WE CLAIM:

1. A method of controlling an $^{82}Sr/^{82}Rb$ elution system having a generator valve for proportioning a flow of saline solution between an $^{82}Sr/^{82}Rb$ generator and a bypass line coupled to an outlet of the generator such that saline solution traversing the bypass line will merge with eluted saline solution emerging from the generator to provide an active saline solution, the method comprising steps of:

during each elution run:

obtaining a plurality of successive concentration parameter values at predetermined intervals, each concentration parameter value being indicative of a respective instantaneous activity concentration of the active saline solution;

computing respective error values between each concentration parameter value and a target activity concentration value of the elution run; and

accumulating error data based on a plurality of the computed error values; and

between successive elution runs, adjusting at least one performance parameter of the elution system based on the accumulated error data.

2. A method as claimed in claim 1, wherein the step of adjusting at least one performance parameter of the elution system comprises a step of tuning a performance model of the generator valve.

3. A method as claimed in claim 2, wherein the accumulated error data comprises the computed error values as a function of an estimated flow ratio.

4. A method as claimed in claim 3, wherein the step of tuning a performance model of the generator valve comprises steps of:

calculating a slope of the error data; and

adjusting a response slope parameter of the generator valve model based on the calculated slope of the error data.

5. A method as claimed in claim 2, wherein the error data comprises one or more error values accumulated during a period in which a target activity concentration of an elution exceeds the predicted activity concentration of that elution.

6. A method as claimed in claim 5, wherein the step of tuning a performance model of the generator valve comprises steps of:

calculating a slope of the error data; and

adjusting an upper limit parameter of the generator valve based on the calculated slope of the error data.

7. A method as claimed in claim 6, wherein the step of adjusting the upper limit parameter comprises steps of:

if the calculated slope is zero, reducing the upper limit parameter by a predetermined increment; and

otherwise, calculating an adjusted upper limit parameter value using the calculated slope.

8. A method as claimed in claim 2, wherein the error data comprises a difference between a predicted elution duration required to achieve a desired total activity dose and an actual elution duration.

9. A method as claimed in claim 8, wherein the step of tuning a performance model of the generator valve comprises a step of adjusting a hysteresis factor H based on the difference between the predicted and actual elution durations.

10. A method as claimed in claim 1, further comprising a step of enforcing a predetermined delay between successive elution runs.

11. A method as claimed in claim 1, further comprising steps of:

defining a plurality of operating modes of the elution system; and

during each elution run, automatically transitioning between selected ones of the operating modes, in accordance with user-input parameters of the elution run.

12. A method as claimed in claim 11, wherein the plurality of operating modes comprise:

a "Bypass-to-waste" mode in which the entire saline flow is directed through the bypass line and into a waste reservoir;

a "patient line flush" mode in which the saline flow is directed through the bypass line and out through a patient outlet;

a "waiting for threshold" mode in which the saline flow is directed through the generator, and the active saline solution directed into the waste reservoir; and

an "elution" mode in which the saline flow is proportioned between the generator and the bypass line, and the active saline solution directed out through the patient outlet.

13. A method as claimed in claim 11, wherein the user-input parameters comprise:

at least one of a desired duration of the elution, and a desired saline flow rate; and

at least one of a target activity concentration profile, and a total eluted activity dose.

14. A method as claimed in claim 1, further comprising steps of:

defining a set of one or more predetermined elution runs, each having respective set of predetermined parameters; and

executing the set of predetermined elution runs in accordance with a predetermined schedule.

15. A method as claimed in claim 14, wherein the predetermined schedule defines a daily protocol.

16. A method as claimed in claim 14, wherein the set of one or more predetermined elution runs comprises a

calibration elution for calibrating any one or more of:

a performance of the generator;

a proportionality constant between the concentration parameter value and the instantaneous activity concentration of the active saline solution.

17. A method as claimed in claim 16, wherein the calibrated performance of the generator comprises either one or both of:

^{82}Rb activity concentration vs. eluted volume; and

^{82}Sr breakthrough.

18. A positron detector for detecting instantaneous ^{82}Rb activity concentration of an active saline solution generated by an ^{82}Sr/^{82}Rb elution system, the positron detector comprising:

a scintillation fiber disposed adjacent a feed line for conveying the active saline solution;

a photon counter operatively coupled to the scintillation fiber for detecting photons generated by positron annihilation within the scintillation fiber; and

a radiation shield surrounding the scintillation fiber and at least a portion of the feed line, for shielding at least the scintillation fiber from spurious radiation.

19. A positron detector as claimed in claim 18, wherein a thickness of the radiation shield is on the order of ½ inch.

20. A positron detector as claimed in claim 18, wherein the radiation shield surrounds a length of the feed line corresponding to at least five times an outer diameter or the feed line, in each direction from the scintillation fiber.

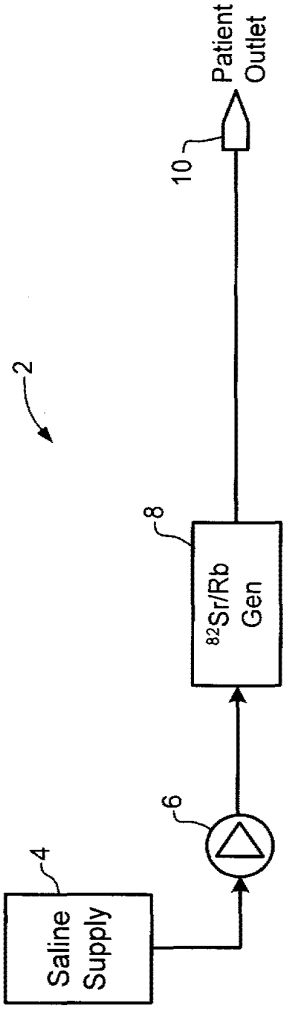


Figure 1a
(Prior Art)

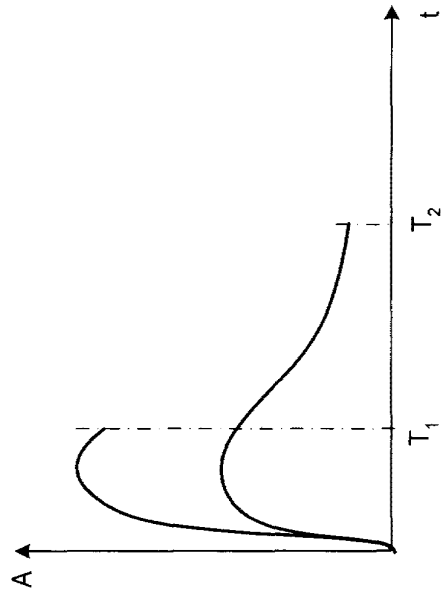


Figure 2b
(Prior Art)

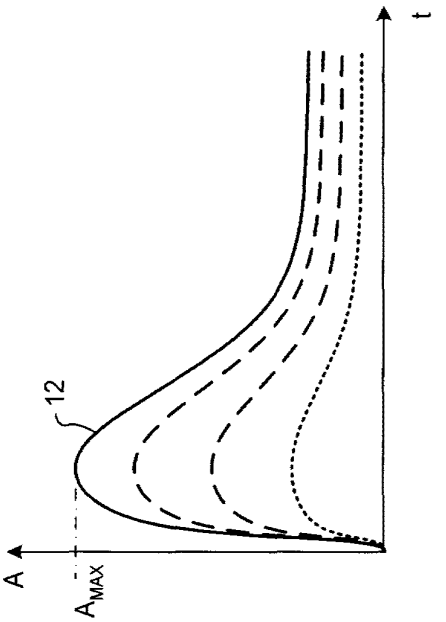


Figure 2a
(Prior Art)

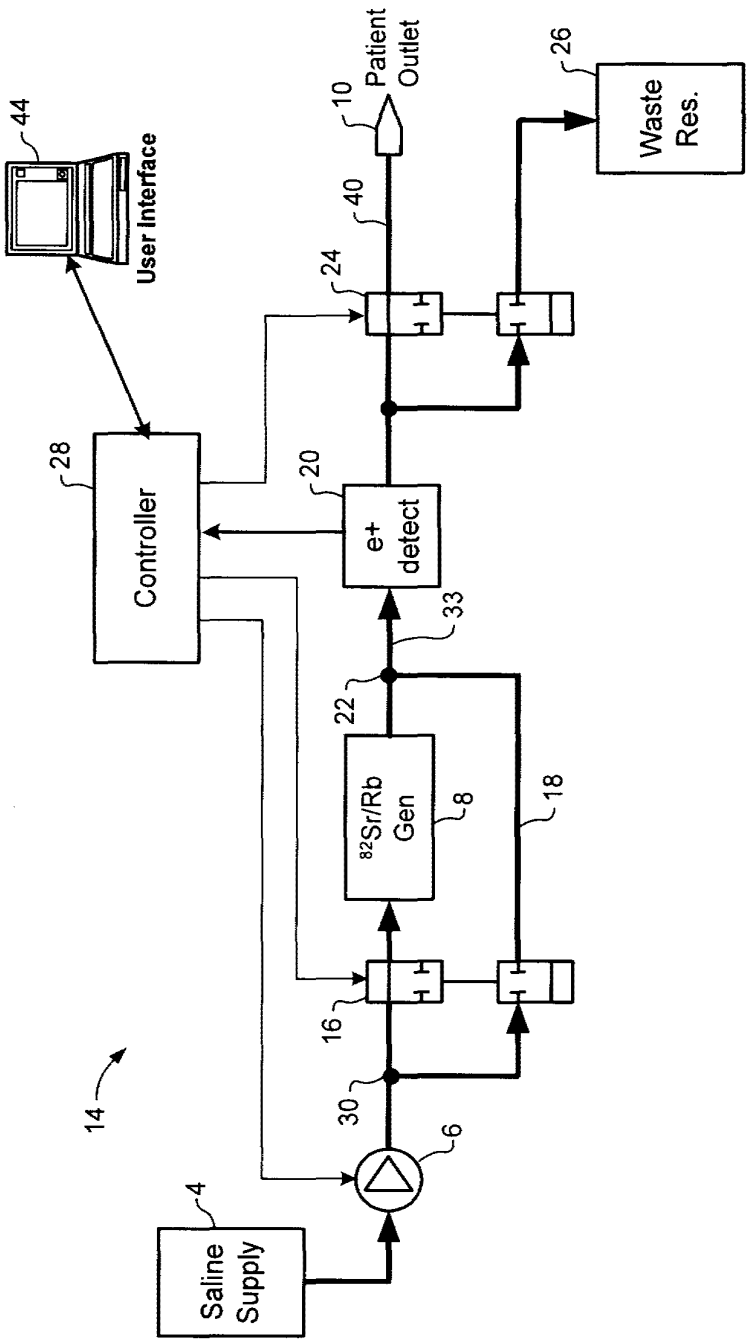

Saline Supply
4
Waste Res.
26
Patient Outlet
10
User Interface
44
40
24
Controller
28
e+ detect
20
33
22
^{82}Sr/Rb Gen
8
18
16
30
6
14

Figure 3

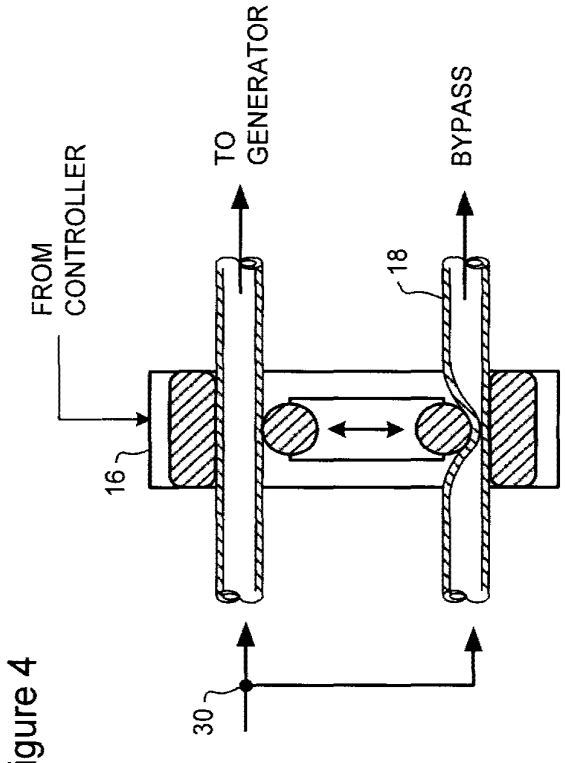


Figure 4

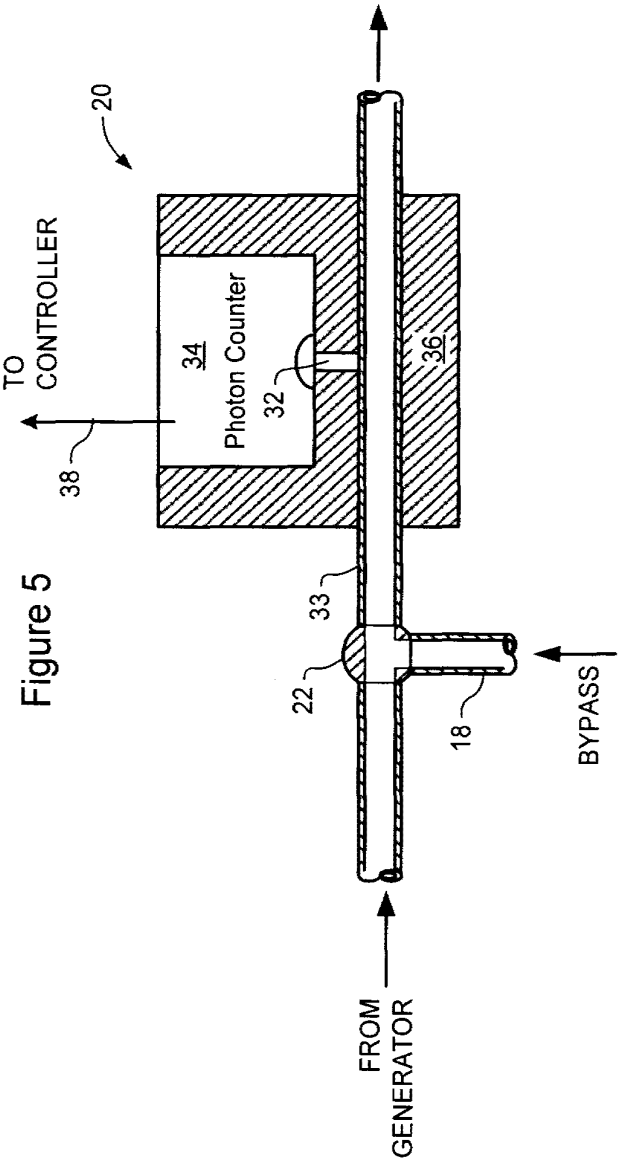


Figure 5

Figure 6a

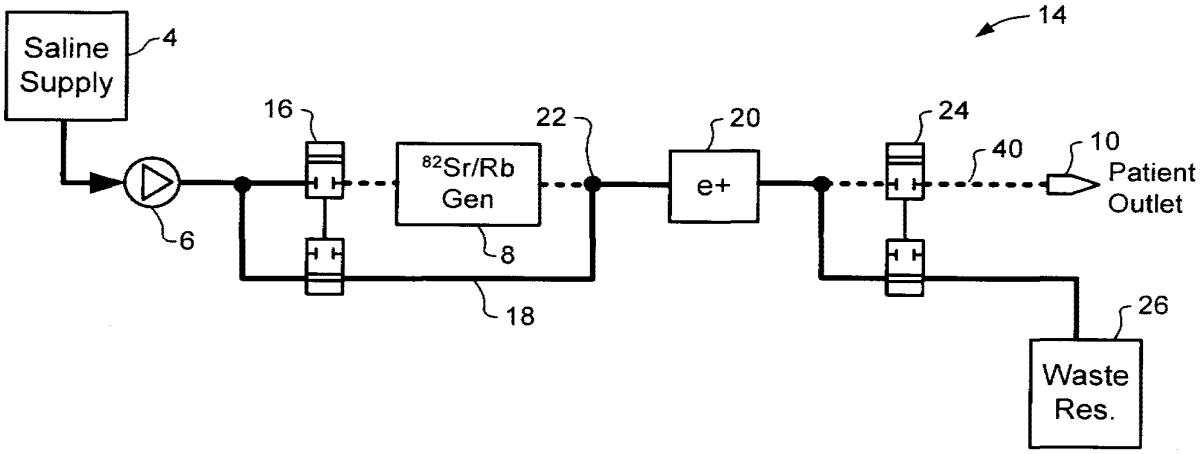


Figure 6b

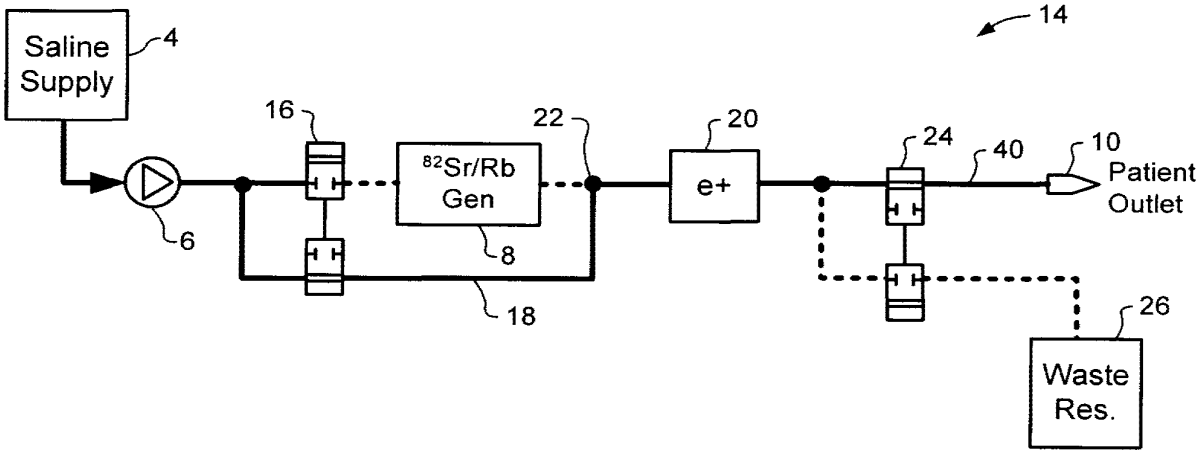


Figure 6c

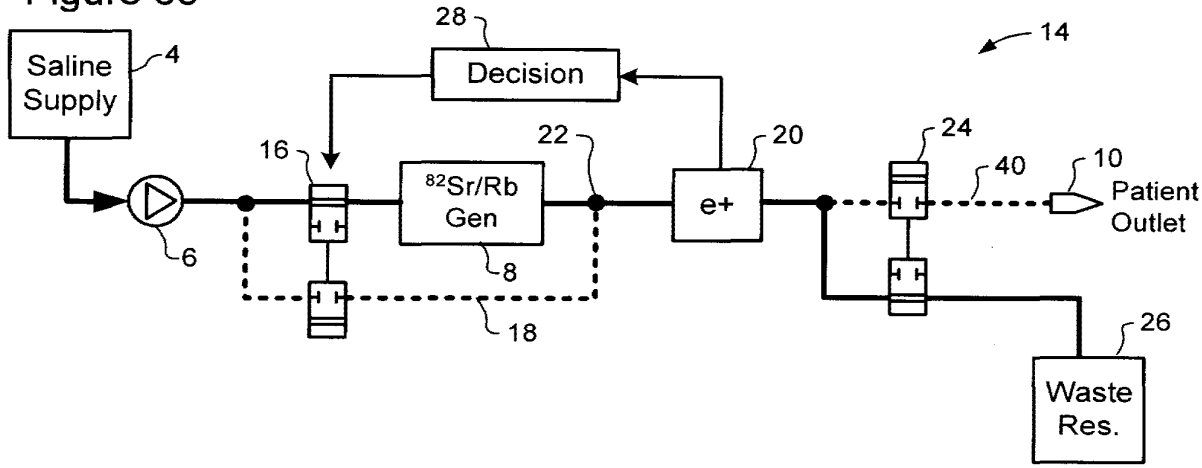


Figure 6d

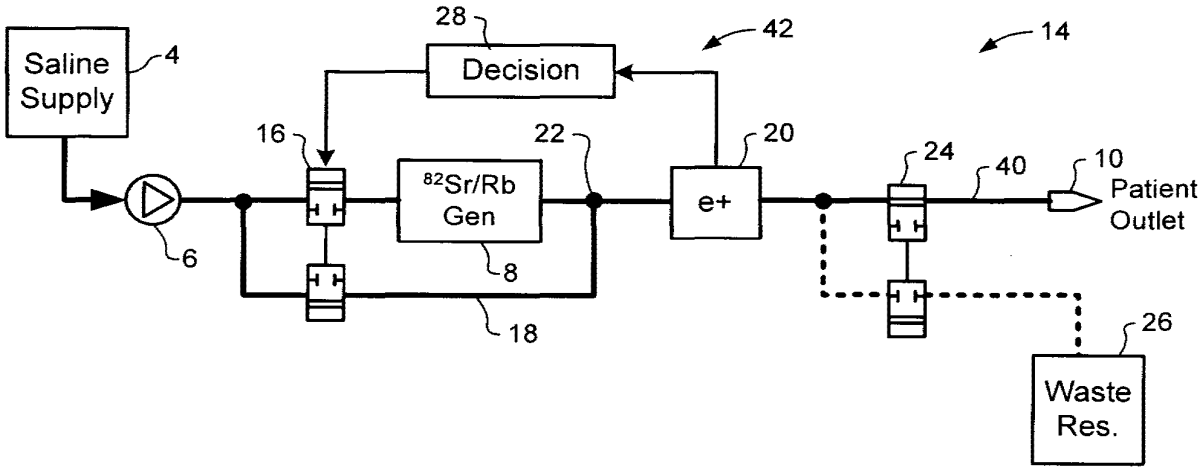

Saline Supply
4
28
Decision
42
14
16
22
20
24
40
10
Patient Outlet
^{82}Sr/Rb Gen
e+
6
8
18
26
Waste Res.

Figure 7a

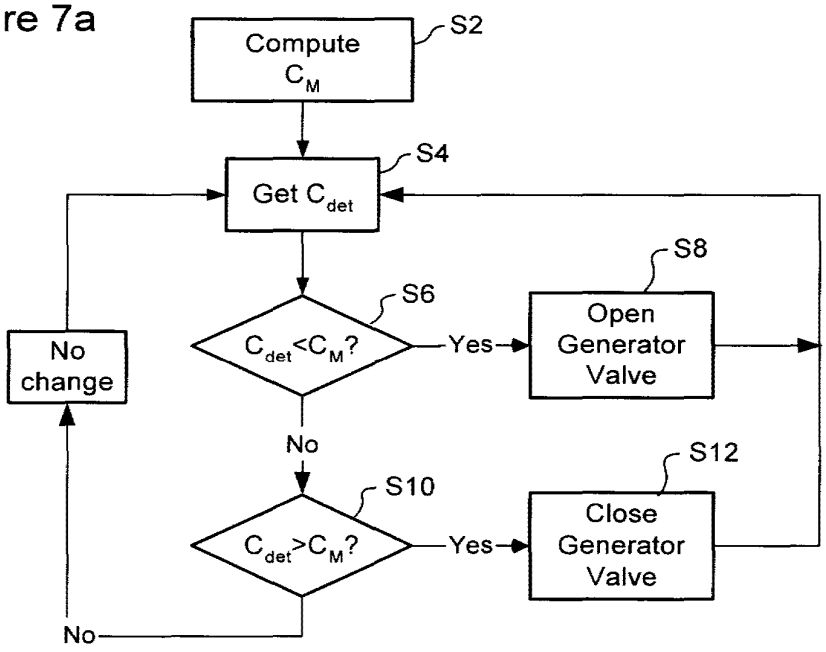


Figure 7b

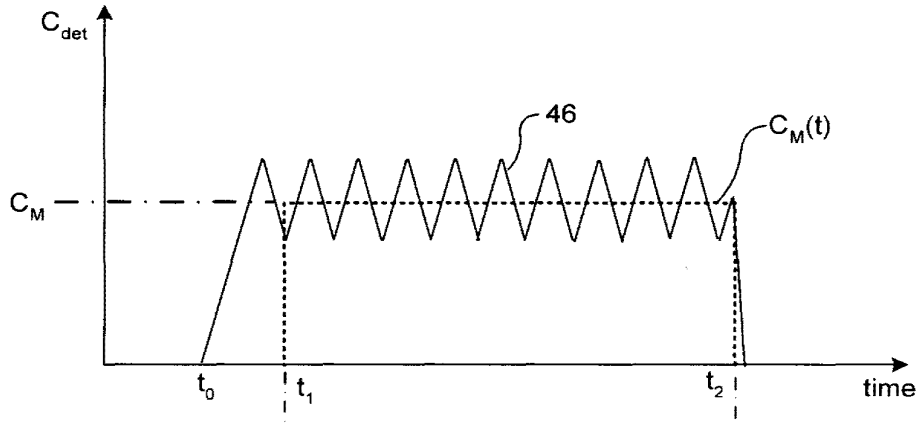


Figure 7c

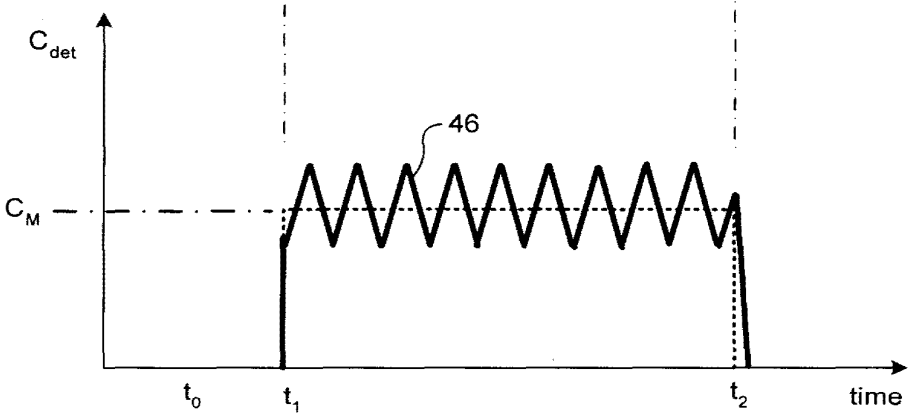


Figure 8a

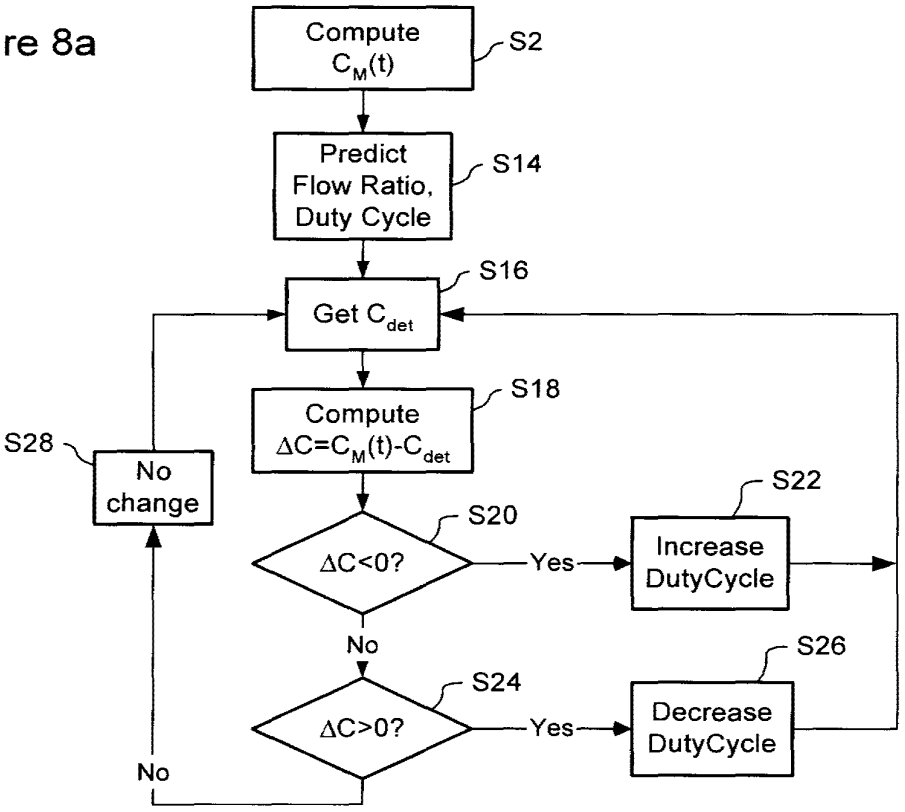


Figure 8b

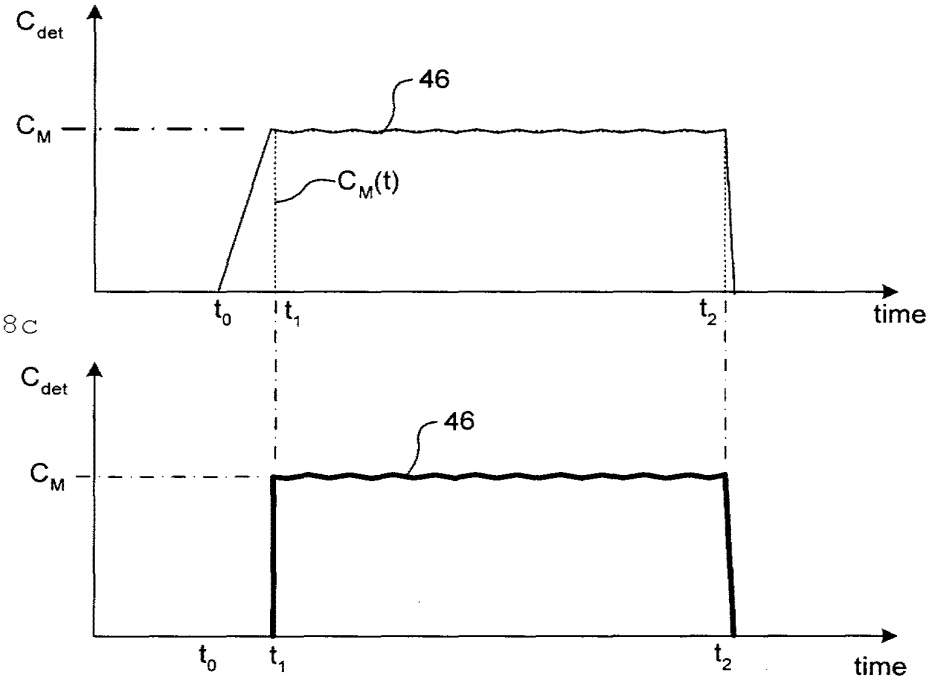


Figure 8c

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/000295

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61M 36/06*** (2006.01) , ***A61M 36/08*** (2006.01) , ***G01T 1/164*** (2006.01) , *G01T 1/20* (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61M All (2006.01) + G01T All (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
QPat, QWeb, Delphion (Keywords used: positron emission tomography, myocard* perfusion, radiation detector, scintillation fibre, generator, etc.)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2000131443 A (CHIBA, K. et al.) 12 May 2000 (12-05-2000) * Figs 1-6; Abstract; Machine translation *	18-20
A	JP 7231884 A (OKADA, H. et al.) 5 September 1995 (05-09-1995) * Figs. 1-7; Abstract *	18-20
A	US 4975583 A (SPOWART, A.R.) 4 December 1990 (04-12-1990) * Fig. 2; Abstract; Columns 2-3 *	18-20
A	US 6713765 B2 (TESTARDI, L.R.) 30 March 2004 (30-03-2004) * Whole document *	18-20
A	ALVAREZ-DIAZ, Teresa M. et al., Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion imaging in patients using positron emission tomography, Applied Radiation and Isotopes, vol. 50, no. 6, 1999, pp. 1015-1023	1-17

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

*	Special categories of cited documents :	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
13 April 2007 (13-04-2007)	18 May 2007 (18-05-2007)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 001-819-953-2476

Authorized officer
Valérie Dubé 819- 934-4261

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/000295

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [ ] Claim Nos. :
because they relate to subject matter not required to be searched by this Authority, namely :

2. [ ] Claim Nos. :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3. [ ] Claim Nos. :
because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

- Claims 1-17 pertain to a method of controlling an 82Sr/82Rb elution system, the system comprising a generator valve, an 82Sr/82Rb generator and a bypass line and providing an active saline solution, the method comprising: during each elution run, obtaining concentration values, computing error values between the obtained values and a target value, accumulating error data and adjusting a system parameter accordingly.
- Claims 18-20 pertain to a positron detector for detecting 82Rb activity concentration of an active saline solution generated by an 82Sr/82Rb elution system, the detector comprising a scintillation fibre adjacent a feed line, a photon counter and a radiation shield.

The common feature between aforesaid groups of claims is an 82Sr/82Rb elution system generating an active saline solution. However, such a system is already well known in the art and therefore cannot be regarded as constituting a single common inventive feature linking

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	YANO, Y, et al., A Precision Flow-Controlled Rb-82 Generator for Bolus or Constant-Infusion Studies of the Heart and Brain, The Journal of Nuclear Medicine, vol. 22, no. 11, 1981, pp. 1006-1010	1-17
A	YANO, Y, Essentials of a Rubidium-82 Generator for Nuclear Medicine, International journal of radiation applications and instrumentation. Part A, Applied radiation and isotopes, vol. 38, no. 3, Great Britain, 1987, pp. 205-211	1-17
A	KENSETT, M. J. et al., Experience with a 82Sr/82Rb Generator for Clinical Use, International journal of radiation applications and instrumentation. Part A, Applied radiation and isotopes, vol. 38, no. 3, Great Britain, 1987, pp. 227-231	1-17
A	SAHA, G. et al., Use of the 82Sr/82Rb Generator in Clinical PET Studies, International journal of radiation applications and instrumentation. Part B, Nuclear medicine and biology, vol. 17, no. 8, Great Britain, 1990, pp. 763-768	1-17

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2007/000295

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
JP 2000131443 A	12-05-2000	NONE	
JP 7231884 A	05-09-1995	NONE	
US 4975583 A	04-12-1990	AU1299288 A EP0346369 A1 GB8704074 D0 JP2502217 T WO8806297 A1	14-09-1988 20-12-1989 25-03-1987 19-07-1990 25-08-1988
US 6713765 B2	30-03-2004	NONE	

Electronic Acknowledgement Receipt

EFS ID:	5367356
Application Number:	12137364
International Application Number:	
Confirmation Number:	7377
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Elisabeth Lacy Belden
Filer Authorized By:	
Attorney Docket Number:	56782.1.7
Receipt Date:	20-MAY-2009
Filing Date:	11-JUN-2008
Time Stamp:	13:57:41
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) Filed (SB/08)	56782_1_7_IDS3.pdf	806227 3b12bc5796e1a050f31409e9b41d642ca0d92757	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.

2	Foreign Reference	56782_1_WO07071022A1.pdf	994962 47ddcf6b6a69dde75265b82836f3bcb67c12bf04	no	24
Warnings:					
Information:					
3	Foreign Reference	56782_1_WO07104133A1.pdf	1590246 8d23d4809a08099ece4791dcd9a549165275715a	no	42
Warnings:					
Information:					
			Total Files Size (in bytes):	3391435	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/08a (03-08)
Approved for use through 06/30/2008. 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	12137364
Filing Date	2008-06-11
First Named Inventor	Stephen E. Hidem
Art Unit	2628
Examiner Name	
Attorney Docket Number	56782.1.7

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	2008140351	WO	A1	2008-11-20			☒

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

NON-PATENT LITERATURE DOCUMENTS Remove

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137364
	Filing Date	2008-06-11
	First Named Inventor	Stephen E. Hidem
	Art Unit	2628
	Examiner Name	
	Attorney Docket Number	56782.1.7

	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	12137364
	Filing Date	2008-06-11
	First Named Inventor	Stephen E. Hidem
	Art Unit	2628
	Examiner Name	
	Attorney Docket Number	56782.1.7

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.

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

☒ None

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	/Elisabeth Lacy Belden/	Date (YYYY-MM-DD)	2009-01-19
Name/Print	Elisabeth Lacy Belden	Registration Number	50,751

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.

AUTOMATED STRONTIUM-RUBIDIUM INFUSION SYSTEM

The invention relates to medical engineering, and particularly to means for automation of a process for producing a diagnostic solution from a radionuclide strontium-rubidium generator and remote carrying out a checked infusion with automatic checking main process characteristics, such as an introduced activity value, presence of air bubbles as well as a solution weight and activity in a waste container.

One of the most perspective directions in the nuclear diagnostics is the positron emission tomography (PET). Such short and ultra-short living isotopes as C-11, O-15, N-13, and F-18 are used in the PET centers. This obliges to have cyclotrons at the place of diagnostic for making such isotopes. It is possible to widen the functionality of the PET diagnostics in use of generator systems having a parent radionuclide lifetime significantly longer that a lifetime of radionuclides made in cyclotrons of the PET centers. Generator systems ^{82}Sr ($t_{1/2}$ = 25.6 days) $\rightarrow$ ^{82}Rb ($t_{1/2}$ = 75 seconds) and ^{68}Ge ($t_{1/2}$ = 271 days) $\rightarrow$ ^{68}Ga ($t_{1/2}$ = 78.3 minutes) are the most promising systems among the PET isotope generators.

Therefore, it is possible to say with respect to generator isotopes that any clinics having PET scanners within a region, a country or a group of countries are to be provided with said isotopes.

Generator systems can find the widest use in so called mobile PET scanners mounted in auto-trailers and called for servicing clinics that have no both own cyclotrons and own PET scanners. Absence of "affixment" of such a mobile PET scanner to an isotope base substantially widens a radius of the territory serviced thereby.

A strontium-rubidium infusion system for producing a diagnostic solution from a radionuclide strontium-rubidium generator and carrying out a checked infusion is known (US 4,562,829, 1986), said system comprising: an eluent tank connected by respective pipes of a transporting system via a first three-way valve to a syringe pump; a strontium-rubidium generator with a first filter and a first pressure sensor at an input; a second three-way valve whose first opening is coupled via a second filter to means for infusing an eluent into a patient and whose second opening is coupled to an eluate surplus storing and collecting means; radioactivity measurement means; and a check and control system. The prior art system is not optimal in a degree of radioactive radiation protection and in a service life of a generator column.

The disclosed invention is directed to elimination of the listed disadvantages. The technical result to be accomplished by using the inventive system consists in enhancement of

effectiveness in carrying out of a diagnostic procedure due to automation of the infusion procedure, reducing undesirable irradiation doses for a patient and maintenance personnel, increasing exploitation lifetimes of a generator column.

The essence of the disclosed invention consists in that an automated strontium-rubidium infusion system comprises: an eluent tank, a strontium-rubidium generator with a filter and a pressure sensor at an input; means for infusing an eluent into a patient, said tank, generator and means being connected by a transporting system to pipes and two three-way valves; radioactivity measuring means; and a check and control unit. At the same time, the eluent tank is connected via first and second openings of the first three-way valve to a syringe pump, a first opening of the second three-way valve is coupled by pipes via a second filter to the means for infusing the eluent into the patient and is coupled by a second opening thereof to a waste receptacle. The system further comprises: third and fourth three-way valves; first and second air bubble detectors coupled to the check and control unit being in communication with a computer, said third three-way valve being connected by first and second openings via pipes to a third opening of the first three-way valve and to an input of the strontium-rubidium generator, respectively, an output of the generator being coupled to a first opening of the fourth three-way valve, wherein the third opening of the third valve and a second opening of the fourth valve are in communication by a pipe, the first air bubble detector is mounted on a pipe between the eluent tank and the first opening of the first valve while the second detector is mounted on a pipe between the third openings of the fourth and second valves.

Further, the radioactivity measurement means include first and second activity sensors. At the same time, the first activity sensor is placed on a pipe between the third openings of the fourth and second valves and is embodied as a beta detector.

A radiation protection of the eluate surplus collecting and storing means may be implemented as a protection box including waste weight check means in the form of a force sensor, while the second activity sensor in the form of a gamma detector may be mounted within an opening of the protective box in order to determine a radioactivity level.

A column of the strontium-rubidium generator has a radiation protection including external main and transportation protective containers, said main protection container being mounted stationary on a shelf of a bogie.

The system is mounted in a closed movable housing. Further, the housing is provided with a shifting tabletop.

The essence of the invention is explained by drawings as follows:

Fig. 1 is a diagram of an infusion system;

Fig. 2 is a general side view of a generator plant;

Fig. 3 is a general top view of the generator plant.

Conditional notation used in drawings is listed below:

1 – Eluent tank

2, 3, 4, 5 – three-way valves

6, 7 – activity sensors

8, 9 – pressure sensors

10 – Syringe pump

11 – strontium-rubidium generator

12 – Check and control unit

13 – Weight sensor

14 – Remote computer

15, 16 – filters

17, 18 – air bubble detectors

19 – Means (needle) for infusing an eluent into a patient

20 – Eluent and eluate waste receptacle

21 – Movable housing

22 – Stand

23 – Protective container of strontium-rubidium generator

24 – Protective container for beta detector

25 – Power supply source

26 – Protective box of waste reservoir

27 – Shifting tabletop

An automated strontium-rubidium infusion system includes means for generating rubidium-82 in a solution which can be infused into a patient, exactly, a rubidium-strontium generator 11 (Fig. 1) of a traditional type in a transporting container. This container is placed in a protective external main container 23 and fulfils a main radiation protection function together with the latter. The assembled system may be mounted in a movable housing 21 (Fig. 2) covered by decorative panels (not shown). There is a stand 22 mounted on a tabletop and having an eluent tank fastened thereon. There are a syringe pump 10 and a computer 14 further mounted here. Components mounted on an upper shelf of the movable housing 21 are as follows:

- the main protective container 23 into which a standard transporting container with the strontium-rubidium generator 11 is placed;

- a protective box 24 with a beta activity detector placed therein and measuring the activity of a solution passed through the strontium-rubidium generator 11;

- a power supply source 25.

A protective box 26 is placed at a lower shelf, said box having an eluent and eluate waste receptacle arranged therein.

A top lid of the container 23 is turned back in Fig. 3, which makes it possible to see a cavity into which the transporting container with the strontium-rubidium generator 11 is placed. In order to make easier the access to the main protective container 23 during recharging a generator system (there are removal of the transporting container with the used column of the strontium-rubidium generator 11 and installation of a transporting container with a fresh column), a tabletop part is made as a shifting tabletop 27 which provides convenience in operation.

Further, the system includes means for infusion, exactly (Fig. 1): a remote-controlled syringe pump 10 whose rod is actuated, for example, by a step motor; means for automated filling the syringe pump with an eluent (a 0.9% NaCl solution); a system for transporting an eluent and an eluate to a patient or an eluent and eluate waste receptacle, said transporting system being provided with multi-way (three-way) valves 2 to 5 (Fig. 1) that ramify the transporting system in accordance with a job making program; antibacterial protection means, exactly, antibacterial filters 15 and 16 at an input and at an output of the transporting system; eluate activity measurement means 6 and 7 for monitoring and dozing in infusion into a patient; pressure measurement means 8 and 9 for measurement a pressure in the transporting system, said means being designed for measuring occlusion as well; an eluent and eluate waste receptacle 20 also capable of measuring a solution activity value and a solution weight in a waste reservoir 13; means 12 for automated check throughout the eluation process and components thereof, implemented by on-board or remote computers 14.

The tank 1 with an eluent (for example, brine) is connected by a plastic fitting to a pipe (for example, an infusion tube that has an outer diameter of 2.5 mm with an inner diameter of 1.5 mm). Lengths of such tubes (pipes) are used further to build the transporting system as a whole for infusion. Other end of the pipe is attached via an air bubble detector 17 that generates a signal to a check and control unit 12 in case of passing an air bubble, and said unit generates a control signal to valves 2, 3, 4, and 5 as a result of which the eluent solution comprising the air bubble is removed into the eluent and eluate waste receptacle 20 and does not passes through the column of the strontium-rubidium generator 11.

The valve 2 switches the infusion system into one of two possible operating modes for: (1) filling the syringe when the syringe pump 10 operates for suction the brine from the eluent tank 1 (via the first and second openings of the valve); or (2) infusing, that is, supplying the brine from the filled syringe of the syringe pump 10 into the infusion system (via the first and third openings of the valve).

Further, the three-way valve 2 is connected by a length of a connecting tube to the first opening of the third three-way valve 4 whose second opening is connected via the first filter 15 to an input of the column of the strontium-rubidium generator 11. The first pressure sensor 8 checks a pressure at the input of the column of the strontium-rubidium generator 11.

The third opening of the valve 4 via a length of a connecting tube is connected to the second opening of the fourth three-way valve 5. This valve (the first opening) also has connections to an output tube of the column of the strontium-rubidium generator 11 and an extension of the infusion system in the third opening.

When the syringe pump operates in the operating "infusion" mode, the pair of three-way valves 4, 5, while operating in synchronism, allows either pumping the brine from the syringe 10 via the column of the strontium-rubidium generator 11 further to the infusion system already in the form of an eluate, that is, a Rb-82-enriched solution, or pumping the brine into the infusion system while by-passing the strontium-rubidium generator 11. Thus operating mode is used when a necessary Rb-82 activity amount has been made and should be delivered to a patient 19 while the infusion system should be filled with the inactive brine at the end of infusion into the patient. When the brine pumping mode is used, practically the entire transporting system, exceptive for a connecting pipe from the strontium-rubidium generator output to the fourth three-way valve, will be filled with the non-radioactive brine and will not be a source of additional undesirable radioactivity for the patient and the maintenance personnel; additionally, a brine volume necessary to after-press the made eluate into the patient will not pass through and deplete the column of the strontium-rubidium generator, because it is known that a potency of the generator depends not only upon a time of using thereof but also upon a volume of the brine passed through the generator.

There are a first radioactivity detector 6 (a beta detector) and a second air bubble detector 18 mounted on a pipe from the third opening of the fourth three-way valve 5 to the third opening of the second three-wave valve 3, said air bubble detector being similar to the first air bubble detector 17.. When an air bubble is detected, the detector 18 generates a signal to the check and control unit that generates a control signal to the second three-way valve 3. As a result, an eluate comprising the air bubble is removed into the eluent and eluate waste

receptacle 20. If an air bubble is not detected, the eluate is directed via the first of said three-way valve 3 and the second filter 16 into the patient, that is, onto a needle 19.

The radioactivity detector 6 operates in real time and measures the Rb-82 activity at a location of the detector 18.

The check for filling said waste receptacle with a liquid is carried out by a force sensor (not shown). To measure a radioactivity present in the eluent and eluate waste receptacle, the second radioactivity sensor 7 (a gamma detector) is used. The radiation protection of the eluate surplus collecting and storing means is implemented as a protection box including a force sensor, while the second activity sensor is mounted within an opening of the protective box.

During infusion into the patient, the second three-way valve 3 is switched for passing the eluent to a pipe connected to the needle 19 via a Millipore filter 16. There is a second pressure sensor 9 mounted in this section which allows measurement of an occlusion pressure when an Rb-82-containing solution in administered into the patient.

The process of operating the strontium-rubidium infusion system takes place under control of a control computer program that registers a status of each of devices included in the infusion system at moments of starting and finishing a step, and also registers actions of said devices under condition of their normal functioning and in case if an emergency situation occurs.

To exclude overfilling the eluent and eluate waste receptacle 20 with a radioactive liquid, a level of said liquid is remotely checked using the force sensor; in doing so, there is monitoring of a total container and liquid weight (volume) and a limit value thereof. Additionally, by fixing a weight of the empty waste collection receptacle, a system for scheduled interrogating the check and control unit receives information that the receptacle is mounted in a container. A maximum waste volume in the receptacle is 250 ml.

The check and control unit 12 is coupled to a remote computer whose display displays a graphical mnemonic diagram of the generator device, said diagram providing observation of parameters to be checked in an automatic mode and parameters for operating control of individual members (the electromagnetic three-way valves 2 to 5 and the pump 10) in a manual mode. The diagram makes it possible to observe a current state of all members (the valves 2 to 5, the air bubble detectors 17, 18) of the disclosed infusion system, and operation of the syringe pump 10. The system also allows reception of information about parameters of a pressure in a line from the pressure sensors 8, 9, and reception of information about an

eluate activity at an output of the generator column 11 and a total activity, a weight of the eluate and eluent waste receptacle 20, an activity in said receptacle from the detectors 6, 7.

The check and control unit 12 of the system is connected to control members of the generator plant, that is, the electromagnetic three-way valves 2, 3, 4, 5 and the pump 10, and also includes members for gathering and processing signals from the sensors 6, 7 (the radioactivity sensors), 8, 9 (the pressure sensors), and 17, 18 (the bubble detectors). The control unit 12 is in communication with a panel personal computer (PPC) or any other remote computer (14) through an Ethernet channel. The control unit receives commands from the PPC or remote computer to execute individual steps of the generator plant operating program and informs said computers about a current state of members controlled thereby and a state of system sensors.

The disclosed system improves the safety of use due to the fact that automation of the infusion process has allowed significant reduction in the radioactive irradiation because the system includes additional members that provide ramification of pipes. As a result, it is possible to after-press the made eluate into the patient by the eluent while by-passing the strontium-rubidium generator. At the same time, the pipe is pumped through by the non-radioactive eluent and there is no additional depletion of the strontium-rubidium generator, which makes the life thereof longer. Further, the risk of presence of air bubbles in the eluent delivered into the patient is excluded because of introducing air bubbles into the system of detectors, while detection of said air bubbles immediately results in direction of the eluent and eluate wastes to the eluent and eluate waste receptacle via branches of the pipe without depletion of the strontium-rubidium generator.

CLAIMS

1. An automated strontium-rubidium infusion system comprising:

an eluent tank;

a strontium-rubidium generator with a filter and a pressure sensor at an input;

means for infusing an eluent into a patient, said tank, generator and means being connected by a transporting system to pipes and two three-way valves;

radioactivity measuring means; and

a check and control unit,

wherein the eluent tank is connected via first and second openings of the first three-way valve to a syringe pump, a first opening of the second three-way valve is coupled by pipes via a second filter to the means for infusing the eluent into the patient and is coupled by a second opening thereof to a waste receptacle,

said system being characterized in that it further comprises:

third and fourth three-way valves;

first and second air bubble detectors coupled to the check and control unit being in communication with a computer,

said third three-way valve being connected by first and second openings via pipes to a third opening of the first three-way valve and to an input of the strontium-rubidium generator, respectively, an output of the generator being coupled to a first opening of the fourth three-way valve,

wherein the third opening of the third valve and a second opening of the fourth valve are in communication by a pipe, the first air bubble detector is mounted on a pipe between the eluent tank and the first opening of the first valve while the second detector is mounted on a pipe between the third openings of the fourth and second valves.

2. The system according to claim 2, characterized in that the radioactivity measurement means include first and second activity sensors.

3. The system according to claim 3, characterized in that the first activity sensor is placed on a pipe between the third openings of the fourth and second valves and is embodied as a beta detector.

4. The system according to claim 2, characterized in that the waste receptacle is implemented as a protection box including waste weight check means in the form of a force

sensor, while the second activity sensor in the form of a gamma detector is mounted within an opening of the protective box.

5. The system according to claim 1, characterized in that the strontium-rubidium generator has a radiation protection including external main and transportation protective containers, said main protection container being mounted stationary on a shelf of a bogie.

6. The system according to claim 1, characterized in that it is mounted in a closed movable housing.

7. The system according to claim 6, characterized in that the housing is provided with a shifting tabletop.

(12) МЕЖДУНАРОДНАЯ ЗАЯВКА, ОПУБЛИКОВАННАЯ В СООТВЕТСТВИИ С ДОГОВОРОМ О ПАТЕНТНОЙ КООПЕРАЦИИ (PCT)

(19) Всемирная Организация Интеллектуальной Собственности
Международное бюро

(43) Дата международной публикации
20 ноября 2008 (20.11.2008)

PCT

(10) Номер международной публикации
WO 2008/140351 A1

(51) Международная патентная классификация:
A61M 5/168 (2006.01) *A61B 6/00* (2006.01)
A61M 36/06 (2006.01)

(21) Номер международной заявки: PCT/RU2008/000211

(22) Дата международной подачи:
4 апреля 2008 (04.04.2008)

(25) Язык подачи: Русский

(26) Язык публикации: Русский

(30) Данные о приоритете:
2007113009 9 апреля 2007 (09.04.2007) RU

(71) Заявитель *(для всех указанных государств, кроме US)*: **ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "ПОЗИТОМ-ПРО" (OBSHCHESTVO S OGRANICHENNOY OTVETSTVENNOSTIU "NAUCHNO-PROIZVODSTVENNAYA FIRMA "POZITOM-PRO")** [RU/RU]; ул. Большая Черемушкинская, д. 25, кв. 180, Москва, 117218, Moscow (RU).

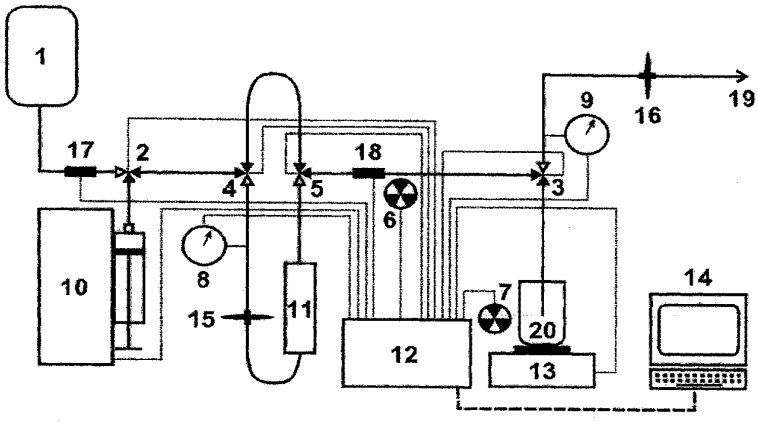
(72) Изобретатели; и

(75) Изобретатели/Заявители *(только для US)*: **ШИМЧУК Геннадий Григорьевич (SHIMCHUK, Gennady Grigorievich)** [RU/RU]; ул. Болотниковская, д. 49, кв. 88, Москва, 117209, Moscow (RU). **ПАХОМОВ Геннадий Аркадьевич (PAKHOMOV, Gennady Arkadyevich)** [RU/RU]; Ореховый бульвар, д. 12, корп. 2, кв.405, Москва, 115582, Moscow (RU). **ШИМЧУК Григорий Геннадьевич (SHIMCHUK, Grigory Gennadyevich)** [RU/RU]; ул. Болотниковская, д. 49, кв. 88, Москва, 117209, Moscow (RU). **УТЕНКОВ Алексей Борисович (UTENKOV, Aleksei Borisovich)** [RU/RU]; ул. Профсоюзная, д. 17, корп. 1, кв. 33, Москва, 117218, Moscow (RU). **ГАЛОЧКИН Валерий Тимофеевич (GALOCHKIN, Valery Timofeevich)** [RU/RU]; ул. Центральная, д. 18, кв. 16, Троицк, Московская обл., 142092, Troitsk (RU). **ОГУРЦОВ Александр Владиславович (OGURTSOV, Aleksandr Vladislavovich)** [RU/RU]; ул. Островитянова, д. 45, корп. 2, кв. 81 , Москва, 109651,

[продолжение на следующей странице]

(54) **Title:** AUTOMATED STRONTIUM-RUBIDIUM INFUSION SYSTEM

(54) **Название изобретения:** АВТОМАТИЗИРОВАННАЯ СТРОНЦИЙ - РУБИДИЕВАЯ ИНФУЗИОННАЯ СИСТЕМА



Фиг. 1

(57) **Abstract:** The invention relates to medical engineering. The inventive automated strontium-rubidium infusion system comprises a container with eluent, a strontium-rubidium generator with a filter and a pressure sensor and an eluate infusion unit, which are connected by means of a transporting system provided with pipes and two three-way valves, radioactivity measuring means and a control and operating unit. An eluent container is connected to a syringe pump via the first valve, the second three-way valve is connected to the eluate infusion unit and a waste receptacle via the second filter. First and second air bubbles detectors are connected to the control and operating unit. The second three-way valve is connected to the first three-way valve and to the input of the strontium-rubidium generator. The generator output is connected to the fourth valve which is connected to the third valve. The first air bubbles detector is placed between the eluent container and the first valve and the second air bubbles detector is placed between the fourth and second valves.

[продолжение на следующей странице]

WO 2008/140351 A1

Moscow (RU). **КОСТЮЧЕНКО Валерий Иванович (KOSTUCHENKO, Valery Ivanovich)** [RU/RU]; ул. Маршала Рыбалко, д. 12, корп. 2, кв. 9, Москва, 123098, Moscow (RU).

(74) **Агент: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "ПАТЕНТ-ГАРАНТ" (OBSCHESTVO S OGRANICHENNOY OTVET-STVENNOSTIU "PATENT-GARANT")**; Шлюзовая набережная, д. 6, стр. 4-5, Москва, 115114, Moscow (RU).

(81) **Указанные государства** *(если не указано иначе, для каждого вида национальной охраны)*: AE, AG, AL, AM, AO, 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, 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) **Указанные государства** *(если не указано иначе, для каждого вида региональной охраны)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), евразийский (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), европейский патент (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, 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).

Декларация в соответствии с правилом 4.17:
— *об авторстве изобретения (правило 4.17 (iv))*

Опубликована:
— *с отчётом о международном поиске*

(57) Реферат: Изобретение относится к медицинской технике. Автоматизированная стронций - рубидиевая инфузионная система содержит емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления, средство для инфузии элюата, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления. Емкость с элюентом через первый клапан соединена со шприцевым насосом, второй трехходовой клапан соединен через второй фильтр со средством для инфузии элюата и со сборником отходов. Первый и второй детекторы воздушных пузырьков подключены к блоку контроля и управления. Второй трехходовой клапан связан с первым трехходовым клапаном и входом стронций-рубидиевого генератора. Выход генератора подключен к четвертому клапану, соединенному с третьим клапаном. Первый детектор воздушных пузырьков установлен между емкостью с элюентом и первым клапаном, а второй детектор - между четвертым и вторым клапанами.

Автоматизированная стронций – рубидиевая инфузионная система

Изобретение относится к медицинской технике, в частности к средствам автоматизации процесса производства диагностического раствора от радионуклидного стронций-рубидиевого генератора и дистанционного проведения контролируемой инфузии, с автоматическим контролем основных характеристик процесса, таких как величина вводимой активности, величина окклюзии, наличие воздушных пузырей, а также вес и активность раствора в контейнере с отходами.

Одним из наиболее перспективных направлений в ядерной диагностике является позитронно-эмиссионная томография (ПЭТ). Для работы в ПЭТ-центрах используют такие коротко и ультра-короткоживущие изотопы как – C-11, O-15, N-13, F-18. Это обязывает иметь на месте проведения диагностики циклотроны для наработки таких изотопов. Возможности ПЭТ-диагностики могут быть существенно расширены при использовании генераторных систем, время жизни материнского радионуклида которых значительно превышает время жизни нарабатываемых на циклотронах ПЭТ-центров радионуклидов. Наиболее перспективными среди изотопных генераторов для ПЭТ стоят генераторные системы ^{82}Sr ($t_{1/2}$=25,6 дней) → ^{82}Rb ($t_{1/2}$=75 сек) и ^{68}Ge ($t_{1/2}$=271 дней) → ^{68}Ga ($t_{1/2}$=68,3 мин).

Поэтому в применении к генераторным изотопам можно говорить о снабжении ими любых клиник, обладающих ПЭТ-сканнерами, в рамках региона, государства или группы государств.

Наибольшее применение генераторные системы могут найти в смонтированных в автотрейлерах так называемых мобильных ПЭТ, вызываемых для обслуживания клиник, не имеющих не только собственных циклотронов, но и собственных ПЭТ-сканнеров. При отсутствии «привязки» такого мобильного ПЭТ-сканнера к изотопной базе существенно расширяется радиус обслуживаемой им территории.

Известна стронций-рубидиевая инфузионая система производства диагностического раствора от радионуклидного стронций-рубидиевого генератора и проведения контролируемой инфузии (US 4562829, 1986), включающая емкость с элюентом, соединенную соответствующими трубопроводами системы транспортировки через первый трехходовой клапан с шприцевым насосом, стронций-рубидиевый генератор с первыми фильтром и датчиком давления на входе, второй трехходовой клапан, первое отверстие которого подключено через второй фильтр к средству для инфузии элюата пациенту, а второе – к средству для сбора и хранения излишков элюата, средства для измерения радиоактивности и система контроля и управления. Известная система не является оптимальной по степени защиты от радиоактивного излучения и по сроку службы генераторной колонки.

Предлагаемое изобретение направлено на устранение перечисленных недостатков. Достигаемый при ее использовании технический результат заключается в повышении эффективности проведения диагностической процедуры за счет автоматизации процедуры инфузии, снижении доз нежелательного радиоактивного облучения пациента и обслуживающего персонала, увеличении сроков эксплуатации генераторной колонки.

Сущность предлагаемого изобретения заключается в том, что автоматизированная стронций – рубидиевая инфузионная система, содержит емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления на входе, средство для инфузии элюата пациенту, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления. Причем емкость с элюентом через первое и второе отверстия первого трехходового клапана соединена с шприцевым насосом, первое отверстие второго трехходового клапана подключено трубопроводами через второй фильтр к средству для инфузии элюата пациенту, а второе отверстие – к сборнику отходов. В систему

дополнительно введены третий и четвертый трехходовые клапаны, первый и второй детекторы воздушных пузырьков, подключенные к блоку контроля и управления, связанного с компьютером, при этом третий трехходовой клапан связан первым и вторым отверстиями через трубопроводы с третьим отверстием первого трехходового клапана и входом стронций – рубидиевого генератора, соответственно. Выход генератора подключен к первому отверстию четвертого трехходового клапана, причем третье отверстие третьего клапана и второе отверстие четвертого клапана связаны трубопроводом, первый детектор воздушных пузырьков установлен на трубопроводе между емкостью с элюентом и первым отверстием первого клапана, а второй детектор установлен на трубопроводе между третьими отверстиями четвертого и второго клапанов.

Кроме того, средства для измерения радиоактивности включают первый и второй датчики активности. При этом первый датчик активности размещен на трубопроводе между третьими отверстиями четвертого и второго клапанов и выполнен в виде бета-детектора.

Радиационная защита средства для сбора и хранения излишков элюата может быть выполнена в виде защитного бокса, включающего средство контроля веса отходов в виде датчика усилия, а в отверстии защитного бокса установлен второй датчик активности для определения уровня радиоактивности отходов в виде гамма-детектор.

Колонка стронций – рубидиевого генератора имеет радиационную защиту, включающую, предпочтительно, внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

Система устанавливается в закрытом перемещаемом корпусе. Кроме того, корпус снабжен сдвигающейся столешницей.

Сущность изобретения поясняется следующими чертежами:

Фиг. 1 – схема инфузионной системы;

фиг. 2 – представлен общий вид генераторной установки сбоку;

фиг. 3 – общий вид генераторной установки сверху.

Ниже перечислены условные обозначения, используемые на черетже:

1 – емкость с элюентом

2, 3, 4, 5 – трехходовые клапаны

6, 7 – датчики активности

8, 9 – датчики давления

10 – шприцевой насос

11 – стронций-рубидиевый генератор

12 – блок контроля и управления

13 – датчик веса

14 – удаленный компьютер

15, 16 – фильтры

17, 18 – детекторы воздушных пузырьков

19 – средство для инфузии элюата пациенту (игла)

20 – сборник отходов элюента и элюата

21 – перемещаемый корпус

22 – штатив

23 – защитный контейнер стронций – рубидиевого генератора

24 – защитный контейнер для бета – детектора

25 – источник питания

26 – защитный бокс емкости для отходов

27 – сдвигающаяся столешница.

Автоматизированная стронций – рубидиевая инфузионная система включает в себя средства для генерации рубидия-82 в растворе, который может быть введен пациенту, а именно стронций-рубидиевый генератор 11 (фиг.1), обычного типа в транспортном контейнере. Этот контейнер помещается в защитный внешний основной контейнер 23 и совместно с последним осуществляет функцию основной радиационной защиты. Система в сборе может устанавливаться в перемещаемом корпусе 21 (фиг.

2), закрытым декоративными панелями (не показано). На столешнице установлен штатив 22 с укрепленном на нем емкостью с элюентом 1. Кроме того, здесь установлен шприцевой насос 10 и компьютер 14. На верхней полке перемещаемого корпуса 21 установлены:

- основной защитный контейнер 23, внутрь которого помещен стандартный транспортный контейнер со стронций-рубидиевым генератором 11;
- защитный бокс 24 с размещенным внутри него детектором бета-активности, измеряющим активность раствора, прошедшего через стронций-рубидиевый генератор;
- источник питания 25.

На нижней полке размещен защитный бокс 26, внутри которого располагается сборник отходов элюента и элюата.

На фиг. 3 верхняя крышка контейнера 23 откинута, что позволяет увидеть полость, внутрь которой помещается транспортный контейнер со стронций-рубидиевым генератором 11. Для того, чтобы облегчить доступ к основному защитному контейнеру 23 во время перезарядки генераторной системы (извлекается транспортный контейнер с отработавшей колонкой стронций-рубидиевого генератора 11 и устанавливается транспортный контейнер со свежей генераторной колонкой) – часть столешницы выполнена в виде сдвигающейся столешницы 27, обеспечивающей удобство при работе.

Кроме того, система включает в себя средства для проведения инфузии, а именно (фиг. 1): шприцевой дистанционно управляемый инфузионный насос 10, шток которого приводится в действие, например, шаговым двигателем; средства для автоматизированного заполнения шприцевого насоса элюентом 1 (0.9 % раствором NaCl); систему транспортировки элюента и элюата до пациента или сборника отходов элюента и элюата, снабженную многоходовыми (трехходовыми) клапанами 2 – 5 (фиг.1), осуществляющими ветвление системы транспортировки в

соответствии с программой проведения работ; антибактериальные средства защиты, а именно антибактериальные фильтры 15 и 16 на входе и выходе системы транспортировки; средства измерения активности элюата для текущего контроля и дозирования при инфузии в пациента 6 и 7; средства измерения давления 8 и 9 в транспортной системе, в том числе и для измерения окклюзии; сборник отходов элюента и элюата 20, в том числе с измерением величины активности и веса раствора в емкости для отходов 13 и осуществления защиты от радиоактивности; средства автоматизированного контроля всего процесса элюации и его составных частей 12, осуществляемого с помощью бортового или удаленного компьютеров 14.

В описываемой системе емкость с элюентом 1 (соляным раствором) соединена пластиковым фитингом с трубопроводом (например, трубочкой для инфузий, которая имеет внешний диаметр 2.5 мм при внутреннем диаметре 1.5 мм). Отрезки таких трубочек (трубопроводы) далее используются для построения всей транспортной системы для инфузии. Другой конец трубопровода подсоединен через детектор воздушных пузырьков 17, который, в случае прохождения воздушного пузырька, вырабатывает сигнал на блок контроля и управления 12, который вырабатывает управляющий сигнал на клапаны 2, 3, 4 и 5, в результате чего, раствор элюента, содержащий воздушный пузырек, удаляется в сборник отходов элюента и элюата 20, не проходя колонку стронций-рубидиевого генератора 11.

Клапан 2 осуществляет перевод инфузионной системы в один из двух возможных режимов работы: (1) заполнение шприца при работе шприцевого насоса 10 на всасывание соляного раствора из емкости с элюентом 1 (через первое и второе отверстия клапана) или (2) инфузию, т.е. подачу соляного раствора из заполненного шприца шприцевого насоса 10 в инфузионную систему (через первое и третье отверстия клапана).

Трехходовой клапан 2 далее соединен отрезком соединительной трубки с первым отверстием третьего трехходового клапана 4, второе отверстие которого соединено через первый фильтр 15 с входом колонки стронций-рубидиевого генератора 11. Контроль давления на входе в колонку стронций-рубидиевого генератора 11 осуществляется первым датчиком давления 8.

Третьим отверстием клапан 4, через отрезок соединительной трубки, подсоединен ко второму отверстию четвертого трехходового клапана 5. Этот клапан также имеет соединения с выходной трубкой колонки стронций-рубидиевого генератора 11 (первое отверстие) и продолжением инфузионной системы на третьем отверстии.

В режиме работы шприцевого насоса «инфузия» пара трехходовых клапанов 4, 5, работая синхронно, позволяет либо прокачивать соляной раствор из шприца 10 через колонку стронций-рубидиевого генератора дальше в инфузионную систему уже в виде элюата, т.е. раствора, обогащенного Rb-82, либо прокачивать соляной раствор в инфузионную систему, минуя стронций-рубидиевый генератор 11. Этот режим работы используется тогда, когда необходимое количество активности Rb-82 наработано и оно должно быть доставлено пациенту 19, а инфузионная система должна быть заполнена неактивным соляным раствором на конец инфузии в пациента. При использовании режима прокачки соляного раствора практически вся инфузионная система, за исключением соединительного трубопровода от выхода из стронций-рубидиевого генератора до четвертого трехходового клапана, будет заполнена нерадиоактивным соляным раствором и не будет являться источником дополнительной нежелательной радиоактивности на пациента и обслуживающий персонал; кроме того, объем соляного раствора, необходимый для додавливания наработанного элюата в пациента не будет проходить через колонку стронций-рубидиевого генератора и истощать ее, т.к. известно, что потенция генератора зависит не только от времени его

эксплуатации, но также и от объема пропущенного через него соляного раствора.

