between a floor 69 of the hospital room and the portion of headwall unit 32 having central panels 60 associated therewith as shown in Fig. 8. A set of auxiliary medical service outlets 71 are coupled to lower portion 67. In addition, the portions of headwall unit 32 in which cavities 34, 36 are defined overhang underlying portions of floor 69 that are laterally outward of lower portion 67.

As previously mentioned, columns 40, 42 carry patient-care equipment. Column 40 is configured to have patient-care equipment attached thereto and detached therefrom, whereas column 42 has patient-care equipment integrated therewith as shown in Figs. 1 and 2. In the illustrative example, column 40 has a vertical arm 62 and an IV rack 64 coupled to vertical arm 62 by suitable couplers such as, for example, clamps, brackets, latches, grippers, or hooks. IV rack 64 has one or more hooks 66 to which IV bags 68 couple and one or more poles 70 to which infusion pumps 72 couple. It is within the scope of this disclosure for any type of medical equipment capable of coupling to an IV pole to be coupled to IV rack. As shown in Figs. 9 and 10, one or more medical service outlets 73 are mounted to arm 62 of column 40. Services accessible via outlets 73 include electrical services, such as electrical power and data transfer, and pneumatic services, such as medical gases or suction. Illustratively, electrical power is provided to infusion pump 72 from one of outlets 73 as shown in Fig. 9.

In the illustrative example, column 42 has a vertical arm 74 and a housing 76 coupled to arm 74. A display screen 78 is coupled to an upper portion of housing 76 and a plurality of medical service outlets 80 are coupled to a lower portion of housing 76. Services available via outlets 80 include similar electrical and/or pneumatic services as are available from outlets 73. Service-delivery lines 82 are routed from each of outlets 80 through housing 76 and arm 74 of column 42 and through ceiling unit 38 as shown in Figs. 5-7. In addition, service-delivery lines 84 are routed from each of outlets 73 through arm 62 of column 40 and through ceiling unit 38 as shown in Fig. 7. In addition, lines 82, 84 are routed into ceiling 46 through an opening 86 that is formed in ceiling above a central region of ceiling unit 38.

Column 40 has a carriage 88 to which arm 62 is coupled and column 42 has a carriage 90 to which arm 74 is coupled as shown in Fig. 2. In some embodiments, arm 62 and IV rack 64 (or any other patient-care equipment coupled to arm 62) are pivotable about a vertical axis relative to carriage 88 in a first direction as

indicated by arrow 92, shown in Fig. 2, and in an opposite, second direction as indicated by arrow 94, shown in Fig. 4. In other embodiments, arm 62 is fixed relative to carriage 88 but the coupler to which IV rack 64 (or other patient-care equipment) couples is pivotable relative to arm 64 in directions 92, 94. Similarly, in some embodiments, arm 74 and housing 76 are pivotable about a vertical axis relative to carriage 90 in first and second directions and, in other embodiments, arm 74 is fixed relative to carriage 90 and housing 76 is pivotable relative to arm 74 about a vertical axis in first and second directions. Various angular orientations of columns 40, 42 about their respective vertical axes are shown in Fig. 7. In illustrative embodiments, the vertical axes about which IV rack 64 and housing 76 pivot extend through associated vertical arms 62, 74.

Ceiling unit 38 of system 30 has a central portion or canopy 96 and a pair of side portions or tracks 98 as shown, for example, in Figs. 1 and 2. Canopy 96 generally overlies bed 48, whereas tracks 98 are situated laterally outward of canopy 96. Canopy 96 has a set of lights 100 integrated therein. Lights 100 include reading lights and/or examination lights. In some embodiments, reading lights comprise standard incandescent or fluorescent bulbs, whereas examination lights comprise, for example, halogen bulbs and color-correction filters. All types of reading lights and examination lights are contemplated by this disclosure as being included in ceiling unit 38. Illustrative canopy 96 also has a display screen 110 integrated therein. In other embodiments, display screen 110 is omitted. Various images, such as family photos and nature scenes may be displayed on screen 110.

Ceiling unit 38 has a first or proximal end coupled to or overlying portions of headwall unit 32 and an opposite, distal end that is spaced apart from headwall unit 32. Thus, ceiling unit 38 extends from headwall unit 32 along ceiling 46 of the hospital room. Canopy 96 comprises a housing or frame 112 and a cosmetic cover or panel 114 that couples to frame 112 as shown in Figs. 5 and 6. Frame 112 includes portions (not shown) that couple to ceiling 46 and/or to headwall unit 32 with suitable couplers such as, for example, bolts, rivets, welds, clamps, tabs, and the like. The various pieces of equipment carried by ceiling unit 38, including lights 100 and screen 110, are mounted to frame 112 and extend through appropriately sized openings formed in panel 114. In addition, portions of lines 82, 84 loosely drape over frame 112 and cover 114 as shown in Figs. 5 and 6. Lines 82, 84 are routed through

suitably sized slots or spaces 116 that are provided between frame 112 and ceiling 46, or alternatively, between other portions of ceiling unit 38 through which lines 82, 84 are routed.

As columns 40, 42 move between the storage and various use positions, lines 82, 84 move relative to ceiling unit 38 in a somewhat random manner. However, frame 112 and cover 114 are situated beneath portions of lines 82, 84 to shield these portions of lines 82, 84 from view. Other portions of lines 82, 84 are shielded from view by columns 40, 42, respectively. In the illustrative embodiment, panel 114 has lateral side portions 118 that underlie portions of carriages 88, 90 as shown in Fig. 5 with respect to carriage 90. Side portions 118 further shield lines 82, 84 from view. Lines 82, 84 have sufficient slack in the interior region of canopy 96 to permit columns 40, 42 to move from the respective storage positions to the respective farthest use positions adjacent the distal end of associated tracks 98. It is within the scope of this disclosure for one or more line management mechanisms, such as strain reliefs, hoses, conduits, cables, cable ties, articulating segmented channels, and the like, to be coupled to lines 82, 84 either to guide or control the movement of lines 82, 84 or to restrain the movement of lines 82, 84 in a desired manner as columns 40, 42 move between the storage positions in cavities 34, 36, respectively, and the various positions outside of cavities 34, 36.

Each illustrative track 98 comprises a track member 120 and a cosmetic cover or panel 122 coupled to the respective member 120 as shown in Fig. 5. Suitable couplers, such as illustrative bolts 123, couple track member 120 to ceiling 46 or, in alternative embodiments, to portions of frame 112 that overlie tracks 98. The proximal ends of track members 120 overlie respective cavities 34, 36 to permit carriages 88, 90 to move along track members 120 into cavities 34, 36, respectively. Columns 40, 42 each comprise a plurality of rollers 124 some of which engage a first roller-engaging surface 126 of the associated member 120 and others of which engage a second roller-engaging surface 128 of the associated member 120 as also shown in Fig. 5. Surfaces 126, 128 are each elongated and extend generally perpendicularly relative to wall 44 of the hospital room. Thus, surfaces 126 are parallel with surfaces 128. In addition, surfaces 126, 128 lie in a common horizontal plane. In some alternative embodiments, track members 120 are curved and in other alternative embodiments, track members 120 are not parallel to each other.

Carriages 88, 90 are each somewhat U-shaped having central portions 130 that underlie track members 120 and having a pair of side portions 132 that extend upwardly from respective central portions 130 such that track members 120 are situated between respective side portions 132. Rollers 124 each have shafts 134 that are coupled to side portions 132 and that extend horizontally therefrom in a cantilevered manner toward associated track members 120. As columns 40, 42 move along tracks 98, such as, for example, in directions 136 away from respective cavities 34, 36 as shown in Figs. 2, 4, and 6-8, rollers 124 roll along corresponding surfaces 126, 128. Of course, rollers 124 also roll along surfaces 126, 128 when columns 40, 42 move along tracks 98 in directions opposite to directions 136.

According to this disclosure, housing 76 carries electrical circuitry to control the operation of display screen 78. In some embodiments, housing also carries electrical circuitry to control the operation of display screen 110 and lights 100. In other embodiments, some or all of the circuitry that controls the operation of screens 78, 110 and lights 100 are housed in portions of head wall unit 32. Such circuitry includes for example, one or more of a microprocessor or microcontroller, input/output circuitry, signal conditioning circuitry, signal conversion (analog-to-digital and/or digital-to-analog) circuitry, power conditioning circuitry, memory circuitry, and the like. In addition, a user interface is provided on column 42 to permit a user to enter commands and retrieve data for display on screen 78. In the illustrative embodiment, screen 78 is a touch screen and the user input on column 42 comprises user input buttons 138 displayed on screen 78 as shown, for example, in Fig. 8.

In some embodiments, the electrical circuitry that controls the operation of display screen 78 is coupled to the hospital's computer network or ethernet. In such embodiments, any of the information available on the network is viewable on display screen 78. For example, a caregiver is able to retrieve a patient's medical records (e.g., laboratory test results, medical diagnosis, patient charts, x-rays, and so on) from the network for viewing on screen 78. In addition, patient point-of-care data, such as vital signs data (e.g., heart rate, blood pressure, neurological activity, respiration rate, patient temperature, pulse oximetry) and data associated with the operation of patient-care equipment (e.g., data from one or more ventilators, infusion pumps, electrocardiographs, electroencephalographs), may be displayed on

screen 78. Thus, the circuitry associated with screen 78 is programmed and/or configured to receive and process various types of data signals indicative of the information to be displayed on screen 78. It is within the scope of this disclosure for all types of data associated with the care of a patient to be displayed on screen 78. In addition, it is within the scope of this disclosure for screen 78 to display multiple types of data simultaneously, such as in a split screen format. Furthermore, in those embodiments in which the hospital computer network is coupled to the Internet, then information accessible via the Internet is also able to be displayed on screen 78.

An alternative IV rack 164 that is attachable to and detachable from vertical arm 62 is shown in Figs. 8-10. IV rack 164 is similar to IV rack 64 and therefore, where appropriate, like reference numerals are used to denote components of IV rack 164 that are substantially similar to like components of IV rack 64. As was the case with IV rack 64, IV rack 164 couples to arm 62 with suitable couplers such as, for example, clamps, brackets, latches, grippers, hooks, or the like. The main difference between IV rack 164 and IV rack 64 is that IV rack 164 has a horizontal plate 140 coupled to the lower ends of poles 70. Plate 140 has one or more openings or sockets 142 as shown in Fig. 8.

An arm assembly 144 for carrying IV rack 164 includes an arm 146 coupled to bed 48 for pivoting movement about a vertical axis, a horizontal plate 148 coupled to arm 144, and a pair of posts 150 extending vertically upwardly from plate 146. Arm 146 is movable to a first position extending laterally outwardly from bed 48 to support plate 148 and posts 150 at a location which permits coupling of IV rack 164 to arm assembly 144 as shown in Figs. 8 and 9. Vertical arm 62 and carriage 88 are movable along track 98 to position IV rack over plate 148 and posts 150. In addition, IV rack 164, or the combination of arm 62 and IV rack 164, is rotatable about the vertical axis extending through arm 62 to orient IV rack 164 such that sockets 142 are aligned with posts 150. After IV rack 164 is properly oriented over arm assembly 144, as shown in Figs. 8 and 9, IV rack 164 is lowered in the direction of arrow 152, shown in Fig. 8, so that posts 150 are received in sockets 142 and so that plate 140 rests upon plate 148, thereby to couple IV rack 164 to arm assembly 144.

In some embodiments, the coupler that couples IV rack 164 to arm 62 is movable vertically relative to arm 62 to permit raising and lowering of IV rack 164

and, in other embodiments, arm 62 comprises telescoping segments that permit raising and lowering of IV rack 164. Alternatively, IV rack 164 is decoupled from arm 62 and is lowered manually onto arm assembly 144. It is also within the scope of this disclosure for an upper frame 154 of bed 48 to be lifted relative to a base 156 of bed 48 so that posts 150 enter into openings 142 and so that plate 148 moves into engagement with plate 140. In some embodiments, additional mechanisms (not shown), such as latches on plate 142 or plate 150, pins that extend through posts 150, caps that snap or thread onto posts, clamps that grip plates 140, 148, and the like, are provided to lock IV rack 164 to arm assembly 144. After IV rack 164 is coupled to arm assembly 144 and decoupled from arm 62, arm 146 is pivotable relative to bed 48 to a second position having IV rack 164 supported alongside bed 48 as shown in Fig. 10. Thus, bed 48 and IV rack 164 coupled to bed 48 are transportable through the hospital without needing to disconnect IV lines from the patient carried by bed 48.

Referring now to Figs. 11-14, an alternative architectural system 230 has a headwall unit 232 and a ceiling unit 238 that are substantially similar to headwall unit 32 and ceiling unit 38, respectively, of system 30. Therefore, where applicable, like reference numerals are used to denote components of system 230 that are substantially similar to like components of system 30. One of the differences between system 230 and system 30 is that headwall unit 232 of system 230 has a pair of auxiliary cavities 234, 236 (see Figs. 12 and 14) that are laterally outboard of cavities 34, 36, respectively. A pair of doors 235, 237 are each independently movable between a closed position, shown in Fig. 11, in which the respective cavity 234, 236 and any items or equipment stored therein are inaccessible and an opened position in which the respective cavity 234, 236 and any items or equipment stored therein are accessible. In the illustrative embodiment, doors 235, 237 pivot about respective vertical axes when moving between the opened and closed positions. Suitable locking mechanisms are provided in some embodiments for locking doors 235, 237 in the closed positions. As was the case with system 30, doors 58 of system 230 are movable to open and close cavities 34, 36.

Headwall unit 232 has additional medical service outlets 216 mounted on a pair of lower vertical panels 218 which are situated beneath the lowermost pair of doors 58 as shown in Figs. 11, 14, and 14. Headwall unit 232 also has a pair of lower doors 220 that are movable between respective first positions in which doors

220 cover the associated outlets 216 and respective opened positions in which outlets 216 are uncovered for use. It is within the scope of this disclosure for system 30 to also have outlets 216, panels 218, and doors 220. In some embodiments, auxiliary outlets 71 and outlets 216 are included in the headwall unit and, in other embodiments, only one or the other set of outlets 71, 216 are included in the headwall unit.

Another of the differences between system 230 and system 30 is that ceiling unit 238 of system 230 has tracks 198 which are wider than tracks 98 of system 30. Thus, tracks 198 extend laterally outward from canopy 96 of ceiling unit 238 by a greater amount than tracks 98 extend laterally outward from canopy 96 of ceiling unit 38. Each of tracks 198 has a cosmetic cover or panel 210. Each panel 210 has a first elongated slot 212 and a second elongated slot 214. In the illustrative embodiment, slots 212 are parallel with slots 214. Each slot 212 receives a respective side portion 132 of the associated carriage 88, 90 of the respective column 40, 42. Thus, provision of slots 212 in covers 210 allows columns 40, 42 of system 230 to move without interference from panels 210 between the respective storage positions within cavities 34, 36 and the various positions outside of cavities 34, 36.

In some embodiments, slots 214 are situated beneath respective track members (not shown) that are configured to support auxiliary equipment which is moved out of auxiliary cavities 234, 236 and, in other embodiments, auxiliary equipment is situated above slots 214. In the example shown in Fig. 12, a privacy curtain 240 is movable from a storage position in which curtain 240 is situated within cavity 236 to a use position in which a majority of curtain 240 is drawn out of cavity 236. In the use position, curtain 240 hangs downwardly from substantially the entire length of the track member situated above the respective slot 214. Illustrative curtain 240 has a flexible curtain panel 242, a plurality of sliders 244, and a plurality of strands 246. Each strand 246 extends between panel 242 and a respective slider 244. Sliders 244 are movable along the track member situated above slot 214. Thus, when curtain 240 is in the storage position, all of sliders 244 are grouped together within cavity 236 and when curtain 240 is in the use position, sliders 244 are spaced apart along the length of slot 214.

In the example shown in Fig. 13, a privacy curtain 250 is extendable downwardly out of the associated slot 214 to a use position and is retractable

upwardly through slot 214 to a storage position. Curtain 250 has a flexible curtain panel 252 and a bottom member 254 coupled to a bottom portion of panel 252. Member 254 adds weight to curtain 250 to prevent excessive movement of curtain 250 away from a vertical hanging configuration as shown in Fig. 13. A rotatable shaft (not shown) on which panel 252 winds when retracting and unwinds when extending is situated above slot 214. In some embodiments, a motor (not shown) is coupled to shaft and is operated to rotate the shaft in the appropriate directions to wind and unwind panel 252. In such embodiments, a user input, such as one or more switches, buttons, levers, or the like, is accessible on headwall unit 232 to control the motor. In alternative embodiments, curtain 250 is extended and retracted manually, similar to the manner in which conventional window shades are pulled down to cover a window and are manipulated so that a spring causes an associated shaft to wind up the window shade.

In the example shown in Fig. 14, an auxiliary IV pole 160 hangs downwardly from a carriage 162 that is slideable along a track member (not shown) which is situated above the respective slot 214. Pole 160 and carriage 162 are movable between a storage position in cavity 234 and a number of use positions outside of cavity 234. One or more hooks 166 are coupled to pole 160 for holding IV bags 68. In the illustrative embodiment, a dedicated infusion pump 172 is mounted to a bottom end of pole 160. In alternative embodiments, infusion pumps 72 are attachable to and detachable from other portions of pole 160. It is within the scope of this disclosure for any type of patient-care equipment that is capable of coupling to an IV pole to be coupled to pole 160.

Although curtain 240 is shown in Fig. 12 has being associated with cavity 236 and although pole 160 is shown in Fig. 14 as being associated with cavity 234, it is within the scope of this disclosure for curtains, IV poles, and any other type of track-mounted auxiliary equipment, such as exam lights, water hoses, suction hoses, traction devices, and the like, to be associated with either of cavities 234, 236. In addition, it is within the scope of this disclosure for the various walls of headwall unit 232 that bound cavities 234, 236, such as back wall 259, side wall 261, and bottom wall 263 (see Fig. 14), to be appropriately sized and configured so that cavities 234, 236 are large enough to receive the track mounted equipment to be stored therein. In addition, in those embodiments having auxiliary equipment, such as

curtain 250 that extends and retracts out of slots 214, then cavities 234, 236 may have storage shelves therein.

Referring now to Figs. 15 and 16, an alternative architectural system 330 includes a headwall unit 232, that is substantially similar to headwall unit 232 of system 230, and a ceiling unit 338 from which a set of air curtains 270 are directed downwardly around three sides of hospital bed 48. In the illustrative embodiment, the set of air curtains are adjacent foot end 52 and sides 54, 56 of bed 48. A suitable amount of space is provided between air curtains 270 and bed 48 to permit a caregiver to stand therebetween. Air curtains 270 provide a modicum of environmental isolation for the patient on bed 48. Thus, air borne contaminants outside the patient space bounded by air curtains 270 are prevented from entering the patient space. In some embodiments, air curtains 270 are heated and/or humidified to control the temperature and humidity of the patient space. In such embodiments, heating equipment (not shown) and/or humidifying equipment (not shown) is housed in either ceiling unit 338 or headwall unit 232 or both.

An air curtain generator 272, such as a fan, blower, pump, or the like, is housed in canopy 96 of ceiling unit 338 as shown in Figs. 15 and 16. An air-intake opening 274 is formed in cover 114 of canopy 96 and an air filter 276 covers opening 274 to filter contaminants from the ambient environment. Air curtain generator 272 is situated in a central chamber 278 of canopy 96 and an air-inlet duct 280 extends from opening 274 to chamber 278. A network of air-outlet ducts 282 extend from chamber 278 throughout ceiling unit 338, including along the outer regions of lateral side portions 198 and including along the front distal regions of canopy 96 and portions 198. Duct 280 overlies some of ducts 282 as shown in Fig. 16. In the illustrative embodiment of system 330, a plurality of air-exit openings or slots 284 are formed along the side and front peripheral regions of the underside of ceiling unit 338. Operation of air curtain generator 272 moves air from the ambient environment through each of filter 276, duct 280, chamber 278, ducts 282, and openings 284 to form air curtains 270.

A controller (not shown) housed in ceiling unit 338 or headwall unit 232 or both operates to control air curtain generator 272, the heating equipment (if any), and the humidification equipment (if any). A user interface is provided on one or both of columns 40, 42 or on headwall unit 232. A user inputs operational

parameters, such as, for example, fan speed (high, medium, low), air temperature, and air humidity, to the controller via the user interface. In addition, system 330 has various sensors, such as, for example, a fan speed sensor, a temperature sensor, and a humidity sensor that provides feedback to the controller so that appropriate commands from the controller can be provided to air curtain generator 272, the heating system, and the humidification system to adjust the operation of these devices, if appropriate.

According to one aspect of the present disclosure, a patient rests on a hospital bed 534 in an environmentally-controlled hospital room 532 as shown in Fig. 17. Covering the patient is a disposable heating/cooling blanket 536. Blanket 536 is coupled via a pair of heating/cooling hoses 540 to a heating/cooling unit 538 housed in a headwall 542 of room 532. When the patient is to be cooled, unit 538 operates to provide a cooling medium, such as cool air or cool liquid, through one of hoses 540 to blanket 536 and the other of hoses 540 provides the cooling medium back to unit 538 after circulation of the cooling medium through blanket 536. When the patient is to be heated, unit 538 operates to provide a heating medium, such as heated air or heated liquid, through one of hoses 540 to blanket 536 and the other of hoses 540 provides the cooling medium back to unit 538 after circulation of the heating medium through blanket 536. In those embodiments having heated air or cooled air circulated through blanket 536, perforations are formed in the surface of blanket 536 facing the patient so that a portion of the heated or cooled air being circulated through blanket 536 is able to escape from blanket 536 through the perforations and convectively heat or cool, as the case may be, the patient.

Bed 534 includes a pendant controller 544 that a patient uses to control heating/cooling unit 538 in a desired manner when pendant controller 544 is not locked out. In some embodiments, pendant controller 544 also is used to control other bed functions, such as articulation, raising, and lowering of the bed deck, and to control room entertainment and communication functions, such as television, radio, and nurse call. Bed 534 includes a footboard 546 having a control panel 548 that is used by a caregiver to control operation of unit 538, to control operation of various bed functions, and to control various entertainment and communication functions. Control panel 548 is also used by the caregiver to lock out one or more functions of

pendant controller 544. For example, the caregiver can lock out the ability of pendant controller 544 to operate unit 538.

An ceiling unit or overhead canopy 550 is coupled to a ceiling 552 of hospital room 532 above bed 534 as shown in Fig. 17. Canopy 550 includes various systems that control the environment of room 532. For example, canopy 532 includes an overhead temperature sensor (not shown), an overhead air quality sensor (not shown), an overhead air purifier (not shown), aroma therapy equipment (not shown), motion or proximity sensors 554 for detecting the presence of other people in the hospital room, examination lights 556, reading lights (not shown), and a video screen 558 for displaying one or more preselected images. Such images may include a scene from nature or other restful scenes. Such images may also include images that transition at the appropriate times during a 24-hour period from day images, such as clouds and sun, to night images, such as moon and stars. Images of the patients family may also be displayed on screen 558.

In some embodiments of room 532, the room lights are controlled to dim slowly as the daytime turns to evening. In addition, a recording of evening sounds, such as owls, night birds, crickets, and wind in the trees is played by audio equipment housed in overhead canopy 550. Eventually, the room lights are turned completely off and the night sounds fade away. In other embodiments of room 532, a video screen similar to or larger than video screen 558 is mounted to a room wall, preferably a wall that confronts the foot end of bed 534. In such alternative hospital rooms, television images, internet images, educational information, patient schedule, imagery to promote relaxation, and video conferencing images are selectively displayed on the video screen.

Bed 534, unit 538, and ceiling unit 550 each have their own controllers for monitoring and controlling the various functions associated with these devices. Each of such controllers include, for example, one or more microprocessors, microcontrollers, memory circuitry, input/output circuitry, signal conditioning circuitry, signal conversion circuitry, power conditioning circuitry, and the like. It is within the scope of this disclosure for each of the controllers of bed 534, unit 538, and canopy 550 to be coupled to the hospital computer network to exchange data with the network. In some embodiments, parameters for controlling bed 534, unit 538, and canopy 550 are entered by computers that are located remotely from room 532. Thus,

for example, if a patient places a nurse call requesting the heating/cooling function of unit 538 and blanket 536 be adjusted or discontinued, the nurse receiving the call is able to adjust the amount of heating/cooling provided to the patient via blanket 536.

Referring now to Figs. 18-20, a mobile cart 560 includes a somewhat rectangular upstanding pedestal 562, four horizontally extending support legs 564 coupled to the bottom of pedestal 562, and a set of wheels or casters 566 coupled to distal ends of corresponding support legs 564. Pedestal 562 has a fairly small depth dimension between a front face 568 thereof, shown best in Fig. 18, and a rear face 570 thereof, shown in Figs. 19 and 20. Each support leg 564 is pivotable relative to pedestal 562 about a respective vertical axis between a first position extending outwardly from beneath pedestal 562 as shown in Fig. 18 and a second position tucked beneath pedestal 562 as shown in Figs. 18-20.

When legs 564 are in the second positions, legs 564 and casters 566 are positioned to lie completely under and within the foot print of pedestal 562. In addition, when legs 564 are in the second positions, legs 564 extend in substantially parallel relation with front and rear faces 568, 570 of pedestal 562. When legs 564 are in the first positions, a majority of legs 564 are positioned to lie outside the foot print of pedestal 562 and legs 564 extend in substantially perpendicular relation to front and rear faces 568, 570 of pedestal 562. Suitable locking or retention mechanisms are provided either on legs 564 or pedestal 562 to lock or retain legs 564 in the respective first and second positions. The stability of cart 560 on a floor is greater when legs 564 are in the first positions than when legs 564 are in their second positions.

Mobile cart 560 is couplable to and transportable with a wheeled hospital bed or stretcher 572 from an operating room 574, shown in Fig. 19, to an intensive care unit room (not shown), and then to a regular hospital room 578, shown in Fig. 20. Of course, rooms 574, 578 are shown merely as examples of hospital rooms and therefore, cart 560 may be transported with stretcher 572 to any location in a hospital that stretcher 572 is capable of going. Cart 560 may also be transported by itself throughout a hospital when legs 564 are in their first positions having casters 566 rolling along the floor of the hospital.

An asset tracking system (not shown) included in a hospital includes a plurality of transmitters, receivers, and/or transmitter/receiver units 576 (collectively

referred to as "transmitter/receiver units 576") located throughout the hospital. One such transmitter/receiver unit 576 is shown in Fig. 36. Transmitter/receiver units 576 cooperate with remote equipment, such as computers, included in the asset tracking system to track the whereabouts of mobile carts 560 throughout the hospital. Thus, each cart 560 to be tracked includes a transmitter/receiver unit (not shown) that, when prompted by a signal from transmitter/receiver units 576, emits a signal that is sensed by one or more transmitter/receiver units 576 in the vicinity thereof.

Cart 560 is couplable to hospital bed 572 as previously mentioned. Cart 560 is also couplable to arm assemblies 598 included, for example, in operating room 574 and in intensive care unit rooms (not shown). Arm assemblies 598 extend from the ceilings of the respective rooms, such as room 574 as shown in Figs. 19. When cart 560 is coupled to arm assemblies 578, cart 560 is suspended from the ceiling of the respective room so that casters 566 of cart 560 are spaced apart from the floor of the respective rooms. Casters 566 are also spaced apart from the floor of the respective rooms when cart 560 is coupled to bed 572. It is within the scope of this disclosure for cart 560 to be coupled to or included in columns 40, 42 of any of architectural systems 30, 230, 330, as well as any alternatives of these, described above with regard to Figs. 1-16.

Cart 560 includes suitable couplers (not shown) that interface with couplers (not shown) included in bed 572, with couplers (not shown) included in arm assemblies 578, and with couplers (not shown) included in columns 40, 42. Suitable couplers may include, for example, hooks, clips, posts, latches, sockets, rails, channels, slots, bands, straps, fingers, flanges, lugs, bails, wires, magnets, plates, and the like, as well as combinations of these. Cart 560 includes a handle 580 appended to the top of pedestal 562 as shown in Figs. 18 and 19. A caregiver grips handle 580 to maneuver cart 560 along a floor of the hospital and to carry cart 560, such as during attachment to or detachment from bed 572, arm assemblies 578, or columns 40, 42.

A headwall 582 of room 578 is formed to include a cavity 584 that is configured to receive cart 560 as shown in Fig. 20. In addition, cart 560 is received in cavities 34, 36 (or cavities 23, 236) when cart 560 is coupled to or included in columns 40, 42 and columns 40, 42 are moved to the storage positions. When cart 560 is situated in cavity 584, legs 564 are in the respective second positions and

casters 566 rest upon a ledge surface 586 that underlies cavity 584. Pedestal 562 of cart 560 is configured to carry one or more IV poles 588 as shown in Figs. 18-20. Cavity 584 has sufficient height to accommodate cart 560 and any IV poles 588 coupled thereto as shown in Fig. 20. Hooks 587 are provided at the top of IV poles 588 for attachment of IV bags 68.

Pedestal 562 includes recesses or compartments 589 that are adapted to carry various patient-monitoring and patient-care modules or equipment 590, shown best in Fig. 18. Such patient-care equipment includes, for example, infusion pumps, ventilator control units, gas control units, vital signs monitors, and the like. Some modules 590 are coupled to the patient, via sensor lines, to monitor various physiological conditions and vital signs of the patient. In some embodiments, cart 560 includes an on-board computer system that interfaces with modules 590 and with a receiver/transmitter unit on cart 560. In such embodiments, patient-data from modules 590 is either transmitted to the hospital network via the receiver/transmitter unit or the patient-data is stored in the computer system until a hard-wire or optical connection is made to the network. When the computer system is communicatively coupled to the network, a caregiver located in the hospital remote from cart 560 is able to access the network with a remote computer terminal, for example, to obtain the status of the patient being monitored by modules 590 carried by cart 560. Cart 560 includes a battery (not shown) to provide power to any electrical components, such as modules 590 and the computer system, carried by cart 560.

Pedestal 562 is formed to include service delivery ports 592. Tanks (not shown) containing oxygen or other types of medical gases are situated in an interior region of pedestal 562. In some embodiments, such tanks are included in a ventilator system carried by cart 560. In such embodiments, hoses 594, one of which is shown in Fig. 20, are coupled to respective ports 592 and extend from ports 592 either to the patient or to associated medical equipment. Cart 560 is configured to carry other types of medical devices, including drug infusion devices, that are associated with providing intensive care to a patient. Such devices are sometimes referred to as LSTAT (Life Support for Trauma and Transport) devices. Because cart 560 carries most, if not all, of the medical equipment necessary to provide intensive care to the patient and because cart 560 is transported with the patient throughout the hospital, the need to disconnect and reconnect IV lines, ventilator hoses, sensor lines,

and the like from the patient before and after transport is avoided, as is the need to manage multiple wheeled stands or carts during transport of the patient throughout a hospital.

Referring now to Figs. 21-23, a ceiling-mounted overbed table assembly 656 includes a ceiling unit or hub unit 658 coupled to ceiling 46 of a hospital room, an arm assembly 660 coupled to hub unit 658, an overbed table 662 coupled to arm assembly 660, and a patient-care housing 664 coupled to and extending downwardly from an undersurface of table 662. In alternative embodiments, housing 664 is coupled to arm assembly 660 and is situated, at least in part, beneath table 662. Hub unit 658 includes an annular upper portion 666 having a frustoconical shape, an annular lower portion 668 shaped like a disc, and an annular slot 670 defined between portions 666, 668 as shown in Fig. 40. Hub unit 658 further includes a plurality of exam and reading lights 672 coupled to lower portion 668 and arranged to direct light downwardly therefrom. In alternative embodiments, hub 568 has shapes other than annular, such as elliptical, polygonal (i.e., square, rectangular, triangular, and so on), and the like.

Arm assembly 660 includes a first arm 674 extending horizontally from slot 670 and a second arm 676 extending vertically downwardly from a distal end 678 of first arm 674 as shown in Fig. 21. Hub unit 658 includes a shaft assembly (not shown) that interconnects portions 666, 668 of hub unit 658. A proximal end (not shown) of first arm 674 is coupled to the shaft assembly for pivoting movement about a vertical axis 680. Table 662 and housing 664 are coupled to a lower end of arm 676 for pivoting movement about a vertical axis 682, shown in Figs. 21 and 22. Alternatively, table 662 and housing 664 are fixed with respect to arm 676 and arm 676 is coupled to arm 674 for rotation about axis 682.

Second arm 676, table 662, and housing 664 are movable between a first position situated on a first side of a hospital bed 684 and a second position situated on a second side of hospital bed 684 as shown in Fig. 23. During movement between the first and second positions, arm 676, table 662, and housing 664 move along an arcuate path, indicated by a curved double-headed arrow 688 shown in Fig. 23, around a foot end 686 of bed 684. First arm 674 has sufficient length to allow housing 664 to clear foot end of bed 684 during movement between the first and second positions. Assembly 656 includes suitable locking mechanisms to lock arm

assembly 660 and table 662 in the first and second positions. When in either the first position or the second position, table 662 extends horizontally from arm 676 in a cantilevered manner and is positioned, in part, over the lap of a patient supported by bed 684. In some embodiments, assembly 656 includes drive mechanisms that operate to adjust the vertical position of table 662 and housing 664 relative to arm 676.

Assembly 656 includes a telephone 690 having a handset that resides in a recess formed in the upper surface of table 662. Assembly 656 also includes an entertainment-and-control panel 692 that is coupled to arm 676 of arm assembly 660 via a post 694 that extends horizontally away from arm 676 above table 662 as shown in Figs. 40 and 41. Illustrative panel 692 is a touch screen that permits the patient to control, for example, room lighting, room temperature, television functions, nurse call functions, and the like. Panel 692 is also operable to display various images such as, for example, television images, internet images, educational information, patient schedule, patient billing information, and video conferencing images. Controls panels having any combination of the above-mentioned control functions and entertainment functions are within the scope of this disclosure. Telephone 690 is used in a conventional manner for placement of phone calls.

A plurality of medical service outlets 696 and a plurality of patient-monitor modules 698 are coupled to an end face 700 of housing 664 as shown in Fig. 22. Modules 698 are arranged in side-by-side relation along an upper portion of end face 700 and medical service outlets 696 are arranged in side-by-side relation beneath modules 698. Each of modules 698 receive patient-data signals via patient-data lines (not shown) that are coupled to modules 698 and to the patient to monitor various physiological conditions of the patient. Patient conditions to be monitored may include temperature, heart rate, blood oxygenation, respiration, brain activity, and the like. Services provided by outlets 696 may include, for example, medical gases, vacuum, and power. Outlets 696 receive the associated services via lines (not shown) that are routed to outlets 696 from the ceiling of the hospital room, through hub unit 658, though interior regions of arms 674, 676, through an opening in table 662, and into an interior region of housing 664. Outlets 696 and modules 698 are positioned on housing 664 so as to be generally inaccessible to a patient lying on bed 684 when assembly 656 is in either the first position or the second position.

It is contemplated by this disclosure that table 662 and/or housing 664, along with outlets 696 and modules 698 associated with housing 664 may be suspended from a ceiling of a hospital room by other types of arm assemblies or columns. For example, it is within the scope of this disclosure for table 662 and/or housing 664 to be coupled to or included in columns 40, 42 of any of architectural systems 30, 230, 330 described above. In such embodiments, table 662 or a part thereof flips up, such as by pivoting about a horizontal axis, thereby placing table 662 is in a substantially vertical orientation for storage in the associated cavity 34, 36, 234, 236 of the associated headwall unit 32, 232. When the column 40, 42 associated with table 662 is moved out of the associated cavity 34, 36, 234, 236, table 662 is flipped down to a substantially horizontal orientation for use.

Although various apparatus and systems have been described in detail with reference to certain preferred embodiments, variations and modifications of each of these apparatus and systems exist within the scope and spirit of the invention as described and defined in the following claims.

CLAIMS

1. An architectural system adaptable to an acuity level of a patient supported by a hospital bed in a patient room having a wall and a ceiling, the architectural system comprising

a wall unit coupled to the wall and having a cavity,

a ceiling unit coupled to the ceiling, and

a column coupled to the ceiling unit for movement between a first position in which at least a majority of the column is situated in the cavity and a second position in which the column is situated outside the cavity.

2. The architectural system of claim 1, wherein the column includes a vertical member and a patient care device coupled to the vertical member.

3. The architectural system of claim 2, wherein the patient care device comprises an IV rack that is situated in the cavity when the column is in the first position.

4. The architectural system of claim 2, wherein the patient care device comprises a housing having a plurality of medical service outlets and the housing is situated in the cavity when the column is in the first position.

5. The architectural system of claim 4, wherein at least one of the medical service outlets is a medical gas outlet.

6. The architectural system of claim 4, wherein at least one of the medical service outlets is an electrical outlet.

7. The architectural system of claim 4, wherein the wall unit has a door that is movable between a closed position blocking access to the plurality of medical service outlets when the column is in the first position and an opened position allowing access to the medical service outlets when the column is in the first position.

8. The architectural system of claim 2, wherein the patient care device comprises a display screen that is situated in the cavity when the column is in the first position.

9. The architectural system of claim 8, wherein the wall unit has a door that is movable between a closed position covering the display screen to shield the display screen from view when the column is in the first position and an opened

position uncovering the display screen to permit the display screen to be viewed when the column is in the first position.

10. The architectural system of claim 2, wherein the patient care device is pivotable about an axis relative to the vertical member when the column is in the second position.

11. The architectural system of claim 10, wherein the axis is vertical and extends through the vertical member.

12. The architectural system of claim 1, wherein the ceiling unit comprises a track member and the column comprises a carriage that moves along the track member as the column moves between the first and second positions.

13. The architectural system of claim 12, wherein a portion of the track member overlies the cavity.

14. The architectural system of claim 12, wherein the track member comprises elongated first and second roller-engaging surfaces, the first roller-engaging surface is parallel to the second roller-engaging surface, the carriage comprises a housing and a plurality of roller coupled to the housing, at least one of the plurality of rollers engages the first roller-engaging surface, and a least another of the plurality of roller engages the second roller-engaging surface.

15. The architectural system of claim 1, wherein the ceiling unit comprises a housing and a light coupled to the housing.

16. The architectural system of claim 1, wherein the ceiling unit comprises a housing and a display screen coupled to the housing.

17. The architectural system of claim 1, wherein the ceiling unit comprises a housing having a plurality of openings and the ceiling unit comprises an air curtain generator that operates to expel air downwardly from the plurality of openings to create at least one air curtain.

18. The architectural system of claim 17, wherein the housing has an air-intake opening, the ceiling unit comprises an air-permeable filter covering the air-intake opening, and operation of the air curtain generator draws air from the patient room through the filter.

19. The architectural system of claim 1, wherein the column comprises a medical service outlet and further comprising a medical service delivery

line that is routed from the medical service outlet, through the column, and through the ceiling unit.

20. The architectural system of claim 1, further comprising a privacy curtain hanging downwardly from the ceiling unit, the wall unit having a compartment, and the privacy curtain being movable between a storage position in which a majority of the privacy curtain is situated in the compartment and a use position in which a majority of the privacy curtain is situated outside the compartment.

21. The architectural system of claim 1, further comprising a privacy curtain coupled to the ceiling unit and movable between a use position hanging downwardly from the ceiling unit and a storage position retracted into the ceiling unit.

22. An architectural system adaptable to an acuity level of a patient supported by a hospital bed in a patient room having a wall and a ceiling, the architectural system comprising

a wall unit coupled to the wall, the wall unit having a first cavity and a second cavity,

a first track member coupled to the ceiling,

a second track member coupled to the ceiling,

a first column coupled to the first track member for movement between a first position in which at least a majority of the first column is situated in the first cavity and a second position in which the first column is situated outside the cavity alongside a first side of the hospital bed, and

a second column coupled to the second track member for movement between a first position in which at least a majority of the second column is situated in the second cavity and a second position in which the second column is situated outside the cavity alongside a second side of the hospital bed.

23. The architectural system of claim 22, wherein the wall unit has a first door that is movable between a closed position blocking access to at least a portion of the first column when the first column is in the first position and an opened position permitting access to the portion of the first column.

24. The architectural system of claim 22, wherein the first track member is elongated, the second track member is elongated, and the first track member is parallel with the second track member.

25. The architectural system of claim 22, wherein the first track member comprises elongated first and second roller-engaging surfaces, the first roller-engaging surface is parallel to the second roller-engaging surface, the column comprises a carriage having a housing and a plurality of rollers coupled to the housing, at least one of the plurality of rollers engages the first roller-engaging surface, and a least another of the plurality of roller engages the second roller-engaging surface.

26. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and a light coupled to the canopy.

27. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and a display screen coupled to the canopy.

28. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and air curtain generation equipment coupled to the canopy.

29. An apparatus for use in a hospital room having a ceiling, the apparatus comprising

a canopy adapted to be coupled to the ceiling of the hospital room, and environmental control equipment coupled to the canopy.

30. The apparatus of claim 29, wherein the environmental control equipment comprises a temperature sensor.

31. The apparatus of claim 29, wherein the environmental control equipment comprises an air quality sensor.

32. The apparatus of claim 29, wherein the environmental control equipment comprises an air purifier.

33. The apparatus of claim 29, wherein the environmental control equipment comprises aroma therapy equipment.

34. The apparatus of claim 29, further comprising a motion sensor coupled to the canopy.

35. The apparatus of claim 29, further comprising a proximity sensor coupled to the canopy.

36. The apparatus of claim 29, wherein the environmental control equipment comprises at least one examination light.

37. The apparatus of claim 29, wherein the environmental control equipment comprises at least one reading light.

38. The apparatus of claim 29, further comprising a video screen coupled to the canopy.

39. A mobile cart for use in a hospital to provide care to a patient, the mobile cart comprising

an upstanding pedestal,

a plurality of legs coupled to a bottom of the upstanding pedestal,

a plurality of wheels, each wheel being coupled to a respective leg of the plurality of legs, the legs along with the wheels coupled thereto each being movable between a first position extending outwardly from beneath the upstanding pedestal and second position tucked beneath the upstanding pedestal, and

a plurality of patient-care modules coupled to the upstanding pedestal.

