84), der außerhalb des Reaktorgehäuses (4) angeordnet ist und der über das Filtermodul (60) in Fluidverbindung mit der ersten chromatographischen Säule (18) steht,
(iii) eine Adapterscheibe (28), die auf dem Reaktorgehäuse (4) angeordnet ist und einen Materialwulst (30) aufweist, der sich um die Eintrittsöffnung (22) herum erstreckt, und einen Materialwulst (34), der sich um die Austrittsöffnung (24) herum erstreckt, und
(iv) einen Wagen (92), umfassend einen oder mehrere aus einer Mehrzahl von Abgabebehältern (68), von denen jeder unabhängig voneinander einen Reaktorbehälter aufweist,
einer Mehrzahl von Abgabebehältern, von denen jeder unabhängig voneinander eine Lösung von zumindest einem Radioisotop aufweist und in einem Abgabegehäuse enthalten ist, welches aus einem Radioaktivität abschirmenden Material hergestellt ist,
einer Mehrzahl von evakuierten Sammelbehältern (84) und
einer Mehrzahl von Salzbehältern (82).

3. Verfahren, welches die Schritte aufweist:

Bereitstellen eines Systems, umfassend:

ein Reaktorgehäuse (4), das aus einem Radioaktivität abschirmenden Material hergestellt ist und das sowohl ein inneres Volumen (12) als auch eine Oberfläche (14) mit einer Eintrittsöffnung (22) und einer Austrittsöffnung (24) aufweist,
eine erste chromatographische Säule (18), die in dem inneren Volumen (12) angeordnet ist, wobei
die erste chromatographische Säule (18) in einer Säulenanordnung (20) angeordnet ist, die:

ein Säulengehäuse (50), das einen inneren Raum zum Aufnehmen der ersten chromatographischen Säule (18) definiert,
eine Säulenanschlussplatte (40),
ein Austrittsröhrchen (66), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Austrittsverbindung (46), die auf der Säulenanschlussplatte (40) montiert ist, und
ein Eintrittsröhrchen (62), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Eintrittsnadel (52), welche in einer Anschlussplatteneintrittsöffnung (44) angeordnet ist, die auf der
Anschlussplatte (40) montiert ist, umfasst,

wobei die Säulenanordnung (20) zum Einführen als eine Einheit in das innere Volumen (12) des Reaktorgehäuses (4) durch eine Öffnung in einem oberen Abschnitt des Reaktorgehäuses (4) ausgestaltet ist, und
ein erstes Filtermodul (60), das außerhalb des Reaktorgehäuses (4)
angeordnet ist und in Fluidverbindung mit der Säule (18) steht, und Anordnen eines ersten Abgabebehälters (68), der eine Lösung von zumindest einem Radioisotop aufweist, außerhalb des Reaktorgehäuses (4) und derart in Fluidverbindung mit der ersten chromatographischen Säule (18) für eine Zeitspanne und unter Bedingungen, die ausreichen, um die erste chromatographischen Säule (18) mit zumindest einem Teil der Lösung zu eluieren, und

Anordnen eines Sammelbehälters (84) außerhalb des Reaktorgehäuses (4) derart, dass der Sammelbehälter über das Filtermodul (60) in Fluidverbindung mit der Austrittsöffnung (24) steht.

4. Verfahren nach Anspruch 3, welches weiter umfasst

(i) Entfernen des ersten Abgabebehälters (68) aus der Anordnung relativ zu dem Reaktorgehäuse (4) und/oder
(ii) Entfernen des Filtermoduls (60).

5. Verfahren nach Anspruch 3, welches die Schritte aufweist:

Bereitstellen des Systems und
Anordnen eines ersten Abgabebehälters (68), der eine Lösung von zumindest einem Radioisotop enthält, außerhalb des Reaktorgehäuses (4) und derart in Fluidverbindung mit der Eintrittsöffnung (44) für eine Zeitspanne und unter Bedingungen, die ausreichen, um die chromatographische Säule (18) mit zumindest einem Teil der Lösung zu eluieren.

6. Verfahren nach Anspruch 3, welches die Schritte

aufweist:

Bereitstellen des Systems und
Entfernen der ersten chromatographischen Säule (18) von dem Reaktorgehäuse (4).

7. Verfahren nach Anspruch 3, welches weiter aufweist: Anordnen einer nachfolgenden chromatographischen Säule in dem Reaktorgehäuse (4) derart, dass ein erstes Ende der Säule in Fluidverbindung mit der Eintrittsöffnung (22) und ein zweites Ende der Säule in Fluidverbindung mit der Austrittsöffnung (24) steht.

8. Verfahren nach Anspruch 3, welches die Schritte aufweist:

Bereitstellen des Systems und
Entfernen des ersten Filtermoduls (60).

9. Verfahren nach Anspruch 3, welches weiter das Anordnen eines nachfolgenden Filtermoduls außerhalb des Reaktorgehäuses (4) und in Fluidverbindung mit der Austrittsöffnung (24) umfasst.

10. Verfahren nach Anspruch 3, welches die Schritte aufweist:

Bereitstellen des Systems und
Anordnen eines Sammelbehälters (84) außerhalb des Reaktorgehäuses (4) derart,
dass der Sammelbehälter über das Filtermodul (60) in Fluidverbindung mit der Austrittsöffnung (24) steht.

11. Verfahren nach Anspruch 3, welches weiter die Schritte aufweist:

Empfangen von Benutzerinformationen einschließlich einer anvisierten Ausgabemenge eines Radioisotops und
Hinzufügen einer Lösung eines Ausgangsradioisotops in einen Abgabebehälter (68) in einer Menge ausreichend zum Herstellen der anvisierten Ausgabemenge aus der Verfallsreihe des Ausgangsradioisotops.

12. Verfahren nach Anspruch 11, welches weiter das Abgeben des Abgabebehälters (68) an den Benutzer umfasst.

13. Verfahren, welches die Schritte aufweist:

Bereitstellen eines Systems, umfassend:

ein Reaktorgehäuse (4), das aus einem Radioaktivität abschirmenden Material hergestellt ist und das sowohl ein inneres Volumen (12) als auch eine Oberfläche (14) mit einer Eintrittsöffnung (22) und einer Austrittsöffnung (24) aufweist, und
eine erste chromatographische Säule (18), die in dem inneren Volumen (12) angeordnet ist, wobei die erste chromatographische Säule (18) in einer Säulenanordnung (20) angeordnet ist, die:

ein Säulengehäuse (50), das einen inneren Raum zum Aufnehmen der ersten chromatographischen Säule (18) definiert,
eine Säulenanschlussplatte (40),
ein Austrittsröhrchen (66), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Austrittsverbindung (46), die auf der Säulenanschlussplatte (40) montiert ist, und
ein Eintrittsröhrchen (62), das in Fluidverbindung steht mit der ersten chromatographischen Säule (18) über das Säulengehäuse (50) und mit einer Eintrittsnadel (52), welche in einer Anschlussplattentrittsöffnung (44) angeordnet ist, die auf
der Anschlussplatte (40) montiert ist, umfasst,

wobei die Säulenanordnung (20) zum Einführen als eine Einheit in das innere Volumen (12) des Reaktorgehäuses (4) durch eine Öffnung in einem oberen Abschnitt des Reaktorgehäuses (4) ausgestaltet ist,

Entfernen der ersten chromatographischen Säule (18) aus dem inneren Volumen (12) durch Entnehmen der Säulenanordnung (20) durch eine Öffnung in einem oberen Abschnitt des Reaktorgehäuses (4),
Anordnen einer zweiten chromatographischen Säule innerhalb des inneren Volumens (12) durch Einführen einer zweiten Säulenanordnung durch die Öffnung in dem Reaktorgehäuse (4),
Anordnen eines ersten Abgabebehälters (68), der eine Lösung von zumindest einem ersten Radioisotop enthält, außerhalb des Reaktorgehäuses (4) und derart in Fluidverbindung mit der zweiten Säulenanordnung für eine Zeitspanne und unter Bedingungen, die ausreichen, um die zweite Säulenanordnung mit zumindest einem Teil der Lösung zu eluieren, und
Anordnen eines ersten Sammelbehälters (84) außerhalb des Reaktorgehäuses (4) und in Fluidverbindung mit der zweiten chromatogra-

phischen Säule.

14. Verfahren nach Anspruch 13, welches weiter aufweist: Entfernen des ersten Abgabebehälters (68) aus dessen Anordnung relativ zu dem Reaktorgehäuse (4).

15. Verfahren nach Anspruch 13, welches weiter umfasst: Anordnen eines zweiten Abgabebehälters, der eine Salzlösung enthält, außerhalb des Reaktorgehäuses (4) und derart in Fluidverbindung mit der zweiten chromatographischen Säule für eine Zeitspanne und unter Bedingungen, die ausreichen, um die zweite chromatographische Säule mit zumindest einem Teil der Salzlösung zu eluieren.

16. Verfahren nach Anspruch 13, welches weiter umfasst: Weitergabe der anvisierten Ausgabemenge zumindest eines zweiten Radioisotops an einen Lieferanten der Lösung zumindest eines ersten Radioisotops.

Revendications

1. Système comprenant :

un logement de réacteur (4) qui est fabriqué à partir d'un matériau de blindage radioactif et qui présente à la fois un volume interne (12) et une surface (14) qui comprend un orifice d'entrée (22) et un orifice de sortie (24) ;
une première colonne chromatographique (18) qui est positionnée à l'intérieur dudit volume interne (12) ; dans lequel
ladite première colonne chromatographique (18) est logée à l'intérieur d'un ensemble de colonne (20) comprenant :

un logement de colonne (50) définissant un espace interne pour recevoir ladite première colonne chromatographique (18) ;
une plaque d'adaptation de colonne (40) ;
un tuyau de sortie (66) en communication fluide avec ladite première colonne chromatographique (18) par l'intermédiaire dudit logement de colonne (50) et avec un raccord de sortie (46) qui est monté sur ladite plaque d'adaptation de colonne (40) ; et
un tuyau d'entrée (62) en communication fluide avec ladite première colonne chromatographique (18) par l'intermédiaire dudit logement de colonne (50) et avec une aiguille d'entrée (52) qui est disposée dans un orifice d'entrée de plaque d'adaptation (44) qui est monté sur ladite plaque d'adaptation de colonne (40) ;

dans lequel ledit ensemble de colonne (20) est configuré pour être inséré en tant qu'unité dans le volume interne (12) dudit logement de réacteur (4) à travers une ouverture dans une partie supérieure dudit logement de réacteur (4) ; et
un module de filtre (60) qui est disposé à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite colonne (18).

2. Système selon la revendication 1, comprenant en outre un ou plusieurs des éléments suivants :

(i) une cuve de distribution (68) qui est disposée à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite première colonne chromatographique (18) ;
(ii) une cuve de collecte (84) qui est disposée à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite première colonne chromatographique (18) par le biais dudit module de filtre (60) ;
(iii) un disque d'adaptation (28) disposé sur ledit logement de réacteur (4), comprenant un bourrelet de matière (30) qui s'étend autour dudit orifice d'entrée (22) et un bourrelet de matière (34) qui s'étend autour dudit orifice de sortie (24) ; et
(iv) un chariot (92) qui comprend un ou plusieurs d'une pluralité de cuves de distribution (68) qui comprennent chacune indépendamment une cuve de réacteur ;
d'une pluralité de cuves de distribution qui comprennent chacune indépendamment une solution d'au moins un radio-isotope et sont contenues à l'intérieur d'un logement de distribution qui est fabriqué à partir d'un matériau de blindage radioactif ;
d'une pluralité de cuves de collecte sous vide (84) ; et
d'une pluralité de cuves de solution saline (82).

3. Procédé comprenant les étapes de :

fournir un système qui comprend :

un logement de réacteur (4) qui est fabriqué à partir d'un matériau de blindage radioactif et qui présente à la fois un volume interne (12) et une surface (14) qui comprend un orifice d'entrée (22) et un orifice de sortie (24) ;
une première colonne chromatographique (18) qui est positionnée à l'intérieur dudit volume interne (12) dans lequel
ladite première colonne chromatographique (18) est logée à l'intérieur d'un ensemble de colonne (20) comprenant :
un logement de colonne (50) définissant un espace interne pour recevoir ladite premiè-

re colonne chromatographique (18) ;
une plaque d'adaptation de colonne (40) ;
un tuyau de sortie (66) en communication fluide avec ladite première colonne chromatographique (18) par le biais dudit logement de colonne (50) et avec un raccord de sortie (46) qui est monté sur ladite plaque d'adaptation de colonne (40) ; et
un tuyau d'entrée (62) en communication fluide avec ladite première colonne chromatographique (18) par le biais dudit logement de colonne (50) et avec une aiguille d'entrée (52) qui est disposée dans un orifice d'entrée de plaque d'adaptation (44) qui est monté sur ladite plaque d'adaptation de colonne (40) ;
dans lequel ledit ensemble de colonne (20) est configuré pour être inséré en tant qu'élément dans le volume interne (12) dudit logement de réacteur (4) à travers une ouverture dans une partie supérieure dudit logement du réacteur (4) ; et
un premier module de filtre (60) qui est disposé à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite première colonne chromatographique (18) ; et

positionner une première cuve de distribution (68) comprenant une solution d'au moins un radio-isotope à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite première colonne chromatographique (18) pendant une durée et dans des conditions efficaces pour éluer ladite première colonne chromatographique (18) avec au moins une partie de ladite solution ; et
positionner une cuve de collecte (84) à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ledit orifice de sortie (24) par le biais dudit module de filtre (60).

4. Procédé selon la revendication 3, comprenant en outre :

(i) retirer ladite première cuve de distribution (68) de ladite position par rapport audit logement de réacteur (4) ; et/ou
(ii) retirer ledit premier module de filtre (60).

5. Procédé selon la revendication 3, comprenant les étapes de :

fournir ledit système ; et
positionner une première cuve de distribution (68) comprenant une solution d'au moins un radio-isotope à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ledit orifice d'entrée (44) pendant une durée et dans des conditions efficaces pour éluer ladite colonne chromatographique (18) avec au moins une partie de ladite solution.

6. Procédé selon la revendication 3, comprenant les étapes de :

fournir ledit système ; et
retirer ladite première colonne chromatographique (18) dudit logement de réacteur (4).

7. Procédé selon la revendication 3, comprenant en outre le positionnement d'une colonne chromatographique subséquente dans ledit logement de réacteur (4) de telle sorte qu'une première extrémité de ladite colonne est en communication fluide avec ledit orifice d'entrée (22) et qu'une seconde extrémité de ladite colonne est en communication fluide avec ledit orifice de sortie (24).

8. Procédé selon la revendication 3, comprenant les étapes de :

fournir ledit système ; et
retirer ledit premier module de filtre (60).

9. Procédé selon la revendication 3, comprenant en outre le positionnement d'un module de filtre subséquent à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ledit orifice de sortie (24).

10. Procédé selon la revendication 3, comprenant les étapes de :

fournir ledit système ; et
positionner une cuve de collecte (84) à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ledit orifice de sortie (24) par le biais dudit module de filtre (60).

11. Procédé selon la revendication 3 comprenant en outre les étapes de :

recevoir des informations de client comprenant une activité cible d'un radio-isotope ; et
ajouter une solution d'un radio-isotope parent dans une cuve de distribution (68) dans une quantité suffisante pour produire ladite activité cible lors de la dégradation dudit radio-isotope parent.

12. Procédé selon la revendication 11, comprenant en outre l'expédition de ladite cuve de distribution (68) audit client.

13. Procédé comprenant les étapes de :

fournir un système qui comprend :

un logement de réacteur (4) qui est fabriqué à partir d'un matériau de blindage radioactif et qui présente à la fois un volume interne (12) et une surface (14) qui comprend un orifice d'entrée (22) et un orifice de sortie (24) ; et
une première colonne chromatographique (18) qui est positionnée à l'intérieur dudit volume interne (12),
dans lequel ladite première colonne chromatographique (18) est logée à l'intérieur d'un ensemble de colonne (20) comprenant :
un logement de colonne (50) définissant un espace interne pour recevoir ladite première colonne chromatographique (18) ;
une plaque d'adaptation de colonne (40) ;
un tuyau de sortie (66) en communication fluide avec ladite première colonne chromatographique (18) par le biais dudit logement de colonne (50) et avec un raccord de sortie (46) qui est monté sur ladite plaque d'adaptation de colonne (40) ; et
un tuyau d'entrée (62) en communication fluide avec ladite première colonne chromatographique (18) par le biais dudit logement de colonne (50) et avec une aiguille d'entrée (52) qui est disposée dans un orifice d'entrée de plaque d'adaptation (44) qui est monté sur ladite plaque d'adaptation de colonne (40) ;
dans lequel ledit ensemble de colonne (20) est configuré pour être inséré en tant qu'élément dans le volume interne (12) dudit logement de réacteur (4) à travers une ouverture dans une partie supérieure dudit logement de réacteur (4) ; et
retirer ladite première colonne chromatographique (18) dudit volume interne (12) en extrayant ledit ensemble de colonne (20) à travers une ouverture dans une partie supérieure dudit logement de réacteur (4) ;
positionner une seconde colonne chromatographique à l'intérieur dudit volume interne (12) en insérant un second ensemble de colonne à travers ladite ouverture dans ledit logement de réacteur (4) ;
positionner une première cuve de distribution (68) comprenant une solution d'au moins un premier radio-isotope à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite seconde colonne chromatographique pendant une durée et dans des conditions efficaces pour éluer ladite seconde colonne chromatographique avec au moins une partie de ladite solution ; et
positionner une première cuve de collecte (84) à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite seconde colonne chromatographique.

14. Procédé selon la revendication 13, comprenant en outre le retrait de ladite première cuve de distribution (68) de ladite position par rapport audit logement de réacteur (4).

15. Procédé selon la revendication 13, comprenant en outre le positionnement d'une seconde cuve de distribution comprenant une solution saline à l'extérieur dudit logement de réacteur (4) et en communication fluide avec ladite seconde colonne chromatographique pendant une durée et dans des conditions efficaces pour éluer ladite seconde colonne chromatographique avec au moins une partie de ladite solution saline.

16. Procédé selon la revendication 13, comprenant en outre la communication d'une activité cible d'au moins un second radio-isotope à un fournisseur de ladite solution d'au moins un premier radio-isotope.

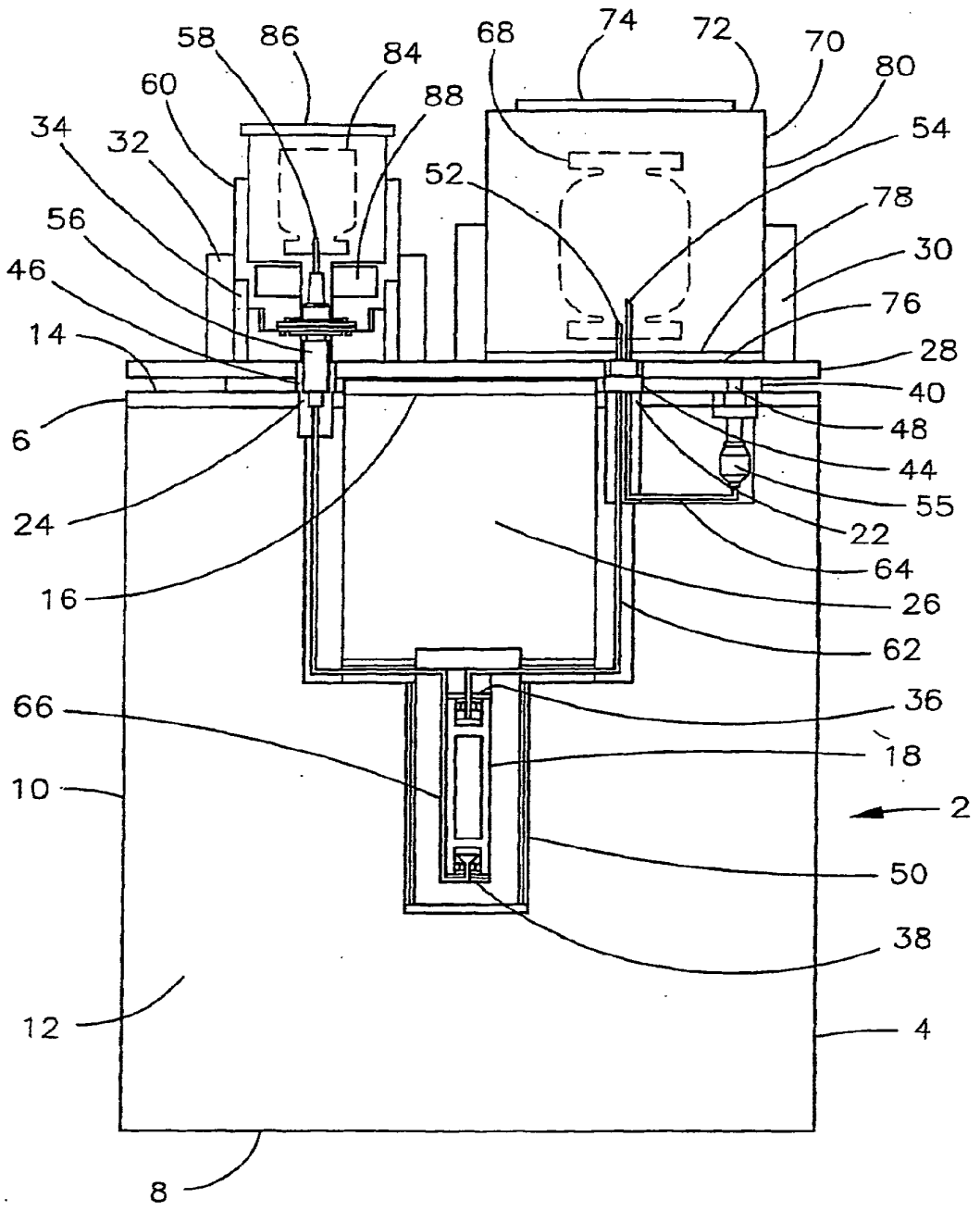
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Fig. 1

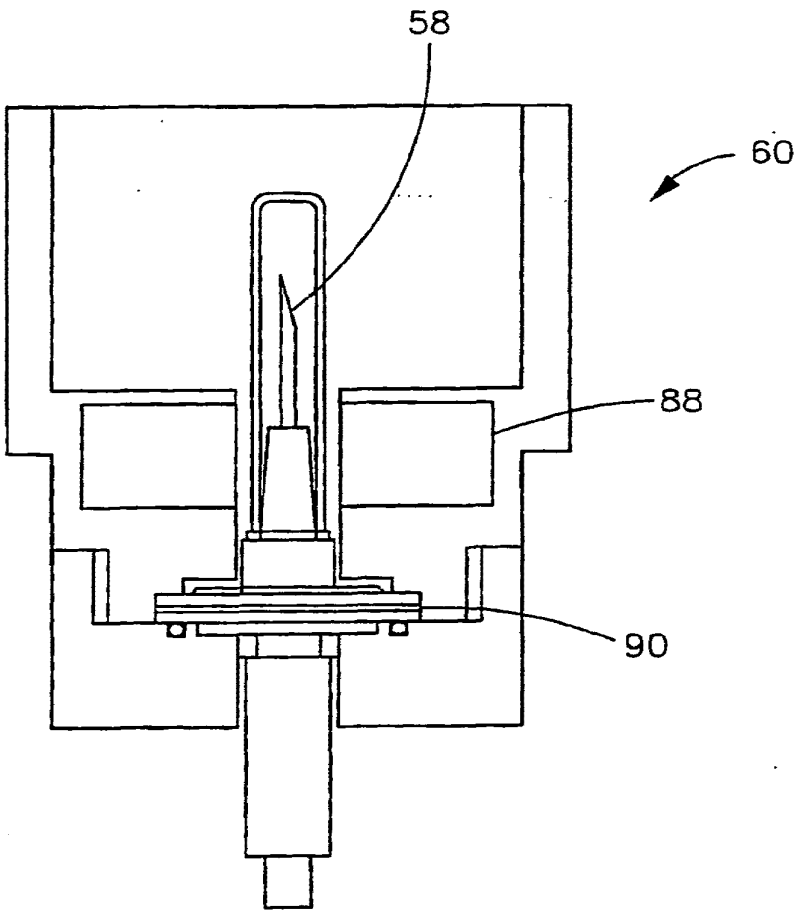

Fig. 2

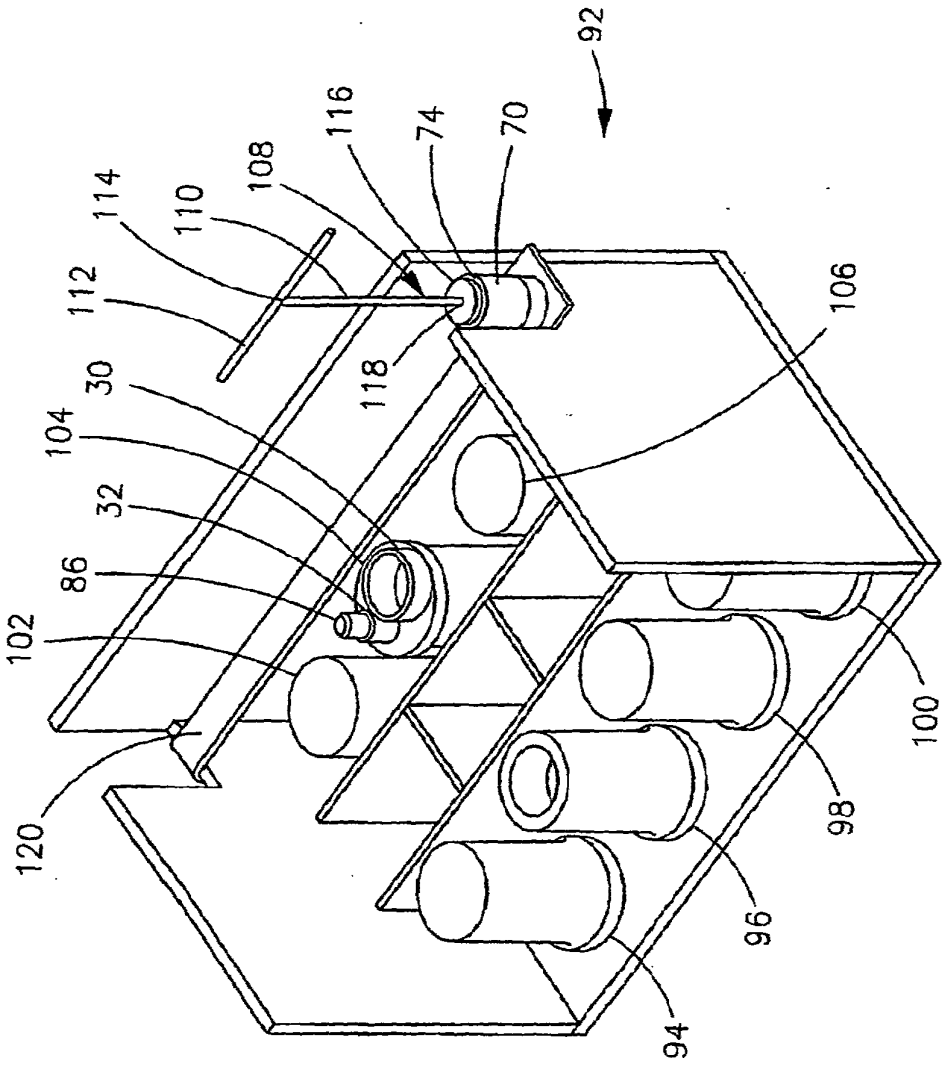
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Fig. 3

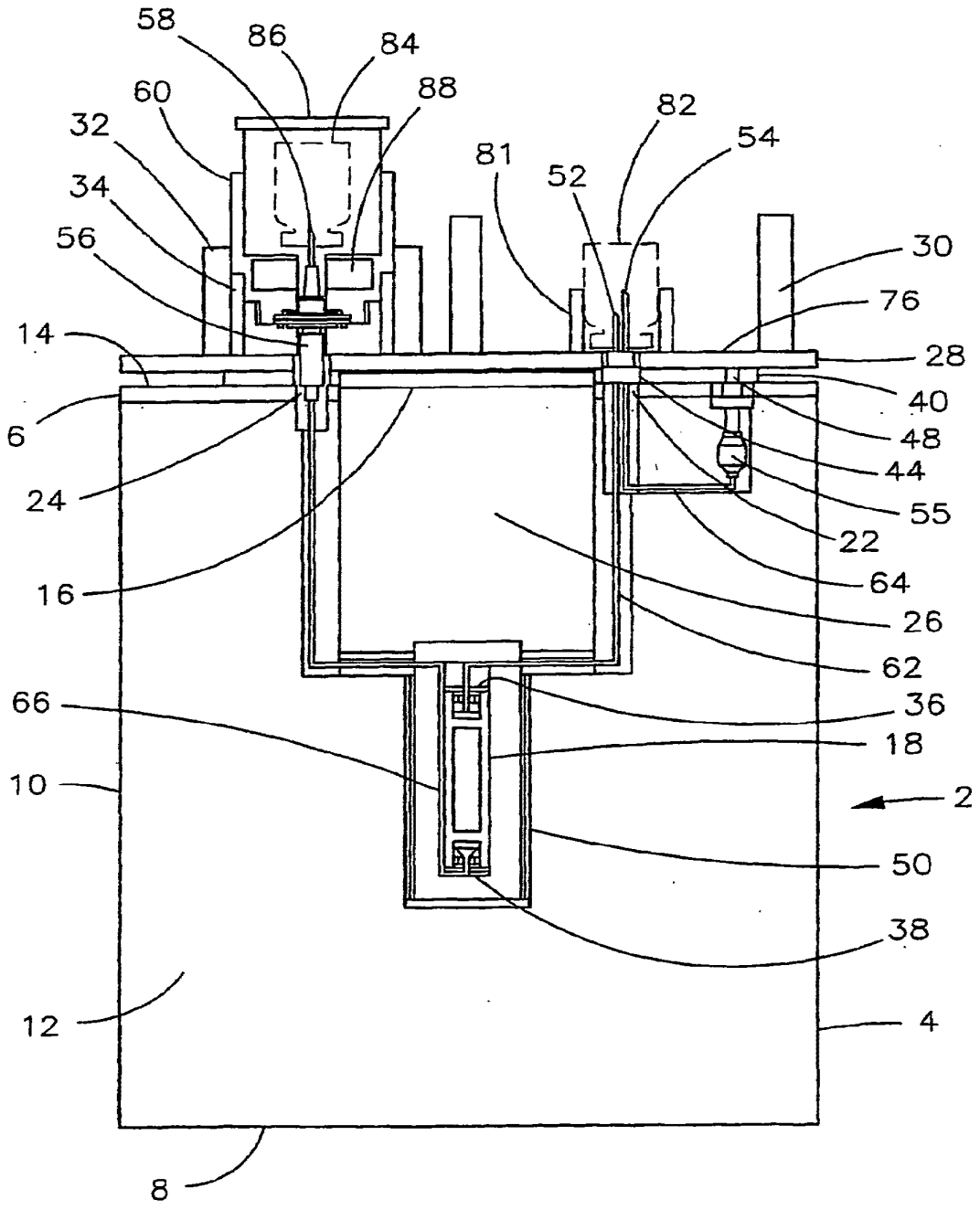
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Fig. 4

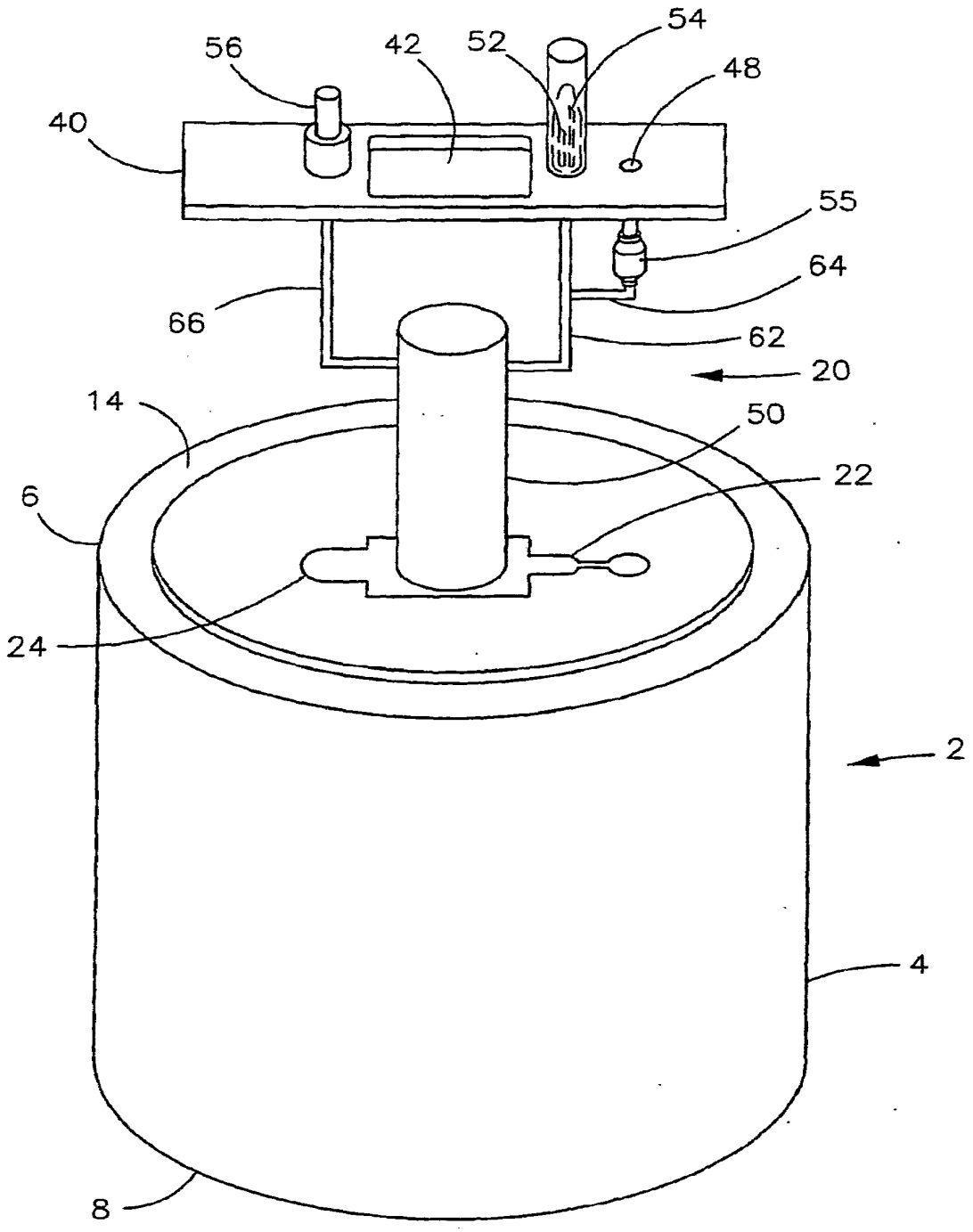

Fig. 5

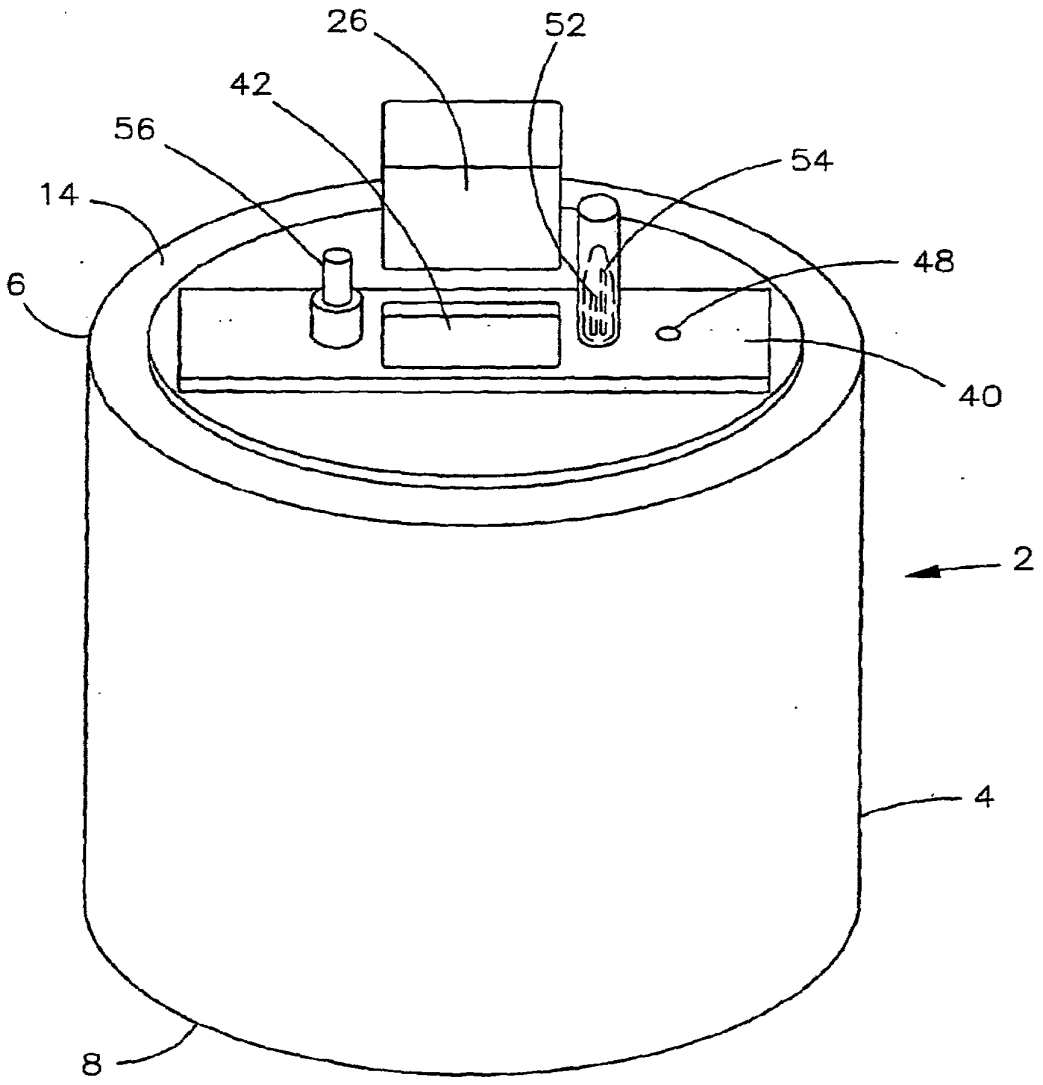

Fig. 6

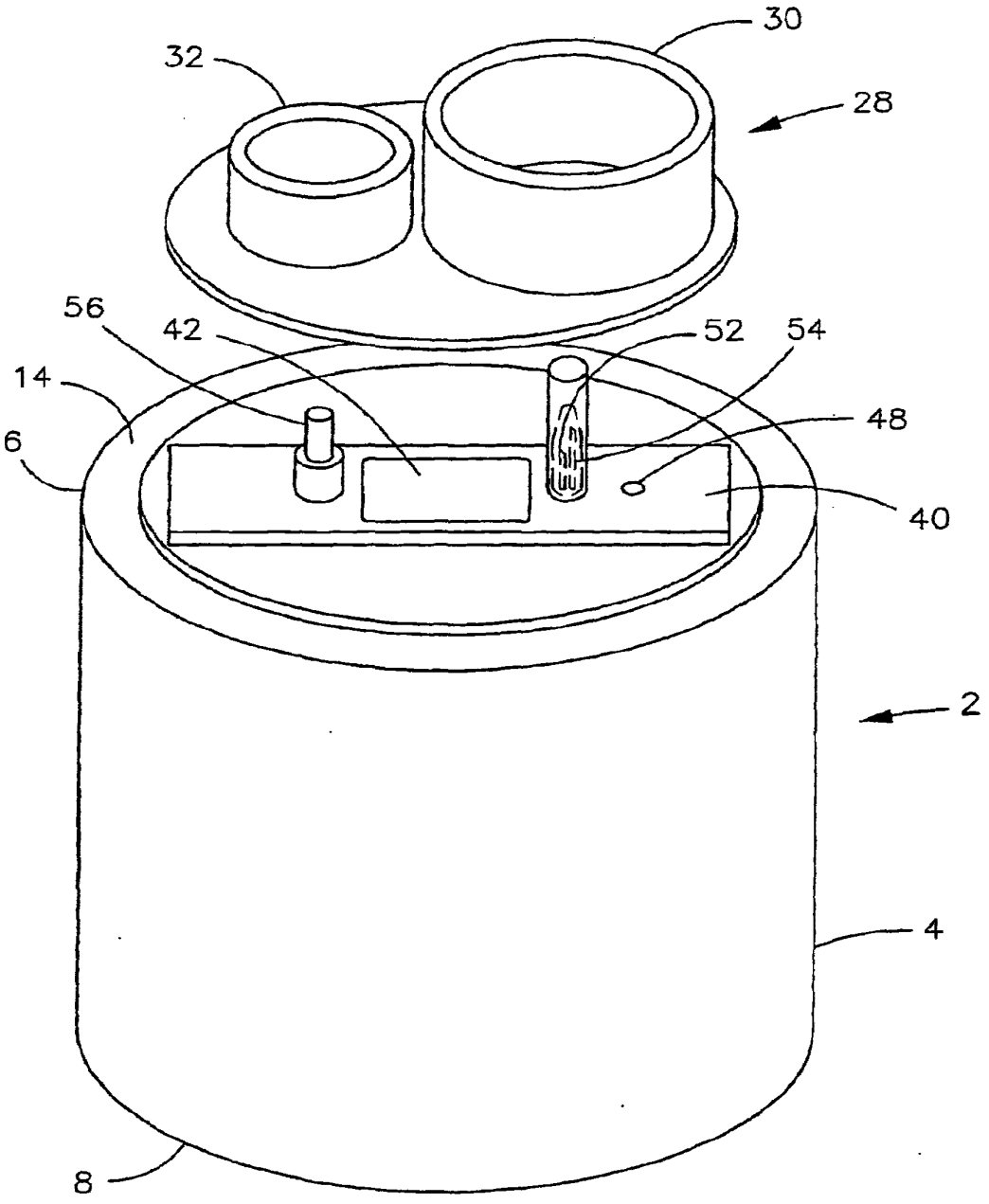

Fig. 7

REFERENCES CITED IN THE DESCRIPTION

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Non-patent literature cited in the description

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Espacenet

Bibliographic data: CN1968653 (A) — 2007-05-23

Method system and apparatus for operating a medical injector and diagnostic imaging device

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Applicant(s): E Z EM INC [US] ± (E-Z-EM INC, ; ACIST MEDICAL SYSTEMS, INC)

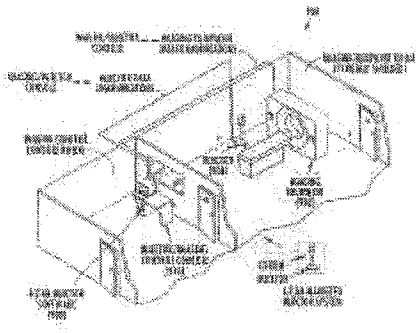
Classification: - international: ***A61B6/00; A61M5/00; A61M5/172;*** *A61B6/03*
- cooperative: **A61B6/463; A61B6/481; A61B6/504; A61M5/007; A61M5/172;** A61B6/032; A61B6/4085; A61B6/467; A61B6/468; A61M2205/3561; A61M2205/502

Application number: CN2005810953 20050125

Priority number(s): WO2005US02282 20050125 ; US20040543601P 20040211

Also published as: CN1968653 (B) WO2005076810 (A2) WO2005076810 (A3) US2005203389 (A1) KR20060111719 (A) KR100811667 (B1) JP2011045731 (A) JP2007523697 (A) EP1750583 (A2) EP1750583 (A4) CN101579239 (A) CA2555764 (A1) less

Abstract of CN1968653 (A)



The invention is generally directed, but not limited to, a method system and apparatus that allows an operator to control an injection device and imaging equipement from a common control console. The injection device may be used to administer a contrast medium into a patient so that imaging equipment can acquire internal images of the patient. The invention may include an injection system that can be bundled with software and/or hardware that can be used to modify an existing imaging control console so that it can be used to operate both the injection device and imaging device. In one embodiment, the common control console can access stored protocols that can contain operational parameters for the injection device, the imaging device, or both. Consequently, the efficiency of the test and final quality of the images can be improved.; Additionally, the combined control console will aid in the overall process of caring out the imaging tests.

