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.

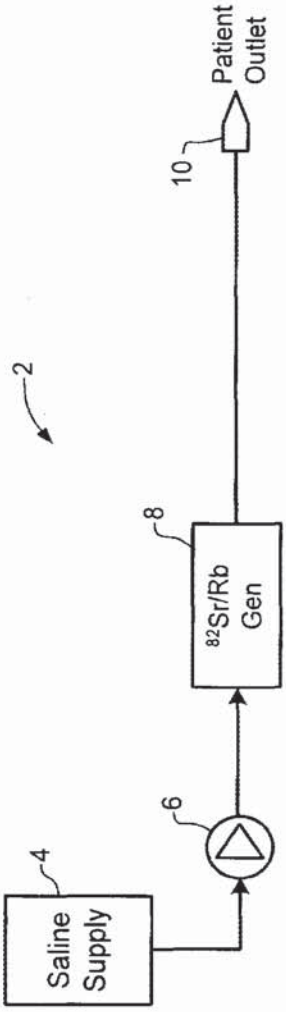


Figure 1a
(Prior Art)

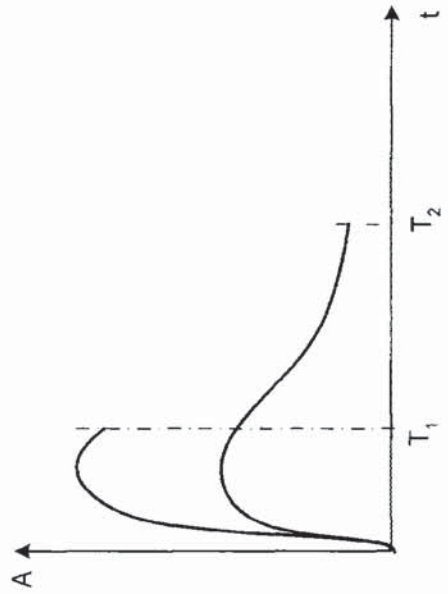


Figure 2b
(Prior Art)

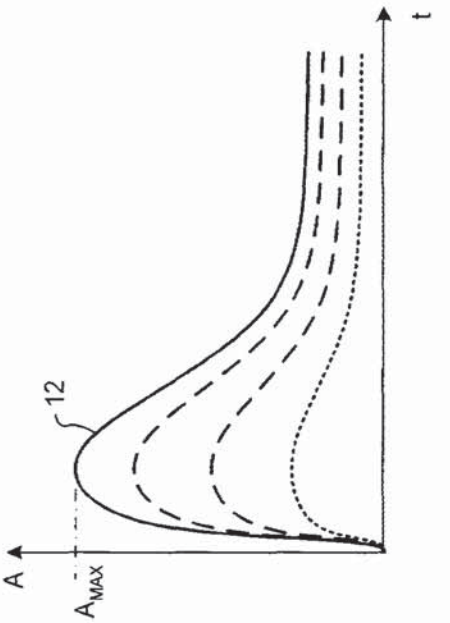


Figure 2a
(Prior Art)

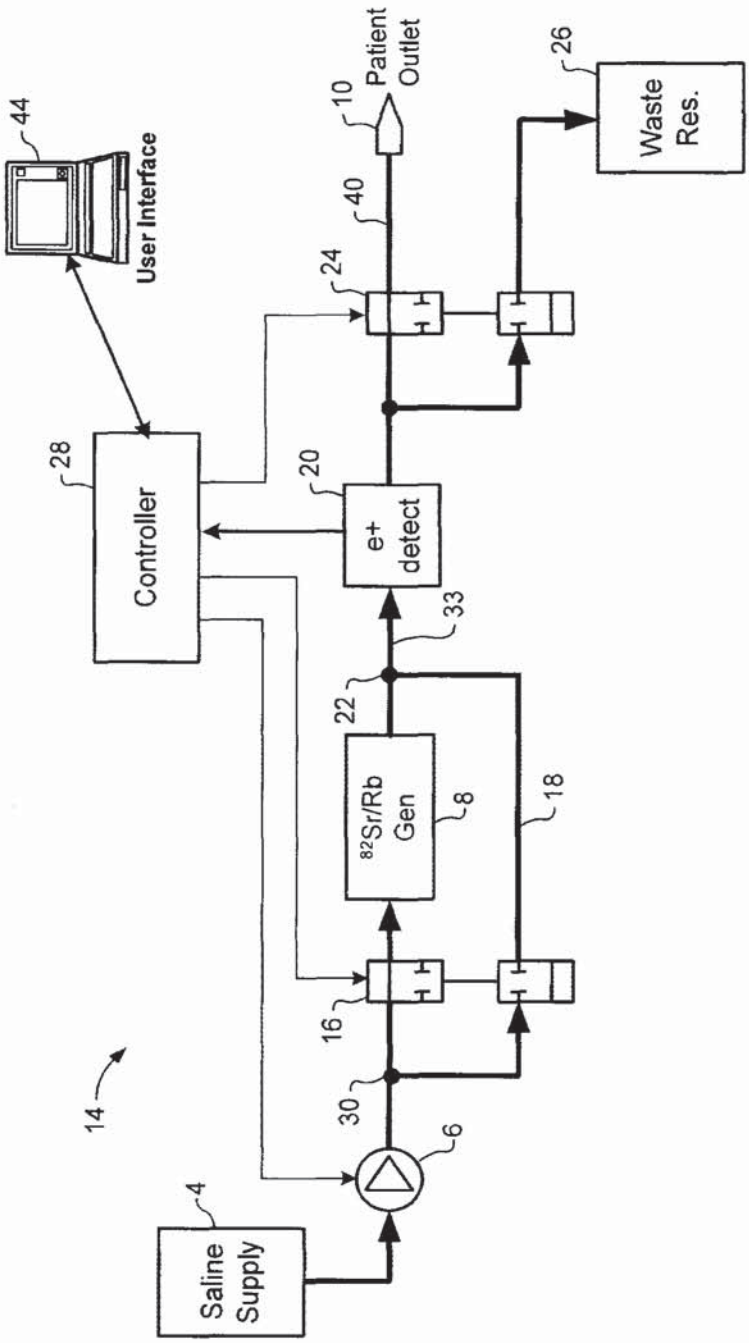

44
User Interface
10
Patient Outlet
26
Waste Res.
40
24
28
Controller
20
e+ detect
33
22
82Sr/Rb Gen
8
18
16
30
6
14
4
Saline Supply

Figure 3

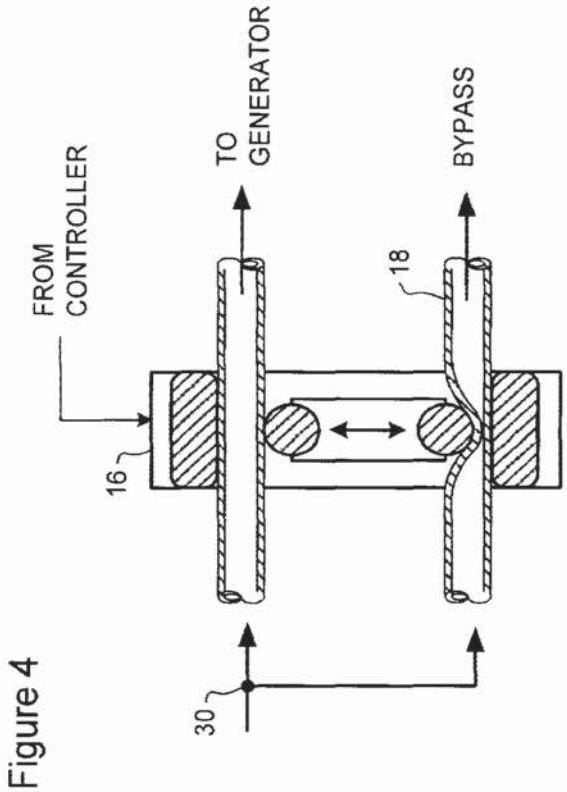


Figure 4

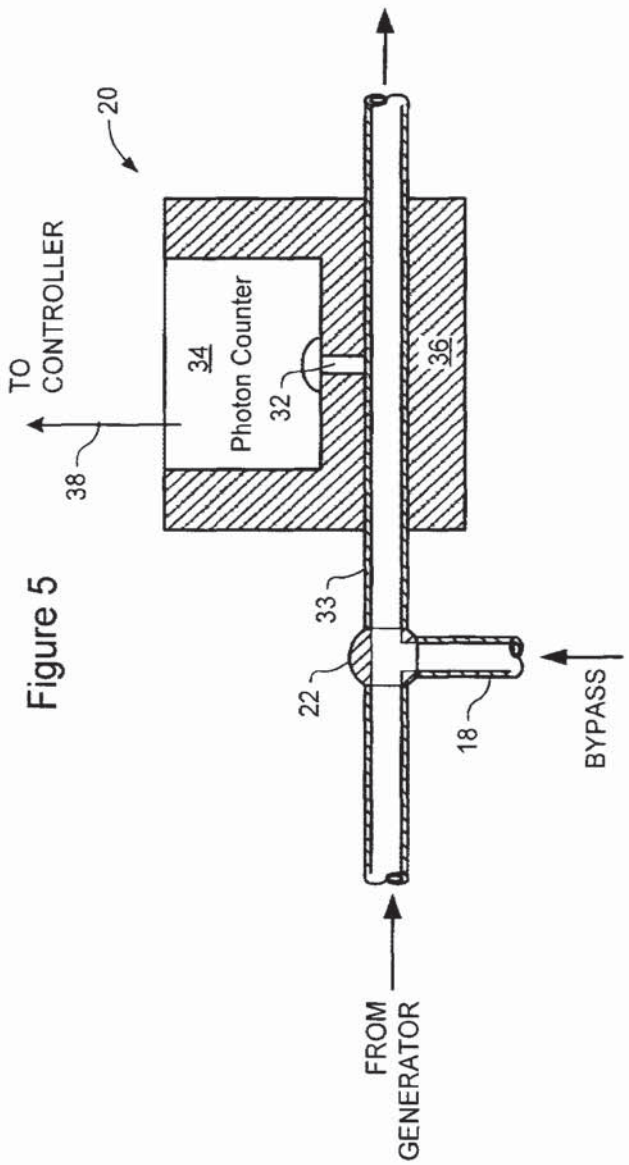


Figure 5

Figure 6a

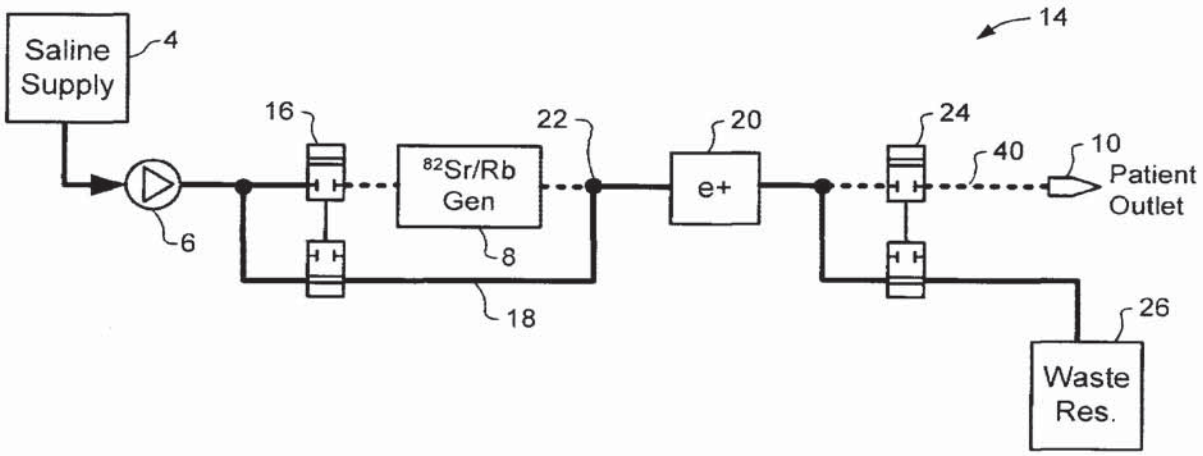


Figure 6b

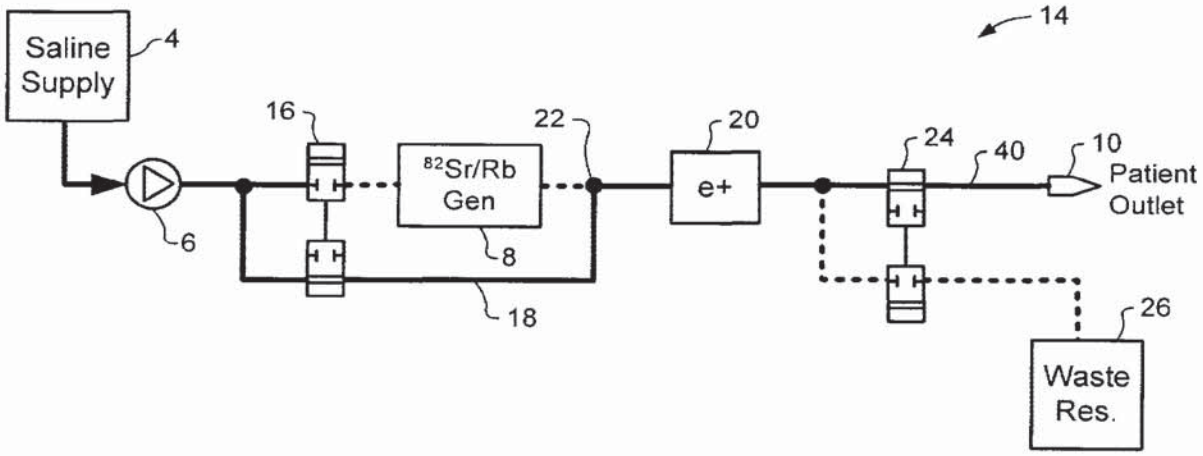


Figure 6c

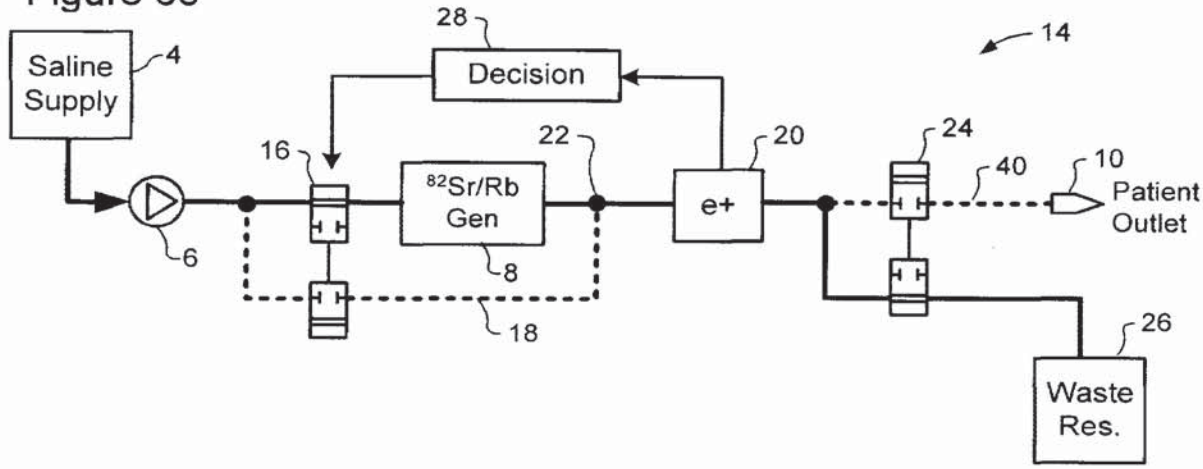


Figure 6d

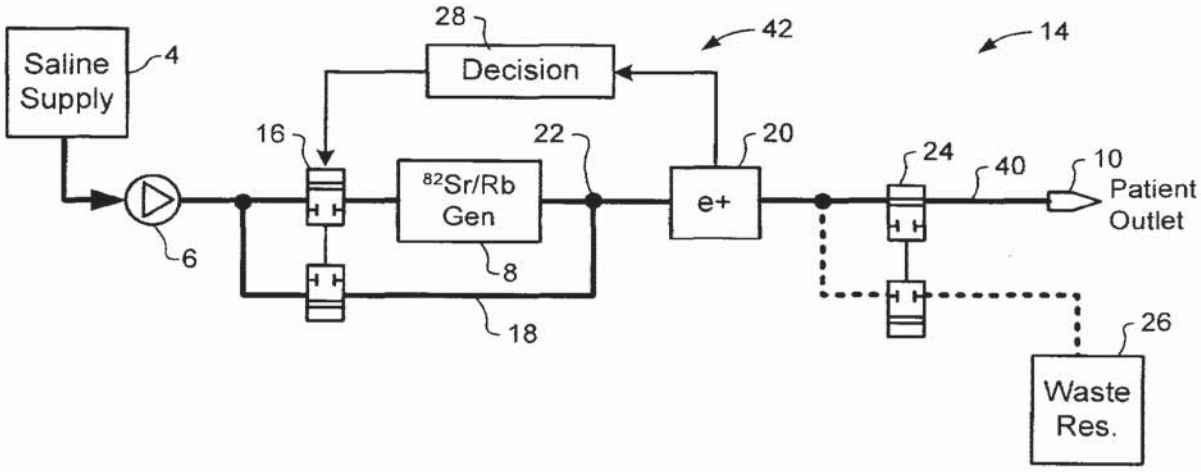

Saline Supply
4
28
Decision
42
14
16
22
20
24
40
10
Patient Outlet
82Sr/Rb Gen
e+
6
8
18
26
Waste Res.