На трубопроводе от третьего отверстия четвертого трехходового клапана 5 до третьего отверстия второго трехходового клапана 3 установлены первый детектор радиоактивности 6 (бета-детектор) и второй детектор воздушных пузырьков 18, аналогичный первому детектору пузырьков 17. При обнаружении воздушного пузырька, детектор 18 вырабатывает сигнал на блок контроля и управления, который вырабатывает управляющий сигнал на клапан второго трехходового клапана 3. В результате, элюат содержащий воздушный пузырек, удаляется в сборник отходов элюента и элюата 20. Если воздушный пузырек не обнаружен, элюат направляется через первое отверстие трехходового клапана 3 и второй фильтр 16 в пациента, т.е. на иглу 19

Детектор радиоактивности 6 работает в режиме реального времени и измеряет активность Rb-82 в месте расположения детектора 18.

Контроль за наполнением сборника для отходов жидкостью осуществляется с помощью датчика усилий (не показан). Для измерения радиоактивности, содержащейся в сборнике для отходов элюента и элюата используется второй датчик радиоактивности 7 (гамма-детектор). Радиационная защита средства для сбора и хранения излишков элюата выполнена в виде защитного бокса, в состав которого включен датчик усилия, а в отверстии защитного бокса установлен второй датчик активности.

При осуществлении инфузии в пациента второй трехходовой клапан 3 переключен на пропускание элюата на трубопровод соединенный с иглой 19 через миллипоровский фильтр 16. На этом отрезке установлен второй датчик давления 9, позволяющий измерять давление окклюзии при введении раствора, содержащего Rb-82, в пациента.

Процесс работы стронций-рубидиевой инфузионной системы происходит под управлением управляющей компьютерной программы, в которой прописывается состояние каждого из устройств, входящих в инфузионную систему, на момент начала и окончания выполнения шага, также прописываются действия этих устройств и условия их функционирования в нормальных условиях и в случае возникновения аварийной ситуации.

Для исключения переполнения в сборнике отходов элюента и элюата 20 радиоактивной жидкости, осуществляется дистанционный контроль за предельным значением ее уровня с помощью датчика усилия, при этом контролируется общий вес тары и жидкости, осуществляется текущий контроль за значением веса (объема) жидкости и за предельным его значением. Кроме того, фиксируя вес пустой тары для сбора отходов, система регламентного опроса блока контроля и управления установки получает информацию о том, что тара установлена в контейнере. Максимальный объём отходов в таре составляет 250 мл.

Блок контроля и управления подключен к удаленному компьютеру, на дисплее которого отображается графическая мнемосхема генераторного устройства, обеспечивающая наблюдение контролируемых параметров в автоматическом режиме и оперативного управления отдельными элементами (электромагнитными трехходовыми клапанами 2 - 5, насосом 10) в ручном режиме. Схема позволяет наблюдать за текущим состоянием всех элементов описываемой системы инфузии (клапанов 2-5, детекторов воздушных пузырьков 17, 18) и за работой шприцевого насоса 10. Также она позволяет получать информацию о параметрах давления в магистралях от датчиков давления 8, 9, активности элюата на выходе из генераторной колонки 11 и суммарной активности, веса емкости сборника отходов элюента и элюата 20, активности в емкости с отходами от детекторов 6,7.

Блок контроля и управления 12 системы связан с управляющими элементами генераторной установки – электромагнитными трехходовыми

клапанами 2, 3, 4, 5 и насосом 10, а также включает элементы для сбора и обработки сигналов с датчиков 6, 7 (датчики радиоактивности), 8, 9 (датчики давления), 17, 18 (детекторы воздушных пузырьков). Блок управления 12 связан с панельным персональным компьютером (PPC) или любым другим удаленным компьютером (14) по каналу Ethernet. Он получает команды от PPC или удаленного компьютера на выполнение отдельных шагов программы работы генераторной установки и информирует их о текущем состоянии управляемых им элементов и состоянии датчиков системы.

Описываемая система повышает безопасность эксплуатации, так как автоматизация процесса инфузии позволила значительно сократить радиоактивное облучение за счет введения в систему дополнительных клапанов, обеспечивающих ветвление трубопроводов. В результате, появилась возможность додавливания наработанного элюата в пациента элюентом, минуя стронций – рубидиевый генератор. При этом трубопровод прокачивается нерадиоактивным элюентом и не происходит дополнительного истощения стронций – рубидиевого генератора, что увеличивает срок его эксплуатации. Кроме того, исключается риск содержания воздушных пузырьков в элюанте, доставляемого пациенту, за счет введения в систему детекторов воздушных пузырьков, при обнаружении которых, элюент сразу направляется к сборнику отходов элюента и элюата через ответвления трубопровода, не истощая стронций – рубидиевый генератор.

Формула изобретения

1. Автоматизированная стронций – рубидиевая инфузионная система, содержащая емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления на входе, средство для инфузии элюата пациенту, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления, причем емкость с элюентом через первое и второе отверстия первого трехходового клапана соединена с шприцевым насосом, первое отверстие второго трехходового клапана подключено трубопроводами через второй фильтр к средству для инфузии элюата пациенту, а второе отверстие – к сборнику отходов, отличающаяся тем, что дополнительно введены третий и четвертый трехходовые клапаны, первый и второй детекторы воздушных пузырьков, подключенные к блоку контроля и управления, связанного с компьютером, при этом третий трехходовой клапан связан первым и вторым отверстиями через трубопроводы с третьим отверстием первого трехходового клапана и входом стронций – рубидиевого генератора, соответственно, выход генератора подключен к первому отверстию четвертого трехходового клапана, причем третье отверстие третьего клапана и второе отверстие четвертого клапана связаны трубопроводом, первый детектор воздушных пузырьков установлен на трубопроводе между емкостью с элюентом и первым отверстием первого клапана, а второй детектор установлен на трубопроводе между третьими отверстиями четвертого и второго клапанов.

2. Система по п.1, отличающаяся тем, что средства для измерения радиоактивности включают первый и второй датчики активности.

3. Система по п.2, отличающаяся тем, что первый датчик активности размещен на трубопроводе между третьими отверстиями четвертого и второго клапанов и выполнен в виде бета-детектора.

4. Система по п.1, отличающаяся тем, что радиационная защита сборника отходов выполнена в виде защитного бокса, включающего

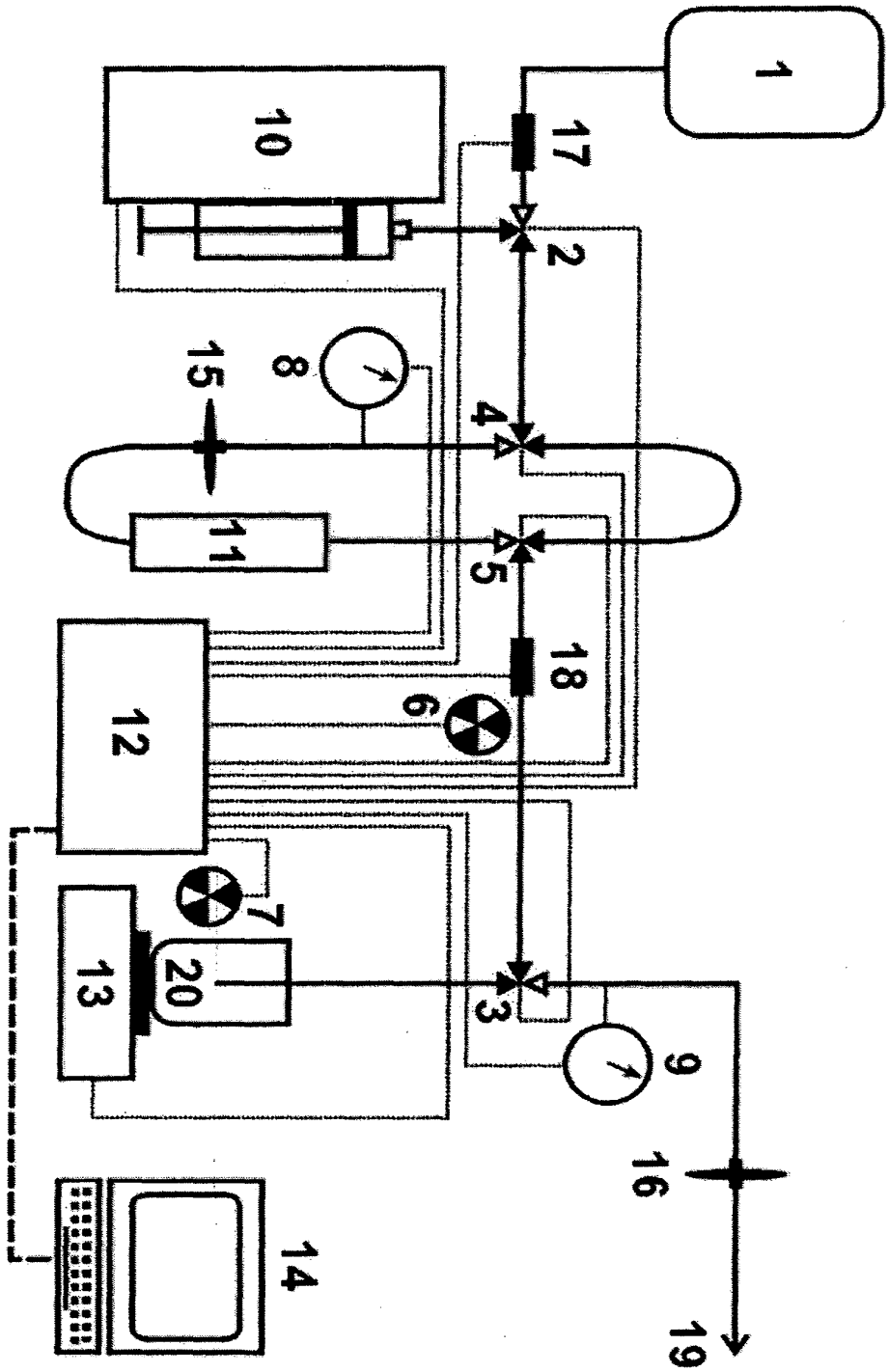
средство контроля веса отходов, выполненного в виде датчика усилия, а в отверстии

защитного бокса установлен второй датчик активности для определения радиоактивности отходов, в виде гамма-детектора.

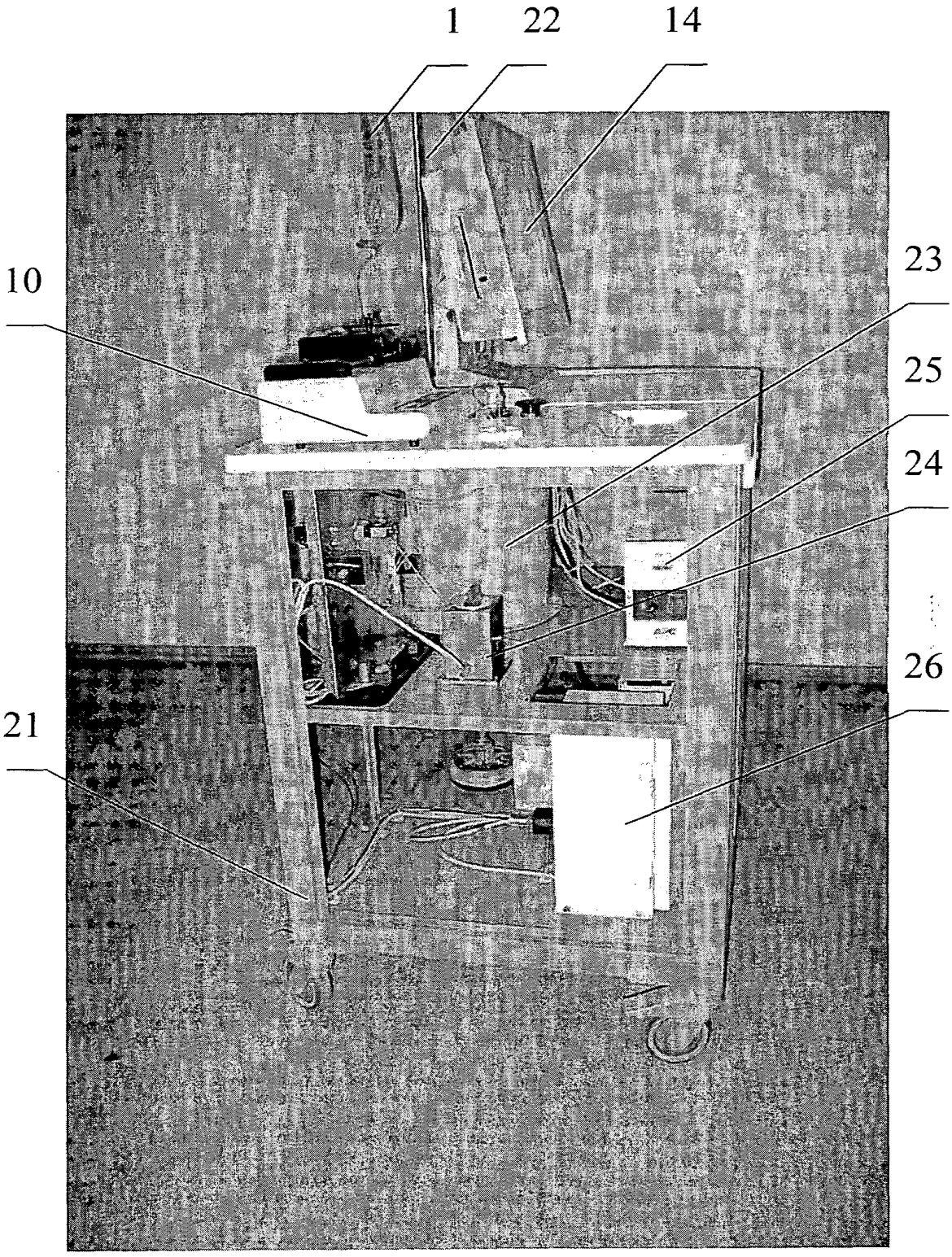
5. Система по п.1, отличающаяся тем, что стронций – рубидиевый генератор имеет радиационную защиту, включающую внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

6. Система по п.1, отличающаяся тем, что она установлена в закрытом перемещаемом корпусе.

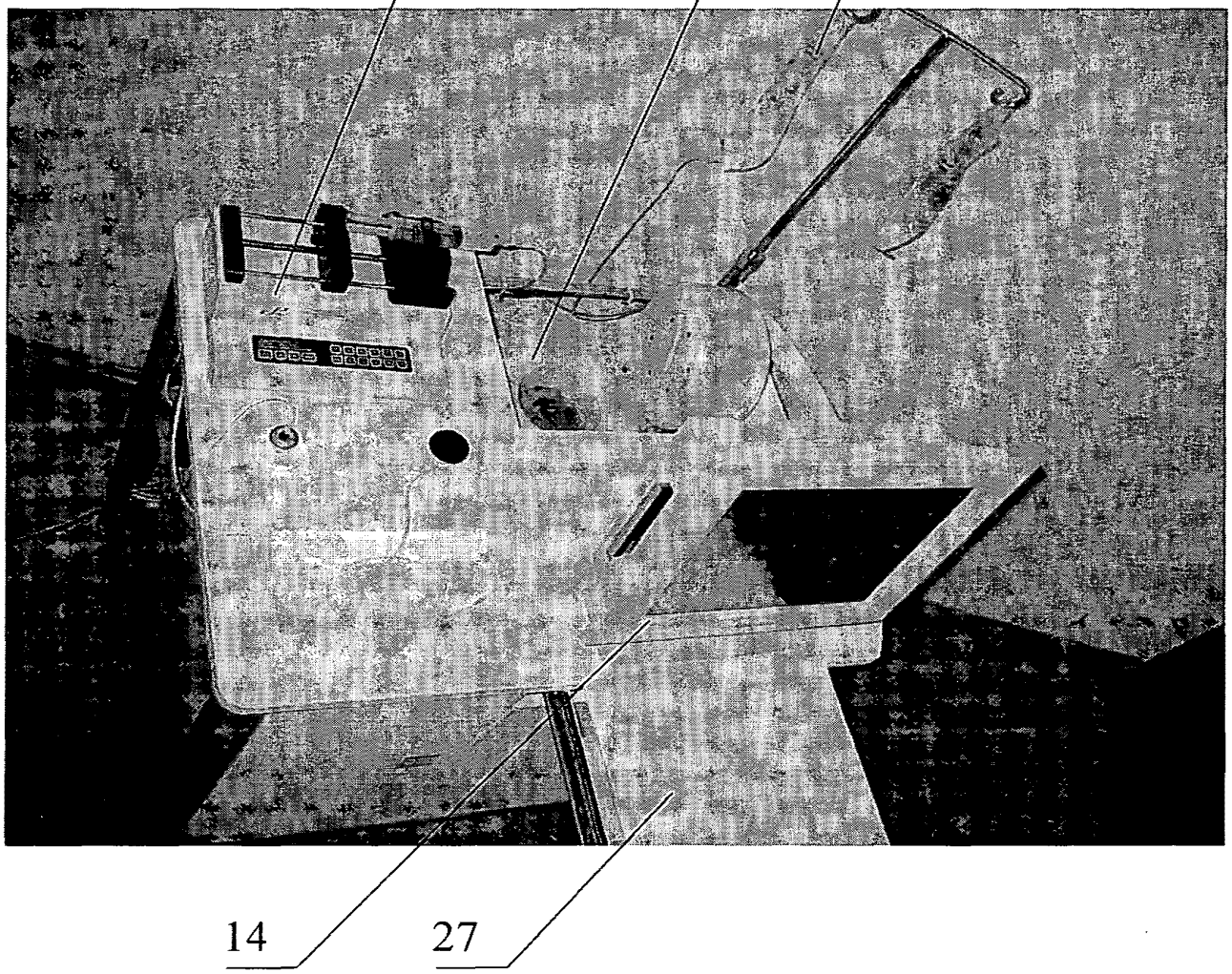
7. Система по п.6, отличающаяся тем, что корпус снабжен сдвигающейся столешницей.



Фиг. 1



Фиг. 2



Фиг. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/RU2008/000211

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/168 (2006.01)
A61M 36/06 (2006.01)
A61B 6/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 36/00-36/06, 5/00-5/155, AGIB 6/00-6/10, A61M 5/168

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
http://www. uspto. gov; http://depatisnet.dpma.de; http://ep.espacenel.com; http://www.fips.ru; http://www.eapatis.com

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4562829 A (E.R. SQUIBB & SONS, INC.), 07.01.1986, the abstract, figure 1	1-7
A	EP 0310148 A (E.R. SQUIBB & SONS, INC), 05.04.1988, the claims, figure	1-7
A	RU 2219959 C2 (FEDERALNOE GOSUDARSTVENNOE UNITARNOE PREDPRIYATIE NAUCHNO-ISSLEDOVATELSKY INSTITUT ELEKTROMEKHANIKI) 27.12.2003, the claims, figure 1	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 July 2008	04 September 2008
Name and mailing address of the ISA/ RU	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (April 2005)

ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка № PCT/RU 2008/000211

А. КЛАССИФИКАЦИЯ ПРЕДМЕТА ИЗОБРЕТЕНИЯ: ***A61M 5/168*** *(2006.01)*
A61M 36/06 *(2006.01)*
Согласно Международной патентной классификации МПК ***A61B 6/00*** *(2006.01)*

В. ОБЛАСТИ ПОИСКА:

Проверенный минимум документации (система классификации с индексами классификации):

Другая проверенная документация в той мере, в какой она включена в поисковые подборки:

A61M 36/00-36/06, 5/00-5/155, A61B 6/00-6/10, A61M 5/168

Электронная база данных, использовавшаяся при поиске (название базы и, если, возможно, используемые поисковые термины): http://www. uspto. gov; http://depatisnet.dpma.de; http://ep.espacenet.com; http://www.fips.ru; http://www.eapatis.com

С. ДОКУМЕНТЫ, СЧИТАЮЩИЕСЯ РЕЛЕВАНТНЫМИ:

Категория*	Цитируемые документы с указанием, где это возможно, релевантных частей	Относится к пункту №
A	US 4562829 A (E.R. SQUIBB & SONS, INC.) 07.01.1986, реферат, фиг. 1	1-7
A	EP 0310148 A (E.R. SQUIBB & SONS, INC) 05.04.1989, формула, фиг.	1-7
A	RU 2219959 C2 (ФЕДЕРАЛЬНОЕ ГОСУДАРСТВЕННОЕ УНИТАРНОЕ ПРЕДПРИЯТИЕ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ ИНСТИТУТ ЭЛЕКТРОМЕХАНИКИ) 27.12.2003, формула, фиг. 1	1-7

☐ последующие документы указаны в продолжении графы С. ☐ данные о патентах-аналогах указаны в приложении

* Особые категории ссылочных документов:

A документ, определяющий общий уровень техники и не считающийся особо релевантным

E более ранняя заявка или патент, но опубликованная на дату международной подачи или после нее

L документ, подвергающий сомнению притязание (я) на приоритет, или который приводится с целью установления даты публикации другого ссылочного документа, а также в других целях (как указано)

O документ, относящийся к устному раскрытию, использованию, экспонированию и т.д.

P документ, опубликованный до даты международной подачи, но после даты испрашиваемого приоритета

T более поздний документ, опубликованный после даты международной подачи или приоритета, но приведенный для понимания принципа или теории, на которых основывается изобретение

X документ, имеющий наиболее близкое отношение к предмету поиска; заявленное изобретение не обладает новизной или изобретательским уровнем, в сравнении с документом, взятым в отдельности

Y документ, имеющий наиболее близкое отношение к предмету поиска; заявленное изобретение не обладает изобретательским уровнем, когда документ взят в сочетании с одним или несколькими документами той же категории, такая комбинация документов очевидна для специалиста

& документ, являющийся патентом-аналогом

Дата действительного завершения международного поиска: 24 июля 2008 (24.07.2008)	Дата отправки настоящего отчета о международном поиске: 04 сентября 2008 (04.09.2008)
Наименование и адрес ISA/RU ФГУ ФИПС, РФ,123995, Москва, Г-59, ГСП-5, Бережковская наб., 30,1 Факс:(499) 243-3337	Уполномоченное лицо: Л. Черепанова Телефон № (499) 240-25-91

Форма PCT/ISA/210 (второй лист)(июль 2008)

Electronic Acknowledgement Receipt

EFS ID:	4634336
Application Number:	12137364
International Application Number:	
Confirmation Number:	7377
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Stephen E. Hidem
Customer Number:	22859
Filer:	Elisabeth Lacy Belden
Filer Authorized By:	
Attorney Docket Number:	56782.1.7
Receipt Date:	20-JAN-2009
Filing Date:	11-JUN-2008
Time Stamp:	11:41:18
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) Filed (SB/08)	56782_1_7_IDS2.pdf	929999 ff608863cd80a3dd3a41a7768822678336383be2	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.

2	Foreign Reference	56782_1_WO08140351A1.pdf	2108847 898d2e8296aea121d5dbb5ba800d0676d167dda4	no	28

Warnings:

Information:

Total Files Size (in bytes):	3038846

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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/137,364	06/11/2008	2628	1780	56782.1.7	24	5

CONFIRMATION NO. 7377

UPDATED FILING RECEIPT

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

OC000000032992685

Date Mailed: 11/17/2008

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)

Stephen E. Hidem, Plymouth, MN;
Aaron M. Fontaine, Fridley, MN;
Janet L. Gelbach, New Albany, IN;
Patrick M. McDonald, Omaha, NE;
Kathryn M. Hunter, Knoxville, TN;

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

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 12/137,364**

Projected Publication Date: 12/17/2009

Non-Publication Request: No

Early Publication Request: No

Title

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

Preliminary Class

345

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

NOT GRANTED

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

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/137,364	06/11/2008	Stephen E. Hidem	56782.1.7

CONFIRMATION NO. 7377

POA ACCEPTANCE LETTER

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

OC000000032992659

Date Mailed: 11/17/2008

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/24/2008.

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.

/hnguyen/

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

22859
Customer Number

Patent
Case No.: 56782.1.7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Stephen E. Hidem		
Application No.:	12/137,364	Group Art Unit:	2628
Filed:	June 11, 2008	Examiner:	
Title:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		

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

RESPONSE TO NOTICE TO FILE MISSING PARTS
OF A NON-PROVISIONAL APPLICATION

In response to the Notice to File Missing Parts of Application - Filing Date Granted mailed June 24, 2008, submitted herewith is an executed Declaration and replacement sheets (23 sheets). Submitted herewith in the amount of $130 is the surcharge fee. The Commissioner is hereby authorized to grant any extensions of time, including those that may be due under 37 C.F.R. §1.136, and to charge any fees that may be required, including those under 37 C.F.R. §§ 1.16 and 1.17, during the entire pendency of this application to Deposit Account No. 06-1910.

Entry of this document should complete all of the filing formalities and fully satisfy all requirements of the Notice to File Missing Parts. Accordingly, examination and allowance of this application in due course are respectfully solicited.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1910.

Respectfully submitted,

October 24, 2008
Date

/Elisabeth Lacy Belden/
Elisabeth Lacy Belden
Registration No. 50,751

Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7000
Facsimile: (612) 492-7077

PTO/SB/96 (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Stephen E. Hidem et al.

Application No./Patent No.: 12/137,364 Filed/Issue Date: June 11, 2008

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

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

in 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 021699, Frame 0797, 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: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. 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.

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.

☑ 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.

/Elisabeth Lacy Belden/ October 24, 2008
Signature Date

Elisabeth Lacy Belden 612-492-7000
Printed or Typed Name Telephone Number

Patent Agent
Title

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.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☒ Practitioners associated with the Customer Number: 22859

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

The practitioners associated with customer number 022859 (Fredrikson & Byron, P.A.) are hereby granted authorization to sign the attached statement under 37 CFR §3.73(b) that evidences ownership by **Bracco Diagnostics, Inc.**

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☒ The address associated with the Customer Number: 22859

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

Bracco Diagnostics, Inc.
107 College Road East
Princeton, NJ 08540

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature			
Name	Michael R. von Ohlen	Date 5/9/08	
Title	Corporate Counsel	Telephone 609-514-2303	

Doc Code: OATH

PTO/SB/01 (05-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (f)) required)

Attorney Docket Number	56782.1.7
First Named Inventor	Stephen E. Hidem
COMPLETE IF KNOWN	
Application Number	12/137,364
Filing Date	June 11, 2008
Art Unit	2628
Examiner Name	

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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

(Title of the Invention)

the application of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 06/11/2008 as United States Application Number or PCT International Application Number 12/137,364 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, or other intellectual property office in which a foreign application claming priority to the above-identified application is filed to have access to the application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the application-as-filed with respect to: 1) the above-identified application, 2) any foreign application to which the above-identified application claims priority under 35 USC 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified US application, and 3) any U.S. application from which benefit is sought in the above-identified application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

PTO/SB/01 (05-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

PTO/SB/01 (05-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	☑ The address associated with Customer Number:	22859	OR ☐	Correspondence address below

Name		
Address		
City	State	ZIP
Country	Telephone	Email

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files*. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any]): Stephen E.	Family Name or Surname: Hidem
Inventor's Signature: S. E. Hidem	Date: 9/26/08
Residence: City: Plymouth	State: MN	Country: US	Citizenship: US
Mailing Address: 4710 Juneau Lane N.			
City: Plymouth	State: MN	Zip: ~~DS~~ 55446	Country: US

☑ Additional inventors or a legal representative are being named on the 2 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
Aaron M.	Fontaine
Inventor's Signature: Aaron M Fontaine	Date: 9/26/08
Residence: City: Fridley	State: MN	Country: US	Citizenship: US
Mailing Address: 5663 W. Bavarian Pass	
City: Fridley	State: MN	Zip: 55432	Country: US

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
Janet L.	Gelbach
Inventor's Signature: Janet L Gelbach	Date: Aug 27, 2008
Residence: City: New Albany	State: ~~NY~~ IN	Country: US	Citizenship: US
Mailing Address: 4204 Shetland Court	
City: New Albany	State: ~~NY~~ IN	Zip: 47150	Country: US

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
Patrick M.	McDonald
Inventor's Signature	Date
Residence: City: Omaha	State: NE	Country: US	Citizenship: US
Mailing Address: 15395 Nicholas Street	
City: Omaha	State: NE	Zip: 68154	Country: US

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Kathryn M.	Hunter		
Inventor's Signature			Date
Knoxville Residence: City	TN State	US Country	US Citizenship
1312 Judy Reagan Lane Mailing Address			
Knoxville City	TN State	37931 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

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.

Doc Code: OATH

PTO/SB/01 (05-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (f)) required)

Attorney Docket Number	56782.1.7
First Named Inventor	Stephen E. Hidem
COMPLETE IF KNOWN	
Application Number	12/137,364
Filing Date	June 11, 2008
Art Unit	2628
Examiner Name	

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

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

(Title of the Invention)

the application of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 06/11/2008 as United States Application Number or PCT International Application Number 12/137,364 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, or other intellectual property office in which a foreign application claming priority to the above-identified application is filed to have access to the application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the application-as-filed with respect to: 1) the above-identified application, 2) any foreign application to which the above-identified application claims priority under 35 USC 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified US application, and 3) any U.S. application from which benefit is sought in the above-identified application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

DECLARATION — Utility or Design Patent Application

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

PTO/SB/01 (05-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	☑ The address associated with Customer Number:	22859	OR ☐	Correspondence address below

Name		
Address		
City	State	ZIP
Country	Telephone	Email

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files*. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any]) Stephen E.	Family Name or Surname Hidem
Inventor's Signature	Date

Residence: City Plymouth	State MN	Country US	Citizenship US
Mailing Address 4710 Juneau Lane N.			
City Plymouth	State MN	Zip US	Country US

☑ Additional inventors or a legal representative are being named on the 2 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Aaron M.	Fontaine		
Inventor's Signature			Date
Fridley Residence: City	MN State	US Country	US Citizenship
5663 W. Bavarian Pass Mailing Address			
Fridley City	MN State	55432 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Janet L.	Gelbech		
Inventor's Signature			Date
New Albany Residence: City	NY State	US Country	US Citizenship
4204 Shetland Court Mailing Address			
New Albany City	NY State	47150 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Patrick M.	McDonald		
Inventor's Signature Patrick M. McDonald			Date 24-AUG-08
Omaha Residence: City	NE State	US Country	US Citizenship
15395 Nicholas Street Mailing Address			
Omaha City	NE State	68154 Zip	US Country

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Kathryn M.	Hunter		
Inventor's Signature: Kathryn Hunter			Date: Aug 25, 2005
Knoxville Residence: City	TN State	US Country	US Citizenship
1312 Judy Reagan Lane Mailing Address			
Knoxville City	TN State	37931 Zip	US Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))	Family Name or Surname		
Inventor's Signature			Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

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.

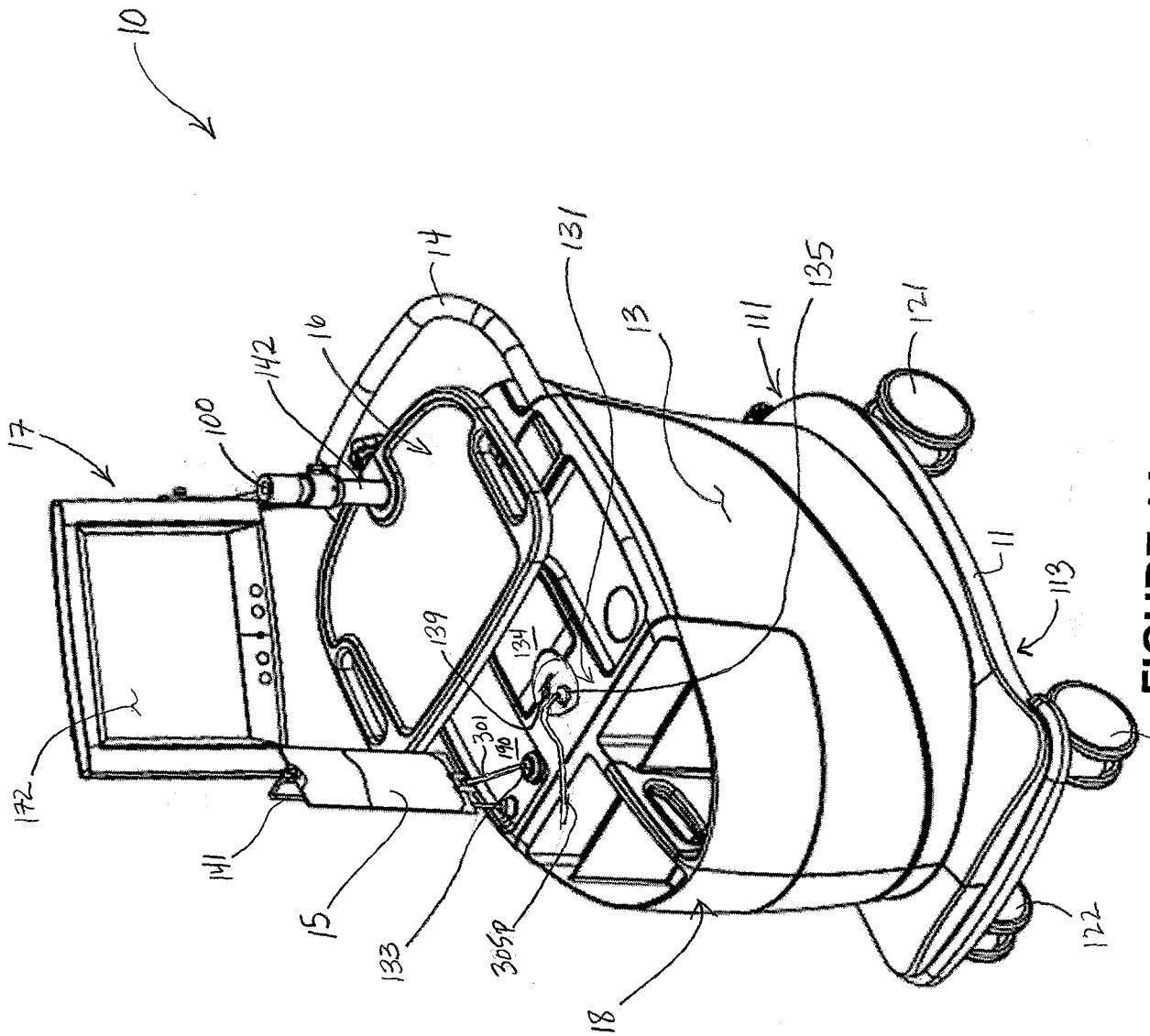

10
17
100
142
16
14
131
13
111
135
121
11
113
122
172
141
15
133
3059
18
139
134
301
190

FIGURE 1A

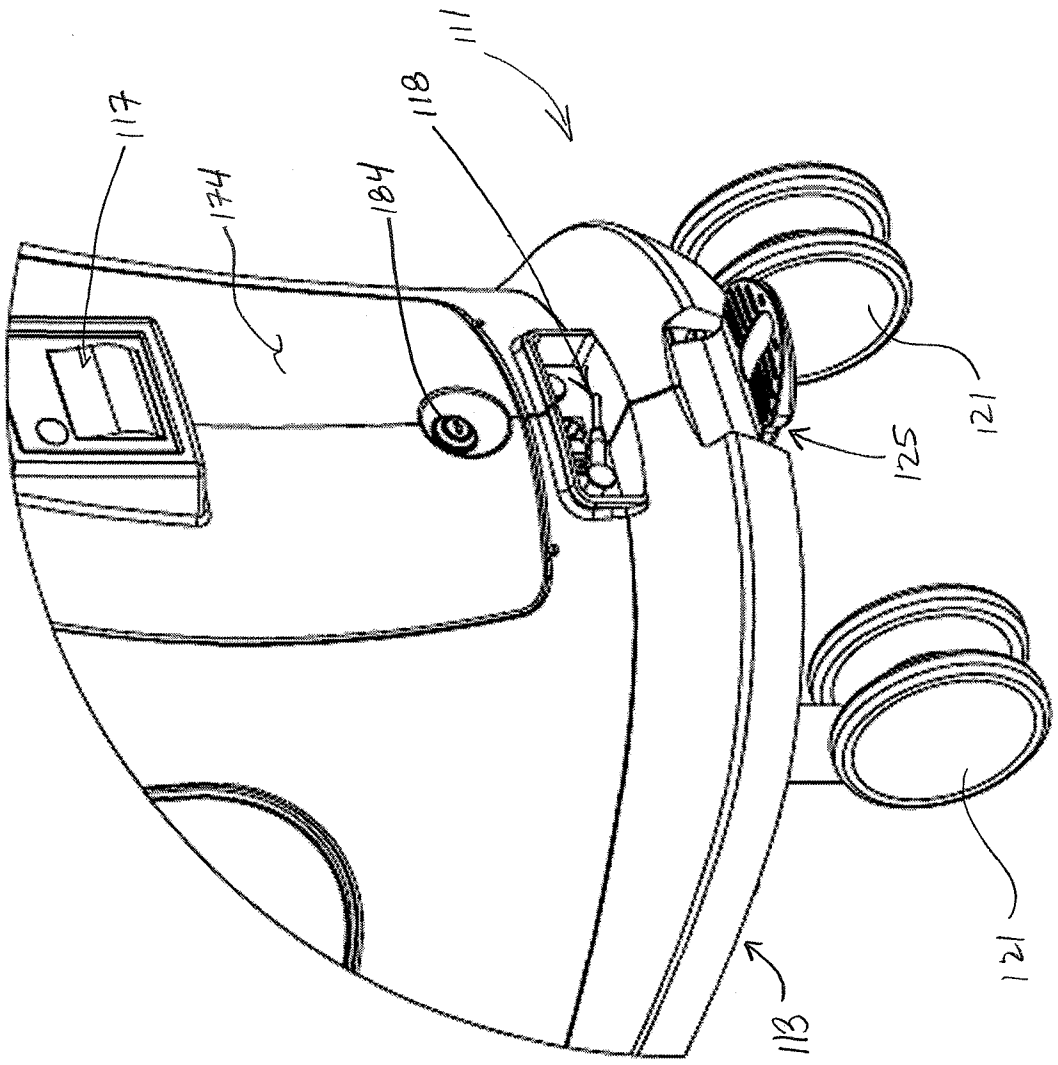


FIGURE 1B

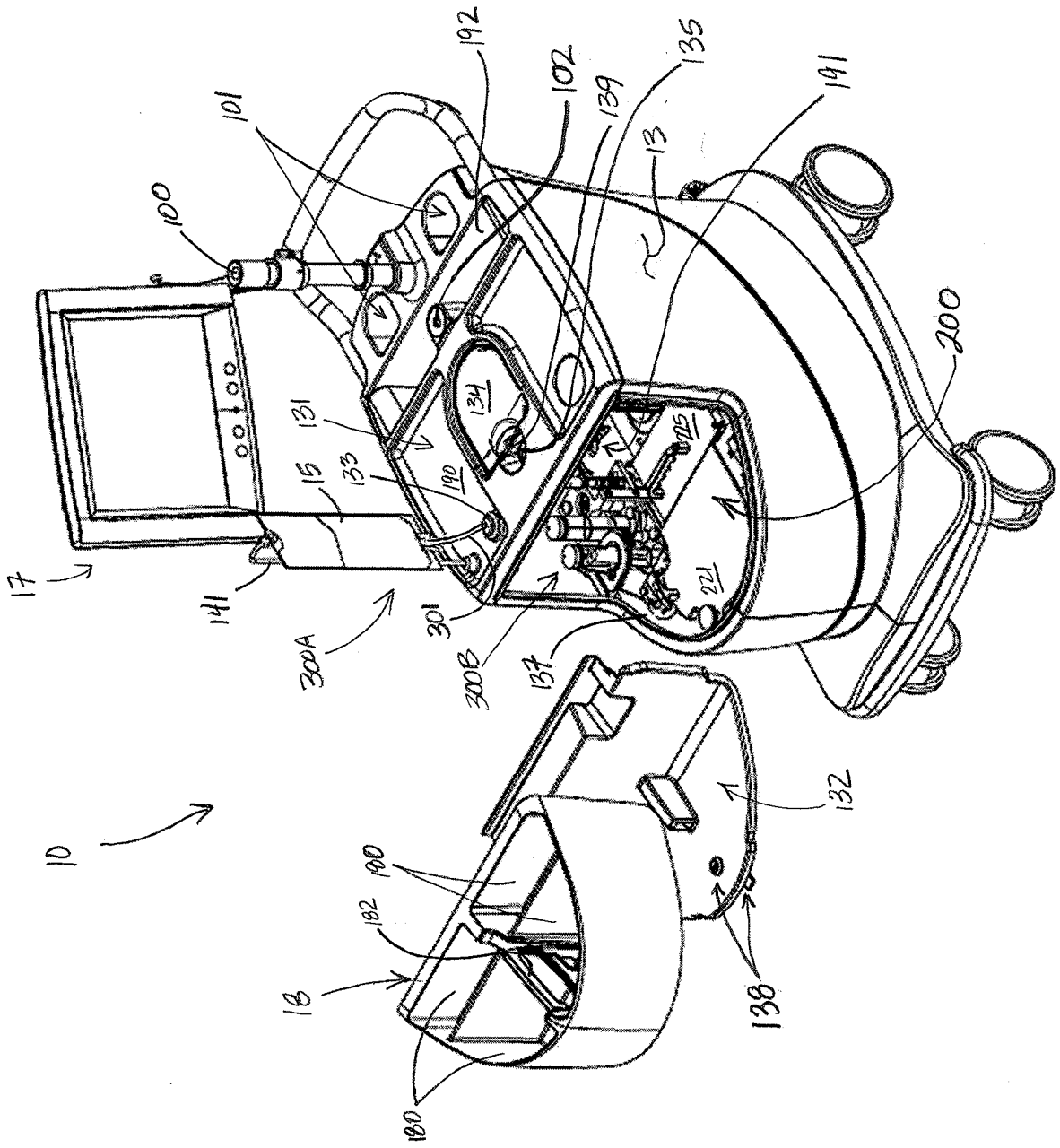

10
17
100
101
102
131
133
134
135
137
138
139
141
180
182
190
191
192
200
300A
300B
301
132
18
13
16

FIGURE 1C

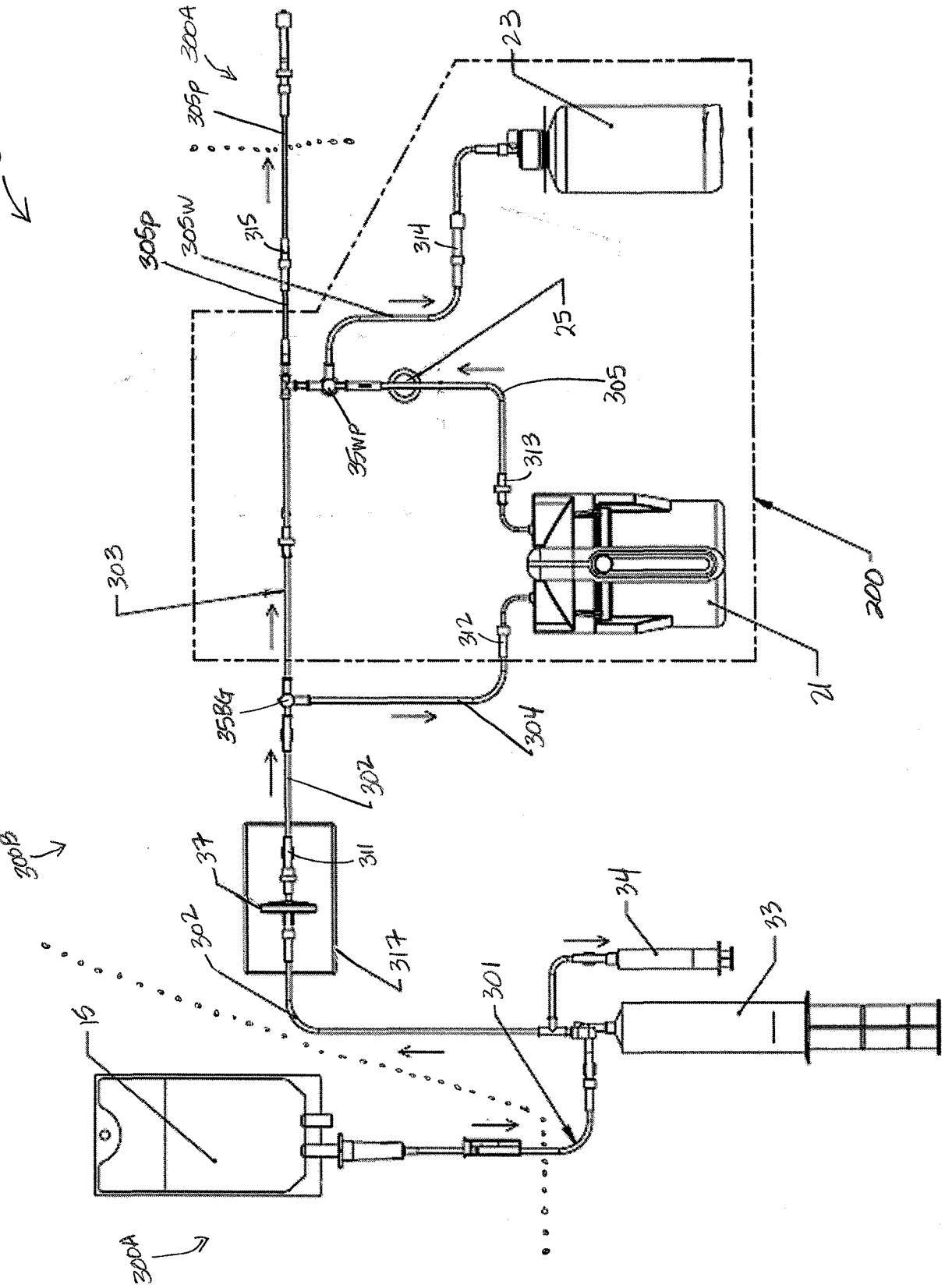

300
300A
300B
305P
305W
305P
315
314
23
25
305
35WP
313
303
312
35BG
304
302
311
37
317
34
33
301
15
21
200

FIGURE 1D

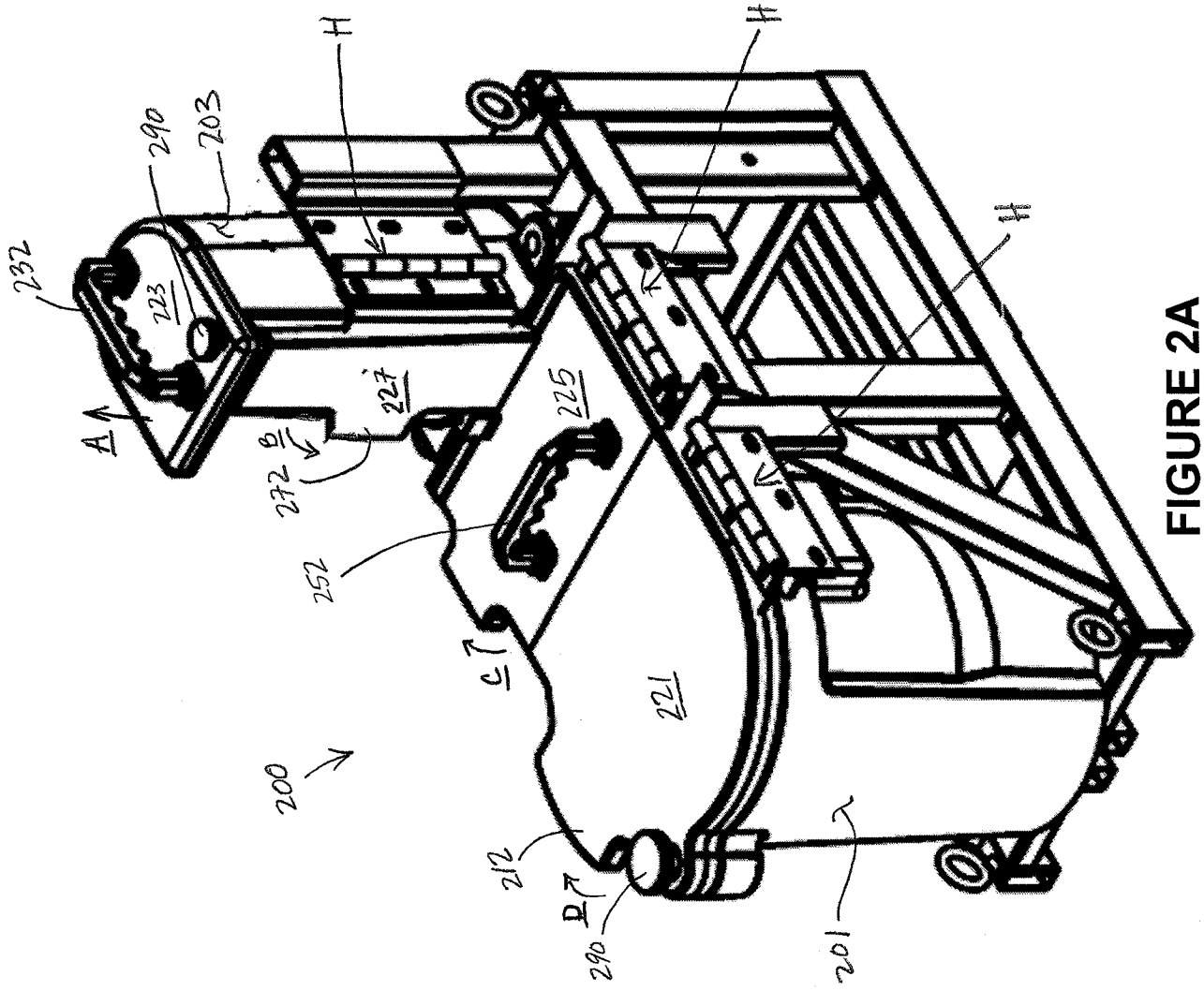


FIGURE 2A

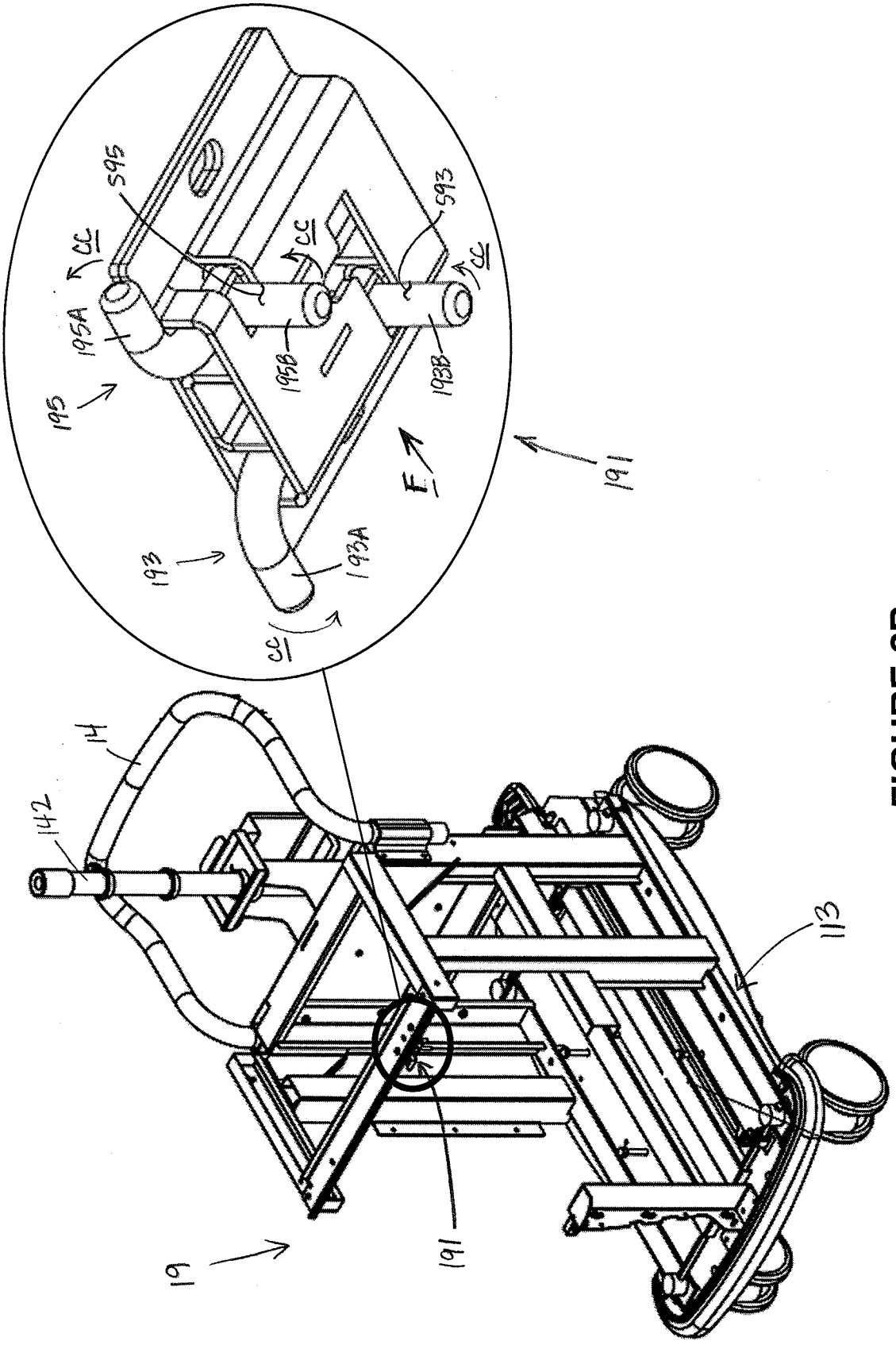


FIGURE 2B

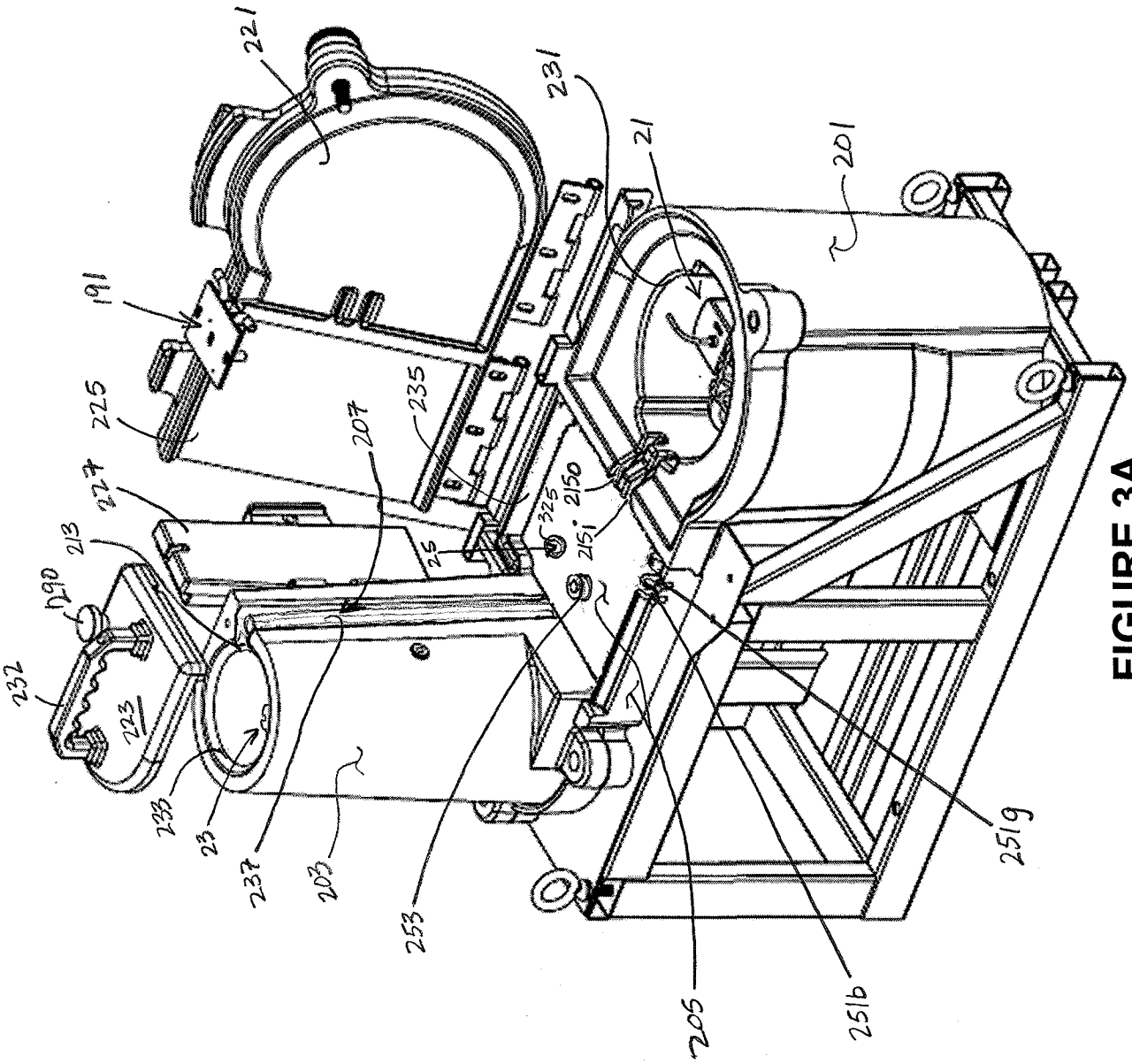

221
231
21
201
191
225
235
207
227
213
190
232
223
233
23
237
203
253
325
215i
2150
25
2519
2516
206

FIGURE 3A

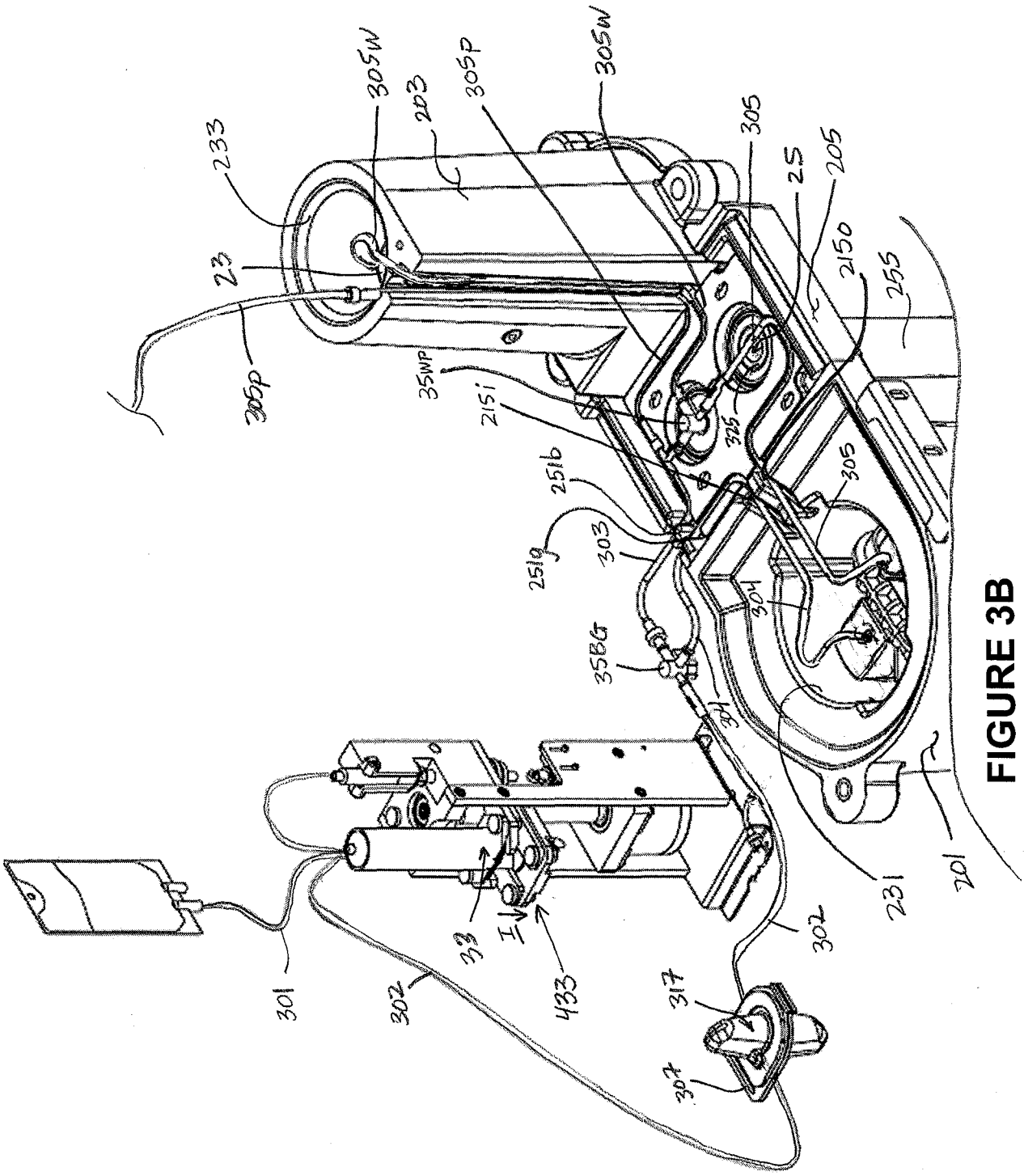

305W
203
305P
305W
233
305
25
205
23
2150
255
305P
35WP
2151
325
2516
306
2519
303
304
35BG
33
I
433
317
307
302
301
231
201

FIGURE 3B

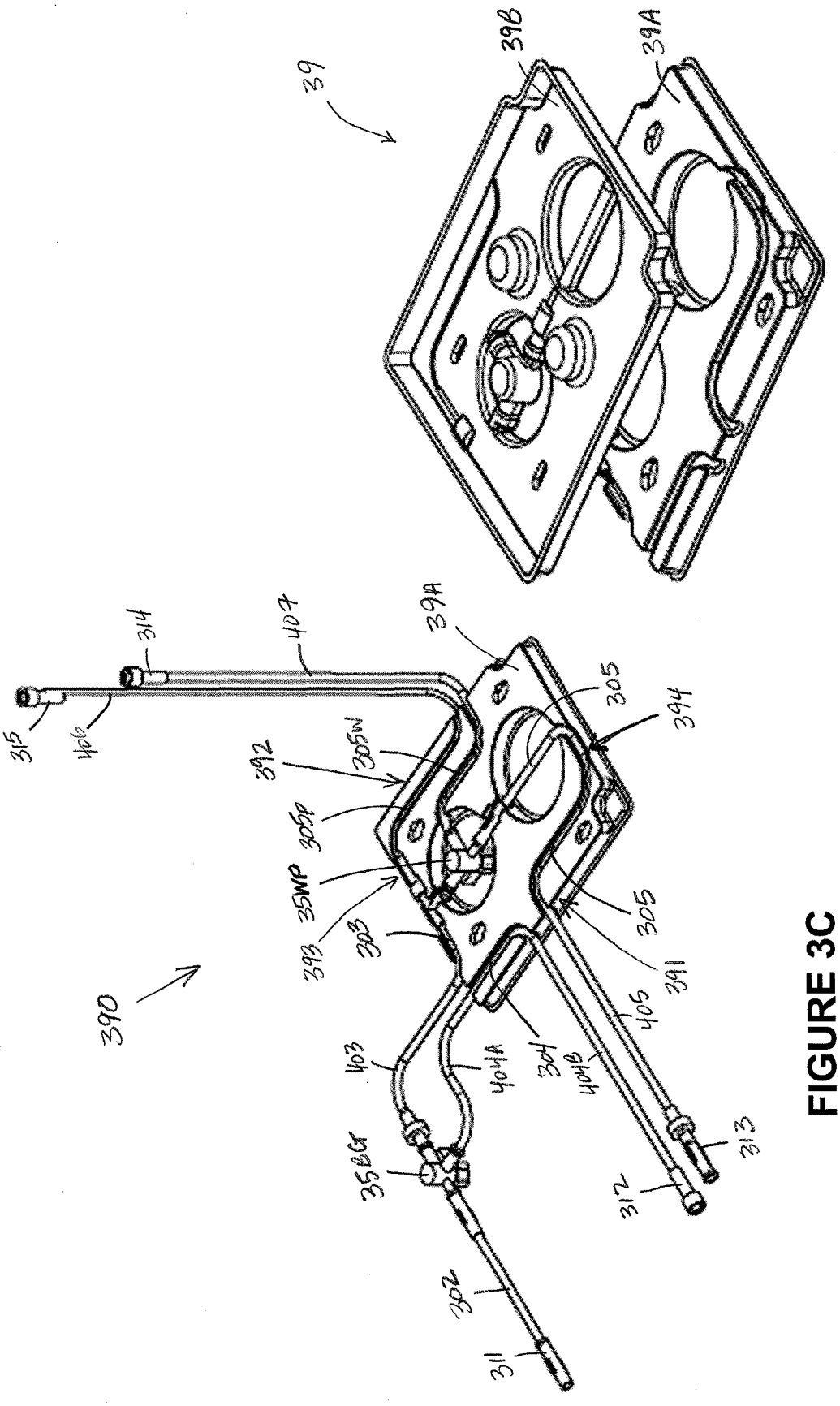
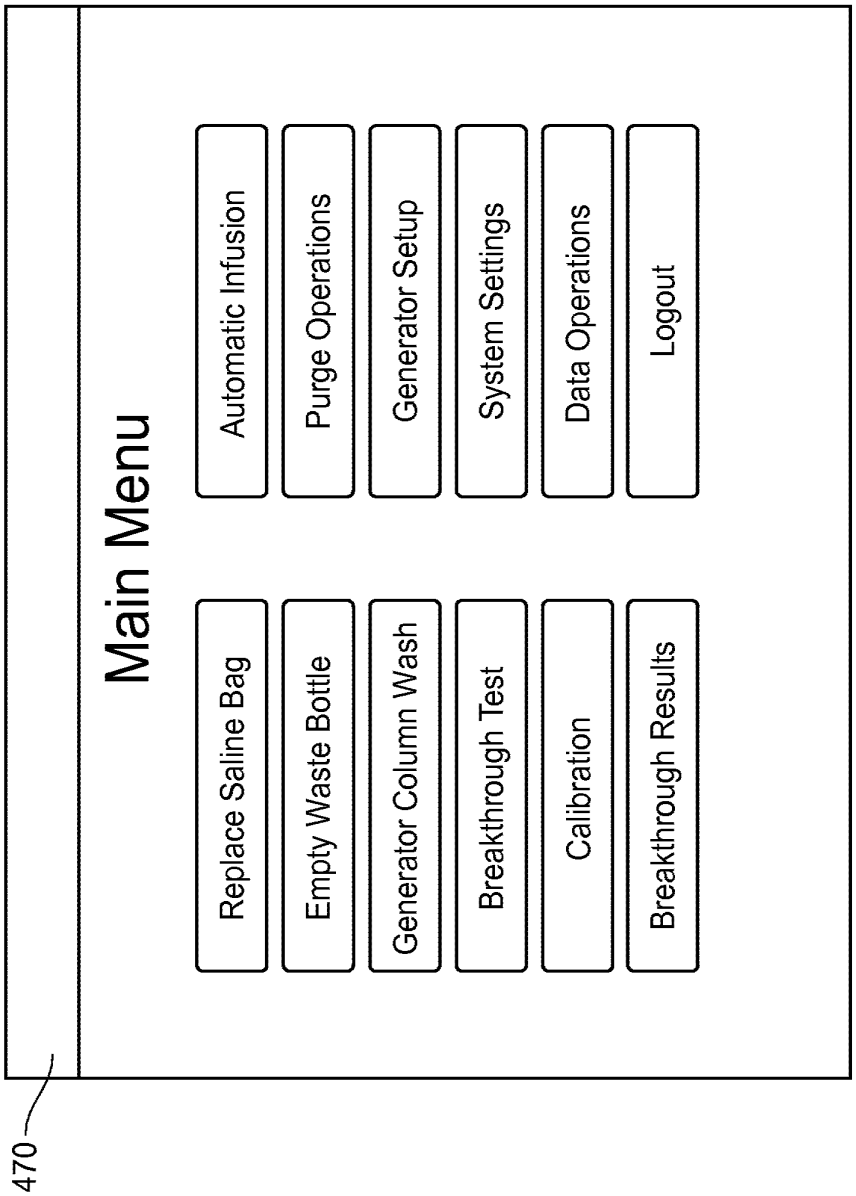