40. The mobile cart of claim 39, further comprising at least one IV pole coupled to the upstanding pedestal.

41. The mobile cart of claim 39, wherein the upstanding pedestal has a top wall and further comprising a handle coupled to the top wall, the handle being grippable to maneuver the mobile cart.

42. The mobile cart of claim 39, wherein each wheel of the plurality of wheels is able to swivel about a respective vertical axis.

43. The mobile cart of claim 39, wherein each leg of the plurality of legs is able to swivel about a respective vertical axis.

44. The mobile cart of claim 39, wherein the upstanding pedestal has a compartment adapted to carry at least one of the plurality of patient-care modules.

45. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is an infusion pump.

46. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a ventilator control unit.

47. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a gas control units.

48. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a vital signs monitor.

49. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is configured to monitor a physiological condition of the patient.

50. The mobile cart of claim 39, further comprising an on-board computer system that interfaces with at least one of the plurality of patient-care modules.

51. The mobile cart of claim 50, further comprising a receiver and a transmitter and the on-board computer system interfaces with the receiver and the transmitter.

52. The mobile cart of claim 50, wherein the on-board computer system is configured to transmit wirelessly patient data from at least one of the plurality of patient-care modules.

53. The mobile cart of claim 50, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until a hard-wire connection is made between the on-board computer system and an external computer network.

54. The mobile cart of claim 50, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until an optical connection is made between the on-board computer system and an external computer network.

55. The mobile cart of claim 50, further comprising a battery configured to provide power to the on-board computer system and to at least one of the plurality of patient-care modules.

56. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules comprises a medical gas tank housed in the upstanding pedestal and further comprising a service delivery port that is coupled to the upstanding pedestal and through which medical gas from the medical gas tank is accessible.

57. A set of equipment for use in a hospital room having a floor, the set of equipment comprising

a hospital bed supported by the floor,

an arm assembly hanging in the hospital room, and

a mobile cart that is selectively couplable to the hospital bed and to the arm assembly and that is selectively decouplable from the hospital bed and from the arm assembly, the mobile cart having wheels that are spaced apart from the floor when the mobile cart is coupled to the hospital bed and when the mobile cart is coupled to the arm assembly, the wheels engaging the floor when the mobile cart is decoupled from the hospital bed and decoupled from the arm assembly.

58. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal and at least one IV pole coupled to the pedestal.

59. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal having a top wall, the mobile cart has a handle coupled to the top wall, and the handle is grippable to maneuver the mobile cart.

60. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal and a patient-care module coupled to the pedestal.

61. The set of equipment of claim 60, wherein the pedestal has a compartment adapted to carry the patient-care module.

62. The set of equipment of claim 60, wherein the patient-care module is an infusion pump.

63. The set of equipment of claim 60, wherein the patient-care module is a ventilator control unit.

64. The set of equipment of claim 60, wherein the patient-care module is a gas control unit.

65. The set of equipment of claim 60, wherein the patient-care module is a vital signs monitor.

66. The set of equipment of claim 60, wherein the patient-care module is configured to monitor a physiological condition of the patient.

67. The set of equipment of claim 60, wherein the mobile cart has an on-board computer system that interfaces with the patient-care module.

68. The set of equipment of claim 60, wherein the mobile cart has a receiver, the mobile cart has a transmitter, and the on-board computer system interfaces with the receiver and the transmitter.

69. The set of equipment of claim 60, wherein the on-board computer system is configured to transmit wirelessly patient data from the patient-care module.

70. The set of equipment of claim 60, wherein the on-board computer system is configured to store patient data from the patient-care module until a hard-wire connection is made between the on-board computer system and an external computer network.

71. The set of equipment of claim 60, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until an optical connection is made to an external computer network.

72. The set of equipment of claim 60, wherein the mobile cart has a battery configured to provide power to the on-board computer system and to the patient-care module.

73. The set of equipment of claim 60, wherein the patient-care module comprises a medical gas tank housed in the pedestal, the mobile cart has a service delivery port coupled to the pedestal, and medical gas from the medical gas tank is accessible via the service delivery port.

74. The set of equipment of claim 57, wherein the arm assembly has a plurality of articulated arm segments.

75. The set of equipment of claim 57, wherein the arm assembly comprises a vertical column.

76. The set of equipment of claim 75, further comprising a track member along which the vertical column is movable.

77. A set of hospital equipment comprising

a mobile cart carrying patient-care equipment and having a plurality of wheels, and

a headwall formed to include a cavity that receives the mobile cart, the headwall having a ledge surface, the plurality of wheels of the mobile cart engaging the ledge surface when the mobile cart is received in the cavity.

78. The set of hospital equipment of claim 77, wherein a portion of the headwall overlies the cavity.

79. The set of hospital equipment of claim 77, wherein the mobile cart has a pedestal and an IV pole coupled to the pedestal and wherein the cavity is sized to receive the pedestal and the IV pole.

80. The set of hospital equipment of claim 77, wherein the mobile cart has a pedestal and a plurality of legs coupled to the pedestal and wherein each wheel of the plurality of wheels is coupled to a respective leg of the plurality of legs.

81. The set of hospital equipment of claim 80, wherein the plurality of legs, along with the wheels coupled thereto, are each movable between a first position extending outwardly from beneath the pedestal and second position tucked beneath the pedestal.

82. The set of hospital equipment of claim 77, wherein the headwall has a panel and at least one medical service outlet that is coupled to the panel and through which a medical service is accessible.

83. An apparatus comprising

an arm assembly adapted to be suspended from a ceiling of a hospital room, and

an overbed table coupled to the arm assembly to be supported by the arm assembly above a floor of the hospital room.

84. The apparatus of claim 83, wherein the overbed table has a table surface that is substantially horizontal, the arm assembly is configured to permit repositioning of the overbed table in the hospital room, and the table surface remains at a substantially constant elevation above the floor as the overbed table is repositioned.

85. The apparatus of claim 83, further comprising a control panel coupled to the arm assembly and the control panel having a user input.

86. The apparatus of claim 85, wherein the user input is engageable to control a light in the hospital room.

87. The apparatus of claim 85, wherein the user input is engageable to control a temperature of the hospital room.

88. The apparatus of claim 85, wherein the user input is engageable to control at least one function of a television situated in the hospital room.

89. The apparatus of claim 85, wherein the user input is engageable to place a nurse call signal.

90. The apparatus of claim 85, wherein the control panel has a screen on which video images are displayed.

91. The apparatus of claim 85, wherein the control panel has a screen on which images accessed via the internet are displayed.

92. The apparatus of claim 85, wherein the control panel has a screen on which a patient schedule is displayed.

93. The apparatus of claim 85, wherein the control panel has a screen on which education information is displayed.

94. The apparatus of claim 85, wherein the control panel has a screen on which patient billing information is displayed.

95. The apparatus of claim 85, wherein the control panel has a screen on which video conferencing images are displayed.

96. The apparatus of claim 85, wherein the control panel is situated above the overbed table.

97. The apparatus of claim 85, wherein the control panel comprises a touch screen and the user input comprises an area on the touch screen.

98. The apparatus of claim 83, further comprising a telephone, the overbed table having a recess, and the telephone having a handset that resides in the recess.

99. The apparatus of claim 83, further comprising a housing coupled to the overbed table, a medical service outlet coupled to the table, and a service-delivery line routed from the medical service outlet, through the housing, and through the arm assembly.

100. The apparatus of claim 99, wherein the housing extends downwardly from the overbed table and terminates at a bottom end that is spaced apart from the floor.

101. The apparatus of claim 83, further comprising a housing coupled to the overbed table and a patient-monitor module coupled to the housing, the patient-monitor module being configured to receive a patient-data signal indicative of a physiological condition of a patient.

102. An apparatus comprising

a hub unit adapted to mount to a ceiling of a hospital room,

an arm assembly coupled to the hub unit,

an overbed table coupled to the arm assembly, and

a housing coupled to one of the arm assembly and the overbed table, the housing carrying one of a medical service outlet and a patient-monitor module.

103. The apparatus of claim 102, wherein the hub unit comprises an upper portion, a lower portion, and an annular slot defined between the upper and lower portions and wherein the arm assembly comprises a first arm segment that is rotatable relative to the first and second portions within the slot.

104. The apparatus of claim 103, wherein the first arm segment extends from the slot and terminates at a distal end and the arm assembly comprises a second arm segment extending downwardly from the distal end of the first arm segment.

105. The apparatus of claim 104, wherein the overbed table is coupled to a lower end portion of the second arm segment.

106. The apparatus of claim 104, wherein the second arm, the overbed table, and the housing rotate as a unit relative to the first arm segment.

107. The apparatus of claim 104, wherein the overbed table and the housing rotate as a unit relative to the second arm segment.

108. The apparatus of claim 103, wherein the hub unit further includes a plurality lights coupled to the lower portion and arranged to direct light downwardly from the lower portion.

109. A set of hospital equipment comprising

a headwall,

a blanket,

a unit housed in the headwall, and

a hose coupled to the blanket and coupled to the unit, a thermoregulation medium being moved between the blanket and the unit through the hose.

110. The set of hospital equipment of claim 107, wherein the thermoregulation medium comprises a cooled liquid.

111. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises cooled air.

112. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises a heated liquid.

113. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises heated air.

114. The set of hospital equipment of claim 109, wherein the blanket has internal passages through which the thermoregulation medium travels.

115. The set of hospital equipment of claim 114, wherein the blanket has a plurality of perforations through which a portion of the thermoregulation medium escapes from the internal passages of the blanket.

116. The set of hospital equipment of claim 109, wherein the thermoregulation medium is a heated medium when the patient is to be heated and the thermoregulation medium is a cooled medium when the patient is to be cooled.

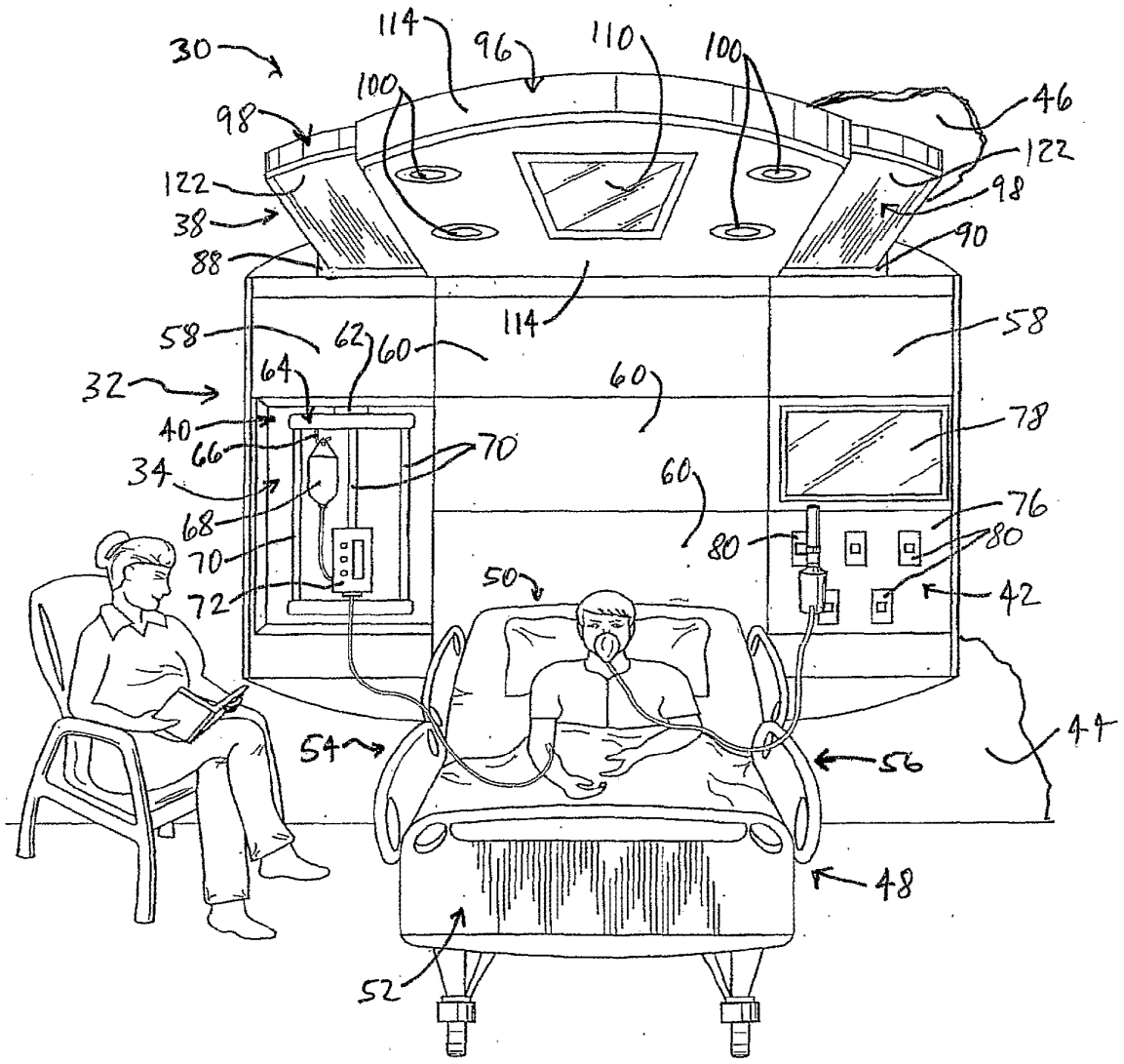
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Fig. 1

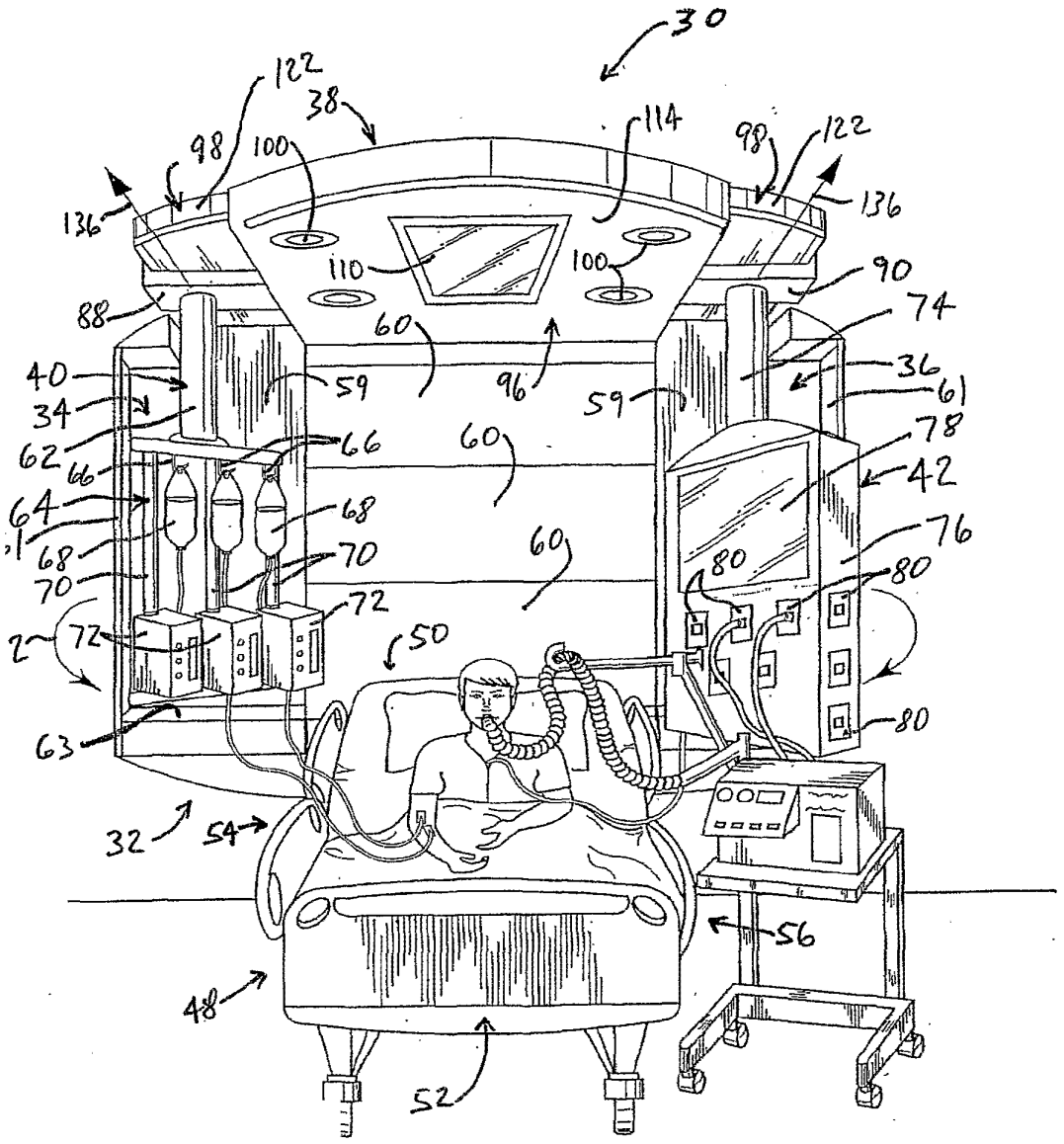
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Fig. 2

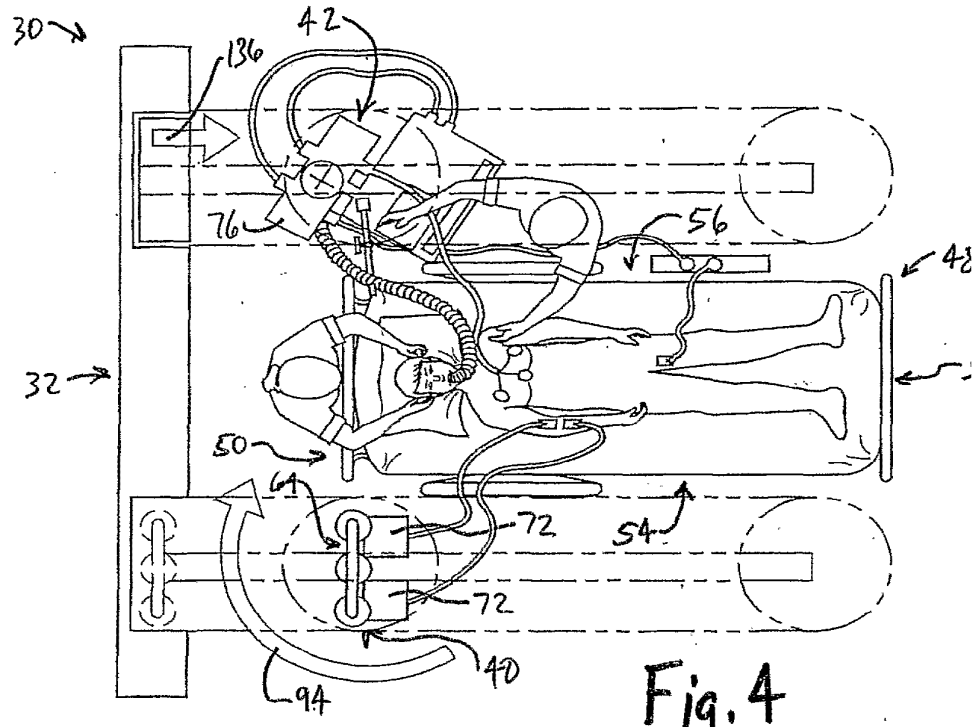
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Fig. 4

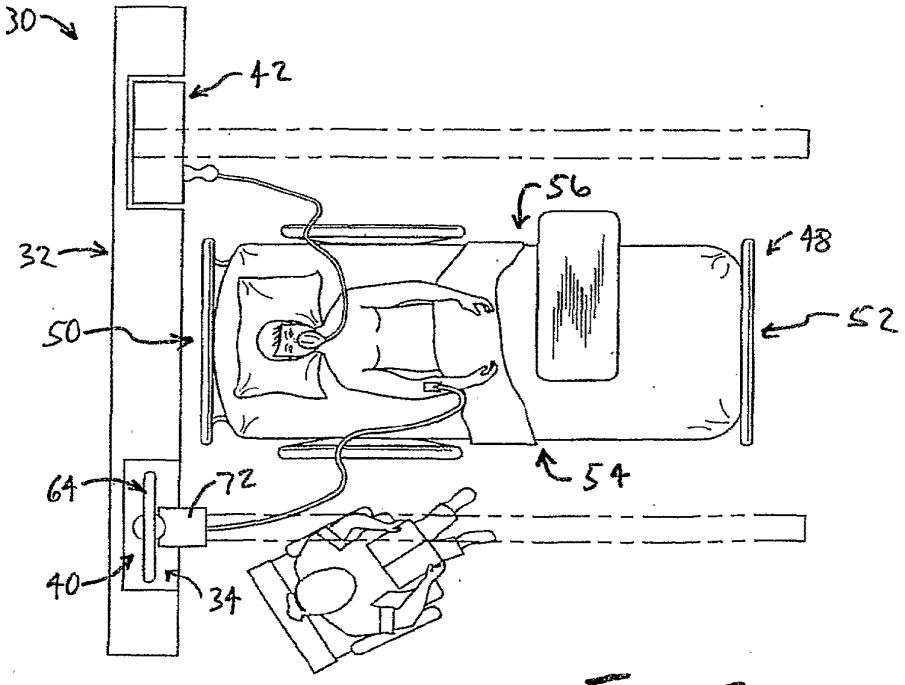
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Fig. 3

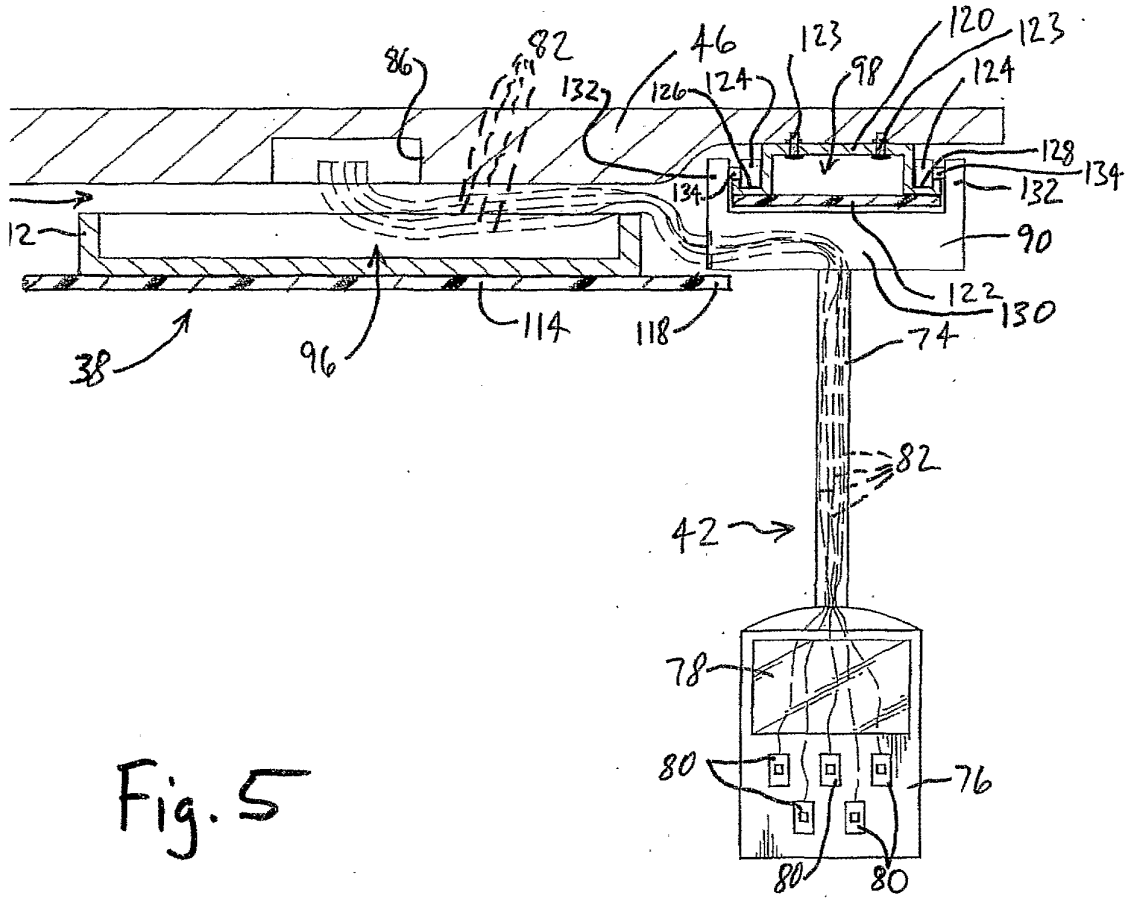
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Fig. 5

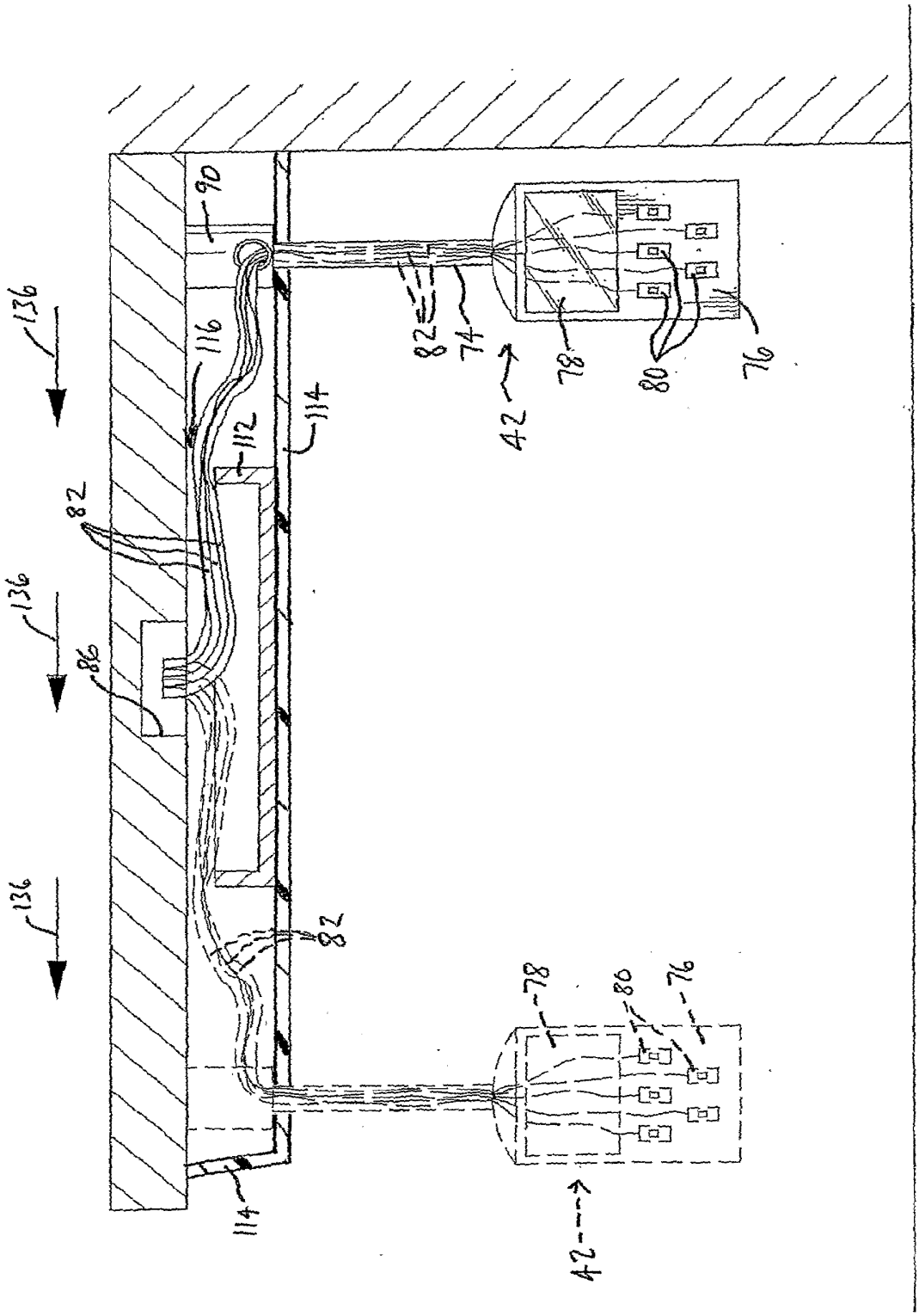

Fig. 6

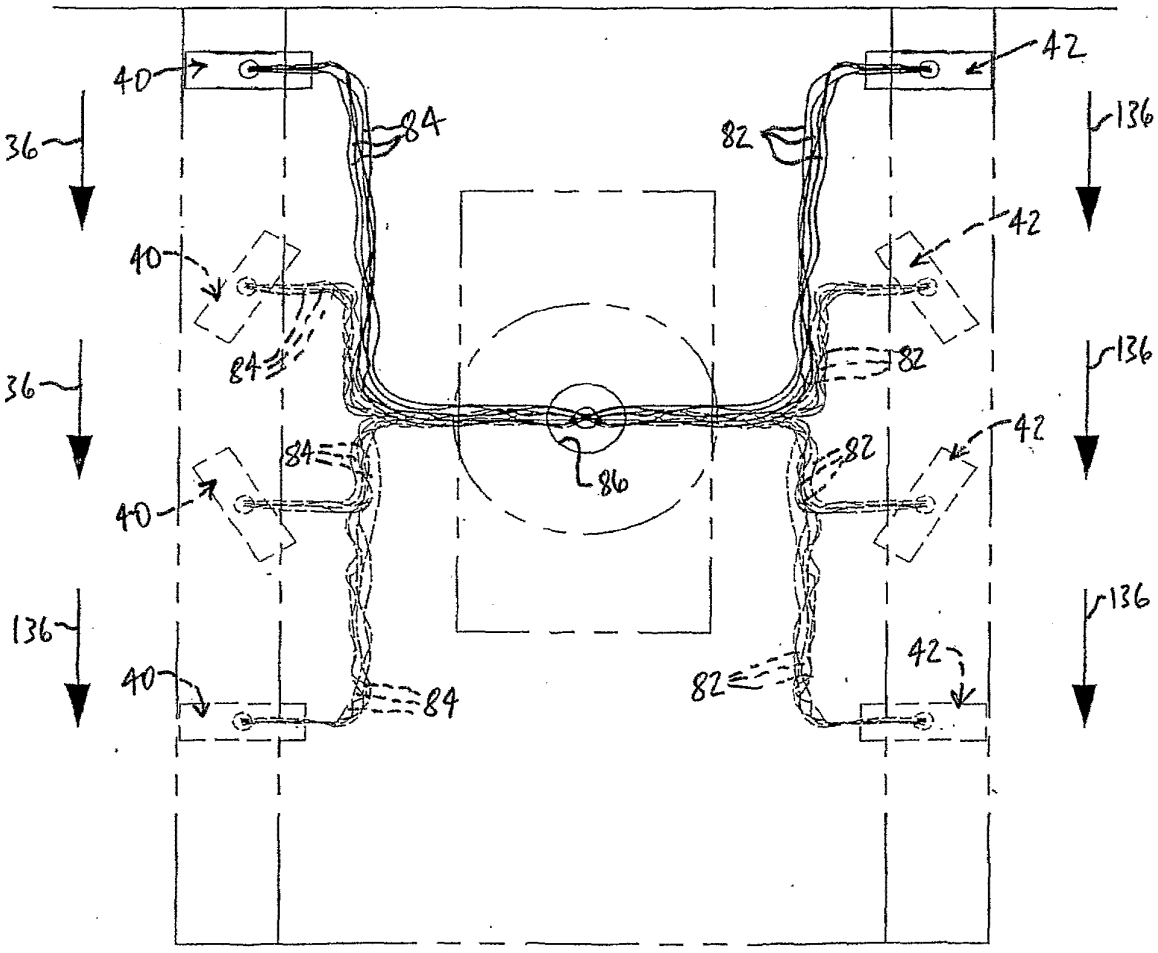

Fig. 7

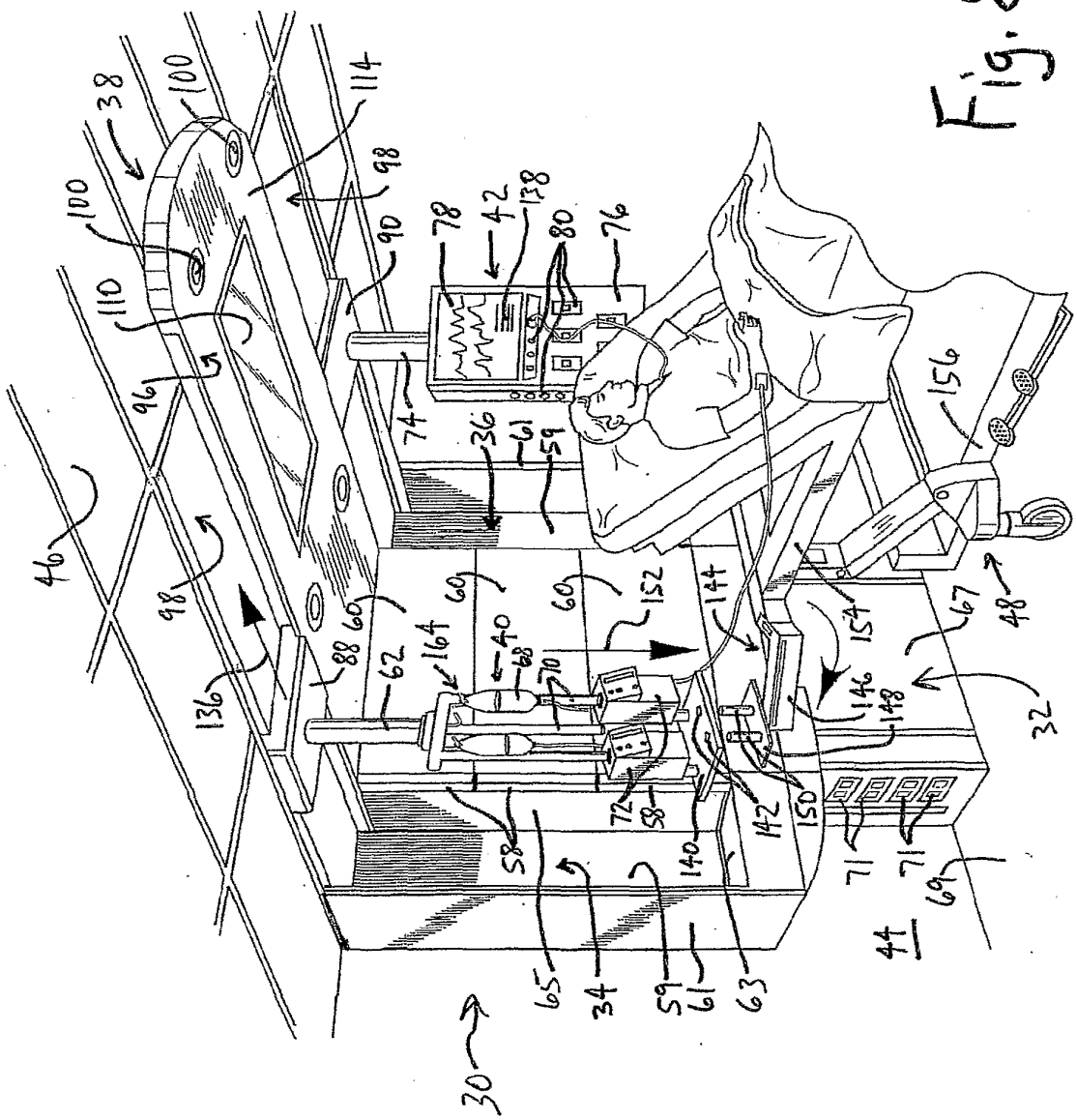
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Fig. 8

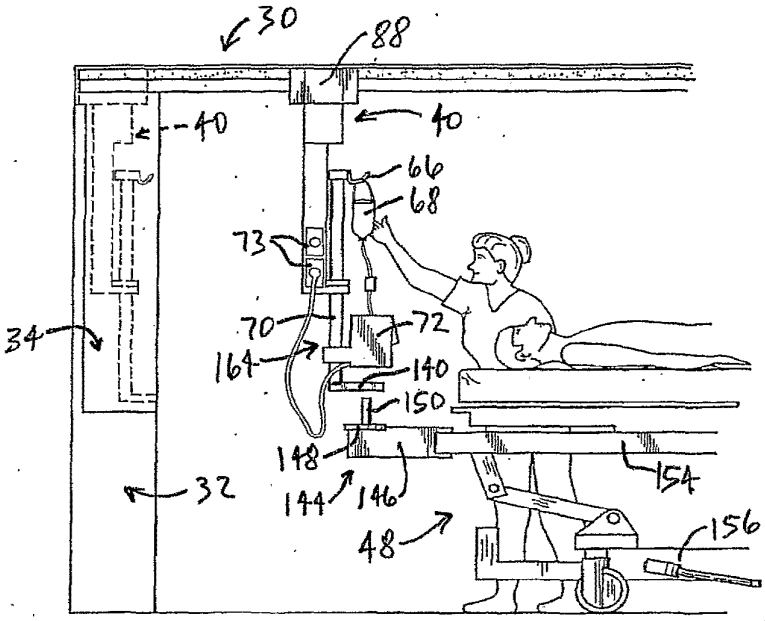
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Fig. 9

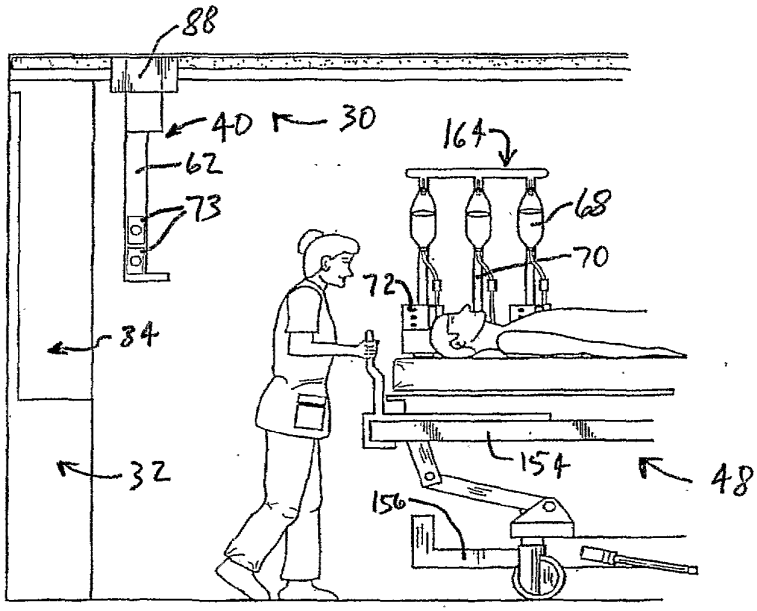
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Fig. 10

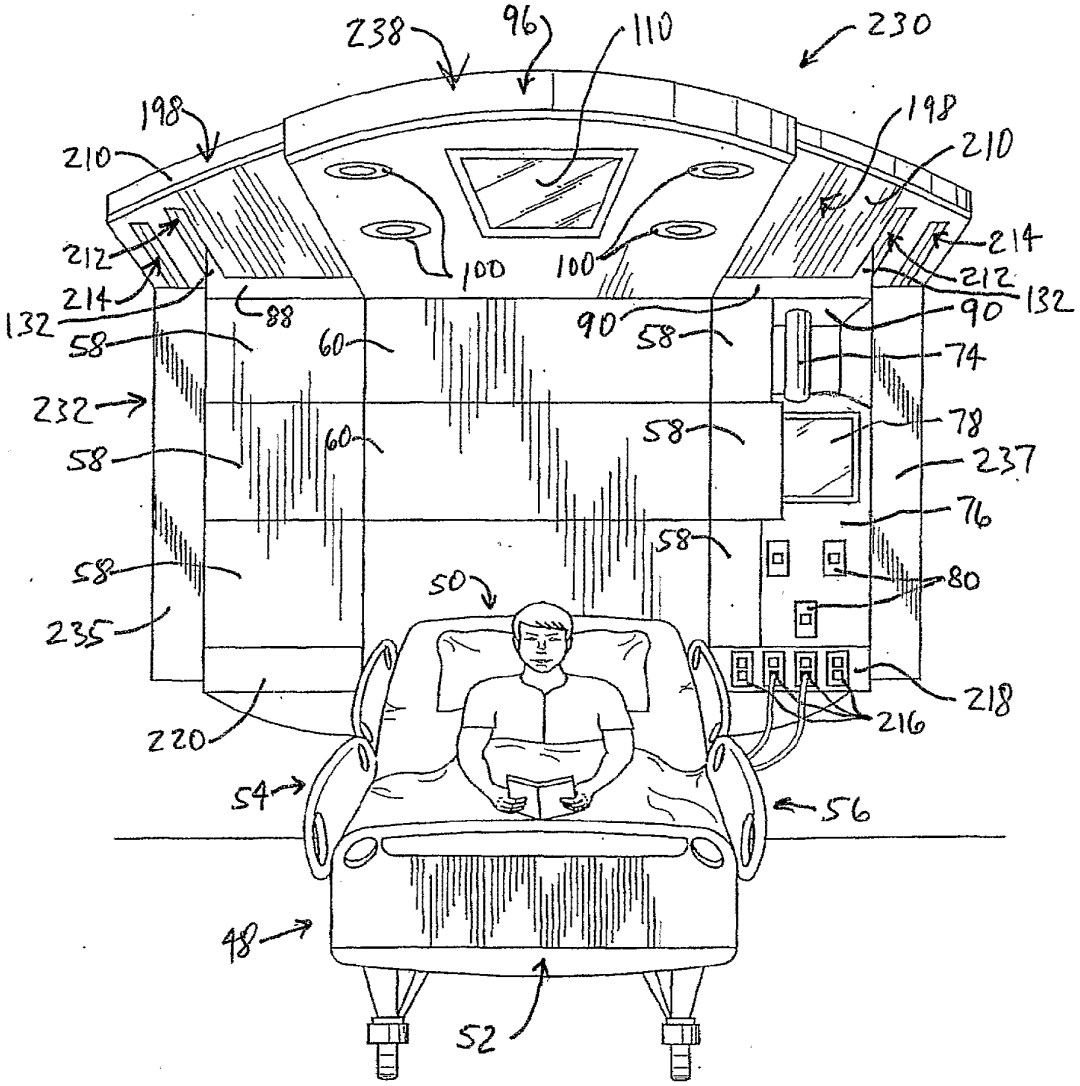
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Fig. 11