Figure 7a

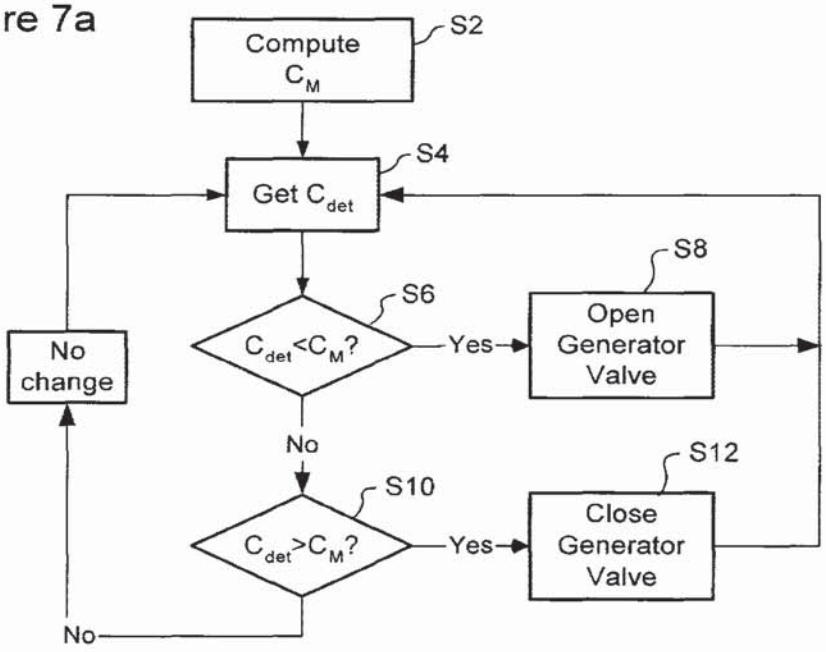


Figure 7b

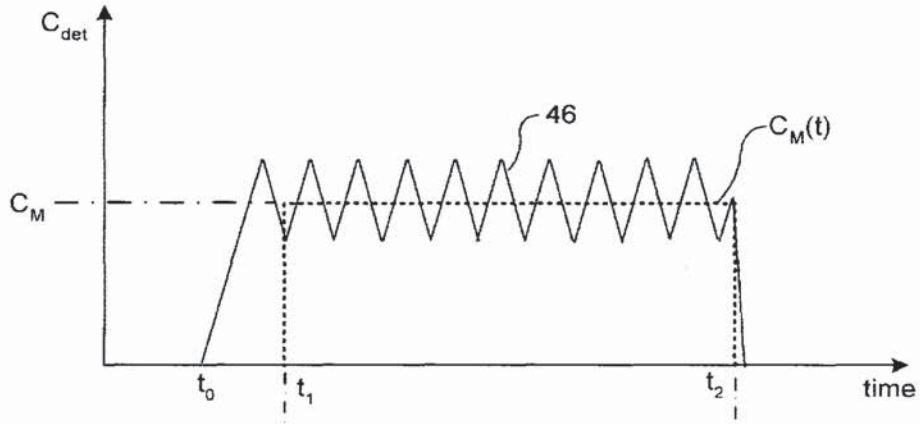


Figure 7c

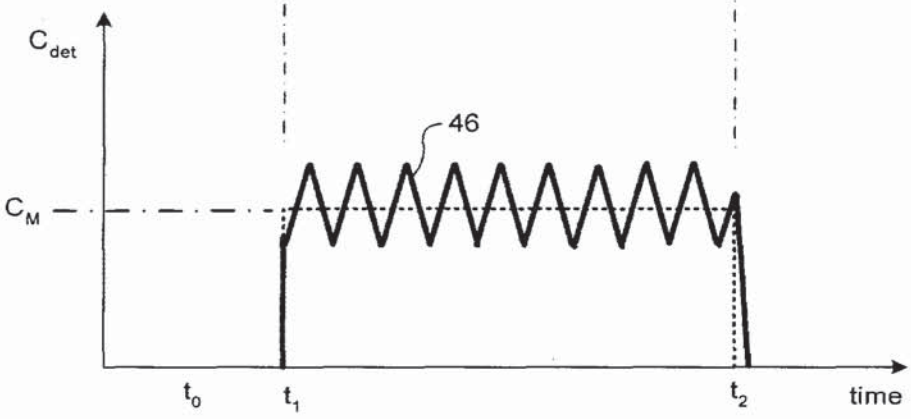


Figure 8a

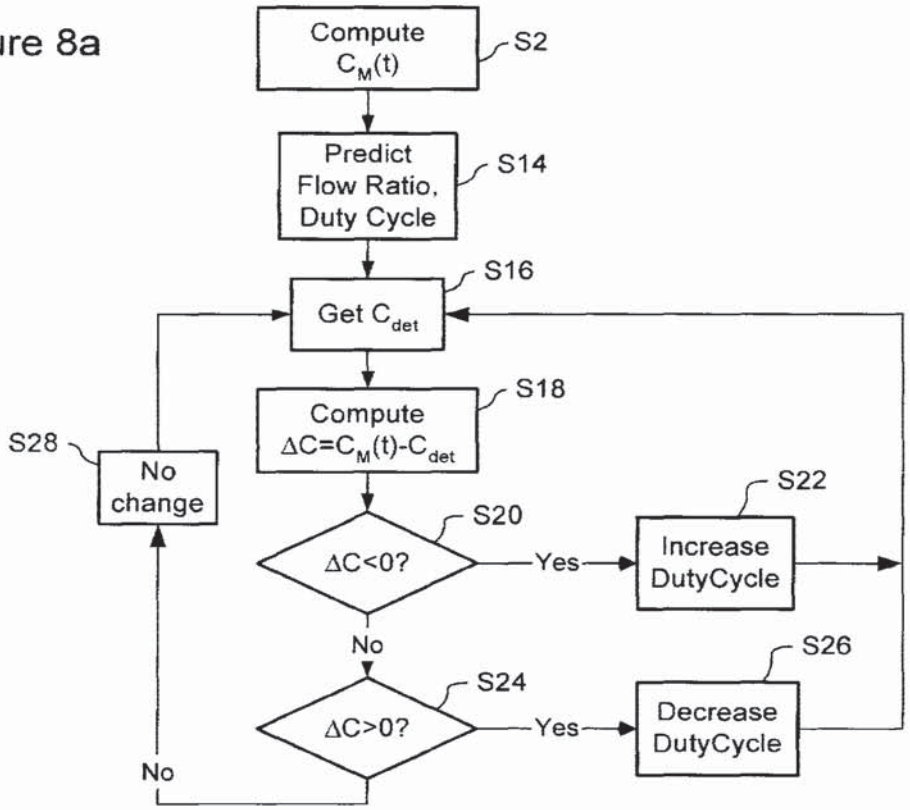


Figure 8b

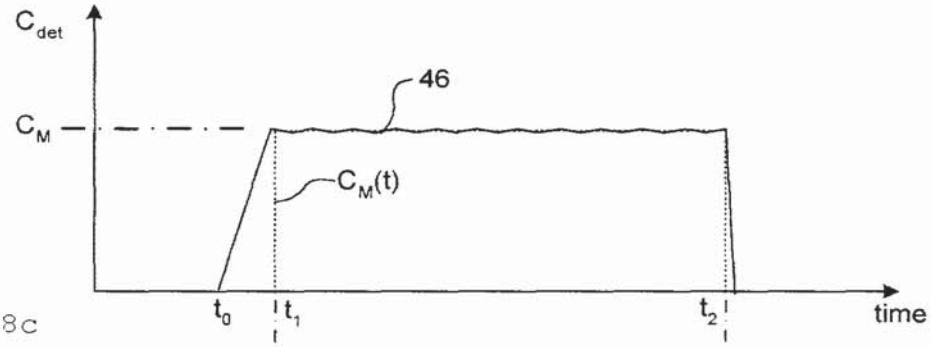
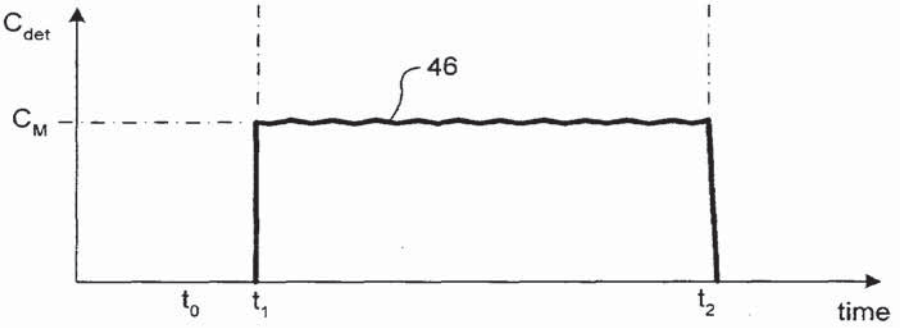


Figure 8c



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 :

"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
13 April 2007 (13-04-2007)	18 May 2007 (18-05-2007)

Name and mailing address of the ISA/CA	Authorized officer
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	Valérie Dubé 819- 934-4261

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:	5366014
Application Number:	12137356
International Application Number:	
Confirmation Number:	7360
Title of Invention:	SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Elisabeth Lacy Belden
Filer Authorized By:	
Attorney Docket Number:	56782.1.5
Receipt Date:	20-MAY-2009
Filing Date:	11-JUN-2008
Time Stamp:	13:54:24
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_5_IDS3.pdf	796240 478a2611d3d16c53dce555fd27b80b55b64a27c8	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):	3381448		

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.

Stmt (52) 5/6/09

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) Charles R. Quirico

citizens of US

residing at 19 Robin Road, Warren, New Jersey 07059

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc. That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Bracco Diagnostics, Inc.
Other relevant facts are Bracco contracted with Worrell, Inc. in the design of the invention, for which Worrell assigned all rights to Bracco.

--AND/OR--

That to the best of my (our) knowledge and belief (and/or) based upon information provided by _____ of Bracco Diagnostics, Inc.

--OR--

☐ II. *(For Self-Employed Inventors)* That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant factors are _____

(check III and/or IV below as appropriate)

That to the best of my (our) knowledge and belief:

☒ III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration, or the Department of Energy.

☐ IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

RECEIVED
MAY - 4 2009
LICENSING & REVIEW

The undersigned inventor(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's Signature: Charles R. Quirico
Charles R. Quirico

Post Office Address: 19 Robin Road, Warren, New Jersey 07059

Date: 4/28/09

Inventor's Signature: _____

Post Office Address: _____

Date: _____

FORM PTOL-458 (Rev. 07-06)

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) Daniel Darst

citizens of US

residing at 25540 96th Street NW, Zimmerman, MN 55398

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc. That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Bracco Diagnostics, Inc.
Other relevant facts are Bracco contracted with Worrell, Inc. in the design of the invention, for which Worrell assigned all rights to Bracco.

--AND/OR--

That to the best of my (our) knowledge and belief (and/or) based upon information provided by

of Bracco Diagnostics, Inc.

--OR--

☐ II. *(For Self-Employed Inventors)* That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant factors are

(check III and/or IV below as appropriate)

That to the best of my (our) knowledge and belief:

☒ III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

☐ IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

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MAY - 4 2009
LICENSING & REVIEW

The undersigned inventors(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's Signature: Daniel Darst 4/22/09
Daniel Darst

Post Office Address: 25540 96th Street NW, Zimmerman, MN 55398

Date:

Inventor's Signature:

Post Office Address:

Date:

FORM PTOL-455 (Rev. 07-06)

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) Daniel V. Clements

citizens of US

residing at 10792 ERIE DR., CROWN POINT, IN 46307

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc. That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Bracco Diagnostics, Inc. Other relevant facts are Bracco contracted with Worrell, Inc. in the design of the invention, for which Worrell assigned all rights to Bracco.

--AND/OR--

That to the best of my (our) knowledge and belief (and/or) based upon information provided by

of Bracco Diagnostics, Inc.

--OR--

☐ II. *(For Self-Employed Inventors)* That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant factors are

(check III and/or IV below as appropriate)

That to the best of my (our) knowledge and belief:

☒ III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

☐ IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

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MAY - 4 2009
LICENSING & REVIEW

The undersigned inventor(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's Signature: Daniel V. Clements

Post Office Address: 10792 Erie Drive Crown Point IN 46307

Date: 4/29/09

Inventor's Signature:

Post Office Address:

Date:

FORM PTOL-456 (Rev. 07-08)

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) Eric J. Krause

citizens of US

residing at 3360 Lake Ridge Drive, Big Lake, MN 55309

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

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of Bracco Diagnostics, Inc.

--OR--

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Inventor's Signature: 4/22/09
Eric J. Krause
Post Office Address: 3360 Lake Ridge Drive, Big Lake, MN 55309
Date:

Inventor's Signature:
Post Office Address:
Date:

FORM PTOL-456 (Rev. 07-08)

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I(We) Ernest Balestracci

citizens of US

residing at 404 Hampton Lane, Iselin, NJ 08830

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

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Inventor's Signature: Ernest Balestracci
Ernest Balestracci

Post Office Address: 404 Hampton Lane Iselin, NJ 08830

Date: 4-27-09

Inventor's Signature:

Post Office Address:

Date:

FORM PTOL-456 (Rev. 07-09)

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) Jacob S. Childs

citizens of US

residing at 13 NORUMBEGA ST, CAMBRIDGE, MA 02138

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc.
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--OR--

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Inventor's Signature Jacob S. Childs

Post Office Address 13 NORUMBEGA ST, CAMBRIDGE, MA 02138

Date: 4-27-2009

Inventor's Signature

Post Office Address

Date:

FORM PTDL-458 (Rev. 07-08)

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I(We) Peter B. Madson

citizens of US

residing at 388 Furongjiang Lu, Building 3, Apt. 601, Changning District, Shanghai, 200051, China

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc.
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–OR–

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Inventor's Signature: Peter B. Madson

Post Office Address: 388 Furongjiang Lu, Building 3, Apt. 601, Changning District, Shanghai 20051, China

Date: 04.23.2009

Inventor's Signature: _____

Post Office Address: _____

Date: _____

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I(We) Vishal N. Lokhande

citizens of India

residing at 100 N WHISMAN ROAD, MOUNTAIN VIEW, CA-94043

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number 12/137,356 filed in the United States of America on June 11, 2008

titled SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(check and complete either I or II below)

☒ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by Bracco Diagnostics, Inc. That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Bracco Diagnostics, Inc.
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--OR--

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Inventor's Signature: Lokhande
Vishal N. Lokhande

Post Office Address: 100 N WHISMAN ROAD, MOUNTAIN VIEW, CA-94043

Date: 04/22/2009

Inventor's Signature: _____

Post Office Address: _____

Date: _____

Fredrikson & BYRON, P.A.

FAX

DATE: May 4, 2009

TO: Crystal Jeter
COMPANY: US PTO
FAX: 1-571-273-0314
DIRECT DIAL: 1-571-272-8203

FROM: Charles D. Segelbaum
DIRECT DIAL: (612) 492-7115
FAX: (612) 492-7077
TOTAL NUMBER OF PAGES (including this page): 9

COMMENTS:

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,356	06/11/2008	Charles R. Quirico	56782.1.5	7360

EXAMINER	
ART UNIT	PAPER NUMBER
MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

04/06/2009
INTELLECTUAL PROPERTY GROUP
FREDRIKSON & BYRON, P.A.
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

TITLE:
SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

This is in response to the Requirement For Statement Under §152 Of The Atomic Energy Act dated April 6, 2009.

Enclosed are eight statements signed by the inventors listed in the above referenced application.

The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

/s/ Charles D. Segelbaum/Atty. Reg. No. 42,138

Attorneys & Advisors
main 612.492.7000
fax 612.492.7077
www.fredlaw.com

Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, Minnesota
55402-1425

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EMPL:	1731
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NAME:	Lisa Hengen
EXT.	7521 / 33
VERIFIED:	lah

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,356	06/11/2008	Charles R. Quirico	56782.1.5	7360

04/06/2009

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

EXAMINER	
ART UNIT	PAPER NUMBER
MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

TITLE:
SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

REQUIREMENT FOR STATEMENT UNDER §152 OF THE ATOMIC ENERGY ACT

The subject matter of this application is considered "useful in the production or utilization of special nuclear material or atomic energy".

No patent for any invention "useful in the production or utilization of special nuclear material or atomic energy" may issue unless the applicant files a statement WITHIN THIRTY DAYS from request thereof by the Commissioner for Patents setting forth the full facts surrounding the making or conception of the invention described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Energy Research and Development Administration or the Department of Energy as required under §152 of the Atomic Energy Act of 1954, 42 U.S.C. section 2182.

Applicant is hereby given a period of THIRTY DAYS from the mailing date of this letter to file the required statement under 42 U.S.C. §2182. Failure to submit the required statment within the thirty day period will result in ABANDONMENT of the application. The thisty day period is fixed by §2182 of the Act and **cannot be extended.** Thus, no extension of this period may be obtained under either 37 CFR §1.136(a) or (b).

Respectfully,

/C. Jeter/

Crystal Jeter

Supervisory Applications Examiner
Special Laws Administration
TC 3600

Please direct all written communications regarding this matter to:
Commissioner for Patents
Mailstop L&R
P.O.Box 1450
Alexandria, Virginia 22313-1450
Please direct all telephone calls regarding this matter to:
(571)-272-8203.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,356	06/11/2008	Charles R. Quirico	56782.1.5	7360

04/06/2009

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

EXAMINER	
ART UNIT	PAPER NUMBER
MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

TITLE:
SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

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Respectfully,

/C. Jeter/

Crystal Jeter
Supervisory Applications Examiner
Special Laws Administration
TC 3600

Please direct all written communications regarding this matter to:
Commissioner for Patents
Mailstop L&R
P.O.Box 1450
Alexandria, Virginia 22313-1450
Please direct all telephone calls regarding this matter to:
(571)-272-8203.

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	12137356
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	3763
Examiner Name	
Attorney Docket Number	56782.1.5

U.S.PATENTS Remove

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137356
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	56782.1.5

	1		☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137356
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	56782.1.5

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.**

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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)

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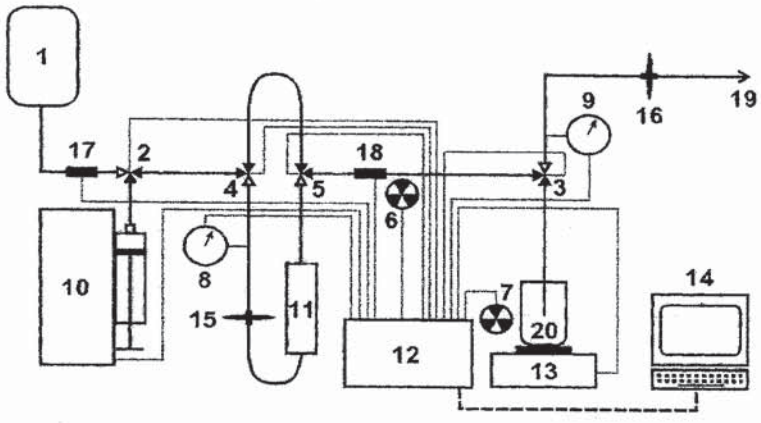
[продолжение на следующей странице]

(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]

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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 циклотро́нов, 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