[19] 中华人民共和国国家知识产权局

[51] Int. Cl.
A61B 6/00 (2006.01)

[12] 发明专利申请公布说明书

[21] 申请号 200580010953.5

[43] 公开日 2007 年 5 月 23 日

[11] 公开号 CN 1968653A

[22] 申请日 2005.1.25
[21] 申请号 200580010953.5
[30] 优先权
[32] 2004. 2.11 [33] US [31] 60/543,601
[86] 国际申请 PCT/US2005/002282 2005.1.25
[87] 国际公布 WO2005/076810 英 2005.8.25
[85] 进入国家阶段日期 2006.10.11
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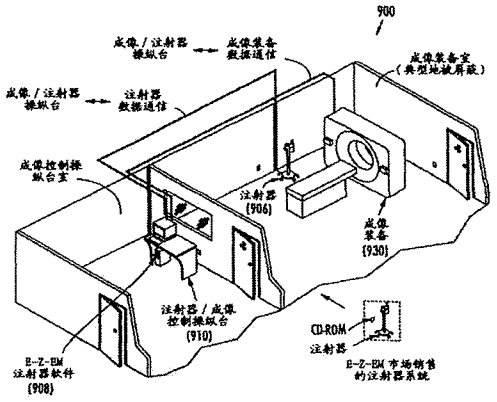
代理人 李 辉
权利要求书 9 页 说明书 22 页 附图 19 页

[54] 发明名称

用于操作医疗注射器和诊断成像装置的方法系统和设备

[57] 摘要

本发明涉及用于操作医疗注射器和诊断成像装置的方法系统和设备，总体上致力于但不限于允许操作员从公共控制操纵台控制注射装置和成像装置的方法系统和设备。 所述注射装置可以被用于向病人施用造影剂，使得成像装置可以获取该病人的内部影像。 本发明可以包括注射系统，该注射系统可封包有软件和/或硬件，该软件和/或硬件可用于将现有成像控制操纵台修改成可用于操作注射装置和成像装置两者。 在一个实施例中，所述公共控制操纵台可以访问存储的协议，该存储的协议可以包括用于注射装置、成像装置、或这两者的操作参数。因此，可改进检验的效率和影像的最终质量。 另外，组合的控制操纵台有助于执行成像检验的整个过程。



1、一种用于将造影剂注入人体并对所述造影剂成像的系统，所述系统包括：

a）注射器装置；

b）成像装置；以及

c）公共控制操纵台，所述公共控制操纵台可操作地连接到所述注射器装置和所述成像装置，所述公共控制操纵台包括显示单元和输入装置，由此，该公共控制操纵台可用于控制所述注射器装置和所述成像装置，并且从所述注射器装置和所述成像装置接收数据。

2、根据权利要求1所述的系统，其中，所述公共控制操纵台包括存储介质，所述存储介质用于记录来自所述注射器装置和所述成像装置的数据。

3、根据权利要求1所述的系统，其中，所述显示单元是计算机监视器、LCD显示器、等离子显示器、或者电视监视器。

4、根据权利要求1所述的系统，其中，所述公共控制操纵台包括能够同时在单个显示单元上进行显示的注射器装置控制接口和成像装置控制接口。

5、根据权利要求3所述的系统，其中，所述注射器装置控制接口显示在所述显示单元上的第一区中，而所述成像装置控制单元显示在所述显示单元上的第二区中。

6、根据权利要求4所述的系统，其中，所述公共控制操纵台包括注射器装置应用和单独的成像装置应用，其中，所述注射器装置应用和所述成像装置应用可同时运行。

7、根据权利要求6所述的系统，其中，所述注射器装置应用可与所述成像装置应用共享数据和文件。

8、根据权利要求6所述的系统，其中，所述成像装置应用可与所述注射器装置应用共享数据和文件。

9、根据权利要求1所述的系统，其中，所述公共控制操纵台是计算

机系统。

10、根据权利要求 9 所述的系统，其中，所述计算机系统包括能够操作所述注射器装置和所述成像装置的操作系统。

11、根据权利要求 10 所述的系统，其中，所述操作系统是 Linux、Windows、Mac OS、或者 Unix。

12、根据权利要求 1 所述的系统，其中，所述注射器装置、所述成像装置、以及所述公共控制操纵台通过网络可操作地连接。

13、根据权利要求 12 所述的系统，其中，所述网络是有线网络或无线网络。

14、根据权利要求 1 所述的系统，其中，所述公共控制操纵台包括能够操作所述注射装置和所述成像装置的公共软件应用。

15、根据权利要求 14 所述的系统，其中，所述公共软件应用包括存储的注射装置操作参数和成像装置操作参数。

16、根据权利要求 15 所述的系统，其中，所述注射装置操作参数包括从如下组中选择的操作参数，所述组包括流速、介质、体积、压力、相位、保持静脉通畅、暂停、保持、延迟、开始、以及停止的操作参数。

17、根据权利要求 15 所述的系统，其中，所述成像装置操作参数包括从如下组中选择的操作参数，所述组包括管电流、管电压、准直、节距、检测器配置、转动、暂停、扫描延迟、开始、以及停止的操作参数。

18、根据权利要求 15 所述的系统，其中，所述公共软件应用包括具有可在所述公共控制操纵台上创建、存储、以及调用的多个注射装置协议的数据库，所述注射装置协议包括用于操作所述注射装置的操作参数。

19、根据权利要求 15 所述的系统，其中，所述公共软件应用包括具有可在所述公共控制操纵台上创建、存储、以及调用的多个成像装置协议的数据库，所述成像装置协议包括用于操作所述成像装置的操作参数。

20、根据权利要求 15 所述的系统，其中，所述公共软件应用包括具有可在所述公共控制操纵台上创建、存储、以及调用的多个组合协议的数据库，所述组合协议包括用于操作所述注射装置和所述成像装置的操作参数。

21、一种用于获取主体的多幅内部影像的系统，所述系统包括：

a）注射器装置，其用于将造影剂注入所述主体内；

b）成像装置，其用于获取所述主体的内部影像；

c）处理单元，其可操作地连接到所述注射器装置，用于向所述注射器装置发送数据并从所述注射器装置接收数据；以及

d）公共控制操纵台，其可操作地连接到所述处理单元和所述成像装置，所述公共控制操纵台能够向所述处理单元和所述成像装置发送数据并从所述处理单元和所述成像装置接收数据。

22、根据权利要求21所述的系统，其中，所述公共控制操纵台包括显示单元。

23、根据权利要求22所述的系统，其中，所述处理单元被设置在所述注射装置中。

24、根据权利要求21所述的系统，其中，所述处理单元包括操作系统。

25、根据权利要求24所述的系统，其中，所述处理单元还包括在所述操作系统上运行的远程软件。

26、根据权利要求25所述的系统，其中，所述远程软件被用于控制所述注射装置，所述远程软件包括：PPREMOTE 软件模块、显示图形软件模块、ODBC 数据库软件模块、PPCOMM 软件模块、PPRESET 软件模块、以及 GINA.DLL 软件模块。

27、根据权利要求21所述的系统，其中，公共控制操纵台经由所述处理单元向所述注射器装置发送数据和指令。

28、根据权利要求27所述的系统，其中，所述处理单元通过网络连接可操作地连接到所述公共控制操纵台。

29、根据权利要求28所述的系统，其中，所述网络连接是有线网络连接或无线网络连接。

30、根据权利要求29所述的系统，其中，所述控制操纵台通过因特网连接或 web 浏览器从所述处理单元发送并接收数据。

31、根据权利要求26所述的系统，其中，所述远程软件包括多个存

储的协议，所述协议包括用于操作所述注射装置的操作参数。

32、根据权利要求 21 所述的系统，其中，所述公共控制操纵台可以同时控制所述注射装置和所述成像装置。

33、根据权利要求 21 所述的系统，其中，所述控制操纵台包括用于操作所述成像装置的多个存储的协议，并且所述处理单元包括用于操作所述注射装置的多个存储的注射器协议，所述公共控制操纵台能够选择性地检索并运行所述成像协议和所述注射协议，由此，所述公共控制操纵台能够同时操作所述注射装置和所述成像装置。

34、根据权利要求 26 所述的系统，其中，所述 PPREMOTE 软件模块包括具有用于对注射器数据变量进行存储、管理以及数学运算的程序例程的可执行程序。

35、根据权利要求 34 所述的系统，其中，所述 PPREMOTE 软件还包括用于对所述 ODBC 数据文件进行读取和写入的程序例程。

36、一种用于将现有成像控制操纵台修改成公共控制操纵台的设备，由此，该公共控制操纵台能够操作注射器装置和成像装置，所述设备包括：

注射器装置；和

远程软件应用，其用于操作所述注射器装置，其中，所述远程软件能够在成像控制操纵台上运行，由此，所述公共控制操纵台可以远程地操作所述注射器装置。

37、根据权利要求 36 所述的设备，其中，所述远程软件能够在 Windows、Unix、Mac OS、或者 Linux 环境下运行。

38、根据权利要求 36 所述的设备，其中，所述远程软件包括用于操作所述注射器装置的模块。

39、根据权利要求 38 所述的设备，其中，所述用于操作所述注射器装置的模块包括：PPREMOTE 软件模块、显示图形软件模块、ODBC 数据库软件模块、PPCOMM 软件模块、PPRESET 软件模块，以及 GINA.DLL 软件模块。

40、根据权利要求 36 所述的设备，其中，所述远程软件被存储在介

质存储装置上。

41、根据权利要求 40 所述的设备，其中，所述介质存储装置与所述注射器装置一起分布，并且所述设备的特征在于没有单独的注射器控制装置。

42、一种用于操作注射装置和成像装置的设备，该设备包括：

a）注射装置控制接口；

b）成像装置控制接口；以及

c）显示单元，其被配置成显示所述注射装置控制接口和所述成像装置控制接口。

43、根据权利要求 42 所述的设备，其中，所述注射装置控制接口和所述成像装置控制接口同时显示在所述显示单元上。

44、根据权利要求 42 所述的设备，其中，所述显示单元包括：

第一显示区，其被配置成显示所述注射装置控制接口；和

第二显示区，其被配置成显示所述成像装置控制接口。

45、根据权利要求 42 所述的设备，该设备进一步包括：

从所述显示单元到成像装置的第一通信连接部；和

从所述显示单元到注射装置的第二通信连接部。

46、根据权利要求 45 所述的设备，其中，所述第一通信连接部包括：

所述第二通信连接部；和

从所述注射装置到所述成像装置的第三通信连接部。

47、根据权利要求 45 所述的设备，其中，所述第二通信连接部包括：

所述第一通信连接部；和

从所述成像装置到所述注射装置的第三通信连接部。

48、根据权利要求 45 所述的设备，其中，所述第一通信连接部经由网络建立。

49、根据权利要求 48 所述的设备，其中，所述网络的一个链路是无线链路。

50、根据权利要求 45 所述的设备，其中，所述第二通信连接部经由网络建立。

51、根据权利要求 50 所述的设备，其中，所述网络的一个链路是有线链路、无线链路、或有线链路与无线链路的组合。

52、一种适于可操作地连接到成像装置显示器的注射器控制装置，所述注射器控制装置包括：

处理单元，其包括能够操作注射器装置的可执行程序模块；和

多个输入部和多个输出部，其用于向注射器装置发送数据并从注射器装置接收数据，并且用于向成像装置显示器发送数据并从成像装置显示器接收数据。

53、根据权利要求 52 所述的注射器控制装置，其中，在所述注射器控制装置与所述成像装置显示器之间的连接是有线连接、无线连接、或有线连接与无线连接的组合。

54、根据权利要求 52 所述的注射器控制装置，其中，所述成像装置显示器包括公共控制操纵台，该公共控制操纵台被配置成经由所述注射器控制装置远程地操作注射器装置。

55、根据权利要求 52 所述的注射器控制装置，其中，所述可执行程序模块包括从以下组中选择的操作参数，所述组包括流速、介质、体积、压力、相位、保持静脉通畅、暂停、保持、延迟、开始、以及停止的操作参数。

56、根据权利要求 52 所述的注射器控制装置，其中，所述成像装置显示器通过网络连接可操作地连接到所述注射器控制装置。

57、根据权利要求 56 所述的注射器控制装置，其中，所述网络连接包括通过 web 浏览器发送并接收数据。

58、一种用于操作医疗装备的方法，该方法包括以下步骤：

a）与注射装置控制接口交互；

b）与成像装置控制接口交互；以及

c）在公共显示单元上显示所述注射装置控制接口和所述成像装置控制接口。

59、根据权利要求 58 所述的方法，其中，在所述显示单元上同时显示所述注射装置控制接口和所述成像装置控制接口。

60、根据权利要求 59 所述的方法，其中，所述显示步骤包括以下步骤：

a）在第一显示区中显示所述注射装置控制接口；和

b）在第二显示区中显示所述成像装置控制接口。

61、根据权利要求 58 所述的方法，该方法进一步包括以下步骤：

a）建立从所述显示单元到成像装置的通信；和

b）建立从所述显示单元到注射装置的通信。

62、根据权利要求 61 所述的方法，其中，所述建立从所述显示单元到所述成像装置的通信的步骤包括以下步骤：

a）从所述显示单元向所述注射装置发送数据；和

b）从所述注射装置向所述成像装置中继传输所述数据。

63、根据权利要求 61 所述的方法，其中，所述建立从所述显示单元到所述注射装置的通信的步骤包括以下步骤：

a）从所述显示单元向所述成像装置发送数据；和

b）从所述成像装置向所述注射装置中继传输数据。

64、根据权利要求 61 所述的方法，其中，所述建立从所述显示单元到所述成像装置的通信的步骤包括以下步骤：

经由网络从所述显示单元向所述成像装置发送数据。

65、根据权利要求 64 所述的方法，其中，所述网络是有线网络、无线网络、或有线网络与无线网络的组合。

66、根据权利要求 61 所述的方法，其中，所述建立从所述显示单元到所述注射装置的通信的步骤包括以下步骤：

经由网络从所述显示单元向所述注射装置发送数据。

67、根据权利要求 66 所述的方法，其中，所述网络的一个链路是无线链路、有线链路、或无线链路与有线链路的组合。

68、一种从公共控制操纵台操作注射器装置和成像装置的方法，该方法包括以下步骤：

a）在显示单元上显示注射器装置控制接口；

b）在所述显示单元上显示成像装置控制接口；

c）从所述公共控制操纵台向所述注射器装置发送操作指令，并且任选地，接收从所述注射器装置到公共控制操纵台的数据；

d）从所述公共控制操纵台向所述成像装置发送操作指令；

e）利用所述注射器装置将造影剂注入主体内；

f）利用所述成像装置扫描所述主体；

g）获取所述主体的多个内部影像；以及

h）从所述成像装置向所述公共控制操纵台发送所述影像。

69、根据权利要求 68 所述的方法，其中，所述显示单元包括用于所述注射器装置控制接口的第一显示区，和用于所述成像装置控制接口的第二显示区。

70、根据权利要求 68 所述的方法，其中，所述注射器装置和所述成像装置共享公共接口。

71、根据权利要求 68 所述的方法，其中，所述公共控制操纵台包括用于存储操作所述注射器装置和所述成像装置的操作参数的数据库。

72、根据权利要求 71 所述的方法，其中，所述数据库包括能够通过所述公共控制操纵台检索的多个协议，所述多个协议包括预先存储的用于操作所述注射器装置、所述成像装置的操作参数，或者包括用于同时操作所述注射器装置和所述成像装置的组合协议。

73、根据权利要求 72 所述的方法，其中，所述向所述注射器装置或所述成像装置发送指令的步骤还包括以下步骤：

从所述数据库中选择并检索协议；

将所述协议加载到所述公共控制操纵台上；以及

开始所述协议，由此，所述协议向所述注射器装置、所述成像装置、或者所述注射器装置和所述成像装置两者发送指令。

74、根据权利要求 68 所述的方法，其中，所述注射器装置控制接口和所述成像装置控制接口同时运行在所述公共控制操纵台上。

75、根据权利要求 68 所述的方法，其中，所述公共控制操纵台通过网络连接与所述注射器装置和所述成像装置之间发送并接收数据。

76、根据权利要求 75 所述的方法，其中，所述网络连接是有线网络

连接或无线网络连接。

77、根据权利要求 68 所述的方法，该方法进一步包括在所述显示单元上显示所述影像的步骤。

用于操作医疗注射器和诊断成像装置的方法系统和设备

技术领域

本发明总体上涉及医疗成像领域，更具体地，涉及用于操作医疗注射器和诊断成像装置的方法和设备。

背景技术

成像装备可与将造影剂引入待检查的主体内的注射装置一起使用。然而，因为成像装备和注射装置是分立的系统，所以各自可具有其自己的接口显示装置。因此，在控制室中，技术员在试图通过分立的接口显示装置同时操作两个系统时可能遇到困难。根据对注射系统的概括评述，可更好地理解所述问题。

例如，与成像装备（例如，CT、MRI、超声波、荧光透视等）一起使用的用于施用造影剂的注射系统，通常具有在机电注射器附近的注射器装置控制接口。在某些情况下，该注射器装置控制接口与一件成像装备相邻。另外，注射系统可以具有远程定位装置控制接口。例如，该注射器装置控制接口可以设置在用于所述诊断放射和/或成像装备的相应成像控制室内。基于成像组（imaging suit）的程序方面或设计功能，多个用户接口可能是必需或有利的。例如，接口可位于病人侧和无电离辐射或其它诊断能量的控制室内。

在这点上，图 1 例示了与成像系统一起使用的现有技术的注射系统。注射器装置 100 通过数据通信线路 120 耦合到注射器装置控制接口 110，并且成像装备 130 通过数据通信线路 150 耦合到成像装置控制接口 140。有线成像组远程控制信号包括数字信号、模拟信号、TTL（晶体管-晶体管逻辑）信号以及/或这些信号类型的混合。

与成像装备在同一房间的针对注射器和/或成像装备的用户接口控制的应用是主要的，但不总是限于在将病人暴露于成像装备的能量之前或

其早期设置的与病人相关联的特征。对于其中病人已被安排好并且位于成像装备室中的诊断成像过程部分，临床医生通过两个不同的接口（即，注射器装置控制接口 110 和成像装置控制接口 140）远程地编程、开始、监视、控制以及终止成像过程。因此，在成像控制室中的临床医生需要同时并且有时要根据临床情况困难地监视用于成像控制单元和注射器控制单元的两个用户接口。

对于不同成像过程，存在这样一种需要，即，将注射的定时与成像能量的暴露定时同步。例如，在 CT 扫描期间，最初，可利用注射器以特定流速（例如，大约 3 cc/sec）对病人静脉施用规定剂量的碘化造影剂（例如，大约 100 cc）。在注射之后的一定最优时段（例如，在大约 10 到 45 秒的范围内）将该病人暴露于成像装备的能量。该最优时段何时出现取决于通过运行注射器施用给病人的造影剂的流体动力特性、病人的具体生理机能，以及要成像的关注组织区域。

当工作在成像组中的临床医生试图实现注射与成像暴露之间的同步时，具有用于注射器和成像装备的两个用户接口给他们带来了负担。为了解决该负担，一些成像装备制造者已经在他们的装备上设置了连接端口，以使注射器装置能够连接到成像装置。这些连接端口典型地提供 TTL 连接，由此实现有限的注射器和成像装备功能。然而，这种连接的功能性仅限于对注射的相应开始与扫描仪的随后开始进行同步。

在这点上，图 2 例示了连接到成像装置的注射装置。注射器装置 200 通过数据通信线路 220 耦合到注射器装置控制接口 210，并且成像装备 230 通过数据通信线路 250 耦合到成像装置控制接口 240。此外，注射器装置 200 还通过信号或数据通信线路 260 耦合到成像装备 230，但是，典型地，数据仅经由信号或数据通信线路 260 单向发送，并且仅用于注射器装置 200 和成像装置 230 的相应开始时间的同步。

由此，存在对一种系统的需求，通过该系统可以从单个接口或显示同时控制注射装置和成像装备的操作参数。

发明内容

在一个可选实施例中，本发明致力于一种从公共控制操纵台控制注射器装置和成像装备的系统和方法。该公共控制操纵台可包括多个接口或单个接口，由此，操作员可以同时控制注射和扫描参数。因此，该系统允许操作员更有效地控制并管理注射和扫描装置及过程。

公共控制操纵台可包括计算机或处理装置，所述计算机或处理装置可操作地与注射装置和成像装置相连接并且相通信。公共控制操纵台可与注射器装置和成像装备/装置之间发送并接收数据。公共控制操纵台可具有显示器或监视器，该显示器或监视器用于查看操作命令并且将操作命令输入至注射器装置和成像装备。公共控制操纵台可采用宽泛的各种不同方式（包括但不限于有线或无线方式）与注射装置通信。注射装置和成像装备可以是网络的一部分，由此，在控制操纵台与注射装置和成像装备之间共享数据。另选地，注射装置或成像装备可以用作彼此与公共控制操纵台之间的中介部（intermediary）。

注射器装置和成像装备可以单独具有处理能力，或者另选地，可由公共处理器控制。在本发明的一个另选实施例中，注射器装置包括数字介质，该数字介质包括可加载到现有成像控制操纵台上以便可远程控制注射装置的软件应用。在本实施例中，所述软件可以允许成像控制操纵台用作同时控制注射器装置和成像装备的公共控制器。所述软件可包括可用于控制并最优化注射器装置的广泛的各种模块。

公共控制操纵台可包括计算机，该计算机在可支持图形用户接口的操作系统下运行。操作系统可包括 Windows、Linux 等及其任意组合。图形用户接口可允许操作员同时管理并运行多个程序。例如，在本发明的一个实施例中，公共控制操纵台可具有同时显示的用于注射装置的接口和用于成像装备的接口。因此，操作员可以同时操作并控制注射装置和成像装备。另外，公共控制操纵台可以存储并检索可以用于操作装置和成像装备的协议。这种协议可包括为进行特定检验（例如，诸如 CT 扫描）而组合在一起的操作参数。可创建包括既用于注射装置也用于成像装备的操作指令的组合协议。所述协议可帮助改进检验的效率和质量。用于注射器的操作参数包括但不限于流速、介质、体积、压力、相位、保持

静脉通畅（KVO）、暂停、保持、延迟、开始，以及停止。用于成像装置的操作参数包括但不限于管电流、管电压、准直、节距、检测器设置、转动、暂停、扫描延迟、开始，以及停止。

在一个另选实施例中，本发明可包括同时控制注射器装置和成像装备的系统和方法。本发明还可提供在公共显示器上监视并控制装备的系统。另外，本发明可提供创建可用于操作注射装置和成像装备的存储协议的系统。在附图和详细描述中阐述了本发明的其它特征。

附图说明

已经概括地描述了本发明，现在对附图进行说明，所述附图不一定是按照比例绘制的，并且其中：

图 1 是在成像组内与成像系统一起使用的现有技术注射系统的例示图；

图 2 是在成像组内连接到成像装置的现有技术注射装置的例示图；

图 3 是示出根据本发明在成像组内共享成像/注射器控制操纵台的成像装置和注射器装置的例示图的对本发明一个另选实施例的非限制性描述；

图 4 是根据本发明至少一个另选实施例的，其中注射器和成像装置由公共控制器控制的系统的非限制性框图；

图 5 是根据本发明至少一个另选实施例的，其中注射器或者成像装备用作中介部的两种系统设计的非限制性框图；

图 6 是根据本发明至少一个另选实施例的，其中注射器和成像装备控制器、注射器、以及成像装备利用网络通信的系统的非限制性框图；

图 7 是根据本发明至少一个另选实施例的，其中各包括至少一个注射器和成像装备的多个成像组被连网在一起的系统的非限制性框图；

图 8 是根据本发明至少一个另选实施例的控制系统架构的非限制性框图；

图 9 是用于根据本发明至少一个另选实施例的包括注射器系统和软件的成像组的市场销售的注射器系统的非限制性例示图；

图 10 是根据本发明至少一个另选实施例的，具有其中存储介质上提供有控制软件的，用于注射器和成像装备的成像组控制的单个计算装置的系统的非限制性框图；

图 11 是根据本发明至少一个另选实施例的，利用网络设备的注射系统的非限制性框图；

图 12 是根据本发明至少一个另选实施例的，如何配置网络设备的示例的非限制性例示图；

图 12A 是根据本发明至少一个另选实施例的，如何将注射器和成像装备视为网络设备的示例的非限制性示意图；

图 13 是根据本发明至少一个另选实施例的，注射器/成像装备操纵台同时显示用于注射器的一专用显示区和用于成像装备的另一专用显示区的非限制性示意图；

图 14 是根据本发明至少一个另选实施例的系统的非限制性框图，其中，注射器控制应用和成像装备控制应用同时运行在一个计算机平台上，该计算机平台具有充足的处理资源、操作系统性能连接端口以及可选专用控制单元，该可选专用控制单元处理仅用于成像装备、仅用于注射器或者用于注射器和成像装备两者的指定控制功能；

图 15 是根据本发明至少一个另选实施例的接口设置的非限制性框图；

图 16 是根据本发明至少一个另选实施例的，其中用户接口应用程序包括注射器属性和成像装备属性的软件架构设置的非限制性框图；

图 17 是根据本发明至少一个另选实施例的，其中单个显示窗口包括注射器和相关联的成像装备两者的用户接口功能的公共注射器/成像装备操纵台的显示区的非限制性例示图；

图 18 是根据本发明至少一个另选实施例的，利用 web 浏览器的注射器系统的非限制性例示图；

图 19 是根据本发明至少一个另选实施例的单个用户接口上的整理存储过程的非限制性图，在该整理存储过程中存在用于注射器和成像装备的单独显示处理；以及

图 20 是根据本发明至少一个另选实施例的，把一个显示处理用于注射器和成像装备两者的单个用户接口上的整理存储过程，和该接口上的包括注射器操作参数和成像装备操作参数的存储过程的非限制性图。

具体实施方式

下面，参照附图对本发明进行描述。可以多种不同形式具体实现本发明，并且在此不应将附图和描述解释为限于在此阐述的实施例。贯穿全文相同标记都指示相同部件。当在此使用时，术语“示例性”指本发明的非限制性另选实施例。

在一个另选实施例中，本发明致力于一种从单个接口或显示部操作医疗注射器和诊断成像装置的方法和系统。所述注射/成像系统可包括注射器系统和成像系统，所述注射系统和成像系统与公共成像控制操纵台或公共接口装置通信并且可操作地受该公共成像控制操纵台或公共接口装置控制。

注射器系统可包括注射器装置和控制接口，该注射器装置可用于施用有效剂量的造影剂，而该控制接口可操作地连接到该注射器装置。该注射器系统可具有一个或更多个控制接口。该控制接口可与注射器装置之间发送并且接收数据。该注射器装置可以是用于将造影剂传递到病人体内或主体内的任何类型的注射器机构（例如，E-Z-EM EMPOWER CT 注射器）。成像系统可包括成像控制操纵台、成像装置或装备，所述成像装置或装备可以用于监视并显示病人体内或主体内的造影剂，获取病人或主体的内部影像，并且将其它诊断数据提供到控制操纵台或存储介质。该成像系统可具有可操作地连接到成像装备的成像接口。

术语“造影剂”包括任何合适的介质，其可被注入到人体或主体内，用于加亮和/或标识人体的选定区域。造影剂可包括但不限于盐介质、冲洗介质等及其任意组合。造影剂可与用于执行诸如 CT 扫描、MRI、超声波等的医疗诊断成像的成像装置一起使用。

参照图 3，示出了描述医学成像组的本发明的另选实施例。如图 3 所示，成像组 300 可包括公共控制操纵台室 304 和成像装备室 302。成像装

备室可包括成像装备装置 330 和注射器装置 306。成像装备装置 330 和注射器装置 306 可与公共控制操纵台 310 通信，并且可操作地受公共控制操纵台 310 控制。公共控制操纵台可以按广泛的各种方式与装置 306、330 通信。如图 3 所示，装置 306、330 可经由通信信道 320、340 分别与控制操纵台通信。在成像装备产生磁场的实施例中，可将装置与控制操纵台和任何附加装置之间的通信信道调整为与本发明的磁场基本上无反应。这种基本上无反应的通信信道包括例如光纤线路、诸如红外线的电磁发送器/接收器等及其任意组合。另外，在成像装备产生磁场的实施例中，成像装备室中的诸如注射器的装置可包括诸如黄铜的材料，该材料基本与磁场无反应。在其它实施例中，成像装备室中的装置可以在室内以基本上不干扰成像装备的方式来取向。

可使用公共控制操纵台从成像控制操纵台室远程地控制注射器装置和成像装置两者。公共控制操纵台可以是已经修改成也可远程操作注射器装置的成像控制操纵台。经修改的控制操纵台可同时控制注射装置和成像装备两者。可通过增加软件和/或硬件来修改成像控制装置。公共控制操纵台可与注射器装置之间发送并接收数据。在此限定的术语“远程”、“远程控制”，以及“远程地”定位，包括彼此没有物理接触的、彼此没有可操作地接合的，以及/或不同位于同一房间中但仍然可通过许多不同的通信技术电子地、机械地以及/或电子机械地进行通信的组件，上述通信技术包括但不限于诸如 Bluetooth®的无线连接装置，即，可将各种控制组件与注射器装置、成像装置、或者可位于医学成像组内部或外部的其它医学装置相连接的计算机网络。

注射器装置和成像装置还可以共享单个处理系统，或者另选地，注射器和成像装置两者可具有独立的处理系统。在本发明一个另选实施例中，如果两个装置具有一个处理系统，则可使用单个系统来控制两个装置。例如，单个系统可具有允许通过其它计算系统远程控制其的软件平台。在该实施例中，例如，操作员可从单个用户接口远程建立并监视注射和成像过程。在一个另选实施例中，该系统可以是专有系统计算架构或者使用市场上可买到的计算平台（例如，运行 Windows 或类似操作系

统的 PC 架构）的开放系统计算架构。在本发明的背景下，开放系统计算架构在其涉及任何注射器或成像装备或任何其它装置（医疗或其它）的控制时，可包括非特定硬件和没有并入预定功能的操作软件。开放系统可包括处理单元和输入-输出装置，诸如例如显示器、键盘，以及诸如鼠标器的定点装置。操作系统可包括现有开放系统计算架构。在另一另选实施例中，操作系统软件可提供限于执行计算平台自身的的基本功能的普通的易于解释的接口，和非专用于任何应用的内部电路的低级软件例程建立功能，如本发明的各个实施例中存在的功能。本发明还可致力于一种在公共显示器上操作注射器和成像装备系统的专用应用。

在一个实施例中，单个计算系统可用于运行多个处理，包括用于成像装备的第一处理，和用于注射器装置的第二处理。本系统可用于通过单个接口同时控制成像装备和注射器装置两者。在这点上，图 4 是例示可以通过公共接口 400 控制注射器装置 410 和成像装置 430 两者的框图。

公共控制操纵台可包括用于提供对成像装备和注射器的装置功能进行操作员控制的操作员接口。操作员接口可包括显示诸如操作控制、装置状态、所获影像等及其任意组合的注射器装置数据和成像装备数据的显示单元。典型地，该显示单元可包括可用于以操作员可读取的格式输出并显示数据、影像、程序等及其任意组合的任何类型的装置。这种装置可包括但不限于计算机和电视监视器、LCD 显示器、等离子显示器、视频显示器等。该显示装置还可包括诸如触摸屏的输入装置。显示单元可以用于观察影像并控制可用于同时操作多个装置的功能。

在另一另选实施例中，公共控制操纵台可包括市场上可买到的诸如 pc 的计算系统。诸如 PDA（个人数字助理）的其它计算系统和装置也可用于控制注射器和成像装置。公共控制操纵台可包括用于与注射器装置和成像装备之间发送并接收数据的多个输入部和多个输出部。这种输入部可包括但不限于键盘、触摸屏、按钮、诸如鼠标的定点控制装置、话音识别软件、专用控制器等及其任意组合。公共控制操纵台还可包括用于存储影像、统计数据、装置操作参数、数据、错误日志、个人备忘等及其任意组合的存储介质（例如，磁介质、光学介质、打印介质，或其

它)。

在另一另选实施例，控制操纵台和注射器及成像装置都可利用有线和无线通信协议可操作地彼此连接并通信。这种通信协议包括但不限于诸如 I2C、ACCESS.bus、RS-232、通用串行总线（USB）、IEE-488（GPIB）的串行通信协议，诸如 TCP/IP 的 LAN/因特网协议，诸如 802.11x 的无线协议；以及蓝牙（Bluetooth）等。通信协议还可包括专有系统。控制操纵台还可利用专用通信信道连接到装置。在这点上，图 4 例示了系统可包括可用于将公共控制操纵台连接到装置的专用通信信道 420、440。另选地，注射器和成像装备可利用不同通信协议与公共控制操纵台通信。例如，串行数据通信信道可以用于在公共控制操纵台与注射器装置之间传递数据，而 TCP/IP 网络可以用于在公共控制操纵台与成像装备之间传递数据。