FIGURE 3D

FIGURE 3C

Fig. 4


Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470

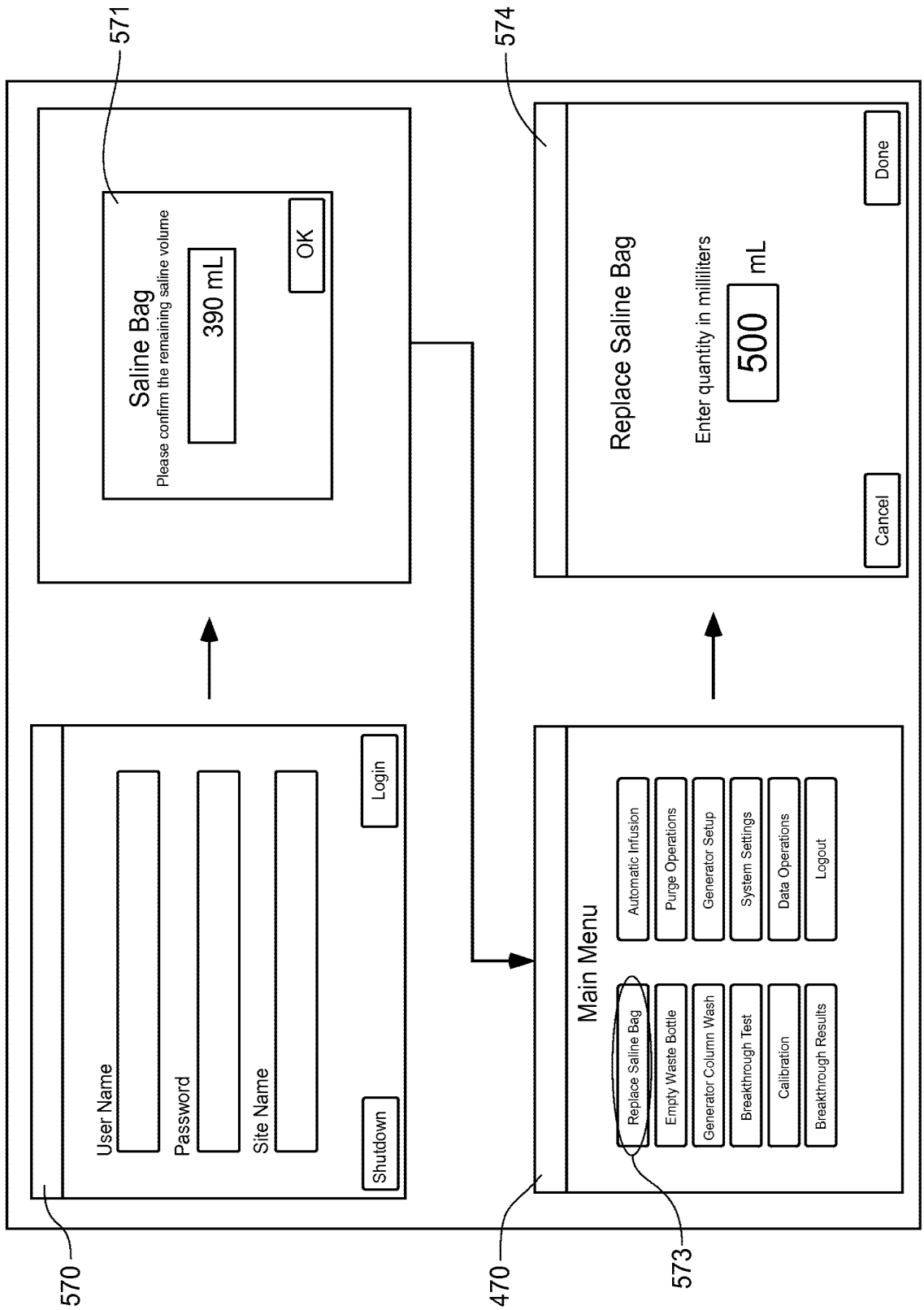

571
574
Saline Bag
Please confirm the remaining saline volume
390 mL
OK
Replace Saline Bag
Enter quantity in milliliters
500
mL
Done
Cancel
User Name
Password
Site Name
Login
Shutdown
Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag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

Fig. 5A

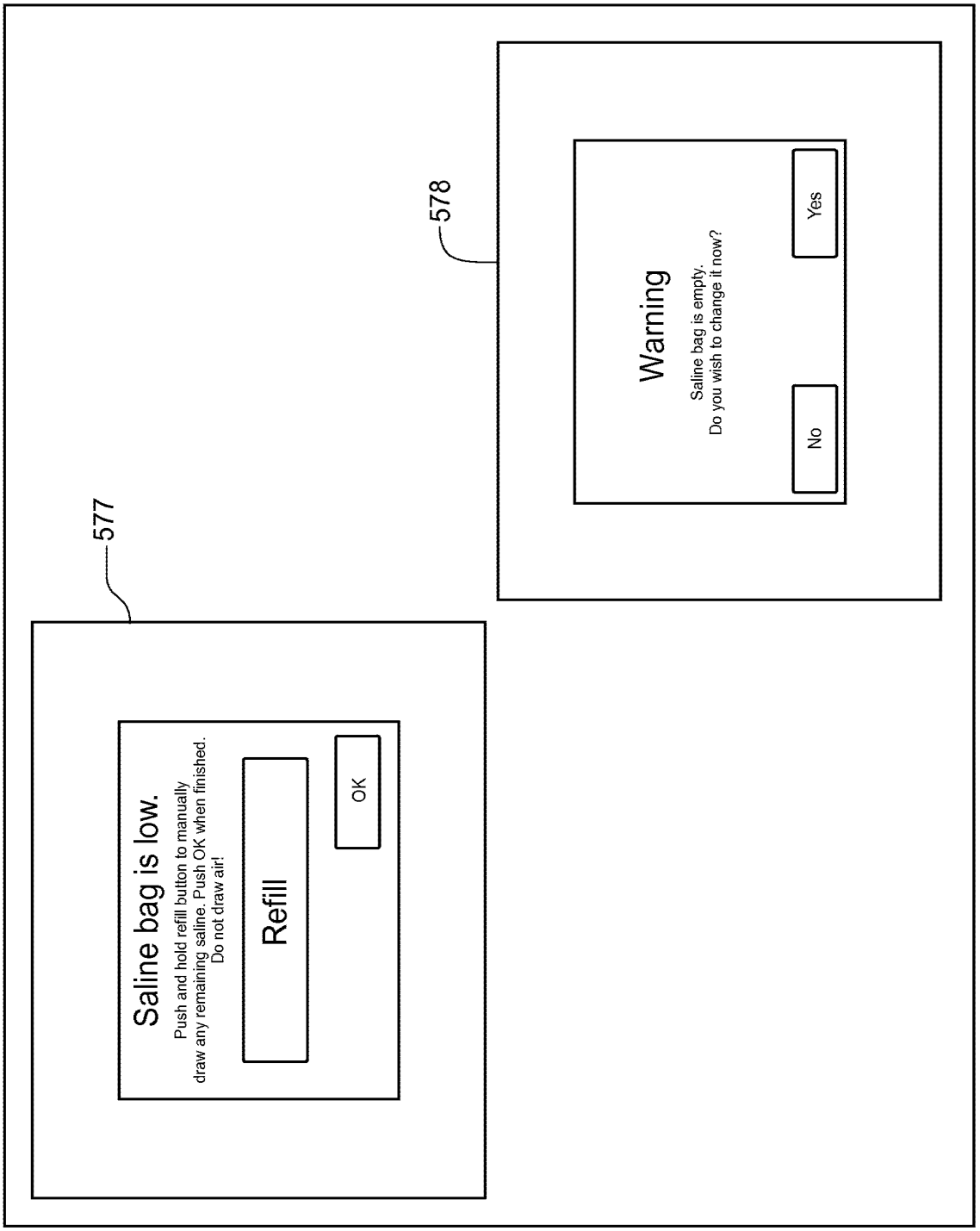

577
Saline bag is low.
Push and hold refill button to manually draw any remaining saline. Push OK when finished.
Do not draw air!
Refill
OK
578
Warning
Saline bag is empty.
Do you wish to change it now?
No
Yes

Fig. 5B

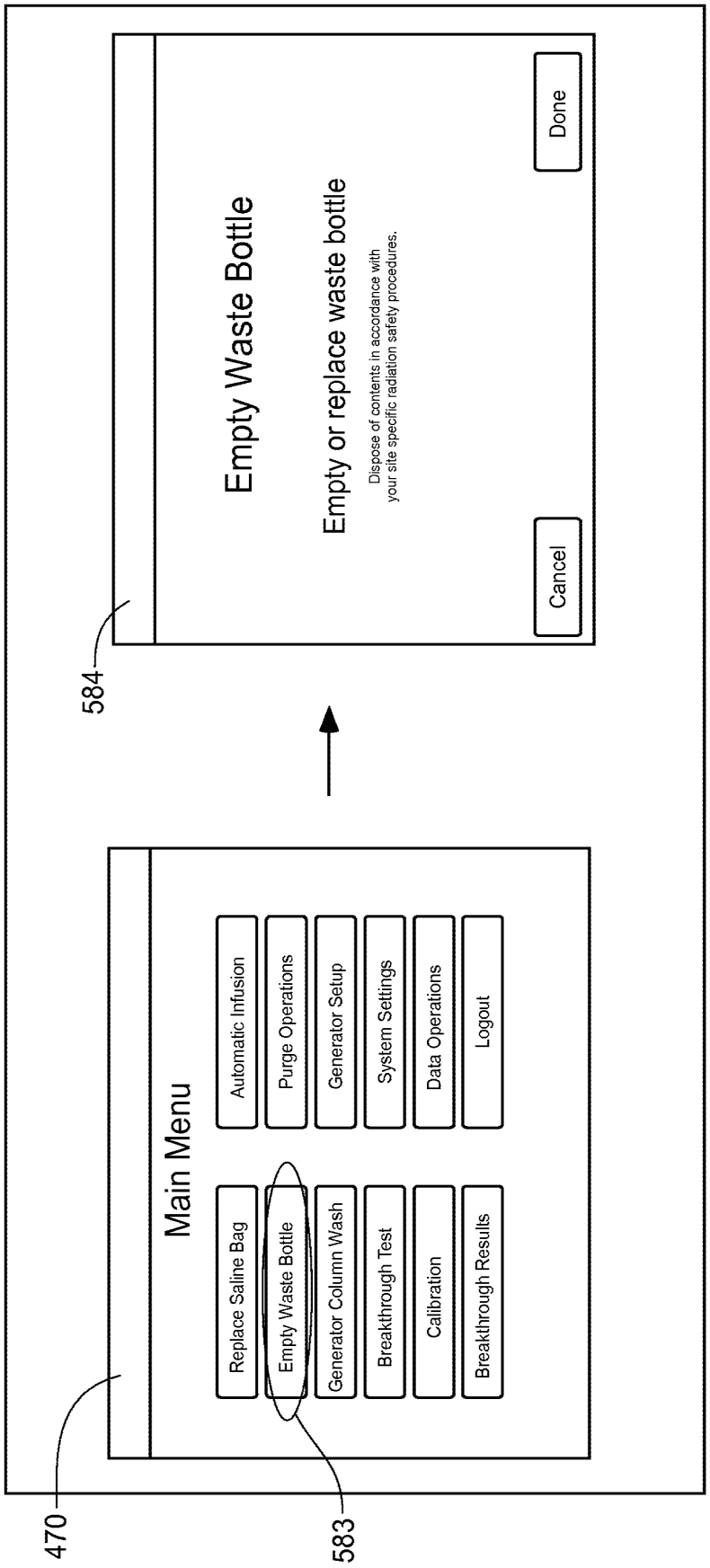

Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
470
583
584
Empty Waste Bottle
Empty or replace waste bottle
Dispose of contents in accordance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

Fig. 5C

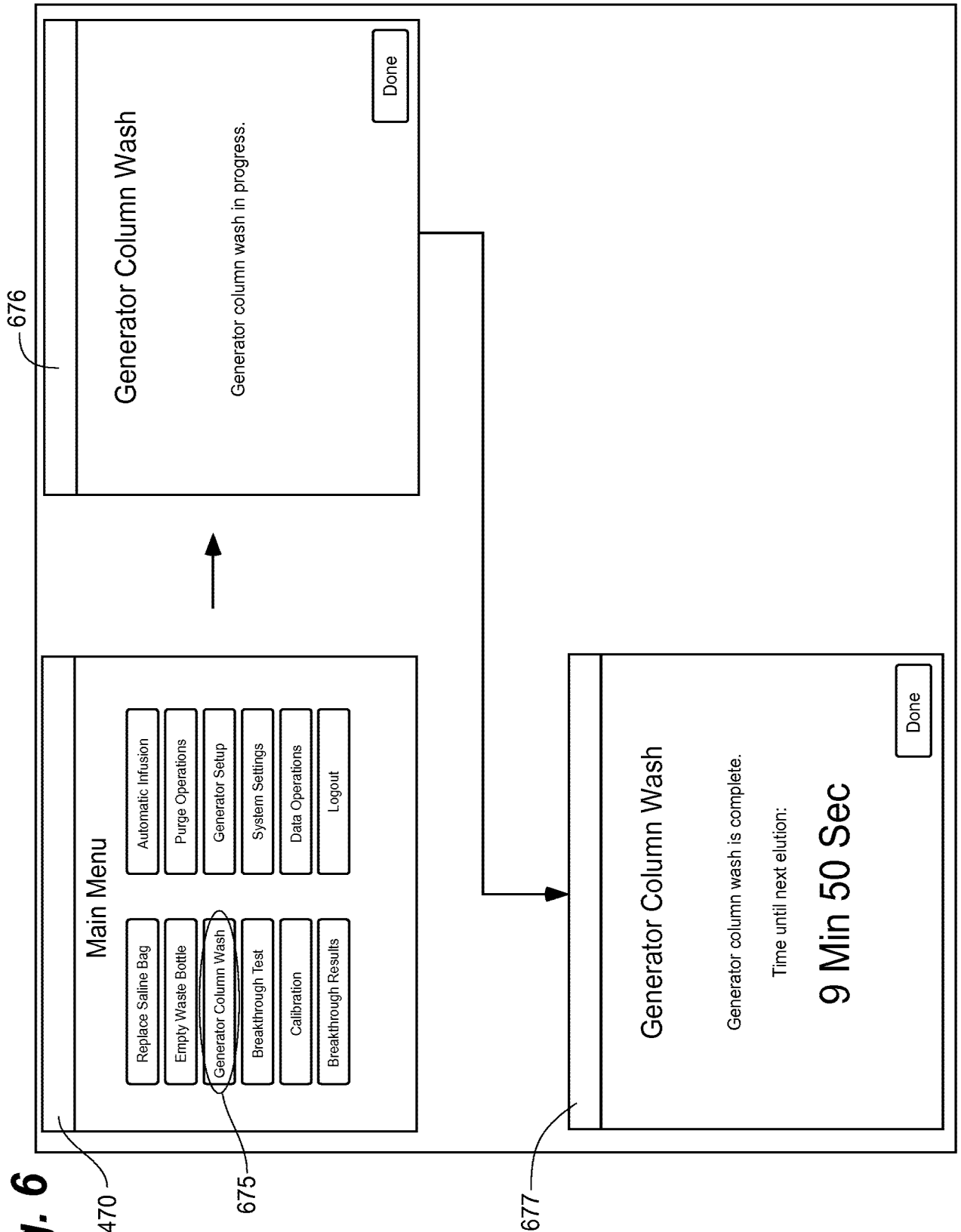

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Generator Column Wash
Generator column wash in progress.
Done
Generator Column Wash
Generator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

Fig. 6

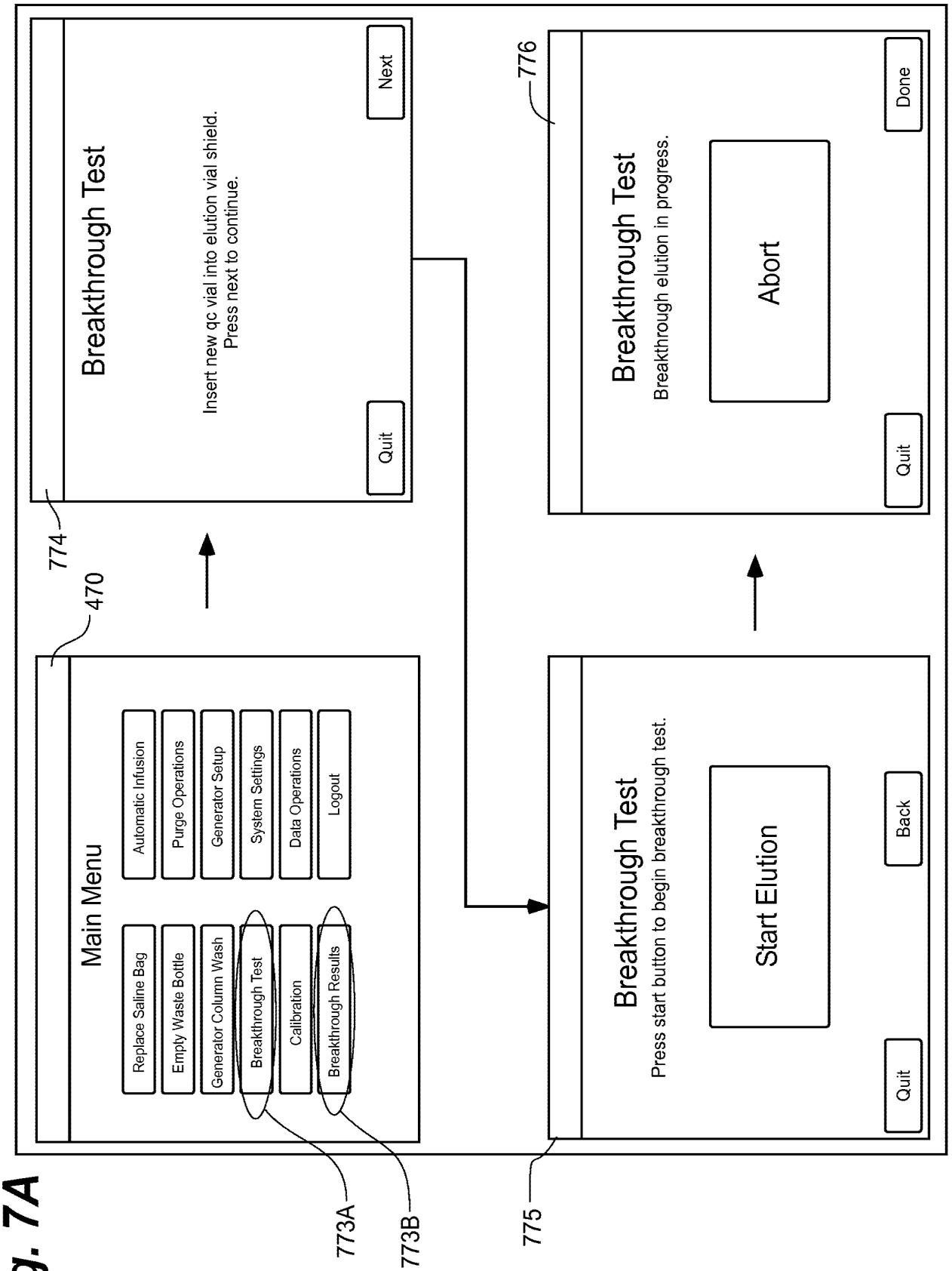

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470
Breakthrough Test
Insert new qc vial into elution vial shield.
Press next to continue.
Next
Quit
774
Breakthrough Test
Press start button to begin breakthrough test.
Start Elution
Back
Quit
775
Breakthrough Test
Breakthrough elution in progress.
Abort
Done
Quit
776
773A
773B

Fig. 7A

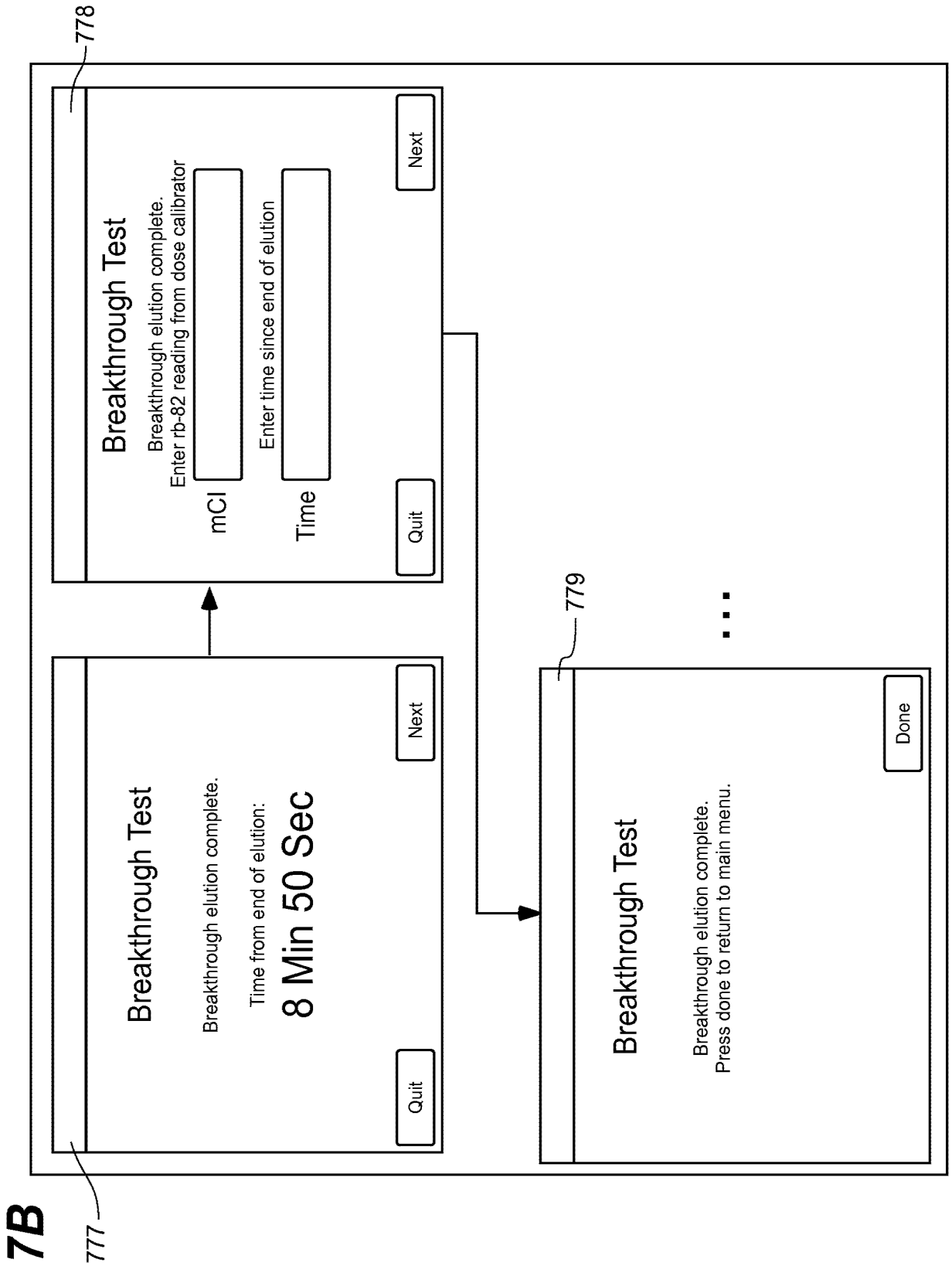

777
Breakthrough Test
Breakthrough elution complete.
Time from end of elution:
8 Min 50 Sec
Quit
Next
778
Breakthrough Test
Breakthrough elution complete.
Enter rb-82 reading from dose calibrator
mCI
Enter time since end of elution
Time
Quit
Next
779
Breakthrough Test
Breakthrough elution complete.
Press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

Fig. 7B

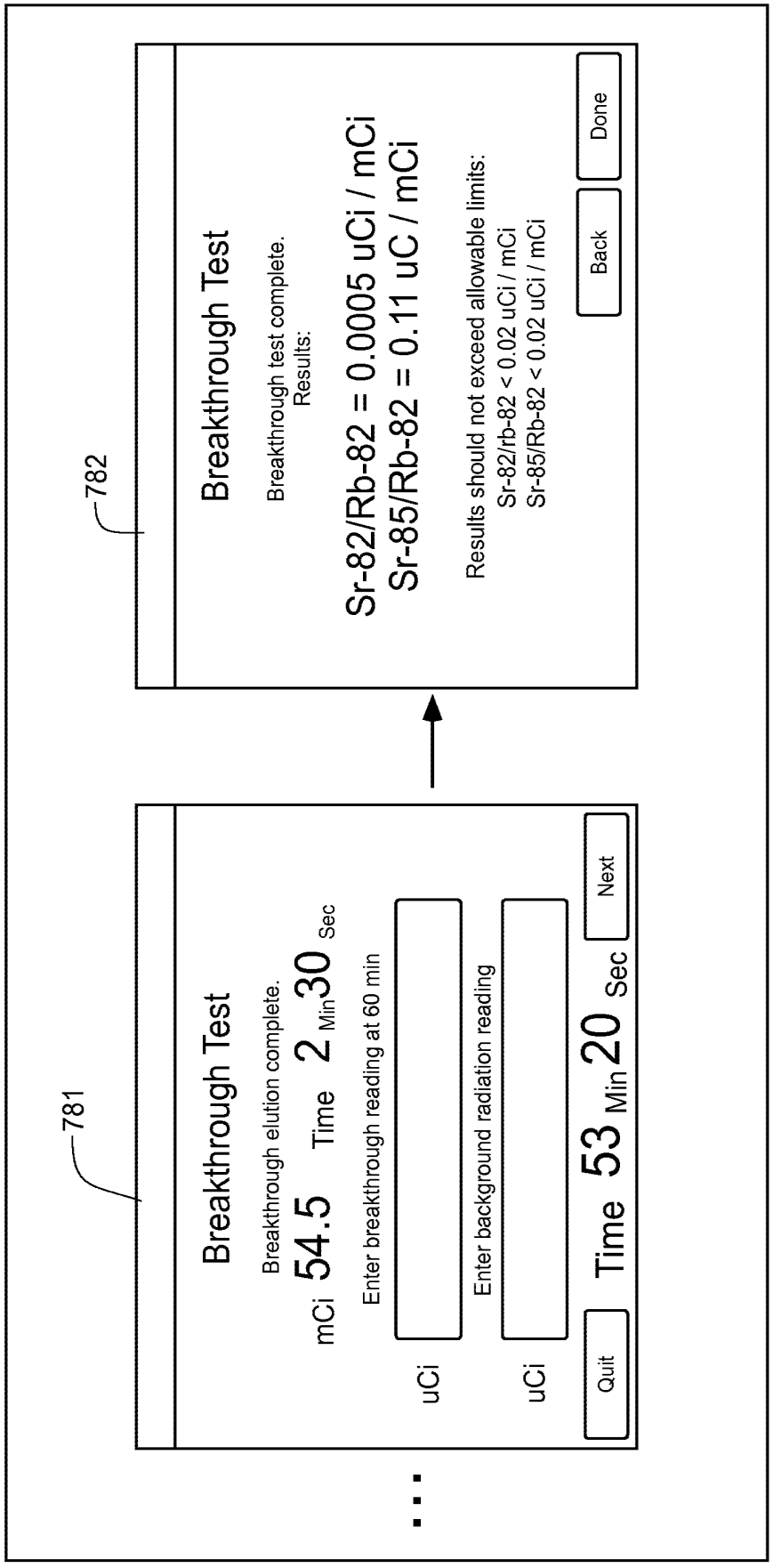

781
Breakthrough Test
Breakthrough elution complete.
mCi 54.5 Time 2 Min 30 Sec
Enter breakthrough reading at 60 min
uCi
Enter background radiation reading
uCi
Quit
Time 53 Min 20 Sec
Next
782
Breakthrough Test
Breakthrough test complete.
Results:
Sr-82/Rb-82 = 0.0005 uCi / mCi
Sr-85/Rb-82 = 0.11 uC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

Fig. 7C

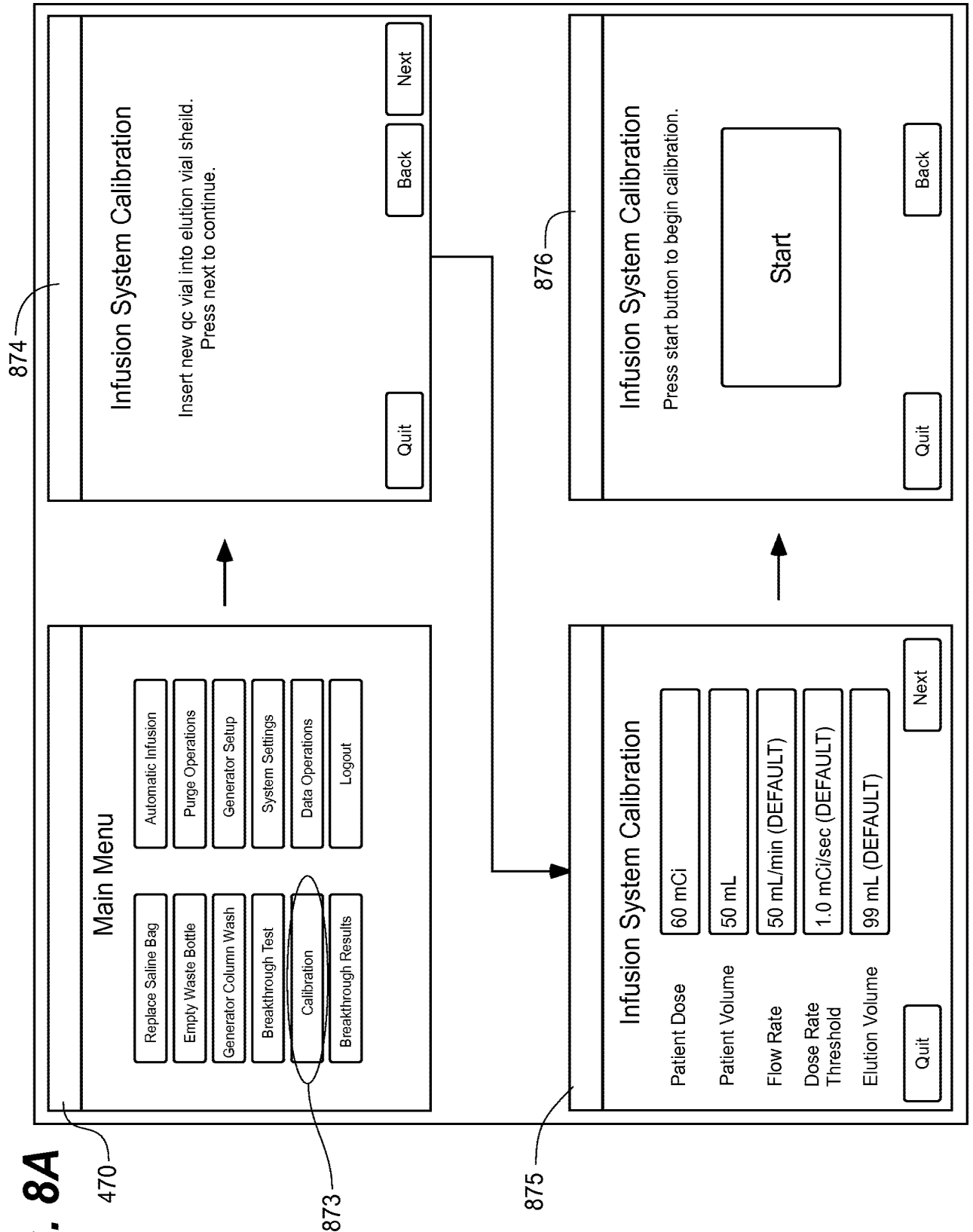

Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Infusion System Calibration
Insert new qc vial into elution vial sheild.
Press next to continue.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

Fig. 8A

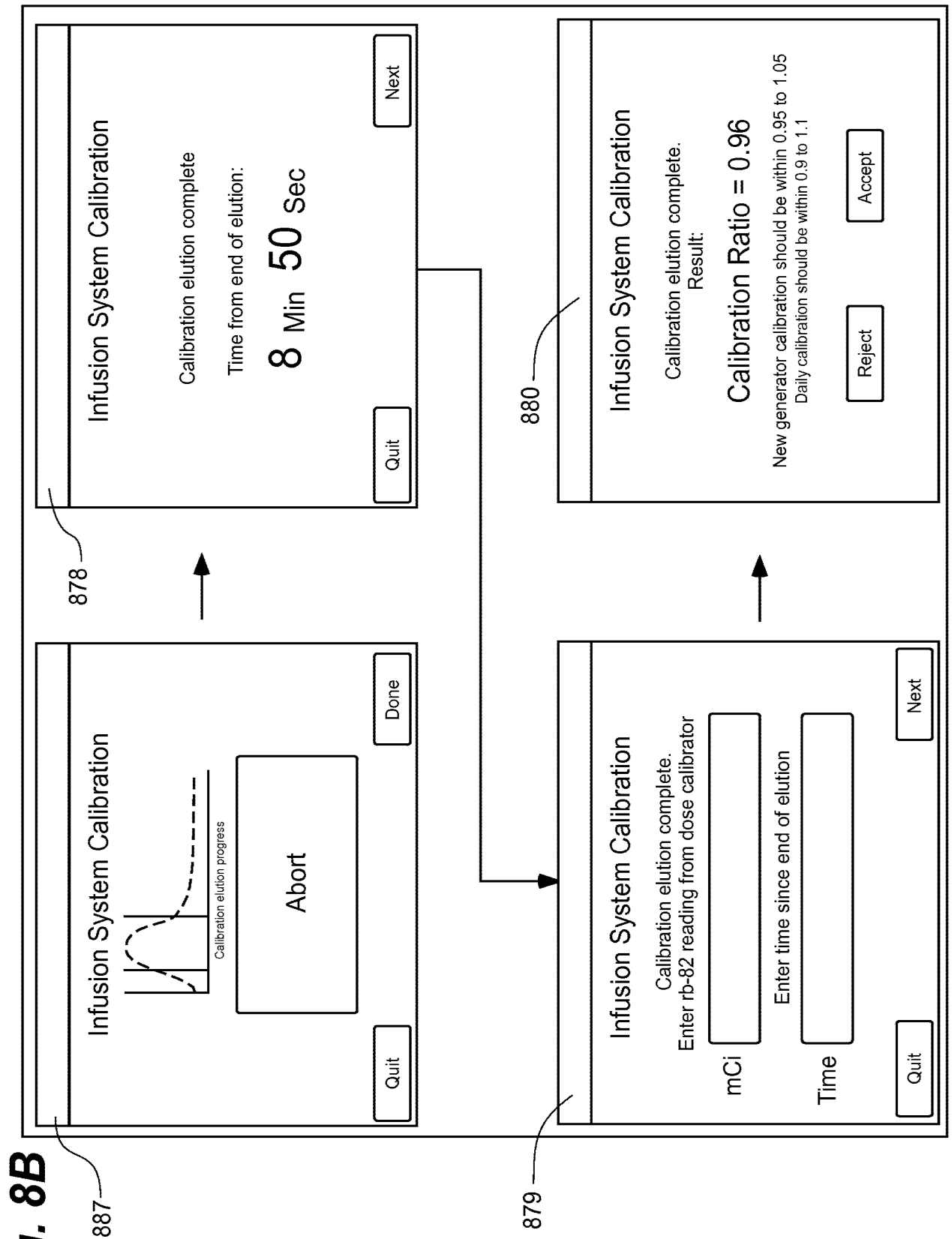

Infusion System Calibration
Calibration elution progress
Abort
Done
Quit
887
Infusion System Calibration
Calibration elution complete
Time from end of elution:
8 Min 50 Sec
Next
Quit
878
Infusion System Calibration
Calibration elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time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

Fig. 8B

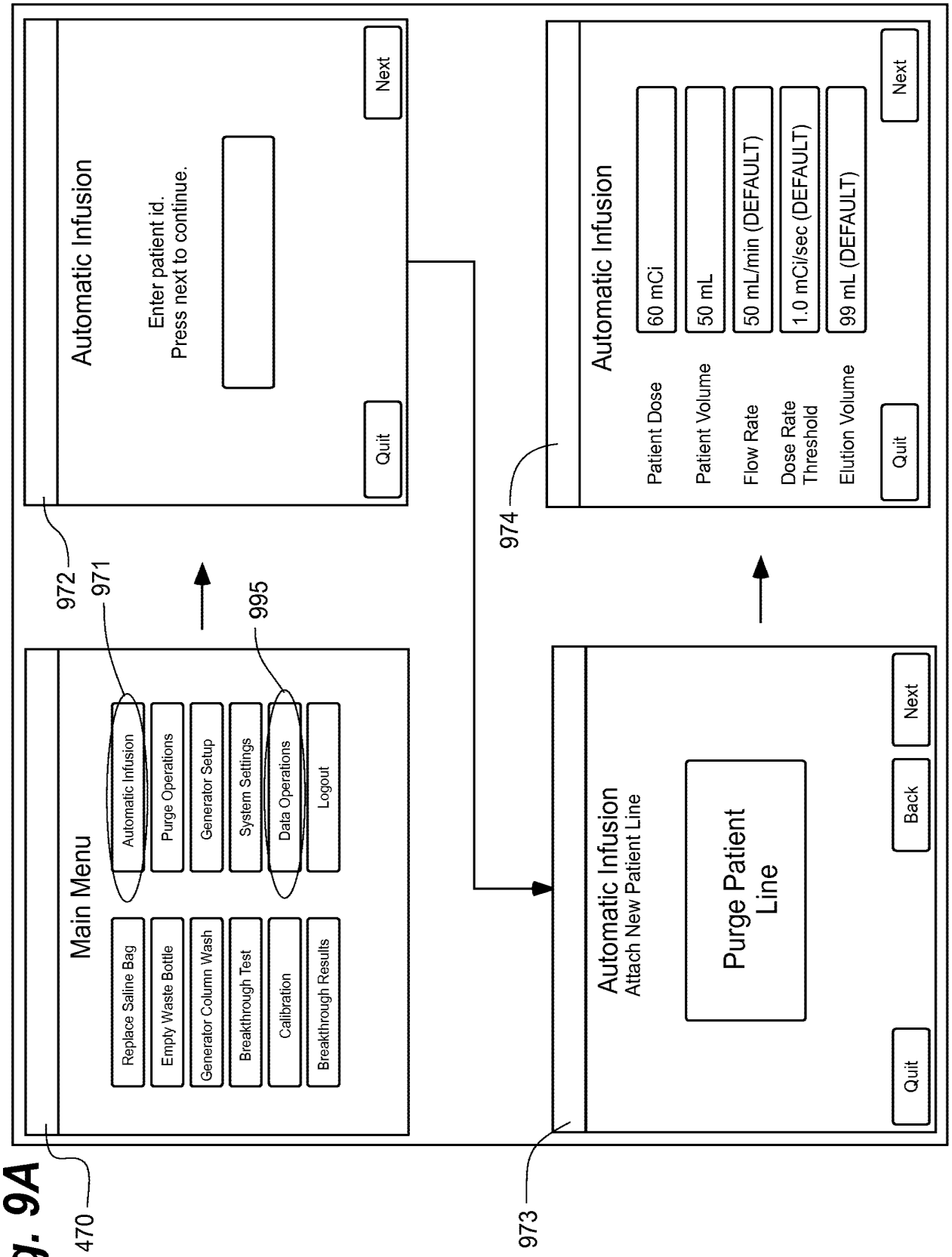

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470
971
972
995
Automatic Infusion
Enter patient id.
Press next to continue.
Quit
Next
973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

Fig. 9A

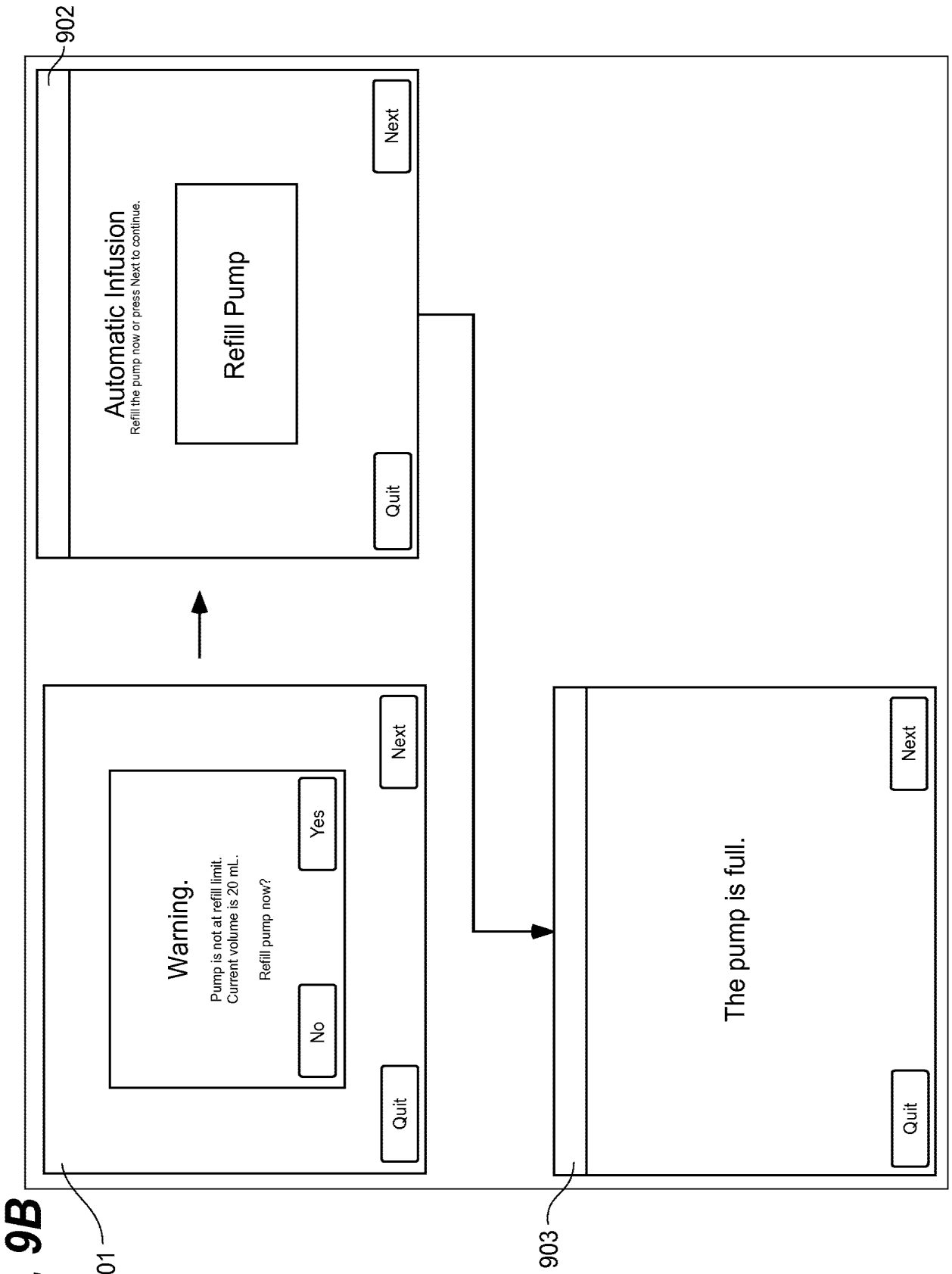

902
Automatic Infusion
Refill the pump now or press Next to continue.
Refill Pump
Next
Quit
Warning.
Pump is not at refill limit.
Current volume is 20 mL.
Refill pump now?
Yes
No
Next
Quit
The pump is full.
Next
Quit
901
903

Fig. 9B

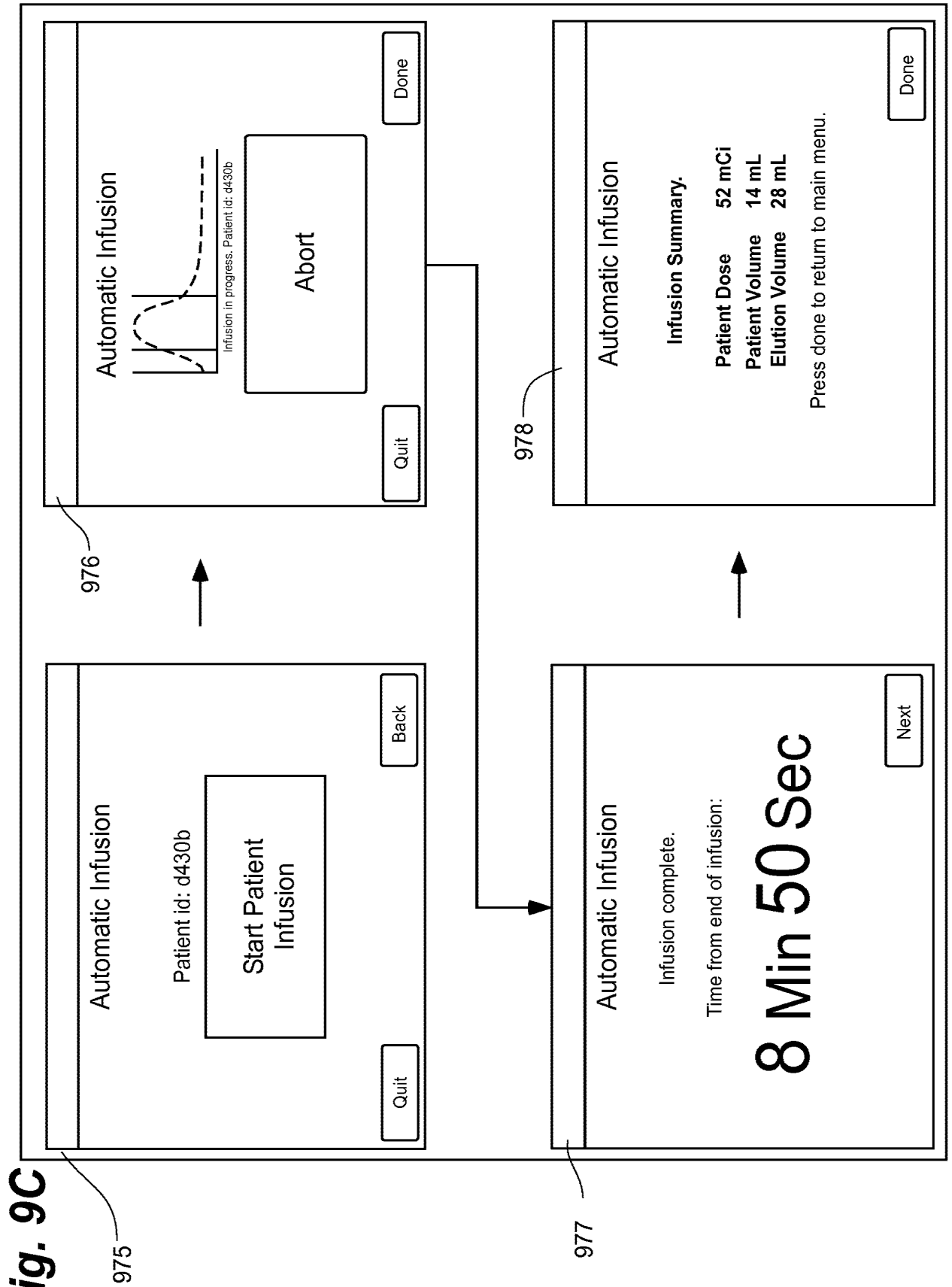

Automatic Infusion
Patient id: d430b
Start Patient Infusion
Back
Quit
975
Automatic Infusion
Infusion in progress. Patient id: d430b
Abort
Done
Quit
976
Automatic Infusion
Infusion complete.
Time from end of infusion:
8 Min 50 Sec
Next
977
Automatic Infusion
Infusion Summary.
Patient Dose 52 mCi
Patient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

Fig. 9C

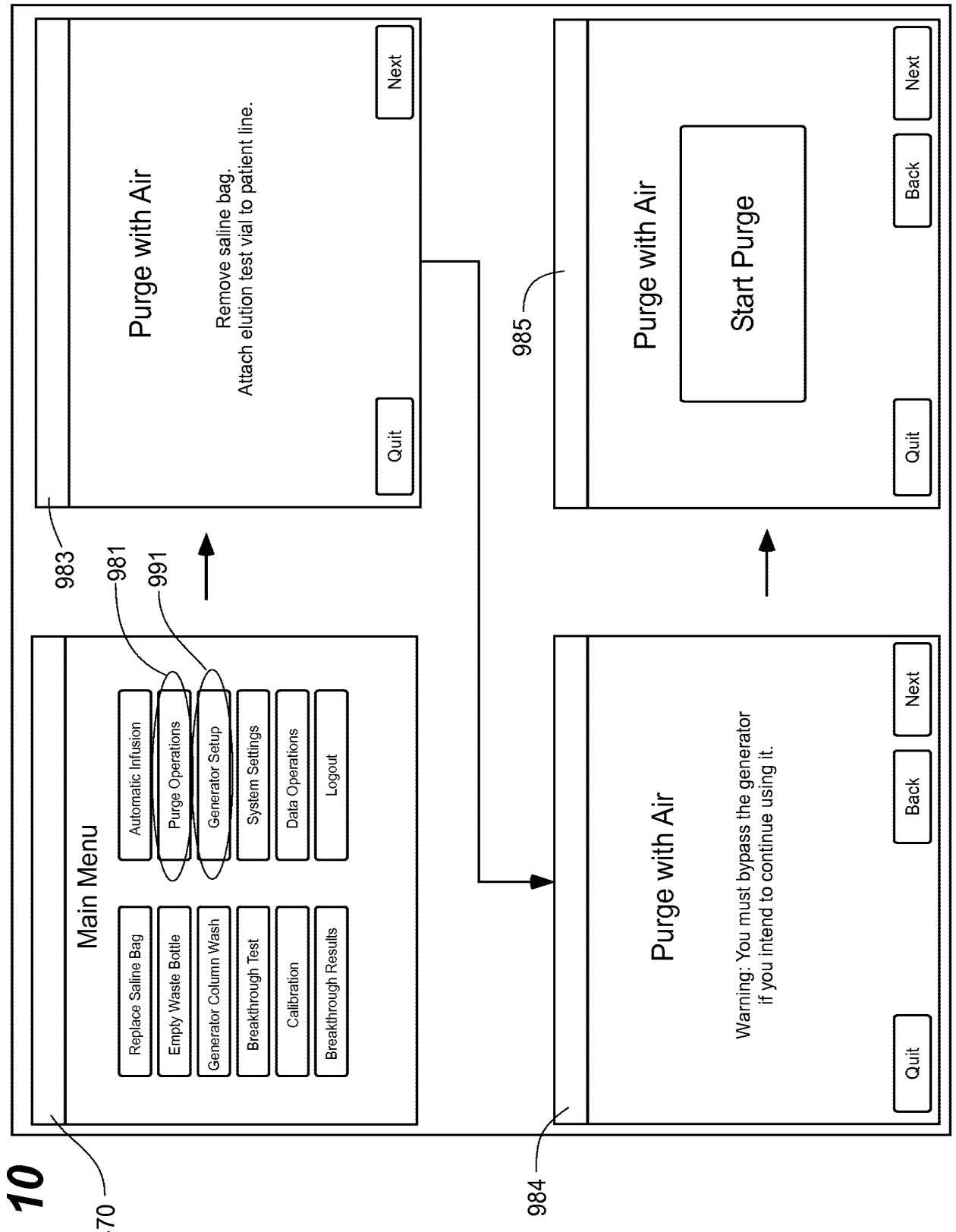

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Purge with Air
Remove saline bag.
Attach elution test vial to patient line.
Quit
Next
Purge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

Fig. 10

PTO/SB/08a (03-08)
Approved for use through 06/30/2008. 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	12137364
Filing Date	2008-06-11
First Named Inventor	Stephen E. Hidem
Art Unit	2628
Examiner Name	
Attorney Docket Number	56782.1.7

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	3710118		1973-01-09	Holgate et al.	
	2	4562829		1986-01-07	Bergner	
	3	4585009		1986-04-29	Barker et al.	
	4	4585941		1986-04-29	Bergner	
	5	6870175	B2	2005-03-22	Dell et al.	
	6	7204797	B2	2007-04-17	Reilly et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137364
	Filing Date	2008-06-11
	First Named Inventor	Stephen E. Hidem
	Art Unit	2628
	Examiner Name	
	Attorney Docket Number	56782.1.7

	1	20050278066	A1	2005-12-15	Graves et al.		

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

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	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	0102121	EP	A1	1984-03-07	DeJong, Rudolf et all		☐
	2	2007016170	WO	A1	2007-02-08	Fago		☐
	3	2007030249	WO	A2	2007-03-15	Gibson		☐
	4	2007149108	WO	A2	2007-12-27	Pollard		☐

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	BRACCO Brochure, "Rubidium 82 Infusion System, Easy to Operate...Automated...Complete", (C)Bracco Diagnostics, Inc., 0605-002NA, June 2001. (2 pages)	☐
	2	BRACCO, "Cardio-Gen82(R) Infusion System User's Guide", pages 1-42	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137364
	Filing Date	2008-06-11
	First Named Inventor	Stephen E. Hidem
	Art Unit	2628
	Examiner Name	
	Attorney Docket Number	56782.1.7

	3	IMAGING TECHNOLOGY NEWS, web exclusive: "FDG-PET Injector Thrusts New Life into Molecular Imaging", April 2008, 2 pages.	☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137364
	Filing Date	2008-06-11
	First Named Inventor	Stephen E. Hidem
	Art Unit	2628
	Examiner Name	
	Attorney Docket Number	56782.1.7

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.

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

☒ None

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	/Elisabeth Lacy Belden/	Date (YYYY-MM-DD)	2008-10-24
Name/Print	Elisabeth Lacy Belden	Registration Number	50,751

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.

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

(11) Publication number: 0 102 121
A1

(12) # EUROPEAN PATENT APPLICATION

(21) Application number: 83201201.7

(51) Int. Cl.³: G 21 G 1/04

(22) Date of filing: 18.08.83

(30) Priority: 26.08.82 NL 8203349

(43) Date of publication of application:
07.03.84 Bulletin 84/10

(84) Designated Contracting States:
AT BE CH DE FR GB IT LI NL SE

(71) Applicant: Byk-Mallinckrodt CIL B.V.
Westerduinweg 3
NL-1755 LE Petten(NL)

(72) Inventor: De Jong, Rudolf Barend Jan, Drs.
c/o OCTROOIBUREAU ZOAN B.V. Apollolaan 151
NL-1077 AR Amsterdam(NL)

(74) Representative: Swsters, Pieter D., Drs. et al,
Octrooibureau ZOAN B.V. Apollolaan 151
NL-1077 AR Amsterdam(NL)

(54) **Shielding device for a reservoir comprising a radioactive material.**

(57) The invention relates to a shielding device for a reservoir comprising a radioactive material and having an inlet and an outlet aperture, in particular a column for a radio-isotope generator, comprising a lead cover for the reservoir in which a closable access for the reservoir is recessed. The shielding device furthermore is provided with means which the device can be moved forward.

EP 0 102 121 A1

Croydon Printing Company Ltd.

Shielding device for a reservoir comprising a radioactive material.

The invention relates to a shielding device for a reservoir comprising a radioactive material and having an inlet and an outlet aperture, in particular a column for a radio-isotope generator, comprising a lead cover for the reservoir in which a closeable access for the reservoir is recessed.

A radioisotope generator is to be understood to mean herein a device for generating a radioactive isotopes comprising liquid. Such a liquid is prepared by eluting a column in which a parent isotope is present which produces a daughter isotope by decay. In this elution only the daughter isotope is eluted from the column by means of a suitable eluent.

Radioactive isotopes having a half-life up to a few days are frequently used in medicine for diagnostic purposes. One radioactive isotope frequently used for diagnostic examinations is technetium-99m. However, for certain applications, for example, for cardiological examinations, the comparatively long half-life of technetium-99m, namely 6 hours, is a disadvantage. As a result of this the radioactive material remains circulating in the body for a long period of time, so that an immediate repetition of a certain diagnostic examination with the same isotope is not possible.
However, very short-living radioactive isotopes having a half-life up to a few minutes, for example gold-195m, rubidium-82 and krypton-81m, are suitable for such above-mentioned examinations. Krypton-81m is used for lung function examinations, while rubidium-82 and gold-195m have proved suitable for blood circulation studies. An interesting application of gold-195m was described recently in Netherlands non-prepublished Patent Application 8201591 in the name of Applicants.

Gold-195m is an isotope having a half-life of 30.6 sec. and emits gamma rays of 261 keV which, due to the energy and intensity, are suitable to enable a good observation with apparatus usual for this purpose, for example, a gamma camera.

It is known from Netherlands Patent Application 8002235 in the name of Applicants to generate gold-195m from the radioactive parent isotope mercury-195m in a satisfactory manner. This process is preferably carried out in a so-called radio-isotope generator, in this case a Hg/Au generator, from which the user can withdraw a quantity of radioactive isotope-containing liquid at any desired instant. Such an instantaneous production is of great practical importance due to the rapid decay of the comparatively short-living isotope.

An improved method of preparing gold-195m is described in Netherlands non-prepublished Patent Application 8202407 also in the name of Applicants.

In view of the high radiation intensity, extensive safety measures have to be taken to shield the parent isotope present in the generator. Therefore the generator comprises a lead screening jacket which provides a sufficient safety upon storage and transport. The screening jacket surrounding the generator is generally considered to be an insufficient safety against radioactive radiation for hospital or laboratory personnel who are regularly in the direct proximity of the generator. It is therefore necessary to surround the generator with an extra lead shielding device.

Such a device should not only provide a good shielding from radioactive radiation, but, in connection with the necessity of a regular replacement, should also be readily accessible for the reservoir with radioactive material, in particular the generator column.

Therefore, various shielding devices are known from literature substantially all of which are destined for a column for generating technetium-99m, a radioactive isotope having a comparatively long half-life, and all of which are fixedly arranged.

When a very short-living radioactive isotope is used for diagnostic purposes, the time between the preparation of the isotope and the administration to a patient

should be minimized. In the case of the above-mentioned gold-195m isotope having a half-life of approximately 30 seconds, it is very much desired, if not necessary, to administer said isotope directly from the generator to the patient. In a clinic in which radioactive isotopes for diagnostic purposes are used, the apparatus necessary for detection, for example, a gamma camera with special collimator and a computer, is usually fixedly arranged. For a radiodiagnostic examination the patient is then brought (wheeled) to the detection apparatus.

It is therefore obvious to give the very short-living material to be used for the examination, in particular a generator for producing a very short-living isotope, a fixed place close to the detection apparatus. It is feasible that high requirements as regards the shielding from radioactive radiation have to be imposed upon such a device beside the patient to be examined ("bed-side arrangement"). In fact, not only the hospital personnel familiar with handling radioactive material will have to be present near the radiation source for a longer period of time, but also other personnel accompanying the patient will have to be shielded from unnecessary radioactive radiation. Moreover it is of utmost importance for the examination that the source of radiation should be shielded carefully from the gamma camera which is very disturbance--sensitive to background radiation.

A fixed arrangement as suggested above which would satisfy these requirements, however, has important practical disadvantages, namely:

(1) it is not possible to move the device around the patient's bed. This is a disadvantage because in examinations with very short-living radioactive isotopes, the organ, for example, the heart, has to be inspected usually in various directions by means of the gamma camera, so as to gain optimum insight in the function of the organ. A fixed bed-side arrangement of the radioactive material to be administered considerably

restricts the possibilities of moving the bed with the patient with respect to the gamma camera. This disadvantage is the larger since, for reasons which will be stated hereinafter, the connection between the source of the radioactive material and the patient should be as short as possible.

(2) Assembling of the device must take place for the greater part under aseptic conditions because the radioactive material must be introduced into the patient's body directly and cannot be previously subjected to a separate sterilization.
Because the device with radioactive material, in particular the radio isotope generator, will be used for a longer period of time, such an assembling should be carried out under so-called laminar flow conditions, and therefore requires provisions which are particularly difficult to realize in an examination room.

(3) Another important disadvantage relates to the working with radioactive material upon assembling the device. As a matter of fact, the shielding from radioactive radiation is not yet optimum during the assembly, so that such an assembly, in which large quantities of not yet optimally shielded activity are handled, should therefore take place in a so-called hot-lab of a nuclear medical department of a clinic and not in an examination room for patients where in addition disturbance-sensitive detection apparatus is arranged.

It is the object of the present invention to provide a shielding device for a reservoir comprising radioactive material, in particular a column for a radioisotope generator, which does not exhibit the above-mentioned disadvantages.

For that purpose, the shielding device according to the invention is provided with means with which the device can be moved forward. The complete device comprising radioactive material can now be assembled in suitable rooms intended for this purpose and can then be wheeled to

the examination room beside the patient's bed. Because the shielding device can be freely shifted, the device can be moved at will around the patient during the examination. Such a movable shielding device for a column for a radioisotope generator is moreover more flexible because the device can be used, if desired, for any generator, for example, a rubidium-krypton-81m, a strontium-rubidium 82 or a mercury-gold 195m generator.

It is of course necessary that the shielding device should also satisfy all conventional safety requirements in addition to the above-mentioned radiological safety requirements. This involves, for example, that the device should be sufficiently stable and be protected as well as possible from calamities, for example, a fire; in the latter case, of course, it should be prevented that the radioactive radiation can pass the shielding device and enter the examination room.

Preferably the device in addition comprises provisions for the safe handling of radioactive material, such as a receptacle for waste fluid, a work-top, etc. These provisions enable the user to carry out various manipulations with radioactive materials at different places without risky manually displacing these materials, because, as a matter of fact, the device can be moved forward.

On its lower side the shielding device preferably comprises at least three, preferably five, casters to be able to easily turn and manoeuvre the heavy device in the restricted space around a patient. As a result of the lead cover, a shielding device according to the invention approaches a weight of approximately 360 kg.

Furthermore it is desired to provide the device with a grip at a height which is suitable for hand-movement. For this purpose, a grip consisting of a circumferential tubular or rod-shaped member connected to the outside of the lead cover has proved particularly suitable. When such a grip having no projections is used, it is

avoided that components of the device or connections can be drawn along or loose during movement of the shielding device.

When using the device it is often necessary to temporarily store radioactive waste material. For example, when a gold-195m generator is used, the generator column must first be rinsed several times with eluent before an eluate is obtained having a composition which is sufficiently constant for administration to a patient. It is therefore advantageous that the device moreover comprises a separate lead-shielded space for a receptacle for radio-active waste material.

Because the radioactive liquid has to be introduced directly into the patient's body, the means for doing this are preferably connected on or to the shielding-device.

In a suitable embodiment the shielding device according to the invention comprises a base in which the means to move the device are present, a central part of reduced outside diameter in which the lead cover for the reservoir containing radioactive material is present, and a top part which comprises: the lead closure for the access in the cover, the grip, the access to the shielded space for the waste reservoir and the means to introduce a radioactive liquid into a patient's body.

As a result of the large diameter of grip and base as compared with that of the reservoir shielded by means of a lead cover, the distance between the radiation source and the operating personnel is increased, for example, by a factor of approximately 2. As a result of this the radiation received is still further reduced, for example, by a factor of approximately 4 as compared with the radiation at the outer surface of the shielded reservoir.

Lead is vulnerable because is is a soft metal. Moreover, it has a low melting-point, 327°C, so that in the case of a fire, it will melt and drip away, thus allo-

wing radioactive radiation to be released from the cover. Therefore, the lead cover for the reservoir consists preferably and in agreement with the requirements which are imposed upon the storage of radioactive material in various countries, of a lead vessel which is open at its top and which is enclosed between sheet material of iron or steel, protected on the outside against corrosion, or of stainless steel, while the open top end accessible for the reservoir can be closed by a lead lid provided with the same sheet material on the outside, an aperture for a connection between the reservoir and the means for introducing a radioactive liquid into a patient's body being present in the lid or between the vessel and the lid. The sheet material which can withstand high temperatures ensures sufficient safety for the ambience in the case of a calamity, for example, a fire, so that the lead shielding remains contained and no undesired radioactive radiation can get out of the shielding system.

It cannot always be avoided that a little radioactive liquid is spilled when installing or using the source of the radioactive material. Then it is difficult to thoroughly clean the vessel which forms part of the heavy shielding device. Therefore, a stainless steel vessel is preferably present between the substantially lead vessel and the reservoir, which stainless steel vessel comprises on its open top a radially outwardly projecting flange to which the lid can be sealingly connected.

The shielding device in accordance with the invention serves in particular for shielding a radio isotope generator. The provisions necessary upon eluting a generator column are preferably connected on or to the above-mentioned top part of the device, namely a reservoir for the eluent for the generator column which communicates with the column; means for pumping or injecting the eluent out of the eluent reservoir into the column; means for bringing the resulting eluate out of the column into a patient's body; means for adding a rinsing of formulating

liquid to the eluate; and a tube which is connected on one side to the means for adding the rinsing or formulating liquid and which on its other side has a member which can be connected to an auxiliary means to admit liquids to the blood vessels or body cavities of a patient.

In order to be able to handle all operating members easily, rapidly and safely, a connection and operating block or tray is connected to the top part, in which block are accommodated injection means for the eluent and the eluate, valves to prevent undesired directions of flow of liquids, cocks to enable or block the passage of liquids, and connection provisions for the means provided in the block both mutually and to the tubes which are connected to the reservoirs, the column and the auxiliary means to be used for the administration to a patient. Preferably the operating block or tray is attached on top of the lid of the lead vessel and the lid is provided with a bore to let pass connecting tubes from the generator to the auxiliary means for injection and from the auxiliary means to the waste fluid receptacle thereby shielding the environment as far as possible from radiation emanating from these tubes when radioactive liquid passes through them. The above embodiment has the advantage that an optimum safety can be reached inspite of the excess pressure at which generally the radioactive liquid is administered to a patient. Moreover, the path which the eluate has to cover, hence the distance between the generator and the patient, can be kept as short as possible. This latter is of importance in particular because, when very short-living radio-isotopes are used, high requirements are generally imposed upon the volume to be administered to the patient and in which the radioactive material is present. As described in the above-mentioned Netherlands Patent Application 8201591, repeated administrations within a short period of time are necessary for various applications. In order to enable such examinations, the volume in which the reactivity is

present must be as small as possible.

The invention will now be described in greater detail with reference to an embodiment which is shown in the accompanying drawings.

Figure 1 is a side-view of a shielding device according to the invention; figure 2 shows the same shielding device from top. Figure 1 is for the greater part a longitudinal sectional view of the shielding device taken on the line I-I of fig. 2, viewed in the direction of the arrows. Figure 3 is a longitudinal sectional view of a part of the device taken on the line III-III of fig. 2.

The operation of the device will be described in detail with reference to figure 4. Figure 4 shows an exploded view of a part of the device.

The base 21 of the screening device shown in Figure 1 comprises a base plate 23 which is hooded with a stove-enamelled sheet iron cap 22 below which five casters 24 are connected so as to be rotatable.

The central part 25 is mounted on said base plate and comprises a lead vessel 26 which is enclosed between stove-enamelled sheet iron 27. A second vessel 29 which is manufactured from stainless steel and comprises a radially outwardly projecting flange 28 is provided in the vessel. The generator 31 is placed in vessel 29. Between the bottoms of the vessels 27 and 29 a space 30 remains in which heating elements, for example a heating plate, can be accommodated. As described in the above-mentioned Netherlands Patent Application 8202407 it may be useful when certain radio isotope generators are used, for example, a gold-195m generator, to heat the generator column during the elution. If desired, a bore may be recessed in vessel 26 for leading through a supply for the heating means.

As shown in figures 1 and 2 a grip 33 in the form of a circumferential tube which is connected to the vessel by means of three spoke-shaped elements 34 is provided around the top part of the device. The vessel 26 can be closed on its top side by means of a lead lid 36 mounted

in stove-enamelled sheet iron 35 and connected to the vessel so as to be pivotable at 37. For compensation of the weight of the lid, a spring mechanism 38 is provided. The lid can be clamped sealingly on the vessel (flange 28) by means of a clamping lock 39 provided with a handle. A bore 32 is present in lid 36 for leading through two connection tubes, the outlets of which are framed in a suitable mount 45, comprising a steel tube encased in lead, erected on the lid of the lead vessel and forming a base for an operating block or tray. Between the circumferential grip and the upper edge of the lead vessel, a circumferential stainless steel top 40 having upright edges is present on which auxiliary means necessary for using the device can be placed.

A small lead vessel 41, also mounted in stove--enamelled sheet iron, for a receptacle 12a for waste material is present in an aperture of the top 40, which vessel is connected to the large vessel 27 and can be closed by means of a lead lid 43 provided with a grip 44.

On top of mount 45 is connected an operating block or tray 46 in or on which two syringes can be accomodated, as well as other auxiliary means needed during operation of the device.

Figure 3 shows a waste overflow bottle 12b placed on top 40. The inlet of the overflow bottle is connected to the outlet tube 11b of receptacle 12a.

As shown in Figure 1, two reservoirs 1 and 2 for eluent and rinsing or formulating liquid, respectively, are clamped in a stand 16 mounted on the edge of vessel 27.

As shown in Figure 4, two syringes 5 and 9 provided on their front sides with connection means in the form of Luer cones are connected to three-way cocks, the former directly to a three-way cock 4a and the latter to a three--way cock 4b via two valves 8a and 8b.

The use of the device shown will be explained with reference to figure 4. All connections between the various components, for the greater part tube connections

and Luer connections, are produced under laminar flow conditions.

During operation of the device the tube connections are provided between eluent reservoir 1 and an outlet of three-way cock 4a, the inlet aperture of the generator column 13 and the other outlet of three-way cock 4a, the reservoir with rinsing or formulating liquid 2 and valve 8a, the drain aperture of the generator column 15 and valve 8b, the receptacle for waste fluid 12a and an outlet of three-way cock 4b and the auxiliary means to be used for administration to a patient and the other outlet of three-way cock 4b.