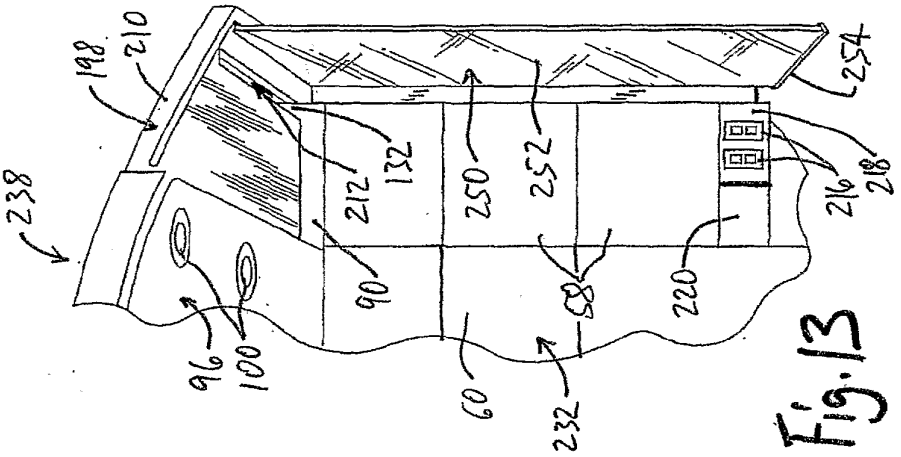


Fig. 13

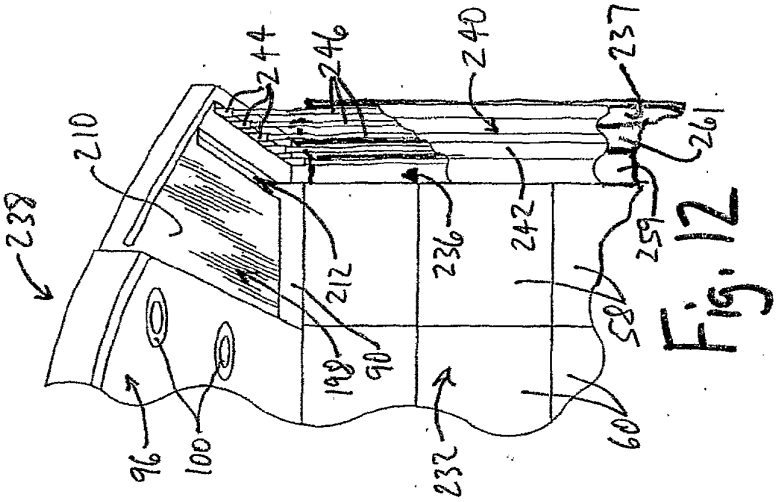
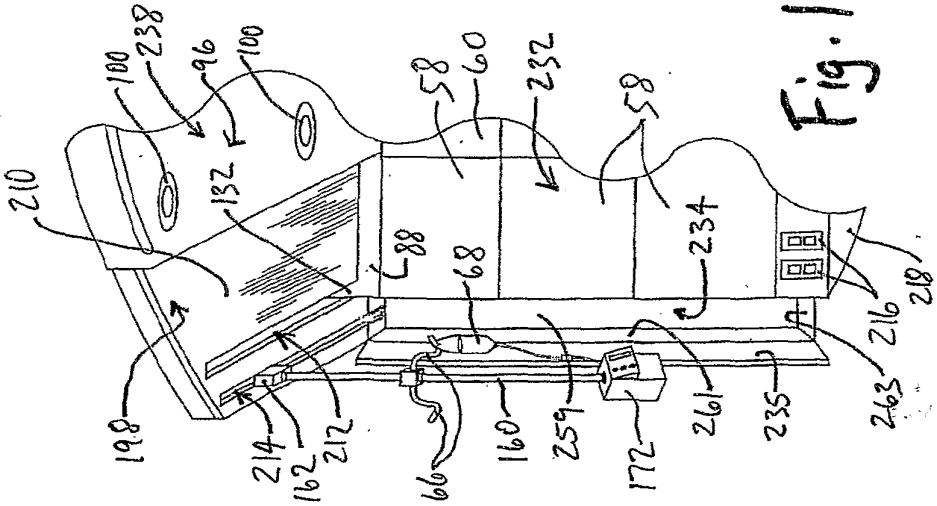


Fig. 12



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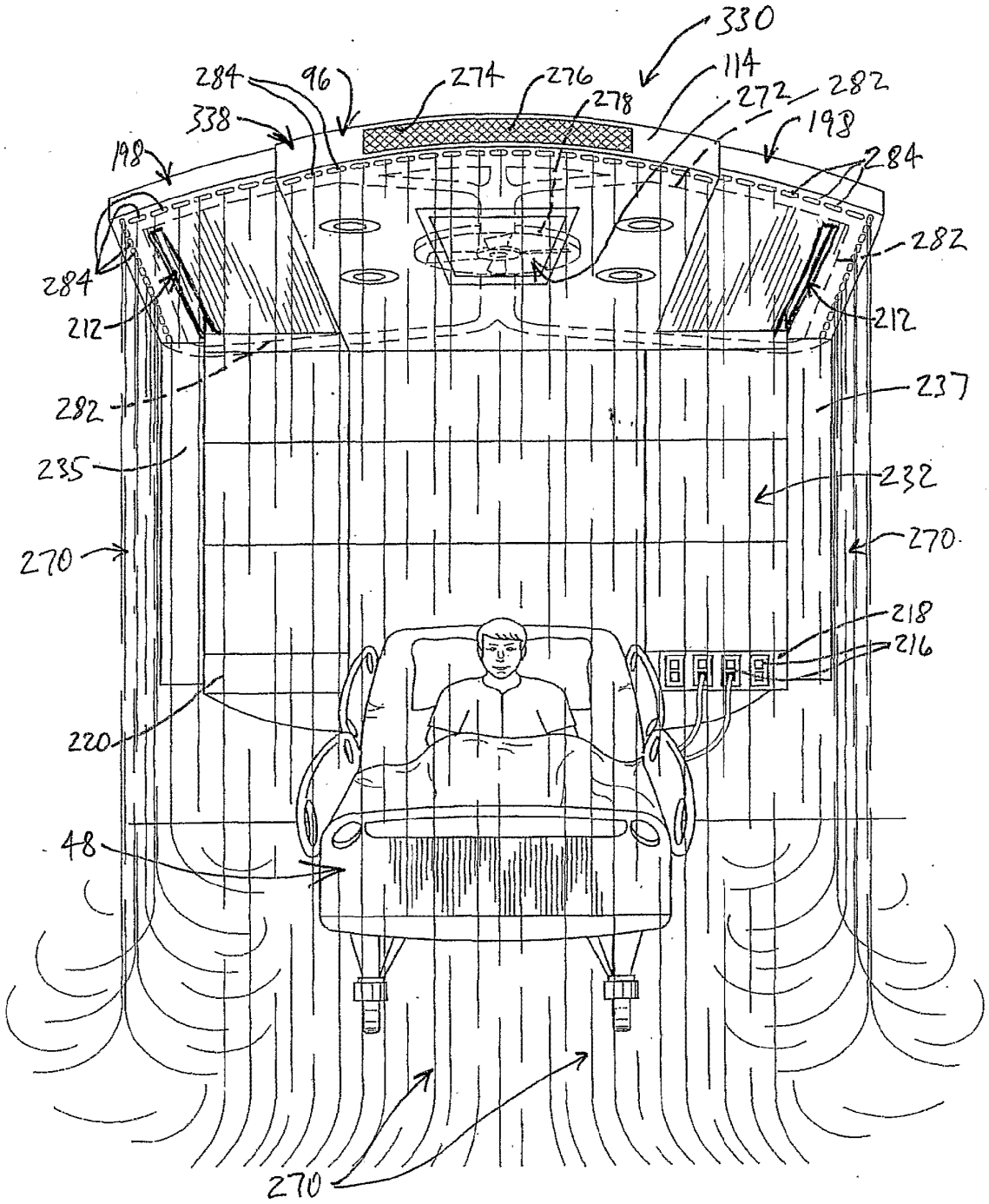
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Fig. 15

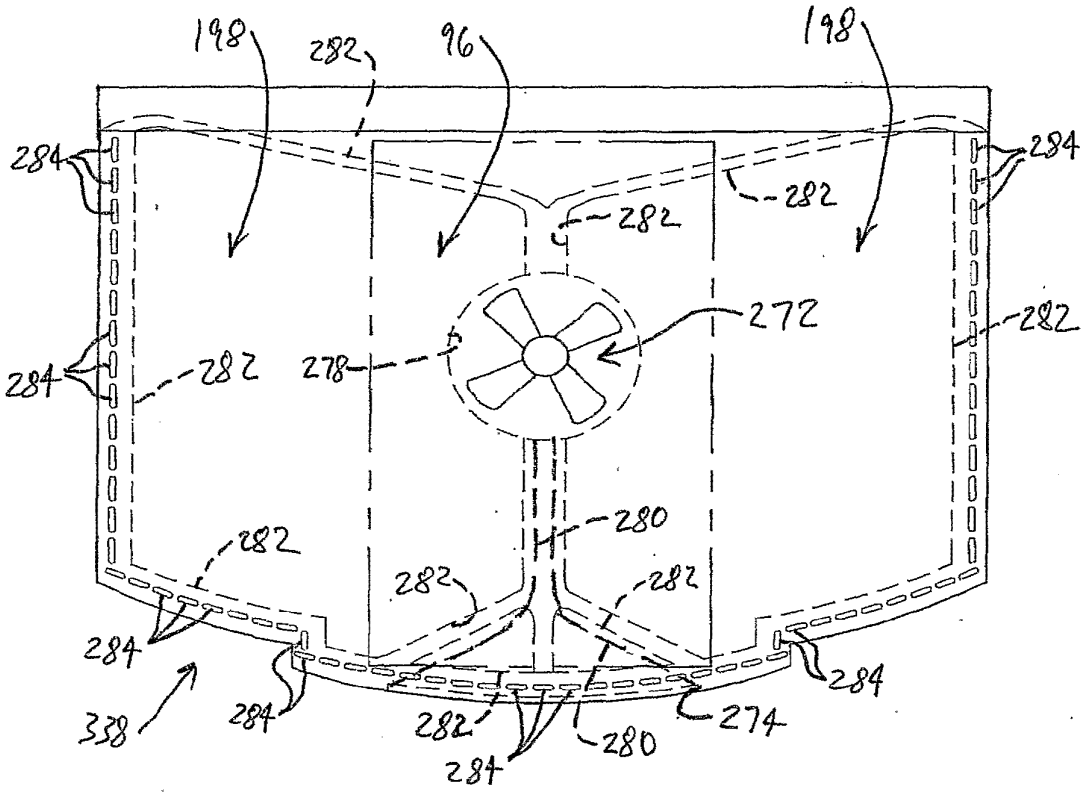
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Fig. 16

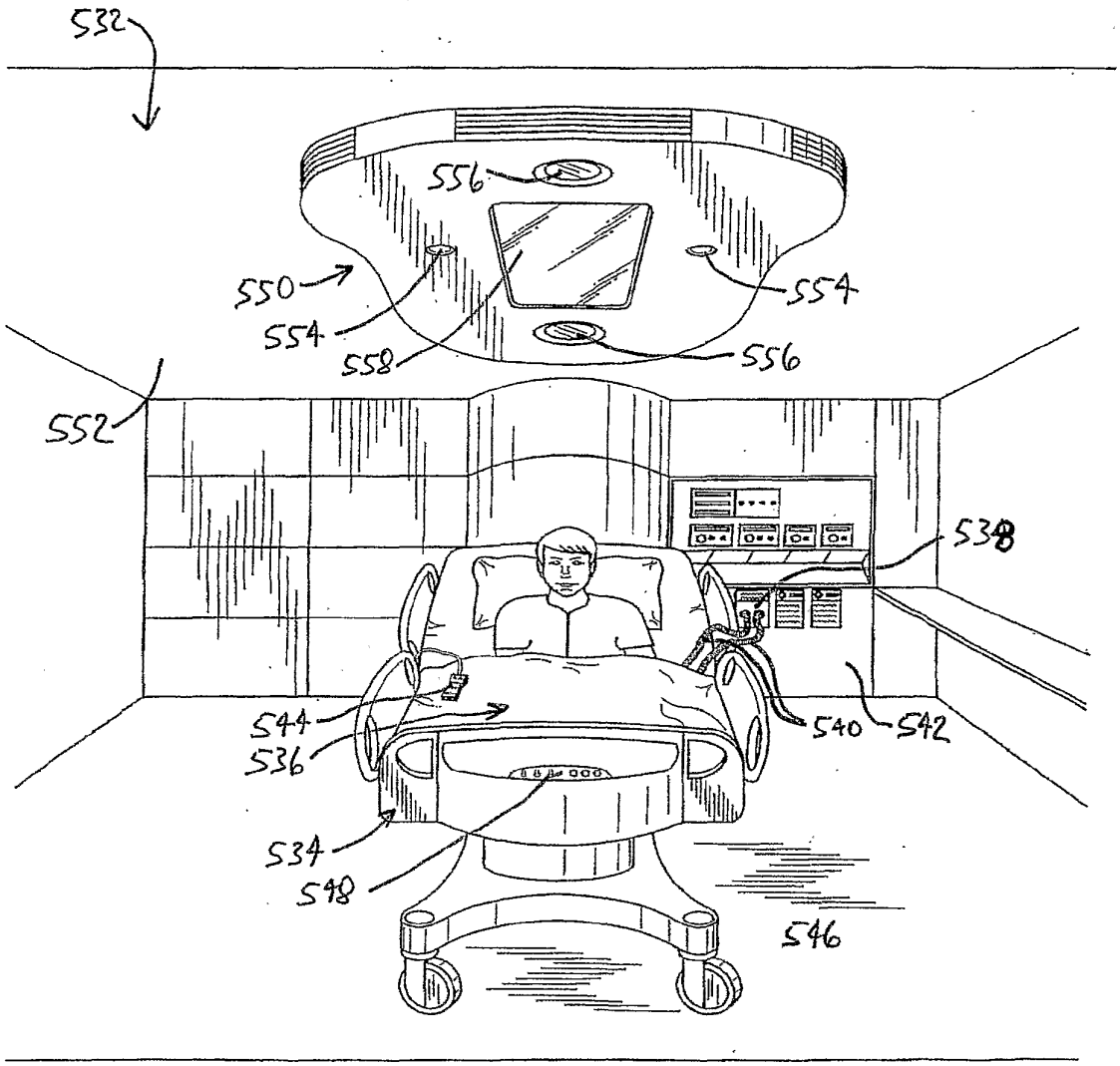

Fig. 17

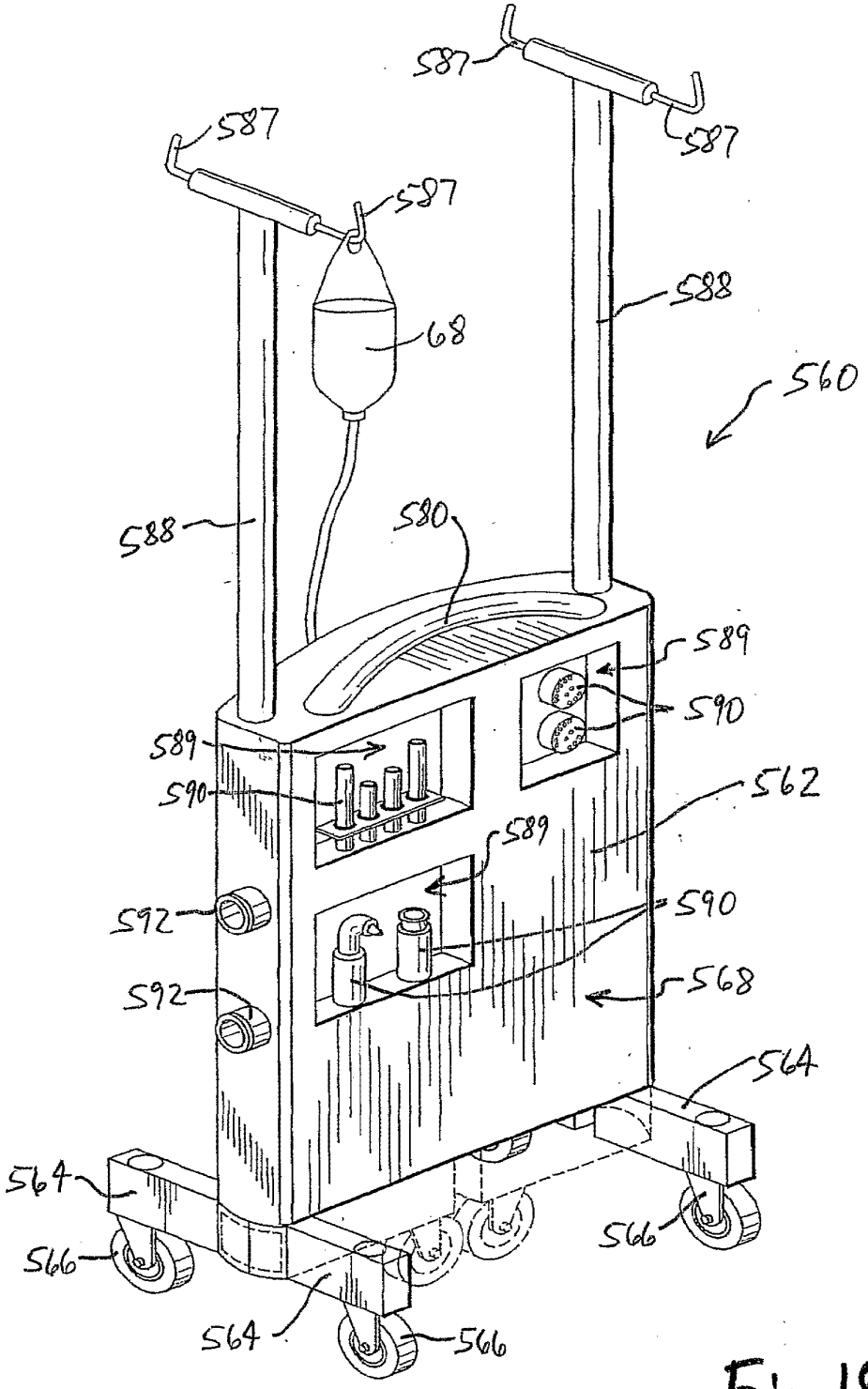
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Fig. 18

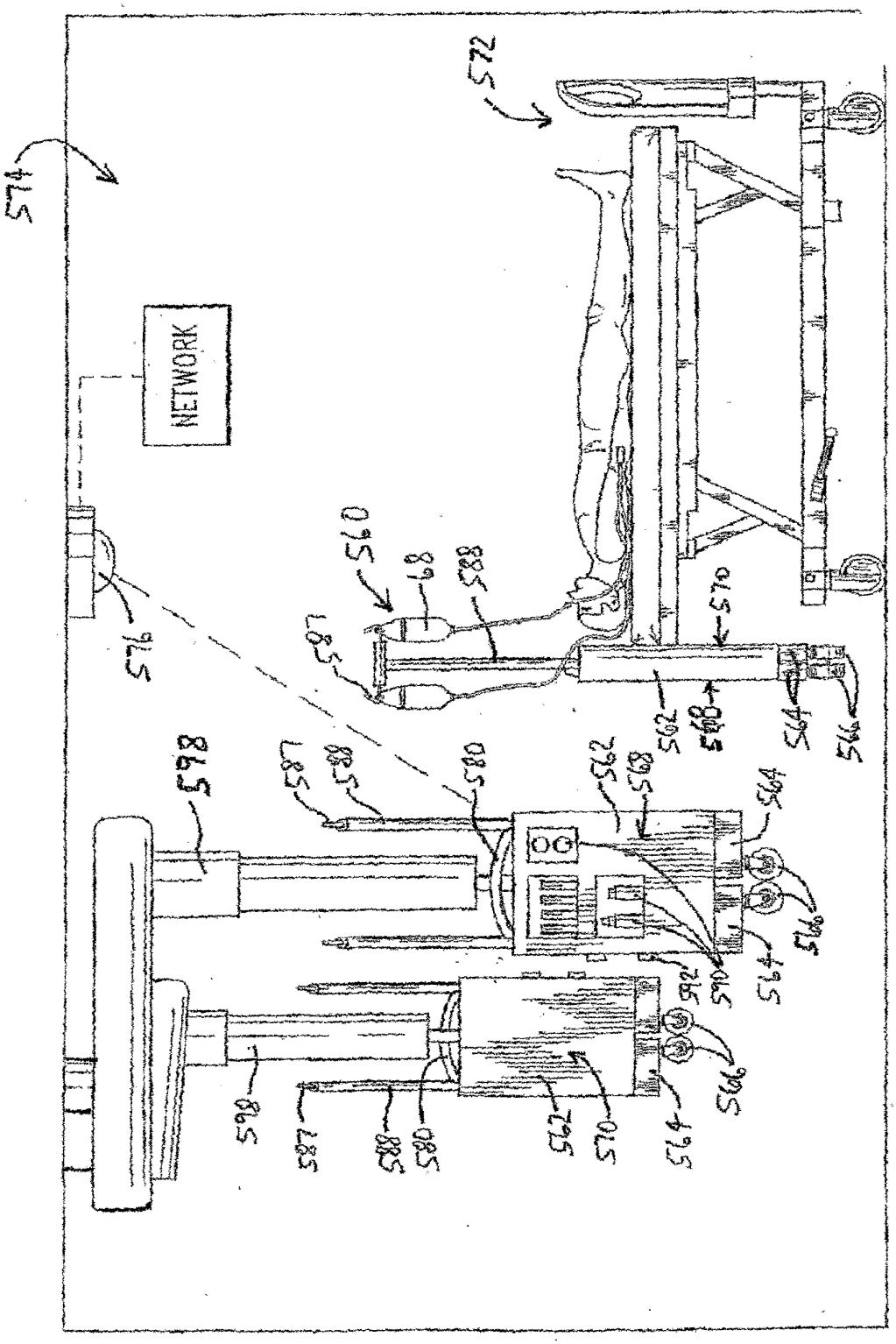
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Fig. 19

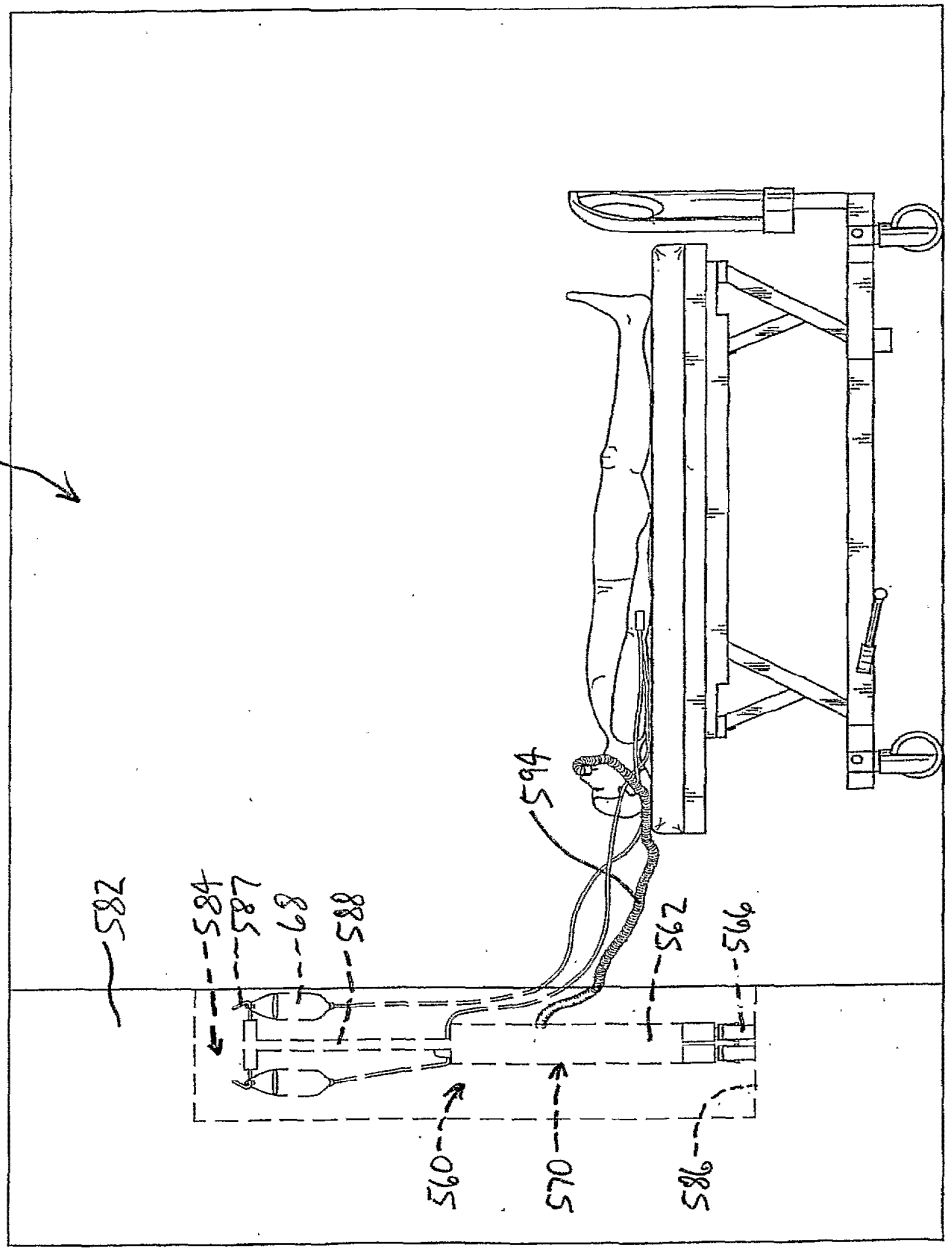

Fig. 20

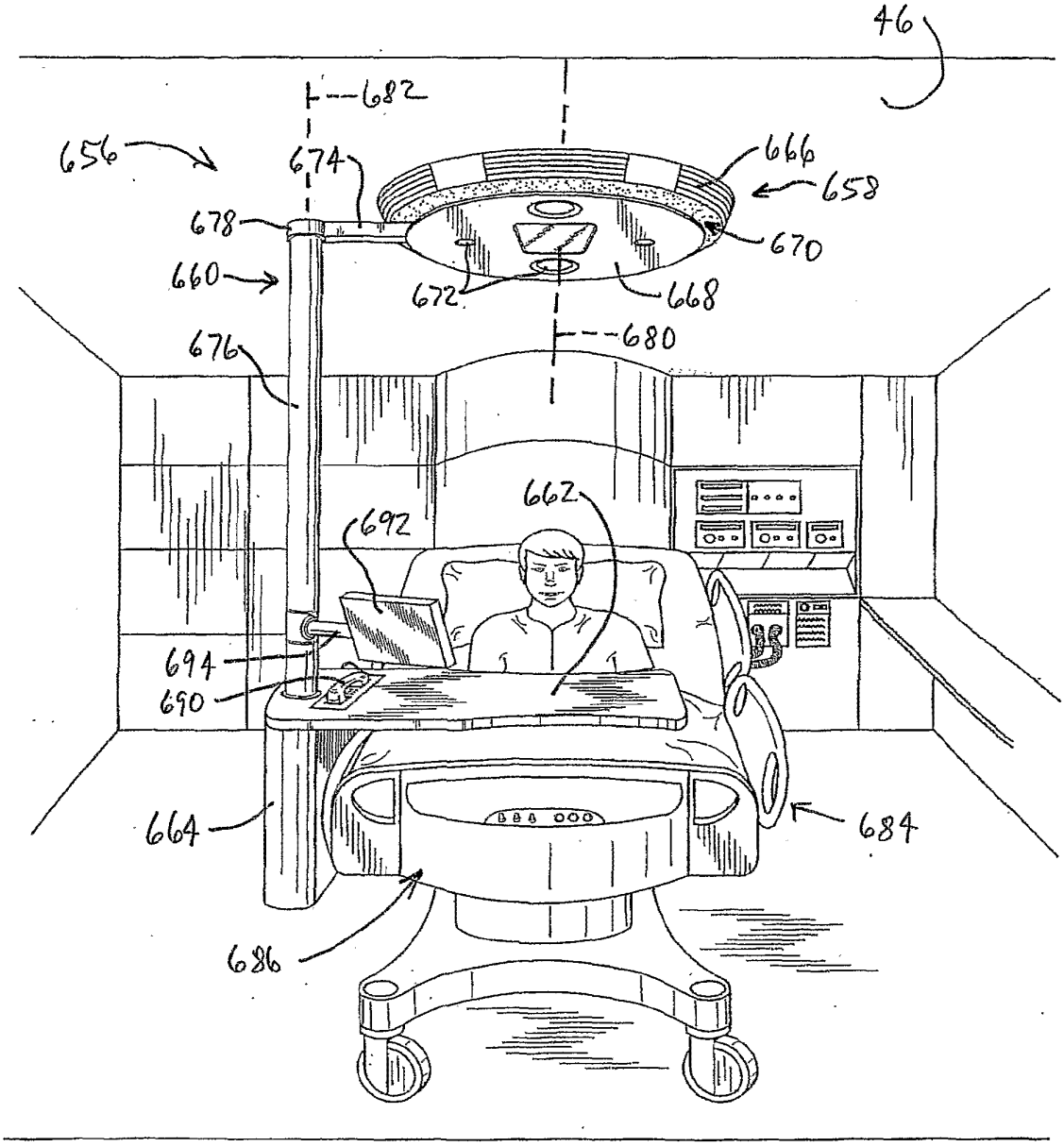
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Fig. 21

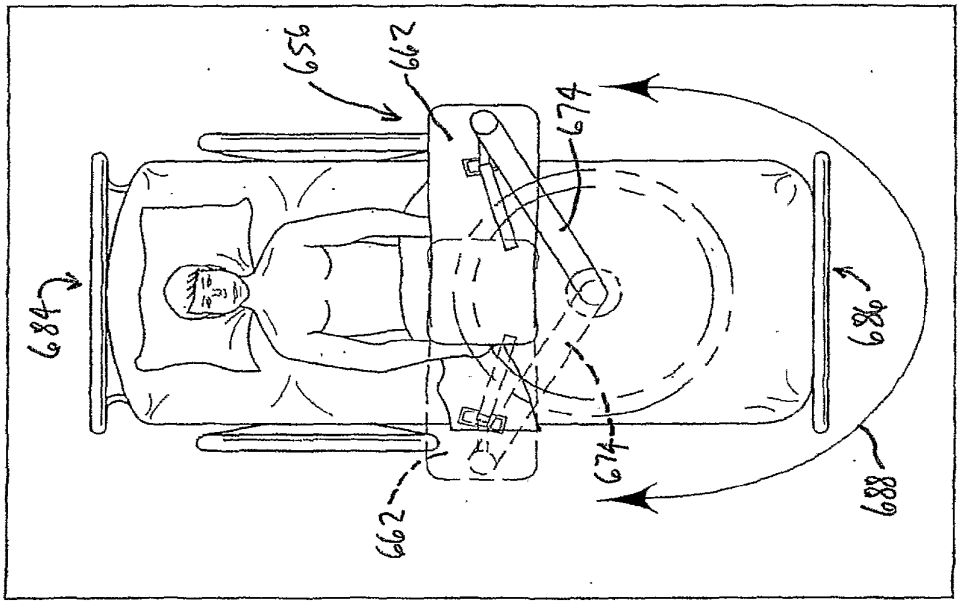
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Fig. 23

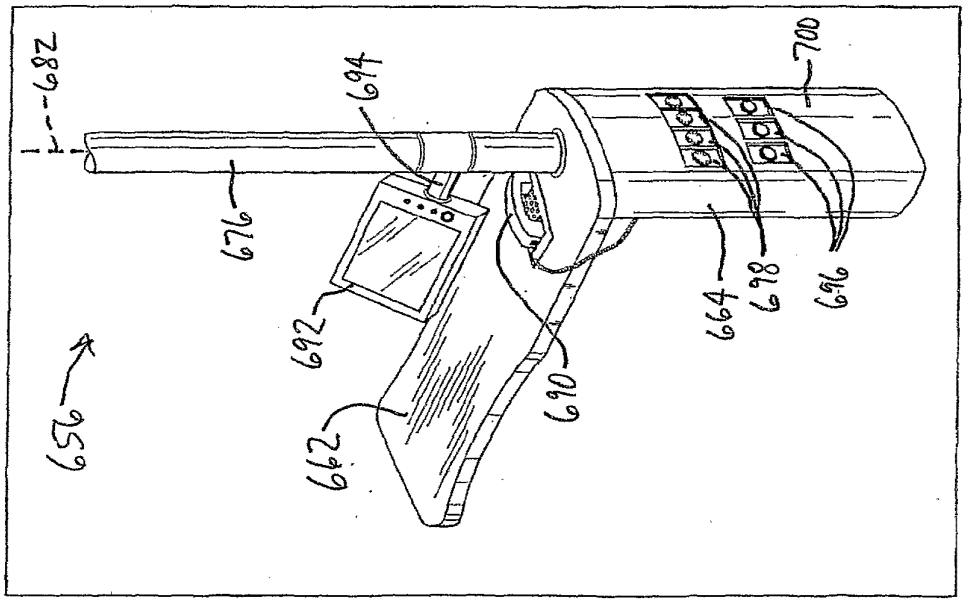
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Fig. 22

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(72) Inventors; and

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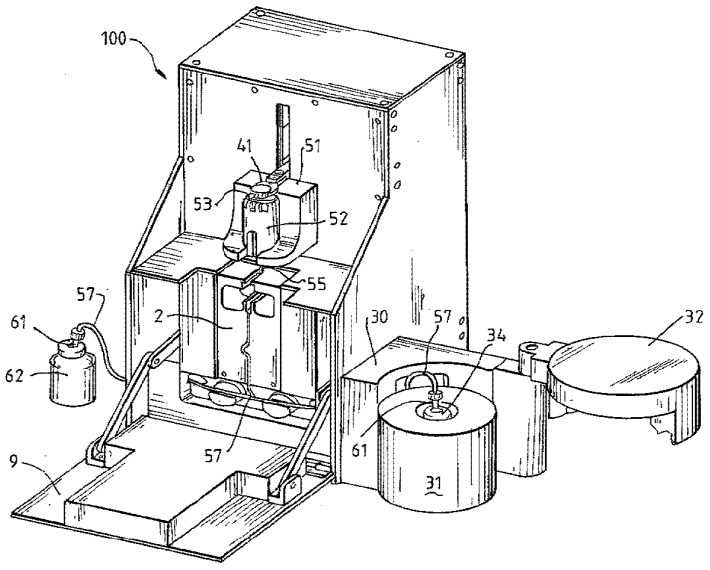
[Continued on next page]

(54) Title: PROCESS AND DEVICE FOR THE DOSE DISPENSING OF A RADIOACTIVE SOLUTION



(57) Abstract: A method of and a device (100) for automatically dispensing radioactive doses by filling a container (53), being a vial or disposable syringe, with a required radioactive dose in a sterile environment, the device (100) being stand alone and radiation shielded. The device (100) further includes control means to accurately dispense and dilute the requested radioactive dose using an on-line radioactivity measurement without any need for knowledge of the volumetric radioactivity of the stock solution.

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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Published:

— *with international search report*

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PROCESS AND DEVICE FOR THE DOSE DISPENSING OF A RADIOACTIVE SOLUTION

Area Of The Invention

This invention relates to apparatus used in nuclear medicine and in particular to a means whereby a radioactive dose required can be provided to a syringe in an automated fashion which obviates the need for a person to actually handle the radioactive material.

Background To The Invention

Radioactive solutions called radiotracers or radiopharmaceuticals, have found applications in various medical fields, in particular in medical diagnostic and therapeutic fields. In recent years the advance of Positron Emission Tomography (PET), which use radionuclides (radioisotopes) of significant higher radiation energy than more conventional nuclear medicine isotopes, has raised some concerns about hand and body radiation exposure received by the persons preparing the dose.

The dangers of ionising radiation are well known and apply to all persons being exposed to radiation, including the staff involved in the preparation of radioactive solutions. Dose fractionation of the radioactive solutions is usually a manual process, performed behind a lead shielded screen to minimal exposure to radiation. However, the performance of this task is time consuming, as the operator needs to withdraw

by successive iterations, small volumes of the radiotracer, until he reaches the targeted dose.

After each withdrawal the needle needs to be re-capped and the syringe placed in a dose calibrator to determine if more or less of the radioactive solution should be processed in or out of the syringe. When the targeted dose has been achieved (within ± 10%), the syringe may be topped up with saline to obtain a reasonable volume.

Before being released or dispatched for clinical use, the syringe is placed again in the dose calibrator to print out the accurate dose record. To date, very little attempt has been made by manufacturers to design automated equipment capable of withdrawing a dedicated radioactive dose into a disposable sterile syringe or vial.

The very few systems currently on the market are expensive and bulky and are not widely available. Other more affordable systems are either not technically practical or do not achieve efficient radiation protection and need to be operated in a shielded environment. In addition, most of these apparatus rely on the pre-requisite knowledge of the volumetric radioactivity (Ci/mL or Bq/mL) of the stock solution to determine the corresponding volume and hence the radioactive dose to be dispensed.

Outline of The Invention

It is an object of this invention to provide an accurate means of automatically dispensing individual doses of a radioactive solution into vials or syringes under

aseptically controlled conditions while minimising the exposure to radiation of an operator which would otherwise be associated with the manipulation of radioactive solutions.

The invention in one aspect is a radioactive dose dispensing device for automatically filling a container with a required radioactive dose in a sterile environment, said device being stand alone and radiation shielded and including control means to control a mix of radioactive stock solution and dilution stock solution, the radioactivity of which mix is monitored by radiation detection means.

The invention in a second aspect is a method of automatically dispensing a dose of a radioactive solution using a software controlled lead shielded device which includes the steps of

- providing the device with a radioactive stock solution and a dilution stock solution
- using a computer software interface to the device to control the dose dispensed automatically into a syringe or vial in the device.

It is preferred that the radioactive dose dispensing device be used for filling a disposable syringe. It is further preferred that a shielded receptacle be provided to receive the syringe.

It is also preferred that a fork shaped arm be provided to actuate the plunger of the disposable shielded syringe. It is further preferred that a high precision linear drive mechanism to move either the syringe or its plunger in a vertical direction.

It is preferred that a customised disposable T shaped tubing assembly be used to provide a sterile fluid pathway. It is further preferred that pinch valves be provided to switch between the radioactive stock solution and the dilution stock solution.

It is also preferred that the automation of the device be controlled by a programmable logic controller (PLC) in association with a radiation detector which monitors on-line the radioactive dose passing through the tubing and being dispensed into the syringe.

It is further preferred that the PLC controls the automation tasks and relevant mathematical calculations for dispensing a requisite dose and that this be operable by computer means with an associated printer although any desired arrangement could be used.

In order that the invention may be more readily understood an embodiment of it will be described herein by way of non limiting example with reference to the accompanying drawings

Brief Description Of The Drawing Figures

Fig. 1 Shows a perspective view of the components of the radioactive dose dispensing device of the invention in its "open" orientation;

Fig. 2 Shows a cross-section though the device of the invention as shown in Figure 1.;

Fig. 3 Shows the pre assembled sterile disposable tubing kit used in the device;

Fig. 4 Shows the device of the invention in its "closed" orientation;

Brief Description of an Embodiment of the Invention

The invention 100 in one embodiment is a device for the automatic filling of disposable syringes with a radioactive solution (radiopharmaceutical) for injection or infusion into a patient.

The device 100 is a stand alone equipment that does not require any additional lead shielding and can be directly used on a bench or inside a conventional, unshielded, laminar flow cabinet.

The device includes a concave lead block 30 and a swinging lead lid 32 designed to accommodate standard lead shielded pots 31 commonly used for the transport of radioactive solutions. It also includes a receptacle 51 that can accommodate various shapes of commercially available tungsten syringe shields and provides an easy and safe installation of the syringe shield 52.

The device further includes a fork-shape arm 41 that can hold or release the plunger of the syringe and an electro-actuator that can link the linear drive 36 to the receptacle 51, and drive up/down the syringe and its needle 55 to pierce the Luer Slip Injection Site 59.

The device provides a permanent link between the linear drive 36 and the fork-shape arm 41 and allows both the radioactive solution and the diluting solution to be drawn at a constant fluid flow rate through the tubing and into the syringe.

The Luer Slip Injection Site 59 is attached to the upper tubing assembly and two Luer-lock fittings 61 (with needles) are attached to the lower tubes assembly (see Fig.3 for view of the pre-assembled sterile disposable kit).

The tubing assembly is held in its appropriate position by a small groove and a dedicated shaped recess 2 to accurately position the Luer Slip Injection Site 59, in regard to the needle 55.

The device is provided with both radioactive and diluting stock solutions which are dispensed from their respective vials 34 and 62, up to the syringe by passing through a disposable, sterile and non-pyrogenic fluid pathway with the radioactive amount controlled by a radiation detector 63, which in this embodiment of the invention is a Geiger-Muller tube or PIN photodiode and located behind a portion of the tube assembly leading to the injection site (behind the plate holder 2).

The device is automated via a programmable PLC and is connected to a computer serving as a user interface, and preferably is provided with a printer to print the syringe or vial label showing the activity, date, time, batch, patient name, etc. or whatever may be required.

The dispensing of the radioactive dose is done on-line by measuring the true amount of radioactivity passing in front of the radiation detector 63 and the total volume required into the syringe is automatically adjusted by dilution.

The device also includes a safety cross-evaluation of the delivered radioactive dose which is automatically performed using the traditional volumetric dispensing method, and the volumetric method can also be used as the main dispensing method.