在本发明另一另选实施例中，注射器装置或成像装备也可用作中介部，使得公共控制操纵台能够通过成像装备与注射器通信，或者相反通过注射器与成像装备通信。在这点上，图 5 例示了其中注射器或成像装备可用作中介部的两种另选系统设计。在系统 500 中，公共控制操纵台 505 经由通信信道 515 与成像装备 510 直接通信。成像装备 510 又经由通信信道 525 与注射器装置 520 直接通信。在系统 530 中，控制操纵台 535 与注射器装置 540 直接通信，注射器装置 540 又与成像装备 550 直接通信。注射器装置和成像装备还可各自独立具有处理能力。这样，每个装置都可以代表另一装置作为通信网络集线器或中介部来处理数据。在本发明的其它另选实施例中，注射器和成像装备都可具有可编程的架构和处理能力，以在向控制操纵台传送应用特定数据之前、期间以及之后对该应用特定数据进行处理。

在本发明的另选实施例中，成像装备、注射器装置、以及公共控制操纵台可通过网络环境可操作地彼此连接并通信。在这种环境下，典型地利用诸如网络集线器、交换机或路由器的独立连网装置互连控制操纵台和装置。在这点上，图 6 例示了其中使用连网装置以便于各个装置与控制操纵台之间的通信的系统。如图 6 所示，公共控制操纵台 606 经由

连网装置 630 与注射器装置 610 和成像装备 620 通信。在例示的实施例中，来自注射器装置和成像装备的数据可以同时显示在单个操作员接口上，并且利用公共通信协议（例如，有线或无线）将该数据传送到网络集线器。

在本发明的另一另选实施例中，用于互连装置和控制操纵台的连网系统可从广泛的各种网络形式中选择。连网形式可包括但不限于 LAN（局域网）、WAN（广域网）、CAN（校域网）、WWW（万维网）等及其组合。装置的网络拓扑还可根据设计者的偏好而改变。网络拓扑图可包括但不限于总线拓扑、环形拓扑、星形拓扑等及其组合。

参照图 7，例示了由多个成像组组成的系统。在成像组 700 中，示出了利用通信连网装置 720 与注射器装置 710 和成像装备 715 互连的公共控制操纵台 705。另选地，可以通过网络或连网装置互连多个成像组。在这点上，图 7 例示了成像组 700 可以可操作地连接到第二成像组 725。如图 7 所示，连网装置 720 与位于独立成像组 725 中的第二连网装置 755 通信。多个成像组可以被连网在一起并且经由任何数量的公共控制操纵台进行控制。在一个实施例中，控制操纵台和成像装备及注射器装置可都连接在公共子网上，该公共子网是共享公共地址部分的网络的一部分。例如，在诸如因特网的 TCP/IP 网络中，子网被限定为其 IP 地址具有相同前缀的全部装置。由此，与控制操纵台和成像/注射器装置的网络连接在同一子网上的操作员可以控制并访问装置。

图 7 还例示了公共控制操纵台可用于控制多个成像装置和/或注射器装置。在这点上，图 7 示出了具有可操作地连接到多个注射器装置 735、740 和多个成像装备装置 745、750 的公共控制操纵台 730 的成像组 725。如图 7 所示，利用诸如网络集线器、路由器或交换机的连网装置将多个装置连网到公共控制操纵台 730。控制操纵台 730 可包括允许操作员同时控制注射器装置和成像装备装置的单个接口。还应当认识到，控制操纵台 730 可以在缺少网络时用于控制多个注射器装置和成像装备装置。在这种系统中，装置可与公共控制操纵台直接通信，或者可通过用作中介部的多个装置之一间接地择路。

本发明还可提供能够执行用于操作注射器和成像装备的各种协议的各种计算机程序产品实施例。在一个另选实施例中，计算机程序产品能够从远程位置控制注射器装置。该计算机程序产品可包括用于接收来自输入装置的用户输入的可执行部分。

在一个实施例中，注射器装置可封包成包括注射器装置和远程计算机程序产品或者可与现有成像控制操纵台一起使用的硬件的封包。该远程计算机程序产品允许成像控制操纵台可操作地连接到成像装备和注射器装置。因此，在本发明的一个另选实施例中，注射器装置可与计算机程序一起分布，而不需要相关注射器控制操纵台。公共控制操纵台可包括可用于控制、显示、分析以及监视各种成像和注射装置的控制系统架构。该控制系统架构还可包括硬件和软件部件。参照在此描述的计算机程序产品，应当认识到，有广泛的各种平台和语言可用于创建执行在此概述的过程的软件。还应当认识到，选择准确平台和语言通常由构造实际系统的特定需要规定。该计算机程序产品典型地包括用于远程控制注射装置的模块和组件。

参照图 8，例示了如建立在 E-Z-EM EmpowerCT™ CT Injector 上的示例性的控制系统架构。如图所示，该控制系统架构可包括多个可执行程序模块，共同用标号 814 表示。该可执行程序模块 814 可位于公共控制操纵台上，或者位于可操作地连接到公共控制操纵台的硬件装置 810 上。在这点上，图 8 例示了可操作地连接到注射器 816 和扫描装置的具有可执行程序模块的远程控制部 810。该远程控制部还可包括多个 I/O 连接部 820，用于与包括扫描仪、成像显示装置、医院网络等及其组合的各种网络和装置通信。在本发明的一些实施例中，公共控制操纵台还可适配成能够与位于过程室（如成像室 302）（参见图 3）内的外渗检测装置（EDA）818 通信，以便能够可操作地与病人从注射器装置 816 接收介质注射的处理相配合。EDA 818 还可以经由有线和/或无线计算机网络与注射器装置 816、远程控制部 810、成像显示器、以及/或其它计算机装置通信。而且，该远程控制部 810 还可被设置成能够发送和/或接收从 EDA 818 设置的外渗数据。尽管图 8 例示了通过 RS-232C 串行通信协议可操作地

连接到注射器装置和 EDA 的远程控制，但是，应当认识到可以利用许多不同协议（包括如 I2C、ACCESS.bus、RS-232、通用串行总线（USB）、IEE-488（GPIB）的串行通信协议，如 TCP/IP 的 LAN/因特网协议，如 802.11x 的无线协议，以及蓝牙等及其任意组合）来连接装置、远程控制部，以及成像控制操纵台。

如图 8 所示，控制系统架构可包括广泛的各种可执行程序模块 814，该可执行程序模块 814 允许公共控制操纵台远程地控制诸如注射器的装置。该可执行程序模块可包括执行特定任务或实现特定数据类型的例程、程序、组件、数据结构等及其任意组合。模块可包括但不限于 PPREMOTE、显示图形、ODBC 数据库、PPCOMM、PPRESET，以及 GINA.DLL 等及其任意组合。下面对这些模块进行讨论。这些模块可以在如 Windows、Unix、Linux、MACOS 等及其任意组合的操作系统层操作。

PPREMOTE 包括可执行程序模块或能够在控制操纵台上执行和运行有关处理的基本应用软件。PPREMOTE 包括关于显示和接收用户输入（例如，键盘、鼠标器、触摸屏等）的用户接口可视组件。该可执行程序还可包括程序例程，该程序例程用于在易失性和非易失性存储器中存储、管理以及算术地操作与注射器的操作有关的数据变量。例程包括这种数据的管理功能以对 ODBC 数据库文件进行读取和写入。该模块也在注射器操作的各种接合的过程中，根据需要与 PPCOMM 模块之间传递数据并且与之共享数据。

显示图形可包括由 PPREMOTE 选择访问和使用以生成用户接口显示的可视组件库。可视组件可包括但不限于文本、触摸板按钮、帮助文件、帮助图形、图标、动画等及其任意组合。该可视组件可包括单个影像文件。

ODBC 数据库文件可以由 PPREMOTE 处理来创建和操作。ODBC 数据库文件可存储例如关于注射器诊断信息、错误状态、使用统计、EDA 性能、EDA 生物阻抗配置、用户保存的注射协议、外语消息等或其任何组合的归档数据。这种文件可以存储在诸如包括例如硬盘驱动器的磁存储装置的可读写介质上，或者存储在诸如 CD-ROM 或 DVD 驱动器的光

学存储装置上。另选地，这种文件还可存储在诸如闪速存储装置的数字介质上。

PPCOMM 包括能够在控制操纵台上执行和运行有关处理的通信软件模块。PPCOMM 可用于建立注射器装置的控制并维持与注射器的数据通信。该模块可以组织基于预定周期向注射器发送的数据序列和消息。该 PPCOMM 模块还可以基于预定周期接收并解析来自注射器的附赠（complimentary）数据序列或消息。PPCOMM 还可以具有逻辑以识别何时和是否发生了数据传输问题。基于编程到该模块中的逻辑，该模块可以具有在双向通信应当保持完好时干涉并试图改正问题的能力。另选地，该模块的编程的逻辑可以通知 PPREMOTE 应用发生了通信故障状况，由此，迫使注射器操作自动中止，直到问题可以解决为止。

PPREST 可包括能够在控制操纵台上执行和运行有关处理的软件模块。PPRESET 可以提供用于控制操纵台的故障处理和重置能力。

GINA.DLL 可包括动态链接库，该动态链接库针对运行在操作系统（诸如 Windows、Unix、Linux、MACOS 等及其任意组合）下的控制操纵台软件部件或模块提供系统功能性。

在一个另选实施例中，上述模块都可以封装并制备成可以设置在可移动数字介质（例如，CD-ROM、闪速卡等）上的软件包。该软件可以并入远程控制注射器所需的模块。在一个另选实施例中，预想软件可以与注射器一起销售，使得可升级现有成像控制操纵台，以便可以将现有成像控制操纵台可操作地与注射器装置和成像装备相连接。在这点上，图 9 例示了已设置有注射器 906 和用于利用控制操纵台 910 远程控制注射器的软件 908 的成像组 900。因此，可以从注射器/成像控制操纵台 910 监视并控制成像装备 930 和注射器装置 906。图 10 还例示了远程控制软件可以设置在存储介质上，并且可以安装在用于控制注射器装置和成像装备两者的单个计算装置中。

另选地，注射器远程软件可以结合具有网络能力的计算机或处理单元（也称为网络或 PC 模块）来使用。例如，在本发明的一个另选实施例中，处理单元可包括在注射器装置中，或者可以包含在独立封装中。在

其它现有实施例中，处理单元可以与成像控制操纵台通信并由成像控制操纵台控制。成像控制操纵台可以经由网络连接和协议与处理单元通信。在这点上，图 11 例示了通过与公共控制操纵台通信的示例性处理单元(可连网 PC 模块）将注射装置连网。在该非另选实施例中，注射器装置可与处理单元/可连网 PC 模块通信，该处理单元/可连网 PC 模块又与公共控制操纵台通信。如图 11 所示，处理单元可以通过网络连接与公共控制操纵台通信。在另一非另选实施例中，公共控制操纵台接口可利用诸如浏览器的网络应用或其它应用来控制注射器。在该实施例中，处理单元可包括远程软件，该远程软件可包括控制注射器并且与公共控制操纵台之间发送数据的模块或部件。该模块和部件都运行在如 Windows、Linux、Mac OS、Unix 等或其任意组合的操作系统上。

另选地，注射器控制部可被配置成网络客户端或服务器。在本发明的一个另选实施例中，如果注射器控制部被配置成客户端，则可直接从成像控制单元、或者经由另一服务器装置、代理，或根据本发明的其它方面提供控制注射器操作的相关操作数据。如果注射器控制部被配置成服务器，则可连网 PC 模块（参见图 12）可以从注射器向成像控制操纵台提供相关数据。因此，成像控制操纵台可用作注射器装置和成像装备的公共控制操纵台。

另外，在本发明的另一另选实施例中，注射器处理单元还可与检验设施内部网络（诸如例如本地医院网络）相连接并与其通信。在该实施例中，处理单元/可连网 PC 模块可连接到本地网络，而注射系统可以被配置成网络内的网络设备。在此配置中，注射器可通过成像组中的可用网络空间间接地与成像控制站通信。处理单元到网络的连接可以是有线网络或无线的。图 12 还例示了通过本地网络将注射系统作为网络设备进行控制。在该另选实施例中，利用网络连接的成像控制操纵台可以用作注射器装置和成像装备的公共控操纵台。

在图 12A 例示的另一实施例中，注射器装置和成像装备可作为网络设备通过网络空间共享操作参数。在该设置中，例如，公共控制操纵台可同时从注射器和成像装备中获得操作参数和控制信息。成像装备、注

射装置、以及控制操纵台共享公共网络。

在本发明的另一另选实施例中，成像装备接口和注射器接口可包括在利用多任务操作系统的计算机系统内运行的独立处理。在这点上，图13和14例示了同时显示用于注射器的专用显示区，和用于成像装备的专用显示区的公共控制操纵台。在此实施例中，该显示器可用于同时显示分别与注射器装置或者成像装备独立通信的应用。

应当认识到，本发明中可以使用各种不同的计算机平台和系统。该计算机平台可包括但不限于基于诸如例如 Windows 或 Linux 的操作系统运行图形用户接口（GUI）的 PC 或其它工作站。用户接口设计可以允许用户在注射器控制应用与成像控制应用之间自由地切换。注射器装置和成像装备两者的全部用户接口可经由单个显示器、键盘、定点装置或其它公用用户接口硬件装置来显示并管理。控制操纵台和图形接口还可包括可用于使注射器装置和成像装备执行特定命令的专用控制操纵台。对于成像装备来说，这种特定命令是已知的，并且包括频繁使用的专用按钮或键，或者与安全相关的操作功能。这种操作功能包括但不限于开始、暂停、以及停止影像装备，影像恢复，影像装备相互通信等及其任意组合。图 13 和 14 例示了也包括一个或更多个专用控制装置的公共控制操纵台。如图 13 和 14 所示，专用控制装置可包括可用于与影像装备和 GUI 接口连接的接口装置。所述系统还包括频繁使用的专用控制操纵台或关于注射系统的安全的操作功能。类似地，频繁使用或与安全相关的操作功能可以并入用于注射器装置和成像装备两者的单个专用控制部中。如图 14 所示，专用控制操纵台可包括用于注射器装置的专用控制部、用于成像装备的专用控制部，或者用于注射器装置和成像装备两者的专用控制部。

专用控制操纵台可采用广泛的各种方法与注射器装置和成像装备通信，所述各种方法包括但不限于直接连接到成像装备和注射器装置的专用通信信道、经由逻辑互连到公共成像装备/注射器操纵台的间接连接及其组合和交换。

图 13 和 14 中例示的接口设计可以是在公共控制操纵台上执行的独

立处理。该公共控制操纵台可包括计算机平台 CPU、存储器、I/O、键盘、显示器、定点装置等及其任意组合。公共控制操纵台与通过其可操作地连接注射器装置和成像装备的输入/输出装置相关联。注射器装置和成像装备可以共享公共显示接口，并且它们也可在功能上彼此独立。在本发明的一个实施例中，成像装备应用可以访问运行在公共控制操纵台上的注射器数据文件。例如，公共控操纵台可包括诸如可从 E-Z-EM 得到的 EMPOWERCT 的软件应用，所述软件应用允许成像装备用户接口访问注射器数据、统计，以及来自数据库或类似文件（诸如与注射器装置相关联的 ODBC 数据库文件）的其它相关数据。

类似地，在本发明的另一另选实施例中，如果成像装备用户接口也包括允许其对成像装备数据和统计进行创建、存取，以及归档到可比较数据库文件的软件应用，则注射器接口应用也可访问这些文件。这是一种另选方法，通过该方法独立的注射器和成像装备应用可在它们中间共享数据，以增强它们各自的显示，或者取代它们中之一。在这点上，图 15 例示了其中注射器接口应用可以访问与成像装备应用相关联的文件的公共控制操纵台。在该另选非限制实施例中，成像装备应用也可存取与注射器装置接口相关联的文件。

另选地，公共控制操纵台可包括组合的接口应用、程序、或处理，该组合的接口应用、程序、或处理包括注射器和成像装备属性并且可以用于控制并管理该两个装置。在这点上，图 16 例示了具有能够控制注射器装置和成像装备两者的组合接口应用的公共控制操纵台。如图 16 所示，公共应用程序典型地包括与注射器接口和成像装备接口相关联的模块和程序部件。这种模块可包括例如数据库文件、显示图形、库、装置驱动程序、装置专用通信驱动程序等或其任意组合。

在本发明的另一另选实施例中，用户接口包括可具体实现注射器和成像装备功能的在关键处聚合设置的单个公共用户接口。因此，在该公共控制操纵台上可以例行地自动运行需要同步或任何其它操作上的相互依赖的远程控制的注射器和成像装备的功能。在这点上，图 17 例示了根据本发明一个非限制实施例的公共注射器/成像装备操纵台的显示区，在

该显示区中，单个显示窗包括注射器和相关联的成像装备的用户接口功能。

另选地，注射器装置和/或成像装备接口可被配置成 web 或网络端口。在该另选的非限制性实施例中，在公共控制操纵台上可使用基于普通 web 浏览器或专用网络的应用，以显示注射器装置和成像装备接口。可以广泛的各种方式使用 web 浏览器。例如，可与图 11 中例示的网络模块设置一起来使用网页浏览器。另选地，成像装备、CPU、以及注射器都是可以通过网络协议互连的网络设备装置。这些连接例如可以是例如点对点、LAN、WAN、以及/或因特网。另外，这些连接可以是有线连接或无线连接。在建立连接之后，注射器用户接口显示可显示在采用支持诸如 HTML、XML、JAVA、.NET 等或其任意组合的标准的 web 浏览器的成像装备操纵台上。

图 18 例示了利用 web 浏览器的注射装置。如图所示，注射器用户接口与成像装备应用一起同时显示在 web 浏览器上。成像装备接口也可以与注射器应用一起同时显示在公共用户接口上的 web 浏览器上。另选地，在具有显示器和输入装置的公共处理装置上，注射器和成像装备接口可提供到两个 web 浏览器窗口。这种混合接口设计可适于在被提供在 web 浏览器上的注射器接口与直接在公共显示接口 CPU 上运行处理的成像装备接口之间的预编程数据传送，或者可适于在被提供在 web 浏览器上的成像装备接口与直接在公共显示接口 CPU 上运行处理的注射器接口之间的预编程数据的传送。

在本发明的一个有利形式中，系统可包括诸如 CT 注射器的注射器、成像装备，以及公共控制操纵台。在该实施例中，注射器操作参数可以存储并显示在用户接口处。可对操作参数进行处理以最优化成像和检测数据。特定的参数取决于被注射的特定介质、待成像的主体的区域等及其任意组合。介质典型地包括造影剂、盐介质等及其任意组合。这种操作参数包括但不限于针对 x 射线曝光的相位、流速、体积、压力、定时暂停、保持，以及延迟。可为了特定检验而将操纵参数分组在一起并且将其存储以便稍后调用。这种参数也可以置于各个组中。操作参数的这

些组一般最常称为协议。在本发明一个实施例中，存储的协议允许操作员快速调用可用于后续检验的最优化参数。因此，可改进检验效率和成像质量。

类似地，也可将用于成像装备的操作参数分组到协议中以便用于后续检验。对于 CT 扫描仪的情况，这种参数典型地包括但不限于 kV（施加到 x 射线管的电压）、mA（x 射线管电流）、检测器准直、节距（pitch）（工作台速度）、起重台（gantry）转速、检测器配置（检测器片数、合成尺寸数）、自动控制参数（剂量）、定时暂停、保持、以及/或延迟等及其任意组合。成像参数可以显示在用户接口上。

参照图 19，例示了可以同时显示用于注射器装置和成像装备两者的操作参数的用户接口。如图 19 所示，该用户接口可用于访问包括用于注射器装置和成像装备两者的各种协议的数据库文件。该用户接口可以用于允许操作员易于调用用于注射器和成像装备的协议。上述和图 19 中例示的操作参数包括用于 CT 注射和扫描的参数。应当明白，本发明不限于 CT 扫描和成像，并且在本发明的具体实践中还可使用用于广泛的各种其它检验的操作参数和协议。

例如，在现有 CT 或计算 x 线体层照相术（tomography）成像实践中，由于使用两个显示操纵台，所以执行例如心脏 CT 血管造影术（angiography）过程的临床医生将一方面在设置处理中访问成像操纵台，而另一方面及时地访问与成像操纵台彼此独立的注射器远程控制部。在成像操纵台上，临床医生将手动输入 CT 扫描参数或调用预存储的 CT 扫描参数。对于心脏 CT 血管造影术过程来说，在下面的表 1 中呈现了现今的 16 片多检测器行 CT 扫描仪的典型过程变量。

表 1：CT 扫描仪参数

CT 扫描仪参数	在成像操纵台处输入/存储/调用的值
管电流	150 mAs
管电压	120 Kvp
准直	16 片×0.625 mm 片厚度

节距	1.0
起重台转动	0.5 秒每转
扫描触发	制造者指定

上面列出的CT扫描仪控制参数对于各种CT扫描仪制造者平台和工业领域一般通用。然而，各制造者都可具有若干辅助或专用参数作为他们的CT扫描仪设计的一部分，所以上面列表不应视为详尽的，而且将任何其它辅助参数包括到用于输入、存储或调用这种参数的成像操纵台接口设计中是非常容易的。例如，可在用户命名的协议标识符下电子地保存并且检索上述分组的CT扫描仪参数。在此情况下，可以使用“心脏”来命名有关CT操纵台的协议。

类似地，对于独立于并且远离成像操纵台的注射器远程控制部，临床医生将手动输入CT注射参数或调用预存储的CT注射参数。针对心脏CT血管造影术过程，在下面的表2中呈现了用于现今的两相位对比注射盐冲洗介质的典型过程变量。

表2：CT注射器参数

CT注射器参数	在注射器远程控制部输入/存储/调用的值
相位1对比流速	4 ml/sec
相位1对比体积	100 ml
相位2盐介质流速	4 ml/sec
相位2盐介质体积	30 ml
压力	300 psi
扫描延迟	15 秒

上面列出的CT注射器控制参数对于各种CT注射器制造者平台和工业领域一般通用。然而，各制造者可具有若干辅助或专用参数，作为他

们的 CT 注射器设计的一部分，所以上面列表不应视为详尽的，而且将任何其它辅助参数包括到用于输入、存储或调用这种参数的注射器远程接口设计中是非常容易的。例如，可在用户命名的协议标识符下电子地保存和检索上面分组的 CT 扫描仪参数。在此情况下，可使用相同名字，即，用于命名关于 CT 操纵台的协议的“心脏”。

对于所建议的利用满足 CT 扫描仪和 CT 注射器两者需求的公共操纵台来获取心脏 CT 影像的实践，理想的是在一个唯一标识符下对用于 CT 扫描仪和 CT 注射器两者的过程变量进行调用。例如，本发明有利于在用户特定的名称下单个组合的装置协议的设计和形式。例如，用于 CT 扫描仪和 CT 注射器的公共操纵台可具有命名“心脏”的协议，该协议“心脏”具有如下的前述参数：

表 3：组合的 CT 成像和扫描协议

用于扫描和对比注射的 CT 过程参数	在同时提供 CT 扫描仪和 CT 注射器的操作台处输入/存储/调用的值
管电流	150 mAs
管电势	120 Kvp
准直	16 片×0.625 mm 片厚度
节距	1.0
起重台转动	0.5 秒每转
相位 1 对比流速	4 ml/sec
相位 1 对比体积	100 ml
相位 2 盐介质流速	4 ml/sec
相位 2 盐介质体积	30 ml
压力	300 psi
扫描触发/扫描延迟	制造者指定

在具有此能力的用于成像和注射器装置的公共操纵台的接口内的过程参数存储和调用的设计提供协议组织，从而提供益于临床医生的便利

性以及生产率。

另选地，可将用于注射装置和成像装备的操作参数合并到单个协议中。在这点上，图 20 示出了包括用于注射器装置和成像装备两者的操作参数的各种协议。如图 20 所示，可在单个显示器上显示组合的协议。操作员可以使用组合的协议来操作注射器装置和成像装备。这些组合的协议将允许操作员有效地调用已针对特定检验被最优化的用于注射器装置和成像装备的操作参数。因此，可以改进检验的效率和影像的质量。在图 20 中，仅出于示例的目的而给出 CT 扫描和注射参数，而不应视为对本发明的限制。

注射/成像系统可特别用于从病人或主体内部获得一个或更多个内部影像。为了获取多个影像，可将病人安置在注射器装置和成像装备附近的诸如床的表面上。公共控制操纵台典型地用于从存储器中选择并检索用于将造影剂注射到病人体内的所需操作参数。操作员可在接口处改变该参数，或者另选地，该参数可被包括在包含操作参数分组的存储协议中。典型地，用于图像装备的操作参数可由操作员检索或者加载到系统上。这些参数也可由操作员在接口处单个改变并控制，或者可被分组到可从存储器或另一装置检索的存储协议中。用于成像装备和注射装置的协议被同步，使得注射/成像系统协调且同时地运行，从而有效地执行检验。另选地，可以创建并且从存储器检索包括用于注射器装置和成像装备的操作指令的组合协议。

当病人准备好时，可使用公共控制操纵台向注射装置和成像装置传送指令。注射装置可根据其从公共控制操纵台接收到的指令将有效量的造影剂注射到病人体内。成像装备可以扫描病人以获取内部影像。在扫描期间，成像装备可将扫描影像数据传送到可对该数据进行存储、分析、打印等的公共控制操纵台。如果希望，则操作员典型地可以采用广泛的各种方式来控制扫描仪以获得所希望的影像。

本发明所属领域的技术人员容易想到具有在前文说明和相关附图中呈现的教导的益处的，在此阐述的本发明的其它修改例和其它实施例。因此，应当明白，本发明不限于公开的特定实施例，而是旨在将修改例

和其他实施例包括在所附权利要求中。尽管在此采用了特定的术语，但是它们仅用于一般和描述的意义，而不是用于限制的目的。

此外，在整个说明书中，在构成被描述为具有、包括、或包含特定组件，或者处理或方法被描述为具有、包括、或包含特定步骤的情况下，认为本发明的构成也基本上由所述组件组成或者由所述组件组成，而且认为本发明的处理和方法也基本上由所述步骤组成或者由所述步骤组成。此外，应当理解，步骤的顺序和执行特定动作的顺序并不重要，只要本发明保持可操作性即可。此外，关于在此公开的本发明，可以同时进行两个或更多个步骤或动作。

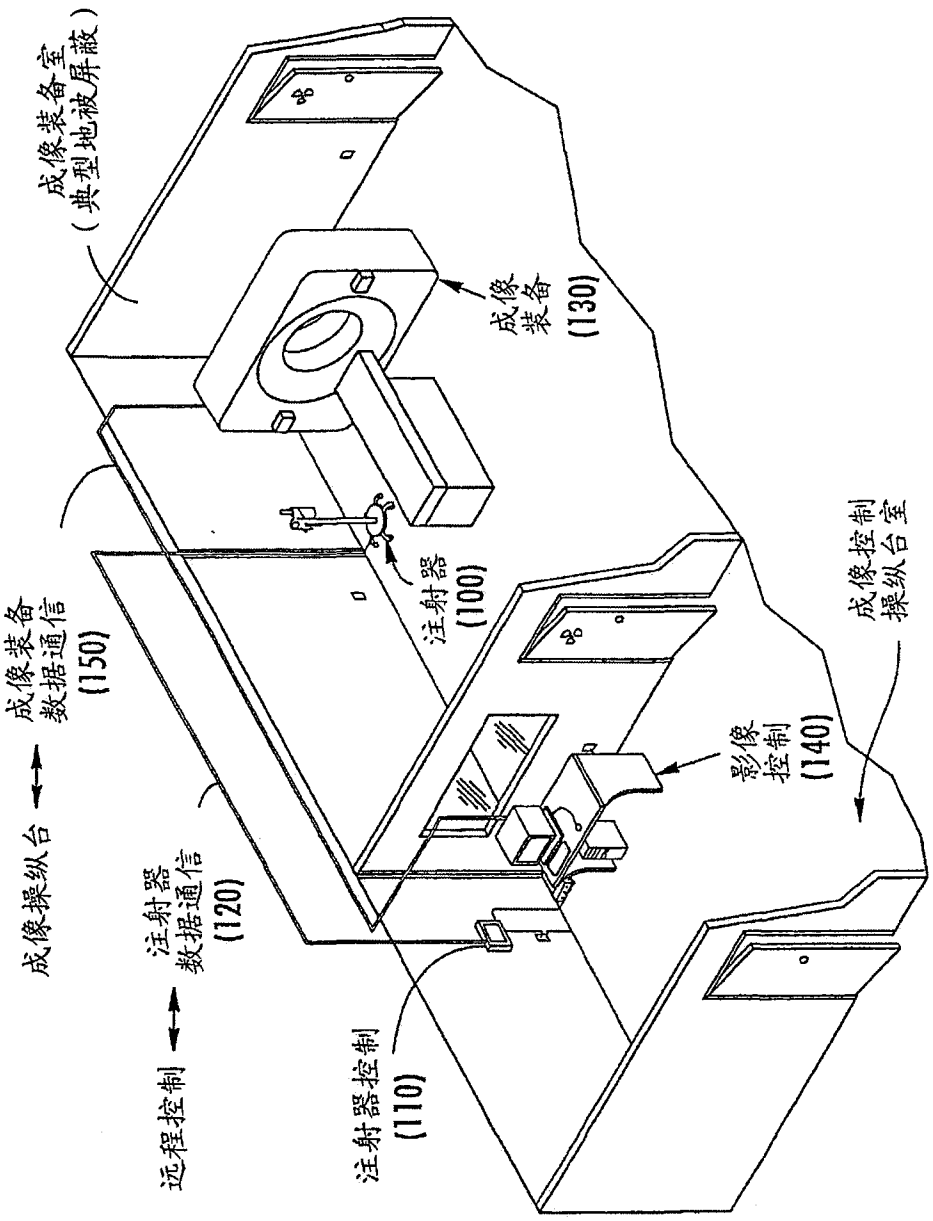

成像装备室
（典型地被屏蔽）
成像装备
(130)
注射器
(100)
成像装备
数据通信
(150)
成像操纵台
注射器
数据通信
(120)
远程控制
注射器控制
(110)
影像
控制
(140)
成像控制
操纵台室

图 1

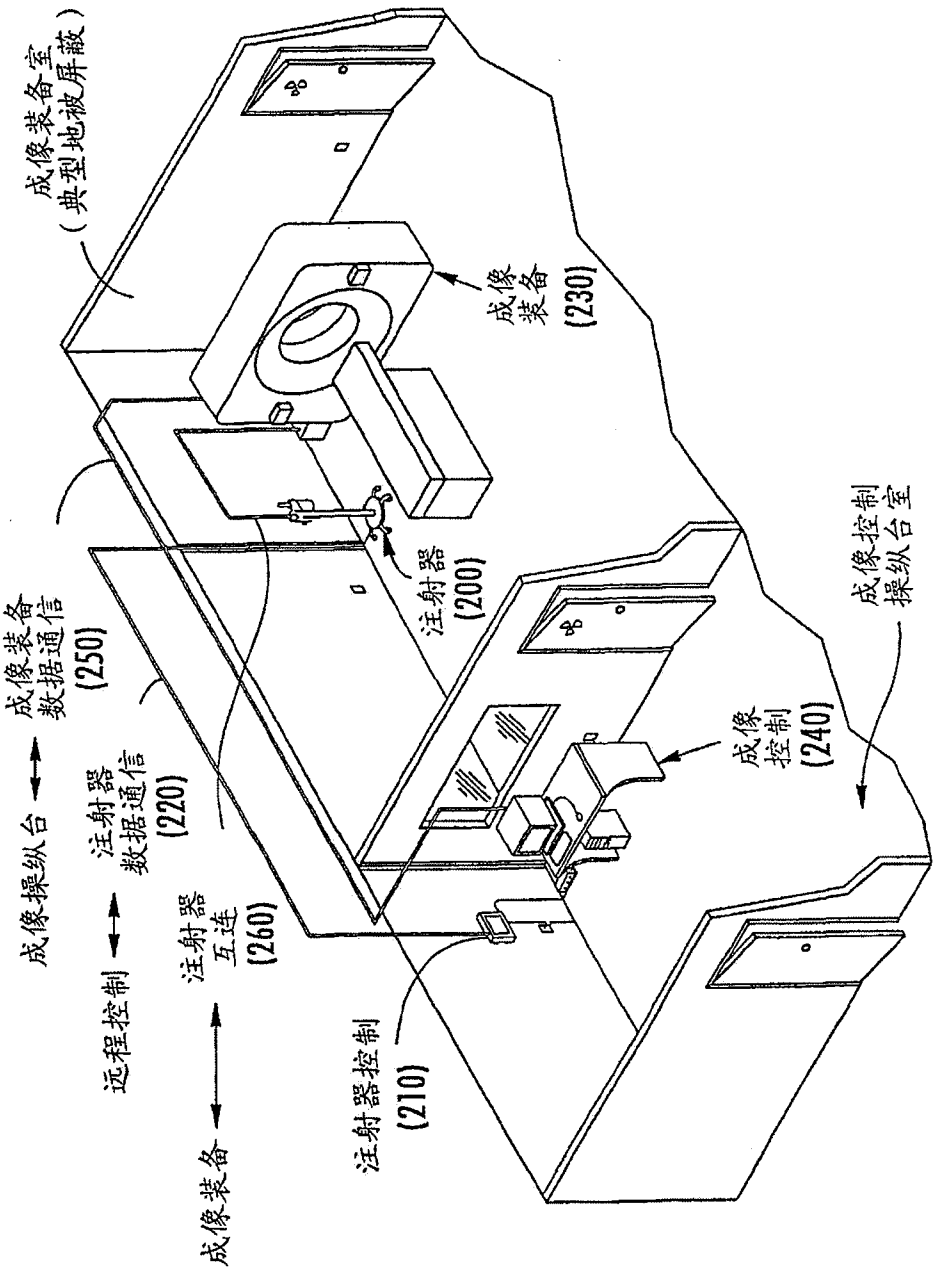

成像装备室
(典型地被屏蔽)
成像装备
(230)
注射器
(200)
成像控制
操纵台室
成像控制
(240)
注射器控制
(210)
成像操纵台
成像装备
数据通信
(250)
远程控制
注射器
数据通信
(220)
成像装备
注射器
互连
(260)

图 2

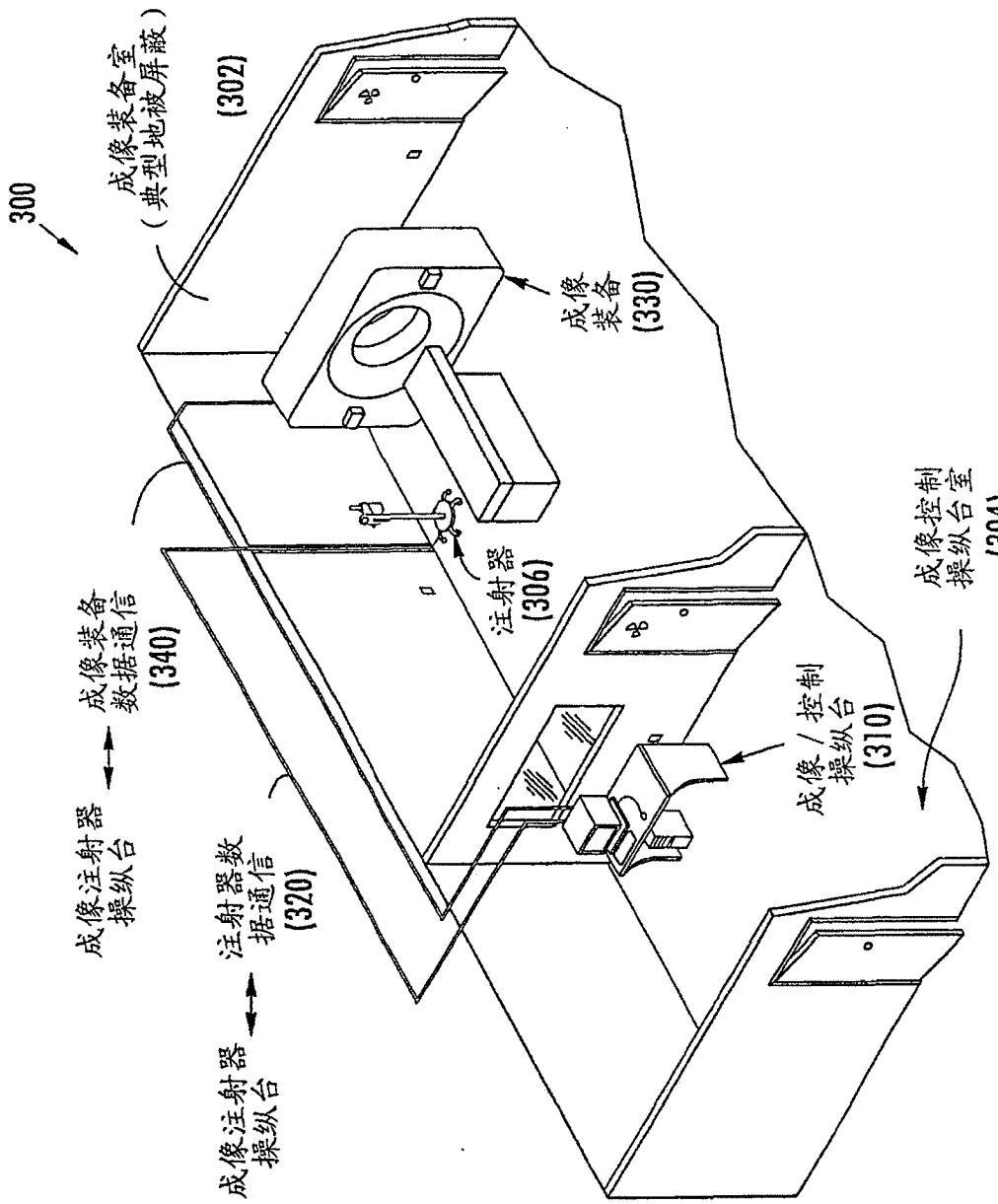

300
成像装备室
（典型地被屏蔽）
(302)
成像装备
(330)
注射器
(306)
成像控制
操纵台室
(304)
成像/控制
操纵台
(310)
成像装备
数据通信
(340)
成像注射器
操纵台
注射器数
据通信
(320)
成像注射器
操纵台