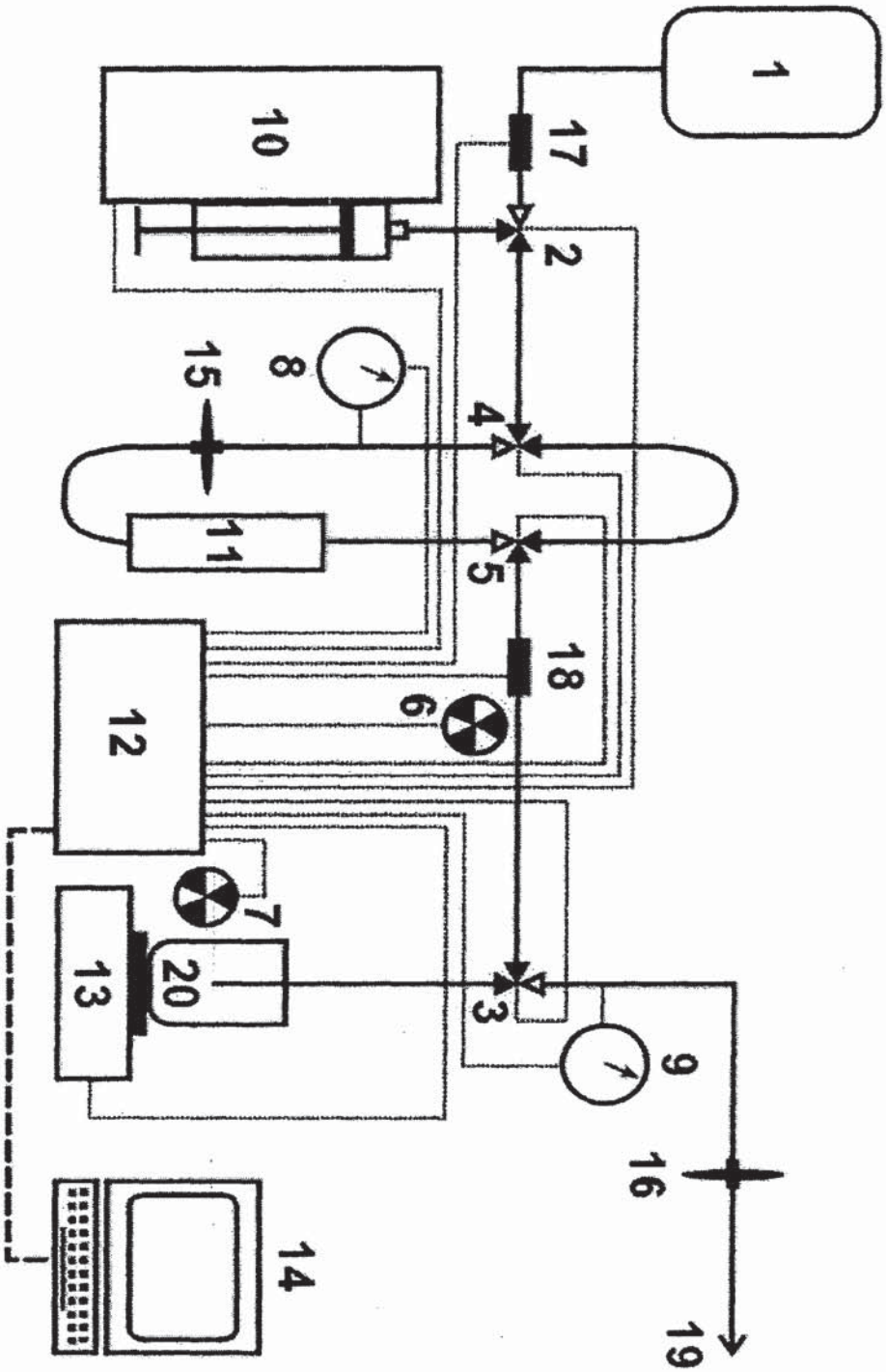
средство контроля веса отходов, выполненного в виде датчика усилия, а в отверстии

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

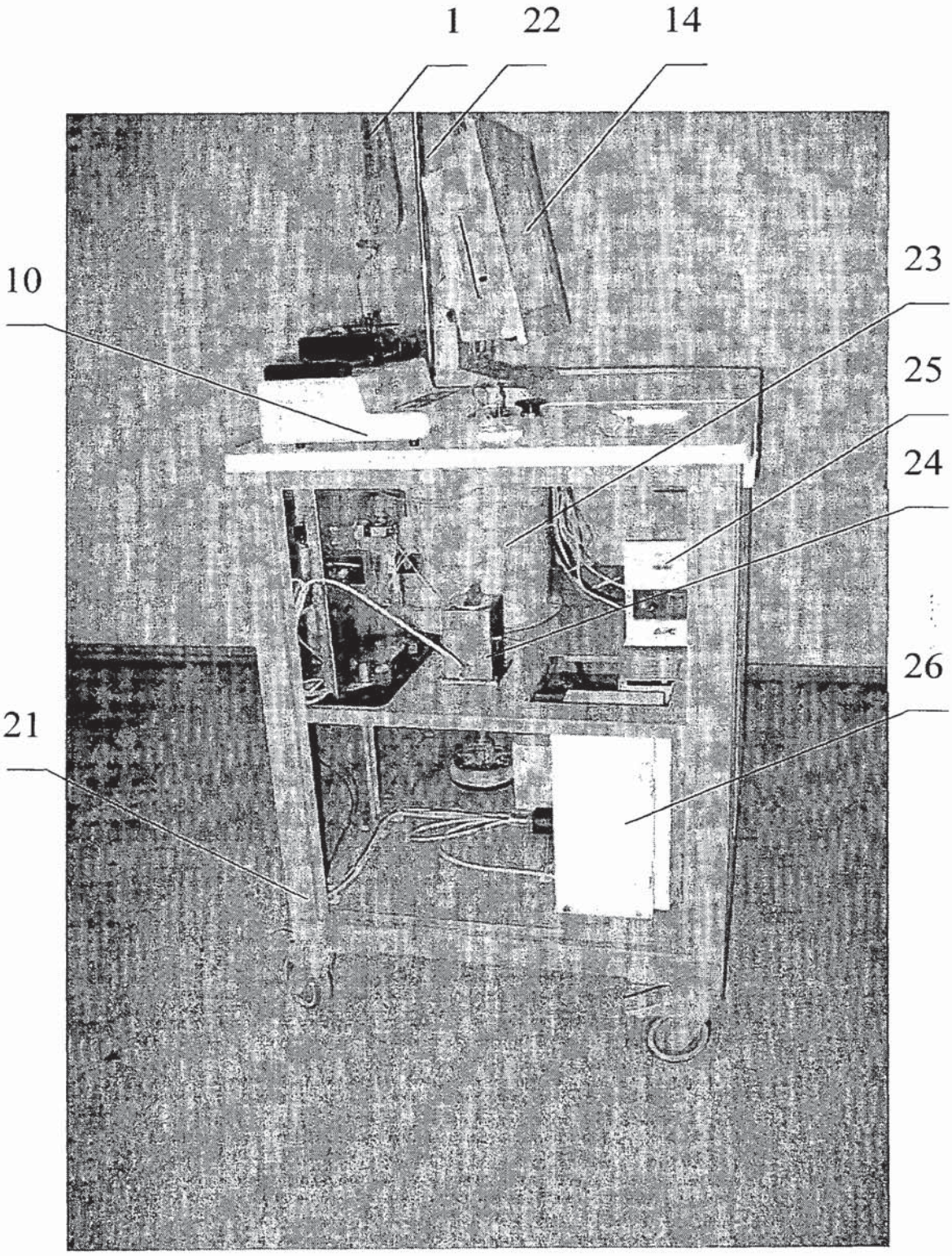
5. Система по п.1, отличающаяся тем, что стронций – рубидиевый генератор имеет радиационную защиту, включающую внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

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

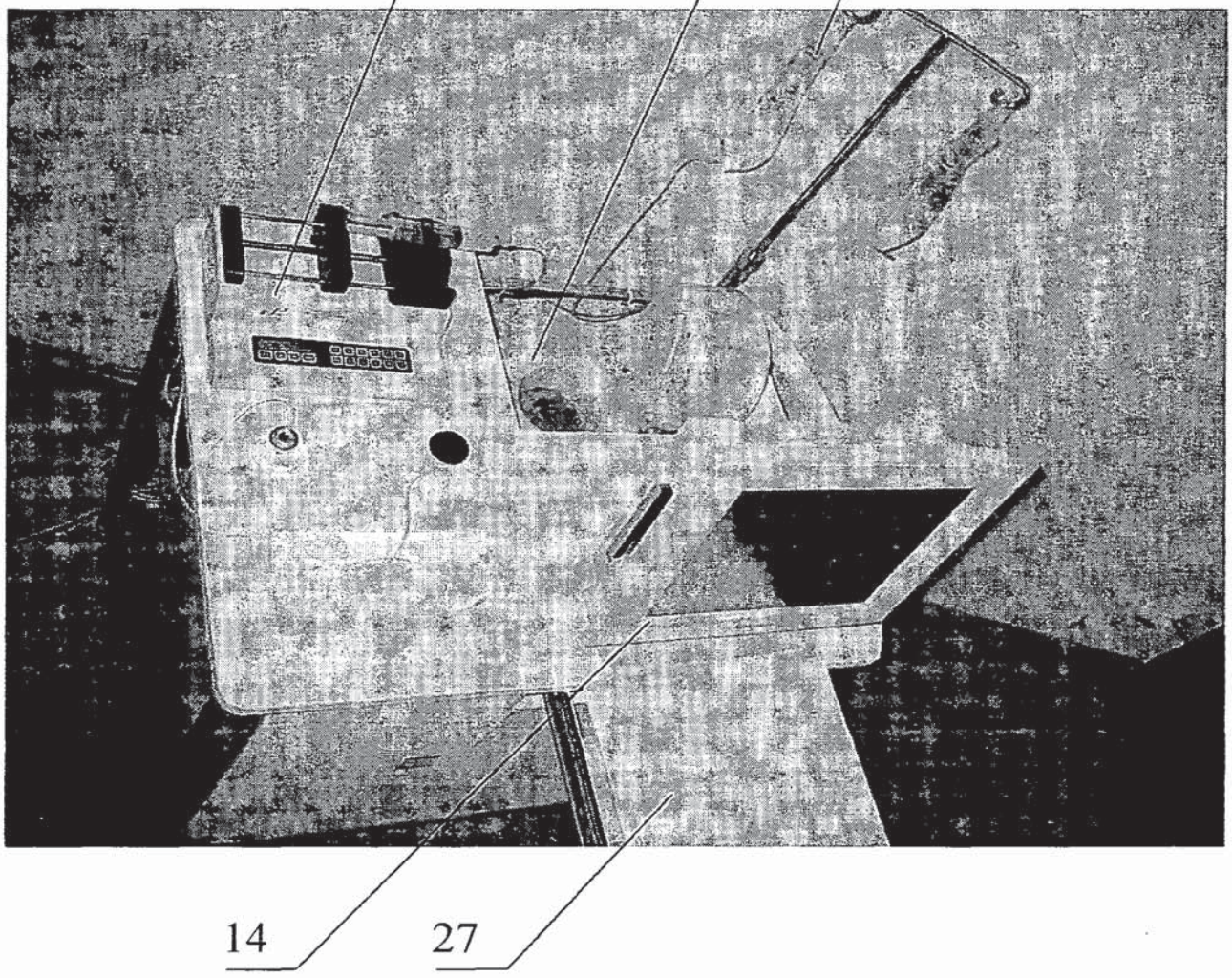
7. Система по п.6, отличающаяся тем, что корпус снабжен сдвигающейся столешницей.



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:	4634331
Application Number:	12137356
International Application Number:	
Confirmation Number:	7360
Title of Invention:	SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS
First Named Inventor/Applicant Name:	Charles R. Quirico
Customer Number:	22859
Filer:	Elisabeth Lacy Belden
Filer Authorized By:	
Attorney Docket Number:	56782.1.5
Receipt Date:	20-JAN-2009
Filing Date:	11-JUN-2008
Time Stamp:	11:37:52
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_5_IDS2.pdf	756417 3f679ea0a49425772f8dbc3538d57c2c2e5c068c	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):	2865264

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/137,356	06/11/2008	Charles R. Quirico	56782.1.5	7360

EXAMINER

11/25/2008

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

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
11/25/2008	PAPER

IF NO RESPONSE TO THIS NOTICE IS RECEIVED WITHIN FORTY-FIVE DAYS, A FORMAL REQUIRMENT WILL BE ISSUED

The subject matter of this application appears to be "useful in the production or utilization of special nuclear material or atomic energy" as recited in 42 U.S.C. 2182 (Department of Energy (DOE)).

Accordingly, no patent can issue on this application unless applicant(s) file a statement (under oath or in the form of a declaration as provided by 37 CFR 1.68) setting forth (1) the full facts concerning the circumstances under which the invention was made and conceived and (2) the relationship (if any) of the invention to the performance of any work under any contract or other arrangement with the Agency(ies) noted above. On the 2nd page of this form is an example of an acceptable format for this statement. The language appearing in paragraphs III and/or IV of the example must appear if applicant is attempting to establish that no relationship (under item 2 above) exists.

If the invention disclosed in this application was developed under a contract, grant or cooperative agreement between the Agency indicated above and a person, small business or non-profit organization and rights to the invention have been determined by specific reference to 35 U.S.C. 202 in the contract, grant or cooperative agreement, then the applicant need not submit the statement described above. Instead, applicant may file a verified statement (under oath or in the form of a declaration, 37 CFR 1.68) setting forth the information required by 35 U.S.C. 202(c)(6).

IF NO STATEMENT HAS BEEN RECIEVED WITHIN FORTY-FIVE DAYS OF THE MAIL DATE INDICATED ABOVE, a formal 30 day requirement for statement will then be issued. No provision is made for extension of the statutory thirty-day period for response to the formal requirement and the penalty for failure to file an acceptable and timely statement is abandonment of the application. Therefore, applicants are strongly encouraged to submit a statement at this time in order to avoid the issuance of a formal requirement.

IT IS IMPORTANT TO NOTE that the statement must accurately represent the property rights situation of the claimed invention if and when the application is found allowable. Thus, if during prosecution before the examiner, the claimed invention is so altered or the property rights situation so changes to impact the accuracy of a statement submitted earlier, a supplemental statement must be filed. Failure to submit such additional information where appropriate may be considered a false representation of material facts and render the patent owner vulnerable to loss of patent rights and other sanctions as set forth in the statutes. The PTO will not review allowed applications for this possibility. The responsibility for complying with the statutes rests with the applicants.

Any questions regarding this requirment should be directed to Licensing and Review at (571)-272-8203.

PLEASE DIRECT ALL COMMUNICATIONS RELATING TO THIS MATTER TO THE ATTENTION OF MAIL STOP L&R.

The following is an example of an acceptable property rights statement. Statements of this type are, of course, only suitable for situations in which NO Agency funds or other considerations were involved in the making or conception of the invention. While this example is in the form of a declaration, a sworn document is equally acceptable.

I(We) _____

citizens of _____

residing at _____

declare:

That I(we) made and conceived the invention described and claimed in patent application:

Serial Number _____ filed in the United States of America on _____

titled _____

(check and complete either I or II below)

❑ I. *(For Inventors Employed by an Organization)* That I(We) made and conceived this invention while employed by _____. That the invention is related to the work I am (we are) employed to perform and was made within the scope of my (our) employment duties; That the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of _____. Other relevant facts are _____ _____. That to the best of my (our) knowledge and belief (and/or) based upon information provided by _____ of _____.

--OR--

❑ II. *(For Self-Employed Inventors)* That I (we) made and conceived this invention on my (our) own time using only my (our) own facilities, equipment, materials, funds, information and services. Other relevant factors are _____ _____.

(check III and/or IV below as appropriate)

That to the best of my (our) knowledge and belief:

❑ III. The invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors: Energy Research and Development Administration or the Department of Energy.

--AND/OR--

❑ IV. The invention was not made (conceived or first actually reduced to practice) under nor is there any relationship of the invention to the performance of any work under any contract of the National Aeronautics and Space Administration.

The undersigned inventors(s) declare further that all statements made herein of his or her (their) own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Inventor's Signature: _____

Post Office Address: _____

Date: _____

Inventor's Signature: _____

Post Office Address: _____

Date: _____

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
12/137,356	06/11/2008	3763	2430	56782.1.5	37	5

CONFIRMATION NO. 7360

UPDATED FILING RECEIPT

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

Date Mailed: 11/14/2008

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)

Charles R. Quirico, Warren, NJ;
Ernest Balestracci, Iselin, NJ;
Daniel Darst, Zimmerman, MN;
Eric J. Krause, Big Lake, MN;
Vishal N. Lokhande, Mountain View, CA;
Jacob S. Childs, Minneapolis, MN;
Peter B. Madson, Shanghai, CHINA;
Daniel V. Clements, Minneapolis, MN;

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.

Projected Publication Date: To Be Determined - pending completion of Security Review

Non-Publication Request: No

Early Publication Request: No

Title

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

Preliminary Class

604

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
12/137,356	06/11/2008	Charles Quirico	56782.1.5

CONFIRMATION NO. 7360

POA ACCEPTANCE LETTER

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

OC000000032895166

Date Mailed: 11/03/2008

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.

/tha/

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.: 56782.1.5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Charles R. Quirico		
Application No.:	12/137,356	Group Art Unit:	3763
Filed:	June 11, 2008	Examiner:	
Title:	SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS		

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 July 1, 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

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
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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	56782.1.5
First Named Inventor	Charles R. Quirico
COMPLETE IF KNOWN	
Application Number	12/137,356
Filing Date	June 11, 2008
Art Unit	3763
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:

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(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 12/137,356 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 claiming 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)
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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)
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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]) Charles R.	Family Name or Surname Quirico
Inventor's Signature Charles Quirico	Date 9/30/08

Residence: City Warren	State NJ	Country US	Citizenship US
Mailing Address 19 Robin Road			
City Warren	State NJ	Zip 07059	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		
Ernest	Balestracci		
Inventor's Signature *Ernest Balestracci*			Date 9-25-08
Iselin Residence: City	NJ State	US Country	US Citizenship
404 Hampton Lane Mailing Address			
Iselin City	NJ State	08830 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		
Daniel	Darst		
Inventor's Signature			Date
Zimmerman Residence: City	MN State	US Country	US Citizenship
25540 96th Street NW Mailing Address			
Zimmerman City	MN State	55398 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		
Eric J.	Krause		
Inventor's Signature			Date
Big Lake Residence: City	MN State	US Country	US Citizenship
3360 Lake Ridge Drive Mailing Address			
Big Lake City	MN State	55309 Zip	US Country

PTO/SB/02A (07-07)
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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		
Vishal N.	Lokhande		
Inventor's Signature			Date
Mountain View Residence: City	CA State	US Country	India Citizenship
100 N. Whisman Road, Apt. 1412 Mailing Address			
Mountain View City	CA State	94043 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		
Jacob S.	Childs		
Inventor's Signature			Date
Minneapolis Residence: City	MN State	US Country	US Citizenship
30 W. 22nd Street, Apt. 202 Mailing Address			
Minneapolis City	MN State	55404 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		
Peter B.	Madson		
Inventor's Signature			Date
Shanghai Residence: City	State	CN Country	US Citizenship
388 Furongjiang Lu, Building 3, Apt. 601, Changning District Mailing Address			
Shanghai City	State	200051 Zip	CN 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		
Daniel V.	Clements		
Inventor's Signature			Date
Minneapolis Residence: City	MN State	US Country	US Citizenship
4707 Emerson Avenue N. Mailing Address			
Minneapolis City	MN State	55430 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

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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	56782.1.5
First Named Inventor	Charles R. Quirico
COMPLETE IF KNOWN	
Application Number	12/137,356
Filing Date	June 11, 2008
Art Unit	3763
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:

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(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 12/137,356 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 claiming 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 08/30/2010. 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])	Family Name or Surname
Charles R.	Quirico
Inventor's Signature	Date