It is further envisaged that the device of the invention may include a built-in sterile air flow, designed to allow the device to be operated on a bench in a conventional room but still maintaining full compliance with a 3.5 class (A class) dispensing environment, characterized by a sterile air flow directed towards the Luer Slip Injection Site 59 and needle 55.

It is also envisaged that in another embodiment of the invention a sterile disposable double check-valve could be located between the syringe 53 and needle 55, or underneath the Luer Slip Injection Site 59 to allow the transfer of an accurate dose of radioactive solution through a tube, to externally located vials or containers.

Operation of the device

When the device is being operated the user opens the door 9 of the device and installs a new tubing kit 57 onto the tubing holder 2. The Luer Slip Injection Site 59 attached to the upper T-shape tube is slid into the appropriate recess and both needles 61 attached to the lower T-shape tubes are fed through each lead channel and connected to the radioactive stock solution 34 and the dilution stock solution 62.

The user then rotates the lid 32 and closes the door 9 and introduces a disposable syringe 53 with its appropriate needle 55 into a tungsten syringe shield 52. At this point the needle is un-capped and the tungsten syringe shield is placed onto the receptacle 51 on the front face of the device. The operator then enters on the computer the requested radioactive dose and total volume.

The device lowers the receptacle 51 enabling the syringe to pierce the Luer Slip Injection Site with the needle. The filling sequence will automatically dispense the desired radioactive dose into the syringe and dilute it to match the requested volume by actuation of the syringe plunger. Once the syringe has been filled (less than one minute), the syringe and syringe shield are lifted away from the Luer Slip Injection Site, and the syringe and syringe shield is removed from the device and needle re-capped. At the end of the process, a syringe label is printed with the appropriate dose data.

Summary of the embodiment of invention

Traditionally the accurate knowledge of the volumetric radioactivity (specific activity: Ci/mL or Bq/mL) of a radioactive stock solution is required for the accurate dispensing of any radioactive dose.

For example, a dose of 3mCi (111MBq) of a radioactive solution with a volumetric radioactivity of 50 mCi/mL (1850MBq/mL) will be precisely achieved by dispensing a volume of 0.06mL. However, volumetric radioactivity of solutions is not always determined with great accuracy at the time of the manufacturing of the product, and post measurement of the volumetric radioactivity at the customer site is regarded as a critical operation.

The invention has the novel feature in that it can accurately dispense a requested radioactive dose without any knowledge of the volumetric radioactivity of the stock solution by an on-line radioactivity measurement and without exposing an operator to the radiation.

In the invention, a radiation detector 63 being a Geiger-Muller tube, a PIN photodiode or other fast measuring device is located behind a portion of the tubing leading to the injection site 59 and then to the syringe 53. The radiation detector continuously monitors the radioactive dose passing through the tube and into the syringe at a very constant liquid flow rate and the PLC 11 determines the appropriate switching sequence of the valves to dispense the requested dose and volume.

The program also calculates online the corresponding radioactivity contained in the dead volume of the tubing which will be inevitably added-on during the dilution phase of the syringe filling. That corresponding radioactivity is subtracted from the required dose by the PLC 11 to identify the amount of radioactivity allowed to pass the radiation detector 63. At the end of the filling process, the sum of the amount of activity allowed to pass by the detector before the dilution phase and the resultant activity gained during the dilution phase due to the dead volume of the tubing kit, translates to the required dose.

Below is the formula used to determine how much of the stock solution needs to be drawn-up into the syringe to achieve the desired dose (this calculation is performed continuously during the filling process):

Let RD = Requested dose

ADV = Activity contained in the dead volume of the tubing

RMT = Radioactivity measured passing through the tubing

VA = Volumetric activity of the stock solution

DV = Dead volume of the tubing

SA = Volumetric radioactivity

VSW = Volume of stock solution withdrawn from vial

Therefore the radioactive amount of stock solution to draw-up into syringe:

= RD – ADV

= RD – (DV x SA)

$$= RD - (DV \times (RMT/(VSW-DV))$$

Using the above method of filling a syringe with a radioactive solution, it is not necessary to know the specific activity of the stock solution prior to the filling process, as it is calculated during the filling process.

The accuracy of the dose dispensed is a function of the volumetric radioactivity of the radioactive stock solution, and experiments have shown accuracy better than 5% for volumetric radioactivity in the range of 0-50 mCi/mL (0-1850MBq/mL) and better than 10% for volumetric radioactivity in the range of 50-100 mCi/mL (0-3700MBq/mL).

The invention lies in an automated means of preparing a dose of a radiopharmaceutical into a disposable syringe under computer control by means of a radiation detector to determine the radioactive dosage and dilution by a non radioactive solution to achieve a desired volume. By this means such a dose can be prepared without unnecessary radiation exposure occurring to the person preparing the dose.

The precise components of the apparatus of the invention may be varied provided they achieve the method of the invention as described. It is further envisaged that other embodiments of the invention will exhibit any number of and any combination of the features of those previously described and whilst we have described herein one specific embodiment of the invention it is to be understood that variations and modifications in this can be made without departing from the spirit and scope thereof.

The claims defining the invention are as follows:

1. A radioactive dose dispensing device for automatically filling a container with a required radioactive dose in a sterile environment, said device being stand alone and radiation shielded and including control means to control a mix of radioactive stock solution and dilution stock solution, the radioactivity of which mix is monitored by radiation detection means.

2. A radioactive dose dispensing device as claimed in claim 1 wherein the container is a plunger operated disposable syringe.

3. A radioactive dose dispensing device as claimed in claim 2 wherein a shielded receptacle is provided in the device to receive the syringe.

4. A radioactive dose dispensing device as claimed in claim 3 wherein drive means are provided to actuate the plunger of the syringe.

5. A radioactive dose dispensing device as claimed in claim 4 wherein the drive means is a linear drive mechanism adapted to move either the syringe or its plunger relative to one and other.

6. A radioactive dose dispenser device as claimed in any one of claims 1 to 5 wherein a disposable tubing assembly is used to provide a sterile fluid pathway for the stock solutions.

7. A radioactive dose dispenser device as claimed in claim 6 wherein pinch valves are provided to switch between the radioactive stock solution and the dilution stock solution.

8. A radioactive dose dispenser device as claimed in any one of claims 1 to 7 wherein the automation of the device and its calculation of a requisite dose is controlled by a programmable logic controller (PLC) in association with a radiation detector which controls the radioactive dose passing through the tubing and being dispensed into the syringe.

9. A radioactive dose dispenser device as claimed in claim 8 wherein the device and its PLC are operable by means of a computer interface.

10. A method of automatically dispensing a dose of a radioactive solution using a software controlled lead shielded device which includes the steps of

- providing the device with a radioactive stock solution and a dilution stock solution
- using a computer software interface to the device to control the dose dispensed automatically into a syringe or vial in the device.

FIG. 1.

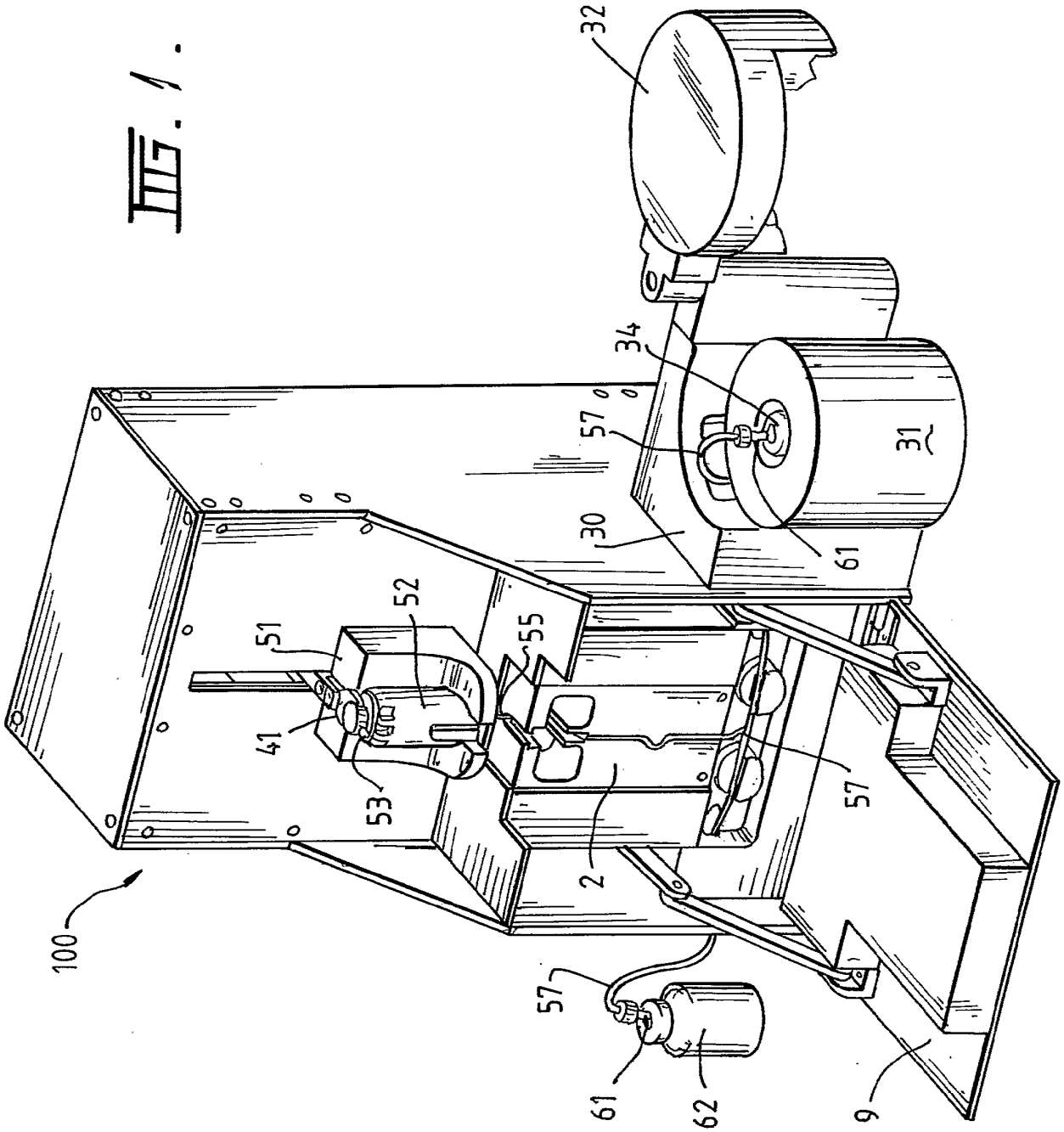
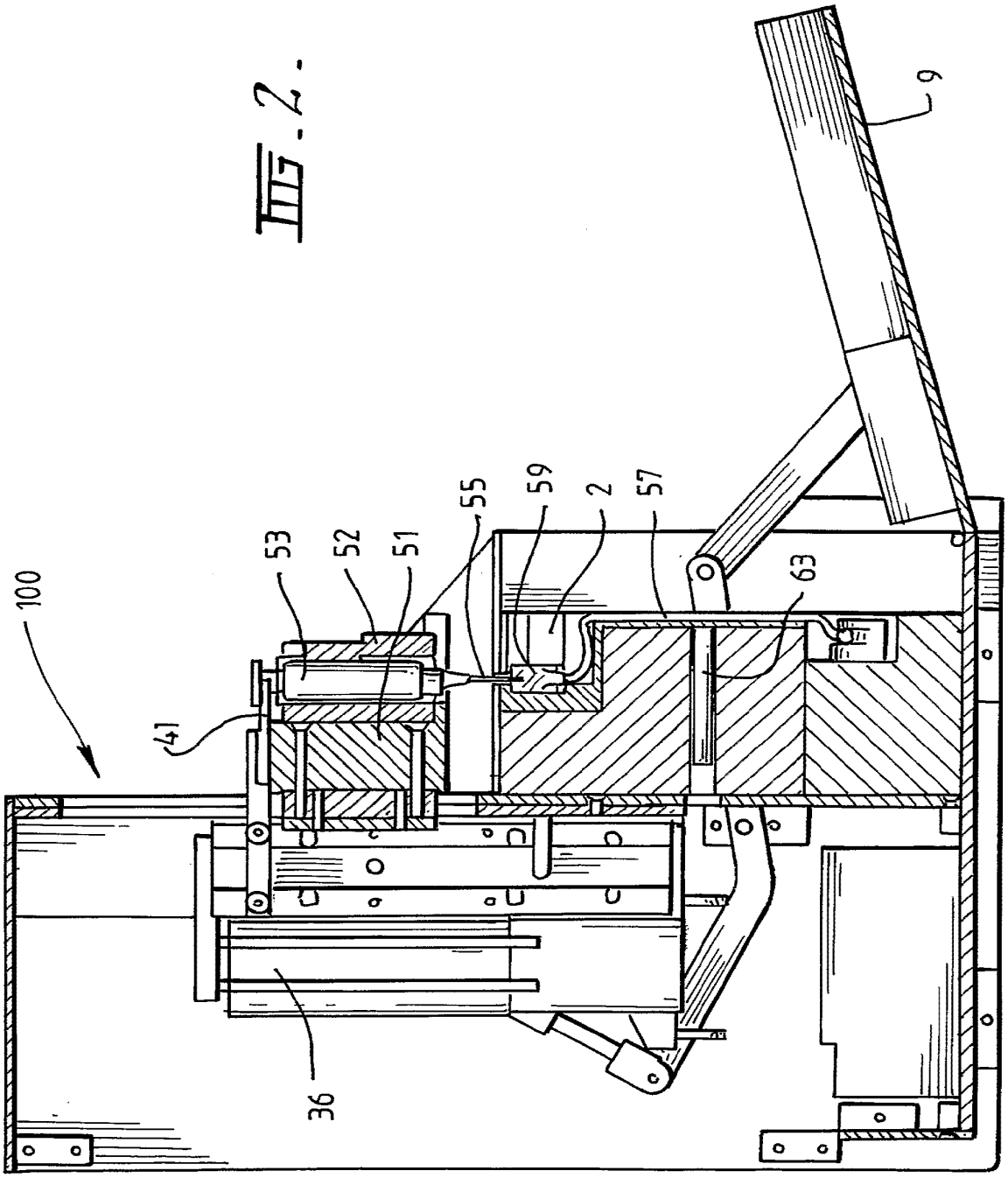


Fig. 2.



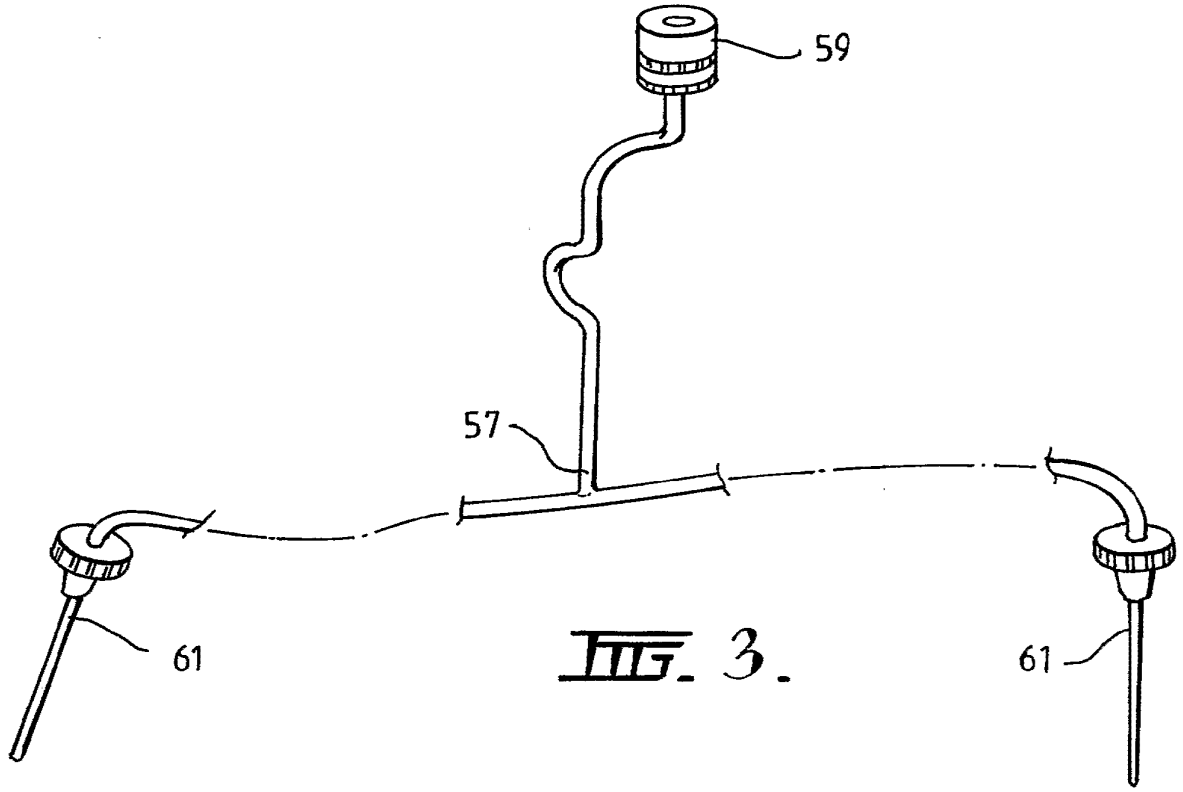


FIG. 3.

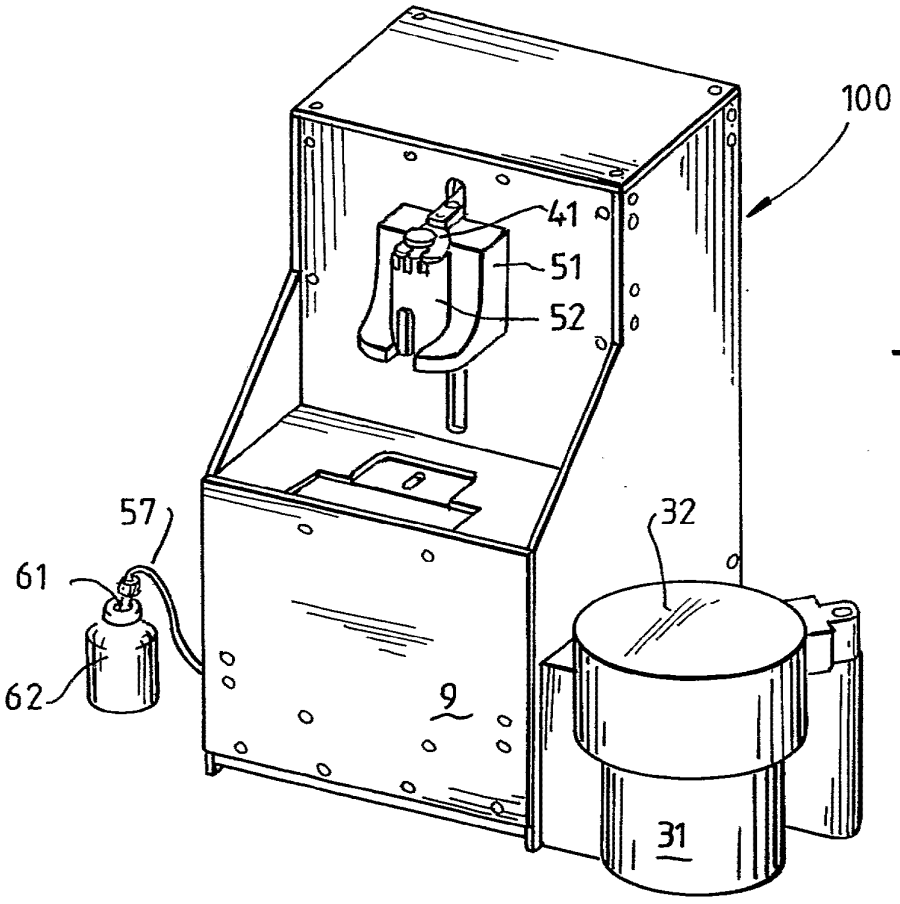


FIG. 4.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: B65B 3/30

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)
See below under "Electronic database consulted"

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: IPC : B65B 3/- with keywords: radioactive, nuclear

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5911252A (CASSEL) 15 June 1999	
X	The whole document	10
Y	The whole document	1-9
	US 4041994A (HORWITZ et al.) 16 August 1977	
Y	The whole document	1-9
A	US 4662231A (SCHAARSCHMIDT et al.) 5 May 1987	1-10
A	GB 1415804A (COMMISSARIAT A L'ENERGIE ATOMIQUE) 26 November 1975	1-10

☐ 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
22 July 2004

Date of mailing of the international search report
- 3 AUG 2004

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

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

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

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

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

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

Box 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:
See the Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-9 is directed to a radioactive dose dispensing device including control means to control a mix of radioactive stock solution and dilution solution. It is considered that the monitoring the radioactivity of a mix by radiation detection means comprises a first "special technical feature".

2. Claim 10 is directed to a method of automatically dispensing a dose of radioactive solution. It is considered that the steps providing the device with a radioactive stock solution and dilution solution and using a computer software interface to control the dispensed dose comprises a second "special technical feature".

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is controlling a mix of radioactive stock solution and dilution solution in a dispensing device. However this concept is not novel in the light of US 5911252A. Therefore these claims lack unity a posteriori.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5911252						
US	4041994						
US	4662231	BE	900719	BE	902407	BR	8405970
		BR	8505220	DE	3342470	DE	3438303
		FR	2555746	FR	2572179	GB	2151780
		GB	2167736	JP	60179624	JP	61099836
		US	4665758				
GB	1415804	BE	805777	CH	576845	FR	2205038

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
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PCT

(10) International Publication Number
WO 2006/007750 A1

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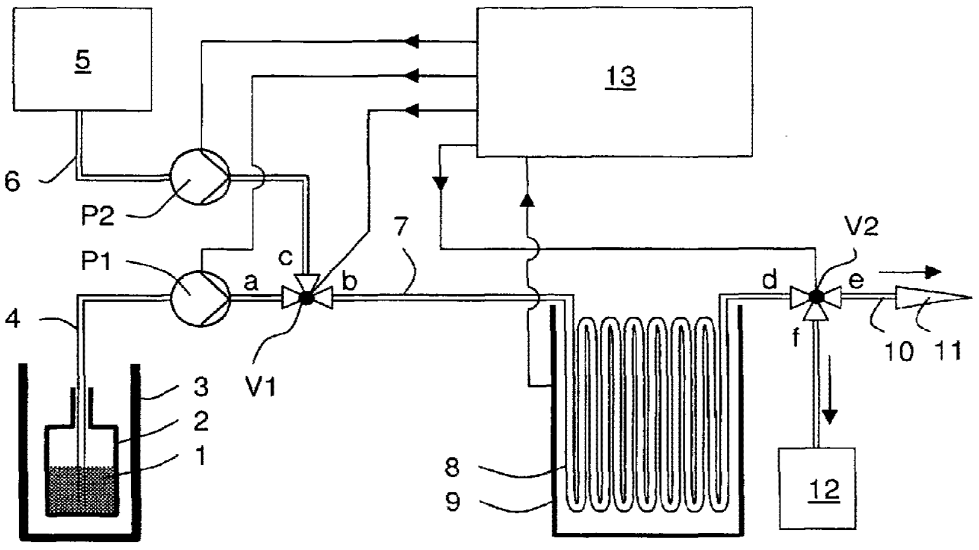
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK,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

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

Published:
— *with international search report*

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

(54) **Title:** METHOD AND DEVICE FOR ACCURATE DISPENSING OF RADIOACTIVITY



(57) **Abstract:** A device and a method for accurate and remote dispensing of a radioactive liquid are disclosed. A source of a radioactive liquid (1) and a source of a flushing liquid (5) are selectively connected to a fluid delivery path (7, 8, 10) by way of valve means (V1). An activity metering unit (9) is operable to determine a level of radioactivity in a metering section (8) of the fluid delivery path downstream from the valve means (V1). The device is operated by transporting a first amount of radioactive liquid (1) to the metering section (8), using the activity metering unit (9) to measure a reference level of radioactivity, calculating a second amount of the radioactive liquid still to be delivered such that the first and second amounts of radioactive liquid together have some predetermined level of radioactivity, and delivering the first and second amounts of radioactive liquid to the destination (11).

WO 2006/007750 A1

Method and device for accurate dispensing of radioactivity

Background of the invention

The present invention relates to a device and a method for dispensing a radioactive liquid to a destination. In particular, the invention relates to the problem of accurately dispensing a well-determined dose of radioactivity, e.g., for injection to a living body.

In a number of medical applications, it is necessary to deliver a radiopharmaceutical containing a radionuclide to a patient. Due to the ionizing radiation emitted by the radionuclide, such pharmaceuticals pose a danger to both the patient and the personnel administering the radiopharmaceutical if not handled properly.

Examples for diagnostic uses of radiopharmaceuticals include positron emission tomography (PET) and single-photon emission computerized tomography (SPECT). In these methods, a patient is injected a dose of a radiopharmaceutical which can be absorbed by certain cells in the brain or in other organs. The concentration of the accumulated radiopharmaceutical in a specific body part will often depend on factors of diagnostic interest, such as cell metabolism or other physiological or biochemical processes. Thus, such processes can be imaged in a non-invasive fashion by determining the spatio-temporal distribution of radioactivity within the body part of interest. In PET, this is achieved by monitoring pairs of temporally coincident gamma rays emitted in opposite directions resulting from the annihilation of positrons, which are emitted through beta-plus decays of the (proton-rich) radionuclide. The most common radionuclides (radioisotopes) for use

with PET are ^{15}O, ^{18}F, ^{11}C, ^{13}N and ^{82}Rb. Radiopharmaceuticals of interest for PET include, but are not limited to, substances like [^{15}O]-H_2O, [^{18}F]-fluorodeoxyglucose ([^{18}F]-FDG), [^{18}F]-fluoromisonidazole ([^{18}F]-FMISO), [^{11}C]-labeled amino acids, [^{13}N]-ammonia etc.

The most common therapeutic uses of radiopharmaceuticals are the ^{131}I therapies in thyroid diseases.

In these applications, it is desirable to administer an exactly determined dose of radiopharmaceutical to the body. Often the radiopharmaceutical is delivered in a vial from which it has to be dispensed into individual patient doses. In many centers this is a manual process done by the technical personnel. Since the concentration of the radiopharmaceutical in the vial can be very high, the manual dispensing is associated with considerable radiation burden to the hands. Furthermore the accuracy of the manual dispensing is limited and dependent on the experience of the person in charge.

As an example, U.S. patent No. 4,410,108 discloses a syringe shield equipped with a radiation detector. A liquid radiopharmaceutical is drawn from a vial into the barrel of a syringe placed within the syringe shield, while the level of radioactivity within the barrel is monitored by the radiation detector. In this way, an aliquot of the radiopharmaceutical having exactly the required dose of radioactivity can be drawn into the syringe. Subsequently, the syringe with its shield is manually removed from the vial, and the radiopharmaceutical is injected to the patient. This device is unsatisfactory in requiring manual transfer of the syringe after it has been filled with the radiopharmaceutical, as this may expose the personnel handling the syringe to ionizing radiation. Although the half-life of the radiopharmaceutical is usually rather short and the applied dosages are themselves not harmful, constant and repeated exposure over an extended period of time can be harmful.

A number of techniques have been proposed to reduce exposure by minimizing the time of exposure of personnel, by maintaining distance between personnel and the source of radiation, and by shielding personnel from the source of radiation. As

an example, European patent application EP 0 486 283 discloses a system for delivering $H_2{}^{15}O$. A collection bottle is filled with saline, then a fluid stream comprising $H_2{}^{15}O$ is passed through the collection bottle while the activity in this bottle is monitored by a radiation detector. When a desired level of radiation is reached, the liquid in the bottle is transferred to a motor-driven syringe and then injected to the patient body. U.S. patent application publication No. 2003/0004463 also discloses a system for dispensing a radiopharmaceutical in a remote fashion, without the need of manual intervention. The radiopharmaceutical is drawn from a vial into a syringe surrounded by a radiation detector, and the level of radioactivity in the syringe is determined. Through specially adapted tubing and valves, the radiopharmaceutical is subsequently delivered to a patient without the need of moving the syringe to another location.

While these systems obviate the need of manual handling of a syringe, they tend to be imprecise in situations where small amounts of radioactive liquid, possibly with a very high concentration of activity, need to be handled, due to the presence of dead volumes. By the way of example, the radiopharmaceutical may come in a vial at an activity concentration of 2 GBq/ml (one billion Becquerels per milliliter). If the required activity for injection to the patient is, say, 100 MBq, a volume of just 50 microliters needs to be transferred from the vial to the patient. Such small amounts of liquid are difficult to handle with the systems of the prior art.

U.S. patents No. 4,562,829 and 4,585,009 disclose strontium-rubidium infusion systems equipped with an in-line radiation detector. A radiopharmaceutical exiting a strontium-rubidium generator flows past the radiation detector, which monitors the activity of the radiopharmaceutical in passing. From there, the radiopharmaceutical is either administered to a patient or is sent to waste. In U.S. patent No. 4,409,966, a flow of patient blood is shunted through a radiation detector during injection of the radiopharmaceutical, and the level of radioactivity in the blood is monitored. Also with such systems, it is difficult to administer an exactly determined dose, especially for concentrated radiopharmaceuticals with high specific activities, as the volume of the tubing already may exceed the desired volume to be injected.

Summary of the invention

It is therefore an object of the invention to provide a device which is capable of accurately dispensing a desired level of radioactivity in a liquid, and which may be operated remotely. This object is achieved by a device with the features of claim 1.

Thus, according to the invention, a source of a radioactive liquid and a source of a flushing liquid can be selectively connected to a fluid delivery path by way of valve means. An activity metering unit is operable to determine a level of radioactivity in a metering section of the fluid delivery path downstream from the valve means. In this way, it is possible to provide some amount, even a very small amount, of the radioactive liquid to a section of the fluid delivery path adjacent to the valve means. The flushing liquid can then be used to flush this amount of radioactive liquid to the metering section, where its activity can be determined and further steps to be taken can be decided based on this determination of activity. By use of valve means adapted for remote control (e.g. an electromagnetically or pneumatically operated valve), operation of the inventive device can be performed remotely.

It is a further object of the present invention to provide a method of operation of such a device. This object is achieved by a method with the features of claim 7.

Thus, according to the invention, the device is operated by transporting a first amount of radioactive liquid to the metering section, using the activity metering unit to measure a reference level of radioactivity, calculating a second amount of the radioactive liquid still to be delivered such that the first and second amounts of radioactive liquid together have some predetermined level of radioactivity, and delivering the first and second amounts of radioactive liquid to the destination. In this way, it is possible to deliver an exactly known level of radioactivity to the destination, independent of the activity concentration of the radioactive liquid. Preferably, the first amount of radioactive liquid is between 20% and 80% of the sum of the first and second amounts of radioactive liquid, more preferably between 30% and 70%, most preferably between 40% and 60%. In this way, high precision can be achieved.

In an advantageous embodiment of the inventive device, the device additionally comprises a control unit. The unit receives signals from the activity metering unit and controls operation of the valve means between at least two states. In the first state, the source of radioactive liquid is connected to the fluid delivery path for flow of the radioactive liquid into the fluid delivery path. In the second state, the source of flushing liquid is connected to the fluid delivery path for flow of flushing liquid into the fluid delivery path. If any other actively driven components are present in the device, such as additional valves or pumps, they may also be controlled by the control unit.

Advantageously, second valve means are provided downstream from the metering section for directing flow in the fluid delivery path either to the destination or to a waste reservoir. In this way it is avoided that the destination receives excessive amounts of flushing liquid during operation of the device, and in case of malfunctioning of components of the device, the radioactive liquid can be dumped to the waste reservoir.

Advantageously, a first and/or a second pump are provided for pumping the radioactive liquid or the flushing liquid, respectively, through the first valve means and into the fluid delivery path. Preferably, the first pump and/or the second pump is operable to receive a control signal and to deliver a predetermined volume of liquid based on the control signal. In this way, exactly known amounts (volumes) of the radioactive liquid and/or of the flushing liquid can be dispensed to the fluid delivery path.

The fluid delivery path may comprise a fill-in section extending from the first valve means to the metering section. Advantageously, the metering section is capable of holding a fluid volume which is at least three times, more preferably at least five times the volume of the fill-in section. This enables the metering section to hold at least two, preferably three, fractions of radioactive liquid, each with a volume up to the volume of the fill-in section, plus the flushing liquid required to flush these fractions into the metering section. Thereby, the total activity of two, preferably three,

fractions of radioactive liquid may be determined in a single measurement by the activity metering unit.

Advantageously, the device is adapted for delivering a radiopharmaceutical for injection to a living body (i.e., for delivering the radiopharmaceutical to an injection needle). This encompasses, among other things, the use of compatible materials, which must be resistant to the radiopharmaceutical and the flushing liquid (usually saline solution in this case), and which must be able to withstand sterilization procedures. Such materials are well known.

As used herein, the term "pharmaceutical" refers to any substance to be injected or otherwise delivered into the body (either human or animal) in a medical procedure and includes, but is not limited to, substances used in imaging procedures and therapeutic substances. The term "radiopharmaceutical" refers to any pharmaceutical emitting ionising radiation by radioactive decay.

Further advantageous embodiments of the invention are laid down in the dependent claims. In particular, the inventive method may comprise an additional initialization procedure, in which an offset amount of radioactive liquid is transported to the metering section, an offset level of radioactivity is determined, and the predetermined level of radioactivity for the main procedure is determined from this offset level and a desired level of radioactivity to be dispensed.

Brief description of the drawings

The invention will be described in more detail in connection with an exemplary embodiment illustrated in the drawings, in which

Fig. 1 shows a schematic and simplified illustration of a device according to the present invention;

Fig. 2 shows a schematic and simplified illustration of a dose calibrator;

Fig. 3A and 3B show simplified illustrations of a pinch valve;

Fig. 4 illustrates a first state of operation of the device of Fig. 1;

Fig. 5 illustrates a second state of operation of the device of Fig. 1;

Fig. 6 illustrates a third state of operation of the device of Fig. 1;

Fig. 7 illustrates a fourth state of operation of the device of Fig. 1;

Fig. 8 illustrates a fifth state of operation of the device of Fig. 1;

Fig. 9 shows a flow diagram of a process according to the present invention; and

Fig. 10 illustrates the levels of activities measured in various stages of the process of Fig. 9.

Detailed description of the invention

Fig. 1 shows, in a highly schematic manner, a device for dispensing a radioactive liquid according to a preferred embodiment of the present invention. The device is designed for dispensing a radiopharmaceutical for injection to a patient.

The radiopharmaceutical 1 is provided in a vial 2. In order to protect the surroundings from radioactivity originating from the vial 2, the vial 2 is placed inside a shield 3. Suitable vials and shields for various kinds of radiopharmaceuticals are well known in the art and are available commercially.

A section 4 of tubing, comprising a needle at its end for puncturing a septum closing off vial 2, extends from the inside of vial 2 through a first peristaltic precision pump P1 and to a first three-way pinch valve V1. At its first port "a", the valve V1 is connected to the section 4 of tubing from the vial 2; at its second port "b", it is connected to a section of tubing 7 extending from the valve V1 to an activity metering unit 9 (in the following shortly called a "dose calibrator"). The third port "c" is connected to a section 6 of tubing leading from a saline reservoir 5 through a second peristaltic precision pump P2 to the valve V1. The valve V1 is operable to connect port "a" with port "b" or to connect port "c" with port "b".

Fig. 3A and 3B illustrate, in a highly schematic manner, the mode of operation of the pinch valve V1 as advantageously used in the present embodiment. A sliding element 31 can be moved up or down, pressing either on an upper or on a lower section of flexible tubing which is passed through the pinch valve. Thereby, either port "c" or port "a" is closed off from port "b", and the other port is connected to port "b". The sliding element 31 may, e.g., be operated electromechanically or

pneumatically. A similar pinch valve is used as valve V2. Such pinch valves are advantageous because no moving parts get into contact with the liquid within the tubing. Thus the valve cannot get contaminated by radioactive liquid possibly present in the tubing.

The pumps P1 and P2 are preferably peristaltic precision pumps. In a peristaltic pump, a section of flexible tubing is passed through the pump unit. Fluid is forced along the tubing by waves of contraction produced mechanically on the flexible tubing. Peristaltic pumps offer the advantage that the liquid is always contained in the tubing, and no moving parts get into contact with the liquid to be delivered. Thus the pump itself cannot be contaminated by radioactive liquid present in the tubing. By the use of peristaltic pumps and pinch valves, the connections from the saline reservoir 5 to the metering section 7 and from the vial 2 to the metering section 7 may consist of a single piece of flexible tubing each, which can be easily replaced in regular intervals to avoid cross-contamination, without the need to replace the much more expensive pump and valve assemblies themselves.

The section 7 of tubing may be called a "fill-in section". This fill-in section 7 is connected to a section 8 of tubing placed inside the dose calibrator 9, section 8 being called a "metering section". The metering section 8 is relatively long, providing a volume of at least five times the volume of the fill-in section, by having a meander-like shape or, preferably, a coil shape as illustrated for a metering section 8' in Fig. 2. A coil shape is preferred in practice because it minimizes pressure losses during fluid flow. The meander-like shape has been chosen in Figs. 1 and 3-7 for illustrative purposes.

The tubing exits the dose calibrator 9 and connects to the first port "d" of a second three-way valve V2. The second port "e" of this valve is connected to a section 10 of tubing leading to an injection needle 11, only crudely symbolized by a triangle in Fig. 1. The third port "f" of valve V2 leads to a waste reservoir 12. The waste reservoir 12 is preferably shielded, as radioactivity may enter in operation.

The dose calibrator 9 is connected to a controller 13 and provides signals to the

controller 13 which are indicative of the level of activity within the dose calibrator 9. The outputs of the controller 13 are connected to the pumps P1 and P2 as well as to the valves V1 and V2 for control of these.

A method of operation of the device is illustrated in Figs. 4 to 8 and symbolized in a flow diagram in Fig. 9. Operation can generally be divided into five phases: in an initialisation phase 910, the device is brought into a well-defined initial state. In a calibration phase 920, steps are performed for calibrating the radioactivity in vial 2. In a delivery phase 930, the radiopharmaceutical is delivered to the destination. In a step 940, it is decided whether another injection shall be performed. If yes, operation will continue again with the calibration phase 920; if not, a shutdown phase 950 will follow.

Before starting the operation, the operator will have to determine two quantities: the desired activity Ar to be injected to the patient, and the estimated concentration of activity in the vial (activity per unit of volume, e.g., expressed in MBq/ml), Cv. These data are provided to the controller 13. Operation then starts with the initialisation period 910.

The initialisation period 910 comprises the following steps:

Step 911 (Initial filling of radiopharmaceutical to point C): In a first step, the complete tubing is filled with saline, thereby excluding air from the tubing system. For this, valve V1 is switched into a state connecting ports "c" and "b", while valve V2 connects "d" and "e". Pump P2 flushes saline up to point B (cf. Fig. 4). Then the tubing section 4 is inserted into a vial containing saline. Valve V1 is brought into a state connecting ports "a" and "b", while valve V2 still connects "d" and "e". Pump P1 now flushes saline until the tubing is completely filled with saline from point A (cf. Fig. 4) to the destination beyond valve V2, and air is thus completely purged from the system. The tubing section 4 is then inserted into the vial 2 containing the radiopharmaceutical. Valve V1 is brought into a state connecting ports "a" and "b", while valve V2 connects ports "d" and "f". Pump P1 is operated to pump radiopharmaceutical 1 from inlet point A and past point B at valve V1 to some point C in the fill-in section 7. The volume of radiopharmaceutical between points B and C in

the fill-in section 7 does not need to be known exactly; it suffices to ensure that the section of tubing from A to B is filled completely with radiopharmaceutical, and that the activity in the volume between B and C is not larger than the desired end activity Ar. The situation at the end of step 911 is illustrated in Fig. 4, where the volume of radiopharmaceutical between points B and C is designated by reference number 21.

Step 912 (Flushing of offset volume to dose calibrator): Valve V1 is now switched to a state in which it connects ports "c" and "b". Pump P2 is operated to pump saline from the saline reservoir 5 towards valve V1. The volume to be pumped is slightly larger than the volume in the fill-in section 7 of the tubing, i.e. slightly larger than the volume between points B and D. This volume need not be known exactly. Thereby, the "offset volume" 21 is moved into the metering section 8. The situation at the end of this step is illustrated in Fig. 5.

Step 913 (Initial determination of activity): The activity of volume 21 in the metering section 8 is measured by the dose calibrator 9 (measurement M1). This activity will be called the "offset activity" A1. The controller 13 now calculates the missing activity Am required to reach a total activity of Ar: Am = Ar – A1. This is illustrated in Fig. 10 in the leftmost column. From this and the estimated concentration of activity in the vial, Cv, the estimated missing volume Va1 still to be delivered is calculated: Va1 = Am / Cv. It is important to note that this calculation is still based on the estimate of the concentration of activity in the vial, and the result cannot be expected to be highly accurate. It is further important to note that no knowledge about the offset volume 21 is required in this calculation.

This step concludes initialisation 910. In the following calibration phase 920, the following steps are performed:

Step 921 (Filling of radiopharmaceutical to point C'): Valve V1 is switched to a state in which it connects ports "a" and "b". Pump P1 is operated to pump a volume Vc' through valve V1, filling the fill-in section to point C'. This situation is illustrated in Fig. 6, where this volume is designated by reference number 22. Volume

Vc' is chosen to be approximately half of the estimated missing volume Va1: Vc' ≈ Va1 / 2. It is important to note that volume Vc' is known exactly in system internal units. The exact nature of these units depends on the type of pump used, e.g., the units could be pump revolutions, pump cycles etc. If a volume flow meter is placed in-line with the pump, the units provided by the flow meter can be used as system internal units. Depending on the type of pump and the type of tubing, the resolution of volume in this step can be very small, and even small volumes can be delivered accurately.

Step 922 (Flushing of volume Vc' to dose calibrator): Valve V1 is switched to connect ports "c" and "b". Pump P2 is operated to pump slightly more than the volume between points B and D of saline through valve V1. Thereby, volume 22 (= Vc') of radiopharmaceutical is moved into the metering section 8. The situation at the end of this step is illustrated in Fig. 7.