图 3

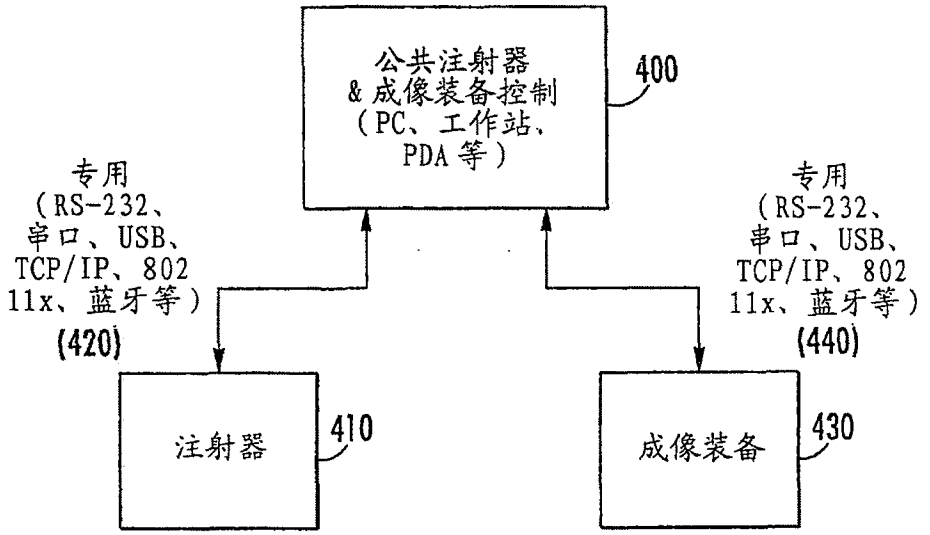

公共注射器
& 成像装备控制
(PC、工作站、
PDA 等)
400
专用
(RS-232、
串口、USB、
TCP/IP、802
11x、蓝牙等)
(420)
专用
(RS-232、
串口、USB、
TCP/IP、802
11x、蓝牙等)
(440)
注射器
410
成像装备
430

图 4

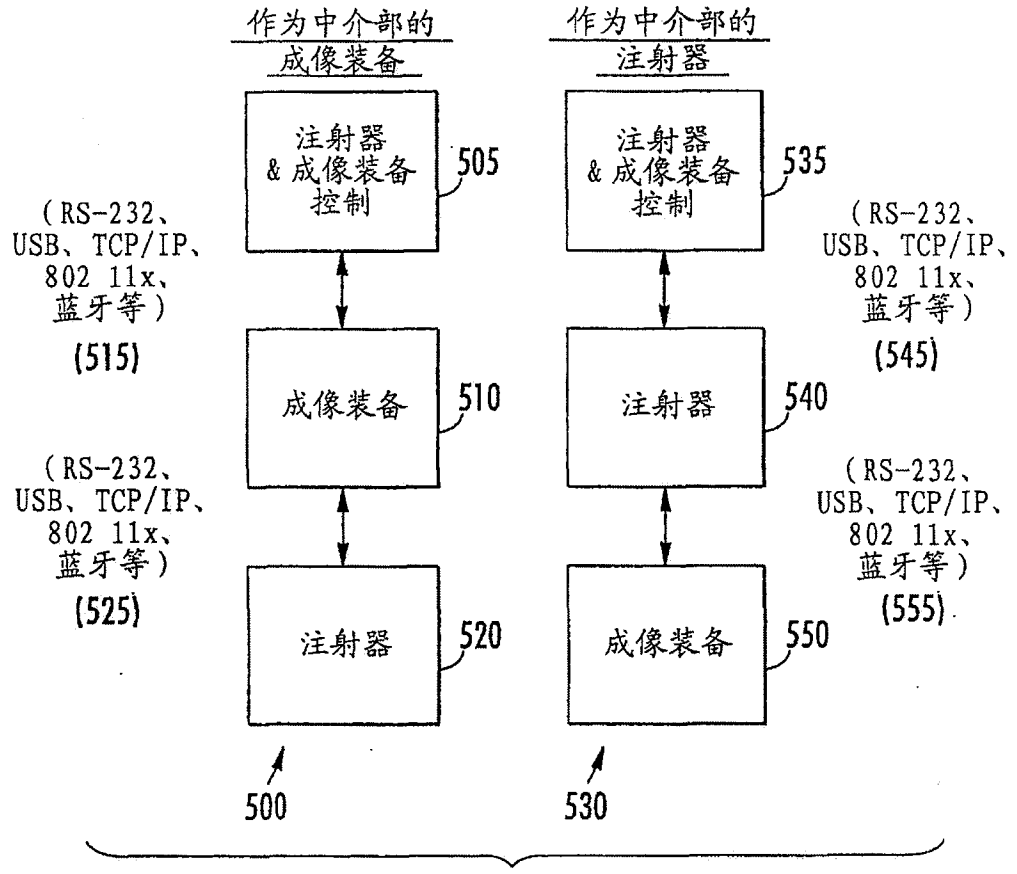

作为中介部的
成像装备
作为中介部的
注射器
注射器
& 成像装备
控制
505
注射器
& 成像装备
控制
535
(RS-232、
USB、TCP/IP、
802 11x、
蓝牙等)
(515)
(RS-232、
USB、TCP/IP、
802 11x、
蓝牙等)
(545)
成像装备
510
注射器
540
(RS-232、
USB、TCP/IP、
802 11x、
蓝牙等)
(525)
(RS-232、
USB、TCP/IP、
802 11x、
蓝牙等)
(555)
注射器
520
成像装备
550
500
530

图 5

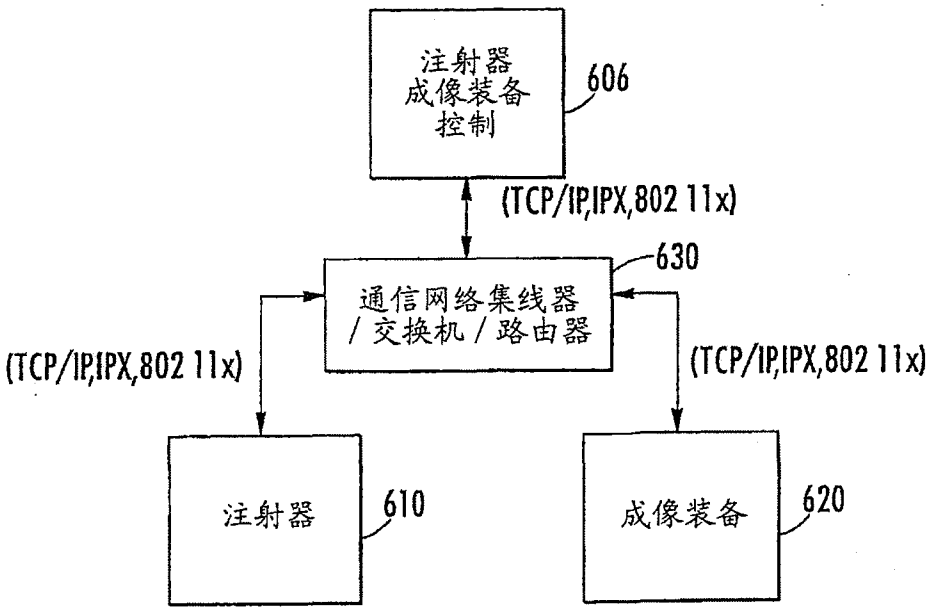

注射器
成像装备
控制
606
(TCP/IP,IPX,802 11x)
630
通信网络集线器
/ 交换机 / 路由器
(TCP/IP,IPX,802 11x)
(TCP/IP,IPX,802 11x)
注射器
610
成像装备
620

图 6

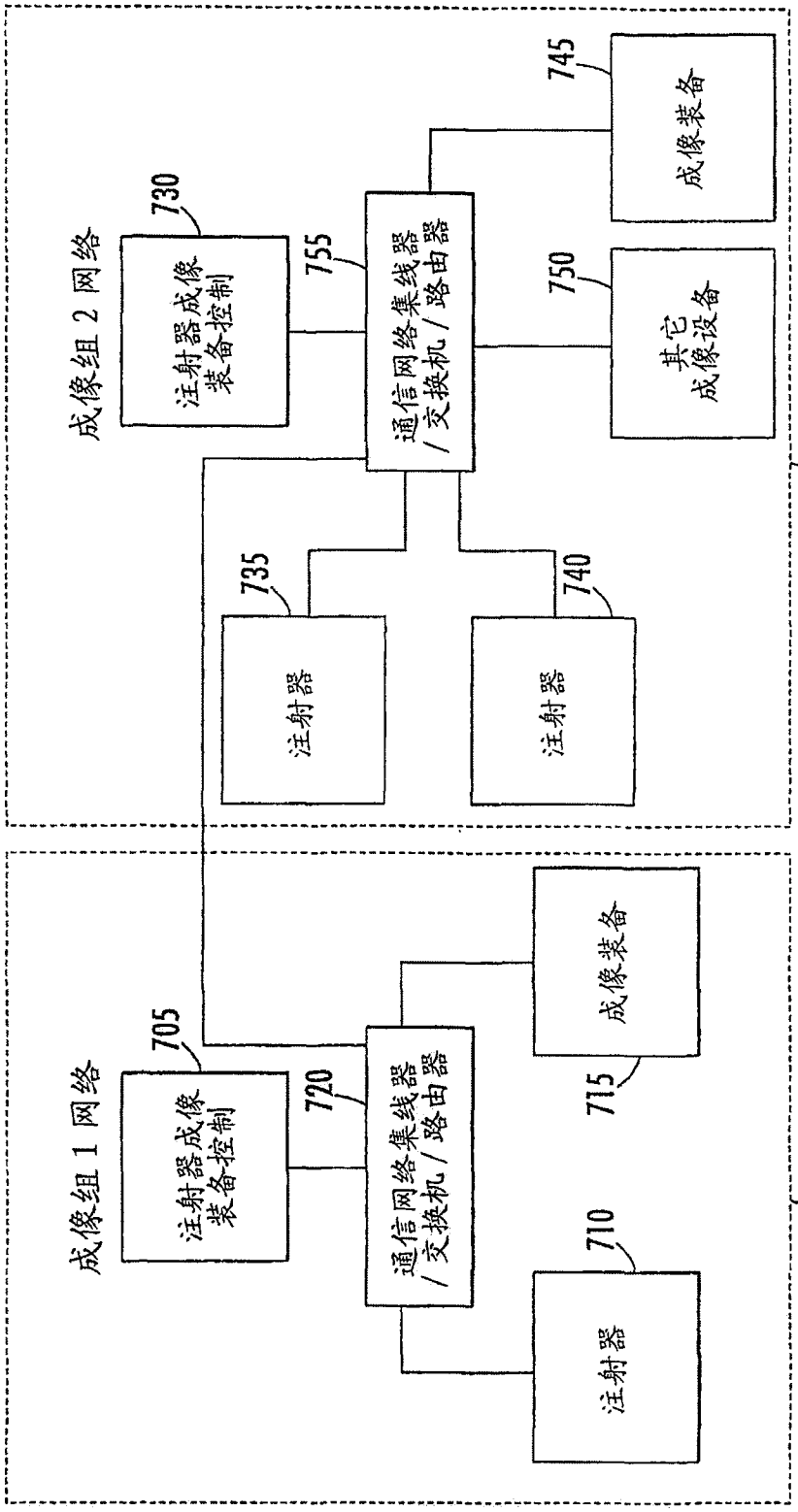

成像组 1 网络
注射器成像装备控制
705
通信网络集线器/交换机/路由器
720
成像装备
715
注射器
710
700
成像组 2 网络
注射器成像装备控制
730
通信网络集线器/交换机/路由器
755
成像装备
745
其它成像设备
750
注射器
735
注射器
740
725

图 7

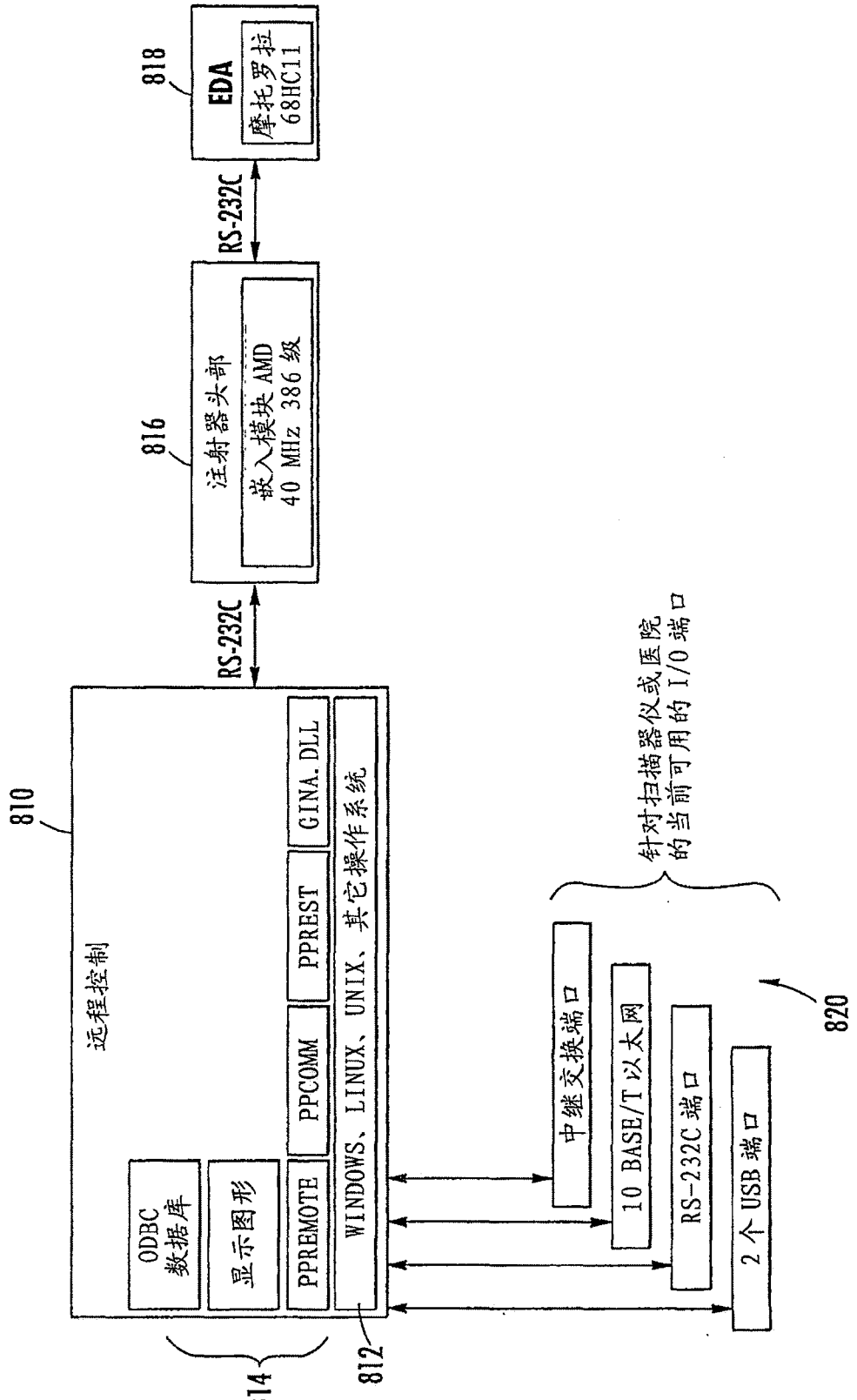

818
EDA
摩托罗拉
68HC11
RS-232C
816
注射器头部
嵌入模块 AMD
40 MHz 386 级
RS-232C
810
远程控制
ODBC
数据库
显示图形
PPREMOTE
PPCOMM
PPREST
GINA.DLL
WINDOWS、LINUX、UNIX、其它操作系统
814
812
中继交换端口
10 BASE/T 以太网
RS-232C 端口
2 个 USB 端口
820
针对扫描器仪或医院
的当前可用的 I/O 端口

图 8

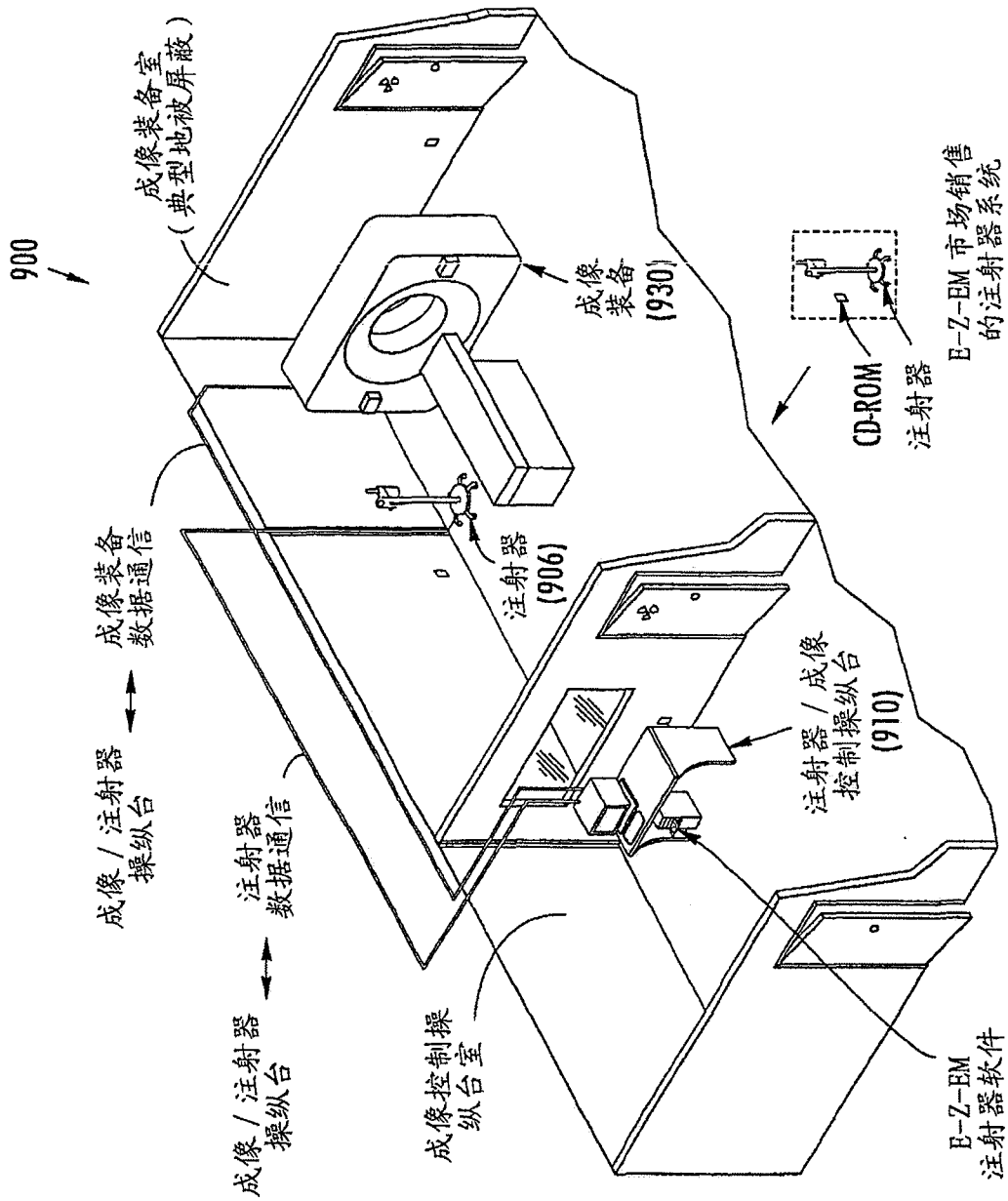

900
成像装备室
(典型地被屏蔽)
成像装备
(930)
成像装备
数据通信
成像/注射器
操纵台
注射器
(906)
CD-ROM
注射器
E-Z-EM 市场销售
的注射器系统
注射器/成像
控制操纵台
(910)
注射器
数据通信
成像/注射器
操纵台
成像控制操
纵台室
E-Z-EM
注射器软件
(908)

图 9

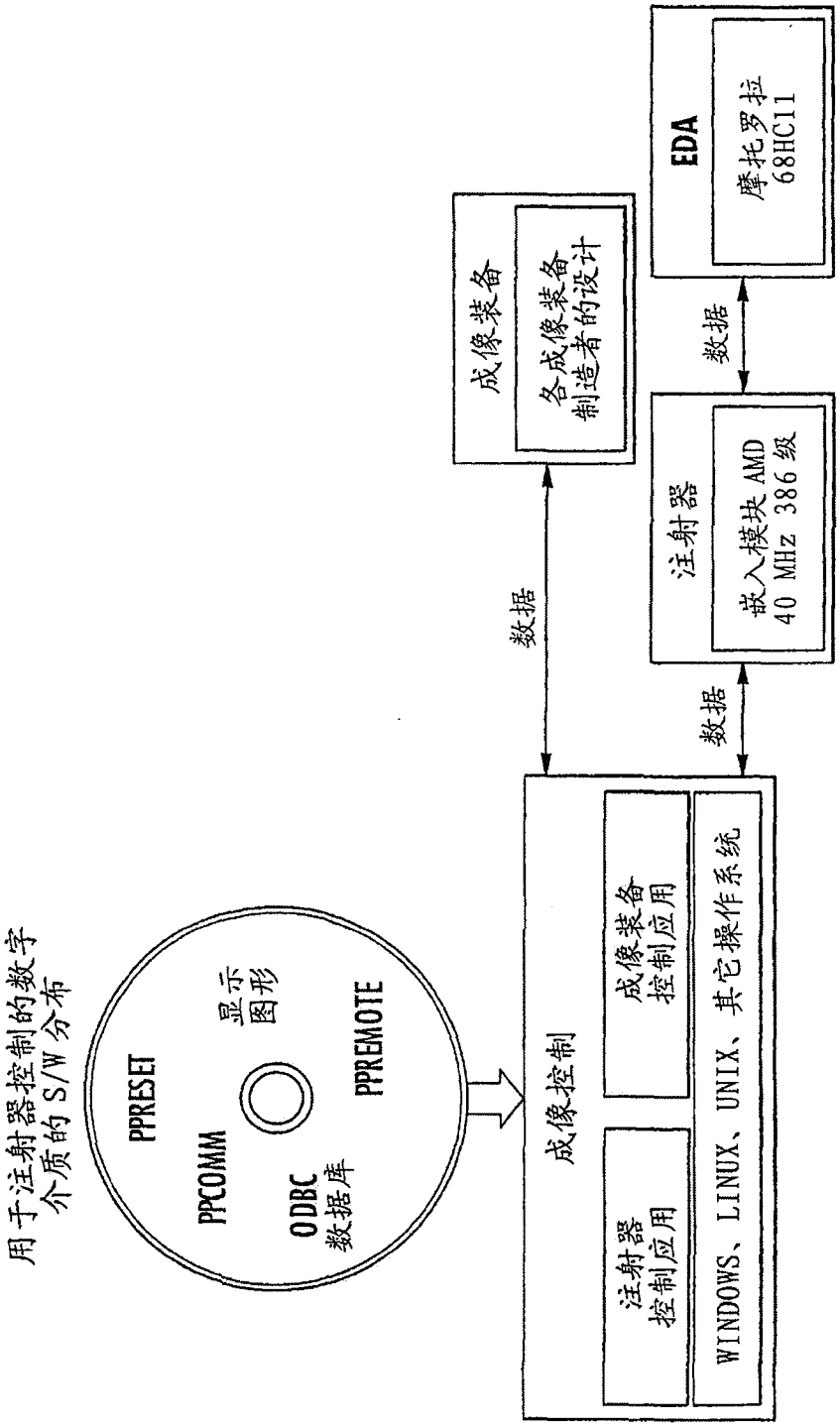

用于注射器控制的数字介质的S/W分布
PPRESET
PPCOMM
显示图形
ODBC数据库
PPREMOTE
成像控制
注射器控制应用
成像装备控制应用
WINDOWS、LINUX、UNIX、其它操作系统
数据
成像装备
各成像装备制造者的设计
数据
注射器
嵌入模块 AMD 40 MHz 386级
数据
EDA
摩托罗拉68HC11

图 10

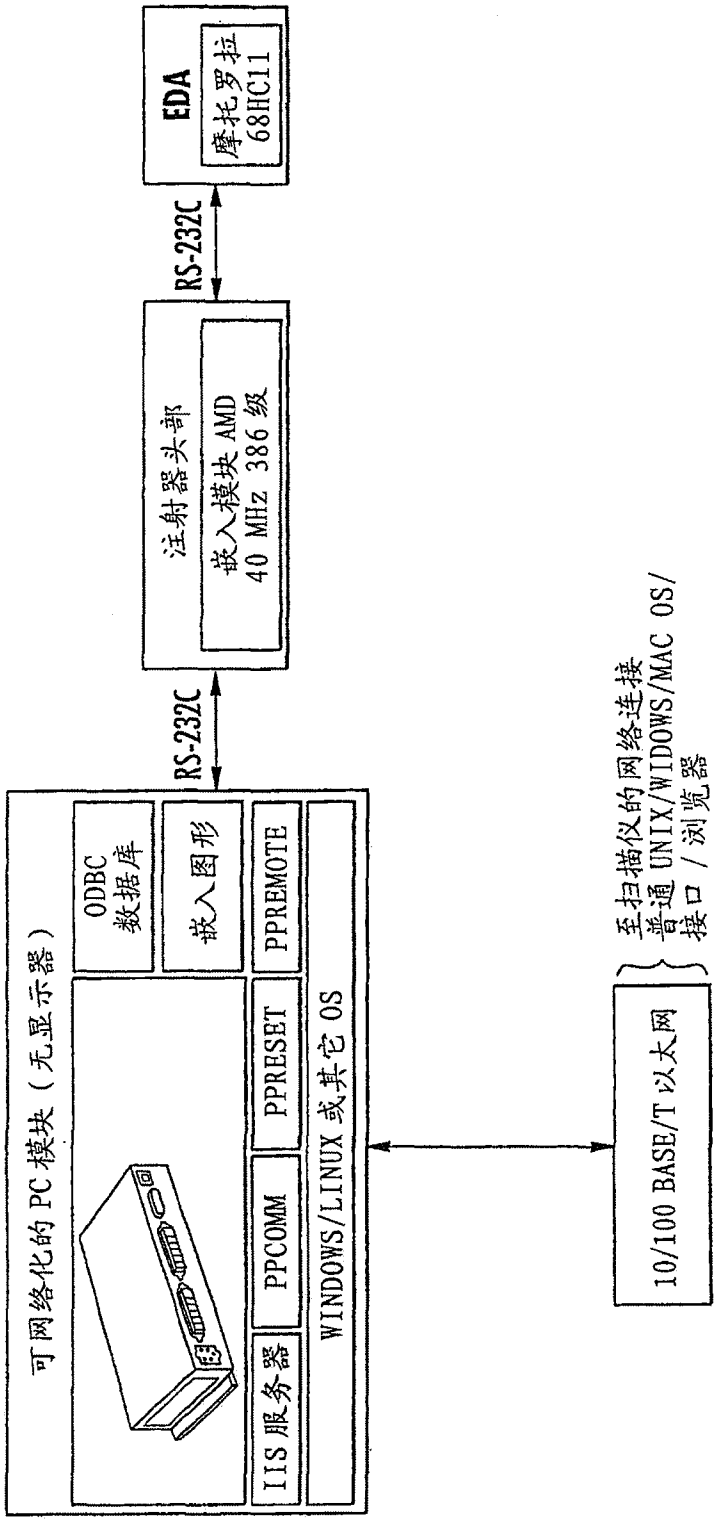

可网络化的 PC 模块（无显示器）
ODBC 数据库
嵌入图形
IIS 服务器
PPCOMM
PPRESET
PPREMOTE
WINDOWS/LINUX 或其它 OS
RS-232C
注射器头部
嵌入模块 AMD 40 MHz 386 级
RS-232C
EDA
摩托罗拉 68HC11
10/100 BASE/T 以太网
至扫描仪的网络连接
普通 UNIX/WIDOWS/MAC OS/
接口 / 浏览器

图 11

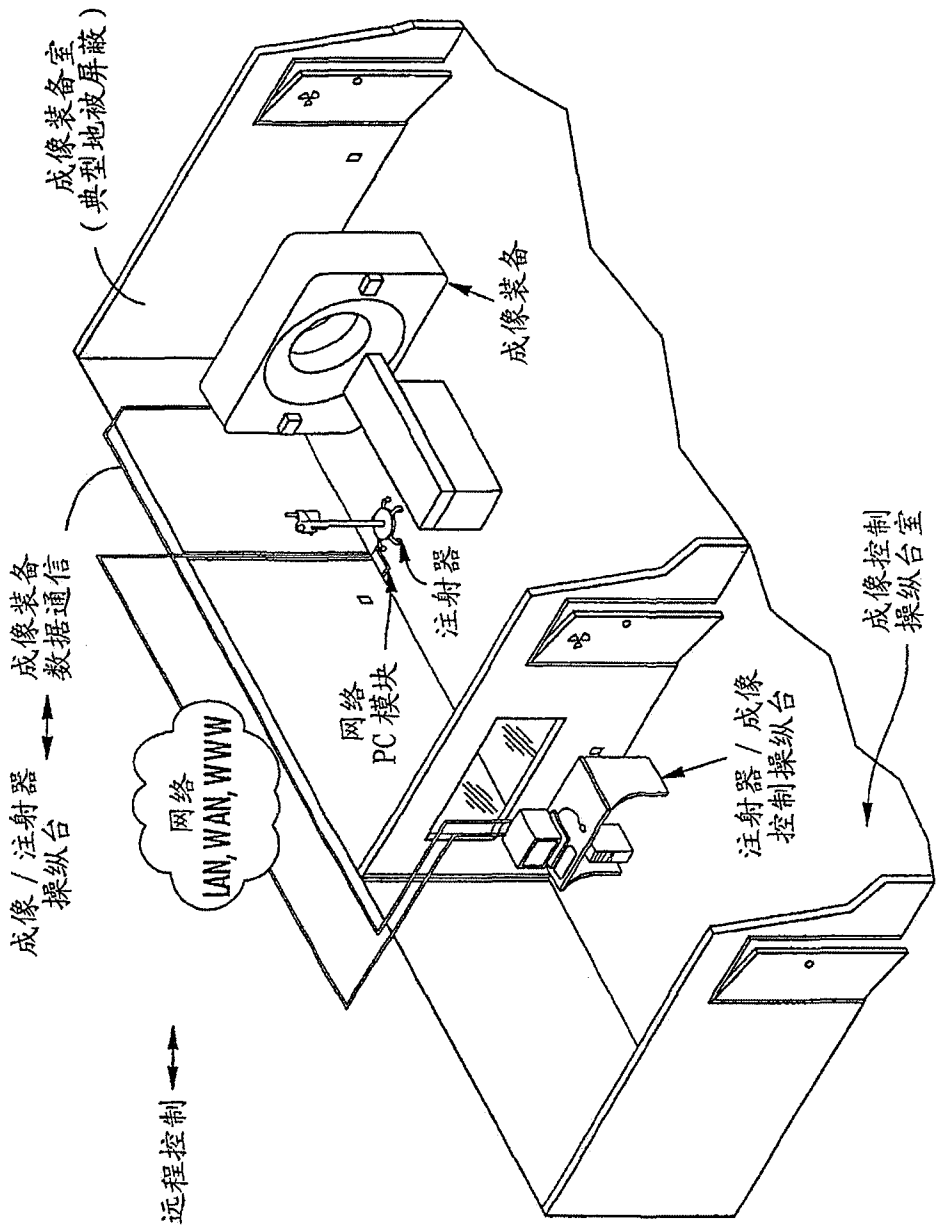

成像装备室
（典型地被屏蔽）
成像装备
注射器
网络
PC模块
成像装备
数据通信
成像/注射器
操纵台
网络
LAN, WAN, WWW
远程控制
注射器/成像
控制操纵台
成像控制
操纵台室

图 12

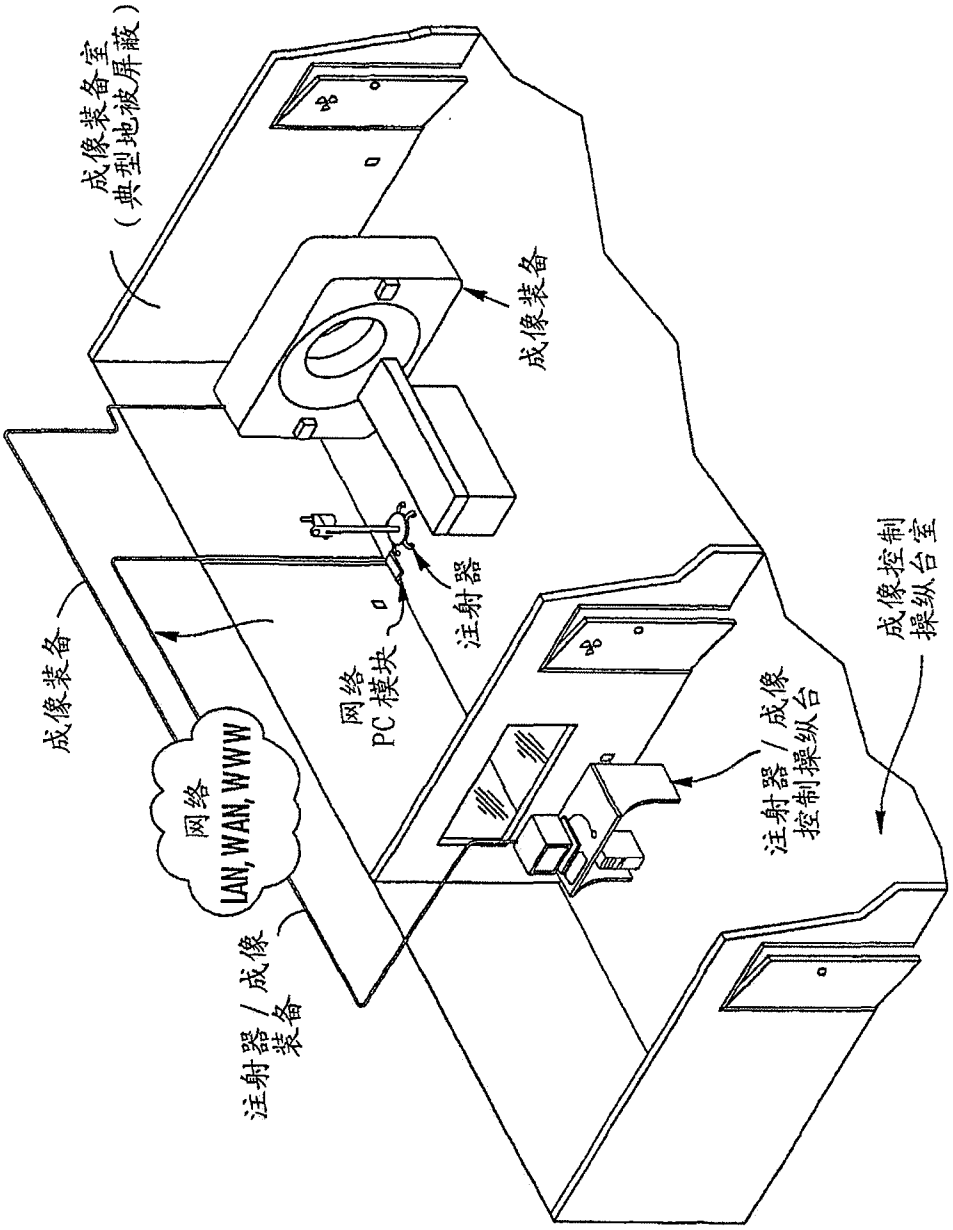

成像装备室
（典型地被屏蔽）
成像装备
网络
LAN, WAN, WWW
注射器 / 成像
装备
网络
PC 模块
注射器
成像装备
注射器 / 成像
控制操纵台
成像控制
操纵台室

图 12A

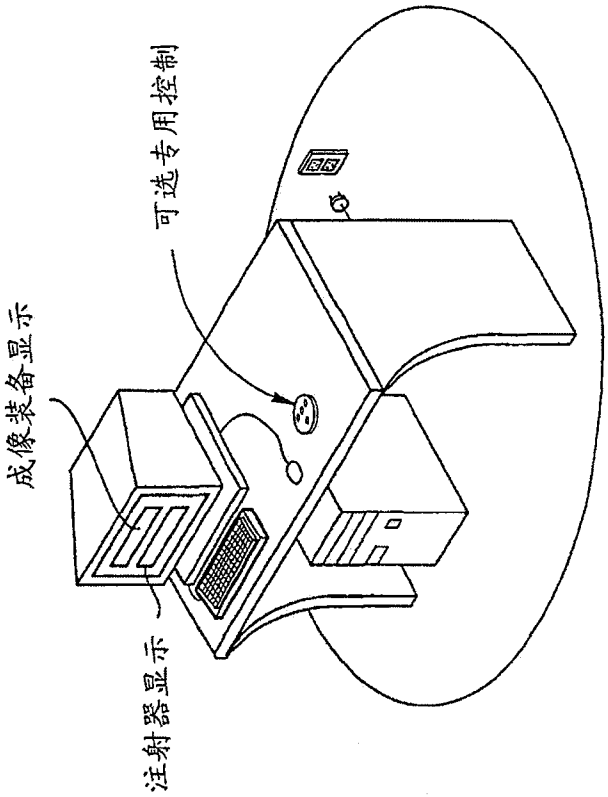


图 13

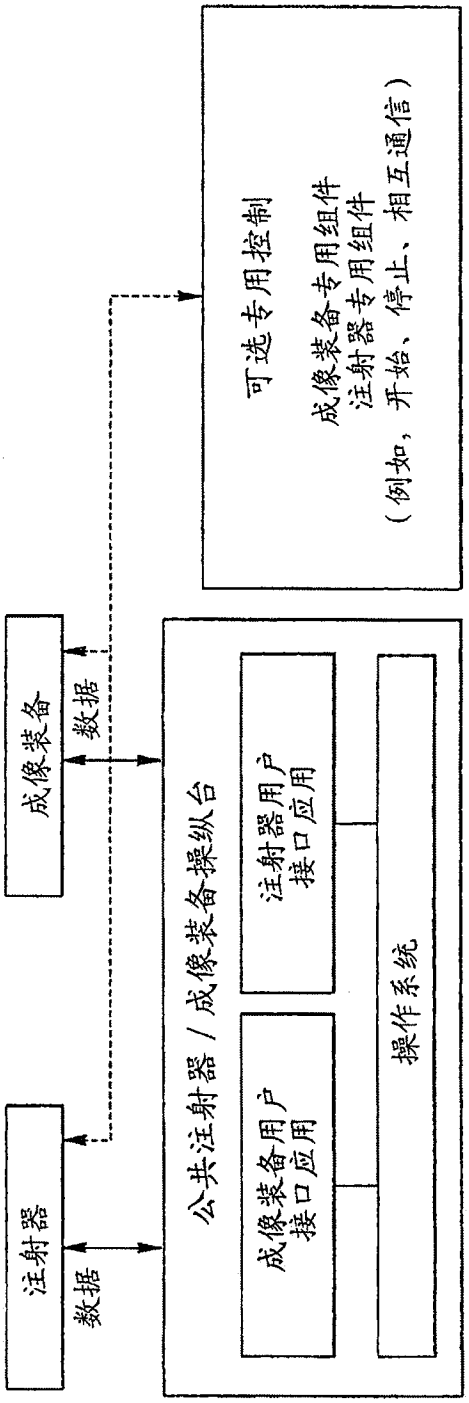

可选专用控制
成像装备专用组件
注射器专用组件
（例如，开始、停止、相互通信）
成像装备
数据
公共注射器 / 成像装备操纵台
注射器用户
接口应用
成像装备用户
接口应用
操作系统
注射器
数据