When the device is used, first three-way cock 4b is opened to communicate the eluate duct 7 through cock 10b and valve 8b with the waste fluid receptacle 12a. Overflow bottle 12b is connected to receptacle 12a through a tube 11b and serves as an extra safety. By means of three-way cock 4a, syringe 5 is communicated with eluent reservoir 1, after which the syringe is filled with 2 ml of eluent. Eluent reservoir 1 and rinsing agent reservoir 2, clamped in stand 16, are provided with dropping chambers 3a and 3b. After opening the cock 10a, syringe 9 is filled with a saline solution from reservoir 2 (through valve 8a); the tube is then closed by clamping by means of clamb 17. After having turned three-way cock 4a, the contents of syringe 5 are injected through tube 6 into the generator column 14 at 13; after-rinsing is carried out with 2 ml of saline solution from syringe 9. All the wash liquid (eluate) rinsed through the column and leaving the generator column at 15, as well as the rinsing liquid is collected through tubes 7 and 11a in the waste receptacle 12a.

After having repeated this operation several times, the generator is ready for connection to a patient. For that purpose, a sterile tube, connected to three-way cock 4b, is filled with a saline solution from syringe 9 after opening said valve, and is then connected to an

auxiliary means to administer the radioactive liquid to a patient, for example, a needle or a catheter. After having placed the patient in a suitable position below a gamma camera, the generator is eluted with 2 ml of eluent by means of syringe 5, the eluate being injected directly into the patient. All remaining radioactivity is then removed from the device by rinsing with 10 ml of saline solution from reservoir 2 by means of syringe 9.

The examination may be repeated any desirable number of times.

CLAIMS:

1. A shielding device for a reservoir comprising a radioactive material and having an inlet and an outlet aperture, in particular a column for a radio-isotope generator, comprising a lead cover for the reservoir in which a closable access for the reservoir is recessed, characterized in that the shielding device is provided with means with which the device can be moved forward.

2. A device as claimed in Claim 1, characterized in that the device comprises in addition provisions for the safe handling of radioactive material.

3. A device as claimed in Claim 1 or 2, characterized in that the device comprises on its lower side at least three, preferably five, casters.

4. A device as claimed in any of the preceding Claims, characterized in that the device comprises a grip, preferably consisting of a circumferential tubular or rod-shaped member connected to the outside of the lead cover.

5. A device as claimed in any of the preceding Claims, characterized in that the device comprises in addition a separate lead-shielded space for a reservoir for radioactive waste material.

6. A device as claimed in any of the preceding Claims, characterized in that the device is provided with means for introducing a radioactive liquid into a patient's body, while the environment is shielded as far as possible from radiation emanating from these means when radioactive liquid passes through them.

7. A device as claimed in Claim 6, characterized in that the device comprises a base in which the means to move the device are present, a central part of reduced outside diameter in which the lead cover for the reservoir containing the radioactive material is present, and a top part which comprises: the lead closure for the access in the cover, the grip, the access to the shielded space for the waste reservoir and the means to introduce a radioactive liquid into a patient's body.

8. A device as claimed in Claim 7, characterized in that the lead cover for the reservoir consists of a lead vessel which is open at its top and which is enclosed between sheet material of iron or steel treated externally against corrosion, or of stainless steel, while the open top end accessible for the reservoir can be closed by means of a lead lid provided on its outside with the same sheet material, an aperture for a connection between the reservoir and the means for introducing a radioactive liquid into a patient's body being present in the lid or between the vessel and the lid.

9. A device as claimed in Claim 8, characterized in that a vessel of stainless steel which at its open top side comprises a radially outwardly projecting flange to which the lid can be sealingly connected, is present between the substantially lead vessel and the reservoir.

10. A shielding device as claimed in any of the Claims 7-9 for a radio-isotope generator, characterized in that there are additionally connected on or to the top part: a reservoir for an eluent for the generator column which communicates with the column; means for pumping or injecting the eluent out of the eluent reservoir into the column; means to bring the resulting eluate out of the column into a patient's body; means to add a rinsing or formulating liquid to the eluate; and a tube which is connected on one side to the means for adding the rinsing or formulating liquid and which comprises on the other side a member which can be connected to an auxiliary means to admit liquid to blood vessels or body cavities of a patient.

11. A device as claimed in Claim 10, characterized in that a connection and operating block or tray is connected to the top part, in which block are accomodated injection means for the eluent and the eluate, valves to prevent undesired directions of flow of liquids, cocks to enable or block the passage of liquids, and connection means for the means accomodated in the block both mutually

and to the tubes which are connected to the reservoirs, the column and the auxiliary means to be used for administering to a patient.

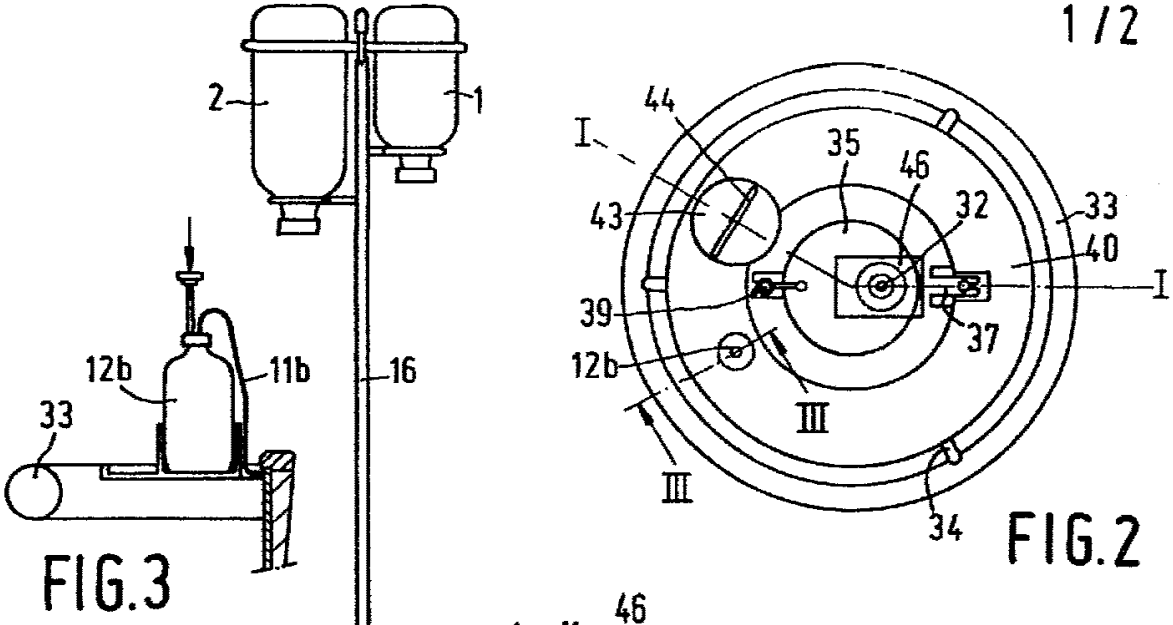


FIG.3

FIG.2

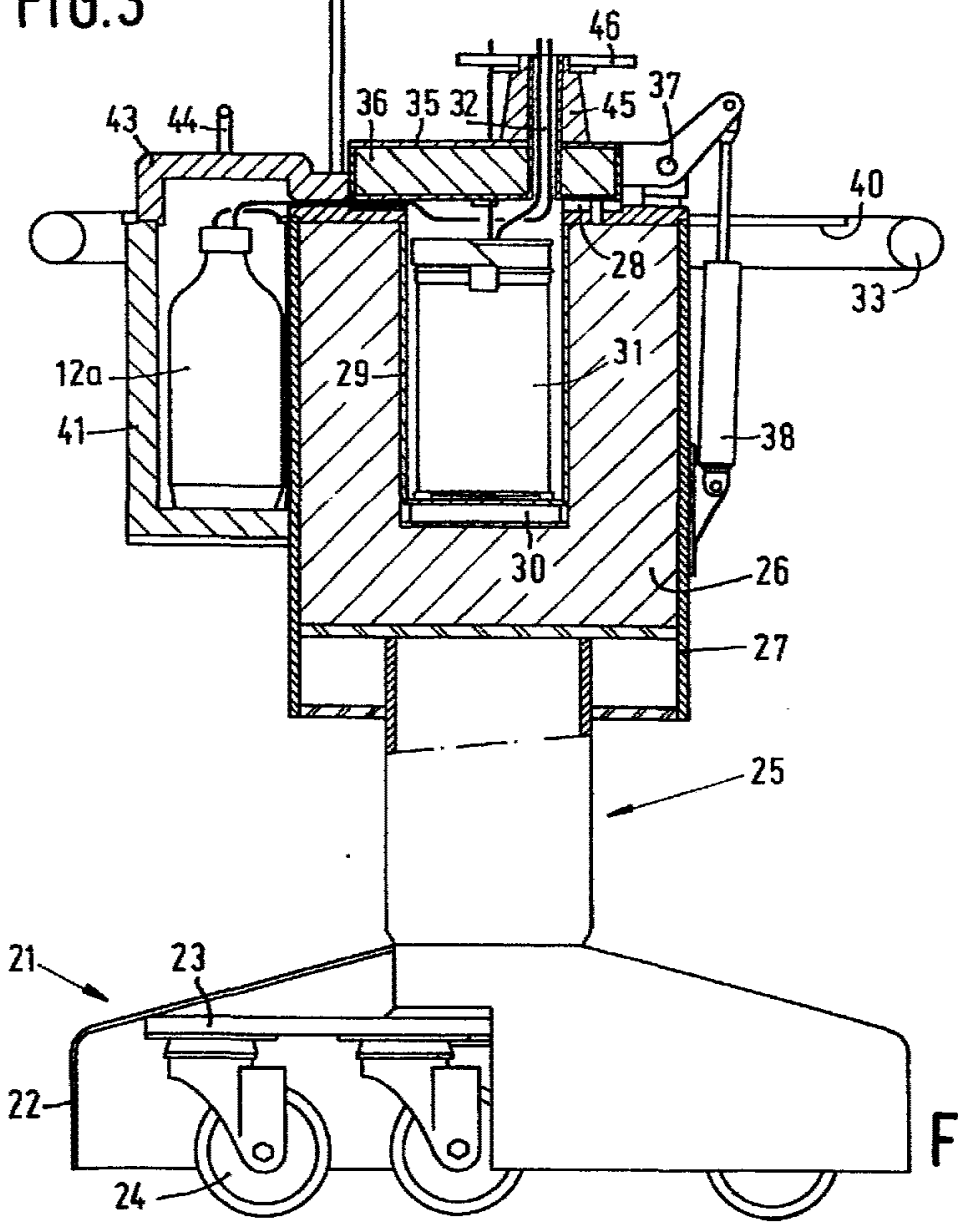


FIG.1

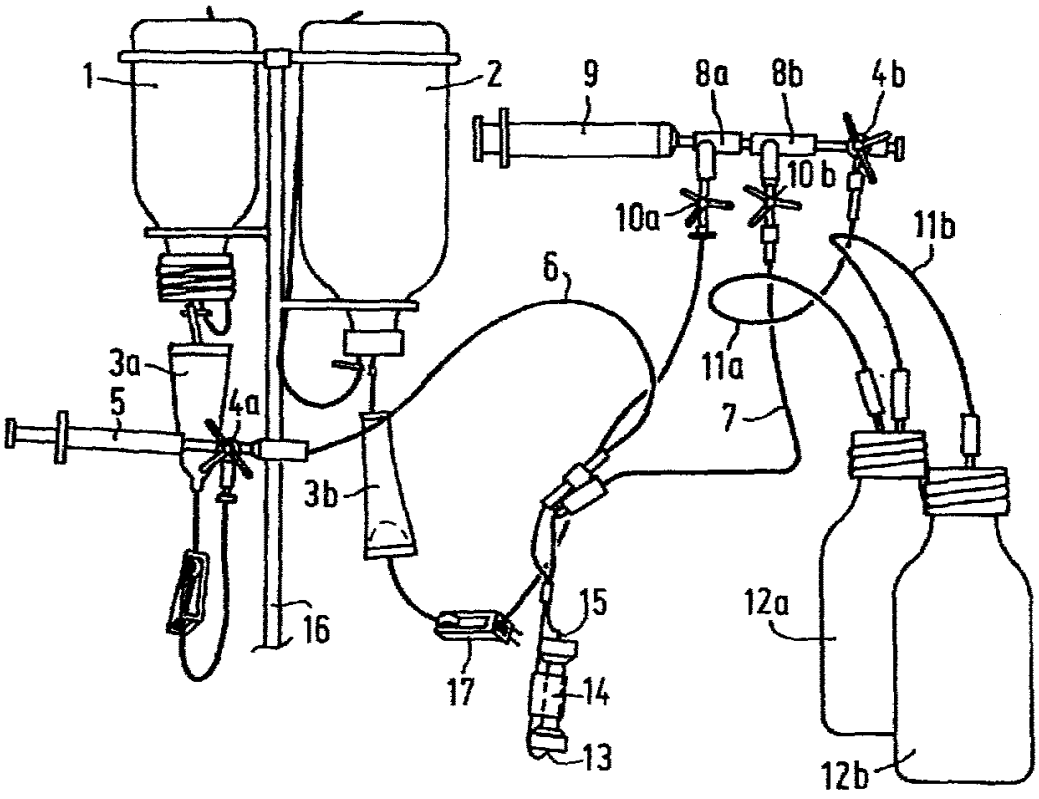


FIG. 4

European Patent Office

0102121

Application number

EP 83 20 1201

EUROPEAN SEARCH REPORT

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. ³)
A	GB-A-1 234 020 (C.E.A.) * Claim 1; figure 1; page 2, lines 83-90; page 3, lines 68-76 *	1,2,7	G 21 G 1/04
A	GB-A-2 033 288 (BYK MALLINCKRODT) * Claim 1; figure 1; page 3, lines 29-40 *	1,2	
A	US-A-3 710 118 (R.L. HOLGATE) * Claims 1,2 *	1,10	

TECHNICAL FIELDS SEARCHED (Int. Cl. ³)

G 21 G
G 21 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17-11-1983	NICOLAS H.J.F.

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
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO Form 1503. 03.82

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

(19) World Intellectual Property Organization
International Bureau

PCT

(43) International Publication Date
8 February 2007 (08.02.2007)

(10) International Publication Number
WO 2007/016170 A1

(51) International Patent Classification:
A61N 5/00 (2006.01) *G21G 4/08* (2006.01)
G21F 5/015 (2006.01)

(21) International Application Number:
PCT/US2006/029055

(22) International Filing Date: 26 July 2006 (26.07.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/702,927 27 July 2005 (27.07.2005) US

(71) Applicant *(for all designated States except US)*: **MALLINCKRODT INC.** [US/US]; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, Missouri 63134 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **FAGO, Frank** [US/US]; 4508 Estate Court, Mason, Ohio 45040 (US).

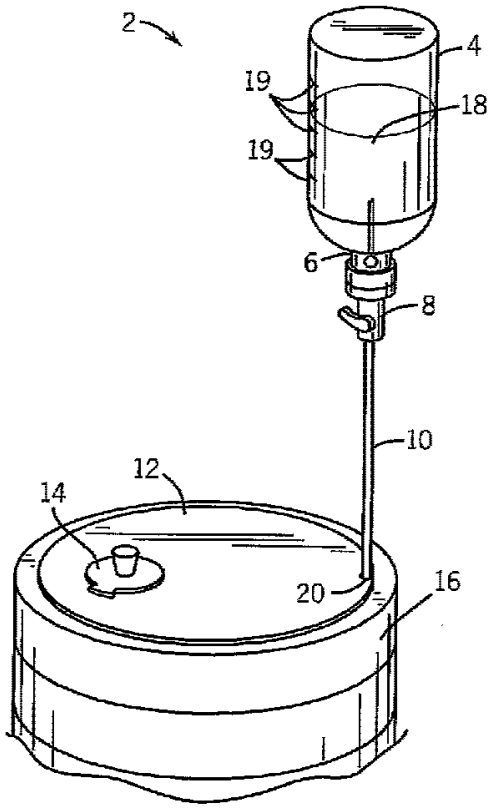
(74) Agents: **SEURER, Jerad, G.** et al.; Mallinckrodt Inc., 675 Mcdonnell Boulevard, P.O. Box 5840, St. Louis, Missouri 63134 (US).

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

[Continued on next page]

(54) Title: SYSTEM AND METHOD OF IDENTIFYING ELUANT AMOUNTS SUPPLIED TO A RADIOISOTOPE GENERATOR



(57) Abstract: The invention, is directed to a system including a shielded container (16) , a radioisotope generator disposed within the shielded container, and an elution supply mechanism. The elution supply mechanism may include an eluant supply container (4) at least partially external to the shielded container (16) , a conduit (10) extending between an inlet (20) of the radioisotope generator and an outlet (6, 8) of the eluant supply container, and an eluant visualization portal.

WO 2007/016170 A1

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, 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:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEM AND METHOD OF IDENTIFYING ELUANT AMOUNTS SUPPLIED TO A RADIOISOTOPE GENERATOR

FIELD OF THE INVENTION

[0001] The invention relates generally to the field of nuclear medicine. Specifically, the invention relates to a system and method of identifying an amount or flow of eluant in an elution system configured to enable extraction of a radioactive material from a radioisotope generator for use in the practice of nuclear medicine.

BACKGROUND

[0002] 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.

[0003] 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 the 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.

[0004] A variety of elution systems are used to generate radiopharmaceuticals. Unfortunately, radioactive shielding containers of these systems tend to block visualization of the state and progress of the elution process. For example, the amount of available eluant

and/or the amount of extracted eluate are generally unknown without opening one or more of the radioactive shielding containers. Rather, the pharmacist typically has to wait an estimated amount of time to ensure the process is complete, which results in wasted time or premature termination of the process. If a specific amount of eluate is desired, then the time estimation may tend to result in too much or too little of the eluate.

SUMMARY

[0005] The present invention, in certain embodiments, is directed to identifying or monitoring a volume, mass, weight, displacement or flow of a supply element (e.g., eluant) and/or an output eluate associated with eluting a radioisotope from a generator product in the field of nuclear medicine. Specifically, in some embodiments, visual access may be provided into an eluant supply container to facilitate performance of elution procedures. For example, a visual portal into an eluant supply container during an elution can provide data for measuring and calculating metrics relating to completion of full or partial elutions and data relating to when a generator is available for milking. Other embodiments may measure an amount or flow of eluant and/or eluate, such that a user can directly view the measurement (e.g., scale or flow meter) or indirectly view the measurement on a remote display screen or computer.

[0006] 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.

[0007] In accordance with a first aspect of the present invention, there is provided a system having a shielded container, a radioisotope generator disposed within the shielded container, and an elution supply mechanism. The elution supply mechanism has an eluant supply container at least partially (and in some cases, completely) external to the shielded container, a conduit extending between an inlet of the radioisotope generator and an outlet of the eluant supply container, and an eluant visualization portal.

[0008] In accordance with a second aspect of the present invention, there is provided a system that includes a radiation shielded container having a receptacle and a cover disposed over an opening in the receptacle, a radioisotope generator disposed within the receptacle below the cover, and an eluant supply mechanism. The eluant supply mechanism includes an eluant supply container and a conduit coupled with the eluant supply container and the

radioisotope generator. The conduit is disposed at least partially within the shielded container, and an eluant measurement device is coupled to the eluant supply mechanism.

[0009] A third aspect of the present invention is directed to a method of using a radioisotope elution system. With regard to this third aspect, a radioisotope generator that is disposed inside a radiation shielded container receives an amount of eluant. The amount of eluant received by the radioisotope generator is visually indicated outside the radiation shielded container. In addition, radioactive material is eluted from the radioisotope generator.

[0010] In accordance with a fourth aspect of the present invention, there is provided a system including an eluant supply mechanism and a radiation shielded lid having an aperture defined therein. The eluant supply mechanism includes an eluant supply container, a conduit coupled to the eluant supply container and at least partially disposed in the aperture, and an eluant measurement feature.

[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. 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 perspective view of an exemplary embodiment of a generator product including a visually accessible eluant supply bottle, a vented spike, a stop cock, tubing, a shielded lid, a shielded lid plug, and a shielded container;

[0014] FIG. 2 is a partial cross-sectional side view of an exemplary embodiment of the generator product, wherein the tubing may pass through an aperture defined along an edge of the lid and into the shielded container;

[0015] FIG. 3 is a top view of an exemplary embodiment of a portion of the generator product, wherein the lid may be mounted over an opening in the shielded container;

[0016] FIG. 4 is a cross-sectional side view of an exemplary embodiment of the generator product, wherein the tubing may be coupled to the generator via an inlet needle and the lid plug may be replaced by an elution assembly;

[0017] FIG. 5 is a partial perspective view of an exemplary embodiment of the generator product, wherein a syringe pump may be incorporated in the place of the eluant supply bottle;

[0018] FIG. 6 is a partial perspective view of an exemplary embodiment of the generator product, wherein a drip chamber may be incorporated in the tubing;

[0019] FIG. 7 is a partial perspective view of an exemplary embodiment of the generator product that may include the drip chamber, an electronic drop counter, a display, and a computer, wherein the electronic drop counter may be utilized to count the drops passing through the drip chamber;

[0020] FIG. 8 is a partial perspective view of an exemplary embodiment of the generator product, wherein the eluant supply may be utilized with a splitter or manifold to supply a plurality of generators, each disposed within a shielded container;

[0021] FIG. 9 is a partial perspective view of an exemplary embodiment of the generator product, wherein the eluant supply bottle may be at least partially shielded and may include a visualization window that facilitates viewing and measurement of eluant levels in the bottle, and wherein the drip chamber and drop counter may be disposed within the shielded container; and

[0022] FIG. 10 is a partial perspective view of an exemplary embodiment of the generator product, wherein the eluant supply bottle, the drip chamber, and the drop counter may be disposed within the shielded container, and wherein the display may be positioned external to the shielded container along with a portion of a level gauge coupled to the eluant supply bottle.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0023] 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.

[0024] The embodiments discussed in detail below relate to a system and method for facilitating efficient extraction of radioactive material (e.g., a radioisotope) from a radioisotope generator during a radioisotope elution process. Indeed, embodiments of the present invention facilitate efficient use of time and resources by providing direct or indirect visual access to an eluant supply and/or an eluate output during a radioisotope elution process. In other words, techniques are disclosed for identifying or tracking a volume, mass, weight, displacement, and/or flow of a supply eluant and/or an output eluate associated with eluting a radioisotope from a radioisotope generator via direct visualization or non-visual measurements that can be visualized remotely. As discussed below, these techniques may include a scale to monitor changes in weight of a supply eluant and/or an output eluate. Additionally or alternatively, these techniques may include a flow meter or displacement gauge, graduated volume marks on the supply and/or output container, and so forth.

[0025] FIG. 1 shows an exemplary embodiment of a generator product 2 that includes a visually accessible eluant supply container (here, a bottle) 4, a vented spike 6, a stop cock 8, tubing 10, a radioactivity shielded lid 12, a radioactivity shielded lid plug 14, and a radioactivity shielded container 16 (e.g., an auxiliary shield). In some embodiments, the lid plug 14 may be replaced by an elution assembly. It should be noted that the term "generator product" herein interchangeably refers to both a radioisotope elution system and/or a radioisotope generator assembly. A radioisotope generator assembly may include a radioisotope generator, a radioactivity shielded container, an eluant supply container, a radioactivity shielded lid, and a lid plug. A radioisotope elution system may include the radioisotope generator assembly, wherein the lid plug is replaced with an elution assembly that includes an eluate output container and an elution shield surrounding the eluate output container.

[0026] As illustrated in FIG. 1, the eluant supply container 4 may be entirely or at least partially transparent (or translucent) and external to the shielded container 16, thereby providing a visualization portal into the bottle 4. In some embodiments, the supply bottle 4 may be partially external and/or partially internal to the shielded container 16. The supply bottle 4 can be fully or partially composed of glass, hard plastic, soft plastic, and other appropriate material(s) that allow visual access. As such, a user can visualize eluant 18 disposed within the bottle 4. Because the eluant 18 is visible, a user can observe how much of it has been used during an elution process and/or how much of it remains after an elution process. For example, in the illustrated embodiment, a user can visually monitor the level of eluant in the bottle 4 with respect to index marks 19, which correspond to predefined metrics

(e.g., volume). This facilitates determination of when an elution process is complete. Further, if a partial elution (e.g., an elution to partially fill a standard sized eluate output container) is desired, visual access to the eluant supply may facilitate accurate performance of the partial elution. The eluant supply container 4 may be coupled to a generator disposed within the shielded container 16 via the tubing 10. Incidentally, "coupled" or the like herein generally refers to two or more components that are either directly or indirectly connected to one another. In this particular example, the coupling of the eluant supply container 4 and the generator may be characterized as a fluid coupling of those components. Incidentally, "fluidly coupling" or the like refers to a coupling of first and second components so that molecules of a substance(s) (such as a liquid or gas) may be substantially confined within and capable of flowing between the first and second components.

[0027] The tubing 10 can be a rigid or flexible conduit (e.g., flexible tubing or a needle) capable of enabling flow of the eluant 18 from the eluant supply container 4 to the generator. In some embodiments, the tubing 10 is transparent and/or translucent, which further facilitates observation of the eluant flow from the eluant supply 18 to the generator. The tubing 10 may be coupled to the eluant supply container 4 in any appropriate manner, such as via a stopcock 8 and a vented spike 6. In the illustrated embodiment, the eluant supply container 4 may be made of a generally rigid material that does not collapse as the eluant 18 is evacuated. Accordingly, the vented spike 6 may allow filtered air to enter into the bottle 4 to reduce the likelihood of a vacuum (e.g., a state of negative pressure) inside the bottle 4 when the eluant 18 flows out. In other embodiments, the eluant supply container 4 may be made of flexible material that collapses as it is evacuated with or without aid by the vented spike 6. The stopcock 8 may enable a user to regulate flow of the eluant 18 from the bottle 4 through the tubing 10 and into the generator. For example, the stopcock 8 may include a valve that opens and closes by means of a tapered plug, enabling a user to control flow of eluant 18 between the bottle 4 and the generator.

[0028] The tubing 10 may pass into the shielded container 16 through the lid 12 via an aperture 20 in the lid 12. In some embodiments, the aperture 20 may be formed in a central portion of the lid 12 and may include a nipple or other connection mechanism. However, in the illustrated embodiment, the aperture 20 is disposed along the circumference of the lid 12 such that a gap is formed between the edge of the lid 12 and the shielded container 16. The aperture 20 is illustrated in FIG. 2, which is a partial cross-sectional view of the generator product 2, wherein the tubing 10 passes through the aperture 20 disposed along the edge of the lid 10 and into the shielded container 16. Specifically, FIG. 2 illustrates the tubing 10 passing between the lid 10 and a top section of the shielded container 16 through the aperture 20 and coupling with a generator 22 via a coupling mechanism 24 (e.g., a needle, a nipple,

threaded fastener, flange, and/or the like). In some embodiments, the coupling mechanism 24 may include a check valve that reduces the likelihood of backflow of eluant and/or eluate from the generator 22 to the tubing 10 (and possible even the eluant supply container 4). In some embodiments, the tubing 10 may include a check valve disposed therein to reduce the likelihood of backflow from downstream tubing to upstream tubing and/or to the eluant supply container 4. It should be noted that in some embodiments, the tubing 10 may pass through an opening in the side of the shielded container 16. For example, in some embodiments, the tubing 10 may pass through an opening formed between sectional rings 26 that are stacked to form the shielded container 16.

[0029] FIG. 3 is a top view of a portion of the generator product 2, wherein the lid 12 is mounted over an opening in the shielded container 16. Specifically, FIG. 3 illustrates the aperture 20 disposed along an edge of the lid 12 and forming a gap between the lid 12 and the shielded container 16. As noted above, in some embodiments, the aperture 20 may be located in a generally central location on the lid 12 or in a side portion of the shielded container 16. In some embodiments, the aperture 20 and the tubing 10 may correspond in size so that the tubing 10 is tightly secured when engaged with the aperture 20. In other embodiments, the aperture 20 may be larger than the tubing 10, allowing maneuverability of the tubing 10 while it is engaged in the aperture 20. In still other embodiments, the tubing 10 includes one or more seals or the like that operate to secure the tubing 10 in the aperture 20 and prevent flow (e.g., air flow) in and out of the shielded container 16 through the aperture 20.

[0030] FIG. 4 is a cross-sectional side view of the generator product 2, wherein the tubing 10 is shown coupled to the generator 22 via a hollow inlet needle 28 and the lid plug 14 has been be replaced by an elution assembly 28. The illustrated elution assembly 28 includes an elution shield 32 at least generally disposed about an eluate collection bottle 34. The elution shield 32 is designed to shield users from radioactive elements that are received by elution into the bottle 34. The eluate collection bottle 34 may be coupled to the generator 22 via a hollow outlet needle 36. During a wet elution process (e.g., an elution process wherein the generator generally remains charged), the eluate collection bottle 34 may be coupled to the generator 22 to enable eluate residing in the generator 22 to circulate through the generator 22 and into the evacuated collection bottle 34. The generator 22 is a shielded container that holds a parent radioisotope, such as Molybdenum-99 absorbed to alumina beads or another suitable exchange medium. The daughter radioisotope (e.g., Technetium-99M) is held chemically less tightly than the parent, thereby enabling flowing eluant to flush the desired radioisotope from the radioisotope generator 22 into the collection bottle 34 as eluate.

[0031] The eluate collection bottle 34 may have a standard or predefined volume, which may begin in an evacuated condition. A pressure drop into the evacuated eluate collection bottle 34 may facilitate eluate residing in the generator 22 to begin filling the bottle 34. Correspondingly, eluant 18 from the eluant supply container 4 may begin flowing into the generator 22 to replace the eluate passing to the collection bottle 34. Indeed, once the eluate collection bottle 34 is connected to the generator 22, a user can observe that eluant levels in the eluant supply container 4 go down in an amount generally corresponding to the amount of eluate received in the eluate collection bottle 34. For example, a user can observe the volume of eluant 18 leaving the eluant supply container 4 by comparing the eluant level in the supply bottle 4 over time with the index marks 19. This visualization may tend to facilitate determining when the elution process is complete (e.g., the eluate collection bottle 34 is full), and/or may facilitate performance of partial elutions, in which the eluate collection bottle 34 is partially filled with eluate. It should be noted that in some embodiments, the eluate collection bottle 34 may not begin in an evacuated condition. For example, in some embodiments, other system conditions (e.g., generated pressure and/or gravity) may cause flow into the eluate collection bottle 34.

[0032] FIG. 5 illustrates an alternative embodiment of the generator product 2, wherein a graduated syringe pump 40 may be incorporated in the place of the eluant supply container 4. The syringe pump 40 is adapted to inject the eluant 18 into the generator 22 via the tubing 10. Because the syringe pump 40 generates pressure, an evacuated eluate collection bottle 34 may or may not be used in this embodiment. For example, a collection bottle 34 with a vent for expelling air may be used to collect the eluate. While the syringe pump 40 may drive the elution, the graduations or volumetric marks 19 may enable a user to measure and/or observe the amount of eluant injected into the generator 22. In other embodiments, other electrical and/or mechanical pumps and measurement systems may be used to supply and measure amounts of eluant supplied to the generator 22. For example, the system may include an electrical/mechanical scale, flow meter, and so forth. Moreover, the measurements may be visualized by a user directly or indirectly via a remote monitoring system, e.g., a computer. It should be noted that FIG. 5 also illustrates that the aperture 20 may be disposed in a generally central portion of the lid 12. Additionally, as shown in FIG. 5, the tubing 10 may be coupled to a nipple 42 that passes through the lid 12 and couples to the generator 22 within the shielded container 16.

[0033] FIG. 6 shows an exemplary embodiment of the generator product 2, wherein a drip chamber 44 is incorporated in the tubing 10 to facilitate tracking or identification of an amount of eluant flowing into the generator 22. The drip chamber 44 may facilitate measurement of the eluant passing between the eluant supply container 4 and the generator 22 in a variety of

ways. For example, an observer can manually calculate the amount of transferred eluant by counting the drops that pass through the drip chamber 44. For instance, thirty drops of the eluant may correspond to one milliliter of eluant. As another example, in the embodiment illustrated in FIG. 7, an electronic drop counter 46 may be utilized to count the drops passing through the drip chamber 44 by, for example, detecting motion in the drip chamber 44. In one embodiment, the drop counter 46 may include an infra-red light emitting diode (LED) 48 and a photo detector 50. The LED 48 and photo detector 50 are aligned such that the photo detector 50 receives a light beam from the LED 48. When a drop passes through the drop counter 46, it breaks the light beam and the drop counter 46 outputs and/or stores data corresponding to the break. This facilitates measurement of the number of drops and the provision of metrics relating to the amount of eluant being passed from the eluant supply container 4 through the drip chamber 44 and into the generator 22. Metrics can be calculated from the data retrieved by the drop counter 46 manually, in the drop counter 46 itself, or in other devices capable of receiving data and performing calculations.

[0034] As illustrated in FIG. 7, the drop counter 46 may be communicatively coupled to a display 52 for display of metrics relating to the elution process. The drop counter 46 may be coupled to an electronic device and/or computer 54 (e.g., a laptop computer) to store data, facilitate communication with other devices, and/or perform calculations relating to the elution process. It should be noted that in some embodiment, the display 52 may be incorporated into the computer 54. In other words, rather than having a separate display 52, a computer screen 56 of the computer 54 may be utilized for displaying data associated with the elution process. For example, a volume associated with the number of counted drops (e.g., thirty drops corresponds to one milliliter) can be calculated and displayed on the computer screen 56. A time associated with each counted drop can be displayed on the computer screen 56. The volume and/or time associated with each elution process may be tracked and displayed to enable a user (or the computer 54) to estimate when the generator will be ready for another elution process. For example, a value corresponding to an expected radioactivity level of an elution at a certain time can be calculated and displayed on the computer screen 56. By further example, a user (or the computer) can determine an actual radioactivity level of an eluate at a given time. The radioactivity level information can be programmed into the computer 54 if that information is not already in the computer, for example, which can incorporate other data (e.g., time data from the drop counter 46) to determine an expected radioactivity level at a specified future time. In some embodiments, a certain time when an elution should be performed, based on data from the drop counter 46 and/or predefined data (e.g., a calculated expected radioactivity level), can be calculated and displayed on the computer screen 56.

[0035] FIG. 8 shows another exemplary embodiment of the generator product 2, wherein the eluant supply container (here, a bag) 4 may be utilized with a manifold or splitter 60 to supply a plurality of generators 22, each disposed within a shielded container 16. As illustrated, this generator product 2 may have a variety of different measurement and visualization features that may complement or supplement one another. The single bulk supply of eluant (e.g., eluant supply container 4) may increase the likelihood that the individual generators 22 have sufficient eluant during individual or simultaneous operation. In addition, the total eluate output from all of the generators may be tracked or visualized by comparing the eluant level inside the bag 4 against the index marks 19.

[0036] Still referring to FIG. 8, the computer 54 may be coupled to each of a plurality of drop counters 46 and/or displays 52 that provide data relating to elution processes in each of the generators 22, thus enabling collection and provision of data relating to generator usage individually and/or collectively. For example, based on time stamped usage data and related calculations, the computer 54 may indicate that a particular generator 22 in a set of generators should be milked before the others based on a greater likelihood that it may produce an eluate with an appropriate and/or desired radioactivity level. Further, having a single source of eluant may facilitate rapid replacement of the eluant source (e.g., eluant supply container or bag 4) for multiple generators 22. It should be noted that in the embodiment illustrated in FIG. 8, the eluant supply container or bag 4 may be a transparent or translucent rigid container or a collapsible plastic bag with or without a vent to facilitate flow. Thus, the level of eluant may be directly visualized in the container or bag 4. In some embodiments, the container or bag 4 may be mounted on or hung from a scale 57 to measure weight changes in the container or bag 4 and, thus, track the amount of eluant flowing into the generators. For example, an initial weight of the container or bag 4 may be weighed as a reference, followed by a manual or electronic tracking of reduced weight of the container or bag 4. Alternatively, a separate scale 57 may be attached independently to each of a plurality of eluate supply containers for the generators 22.

[0037] FIG. 9 shows an exemplary embodiment of the generator product 2, wherein the eluant supply container 4 may be at least partially shielded and may include a visualization window 66 that facilitates viewing and measurement of eluant levels in the bottle 4. The window 66 may operate as a visualization portal, which may include index marks 19 that can operate as a measurement feature corresponding to volume or another metric. Further, the illustrated embodiment may include the drip chamber 44 and drop counter 46 disposed within the shielded container 16. Again, the drop counter 46 may be communicatively coupled to the display 52, which may be disposed on the outside of the shielded container 16 to facilitate visual access or identification of the eluant level. Indeed, because the display 52 provides

virtual visual access to the eluant supply, the eluant supply container 4 can be disposed within the shielded container, as illustrated by FIG. 10. It should be noted that in FIG. 10 additional access to the eluant level in the eluant supply container 4 may be provided by a level gauge 68 at least partially external to the shielded container. The level gauge 68 can be electronic (e.g., sensor, switches, and electronic display) or manual (e.g., sight glass, circular sight port, or float).

[0038] While the 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 system, comprising:

a radioactivity shielded container;

a radioisotope generator disposed within the radioactivity shielded container; and

an elution supply mechanism comprising:

an eluant supply container at least partially external to the radioactivity shielded container;

a conduit extending between an inlet of the radioisotope generator and an outlet of the eluant supply container; and

an eluant visualization portal.

2. The system of claim 1, wherein the elution supply mechanism comprises a drip chamber.

3. The system of claim 2, wherein the eluant visualization portal comprises a transparent or translucent portion of the drip chamber.

4. The system of claim 2, comprising a drop counter coupled to the drip chamber.

5. The system of claim 4, comprising an electronic measurement device communicatively coupled to the drop counter.

6. The system of claim 4, wherein the electronic measurement device comprises a computer.

7. The system of claim 1, wherein the radioactivity shielded container comprises a radioactivity shielded lid including an aperture having the conduit extending therethrough.

8. The system of claim 7, wherein the aperture is disposed along an edge of the radioactivity shielded lid.

9. The system of claim 1, wherein the radioactivity shielded container comprises a radioactivity shielded lid having a hollow nipple coupled to the conduit.

10. The system of claim 1, wherein the eluant visualization portal comprises a transparent or translucent portion of the eluant supply container having demarcations corresponding to levels of eluant in the eluant supply container.

11. The system of claim 1, wherein the outlet of the elution supply container comprises a conduit splitter coupled to the conduit and at least one other conduit that leads to a different radioisotope generator.

12. The system of claim 1, wherein the elution supply mechanism comprises a pump.

13. The system of claim 12, wherein the pump comprises an eluant measurement system.

14. A system, comprising:

a radiation shielded container comprising a receptacle and a cover disposed over an opening in the receptacle;

a radioisotope generator disposed within the receptacle; and

an eluant supply mechanism comprising:

an eluant supply container;

a conduit coupled with the eluant supply container and the radioisotope generator, the conduit disposed at least partially within the shielded container; and

an eluant measurement device coupled to the eluant supply mechanism.

15. The system of claim 14, wherein the cover includes an aperture having the conduit extending therethrough.

16. The system of claim 14, wherein the conduit comprises a length of flexible tubing.

17. The system of claim 14, wherein the conduit comprises a hollow needle.

18. The system of claim 14, wherein the eluant measurement device comprises an eluant level gauge coupled with the eluant supply container.

19. The system of claim 14, wherein the eluant measurement device comprises a drip chamber.

20. The system of claim 19, wherein the eluant measurement device comprises a drop counter coupled to the drip chamber.

21. The system of claim 14, wherein the eluant measurement device is at least partially disposed inside the radiation shielded container.

22. The system of claim 21, wherein the eluant measurement device comprises a drop counter disposed within the radiation shielded container.

23. The system of claim 14, comprising an electronic display disposed at least partially external to the radiation shielded container and coupled to the eluant measurement device.

24. The system of claim 14, wherein the eluant measurement device comprises a scale.

25. A method of operating a radioisotope elution system, comprising:

receiving an amount of eluant into a radioisotope generator disposed inside a radiation shielded container;

visually indicating an amount of the eluant received by the radioisotope generator, wherein the visually indicating occurs at a location outside the radiation shielded container; and

eluting radioactive material from the radioisotope generator.

26. The method of claim 25, comprising calculating a metric based on the amount of eluant received into the radioisotope generator.

27. The method of claim 26, comprising calculating a suggested time for performing a future elution based on the metric.

28. The method of claim 25, comprising creating a time stamp when the amount of eluant is received.

29. The method of claim 25, comprising measuring the amount of eluant received from within the radiation shielded container.

30. The method of claim 29, wherein measuring comprises counting drops of the eluant.

31. The method of claim 25, wherein visually indicating comprises electronically displaying a metric of the amount of eluant received.

32. The method of claim 25, wherein visually indicating comprises providing a visual line of sight to the eluant.

33. The method of claim 25, wherein measuring comprises weighing the eluant with a scale.

34. A system, comprising:

a radiation shielded lid comprising an aperture; and

an eluant supply mechanism comprising:

an eluant supply container;

a conduit coupled to the eluant supply container and at least partially disposed in the aperture; and

an eluant measurement feature.

35. The system of claim 34, wherein the eluant measurement feature comprises a drip chamber and an electronic drop counter coupled to the drip chamber.

36. The system of claim 34, wherein the eluant measurement feature comprises an eluant visualization portal.

37. The system of claim 34, wherein the eluant measurement feature comprise a scale.

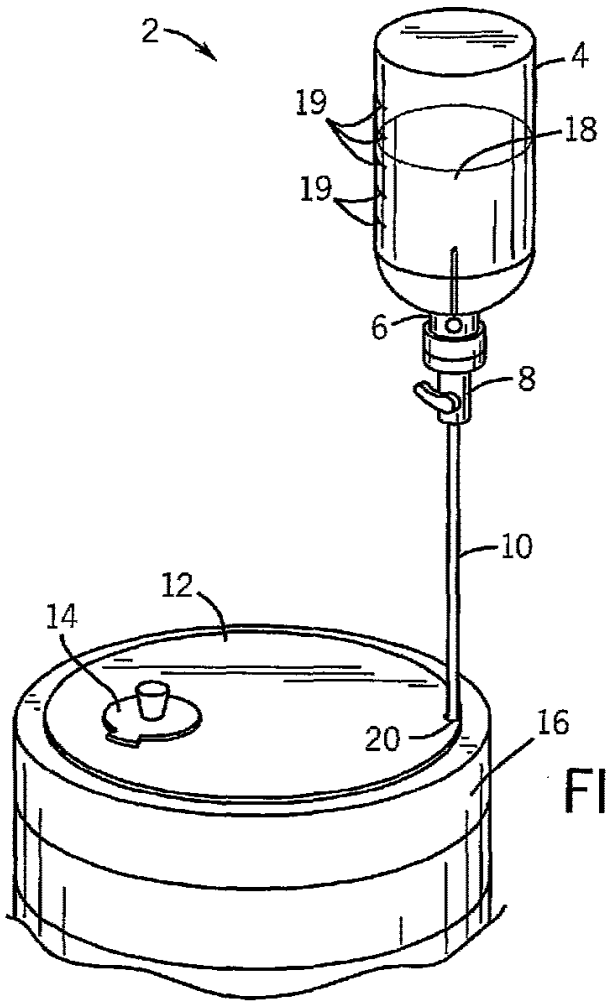


FIG. 1

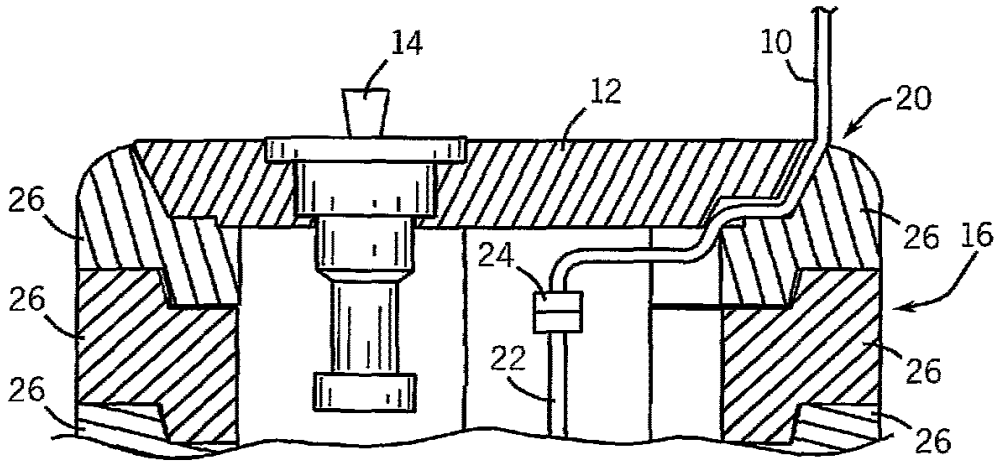


FIG. 2

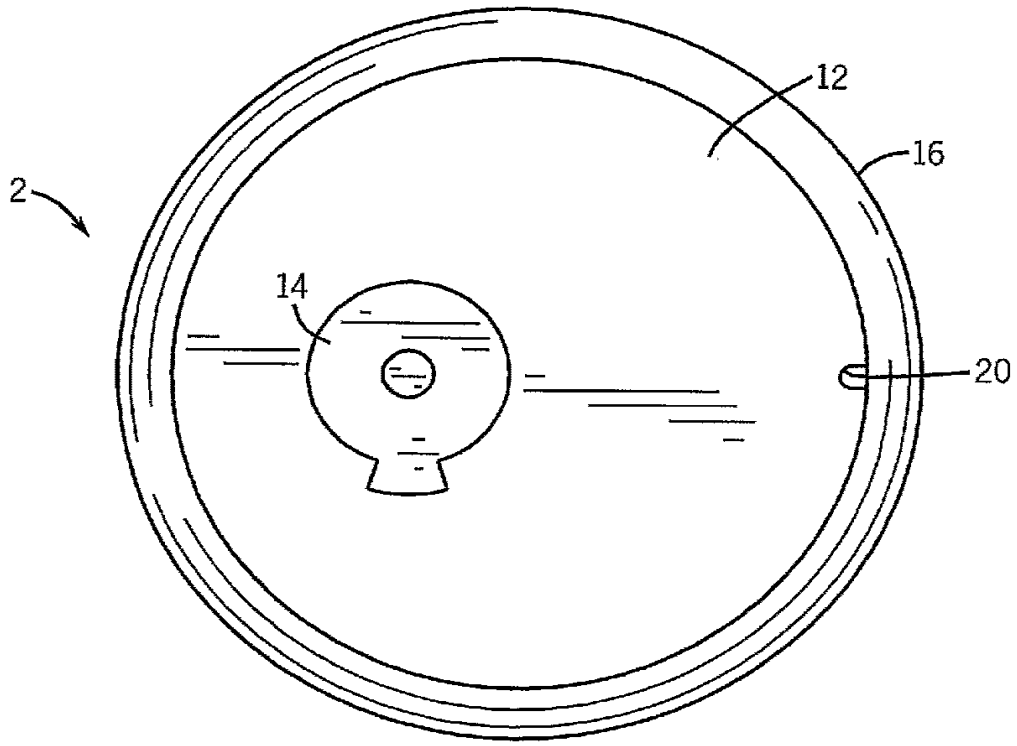


FIG. 3

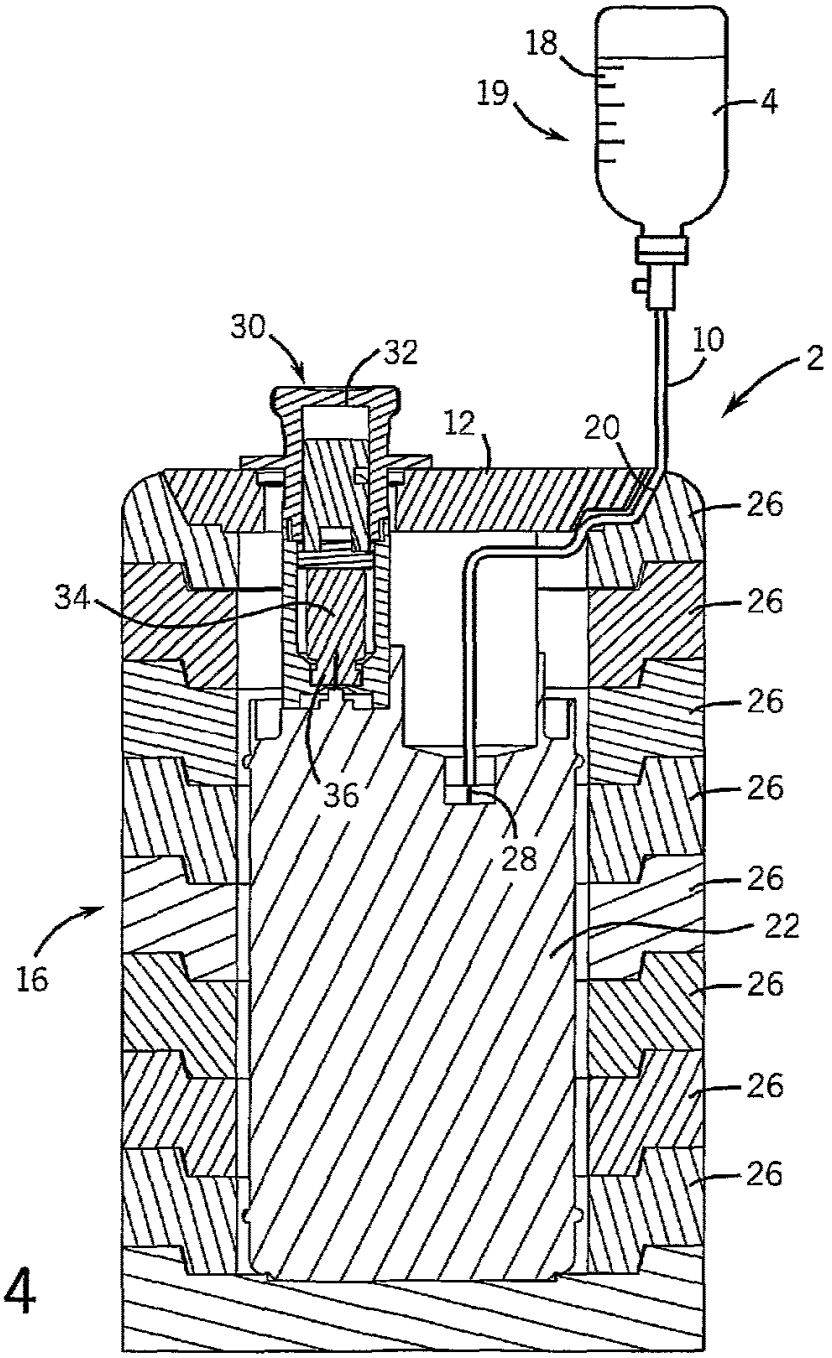
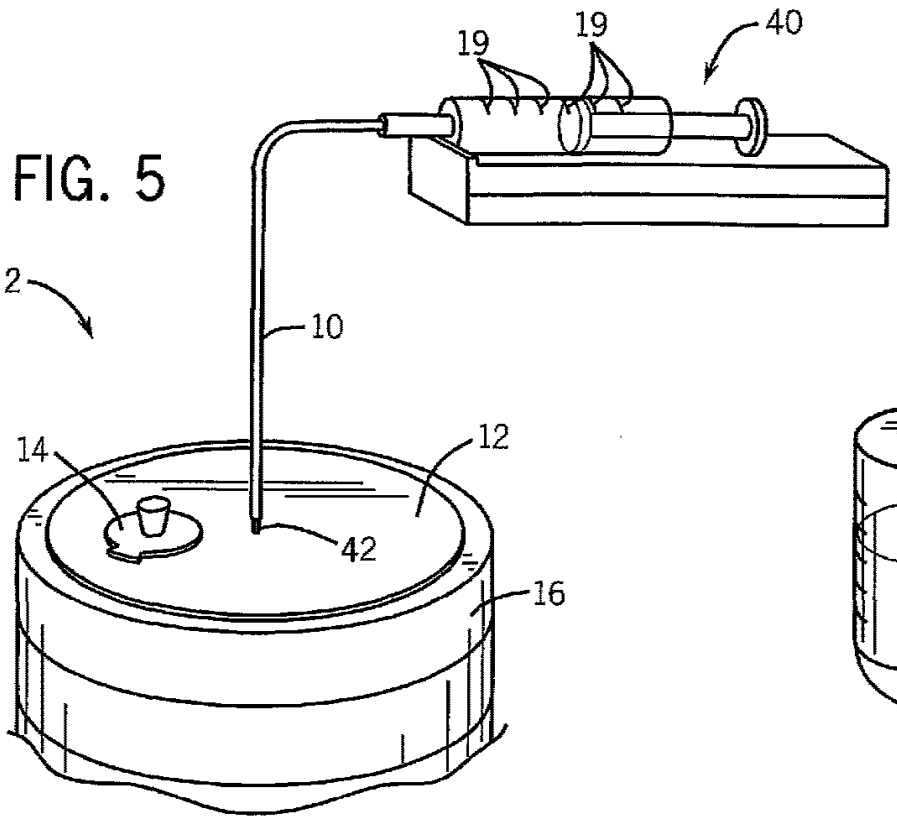


FIG. 4

FIG. 5



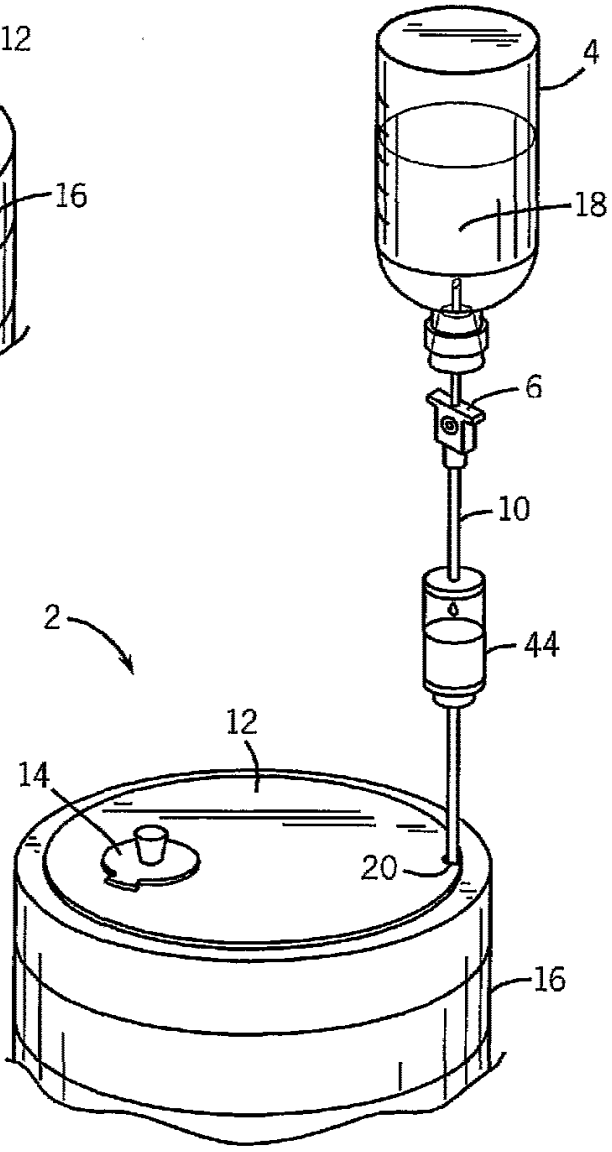


FIG. 6

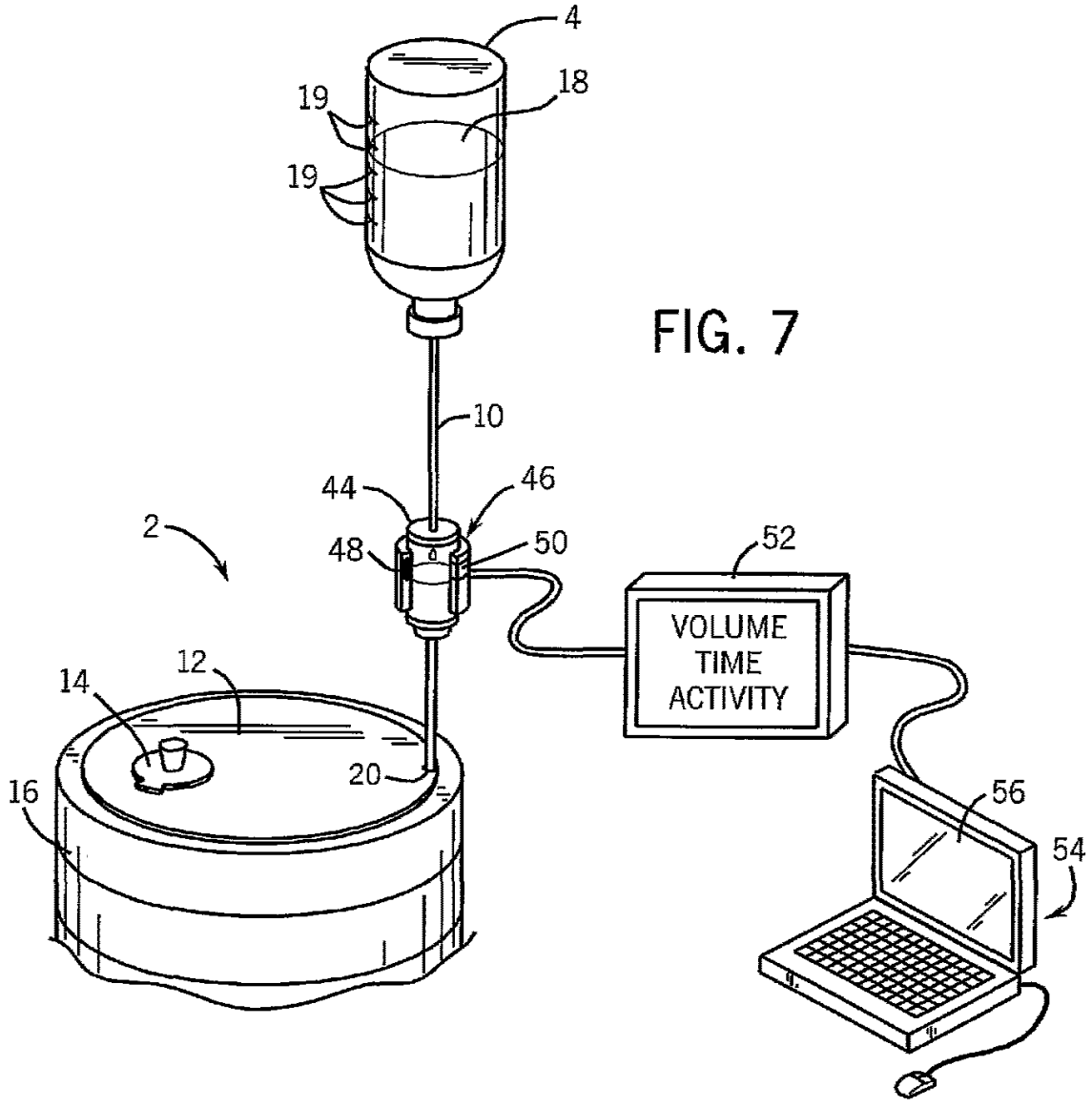

4
19
18
19
10
44
46
2
48
50
52
VOLUME
TIME
ACTIVITY
14
12
16
20
56
54

FIG. 7

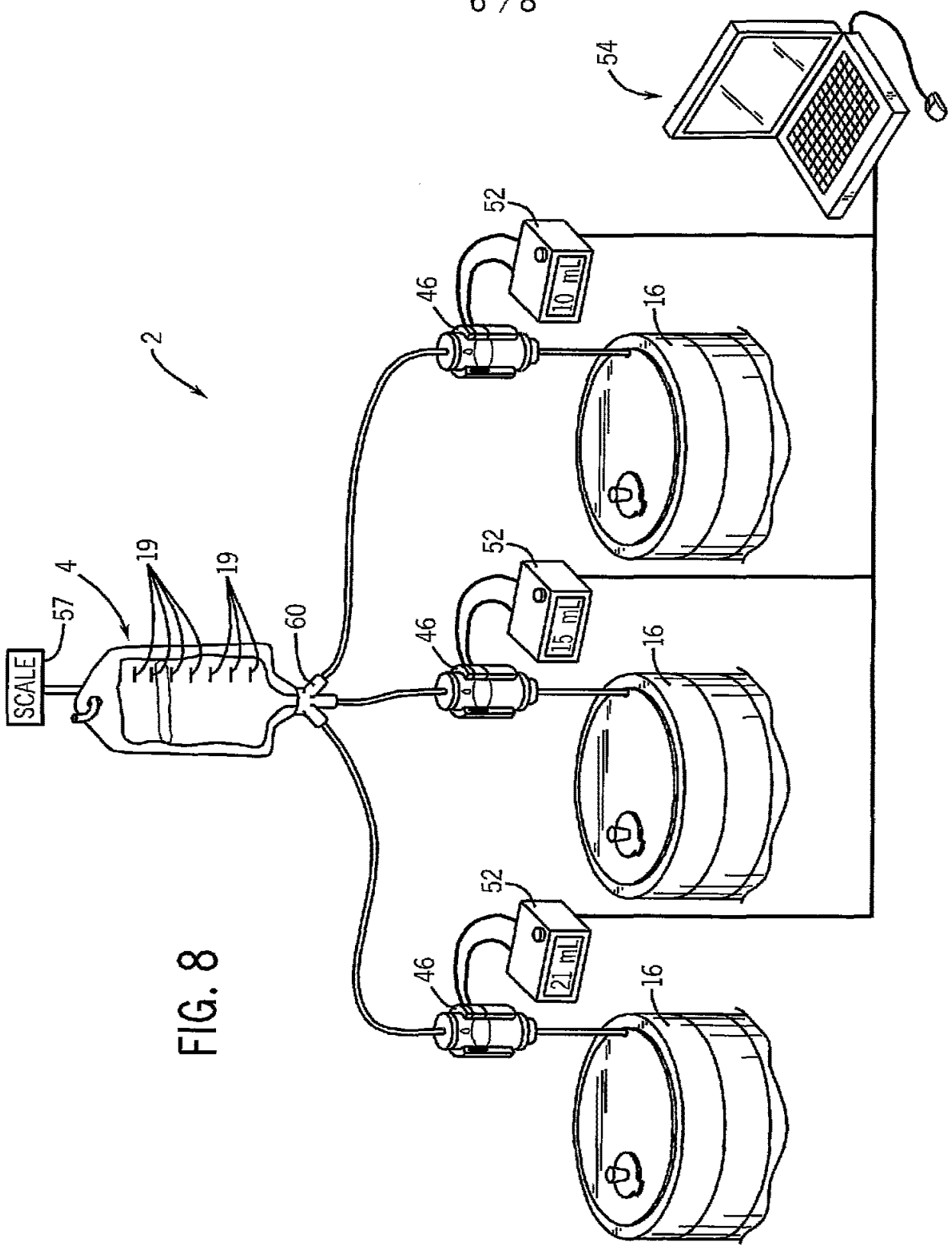


FIG. 8

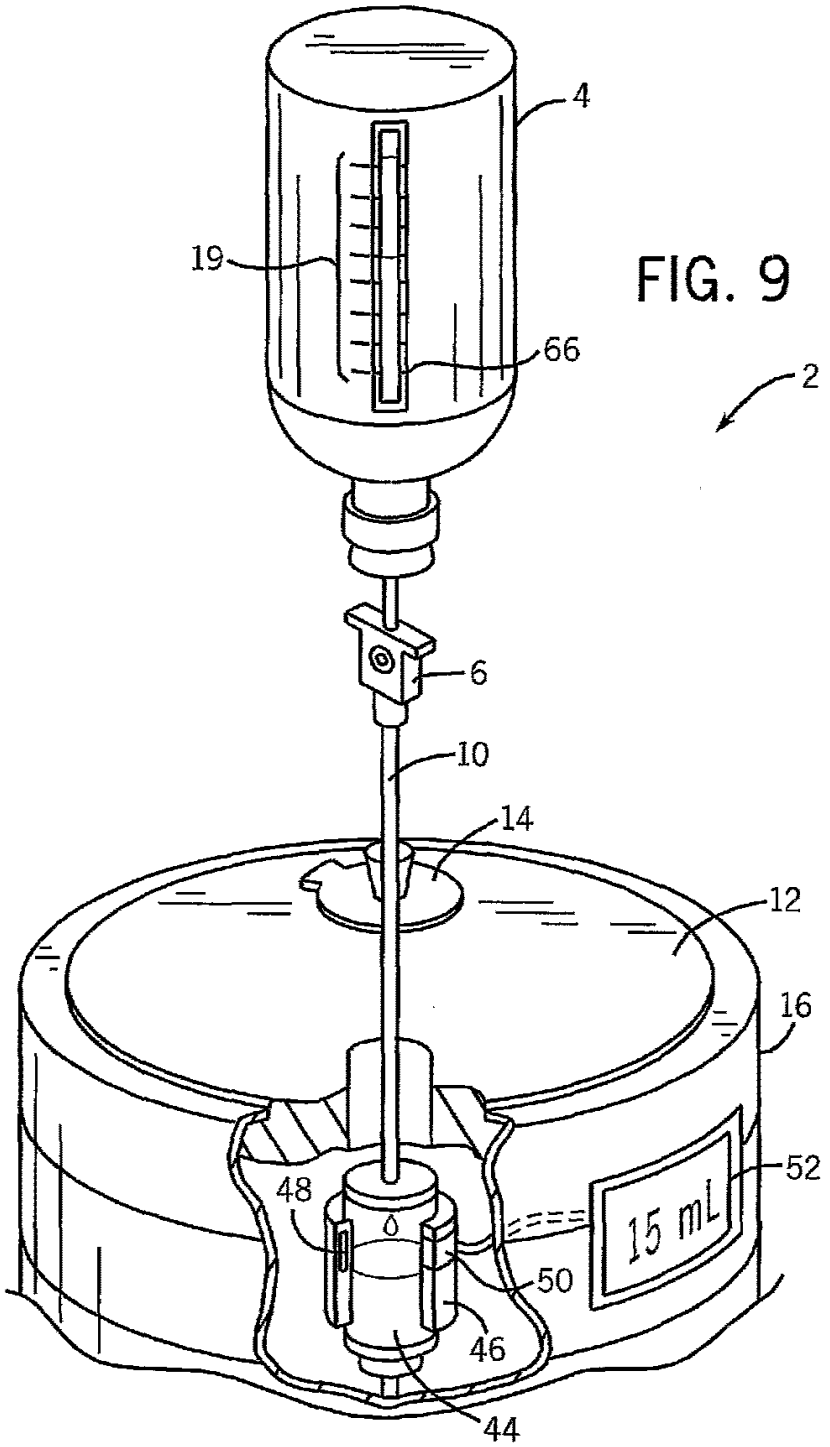


FIG. 9

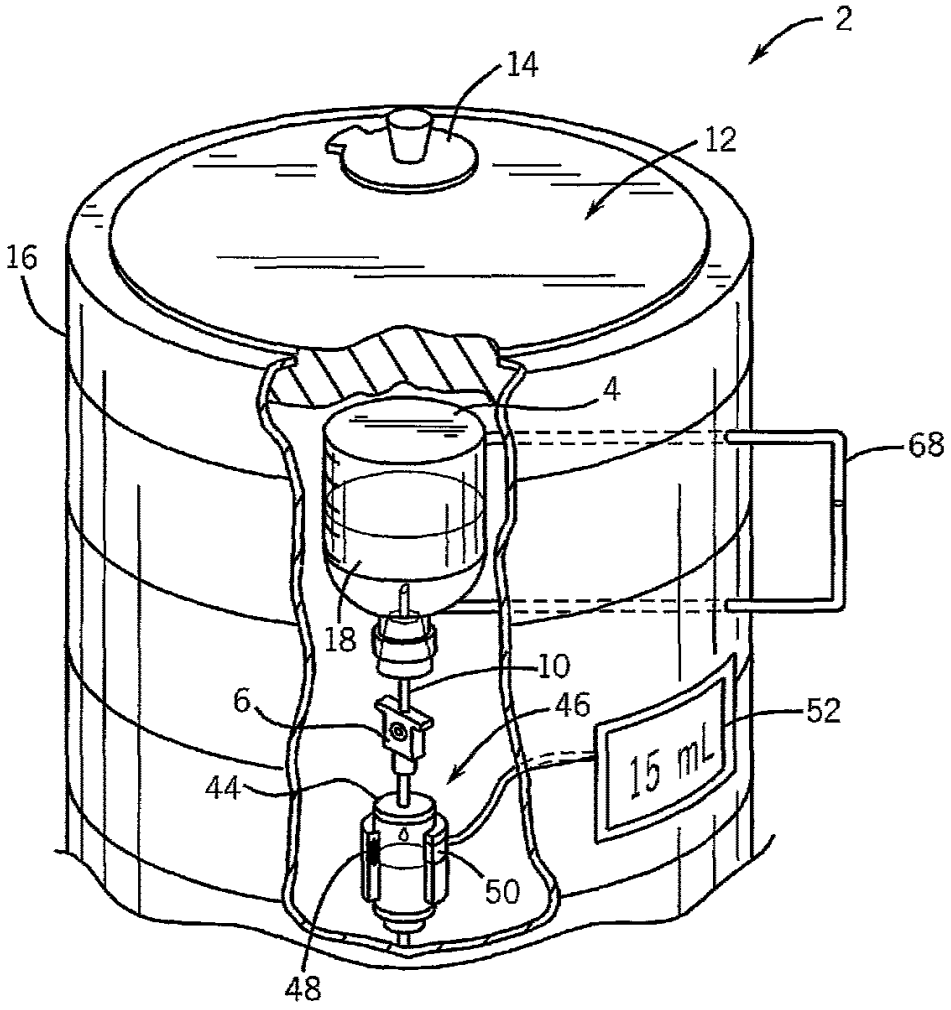


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/029055

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N5/00 G21F5/015 G21G4/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N G21F G21G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 102 121 A (BYK MALLINCKRODT CIL BV [NL]) 7 March 1984 (1984-03-07)	1-3, 7-10, 14-19, 24,25, 32,34, 36,37
Y	page 11, line 13 - line 32; figures 1,4	20,23, 31,35
Y	US 4 321 461 A (WALTER JR DAVID E ET AL) 23 March 1982 (1982-03-23) abstract; claims 1-14; figures 1,3	20,23, 31,35
X	US 3 774 036 A (GERHART J) 20 November 1973 (1973-11-20)	1,12,13, 25,32
Y	abstract; column 4, line 47 - line 49; claims 1,12; figures 1,4	1-3,7, 10,14-19

-/--

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 November 2006	05/12/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, Christopher

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/029055

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 03/069632 A2 (SIGMA TAU IND FARMACEUTI [IT]; PAGANELLI GIOVANNI [IT]; CHINOL MARCO [) 21 August 2003 (2003-08-21) page 3, line 13 - line 33; claims 1,7; figures 1-5	1-3,7, 10,14-19
A	EP 0 005 606 A (SHUKLA VISHNU SHANKER) 28 November 1979 (1979-11-28)	

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/029055

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-20, 23-26, 28, 31-32, 34-37

A splitter in the conduit coupled to at least one other radioisotope generator.