Step 923 (Calibration of activity): The activity in the metering section 8 is measured by the dose calibrator 9 (measurement M2). This activity level will be called A2. It corresponds to the sum of the offset activity A1 and the activity of the volume Vc', which will be called the "reference activity" Ac'. This is illustrated in the second column of Fig. 10. Now the activity concentration in the vial in system internal units, Cs, is calculated: $Cs = Ac' / Vc' = (A2 - A1) / Vc'$. The system is now calibrated in system internal units.

Step 924 (Determination of volume Vc''): The activity Ac'' still required to reach a total activity of Ar is determined: $Ac'' = Ar - A2$. From this, the volume Vc'' still to be delivered is calculated in system internal units: $Vc'' = Ac'' / Cs = (Ar - A2) / Cs = (Ar - A2) / (A2 - A1) * Vc'$.

This completes the calibration phase 920. In the following delivery phase 930, the following steps are performed:

Step 931 (Filling of radiopharmaceutical to point C''): Valve V1 is switched to a state in which it connects ports "a" and "b". Pump P1 is operated to pump the vol-

ume Vc" through valve V1, filling the fill-in section to point C". This situation is illustrated in Fig. 8, where this volume is designated by reference number 23.

Step 932 (Flushing of volume Vc" to dose calibrator): Valve V1 is switched to connect ports "c" and "b". Pump P2 is operated to pump slightly more than the volume between points B and D of saline through valve V1. Thereby, volume 23 (= Vc") of radiopharmaceutical is moved into the metering section 8. Optionally, the total activity in the metering section is now measured (optional measurement M3, see right column of Fig. 10). It should correspond exactly to the total desired activity Ar, provided that the volume of the metering section is large enough to hold all three volumes 21, 22 and 23 within this section. The latter condition is can always be fulfilled if the volume of the metering section 8 is at least five times the volume of the fill-in section 7. If a significant discrepancy is detected, the system is stopped.

Step 933 (Delivery to injection needle): Valve V2 is switched to connect ports "d" and "e". Pump P2 is operated to pump at least the volume of the metering section 8, plus the volume of the tubing from the metering section to the injection needle and of the injection needle itself, of saline through valve V1. Thereby, all liquid in the metering section 8 is flushed to the patient, and exactly the required dose of radioactivity is delivered to the patient.

This completes the delivery phase 930. If another injection of the same radiopharmaceutical (to the same or a different patient) is required, operation continues by repeating the calibration and delivery phases 920 and 930. Otherwise, operation stops by a suitable shutdown procedure, which may involve additional cycles of flushing with saline.

When repeating calibration phase 930, no additional initialisation as in phase 910 is necessary, since the metering section 8 has been flushed with saline, and the radiopharmaceutical extends exactly to point B. No activity is present in the metering section 8. Therefore, in the above calculations, A1 can be set to zero in this case, and Am is set to Ar. No further changes are necessary. The three-phase

procedure with phases 910, 920 and 930 now simplifies to a two-phase procedure with phases 920 and 930 only.

It will be appreciated that the device of the present invention and the associated method of operation provide a number of inherent safety features. Specifically, there is a high degree of redundancy in the operation of the device, such that even in case of failure of one component, such as a pump or a valve, it is impossible that more than the desired dose will be delivered to the patient. Specifically, by its design the system will only allow the dose present within the metering section 8 to be delivered to the patient. This is because during the actual delivery of the radiopharmaceutical there is no connection between the vial 2 and the fluid delivery line. The discrete nature of the sequential measurements of activity within the metering section 8 is another feature which increases safety: In step 932, the activity in the metering section 8 is actually known beforehand, and measurement M3 just serves to confirm that the right amount of activity is present in the metering section 8. If significant discrepancies are detected between the expected result and the actual measurement, operation will be stopped immediately, and an alarm will be given.

It will also be appreciated that, in normal operation, no radiopharmaceutical will enter the waste reservoir 12. Thus, generation of radioactive waste is minimized.

A device according to the present invention in the embodiment of Fig. 1 has been set up and tested in practice. The device was assembled from standard components available commercially. For the tubing sections 4 and 6, flexible tubing made from silicone with an inner diameter of 1.52 mm was used. The pumps P1 and P2 were peristaltic precision pumps (P1: Ismatec™ ISM 596B, P2: Arcomed™ Volumed™ mVp 5000). The valves V1 and V2 were electrically operated pinch valves available from Bio-Chem Valve Inc. The metering section 8' of tubing had a coil shape with nine windings and a diameter of 3.5 cm, made from fluoroethylene-propylene. A Veenstra VDC 405 dose calibrator was used as activity metering unit/dose calibrator 9. The complete assembly was shielded by a 5 cm lead shield. As a controller 13, a standard personal computer (Compaq Armada E500)

equipped with a standard interface card was used. The control algorithm was implemented in LabVIEW™, available from National Instruments™.

This embodiment is especially suitable for the use with radiopharmaceuticals typically used in PET and SPECT applications. The device has been used to deliver radiopharmaceuticals with activity concentrations as high as 1000 MBq/ml to patients, with an absolute precision of as good as 100 microliters and a relative precision of better than 2 % of the total activity delivered to the patient.

From the above description, it is clear that numerous variations of the described device and method are possible, and the invention is in no way limited to the above examples.

While the method has been described in a way that the volume of the metering section 8 of tubing is large enough to hold at the same time all volumes of radiopharmaceutical to be injected together, the method can readily be adapted for use with a dose calibrator which measures only one of these volumes at a time. In this case, the activities A1, Ac' and, optionally, Ac'' are measured directly and sequentially and need not be calculated. Both variants of the method have in common that the activity of a precisely known volume (in some arbitrary units) is measured, enabling determination of the activity concentration of the radiopharmaceutical.

The method can be extended to take into account the decrease of activity during the dispensing procedure, in a straightforward manner by calculating the decay during the (predetermined) time needed for the dispensing procedure.

The inventive device and method are not only useful for delivering a radiopharmaceutical to a human or animal body, but also in other applications, also of a non-medical nature, in which a precisely known amount of activity is to be delivered to some destination. Accordingly, many variations of the types of tubing, valves, pumps etc. are possible. Specifically, other pump types than peristaltic pumps may be used. In fact, while the use of pumps is preferred, pumps may be omitted if the vial 2, the saline reservoir 5 or both are placed "top-down" in a position higher than

valves V1, V2 and the destination 16. Fluid flow is then effected by gravity alone. Instead of pumps, flow meters should then be provided, yielding volume information to the controller 13.

Different types of valves than the above-described two-way pinch valves may be used. Specifically, it may be advantageous to provide, as valve V1, a valve which can be switched to a third state such that liquid can flow between ports "a" and "c". In this way, the sections of tubing between points A and B may be flushed with saline from reservoir 5, without the need of inserting a vial with saline instead of the vial with the radiopharmaceutical during initialisation.

Any suitable activity detector may be used as a dose calibrator 9. Such detectors include standard Geiger-Müller counters, scintillating counters etc., which should be calibrated to yield a sufficiently precise measure of the actual activity in the metering section 8.

Additional safety measures may be taken, such as providing bubble detectors in the fluid delivery path which stop operation immediately if bubbles are detected. Bubble detectors are well known in the art.

List of reference signs

P1	first pump
P2	second pump
V1	first valve
V2	second valve
a, b, c	connections of first valve
d, e, f	connection of second valve
A	inlet of radiopharmaceutial
B, C, C', C''	reference points
D	start of metering section
E	end of metering section

M1, M2, M3 measurements

A1, A2, Ar, Am, Ac', Ac'' activities

1	radiopharmaceutical
2	vial
3	shield
4	tubing
5	saline container
6	tubing
7	tubing
8, 8'	metering section
9	dose calibrator
10	tubing
11	injection needle
12	waste
13	controller
21, 22, 23	volumes of radiopharmaceutical
31	sliding element

Claims

1. Device for dispensing a radioactive liquid (1) to a destination (11), comprising

- first valve means (V1);
- a fluid delivery path (7, 8, 10) for fluid flow from said first valve means (V1) to said destination (11); and
- an activity metering unit (9) operable to determine a level of radioactivity within a metering section (8) of said fluid delivery path (7, 8, 10);

wherein said first valve means (V1) are adapted for selectively connecting a source (2) of said radioactive liquid (1) and a source of a flushing liquid (5) to said fluid delivery path (7, 8, 10) upstream of said metering section (8).

2. Device according to claim 1, characterized in that said first valve means (V1) are adapted for remote operation and that said device further comprises a control unit (13) receiving signals from said activity metering unit (9) and controlling operation of said first valve means (V1) between at least the following states:

- a state in which said source (2) of radioactive liquid (1) is connected to said fluid delivery path (7, 8, 10); and
- a state in which said source of flushing liquid (5) is connected to said fluid delivery path (7, 8, 10).

3. Device according to claim 1 or 2, characterized in that said device further comprises second valve means (V2) for selectively connecting said fluid delivery path (7, 8, 10) downstream from said metering section (8) to said destination (11) or to a waste reservoir (12).

4. Device according to one of claims 1 to 3, characterized in that said device further comprises a first pump (P1) for pumping said radioactive liquid (1) from its source (2) toward said first valve means (V1) and/or a second pump (P2) for pumping said flushing liquid from its source (5) toward said first valve means (V1).

5. Device according to one of claims 1 to 4, characterized in that said fluid delivery path comprises a fill-in section (7) extending from said first valve means (V1) to said metering section (8), and that said metering section (8) is capable of holding a fluid volume (D-E) which is at least three times the volume (B-D) of said fill-in section (7).

6. Device according to one of claims 1 to 5, characterized in that said device is adapted for delivering a radiopharmaceutical to an injection needle for injection of liquid into a human or animal body.

7. Method of operation of a device according to claim 1, comprising the steps of

- transporting a first amount (22) of said radioactive liquid to said metering section (8) of said fluid delivery path (7, 8, 10);
- with said activity metering unit (9), measuring a reference level of radioactivity (A2) present in said metering section (8);
- - from said reference level of radioactivity (A2), calculating a second amount (23) of said radioactive liquid still to be delivered such that said first and second amounts of radioactive liquid together have a predetermined level of radioactivity (Am); and
- delivering at least said first and second amounts of radioactive liquid (1) to said destination (11).

8 Method according to claim 7, characterized in that said first amount of ra-

dioactive liquid is between 20% and 80% of the sum of the first and second amounts of radioactive liquids.

9. Method according to claim 7 or 8, characterized in that said step of transporting said first amount of said radioactive liquid comprises:

- operating said first valve means to connect said source (2) of radioactive liquid (1) to said fluid delivery path (7, 8, 10);
- allowing said first amount of radioactive liquid (1) to flow from said first valve means (1) into said fluid delivery path (7, 8, 10);
- operating said first valve means to connect said source of flushing liquid (5) to said fluid delivery path (7, 8, 10); and
- allowing flushing liquid (5) to flow into said fluid delivery path (7, 8, 10), whereby said first amount of radioactive liquid is moved into said metering section (8) of said fluid delivery path (7, 8, 10).

10. Method according to one of claims 7 to 9, characterized in that said step of delivering said first and second amounts of said radioactive liquid (1) comprises:

- operating said first valve means to connect said source (2) of radioactive liquid (1) to said fluid delivery path (7, 8, 10);
- allowing said second amount of radioactive liquid (1) to flow from said first valve means (1) into said fluid delivery path (7, 8, 10);
- operating said first valve means to connect said source of flushing liquid (5) to said fluid delivery path (7, 8, 10); and
- allowing flushing liquid (5) to flow into said fluid delivery path (7, 8, 10), whereby said first and second amounts of radioactive liquid are moved to said destination (11).

11. Method according to one of claims 7 to 10, additionally comprising the fol-

lowing steps:

- before transporting said first amount (22) of radioactive liquid (1) to said metering section (8), transporting an offset amount (21) of said radioactive liquid (1) to said metering section (8);
- with said activity metering unit (9), measuring an offset level of radioactivity (A1) of said offset amount (21) of radioactive liquid;
- from said offset level of radioactivity (A1) and a desired level of radioactivity to be dispensed (Ar), calculating said predetermined level of radioactivity (Am); and
- delivering said offset amount (21) of radioactive liquid to said destination.

12. Method according to one of claims 7 to 11, wherein said radioactive liquid is a liquid comprising a radiopharmaceutical and wherein said destination is an injection needle for injection of liquid into a human or animal body.

13. Method of operation of a device to deliver a radioactive liquid to a destination (11), comprising:

- determining a predetermined level of radioactivity (Am) to be delivered to said destination (11);
- transporting a first amount (22) of said radioactive liquid to a metering section (8) of a fluid delivery path (7, 8, 10) for fluid flow to said destination (11), said metering section (8) having a metering unit (9) in operative connection therewith and being operable to determine a level of radioactivity within the metering section (8), the first amount (22) of said radioactive liquid having a reference level of radioactivity (A2) less than the predetermined level of radioactivity (Am);
- with said activity metering unit (9), measuring the reference level of radioactivity (A2) present in said metering section (8);
- from said reference level of radioactivity (A2), calculating a second

amount (23) of said radioactive liquid still to be delivered such that first and second amounts of radioactive liquid together have the predetermined level of radioactivity (Am); and

- delivering at least said first and second amounts of radioactive liquid (1) collectively from said fluid delivery path (7, 8, 10) to said destination (11).

14. System for dispensing a radioactive liquid (1) to a destination (11), comprising:

- a first valve (V1) adapted for remote operation;

- a fluid delivery path (7, 8, 10) for fluid flow from said first valve (V1) to said destination (11);

- an activity metering unit (9) operable to determine a level of radioactivity within a metering section (8) of said fluid delivery path (7, 8, 10); wherein said first valve (V1) is adapted for selectively being placed in one of at least two states: a first state in which a source (2) of said radioactive liquid (1) is connected to said fluid delivery path (7, 8, 10) upstream of said metering section (8) and a second state in which a source of a flushing liquid (5) is connected to said fluid delivery path (7, 8, 10) upstream of said metering section (8); and

- a control unit (13) adapted to receive signals from said activity metering unit (9) and control operation of said first valve (V1) between the first state and the second state; said control unit being adapted to:

i. place said first valve (V1) in the first state to transport a first amount (22) of said radioactive liquid through said first valve (V1), the first amount (22) of said radioactive liquid having a level of radioactivity less than a predetermined level of radioactivity (Am) input into said control unit (13);

ii. place said first valve (V1) in the second state to transport an amount of flushing liquid (5) through said first valve (V1) to transport said first amount of said radioactive liquid to said metering section (8) of said fluid delivery

path (7, 8, 10);

iii. receive a signal from said activity metering unit (9) of a measured reference level of radioactivity (A2) present in said metering section;

iv. calculate from said reference level of radioactivity (A2) a second amount (23) of said radioactive liquid still to be delivered such that said first and second amounts of radioactive liquid together have a predetermined level of radioactivity (Am) input into said control unit (13);

v. place said first valve (V1) in said first state and transport through said first valve (V1) said second amount (23) of said radioactive liquid;

vi. place said first valve (V1) in said second state to transport an amount of flushing liquid (5) through valve (V1) to transport said second amount (23) of said radioactive liquid to said metering section (8) of said fluid delivery path (7, 8, 10) while maintaining said first amount (22) of said radioactive liquid in said metering section (8); and

vii. place said first valve (V1) in said second state and transport through said first valve (V1) sufficient flushing liquid to deliver at least said first and second amounts of radioactive liquid (1) through said fluid delivery path (7, 8, 10) to said destination (11).

15. System for dispensing a radioactive liquid (1) to a destination (11), comprising:

- a source of a radioactive liquid (1);
- a source of a flushing liquid (5);
- a fluid delivery path (7, 8, 10) for fluid flow of said radioactive liquid and said flushing fluid to said destination (11), the fluid delivery path including a metering section (8);
- an activity metering unit (9) operable to determine a level of radioactivity within said metering section (8) of said fluid delivery path (7, 8, 10); and
- a control unit (13) adapted to receive signals from said activity meter-

ing unit (9) and control flow of said radioactive liquid and said flushing fluid through said fluid delivery path (7, 8, 10); said control unit being further adapted to:

i. transport a first amount (22) of said radioactive liquid having a level of radioactivity less than a predetermined level of radioactivity (Am) to said metering section (8) of said fluid delivery path (7, 8, 10);

ii. receive a signal from said activity metering unit (9) of a measured reference level of radioactivity (A2) present in said metering section;

iii. calculate from said reference level of radioactivity (A2) a second amount (23) of said radioactive liquid still to be delivered such that first and second amounts of radioactive liquid together have a predetermined level of radioactivity (Am) input into said control unit (13);

iv. transport said second amount (23) of said radioactive liquid to said metering section (8) of said fluid delivery path (7, 8, 10) while maintaining said first amount (22) of said radioactive liquid in said metering section (8); and

v. transport sufficient flushing fluid through said fluid delivery path (7, 8, 10) to deliver at least said first and second amounts of radioactive liquid (1) through said fluid delivery path (7, 8, 10) to said destination (11).

16. Method of delivering a radioactive liquid to a destination (11), comprising:

- determining a level of radioactivity (Am) to be delivered to said destination (11);

- transporting a first amount (22) of said radioactive liquid having a level of radioactivity less than the determined level of radioactivity (Am) to a metering section (8) of a fluid delivery path (7, 8, 10), said metering section (8) having an activity metering unit (9) in operative connection therewith to measure radioactivity in said metering section (8);

- measuring a reference level of radioactivity (A2) present in said metering section (8);

- calculating from said reference level of radioactivity (A2) a second amount (23) of said radioactive liquid still to be delivered such that first and second amounts of radioactive liquid together have the predetermined level of radioactivity (Am);

- transporting said second amount (23) of said radioactive liquid to said metering section (8) of said fluid delivery path (7, 8, 10) while maintaining said first amount (22) of said radioactive liquid in said metering section (8); and

- delivering said first amount and said second amount of radioactive liquid (1) through said fluid delivery path (7, 8, 10) to said destination (11).

17. Method of delivering a radioactive liquid to a destination (11), comprising:

- determining a level of radioactivity (Am) to be delivered to said destination (11);

- estimating a concentration of activity (Cv) in a source of radioactive liquid (1);

- transporting from said source of radioactive liquid (1) a first amount (21) of said radioactive liquid having a level of radioactivity, based upon the estimated concentration of activity (Cv), less than the determined level of radioactivity (Am) to a metering section (8) of a fluid delivery path (7, 8, 10), said metering section (8) having an activity metering unit (9) in operative connection therewith to measure radioactivity in said metering section (8);

- measuring a level of radioactivity (A1) present in said metering section (8);

- based upon the estimated concentration of activity (Cv), transporting a second amount (22) of said radioactive liquid having a reference level of activity (Ac') such that the total activity (A2) of said first amount (21) and said second amount (22) is less than the determined level of radioactivity (Am) to said metering section (8);

- measuring a level of radioactivity (A2) present in said metering section (8);

- based upon the measured level of radioactivity (A2), calculating the concentration of radioactivity (Cs) in said source of radioactive liquid (5);

- based upon the calculated concentration of activity (Cs), transporting a third amount (23) of said radioactive liquid having a level of activity (Ac'') such that the total activity of said first amount (21), said second amount (22) and said third amount (23) is the determined level of radioactivity (Am) to said metering section (8); and

- delivering said first amount, said second amount and said third amount of said radioactive liquid (1) through said fluid delivery path (7, 8, 10) to said destination (11).

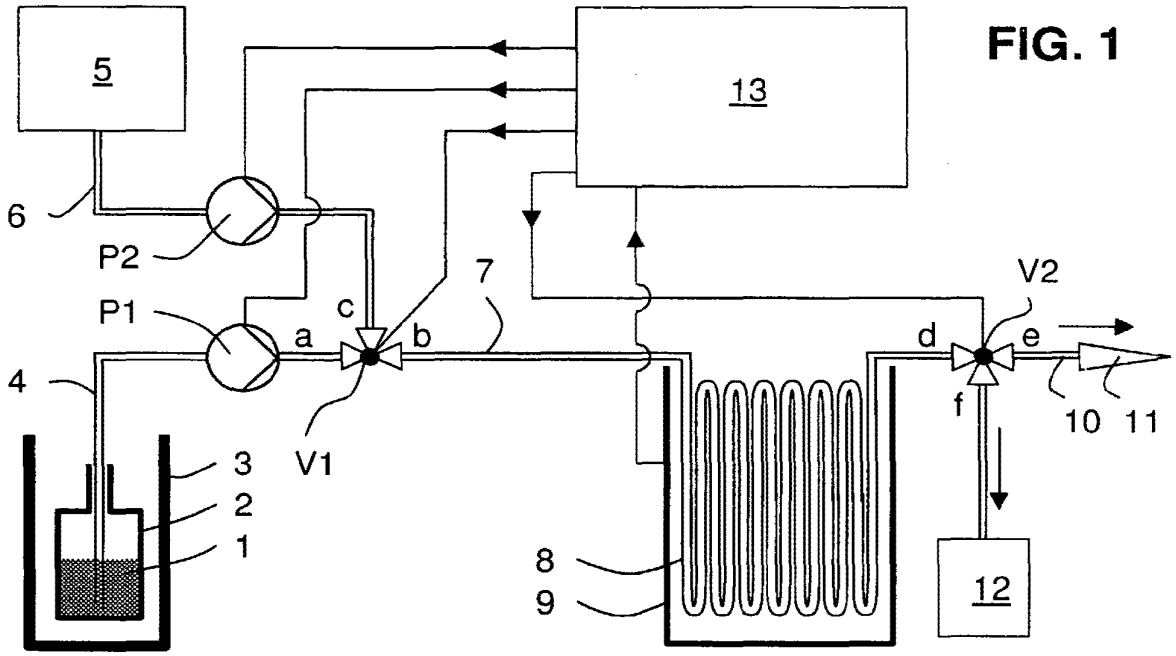


FIG. 1

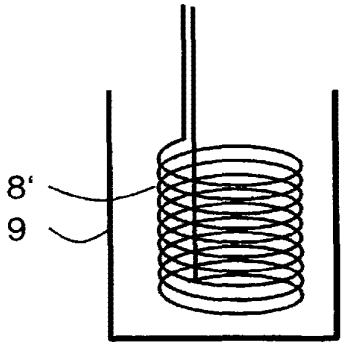


FIG. 2

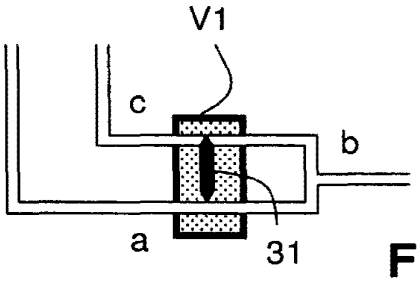


FIG. 3A

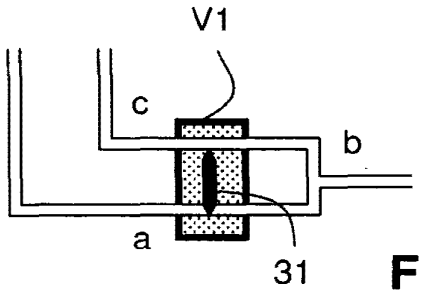


FIG. 3B

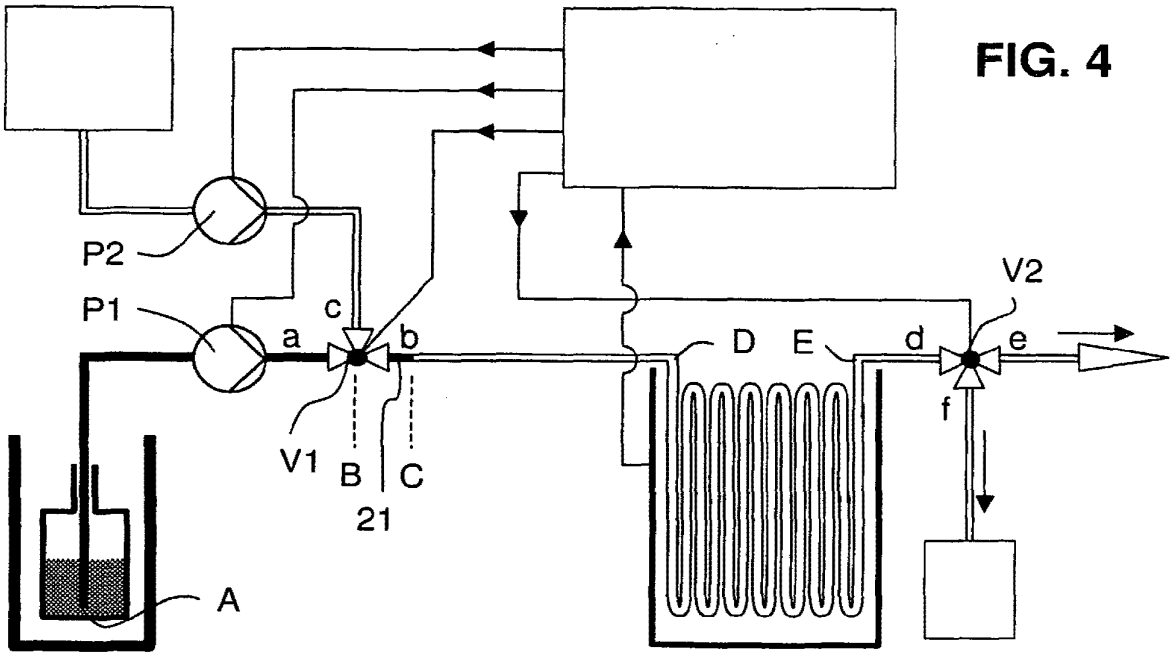


FIG. 4

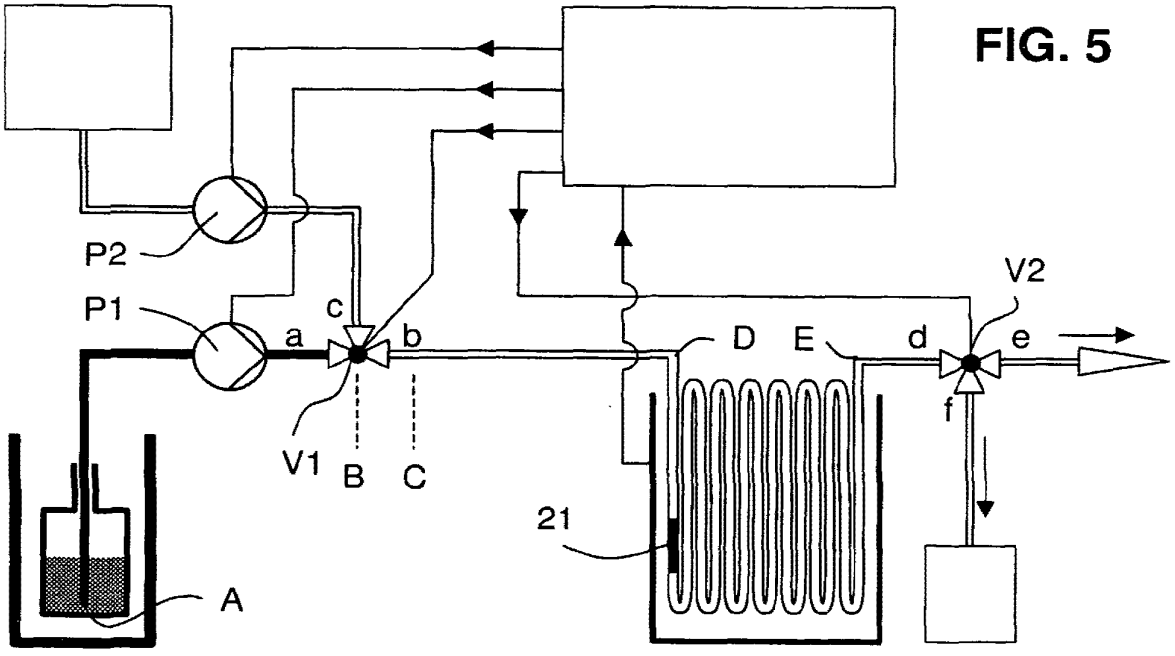


FIG. 5

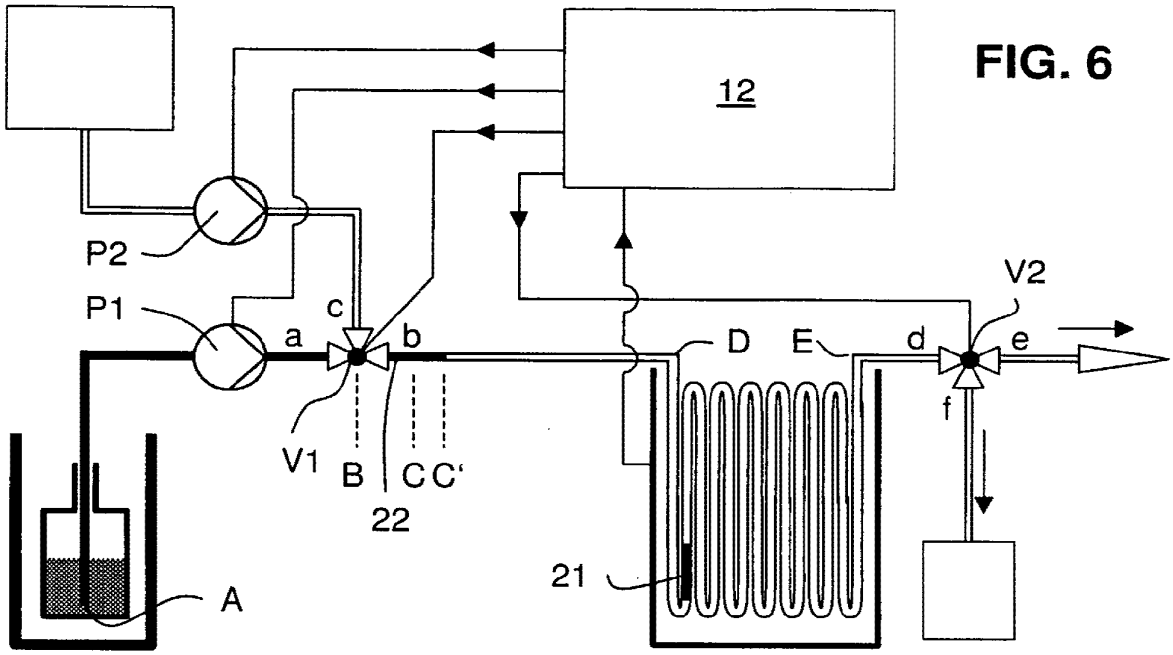

12
P2
P1
a
c
b
V1
B
C
C'
22
A
D
E
d
e
V2
f
21

FIG. 6

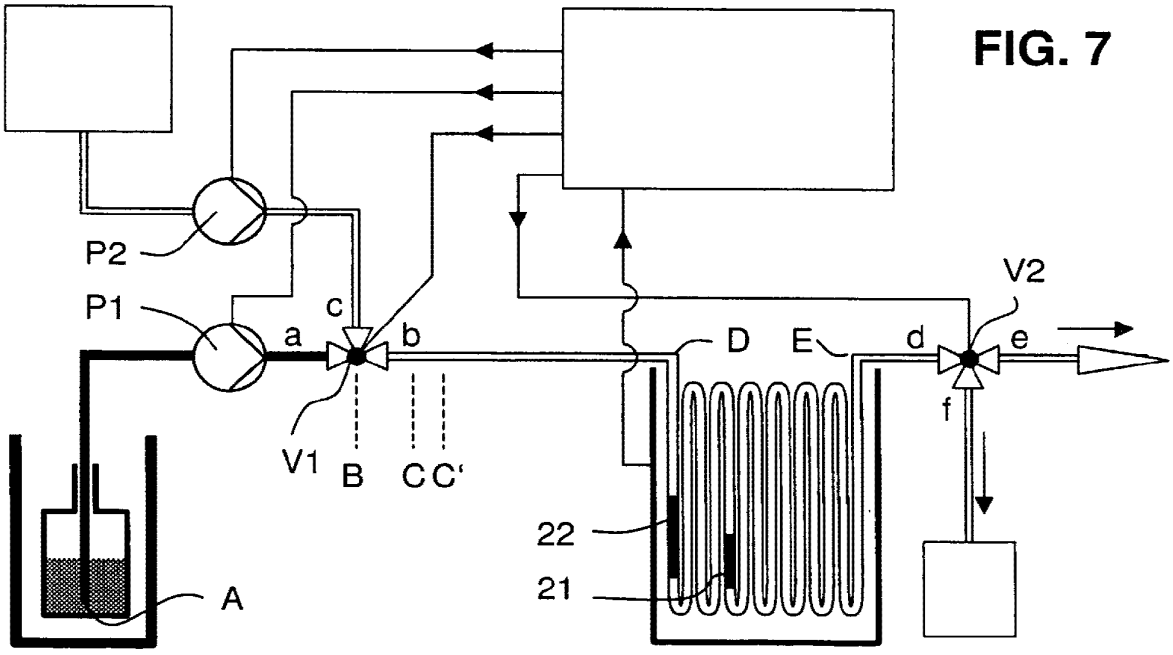

P2
P1
a
c
b
V1
B
C
C'
A
D
E
d
e
V2
f
22
21

FIG. 7

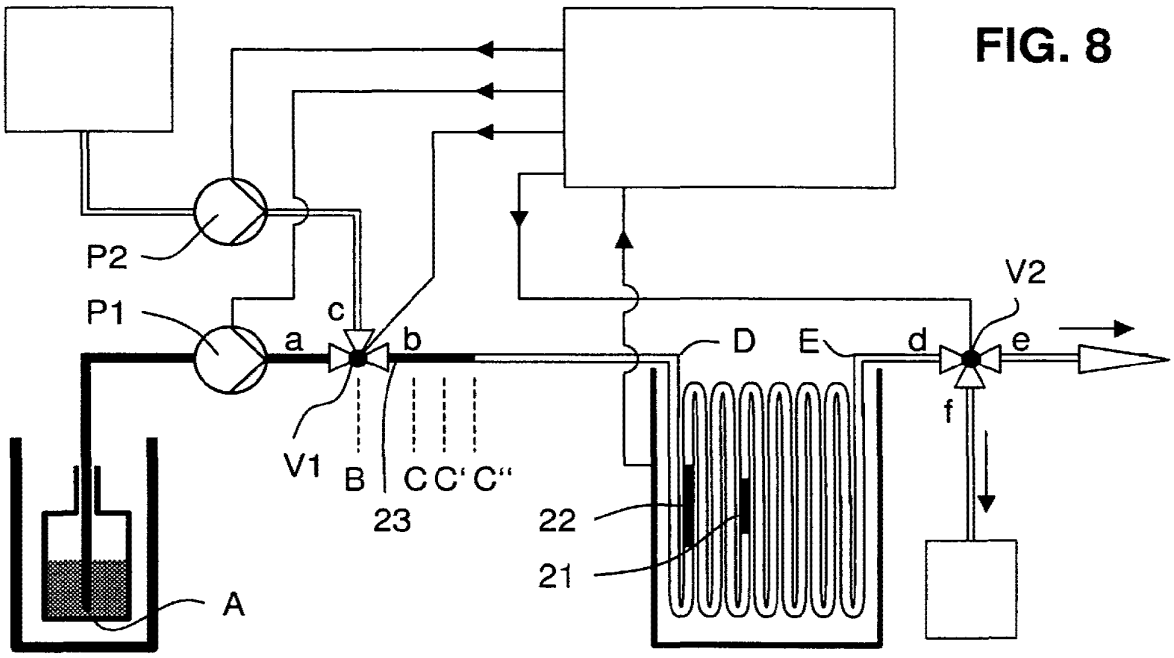


FIG. 8

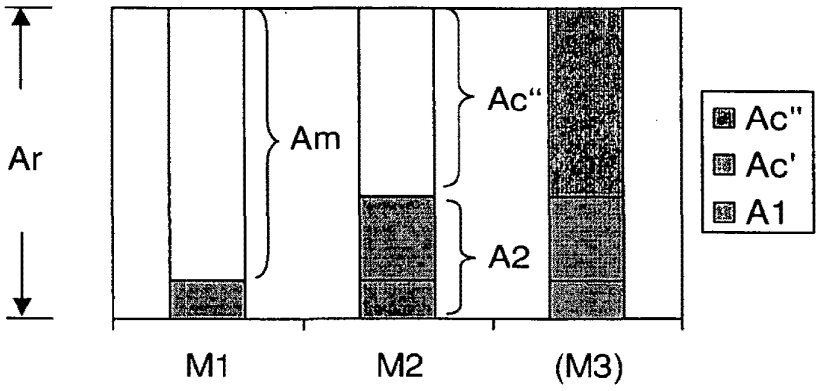


FIG. 10

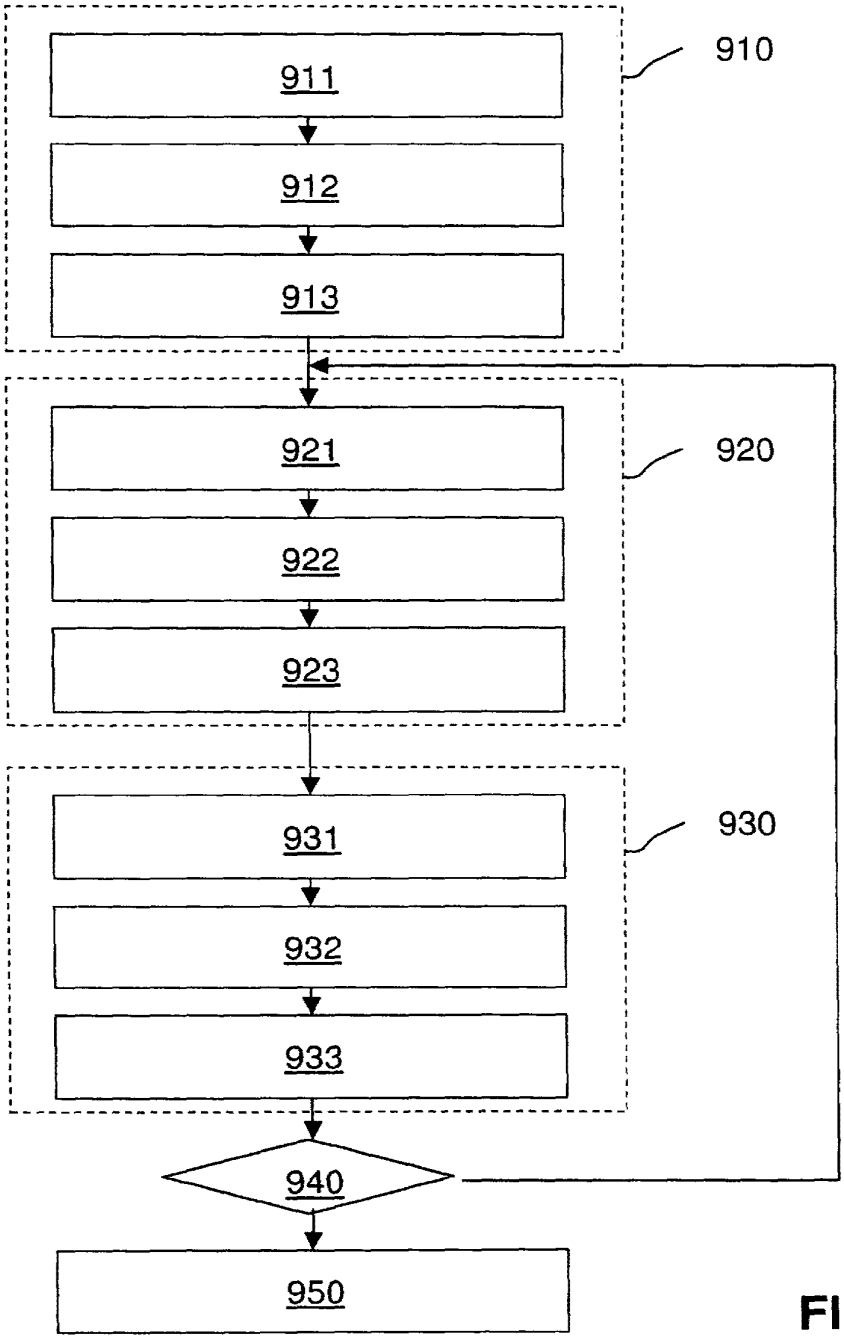


FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2005/000403

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/14 A61M5/00 A61M5/172

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 7 A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PATENT ABSTRACTS OF JAPAN vol. 2003, no. 02, 5 February 2003 (2003-02-05) -& JP 2002 306609 A (SUMITOMO HEAVY IND LTD), 22 October 2002 (2002-10-22) the whole document	1-6,14, 15
X	PATENT ABSTRACTS OF JAPAN vol. 2000, no. 15, 6 April 2001 (2001-04-06) -& JP 2000 350783 A (SUMITOMO HEAVY IND LTD), 19 December 2000 (2000-12-19) the whole document	1-6,14, 15
A	EP 0 486 283 A (UEMURA, KAZUO; THE JAPAN STEEL WORKS, LTD) 20 May 1992 (1992-05-20) the whole document	1-6,14, 15

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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"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
6 September 2005	15/09/2005

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

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2005/000403

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 562 829 A (BERGNER ET AL) 7 January 1986 (1986-01-07) the whole document	1-6,14, 15
A	US 2003/004463 A1 (REILLY DAVID M ET AL) 2 January 2003 (2003-01-02) the whole document	1-6,14, 15

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH2005/000403

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

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

1. [X] Claims Nos.: 7-13,16,17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

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

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

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

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

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

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

Remark on Protest

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

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

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2005/000403

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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JP 2000350783 A	19-12-2000	NONE	
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US 2003004463 A1	02-01-2003	US 2004260143 A1	23-12-2004
		US 2003216609 A1	20-11-2003

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(10) International Publication Number
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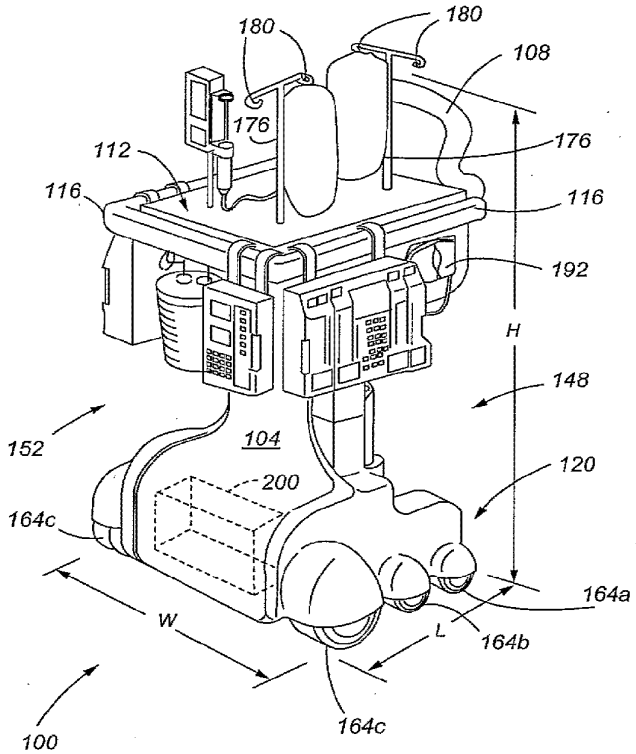
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: MODULAR PATIENT SUPPORT SYSTEM



(57) Abstract: A patient support platform provides a solution for healthcare facilities and nursing staff to address patient and staff safety, patient mobility, patient comfort, the availability of patient information, monitoring drugs and therapy provided, and controlling health care expenses. The patient support platform preferably includes a transmission system that allows the patient and/or medical staff member to choose a stop, walk or roll mode. The transmission system preferably includes a drag wheel for applying a braking force in response to a voltage generated by a braking motor. The platform supports a plurality of devices that may be attached or associated with a patient throughout their stay at a healthcare facility. The support platform also preferably includes a mechanism for releasably attaching the support platform to another structure, such as a bed. Embodiments of the present invention include multiple non-medical uses of the platform.