图 14

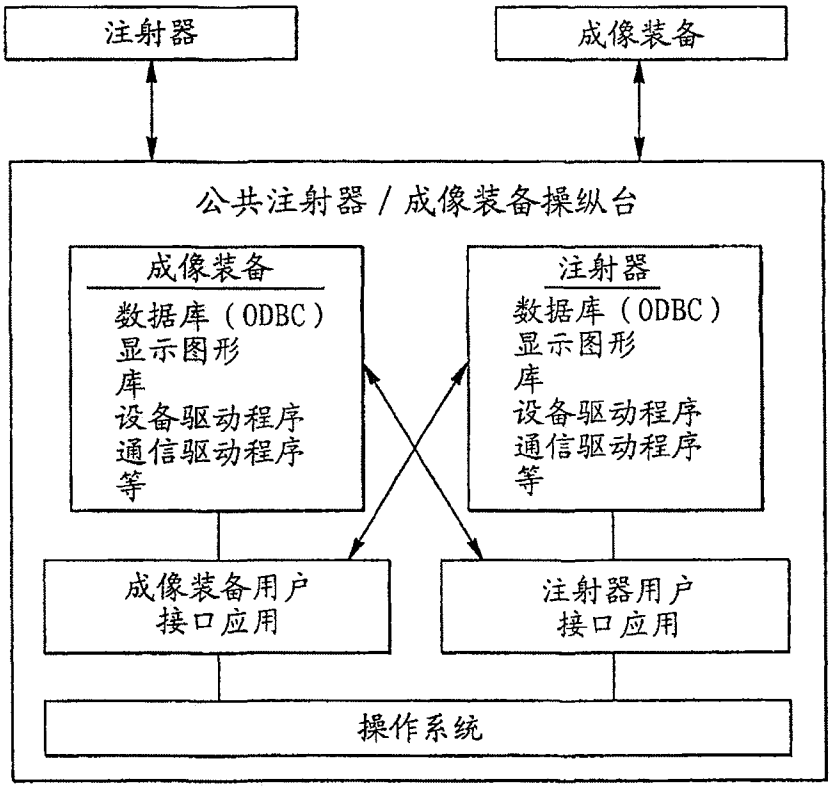

注射器
成像装备
公共注射器/成像装备操纵台
成像装备
数据库（ODBC）
显示图形
库
设备驱动程序
通信驱动程序
等
注射器
数据库（ODBC）
显示图形
库
设备驱动程序
通信驱动程序
等
成像装备用户
接口应用
注射器用户
接口应用
操作系统

图 15

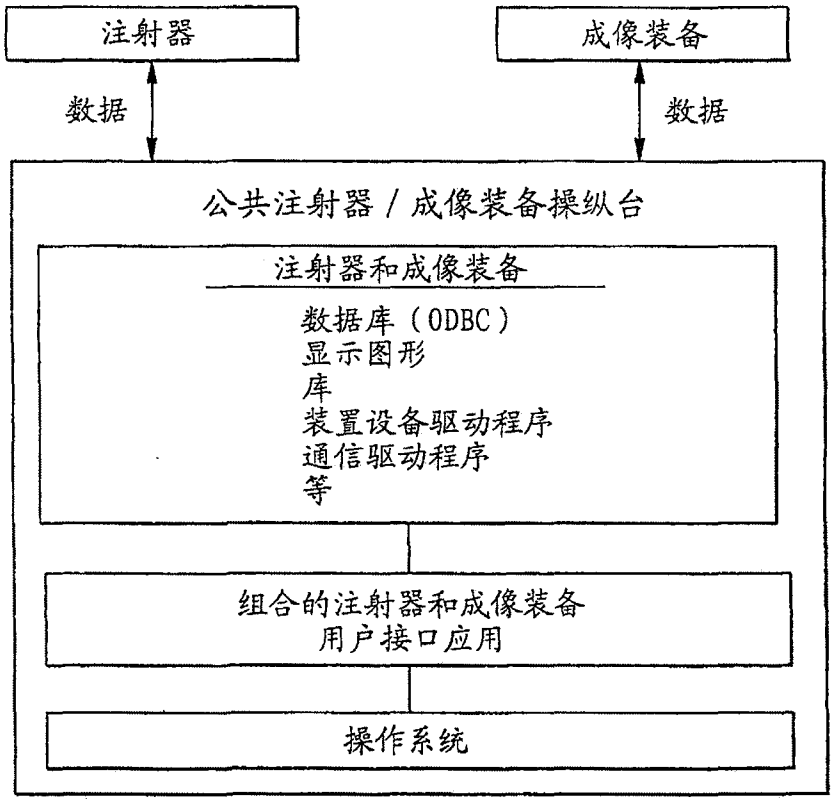

注射器
成像装备
数据
数据
公共注射器 / 成像装备操纵台
注射器和成像装备
数据库（ODBC）
显示图形
库
装置设备驱动程序
通信驱动程序
等
组合的注射器和成像装备
用户接口应用
操作系统

图 16

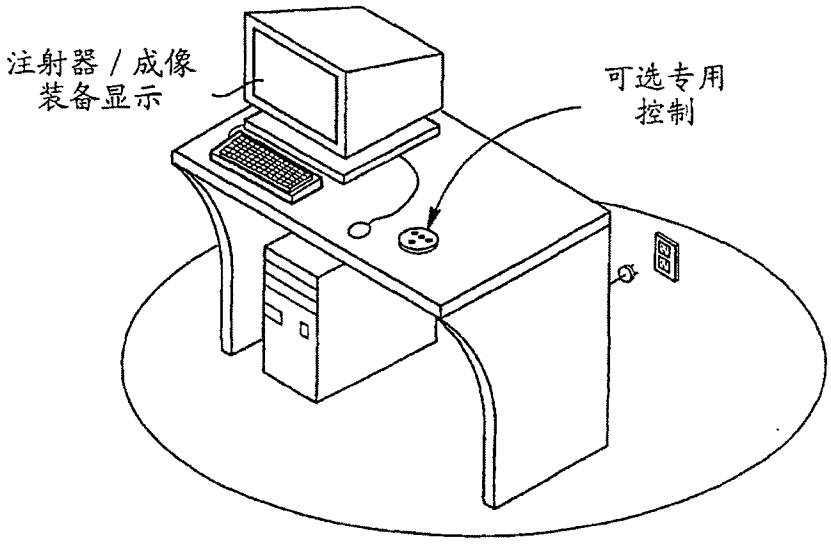


图 17

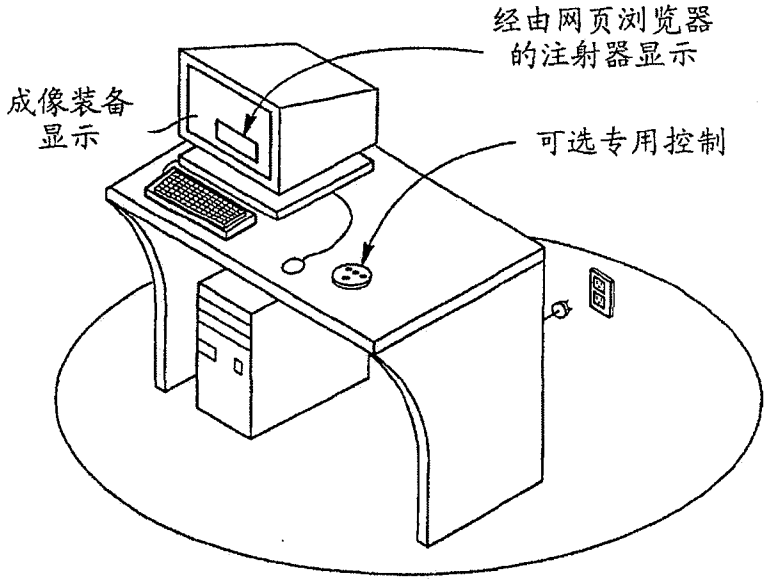
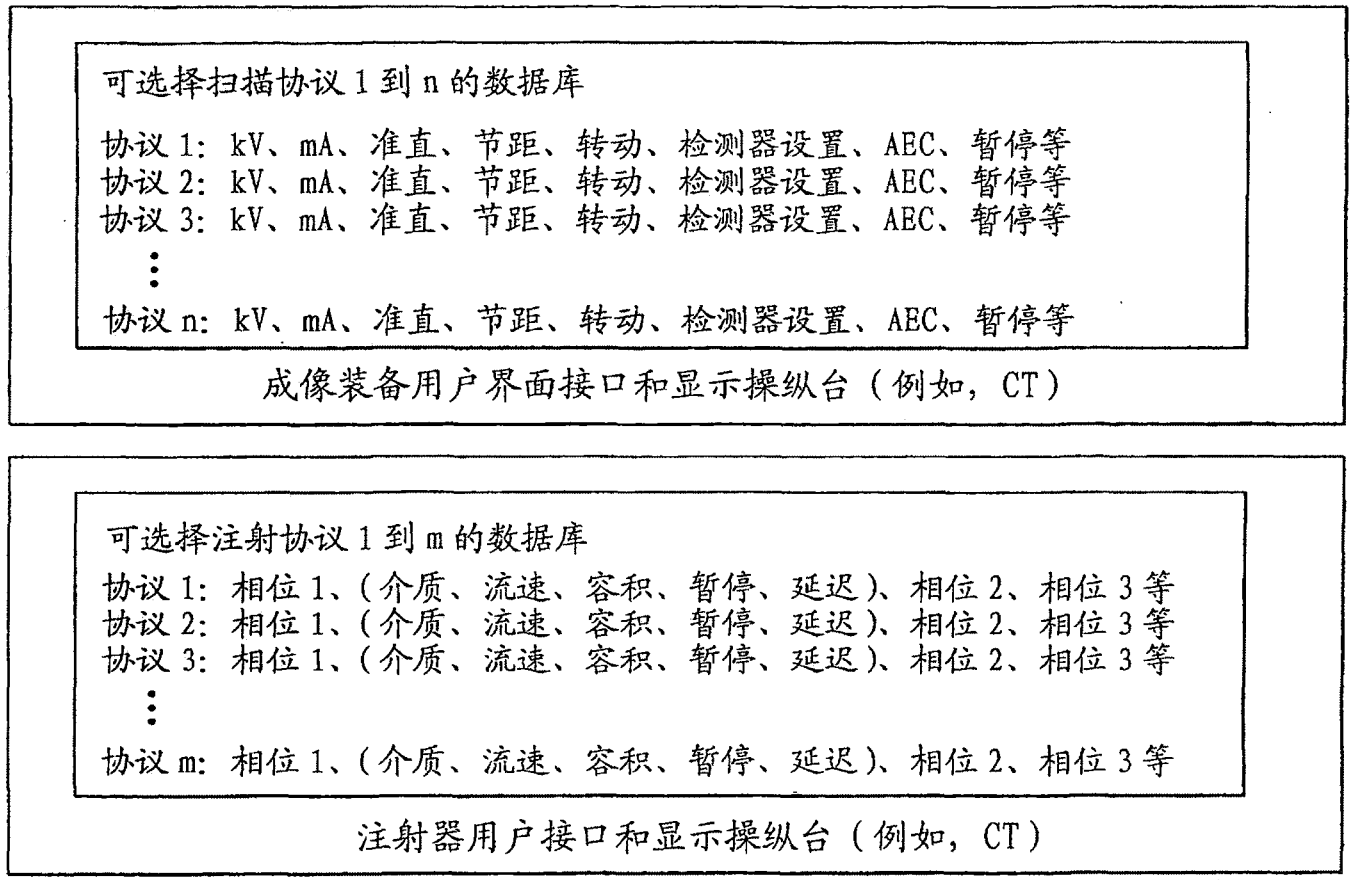
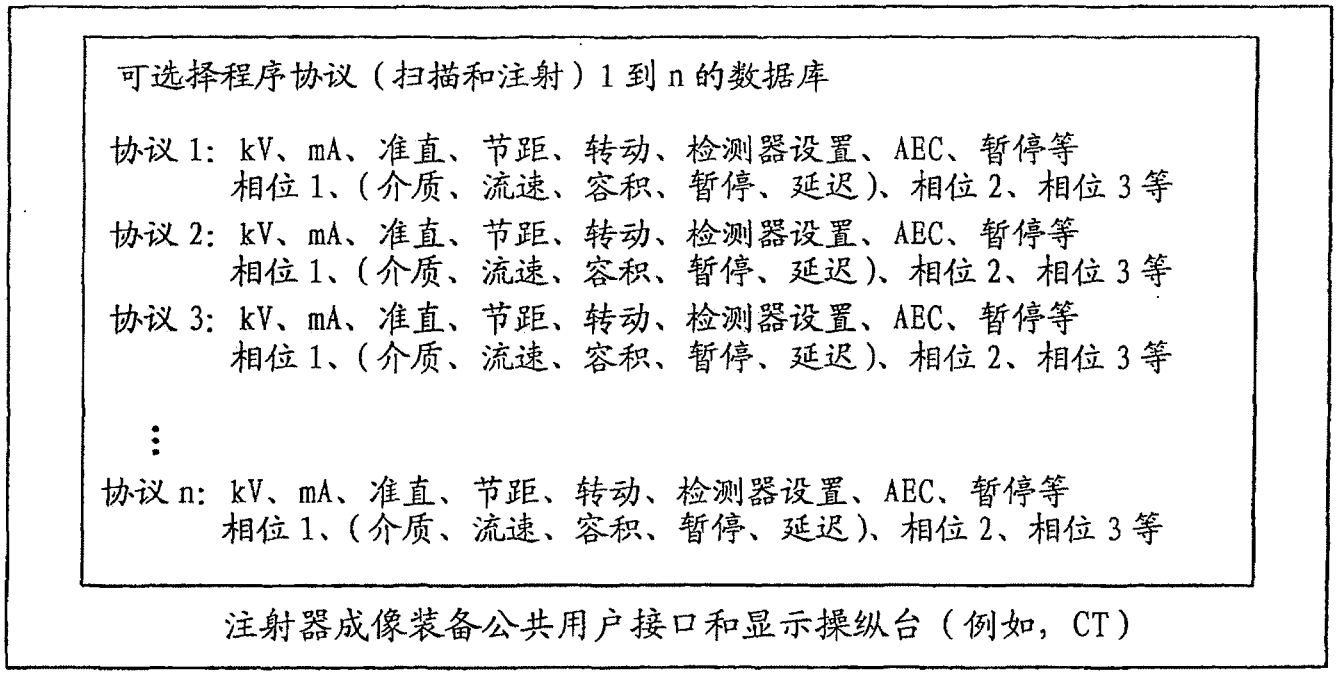


图 18



当前实践（2 个单独的用户接口）

图 19



建议的实践应用（公共用户接口）

图 20

Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt

EFS ID:	15659185
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	02-MAY-2013
Filing Date:	11-JUN-2008
Time Stamp:	10:42:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1700
RAM confirmation Number	8799
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Continued Examination (RCE)	RCE_56782-1-8.pdf	697795 7bf1d4b6886307f357f8c2ebe68918480e205dab	no	3
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	11thSIDS_56782-1-8.pdf	612327 7d0df420db121f6eada70c4a7d19709e2cf29083	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Foreign Reference	EP2492920A2.pdf	939755 f392d9dfd6a3af1a57a64bdbb59bb0daa3908ff2	no	18
Warnings:					
Information:					
4	Foreign Reference	EP2011126B1.pdf	1076709 ec5b68efe10ef02ab075d96166c74033b68b06ca	no	21
Warnings:					
Information:					
5	Foreign Reference	CN1968653A.pdf	2877932 a63ad8826f35837047f35dfce5caa2ae41697427	no	52
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30239 2a63e995a2099ca80e7fd12163cc6f9df21be1fc	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	6234757	

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

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New International Application Filed with the USPTO as a Receiving Office

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NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 02/05/2013

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

EXAMINER	
GURARI, EREZ	
ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 02/05/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1770	$300	$0	$2070	05/06/2013

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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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.

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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 02/05/2013
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1770	$300	$0	$2070	05/06/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
GURARI, EREZ	3618	280-047350

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.

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1 _____

2 _____

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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 _____

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❑ 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 credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

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Typed or printed name _____ Registration No. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

22859 7590 02/05/2013

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MINNEAPOLIS, MN 55402

EXAMINER	
GURARI, EREZ	

ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 02/05/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 790 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 790 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.	Applicant(s)	
	12/137,377	QUIRICO ET AL.	
	Examiner	Art Unit	
	EREZ GURARI	3618	

-- 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 *6/13/2013*.

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 *1,2,5-7,10-15,17,23,25,27 and 33*. 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).
   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 11/7/12, 10/17/12, 6/13/12, 1/18/13, 5/12/11
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 _____.

EREZ GURARI Examiner Art Unit: 3618	/J. ALLEN SHRIVER II/ Supervisory Patent Examiner, Art Unit 3618

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	
	Examiner	Art Unit
	J. ALLEN SHRIVER II	3618

✓	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	05/03/2011	09/01/2011							
	1	✓	=							
	2	✓	=							
	3	-	-							
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	29	-	-							
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	32	-	-							
	33	✓	=							

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	6450936		2002-09-17	Smith, III	

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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					

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

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

Receipt date: 11/07/2012	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Erez Gurari/	Date Considered	01/27/2013

*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.G./

Receipt date: 11/07/2012	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

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)	2012-10-31
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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

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

Issue Classification	Application/Control No. 12137377	Applicant(s)/Patent Under Reexamination
	Examiner J. ALLEN SHRIVER II	Art Unit 3618

CPC				
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CPC Combination Sets							
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US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
280	47.35

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
280	79.3	79.5			

INTERNATIONAL CLASSIFICATION					
CLAIMED					NON-CLAIMED
B	6	2	B	3 / 04 (2006.01.01)	

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618 (Primary Examiner)	01/28/2013 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office

Part of Paper No. 20130127

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	
	Examiner	**Art Unit**
	J. ALLEN SHRIVER II	3618

(Assistant Examiner)	(Date)	**Total Claims Allowed:** 16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	
	Examiner	**Art Unit**
	J. ALLEN SHRIVER II	3618

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	12	17	16	33										
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11	15		31												
	16		32												

		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618	01/28/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	7996068		2011-08-09	Telischak	

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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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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]

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Receipt date: 01/18/2013	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1	R. Klein, "Precise 82RB infusion system for cardiac perfusion measurement using 3D positron emission tomography", Ottawa-Carleton Institute for Electrical and Computer Engineering School of Information Technology and Engineering (Electrical & Computer Engineering), February, 2005, 147 pages	☐
	2	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (copyright date May 2008)	☐

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EXAMINER SIGNATURE

Examiner Signature	/Erez Gurari/	Date Considered	01/27/2013

*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.

Receipt date: 01/18/2013	Application Number	12137377	12137377 - GAU: 3618
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	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
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☐ See attached certification statement.

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SIGNATURE

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-01-17
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. QUIRICO
Art Unit	3618
Examiner Name	GURARI, Erez
Attorney Docket Number	56782.1.8

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	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	20080177126		2008-07-24	TATE	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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Receipt date: 06/13/2012	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, Erez
	Attorney Docket Number	56782.1.8

	1		☐

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Examiner Signature	/Erez Gurari/	Date Considered	01/27/2013

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

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Receipt date: 06/13/2012	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	Charles R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, Erez
	Attorney Docket Number	56782.1.8

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)	2012-06-13
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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(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	5395320		1995-03-07	Padda	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030139640		2003-07-24	Whittacre	
	2	20050187515		2005-08-25	Varrichio	
	3	20050277833		2005-12-15	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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Receipt date: 10/17/2012	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11	
	First Named Inventor	Charles R. Quirico	
	Art Unit	3618	
	Examiner Name	Erez Gurari	
	Attorney Docket Number	56782.1.8	

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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	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (date unknown).	☐

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Examiner Signature	/Erez Gurari/	Date Considered	01/27/2013

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	Art Unit
	EREZ GURARI	3618

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
280	47.34,47.35,79.11,79.3,638,651,33.992,79.5,79.6	5/1-2, 9/1/2011	eg

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST	5/1-2	eg

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See EAST	9/1/2011	eg

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	107	("20030004463" | "20030004463" | "20050278066" | "20070140958" | "20070213848" | "20070140958" | "20070232980" | "20070282263" | "20080093564" | "20080242915" | "20080071219" | "20080166292" | "20090312635" | "3710118" | "3774036" | "3997784" | "4286169" | "4562829" | "4585009" | "4585941" | "4625118" | "4679142" | "4755679" | "4853546" | "5590648" | "5039863" | "5258906" | "5274239" | "5475232" | "5485831" | "5739508" | "5840026" | "5885216" | "6157036" | "6442418" | "6626862" | "6767319" | "6870175" | "6901283" | "6908598" | "7163031" | "7169135" | "7204797" | "7256888" | "7413123" | "7476377" | "7504646").PN.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2013/01/27 23:09
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S6	447	(medical with cart).ab.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 17:49
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S9	88	(280/79.6).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 18:35
S10	182	(280/79.5).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 18:38
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S15	6	access panel with handle and ("280"/$).ccls.	US-PGPUB; USPAT;	ADJ	ON	2011/05/02 16:07

			DERWENT			
S16	3	bin with connect$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:14
S17	2	bin with mat$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:15
S18	6	basket with (mat$4 or connect$4) with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:16
S19	99	basket with (mat$4 or connect$4) with top and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:17
S20	0	("2007/0194543").URPN.	USPAT	ADJ	ON	2011/05/02 16:17
S21	13	("20030062232" | "20040211634" | "20040211634" | "20060027475" | "20060012139" | "20060027475" | "5011013" | "5209384" | "5240264" | "5664652" | "5833065" | "5011013" | "5209384" | "5664652" | "5833065" | "6176559" | "6347847" | "6371320" | "6371320" | "6601930" | "6761366" | "6126003" | "6176559" | "6371320" | "6761366" | "7004481" | "7210689" | "7004481" | "7210689").PN.	USPAT	ADJ	ON	2011/05/02 16:19
S22	79	("0996636" | "1722456" | "2926022" | "3257155" | "3472392" | "3491381" | "3505692" | "3610429" | "3748437" | "3853239" | "3920260" | "3983583" | "4130123" | "4398310" | "4652062" | "4670010" | "4875696" | "4894874" | "4942631" | "4974500" | "4986555" | "5259668" | "5290058" | "5301376" | "5465438" | "D188845" | "D273906").PN. OR ("5702115").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2011/05/03 13:45
S23	5	"2008082966".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2011/05/03 16:33
S24	87	("20030004463" | "20030036674" | "20030036713" | "20030175196" | "20030216609" | "20040015038" | "20040260143" | "20050029465" | "20050203329" | "20050277833" | "20060100578" | "20060106345" | "20060195045" | "4307713" | "4562829" | "4857728" | "4968305" | "4994012" | "5017191" | "5039863" | "5112327" | "5254094" | "5274239" | "5288285" | "5489931" | "5494036" | "5514071" | "5569181" | "5611785" | "5739508" | "5806519" | "5820614" | "5840026" | "5843037" | "5911252" | "5927351" | "5928194" | "6339718" | "6397098" | "6767319" | "6767319" | "6870175" | "7094216" | "7151267").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2011/05/03 16:35
S25	72	("3997784" | "4625118" | "4679142" | "5885216" | "6767319" | "20070140958" | "6908598" | "20090318745" | "5827429" | "5485831" |	US-PGPUB; USPAT;	ADJ	OFF	2012/05/06 20:57

		"5739508" | "6157036" | "7504646" | "5765842" | "20090312630" | "7862534" | "3714429" | "4562829" | "4853546" | "5258906" | "20070140958" | "20070213848" | "20080242915" | "20070232980" | "20090312635" | "7163031" | "5702115" | "4096859" | "4769008" | "4585941" | "5039863" | "7169135" | "20080093564" | "20060151048" | "20100125243" | "20100270226" | "3774036" | "4286169" | "6626862" | "20100312039" | "3483867" | "4336036" | "6870175" | "7204797" | "20070282263" | "5475232" | "6901283" | "7256888" | "20030004463" | "20060015056" | "4994056" | "6347711" | "6558125" | "20080071219" | "4755679" | "20030004463" | "7476377" | "7612999" | "20040104160" | "20110071392" | "20050278066" | "3710118" | "4585009" | "20080166292" | "5274239" | "5840026" | "6442418" | "7413123" | "5590648" | "20110172524" | "4466888" | "4623102").PN.	USOCR				

EAST Search History (Interference)

< This search history is empty>

1/ 27/ 2013 11:10:47 PM
C:\ Users\ egurari\ Documents\ EAST\ Workspaces\ 12137377.wsp

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	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	7996068		2011-08-09	Telischak	

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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 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]

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	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1	R. Klein, "Precise 82RB infusion system for cardiac perfusion measurement using 3D positron emission tomography", Ottawa-Carleton Institute for Electrical and Computer Engineering School of Information Technology and Engineering (Electrical & Computer Engineering), February, 2005, 147 pages	☐
	2	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (copyright date May 2008)	☐

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Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2013-01-17
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 Acknowledgement Receipt

EFS ID:	14701043
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	18-JAN-2013
Filing Date:	11-JUN-2008
Time Stamp:	15:00:40
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	Non Patent Literature	RKlein-MASc-thesis-2005.pdf	2226047 5199c027c97cd1df37f9296f66665c3d7029ed98	no	147

Warnings:	
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2	Non Patent Literature	Posijet.pdf	4244122 f4131e1134a2c00962cd96c7bfa6d81d41d39b39	no	4
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	10thSIDS_56782-1-8.pdf	612422 57eba452e2f3ab37f1505fd548093fb17a07bbf2	no	4
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			Total Files Size (in bytes):	7082591	

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

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

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

PTO/SB/08a (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	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	6450936		2002-09-17	Smith, III	

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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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

	1		☐

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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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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)	2012-10-31
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

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

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	14109926
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	07-NOV-2012
Filing Date:	11-JUN-2008
Time Stamp:	10:49:25
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)	9thSIDS_56782-1-8.pdf	612188 7b6fe53dc0c6592001969 6d64400116a60af34a8	no	4

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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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First Named Inventor	Charles R. Quirico
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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	5395320		1995-03-07	Padda	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030139640		2003-07-24	Whittacre	
	2	20050187515		2005-08-25	Varrichio	
	3	20050277833		2005-12-15	Williams	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	LEMER PAX, POSIJET® Integrated FDG dispensing and infusion system, www.lemerpax.com (date unknown).	☐

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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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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)	2012-10-17
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 Acknowledgement Receipt

EFS ID:	13946977
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	17-OCT-2012
Filing Date:	11-JUN-2008
Time Stamp:	12:11:15
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	Non Patent Literature	Posijet.pdf	4244122 f4131e1134a2c00962cd96c7bfa6d81d41d39b39	no	4

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	8thSIDS_56782-1-8.pdf	612378 1501a77be7759e8900dcb67c076e44920798349a	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	4856500

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/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Number	12137377	Filing Date	2008-06-11	Docket Number (if applicable)	56782.1.8	Art Unit	3618
First Named Inventor	Charles R. QUIRICO			Examiner Name	GURARI, Erez		

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☒ Enclosed

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

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2012-06-13
Name	Paul J. LaVanway, Jr.	Registration Number	64610

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

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	Charles R. QUIRICO
Art Unit	3618
Examiner Name	GURARI, Erez
Attorney Docket Number	56782.1.8

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
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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	20080177126		2008-07-24	TATE	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, Erez
	Attorney Docket Number	56782.1.8

	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	12137377
	Filing Date	2008-06-11
	First Named Inventor	Charles R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, Erez
	Attorney Docket Number	56782.1.8

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)	2012-06-13
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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Electronic Patent Application Fee Transmittal

Application Number:	12137377
Filing Date:	11-Jun-2008
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Filer:	Paul J. LaVanway Jr.
Attorney Docket Number:	56782.1.8

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	930	930
		Total in USD ($)		**930**

Electronic Acknowledgement Receipt

EFS ID:	13000902
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	13-JUN-2012
Filing Date:	11-JUN-2008
Time Stamp:	14:30:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$930
RAM confirmation Number	12309
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Continued Examination (RCE)	56782_1_8RCE.pdf	797920 2832e0608b67c8576432a1be023643a9ff23e425	no	3
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	56782_1_8IDS.pdf	612137 258d60656eb244049b8666e9b17aa772a50d983c	no	4
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30581 d1dc743faf5c935125572c890db36627379bbcd8	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1440638	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 05/22/2012

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

EXAMINER	
GURARI, EREZ	
ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 05/22/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

TITLE OF INVENTION: CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	08/22/2012

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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 05/22/2012
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,377	06/11/2008	Charles R. Quirico	56782.1.8	7402

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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	08/22/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
GURARI, EREZ	3618	280-047350

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 credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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22859 7590 05/22/2012

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MINNEAPOLIS, MN 55402

EXAMINER	
GURARI, EREZ	

ART UNIT	PAPER NUMBER
3618	

DATE MAILED: 05/22/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 675 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 675 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.	Applicant(s)	
	12/137,377	QUIRICO ET AL.	
	Examiner	Art Unit	
	EREZ GURARI	3618	

-- 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 *12/16/2011 & 3/2/2012*.
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 *1,2,5-7,10-15,17,23,25, 27, 33*.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).
7. ☐ 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. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/16/2011 & 3/2/2012
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/EREZ GURARI/ Examiner, Art Unit 3618	/J. ALLEN SHRIVER II/ Supervisory Patent Examiner, Art Unit 3618

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	**Art Unit**
	EREZ GURARI	3618

✓	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	05/03/2011	09/01/2011							
	1	✓	=							
	2	✓	=							
	3	-	-							
	4	-	-							
	5	✓	=							
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	7	✓	=							
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	32	-	-							
	33	✓	=							

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
12137377	QUIRICO ET AL.
Examiner	**Art Unit**
EREZ GURARI	3618

ORIGINAL		INTERNATIONAL CLASSIFICATION	
CLASS	SUBCLASS	CLAIMED	NON-CLAIMED
280	47.35	B 6 2 B 3 / 04 (2006.01)	

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
280	79.3	79.5			

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	12	17	16	33										
2	2		18												
	3		19												
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8	12		28												
9	13		29												
10	14		30												
11	15		31												
	16		32												

/EREZ GURARI/ Examiner.Art Unit 3618 (Assistant Examiner)	05/09/2012 (Date)	**Total Claims Allowed:** 16	
/J. ALLEN SHRIVER II/ Supervisory Patent Examiner.Art Unit 3618 (Primary Examiner)	09/05/2011 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	CHARLES R. QUIRICO
Art Unit	3618
Examiner Name	GURARI, EREZ
Attorney Docket Number	56782.1.8

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		1969-12-16	Markovitz	
	2	4096859		1978-06-27	Agarwal	
	3	4336036		1982-06-22	Leeke	
	4	4466888		1984-08-21	Verkaart	
	5	4623102		1986-11-18	Hough, Jr.	
	6	4769008		1988-09-06	Hessel	
	7	4994056		1991-02-19	Ikeda	
	8	5827429		1998-10-27	Ruschke	

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

Receipt date: 12/16/2011	Application Number	12137377	12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11	
	First Named Inventor	CHARLES R. QUIRICO	
	Art Unit	3618	
	Examiner Name	GURARI, EREZ	
	Attorney Docket Number	56782.1.8	

	9	6347711		2002-02-19	Goebel	
	10	6558125		2003-05-06	Futterknecht	
	11	7862534		2011-01-04	Quirico	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040104160		2004-06-03	Scagliarini	
	2	20060015056		2006-01-19	Ellingboe	
	3	20090312630		2009-12-17	Hidem	
	4	20090318745		2009-12-24	Quirico	
	5	20100125243		2010-05-20	Balestracci	
	6	20100270226		2010-10-28	Balestracci	

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

Receipt date: 12/16/2011	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, EREZ
	Attorney Docket Number	56782.1.8

	7	20100312039		2010-12-09	Quirico	
	8	20110071392		2011-03-24	Quirico	
	9	20110172524		2011-07-14	Hidem	
	10	20060151048		2005-12-27	Tochon-Danguy	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0919249	EP		1999-06-02	NISSHO KK		☐
	2	1421960	EP		2004-05-26	GVS S P A		☐
	3	2009152320	WO		2009-12-17	BRACCO DIAGNOSTICS INC		☐

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

NON-PATENT LITERATURE DOCUMENTS Remove

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

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

Receipt date: 12/16/2011	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, EREZ
	Attorney Docket Number	56782.1.8

	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%.... taken off of web on 11/11/2008	☐
	2	International Search Report and Written Opinion, dated 01-04-2010 for PCT Application No. PCT/US2009/063788, 13 pages	☐

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

EXAMINER SIGNATURE

Examiner Signature	/Erez Gurari/	Date Considered	05/06/2012

*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.G./

Receipt date: 12/16/2011	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, EREZ
	Attorney Docket Number	56782.1.8

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)	2011-12-16
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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

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The 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.

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12137377
Filing Date	2008-06-11
First Named Inventor	CHARLES R. QUIRICO
Art Unit	3618
Examiner Name	Erez Gurari
Attorney Docket Number	56782.1.8

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3714429		1973-01-30	Mozley	

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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]

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Receipt date: 03/02/2012	Application Number	12137377 12137377 - GAU: 3618
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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EXAMINER SIGNATURE

Examiner Signature	/Erez Gurari/	Date Considered	05/06/2012

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Receipt date: 03/02/2012

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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	72	("3997784" | "4625118" | "4679142" | "5885216" | "6767319" | "20070140958" | "6908598" | "20090318745" | "5827429" | "5485831" | "5739508" | "6157036" | "7504646" | "5765842" | "20090312630" | "7862534" | "3714429" | "4562829" | "4853546" | "5258906" | "20070140958" | "20070213848" | "20080242915" | "20070232980" | "20090312635" | "7163031" | "5702115" | "4096859" | "4769008" | "4585941" | "5039863" | "7169135" | "20080093564" | "20060151048" | "20100125243" | "20100270226" | "3774036" | "4286169" | "6626862" | "20100312039" | "3483867" | "4336036" | "6870175" | "7204797" | "20070282263" | "5475232" | "6901283" | "7256888" | "20030004463" | "20060015056" | "4994056" | "6347711" | "6558125" | "20080071219" | "4755679" | "20030004463" | "7476377" | "7612999" | "20040104160" | "20110071392" | "20050278066" | "3710118" | "4585009" | "20080166292" | "5274239" | "5840026" | "6442418" | "7413123" | "5590648" | "20110172524" | "4466888" | "4623102").PN.	US-PGPUB; USPAT; USOCR	ADJ	OFF	2012/05/06 20:57
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S5	1642	medical with cart	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 17:48
S6	447	(medical with cart).ab.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 17:49
S7	31	("20020165641" | "3910659" | "4071740" |	US-	ADJ	ON	2011/05/01

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S8	4060	(280/47.34,47.35,79.11,79.3,638,651,33.992).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 18:34
S9	88	(280/79.6).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 18:35
S10	182	(280/79.5).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/01 18:38
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S12	39	("0886537" | "0913943" | "1178597" | "2667392" | "2672391" | "2683639" | "2833550" | "3472392" | "3721349" | "3853329" | "4872410" | "4993726" | "5082301" | "5186479" | "5190303" | "5269545").PN. OR ("5460391").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2011/05/02 14:34
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S14	0	access panel with bin and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:07
S15	6	access panel with handle and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:07
S16	3	bin with connect$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:14
S17	2	bin with mat$4 with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:15
S18	6	basket with (mat$4 or connect$4) with lid and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:16
S19	99	basket with (mat$4 or connect$4) with top and ("280"/$).ccls.	US-PGPUB; USPAT; DERWENT	ADJ	ON	2011/05/02 16:17

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S22	79	("0996636" | "1722456" | "2926022" | "3257155" | "3472392" | "3491381" | "3505692" | "3610429" | "3748437" | "3853239" | "3920260" | "3983583" | "4130123" | "4398310" | "4652062" | "4670010" | "4875696" | "4894874" | "4942631" | "4974500" | "4986555" | "5259668" | "5290058" | "5301376" | "5465438" | "D188845" | "D273906").PN. OR ("5702115").URPN.	US-PGPUB; USPAT; USOCR	ADJ	ON	2011/05/03 13:45
S23	5	"2008082966".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2011/05/03 16:33
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EAST Search History (Interference)

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5/6/2012 9:05:58 PM
C:\Users\egurari\Documents\EAST\Workspaces\12137377.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12137377	QUIRICO ET AL.
	Examiner	Art Unit
	EREZ GURARI	3618

SEARCHED			
Class	Subclass	Date	Examiner
280	47.34,47.35,79.11,79.3,638,651,33.992,79.5,79.6	5/1-2, 9/1/2011	eg

SEARCH NOTES		
Search Notes	Date	Examiner
See EAST	5/1-2	eg

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
	See EAST	9/1/2011	eg

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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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	12137377
	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	Erez Gurari
	Attorney Docket Number	56782.1.8

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)	2012-03-02
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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

Privacy Act Statement

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:	12211278
Application Number:	12137377
International Application Number:	
Confirmation Number:	7402
Title of Invention:	CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	56782.1.8
Receipt Date:	02-MAR-2012
Filing Date:	11-JUN-2008
Time Stamp:	13:19:05
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)	7thSIDS_56782-1-8.pdf	754305 0dbd31b10520f30c78141bb5d5501daf75286e36	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	754305

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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INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS MN 55402

MAILED
JAN 31 2012
OFFICE OF PETITIONS

In re Application of
Charles R. Quirico et al.
Application No. 12/137,377
Filed: June 11, 2008
Attorney Docket No. 56782.1.8

DECISION GRANTING STATUS UNDER 37 CFR 1.48(a) AND DISMISSED AS MOOT UNDER 37 CFR 1.47(a)

This is a decision on the petitions filed December 14, 2011 which are collectively being treated as (1) a request under 37 CFR 1.48(a) to amend the inventive entity by the addition of Janet L. Gelbach as inventor, and (2) as authorized by 37 CFR 1.48(a)(3), a petition under 37 CFR 1.47(a).

The petition under 37 CFR 1.48(a) is **GRANTED**.

If the inventive entity is set forth in error in an executed § 1.63 oath or declaration in a nonprovisional application, and such error arose without any deceptive intention on the part of the person named as an inventor in error or on the part of the person who through error was not named as an inventor, the inventorship of the nonprovisional application may be amended to name only the actual inventor or inventors.