---

2. claims: 1-10, 12-26, 28-32, 34-37

A measurement device within the shielded container.

---

3. claims: 1-10, 12-20, 23-28, 31-32, 34-37

Calculation of a future elution time based on a metric.

---

4. claims: 1-10, 12-20, 23-26, 28, 31-37

Weiging the eluant with a scale.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/029055

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0102121	A	07-03-1984	NONE		
US 4321461	A	23-03-1982	NONE		
US 3774036	A	20-11-1973	NONE		
WO 03069632	A2	21-08-2003	AU	2003209692 A1	04-09-2003
			BR	0307561 A	11-01-2005
			CA	2472777 A1	21-08-2003
			CN	1630914 A	22-06-2005
			EP	1474809 A2	10-11-2004
			IT	RM20020071 A1	11-08-2003
			JP	2005517936 T	16-06-2005
			MX	PA04007693 A	10-11-2004
			US	2005154275 A1	14-07-2005
EP 0005606	A	28-11-1979	AU	4690379 A	15-11-1979
			US	4233973 A	18-11-1980

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 March 2007 (15.03.2007)

PCT

(10) International Publication Number
WO 2007/030249 A2

(51) International Patent Classification:
G21G 4/08 (2006.01) *B65B 3/00* (2006.01)

(21) International Application Number:
PCT/US2006/030766

(22) International Filing Date: 8 August 2006 (08.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/706,793 9 August 2005 (09.08.2005) US

(71) Applicant *(for all designated States except US)*: **MALLINCKRODT INC.** [US/US]; 675 Mcdonnell Boulevard, P.o. Box 5840, St. Louis, Missouri 63134 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **GIBSON, Chad, M.** [US/US]; 1533 Northview Avenue, Cincinnati, Ohio 45223 (US).

(74) Agents: **SEURER, Jerad, G.** et al.; Mallinckrodt Inc., 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, Missouri 63134 (US).

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2007/030249 A2

(54) Title: RADIOISOTOPE GENERATION SYSTEM HAVING PARTIAL ELUTION CAPABILITY

(57) Abstract: In a radioisotope generation system and method for dispensing a radioactive eluate, a radioisotope generator is operable to dispense the eluate. During dispensing, a monitoring system may monitor the dispensed amount of eluate and may generate a signal indicative of the amount of eluate dispensed. In particular embodiments, the monitoring system may generate a signal corresponding to the dispensing of a desired amount of eluate. The monitoring system may particularly monitor the level of fluid in a cavity or container into which the eluate is dispensed, the weight of the eluate dispensed, an elapsed time during which the eluate is dispensed, and/or other characteristic of the dispensed eluate, each of which may be corresponded to the amount of dispensed eluate. The system may be equipped with an interruption system that interrupts the dispensing of the eluate in response to the signal generated by the monitoring system.

RADIOISOTOPE GENERATION SYSTEM HAVING PARTIAL ELUTION CAPABILITY

FIELD OF THE INVENTION

The present invention relates generally to radioisotope generation systems, and more particularly to radioisotope generation systems that facilitate dispensing of a desired amount of eluate from a radioisotope generator.

BACKGROUND

Radioisotope generators are used to obtain a solution comprising a daughter radioisotope (e.g., technetium-99) from a parent radioisotope (e.g., molybdenum-99) which produces the daughter radioisotope by radioactive decay. One common radioisotope generator includes a column containing the parent radioisotope adsorbed on a carrier medium (e.g., alumina). The carrier medium has a relatively higher adsorptive capacity for the parent radioisotope and a relatively lower adsorptive capacity for the daughter radioisotope. As the parent radioisotope decays, a quantity of the desired daughter radioisotope is produced in the column. The column can be washed by passing a suitable eluant (e.g., a sterile saline solution) through the column such that the resulting eluate contains the daughter radioisotope (e.g., in the form of a dissolved salt), which makes the eluate useful in nuclear medicine. For example, the eluate may be adapted for intravenous administration for any of a variety of diagnostic and/or therapeutic procedures.

To obtain a quantity of the eluate from the generator, a container (e.g., a vial) may be connected to an outlet of the column at a tapping point of the generator to receive the eluate containing the daughter radioisotope. The container may be an evacuated container, in which case the partial vacuum in the container is used to draw eluant through the column from an eluant reservoir in fluid communication with an inlet to the column, thereby eluting the daughter radioisotope from the column. Using vacuum pressure in the container to draw eluate out of the generator avoids the need to pressurize the radioactive materials, as would be the result if the fluids were pumped through the column, thereby reducing the risk of accidental release of radioactive materials.

Another advantage of using vacuum pressure in the container to draw eluate out of the generator column is the elimination of the need for moving parts to cause the fluid flow. This may make the system more resistant to mechanical failure and may also render operation of the system relatively simple and clean. Because the eluate may be dispensed directly from the outlet of the generator column to the container, there is no need to clean an intermediate chamber/reservoir of the type used in some prior art systems (e.g., U.S. Patent No. 4,625,118). Unnecessary cleaning is not only undesirable from the standpoint of the cost (in materials and time) of the cleaning itself, but in some circumstances trace residues of cleaning chemicals can also have a negative impact of the yield from the system, as noted in

U.S. Patent No. 5,580,541. Thus, the simplicity of using vacuum pressure in an evacuated container to draw eluate from the generator directly into the container is desirable for a variety of reasons.

The same generator column may be used to fill a number of containers with eluate before the radioisotopes in the column are spent. The amount of eluate needed at any time may vary depending on the number of prescriptions that need to be filled by the radiopharmacy and/or the remaining concentration of radioisotopes in the generator column. One way to vary the amount of eluate drawn from the column is to vary the volume of the containers. For example, different sized containers having volumes ranging from about 5 mL to about 30 mL are common. In particular, standard elution vials having volumes of 5 mL, 10 mL, or 20 mL are currently available in the industry and may be used to facilitate dispensing of the corresponding amount of eluate from the generator column.

Unfortunately, the use of multiple different types of containers has significant disadvantages. For example, a radiopharmacy may use different labels, rubber stoppers, flanged metal caps, lead shields, and/or spacers to handle different sized containers, requiring the radiopharmacy to keep supplies of these items in stock for each type of container. Likewise, packaging for transport of the filled containers to healthcare facilities must also account for the different dimensions of the containers.

Another way to vary the amount of eluate dispensed to a container is to interrupt the elution process before the container is completely filled. For example, U.S. Pat. No. 4,387,303 discloses a system that permits an elution process to be interrupted before the container is completely filled. In particular, the radiopharmacist estimates when to interrupt the dispensing process based on a desire to only partially fill the container to a certain amount. The process is interrupted simply by manually removing the container from the generator tap. By interrupting the elution process at the right time, the container could be partially filled to obtain any desired amount of eluate equal to or less than the capacity of the vial. Another advantage of interrupting the elution process before a container is filled to capacity is that it is easier to draw the eluate from the container when it is not completely filled.

Unfortunately, it is not easy to identify the level of the eluate in a partially filled container. For instance, the container may be housed in a radiation shield that prevents visual inspection of the level of eluate in the container. Educated guesswork and/or trial and error are generally used to interrupt the elution based on an estimate of how much eluate is in the container. However, use of this method can easily lead to overfilling or underfilling of a container, both of which may result in undesirable inefficiencies. Even if it is possible for a person to visually monitor the level of eluate in the container (e.g., through a leaded glass window in the radiation shield), a person would have to dedicate some of his or her attention to monitoring the elution process to stop it at the right time. This would detract from the person's ability to do other things. Further, if the person were distracted, it would be easy to fill the container more than intended.

Thus, some may say there is a need for a radioisotope generation system that facilitates dispensing of a desired amount of eluate from a radioisotope generator.

SUMMARY

One aspect of the invention is directed to a radioisotope generation system for dispensing a radioactive eluate (i.e., an eluate including a radioisotope) into a container for holding such an eluate. A radioisotope generator of the system is operable to dispense the eluate into the container. While the eluate is being dispensed by the generator into the container, a monitoring system monitors the amount of eluate dispensed into the container and generates a signal indicative of the amount of eluate dispensed into the container.

Another aspect of the invention is directed to a radioisotope generation system having a radioisotope generator that is operable to dispense radioactive eluate. An elution shield of the system has an internal cavity for receiving the eluate dispensed from the generator and is constructed at least in part of a radiation-absorbing material. A monitoring system monitors the dispensing of eluate by the generator to the cavity of the shield and is operable to generate a signal in response to the dispensing of a desired amount of eluate into the cavity and/or the elapsing of a predetermined elapsed time during which eluate is dispensed into the cavity.

Still another aspect of the invention is directed to a radioisotope generation system that includes a radioisotope generator for dispensing radioactive eluate. This system also includes a dispensed eluate sensor that may be used to sense an amount of eluate that has been dispensed from the generator, and a signaling device that is communicatively connected with the sensor. Incidentally, "communicatively connected" or the like herein refers to a relationship of first and second components characterized in that at least an electrical signal can be conveyed at least from one of the components to the other.

Yet another aspect of the invention is directed to a method for dispensing a radioactive eluate. In this method, eluate is dispensed from a radioisotope generator into a container while the container and the generator are in fluid communication. Incidentally, "fluid communication" or the like herein refers to a relationship between at least first and second components of a system; this relationship being such that a substance(s) (e.g., a liquid and/or gas) may flow through the system at least from one of the components to the other. In any event, in this method, the dispensing of the eluate into the container is monitored (e.g., using one or more appropriate sensors). Further, a signal (e.g., visible and/or audible) indicative of an amount of eluate dispensed is provided.

Still yet another aspect of the invention is directed to a method of providing a radioactive eluate. In this method, eluate is dispensed from a radioisotope generator into a cavity of an elution shield. An amount of eluate in the cavity is monitored during at least a portion of the eluate being dispensed. A signal (e.g., visible and/or audible) is automatically generated in response to detecting a desired amount of eluate in the cavity and/or a passing of a predetermined elapsed time during which the eluate is dispensed.

In yet another aspect, the present invention is directed to a method of providing a radioactive eluate. In this method, eluate is dispensed from a radioisotope generator into a container while the container and the generator are in fluid communication. An amount of the eluate that is dispensed into

the container is determined, and a signal (e.g., visible and/or audible) is electronically triggered as a result of the amount of eluate that is determined (e.g., a threshold amount).

In still yet another aspect of the invention, an amount of radioactive eluate eluted from a radioisotope generation system in an elution procedure is determined. In addition, an electrical condition of the system is changed based on the amount of eluate that is determined to be eluted. By way of example, a change in electrical condition may refer to a closing and/or opening of an electrical circuit of the system. As another example, a change in electrical condition may refer to an alteration of an electrical signal between first and second components of the system. As still another example, a change in electrical condition may refer to a change in capacitance between first and second electrical conductors of the system.

Various refinements exist of the features noted in relation to the above-mentioned aspects of the present invention. Further features may also be incorporated in the above-mentioned aspects of the present invention as well. These refinements and additional features may exist individually or in any combination. For instance, various features discussed below in relation to any of the illustrated embodiments of the present invention may be incorporated into any of the aspects of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram of a radioisotope generation system according to one embodiment of the present invention;

Fig. 2 is an enlarged view of a portion of the system of Fig. 1 illustrating a monitoring system thereof;

Fig. 3 is a schematic diagram of a radioisotope generation system similar to the system of Fig. 1 but further having an automatic interruption system.

Fig. 4 is an enlarged schematic diagram of an alternative embodiment of the monitoring system of Figs. 1 and 3;

Fig. 5 is an enlarged schematic diagram of a monitoring system according to another alternative embodiment;

Fig. 6 is an enlarged schematic diagram of a monitoring system of still another alternative embodiment;

Fig. 7 is a schematic diagram of an alternative embodiment of a radiation generation system of the present invention; and

Fig. 8 is a schematic diagram of one embodiment of a selector useful with the radiation generation system of Figs. 1, 3 and 7.

Corresponding reference characters indicate corresponding parts throughout the drawings.

DETAILED DESCRITPTION OF ILLUSTRATED EMBODIMENTS

Referring now to the drawings, an in particular to Fig. 1, a radioisotope generation system of the present invention is generally designated 101. The system comprises a radioisotope generator having a column 103 containing a carrier, having a parent radioisotope (e.g., Molybdenum - 99) that decays into a daughter radioisotope (e.g., Technetium - 99m), adsorbed thereon. The generator column 103 may be enclosed in a conventional radiation-shield 105 as shown in the embodiment of Fig. 1. The generator column 103 has an inlet 107, which may be connected to an eluant reservoir 111 by a suitable inlet conduit 113. The column 103 also has an outlet 117 that may be connected to a tapping point 119 by a suitable outlet conduit 121.

The eluant reservoir 111 contains eluant (e.g., saline solution or other fluid capable of eluting the daughter radioisotope from the generator column), with the reservoir sized to contain enough eluant for multiple elutions. However, the eluant reservoir may alternatively be sized to contain no more eluant than is sufficient for a single elution without departing from the scope of the invention. The eluant reservoir may be a flexible (e.g., collapsible) bag or a substantially rigid container without departing from the scope of the invention. Where the container is rigid, a pressure relief system (e.g., a filtered vent to atmosphere) may be used so that withdrawal of eluant from the eluant reservoir does not create a vacuum in the eluant reservoir. The eluant reservoir 111 may be suitably mounted on the system 101 above the level of the generator column 103 as shown in Fig. 1.

The tapping point 119 may be constructed to allow a container 125 to be mounted thereon for fluid communication between the container and the generator column 103 via the outlet conduit 121. For example, in one embodiment (illustrated in Fig. 1) a hollow needle 127 capable of piercing a septum on the container 125 may be attached to the end of the outlet conduit 121 to serve as the tapping point. The system 101 may be configured so the tapping point 119 is above the level of the generator column 103 as in the illustrated embodiment. The system 101 may be configured so that the tapping point 119 is also at about the same level as the eluant reservoir 111.

The radioisotope generation system 101 may further comprise an elution shield 131 constructed to have an internal cavity 133 for receiving the eluate from the generator column 103 via the output conduit 121 and tapping point 119. In particular embodiments, the elution shield 131 may be constructed to house the container 125 within the internal cavity 133 thereof with the container connected to the generator at the tapping point as illustrated in Fig. 1. For example, the elution shield 131 shown in the drawings is constructed to have a cavity 133 sized and shaped to hold the container 125 and an opening 139 through which the needle 127 may be inserted to provide fluid communication between the container and the generator column 103 while the container is in the cavity. Other configurations of the radioisotope generation system are also contemplated to be within the scope of the invention, as long as the system is operable to dispense eluate to the cavity of the elution shield, and in particular embodiments to a container disposed in the cavity.

Fluid flow through the system 101 may be suitably controlled by one or more valves. For example, the system 101 may include at least one pinch valve 141, which is operable to selectively block the flow of eluate through the outlet conduit 121 to the container 125 (broadly, the internal cavity 133 of the elution shield 131). The pinch valve 141 may in part define an interruption system of the type described in U.S. Patent No. 4,387,303, which is hereby incorporated by reference to the extent it is consistent, for allowing the flow of eluate to from the generator column 103 to the container 125 to be interrupted before the container is filled to its maximum volume. The term "maximum volume" as used in reference to the container 125 refers to that volume to which an evacuated container would be filled if the elution process were allowed to proceed until the pressure in the container increased enough to stop the inflow of fluids.

The elution shield 131 may comprise one or more radiation-absorbing materials (e.g., lead, tungsten, depleted uranium, etc.) to protect workers from radiation emitted by the eluate after it is received in the container 125. Those skilled in the art will know how to construct an elution shield having a sufficient amount of radiation-absorbing material in view of the type and amount of radiation expected to provide a desired level of protection against radiation exposure. The elution shield 131 may be substantially opaque, as indicated in the drawings, which inhibits manual monitoring of the amount of eluate in the container 125. However, the present invention is not limited to generation systems having opaque elution shields. Accordingly, an elution shield having a viewing window (e.g., leaded glass window) that allows viewing of the contents of the elution shield is contemplated to be within the scope of the invention.

The generation system 101 also comprises a monitoring system 151 capable of automatically monitoring the dispensing of eluate from the generator column 103 to the container 125, e.g., to monitor the amount of eluate dispensed into the container (broadly, into the cavity 133). The monitoring system 151 may generally be any system operable to automatically determine (e.g., sense, measure, meter, calculate, or otherwise gauge) the amount of eluate in the container 125 as eluate is dispensed from the generator column 103 into the container. For example, a radioisotope generation system may include a dispensed eluate sensor capable of determining the amount of eluate eluted from a generator communicatively connected to a signaling device. The dispensed eluate sensor may be a component of the elution shield 131, associated with other components of a radioisotope generation system or even be characterized as a component of the system in and of itself. It is contemplated that the monitoring system 151 may be operable to monitor the dispensing of eluate on a substantially continuous basis or on an intermittent basis.

Referring to Fig. 2, one embodiment of a suitable monitoring system comprises a liquid level sensor 161 capable of detecting the level of the eluate in the container 125. For example, an infrared LED 163 and corresponding infrared detector 165 (e.g., photo diode) may be mounted inside the cavity 133 of the elution shield 131 in spaced relation to one another. The LED 163 (upon operation of the monitoring system) emits light (e.g., infrared light) which reflects off the upper surface 167 of the

liquid back to the detector 165. Data from the detector 165 is transmitted (e.g., by hardwiring or wireless transmission) to a suitable processor 171 having circuitry and/or software enabling it to determine the path length of the reflected light based on the data, and thereby to determine the fluid level of the eluate in the container 125 as a function of the path length of the reflected light. The teachings disclosed in U.S. Patent No. 5,291,031, which is hereby incorporated by reference to the extent it is consistent, may be used to construct a suitable processor capable of measuring the path length of the reflected light. It is contemplated that the container may be configured (e.g., contoured) to alter the path of light from the LED 163 to the upper surface 167 of the liquid and/or from the upper surface of the liquid to the infrared detector 165 to facilitate operation of level sensor 161. For example, the container may focus the light in a manner analogous to a lens. It is also contemplated that one or more lenses that are distinct from the container may be used to focus the light. Further, the use of the level sensor 161 without any lenses and/or with a container that is not configured to modify the path of light in any particular way is within the scope of the invention.

The fluid level in the container 125 corresponds to the amount of eluate in the container. Accordingly, the processor 171 (Fig. 1) is also capable of determining the corresponding amount of eluate in the container 125 based at least in part on the determined fluid level in the container. In particular embodiments, the processor 171 may further compare the determined amount of eluate in the container 125 to a desired amount of eluate to be dispensed into the container.

The monitoring system 151 is further operable to generate a signal once it determines that a desired amount of eluate has been received by (e.g., dispensed into) the container 125 (broadly, the internal cavity 133 of the elution shield 131). In one embodiment, the signal may be perceptible exterior of the elution shield 131, and in particular it may be perceptible to humans (such as radiopharmacists or other operators of the generation system). For example, the signal may be a light (broadly, a visual signal) or noise (broadly, an audible signal) perceptible to workers to alert them that it is time to interrupt the elution process. The monitoring system 151 illustrated in Figs. 1 and 2, for instance, comprises a piezoelectric speaker 175 (broadly, a signaling device) activated by the processor 171 once the processor determines that the desired amount of eluate has been dispensed into the container 125 to make an audible noise perceptible to a worker in the vicinity. The signaling device may be a component of the elution shield 131, as indicated for example by connection of the piezoelectric speaker 175 to the elution shield in Fig. 2. In some embodiments, the processor 117 may function as a signaling device and may be operable to change an electrical condition of the system (e.g., open and/or close a circuit of the system, change a voltage applied to one or more components of the system, etc.) in a manner that is in and of itself imperceptible to unaided humans, although such a change in an electrical condition of the system by the processor may ultimately produce a tangible result (e.g., activation of an interruption system as described below) that may be perceptible to humans, if any are in a position to observe the result.

The generation system 101 may also comprise a selector in communication with the processor 171 and operable to allow a user to pre-select (e.g. prior to operation of the radioisotope generator to dispense eluate into the container) the desired amount of eluate to be dispensed into the container 125. Virtually any device capable of providing user input to the processor 171 can be used as the selector. For example, the selector may comprise a hall effect sensor dial 181 as illustrated in Fig. 8, a set of buttons, a potentiometer, a touch screen display, a computer terminal, or the like. The selector may be operable to allow the user to pre-select the desired amount of eluate from a set of predetermined desired amounts. For example, in the illustrated embodiment of Fig. 8, the hall effect sensor dial has indicia 183 that indicates the desired amount of eluate to be dispensed and a set of magnetic elements 185 and hall effect sensors 187 positioned to determine which of the indicia is aligned with a fixed marking 189 (e.g., a selection arrow). In other embodiments, the selector may instead be operable to allow the user to select any desired amount of eluate within a range of permissible amounts. For example, the selector may allow the user to select a set amount of eluate, or the selector may allow the user to select a certain fill percentage (e.g., 25%, 50%, etc.) of the container.

It is understood that the system 101 may also permit the user to opt to fill the container 125 to its maximum volume, such as by including on the selector a setting for disabling the monitoring system 151 or selecting a desired amount of eluate about equal to the maximum volume of the container. It may be more desirable to stop the dispensing just before the container 125 is filled to its maximum volume (e.g., to facilitate piercing the septum of the container to draw eluate into a syringe) rather than disable the monitoring system 151.

According to one embodiment of a method of the present invention for dispensing a desired amount of eluate to the container 125 (broadly, the cavity 133 of the elution shield 131), a user uses the selector to pre-select a desired amount of eluate to be dispensed from the generator column 103 into the container. An evacuated container 125 may be loaded into the elution shield 131 and connected to the generator column 103 by insertion of the needle 127 through a septum of the container. The pinch valve 141 may be opened (if it was initially closed) such that the vacuum pressure in the container 125 induces the eluant to flow from the eluant reservoir 111, through the inlet conduit 113 and into generator column 103 while eluate comprising the desired daughter radioisotope flows out of the generator column, through the outlet conduit 121, and into the cavity 133, and in the illustrated embodiment into the container. The vacuum pressure in the evacuated container 125 may induce the flow without pressurizing either the eluant or eluate above atmospheric pressure.

The monitoring system 151 monitors the dispensing of eluate into the container 125. For example, for the embodiment illustrated in Figs. 1 and 2, the infrared LED 163 may emit light that is detected by the detector 165 after reflecting off of the upper surface 167 of the eluate in the container 125. The processor 171 determines the amount of eluate in the container 125 based on the fluid level data it receives from the detector 165. When the processor 171 determines that the amount of eluate in the container 125 is in a range from about equal to through greater than the pre-selected desired amount

of eluate, the processor activates the piezoelectric speaker 175 (e.g., by changing a voltage applied to one or more electrodes of the piezoelectric speaker) to produce an audible signal. The processor 117 may activate the piezoelectric speaker when it determines a threshold amount of eluate has been eluted from the generator 103. In one embodiment, the processor 117 activates the piezoelectric speaker just before the amount of eluate in the container reaches the desired amount of eluate to account for the expected delay between activation of the speaker 175 and manual interruption of the elution process.

A person in the vicinity of the radioisotope generation system 101 (e.g., a radiopharmacist or other worker) may perceive the signal (e.g., see in the case of a visual signal and/or hear in the case of an audible signal) from the monitoring system 151 and thereby be alerted to the fact that the desired quantity of eluate has been dispensed into the container 125. The person may then interrupt the flow of eluate into the container 125 (e.g., by manually closing the pinch valve 141 and/or by disconnecting the container 125 from the outlet conduit 121). After the radioisotope generation process is complete, the user may use the selector to change the desired amount of eluate to a different amount and repeat the process to obtain a different amount of eluate in another container.

With reference now to Fig. 3, in another embodiment of a radioisotope generation system 201 of the present invention the system may further comprise an interruption system operable to automatically (as opposed to manually) interrupt the dispensing of eluate into the container 125 in response to an electronic signal generated by the monitoring system 151 once the determined amount of eluate in the container is approximately equal to the desired amount of eluate. For example, the processor 117 may alter an electrical condition of the system (e.g., open and/or close a circuit of the system, change a voltage applied to a component of the system, etc.) to activate the interruption system. It is understood that the electronic signal generated by the monitoring system 151 to activate the interruption system may be instead of, or in addition to, a signal that is perceptible exterior of the elution shield 131 (e.g., an audible or visible signal).

The interruption system may comprise a valve actuator 209 operable to close the pinch valve 141 in response to the signal from the monitoring system 151. Other suitable interruption systems may comprise an actuator (not shown) operable to disconnect the container 125 from the generator column 103 by withdrawing the needle 127 from the container in response to the signal from the monitoring system 151, such as by movement of the container, movement of the needle, or both. Construction and operation of the generation system 201 of Fig. 3 is otherwise substantially the same as the construction and operation of the system 101 of Fig. 1.

It is understood that suitable monitoring systems other than that illustrated in Figs. 1-3 and described previously may be used without departing from the scope of this invention. For example, Fig. 4 illustrates a portion 351 of one alternative embodiment of a suitable monitoring system comprising an ultrasonic liquid level sensor 361 having an ultrasonic transmitter and receiver (e.g., a resonator 363 that transits ultrasound in an active mode and receives ultrasound in a passive mode) mounted in the cavity 133 of the elution shield 131. Operation of the liquid level sensor 361 shown in

Fig. 4 involves emitting ultrasonic energy (e.g., a burst or chirp) from the transmitter 363 and detecting the echo of the ultrasonic energy reflecting off the fluid level surface 167 of the eluate. Data from the ultrasonic detector 363 may be transmitted (by wire or wirelessly) to the processor 171 whereby the processor determines the level of the eluate based on the data relating to the echo. The processor 171 may determine the amount of eluate in the container 125 (broadly, the cavity 133 of the elution shield 131) based at least in part on the determined fluid level of the eluate.

Another embodiment of a suitable monitoring system 451 is illustrated in part in Fig. 5. Such a monitoring system 451 comprises an inductive liquid level sensor 461. The inductive sensor comprises a conductive coil 463 turning about at least a part of the cavity 133 of the elution shield 131, and in the illustrated embodiment about the outer surface of the container 125 within the cavity. The inductance of the coil 463 may vary depending on the fluid level of eluate in the container 125. Operation of the monitoring system 451 of Fig. 5 may include measuring the inductance of the coil 463 and using the processor 171 to determine the level of eluate in the container 125 based on the inductance of the coil. Similarly, a capacitive sensor (not shown) comprising a pair of parallel conductors in opposing relation to one another may be positioned in the cavity so that the capacitance of the conductors varies depending of the level or eluate in the container 125, in which case the monitoring may include measuring the capacitance of the conductors and using the processor 171 to determine the level of eluate as a function thereof. As in previous embodiments, the fluid level of eluate corresponds to the amount of eluate in the container 125 (broadly, the cavity 133).

Fig. 6 illustrates part of yet another embodiment of a suitable monitoring system 551 in which the monitoring system comprises one or more pressure sensors 563 operable to determine the weight of the eluate in the container 125 (broadly, the cavity 133). For example, a pressure sensor 563 may be positioned in the cavity 133 of the elution shield 131 with the weight of the container 125 bearing down against the sensor. Data from the pressure sensor 563 may be sent to the processor 171, which correlates the pressure exerted on the pressure sensor to the weight of eluate in the container 125. The weight of the eluate corresponds to the amount of eluate in the container 125. A system incorporating the monitoring system 551 of Fig. 6 may otherwise operate substantially the same as the systems 101, 201 shown in Figs. 1-3.

Fig. 7 illustrates another embodiment of a radioisotope generation system 601 of the present invention similar to the systems of Figs. 1 and 3. The monitoring system of this embodiment, however, comprises a timer 691 operable to monitor an elapsed time during which eluate is dispensed from the generator column 103 into the container 125 (broadly, the cavity 133 of the elution shield 131). In particular, the elapsed time may be monitored relative to the time at which dispensing of eluate into the container 125 is initiated. The timer 691 can be used to gauge the amount of eluate dispensed into the container 125 based on previously calibrated data regarding the amount of time required for eluate to accumulate in the container under similar operating conditions. In this case, the monitoring system 651 may be operable to generate a signal in response to a predetermined elapsed time corresponding to a

desired amount of eluate to be dispensed into the container 125. The selector may be operable to pre-select the predetermined elapsed time during which eluate is to be dispensed into the container 125.

In one embodiment the timer 691 may comprise a timer initiation system 693 adapted to start the timer automatically upon connection of the container 125 (and/or the elution shield 131) to the outlet conduit 121. For example, one or more sensors 695 (e.g., a hall effect sensor, optical sensor, RFID sensor, proximity sensor, or the like) may generate a signal upon connection of the container 125 to the outlet conduit 121. The timer 691 may be operable to begin monitoring the elapsed time in response to the signal indicating that the container 125 has been connected to the outlet conduit 121. Alternatively, the timer 691 may be started manually by a person when he or she connects the container 125 to the outlet conduit 121 without departing from the scope of the invention.

It is understood that the configuration of the radioisotope generation system can be different from the configurations discussed above and shown in the drawings without departing from the scope of the invention. Although the systems described and shown above involve dispensing of eluate into a container housed within an elution shield, it is understood that the elution system can dispense eluate directly into the cavity of the shield, or that the container may be unshielded, without departing from the scope of the invention.

Although a pinch valve is used to facilitate interruption of the elution in the illustrated embodiments, other types of valves could be used instead without departing from the scope of the invention. Likewise, the invention is operable without any valving as disconnection of the vacuum pressure source (e.g., the partially filled container) may be sufficient to interrupt the elution process in and of itself.

While in each of the illustrated embodiments the monitoring system generates a signal upon determining that the amount of eluate dispensed into the container is approximately equal to a desired amount of eluate, it is contemplated that the monitoring system may instead, or may additionally, generate a continuous or intermittent signal prior to the desired amount of eluate being dispensed into the container, e.g., indicative of the determined amount of eluate in the container (broadly, the cavity). For example, in one embodiment the signal may comprise visual or audible signals that indicate various incremental amounts of eluate dispensed into the container. Examples of such signals include, without limitation, lights, digital displays, alphanumeric displays or other suitable visual indicators of the amount of eluate dispensed into the container. Other examples include audible signals that may or may not increase in intensity as the amount of eluate in the container increases.

When introducing elements of the present invention or the preferred 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" and "bottom" and variations of these terms is made for convenience, but does not require any particular orientation of the components.

As various changes could be made in the above products and methods without departing from the scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

CLAIMS:

What is claimed is

1. A radioisotope generation system comprising:

a radioisotope generator operable to dispense radioactive eluate into a container; and

a monitoring system operable while the radiation generator system dispenses eluate into the container to monitor the amount of eluate dispensed into the container and to generate a signal indicative of the amount of eluate dispensed into the container.

2. A radioisotope generation system as in claim 1 wherein the monitoring system is operable to generate a signal when a desired amount of eluate has been dispensed into the container.

3. A radioisotope generation system as in claim 2 further comprising a selector for selectively setting the desired amount of eluate to be dispensed into the container.

4. A radioisotope generation system as in claim 2 wherein the generation system is operable to automatically interrupt dispensing of the eluate into the container in response to the signal.

5. A radioisotope generation system as in claim 1 wherein the signal is perceptible exterior of the container.

6. A radioisotope generation system as in claim 5 wherein the signal is at least one of visually and audibly perceptible exterior of the container.

7. A radioisotope generation system as in claim 1 wherein the signal is perceptible by a human.

8. A radioisotope generation system as in claim 1 wherein the monitoring system comprises a level sensor operable to sense a level of eluate in the container, the level corresponding to the amount of eluate in the container.

9. A radioisotope generation system as in claim 8 wherein the level sensor is selected from the group consisting of optical sensors, infrared sensors, ultrasonic sensors, inductive sensors, and capacitive sensors.

10. A radioisotope generation system as in claim 1 wherein the monitoring system comprises a timer operable to monitor an elapsed time during which eluate is dispensed into the container, the elapsed time being relative to a time at which the dispensing of eluate into the container is initiated, the elapsed time corresponding to the amount of eluate in the container.

11. A radioisotope generation system as in claim 10 wherein the monitoring system is operable to generate a signal following dispensing of eluate into the container for a predetermined elapsed time wherein the predetermined elapsed time corresponds to a desired amount of eluate to be dispensed into the container.

12. A radioisotope generation system as in claim 11 wherein the predetermined elapsed time is selectively adjustable at least prior to the dispensing of eluate into the container being initiated.

13. A radioisotope generation system as in claim 10 further comprising a timer initiation system operable to automatically start the timer when dispensing of eluate into the container is initiated.

14. A radioisotope generation system as in claim 13 wherein the timer initiation system comprises a sensor selected from the group consisting of hall effect sensors, optical sensors, and RFID tags.

15. A radioisotope generation system as in claim 1 wherein the monitoring system comprises a sensor operable to determine the weight of eluate in the container, the weight corresponding to the amount of eluate in the container.

16. A method for dispensing radioactive eluate, the method comprising:

dispensing eluate from a radioisotope generator into a container while the container and the generator are in fluid communication;

monitoring the dispensing; and

providing a signal indicative of an amount of the eluate dispensed into the container.

17. A method as in claim 16 wherein the providing comprises providing a signal when the amount of eluate in the container is approximately equal to a desired amount of eluate, the method further comprising interrupting the dispensing of eluate into the container in response to the signal.

18. A method as in claim 17 wherein the interrupting comprises automatically interrupting the dispensing of eluate into the container in response to the signal.

19. A method as in claim 17 wherein the interrupting comprises manually interrupting the dispensing of eluate into the container in response to the signal.

20. A method as in claim 17 further comprising selectively adjusting the desired amount of eluate to be dispensed into the container, the selectively adjusting being conducted prior to the operating of the radioisotope generator.

21. A method as in claim 16 wherein the monitoring comprises monitoring an elapsed time, starting from initiation of the dispensing, during which eluate is dispensed into the container, the elapsed time corresponding to the amount of eluate dispensed into the container.

22. A method as in claim 16 wherein the monitoring comprises sensing a level of eluate in the container, the level corresponding to an amount of eluate dispensed into the container.

23. A method as in claim 16 wherein the monitoring comprises sensing a weight of the eluate in the container, the weight corresponding to an amount of eluate dispensed into the container.

24. A method as in claim 16 further comprising generating an electrical signal based on the monitoring.

25. A method as in claim 24 wherein the providing results from the electrical signal generated.

26. A radioisotope generation system comprising:

a radioisotope generator operable to dispense eluate;

an elution shield having an internal cavity for receiving eluate dispensed from the generator, the elution shield being constructed at least in part of a radiation-absorbing material; and

a monitoring system for monitoring the dispensing of eluate by the generator to the cavity of the shield, the monitoring system being operable to generate a signal in response to at least one of receipt of a desired amount of eluate in the cavity and elapse of a predetermined time period during which eluate is dispensed into the cavity.

27. A radioisotope generation system as in claim 26 further comprising a container disposed in the cavity for receiving the eluate therein, the container being adapted to hold a maximum volume of eluate, the monitoring system being capable of generating the signal in response to receipt of a desired amount of eluate in the container, the desired amount of eluate being less than the maximum volume of the container.

28. A radioisotope generation system as in claim 26 further comprising a container disposed in the cavity for receiving the eluate therein, the container being adapted to hold a maximum volume of eluate, the monitoring system being capable of generating the signal in response to a predetermined

elapsed time during which eluate is dispensed into the container, the predetermined elapsed time corresponding to a desired amount of eluate to be dispensed into the container.

29. A radioisotope generation system as in claim 26 wherein the generation system is operable to automatically interrupt dispensing of the eluate into the cavity in response to the signal.

30. A radioisotope generation system as in claim 26 wherein the signal is perceptible exterior of the elution shield.

31. A radioisotope generation system as in claim 30 wherein the signal is at least one of visually and audibly perceptible exterior of the elution shield.

32. A radioisotope generation system as in claim 26 wherein the signal is perceptible by a human.

33. A radioisotope generation system as in claim 26 wherein the monitoring system comprises a level sensor operable to sense the level of eluate in the cavity, the level corresponding to the amount of eluate in the cavity.

34. A radioisotope generation system as in claim 26 wherein the monitoring system comprises a timer operable to monitor an elapsed time during which eluate is dispensed into the cavity, the elapsed time being relative to a time at which the dispensing of eluate into the cavity is initiated, the elapsed time corresponding to the amount of eluate in the cavity, the monitoring system being operable to generate a signal following dispensing of eluate into the cavity for a predetermined elapsed time wherein the predetermined elapsed time corresponds to the desired amount of eluate in the cavity.

35. A radioisotope generation system as in claim 34 further comprising a timer initiation system operable to automatically start the timer when dispensing of eluate into the cavity is initiated.

36. A radioisotope generation system as in claim 34 wherein the predetermined elapsed time is selectively adjustable at least prior to the dispensing of eluate into the cavity being initiated.

37. A radioisotope generation system as in claim 26 wherein the monitoring system comprises a sensor operable to determine the weight of eluate in the cavity, the weight corresponding to the amount of eluate in the cavity.

38. A method of producing radioactive eluate, the method comprising:

dispensing eluate from a radioisotope generator into a cavity of an elution shield;

monitoring an amount of eluate in the cavity during at least a portion of the dispensing; and

automatically generating a signal in response to detecting at least one of a desired amount of eluate in the cavity and a passing of a predetermined elapsed time during the dispensing.

39. A method as in claim 38 wherein the dispensing comprises dispensing eluate into a container disposed in the cavity of the elution shield, the container being adapted to hold a maximum volume of eluate, wherein the automatically generating occurs in response to receipt of a desired amount of eluate in the container, the desired amount being less than the maximum volume.

40. A method as in claim 38 wherein the dispensing comprises dispensing eluate into a container disposed in the cavity of the elution shield, the container being adapted to hold a maximum volume of eluate, wherein the automatically generating occurs in response to the passing of a predetermined elapsed time during which eluate is dispensed into the container, the predetermined elapsed time corresponding to an amount of eluate in the container less than the maximum volume.

41. A method as in claim 38 further comprising manually interrupting the dispensing in response to the signal.

42. A method as in claim 38 further comprising automatically interrupting the dispensing in response to the signal.

43. A method as in claim 38, wherein the monitoring comprises sensing a level of dispensed eluate in the cavity, the level corresponding to the amount of eluate in the cavity.

44. A method as in claim 38, wherein the monitoring comprises sensing a weight of the eluate in the cavity, the weight corresponding to the amount of eluate in the cavity.

45. A method as in claim 38 further comprising selectively varying at least one of the desired amount of eluate in the cavity and the predetermined elapsed time during which eluate is dispensed into the cavity, wherein the selectively varying occurs prior to the dispensing.

46. A radioisotope generation system comprising:

a radioisotope generator for dispensing radioactive eluate; and

a dispensed eluate sensor capable of determining an amount of eluate eluted from the generator; and

a signaling device communicatively connected with the sensor.

47. A system as in claim 46 wherein the sensor comprises at least one of an optical sensor, an infrared sensor, an ultrasonic sensor, an inductive sensor, and a capacitive sensor.

48. A system as in claim 46 wherein the signaling device is capable of providing at least one of an audio signal and a visual signal.

49. A system as in claim 46 further comprising an elution shield having an internal cavity for receiving eluate dispensed from the generator, wherein the elution shield is constructed at least in part of a radiation-shielding material, and wherein at least one of the dispensed eluate sensor and the signaling device is a component of the elution shield.

50. A system as in claim 49 wherein the dispensed eluate sensor and the signaling device are components of the elution shield.

51. A method of dispensing a radioactive eluate comprising:

determining an amount of radioactive eluate eluted from a radioisotope generator of a radioisotope generation system in an elution procedure; and

changing an electrical condition of the system based on the determining.

52. A method as in claim 51, wherein the changing comprises closing an electrical circuit of the system.

53. A method as in claim 51, wherein the changing comprises opening an electrical circuit of the system.

54. A method as in claim 51, wherein the changing occurs as a result of determining a threshold amount of the eluate.

55. A method as in claim 51, further comprising providing at least one of an audible signal and a visual signal as a result of the changing.

56. A method as in claim 51, wherein the changing comprises altering an electrical signal between first and second components of the system.

57. A method as in claim 51, wherein the changing comprises changing a voltage applied to a component of the system.

FIG. 1

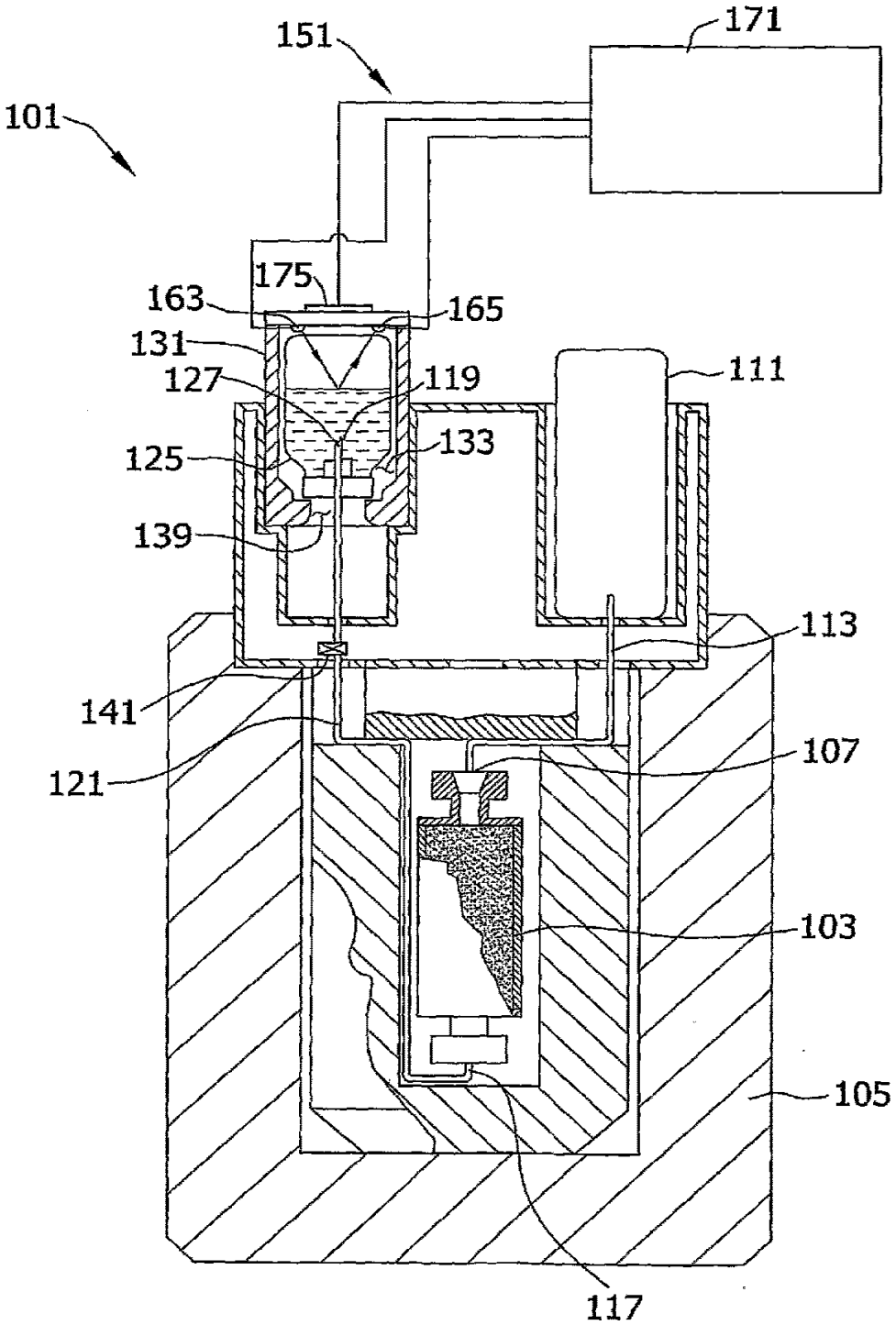

151
171
101
175
163
165
131
127
119
111
133
125
139
113
141
107
121
103
105
117

FIG. 2

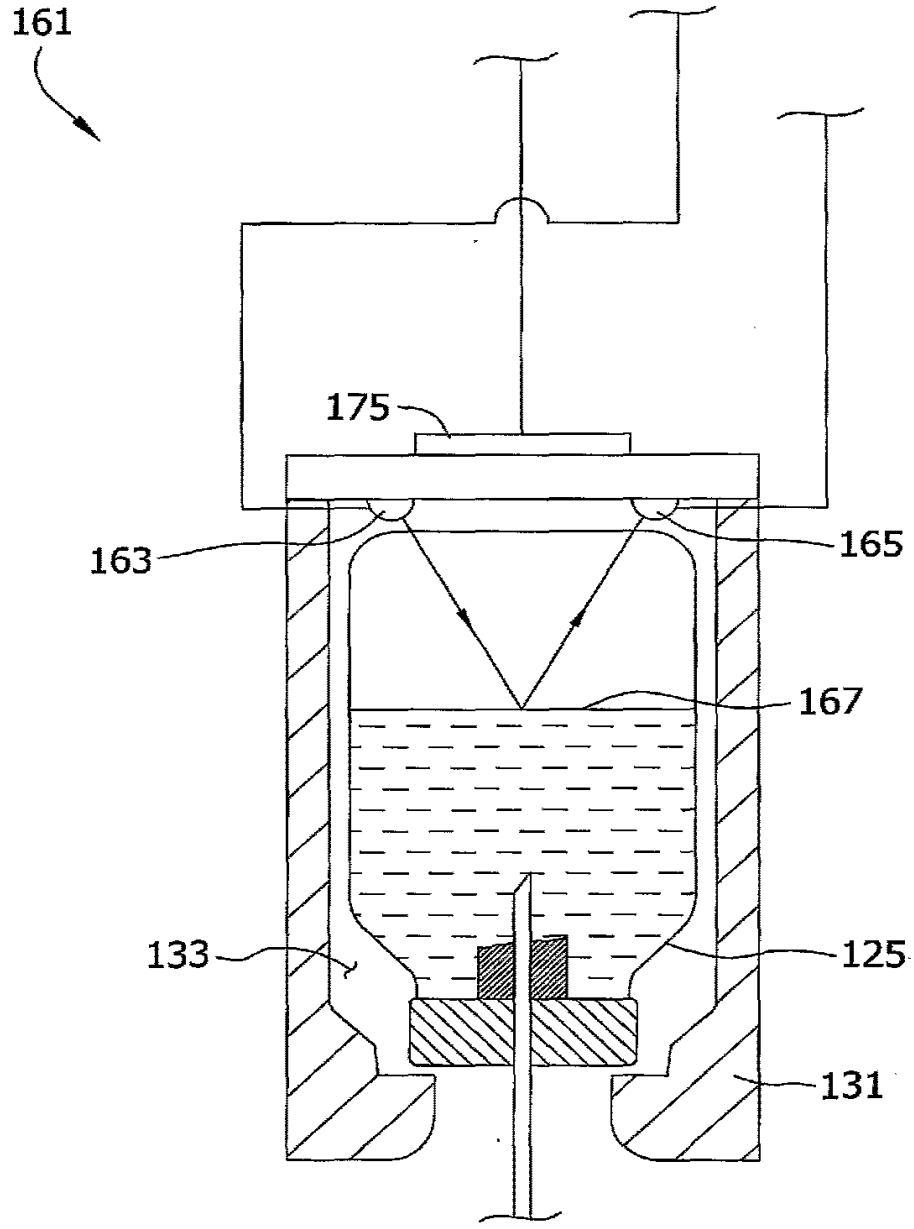


FIG. 3

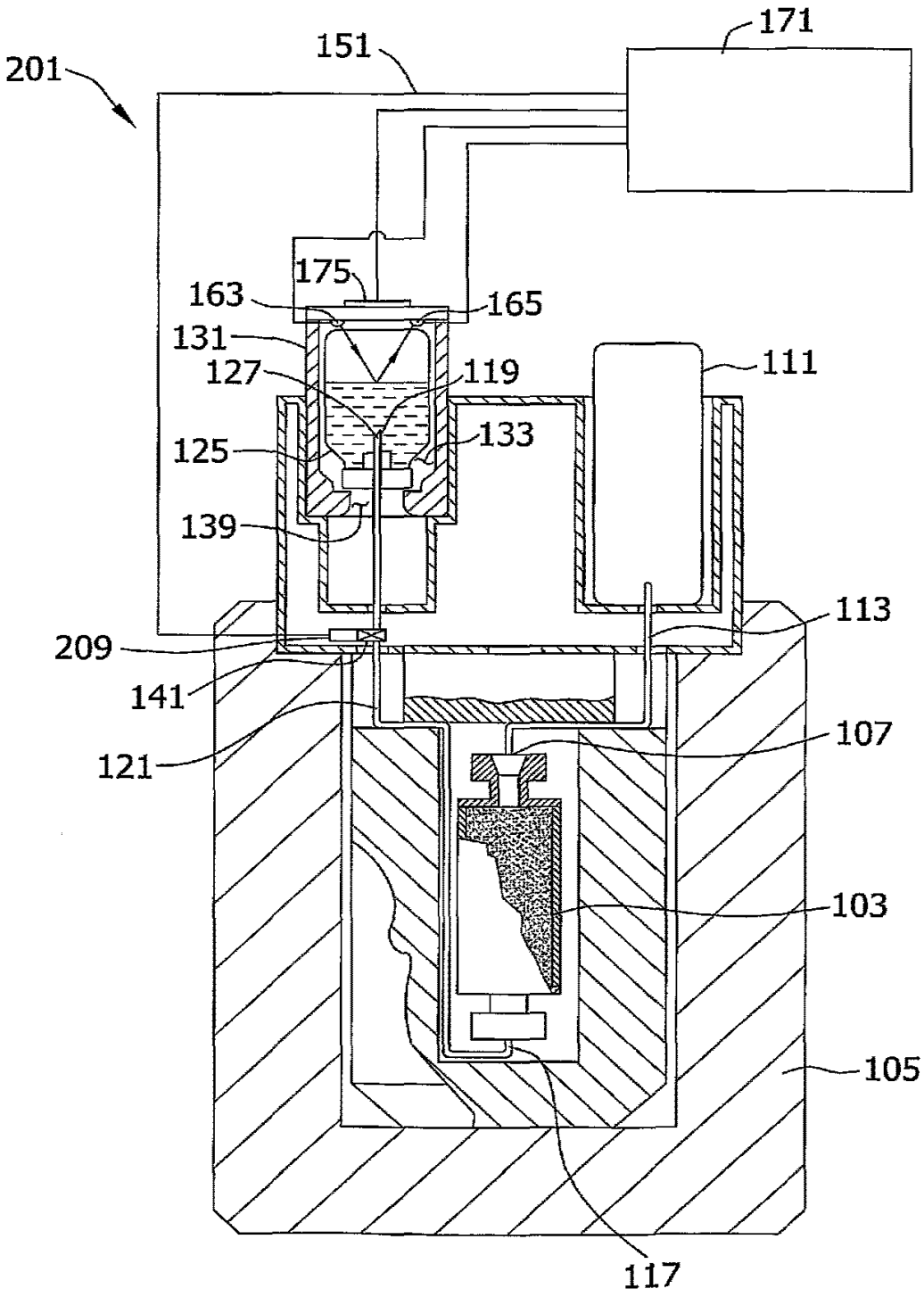

171
151
201
175
163
165
131
127
119
111
125
133
139
113
209
141
107
121
103
105
117

FIG. 4

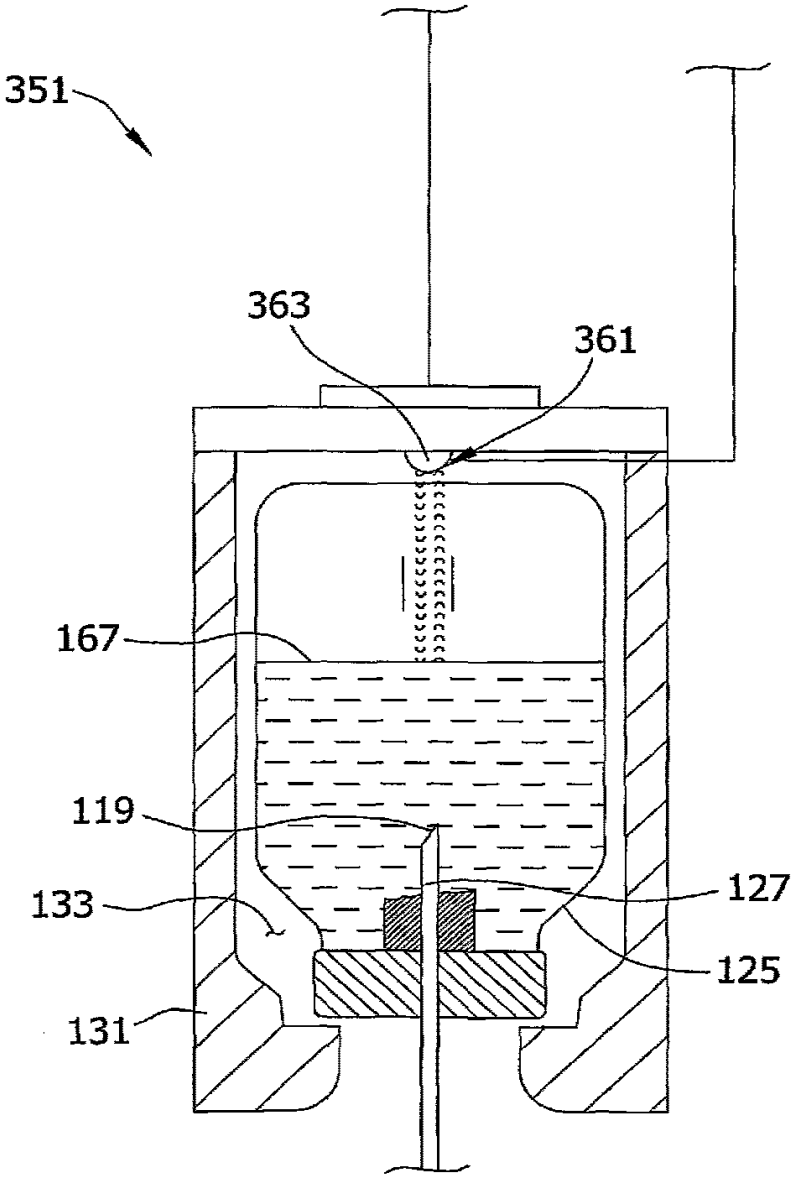


FIG. 5

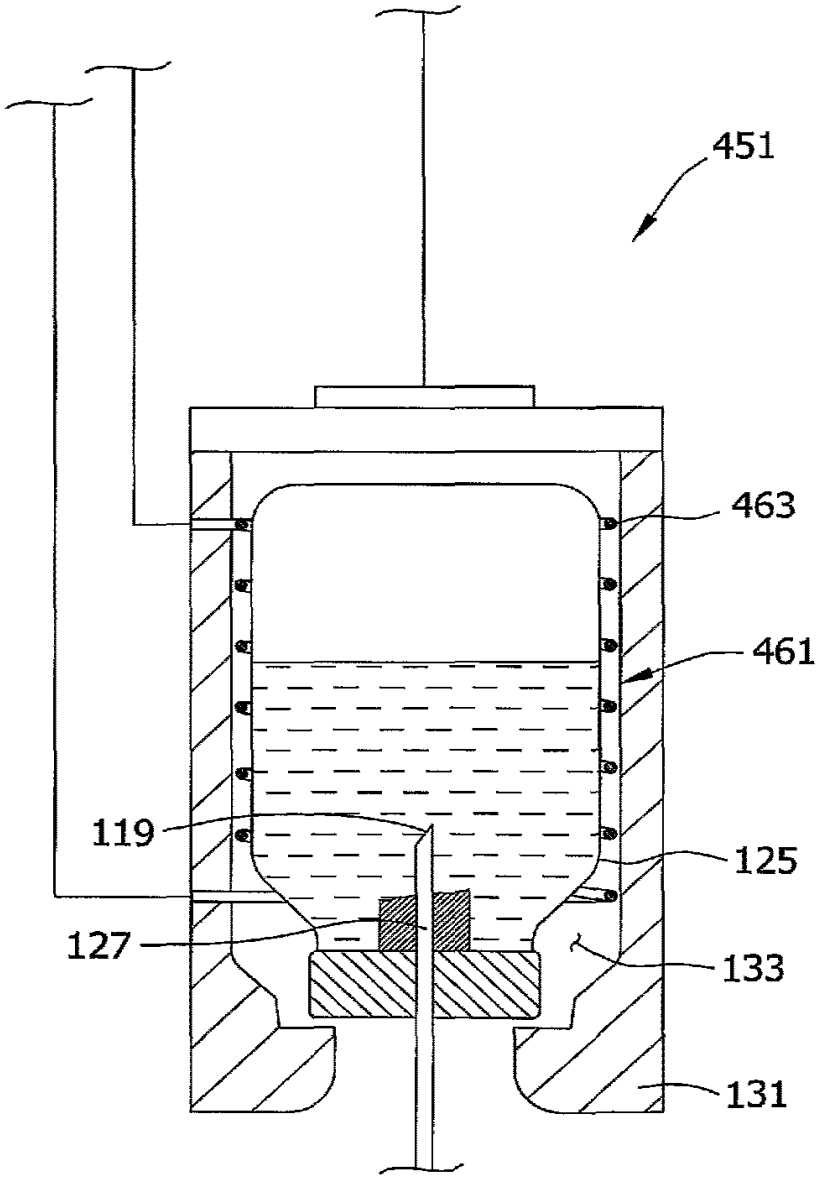


FIG. 6

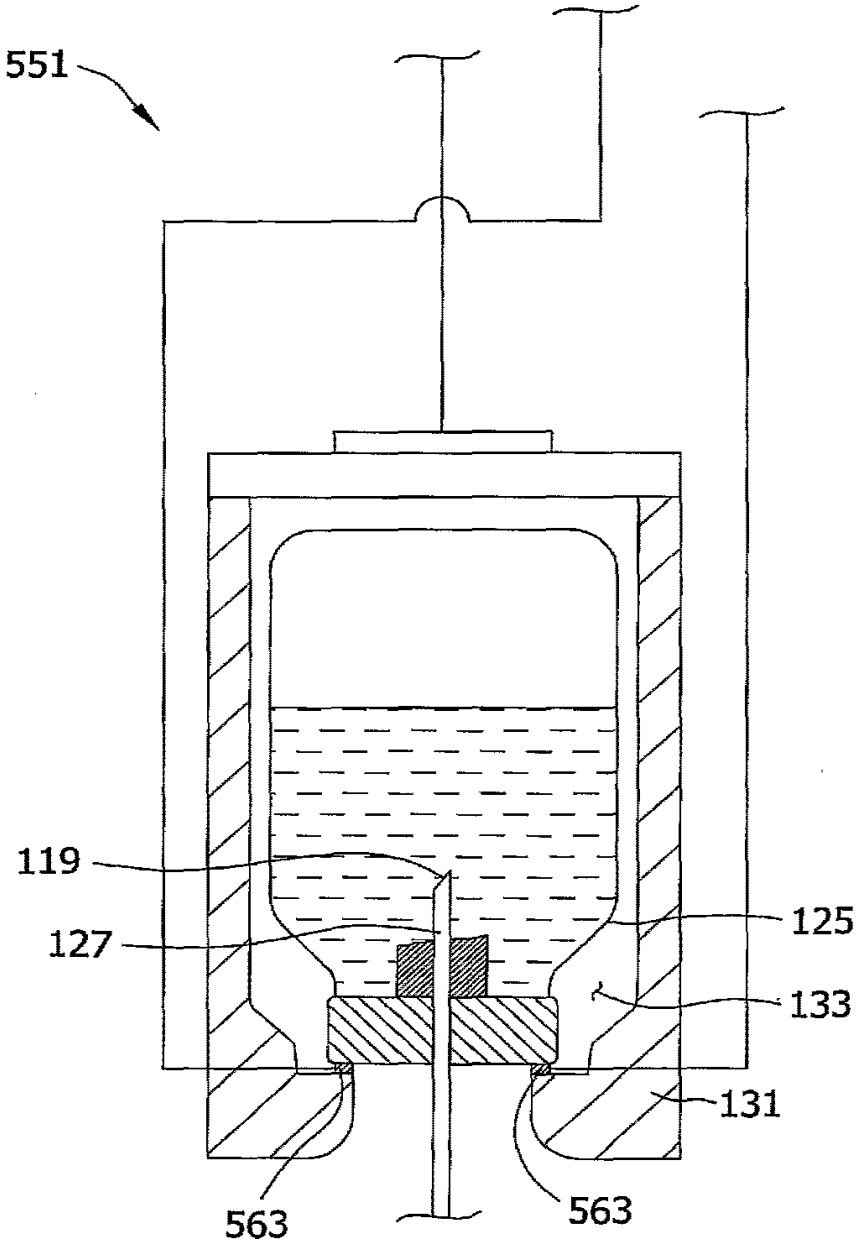


FIG. 7

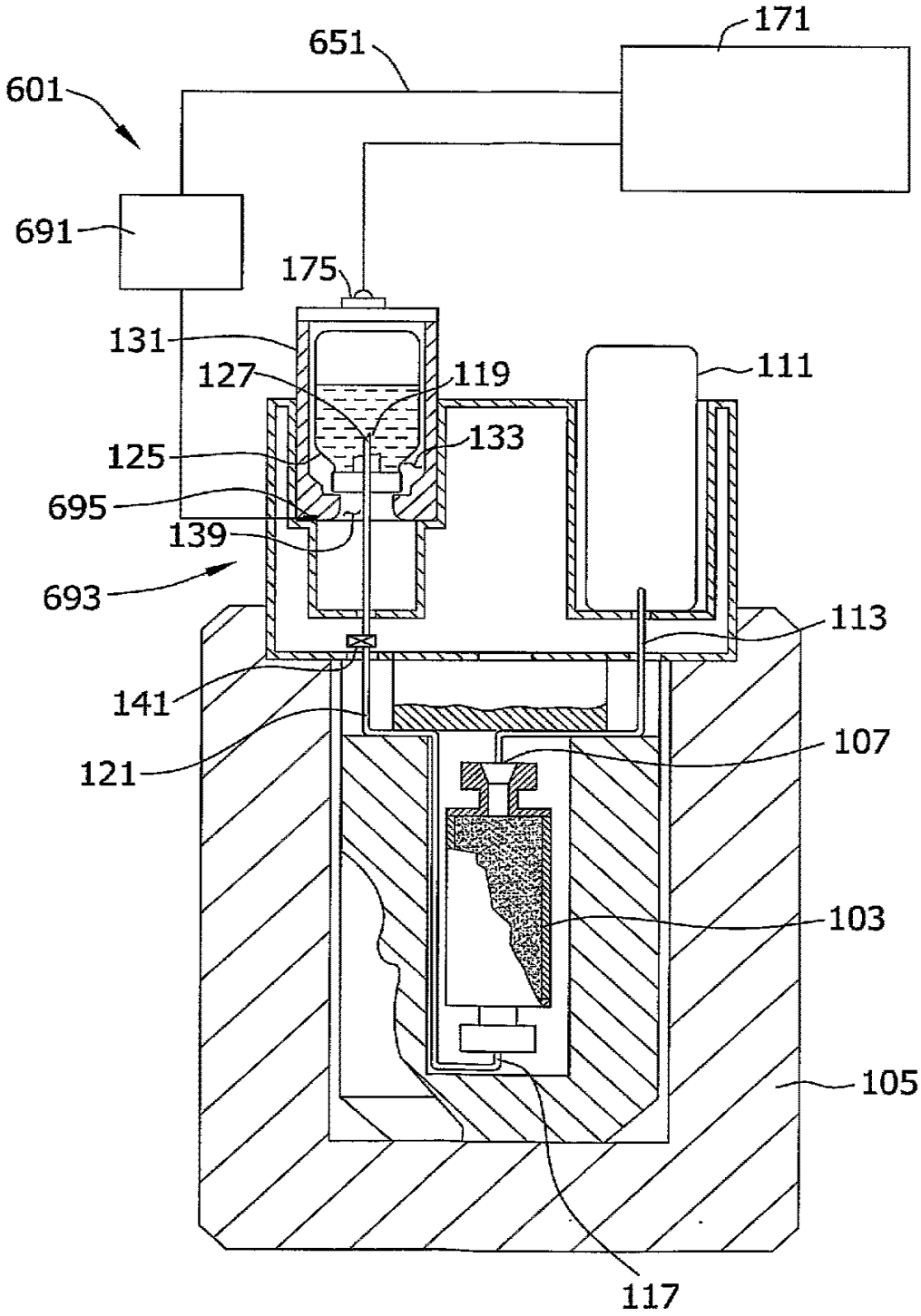
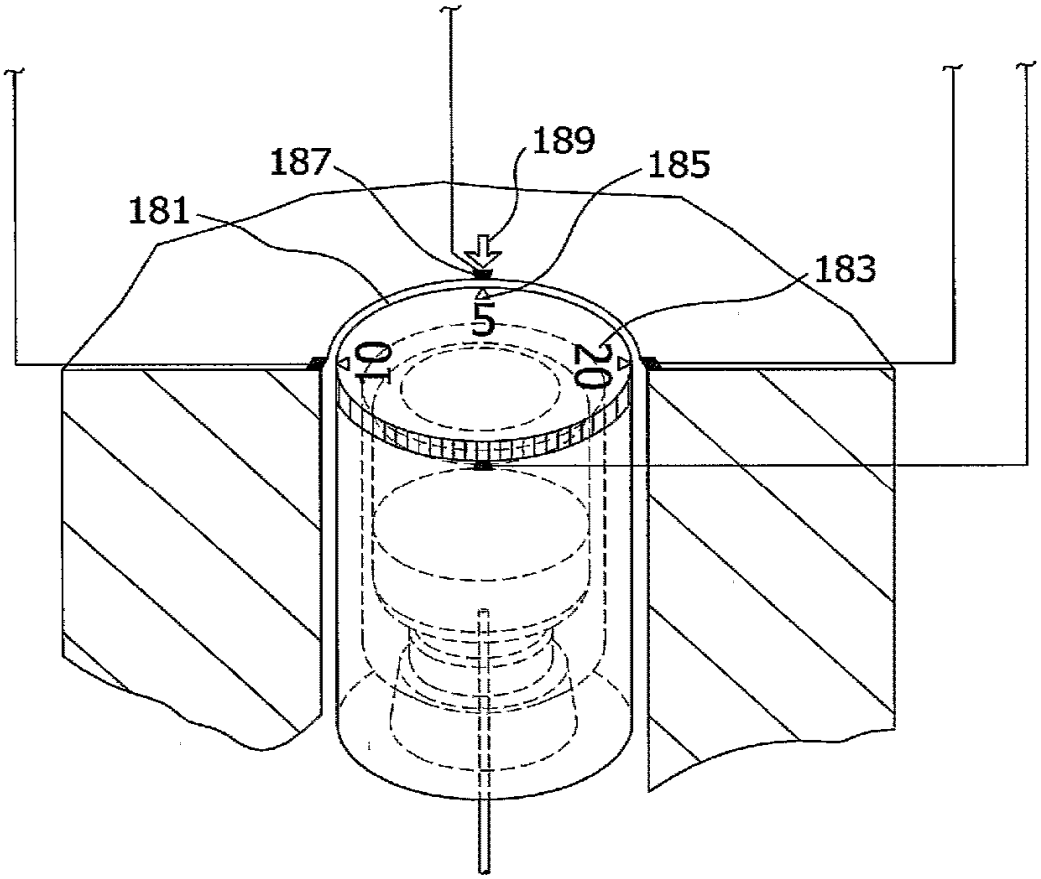

171
651
601
691
175
131
127
119
111
125
133
695
139
693
113
141
107
121
103
105
117

FIG. 8



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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2007 (27.12.2007)

PCT

(10) International Publication Number
WO 2007/149108 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2006/033442

(22) International Filing Date: 28 August 2006 (28.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/712,106 29 August 2005 (29.08.2005) US

(71) Applicant *(for all designated States except US)*: **MALLINCKRODT INC.** [US/US]; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, Missouri 63134 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **POLLARD, Ralph, E., Jr.** [US/US]; 6554 East River Road, Fairfield, Ohio 45014 (US).