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European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

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

MODULAR PATIENT SUPPORT SYSTEM

FIELD OF THE INVENTION

The present invention is directed to an apparatus used in the field of medicine, and more particularly, to a moveable and modular patient support system with a relatively small form factor.

BACKGROUND OF THE INVENTION

Current practice for patients in a healthcare facility involves having multiple unrelated treatment, maintenance and/or monitoring devices that are attached to the patient. These include intravenous fluids and drugs, drainage catheters, suction catheters, leg compression stockings and vital sign monitoring devices. Such devices often create a hazard for the patient both directly and indirectly. The myriad of devices may become entangled and inadvertently removed if not adequately accounted for by the patient or caregiver. This may require an invasive intervention, including surgery, in order to replace the removed device.

The number of devices generally associated with the patient require the patient to have the physical and mental ability to manage organizing or carrying the devices to ambulate even as far as the bathroom. Since patients are debilitated by the nature of their illness and medications, two staff persons are frequently required to help the patient move even short distances. One staff member must assist the patient, providing physical support, while the other manages the attached devices. The patients thus do not get out of bed and ambulate as often since the staff of the typical health facility is not able to provide this kind of support readily to all of the patients at all times.

The resulting immobility increases the patient's risk for deep venous thrombosis, pulmonary embolus and pneumonia. Additionally, mobility improves gut motility and decreases the time a patient must wait before obtaining enteral nutrition and ultimately discharge from the healthcare facility. Patients that require prolonged hospital stays or admission to skilled-nursing facilities for non-medical indications related to mobility and personnel support may be able to be discharged home sooner with a device that provides the

same type of care. The cost to the healthcare system may be reduced by decreasing the stays in expensive healthcare facilities and decreasing complications that are costly both in patient morbidity and monetary value.

The patient-care staff is also at risk for injury, as they must provide physical support to the debilitated patient. Back injuries are frequent in healthcare staff as a result of the physical nature of assistance provided. Allowing the patient to rely on an ambulatory assist device will help the patient-care staff as well by keeping them out of harm's way.

Current poles that provide an intravenous ("IV") fluid and/or liquid medication delivery source are often times taken with patients when the patient moves around, such as when a patient walks in a hospital hallway. The patient typically places at least one hand on the IV pole to move the IV pole while walking. However, typical IV poles are approximately 6 to 7 feet tall, and are often unstable for providing weight support to a patient, particularly when one or more substantially full IV bags are positioned near the top of the pole. As a result, a patient is at risk of further injury by falling if the IV pole tips and/or falls over. In addition, in order to prevent tipping, conventional IV poles have widely spread wheels, which require a large amount of floor space. IV poles are completely unable to manage uneven terrain as is found outside the confines of the patient care facility, and as may be found at home or in the field for disasters or military operations.

In addition to being relatively unstable, current IV poles do not provide for the additional needs of a patient that is moving about. For example, IV poles do not include an oxygen source for assisting the patient with breathing. Current IV poles also do not include various pumps or suction devices that may be necessary for continuous operation to provide proper medical treatment to the patient. In addition, vitals monitoring equipment and communication devices are typically not present on a standard IV pole. Furthermore, even if an IV pole is adapted to include a monitoring device or pump, the IV pole tends to become even more unstable because the resulting added weight of the device typically is positioned

relatively high along the pole.

In connection with patients that require assistance walking, various "walker" devices are available. A typical walker includes handrails interconnected to a stable base. However, because use of a walker usually requires both hands of the patient, a patient is typically unable to take an IV pole with them when using a walker.

A further difficulty exists when a patient needs to be moved from one room to another while in their bed. If the patient requires oxygen, an oxygen bottle must be provided, and is typically placed on the bed while moving the bed. This can create difficulties depending upon the size of the bed and the patient. Additionally, portable suction and vitals monitoring are not readily available for every patient. Accordingly, it would be advantageous to provide an apparatus that includes oxygen and other physiological support adjacent to the bed, wherein the apparatus can be attached to the bed while moving the bed. Such an apparatus would therefore also be advantageous to overcome the difficulty of maintaining monitoring equipment and/or IV fluids adjacent to the patient while moving the patient's bed. The efficiency of the staff will benefit since only a single staff member will be required to move a patient since a second staff member is not required to push the IV pole and attachments. This also prevents the need for the staff member to move the patient to a wheelchair for transfer as is currently often done in order for a single staff member to manage the transfer. Eliminating this move prevents an opportunity for a patient fall resulting in injury with only a single staff member assisting.

Patient care devices and services such as suction and oxygen are not built in to the facilities of several countries and regions. This is also true in field situations of military conflict or civilian disaster. Patients may be far from a medical facility or in the hallway of a medical facility not equipped with patient support equipment/services.

Yet a further difficulty exists in maintaining electrical power to electronic devices such as monitoring equipment, suction pumps and/or injection pumps while the patient is

walking with an IV pole or walker, or while the patient is being moved in their bed or while the patient is not located next to an electrical outlet. This may occur in: 1) the operating room while needing to adjust the bed height or keep the pumps charged during a long procedure, 2) during a disaster when patients may be stationed in hallways or temporary areas, 3) during military conflict or civilian situations that require creation of field hospitals with limited generator availability, and 4) in countries or regions that do not have consistent access to power. Accordingly, an apparatus that maintains electrical power to these devices would be advantageous, as would an apparatus that provides power in case of an electrical outage or blackout.

SUMMARY OF THE INVENTION

The present invention solves the above-mentioned deficiencies by providing a mobile cart or platform that is structurally stable, and can thereby provide weight-bearing assistance to a patient without being predisposed to tipping over. In addition, the platform preferably includes one or more additional features, such as an oxygen source, power supply, injection pump, suction pump, body fluid collection devices, vital monitoring equipment, integrated IV pole and communication equipment.

In accordance with embodiments of the present invention, a modular patient support system is provided, wherein the support system typically resembles a platform, and includes a handrail interconnected to a base having three or more wheels. The support system or platform additionally may include a battery or uninterruptible power supply for serving as an emergency power supply, and/or for powering associated equipment, including the bed, while the patient is walking or being moved in a bed with the support system positioned adjacent the bed. The support platform also may include modular receptacles for receiving a variety of devices, including suction pumps, injection pumps, collection devices, monitoring equipment, and communication devices. An electrical wiring network may be provided such that the

modular devices interconnected to the support platform receive electrical power directly at the modular receptacles, thereby minimizing the presence of numerous power cords. Such additional equipment is powered by the uninterruptible power supply when the support platform is disengaged from a stationary power supply, such as an electrical wall outlet.

In accordance with other embodiments of the present invention, the support platform may include an on-board communication system to send monitoring information or other data to a nurses' PDA, central station or alarm system. The communication system may include wireless communication to transmit a patient's vitals, equipment status, fluid volumes, therapy status and location for providing information while a patient is using the support platform as a walking aid. An interface may be provided for the healthcare providers to be able to access and interact with the facility's electronic medical record system.

In accordance with other embodiments of the present invention, the support platform may include a checkpoint validation system to ensure the correct therapy is administered to the correct patient. This may involve identification of the patient, platform and therapy (such as intravenous fluids, medications or equipment) with devices such as barcodes, radiofrequency identifiers or other similar technology to match and track all therapy provided.

In accordance with other embodiments of the present invention, the support system also may also include an on-board oxygen supply and associated tubing. Additionally, the support platform may include an IV fluids/medication support assembly, such as an IV pole with an attachment hook.

The support platform may be configured in a variety of ways, to include a cabinet or other enclosure for holding items such as a urine collection bag, body fluid collection bag and suction canister. The configuration of the support platform also may include specially sized compartments for bottles or cups, and may include other built-in features such as a tray, radio, television, phone, computer or other communication device, wherein some of these devices may also be interconnected to the support platform's power supply.

In a separate aspect of the invention, an attachment device is provided for detachably attaching the support platform to another structure, such as the patient's bed. The attachment device may include an attachment adapter capable of being interconnected to a variety of bed frame structures, regardless of whether the framing includes square or round rails or posts. The attachment device not only secures the support platform to the bed so that it is not moved when accidentally bumped, but it also enables the support platform to be moved with the bed without the need for a separate attendant to move the support platform. In at least one embodiment, a plurality of bed hooks are used to enable the platform to grasp another object, such as a bed, when the bed is raised to impinge upon the underside of the bed hooks.

In a separate aspect of the invention, the support platform includes an umbilical cord having a common plug for interconnecting a plurality of systems to a single outlet, such as a wall outlet. The umbilical cord may support a variety of systems, including electrical power, oxygen, suction, and/or a communication connection.

In accordance with embodiments of the present invention, a locking brake may optionally be provided to limit movement of the platform if the brake is engaged. The brake may have mechanisms that engage it actively and/or passively. This may include a 'kill-switch' device that detects separation of the patient from the platform in situations that may result in patient injury if such event occurs.

In accordance with embodiments of the present invention, a transmission system may be provided to allow a user or other person to place the platform in one of a plurality of possible translation modes. In at least one embodiment, the transmission system includes stop, walk and roll modes. The stop mode engages a brake to contact the underlying surface, thereby substantially preventing the platform from rolling. In addition, in at least one embodiment, both a drag wheel and a brake are in contact with the floor when the platform is set in the stop mode. The walk mode includes raising the brake, if present, and engaging a drag wheel to contact the floor. Although not prevented from moving, the walk mode helps

prevent undesirable fast movement of the platform. In one embodiment, the drag wheel may comprise a wheel that is preset to turn at a very slow rate. Alternatively, in at least one embodiment the drag wheel may be interconnected to a braking motor, operated as a generator powered by the drag wheel, that applies a resistive force or an increased resistive force to the drag wheel when velocities increase above an undesirable level. For example, if a patient is standing adjacent the support platform and starts to slip while holding the handle of the platform, the braking motor will apply a resistive force to the drag wheel, thereby preventing the support platform from moving away from the patient and/or moving away from the patient at a high rate of speed. A variety of motor braking circuit configurations and braking functions are available for controlling the resistive force applied to the drag wheel using the braking motor. For example, a motor braking circuit may provide different resistive loads to the braking motor based on the velocity of the braking motor. In addition, the motor braking circuit does not require any source of power other than the power generated as a result of the rotation of the braking motor by the drag wheel. In the roll mode the transmission disengages both the brake and the drag wheel, such that the platform may be easily rolled. This setting is anticipated for use, for example, when an attendant is moving the platform.

Thus, in accordance with at least one embodiment of the present invention, a personal support platform for traversing an underlying surface is provided, the platform comprising a frame and a plurality of wheels interconnected to the frame. In addition, the platform comprises a transmission system interconnected to the frame, the transmission system providing a number of user selectable modes, the user selectable modes comprising at least a stop mode, a walk mode and a roll mode. Finally, in at least one embodiment, the platform further comprises a means for selectively choosing one of the stop, walk and roll modes by a user from a standing position adjacent the frame.

In a separate aspect of the invention, a transmission system of the platform comprises

a drag wheel that is selectively moveable from a first raised position in the roll mode to a second lowered position in the walk mode, and wherein the drag wheel is for contacting the underlying surface when in the second lowered position. In addition, in accordance with at least one embodiment, the transmission system comprises a cam interconnected to the frame and the drag wheel, wherein the cam is rotatably movable to raise and lower the drag wheel from the first raised position in the roll mode to the second lowered position in the walk mode. The transmission system may also further comprise an automatic brake interconnected to the drag wheel, wherein the automatic brake comprises a braking motor driven by the drag wheel and circuitry, wherein the circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel. In addition, in at least one embodiment, the resistive load comprises a number of load ranges, wherein a first load range provides a first resistive load within a first velocity range for the braking motor, and wherein a second load range provides a second resistive load within a second velocity range for the braking motor. Also, the second velocity range may be automatically selected once a threshold velocity of the braking motor is reached.

In a separate aspect of the invention, a transmission system of the platform may comprise a brake interconnected to the frame, wherein the brake is selectively moveable from a first raised position in the walk and roll modes to a second lowered position in the stop mode, and wherein the brake is for contacting the underlying surface when in the second position. In at least one embodiment, the brake comprises a stopper frictionally engaging the underlying surface. In yet a separate aspect of the invention, the platform may comprise a cam having a first channel interconnected to the brake. In at least one embodiment of the invention, the cam comprises a second channel interconnected to a drag wheel. In accordance with at least one embodiment of the invention, the first channel comprises a first ramp for raising and lowering a first post interconnecting the drag wheel to the cam, and wherein the second channel comprises a second ramp for raising and lowering a second post

interconnecting the stopper to the cam.

In a separate aspect of the invention, a means for selectively choosing the mode of the transmission system comprises a first handle at a rear portion of the frame, wherein the handle is selectively adjusting a setting of the transmission system. In at least one embodiment, the transmission system may further comprise a second handle at a front portion of the frame, wherein the second handle can also be used for selectively adjusting a setting of the transmission system.

In a separate aspect of the invention, the platform comprises at least one grasping mechanism for interconnecting the frame to another structure. In at least one embodiment of the invention, the grasping mechanism comprises a rotatable gripper arm that engages the other structure. In addition, in at least one embodiment, the rotatable gripper arm rotates about a first axis in a direction away from the frame, and rotates about a second axis to grasp the other structure, wherein the second axis is transverse to the first axis.

It is a further aspect of the present invention to utilize a variety of devices to provide functionality to a personal support platform. Accordingly, in at least one embodiment of the present invention, a personal support platform for traversing an underlying surface is provided, comprising a frame and means for rotating interconnected to said frame and contacting the underlying surface. The platform further comprises means for frictionally engaging the underlying surface and interconnected to said frame; and means for variably controlling a resistance provided by said means for frictionally engaging. In at least one embodiment of the invention, the means for rotating comprises a plurality of wheels. In addition, it in at least one embodiment of the invention the means for frictionally engaging comprises a drag wheel. In accordance with at least one embodiment of the invention, the means for frictionally engaging is interconnected to a means for adjusting a position of said means for frictionally engaging, wherein said means for adjusting may alter a position of said means for frictionally engaging from a first position in contact with the underlying surface to

second position wherein said means for frictionally engaging does not contact the underlying surface. In at least one embodiment of the invention, the means for adjusting comprises a selectably positionable cam for raising and lowering said means for frictionally engaging. In addition, in at least one embodiment of the invention the means for variably controlling a resistance comprises a passive braking motor. In a separate aspect of the invention, the passive braking motor comprises a motor braking circuit interconnected to the passive braking motor. In at least one embodiment, the braking circuit includes a first circuit stage, including a switching mechanism, wherein an activation voltage for the first circuit stage is defined. The circuit also includes, a load resistor, wherein when the passive braking motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

As noted above, embodiments of the present invention may comprise a braking system. Thus, in accordance with at least one embodiment of the invention, a passive variable braking system is provided, comprising:

a motor;

a motor braking circuit interconnected to the motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined; and

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

In a separate aspect of the invention, the motor braking circuit of the passive variable braking system further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor, wherein the activation voltage for the second stage is greater than the activation voltage for the first stage, and wherein when the activation voltage for the second stage is met or exceeded a current continues to be allowed to pass through the load resistor of the first circuit stage.

In yet a separate aspect of the invention, the passive variable braking system further comprises:

a switch, wherein the first and second circuit stages comprise a number of load resistors, wherein the switch is operable to select one of each of the load resistors included in the first and second circuit stages to provide a selected resistance at the motor.

In a separate aspect of the invention, the motor braking circuit of the passive variable braking system further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage, including:

a switching mechanism, wherein an activation voltage for the second stage is defined; and

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load

resistor, and wherein the activation voltage for the second stage has a polarity that is opposite the activation voltage for the first stage.

In a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a zener diode.

In a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a pair of voltage dividing resistors and a transistor, wherein a voltage divided by the pair of resistors is provided to a gate of the transistor.

In yet a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a resistor interconnected to a Silicon Controlled Rectifier.

In yet a separate aspect of the invention, the passive variable braking system further comprises a drag wheel interconnected to the motor, wherein the motor is driven by the drive wheel. In yet a separate aspect of the invention, the drive wheel is interconnected to the motor by a gearbox.

In still yet a separate aspect of the invention, the switching mechanisms of the passive variable braking system of the first and second circuit stages each comprise a zener diode, and wherein the first and second stages each additionally include a blocking diode.

It is a separate aspect of the present invention to provide a method of using a support platform that comprises one or more features of the device described herein. Accordingly, a method of using a personal support platform is provided, the method comprising selecting a transmission mode for a transmission system operably associated with the personal support platform, wherein the transmission system provides a number of user selectable transmission modes, and wherein the user selectable transmission modes comprise at least a stop mode, a walk mode and a roll mode. In accordance with at least one embodiment of the present invention, the personal support platform for use includes a frame, a plurality of wheels interconnected to the frame, and a transmission control device operably interconnected to the transmission system, the transmission control device adapted for allowing a user to selectively

choose one of the stop, walk and roll modes. In the method of use, the selecting step comprises manipulating the transmission control device to one of the stop, walk and roll modes. In addition, in at least one embodiment, the manipulating step comprises moving a control bar operably interconnected to the frame and a cam, wherein the control bar controls positions of a drag wheel and a brake that are operably interconnected with the cam. In a separate aspect of the invention, in at least one embodiment the method of use also comprises inducing a braking force on the drag wheel by at least temporarily increasing a velocity of the frame, wherein the resistive force is imposed by an automatic brake interconnected to the drag wheel, wherein the automatic brake comprises a braking motor driven by the drag wheel and circuitry, and wherein the circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel. In addition, in at least one embodiment, the method also comprises releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the frame, and may further comprise impinging at least a portion of the other structure against the rotatable gripper arm.

In accordance with embodiments of the present invention, a method of using a personal support platform is provided comprising: providing a drag wheel interconnected to the platform, the drag wheel for contacting a surface under the platform; positioning the drag wheel to contact the surface under the platform; and applying a braking to the platform through the drag wheel by applying at least a first braking resistance to the drag wheel for at least a first velocity range of the drag wheel. In at least one aspect of the invention, the method may further comprise providing at least a second braking resistance to the drag wheel for at least a second velocity range of the drag wheel. In another aspect of the invention, the second velocity range is automatically selected once a threshold velocity of a braking motor is reached. In accordance with at least one embodiment of the invention, the positioning step of the drag wheel further comprises manipulating a transmission control device to lower the drag wheel in contact with the surface under the platform. The method may further comprise

engaging a stopper to contact the surface underlying the platform. In addition, the method may comprise releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the platform. In accordance with at least one embodiment of the invention, the step of releasably connecting the platform to another structure may also comprise impinging at least a portion of the other structure against a portion of the grasping mechanism.

Various embodiments of the present invention are set forth in the attached figures and in the detailed description of the invention as provided herein and as embodied by the claims. It should be understood, however, that this Summary of the Invention may not contain all of the aspects and embodiments of the present invention, is not meant to be limiting or restrictive in any manner, and that the invention as disclosed herein is and will be understood by those of ordinary skill in the art to encompass obvious improvements and modifications thereto.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an apparatus in accordance with embodiments of the present invention;

Fig. 2 is a perspective view of another apparatus in accordance with embodiments of the present invention;

Fig. 3 is a front elevation view of yet another apparatus in accordance with embodiments of the present invention;

Fig. 4 is a front perspective view of the platform shown in Fig. 3;

Fig. 5 is a rear perspective view of the platform shown in Fig. 3;

Fig. 6 is a rear perspective view of the platform shown in Fig. 3, wherein the platform

is shown without a surface layer;

Fig. 7 is a bottom view of the wheels of the platform shown in Fig. 3;

Figs. 8 and 9 are bottom views of alternate wheel orientations and platform base shapes;

Fig. 10 is a partial enlarged rear perspective view of an upper portion of the platform shown in Fig. 3;

Figs. 11A and 11B are side elevation views of an embodiment of a bed hook;

Figs. 12-14 are side elevation views of the bed hook of Figs. 11A and 11B in various operable positions with a bed;

Fig. 15 is a transparent rear perspective view of the platform shown in Fig. 3, wherein the platform structure is superimposed over an embodiment of a transmission system;

Fig. 16 is a partial enlarged rear perspective view of the platform shown in Fig. 15, wherein the handle of the transmission control mechanism is shown in its alternate positions;

Fig. 17 is a perspective view of alternate positions of the transmission control mechanism shown in Fig. 15;

Fig. 18 is an enlarged perspective view of a portion of the device shown in Fig. 17;

Fig. 19 is a perspective view of a portion of the transmission system shown in Fig. 15;

Fig. 20 is an enlarged side elevation view of the device shown in Fig. 19;

Fig. 21 is perspective view of an alternate embodiment of the device shown in Fig. 19;

Figs. 22-25 are various embodiments of motor braking circuits associated with the automatic braking system feature;

Fig. 26 is a braking force to velocity diagram associated with the automatic braking system feature; and

Fig. 27 is a schematic depiction of components that may be included in embodiments

of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with embodiments of the present invention, a platform is provided that has application for use in a variety of fields, one of which is in the field of health care. Various embodiments of the platform may include an ergonomic structure suited for a patient to use the platform as a walking aid. In addition, embodiments of the invention may also comprise structure for accommodating on-board health monitoring and/or treatment equipment. These and other features are described in detail below.

Referring now to Fig. 1, an apparatus constructed in accordance with an embodiment of the present invention is generally identified by reference numeral 100. Support platform 100 includes a chassis, support frame or body 104 having a platform handle 108 located at or near a top 112 of the platform 100. The platform 100 also includes a perimeter rail 116 at its top 112, wherein the perimeter rail 116 is adapted for receiving a variety of health monitoring, treatment, or maintenance devices, such as equipment currently available for these purposes. The platform 100 further includes a base 120 described in further detail below.

Referring now to Fig. 2, an embodiment in accordance with the present invention is depicted wherein support platform 100' internalizes at least one of a number of ancillary devices that may be associated with the platform, and more preferably, the platform 100' internalizes a plurality of such ancillary devices. Accordingly, the support platform 100' preferably includes one or more modular receptacles 124 for items such as suction pumps, IV pumps, infusion pumps, and/or monitoring equipment. In addition, the support platform 100' may further included a receptacle or port for a personal computer 128. The receptacles replace the current pump technology and incorporate the devices into the platform to reduce its profile, overall weight and simplify the total set of devices attached to the patient.

Referring now to Figs. 3-5, an embodiment in accordance with the present invention

is depicted as support platform 100″. Support platform 100″ features a substantially open top 112 with a pair of elevated rails 132. In accordance with embodiments of the present invention, the perimeter of the top 112 includes a skirt 136 with one or more openings 138 for receiving hooks or other connecting hardware to attach a variety of health monitoring, maintenance and/or treatment devices.

Thus, embodiments of the present invention may comprise a substantially open configuration, as shown in Fig. 1 as support platform 100, or a modular and substantially internalized configuration, as shown in Fig. 2 as support platform 100′, or an alternate configuration having interior cabinet space with a substantially open top 112, as shown in Figs. 3-5 as support platform 100″, or other configurations, all of which are encompassed by the present invention and this description. Although support platforms 100, 100′, 100″ may have a variety of different features, they may also share similar structure and have various combinations of features. The following text and associated referenced drawings describe features that may be used individually or in combination for various embodiments of the present invention.

Referring to Figs. 1-3, support platform 100, 100′, 100″ include a body 104 having a height H. Height H is preferably a sufficient height for allowing a patient to stand and grasp platform handle 108 at the top 112 of the support platform 100, 100′, 100″ to aid the patient in support and/or balance while walking or standing. Height H is preferably adjustable, thereby allowing the support platform 100, 100′, 100″ to be modified to accommodate the height of the patient. Since patients vary from small children to large adults, the height H of the support platform 100, 100′, 100″ pertains to a functional aspect of the invention. Accordingly, the body 104 may include an adjustable or telescoping means for selectively varying the height H of body 104. The telescoping means may include one or more adjustable columns, and/or otherwise include interchangeable columns 140, such as those shown in Fig. 6, wherein Fig. 6 depicts a skeletonized view support platform 100″. In

accordance with embodiments of the present invention, the columns 140 allow for adjustment of the height of the platform. Further, and in accordance with other embodiments of the present invention, one or more spacers 144 may also be incorporated into the body 104 of the support platform 100, 100′, 100″, wherein each spacer 144 serves to add additional height. In at least one embodiment, the spacer 144 comprises a supplemental height member having a thickness of between about 1-6 inches, and more preferably between about 2 to 4 inches. For the various embodiments of the present invention, the height H of the support platform 100, 100′, 100″ is between about 24 and 48 inches tall, and more preferably, between about 30 and 40 inches tall. However, other heights for short, tall and physically challenged individuals, and/or for platforms having other uses other than in the health care field are all within the scope of the present invention.

As noted above, the frame 104 of support platform 100, 100′, 100″ preferably includes a base 120, wherein the base has a stable configuration for supporting both the items on the support platform 100, 100′, 100″, as well as being able to support the added weight of a patient leaning on the platform handle 108. Accordingly, the base 120 is relatively large, but not too large so as to be clumsy to manipulate. For the embodiments shown in Figs. 1-5, the base 120 is substantially rectangular in shape, with a width W and a length L. For a rectangular base 120, the width W is preferably between about 16 to 28 inches wide, and more preferably between about 18 to 24 inches wide. The length L is preferably between about 16 to 28 inches long, and more preferably between about 18 to 24 inches long. However, it is to be understood that the base 120 may be a variety of shapes and configurations. For example, the base 120 may have a footprint that is substantially circular or hexagonal in shape.

As best seen in Fig. 6, the base 120 has a rear portion 148 and a front portion 152. Rear portion 148 preferably includes spaced apart base beams 156. The base beams 156 are preferably spaced apart to provide a preferential unobstructed area or opening 160 for the

patient to place their feet while holding the platform handle 108 and walking. Accordingly, the base beams 156 are preferably spaced apart a distance D, where distance D preferably varies between about 10 inches and 24 inches, and more preferably between about 14 inches and 20 inches. Providing a properly sized spaced apart distanced D provides for increased safety for the patient so that the patient does not trip when walking with the support platform 100, 100′, 100″.

In accordance with other embodiments of the invention, the base 120 may not be directional, or alternatively, the direction may be determined by the user to maximize the benefit of the wheel design to their health and expected use. For example, the wheel configuration may benefit weaker patients to overcome small obstacles when the base is oriented in a first direction. Conversely, healthier patients that expect to travel farther and faster may find that they have better control of the invention by changing the direction of the platform by 180°.

The base 120 preferably includes a plurality of casters or wheels 164. More preferably, the base 120 includes at least three wheels set in a triangular orientation, and more preferably yet, at least four, five or six wheels spaced apart in various configurations along the bottom of the footprint of base 120. As seen in Fig. 6, and in accordance with embodiments of the present invention, at least some of the wheels 164 preferably include a swivel connector 172 between the wheel 164 and the base 120 of support platform 100, 100′, 100″. For example, the middle pair of wheels 164b and the rear pair of wheels 164a (interconnected by the base beams 156) may include swivel connectors 172, while the orientation of the front wheels 164c may be fixed. Alternatively, all wheels 164 may have a swivel connector 172 between the wheel 164 and the base 120.

Referring now to Fig. 7, the underside of base 120 of a first preferred embodiment is illustrated. Base 120 is shown having a substantially C-shaped overall footprint when viewed from a side of the support platform 100, 100′, 100″. In accordance with at least one

embodiment of the present invention, the base 120 comprises six wheels 164 that provide a means for rotating that is interconnected to the frame and contacting the underlying surface, such as a floor surface. A first pair of wheels 164a is preferably positioned under beams 156 at the rear portion 148 of the base 120, such that one wheel 164a is under a left base beam 156 and another 164a is under the right base beam 156. In addition, a second pair of wheels 164b is preferably positioned at an intermediate position along the length of the support platform 100, 100′, 100″, such as along a mid-axis MA-MA of base 120. Again, one wheel 164b is preferably located under the left side of the platform, and another wheel 164b is located under the right side of the support platform 100, 100′, 100″. Finally, a third set of wheels 164c is preferably located toward a front portion 152 of the support platform 100, 100′, 100″. In at least one embodiment of the invention, the front wheels 164c are set closer to a center longitudinal axis C-C of the platform as compared to the first and second pairs of wheels 164a, 164b at the rear and intermediate positions along the support platform 100, 100′, 100″. In accordance with at least one embodiment of the invention, the third set of wheels 164c preferably comprise a larger diameter than at least one of the first pair of wheels 164a and the second pair or wheels 164b. In addition, for the wheel configuration shown in Fig. 7, the first wheels 164a on the right and left sides are substantially equidistant from the center longitudinal axis C-C as the second wheels 164b on both the right and left sides of the support platform 100, 100′, 100″.

Referring now to Figs. 8 and 9, and in accordance with embodiments of the present invention, alternative arrangements of the wheels 164 are within the scope of the present invention. Fig. 8 depicts a configuration wherein the wheels 164a, 164b, and 164c are all equidistant from the center longitudinal axis C-C of the support platform 100, 100′, 100″. With regard to Fig. 9, a modified shape of the base is shown as base 120'. Base 120' is shown with five wheels 164, wherein the base 120' has a substantially circular footprint but with an arcuate shaped opening 160 bounded by an arcuate shaped front base portion 168 for the

patient's feet as they walk with the support platform 100, 100', 100". Other configurations of the base are considered within the scope of the present invention.

In accordance with various embodiments of the present invention, the wheel positions includes alternate configurations designed to best address the issues of overcoming a raised obstacle such as a carpet/tile transition or door threshold, spanning a gap such as an elevator threshold, maintaining extreme maneuverability in areas with limited space, and maintaining directional tracking to aid with control as a patient ambulates. Accordingly, the alternative wheel configurations of the present invention provide for advantageous maneuverability and stability, and thus increased safety for the patient using the support platform 100, 100', 100".

The wheels 164 are preferably sized to provide added stability to the support platform 100, 100', 100". Accordingly, wheels 164 are preferably between about 2 to 10 inches in diameter, and more preferably between about 3 to 9 inches in diameter, and more preferably yet, a combination of wheels with the smaller wheels 164a, 164b measuring about 3 to 5 inches in diameter and the larger wheels 164c measuring about 7 to 8 inches in diameter.

Referring again to Figs. 1-3, the platform handle 108 is an integral part of the support platform 100, 100', 100". In at least one embodiment of the invention, the handle 108 comprises a particular ergonomic design that allows the user to push and use the platform while their hands are kept in a comfortable position. The design also minimizes the ability of the user to tip the platform when applying a force to the platform handle 108.

In accordance with another aspect of the invention, the support platform 100, 100', 100" includes a platform top 112 for holding a number of optional components (also referred to as "ancillary devices") as discussed hereafter. The platform top 112 is preferably operatively interconnected to a means for holding an IV bag. The means for holding an IV bag preferably includes at least a section of a pole 176, and/or a hook 180, and/or a rail 132, and/or the skirt 136 with a carabiner clip, and/or other hook attachment located either above or below the platform top 112. Additionally, existing IV, enteral and syringe pumps used by

health-care facilities will be accommodated on either a pole 176 or rail system 132 located on top of the platform top 112. The support platform 100, 100′, 100″ will be able to accommodate from zero to six pumps, and more preferably zero to four pumps. For the embodiments depicted in Figs. 1-5, various maintenance and treatment devices are hung or otherwise interconnected to the support platform 100, 100′, 100″, on the rails 132, resting on the top 112, or hanging from the skirt 136.

In accordance with embodiments of the present invention, an attachment device comprising a custom carabiner may be provided and used to releasably attach IV bags or other medical equipment, such as an infusion pump, to the platform's support structure. For example, such attachment devices may be used both on the rail 132 or the skirt 136 the support platform 100, 100′, 100″. In accordance with at least one embodiment of the present invention, the carabiners provide adequate gate clearance to accommodate both the rail 132 or skirt 136, and provide easy interconnectivity and removability of the previously listed devices or IV bags from the support platform 100, 100′, 100″. In another aspect of the invention, the carabiners preferably comprise of different colors in order to categorize IV fluids for rapid easy identification by healthcare providers. For example, IV fluids without added medication may hang from blue carabiners, IV fluids with antibiotic additives may hang from green carabiners, and IV fluids containing vasopressor additives my hang from red carabiners.

The platform top 112 or other portions of the frame 104 can include one or more other devices or apparatus, including such items as fluid reservoirs, metering pumps, cup/bottle holders, trays, a sitting stool, monitoring devices, computers, and communication devices, as well as a television, camera, phone or radio. Power receptacles 184 may also be provided either associated with the platform top 112 or frame 104 that will allow for multiple electronic devices to be plugged into either side of the platform. The consumer may or may not decide the number of receptacles. In addition, a retractable power cord 188 may also be provided on the support platform 100, 100′, 100″.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes communication equipment to receive vital sign information from the patient by wired or wireless means. The information may then be transmitted wirelessly to the appropriate medical staff or alarm systems while the patient is using the support platform 100, 100′, 100″. The support platform 100, 100′, 100″ preferably is interconnected to a stationary outlet while at the patient's bed, and then when disconnected to allow movement, the on-board communication system preferably provides wireless signals.

The vital sign collection equipment is considered an integral part of the invention as these interact explicitly with the support platform 100, 100′, 100″. The devices gather information regarding a patient's heart rate, non-invasive blood pressure, arterial blood pressure, central venous pressure, urine output, abdominal compartment pressure, respiratory rate, oxygen saturation and any other information that may be relevant to a patient's care. Other data from devices such as the bed and ventilator to include patient weight, bed alarms and ventilator parameters may be received and transmitted through the support platform as well.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes an on-board oxygen supply 192. In use, for those patients needing an oxygen supply, the tubing is preferably directly interconnected to the patient. The oxygen supply may be an existing oxygen bottle system or preferably includes tubing connections to allow the support platform 100, 100′, 100″ to be interconnected to a stationary oxygen source, such as a wall outlet that carries and delivers oxygen to a patient's hospital room. Accordingly, the support platform 100, 100′, 100″ can be positioned at the side of the patient's bed, and when the patient leaves his or her bed, the tubing from the support platform 100, 100′, 100″ is disconnected from the stationary oxygen source, without substantial interruption in the flow of oxygen to the patient. Accordingly, the support platform 100, 100′, 100″ preferably includes a bypass connection for utilizing a stationary oxygen source when the support

platform 100, 100′, 100″ has tubing interconnected to the stationary oxygen source.

In yet a separate aspect of the invention, the support platforms 100, 100′, 100″ preferably includes a chargeable battery and/or chargeable uninterruptible power supply, (where a chargeable battery and/or chargeable uninterruptible power supply is herein referred to collectively or singularly simply as "UPS") 200. The UPS 200 is preferably located near the base 120 to provide a relatively low center of gravity for the support platform 100, 100′, 100″. The UPS 200 allows the support platform 100, 100′, 100″ to be unplugged from a stationary power source, such as a wall outlet, with the platform's UPS 200 maintaining power to all of the on-board systems, such as the injection pumps, suction pumps, and vital sign monitoring equipment. In addition, the UPS 200 provides a back-up power supply to the electronic devices interconnected to it. Therefore, in the event of a power outage, the UPS 200 provides emergency power to the electrical devices interconnected to the platform's UPS 200. This is particularly advantageous for site locations that do not have an emergency back-up generator connected to the building's power supply. Preferably, the UPS 200 charges when it is plugged into a wall outlet while the devices remain operational.

For platforms utilizing electrical devices, the support platform 100, 100′, 100″ is preferably pre-wired and includes an electrical system. Therefore, the support platform's built-in modularity and electrical system limits the number of cords to power the modular electrical devices, such as pumps or monitoring devices. Accordingly, in one preferred embodiment, injection pumps, suction pumps, monitoring devices, and/or communication equipment can be quickly snapped into place into the frame 104 of support platform 100, 100′, 100″, such as in the platform top 112 of the support platform, with the power supply to the subject device provided by the hook-up port 184 or receiving connector on the support platform 100, 100′, 100″.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes an umbilical cord (not shown) having common plug for interconnecting a plurality of

systems to a single outlet, such as a wall outlet. The umbilical cord may include a variety of systems, including electrical power, oxygen, suction, and/or a communication connection. When the patient uses the support platform 100, 100′, 100″ as a walking aid, or when the patient is moved in their bed with the support platform 100, 100′, 100″ interconnected to the bed or the support platform 100, 100′, 100″ is otherwise made mobile, the common plug is removed from the wall outlet, thereby not only freeing the support platform from being tethered to the wall, but also engaging the on-board UPS 200 to power any interconnected devices, as well as engaging the on-board oxygen supply and suction pump to the patient, if in use. Therefore, the umbilical cord and associated common plug allows for a quick and easy disengagement from a stationary hook-up. In addition, in order to engage the support platform 100, 100′, 100″ to the systems available from a stationary source, such as a wall outlet, the common plug attached to the umbilical cord is simply engaged with the wall outlet, thus bypassing and/or recharging the support platform's on-board systems.

In yet a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes tube and wiring bundling channels or clips to organize the various tubes or wires that lead from the platform to the patient. The tube and wiring bundles are preferably situated to minimize the potential for the tubes or wires to interfere with objects as the support platform 100, 100′, 100″ is pushed by the patient or the patient is transferred by other personnel.

In yet a separate aspect of the invention, a hip or other body attachment (not shown) or aid can be provided to assist a patient in moving the support platform when the patient has a physical impediment to grasping the platform handle 108, such as may be the case if the patient has a broken arm, leg, pelvis, shoulder, scapula or ribs. Other physical impairments such as arm and leg amputations can be addressed with other attachments either to the platform or patient. A hip attachment would be one such attachment that would interconnect the support platform 100, 100′, 100″ to the patient, such as by a cushioned bar positioned at or

near the patient's hip.

In a separate aspect of the invention, the support platform may include an interior space and/or compartments for holding reservoirs or bags. For example, as shown in Figs. 2-5, the support platform 100', 100" may include a cabinet area 204 or other enclosure, the cabinet area 204 preferably including one or more drawers 208, doors 212 and/or access panels 216. Hooks or modular receptacles can be provided within the cabinet space. The interior space or cabinet area 204 can be configured to receive one or more urine or drainage bags. More preferably, in accordance with embodiments of the invention, the collection chambers can accommodate canister assemblies (not shown) designed to provide a mechanism of measuring the volume of the canisters automatically. This system may include a float, conduction or transmission mechanism. This information could then be converted to electronic data that could be transmitted along with other patient vital statistics as described elsewhere in this document.

Referring now to Figs. 10-14, and in accordance with another aspect of the invention, the support platform 100, 100', 100" comprises a mechanism for being releasably attached to another object, such as a bed, hand rail, vehicle, etc. In accordance with at least one embodiment of the invention, support platform 100, 100', 100" includes at least one bed hook 1000, and more preferably, a plurality of bed hooks 1000. The bed hooks 1000 provide a means for temporarily docking the support platform 100, 100', 100" to a bed when the platform is not being used as walker by a patient. The bed hooks 1000 allow the support platform 100, 100', 100" to remain stationary and attached to the patient's bed if it is inadvertently bumped by a hospital staff member, patient, or visitor. In addition, the bed hooks 1000 can be used to secure the support platform to the patient's bed if the patient is moved while remaining within the bed and the support platform is required to move with the bed. For this type of use, an additional staff member is not needed to roll the support platform 100, 100', 100" adjacent to the moving bed. The bed hooks 1000 allow the support

platform 100, 100′, 100″ to be lifted by another object, such as the patient's bed, such that the wheels 164 the platform are suspended, thereby making transportation easier because only the wheels on the bed need be controlled.

Referring now to Figs. 5 and 10, an upper portion 220 of a support platform 100, 100′, 100″ is shown that includes a pair of bed hooks 1000, wherein a first bed hook 1000 is located adjacent to or at a right side of the support platform 100, 100′, 100″ and a second bed hook 1000 is located adjacent to or at a left side of the support platform 100, 100′, 100″. For the embodiment of the support platform 100″ shown in Figs. 3-5, the bed hooks 1000 are located at the rear portion 148 of the support platform 100″. However, it is to be understood that the bed hooks 1000 may be used on any version of the support platform, including support platform 100, 100′, 100″, and furthermore, the bed hooks 1000 may be located not only at the rear 148 of the support platform, but also at the front 152 or along a side of the support platform.