37 CFR 1.48(a) requires that an amendment to the named inventive entity be accompanied by:

(1) A request to correct the inventorship that sets forth the desired inventorship change;

(2) A statement from each person being added as an inventor and from each person being deleted as an inventor that the error in inventorship occurred without deceptive intention on his or her part;

(3) An oath or declaration by the actual inventor or inventors as required by § 1.63 or as permitted by §§ 1.42, 1.43 or § 1.47;

(4) The processing fee set forth in § 1.17(i); and

(5) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b).

It has been found that this non-provisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Janet L. Gelbach as inventor.

A corrected filing receipt is enclosed.

The petition under 37 CFR 1.47(a) is **DISMISSED AS MOOT.**

Papers filed on December 14, 2011 include a Declaration signed by previously non-signing inventor Daniel V. Clements.

In view of the joinder of the inventor, further consideration under 37 CFR 1.47 (a) is moot; this application does not have any rule 1.47 (a) status. This application need not be returned to this office for any further consideration under 37 CFR 1.47 (a).

This matter is being referred to Technology Center AU 3618 for examination in due course.

Telephone inquiries regarding this decision should be directed to Irvin Dingle at (571) 272-3210.

David Bucci
Petitions Examiner
Office of Petitions

Encl: Corrected Filing Receipt

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/137,377	06/11/2008	3618	2020	56782.1.8	33	4

CONFIRMATION NO. 7402

CORRECTED FILING RECEIPT

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

OC00000005227072O

Date Mailed: 01/30/2012

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**

Applicant(s)

Charles R. Quirico, Warren, NJ;
Ernest Balestracci, Iselin, NJ;
Jacob S. Childs, Minneapolis, MN;
Peter B. Madson, Shanghai, CHINA;
Daniel V. Clements, Minneapolis, MN;
Janet L. Gelbach, New Albany, IN;

Assignment For Published Patent Application

BRACCO DIAGNOSTICS, INC., Princeton, NJ

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

Domestic Priority data as claimed by applicant

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

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 06/23/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/137,377**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS

Preliminary Class

280

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 (1-866-999-4158).

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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

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

NOT GRANTED

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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First Named Inventor	CHARLES R. QUIRICO
Art Unit	3618
Examiner Name	GURARI, EREZ
Attorney Docket Number	56782.1.8

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		1969-12-16	Markovitz	
	2	4096859		1978-06-27	Agarwal	
	3	4336036		1982-06-22	Leeke	
	4	4466888		1984-08-21	Verkaart	
	5	4623102		1986-11-18	Hough, Jr.	
	6	4769008		1988-09-06	Hessel	
	7	4994056		1991-02-19	Ikeda	
	8	5827429		1998-10-27	Ruschke	

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	Attorney Docket Number	56782.1.8

	9	6347711		2002-02-19	Goebel	
	10	6558125		2003-05-06	Futterknecht	
	11	7862534		2011-01-04	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
	1	20040104160		2004-06-03	Scagliarini	
	2	20060015056		2006-01-19	Ellingboe	
	3	20090312630		2009-12-17	Hidem	
	4	20090318745		2009-12-24	Quirico	
	5	20100125243		2010-05-20	Balestracci	
	6	20100270226		2010-10-28	Balestracci	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	7	20100312039		2010-12-09	Quirico	
	8	20110071392		2011-03-24	Quirico	
	9	20110172524		2011-07-14	Hidem	
	10	20060151048		2005-12-27	Tochon-Danguy	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0919249	EP		1999-06-02	NISSHO KK		☐
	2	1421960	EP		2004-05-26	GVS S P A		☐
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137377
	Filing Date	2008-06-11
	First Named Inventor	CHARLES R. QUIRICO
	Art Unit	3618
	Examiner Name	GURARI, EREZ
	Attorney Docket Number	56782.1.8

	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%.... taken off of web on 11/11/2008	☐
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Name/Print	Paul J. LaVanway, Jr.	Registration Number	64,610

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 919 249 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
02.06.1999 Bulletin 1999/22

(51) Int. Cl.[6]: **A61M 1/36**

(21) Application number: **98121181.6**

(22) Date of filing: **13.11.1998**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **20.11.1997 JP 320194/97**
19.12.1997 JP 350381/97
19.06.1998 JP 172805/98

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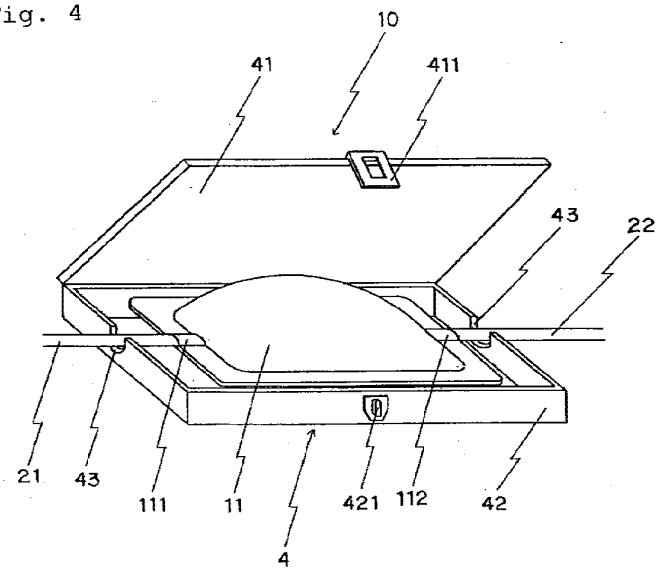
(54) A blood filter set and a method of recovering blood components by use of the same

(57) This invention relates to a blood filter set comprising a bag body having a blood flow inlet and a blood flow outlet and charged with a filter material, and an accommodation vessel for accommodating said bag body and a method of recovering blood components by use of the filter set.

Fig. 4



EP 0 919 249 A1

Description

Field of the Invention

[0001] The present invention relates to a filter set for recovering desired blood components from human blood and a method of recovering blood components by use of the filter set.

Background of the Invention

[0002] It is known that hematopoietic malady occurs as side effects of chemotherapy for hematopoietic organ tumors such as leukemia etc., and solid tumors, and bone marrow transplant and peripheral blood stem cell transplant are applied as therapies for the hematopoietic malady. These therapies are methods of recovering from hematopoietic malady, in which hematopoietic stem cells and/or hematopoietic precursor cells contained in bone marrow and peripheral blood are transplanted into human body. By establishing these transplant therapies, chemotherapy for tumors such as leukemia and solid tumors was made feasible. Further, it was found in recent years that hematopoietic stem cells and/or hematopoietic precursor cells are also contained in umbilical cord blood, and a therapy by transplanting hematopoietic cells and/or hematopoietic precursor cells from umbilical cord blood is also expected to be a promising method.

[0003] Usually, blood used for these transplant therapies is cryopreserved after collecting till transplanting. If cryopreserved blood is contaminated with erythrocytes, the erythrocytes are lyzed to cause side effects after thawing, therefore, before thawing the blood to be transplanted erythrocytes should be removed from the blood.

[0004] Known methods of removing erythrocytes from blood to be transplanted include a centrifugation method and a filter method. A centrifugation method utilizes the difference in specific gravity between erythrocytes and leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells. A filter method of recovering leukocytes utilizes a filter for passing erythrocytes but capturing leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells and the leukocytes captured therein is recovered with a washing solution.

[0005] However, the centrifugation method requires such skills as not to cause disturbance of the interfaces among separated blood components, while the filter method has the disadvantage of low yield because the density of the filter material is so high as to capture hematopoietic stem cell- and/or hematopoietic precursor cell-derived leukocytes at high concentration, thus making it difficult to remove leukocytes which have adhered to the filter material even if a washing solution is used.

[0006] The present invention is to solve these problems, and the object of the present invention is to provide a filter set for efficiently recovering desired blood components from blood and a method of recovering blood components by use of the filter set.

[0007] As a result of their eager study for achieving the above object, the present inventors found that desired blood components can be efficiently recovered from blood with a blood filter set which comprises a bag body charged with a filter material and an accommodation vessel for accommodating said bag body. Further, they found that a filter set comprises preferably a bag body consisting of a flexible sheet charged inside with a filter material and a rigid accommodation vessel for accommodating the bag body in a compressed condition or in a freely expansive and compressive condition. Additionally, they found that mainly leukocytes could be efficiently recovered from blood by a bag body charged inside with a filter material and a flexible tube body accommodating the bag body in a compressed condition in the thickness direction.

Summary of the Invention

[0008] That is, the present invention relates to a filter set comprising a bag body having a blood flow inlet and a blood flow outlet and charged with a filter material, and an accommodation vessel for accommodating said bag body.

[0009] One embodiment of this invention is a filter set comprising a bag body having a blood flow inlet and a blood flow outlet and consisting of a flexible sheet charged inside with a filter material, and a rigid accommodation vessel for accommodating said bag body which is freely removed therefrom and for accommodating said bag body in a compressed condition at the time of accommodation.

[0010] The rigid accommodation vessel is a rectangular parallelepiped vessel provided with a takeout port from which the bag body can be removed or a vessel provided with a lid which can be opened and closed or the like.

[0011] Another embodiment of this invention is a filter set comprising a bag body having a blood flow inlet and a blood flow outlet and consisting of a flexible sheet charged inside with a filter material, and a rigid accommodation vessel for accommodating said bag body, wherein said bag body is compressed by filling with compressed gas, and after blood is passed through said bag body in a compressed condition, the compressed gas is exhausted to relieve the compression of said bag body through which a washing solution is then passed.

[0012] The rigid accommodation vessel includes a vessel compressing said bag body by filling with compressed gas

and relieving the compression of the bag body by exhausting the compressed gas. Otherwise, the vessel is capable of further expanding the bag body by evacuating the inside of the vessel after relieving the compression condition.

[0013] Another embodiment is a filter set comprising a bag body having a blood flow inlet and a blood flow outlet and being charged inside with a filter material and a flexible tube body accommodating the bag body in a compressed condition in the thickness direction, wherein said bag body can be removed from said tube body.

[0014] The tube body is a heat-shrinkable tube or possesses a similar length to that of the bag body and a smaller volume than that of the bag body. If the tube body is heat-shrinkable, the tube body is preferably provided with a ruptured portion. And if the tube body possesses a similar length to that of the bag body and a smaller volume than that of the bag body, the tube body is preferably provided at least one end with a grasping portion for removing the tube body from the bag body.

[0015] The present invention relates to a method of recovering blood components comprises accommodating a bag body into an accommodation vessel, wherein the bag body has a blood flow inlet and a blood flow outlet and is charged inside with a filter material, passing blood flow through said bag body in a condition compressed by said accommodation vessel to adhere blood components to the filter material, removing the bag body from said accommodation vessel, passing a washing solution through the inside of said bag body in an expanded condition so as to wash off the blood components adhered to said filter material, and recovering the blood components.

[0016] One embodiment of the present invention relates to a method of recovering blood components comprises filling a bag body with compressed gas to compress said bag body, wherein the bag body has a blood flow inlet and a blood flow outlet, consists of a flexible sheet and is charged inside with a filter material and accommodated in a rigid accommodation vessel, passing blood flow through said bag body in a compressed condition to adhere blood component to the filter material, exhausting the compressed gas to relieve the compression condition of said bag body, passing a washing solution through the inside of said bag body so as to wash off the blood components adhered to said filter material and recovering the blood components.

[0017] After the compressed gas is exhausted, the inside of the vessel may be evacuated to further expand said bag body through which the washing solution is then passed to wash and recover blood components having adhered to said filter.

[0018] Another embodiment is a method of recovering blood components comprising passing blood through a bag body in a compressed condition, wherein the bag body has a blood flow inlet and a blood flow outlet, consists of a flexible sheet and is charged with a filter material and accommodated in a flexible tubular body in a compressed condition in the thickness direction, removing the bag body from the flexible tubular body to relieve the compression of the bag body, passing a washing solution through the inside of said bag body so as to wash off the blood components adhered to the filter material, and recovering the blood components.

Brief Description of the Drawings

[0019]

Fig. 1 is a drawing showing one example of the filter set of the present invention.
Fig. 2 is a longitudinal section of the filter set shown in Fig. 1.
Fig. 3 is a drawing illustrating the filter set shown in Fig. 1.
Fig. 4 is a drawing showing another example of the filter set of the present invention.
Fig. 5 is a drawing showing the method of recovering blood components according to the present invention.
Fig. 6 is a drawing showing another example of the blood filter set of the present invention.
Fig. 7 is a longitudinal section of the bag body compressed by filling the blood filter set in Fig. 6 with compressed gas.
Fig. 8 is a longitudinal section showing the condition under which the bag body whose compression was relieved by exhausting the compressed gas from the blood filter set shown in Fig. 6.
Fig. 9 shows one example of the filter set of the present invention.
Fig. 10 is a longitudinal section of the filter set shown in Fig. 9.
Fig.11 shows another example of the filter of the present invention.

Description of Preferred Embodiments

[0020] Examples of the present invention are described with reference to the drawings.

[0021] As shown in Figs. 1, 2 and 3, the filter set 1 is composed of bag body 11 charged inside with filter material 12, tube 21 connected to blood flow inlet 111 and tube 22 connected to blood flow outlet 112 for the bag body 11, and an accommodation vessel 3 for accommodating the bag body 11 in a compressed condition. Figs. 1 and 2 show that the bag body 11 has been removed from the accommodation vessel 3 and Fig. 3 shows that the bag body 11 has been

accommodated in the accommodation vessel 3.

[0022] The bag body 11 consists of two flexible sheets welded along the edge thereof. The material of the bag body 11 includes soft polyvinyl chloride, ethylene-vinyl acetate copolymers, styrene-butadiene-styrene copolymers, polyurethane, polyamide, polyester, polyethylene, polypropylene etc. The welding method is preferably thermal welding, high frequency welding, ultrasonic welding, solvent welding or the like.

[0023] The bag body 11 has been charged inside with the filter material 12, and the filter material 12 is sealed along the edge to the weld of the bag body 11. The filter material 12 is to capture desired blood components (mainly leukocytes) from blood, and it is composed preferably of synthetic fibers such as polyester, polypropylene, polyethylene, polymethyl methacrylate, polyamide etc., natural fibers such as cotton etc.

[0024] The diameter of the fiber is preferably in the range of 0.1 to 40 μm, preferably 0.5 to 25 μm, more preferably 0.5 to 10 μm, and most preferably 0.5 to 3 μm, and in the case of a diameter of less than 0.1 μm, spaces between the fibers per unit area tend to become small thus increasing filtration resistance, while in the case of a diameter of more than 40 μm, the volume of the fibers tends to become large thus increasing absorption of undesired blood components.

[0025] The bulk density of fiber agglomerate in compressed bag body 11 is 0.05 to 0.50 g/cm^3, preferably 0.08 to 0.30 g/cm^3, and more preferably 0.10 to 0.20 g/cm^3. If the bulk density is less than 0.05 g/cm^3, the yield of leukocytes recovered in the filter tends to decrease, and if the bulk density exceeds 0.50 g/cm^3, the flow rate of blood passing through the filter tends to decrease.

[0026] The amount of the filter material 12 charged may be any amount enough to achieve degrees of capture possessed by a conventional leukocyte-removing filter in a compressed condition.

[0027] This filter material 12 may be formed of two or more materials or may comprise layers of different substances or different mesh sizes laminated therein. If the filter material 12 is composed of a multi-layer fiber agglomerate, at least one layer has a fiber diameter of 25 μm or less and a bulk density of 0.05 to 0.50 g/cm^3 in a compressed condition. The multi-layer structure is composed of 2 to 6 layers, where a layer near the blood flow inlet consisting of fiber agglomerate having a large fiber diameter and a high bulk density and a layer near the blood flow outlet consisting of a fiber agglomerate having a small fiber diameter and a low bulk density are preferably arranged so that leukocytes can be captured in the order of a decreasing diameter through the layers.

[0028] For example, if the filter material 12 in compressed bag body 11 is a multi-layer fiber agglomerate consisting of a fiber agglomerate with a fiber diameter of 10 μm and a bulk density of 0.23 g/cm^3 as a first layer, a fiber agglomerate with a fiber diameter of 3.5 μm and a bulk density of 0.11 g/cm^3 as a second layer and a fiber agglomerate with a fiber diameter of 1.8 μm and a bulk density of 0.12 g/cm^3 as a third layer, then blood components with large diameters will be captured by the first layer, monocytes and granulocytes by the second layer and lymphocytes by the third layer.

[0029] This filter material 12 may be formed of two or more materials or may comprise layers of different substances or different mesh sizes laminated therein. Further, the filter material 12 is not limited to the structure in which it is sealed along the edge to the weld of the bag body 11, and as shown in e.g. Japanese Laid-Open Patent Publication No. 67952/1995, the filter material may be formed into a hanging-bell form, and its edge is sealed by welding from a lower part to the side while an upper part is open and the end of the upper part is welded with a bag body.

[0030] In the bag body 11, the blood flow inlet 111 and the blood flow outlet 112 are arranged in the opposite side to each other relative to the filter material 12, and blood introduced from the blood flow inlet 111 is passed through the filter material 12 and discharged from the blood flow outlet 112. Similarly, a washing solution introduced from the blood flow inlet 111 or the blood flow outlet 112 is passed through the filter material 12 and discharged from the blood flow outlet 112 or the blood flow inlet 111. The bag body 11 made of a flexible sheet charged with the filter material 12 is freely expansive and compressive, and spaces between the fibers in the filter material 12 are variable, therefore, spaces between the fibers are made small when blood is passed, while spaces between the fibers is made large when a washing solution is passed. Here, the washing solution is to wash away the blood components having adhered to filter material 12 and recover them, and it is preferably physiological saline, Hank's solution, Dulbecco phosphate buffer, dextran etc. which may optionally contain human serum albumin or an anti-coagulation agent.

[0031] Tube 21 is connected to the blood flow inlet 111, and tube 22 is connected to the blood flow outlet 112. The connection method includes welding, adhesion, connection by a connector, etc. In the case of connection by a connector, usually the tube 21 has been connected to the bag body 11, but the tube 21 may be aseptically connected to the bag body 11 just before use. When the filter set of the present invention is used, one end of tubes 21 and 22 is attached to the bag body 11, and a blood bag (not shown) is attached to the other end of tubes 21 and 22, but in place of tubes 21 and 22, syringes etc. may be connected to the blood flow inlet 111 and the blood flow outlet 112.

[0032] The accommodation vessel 3 is a rectangular parallelepiped vessel which is formed of a rigid material so as to accommodate the bag body 11 in a compressed condition and which is provided with the bag body-removing port 31 from which the bag body 11 can be removed. The vessel is attached so as to slide freely in the longitudinal direction on tube 21 attached to the side of the blood flow inlet 111. The material includes synthetic resin such as polycarbonate, polystyrene, rigid polyvinyl chloride, polypropylene etc. or metals. The accommodation vessel 3 preferably has a size enough to compress the bag body 11 to achieve degrees of capture possessed by a conventional leukocyte-removing

filter. However, the accommodation vessel 3 in the present invention is not limited to the shape shown in Figs. 1, 2 and 3, and the accommodation vessel 3 may have any shape by which the bag body 11 is accommodated in a compressed condition so as to capture desired blood components and from which the bag body 11 can be removed so as to efficiently recover blood components captured in the filter material 12.

[0033] The filter set of the present invention may be constituted as shown in Fig. 4. The accommodation vessel 4 has a lid 41, which can be opened and closed freely, the bag body accommodated therein is compressed by closing the lid 41 in Fig.4. A groove 43 in which a tube connected with a bag body 11 is inserted and a connecting means to close a lid 41 are provided with the accommodation vessel 4. The connecting means may be such that can not put out the connection by the resiliency of the compressed bag body when the lid is closed. For instance, they are constituted with an arm 411 provided with the lid 41 and a protuberance 421 connected with said arm 411 and provided with the vessel body 42. In this example this filter set has advantages that there is no risk for damaging the bag body 11 and it may be possible to relieve a compression of the bag body 11 more rapidly because the bag body is not necessarily operated directly and the lid of the accommodation vessel is to be opened simply.

[0034] The method of recovering hematopoietic stem cell- and/or hematopoietic precursor cell-derived leukocytes from umbilical cord blood by use of the filter set 1 shown in Figs. 1, 2 and 3 is described.

[0035] First, the bag body 11 is accommodated in the accommodation vessel 3, and umbilical cord blood is passed from the blood flow inlet 111, through the bag body 11 in a compressed condition, to the blood flow outlet 112. In this step, the filter material 12 is compressed and spaces between the fibers are made small, so leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells can be accurately captured.

[0036] Then, the bag body 11 is removed from the accommodation vessel 3, and a washing solution is passed from the blood flow outlet 112 to the blood flow inlet 111. In this step, the compression of the filter material 12 is relieved and spaces between the fibers are made large, so hematopoietic stem cell-and/or hematopoietic precursor cell-derived leukocytes having adhered to the filter material 12 can be easily removed and easily washed away with the washing solution for recovery. Because spaces between the fibers are made large, the washing solution can be easily passed therethrough to reduce the time necessary for passing the solution. Here, the washing solution may be introduced from the blood flow inlet 111 or blood flow outlet 112.

[0037] The washing solution containing leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells is once recovered in a vessel and then separated by centrifugation or passage through a filter, whereby hematopoietic stem cells and/or hematopoietic precursor cells are recovered. At this step, a filter capturing granulocytes and monocytes but passing hematopoietic stem cells and/or hematopoietic precursor cells is preferably used.

[0038] The blood filter set of the present invention is described with reference to Figs. 6, 7 and 8. The blood filter set 1 is composed of the bag body 11 charged inside with the filter material 12, tube 21 connected to blood flow inlet 111 and tube 22 connected to blood flow outlet 112 for the bag body 11, and the rigid accommodation vessel 3 for accommodating the bag body 11. The accommodation vessel 3 includes ports 31, 32 provided on regions where tubes 21, 22 connected to the bag body 11 penetrate the accommodation vessel 3, in order to maintain the airtightness of the vessel. Introduction and discharge of gas is conducted through the 2-directional stopcock 33.

[0039] The accommodation vessel 3 is a rectangular parallelepiped vessel which is formed of a rigid material so as to accommodate the bag body 11 in a compressed condition by filling the vessel with compressed gas and which is provided with ports 31, 32 for maintaining the airtightness of the tube-connecting portions and with the 2-directional stopcock 33 for introducing and discharging gas. O-rings (not shown) are inserted into between ports 31, 32 and tubes 21, 22 to maintain the airtightness of the accommodation vessel 3. If the accommodation vessel 3 is formed of synthetic resin, the port and the tube may be welded by ultrasonic wave. The compressed gas used includes inert gases such as air, nitrogen, argon etc.

[0040] Because the bag body 11 is compressed to achieve degrees of capture possessed by a conventional leukocyte-removing filter; the accommodation vessel 3 should be formed of a material capable of enduring the compression. The material includes synthetic resin such as polycarbonate, polystyrene, rigid polyvinyl chloride etc. and metals such as stainless steel, aluminum etc. The accommodation vessel 3 is preferably in such a size that it can accommodate the bag body 11 expanded to increase spaces between the fibers in the filter material 12.

[0041] However, the accommodation vessel 3 in the present invention is not limited to the shape shown in the drawings and may have any shape by which the bag body 11 can be accommodated in a compressed condition so as to capture desired blood components and the bag body 11 can be expanded so as to efficiently recover blood components captured in the filter material 12.

[0042] Fig. 5 is a drawing showing the method of collecting blood components by use of the blood filter set in Fig. 6. Blood components collecting apparatus 50 in Fig. 5 includes a filter set of this invention.

[0043] From the blood bag 51 in which whole blood was accommodated, the whole blood is passed through the 3-directional stopcock 55, then tube 21, and introduced from the blood flow inlet 111 into the inside of the bag body 11 in a compressed condition. Leukocytes in the filter material 12 have been captured for example in spaces between the fibers therein, while erythrocytes are passed through the filter material 12, then through the blood flow outlet 112, tube 22

and 3-directional stopcock 56 and are recovered in the erythrocyte-recovering bag 53. The erythrocyte-recovering bag 53 can also accommodate platelets in addition to erythrocytes, depending on the type of the filter material 12. Thereafter, a washing solution in the wash bag 52 is passed through the 3-directional stopcock 55, tube 21, and blood flow inlet 111, thus washing away leukocytes from the filter material 12 having spaces increased between the fibers, whereby the leukocytes are passed through the blood flow outlet 112, tube 22, and 3-directional stopcock 56 and recovered in the leukocyte-recovering bag 54.

[0044] The method of recovering hematopoietic stem cell- and/or hematopoietic precursor cell-derived leukocytes from umbilical cord blood by use of the filter set 1 in Fig.6 is described.

[0045] First, umbilical cord blood is passed from the blood flow inlet 111, through the bag body 11 compressed in the accommodation vessel 3 by filling the vessel with compressed gas, to the blood flow outlet 112. In this step, the filter material 12 is also compressed, and leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells are captured in spaces between the fibers. The compressed gas may be filled by a pump or may be injected by a syringe that was directly connected to the 2-directional stopcock 33.

[0046] Then, the 2-directional stopcock 33 is opened, and the compressed gas is exhausted from the accommodation vessel 3 to relieve the compressed condition of the bag body 11, thus expanding the bag body 11 through which the washing solution is then passed from the blood flow inlet 111 to blood flow outlet 112. During this step, the compression of the filter material 12 is also relieved and spaces between the fibers are made large, so leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells having adhered to the filter material 12 are easily removed, easily washed away with the washing solution, and recovered in the leukocyte-recovering bag 54 in Fig. 6. Here, the washing solution may be introduced from the blood flow inlet 111 or blood flow outlet 112.

[0047] The washing solution containing leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells is once recovered in a blood-recovery vessel and then separated by centrifugation or passage through a filter, whereby hematopoietic stem cells and/or hematopoietic precursor cells are recovered. As the filter used, a filter capturing granulocytes and monocytes but passing hematopoietic stem cells and/or hematopoietic precursor cells is preferably used.

[0048] In this case, the inside of the vessel is further evacuated by exhausting the compressed gas followed by evacuation by a vacuum pump, or by reducing the pressure in the vessel by use of the syringe connected to the 2-directional stopcock 33, whereby the bag body 11 is further expanded and spaces between the fibers in the filter are further enlarged thus facilitating recovery and reducing the time required for recovery.

[0049] As described above, because the filter set of the present invention can relieve the compressed condition by merely opening the 2-directional stopcock 33, its operation is easier than in the prior art. Further, the washing solution can be easily passed by increasing spaces between the fibers to reduce the time necessary for passing the solution.

[0050] As shown in Figs. 9,10 and 11, the filter set is composed of bag body 11 charged inside with filter material 12, tube 21 connected to blood flow inlet 111 and tube 22 connected to blood flow outlet 112 for the bag body 11, and flexible tube body 6 or 7 for accommodating the bag body 11 in a compressed state in the thickness direction.

[0051] The bag body 11 consists of two flexible sheets which were welded along the edge thereof by thermal welding, high-frequency welding, ultrasonic welding, solvent welding or the like. The material of the bag body 11 is preferably synthetic resin such as soft polyvinyl chloride, ethylene-vinyl acetate copolymers, styrene-butadiene-styrene copolymers, polyurethane, polyamide, polyester, polyethylene, polypropylene etc.

[0052] As shown in Fig. 10, the bag body 1 has been charged inside with the filter material 12. The filter material 12 is to capture mainly leukocytes from blood, and it is composed preferably of synthetic fibers such as polyester, polypropylene, polyethylene, polymethyl methacrylate, polyamide etc., natural fibers such as cotton, etc. The diameter of the fiber is preferably in the range of 0.1 to 40 μm, and in the case of a diameter of less than 0.1 μm, spaces between the fibers per unit area tend to become small thus increasing filtration resistance, while in the case of a diameter of more than 40 μm, the volume of the fibers tends to become large thus increasing absorption of excess blood components. The amount of the filter material 12 charged may be any amount enough to achieve degrees of capture possessed by a conventional leukocyte-removing filter in a compressed condition.

[0053] The tube body 6 shown in Fig. 9 consists of a heat-shrinkable tube formed of one or more layers of synthetic resin such as polyvinyl chloride, polyester, polypropylene, polyethylene, polystyrene etc., and after the bag body 11 is accommodated therein, the tube body 3 is heat-shrunk to compress the bag body 11 in a desired shrinkage condition. The tube body 6 may be provided at one end (in the side of tube 22) with a ruptured portion such as V-shaped cutting 61, and a perforation may be provided along the longitudinal direction from the cutting 61 so that after blood is passed through the bag body 11, the tube body 6 can be easily ruptured along the perforation 62. The tube body 6 is not particularly limited, but usually formed to have a thickness of about 10 to 100 μm.

[0054] As shown in Fig. 11, the tube body possessing a similar length to that of the bag body 1 and a smaller volume than that of the bag body 11 can be used to accommodate the bag body 11 in a desired compressed condition. The tube body 7 may be provided at one end (in the side of tube 22) with a grasping portion 63 for removing the tube body 7 from the bag body 11. After blood is passed through the bag body 11, the tube body 7 easily slides so that it can be

removed from the bag body 11. That is, it can easily slide for removal from the bag body 11 by supporting the bag body 11 with one hand and pulling the grasping portion 63 with the other hand. The material of the tube body 7 is preferably synthetic resin such as polyvinyl chloride, polyethylene, polypropylene etc. The grasping portion 63 may be formed of synthetic resin such as polypropylene, polyethylene etc., but the grasping portion 63, if provided in a rib form along the edge of the tube body 7 as shown in this example, is formed preferably into one body using the same material as the tube body 7.

[0055] The tube body may be in any shape enough to compress the bag body 11 to achieve degrees of capture possessed by a conventional leukocyte-removing filter, and the shape is not limited to the shapes shown in Figs. 9 and 11.

[0056] The method of recovering hematopoietic stem cell- and/or hematopoietic precursor cell-derived leukocytes from umbilical cord blood is described with reference to Fig. 9.

[0057] First, umbilical cord blood is passed from the blood flow inlet 111, through the bag body 11 accommodated in the tube body 6, to the blood flow outlet 112. In this step, the filter material 12 is compressed to attain suitable spaces between the fibers, therefore, leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells can be accurately captured.

[0058] Then, the tube body 6 is ruptured along the perforation 62 from the ruptured portion 61 to remove the bag body 11 from the tube body 6, and a washing solution is passed from the blood flow outlet 112 to the blood flow inlet 111. During this step, the compression of the filter material 12 is relieved and spaces between the fibers are made large, therefore, leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells having adhered to the filter material 11 are easily removed and easily washed away with the washing solution for recovery. Because spaces between the fibers are made large, the washing solution can be easily passed therethrough to reduce the time necessary for passing the solution. Here, the washing solution may be introduced from the blood flow inlet 111 or blood flow outlet 112.

Example 1

[0059] The filter set 1 shown in Fig. 1 is used. The filter material 12 charged in the bag body 11 consists of a 3-layer nonwoven fabric (filtration area 12.6 cm^2) using polyethylene terephthalate fibers. The structure of the three layers in the bag body 11 compressed in the accommodation vessel 3 consists of a nonwoven fabric with a fiber diameter of 10 μm and a bulk density of 0.23 g/cm^3 in an upper layer as a first layer, a nonwoven fabric with a fiber diameter of 3.5 μm and a bulk density of 0.09 g/cm^3 in an interlayer as a second layer and a nonwoven fabric with a fiber diameter of 1.8 μm and a bulk density of 0.12 g/cm^3 in a sublayer as a third layer. The weight ratio thereof was 52: 21: 27, and the total thickness was 7.4 mm.

[0060] As shown in Fig. 3, the bag body 11 was accommodated in the accommodation vessel and 100 ml bovine blood containing ACD solution as an anti-coagulation agent was passed therethrough under a compressed condition at a flow rate of 5 ml/min. whereby leukocytes were captured in the inside of the bag body 11 while erythrocytes were passed through the bag body 11 and recovered in the erythrocyte-recovering bag 53 shown in Fig. 5.

[0061] The yield of erythrocytes recovered in the erythrocyte-recovering bag 53 was 92 %, and the yield of platelets therein was 15 %.

[0062] Then, the 3-directional stopcock 56 was closed and then the accommodation vessel was removed as shown in Fig. 1 and the compressed condition of the bag body 11 was relieved. And after the bag body 11 was filled with dextran to widen spaces between the fibers, 150 ml dextran solution was poured out at a flow rate of 15 ml/min. and accommodated into the leukocyte accommodation bag 54. The ratio of enlargement of the filter material 12 due to removing of the bag body 11 from the accommodation vessel 3 and the recovery of leukocytes recovered in the leukocyte-recovering bag 54 are shown in Table 1.

[0063] The volume expansion ratio is the ratio of the inner volume of the bag body 11 in which the compression of the filter material 12 was relieved by removing the accommodation vessel versus the inner volume of the bag body 11 in which the filter material 12 was compressed by accommodating the bag body in the accommodation vessel. The leukocyte recovery ratio is the ratio of the number of leukocytes in the dextran solution recovered in the leukocyte-recovering bag 54 versus the number of leukocytes in blood accommodated in the blood bag 51.

Example 2

[0064] The filter set 1 shown in Fig. 1 is used. A nonwoven fabric with a fiber diameter of 10 μm and a nonwoven fabric with a fiber diameter of 1.83 μm were immersed in 0.25 % 2-hydroxyethyl methacrylate/diethylaminoethyl methacrylate copolymer in ethanol to make a 2-layer laminate. A filter material 12 having a 2-layer structure consisting of said nonwoven fabric having a fiber diameter of 10 μm and a bulk density of 0.32 g/cm^3 as an upper layer (first layer) and said nonwoven fabric with a fiber diameter of 1.8 3 μm and a bulk density of 0.12 g/cm^3 as a sublayer (second layer) in a compressed condition (volume ratio 72.7 : 27.3) was accommodated in a bag body 11 (filtration area 12.6 cm^2).

[0065] The bag body 11 was accommodated in the accommodation vessel 3, and 50 ml umbilical cord blood using a heparin solution as an anti-coagulation agent was passed therethrough at a flow rate of 5 ml/min. whereby leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells were captured in the filter material 12 in the inside of the bag body 11. Erythrocytes and platelets were passed through the bag body 11 and recovered in the erythrocyte-recovering bag 53. The yield of erythrocytes recovered in the erythrocyte-recovering bag 53 was 85 % and the yield of platelets therein was 81 %. Then, after closing the 3-directional stopcock 56, removing the accommodation vessel and relieving the compression of the bag body, dextran solution was passed into the bag body 11 so that leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells were recovered in the leukocyte-recovering bag 54.

[0066] The volume expansion ratio of the bag body 11 and the yield of leukocytes recovered in the leukocyte-recovering bag 54, as determined in the_same manner as in Example 1, are shown in Table 1.

Example 3

[0067] The similar experiment to Example 1 was done by using the filter set 10 shown in Fig. 4. The bag body 11 and the filter material 12 are same as in Example 1.

[0068] The ratio of enlargement of the bag body 11 due to opening the lid and the recovery of leukocytes recovered in the leukocyte-recovering bag 54 are shown in Table 1.

[0069] The volume expansion ratio is the ratio of the inner volume of the bag body 11 in which the compression of the filter material 12 was relieved by opening the lid versus the inner volume of the bag body 11 in which the filter material 12 was compressed by closing the lid. The leukocyte recovery ratio is the ratio of the number of leukocytes in the dextran solution recovered in the leukocyte-recovering bag 54 versus the number of leukocytes in blood accommodated in the blood bag 51.

Example 4

[0070] The similar experiment to Example 2 was done by using the filter set 10 shown in Fig. 4. The bag body 11 and the filter material 12 are same as in Example 2.

[0071] The ratio of enlargement of the bag body 11 due to opening the lid and the recovery of leukocytes recovered in the leukocyte-recovering bag 54 are shown in Table 1.

Table 1

	Volume expansion ratio (fold)	Leukocyte recovery ratio (%)
Example 1	1.00	42.6
	1.51	78.2
Example 2	1.01	41.5
	1.46	76.5
Example 3	1.00	49.6
	1.48	83.2
Example 4	1.00	41.5
	1.51	80.6

Example 5

[0072] The filter set 1 shown in Fig. 6 is used. The filter material 12 charged in the bag body 11 consists of a 3-layer nonwoven fabric (filtration area 12.6 cm^2) using polyethylene terephthalate fibers. The structure of the three layers in the bag body 11 compressed in the accommodation vessel 3 consists of a nonwoven fabric with a fiber diameter of 10 μm and a bulk density of 0.19 g/cm^3 in an upper layer as a first layer, a nonwoven fabric with a fiber diameter of 3.5 μm and a bulk density of 0.05 g/cm^3 in an interlayer as a second layer and a nonwoven fabric with a fiber diameter of 1.8 μm and a bulk density of 0.14 g/cm^3 in a sublayer as a third layer. The weight ratio thereof was 52: 21: 27, and the total thickness was 6.0 mm.

[0073] As shown in Fig. 7, the bag body 11 was compressed by injecting compressed air into the accommodation vessel 3 by use of a syringe, and 100 ml bovine blood containing ACD solution as an anti-coagulation agent was passed therethrough under a compressed condition at a flow rate of 5 ml/min. whereby leukocytes were captured in the inside of the bag body 11 while erythrocytes were passed through the bag body 11 and recovered in the erythrocyte-recovering bag 53 shown in Fig. 5.

[0074] The yield of erythrocytes recovered in the erythrocyte-recovering bag 53 was 90 %, and the yield of platelets therein was 13 %.

[0075] Then, the 3-directional stopcock 56 was closed and then the 2-directional stopcock 33 was opened to exhaust the compressed air from the accommodation vessel 3 so that as shown in Fig. 8, the bag body 11 was expanded due to relieved compression. Thereafter, the bag body 11 was filled with dextran solution to widen spaces between the fibers. After shifting the direction of the 3-directional stopcock 56 to the leukocyte-recovering bag 54, 150 ml dextran solution was passed at a flow rate of 15 ml/min. and recovered in the leukocyte-recovering bag 54. The compressed air was exhausted from the accommodation vessel 3. The ratio of enlargement of the filter material 12 due to the relieved compression of the bag body 11 and the recovery of leukocytes recovered in the leukocyte-recovering bag 54 are shown in Table 2.

[0076] The volume expansion ratio is the ratio of the inner volume of the bag body 11 in which the compression of the filter material 12 was relieved by exhausting the compressed air versus the inner volume of the bag body 11 in which the filter material 12 was compressed by filling the accommodation vessel 3 with the compressed air. The leukocyte recovery ratio is the ratio of the number of leukocytes in the dextran recovered in the leukocyte-recovering bag 54 versus the number of leukocytes in blood recovered in the blood bag 51.

Table 2

Volume expansion ratio (fold)	1.00	1.05	1.20	1.40	1.60	1.80	2.00
Leukocyte recovery ratio (%)	32.0	52.0	75.0	84.0	85.0	84.0	83.0

[0077] As is evident from Table 2, the yield of leukocyte increases with an increasing volume expansion ratio, but when the volume expansion ratio is 1.4 or more, the yield becomes nearly constant.