(74) Agents: **SEURER, Jerad, G.** et al.; Mallinckrodt Inc., 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, Missouri 63134 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, 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, 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*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2007/149108 A2

(54) Title: SYSTEM AND METHOD FOR ELUTING RADIOISOTOPE TO A CONTAINER DISPOSED OUTSIDE OF A RADIOISOTOPE GENERATOR ASSEMBLY

(57) Abstract: The invention, in one characterization, may be said to be directed to a radiopharmaceutical system that may be utilized in radioisotope elution procedures. In some embodiments, the system may include a radioisotope generator assembly having a radiation shield with a receptacle and a cover disposed over the receptacle. The system may also include a radioisotope generator disposed in the receptacle below the cover. Some embodiments of the system may include an eluate extraction mechanism having an eluate conduit fluidly coupled to a hollow output needle of the radioisotope generator, and a radiation shielded housing disposed outside the radiation shield. The eluate extraction mechanism also may include a hollow needle fluidly coupled to the eluate conduit opposite the radioisotope generator, wherein the hollow needle is disposed inside the radiation shielded housing.

SYSTEM AND METHOD FOR ELUTING RADIOISOTOPE TO A CONTAINER DISPOSED OUTSIDE OF A RADIOISOTOPE GENERATOR ASSEMBLY

FIELD OF THE INVENTION

[0001] The invention relates generally to the field of nuclear medicine. Specifically, the invention relates to a system and method for eluting a radioisotope from a radioisotope generator to an eluate container disposed outside of an auxiliary shield containing the radioisotope generator.

BACKGROUND

[0002] 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.

[0003] Nuclear medicine 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 the desired organ or biologic region of the patient. These radioactive materials alone or in combination with a tagging agent may be to as radiopharmaceuticals in the field of nuclear medicine. At relatively lower doses of the radiopharmaceutical, a radiation imaging system (e.g., a gamma camera) provides 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.

[0004] A variety of systems are used to generate, enclose, transport, dispense, and administer radiopharmaceuticals. Unfortunately, these systems often use different containers and shielding structures and, thus, the radiopharmaceuticals tend to be repeatedly exchanged from one container to another during the various steps from elution to eventual administration to a patient. In addition, these systems often involve repeated connection and disconnection of components, such as male and female connectors of containers. Unfortunately, the male connectors can be damaged due to misalignment with the corresponding female connectors. For example, hollow needles can be bent, crushed, or

broken due to misalignment with female connectors. As a result, the systems may operate less effectively or become completely useless. If the systems contain radiopharmaceuticals, then the damaged connectors can result in monetary losses, delays with respect to nuclear medicine procedures, and/or undesired exposure of technicians (or other personnel) to radiation.

SUMMARY

[0005] The present invention, in certain embodiments, is directed to removability and replaceability of a hollow needle that pierces an eluate container (e.g., a septum thereof) in a radioisotope elution system. Specifically, in some embodiments, a removable hollow needle may be coupled to a radioisotope generator via an eluate conduit, which in turn may be coupled to an output needle of the radioisotope generator. Instead of directly coupling the eluate container with the output needle of the generator, the removable hollow needle may be used for connections and disconnections with the eluate container. In this manner, the removable hollow needle may reduce the likelihood of damage to the generator output needle, while possibly reducing the cost and downtime associated with any potential damage to the removable hollow needle. In some embodiments, the removable hollow needle may be disposed outside of a radiation shield that is disposed about the radioisotope generator. As such, a user may access and replace the removable hollow needle without opening the radiation shield. Some embodiments of the present invention may enable a user to access and view the eluate container without opening the radiation shield.

[0006] 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 features and aspects that may not be set forth below.

[0007] A first aspect of the invention is directed to a radiopharmaceutical system that includes a radioisotope generator assembly and an eluate extraction mechanism. The radioisotope generator assembly includes a radiation shield having a receptacle, a cover disposed over the receptacle, and a radioisotope generator disposed in the receptacle below the cover. The eluate extraction mechanism includes an eluate conduit fluidly coupled to a hollow output needle of the radioisotope generator, a radiation shielded housing disposed outside the radiation shield, and a hollow needle fluidly coupled to the eluate conduit opposite the radioisotope generator. The hollow needle of the generator is disposed inside the radiation shielded housing of the eluate extraction mechanism. Incidentally, "fluidly coupled" or the like herein refers to a joining of a first component to a second component or to one or more components which may be connected with the second component, or to joining the first component to part of a system that includes the second component so that the molecules of

a substance(s) (such as a liquid or gas) are capable of flowing through the system, including through both the first and second components.

[0008] A second aspect of the invention is directed to an eluate extraction mechanism that includes a radiation shielded housing and an eluate conduit. The eluate conduit has a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing. The eluate extraction mechanism also includes a hollow injection needle fluidly coupled to the opposite end of the eluate conduit. In addition, the eluate extraction mechanism includes a plunger coupled to the radiation shielded housing movably through a guide structure. The plunger is typically coupled to the hollow injection needle inside the radiation shielded housing.

[0009] Yet a third aspect of the invention is directed to an eluate extraction mechanism that includes a radiation shielded housing and a shielded eluate collection assembly. This shielded eluate collection assembly may be disposed removably inside the radiation shielded housing adjacent a door of the housing. The eluate extraction mechanism includes an eluate conduit having a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing. In addition, the eluate extraction mechanism includes a hollow needle fluidly coupled to the opposite end of the eluate conduit. The hollow needle may be moved between a connected position and a disconnected position relative to the shielded eluate collection assembly.

[0010] Still a fourth aspect of the invention is directed to a method of using a radiopharmaceutical system. In this method, an eluant is supplied into a radioisotope generator, and a radioisotope is eluted in the radioisotope generator. An eluate (including the radioisotope) is received at an output of the radioisotope generator. This eluate flows from the output through an eluate conduit and a hollow needle that is removably inserted, via movement of a plunger, into an eluate container.

[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 specific 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 FIGURES

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

[0013] FIG. 1 is a front perspective view of an exemplary embodiment of a radioisotope elution system including an eluate extraction mechanism disposed outside a radioisotope generator assembly, wherein the eluate extraction mechanism is disposed above a cover of an auxiliary shield containing a radioisotope generator, and the eluate extraction mechanism includes a plunger;

[0014] FIG. 2 is a rear perspective view of the radioisotope elution system as illustrated in FIG. 1, further illustrating a door coupled to the eluate extraction mechanism via a hinge;

[0015] FIG. 3 is a cross-sectional side view of the radioisotope elution system as illustrated in FIGS. 1 and 2, further illustrating the eluate extraction mechanism in an open, non-circulating configuration, wherein the door is rotated open and the plunger includes a hollow injection needle uncoupled from an eluate container;

[0016] FIG. 4 is a cross-sectional side view of the radioisotope elution system as illustrated in FIG. 3, further illustrating the eluate extraction mechanism in a closed, circulating configuration, wherein the door is rotated closed and the hollow injection needle is coupled to the eluate container;

[0017] FIG. 5 is a rear perspective view of the radioisotope elution system as illustrated in FIG. 4, further illustrating an open viewing slot in a shielded eluate assembly having the eluate container disposed inside;

[0018] FIG. 6 is a cross-sectional side view of the radioisotope elution system as illustrated in FIG. 5, further illustrating the shielded eluate assembly removed from the eluate extraction mechanism when the hollow injection needle is uncoupled from the eluate container and the door is disposed in an open position;

[0019] FIG. 7 is an exploded cross-sectional side view of the radioisotope elution system as illustrated in FIG. 6, illustrating the hollow injection needle removed from the plunger of the eluate extraction mechanism;

[0020] FIG. 8 is an exploded cross-sectional view of the eluate extraction mechanism as illustrated in FIG. 7, further illustrating details of the hollow injection needle removed from the plunger of the eluate extraction mechanism;

[0021] FIG. 9 is a top perspective view of an exemplary embodiment of the plunger as illustrated in FIG. 8, further illustrating a removable fluid coupling disposed at a bottom side of the plunger;

[0022] FIG. 10 is a bottom perspective view of the plunger as illustrated in FIG. 9;

[0023] FIG. 11 is an exploded perspective view of the plunger as illustrated in FIGS. 9 and 10, further illustrating the removable fluid coupling having a bossed portion or rail exploded laterally from a slot in the bottom side of the plunger;

[0024] FIG. 12 is a side view of an embodiment of the removable fluid coupling as illustrated in FIGS. 9-11;

[0025] FIG. 13 is a bottom view of an embodiment of the plunger as illustrated in FIGS. 9-11, further illustrating the plunger without the removable fluid coupling;

[0026] FIGS. 14 and 15 are rear perspective views of the eluate extraction mechanism as illustrated in FIGS. 1-8, further illustrating an alignment adapter disposed about an eluate conduit of the eluate extraction mechanism;

[0027] FIG. 16 is a flowchart illustrating an exemplary embodiment of a nuclear medicine process using a radiopharmaceutical acquired by the radioisotope elution system as illustrated in FIGS. 1-15;

[0028] FIG. 17 is a block diagram illustrating an exemplary embodiment of a radiopharmacy or system utilizing the radioisotope elution system as illustrated in FIGS. 1-15; and

[0029] FIG. 18 is a block diagram illustrating an exemplary embodiment of a nuclear imaging system utilizing a radiopharmaceutical acquired by the radioisotope elution system as illustrated in FIGS. 1-15.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0030] One or more specific embodiments of the present invention will be described below. In an effort to provide a concise description of these embodiments, all 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 must 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. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

[0031] FIGS. 1 and 2 are perspective views of an exemplary embodiment of a radioisotope elution system 10 having an eluate extraction mechanism 12 mounted outside, and specifically on top of, a radioisotope generator assembly 14. The radioisotope generator assembly 14 may include a radiation shielded container or auxiliary shield 16, which may receive and at least substantially enclose a

radioisotope generator 18 and an eluant supply container 20 as discussed below with reference to FIG. 3. The eluate extraction mechanism 12 and the auxiliary shield 16 may include a variety of radiation-shielding materials, such as lead, tungsten, tungsten impregnated plastic and/or another suitable radiation shielding material. The eluate extraction mechanism 12 may be mounted at least partially or entirely outside of the auxiliary shield 16 in a variety of configurations, orientations, and positions, such that an elution process may be performed to output an eluate to a position outside of the auxiliary shield 16. For example, the eluate extraction mechanism 12 may be mounted along a generally horizontal surface on top of a cover 22 that generally closes a receptacle 24 of the auxiliary shield 16. Alternatively, the eluate extraction mechanism 12 may be mounted to the auxiliary shield 16 along a generally vertical surface or a side of the auxiliary shield 16. Alternatively, the eluate extraction mechanism 12 may be mounted separate from the radioisotope generator assembly 14. For example, the eluate extraction mechanism 12 may be disposed next to, above, below, or in a variety of remote locations relative to the radioisotope generator assembly 14, wherein an eluate conduit 52 may couple the eluate extraction mechanism 12 to the radioisotope generator assembly 14 as discussed in further detail below with reference to FIG. 3.

[0032] In the illustrated embodiment of FIGS. 1 and 2, the eluate extraction mechanism 12 may be removably coupled to the cover 22, such that the eluate extraction mechanism 12 can be installed and removed without removing the cover 22 from the receptacle 24. In this manner, the eluate extraction mechanism 12 may improve the containment of radioactivity from the radioisotope generator 18 disposed within the auxiliary shield 16. If the radioisotope generator assembly 14 is not being used for an elution process, then the eluate extraction mechanism 12 may be removed and replaced with a radiation shielded plug that may extend into and/or cover the passage 48 in the cover 22. If an elution process is desired now or in the near future, then the radiation shielded plug may be removed and replaced with the eluate extraction mechanism 12 on or over the cover 22. The eluate extraction mechanism 12 may be removably coupled to the cover 22 by a variety of fasteners and alignment structures. For example, the fasteners may include screws, bolts, or other threaded fasteners. The fasteners also may include latches or tool free connectors, such as snap-fit mechanisms, boss members that mate with keyhole slots, and so forth. The fasteners may also include hinges, adhesives, and compressive or interference fits. Alternatively, the eluate extraction mechanism 12 and the cover 22 may be integrally formed as one structure, which may be mounted on top of the auxiliary shield 16.

[0033] FIG. 3 is a cross-sectional side view of an embodiment of the radioisotope elution system 10 as illustrated in FIGS. 1 and 2, further illustrating the eluate extraction mechanism 12 in an open, non-circulating configuration on top of the radioisotope generator assembly 14. As illustrated, the radioisotope generator assembly 14 may include the auxiliary shield 16 and the radioisotope generator 18 disposed in the receptacle 24 below the cover 22 of the auxiliary shield 16. The radioisotope generator assembly 14 also may include the eluant supply container 20 coupled to one or more hollow

input needles 26 of the radioisotope generator 18. For example, the one or more hollow input needles 26 may pierce a flexible insert 28, such as a rubber material, disposed within a head 30 of the eluant supply container 20. In this manner, the one or more hollow input needles 26 fluidly couple the eluant supply container 20 with an internal radioisotope element, such as molybdenum-99, disposed inside the radioisotope generator 18. The eluant supply container 20 may be disposed entirely or at least substantially inside the auxiliary shield 16 in the receptacle 24 below the cover 22, as illustrated in FIG. 3. Alternatively, the eluant supply container 20 may be disposed at least partially or entirely outside the auxiliary shield 16 in other embodiments of the radioisotope elution system 10. As discussed in further detail below, the eluant supply container 20 may hold a variety of eluants, such as a saline solution, suitable for eluting a radioisotope (e.g., technetium-99m) from the radioisotope generator 18 into the eluate extraction mechanism 12.

[0034] As illustrated in FIG. 3, the eluate extraction mechanism 12 may have a shielded eluate assembly 34 disposed removably inside a radiation shielded housing 36 on top of the cover 22. The illustrated radiation shielded housing 36 may have a variety of shapes and configurations. For example, the radiation shielded housing 36 may have a generally L-shaped or angled structure having a top or elongated housing portion 38 and a bottom housing portion 40.

[0035] The radiation shielded housing 36 also may have a cover alignment member 42 disposed about an opening 44 in a base 46. In certain embodiments, the cover alignment member 42 may improve the alignment of the eluate extraction mechanism 12 with a passage 48 through the cover 22 of the auxiliary shield 16. For example, the base 46 may have a generally flat bottom surface 50, and the cover alignment member 42 may protrude outwardly from the flat surface 50. In view of this protruding characteristic, the cover alignment member 42 may fit or extend at least partially inside or through the passage 48 when the eluate extract mechanism 12 is mounted on the cover 22. In this manner, the cover alignment member 42 may increase the likelihood of proper alignment with the radioisotope generator 18 disposed inside the auxiliary shield 16. For example, the cover alignment member 42 may improve alignment between conduits, hollow needles, and various connections between the eluate extraction mechanism 12 and the radioisotope generator 18.

[0036] Regarding the various fluid connections, the eluate extraction mechanism 12 of FIG. 3, for example, may include an eluate conduit 52 that may pass through the radiation shielded housing 36 and the passage 48 in the cover 22. At one end, the eluate conduit 52 may be coupled with a hollow output needle 54 on the radioisotope generator 18. At an opposite end from the hollow output needle 54, the eluate conduit 52 may be coupled to a plunger 56 movably coupled to the eluate extraction mechanism 12 along a path of travel, e.g., a linear path of vertical motion. For example, the plunger 56 may be moveably disposed in a guide structure or passage 58 within the top or elongated housing portion 38 of the eluate extraction mechanism 12. The plunger 56 also may include a hollow injection needle 60 or

another suitable fluid connector. Thus, the plunger 56 and the hollow injection needle 60 may be jointly moved along a path of travel between a connected position and a disconnection position between the hollow injection needle 60 and an eluate container 74 as discussed in further detail below. The hollow injection needle 60, or other suitable fluid connector, may be removably coupled to the eluate conduit 52 via a releasable fastener 62. For example, the fastener 62 may include a luer connection, a compression fit mechanism, a threaded joint, snap-fit members, latches, or another release mechanism.

[0037] As discussed in detail below, the hollow injection needle 60 may be accessed, removed, serviced, or replaced independent and remote from the hollow output needle 54 on the radioisotope generator 18. Moreover, the coupling of the eluate conduit 52 and the hollow output needle 54 may be maintained during the life or use of a radioisotope generator 18, thereby reducing the likelihood of bending or damaging the hollow output needle 54. Instead, over the course of repeated use of the radioisotope elution system 10, the hollow injection needle 60 may be repeatedly connected and disconnected with the shielded eluate assembly 34. In view of the removability of the hollow injection needle 60, any bending or damage may be easily and cheaply serviced by replacing the needle 60 rather than the entire radioisotope generator 18. Moreover, the hollow injection needle 60 is disposed outside the auxiliary shield 16, such that servicing may be performed without removing the cover 22 and being exposed to radiation from the radioisotope generator 18.

[0038] As further illustrated in FIG. 3, the shielded eluate assembly 34 may be inserted and removed from a region 64 generally below the plunger 56 via a door opening 66 along a side of the top or elongated housing portion 38. The radiation shielded housing 36 also includes a selective access door 68 having a hinge 70 coupled to the elongated housing portion 38 adjacent the door opening 66. Accordingly, radiation shielded housing 36 including the door 68 may provide substantially continuous radioactive shielding about the shielded eluate assembly 34 outside of the auxiliary shield 16, while the door 68 and opening 66 may enable a user to view and selectively access the shielded eluate assembly 34 quickly and easily without opening the auxiliary shield 16. In addition, as discussed below, the shielded eluate assembly 34 may have a variety of features, such as a slot 93 and a door 94, to enable viewing of the extracted eluate. As illustrated in FIG. 3, the door 68 can open and close the door opening 66 for selective access, insertion, and removal of the shielded eluate assembly 34. In other embodiments, the door 68 may be coupled to the radiation shielded housing 36 via a sliding mechanism, a spring-loaded mechanism, a swinging mechanism, or another suitable opening and closing mechanism configured to enable selective access, viewing, insertion, and removal of the shielded eluate assembly 34.

[0039] The shielded eluate assembly 34 as illustrated in FIG. 3 may include an eluate container shield 72 disposed about an eluate container 74, such as an evacuated vial, bottle, or other container in a vacuum condition. The eluate container shield 72 may include a variety of radiation-shielding

materials, such as lead, tungsten, tungsten impregnated plastic and/or another suitable radiation shielding material. The eluate container 74 may include a variety of transparent or translucent materials, such as glass. The eluate container shield 72 may include a cap 76 coupled to a shielded cup structure 78, such that the eluate container 74 may be generally aligned with an opening 80 through the cap 76. The cap 76 may be coupled to the shielded cup structure 78 via threads, an interference fit, a snap-fit mechanism, or another suitable attachment mechanism. The eluate container 74 may be aligned with the opening 80 via a variety of alignment mechanisms, such as an alignment adapter or ring 82 disposed about the eluate container 74 inside the shielded cup structure 78. Alternatively, the opening 80 may have a protruding portion facing downwardly toward a head 84 of the eluate container 74, such that the head 84 may be aligned with the opening 80.

[0040] The eluate extraction mechanism 12 as illustrated in FIG. 3 may also include a variety of alignment mechanisms to improve alignment of the shielded eluate assembly 34 relative to the hollow injection needle 60 coupled to the plunger 56. For example, the eluate extraction mechanism 12 may include one or more alignment members or tabs 86 along the base 46 of the radiation shielded housing 84. The alignment members or tabs 86 may increase the likelihood that the shielded eluate assembly 34 fits snugly between the tab 86 and the door 68 when the door 68 is closed over the door opening 66. In addition to the snug fit, the alignment members or tabs 86 may position a center of the head 84 (and longitudinal axis) of the eluate container 74 with a longitudinal axis of the hollow injection needle 60 and the direction of motion of the plunger 56. In this manner, the hollow injection needle 60 may be connected and disconnected in a generally centered and straight direction into and out of the eluate container 74, thereby reducing the likelihood of bending or damaging the hollow injection needle 60. Again, a variety of fasteners, alignment mechanisms, containers, and configurations of the eluate extraction mechanism 12 may be employed to elute a radioisotope to the shielded eluate assembly 34 generally outside the confines of the radioisotope generator assembly 14.

[0041] FIG. 4 is a cross-sectional side view of and embodiment of the radioisotope elution system 10 as illustrated in FIG. 3, further illustrating the eluate extraction mechanism 12 disposed in a closed, fluidly coupled configuration with the radioisotope generator assembly 14. As illustrated by arrow 88, the door 68 has been rotated about the hinge 70 to close the door opening 66, such that the shielded eluate assembly 34 may be snuggly fit between the alignment tab 86 and the door 68. In this manner, the alignment tab 86 and the door 68 can secure and align the opening 80 in the eluate container shield 72 in a generally centered position with the hollow injection needle 60 of the plunger 56. In addition, the head 84 of the eluate container 74 may be generally aligned or centered with the opening 80 and the hollow injection needle 60 via the alignment adapter or ring 82 disposed about the eluate container 74 inside the shielded cup structure 78. With the eluate container 74 generally aligned or centered with the hollow injection needle 60, the plunger 56 may be depressed downwardly as indicated by arrow 90 to

pierce the hollow injection needle 60 into the eluate container 74 through a flexible insert 92, such as a rubber material, in the head 84 of the eluate container 74.

[0042] In certain embodiments, the eluate container 74 may be in vacuum, such that the pressure differential between the eluant supply container 20 and the eluate container 74 facilitates circulation of the eluant 32 through the radioisotope generator 18 and out through the eluate conduit 52 into the eluate container 74. As the eluant 32, e.g., a saline solution, circulates through the radioisotope generator 18, the circulating eluant 32 generally washes out or elutes a radioisotope, e.g., Technetium-99m. For example, one embodiment of the radioisotope generator 18 includes a radiation shielded outer casing (e.g., lead shell) that encloses a radioactive parent, such as molybdenum-99, adsorbed to the surfaces of beads of alumina or a resin exchange column. Inside the radioisotope generator 18, the parent molybdenum-99 transforms, with a half-life of about 67 hours, into metastable technetium-99m. The daughter radioisotope, e.g., technetium-99m, is generally held less tightly than the parent radioisotope, e.g., molybdenum-99, within the radioisotope generator 18. Accordingly, the daughter radioisotope, e.g., technetium-99m, can be extracted or washed out with a suitable eluant, such as an oxidant-free physiologic saline solution. The eluate output from the radioisotope generator 18 into the eluate container 74 generally includes the eluant 32 and the washed out or eluted radioisotope from within the radioisotope generator 18. Upon receiving the desired amount of eluate within the eluate container 74, the plunger 56 may be withdrawn outwardly from the shielded eluate assembly 34, such that the circulation and output of eluate is terminated. As discussed in further detail below, the extracted daughter radioisotope can then, if desired, be combined with a tagging agent to facilitate diagnosis or treatment of a patient (e.g., in a nuclear medicine facility).

[0043] After or during the elution process, the door 68 may be rotated open to view the level or amount of eluate collected within the eluate container 74. For example, the eluate container shield 72 may include one or more viewing windows or openings to enable a user to view the quantity of eluate within the container 74. FIG. 5 is a rear perspective view of an embodiment of the radioisotope elution system 10 of FIG. 4, further illustrating the eluate extraction mechanism 12 with the plunger 56 depressed and the door 68 opened to enable viewing of the eluate through a viewing window or slot 93 in the shielded cup structure 78 of the shielded eluate assembly 34. The slot 93, if included, also may be removably covered by a door 94 disposed along the outer walls of the shielded cup structure 78. In certain embodiments, the door 94 may include a sliding door, a rotating door, a sleeve disposed about the shielded eluate assembly 34, or another suitable mechanism for opening and closing the viewing window or slot 93.

[0044] FIG. 6 is a cross-sectional side view of an embodiment of the elution system 10 of FIGS. 3 and 4, further illustrating the plunger 56 withdrawn in an upward direction as indicated by arrow 96, the door 68 opened in a counterclockwise direction as indicated by arrow 98, and the shielded eluate

assembly 34 withdrawn from the eluate extraction mechanism 12 in an outward direction as indicated by arrow 100. In certain embodiments, the shielded eluate assembly 34 may be a radiopharmaceutical dosing assembly, such that one or more doses of the radioisotope may be extracted directly into a syringe or other container for delivery to a hospital or other medical facility. In other words, the eluate extraction mechanism 12 may reduce the number of shielded containers involved in the radiopharmaceutical preparation process within a radiopharmacy. For example, the eluate extraction mechanism 12 may eliminate the use of a shielded eluate container configured to fit within the passage 48 in the cover 22 and/or with the top side of the radioisotope generator 18 inside the auxiliary shield 16. Thus, the eluate extraction mechanism 12 enables output of the eluate directly into the shielded eluate assembly 34, which may then be used to prepare one or more radiopharmaceutical doses without first transferring the eluate to another shielded container assembly.

[0045] FIG. 7 is an exploded cross-sectional side view of an embodiment of the radioisotope elution system 10 of FIG. 6, further illustrating the removability and replaceability of various components including the hollow injection needle 60 of the eluate extraction mechanism 12. In addition, FIG. 8 is an exploded cross-sectional side view of an embodiment of the eluate extraction mechanism 12, further illustrating the removability and replaceability of the hollow injection needle 60. As illustrated, if the hollow injection needle 60 becomes damaged, bent, clogged, or inoperable during an elution process, then the hollow injection needle 60 may be removed and replaced with another needle 60 to ensure proper circulation of fluids through the elution system 10 into the shielded eluate assembly 34. The eluate extraction mechanism 12 and the removable hollow injection needle 60 may increase the life and operational efficiency of the radioisotope generator assembly 14, for example, by substantially reducing the likelihood of an inoperable generator assembly 14 that may be caused by damage to the hollow output needle 54 coupled to the radioisotope generator 18, among other reasons.

[0046] In other words, after making the initial connection between the hollow output needle 54 of the radioisotope generator 18 and the eluate conduit 52 of the eluate extraction mechanism 12, the connections and disconnections with the eluate container 74 may be made with the plunger 56 and the hollow injection needle 60 rather than the hollow output needle 54. For example, each time an amount of eluate is desired from the radioisotope generator 18, the hollow injection needle 60 may be inserted into the eluate container 74 and then removed after the amount of eluate is collected in the container 74. However, the eluate conduit 52 may remain continuously coupled to the hollow output needle 54 of the radioisotope generator 18 during each elution process. Therefore, any likelihood of potential damage to the eluate output connectors (e.g., hollow needles) may be moved away from the radioisotope generator 18 to the eluate extraction mechanism 12. Any potential damage to hollow injection needle 60 can be easily and cheaply addressed by replacing the hollow injection needle 60, whereas the relatively lower potential for damage to the hollow output needle 54 may be addressed by replacing the entire radioisotope generator 18. For these reasons, the removability and replaceability of the hollow

injection needle 60 may reduce downtime, costs, and difficulty in repairing the system 10 in the event of damage to the eluate output connectors.

[0047] FIGS. 9-13 are various views of an embodiment of the plunger 56, further illustrating connection mechanisms for the eluate conduit 52 and the hollow injection needle 60. FIGS. 9 and 10 are top and bottom perspective views of the plunger 56 illustrating a removable fluid coupling 57 that may be removably coupled to a bottom side 59 of the plunger 56. As illustrated in FIGS. 9 and 10, the removable fluid coupling 57 may include an eluate conduit connector 61 extending laterally from the coupling 57, such that the eluate conduit 52 can fit securely and removably about the connector 61. The illustrated eluate conduit connector 61 also may include a variety of raised and lowered portions, such as a series of rings 63, to resist separation between the eluate conduit 52 (e.g., a flexible tube) and the connector 61. In the illustrated embodiment, the connector 61 is oriented at about 90 degrees relative to the hollow injection needle 60. However, the connector 61 may be oriented at a variety of angles in other embodiments of the plunger 56. The hollow injection needle 60 may be generally aligned with a centerline 65 of the plunger 56, such that the needle 60 can be inserted and removed in a straight direction relative to the centerline of the eluate container 74. In certain embodiments, the hollow injection needle 60 may be removably coupled to the removable fluid coupling 57. Alternatively, the hollow injection needle 60 may be an integral portion of the removable fluid coupling 57. In either embodiment, the hollow injection needle 60 may be quickly removed and inexpensively replaced if the needle 60 becomes damaged during use.

[0048] For example, turning to FIG. 11, the plunger 56 may include a slot 67 (e.g., a T-shaped slot) to receive a bossed portion or rail 69 (e.g., a T-shaped head) of the removable fluid coupling 57. As illustrated in FIG. 11, the slot 67 may include a narrow outer opening 71 leading into an enlarged inner channel 73. Similarly, the bossed portion 69 may include a narrow inner portion 75 leading to an enlarged outer portion 77. FIG. 12 is a side view of the removable fluid coupling 57, further illustrating the geometry of the portions 75 and 77. As indicated by arrow 79 in FIG. 11, the fluid coupling 57 may removably couple with the plunger 56 by laterally or horizontally moving the bossed portion or rail 69 into the slot 67. In this manner, the fluid coupling 57 may be vertically interlocked with the plunger 56. In addition, the top of the bossed portion or rail 69 may include a detent 81 to interlock removably with a protrusion 83 inside the slot 67, as illustrated in FIGS. 11 and 13. In certain embodiments, the detent 81 illustrated in FIG. 11 may be a concave recess, and the protrusion 83 illustrated in FIG. 13 may be a convex protrusion or ball-shaped portion. FIG. 13 is a bottom view of the plunger 56 illustrating an embodiment of the protrusion 83 positioned toward the interior or center of the plunger 56. At this interior position, the protrusion 83 may engage the detent 81 as the bossed portion or rail 69 of the removable fluid coupling 57 slides into the slot 67 of the plunger 56. In certain embodiments, the protrusion 83 and the detent 81 may snap-fit together, thereby removably securing the bossed portion or rail 69 in a lateral or horizontal direction relative to the slot 67. In this manner, a user may quickly

install, remove, and replace the removable fluid coupling 67 relative to the slot 67 and rail 69 via the vertical interlocking between the slot 67 and rail 69 and the horizontal interlocking between the detent 81 and protrusion 83. In other embodiments, the removable fluid coupling 67 may be coupled to the plunger 56 via threads, latches, pin and grooves, and so forth.

[0049] Referring again to FIG. 11, the plunger 56 may include one or more guiding rails 85, which may extend vertically lengthwise along the exterior of the plunger 56. These guiding rails 85 may have a generally rectangular geometry or another suitable geometry, which slides lengthwise along a mating portion of the guide structure or passage 58 within the radiation shielded housing 36. In this manner, the guiding rails 85 may ensure proper alignment of the hollow injection needle 60 relative to the eluate container 74 and, also, ensure proper positioning of the eluate conduit connector 61 relative to the eluate conduit 52. However, other embodiments of the plunger 56 may employ a variety of alternative alignment mechanisms.

[0050] FIGS. 14 and 15 are perspective views of an embodiment of the eluate extraction mechanism 12, further illustrating alignment features that may facilitate alignment with the radioisotope generator assembly 14. As illustrated, the radiation shielding housing 84 has a generally L-shaped or 90 degree elbow-shaped geometry. However, any other suitable shapes, structures, or geometries are within the scope of the disclosed system. Moreover, the cover alignment member 42 may have a variety of shapes and configurations to facilitate alignment of the eluate extraction mechanism 12 and the eluate conduit 52 with the radioisotope generator assembly 14. For example, the cover alignment member 42 may have an elongated portion 102, such as an alignment adapter, that may be configured to fit and align with the passage 48 in the cover 22 and a top portion of the radioisotope generator 18. The elongated portion 102 may be an integral part of the eluate extraction mechanism 12 or the elongated portion 102 may be a removable structure having a suitable fastener, such as threads, latches, or snap-fit members, among other fasteners. In addition, the conduit 52 may be at least partially rigid (or rigidly supported) to facilitate the connection and alignment with the hollow output needle 54 of the radioisotope generator 18. For example, the eluate conduit 52 may be supported along most of its length by the alignment portion 102, such that the eluate conduit 52 may be generally centered with the hollow output needle 54 of the radioisotope generator 18 during insertion and removal of the eluate extraction mechanism 12 relative to the cover 22. However, a variety of mounting mechanisms and alignment devices may be utilized with the eluate extraction mechanism 12.

[0051] FIG. 16 is a flowchart illustrating an exemplary nuclear medicine process utilizing the radioactive isotope produced by the elution system 10 illustrated with reference to FIGS. 1-15. As illustrated, the process 104 begins by providing a radioactive isotope for nuclear medicine at block 106. For example, block 106 may include eluting technetium-99m from the radioisotope generator 18 illustrated and described in detail above. At block 108, the process 104 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 110, the process 104 then 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 and, thus, the radioactive isotope may be characterized as a radiopharmaceutical without adding any supplemental tagging agent. At block 112, the process 104 then may proceed by extracting one or more doses of the 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 114, the process 104 proceeds by injecting or generally administering a dose of the radiopharmaceutical into a patient. After a pre-selected time, the process 104 proceeds by detecting/imaging the radiopharmaceutical tagged to the patient's organ or tissue (block 116). For example, block 116 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.

[0052] FIG. 17 is a block diagram of an exemplary system 118 for providing a syringe having a radiopharmaceutical disposed therein for use in a nuclear medicine application. As illustrated, the system 118 includes the radioisotope elution system 10 previously described with regard to FIGS. 1-15. The system 118 also includes a radiopharmaceutical production system 120, which functions to combine a radioisotope 122 (e.g., technetium-99m solution acquired through use of the radioisotope elution system 10) with a tagging agent 124. In some embodiment, this radiopharmaceutical production system 120 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 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 120 produces or may be utilized to produce a radiopharmaceutical including the radioisotope 122 and the tagging agent 124, as indicated by block 126. The illustrated system 118 may also include a radiopharmaceutical dispensing system 128, which facilitates extraction of the radiopharmaceutical into a vial or syringe 130. In certain embodiments, the various components and functions of the system 118 are disposed within a radiopharmacy, which prepares the syringe 130 of the radiopharmaceutical for use in a nuclear medicine application. For example, the syringe 130 may be prepared and delivered to a medical facility for use in diagnosis or treatment of a patient.

[0053] FIG. 18 is a block diagram of an exemplary nuclear medicine imaging system 132 utilizing the syringe 130 of radiopharmaceutical provided using the system 118 of FIG. 12. As illustrated, the nuclear medicine imagining system 132 includes a radiation detector 134 having a scintillator 136 and a photo detector 138. In response to radiation 140 emitted from a tagged organ within a patient 142, the scintillator 136 emits light that is sensed and converted to electronic signals by the photo detector 138.

Although not illustrated, the imaging system 132 also can include a collimator to collimate the radiation 140 directed toward the radiation detector 134. The illustrated imaging system 132 also includes detector acquisition circuitry 144 and image processing circuitry 146. The detector acquisition circuitry 144 generally controls the acquisition of electronic signals from the radiation detector 134. The image processing circuitry 146 may be employed to process the electronic signals, execute examination protocols, and so forth. The illustrated imaging system 132 also includes a user interface 148 to facilitate user interaction with the image processing circuitry 146 and other components of the imaging system 132. As a result, the imaging system 132 produces an image 150 of the tagged organ within the patient 142. Again, the foregoing procedures and resulting image 150 directly benefit from the radiopharmaceutical produced by the elution system 10 as illustrated and described with reference to FIGS. 1-15.

[0054] 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.

[0055] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the figures 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 radiopharmaceutical system, comprising:

a radioisotope generator assembly, comprising:

a radiation shield having a receptacle and a cover disposed over the receptacle; and

a radioisotope generator disposed in the receptacle below the cover; and

an eluate extraction mechanism, comprising:

an eluate conduit fluidly coupled to a hollow output needle of the radioisotope generator;

a radiation shielded housing disposed outside the radiation shield; and

a hollow needle fluidly coupled to the eluate conduit opposite the radioisotope generator wherein the hollow needle is disposed inside the radiation shielded housing.

2. The radiopharmaceutical system of claim 1, wherein the eluate conduit is disposed at least mostly within the radiation shield and the radiation shielded housing.

3. The radiopharmaceutical system of claim 1, wherein the hollow needle is mounted along a path of movement within the radiation shielded housing.

4. The radiopharmaceutical system of claim 1, further comprising an eluate container, wherein the eluate container is disposed removably inside the radiation shielded housing adjacent a door.

5. The radiopharmaceutical system of claim 4, wherein the radiation shielded housing comprises an alignment member disposed adjacent the eluate container opposite the door.

6. The radiopharmaceutical system of claim 1, further comprising an eluate container, wherein the eluate container is disposed inside an eluate container shield comprising a radiation shielding material, wherein the eluate container shield comprises an eluate container viewing window.

7. The radiopharmaceutical system of claim 1, further comprising an eluate container, wherein the eluate container is disposed inside an eluate container shield comprising a radiation shielding material, wherein an alignment adapter is disposed between the eluate container and the eluate container shield.

8. The radiopharmaceutical system of claim 1, wherein the radiation shielded housing is mounted on top of the cover.

9. The radiopharmaceutical system of claim 8, wherein the radiation shielded housing comprises an alignment portion disposed at least partially into a passage in the cover.

10. The radiopharmaceutical system of claim 9, wherein the eluate conduit extends through the alignment portion and the passage.

11. The radiopharmaceutical system of claim 1, wherein the hollow needle is coupled to a plunger via a releasable fastener.

12. The radiopharmaceutical system of claim 11, wherein the releasable fastener comprises a luer connector.

13. The radiopharmaceutical system of claim 1, comprising an eluant supply container fluidly coupled to the radioisotope generator.

14. The radiopharmaceutical system of claim 13, wherein the eluant supply container is disposed inside the radiation shield.

15. An eluate extraction mechanism, comprising:

a radiation shielded housing;

an eluate conduit having a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing;

a hollow injection needle fluidly coupled to the opposite end of the eluate conduit; and

a plunger coupled to the radiation shielded housing movably through a guide structure, wherein the plunger is coupled to the hollow injection needle inside the radiation shielded housing.

16. The eluate extraction mechanism of claim 15, wherein the hollow injection needle comprises a release mechanism.

17. The eluate extraction mechanism of claim 15, wherein the plunger has a path of travel including a connected position and a disconnected position between the hollow injection needle and an eluate container disposed inside the radiation shielded housing.

18. The eluate extraction mechanism of claim 17, wherein the eluate container is disposed removably inside the radiation shielded housing adjacent a door.

19. The eluate extraction mechanism of claim 17, wherein the eluate container is disposed inside an eluate container shield comprising a radiation shielding material, wherein the eluate container shield comprises a viewing window and the eluate container comprises a transparent or translucent material.

20. The eluate extraction mechanism of claim 15, wherein the eluate extraction mechanism comprises a generator alignment portion protruding from a base of the radiation shielded housing.

21. An eluate extraction mechanism, comprising:

a radiation shielded housing comprising a door;

a shielded eluate collection assembly disposed removably inside the radiation shielded housing adjacent the door;

an eluate conduit having a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing; and

a hollow needle fluidly coupled to the opposite end of the eluate conduit, wherein the hollow needle includes a connected position and a disconnected position relative to the shielded eluate collection assembly.

22. The eluate extraction mechanism of claim 21, comprising an actuator disposed through the radiation shielded housing and coupled to the hollow needle.

23. The eluate extraction mechanism of claim 21, wherein the shielded eluate collection assembly comprises an eluate container disposed inside an eluate container shield comprising a radiation shielding material, wherein the eluate container shield comprises a viewing window and the eluate container comprises a transparent or translucent material.

24. The eluate extraction mechanism of claim 21, wherein the eluate extraction mechanism comprises a generator alignment portion protruding from a base of the radiation shielded housing.

25. A method of using a radiopharmaceutical system, the method comprising:

supplying an eluant into a radioisotope generator;

eluting a radioisotope in the radioisotope generator;

receiving an eluate at an output of the radioisotope generator; and

flowing the eluate from the output along an eluate conduit to a hollow needle that is removably inserted into an eluate container via a plunger.

26. The method of claim 25, wherein flowing comprises transferring the eluate through a radiation shield disposed about the radioisotope generator and directly into a radiation shielded housing disposed outside the radiation shield, wherein the radiation shielded housing is disposed about the eluate container, the hollow needle, and at least a portion of the plunger.

27. The method of claim 25, comprising maintaining a continuous connection between the output and the eluate conduit during connections and disconnections between the hollow needle and the eluate container.

28. The method of claim 25, comprising enabling selective viewing of the eluate within the eluate container via a window.

29. The method of claim 25, comprising enabling selective access to the eluate container via a door.

30. The method of claim 25, comprising guiding the plunger along a path of movement between an engaged position and a disengaged position with the eluate container.

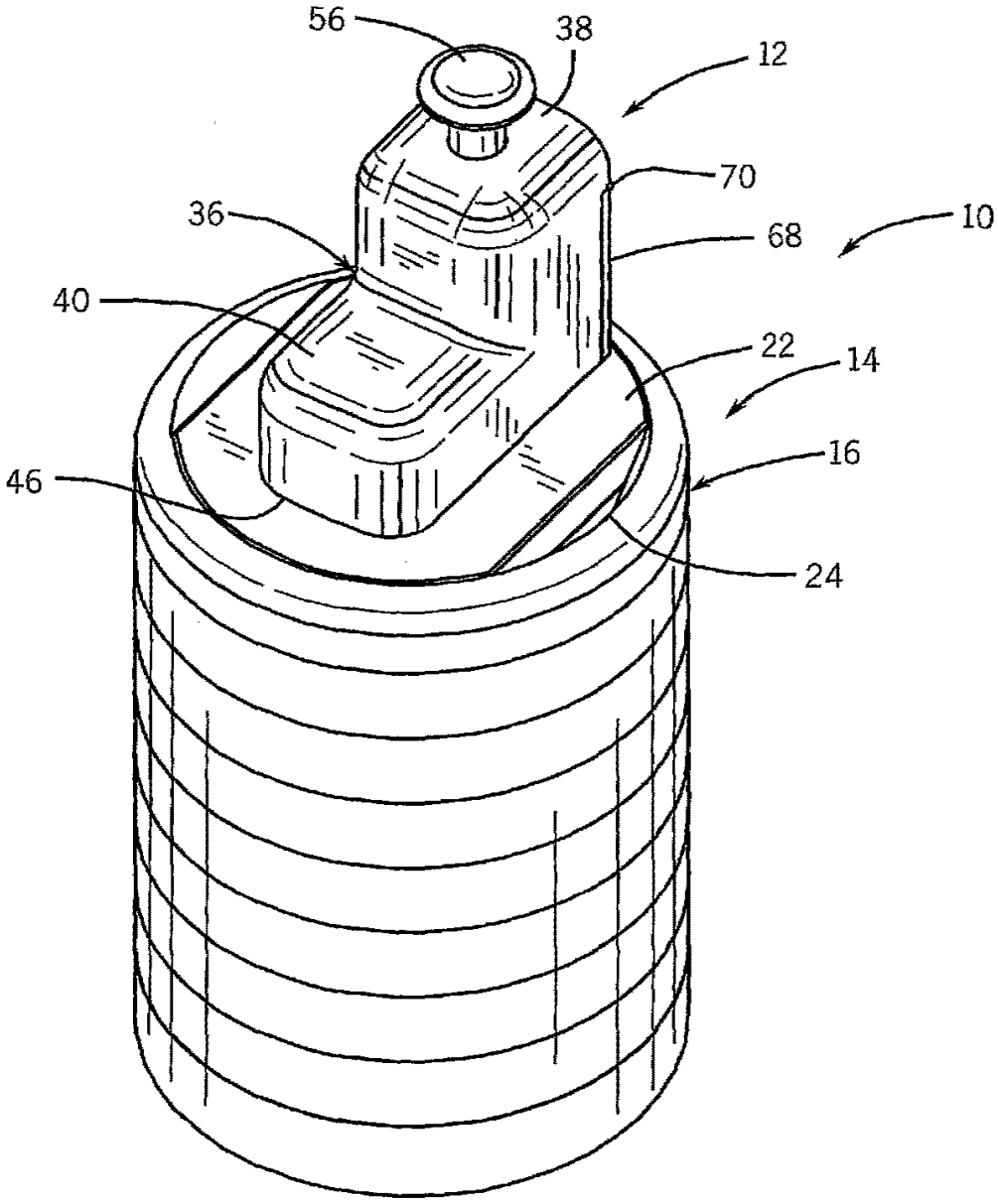


FIG. 1

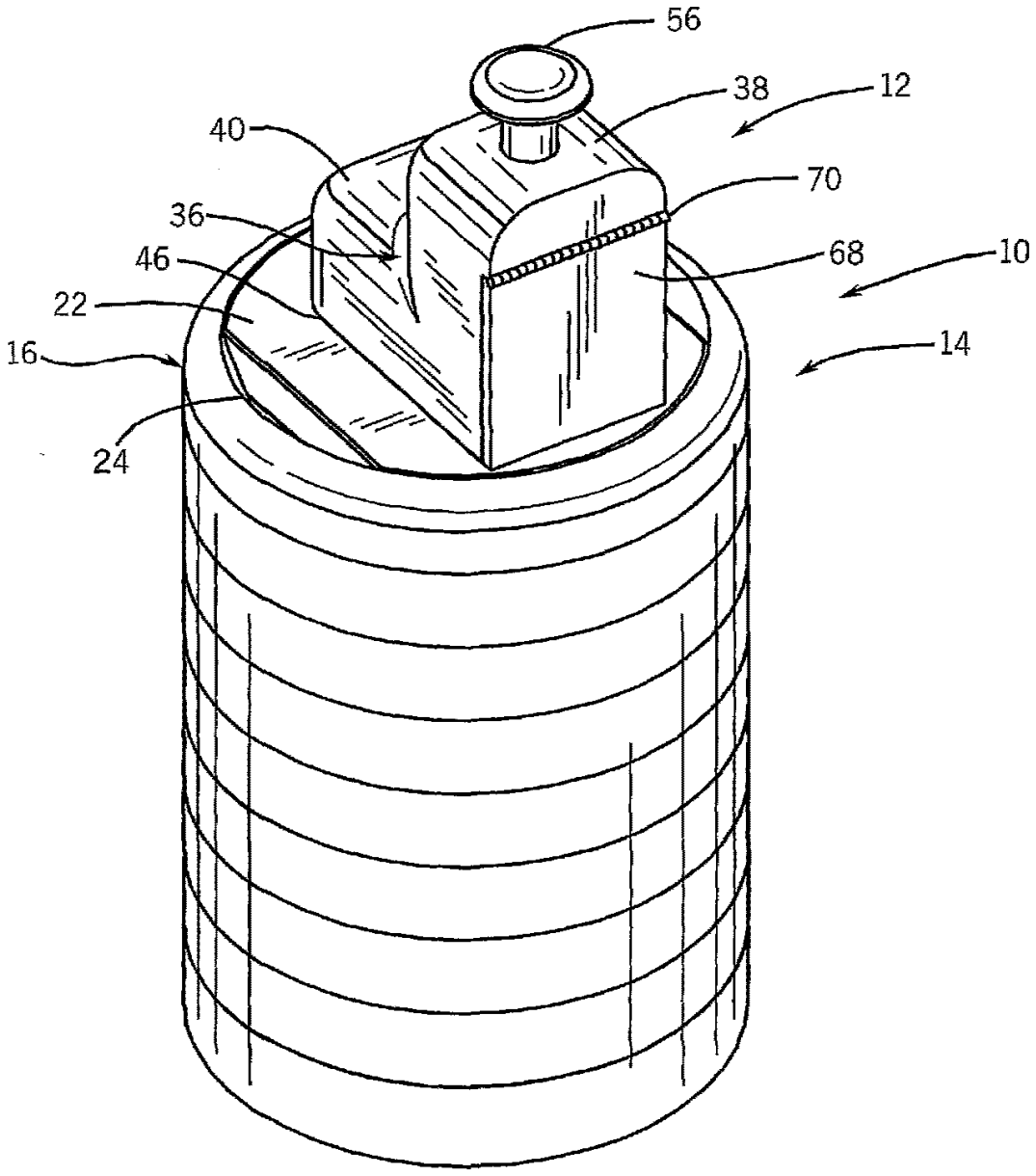


FIG. 2

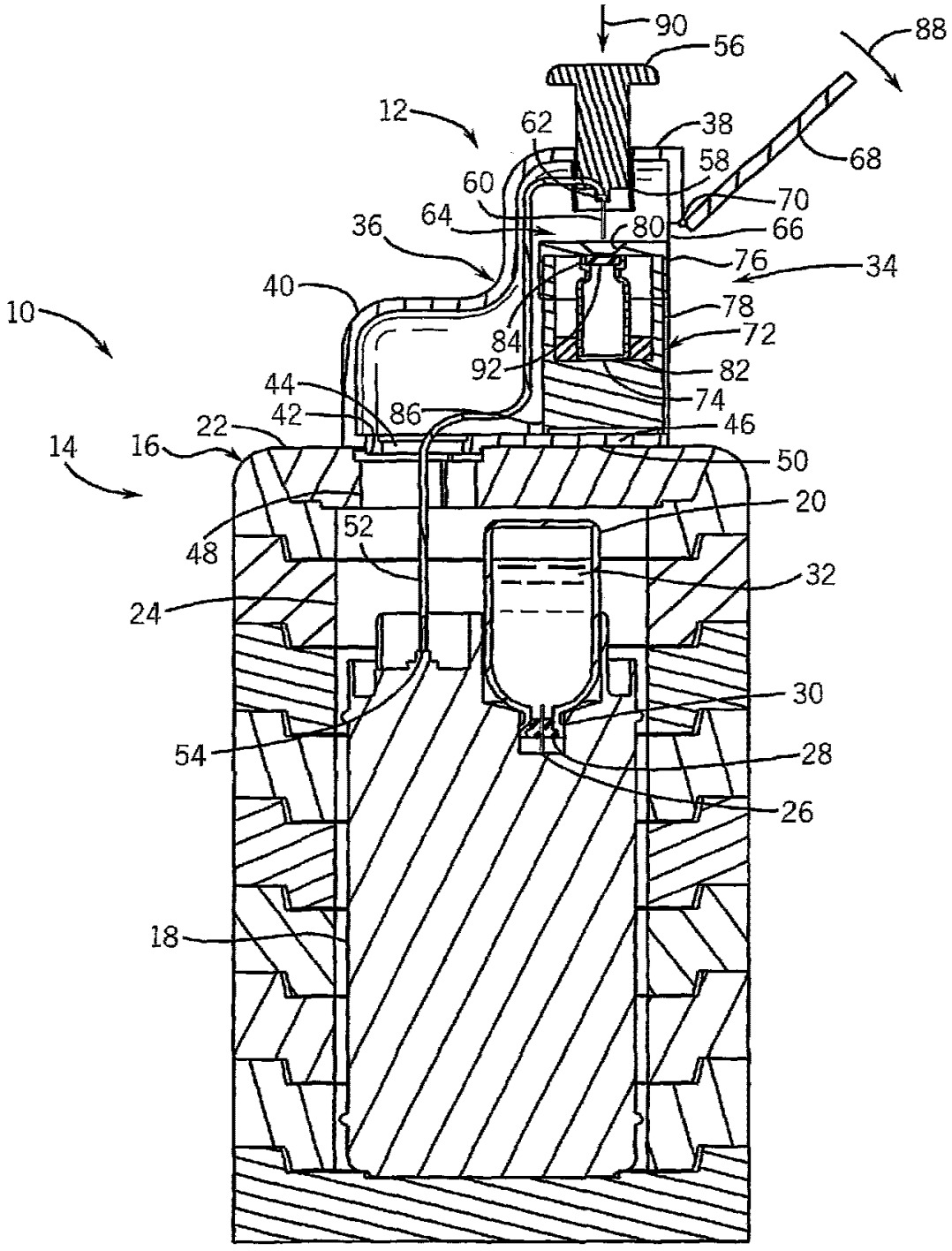

90
56
88
12
62
38
58
68
60
70
64
80
66
36
76
34
40
78
10
84
72
92
82
44
74
42
86
46
22
16
14
50
20
48
52
32
24
30
54
28
26
18

FIG. 3

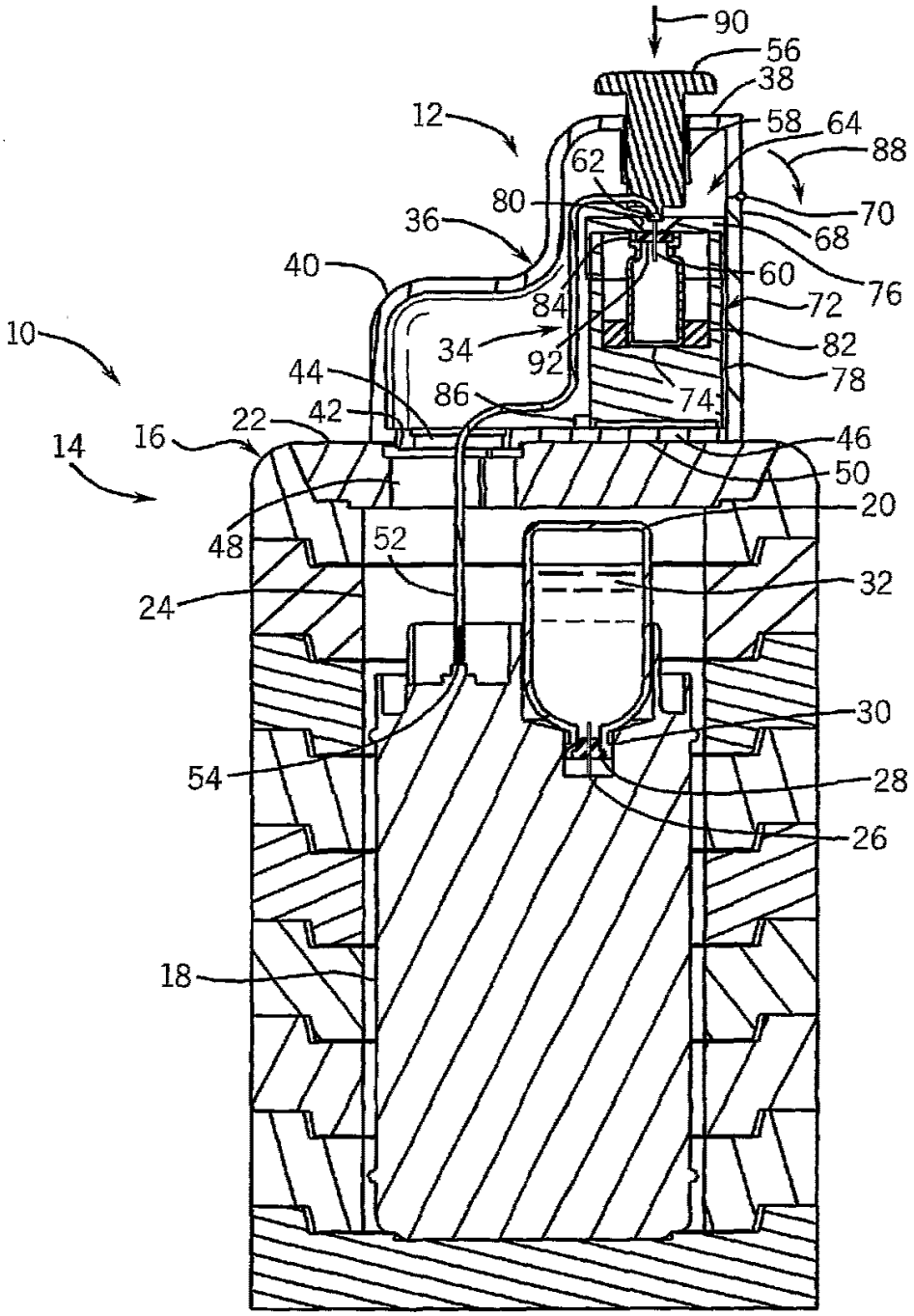

90
56
38
12
58
64
88
62
80
70
36
68
40
60
76
84
72
10
34
92
82
44
86
74
78
42
22
16
46
14
50
20
48
52
32
24
30
54
28
26
18

FIG. 4

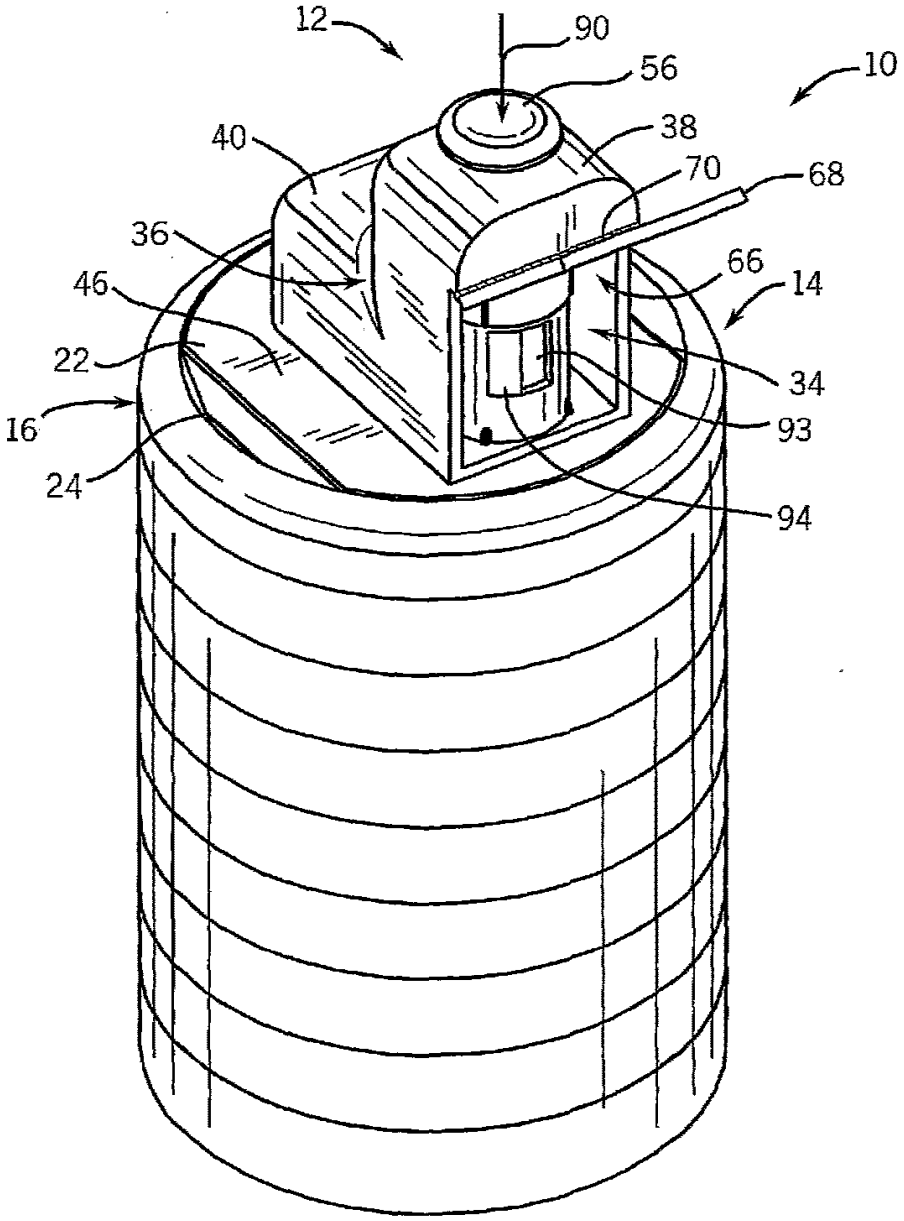


FIG. 5

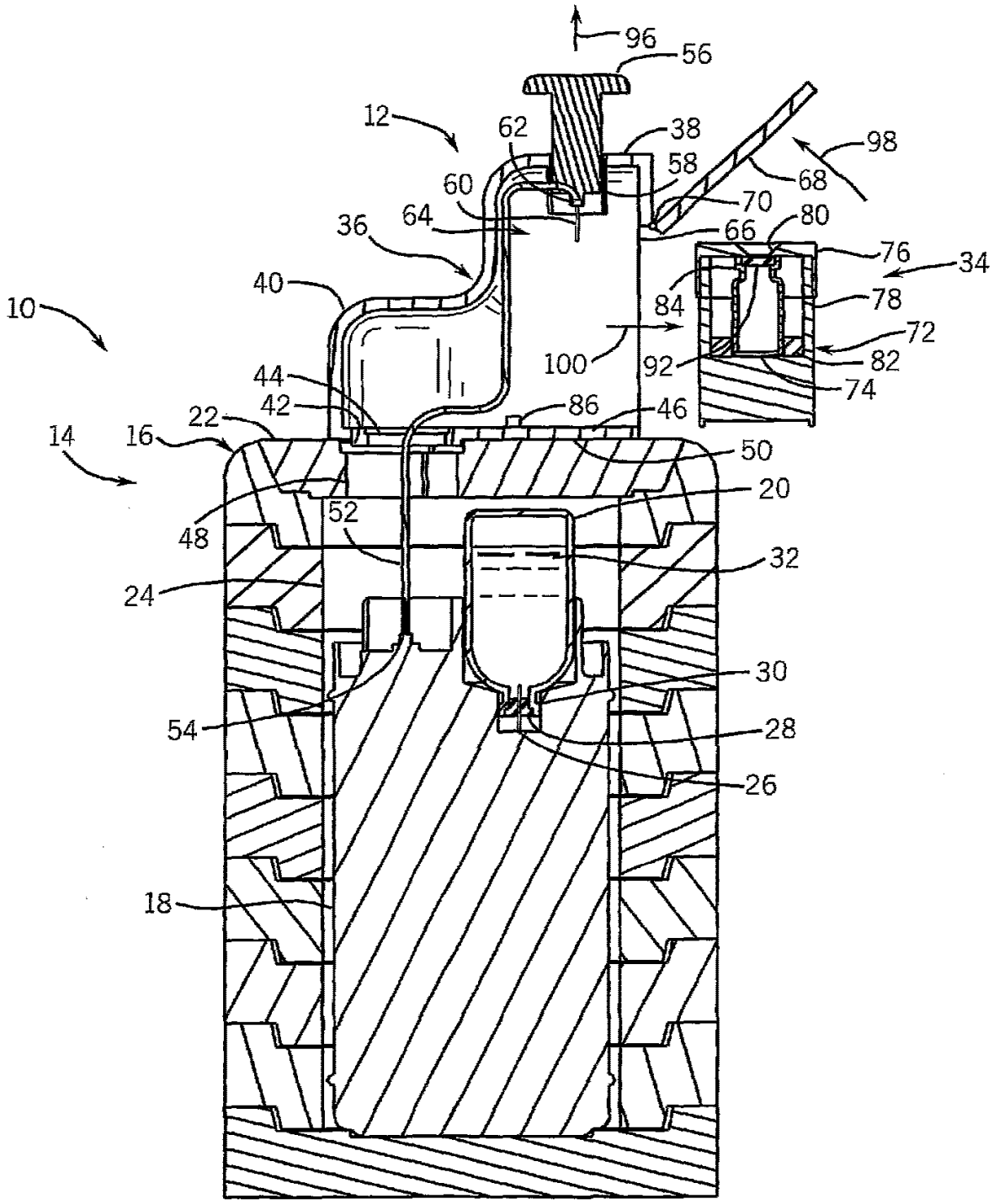

96
56
12
62
38
98
58
60
68
70
64
66
80
36
76
34
40
84
78
10
72
100
92
82
44
74
42
86
46
22
14
16
50
20
48
52
32
24
30
54
28
26
18

FIG. 6

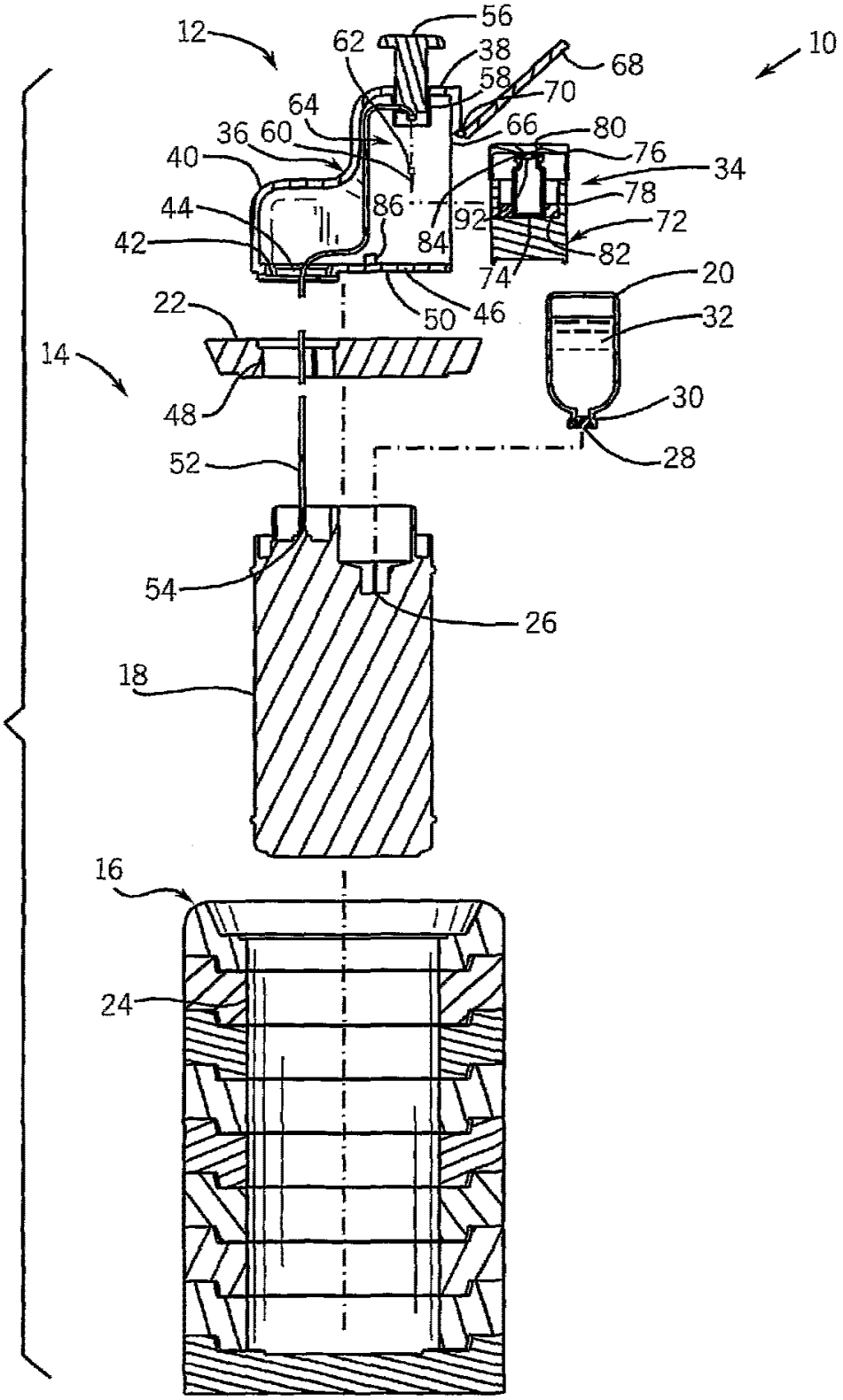

12
10
56
62
38
68
58
70
64
66
80
36
60
76
40
34
78
44
86
92
72
42
84
82
74
20
50
46
22
32
14
30
48
28
52
54
26
18
16
24