Each bed hook 1000 preferably includes an arm member 1004 that is rotatable in at least one direction, or outward from the support platform, such as per arrow A_1. In addition, at least a portion of the arm member 1004 is also rotatable in a second direction when engaging a bed or other object to which it is being attached, such as per arrow A_2. More particularly, and as described in additional detail below, the arm member 1004 is first rotated to extend away from the platform, as per arrow A_1, and then the arm member 1004 may be rotated again as per arrow A_2 to engage the bed or other object. As shown in Fig. 10, arm member 1004 is preferably located in a retracted or first position 1008, wherein the arm member 1004 is closed or positioned substantially adjacent the upper portion 220 of the support platform 100, 100′, 100″. More particularly, when closed, a side surface 1012 of the arm member 1004 is situated adjacent a rear side 1016 of the support platform 100, 100′, 100″. The arm member 1004 is then rotated on a hinge 1020 to an open or second position

1024 for engagement with an object, such as a bed. Thus, the bed hooks 1000 preferably feature a plurality of positions so that they remain unobtrusive when not in use. In addition, the bed hooks 1000 preferably include a material suitable for gripping, such as a plastic or rubber pad (not shown).

Referring now to Figs. 11A and 11B, the arm member 1004 is shown in an extended or open position 1024. In accordance with embodiments of the present invention, the arm member 1004 includes a lateral branch 1100 and a rotatable gripper portion 1104. The gripper portion 1104 is rotatably interconnected to the lateral branch 1100 by a pin 1108. In accordance with embodiments of the present invention, the gripper portion 1104 includes a pinching finger 1112 that has an inside surface 1116 for contacting the bed or object to which the support platform 100, 100′, 100″ is to be attached. In addition, the gripper portion 1104 further includes an upper finger 1120 with an underside 1124 for also contacting the bed or object to which the support platform is to be attached. As shown in Fig. 11A, the gripper portion 1104 is in an unhooked position 1128. Upon rotation of the gripper portion 1104 about pin 1108, the pinching finger 1112 moves toward the support platform to clamp or engage the bed.

Referring now to Figs. 12-14, a support platform 100, 100′, 100″ with bed hooks 1000 is shown in use. As shown in Fig. 12, the bed hooks 1000 are depicted in the open position 1024 prior to engaging a portion of the bed B, such as a head board, foot board or rail. The portion of the bed B to engage the support platform 100, 100′, 100″ is then raised. As seen in Fig. 13, an upper surface BS of the bed B contacts the underside 1124 of the upper finger 1120 of the gripper portion 1104. Referring now to Fig. 14, as the bed B is raised further, the gripper portion 1104 rotates about pin 1108 relative to the lateral branch 1100. In so doing, the pinching finger 1112 rotates toward the rear side 1016 of the support platform 100, 100′, 100″, thereby pinching the bed B between the inside surface 1112 of the pinching finger and the rear surface 1016 of the support platform 100, 100′, 100″. With continued

raising the bed B, the bed B will lift the support platform 100, 100′, 100″ from the floor. The bed B can then be moved with the support platform 100, 100′, 100″ releasably attached to the bed B. The bed hooks 1000 thus provide a means for moving the platform and the bed as a unit, without the need for a separate attendant or nurse to guide the support platform as another person moves the bed.

In accordance with embodiments of the present invention, an alternative attachment device (not shown) may be used to releasably attach the support platform 100, 100′, 100″ to a bed or other object. For example, the platform handle 108 may be modified for engaging a portion the bed or another object. Such alternative attachment device may include an adjustable setting that allows the alternative attachment device to be configured for use with a variety of bed frames or wheelchair configurations or other vehicles, such as automobiles or motorized platforms.

Referring now to Fig. 15, and in accordance with at least one embodiment of the invention, the support platform 100, 100′, 100″ may include a selectable transmission system 1500. Fig. 15 illustrates a number of components of the transmission system 1500 in solid lines, with other aspects of the support platform 100, 100′, 100″ superimposed over the transmission system. It is to be understood that the transmission system 1500 is also applicable to support platform 100, 100′, 100″, as well as other platforms that embody the present invention.

In general, the transmission system 1500 comprises a selectable control bar 1504 that is connected to a control shaft 1508 that controls a transmission applicator mechanism 1512. In accordance with embodiments of the present invention, transmission system 1500 preferably has a plurality of settings or modes that can be selected using the control bar 1504. For the embodiments illustrated in Figs. 15-21, three different settings are provided; however, it is to be understood that a transmission system with an alternate number settings is possible, such as two settings.

Referring now to Figs. 16 and 17 that each show a portion of the transmission system 1500, the control bar 1504 is preferably interconnected to a handle 1600, wherein the handle 1600 is movable along slot 1604, thereby allowing a user or healthcare staff member to select the setting for the transmission system 1500. More particularly, as shown in Fig. 16, a first setting corresponds to a stop mode, a second setting corresponds to a walk mode, and a third setting corresponds to a roll mode. In accordance with the embodiment and view shown in Fig. 16, the stop mode is the left-most position 1608a shown for the handle 1600, the walk mode is an intermediate position 1608b shown for handle 1600, and the roll mode is the right-most position 1608c shown for handle 1600. In general, the stop mode corresponds to having the support platform 100, 100′, 100″ stationary, the walk mode corresponds to placing the support platform 100, 100′, 100″ in a controlled state for a patient to ambulate using the support platform 100, 100′, 100″ as a walking aid, and the roll mode corresponds to a free-rolling state wherein the support platform 100, 100′, 100″ can be quickly and easily rolled, such as by a healthcare staff member moving the support platform 100, 100′, 100″ to a patient's room from a storage area.

In accordance with embodiments of the present invention, and as best seen in Figs. 17 and 18, although not required, a second handle 1600 may be positioned at the front of the support platform 100, 100′, 100″ to allow control of the transmission system 1500 from the front of the support platform 100, 100′, 100″. This configuration offers several advantages, including that a healthcare staff member can set the transmission system 1500 when a patient is at the rear of the support platform 100, 100′, 100″ and substantially blocking the handle 1600 at the rear of the support platform 100, 100′, 100″. Whether at the front or back of the support platform 100, 100′, 100″, the handle 1600 is generally moved transversely to a vertical axis V-V of the support platform 100, 100′, 100″ within the slot 1604. The handle 1600 is preferably interconnected to the control bar 1504 using an interconnection mechanism

1800 comprising connecting hardware 1804 that allows an end 1700 of the control bar 1504 to rotate relative to the handle 1600, such that a longitudinal axis H-H of the handle 1600 remains substantially parallel to a front to rear axis A-A of the support platform 100, 100', 100" as the handle 1600 is moved along slot 1604. The control bar 1504 rotates at pivot point 1704 about a rotational axis that corresponds to the longitudinal axis S-S of the control shaft 1508. Although only one control shaft 1508 is shown, the control bar 1504 may be interconnected to a plurality of shafts that lead to one or more transmission applicator mechanisms.

Referring now to Figs. 19 and 20, and in accordance with at least one embodiment of the present invention, a transmission applicator mechanism 1512 is shown that includes functionality corresponding to the three transmission settings of stop mode 1608a, walk mode 1608b and roll mode 1608c. The transmission applicator mechanism 1512 generally includes a cam 1900 that is connected to the control shaft 1508. In at least one embodiment, the cam 1900 provides at least a means for adjusting the position of the drag wheel. When the handle 1600 is moved along slot 1604, the control bar 1504 rotates the control shaft 1508, and the cam 1900 also rotates. As the cam 1900 rotates, the transmission applicator mechanism 1512 either (1) applies both a brake assembly 1904 and a drag wheel assembly 1908 to the floor (or other surface under the platform) when the transmission system 1500 is set to the stop mode 1608a, (2) maintains the brake assembly 1904 in a raised position while the drag wheel assembly 1908 contacts the floor when the transmission system 1500 is in the walk mode 1608b, or (3) maintains both the brake assembly 1904 and the drag wheel assembly 1908 in raised positions while the transmission system 1500 is in the roll mode 1608c.

The brake assembly 1904 may comprise a variety of configurations, and in one embodiment comprises a post 2000 that is connected to a stopper 2004 at the distal end 2008 of the post 2000. The stopper 2004 may comprise a variety of materials and configurations, but generally includes characteristics that will generate a relatively large frictional force with

the underlying floor. For example, the stopper 2004 may comprise a rubber or plastic structure that tends to generate a large amount friction with the floor. Although the example stopper 2004 shown in Fig. 20 is cylindrical in shape with a circular distal end 2012 for contacting the floor, the stopper 2004 may be elongated in a direction transverse to the post 2000 such that a relatively wide contact area is formed with the floor. The post 2000 extends from the stopper 2004 to the cam 1900, and includes an upper flange 2016 at its proximal end 2020 at the cam 1900, and a lower flange 2024 that resides adjacent and below a base panel 2028. As will be discussed in more detail below, the brake assembly 1904 also preferably includes a biasing member 2032 that resides between the lower flange 2024 and the stopper 2004. As shown in Fig. 20, and in accordance with at least one embodiment, the biasing member 2032 comprises a compression spring, but may also comprise other structure, such as an air cylinder.

The drag wheel assembly 1908 provides a means for frictionally engaging the underlying surface, and in at least one embodiment comprises a wheel 2036 interconnected to the base panel 2028 by a movable linkage arm 2040, wherein the linkage arm 2040 can be lowered and raised to either apply the wheel 2036 to the floor, or to raise the wheel 2036 from contacting the floor. As discussed in more detail below, the drag wheel assembly 1908 preferably incorporates a rotation resistance mechanism that is interconnected to the wheel 2036 such that the wheel 2036 acts as a governor to control the speed of the support platform 100, 100′, 100″. The linkage arm 2040 is preferably interconnected to the cam 1900 by a post 2044 that extends from a pivot point 2048 at the linkage arm 2040 to the cam 1900. The post 2044 includes an upper flange 2016 at its proximal end 2020 at the cam 1900, and a lower flange 2024 that resides adjacent and below the base panel 2028. The assembly for the drag wheel assembly 1908 also preferably includes a biasing member 2032 that resides between the lower flange 2024 and the pivot point 2048 at the linkage arm 2040.

Referring still to Figs. 19 and 20, and in accordance with at least one embodiment of

the present invention, the cam 1900 includes a first curved or arc-shaped channel 1912 to control the brake assembly 1904, and a second curved or arc-shaped channel 1916 to control the drag wheel assembly 1908. When handle 1600 is moved to the stop mode 1608a, the control bar 1504 rotates the control shaft 1508 such that the post 2000 of the brake assembly 1904 and the post 2044 of the drag wheel assembly 1908 are located at first positions 1920 and 1924 of the channels 1912 and 1916, respectively. At these first positions 1920 and 1924, both the brake assembly 1904 and the drag wheel assembly 1908 are engaged such that the stopper 2004 and wheel 2036 are in contact with the floor. When at the first position 1920, the post 2000 is in a lowered position because the cam thickness at the first position 1920 is such that the upper flange 2016 of post 2000 is lower relative to the base panel 2028. When in the first position 1920, the biasing member 2032 of post 2000 forces the stopper 2004 downward and in contact with the floor. Similarly, when post 2044 is in the first position 1924, the upper flange 2016 of post 2044 is also lower relative to the base panel 2028 and the biasing member 2032 of post 2044 forces the linkage arm 2040 downward and places the wheel 2036 in contact with the floor.

Upon sliding handle 1600 to the walk mode 1608b position, the control bar 1504 rotates and turns the control shaft 1508, thereby turning the cam 1900. As the cam 1900 is turned, posts 2000 and 2044 remain laterally stationary and traverse the cam 1900 along channels 1912 and 1916, respectively. The posts 2000 and 2044 are then located at the second positions 1928 and 1932 along the first and second channels 1912 and 1916, respectively. In addition, as the proximal end 2020 of post 2000 for the brake assembly 1904 moves along first curved channel 1912 from the first position 1920 toward the second position 1928, the post 2000 rises because the upper flange 2016 of post 2000 encounters cam transition ramp 1936. The rise in cam transition ramp 1936 pulls the stopper 2004 off the floor and compresses the biasing member 2032 between the stopper 2004 and the lower flange 2024. In addition, as the cam 1900 is turned, the post 2044 remains in its lowered

position because the elevation of the upper flange 2016 of the post 2044 at the second position 1932 is substantially equal in elevation to the elevation of the upper flange 2016 when the post 2044 is in the first position 1924.

Upon sliding handle 1600 from the walk mode 1608b position to the roll mode 1608c position, the control bar 1504 again rotates and turns the control shaft 1508, thereby once again turning the cam 1900. Once again, the posts 2000 and 2044 remain laterally stationary and traverse the cam 1900 further along channels 1912 and 1916, respectively. The posts 2000 and 2044 are then located at the third positions 1940 and 1944 along the first and second channels 1912 and 1916, respectively. In addition, as the proximal end 2020 of post 2044 for the drag wheel assembly 1908 moves along second curved channel 1916 from the second position 1932 toward the third position 1944, the post 2044 rises because the upper flange 2016 of post 2044 encounters a second cam transition ramp 1936. The rise in cam transition ramp 1936 pulls the linkage arm 2040 upward and the wheel 2036 off the floor and also compresses the biasing member 2032 between the pivot point 2048 of the linkage arm 2040 and the lower flange 2024 of post 2044. In addition, as the cam 1900 is turned from the walk mode 1608b to the roll mode 1608c, the post 2000 remains in its upper position because the elevation of the upper flange 2016 of the post 2000 between the second position 1928 and third position 1940 is substantially equal in elevation.

The biasing members 2032 for both posts 2000 and 2044 place the brake assembly 1904 and the friction wheel assembly 1908 in a preferred state of engagement because the biasing members 2032 tend to force the down the stopper 2004 and the wheel 2036. That is, work has to be done against the biasing member 2032 for post 2000 to move the handle 1600 from the stop mode 1608a to the walk mode 1608b, and work also has to be done against the biasing member 2032 for post 2044 to move the handle 1600 from the walk mode 1608b to the roll mode 1608c. Thus, if a person is operating the support platform 100, 100′, 100″ in walk mode 1608b, it is relatively easy to place the handle 1600 in stop mode 1608a and apply

the stopper 2004 to the floor because the biasing member 2032 of post 2000 tends to want to force the post 2000 and stopper 2004 downward. This is a safety feature of the transmission system 1500.

Referring now to Fig. 21, an alternate embodiment of a transmission applicator mechanism 1512′ is shown. For clarity, the base panel 2028 has been omitted from Fig. 21. Similar to that described above for the assembly 1512 shown in Figs. 19 and 20, the cam 1900′ shown in Fig. 21 includes a first channel 1912 for controlling post 2000 of the brake assembly 1904. The transmission applicator mechanism 1512′ further includes a drag wheel assembly 1908′ that utilizes two posts 2004a′ and 2004b′ to control the vertical position of the wheel 2036 through two channels 1916a′ and 1916b′ in cam 1900′. Although a linkage arm 2040 is not used with transmission applicator mechanism 1512′, the operation of the transmission applicator mechanism 1512′ is similar to that described above for transmission applicator mechanism 1512. Thus, upon rotation of the cam 1900′ in stop mode, the stopper 2004 and wheel 2036 are lowered to contact the floor, and in walk mode the stopper 2004 is raised, while in roll mode both the stopper 2004 and the wheel 2036 are raised from contacting the floor. Thus, the transmission system 1500 may take on a variety of configurations, including alternate transmission applicator mechanisms, and such alternate embodiments and modifications are encompassed by the present invention.

Referring now to Figs. 20 and 21, and as mentioned above, the drag wheel assembly 1908 preferably includes a rotation resistance mechanism 2052 that is interconnected to the drive wheel 2036, thereby enabling the wheel 2036 to restrict the speed of the support platform 100, 100′, 100″. In accordance with embodiments of the present invention, the rotation resistance mechanism 2052 may take the form of a friction pad (not shown) that engages at least a portion of the wheel 2036 and/or structure operably interconnected to the wheel 2036. More preferably, however, the rotation resistance mechanism 2052 comprises a braking motor 2056 interconnected to the wheel 2036, such as by way of the wheel's axle. In

accordance with embodiments of the present invention, the braking motor 2056 is interconnected to the wheel 2036 through a gearbox. The braking motor 2056 applies a force to the wheel 2036 to slow the wheel 2036 under the principle that little or no wheel speed requires the application of no braking, but high wheel speed requires the application of braking work on the wheel 2036 by the braking motor 2056. More particularly, as wheel speed increases, the output of the braking motor 2056 increases. The increased output results in an increased load on the braking motor 2056, increasing the braking force applied to the wheel 2036. The braking motor 2056 may comprise a permanent magnet DC motor. Furthermore, as can be appreciated by one of skill in the art after consideration of the present invention, the braking motor 2056 is not connected to a source of electrical power, but is instead driven as a generator (i.e., a source of electrical power) by the wheel 2036.

Referring now to Fig. 22, a schematic of a motor braking circuit 2200 for applying a braking force to the wheel 2036 in response to a voltage generated by the braking motor 2056 in accordance embodiments of the present invention is illustrated. The circuit shown in Fig. 22 is a multi-stage Zener diode auto-transmission system or braking circuit 2200 for automatically applying a braking force to the wheel 2036. In general, use of a number of different Zener diodes allows different stages of resistance to be applied progressively, as the voltage produced by the motor increases. As can be appreciated by one of skill in the art, the voltage produced by the braking motor 2056 will tend to increase as the rotational velocity of the wheel 2036 driving the braking motor 2056 increases. Furthermore, by switching in additional resistive loads as the voltage produced by the braking motor 2056 increases, and therefore drawing more current, the braking effect of the braking motor 2056 can be increased in steps.

In accordance with embodiments of the present invention, each stage 2204 of the circuit 2200 comprises at least one zener diode 2208 and at least one load resistor 2212. The zener diode ZD1 2208 of the first stage 2204a is selected to have a turn on or a breakdown

voltage (*i.e.* a zener voltage) that is relatively low. When the zener voltage is exceeded, the zener diode ZD1 2208 conducts, allowing current to pass through the load resistor R1 2212. Accordingly, the zener diode ZD1 2208 acts as a switching mechanism. The current draw from the introduction of this load will load the braking motor 2056 such that the resistance to rotation of the wheel 2036 (not shown in Fig. 22) will increase essentially linearly with increased speed. The second stage 2204b is in parallel with the first stage 2204a and has a zener diode ZD2 2208 that is selected to have a zener voltage that is higher than the first zener diode ZD1 2208. If the voltage produced by the braking motor 2056 meets or exceeds the zener voltage of the second zener diode ZD2 2208, the second zener diode ZD2 2208 conducts, allowing current to pass through the load resistor R2 2212 associated with the second stage 2204b of the circuit 2200. Accordingly, this zener diode ZD2 2258 also acts as a switching mechanism. Since the first zener voltage is lower than the second zener voltage, the first zener diode ZD1 2208 will continue to conduct while the second zener diode ZD2 2208 is conducting. Accordingly, two current paths through two of the stages 2204 will be active, increasing the rate at which the load increases with increased braking motor 2056 speed as compared to when only the first zener diode ZD1 2208 is conducting. As shown in Fig. 22, additional parallel circuit branches or stages 2204 comprising additional zener diode 2208 and load resistor 2212 pairs can be included, to provide any number of steps in the resistance produced at the wheel 2036 as the rotational speed of the wheel 2036 increases. For example, in Fig. 22 three stages 2204 (stages 2204a, 2204b and 2204c) are included. However, fewer or additional stages 2204 may be included depending on the desired number of steps in the rate of resistance provided by the circuit 2200.

As can be appreciated by one of skill in the art, the zener voltage is generally higher than the voltage at which a zener diode will conduct a forward current. Therefore, if the braking motor 2056 is operated in the opposite direction, such that if a negative voltage is produced at the first terminal of the braking motor 2056, a circuit with branches or stages

configured like the first three branches 2204a-c of Fig. 22 will allow the load introduced by the associated resistors to be applied at a much lower voltage than when the motor is operated in the other direction. This may be desirable, for example where it is desirable to have the platform move only in a forward direction while in the walk mode. In order to allow for resistance to be applied in a similar fashion in either a forward or reverse direction, blocking diodes 2216 can be introduced in the circuit branches. By introducing blocking diodes 2216, current is only conducted by a stage 2204 when a voltage is applied to that stage's 2204 zener diode 2208 as a reverse voltage, because the blocking diode 2216 will prevent a forward voltage from being applied to this zener diode 2208. Additional circuit branches 2204 can then be provided for progressively introducing a load when the braking motor 2056 is operated in the reverse direction. These additional circuit branches 2204 (see branches 2204d, 2204e and 2204f in Fig. 22) are oriented such that the associated zener diode 2208 and blocking diode 2216 are opposite the orientation of those included in the circuit branches for providing progressively increasing braking force in the forward (opposite) direction (branches 2204a, 2204b and 2204c in Fig. 22). Although only three stages or branches 2204 for applying a braking force in a reverse direction are shown, it should be appreciated that fewer or additional of such stages may be provided.

Referring now to Fig. 23, an alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2300 shown in Fig. 23 is a multi-stage metal-oxide semiconductor field-effect transistor (MOSFET) auto-transmission system for automatically applying a braking force to the drive wheel 2036. In general, in the first stage 2302a, when the voltage divided down by resistors R2 2304 and R7 2304 is greater than Vth of transistor Q1 2308, transistor Q1 2308 will turn on and apply the load resistor R8 2312 to the braking motor 2056. Accordingly, the voltage dividing resistors 2304 and the transistor 2308 comprise a switching mechanism. Subsequent stages in parallel with the first stage set to different points will add more load in a similar fashion once the set voltage for such stages is

met or exceeded. For example, a second stage 2302b is illustrated in Fig. 23, which may be configured to turn on at a higher voltage than the first stage 2303a. The transistors Q3 and Q4 2308 in the third 2302c and fourth 2302d stages are set in the opposite direction and will work in the reverse direction. Accordingly, the third and fourth stages 2303 and may be included in order to apply stages of resistance when the braking motor 2056 is turned in a direction opposite the direction the braking motor 2056 is turned to activate the first and second stages 2302a-b. Also, the body diodes of the transistors 2308 may be blocked or protected by a blocking diode 2316. Although four stages 2302 are shown in Fig. 23 (two for activation in a forward direction and two for activation in a reverse direction), it should be appreciated that any number of stages 2302 can be provided.

Referring now to Fig. 24, an additional alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2400 shown in Fig. 24 is a multi-stage Silicon Controlled Rectifier (SCR) braking system for automatically applying a braking force to the wheel 2036 (not shown in Fig. 24). In general, in the first stage 2404a, when the voltage across resistor R15 2408 gets high enough to send a trigger current through SCR D1 2412 allowing current to pass through load resistor R16 2416, SCR D1 2412 latches on and applies the load resistor R16 2415 to the motor 2056 until the motor voltage drops to the point where there is almost no more current through R16. The SCR 2412 and the resistor 2408 therefore comprise a switching mechanism. The second stage 2404b, in parallel with the first stage 2404a, has a resistor R17 2408 selected such that a trigger current is not sent through the associated SCR D5 2412 until after the first stage 2404a has turned on. Accordingly, the resistance to movement of the braking motor 2056 can be stepped up once the output of the braking motor 2056 exceeds a predetermined amount. Third 2404c and fourth 2404d stages, each having an SCR 2412 having an orientation that is opposite the orientation of the SCRs 2412 of the first 2404a and second 2404b stages can be provided to apply stages of braking force in a reverse direction. The third 2404c and fourth 2404d stages also include trigger

resistors R19 and R20 that are connected to an opposite node of the braking motor 2056 as compared to the trigger resistors R15 2408 and R17 2408 of the first 2404a and second 2404b stages. Although only two stages are shown for providing braking resistance in each direction, it can be appreciated that any number of stages maybe provided. Unlike embodiments described in connection with Figs. 22 and 23, the embodiment illustrated by Fig. 24 does not switch out the load resistor of a stage at the trigger voltage for that stage, but instead retains the current path through the load resistor until a much lower voltage is reached (*e.g.* almost zero).

Referring now to Fig. 25, an alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2500 shown in Fig. 25 is a hybrid circuit for automatically applying a braking force to the drive wheel 2036. In general, both an auto-transmission and an auto-braking feature are applied when different set resistances are achieved as a result of the voltage generated by the braking motor 2056. More particularly, the first stage 2502a is a stage incorporating a first switching mechanism for introducing a load resistor at a first voltage, while the second stage 2502b, which is in parallel with the first stage 2502a, incorporates a second switching mechanism for introducing a second load resistor at a second voltage. In the particular example of Fig. 25, the first stage 2502a uses a field effect transistor 2510 that allows current to pass through a first load resistor R23 2504 when the voltage divided down by set resistors R21 and R22 2508 is at a selected value. The second stage 2502b incorporates a silicone controlled rectifier 2512 that is switched on by a trigger current through resistor R24 2516 when the voltage across that resistor reaches a predetermined value, allowing current to pass through the load resistor R25 2520. The particular arrangement illustrated in Fig. 25 may be useful in selected applications, for example where it is desirable to have a mobile platform brought back to a standstill (or near standstill) after it has reached a velocity that exceeds a pre-determined bound. Specifically, the first stage load resistor R23 2504 can be switched in at a relatively low voltage, while the second load

resistor R25 2520 can be switched in at a higher voltage, and the second load resistor will remain switched in until the voltage is almost zero. As can be appreciated by one of skill in the art, additional stages, hybrid or otherwise, can be combined with the illustrated stages 2502a-b, for applying a load resistance in the same or in opposite direction from the illustrated stages 2502.

Fig. 26 is a graph depicting how the braking force produced by a braking motor 2056 can be progressively increased with increased braking motor 2055 velocity by using an auto transmission or braking system circuit in accordance with embodiments of the present invention. With specific reference to plot 2600, in a first speed range 2604, the force may remain essentially constant, for example due to the friction of the various platform wheels and of the unloaded braking motor 2056. The first speed range 2604 corresponds to a platform velocity (and therefore a drive wheel 2036 and braking motor 2056 velocity) at which the output produced by the rotation of the braking motor 2056 produces a voltage that is not high enough to cause a stage of a motor braking circuit to establish a current path across a load resistor. Once the maximum speed in the first speed range is exceeded, a second speed range 2608 may be entered in which the braking motor 2056 is operated to apply a braking force, by applying a load through a braking circuit. More particularly, the minimum speed of the second speed range 2608 occurs at a rotationally velocity of the braking motor 2056 at which the braking motor 2056 produces a voltage sufficient to trigger application of a load stage or branch of the motor braking circuit. The force applied by the braking motor 2056, and therefore the force required to continue moving the platform initially experiences a step increase, and then increases at an essentially linear rate due to the introduction of the resistive load. In a third speed range 2612, the braking motor 2056 is producing a voltage that is high enough to trigger application of a second load branch, as well as the first load branch. Upon application of the second load branch, the resistance takes a step increase, and then increases with the voltage output by the braking motor at a rate that is greater than the rate of increase

when only the first load was active. Where the first and second load branch or branches each add equal resistive loads, the slope of the increase in the force required to continue rotating the braking motor 2056 increases with velocity at approximately twice the previous rate. If a third stage is included in the circuit, a fourth speed range 2616 can be defined. When the fourth range 2616 is entered, another step increase in the force occurs when the third stage load resistor is added, and the resistance then increases at a linear rate that is greater than the rate of increase in the previous range.

When the velocity of the braking motor 2056 is decreasing, the force applied to the drive wheel 2036 by the braking motor 2056 will follow the same curve as when the velocity was increasing if a zener diode or a pair of dividing resistors and a transistor are used as the switching mechanisms. However, where a resistor and an SCR are used as a switching mechanism, the load resistor associated with such a switching mechanism will continue to be applied until the velocity of the braking motor 2056 (and hence its output) is almost zero. For instance, in a three stage braking circuit in which every stage comprises a resistor and an SCR switching mechanism, once the third speed range 2616 is entered, as the velocity of the motor decreases path 2618 will be followed.

In accordance with other embodiments of the present invention, the values of load resistors included in stages of a braking circuit can be selected from a number of different values to provide a selected resistance at the drive wheel 2036. For example, a ganged switch may be used to select from two or more load resistors that are applied at one or more of the speed ranges. In accordance with still other embodiments of the present invention, a switch for selecting a load resistor can be separately provided for selecting the load resistor or resistors that are applied in forward and reverse directions with respect to the platform. User selectable resistance can also be achieved through use of a potentiometer in place of one or more of the provided load resistors, provided the potentiometer has a suitable load rating. An example of the effect of selecting different, higher resistance load resistors applied at different

stages of the braking motor circuit is shown in Fig. 26 as plot 2620. As alternative to being user selectable, the load resistors may be selected or (in the case of a potentiometer) tuned by operation of a switch that is not normally user accessible. In addition, it should be appreciated that a braking motor circuit in accordance with embodiments of the present invention may be tuned such that a load resistor is immediately or almost immediately provided with current by the braking motor 2056, which would eliminate or shorten the first range 2604 during which there is no or almost no increase in the resistive force produced by the braking motor 2056 with increased velocity of the platform. Such tuning may be user adjustable. It can be appreciated by one of skill in the art that the motor braking circuitry provides a means for variably controlling a resistance to the braking motor 2056.

In accordance with embodiments of the present invention, the weight of platform may be adjustable to provide a larger normal force for allowing more braking and/or stopping force to be effectively applied when the brake assembly 1904 and/or drag wheel assembly 1908 are engaged. For example, additional ballast (sand filled articles, weights, etc.) may be located on the support platform 100, 100′, 100″ to increase the weight of the support platform 100, 100′, 100″.

It is noted that the transmission system 1500 and/or the rotation resistance mechanism 2052 have application to a variety of platforms and/or mobile devices. For example, a walker may be adapted to incorporate one or more of the transmission system 1500 and the rotation resistance mechanism 2052. As other possible examples of alternative uses, a wheel chair, a baby stroller, a beverage platform for airlines, and/or a serving platform for cruise ships may incorporate these systems, and such applications and others are within the scope of the present invention.

Referring now to Fig. 27, a block diagram or schematic depiction of some of the possible components of the support platform 100, 100′, 100″ are illustrated. Additional components other than those shown in Fig. 27 are also within the scope of the present

invention, including other components described herein, as well as additional items such as a built-in folding seat or a shade canopy/umbrella.

In use, the support platform 100, 100′, 100″ is initially positioned near the patient's bed. The support platform 100, 100′, 100″ can be then be modified to meet the patient's needs, such as by adding an IV bag, suction pump, injection pump, and/or oxygen supply, and by adding one or more devices to monitor the vital signs of the patient. By plugging the UPS 200 into an electrical outlet, such as a wall outlet, power can be supplied directly to the support platform, and therefore, power is supplied to items interconnected to the electrical system of the platform. In addition, if available and prescribed, oxygen can be directly supplied to the patient by connecting a stationary oxygen supply to the platform. The platform may also be secured to the patient's bed by utilizing bed hooks 1000 mounted on the support platform 100, 100′, 100″ to clamp the platform to the framing of the patient's bed.

When the patient is required to be moved from the room while in bed, the support platform can be disengaged from the provided stationary connections by unplugging or otherwise disengaging the connections to the platform, and then subsequently moving the support platform 100, 100′, 100″ while moving the patient's bed. If the support platform is interconnected to the bed, such as by bed hooks 1000, a separate attendant or nurse may not be needed to move the support platform 100, 100′, 100″ while moving the bed.

As the patient becomes mobile, the support platform can be used as a walking aid by disengaging the support platform systems from the stationary supply sources, such as electrical power or oxygen. By grasping the handle with one or two hands and pushing the platform, the patient can move away from the bed while IV fluids, pumps, and monitoring equipment on the support platform maintain treatment to the patient.

As can be appreciated by one of skill in the art after consideration of the present disclosure, embodiments of the present invention may provide physiological support to a patient that might not otherwise be conveniently available. For example, in connection with

hospitals or clinics in underdeveloped areas, a support platform 100, 100′, 100″ in accordance with the present invention may provide an integrated package for supplying a patient with oxygen, fluids, suction, waste receptacles, monitoring devices, and electrical power. Furthermore, a support platform 100, 100′, 100″ in accordance with embodiments of the present invention provides an integrated structure from which such physiological support can be supplied. As can also be appreciated from the description provided herein, the particular features or modules included as part of a support platform 100, 100′, 100″ in accordance with embodiments of the present invention can be selected according to the particular needs of a patient and can be changed as the needs of the patient change.

In summary, the present invention provides a stable apparatus for assisting a patient walking. Nurses will be able to make better use of their time in the direct care of patients. Patients may have decreased hospital stays, complication rates and less time in skilled-nursing facilities. Fewer therapeutic errors will result and nurses will be at decreased risk for back injuries. The apparatus may include an IV fluids assembly, while also optionally providing modular receptacles for receiving a pump, and further providing an optional uninterruptible power supply for powering one or more electronic devices, such as a pump or one or more pieces of monitoring equipment. The support platform preferably includes adjustable components, including an adjustable handle. The support platform also preferably includes an expandable configuration, such that while the platform may initially be used for simply holding an IV bag, it can be quickly modified to incorporate other prescribed treatments, such as an oxygen supply or injection pump. As the patient progresses through treatment, the support platform transitions from a bedside equipment station and emergency power supply, to a walking aid and wireless communications apparatus.

In accordance with the embodiments of the invention, the platform comprises a ruggedized version that enables the platform to be used in conditions outside of the confines of a healthcare facility. This may include conditions such as military field operations, on-site

disasters and underdeveloped regions. The basic premise of the platform is described above, with one or more of the following modifications:

1) larger wheels between the diameters of 6 to 12 inches to traverse rough terrain;

2) a raised base in order to provide greater ground clearance;

3) a broadened base width in order to provide greater stability on unlevel terrain; and

4) the materials may be altered in order to have greater impact tolerance and protection in extreme environments such as high dust, extreme temperatures, air drops, high humidity and inclement weather.

In accordance with still other embodiments of the invention, the platform can be adapted for use in the operating suite environment. Devices such as a headlamp, cautery device, sequential compression device, suction, laparoscopy equipment and gasses may be incorporated onto the platform. This places all of these devices on a single platform both in their current form and in future forms that are designed to fit in as modules that would reduce the overall size and weight of the device. A UPS would again be provided to power the devices and allow the batteries to be removed from each of the individual devices. This would be of benefit both in current OR's and in conditions such as military field conditions or less-developed regions where a self-contained platform would simplify the equipment and reduce the overall bulk. Each platform would be able to be individually configured to meet the specific needs to the user. The user would be able to easily swap modules at the site of use to change the configuration as well.

In accordance with yet another embodiment of the invention, a platform is provided for use in veterinary medicine. One variation comprises a platform for use in small-animal veterinary medicine that is designed for indoor use with modules specific for the care of smaller animals. A second variation comprises a platform for use with larger animals that is more akin to the ruggedized version described above to address the specific concerns of large-animal veterinary medicine.

In accordance with still other embodiments of the present invention, non-medical applications of the device are within the scope of this invention. Brief descriptions of some of the variations are provided. This is not limiting in nature and other variations which utilize the common core of the platform with modifications of the functions and modules provided are intended to be included in the scope of this invention. Several features may be considered common in the platform design or may be found in several variations. The cosmetic appearance of the platform is flexible and appealing including the ability for the user to select color. The small form factor of the invention is maintained and it is to be portable and remain unobtrusive in the environment of use. The device may be modified in order to be moved up and down stairs by a single user without damage to the platform or stairs. A motorized wheel or wheels may be added to aid in the motion of the invention for certain applications. The invention may be modified to include a stepping stool or mini-ladder that provides a stable system for the user with the brake enabled. Additionally, the invention may be modified to help stabilize a ladder by applying the brake and attaching directly to a taller ladder than provided on the platform. A universal power supply may be provided to power internal and external electrical devices.

A non-medical embodiment of this invention may be for use in a beauty salon. The invention may include a sink with drain, water supply and storage compartments in order to provide a beautician or stylist with all of the elements required to cut, style and wash a client's hair.

A non-medical embodiment of this invention may be for use in pet and animal grooming. The invention may include a sink, drain, grooming surface, hooks and compartments for grooming supplies, food and toys. The device may be expected to be used at professional grooming salons, in showmanship venues and at home.

A non-medical embodiment of this invention may be for use in a garage for auto mechanics. The invention may contain an air compressor, hangar for a light source, tool

compartments, hangar for a sleeper platform and compatibility with diagnostic hardware and software. This may include wireless transmission of data to a central diagnostic unit. This would allow a single mechanic or multiple mechanics with similar devices to work autonomously in a garage with their vital equipment readily available at their side.

A non-medical embodiment of this invention may be for use at home or in a handyman shop as a tool caddy. The invention may contain an air compressor, light source, tool compartments, compartments for accessories such as screws and nails, and an attachment to help stabilize a footstool or ladder.

A non-medical embodiment of this invention may be for use in indoor or outdoor landscaping. The wheel base will be modified to indoor or outdoor as similarly described previously for the medical aspect of this invention. The invention may also include a pressurized liquid tank or tanks for water, pesticides or fertilizers. Additional features may include a debris bin and storage bins for tools.

A non-medical embodiment of this invention may be for use in building maintenance. The invention may include a power supply, air compressor, compressed fluid storage, diagnostic equipment, wireless transmission capability, computer integration, tool compartments, attachments for spools of wire or tubing, a work stool and the ability to stabilize a ladder by enabling the brake and attaching to a ladder. It may also have a built in stepping stool or mini-ladder.

A non-medical embodiment of this invention may be for use by the elderly or handicapped in order to become more independent in or outside of the home. The stability of the structure will provide the user an aide in ambulation. Additionally, the invention will provide support, unlike current ambulatory aide devices, such as oxygen, compartments to hold drainage bags, cellular/wireless support to provide emergency aide, compartments to hold supplies, personals and groceries or other personal goods, a resting stool and an umbrella. Aide devices as in the medical version of the platform will be used for persons with

disabilities such as amputations, paralysis or other chronic conditions to allow them to use the platform effectively. A connector or system, such as the one previously developed to connect the invention to a hospital bed, may be developed to connect to a trailer hitch for easy transport with a vehicle. A portion or portions of the invention may easily detach for transfer of the module to a vehicle or residence without requiring transfer of the entire platform. The hope with this embodiment is to mobilize and reintroduce persons into society that were previously confined or restricted secondary to their disabilities.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

What is claimed is:

1. A personal support platform for traversing an underlying surface, comprising:

a frame;

a plurality of wheels interconnected to said frame;

a transmission system interconnected to said frame, said transmission system providing a number of user selectable modes, said user selectable modes comprising at least a stop mode, a walk mode and a roll mode; and

means for selectively choosing one of said stop, walk and roll modes by a user from a standing position adjacent said frame.

2. The platform as claimed in Claim 1, wherein said transmission system comprises a drag wheel that is selectively moveable from a first raised position in said roll mode to a second lowered position in said walk mode, and wherein said drag wheel is for contacting the underlying surface when in said second lowered position.

3. The platform as claimed in Claim 2, wherein said transmission system comprises a cam interconnected to said frame and the drag wheel, wherein said cam is rotatably movable to raise and lower said drag wheel from said first raised position in said roll mode to said second lowered position in said walk mode.

4. The platform as claimed in Claim 3, further comprising an automatic brake interconnected to said drag wheel, said automatic brake comprising a braking motor driven by said drag wheel and circuitry, wherein said circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel.

5. The platform as claimed in Claim 4, wherein said resistive load comprises a number of load ranges, wherein a first load range provides a first resistive load within a first velocity range for said braking motor, and wherein a second load range provides a second resistive load within a second velocity range for said braking motor.

6. The platform as claimed in Claim 5, wherein said second velocity range is automatically selected once a threshold velocity of said braking motor is reached.

7. The platform as claimed in Claim 1, wherein said transmission system comprises a brake interconnected to said frame, wherein said brake is selectively moveable from a first raised position in said walk and roll modes to a second lowered position in said stop mode, wherein said brake is for contacting the underlying surface when in said second position.

8. The platform as claimed in Claim 7, wherein said brake comprises a stopper frictionally engaging the underlying surface.

9. The platform as claimed in Claim 7, further comprising a cam having a first channel interconnected to said brake.

10. The platform as claimed in Claim 9, wherein said cam comprises a second channel interconnected to a drag wheel.

11. The platform as claimed in Claim 10, wherein first channel comprises a first ramp for raising and lowering a first post interconnecting said drag wheel to said cam,

and wherein said second channel comprises a second ramp for raising and lowering a second post interconnecting said stopper to said cam.

12. The platform as claimed in Claim 1, wherein said means for selectively choosing comprises a first handle at a rear portion of said frame, said handle selectively adjusting a setting of said transmission system.

13. The platform as claimed in Claim 12, further comprising a second handle at a front portion of said frame, said second handle selectively adjusting a setting of said transmission system.

14. The platform as claimed in Claim 1, wherein the user can select stop mode to engage a friction mechanism with the underlying surface.

15. The platform as claimed in Claim 1, further comprising at least one grasping mechanism for interconnecting said frame to another structure.

16. The platform as claimed in Claim 15, wherein said grasping mechanism comprises a rotatable gripper arm that engages the other structure.

17. The platform as claimed in Claim 16, wherein said rotatable gripper arm rotates about a first axis in a direction away from said frame, and rotates about a second axis to grasp the other structure, wherein said second axis is transverse to said first axis.

18. A personal support platform for traversing an underlying surface, comprising:

a frame;

means for rotating interconnected to said frame and contacting the underlying surface;

means for frictionally engaging the underlying surface and interconnected to said frame; and

means for variably controlling a resistance provided by said means for frictionally engaging.

19. The platform as claimed in Claim 18, wherein said means for rotating comprises a plurality of wheels.

20. The platform as claimed in Claim 18, wherein said means for frictionally engaging comprises a drag wheel.

21. The platform as claimed in Claim 18, wherein said means for frictionally engaging is interconnected to a means for adjusting a position of said means for frictionally engaging, wherein said means for adjusting may alter a position of said means for frictionally engaging from a first position in contact with the underlying surface to second position wherein said means for frictionally engaging does not contact the underlying surface.

22. The platform as claimed in Claim 21, wherein said means for adjusting comprises a selectably positionable cam for raising and lowering said means for frictionally engaging.

23. The platform as claimed in Claim 18, wherein said means for variably controlling a resistance comprises a passive braking motor.