Example 6

[0078] The filter set 1 shown in Fig. 6 is used. A nonwoven fabric with a fiber diameter of 10 μm and a nonwoven fabric with a fiber diameter of 1.8 μm were immersed in 0.25 % 2-hydroxyethyl methacrylate/diethylaminoethyl methacrylate copolymer in ethanol to make a 2-layer laminate. A filter material 12 having a 2-layer structure consisting of said nonwoven fabric having a fiber diameter of 10 μm and a bulk density of 0.3 g/cm^3 as an upper layer (first layer) and said nonwoven fabric with a fiber diameter of 1.8 μm and a bulk density of 0.14 g/cm^3 as a sublayer (second layer) in a compressed condition (volume ratio 72.7 : 27.3) was accommodated in a bag body 11 (filtration area 12.6 cm^2).

[0079] The bag body 11 was compressed by injecting compressed air into the accommodation vessel 3 by use of a syringe, and 50 ml umbilical cord blood using a heparin solution as an anti-coagulation agent was passed therethrough at a flow rate of 5 ml/min. whereby leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells were captured in the filter material 12 in the inside of the bag body 11.

[0080] Erythrocytes and platelets were passed through the bag body 11 and recovered in the erythrocyte-recovering bag 53. The yield of erythrocytes recovered in the erythrocyte-recovering bag 53 was 87 % and the yield of platelets therein was 91 %. Then, the 3-directional stopcock 56 was closed and then the 2-directional stopcock 33 was opened to exhaust the compressed air thus relieving the compressed condition of the bag body 11, and dextran solution was passed into the bag body 11 so that leukocytes derived from hematopoietic stem cells and/or hematopoietic precursor cells were recovered in the leukocyte-recovering bag 54.

[0081] The volume expansion ratio of the bag body 11 and the yield of leukocytes recovered in the leukocyte-recovering bag 54, as determined in the same manner as in Example 1, are shown in Table 3.

Table 3

Volume expansion ratio (fold)	1.00	1.05	1.20	1.40	1.60	1.80	2.00
Leukocyte recovery ratio (%)	41.0	48.0	78.0	85.0	87.0	87.0	85.0

[0082] As is evident from Table 3, the yield of leukocyte increases with an increasing volume expansion ratio, but when

the volume expansion ratio is 1.4 or more, the yield becomes nearly constant.

Effects of the Invention

[0083] As is evident from the foregoing description, blood components having adhered to the filter material can be efficiently recovered by the blood filter set of the present invention. Further, the time required for passing the washing solution can be reduced. The filter set of the present invention can relieve the compression of the filter material in simple operation.

Explanation of the Reference signs

[0084]

1,10	filter set,
11	bag body,
12	filter material,
111	blood flow inlet,
112	blood flow outlet,
21,22	tube,
3,4	accommodation vessel
31,32	bag body-removing port
33	2-directinal stopcock
41	lid
411	arm
42	vessel body
421	protuberance
43	groove
50	blood components collecting apparatus
51	blood bag
52	washing solution bag
53	erythrocyte-recovering bag
54	leukocyte-recovering bag
55,56	3-directional stopcock
61	ruptured portion
62	perforation
63	grasping portion

Claims

1. A blood filter set comprising a bag body having a blood flow inlet and a blood flow outlet and charged with a filter material, and an accommodation vessel for accommodating said bag body.

2. The blood filter set of claim 1 wherein the accommodation vessel is for accommodating said bag body which is freely removed therefrom and for accommodating said bag body in a compressed condition at the time of accommodation.

3. The blood filter set of claim 1 wherein the accommodation vessel has a lid, which can be opened and closed easily.

4. The blood filter set of claim 1 wherein said bag body is compressed by filling with compressed gas, and after blood is passed through said bag body in a compressed condition, the compressed gas is exhausted to relieve the compression of said bag body and then a washing solution is passed through the bag body.

5. The blood filter set of claim 4 wherein the accommodation vessel further expands said bag body by evacuating the inside of the accommodation vessel.

6. The blood filter set of claim 1 wherein the bag body consists of a flexible sheet.

7. The blood filter set of claim 1 wherein the accommodation vessel is rigid.

8. The blood filter set of claim 1 wherein the accommodation vessel is a flexible tubular body.

9. The blood filter set of claim 1 wherein the filter material is a fiber.

10. The blood filter set of claim 9 wherein the diameter of the fiber is in the range of 0.1 to 40 μm.

11. The blood filter set of claim 9 wherein the bulk density of fiber agglomerates in compressed bag body is 0.05 to 0.50 g/cm^3.

12. A blood filter set comprising a bag body having a blood flow inlet and a blood flow outlet and consisting of a flexible sheet charged inside with a filter material, and a rigid accommodation vessels for accommodating said bag body which is freely removed therefrom and for accommodating said bag body in a compressed condition at the time of accommodation.

13. A blood filter set comprising a bag body having a blood flow inlet and a blood flow outlet and consisting of a flexible sheet charged inside with a filter material, and a rigid accommodation vessel for accommodating said bag body, wherein said bag body is compressed by filling with compressed gas, and after blood is passed through said bag body in a compressed condition, the compressed gas is exhausted to relieve the compression of said bag body through which a washing solution is then passed.

14. The blood filter set of claim 12 or 13 wherein said accommodation vessel further expands said bag body by evacuating the inside of the vessel.

15. A blood filter set comprising a bag body having a blood flow inlet and a blood flow outlet and being charged with a filter material, and a flexible tube body accommodating the bag body in a compressed condition in the thickness direction, wherein said body can be removed from said tube body.

16. The blood filter set of claim 15 wherein the tube body is heat-shrinkable.

17. The blood filter set of claim 15 wherein the tube is provided with a ruptured portion.

18. The blood filter set of claim 15 wherein the tube body possesses a similar length to that of the bag body and a smaller volume than that of the bag body.

19. The blood filter set of claim 15 wherein the tube body is provided at least one end thereof, with a grasping portion for removing the tube body from the bag body.

20. A method of recovering blood components comprises

accommodating a bag body into an accommodation vessel, wherein the bag body has a blood flow inlet and a blood flow outlet and is charged inside with a filter material,
passing blood flow through said bag body in the condition compressed by said accommodation vessel to adhere blood components to the filter material,
removing the bag body from said accommodation vessel,
passing a washing solution through the inside of said bag body in an expanded condition so as to wash off the blood components adhered to said filter material, and
recovering the blood components.

21. The method of claim 20 wherein the bag body consists of a flexible sheet.

22. The method of claim 20 wherein the accommodation vessel is rigid.

23. The method of claim 20 wherein the filter material is a fiber.

24. The method of claim 20 wherein the blood component is leukocyte.

25. A method of recovering blood components comprises

filling a bag body with compressed gas to compress said bag body, wherein the bag body has a blood flow inlet and a blood flow outlet, consists of a flexible sheet and is charged inside with a filter material and accommodated in a rigid accommodation vessel,

passing blood flow through said bag body in a compressed condition to adhere blood components to the filter material, exhausting the compressed gas to relieve the compression condition of said bag body,

passing a washing solution through the inside of said bag body so as to wash off the blood components adhered to said filter material, and

recovering blood components.

26. The methods of recovering blood components of claim 25 wherein further evacuating the inside of vessel to expand said bag body after the compressed gas is exhausted.

27. A method of recovering blood components comprising

passing blood through a bag body in a compressed condition, wherein the bag body has a blood flow inlet and a blood flow outlet, consists of a flexible sheet and is charged with a filter material and accommodated in a flexible tubular body in a compressed condition in the thickness direction,

removing the bag body from the flexible tubular body to relieve the compression of the bag body,

passing a washing solution through the inside of said bag body so as to wash off the blood components adhered to the filter material, and

recovering the blood components.

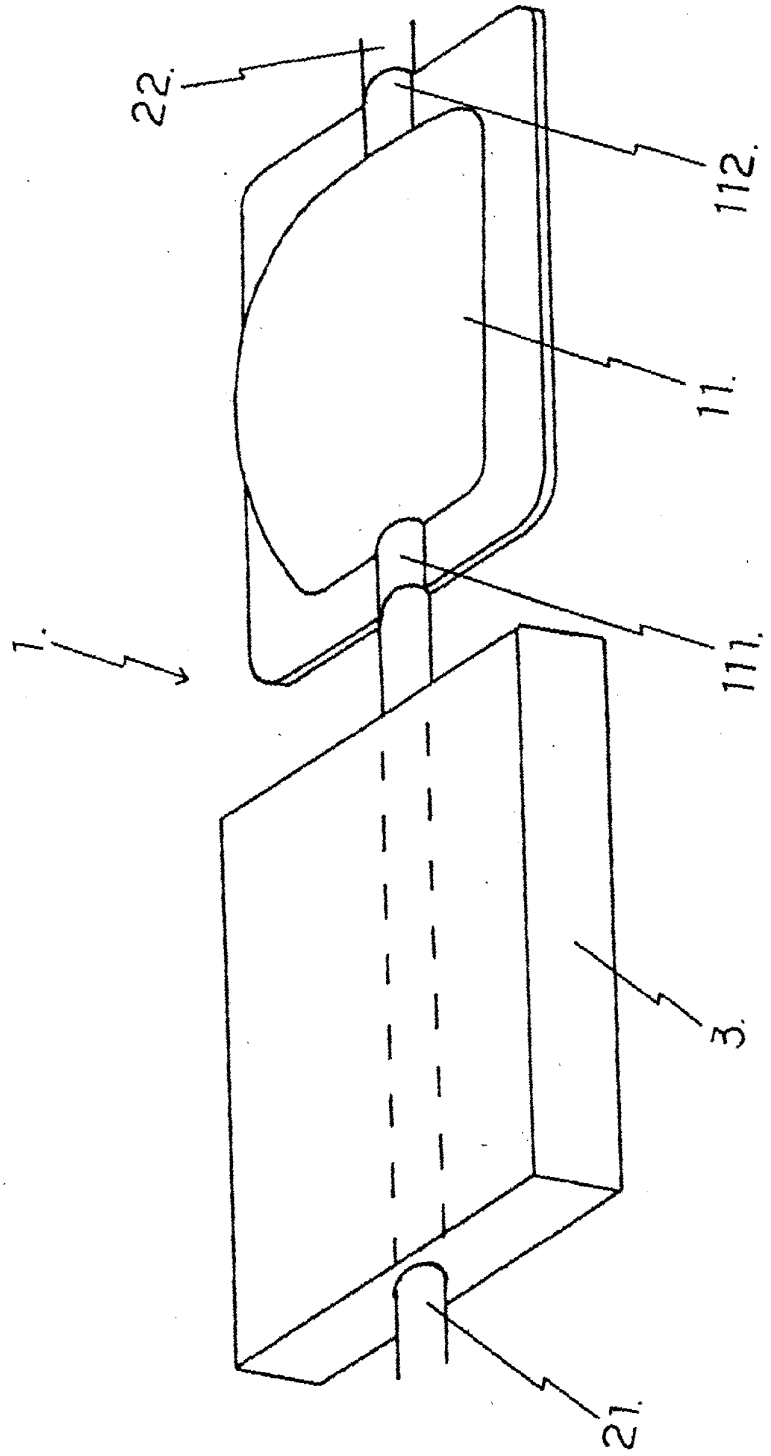


Fig. 1

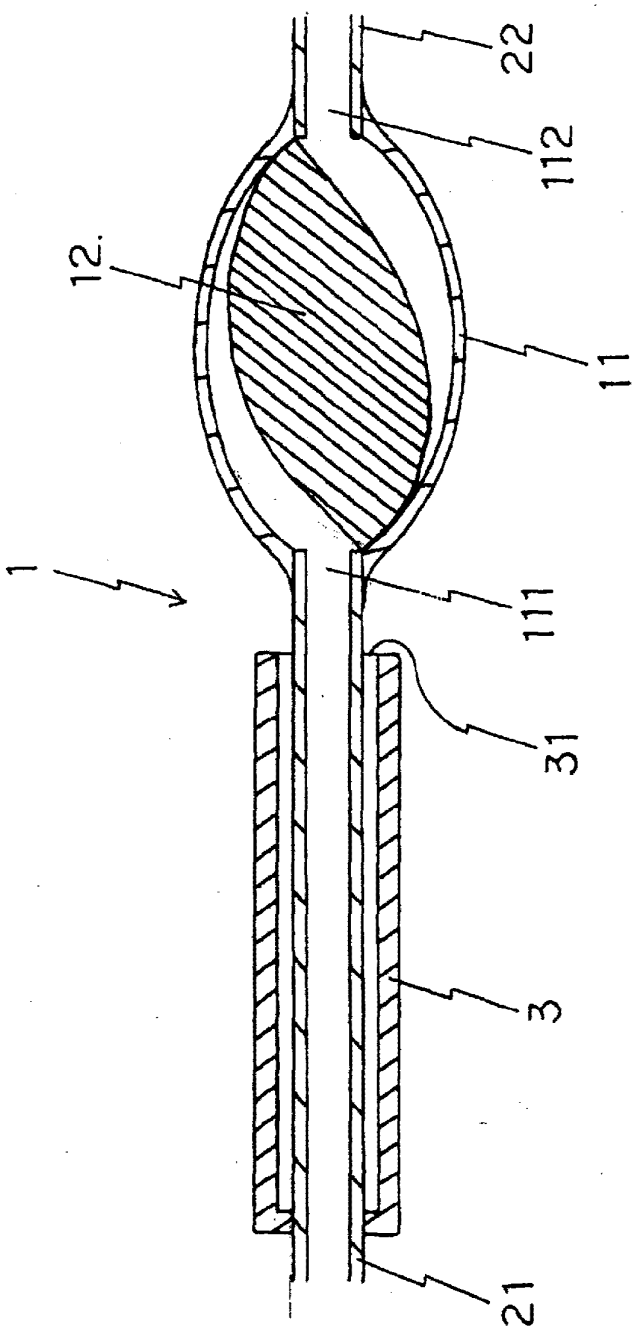


Fig. 2

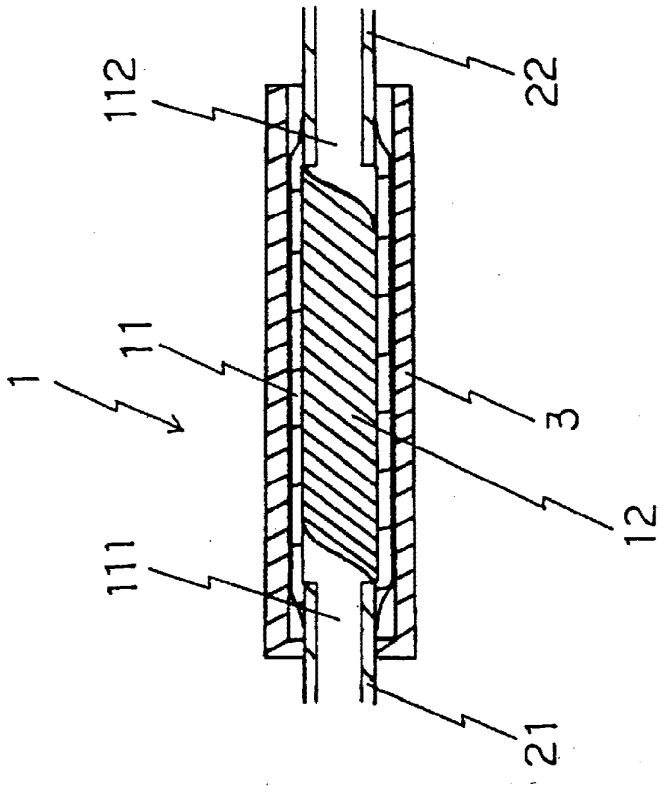


Fig. 3

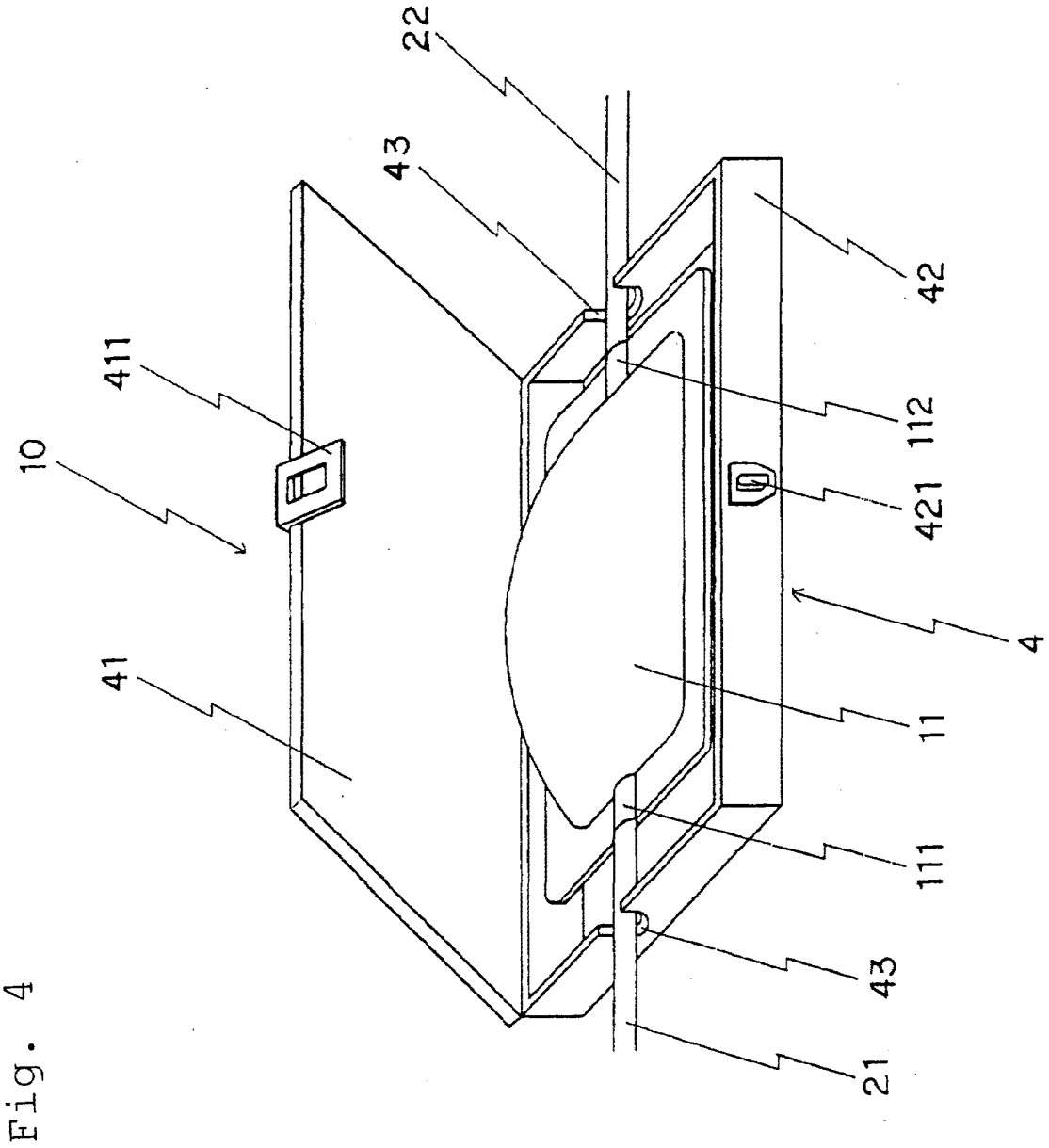
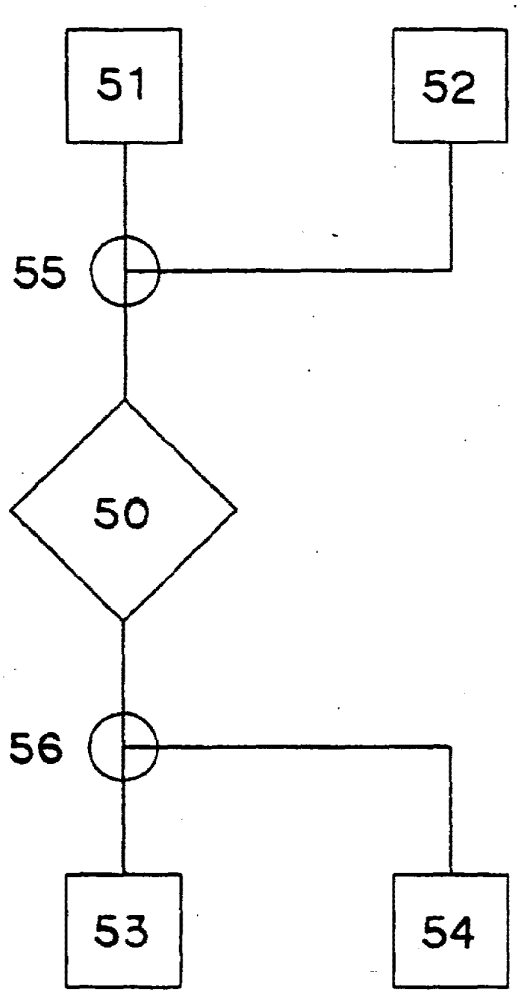


Fig. 4

Fig. 5



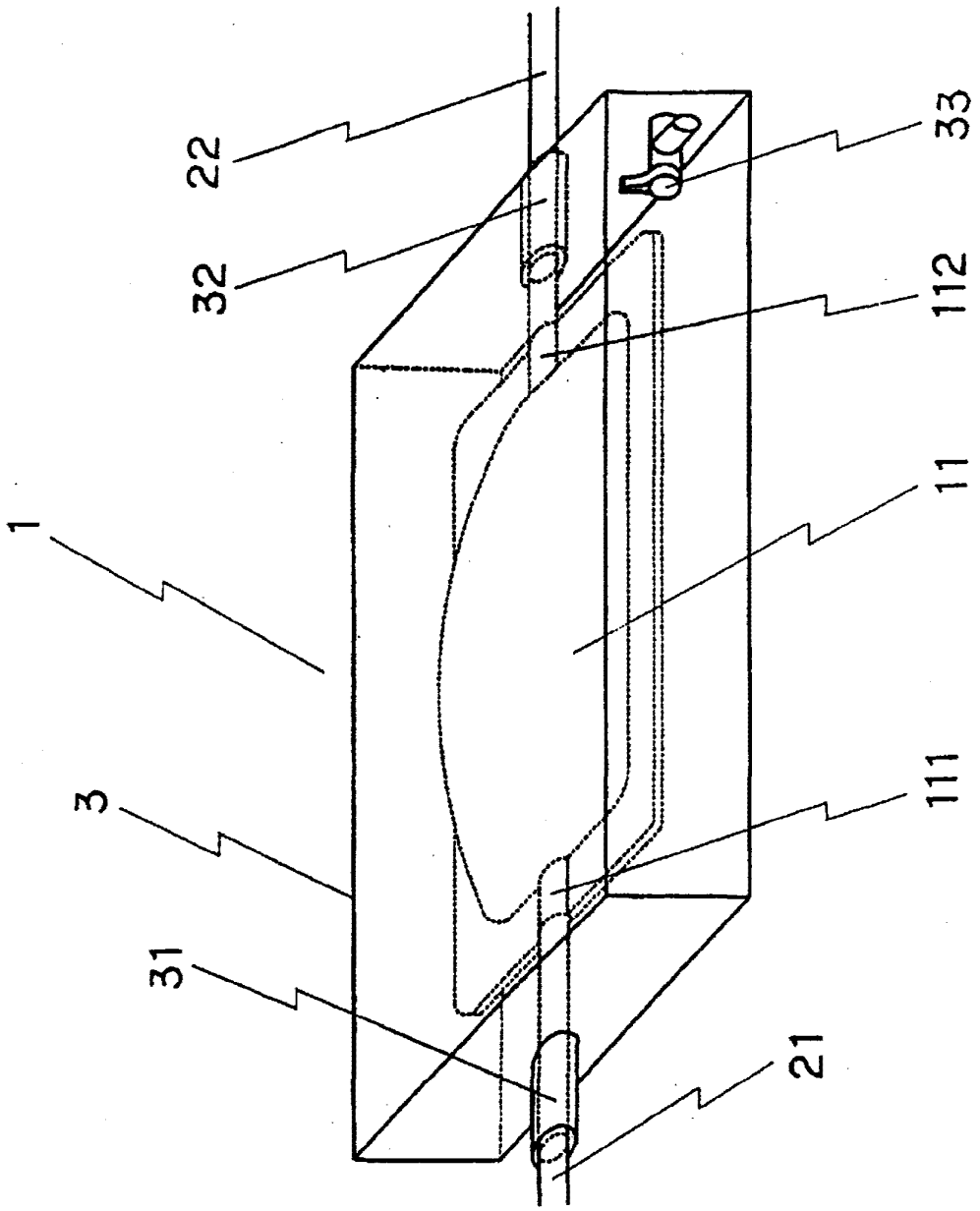


Fig. 6

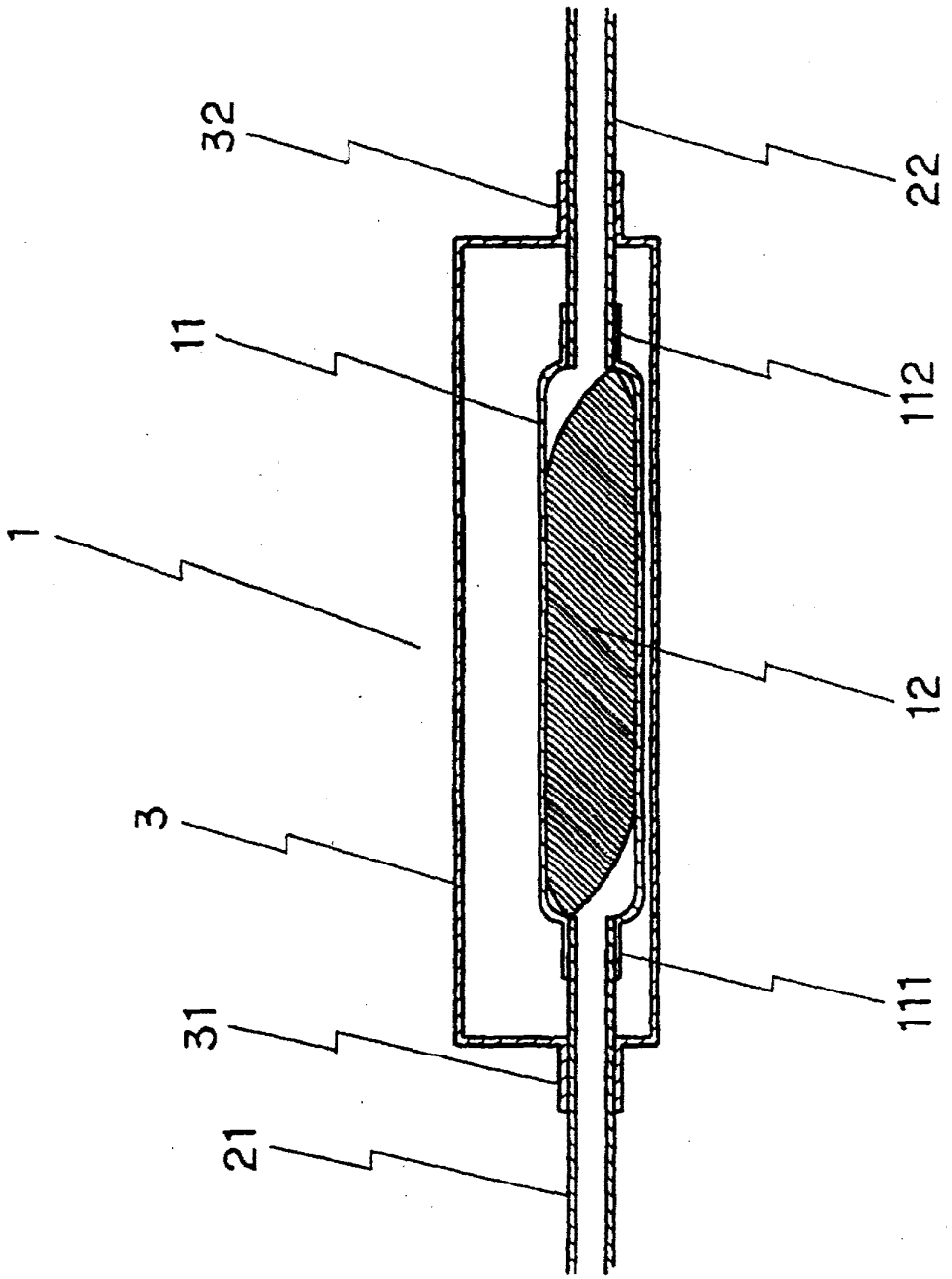


Fig. 7

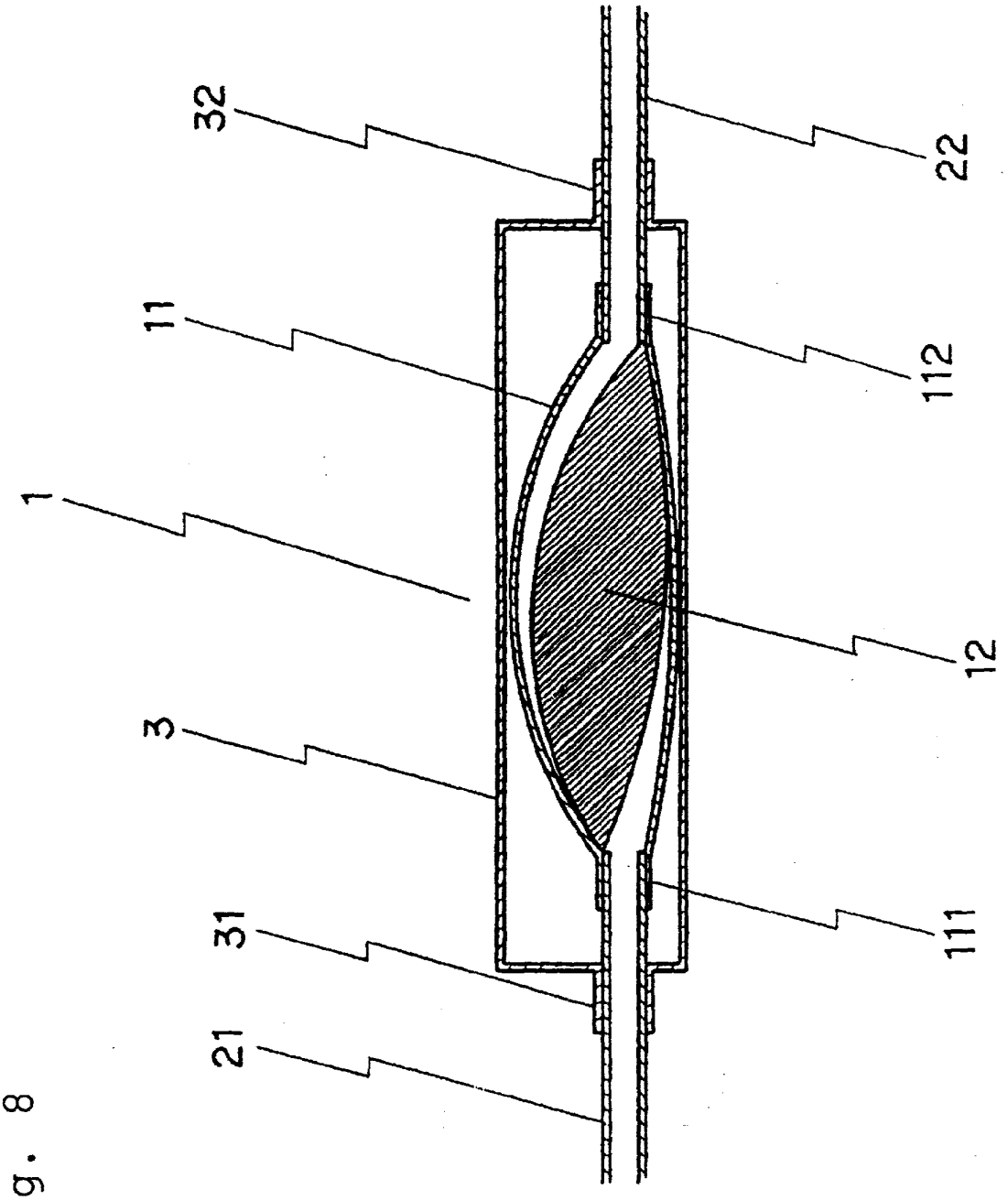


Fig. 8

Fig. 9

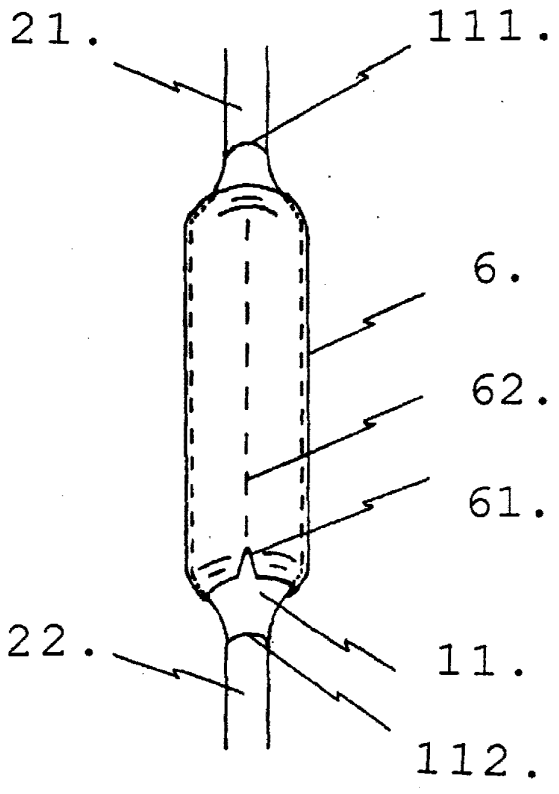


Fig. 10

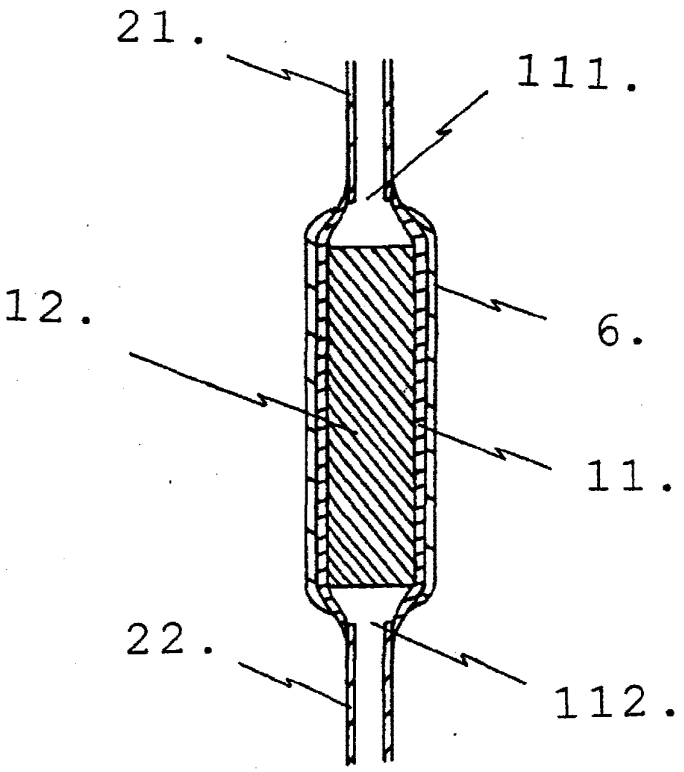
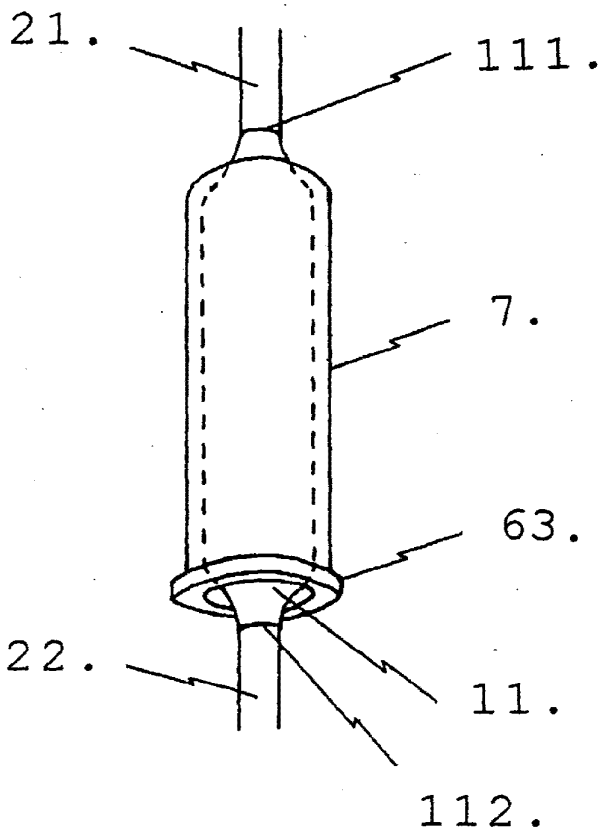


Fig. 11



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 12 1181

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP 0 280 052 A (DONGBEI POWER COLLEGE) 31 August 1988 * column 5, line 17 - line 36 * * column 6, line 9 - line 47 * * figures *	1,4,6,7, 9,12,13, 15,20, 25,27	A61M1/36
A	US 4 416 777 A (KURODA TORU ET AL) 22 November 1983 * column 10, line 6 - line 18 * * column 11, line 3 - line 17 *		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			B01D A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17 February 1999	Vereecke, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 12 1181

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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(11) EP 1 421 960 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
26.05.2004 Bulletin 2004/22

(51) Int Cl.[7]: **A61M 5/165**

(21) Application number: **03025258.9**

(22) Date of filing: **06.11.2003**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR
Designated Extension States:
AL LT LV MK

(30) Priority: **21.11.2002 IT MI20022473**

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(54) Infusion filter operating in various tridimensional positions

(57) A filter (1) comprises a box casing (2) in which at least one cavity (37) is present between an outer element (3, 4) of said casing (2) and an inner surface (5A, 5B) presenting a plurality of channels (21) on which a corresponding hydrophilic filtering membrane (30) lies, said cavity (37) communicating with a conduit (27) for entry of the fluid into the filter (1) and said channels (21) being connected to a conduit (23) for exit of said fluid, in said outer element (3, 4) there being provided through apertures (40, 41) with which hydrophobic membranes (44) are associated. A surface (S1) bounded by the shortest possible ideal closed line (70), which totally comprises all the hydrophobic membranes (44), contains substantially within its interior the projection thereon of the useful hydrophilic surface (S2) of the hydrophilic filtering membrane (30), this enabling the filter (1) to be employed in a plurality of spatial positions during its use.