FIG. 7

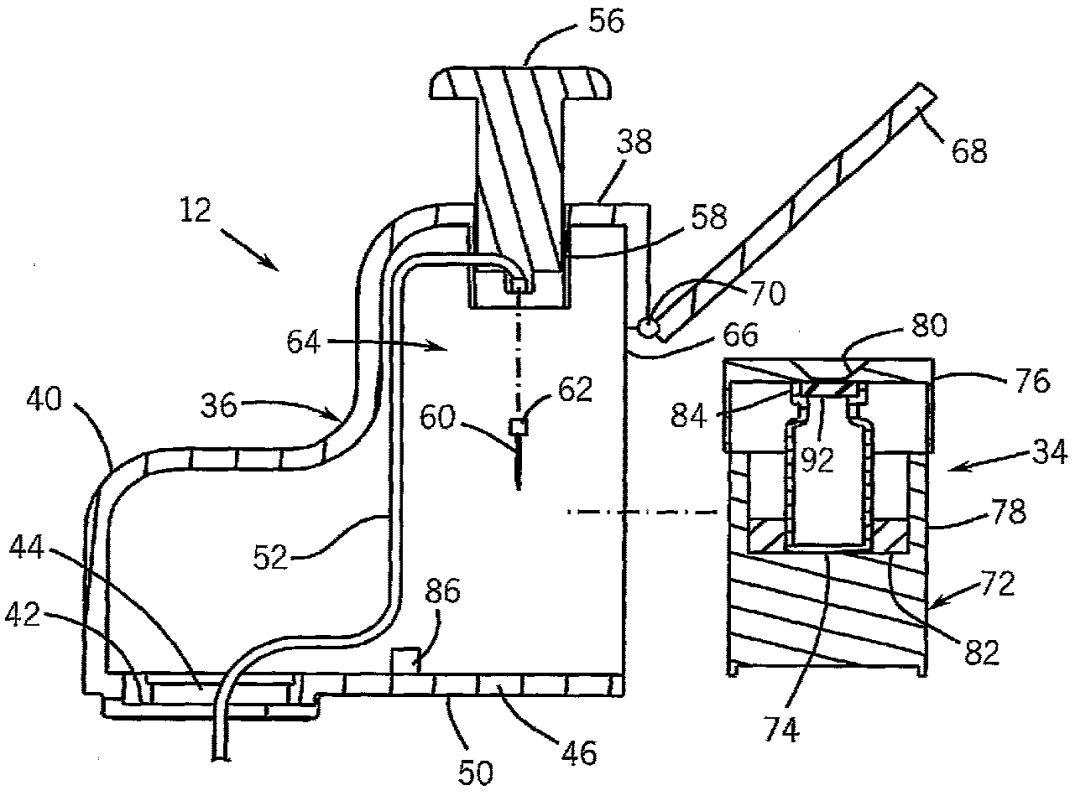
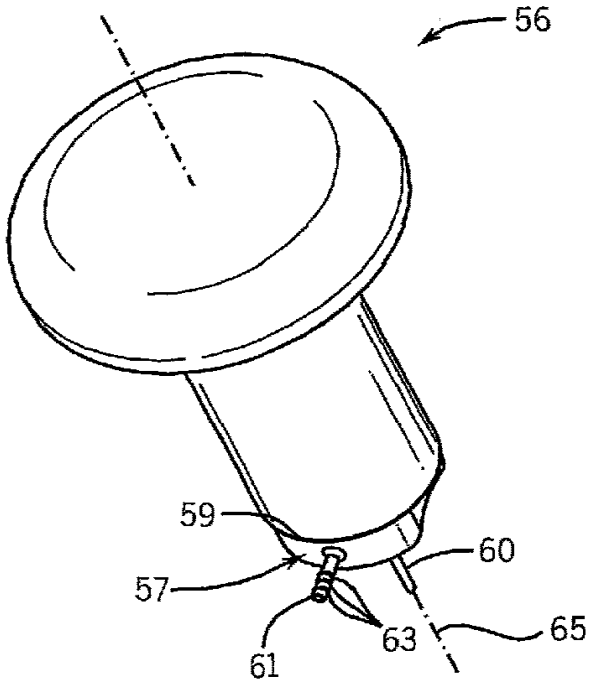

56
38
68
12
58
70
64
66
80
76
40
36
62
60
84
92
34
78
44
52
86
72
42
82
74
50
46

FIG. 8

FIG. 9



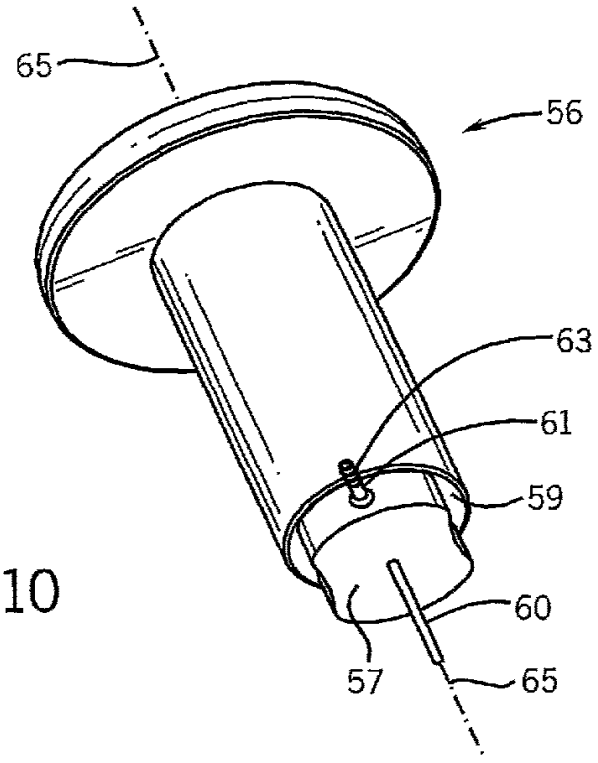


FIG. 10

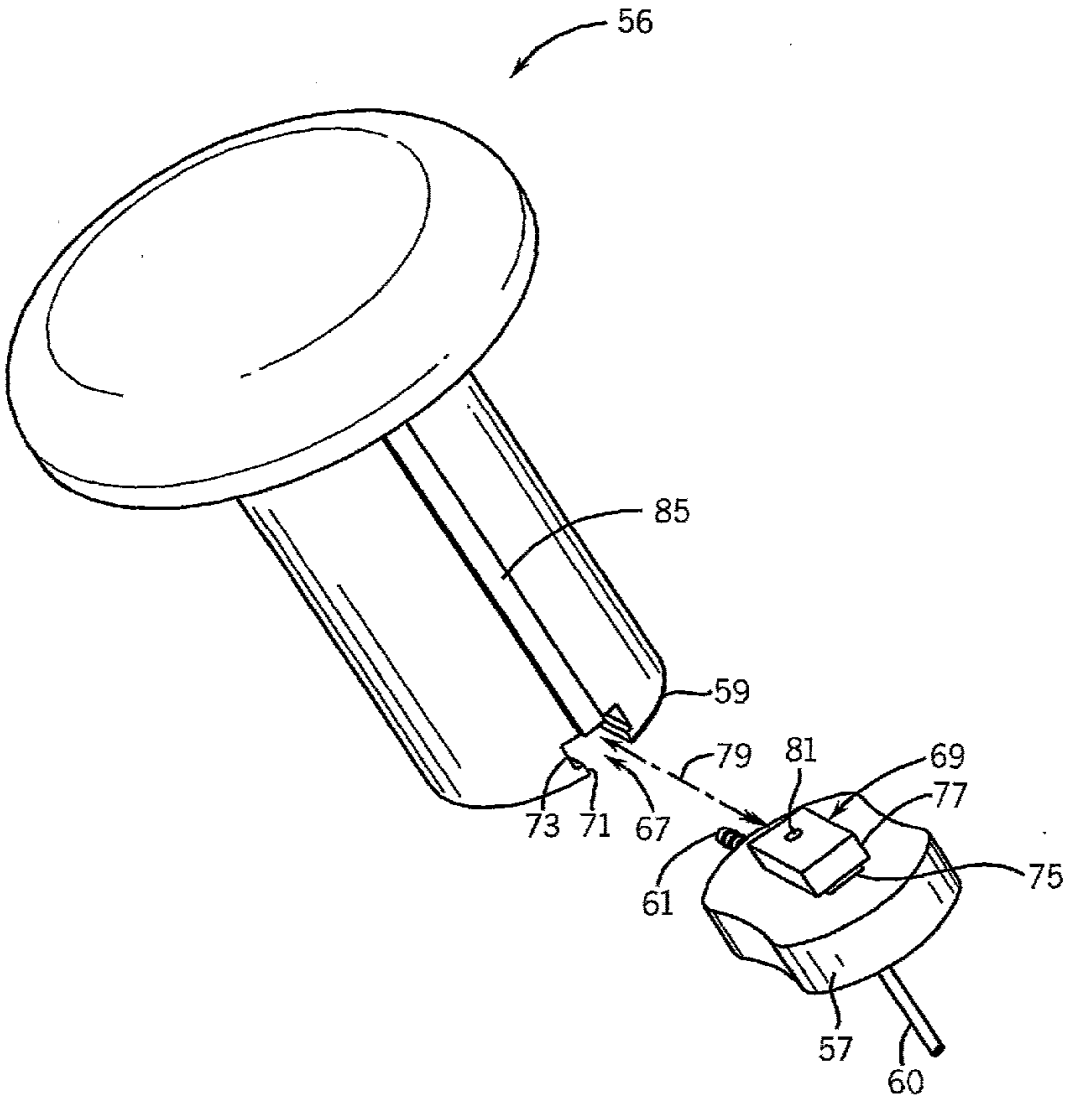


FIG. 11

FIG. 12

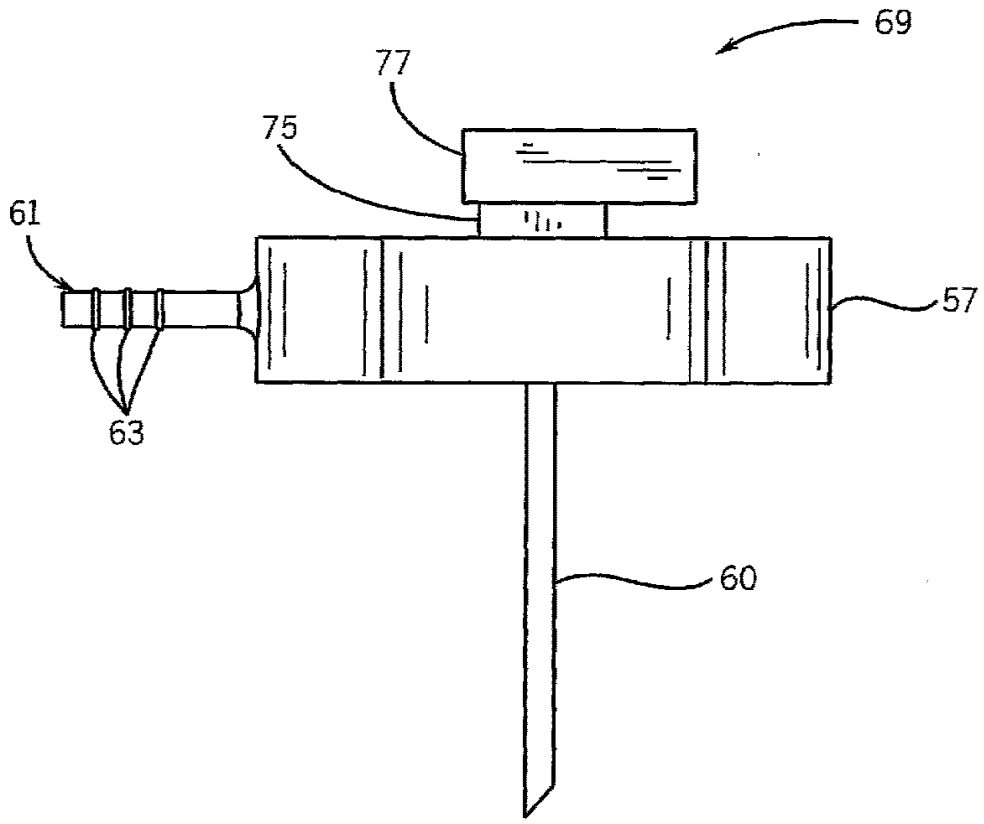


FIG. 13

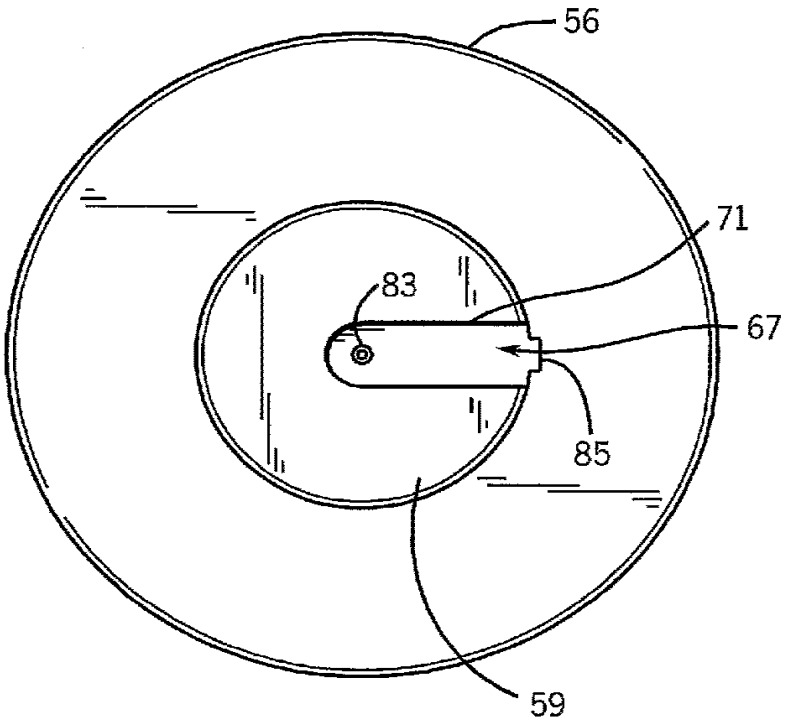
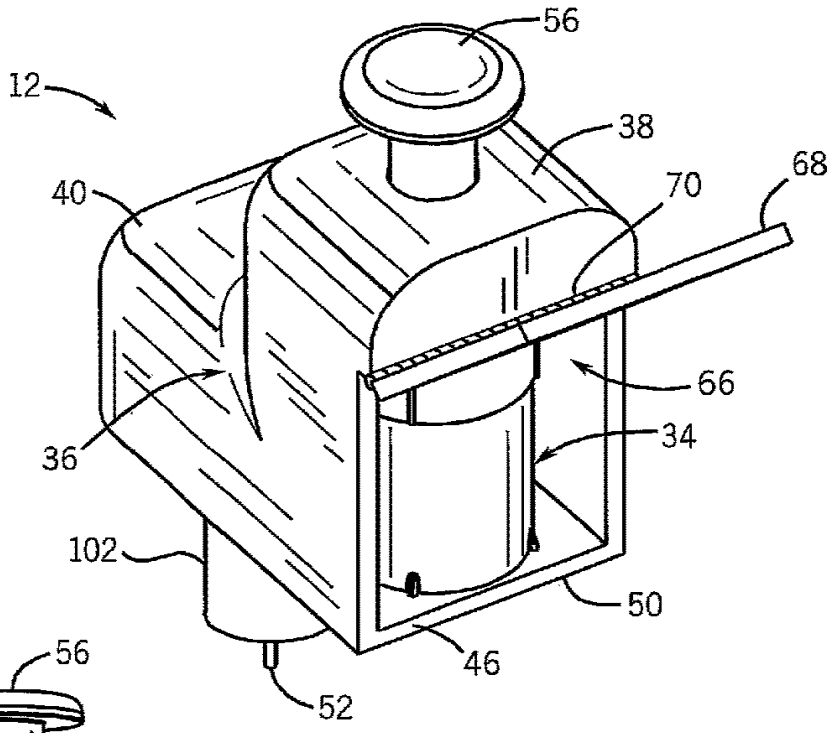


FIG. 14


56
12
38
40
70
68
66
36
34
102
50
46
52

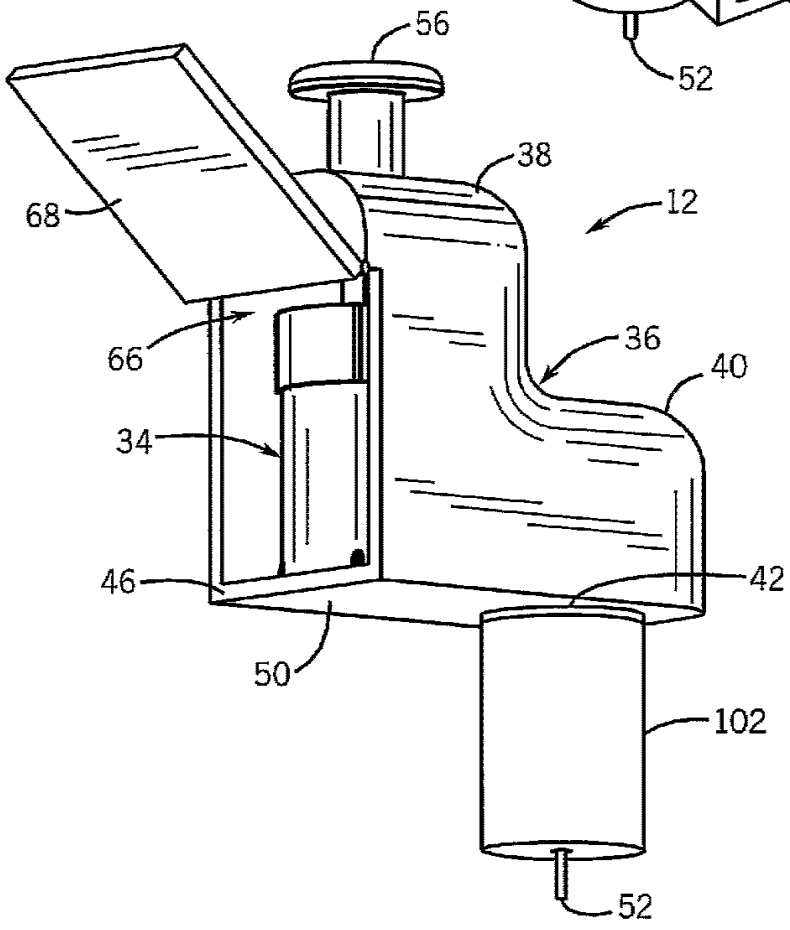

56
38
68
12
66
36
40
34
46
42
50
102
52

FIG. 15

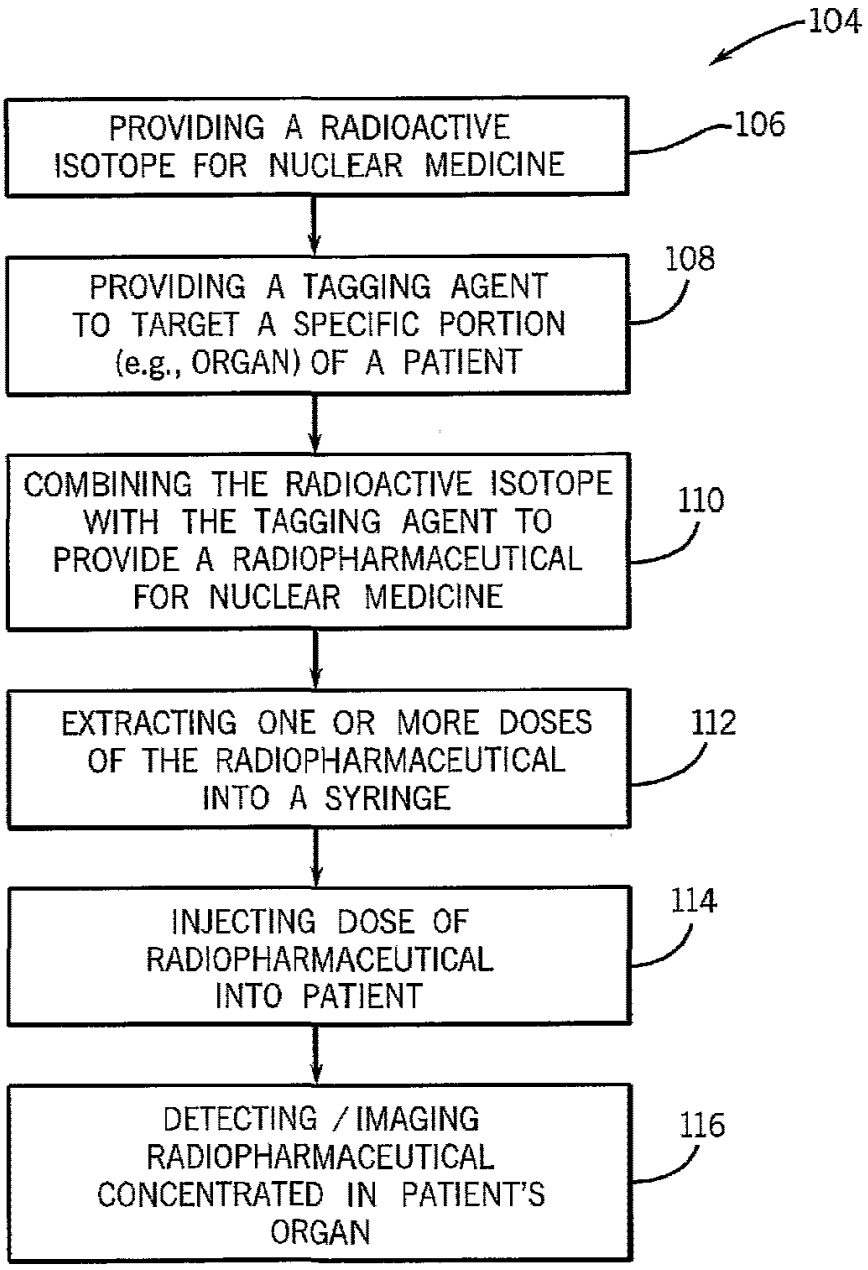

104
PROVIDING A RADIOACTIVE ISOTOPE FOR NUCLEAR MEDICINE
106
PROVIDING A TAGGING AGENT TO TARGET A SPECIFIC PORTION (e.g., ORGAN) OF A PATIENT
108
COMBINING THE RADIOACTIVE ISOTOPE WITH THE TAGGING AGENT TO PROVIDE A RADIOPHARMACEUTICAL FOR NUCLEAR MEDICINE
110
EXTRACTING ONE OR MORE DOSES OF THE RADIOPHARMACEUTICAL INTO A SYRINGE
112
INJECTING DOSE OF RADIOPHARMACEUTICAL INTO PATIENT
114
DETECTING / IMAGING RADIOPHARMACEUTICAL CONCENTRATED IN PATIENT'S ORGAN
116

FIG. 16

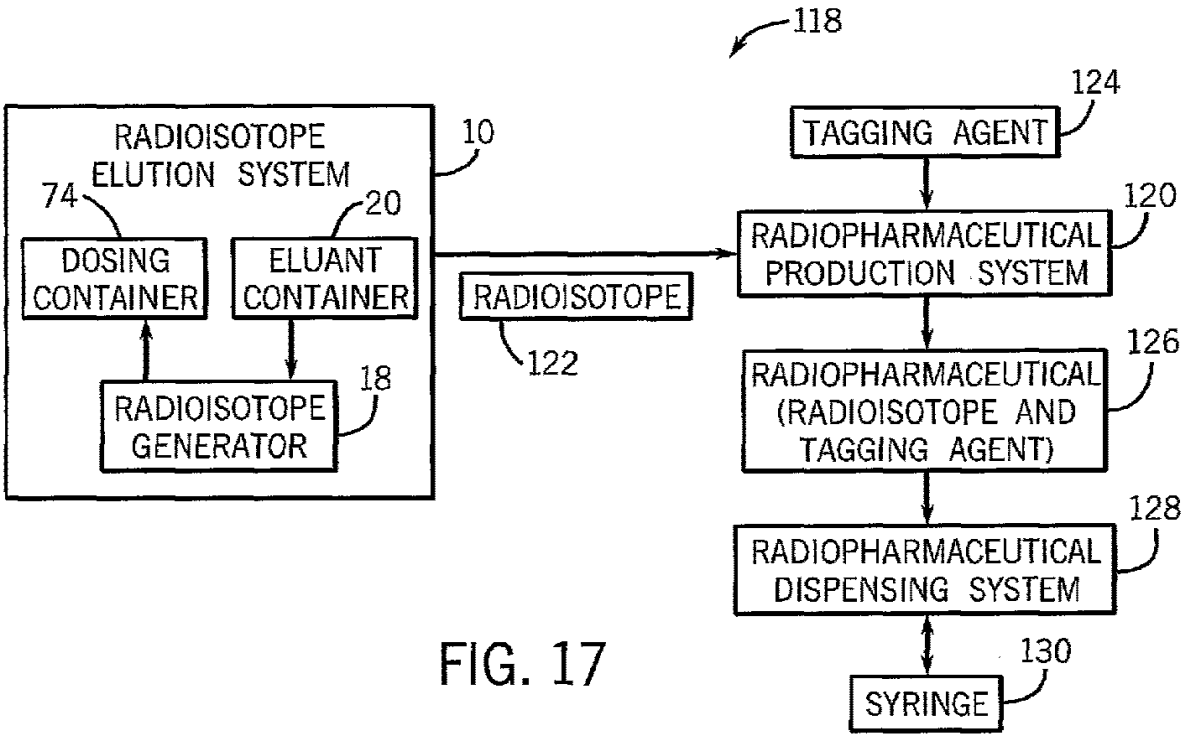

118
RADIOISOTOPE ELUTION SYSTEM
10
74
20
DOSING CONTAINER
ELUANT CONTAINER
RADIOISOTOPE GENERATOR
18
RADIOISOTOPE
122
TAGGING AGENT
124
RADIOPHARMACEUTICAL PRODUCTION SYSTEM
120
RADIOPHARMACEUTICAL (RADIOISOTOPE AND TAGGING AGENT)
126
RADIOPHARMACEUTICAL DISPENSING SYSTEM
128
SYRINGE
130

FIG. 17

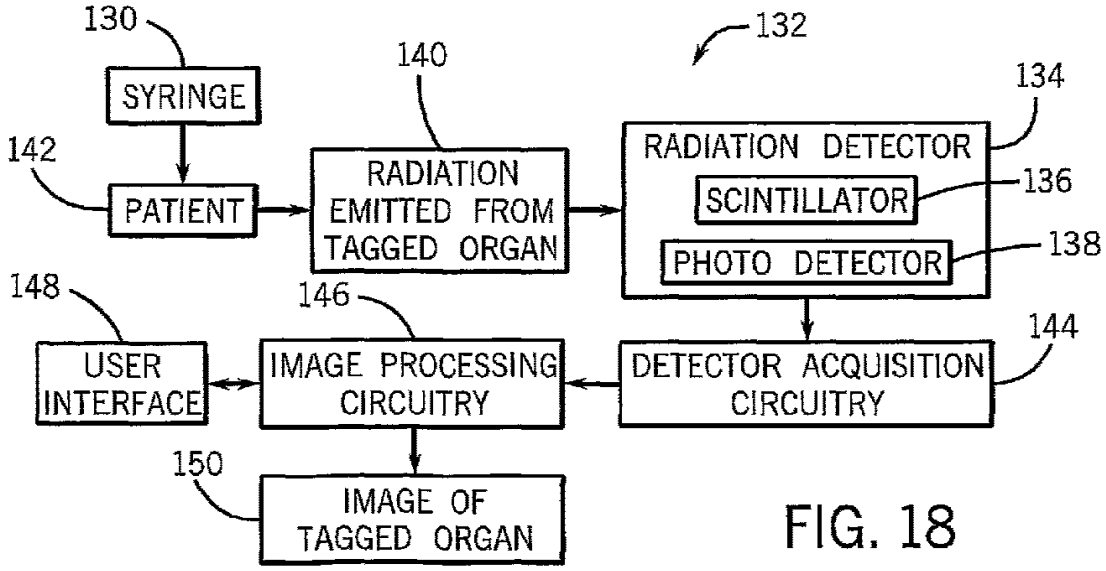

130
SYRINGE
140
132
134
142
PATIENT
RADIATION EMITTED FROM TAGGED ORGAN
RADIATION DETECTOR
SCINTILLATOR
136
PHOTO DETECTOR
138
148
146
USER INTERFACE
IMAGE PROCESSING CIRCUITRY
DETECTOR ACQUISITION CIRCUITRY
144
150
IMAGE OF TAGGED ORGAN

FIG. 18

Electronic Patent Application Fee Transmittal

Application Number:	12137364
Filing Date:	11-Jun-2008
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Steve Hidem
Filer:	Elisabeth Lacy Belden
Attorney Docket Number:	56782.1.7

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:				
Late filing fee for oath or declaration	1051	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	490	490
Miscellaneous:				
			Total in USD ($)	**620**

PTO/SB/22 (10-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** (*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*)	Docket Number (Optional) 56782.1.7
Application Number 12/137,364	Filed June 11, 2008
For Infusion Systems Including Computer-Facilitated Maintenance and/or Operation and Methods of Use	
Art Unit 2628	Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$130	$65	$
☑	Two months (37 CFR 1.17(a)(2))	$490	$245	$ 490
☐	Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 061910.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 50,751

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Elisabeth Lacy Belden/ — Signature

October 24, 2008 — Date

Elisabeth Lacy Belden — Typed or printed name

612-492-7000 — Telephone Number

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 than one signature is required, see below.

☑ Total of 1 forms are submitted.

Privacy Act Statement

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	4173711
Application Number:	12137364
International Application Number:	
Confirmation Number:	7377
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Steve Hidem
Customer Number:	22859
Filer:	Elisabeth Lacy Belden
Filer Authorized By:	
Attorney Docket Number:	56782.1.7
Receipt Date:	24-OCT-2008
Filing Date:	11-JUN-2008
Time Stamp:	16:08:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$620
RAM confirmation Number	1443
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Extension of Time	56782_1_7_Extension_2Mo.pdf	207395 32bfcb9e823720897466818 0ba8646ba23599c95	no	2
Warnings:					
Information:					
2	Applicant Response to Pre-Exam Formalities Notice	56782_1_7_ResponseToMP.pdf	69928 eacb89534052f39fe3ad3da28ff37e9892cf7328	no	1
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73(b).	56782_1_7_Statement.pdf	178905 3b24de2ff7cc456d5e02455225b2ac46fee017f6	no	2
Warnings:					
Information:					
4	Power of Attorney	56782_PowerofAttorney.pdf	58043 283a0d970401b4122cc59ee7ac526c528e684bf5	no	1
Warnings:					
Information:					
5	Oath or Declaration filed	56782_1_7_Declaration_signed.pdf	759158 e487c8d6af4fa0c6656b9e932086e3cf9c13d451	no	12
Warnings:					
Information:					
6	Drawings-only black and white line drawings	56782_1_5_6_7_8_ReplacementDrawings.pdf	3359510 ae834f3ef728a795bd8e3c6fc52bbf8aba052235	no	23
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Filed (SB/08)	56782_1_7_IDS.pdf	854594 203485e5d3547e707fcdaeaa38e2f6640f4d07d3	no	5
Warnings:					
Information:					
8	Foreign Reference	56782_1_EP0102121A1.pdf	513030 2ed3206792c3e4b85d5ea5ac7e216731e1a30015	no	19
Warnings:					
Information:					
9	Foreign Reference	56782_1_WO2007016170A1.pdf	632231 79a7df3d71191d8a1e9ae052dfa293d9ec0d8e8c	no	30
Warnings:					
Information:					

10	Foreign Reference	56782_1_WO2007030249A2.pdf	730545 4b1bc48163a305542f3f34c114cd3a192eab0c8f	no	27
Warnings:					
Information:					
11	Foreign Reference	56782_1_WO2007149108A2.pdf	966637 9f863086ccd268122413dd0bc063a2050e8d1937	no	35
Warnings:					
Information:					
12	NPL Documents	56782_1_9300003_Rev11_User_Guide_highlited.pdf	1610985 73c8467a0013420f88c2810b68bce640a8e5e1d4	no	53
Warnings:					
Information:					
13	NPL Documents	56782_1_CardioGenInfusionSystemSalesPiece.pdf	4907055 7b8216505438b99ff98271b5264c01aa175aef0c	no	2
Warnings:					
Information:					
14	NPL Documents	56782_1_IntegoArticle.pdf	114715 c00696d16ac6f03d84c29c8250c4614949ae295f	no	2
Warnings:					
Information:					
15	Fee Worksheet (PTO-06)	fee-info.pdf	32725 3eb0f71f860b5cfb4d46d891c18656c23855ed26	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	14995456	

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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/137,364	06/11/2008	2628	1650	56782.1.7	24	5

CONFIRMATION NO. 7377

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

FILING RECEIPT

Date Mailed: 06/24/2008

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)

Steve Hidem, Residence Not Provided;
Aaron Fontaine, Residence Not Provided;
Janet Paris, Residence Not Provided;
Patrick McDonald, Residence Not Provided;
Kathryn Hunter, Residence Not Provided;

Assignment For Published Patent Application

BRACCO DIAGNOSTICS, INC., Princeton, NJ

Power of Attorney: None

Domestic Priority data as claimed by applicant

Foreign Applications

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 12/137,364**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

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

Preliminary Class

345

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

NOT GRANTED

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

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/137,364	06/11/2008	Steve Hidem	56782.1.7

CONFIRMATION NO. 7377

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

FORMALITIES LETTER

Date Mailed: 06/24/2008

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

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

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - Numbers, letters, and reference characters on the drawings must measure at least 0.32 cm (1/8 inch) in height. See Figure(s) 5A-10.
  - The drawings submitted to the Office are not electronically reproducible because portions of figures 4-10 are missing and/or blurry.

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

The applicant needs to satisfy supplemental fees problems indicated below.

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

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $**130** for a non-small entity, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $**130** for a non-small entity
- $**130** Surcharge.

Replies should be mailed to:

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

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

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

/mduong/

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

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7
	Application Number	
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

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

Secrecy Order 37 CFR 5.2

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

Applicant Information:

Applicant 1 Remove

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

Prefix	Given Name	Middle Name	Family Name	Suffix
	Steve		Hidem	

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

City		State/Province		Country of Residence [i]	

Citizenship under 37 CFR 1.41(b) [i]	

Mailing Address of Applicant:

Address 1	
Address 2	

City		State/Province	
Postal Code		Country [i]	

Applicant 2 Remove

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

Prefix	Given Name	Middle Name	Family Name	Suffix
	Aaron		Fontaine	

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

City		State/Province		Country of Residence [i]	

Citizenship under 37 CFR 1.41(b) [i]	

Mailing Address of Applicant:

Address 1	
Address 2	

City		State/Province	
Postal Code		Country [i]	

Applicant 3 Remove

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

Prefix	Given Name	Middle Name	Family Name	Suffix
	Janet		Paris	

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

City		State/Province		Country of Residence [i]	

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7
	Application Number	
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Citizenship under 37 CFR 1.41(b) i				
Mailing Address of Applicant:				
Address 1				
Address 2				
City		**State/Province**		
Postal Code		**Country**i		

Applicant 4 Remove

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

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Patrick		McDonald	

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

City		**State/Province**		**Country of Residence** i	

Citizenship under 37 CFR 1.41(b) i				
Mailing Address of Applicant:				
Address 1				
Address 2				
City		**State/Province**		
Postal Code		**Country**i		

Applicant 5 Remove

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

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Kathryn		Hunter	

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

City		**State/Province**		**Country of Residence** i	

Citizenship under 37 CFR 1.41(b) i				
Mailing Address of Applicant:				
Address 1				
Address 2				
City		**State/Province**		
Postal Code		**Country**i		

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

Correspondence Information:

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

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

Customer Number	22859

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7
	Application Number	
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE		
Attorney Docket Number	56782.1.7	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	23	**Suggested Figure for Publication (if any)**	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

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

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

Domestic Benefit/National Stage Information:

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

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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

Foreign Priority Information:

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	56782.1.7
	Application Number	
Title of Invention	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE	

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

Remove

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

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

Assignee Information:

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

Remove

Assignee 1

If the Assignee is an Organization check here. ☒

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

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

Signature:

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

Signature	/Charles D. Segelbaum/			Date (YYYY-MM-DD)	2008-06-11
First Name	Charles D.	Last Name	Segelbaum	Registration Number	42138

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

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

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. 56782.1.5, entitled: SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS; Practitioner Docket No. 56782.1.6, entitled: INFUSION SYSTEM CONFIGURATIONS; and Practitioner Docket No. 56782.1.8, entitled: CABINET STRUCTURES SUPPORTING INFUSION SYSTEMS.

TECHNICAL FIELD

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

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).

[04] Set up, maintenance and operational procedures for infusion systems that both generate and inject doses of radiopharmaceuticals are relatively involved in order

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

BRIEF DESCRIPTION OF THE DRAWINGS

[05] 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.

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

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

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

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

[10] 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.

[11] 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.

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

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

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

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

[16] 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.

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

[18] 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.

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

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

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

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

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

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

DETAILED DESCRIPTION

[25] 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.

[26] 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 included, for example, a keyboard, a series of control buttons or levers, a barcode 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. Operation of system 10, which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

[27] 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.

[28] 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. Figure 1B further illustrates a rear access panel 174, for example, providing access to circuit boards of the aforementioned controller contained within the interior space surrounded 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 one or more additional connectors, or ports (not shown), which allow system 10 to be coupled to, for communication with, other devices used for nuclear imaging procedures.

[29] 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.

[30] 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.

[31] 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, 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.

[32] 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.

[33] 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.

[34] 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.

[35] 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. 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.

[36] 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. According to the illustrated embodiment, 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.

[37] 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.

[38] 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.

[39] 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.

[40] 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.

[41] 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.

[42] 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.

[43] 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.

[44] According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w,

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

[45] As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

[46] With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is

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

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

[48] Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which

radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17 away from radioactive radiation.

[49] According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format.

[50] Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on.

[51] Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a

storage medium (i.e. disk) reader, a scanner, a barcode reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc...).

[52] If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag, which leads computer 17 to prompt the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume, via screen 574, as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished.

[53] In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via

presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied.

[54] In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate it being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.

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

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

[57] Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

[58] Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a

screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

[59] After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may

further direct the user to contact the generator supplier, for example, to order a replacement generator.

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

[61] With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration

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

[62] With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

[63] With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with a option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

[64] Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary of the infusion, which includes the patient

identification number and pertinent system parameters, may be downloaded onto a computer readable storage device to be transferred to one or more remote computers and/or automatically transferred thereto, via wireless communication or a cable connection. The one or more remote computers may be included, for example, in a hospital information system, and/or an inventory system, and/or a billing system, and/or in a medical imaging system. With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data.

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

with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

[66] According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

[67] The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator.

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

We claim:

1. A method for operating an infusion system, the system comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer including a computer interface, the infusion tubing circuit including an eluant line coupled to the pump and to the generator, a waste line coupled to the generator and to the waste bottle, and a patient line coupled to the generator, the method comprising:

entering, into the computer, via the computer interface, a command to activate the pump in order to generate an eluate from a portion of a volume of eluant pumped through the generator, via an elution within the generator;

receiving an indication, from the computer, via the computer interface, that the elution is completed, when the pump has completed pumping the portion of the volume of eluant; and

receiving an indication, from the computer, via the computer interface, of time lapsed since the elution was completed.

2. The method of claim 1, further comprising:

entering, into the computer, via a computer interface, the volume of eluant contained in the reservoir, prior to the elution; and

receiving, from the computer interface, an indication of a volume of eluant in the reservoir, based upon tracking the portion of the volume of eluant that is pumped from the reservoir.

3. The method of claim 1, further comprising:
coupling the patient line of the infusion tubing circuit to a first shielded test vial, in order to collect a first sample of the eluate from the patient line during the elution;
measuring an activity of the first sample; and
entering into the computer, via the computer interface, the measured activity of the first sample and a time between completion of the elution and the measuring of the activity so that the computer may calculate a breakthrough of the generator.

4. The method of claim 3, further comprising:
selecting a breakthrough test procedure of the computer, via the computer interface, prior to entering the command to activate the pump; and
wherein coupling the patient line to the first shielded test vial is instructed by the computer interface, after selecting the breakthrough test.

5. The method of claim 3, further comprising:
exchanging the patient line of the infusion tubing circuit for a first new patient line, after collecting the first sample;
coupling the first new patient line to a second shielded test vial;
repeating the steps of claim 1, after exchanging the patient line, wherein the pump is activated a second time and a second elution takes place, in order to fill the second vial with a second sample of the eluate from the first new patient line;
measuring an activity of the second sample; and
entering into the computer, via the computer interface, the measured activity of the second sample and a time between completion of the second elution and the measuring of the activity of the second sample, so that the computer may calculate a calibration coefficient for the infusion system based on the measured activity of the second sample and an activity of the eluate detected, during the second elution, by the activity detector of the system.

6. The method of claim 5, further comprising:
selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump for the second time; and
wherein coupling the first new patient line to the second shielded test vial is instructed by the computer interface, after selecting the calibration procedure.

7. The method of claim 5, further comprising:
exchanging the first new patient line of the infusion tubing circuit for a second new patient line, after the computer calculates the calibration coefficient;
purging air from the second patient line;
coupling the second new patient line to a patient, after purging; and
repeating the steps of claim 1, after exchanging the first new patient line for the second new patient line, wherein the pump is activated a third time and a third elution takes place, in order to inject a dose of the eluate to the patient from the second patient line.

8. The method of claim 7, further comprising receiving a report from the computer, upon completion of the third elution, the report including a patient identification number and at least one quantification of the dose of the eluate.

9. The method of claim 1, further comprising:
coupling the patient line to a shielded test vial in order to collect a sample of the eluate from the patient line during the elution;
measuring an activity of the sample; and
entering into the computer, via the computer interface, the measured activity of the sample and a time between completion of the elution and measuring of the activity, so that the computer may calculate a calibration coefficient for the infusion system based on the measured activity and an activity of the eluate detected, during elution, by the activity detector of the system.

10. The method of claim 9, further comprising:

selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump; and

wherein coupling the patient line to the shielded test vial is instructed by the computer interface, after selecting the calibration procedure.

11. The method of claim 1, further comprising:

purging air from the patient line;

coupling the patient line to a patient, after purging, in order to inject a dose of the eluate to the patient from the patient line; and

receiving a report from the computer, upon completion of the elution, the report including a patient identification number and at least one quantification of the dose of the eluate.

12. The method of claim 1, wherein the computer interface comprises a touch-activated display screen.

13. The method of claim 1, further comprising:

receiving an indication, from the system, that the eluate is being diverted, from the generator, through the waste line of the infusion tubing circuit, when the pump is activated;

receiving an indication, from the system, that the eluate is being diverted from the generator, through the patient line of the infusion tubing circuit, when the pump is activated;

14. The method of claim 13, wherein:

the system further comprises a light projector;

the indication that the eluate is being diverted through the waste line comprises a flashing light projection from the light projector; and

the indication that the eluate is being diverted through the patient line comprises a solid light projection from the light projector.

15. The method of claim 13, further comprising receiving an indication from the system that a peak bolus of radioactivity has been detected, in the eluate, by the activity detector.

16. The method of claim 15, wherein:

the system further comprises a light projector; and

the indication that the peak bolus of radioactivity has been detected comprises a flashing light from the light projector.

17. The method of claim 1, further comprising:

entering, into the computer, via the computer interface, a command to set a waste bottle level indicator to zero, when the waste bottle is empty and prior to entering the command to activate the pump; and

receiving, from the computer, via the computer interface, an indication that the waste bottle needs to be emptied, based upon the computer tracking a volume of the eluate that is diverted, from the generator, through the waste line of the infusion tubing circuit.

18. A computer readable medium having computer executable instructions for executing a method for maintaining an infusion system, the method comprising:

receiving, via a graphical user interface, a volume of eluant contained in a reservoir of the infusion system prior to activating a pump of the infusion system to pump a portion of the volume of eluant through a radioisotope generator of the system in order to generate, via elution, an eluate;

tracking the portion of the volume of eluant that is pumped from the reservoir;

providing an indication of a volume of eluant within the reservoir; and

tracking a volume of the eluate that is diverted from the generator to the waste bottle;

providing an indication that the waste bottle needs to be emptied.

19 The computer readable medium of claim 18, further including receiving, via the graphical user interface, a command to set a waste bottle level indicator to zero when the waste bottle is empty.

20. A computer readable medium having computer executable instructions for executing a method of calibrating an activity detector of an infusion system, the method comprising:

receiving a calibration command;

receiving calibration parameters relating to an elution process;

activating a pump of the infusion system to initiate the elution process, the elution process producing a sample of an eluate;

tracking a time from the end of the elution process;

receiving from the activity detector of the infusion system an activity level detected during the elution process;

receiving a measured activity level of the eluate sample obtained from a dose calibrator;

receiving a time measured from the completion of the elution process to the measurement of the activity level by the dose calibrator;

calculating a calibration coefficient for the infusion system based on the measured activity level of the eluate sample and activity level detected during the elution process; and

providing the calibration coefficient as an output.

21. A computer readable medium having computer executable instructions for executing a method of conducting a breakthrough test of a radioisotope generator of an infusion system, the method comprising:

receiving a breakthrough test command;

activating a pump of the infusion system to initiate an elution process, the elution process using the generator to produce a sample of an eluate from a patient line;

tracking a time lapsed from the end of the elution process;

receiving a measured activity level of the eluate sample obtained from a dose calibrator;

receiving a time measured from the completion of the elution process to the measurement of the activity level by the dose calibrator;

calculating a breakthrough of the radioisotope generator based on the measured activity level and the time between completion of the elution process and the measuring of the activity level; and

providing the breakthrough of the generator as an output.

22. The computer readable medium of claim 21, further comprising:

receiving a second measured activity level of the eluate sample obtained from a dose calibrator, the second measured activity level being a measurement taken at predetermined time period after the completion of the elution process.

23. The computer readable medium of claim 21, wherein the predetermined time period is 60 minutes after completion of the elution process.

24. A method for purging a tubing circuit of an infusion system with air, the system comprising a pump coupled to the tubing circuit, a radioisotope generator, a waste bottle and a computer including a computer interface, the method comprising:

receiving instructions from the computer, via the computer interface, to disconnect the pump from an eluant reservoir of the system, and to by-pass the generator by disconnecting an eluant line and an eluate line, of the tubing circuit, from the generator, and connecting the eluant line to the eluate line; and

entering, into the computer, via the computer interface, a command to perform an air purge of the tubing circuit, the air purge being automated, via the computer, to perform purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit;

wherein a first valve, of the two divergence valves, is located between a first portion of the eluate line and two downstream portions of the eluate line, a first of the two downstream portions extending to a waste bottle of the system and a second of the two downstream portions extending to a vial outside the system;

a second valve, of the two divergence valves, is located between a first portion of the eluant line, extending from the pump, and two downstream portions of the eluant line, a first of the two downstream portions of the eluant line being connected to the first portion of the eluate line, and a second of the two downstream portions of the eluant line being connected to the second of the two downstream portions of the eluate line.

ABSTRACT

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

4363039_1.DOC

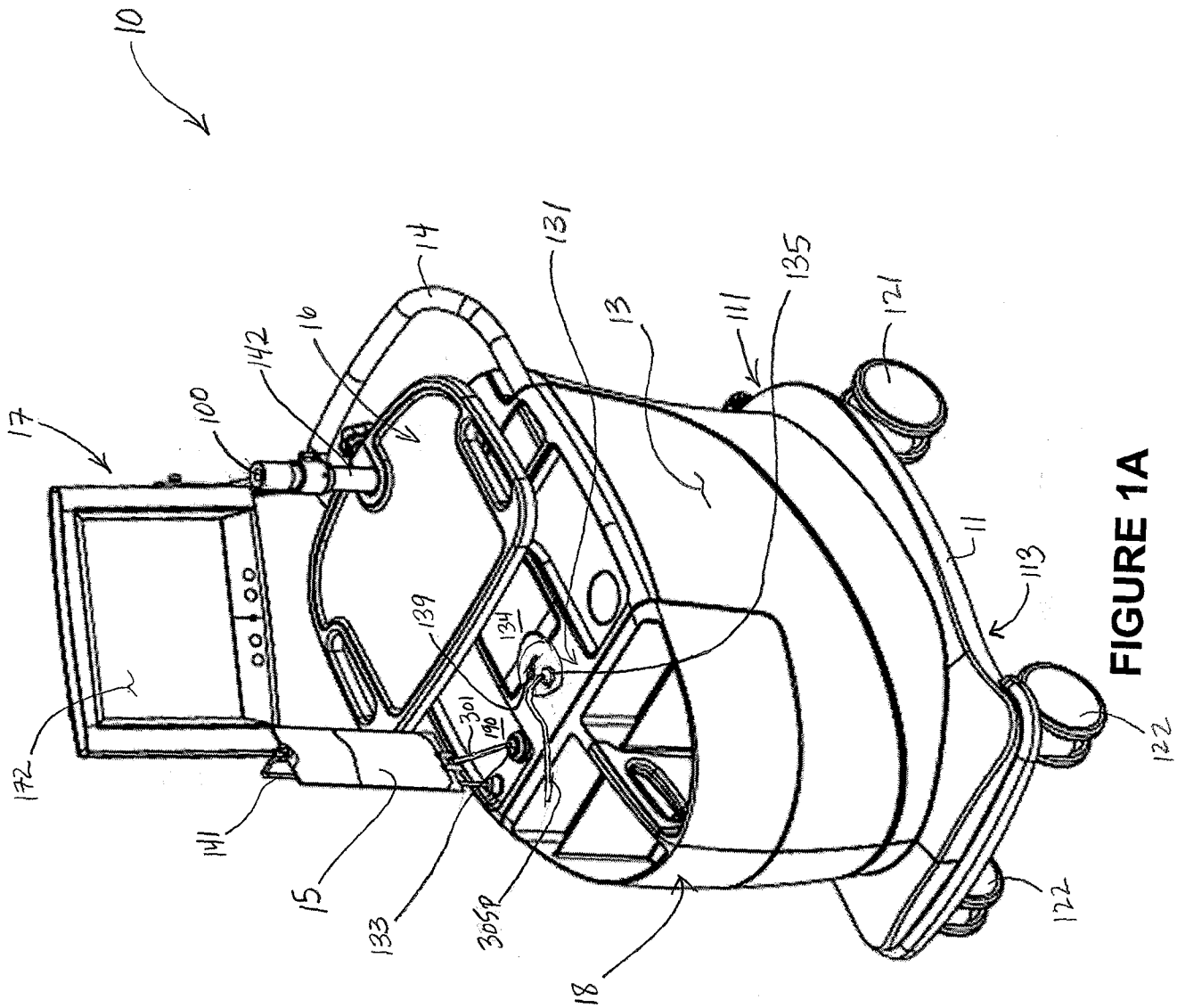

10
17
100
142
16
14
131
13
111
135
121
172
139
134
301
190
11
113
141
15
133
3050
18
122
122

FIGURE 1A

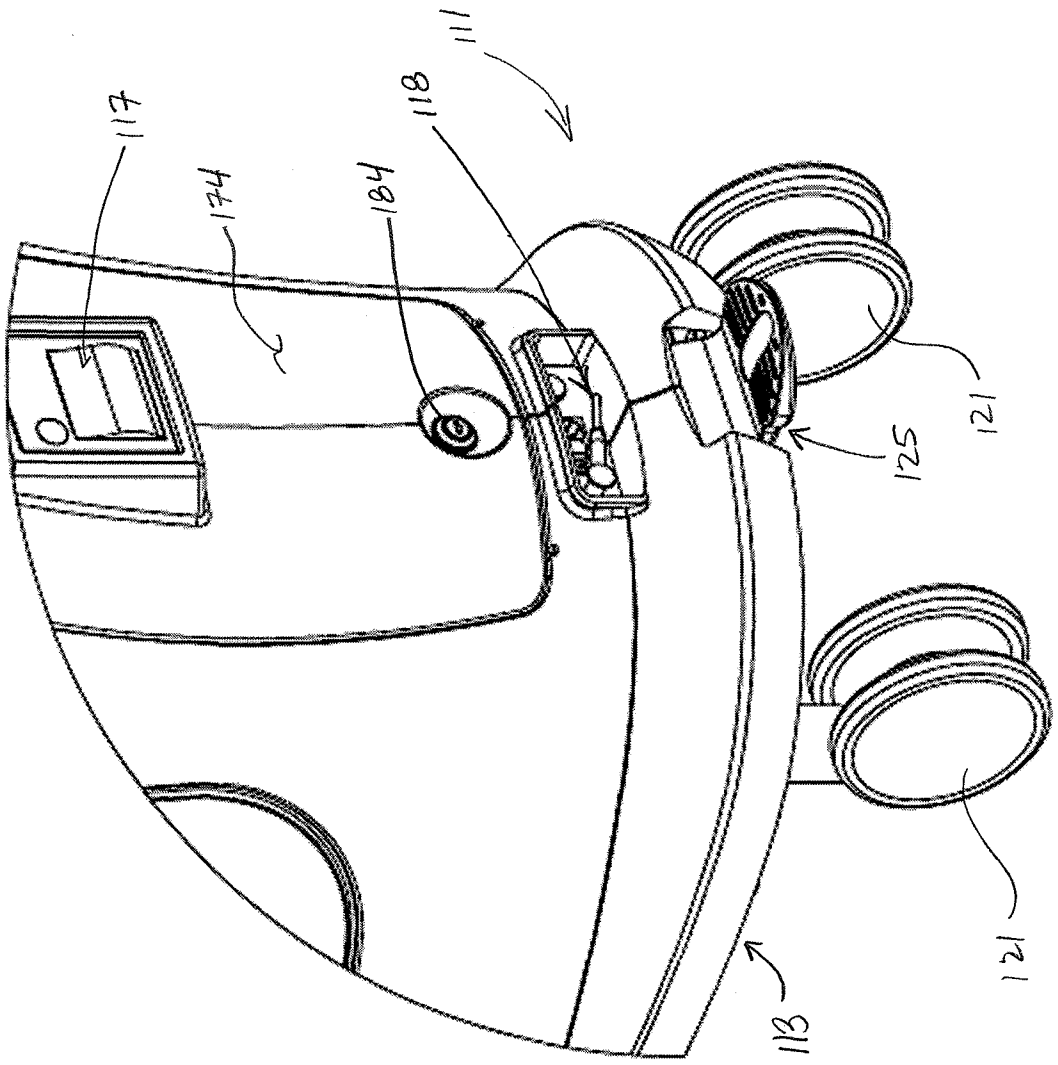


FIGURE 1B

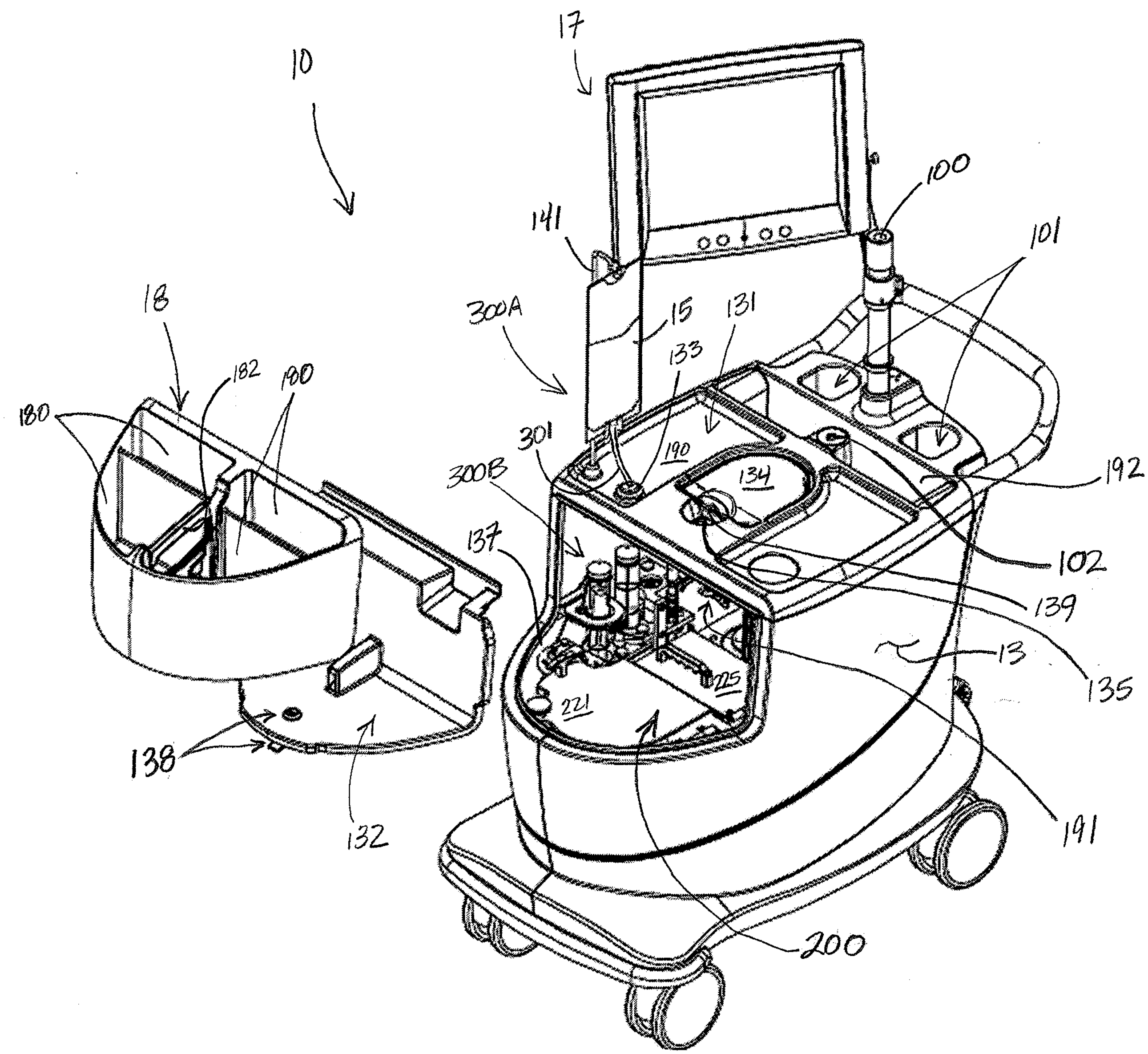

10
17
100
101
141
18
300A
15
131
133
182
190
180
301
190
134
192
300B
137
102
139
13
135
225
221
138
191
132
200

FIGURE 1C

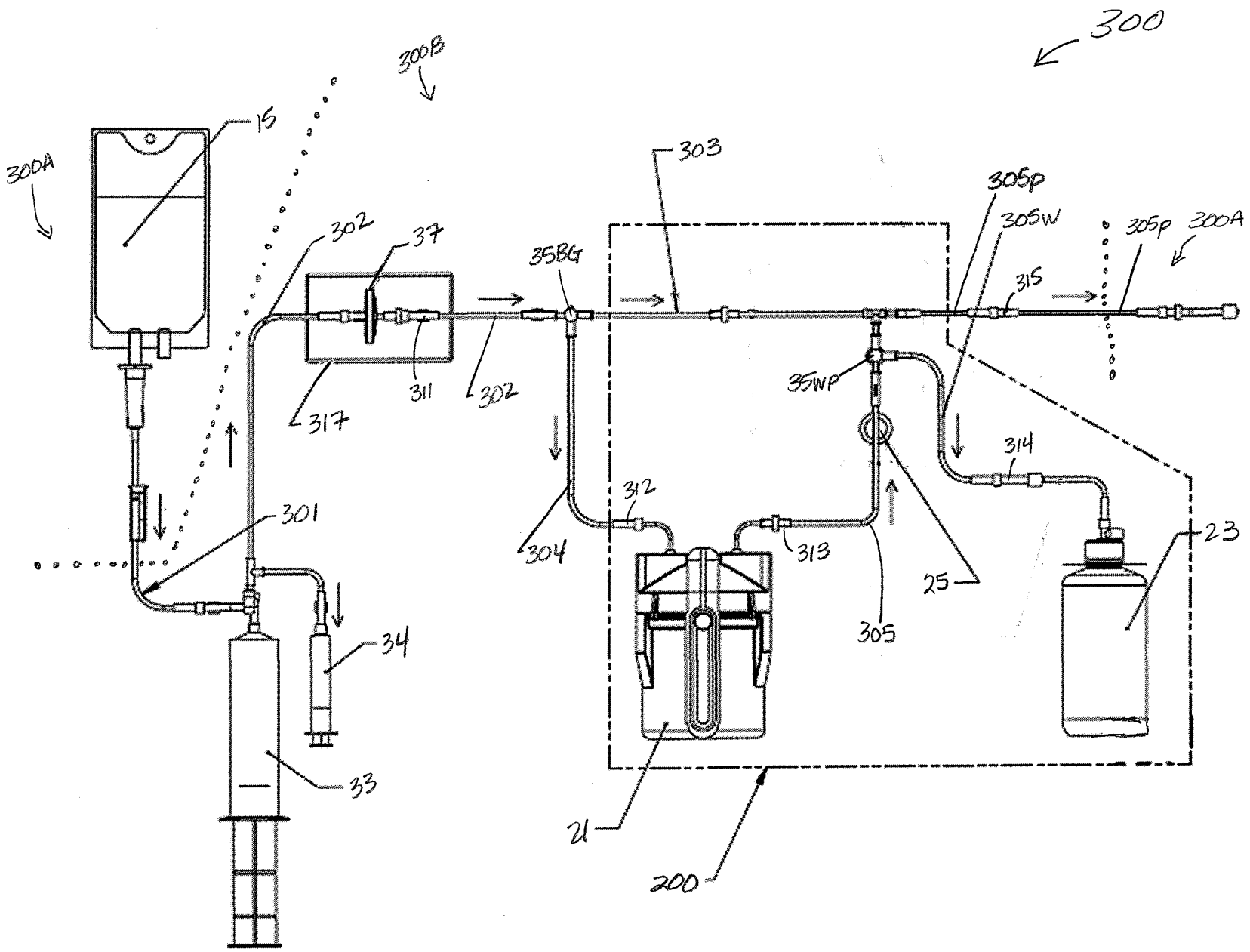

300
300B
300A
15
302
37
303
305p
305W
315
35BG
35WP
311
317
301
304
312
313
314
25
305
23
34
33
21
200

FIGURE 1D

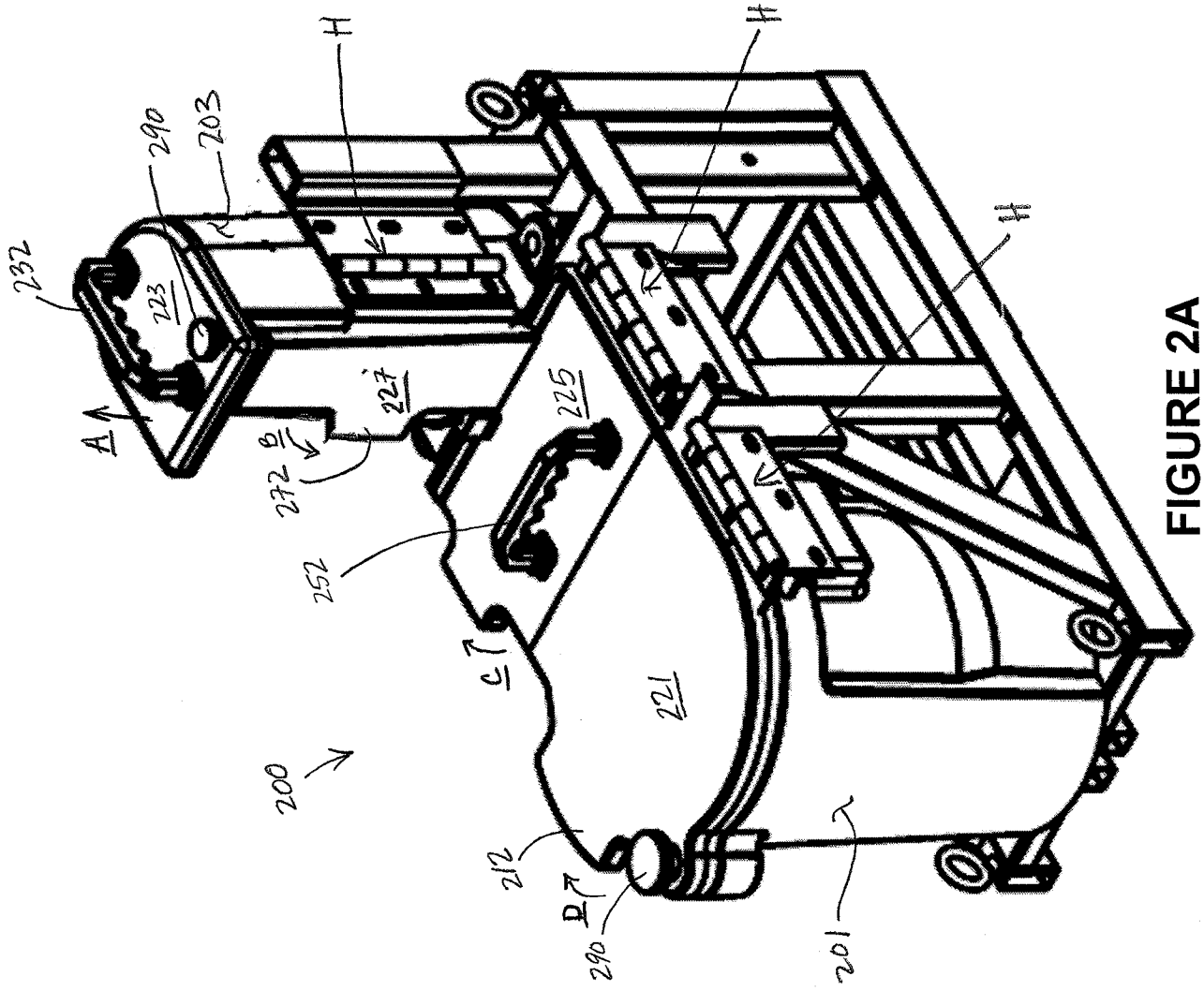


FIGURE 2A

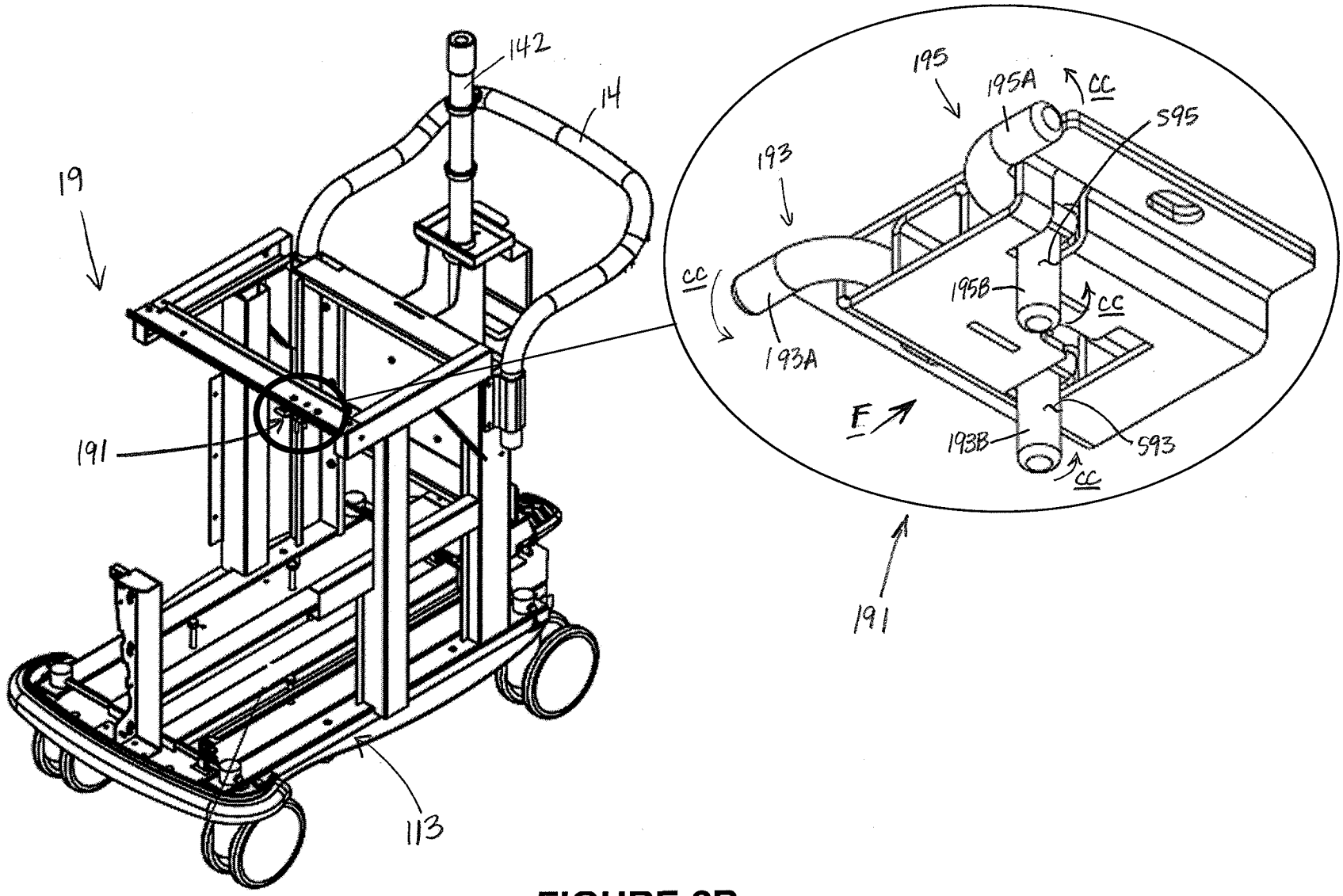

142
14
19
191
113
195
195A
CC
595
193
CC
195B
CC
193A
F
193B
593
CC
191

FIGURE 2B

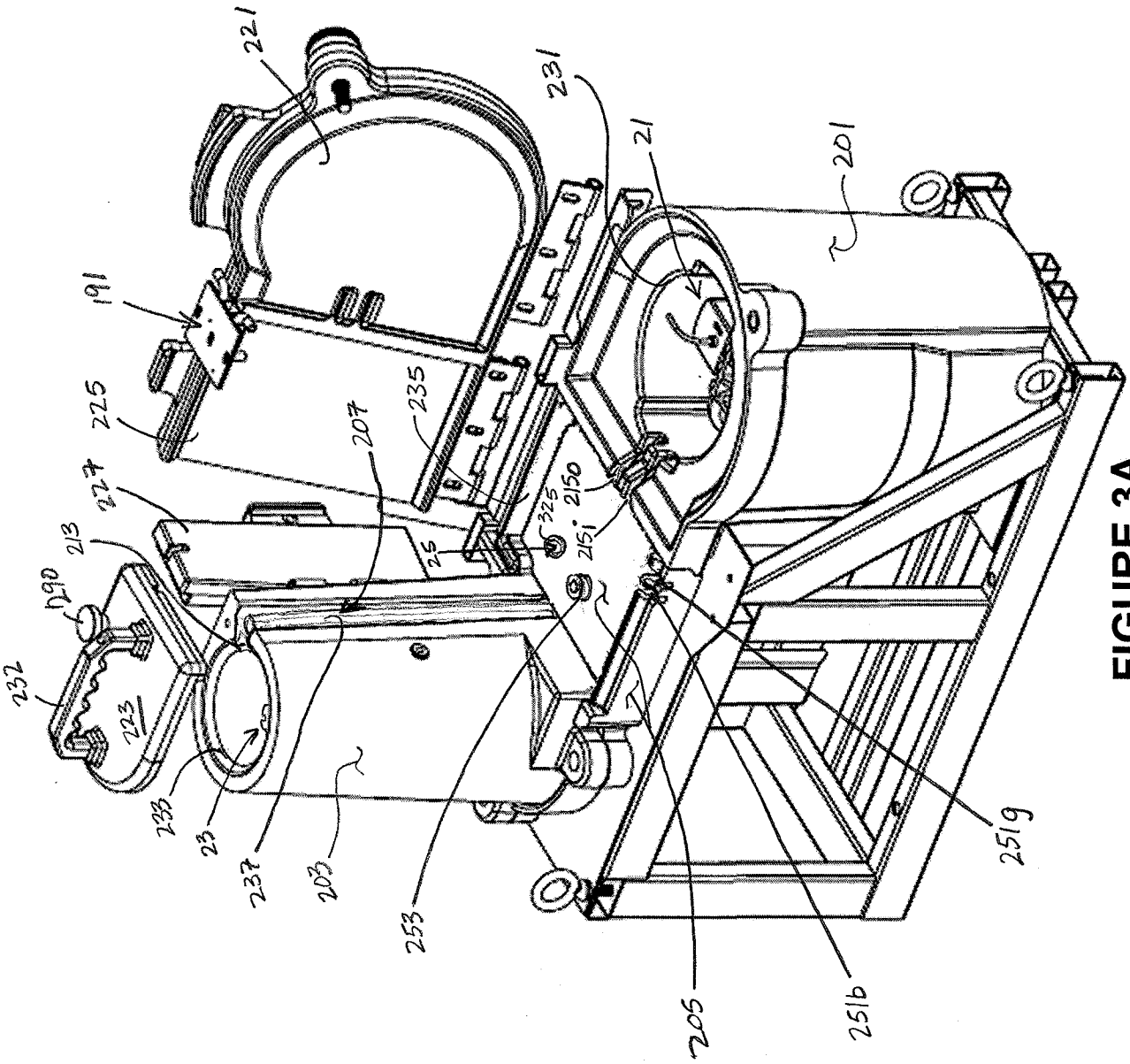

221
231
21
201
191
225
235
207
227
213
190
232
223
233
23
237
203
253
325
215i
2150
25
206
2516
2519