Residence: City	State	Country	Citizenship
Warren	NJ	US	US
Mailing Address			
19 Robin Road			
City	State	Zip	Country
Warren	NJ	07059	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		
Ernest	Balestracci		
Inventor's Signature			Date
Iselin Residence: City	NJ State	US Country	US Citizenship
404 Hampton Lane Mailing Address			
Iselin City	NJ State	08830 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		
Daniel	Darst		
Inventor's Signature			Date 10/20/08
Zimmerman Residence: City	MN State	US Country	US Citizenship
25540 96th Street NW Mailing Address			
Zimmerman City	MN State	55398 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		
Eric J.	Krause		
Inventor's Signature			Date 10/20/08
Big Lake Residence: City	MN State	US Country	US Citizenship
3360 Lake Ridge Drive Mailing Address			
Big Lake City	MN State	55309 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
Vishal N.	Lokhande
Inventor's Signature	Date
Mountain View (Residence: City)	CA (State)	US (Country)	India (Citizenship)
100 N. Whisman Road, Apt. 1412 (Mailing Address)			
Mountain View (City)	CA (State)	94043 (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
Jacob S.	Childs
Inventor's Signature	10·21·2008 (Date)
Minneapolis (Residence: City)	MN (State)	US (Country)	US (Citizenship)
30 W. 22nd Street, Apt. 202 (Mailing Address)			
Minneapolis (City)	MN (State)	55404 (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
Peter B.	Madson
Inventor's Signature	Date
Shanghai (Residence: City)	(State)	CN (Country)	US (Citizenship)
388 Furongjiang Lu, Building 3, Apt. 601, Changning District (Mailing Address)			
Shanghai (City)	(State)	200051 (Zip)	CN (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		
Daniel V.	Clements		
Inventor's Signature			Date 10-23-08
Residence: City: Minneapolis	State: MN	Country: US	Citizenship: US
Mailing Address: 4707 Emerson Avenue N.			
City: Minneapolis	State: MN	Zip: 55430	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		
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

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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	56782.1.5
First Named Inventor	Charles R. Quirico
COMPLETE IF KNOWN	
Application Number	12/137,356
Filing Date	June 11, 2008
Art Unit	3763
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:

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(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 12/137,356 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 claiming 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)
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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)
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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]) Charles R.	Family Name or Surname Quirico
Inventor's Signature	Date

Residence: City	State	Country	Citizenship
Warren	NJ	US	US

Mailing Address			
19 Robin Road			
City	State	Zip	Country
Warren	NJ	07059	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)
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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		
Ernest	Balestracci		
Inventor's Signature			Date
Iselin Residence: City	NJ State	US Country	US Citizenship
404 Hampton Lane Mailing Address			
Iselin City	NJ State	08830 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		
Daniel	Darst		
Inventor's Signature			Date
Zimmerman Residence: City	MN State	US Country	US Citizenship
25540 96th Street NW Mailing Address			
Zimmerman City	MN State	55398 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		
Eric J.	Krause		
Inventor's Signature			Date
Big Lake Residence: City	MN State	US Country	US Citizenship
3360 Lake Ridge Drive Mailing Address			
Big Lake City	MN State	55309 Zip	US Country

PTO/SB/02A (07-07)
Approved for use through 08/30/2010. 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
Vishal N.	Lokhande

Inventor's Signature: Lokhande — Date: 08/22/08

Residence: City	State	Country	Citizenship
Mountain View	CA	US	India

Mailing Address: 100 N. Whisman Road, Apt. 1412

City	State	Zip	Country
Mountain View	CA	94043	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
Jacob S.	Childs

Inventor's Signature — Date

Residence: City	State	Country	Citizenship
Minneapolis	MN	US	US

Mailing Address: 30 W. 22nd Street, Apt. 202

City	State	Zip	Country
Minneapolis	MN	55404	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
Peter B.	Madson

Inventor's Signature — Date

Residence: City	State	Country	Citizenship
Shanghai		CN	US

Mailing Address: 388 Furongjiang Lu, Building 3, Apt. 601, Changning District

City	State	Zip	Country
Shanghai		200051	CN

PTO/SB/02A (07-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 3 of 3

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		
Daniel V.	Clements		
Inventor's Signature			Date
Minneapolis Residence: City	MN State	US Country	US Citizenship
4707 Emerson Avenue N. Mailing Address			
Minneapolis City	MN State	55430 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

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

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

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	56782.1.5
First Named Inventor	Charles R. Quirico
COMPLETE IF KNOWN	
Application Number	12/137,356
Filing Date	June 11, 2008
Art Unit	3763
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:

SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

(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 12/137,356 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 claiming 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)
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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:

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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])	Family Name or Surname
Charles R.	Quirico
Inventor's Signature	Date

Residence: City	State	Country	Citizenship
Warren	NJ	US	US

Mailing Address			
19 Robin Road			
City	State	Zip	Country
Warren	NJ	07059	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		
Ernest	Balestracci		
Inventor's Signature			Date
Iselin Residence: City	NJ State	US Country	US Citizenship
404 Hampton Lane Mailing Address			
Iselin City	NJ State	08830 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		
Daniel	Darst		
Inventor's Signature			Date
Zimmerman Residence: City	MN State	US Country	US Citizenship
25540 96th Street NW Mailing Address			
Zimmerman City	MN State	55398 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		
Eric J.	Krause		
Inventor's Signature			Date
Big Lake Residence: City	MN State	US Country	US Citizenship
3360 Lake Ridge Drive Mailing Address			
Big Lake City	MN State	55309 Zip	US Country

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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		
Vishal N.	Lokhande		
Inventor's Signature			Date
Mountain View Residence: City	CA State	US Country	India Citizenship
100 N. Whisman Road, Apt. 1412 Mailing Address			
Mountain View City	CA State	94043 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		
Jacob S.	Childs		
Inventor's Signature			Date
Minneapolis Residence: City	MN State	US Country	US Citizenship
30 W. 22nd Street, Apt. 202 Mailing Address			
Minneapolis City	MN State	55404 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		
Peter B.	Madson		
Inventor's Signature			Date 08.25.2008
Shanghai Residence: City	State	CN Country	US Citizenship
388 Furongjiang Lu, Building 3, Apt. 601, Changning District Mailing Address			
Shanghai City	State	200051 Zip	CN Country

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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		
Daniel V.	Clements		
Inventor's Signature			Date
Minneapolis Residence: City	MN State	US Country	US Citizenship
4707 Emerson Avenue N. Mailing Address			
Minneapolis City	MN State	55430 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.

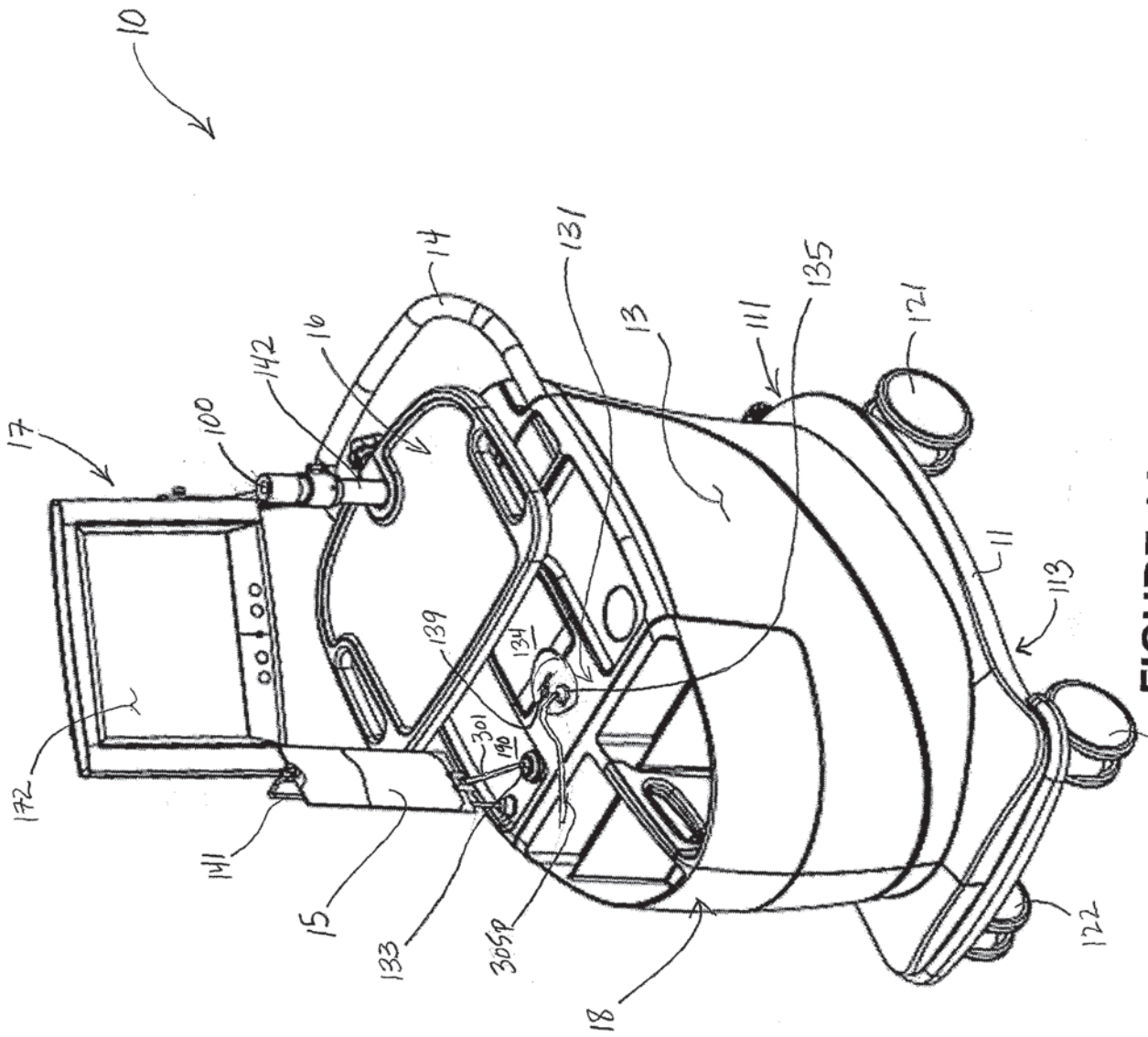

10
17
100
142
16
14
131
13
111
135
121
11
113
122
172
141
15
133
305P
18
139
134
301
140

FIGURE 1A

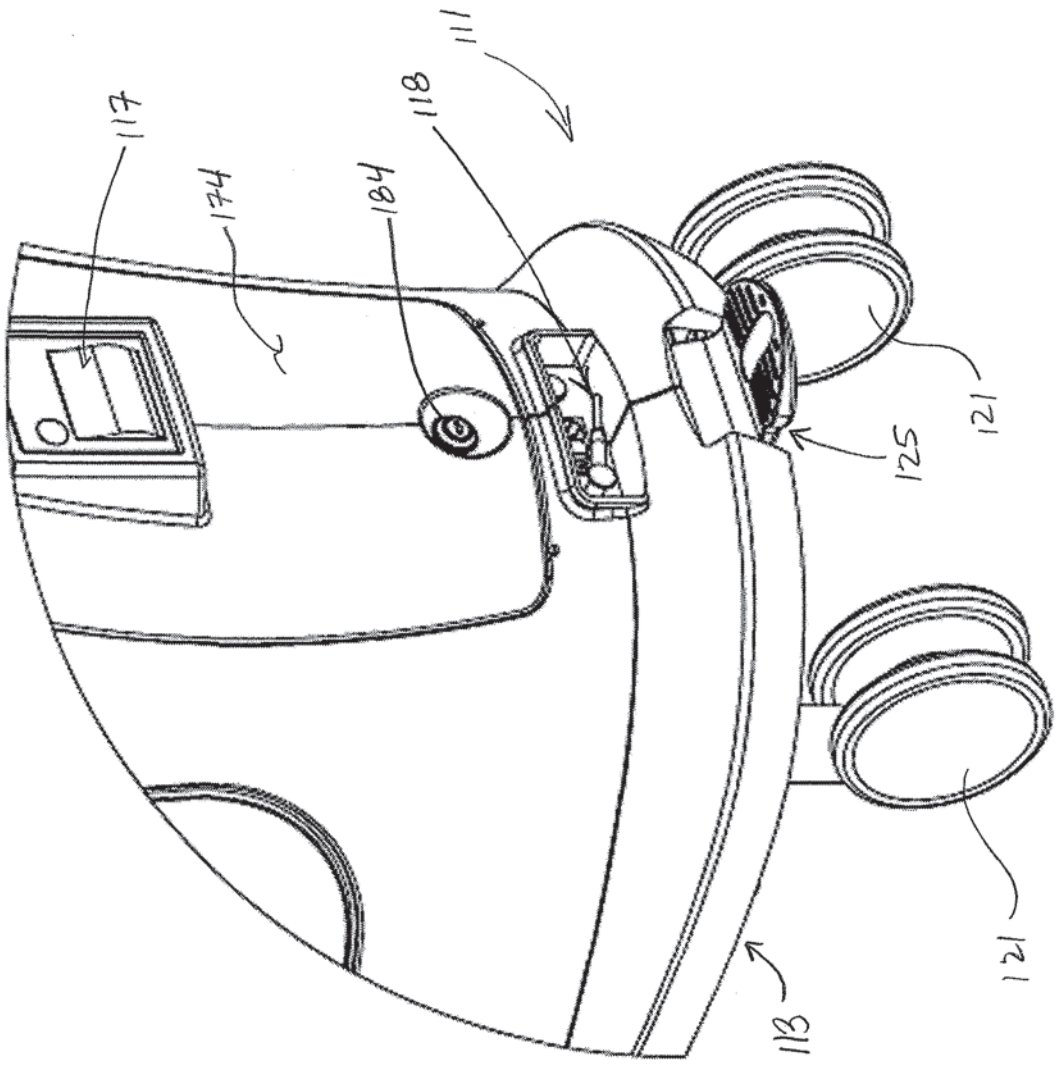
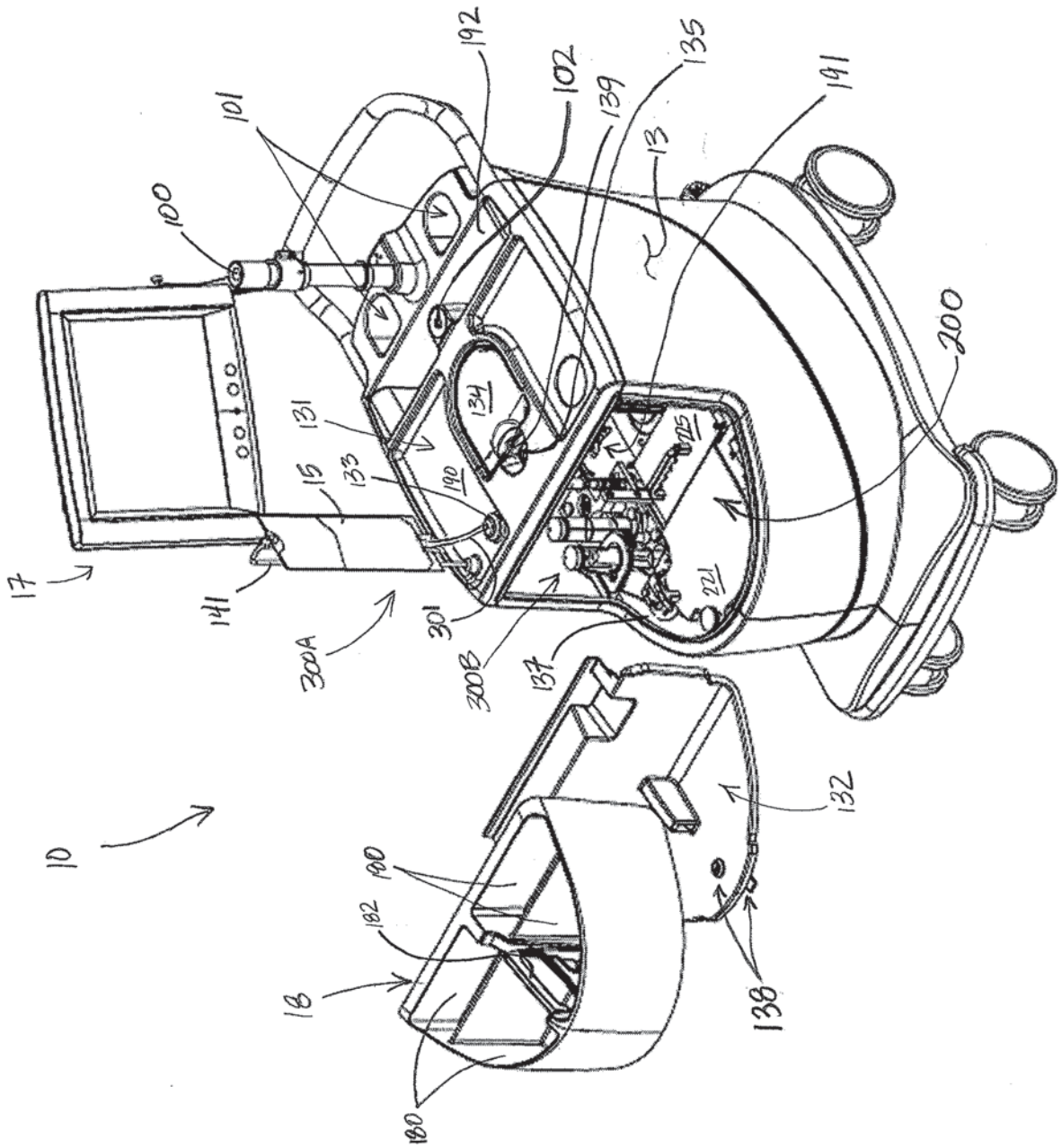