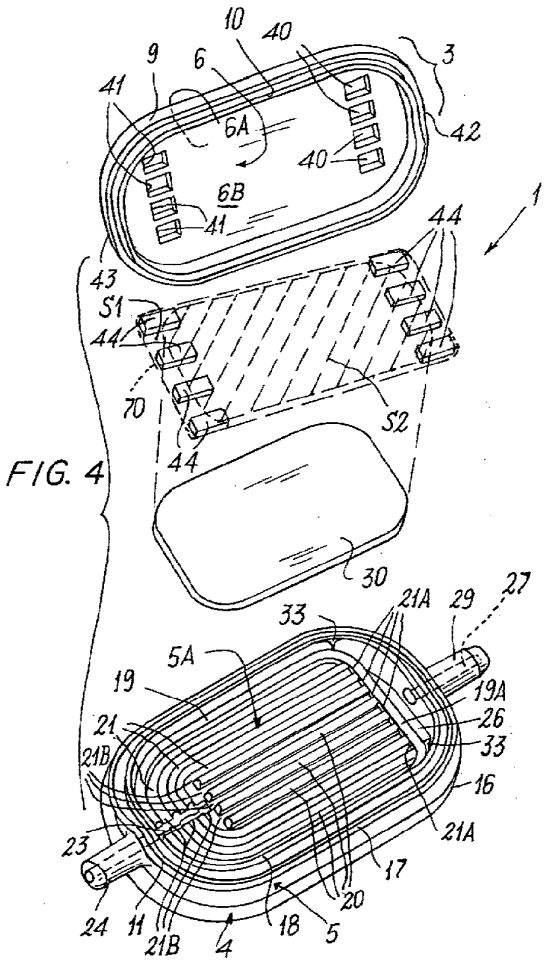

FIG. 4

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Description

[0001] The present invention relaters to an infusion filter in accordance with the introduction to the main claim.

[0002] Filters of the same type as the present invention have been known for some time. They present small dimensions, but must be used in well defined spatial orientations to prevent the formation of air bubbles within the filter which, if they should reach the patient by being conveyed by the fluid, would result in serious well-known problems.

[0003] An object of the present invention is to provide an infusion filter which is improved with respect to similar known filters.

[0004] A particular object of the invention is to provide a filter of the stated type which during use can be disposed in a multiplicity of spatial positions without this involving risks to the correct fluid flow to a patient.

[0005] Another object is to provide a filter of the stated type which can be used reliably and safely.

[0006] These and other objects which will be apparent to the expert of the art are attained by a filter in accordance with the accompanying claims.

[0007] The present invention will be more apparent from the accompanying drawing, which is provided by way of non-limiting example and in which:

Figure 1 is a front view of a filter according to the invention;
Figure 2 is a side view of the filter of Figure 1;
Figure 3 is a section on the line 3-3 of Figure 1;
Figure 4 is an exploded view of the filter of Figure 1;
Figure 5 is a schematic view of a characteristic of Figure 1;
Figure 6 is a perspective view of a variant of the filter of Figure 1;
Figure 7 is a partial perspective view of another variant of the filter of Figure 1;
Figure 8 is a section on the line 8-8 of Figure 7;
Figure 9 is a partial perspective view of a further variant of the filter of Figure 1;
Figure 10 is a section on the line 10-10 of Figure 9;
Figure 11 is a partial perspective view of another variant of the filter of Figure 1;
Figure 12 is a section on the line 12-12 of Figure 11;
Figure 13 is a partial perspective view of another variant of the filter of Figure 1;
Figure 14 is a section on the line 14-14 of Figure 13;
Figure 15 is a perspective view from above of a further variant of the filter of Figure 1; and
Figure 16 is a section on the line 16-16 of Figure 15.

[0008] With reference to said Figures from 1 to 14, a filter according to the invention is indicated overall by 1 and comprises a box casing 2 defined, in the example under examination, by a first and a second outer element 3, 4 closing an intermediate element 5. These box casing elements 3, 4 and 5 are constructed preferably of plastic material in any known manner.

[0009] The outer elements 3 and 4 comprise a flat portion 6 and 7 having opposing faces 6A, 6B and 7A, 7B respectively. In proximity to the edge 9 of said portions 6, 7, there projects from their face 6B, 7B, which is internal with respect to the casing 2 (the face 6A and 7A being an external face of this latter), a shoulder 10 arranged to cooperate with a recess 11 provided in the facing surface of the element 5, in order to secure the elements 3 and 4 to the intermediate element 5. This fixing is obtained in any known manner, for example by ultrasonic bonding, gluing or other means.

[0010] The surface facing the face 6B is indicated in the figures by 5A, while the surface facing the face 7B is indicated by 5B.

[0011] Only one of the surfaces 5A and 5B is described hereinafter as these are identical. Likewise only one of the elements 3 and 4 is described hereinafter, it being understood that everything stated for the surface 5A and for the element 3 is also valid for the surface 5B and for the element 4.

[0012] The intermediate element 5 presents a rounded edge 16 and comprises on the face 5A, starting from its periphery and progressing towards its interior, a pair of spaced-apart parallel annular shoulders 17 and 18 defining the aforesaid recess 11, an annular step 19 and a plurality of parallel ribs 20, circumscribed by the step 19 and defining channels 21 closed at one end 21A by the step 19 and open at their other end 21B where they communicate with a conduit 23 leaving the element 5 via a stem 24 projecting from the edge 16 of said element.

[0013] The step 19 and the parallel ribs 20 have a height less than the shoulders 17 and 18. Between the step 19 and the shoulder 18 a cavity 26 is present communicating with an entry conduit 27 which penetrates into the element 5 (via the shoulders 17 and 18) by passing through a stem 29 projecting from the edge 16. Preferably the stem 29 is coaxial with the stem 24, they both lying along a central axis A of the element 5.

[0014] The step 19 and the ribs 20 can be formed directly in one piece with the element 5 or can be formed on a separate piece inserted within the shoulders 17 and 18 of the element 5 in such a manner as to rest along the shoulder 18 in correspondence with two of its side portions, but spaced from said shoulder 18 so as to define the cavity 26.

[0015] As stated, the free ends of the step 19 and of the ribs 20 lie at least in a plane distant from that in which the ends of the shoulders 17 and 18 lie. Within this space a hydrophilic filter membrane 30 is positioned to rest against the shoulder 18 but not to cover the cavity 26. In this respect, in correspondence with this latter, during filter assembly the hydrophilic membrane 30 is maintained distant from the shoulder 18 by cusp-shaped projections 33 jutting from this shoulder in correspondence with a transverse part 19A of the step 19 perpendicular

to said axis A. The membrane is finally rested on the ends of the ribs 20 and is finally fixed to the transverse part 19A and to the step 10 in known manner, for example by hot bonding.

[0016] When the intermediate element 5 is completed (i.e. also provided with the membranes 30), cavities 37 communicating with the aforesaid cavities 26 are present between its faces 5A and 5B and the adjacent faces 6B and 7B of the outer elements 3 and 4.

[0017] Each outer element 3, 4 (also having a rounded edge 9 such as that of the element 5) comprises at least two through apertures 40 and 41 each provided in proximity to sides 42 and 43 of said element which are perpendicular to the axis A. A hydrophobic membrane 44 of known type is positioned in correspondence with each of these apertures.

[0018] In particular, in Figures 1-4 each outer element 3, 4 comprises four apertures 40 and four adjacent apertures 41. However the number of these apertures can also be different: for example. in Figure 6, in correspondence with the sides 42 and 43 of the elements 3 and 4 a single aperture 40 and 41 is present having an evidently large transverse length. A single aperture 40 and 41 is also present in Figure 7, in proximity to said sides; however each of these apertures is connected to a large underlying recess 45 (rectangular in this example) provided within the interior face 6B of the portion 6 of the element 3 in correspondence with which a hydrophobic membrane 44 is present. In contrast, in Figure 9 in correspondence with each side 42 and 43 (only the side 42 is shown) a pair of apertures 40 and 41 are present, connected to an underlying recess 47 of larger dimensions provided within the face 6B of the portion 6; a step 48 is present between the aperture 40 (or 41) and the underlying recess 47, the hydrophobic membrane 44 being positioned in correspondence with this recess. In Figure 11, within the face 6B of the portion 6 of the element 3, in correspondence with each side 42 and 43, a substantially rectangular recess 50 is present, connected to two conduits 51 opening into the face 6A via corresponding apertures 40 (and 41). Finally in Figure 13, in the face 6B of the portion 6 (in proximity to the sides 42 and 43) a circular recess 53 is provided connected to the apertures 40 (or 41) via channels 54 with their axis inclined to the plane of the face 6A in which the apertures 40 (or 41) are located.

[0019] It should be noted that each membrane is preferably and advantageously associated with the relative aperture 40 or 41 or with the recess 45, 47, 50, 53 by being fixed to the face 6B of the part 3, rather than by being inserted into the respective hole or recess. This enables a filtering surface to be obtained which is larger than that obtained if the membrane were inserted into the corresponding hole or recess in that, in this latter case, a part of the useful volume of the membrane would be occupied by the bond between the membrane and the wall of the corresponding hole or recess.

[0020] The hydrophobic surfaces defined by the membrane 44 can be all connected together by a closed line 70, shown dashed in Figure 4 and full in Figure 5. Preferably, this line is the shortest which ideally connects together all the said surfaces of the membranes 44, i.e. it is defined by rectilinear portions in the example of the figures. According to the invention, this closed line defines a surface S1 within which the projection of the useful hydrophilic surface S2 of the underlying membrane 30 substantially falls, the "useful" surface meaning the effectively filtering surface of the membrane 30. The surface S1 is that enclosed by the line 70, the surface S2 being the hatched surface in Figures 4 and 5.

[0021] By virtue of this characteristic, after a usual line priming phase, proper filter effectiveness is achieved whatever its position in space during its use (vertical to, inclined to or parallel to an underlying plane). This is because the fluid entering the filter 1 is able to completely occupy the cavity 37 by expelling the air present therein and filtering through substantially the entire useful surface of the membrane (in the aforestated sense). In this manner, the filter is completely operative, and effective in filtering the entering fluid, in that substantially the entire useful surface of the hydrophilic membrane 30 (at most except for a peripheral portion) participates in the filtering. In addition, the channels 21 are completely filled by the fluid which filters through the membrane 30 such that from one end 21A (that facing the entry conduit 27) to their other end 21 B (that communicating with the exit conduit 23) they contain no residual air bubbles, with obvious positive implications for the fluid feed to the user.

[0022] It should be noted that at most, under utilization conditions, a possible minimum part of the useful surface S2 of the projection of the hydrophilic membrane 30 can lie outside the surface S1, provided that the geometry of the seat in which the membrane 30 is positioned enables the surface tension effect of the filtered fluid to be utilized, this effect occurring if the distance between the membrane 30 and the face 6B of the portion 6 (i.e. the depth of the cavity 37 measured perpendicular to the axis A) lies between 0.1 mm and 3 mm, preferably between 0.5 and 2 mm and advantageously between 0.5 mm and 1.5 mm. Under these conditions, the possible minimum (peripheral) surface part of the membrane 30, the projection of which does not fall within the surface S1, becomes in any event a fluid passage by capillary effect, with consequent complete use of the capacity of said membrane (i.e. the hydrophilic filtering surface of the membrane 30 is always 100% of its area).

[0023] By virtue of the invention, the described and claimed filter presents high functional capacity, exceeding that of known filters. This is because of the arrangement of the apertures 40 and 41 provided with the hydrophobic membranes 44, by virtue of which a high functional capacity of the filtering surface is obtained; this is also due to the fact that these apertures cooperate directly (as in Figures 1-6) or indirectly (as in Figures 7-14) with membranes 44 of considerable area (even greater

than that of said apertures, as in Figures 7-14), which ensure a high air flow from the casing 2 of the filter 1.

[0024] Other embodiments are evidently possible within the light of the present description, provided they remain within the scope of the accompanying claims. For example, each membrane 30 can be of any form, including complex (as can the arrangement of the underlying channels 21), the filter operating effectively provided the apertures present within the outer element 3 or 4 which face said membrane are such as to define, by means of the closed line which joins them together, the surface S1 with the aforedescribed characteristics. In the limit, a single aperture of large dimensions can be present in said element.

[0025] Another embodiment of the invention is shown in Figures 15 and 16 in which parts corresponding to those of the already described figures are indicated by the same reference numerals. In the figures under examination, the filter presents the apertures 40 and 41 connected to differently shaped recesses: the apertures 40 are associated with a recess 50 in accordance with the embodiment of Figure 11, while the aperture 41 is associated with a recess 45 in accordance with the embodiment of Figure 7.

[0026] The embodiment under examination also presents other differences with those already described; for example, in correspondence with the shoulder 17 and around the stems 24 and 29, the element 5 presents circular rims 93 spaced from the corresponding stems and defining therewith recesses 94 for accepting the end of a corresponding contact or tube connected to a vessel of liquid (for example physiological liquid), in the case of the stem 29, or connected to the patient in the case of the stem 24. The rim 93 is essentially a prolongation of the shoulder 17.

[0027] The shoulder 18 is originally formed of tapered shape (triangular in cross-section) such that when inserted into a recess 10A adjacent to the shoulder 10 and provided in each face 6B, 7B of the elements 3 and 4 towards the interior of the filter, it can be fused into this recess during for example the hot bonding, so securely joining the element 5 to the adjacent elements 3 and 4.

[0028] Finally, the apertures 40 and 41 are connected to recesses 97 formed in the external face 6A, 7A of the flat portions 6 and 7 to facilitate the escape of air from these apertures. These recesses lie parallel to the (longitudinal) axis A of the filter.

[0029] Said apertures, and those of the filter represented in the previously described figures, can be closed by suitable plugs (not shown) which can be maintained connected to the filter casing 2 (for example by a filiform connection element, for example of plastic material) or can be of the type completely separable from the filter. The purpose of these plugs is to prevent air being drawn from the outside into the filter interior when one of the tubes connected to the filter (in particular, that connected to a vessel of liquid) is subjected to vacuum caused for example by a syringe.

[0030] Embodiments in which the membrane element 5 presents two opposing surfaces 5A and 5B provided with channels 21 have been described and shown in the figures. However the scope of the present invention also comprises a filter in which this element 5 presents a single face (for example, 5A) provided with channels, whereas the other (the face 5B) is completely flat. In this case, the outer element 4 is not present and the face 5B of the element 5 closes the filter on the side opposite that on which the element 3 is present.

Claims

1. A filter (1) for filtering a fluid directed towards a patient, comprising a box casing (2) in which at least one cavity (37) is present defined by an outer element (3, 4) of said casing (2) and an inner surface (5A, 5B) presenting a plurality of channels (21) on which a corresponding hydrophilic filtering membrane (30) lies, said cavity (37) communicating with a conduit (27) for entry of the fluid into the filter (1) and said channels (21) being connected to a conduit (23) for exit of said fluid from the filter (1), in said element (3, 4) of the box casing (2) there being provided spaced-apart through apertures (40, 41) close to its opposing ends (42, 43) and with which hydrophobic membranes (44) are associated, **characterised in that** a surface (S1) bounded by an ideal closed line (70), which totally comprises all the hydrophobic membranes (44), contains substantially within its interior the projection thereon of the useful hydrophilic surface (S2) of the hydrophilic filtering membrane (30), this enabling the filter (1) to be employed in a plurality of spatial positions during its use.

2. A filter as claimed in claim 1, **characterised in that** the closed line bounding the surface (S1) comprising the hydrophobic membranes (44) is the shortest line which joins these latter together.

3. A filter as claimed in claim 1, **characterised in that** the distance between said element (3, 4) of the box casing (2) and the hydrophilic filtering membrane (30) lies between 0.1 mm and 3 mm, preferably between 0.5 mm and 2 mm.

4. A filter as claimed in claim 3, **characterised in that** the distance between said element (3, 4) of the box casing (2) and the hydrophilic filtering membrane (30) lies between 0.5 mm and 1.5 mm.

5. A filter as claimed in claim 1, **characterised in that** the through apertures (40, 41) have a size identical to that of the membranes (44) associated with them.

6. A filter as claimed in claim 1, **characterised in that**

the through apertures (40, 41) have a size less than that of the membranes (44) associated with them.

7. A filter as claimed in claim 6, **characterised in that** each membrane (44) is associated with a recess (45, 47, 50, 53) provided within a face (6B, 7B) of the element (3, 4) of the box casing (2) facing the hydrophilic membrane (30), with said recess (45, 47, 50, 53) there being associated at least one aperture (40, 41) opening into the opposing face (6A, 7A) of said element (3, 4), between said aperture and said recess there being present at least one step (48) so that the aperture has a size less than that of the recess.

8. A filter as claimed in claim 7, **characterised in that** the recess is of polygonal shape.

9. A filter as claimed in claim 7, **characterised in that** the recess is of circular shape.

10. A filter as claimed in claim 1, **characterised in that** each hydrophobic membrane (44) has a surface greater than that of the aperture (40, 41) with which it is associated.

11. A filter as claimed in claim 10, **characterised in that** the hydrophobic membrane is fixed to that face (6B, 7B) of the element (3, 4) of the box casing (2) facing the hydrophilic membrane (30), in correspondence with the relative aperture (40, 41).

12. A filter as claimed in claim 1, **characterised in that** the channels (21) of the inner surface (5A, 5B) present a closed end (21A) facing and close to the entry conduit (27), and the other end (21B) connected to the exit conduit (23).

13. A filter as claimed in claim 12, **characterised in that** the closed end (21 A) of said channels (21) is closed by an annular element (19) which surrounds said channels (21).

14. A filter as claimed in claim 1, **characterised in that** the entry conduit (27) and exit conduit (23) are provided within an element (5) of the box casing (2) presenting the surface (5A, 5B) with the channels (21) and connected to the outer element (3, 4) of said casing (2).

15. A filter as claimed in claim 14, **characterised in that** the entry conduit (27) and exit conduit (23) are provided within stems (29, 24) projecting from the box casing element (5) provided with channels (21).

16. A filter as claimed in claim 15, **characterised in that** around each stem (24, 29) an annular rim (93) is present defining with the corresponding stem (24, 29) a recess (94) for receiving the end of a corresponding conduit connected to the filter.

17. A filter as claimed in claim 14, **characterised in that** the element (5) with the surface (5A) provided with channels (21) presents a second surface (5B), opposing the surface (5A) with channels, but not provided with these latter.

18. A filter as claimed in claim 14, **characterised in that** the element (5) with the surface (5A) provided with channels (21) presents a second surface (5B), opposing the surface (5A) with channels (21) and shaped as this latter, to the front of said second surface (5B), also provided with channels (21) on which a hydrophilic membrane (30) is superposed, there being positioned a second outer element (4) of the box casing (2) provided with apertures (40, 41) with which hydrophobic membranes (44) are associated, between said second outer element (4) and the element (5) with the surfaces (5A., 5B) provided with channels (21) there being present a cavity (37) connected to the entry conduit (27), said element (5) with the surfaces (5A, 5B) provided with channels (21) being intermediate between the outer elements (3, 4) of the box casing (2).

19. A filter as claimed in claim 1, **characterised in that** the apertures (40, 41) are connected to recesses (97) provided in a free face (6A, 6B) of the corresponding outer element (3, 4).

20. A filter as claimed in claim 19, **characterised in that** the recesses (97) lie parallel to the longitudinal axis (A) of the filter.

21. A filter as claimed in claim 1, **characterised in that** the apertures (40, 41) cooperate with removable shut-off members.

22. A filter as claimed in claim 21, **characterised in that** the shut-off members are connected to the filter casing (2).

23. A filter as claimed in claim 22, **characterised in that** the shut-off members are completely separable from the filter casing (2).

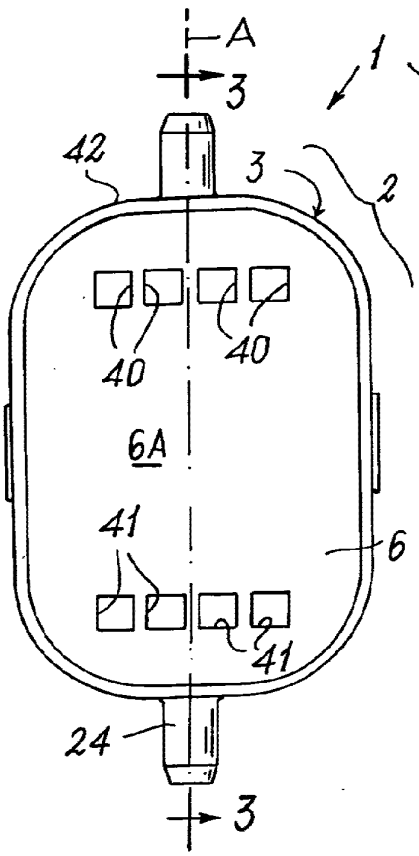


FIG. 1

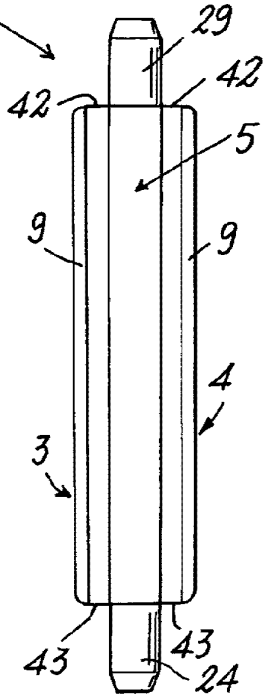


FIG. 2

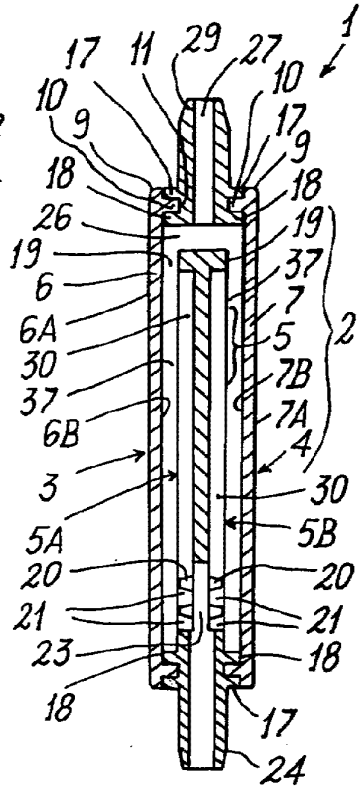


FIG. 3

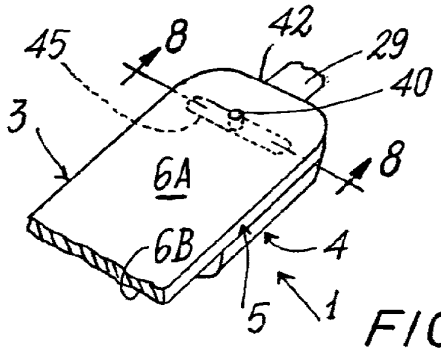


FIG. 7

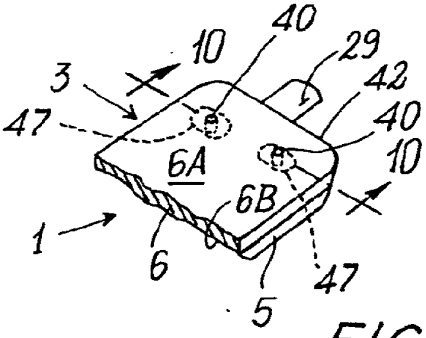


FIG. 9

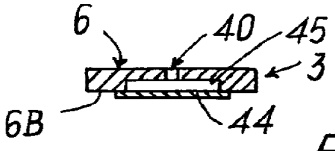


FIG. 8

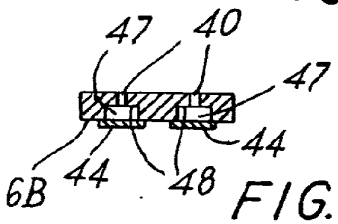


FIG. 10

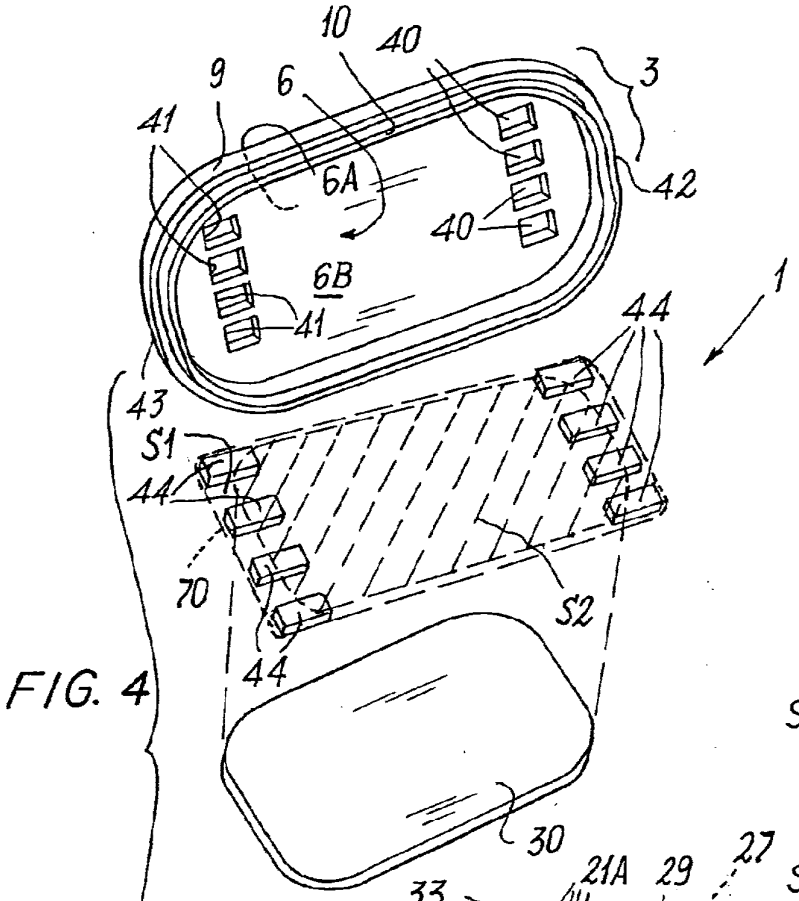


FIG. 4

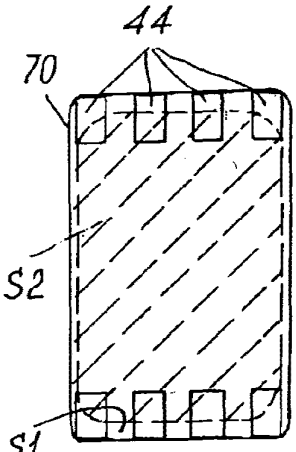
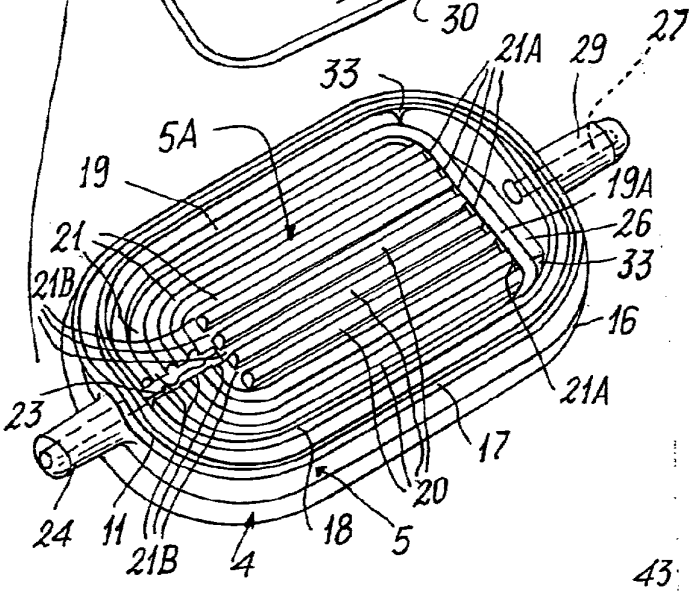


FIG. 5



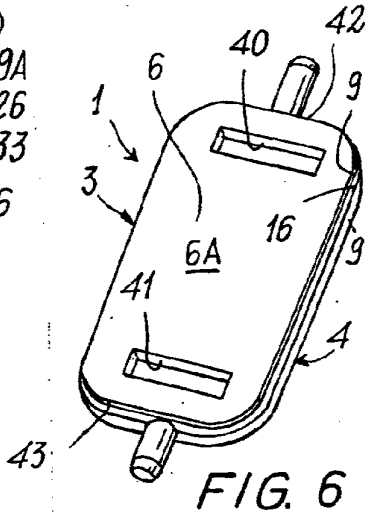


FIG. 6

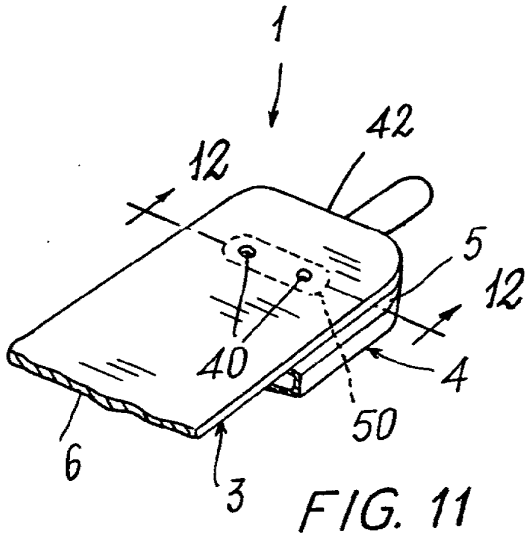


FIG. 11

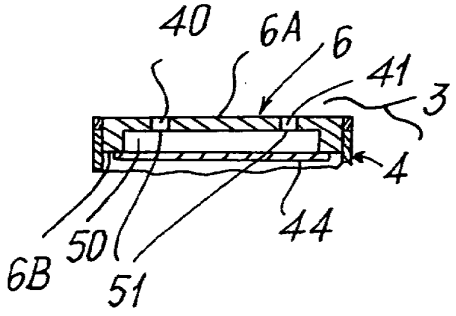


FIG.12

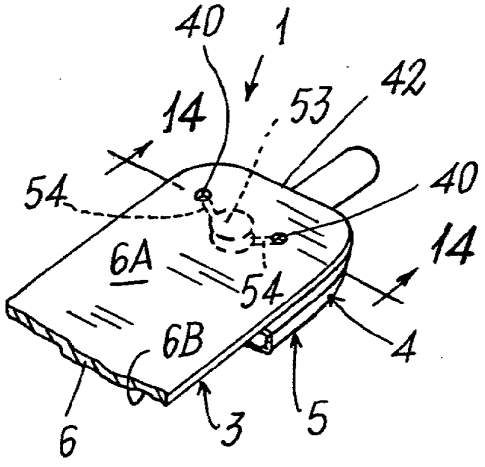


FIG.13

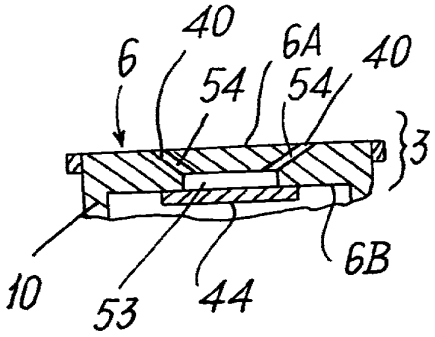


FIG.14

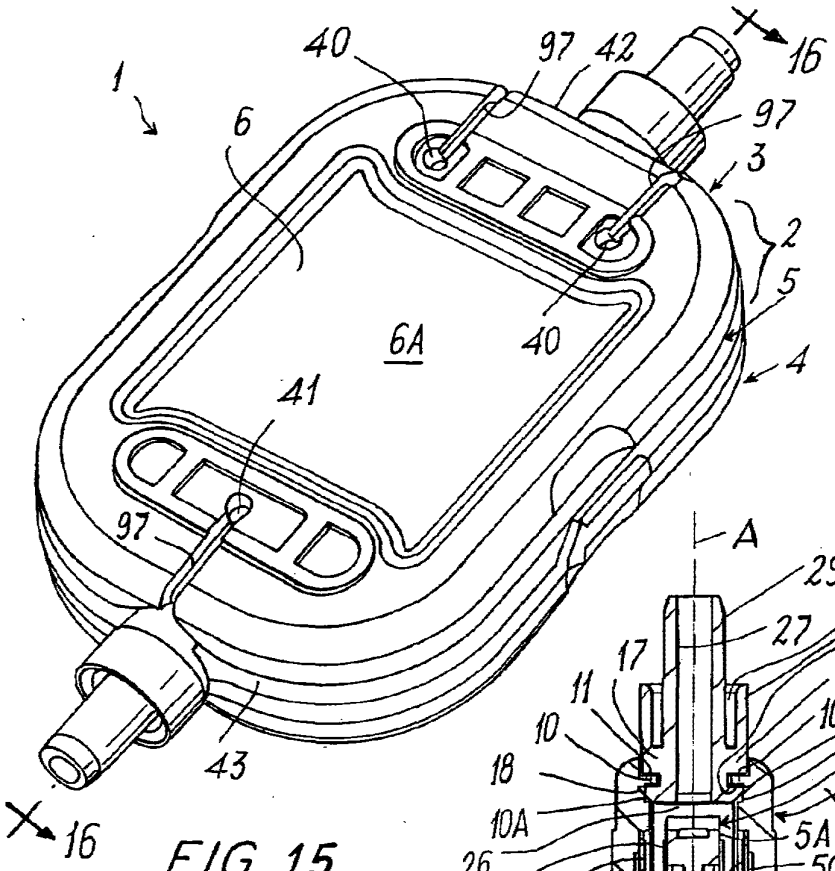

40
97
42
16
1
6
97
3
2
5
6A
40
4
41
97
43
16

FIG. 15

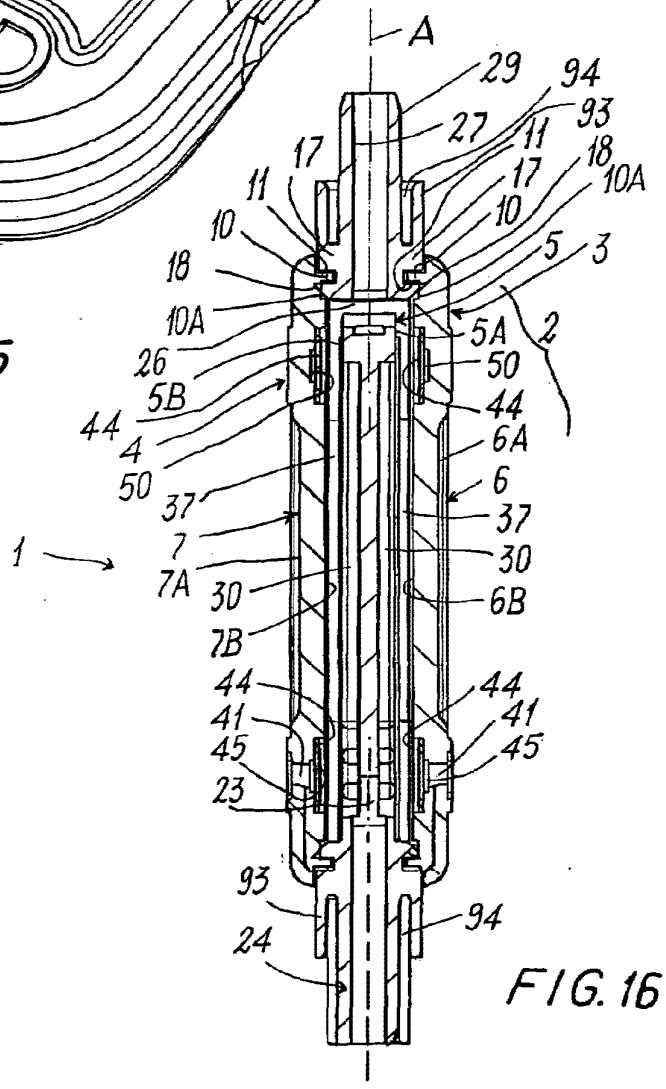

A
29
94
27
93
11
17
18
10A
11
17
10
10
18
5
3
10A
5A
2
26
50
5B
44
44
4
6A
50
6
37
37
7
1
30
7A
30
6B
7B
44
44
41
41
45
45
23
93
94
24

FIG. 16

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 02 5258

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	29 January 2004	Michels, N

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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E : earlier patent document, but published on, or after the filing date
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L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 02 5258

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29-01-2004

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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

(19) World Intellectual Property Organization
International Bureau

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

PCT

(10) International Publication Number
WO 2009/152320 A2

(51) International Patent Classification:
A61M 5/14 (2006.01) *A61M 36/00* (2006.01)
G21F 5/015 (2006.01)

(21) International Application Number:
PCT/US2009/047027

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

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

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

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

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

Published:

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

(54) Title: SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(57) Abstract: A shielding assembly for an infusion system includes a plurality of compartments and a door for each compartment, and provides a radioactive radiation barrier for the compartments. One of the compartments contains one or more radioisotope generators of the infusion system and another of the compartments may contain a waste bottle of the infusion system. An opening into each of the generator and waste bottle compartments may be oriented upward, and the opening into the latter may be at a higher elevation than the opening into the former, for example, to facilitate independent removal and replacement of each. A door of at least one of the compartments, other than the generator compartment, when closed, may prevent the door of the generator compartment from being opened. A cabinet structure for the infusion system may enclose the shielding assembly and secure the generator.

WO 2009/152320 A2

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

RELATED APPLICATIONS

The present application claims priority to the following U.S. patent applications: U.S. Patent Application No. 12/137,356, filed June 11, 2008; U.S. Patent Application No. 12/137,363, filed June 11, 2008; 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.

TECHNICAL FIELD

The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to shielding assemblies thereof.

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 radiopharmaceutical, 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).

Whether the half-life of a particular radioactive isotope, employed by a radiopharmaceutical, is relatively short or long, a patient undergoing a nuclear imaging procedure is not typically exposed to a significant amount of radiation. However those personnel, whose job it is to set up and maintain radiopharmaceutical infusion systems, and to administer doses therefrom, are subject to more frequent exposures to radiation. Therefore, shielding assemblies, which provide a radiation barrier to protect these personnel from excessive exposure to radiation sources, are an important component of radiopharmaceutical generators and infusion systems. These shielding assemblies are typically formed with lead sidewalls, the bulk and weight of which can pose

difficulties for the personnel who regularly set up, maintain and use the systems. Thus, there is a need for improved shielding assemblies employed by systems that generate and infuse radiopharmaceuticals.

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 surrounds an interior space in which a portion of infusion system 10 is contained (-seen in Figure 1C). Shell 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 for 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. 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 122, according to those embodiments in which wheels 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 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 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. On 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, 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 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, an 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