FIGURE 3A

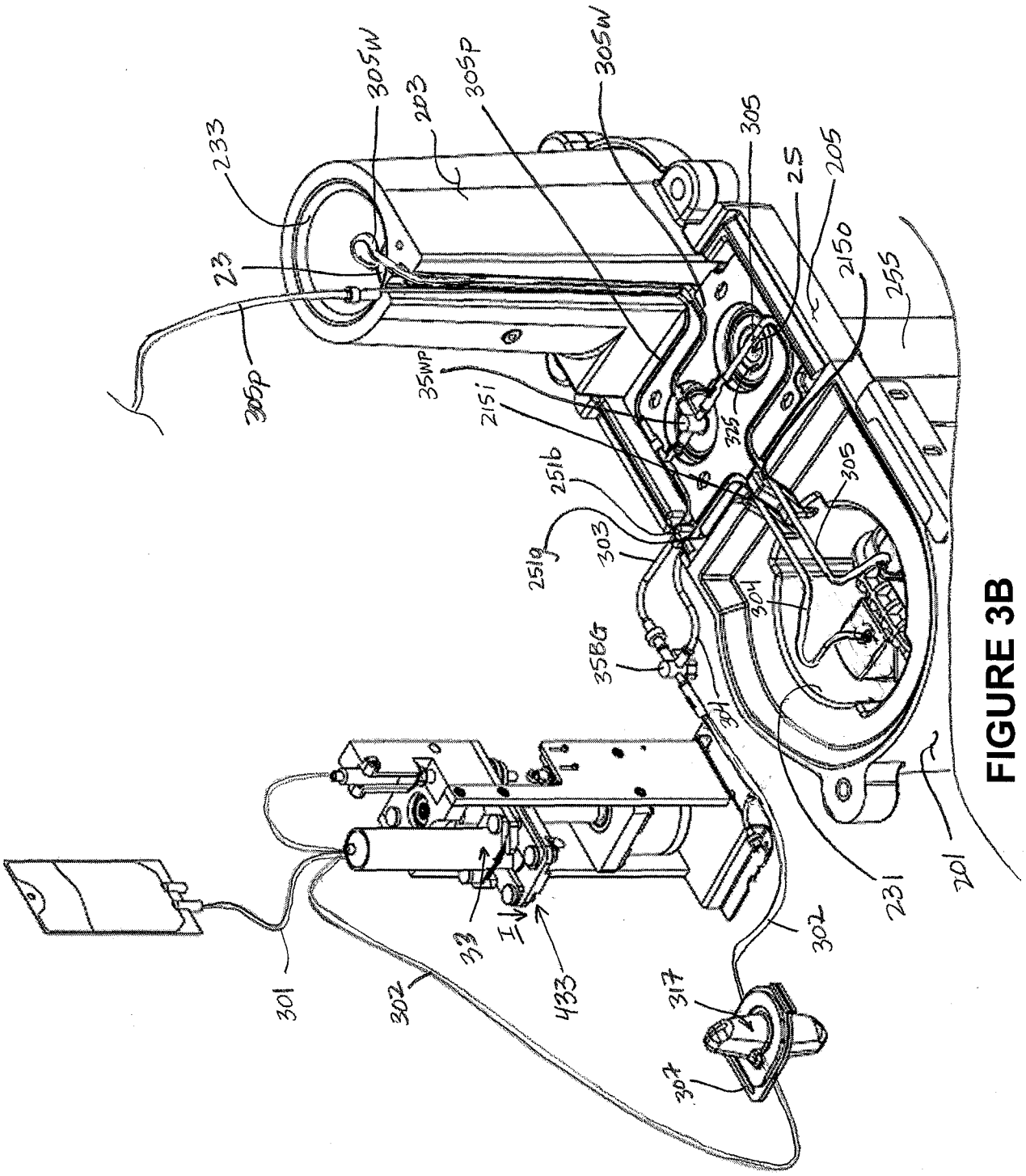

305W
203
305P
305W
233
23
305
25
205
2150
255
305p
35WP
215i
325
306
2516
2519
303
304
35BG
231
201
301
302
33
I
433
317
307
302

FIGURE 3B

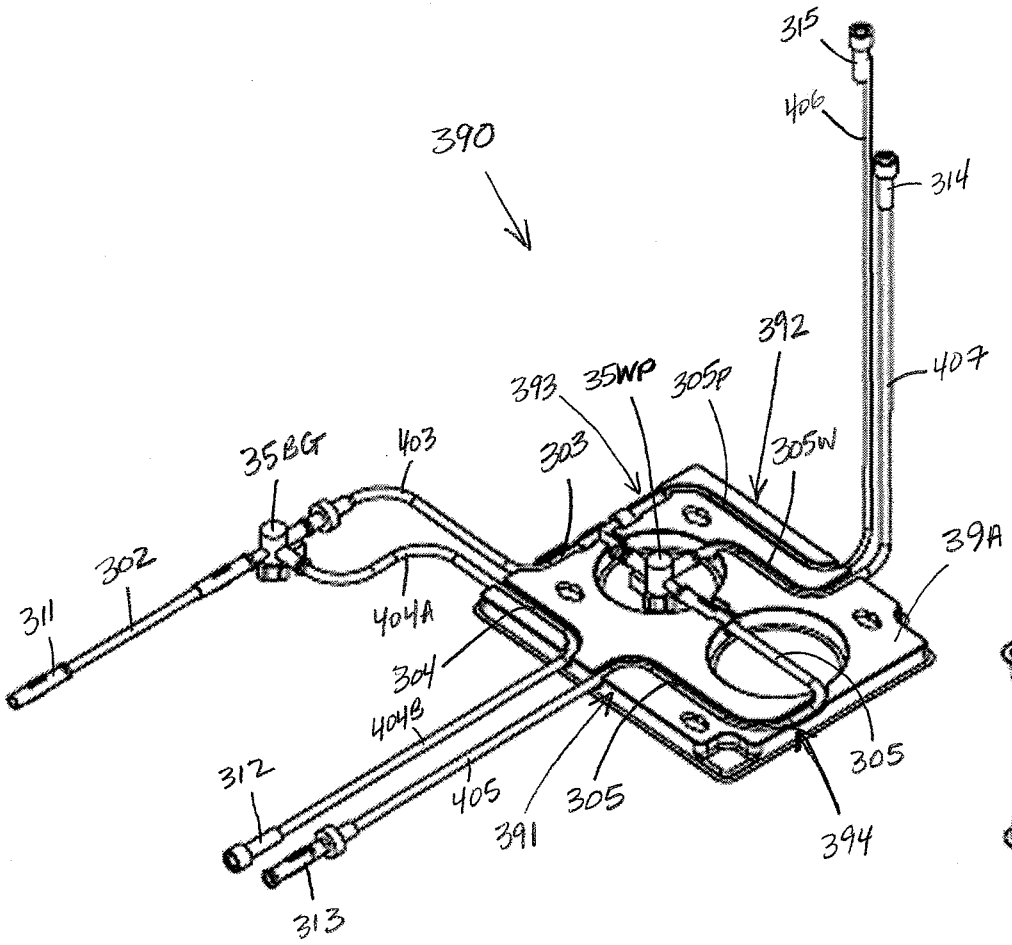


FIGURE 3C

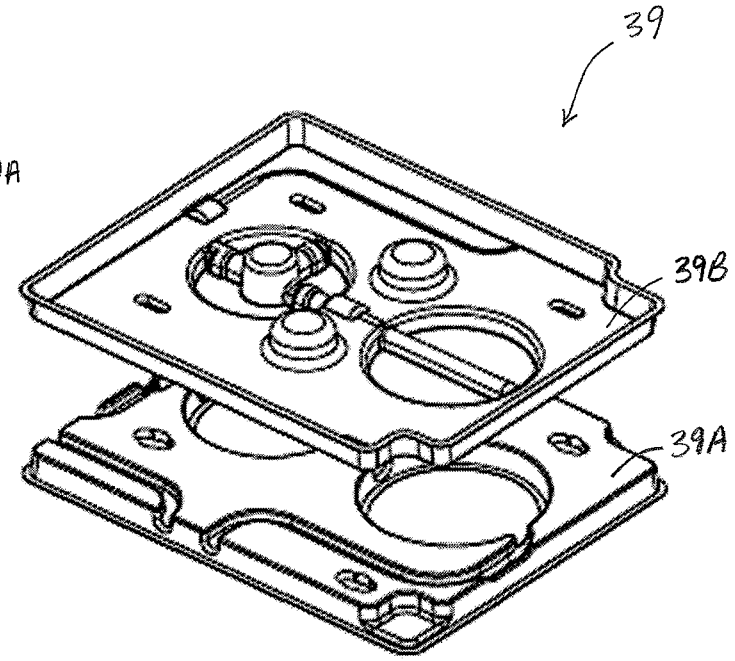


FIGURE 3D

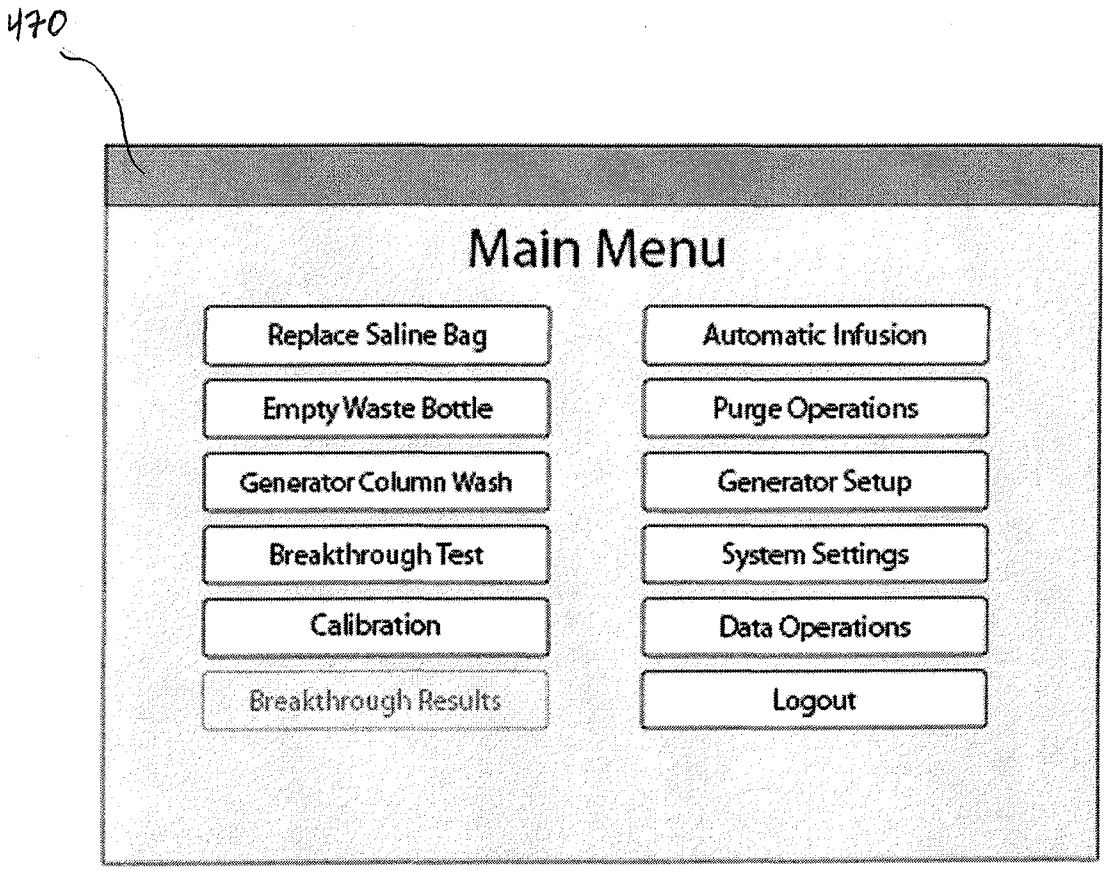

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout

FIGURE 4

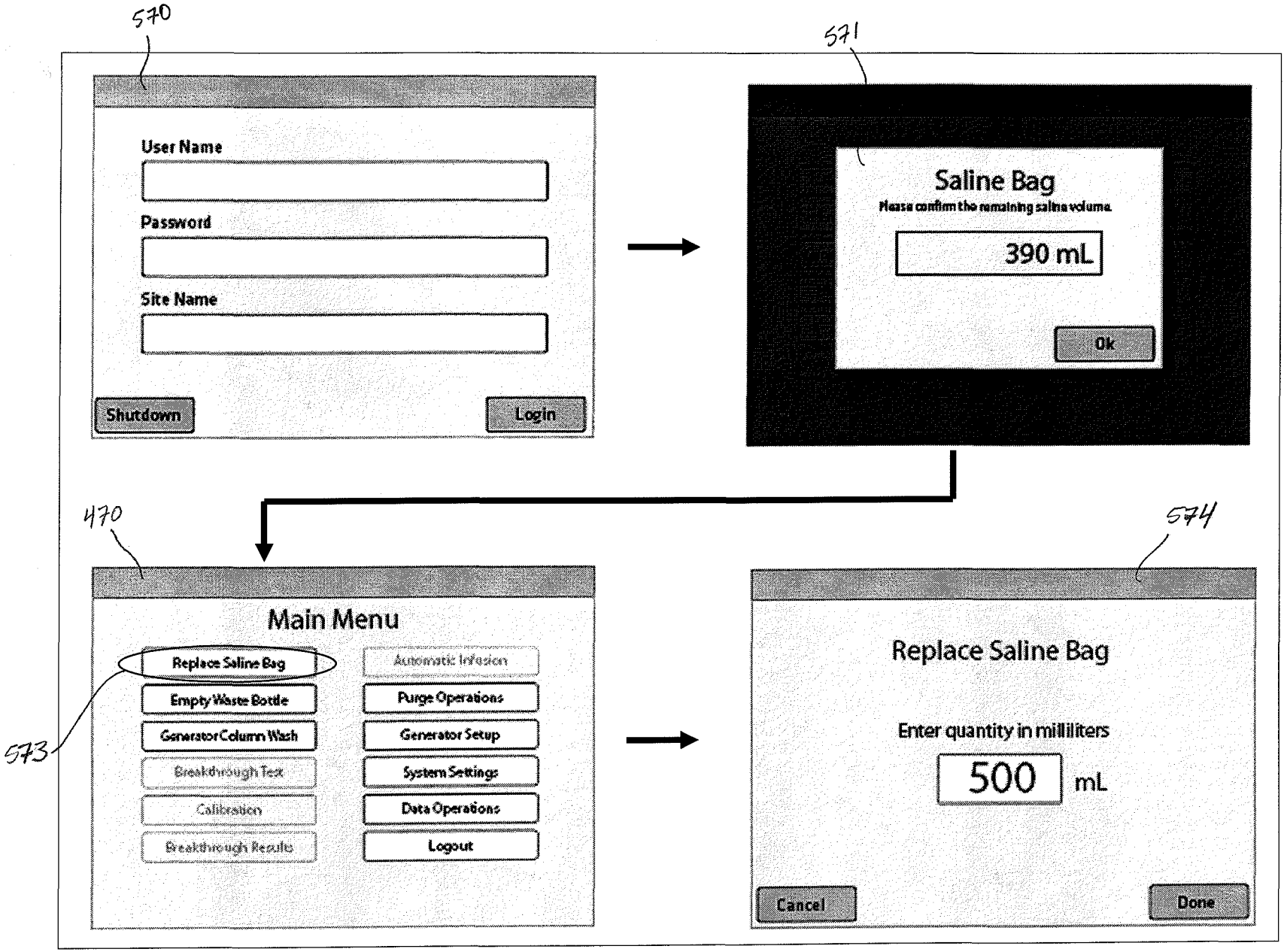

570
User Name
Password
Site Name
Shutdown
Login
571
Saline Bag
Please confirm the remaining saline volume.
390 mL
Ok
470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System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

FIGURE 5A

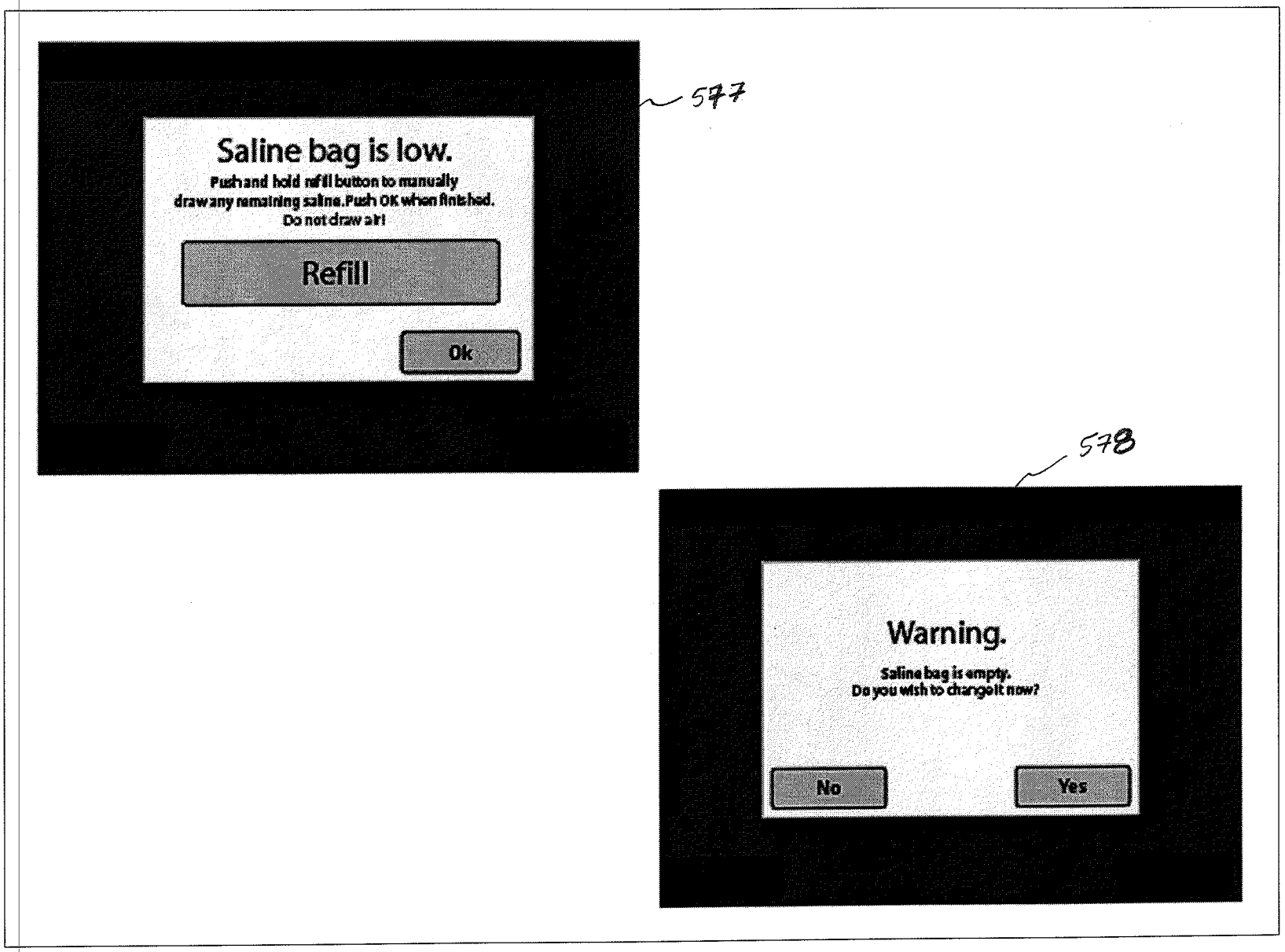

577
Saline bag is low.
Push and hold refill button to manually draw any remaining saline. Push OK when finished.
Do not draw air
Refill
Ok
578
Warning.
Saline bag is empty.
Do you wish to change it now?
No
Yes

FIGURE 5B

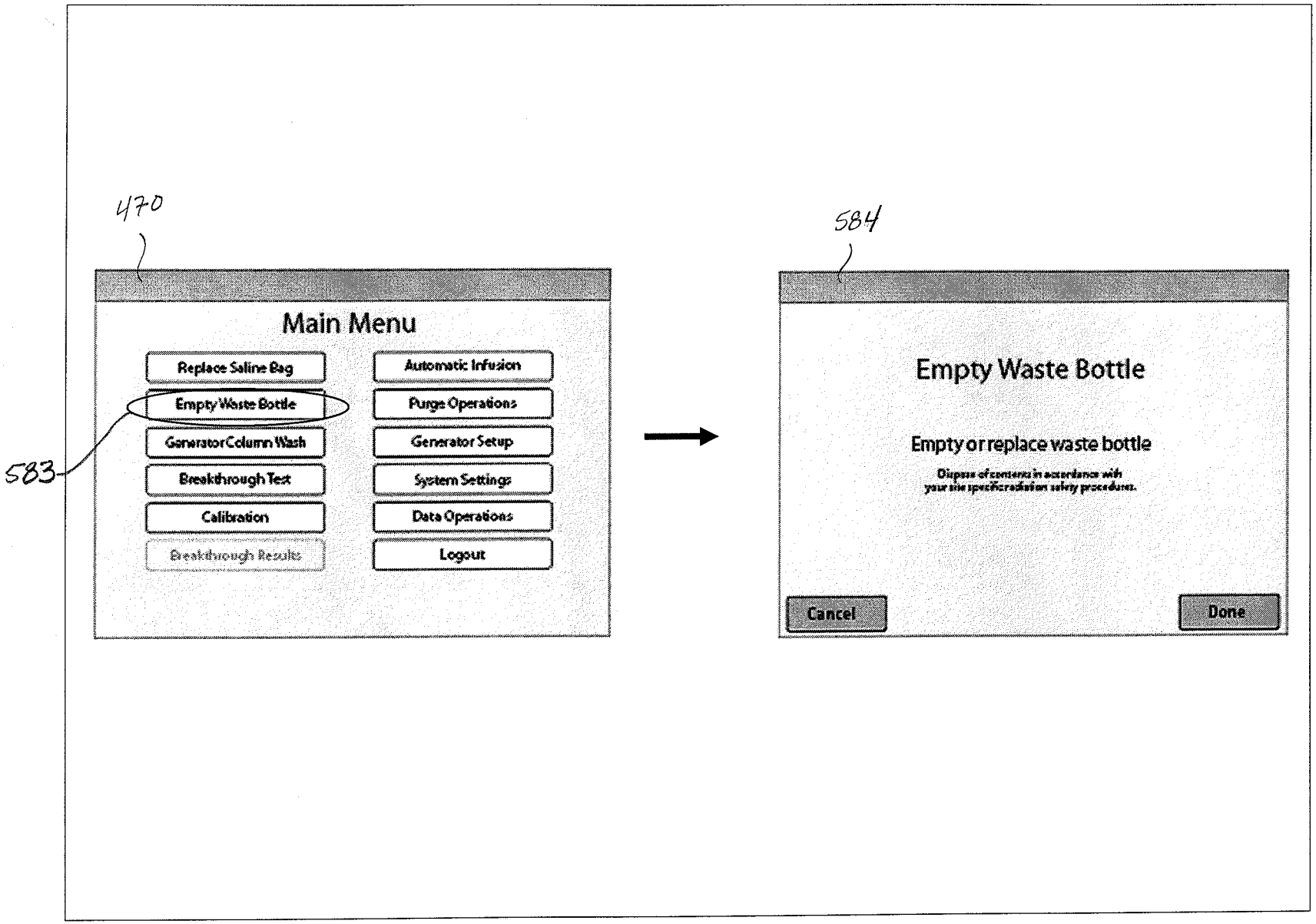

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
583
584
Empty Waste Bottle
Empty or replace waste bottle
Cancel
Done

FIGURE 5C

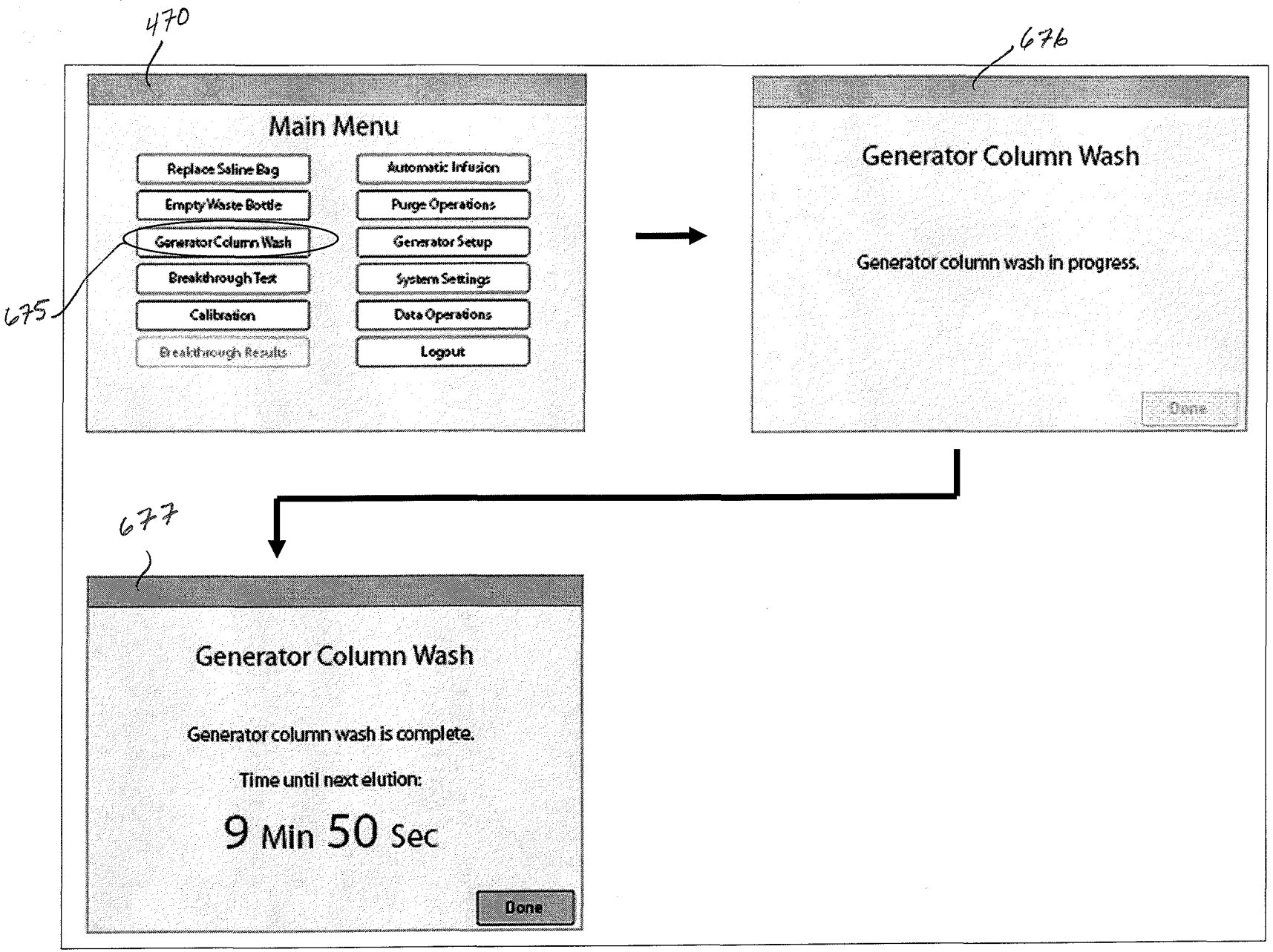

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
675
676
Generator Column Wash
Generator column wash in progress.
Done
677
Generator Column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

FIGURE 6

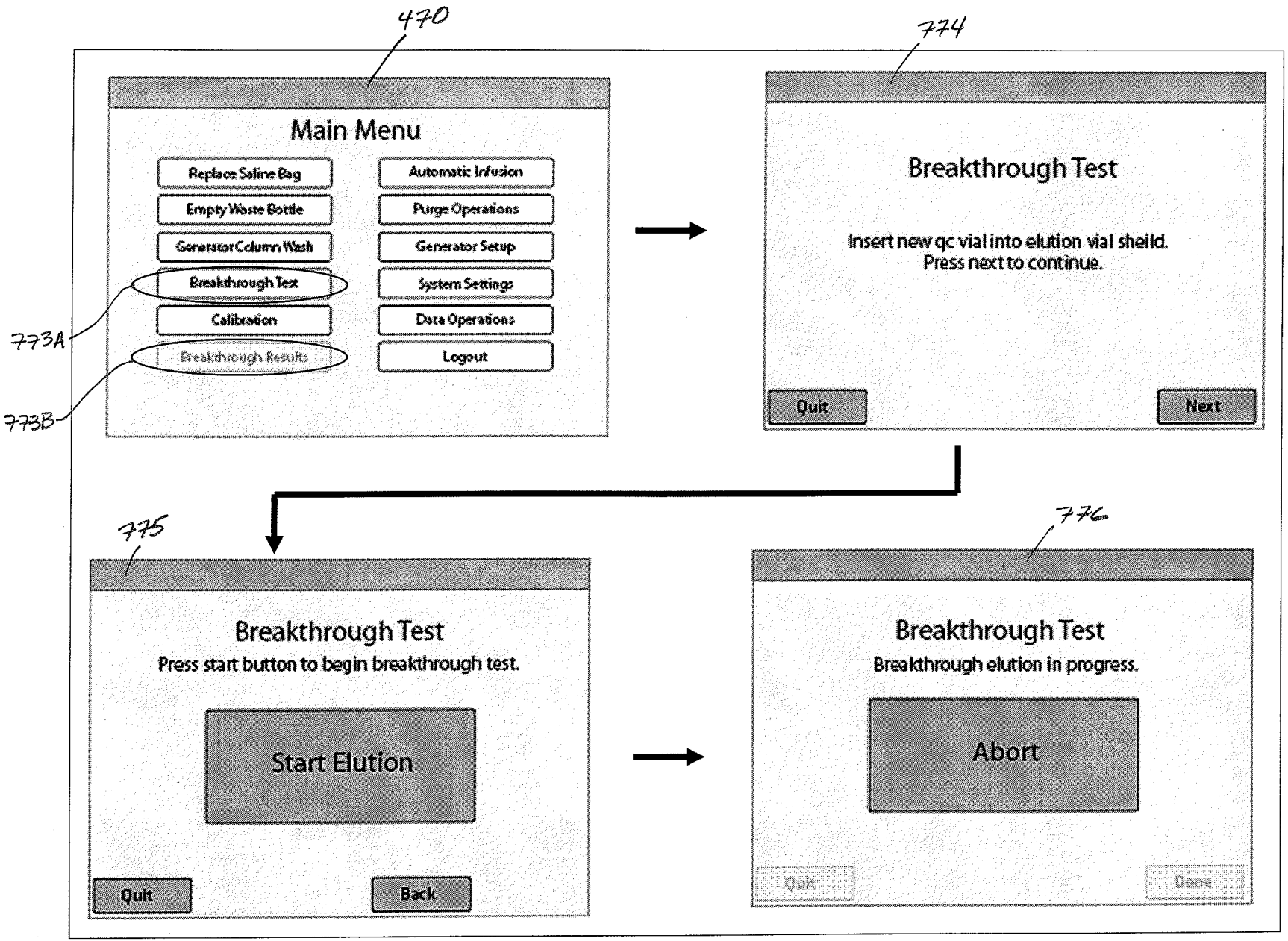

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
773A
773B
774
Breakthrough Test
Insert new qc vial into elution vial sheild.
Press next to continue.
Quit
Next
775
Breakthrough Test
Press start button to begin breakthrough test.
Start Elution
Quit
Back
776
Breakthrough Test
Breakthrough elution in progress.
Abort
Quit
Done

FIGURE 7A

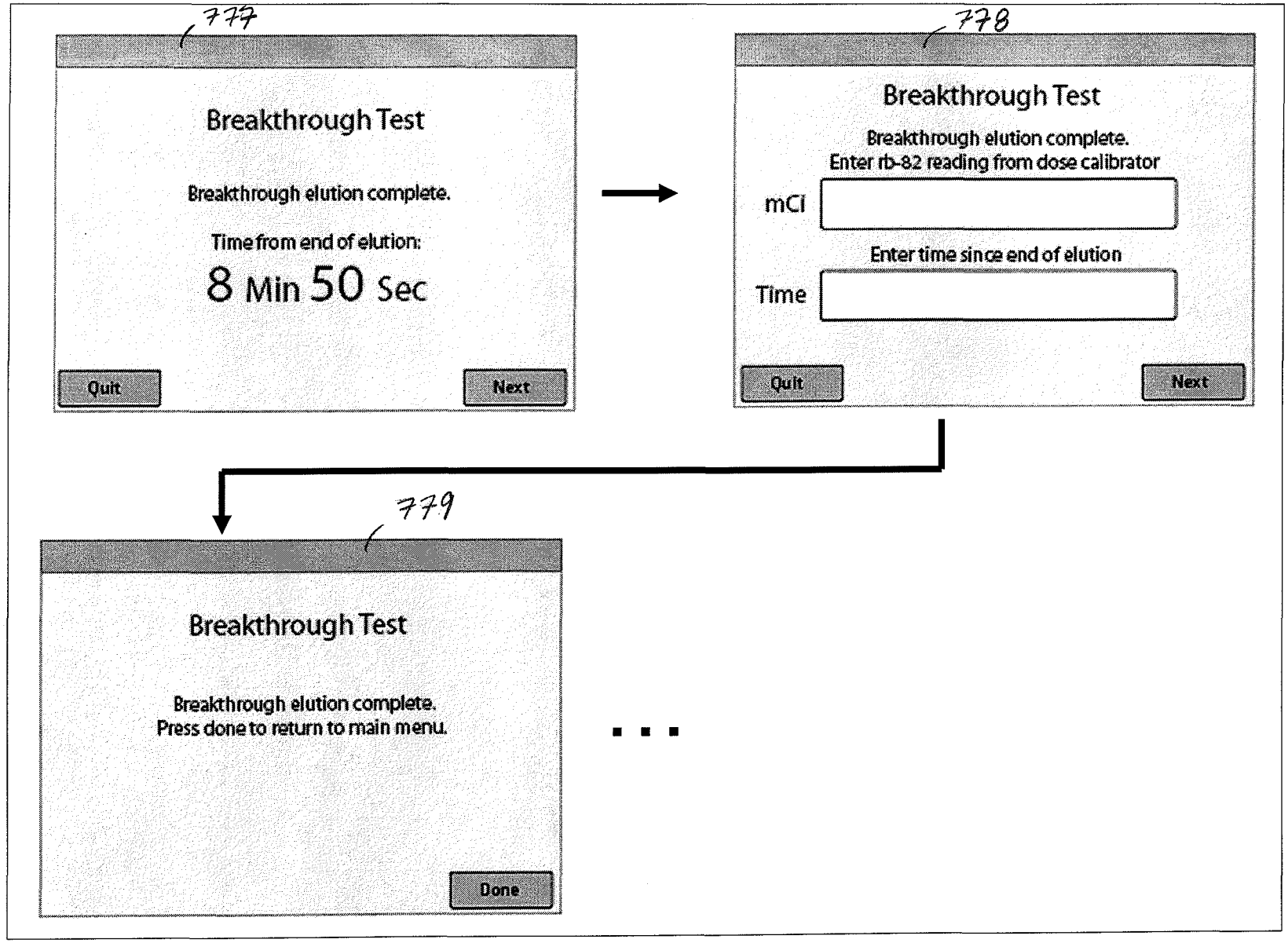

777
Breakthrough Test
Breakthrough elution complete.
Time from end of elution:
8 Min 50 Sec
Quit
Next
778
Breakthrough Test
Breakthrough elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time since end of elution
Time
Quit
Next
779
Breakthrough Test
Breakthrough elution complete.
Press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

FIGURE 7B

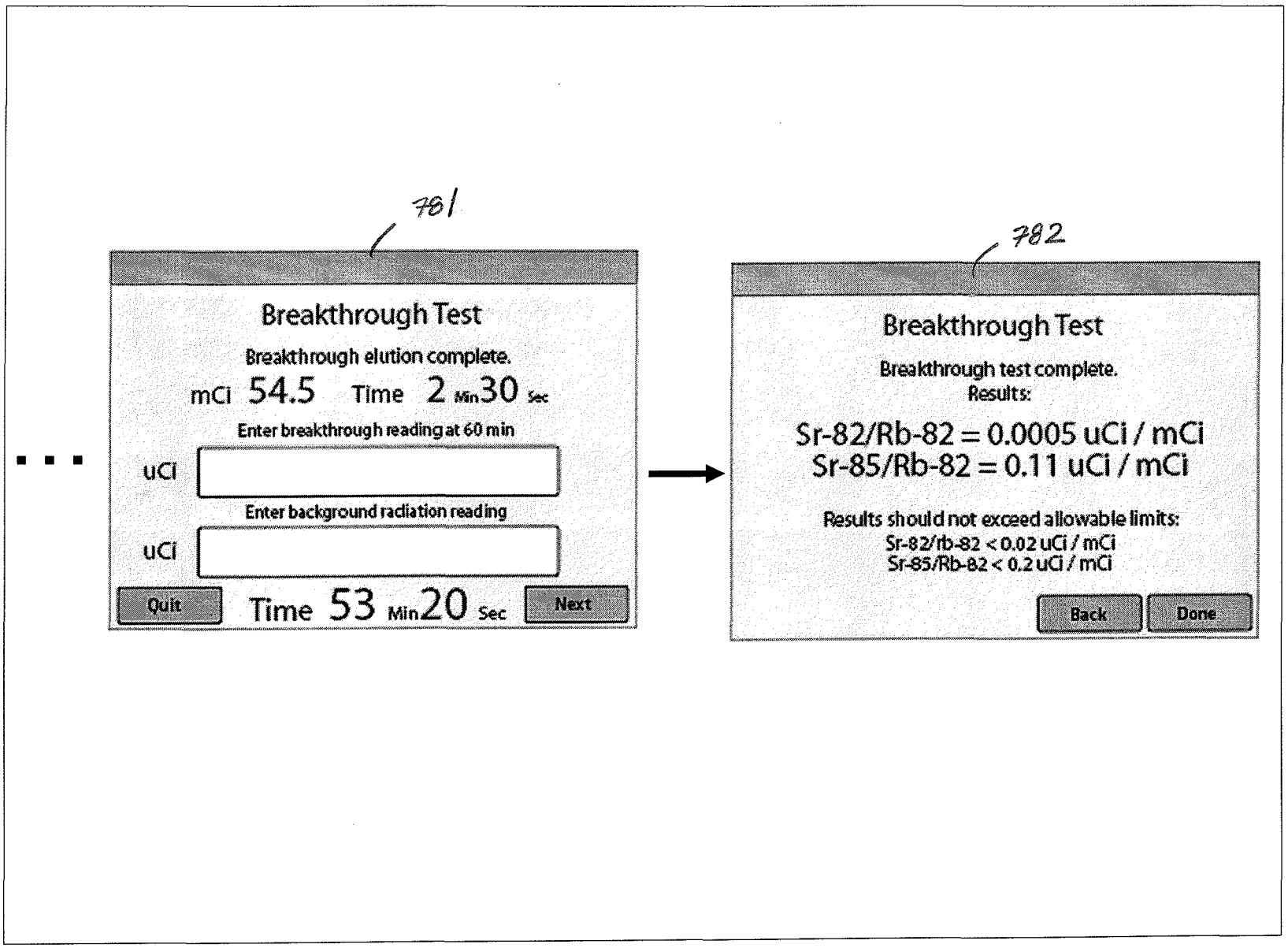

781
Breakthrough Test
Breakthrough elution complete.
mCi 54.5 Time 2 Min 30 Sec
Enter breakthrough reading at 60 min
uCi
Enter background radiation reading
uCi
Quit
Time 53 Min 20 Sec
Next
782
Breakthrough Test
Breakthrough test complete.
Results:
Sr-82/Rb-82 = 0.0005 uCi / mCi
Sr-85/Rb-82 = 0.11 uCi / mCi
Results should not exceed allowable limits:
Sr-82/Rb-82 < 0.02 uCi / mCi
Sr-85/Rb-82 < 0.2 uCi / mCi
Back
Done

FIGURE 7C

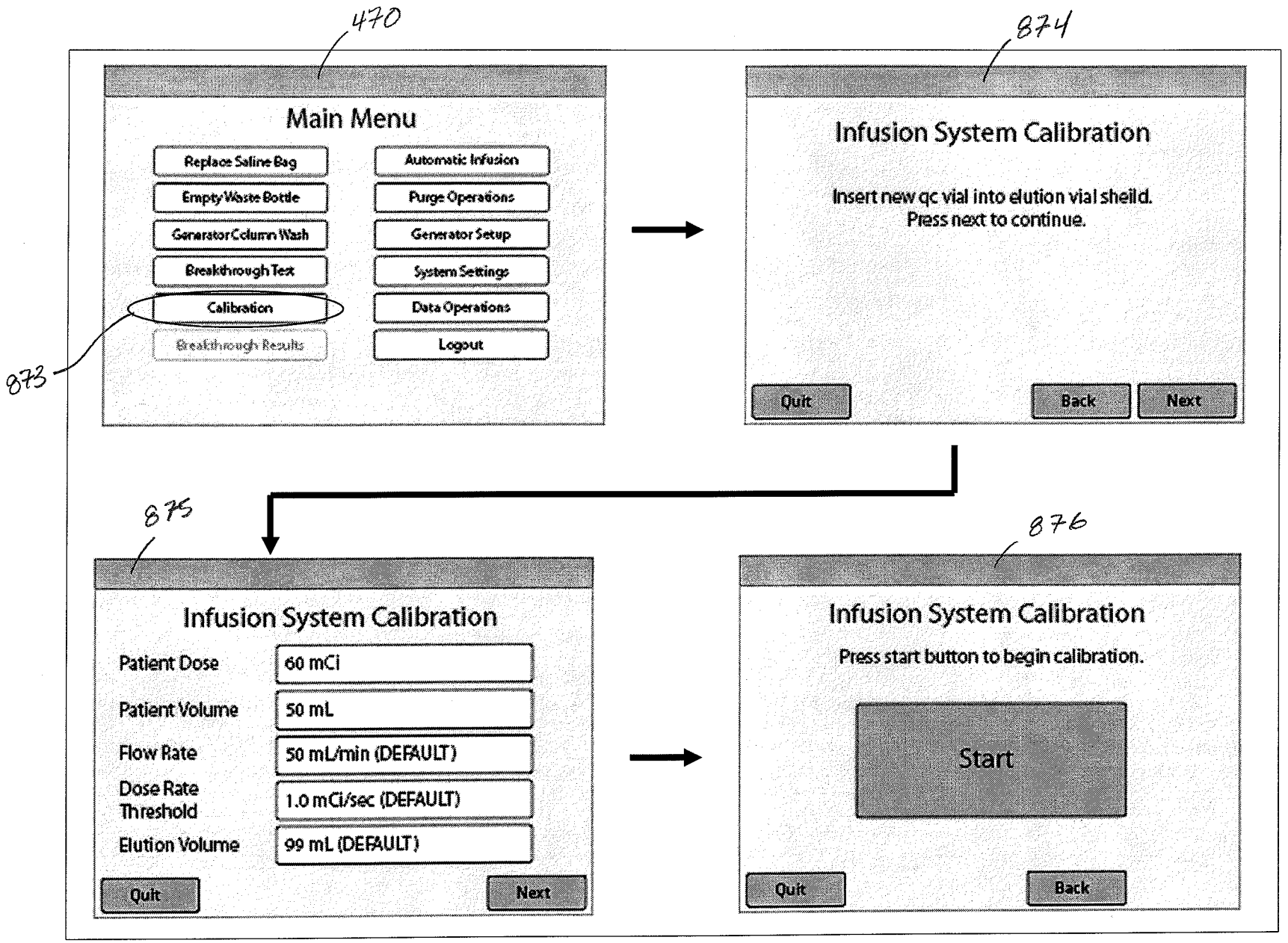

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
873
874
Infusion System Calibration
Insert new qc vial into elution vial sheild.
Press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

FIGURE 8A

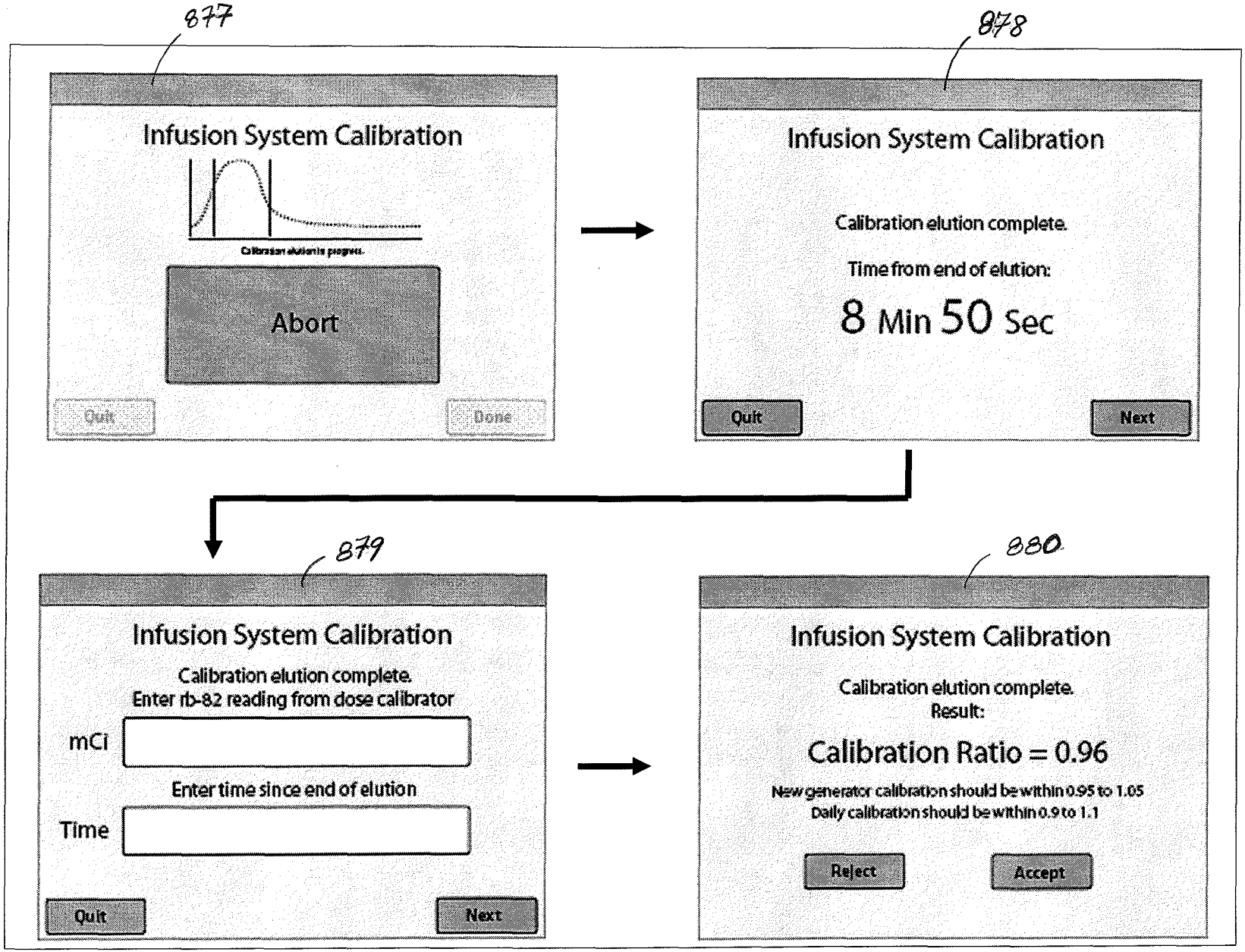

877
Infusion System Calibration
Abort
Quit
Done
878
Infusion System Calibration
Calibration elution complete.
Time from end of elution:
8 Min 50 Sec
Quit
Next
879
Infusion System Calibration
Calibration elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time since end of elution
Time
Quit
Next
880
Infusion System Calibration
Calibration elution complete.
Result:
Calibration Ratio = 0.96
New generator calibration should be within 0.95 to 1.05
Daily calibration should be within 0.9 to 1.1
Reject
Accept

FIGURE 8B

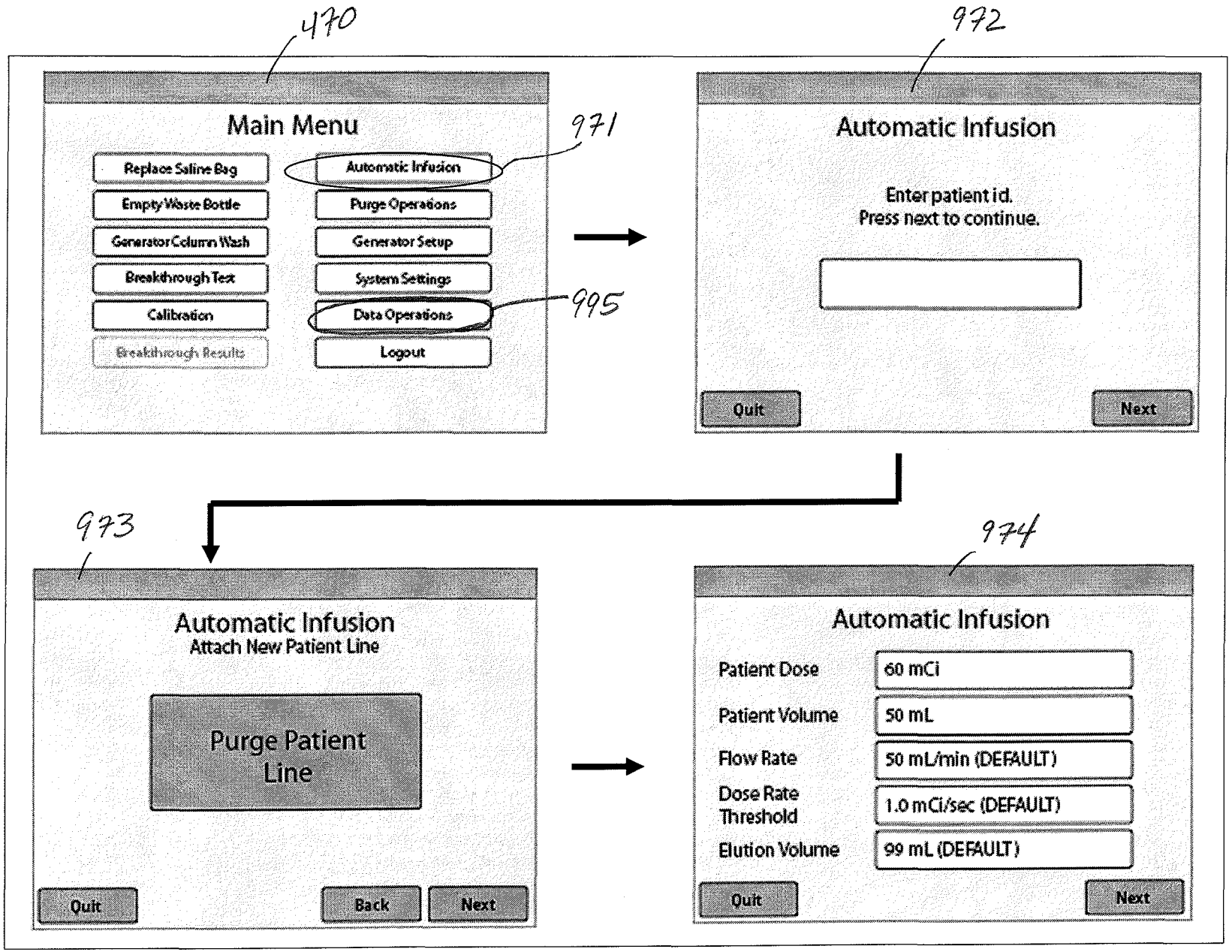

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
971
995
972
Automatic Infusion
Enter patient id.
Press next to continue.
Quit
Next
973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

FIGURE 9A

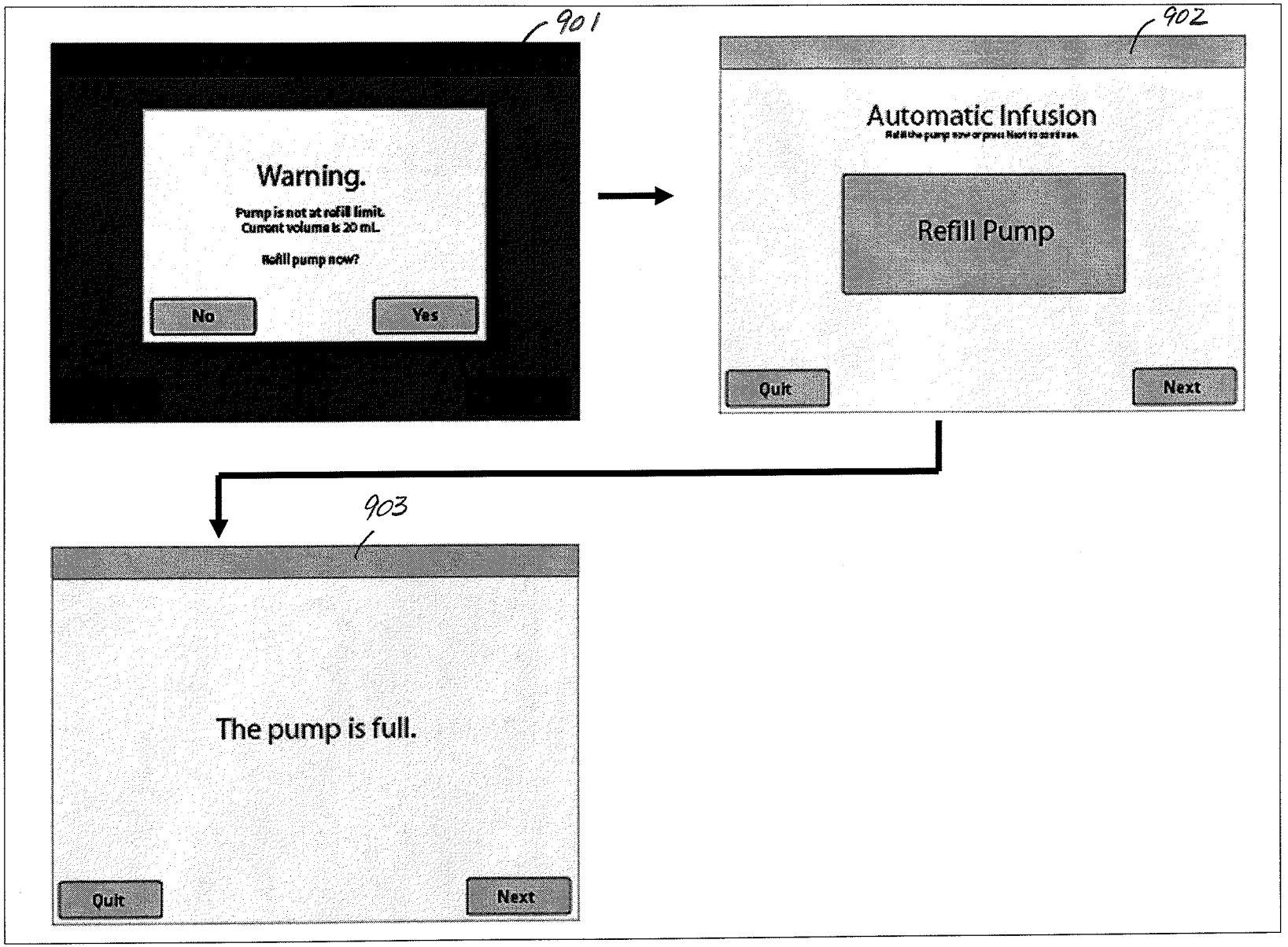

901
Warning.
Pump is not at refill limit.
Current volume is 20 mL.
Refill pump now?
No
Yes
902
Automatic Infusion
Refill the pump now or press Next to continue.
Refill Pump
Quit
Next
903
The pump is full.
Quit
Next

FIGURE 9B

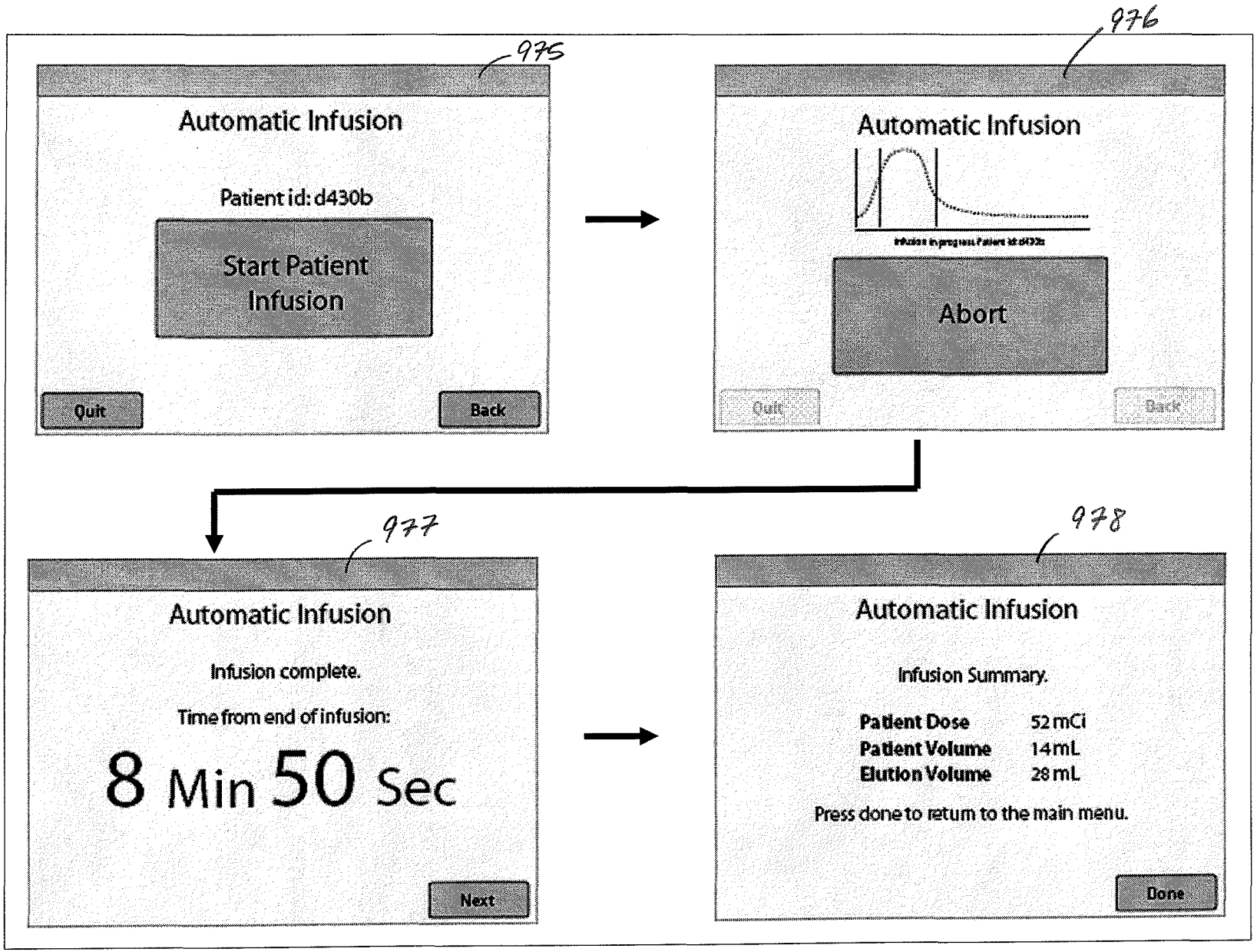

975
Automatic Infusion
Patient id: d430b
Start Patient Infusion
Quit
Back
976
Automatic Infusion
Abort
Quit
Back
977
Automatic Infusion
Infusion complete.
Time from end of infusion:
8 Min 50 Sec
Next
978
Automatic Infusion
Infusion Summary.
Patient Dose 52 mCi
Patient Volume 14 mL
Elution Volume 28 mL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

FIGURE 9C

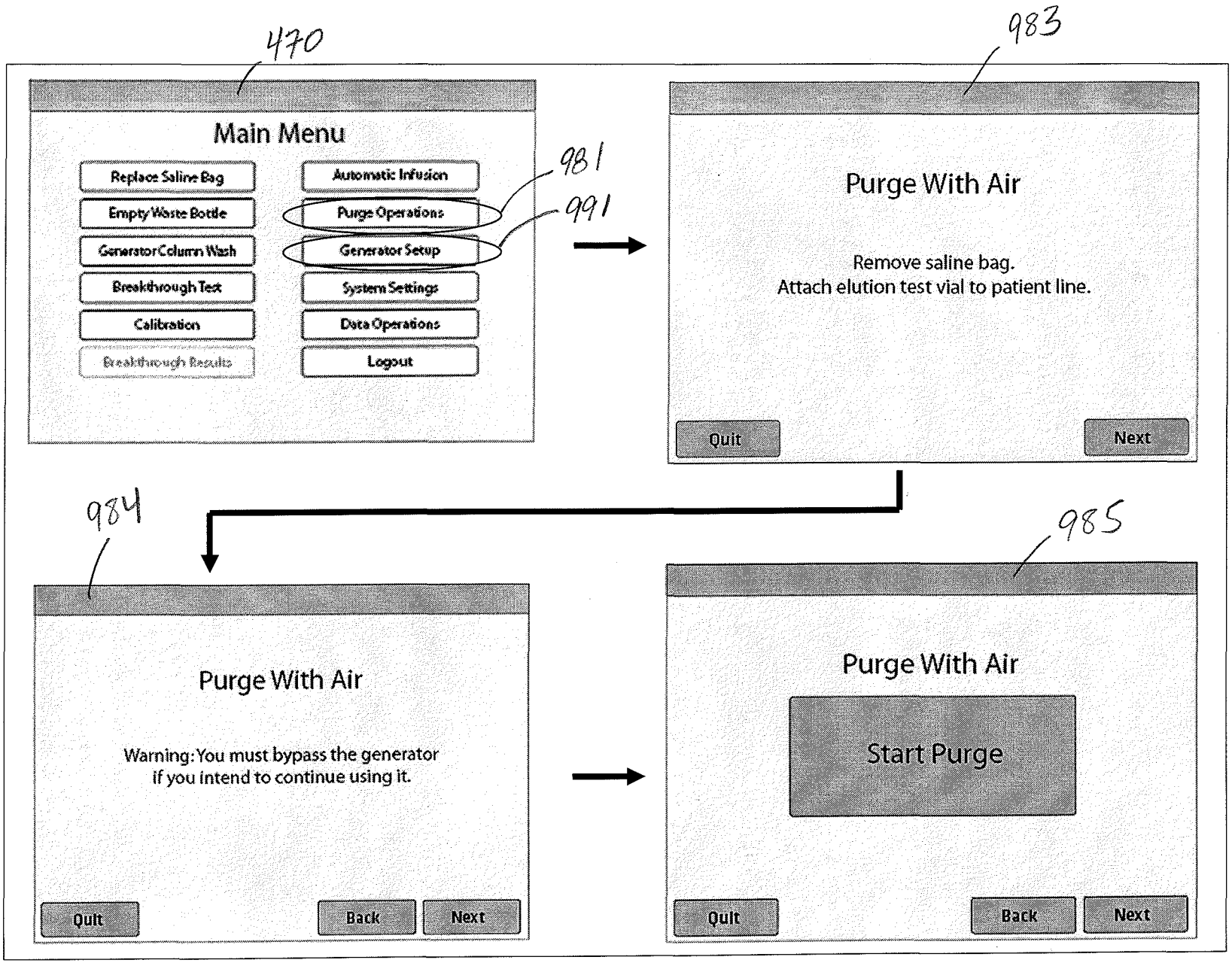

470
Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
981
991
983
Purge With Air
Remove saline bag.
Attach elution test vial to patient line.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

FIGURE 10

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Steve Hidem
Filer:	Charles D. Segelbaum
Attorney Docket Number:	56782.1.7

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	310	310
Utility Search Fee	1111	1	510	510
Utility Examination Fee	1311	1	210	210
Pages:				
Claims:				
Claims in excess of 20	1202	4	50	200
Independent claims in excess of 3	1201	2	210	420
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1650**

Electronic Acknowledgement Receipt

EFS ID:	3440631
Application Number:	12137364
International Application Number:	
Confirmation Number:	7377
Title of Invention:	INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE
First Named Inventor/Applicant Name:	Steve Hidem
Customer Number:	22859
Filer:	Charles D. Segelbaum
Filer Authorized By:	
Attorney Docket Number:	56782.1.7
Receipt Date:	11-JUN-2008
Filing Date:	
Time Stamp:	18:19:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1650
RAM confirmation Number	3857
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)

1	Application Data Sheet	56782_1_7_ApplicationDataSheet.pdf	1222143 3d24736958ff7dcf9ce2b5902b41eb9035b966bb	no	5
Warnings:					
Information:					
2		56782_1_7_Application.pdf	185593 1f40ccbc93d6ea98b2a164fd1ece9f309ea8c1df	yes	35
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	26	
	Claims		27	34	
	Abstract		35	35	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	56782_1_5_6_7_8_Drawings.pdf	3090157 51f728353556654064c53570776bc61a122bc41f	no	23
Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	8598 d7fc8178333f081be8c45132c079b99d54ccfb69	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	4506491	

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.

Filing Date: 06/11/08

Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 12/137,364

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	310
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	510
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	210
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	4	X$ 25		OR	X$50	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	* 2	X$105			X$210	420
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			185			370	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1650

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

1, 18, 20, 21, 24.