FIGURE 1B


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

FIGURE 1C

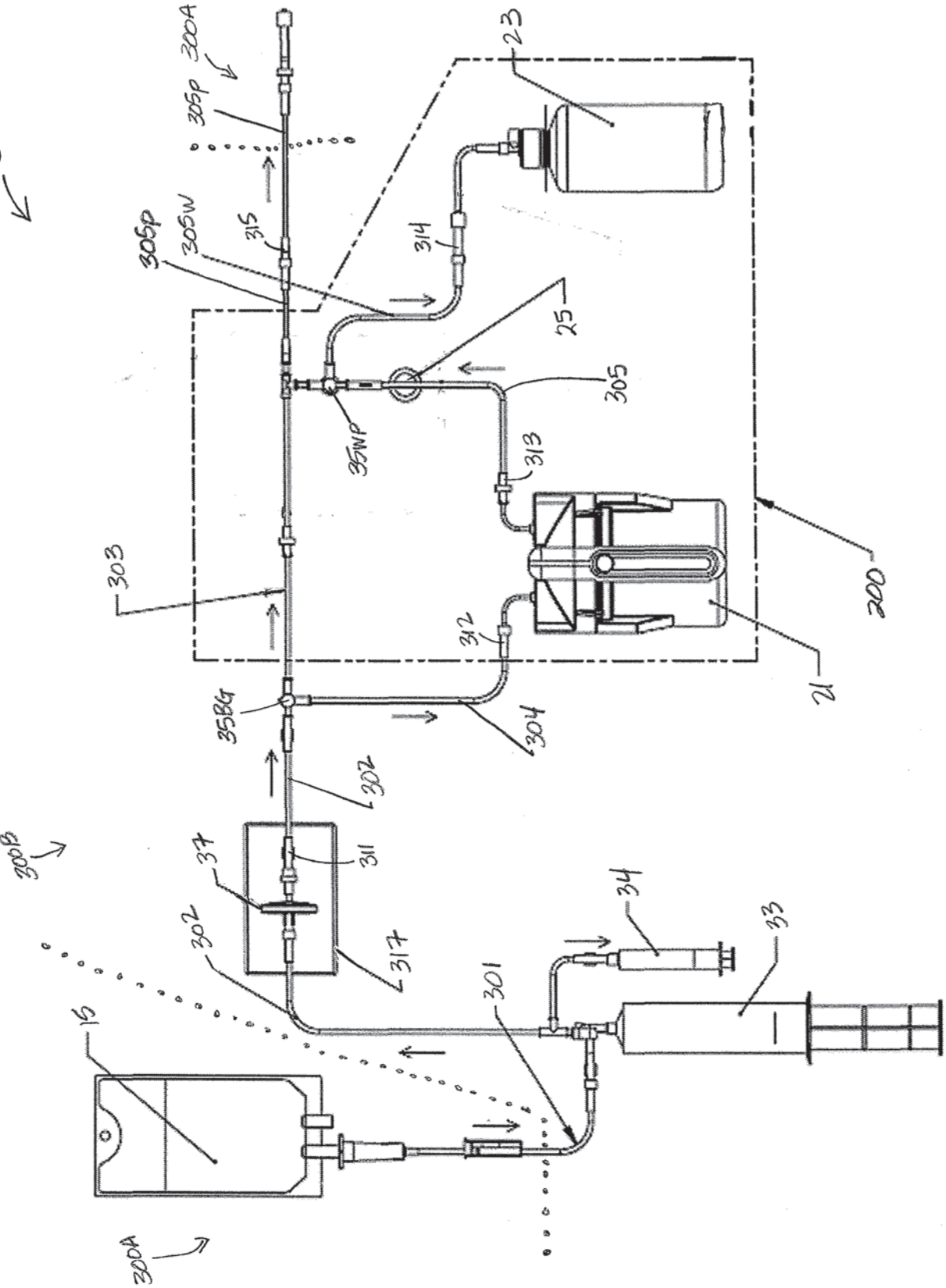

300
300A
305P
23
305P
305W
315
314
25
305
35WP
313
303
312
35BG
304
21
200
302
300B
37
311
302
317
34
33
301
15
300A

FIGURE 1D

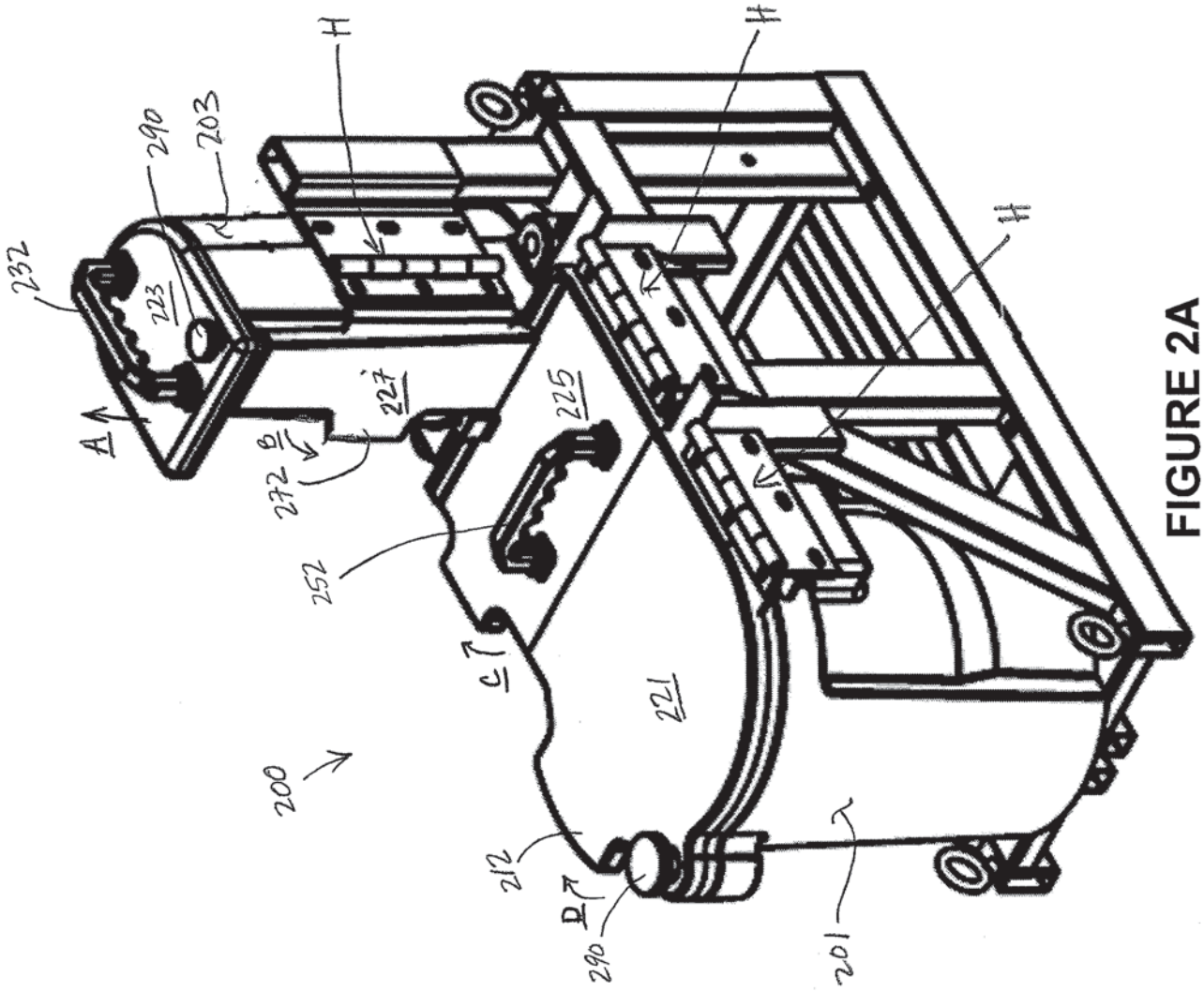


FIGURE 2A

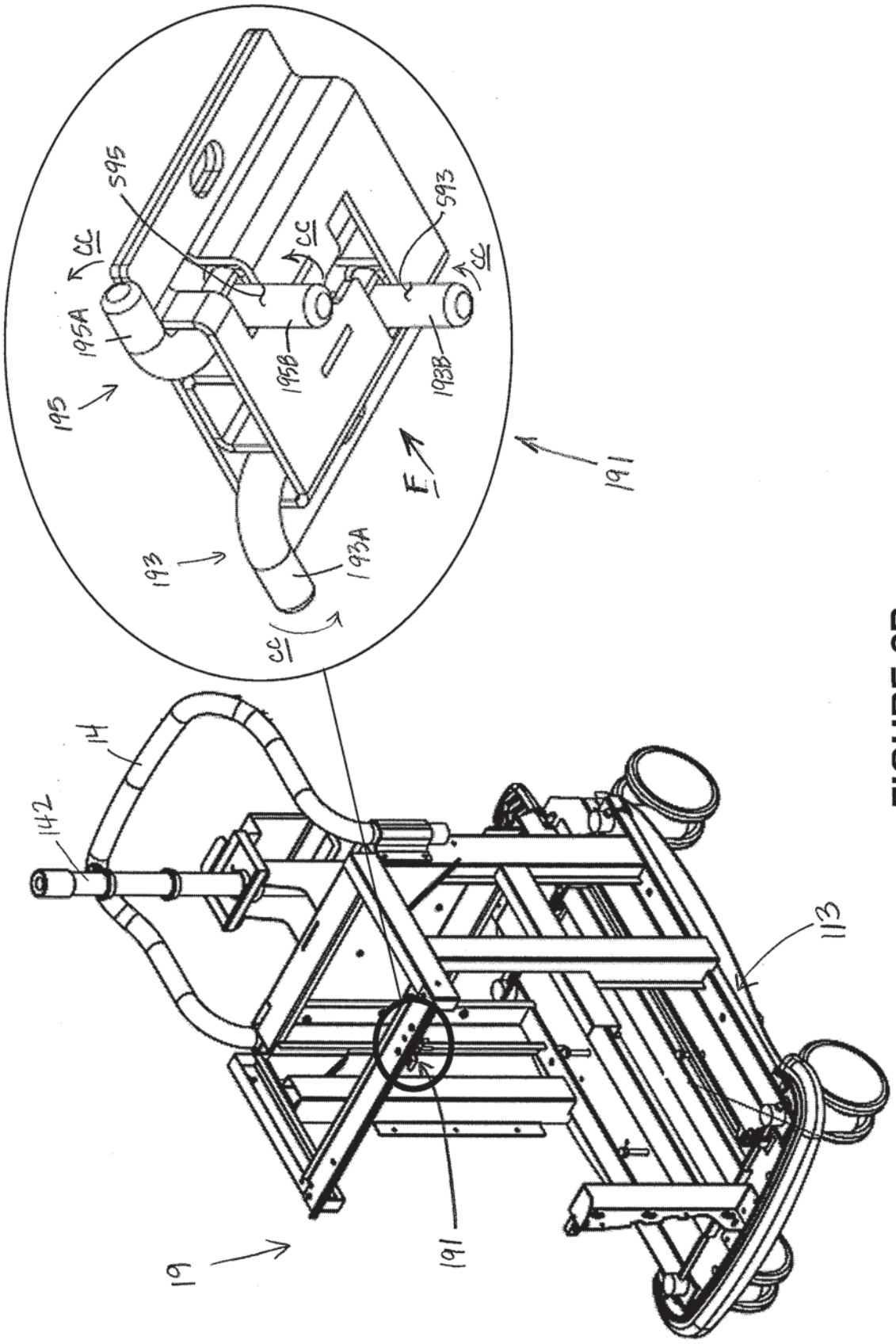


FIGURE 2B

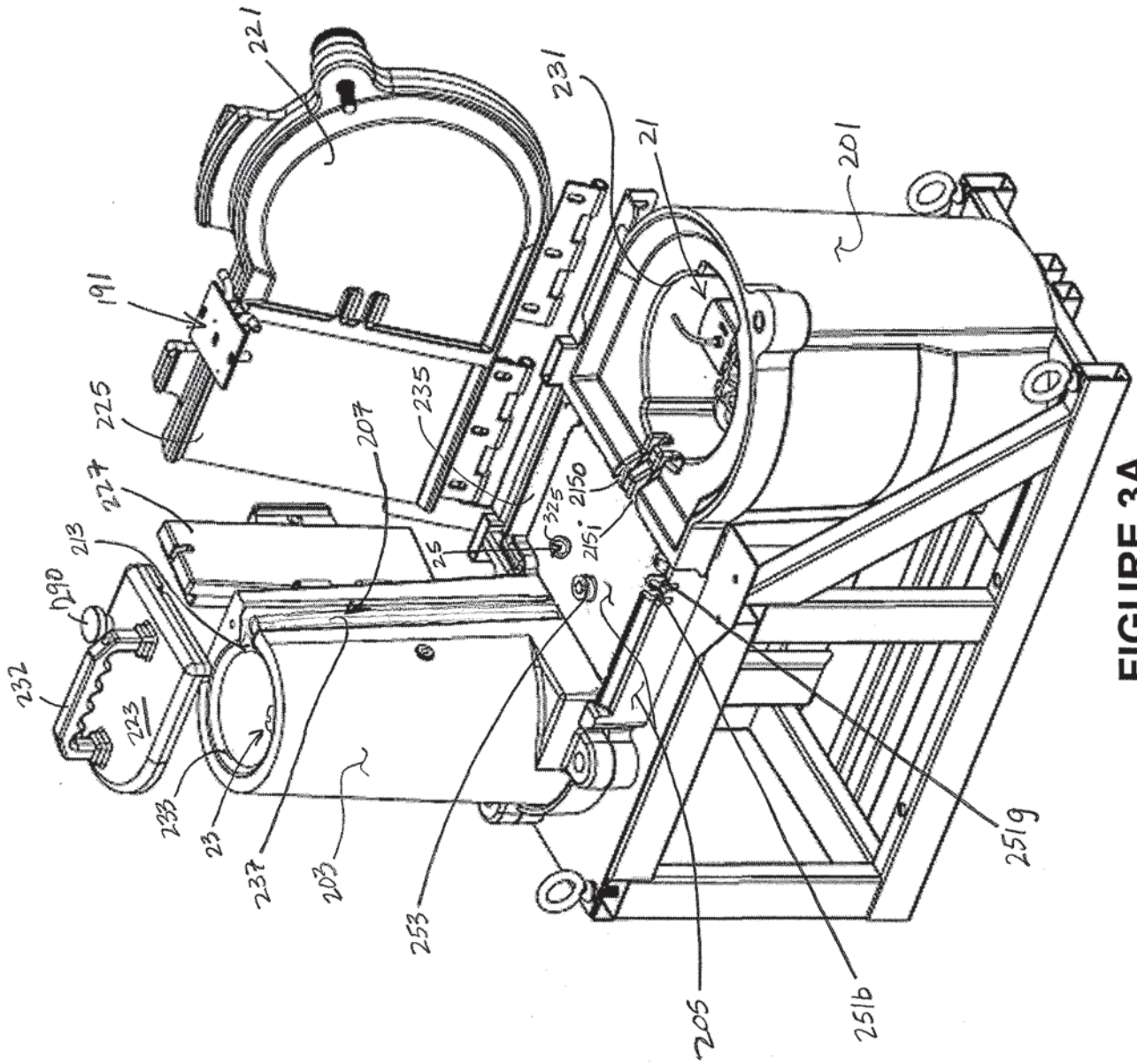
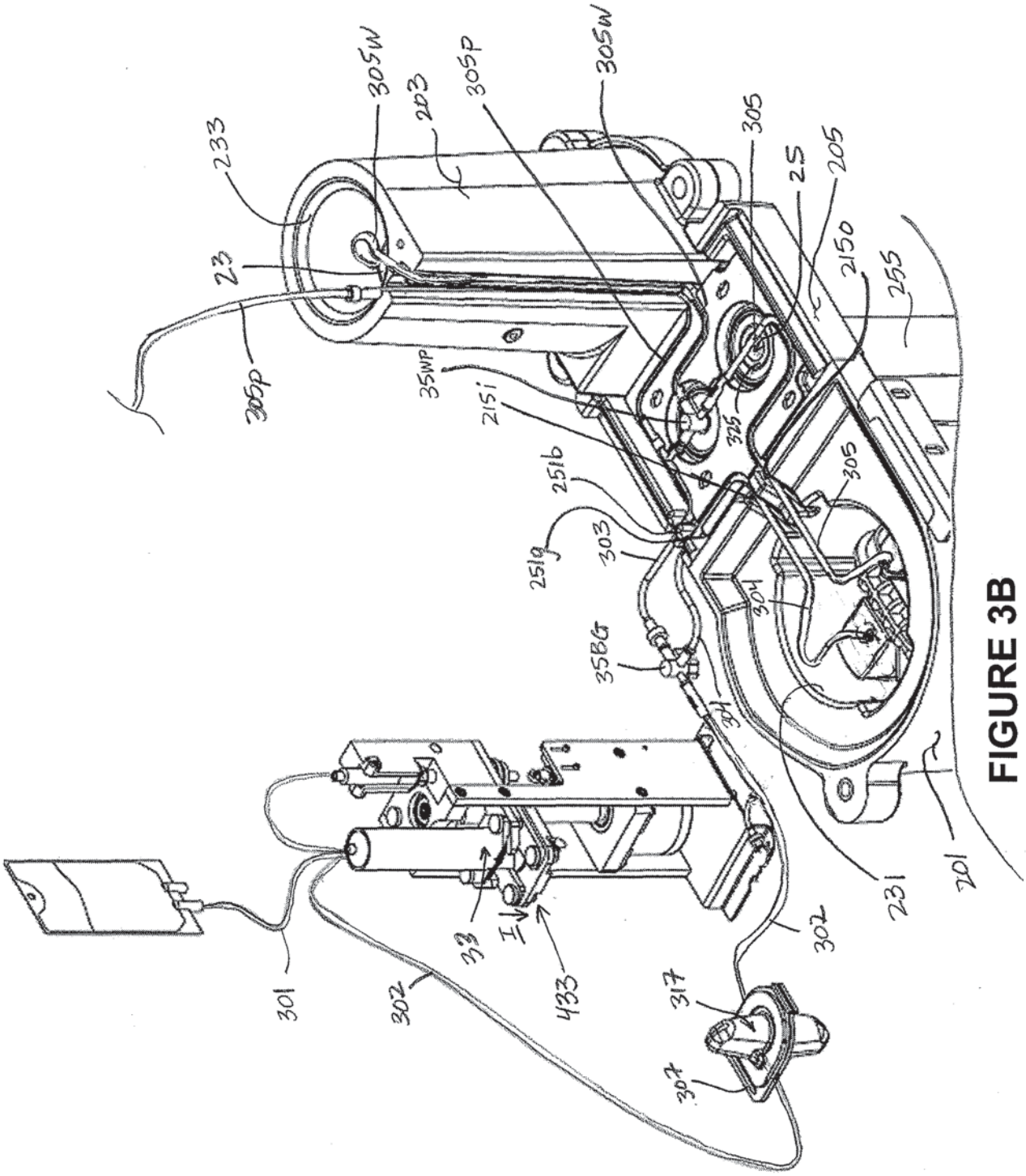

221
231
21
201
191
225
207
235
227
213
290
232
223
238
23
237
203
253
205
2516
2519
2151
2150
325
25

FIGURE 3A


305W
203
305P
305W
233
305
25
205
23
2150
255
305P
35WP
2151
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2519
303
304
358G
301
302
433
317
307
302
231
201

FIGURE 3B

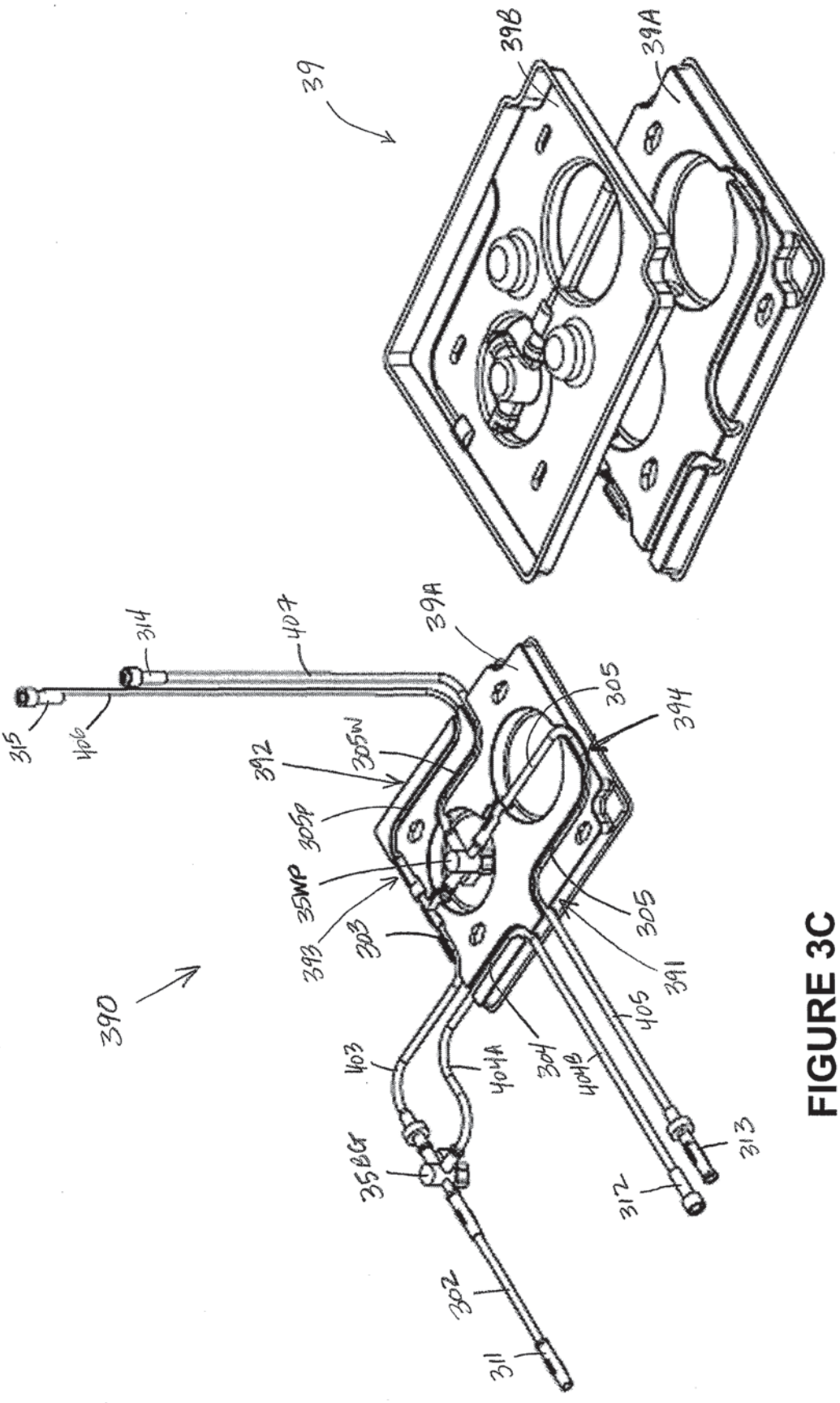


FIGURE 3D

FIGURE 3C

Fig. 4

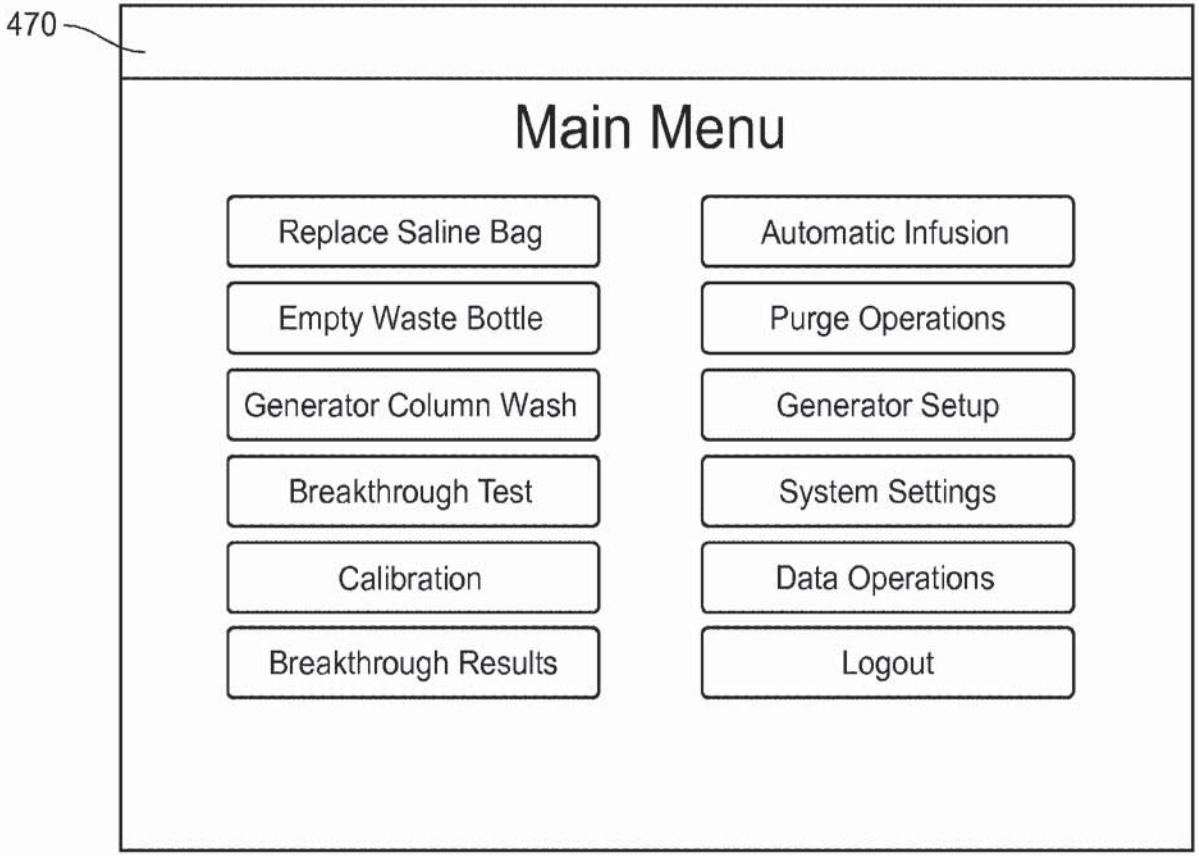


Fig. 5A

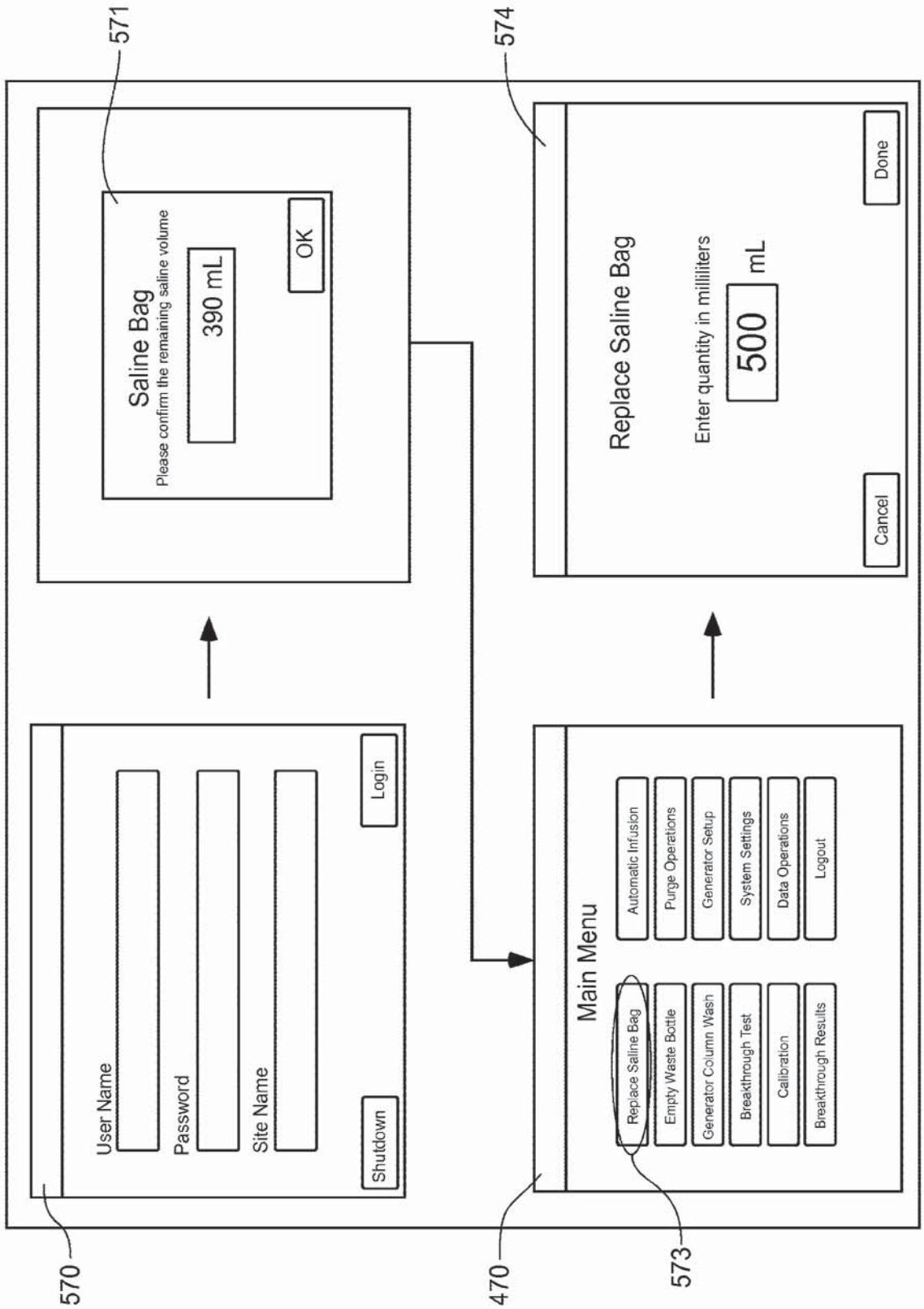

571
574
Saline Bag
Please confirm the remaining saline volume
390 mL
OK
Replace Saline Bag
Enter quantity in milliliters
500 mL
Done
Cancel
User Name
Password
Site Name
Login
Shutdown
Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag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

Fig. 5B

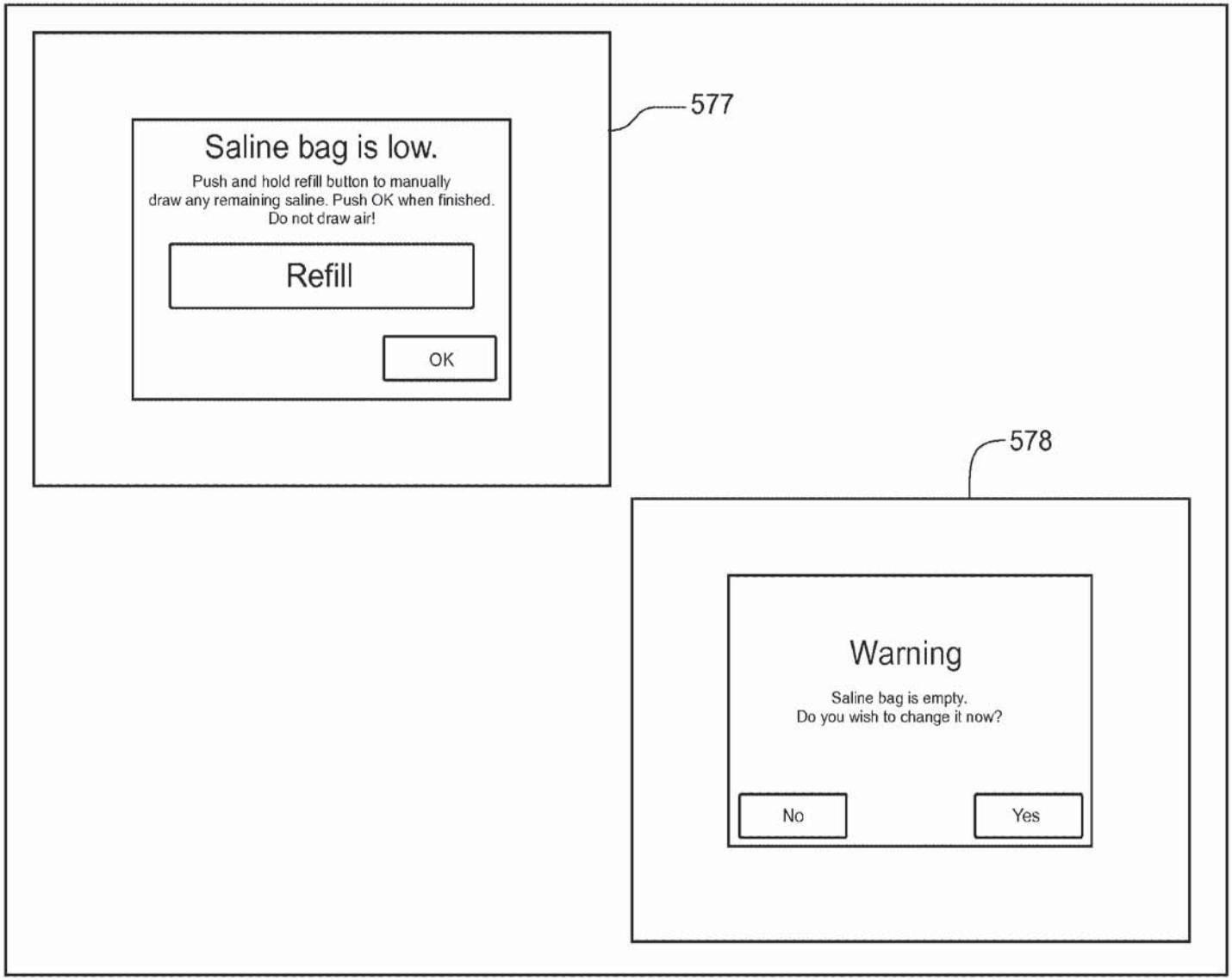
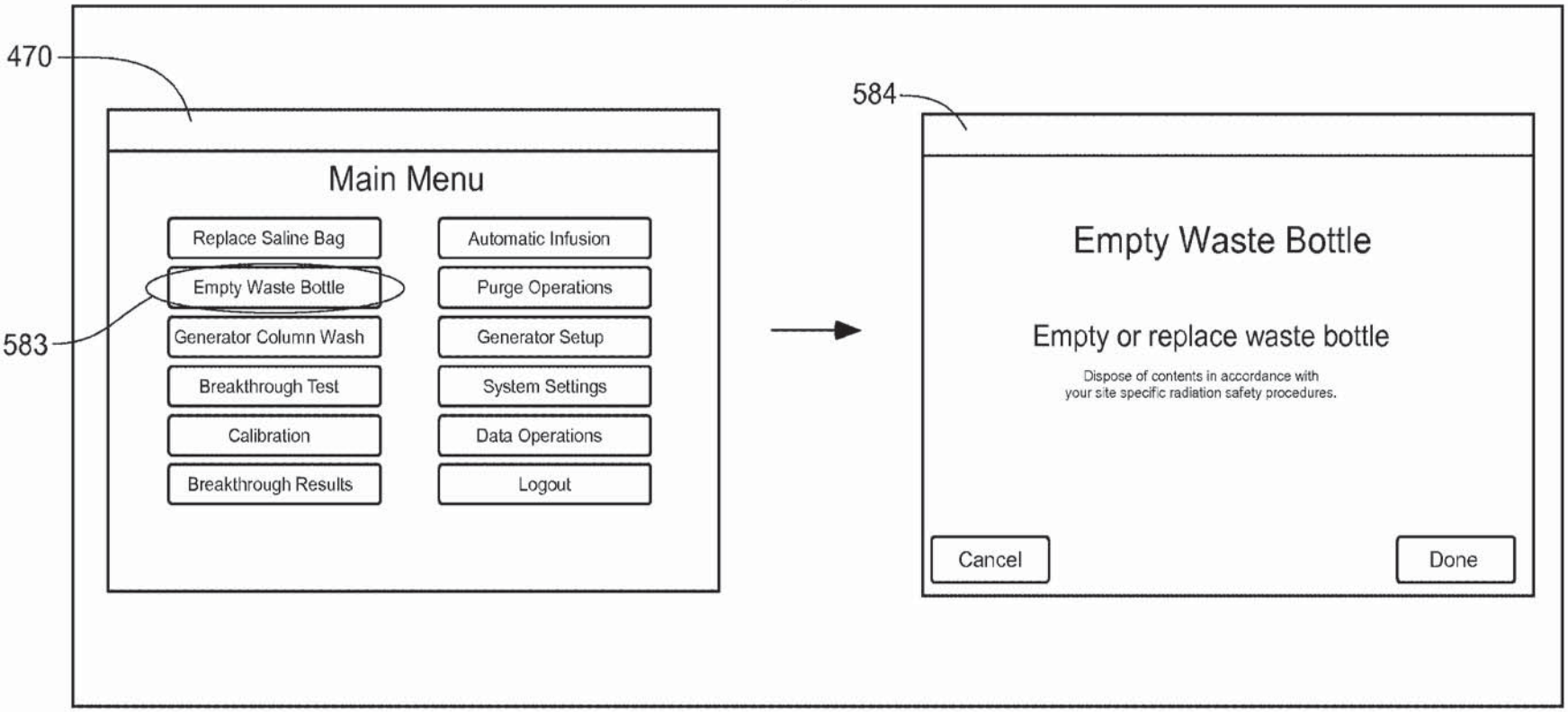


Fig. 5C



Replacement Sheet

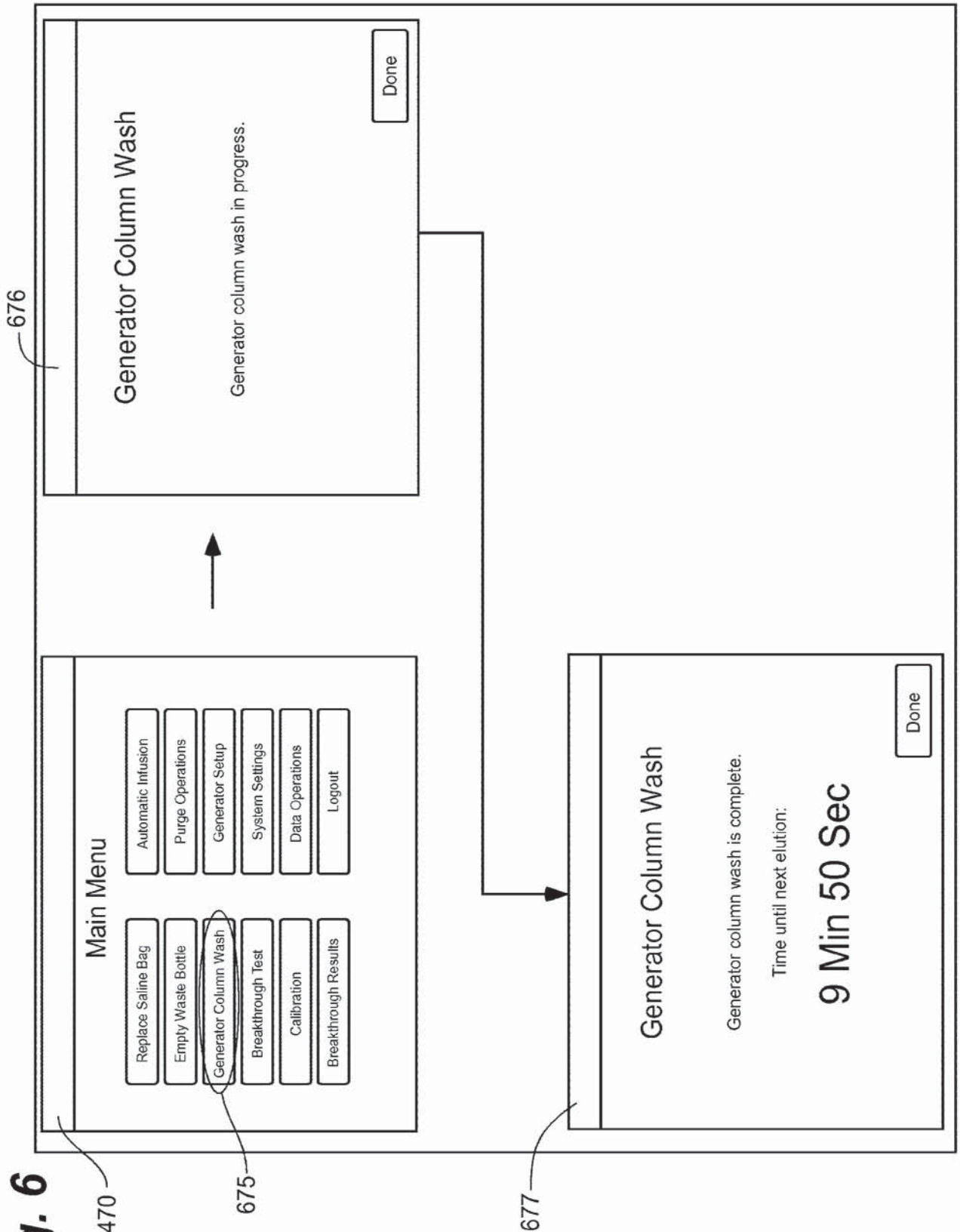

676
Generator Column Wash
Generator column wash in progress.
Done
Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Generator Column Wash
Generator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

Fig. 6

Fig. 7A

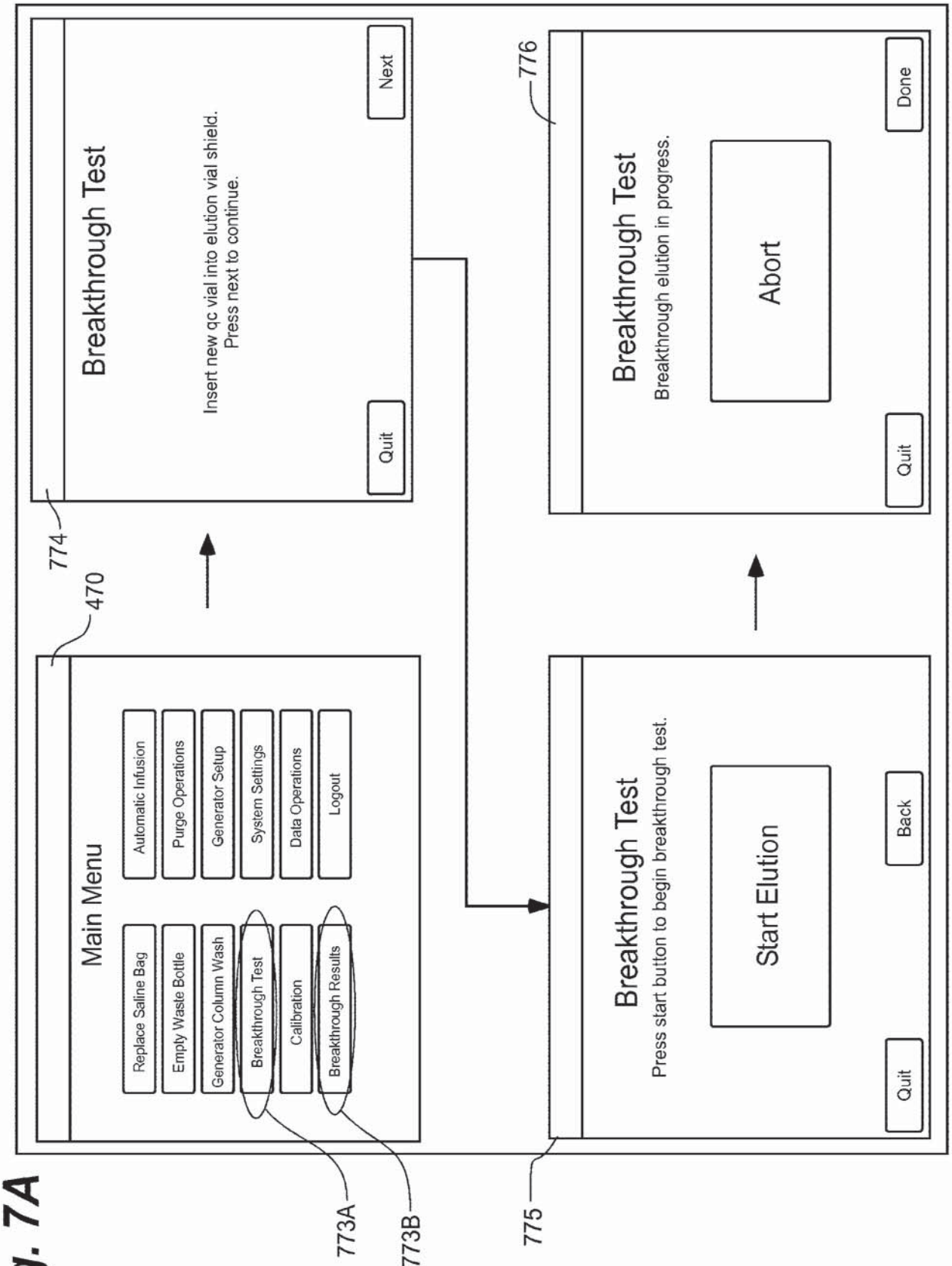
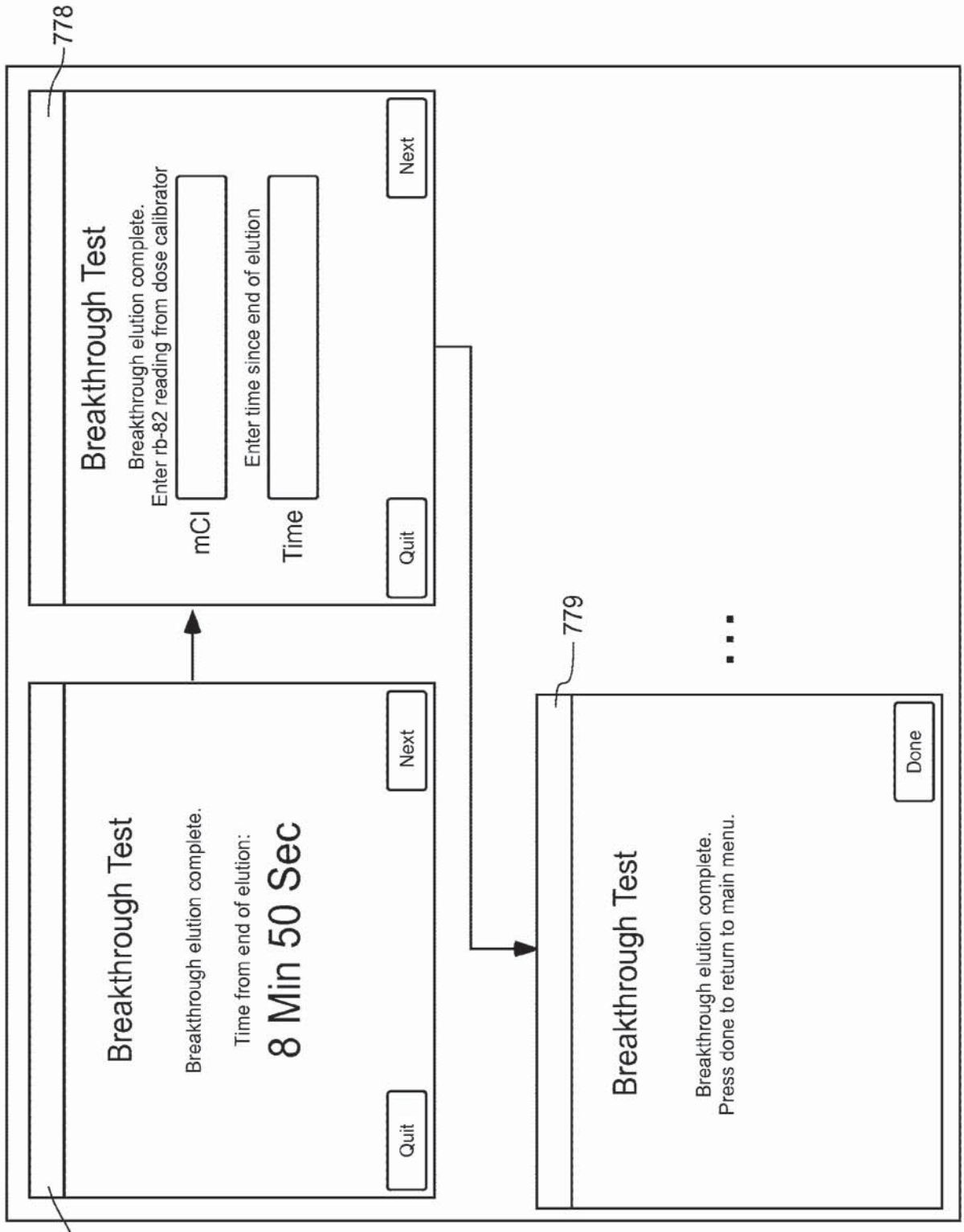

Main Menu
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
470
773A
773B
774
Breakthrough Test
Insert new qc vial into elution vial shield.
Press next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

Fig. 7B


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

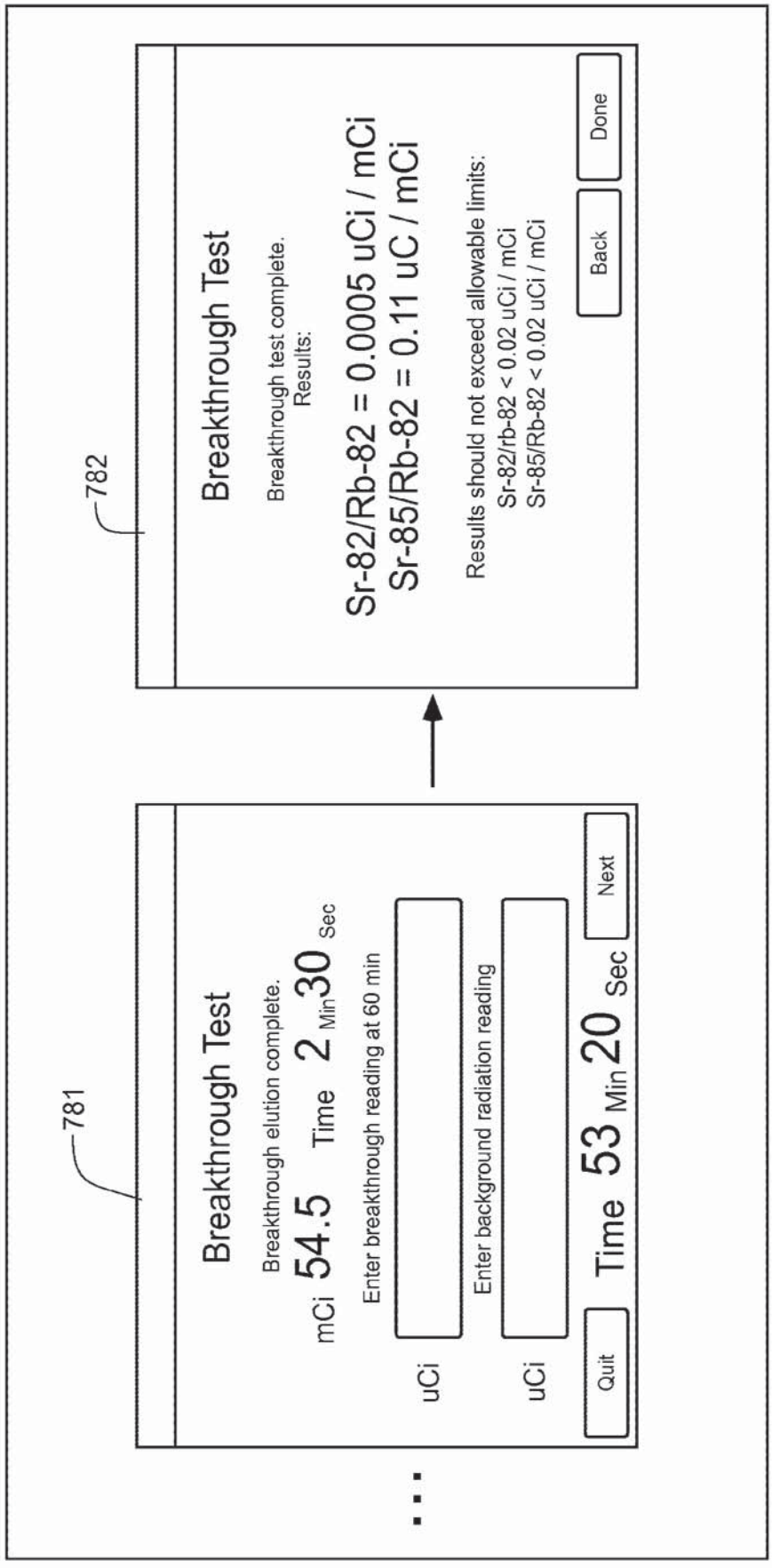

781
Breakthrough Test
Breakthrough elution complete.
mCi 54.5 Time 2 Min 30 Sec
Enter breakthrough reading at 60 min
uCi
Enter background radiation reading
uCi
Quit
Time 53 Min 20 Sec
Next
782
Breakthrough Test
Breakthrough test complete.
Results:
Sr-82/Rb-82 = 0.0005 uCi / mCi
Sr-85/Rb-82 = 0.11 uC / 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

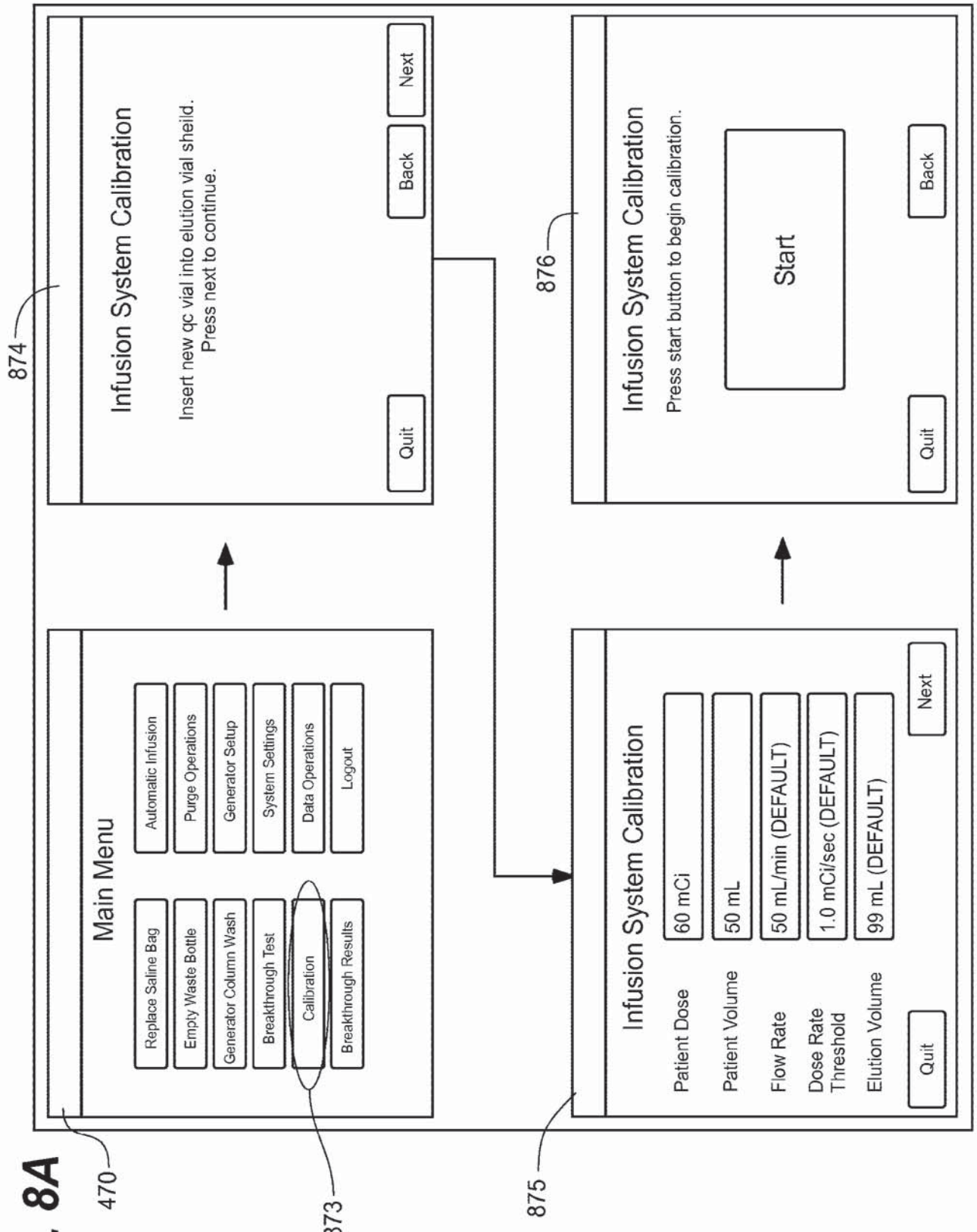

Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Infusion System Calibration
Insert new qc vial into elution vial sheild.
Press next to continue.
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

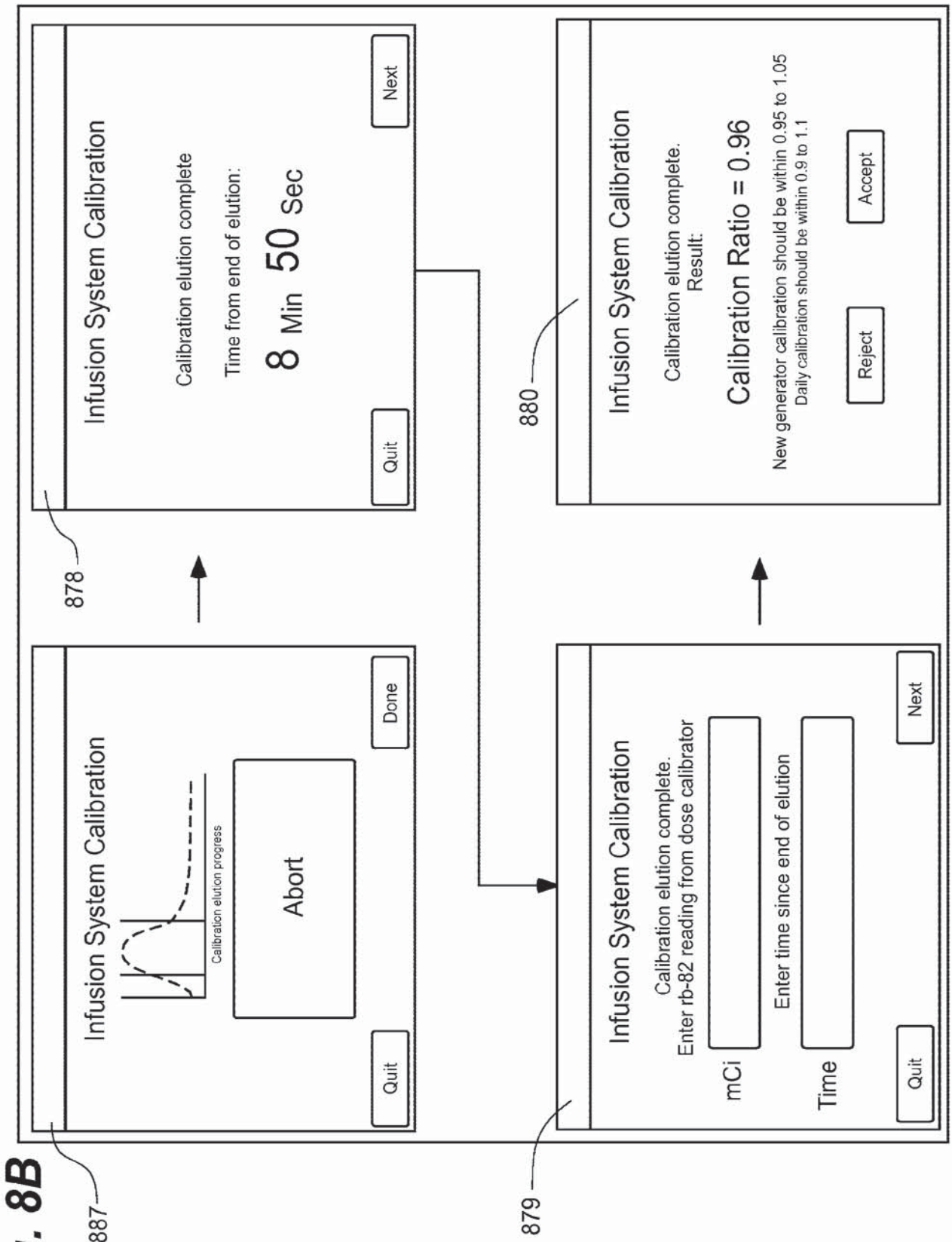

Infusion System Calibration
Calibration elution progress
Abort
Done
Quit
887
Infusion System Calibration
Calibration elution complete
Time from end of elution:
8 Min 50 Sec
Next
Quit
878
Infusion System Calibration
Calibration elution complete.
Enter rb-82 reading from dose calibrator
mCi
Enter time 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

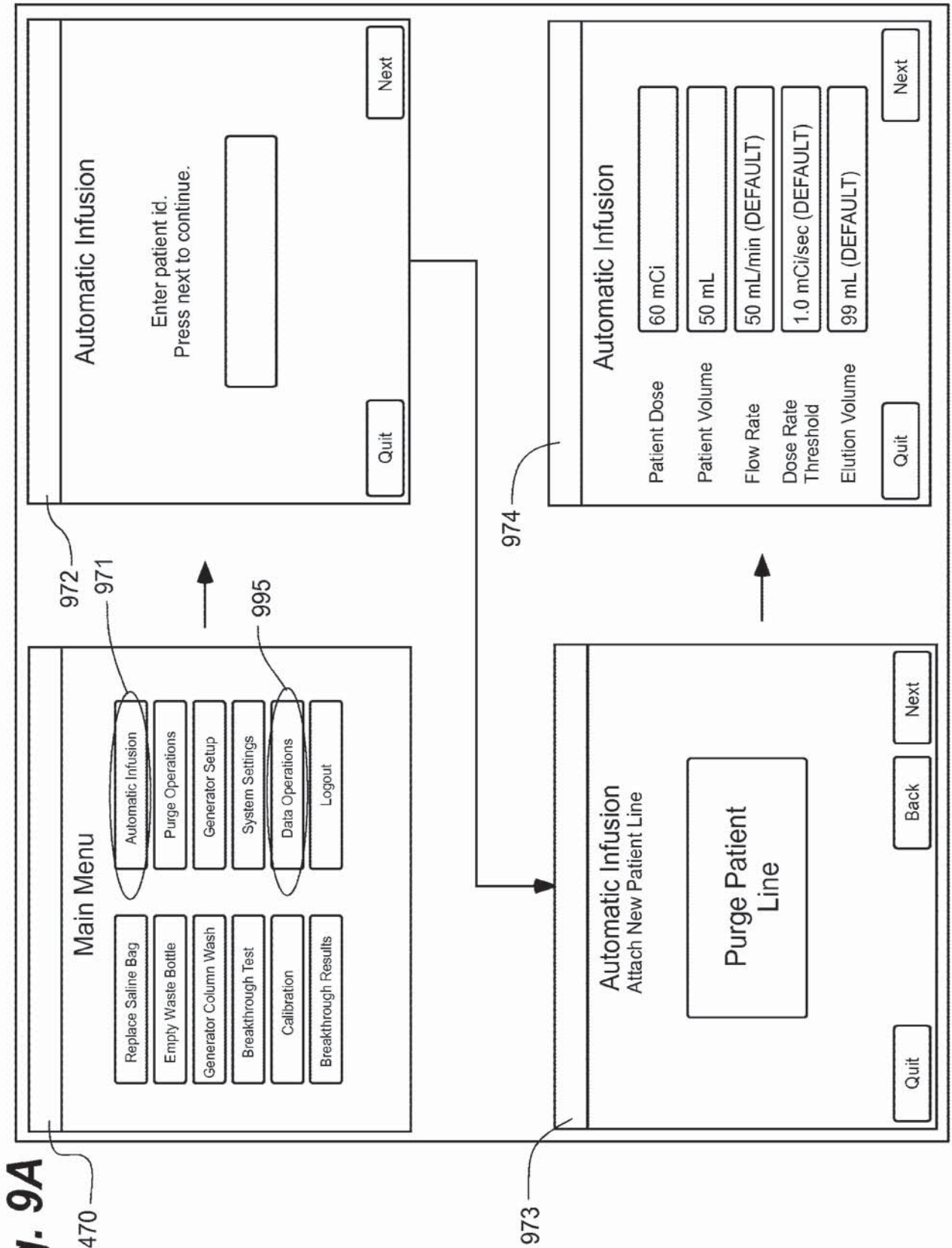

Main Menu
Replace Saline Bag
Empty Waste Bottle
Generator Column Wash
Breakthrough Test
Calibration
Breakthrough Results
Automatic Infusion
Purge Operations
Generator Setup
System Settings
Data Operations
Logout
Quit
Automatic Infusion
Enter patient id.
Press next to continue.
Next
Quit
Automatic Infusion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

Fig. 9A

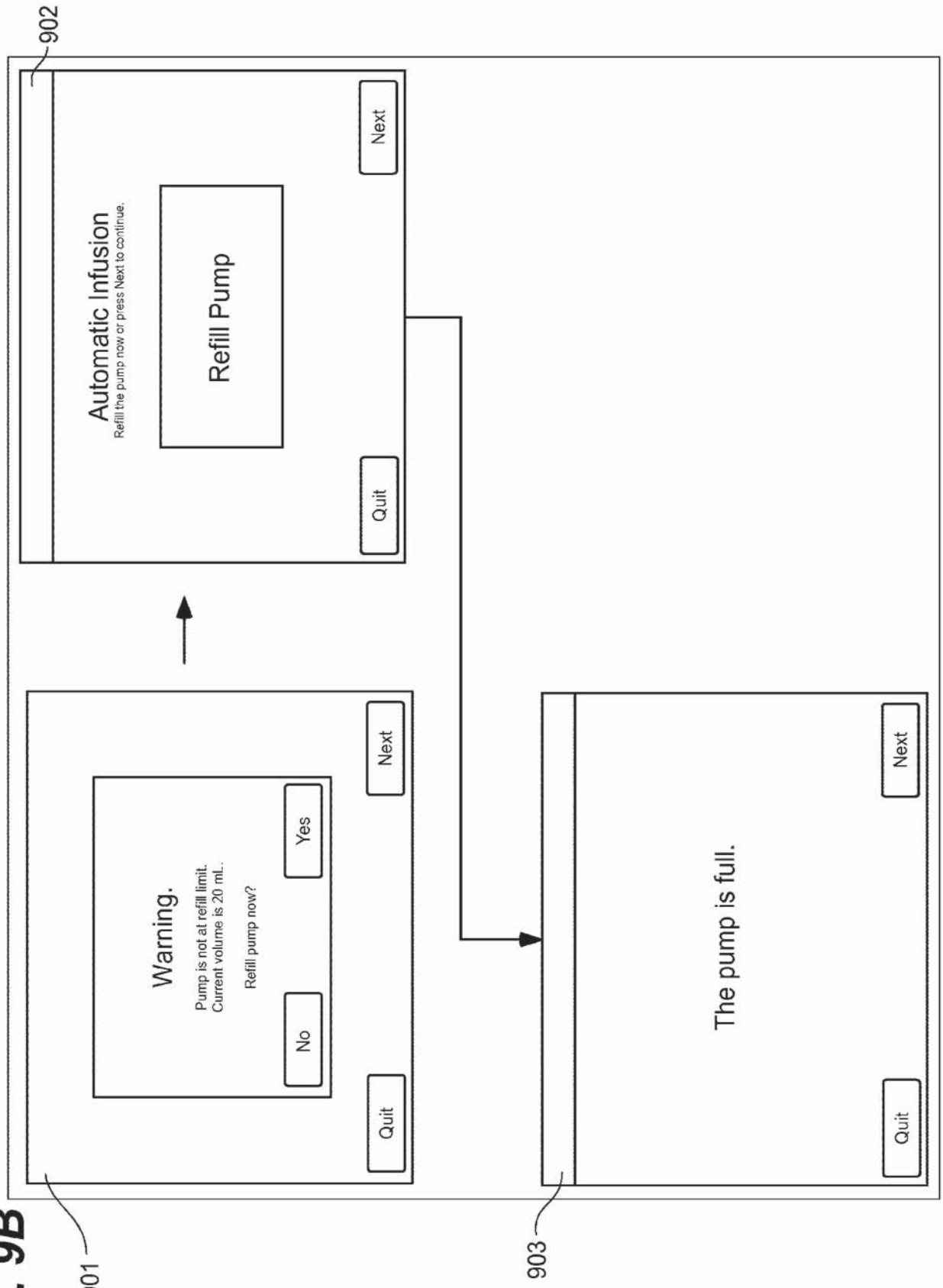
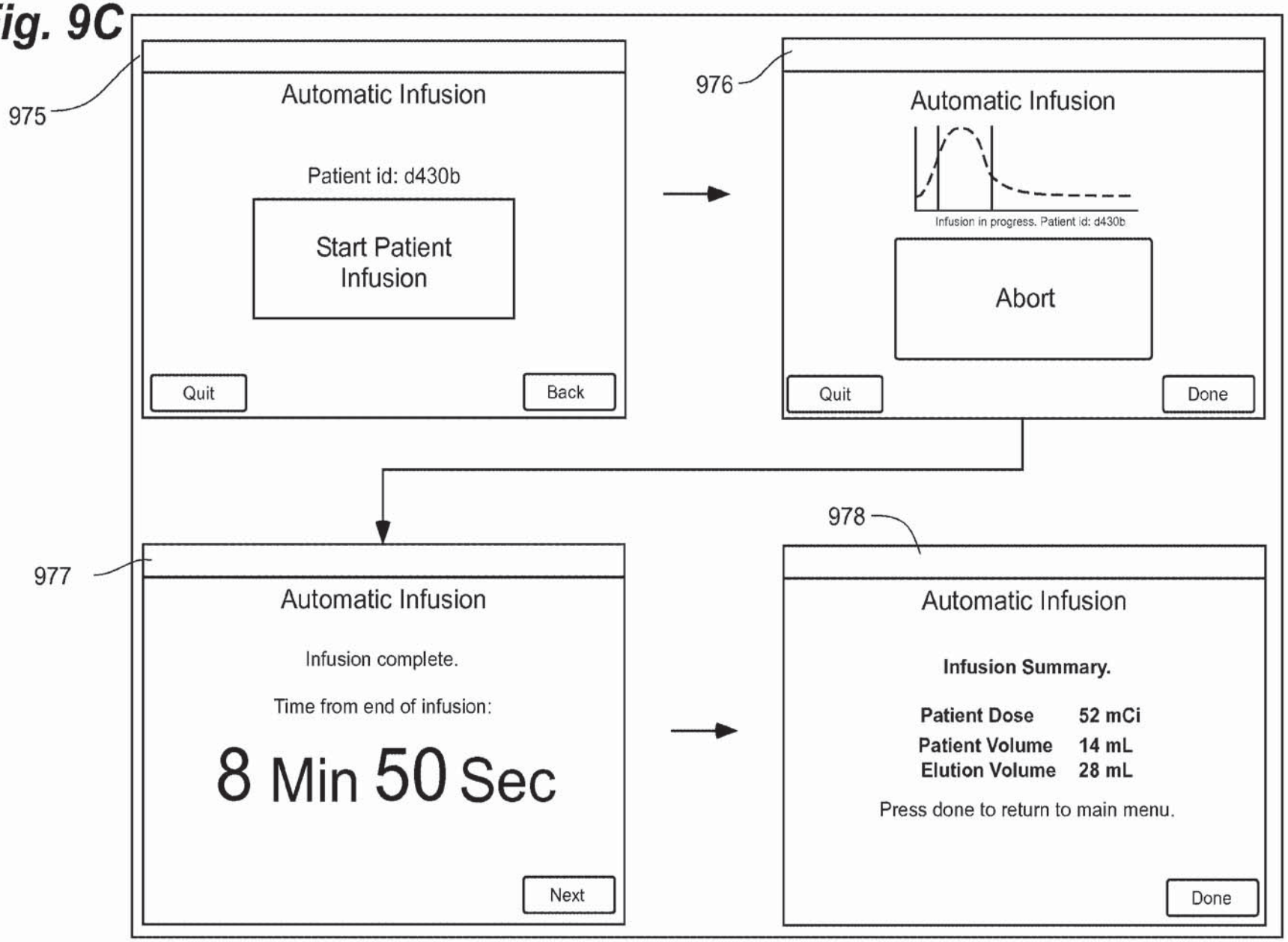

902
Automatic Infusion
Refill the pump now or press Next to continue.
Refill Pump
Next
Quit
Warning.
Pump is not at refill limit.
Current volume is 20 mL.
Refill pump now?
Yes
No
Next
Quit
The pump is full.
Next
Quit
901
903

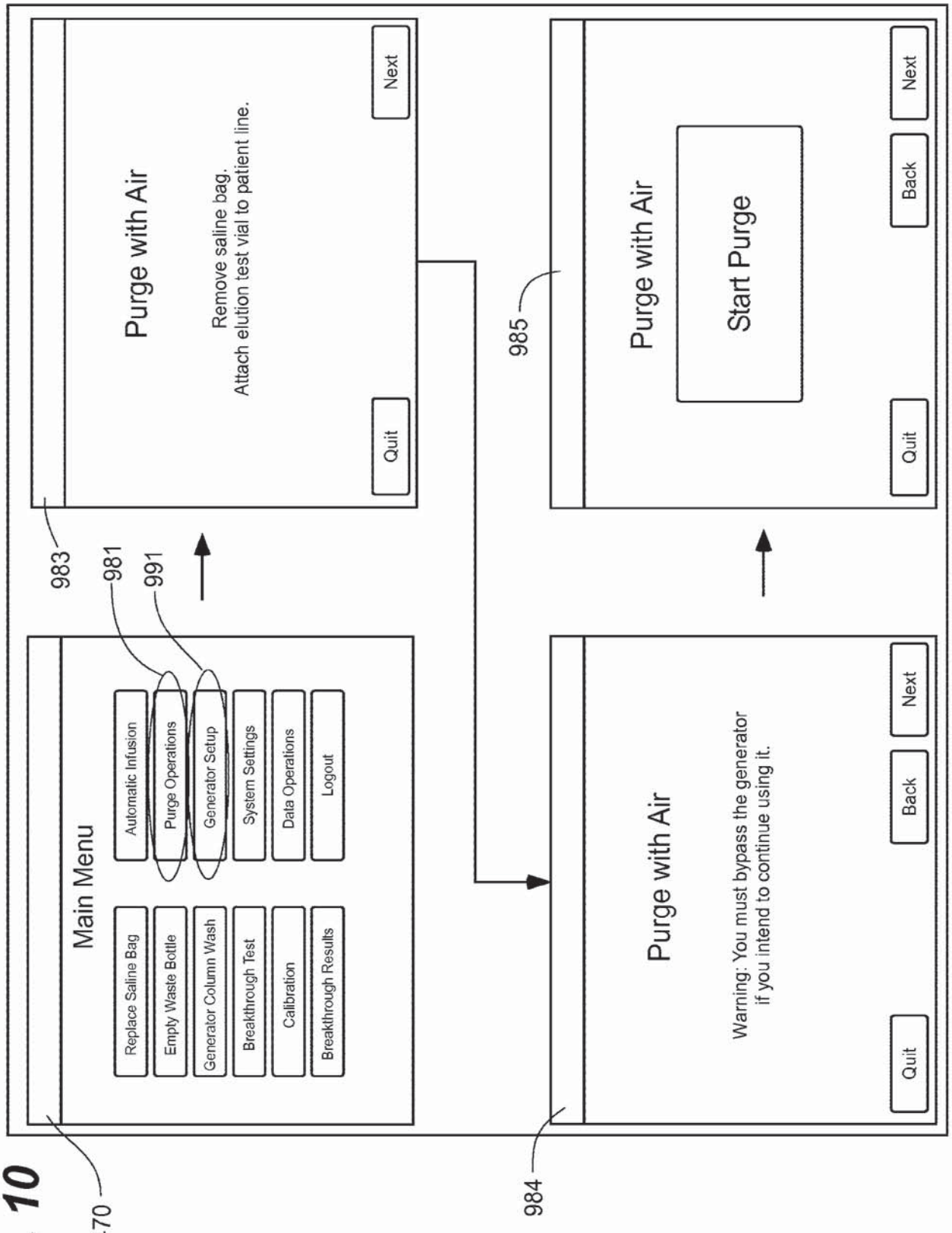
Fig. 9B

Fig. 9C



Replacement Sheet

Fig. 10


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

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) 56782.1.5
Application Number 12/137,356	Filed June 11, 2008
For SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS	
Art Unit 3763	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	$
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☐ 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.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/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	12137356
Filing Date	2008-06-11
First Named Inventor	Charles R. Quirico
Art Unit	
Examiner Name	
Attorney Docket Number	56782.1.5

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	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.	
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	First Named Inventor	Charles R. Quirico
	Art Unit	
	Examiner Name	
	Attorney Docket Number	56782.1.5

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

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	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		☐

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	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	12137356
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	First Named Inventor	Charles R. Quirico
	Art Unit	
	Examiner Name	
	Attorney Docket Number	56782.1.5

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12137356
	Filing Date	2008-06-11
	First Named Inventor	Charles R. Quirico
	Art Unit	
	Examiner Name	
	Attorney Docket Number	56782.1.5

CERTIFICATION STATEMENT

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

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

OR

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☐ See attached certification statement.

☐ 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

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

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

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

(11) Publication number: 0 102 121
A1

(12) # EUROPEAN PATENT APPLICATION

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(51) Int. Cl.³: G 21 G 1/04

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(30) Priority: 26.08.82 NL 8203349

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(84) Designated Contracting States:
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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

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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