24. The platform as claimed in Claim 23, wherein said passive braking motor comprises:

a motor braking circuit interconnected to the passive braking motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined;

a load resistor, wherein when the passive braking motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

25. A method of using a personal support platform, the method comprising:

providing a drag wheel interconnected to the platform, the drag wheel for contacting a surface under the platform;

positioning the drag wheel to contact the surface under the platform; and

applying a braking to the platform through the drag wheel by applying at least a first braking resistance to the drag wheel for at least a first velocity range of the drag wheel.

26. The method as claimed in Claim 25, further comprising providing at least a second braking resistance to the drag wheel for at least a second velocity range of the drag wheel.

27. The method as claimed in Claim 26, wherein said second velocity range is automatically selected once a threshold velocity of a braking motor is reached.

28. The method as claimed in Claim 25, wherein said positioning step further comprises manipulating a transmission control device to lower the drag wheel in contact with the surface under the platform.

29. The method as claimed in Claim 25, further comprising engaging a stopper to contact the surface underlying the platform.

30. The method as claimed in Claim 25, further comprising releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the platform.

31. The method as claimed in Claim 30, further comprising impinging at least a portion of the other structure against a portion of said grasping mechanism.

32. A passive variable braking system, comprising:

a motor;

a motor braking circuit interconnected to the motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined;

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or

greater than the activation voltage and above a current is allowed to pass through the load resistor.

33. The system of Claim 32, wherein the motor braking circuit further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor,

wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor,

wherein the activation voltage for the second stage is greater than the activation voltage for the first stage, and

wherein when the activation voltage for the second stage is met or exceeded a current continues to be allowed to pass through the load resistor of the first circuit stage.

34. The system of Claim 33, further comprising:

a switch,

wherein the first and second circuit stages comprise a number of load resistors,

wherein the switch is operable to select one of each of the load resistors included in the first and second circuit stages to provide a selected resistance at the motor.

35. The system of Claim 32, where the motor braking circuit further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage, including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor,

wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor, and

wherein the activation voltage for the second stage has a polarity that is opposite the activation voltage for the first stage.

36. The system of Claim 32, wherein the switching mechanism comprises a zener diode.

37. The system of Claim 32, wherein the switching mechanism comprises a pair of voltage dividing resistors and a transistor, wherein a voltage divided by the pair of resistors is provided to a gate of the transistor.

38. The system of Claim 32, wherein the switching mechanism comprises a resistor interconnected to a Silicon Controlled Rectifier.

39. The system of Claim 32, further comprising:

a drag wheel interconnected to the motor, wherein the motor is driven by the drive wheel.

40. The system of Claim 39, wherein the drive wheel is interconnected to the motor by a gearbox.

41. The system of Claim 33, wherein the switching mechanisms of the first and second circuit stages each comprise a zener diode, and wherein the first and second stages each additionally include a blocking diode.

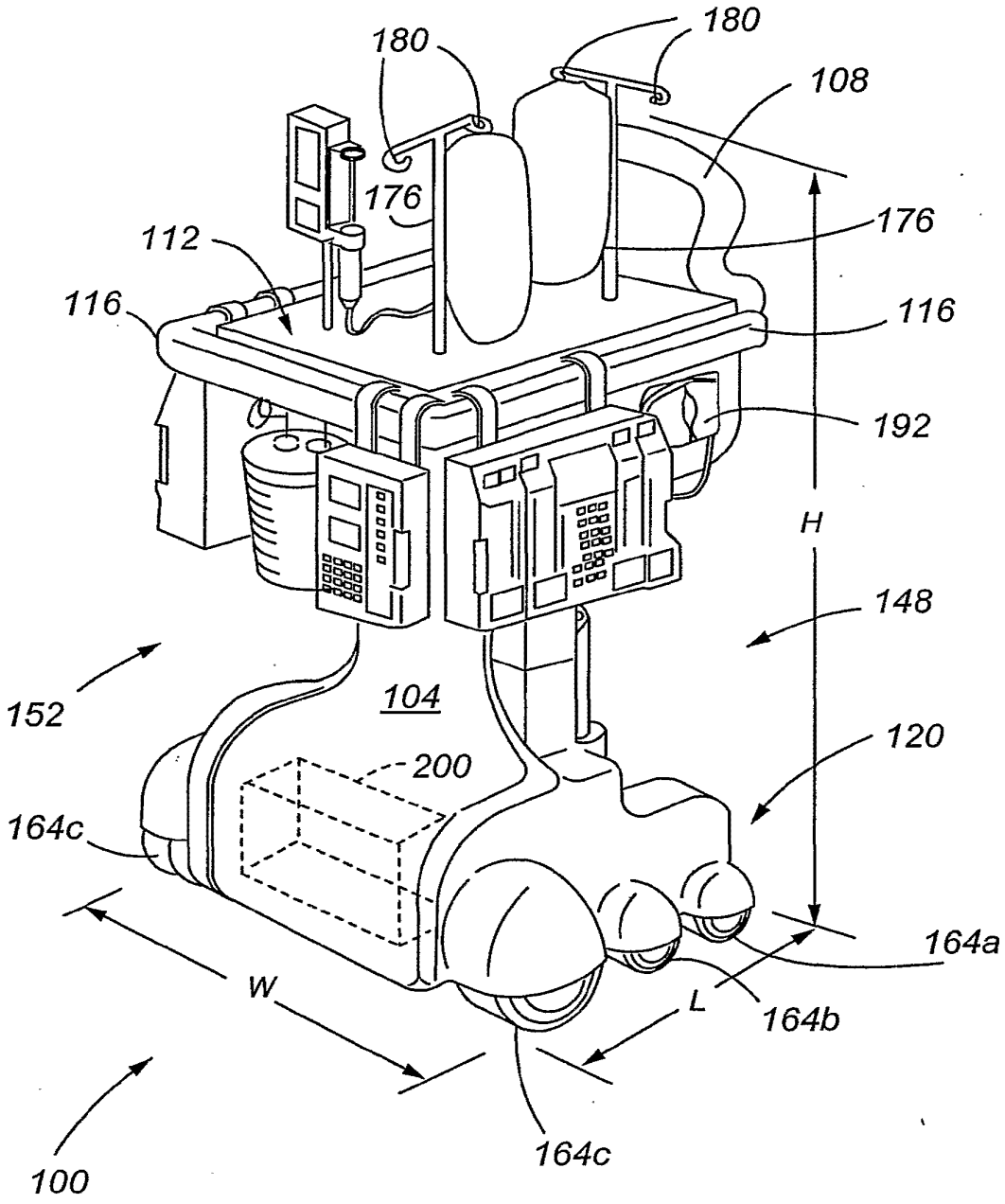
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Fig. 1

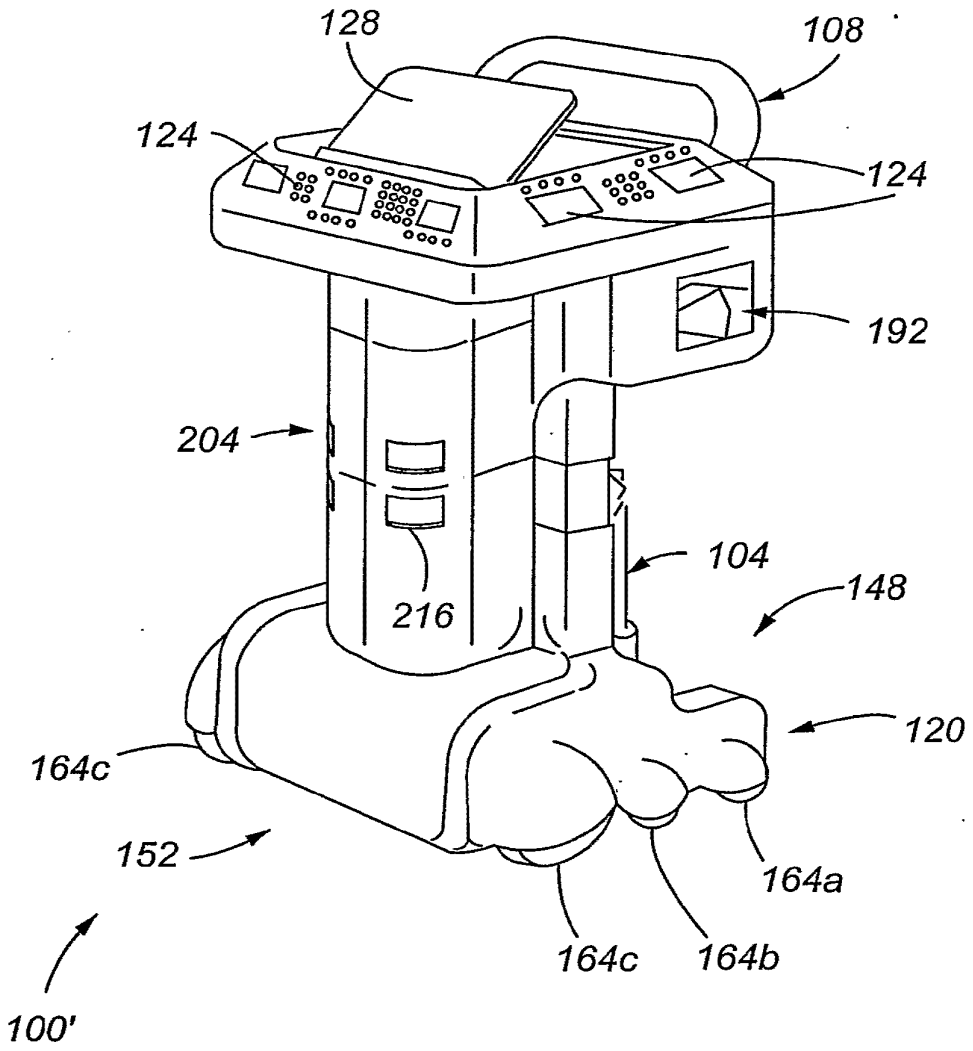
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Fig. 2

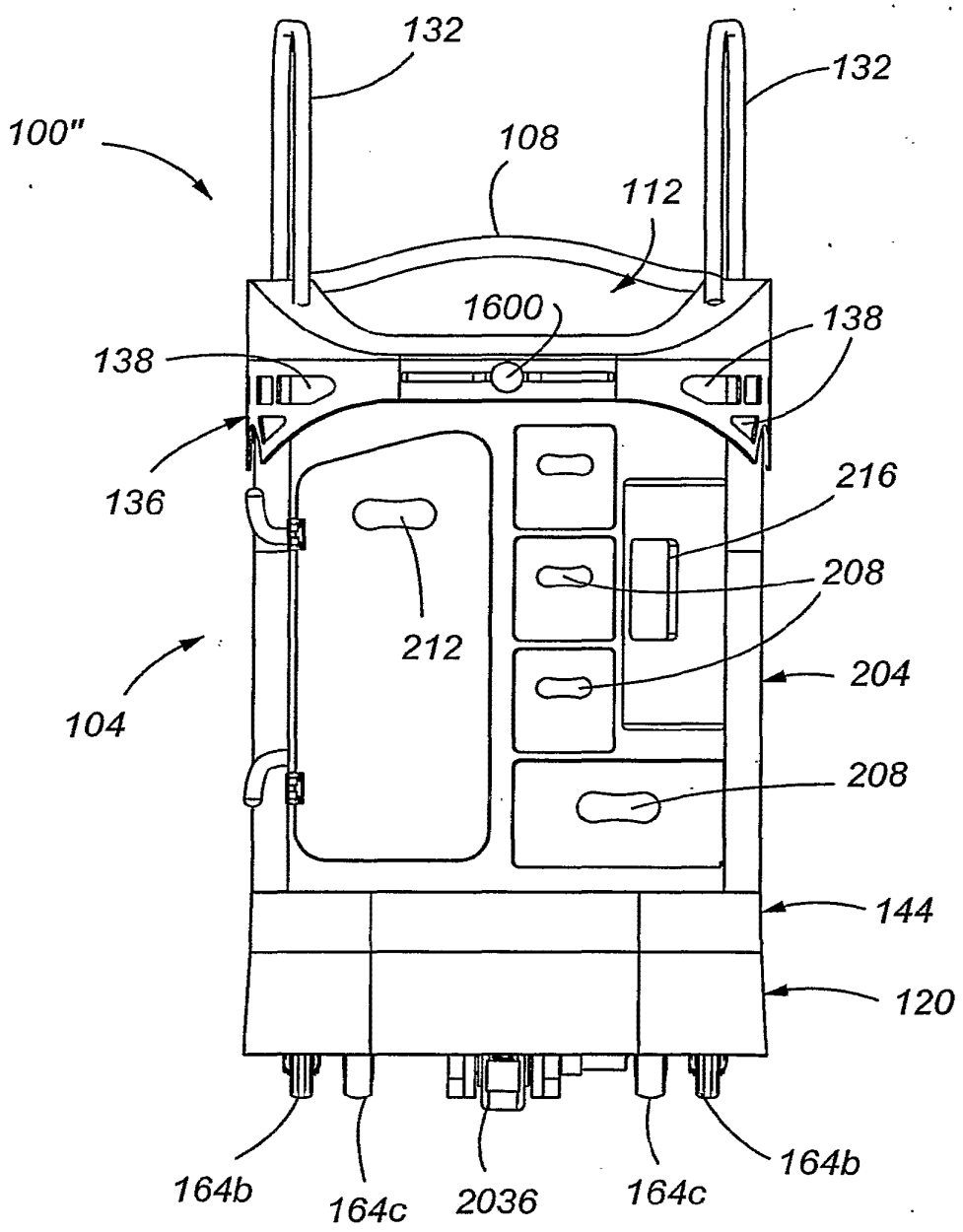
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Fig. 3

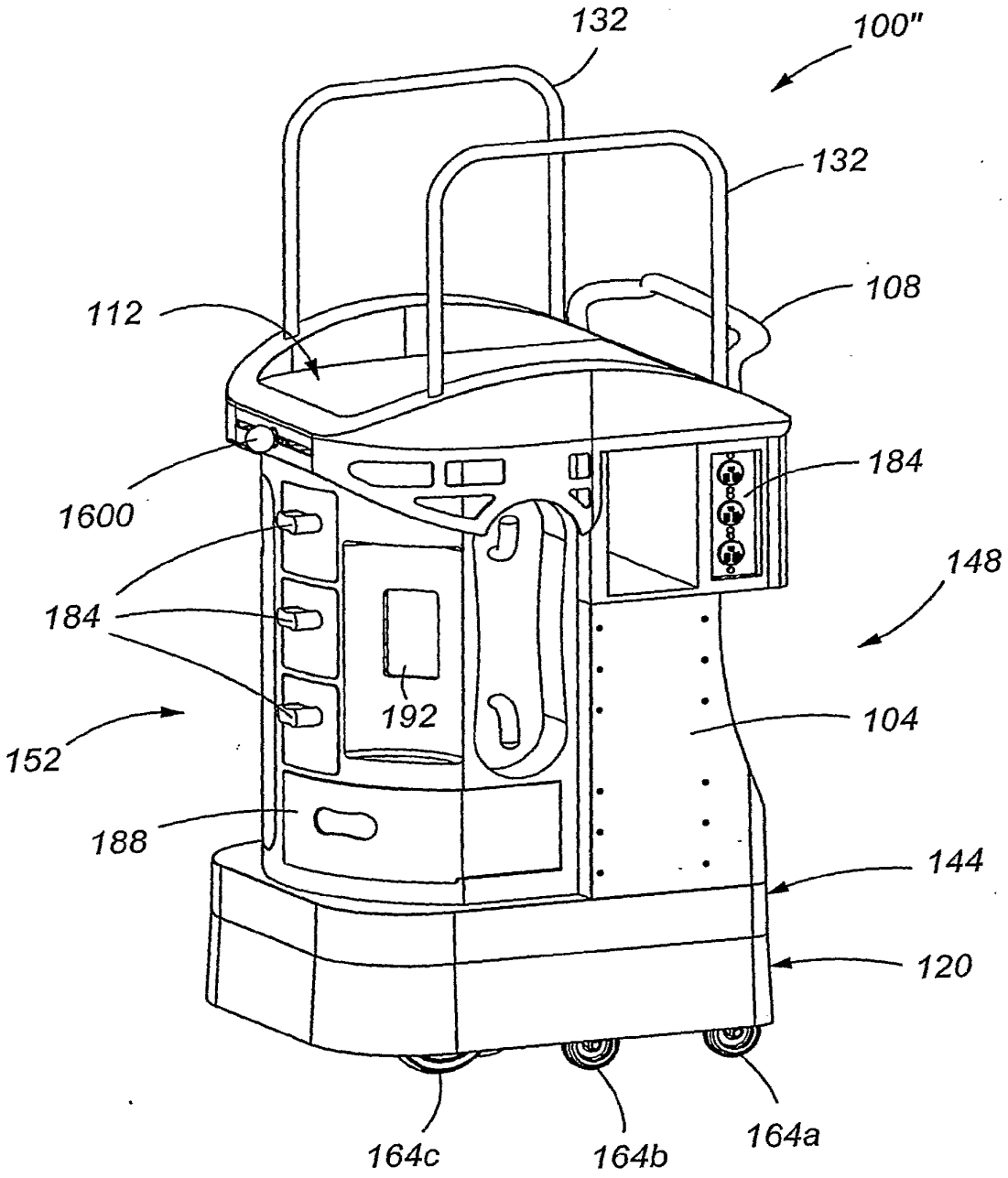
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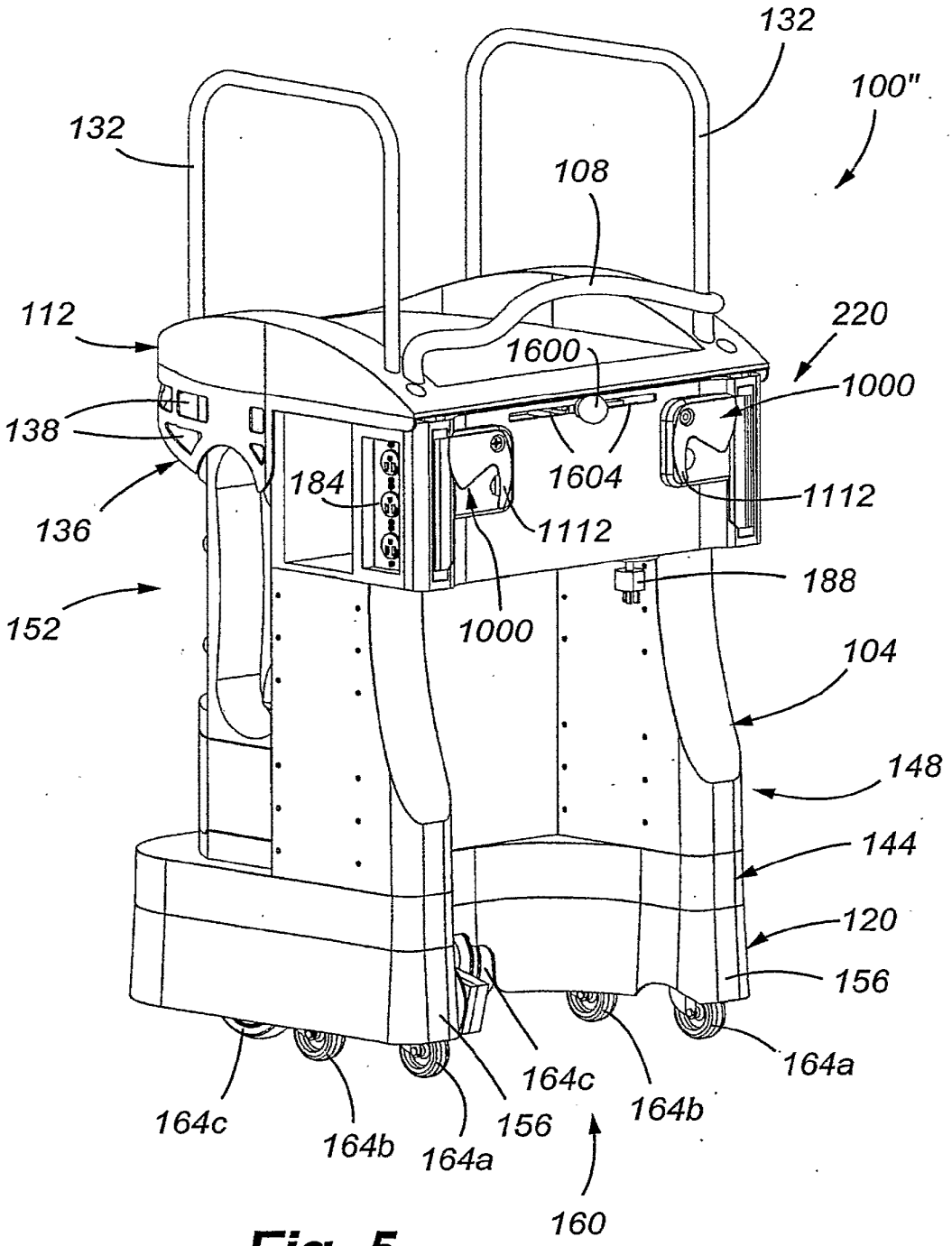
Fig. 4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164b
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164c
164b
164a
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Fig. 5

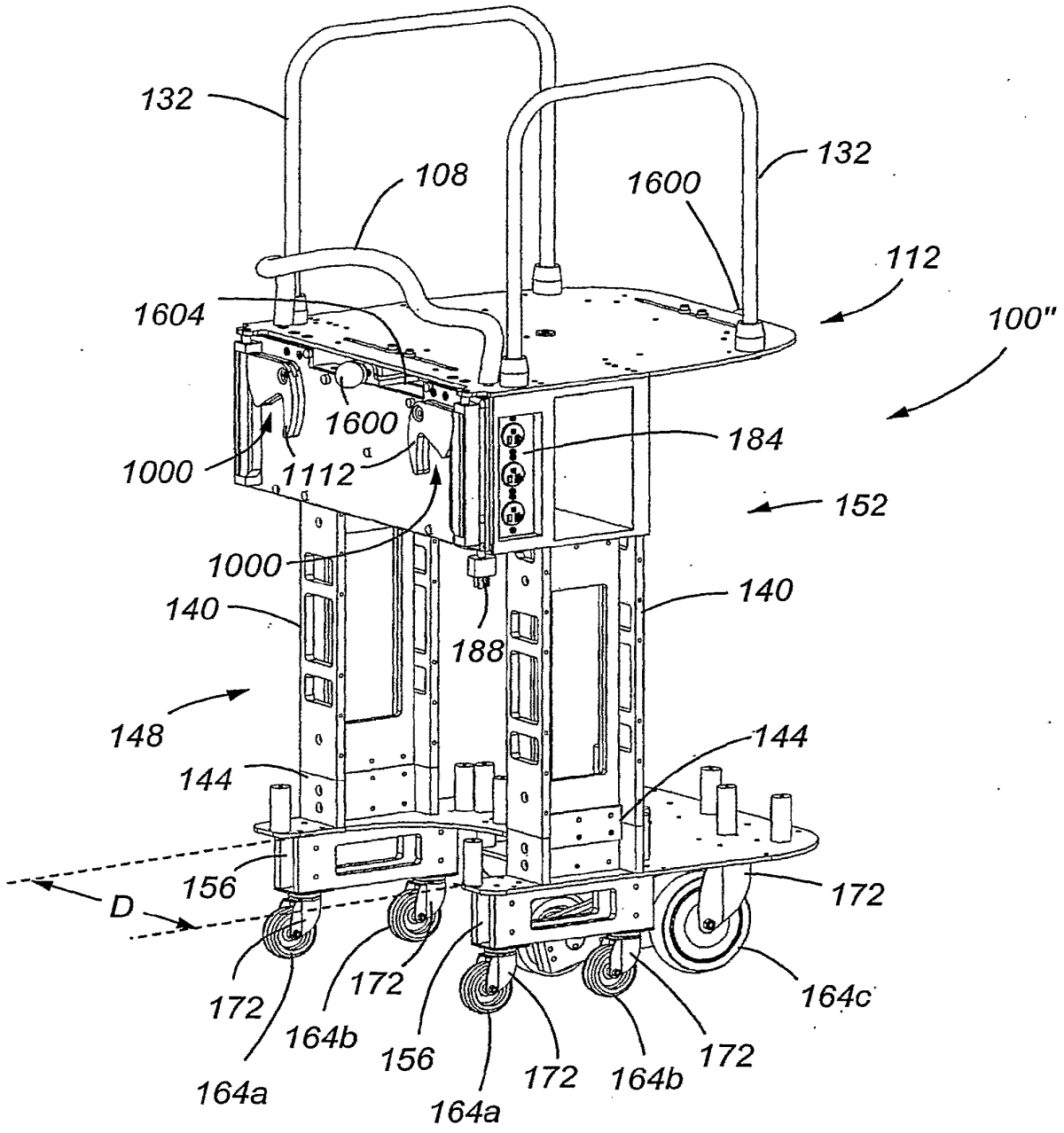
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Fig. 6

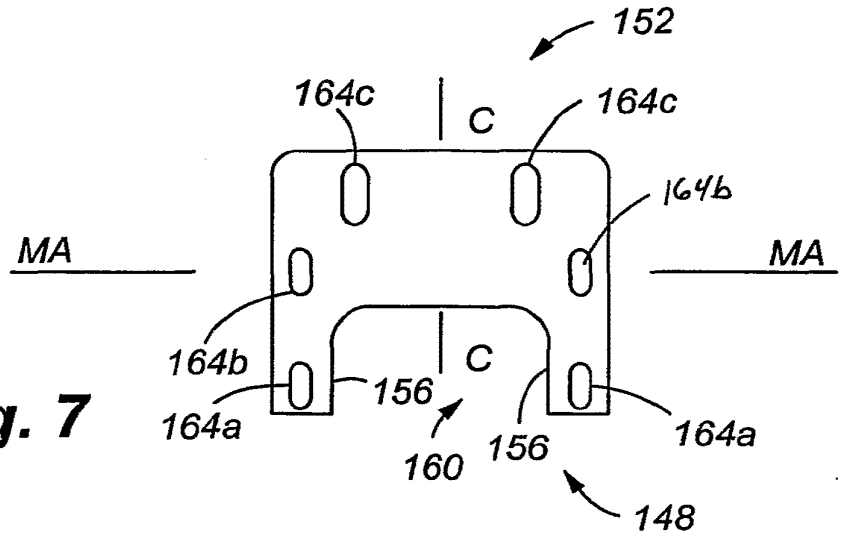


Fig. 7

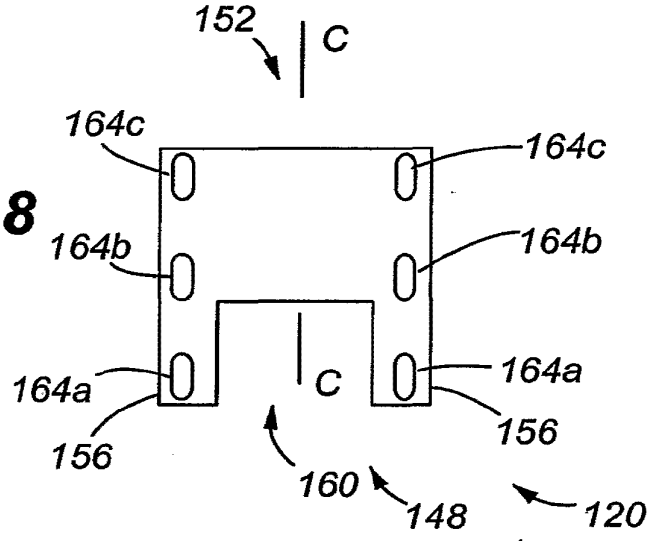


Fig. 8

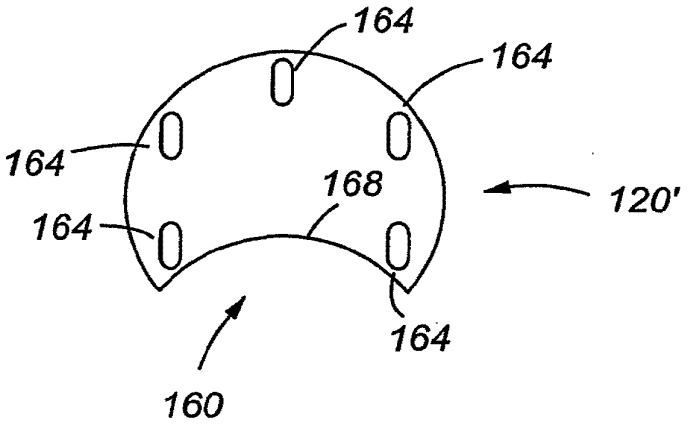


Fig. 9

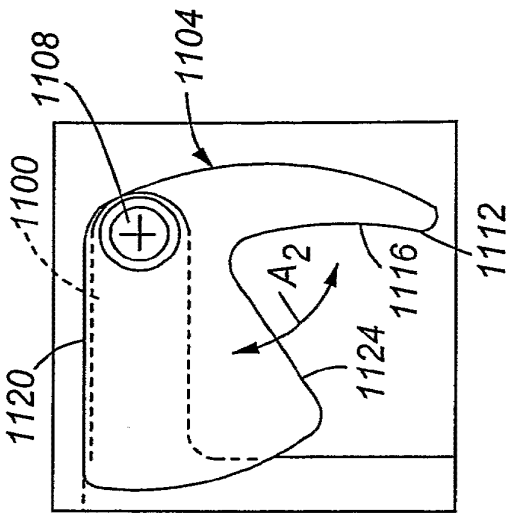


Fig. 11A

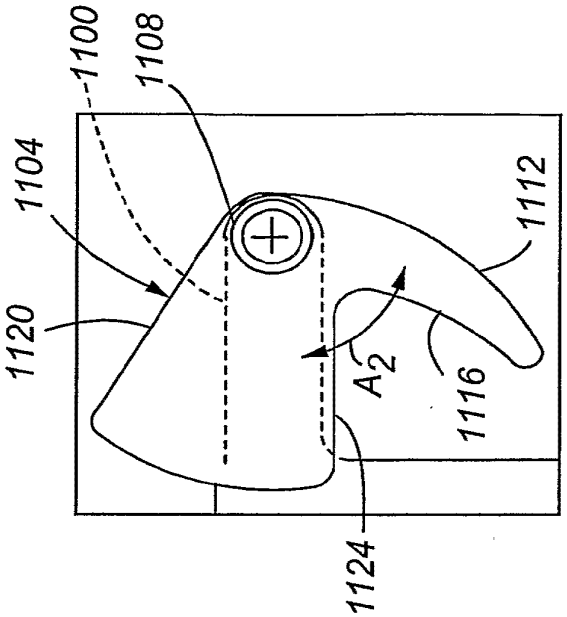


Fig. 11B

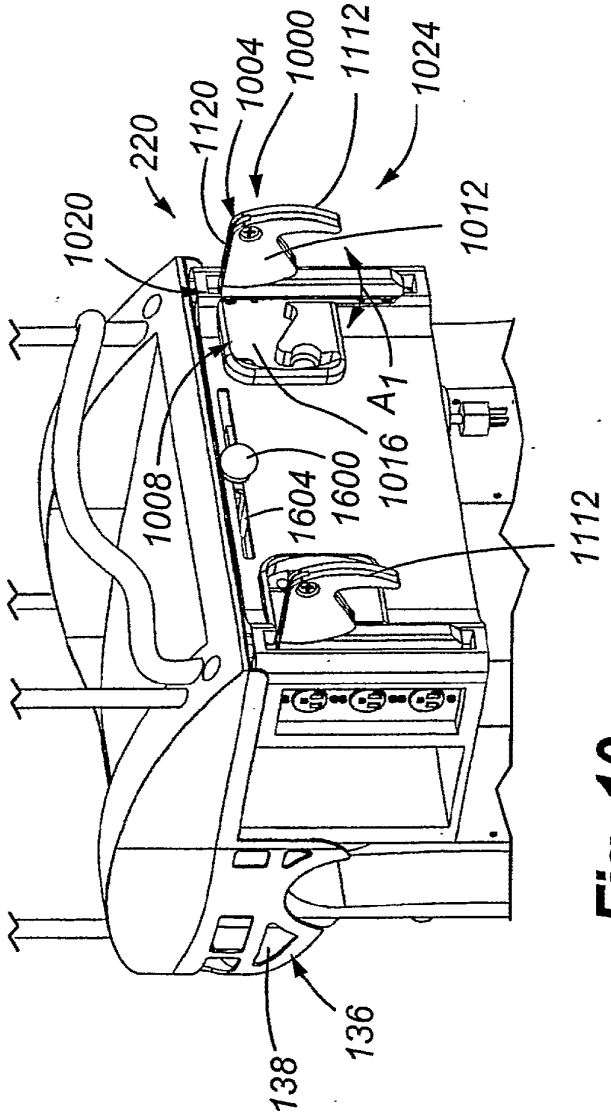


Fig. 10

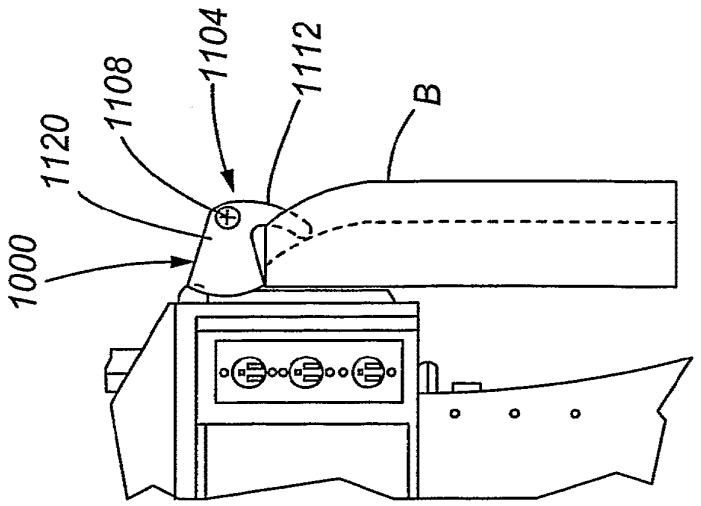


Fig. 14

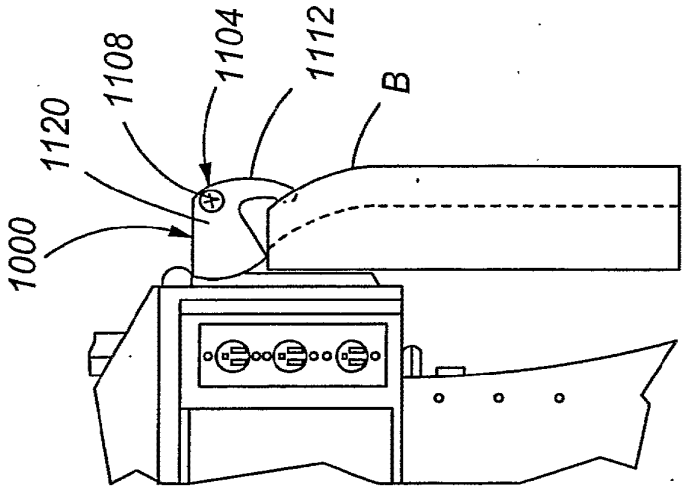


Fig. 13

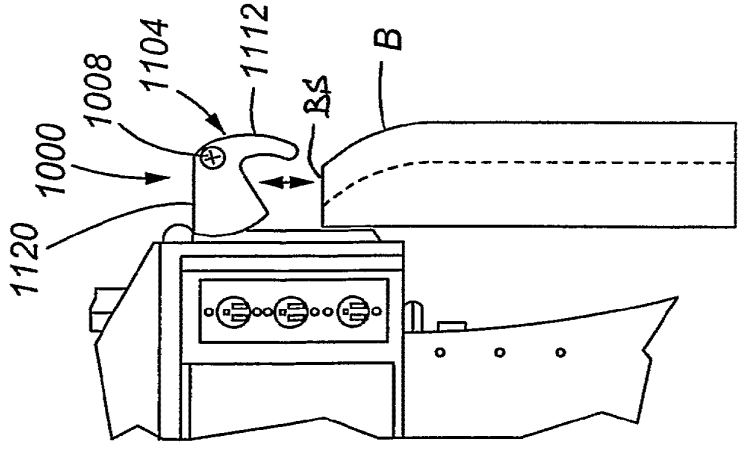
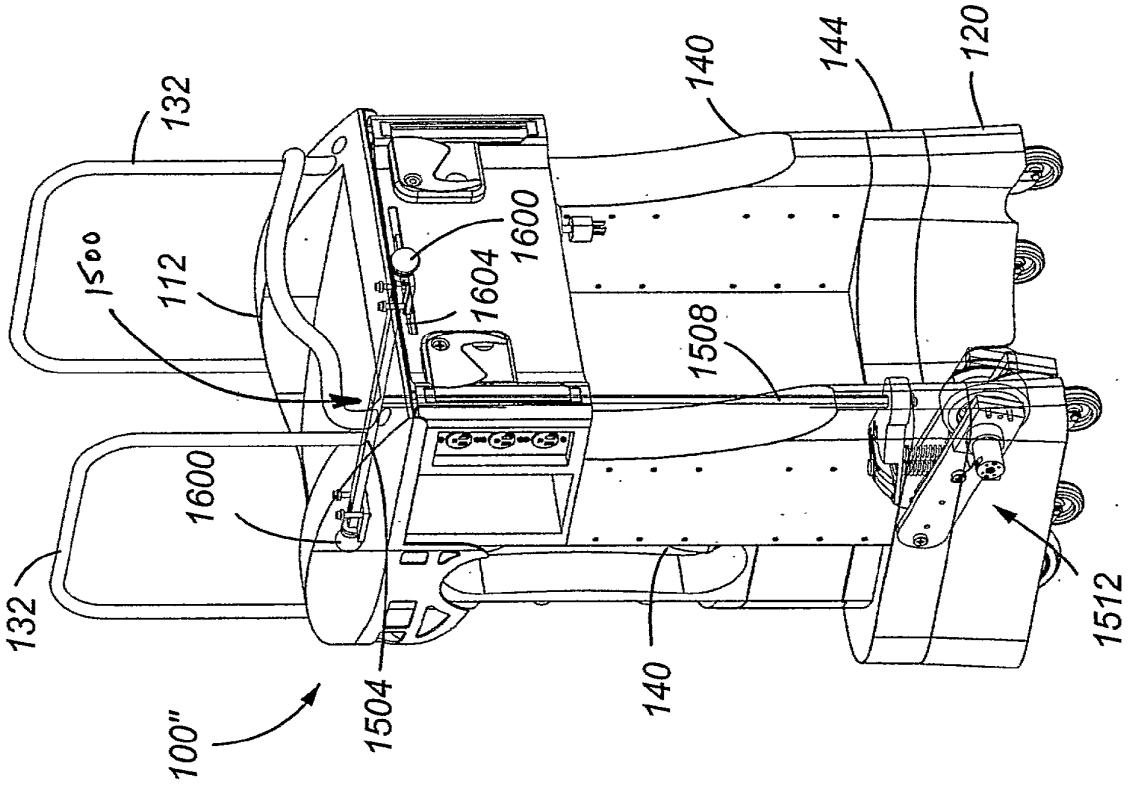


Fig. 12

Fig. 15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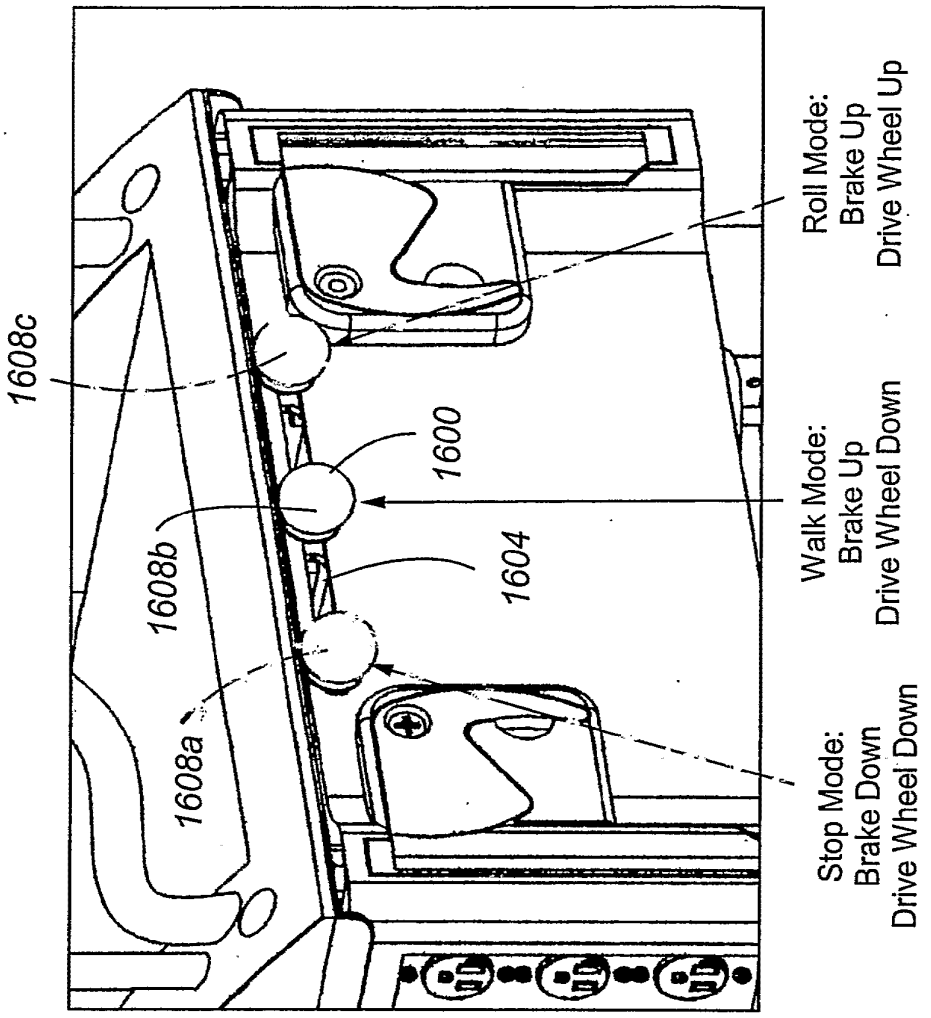
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1600
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Roll Mode:
Brake Up
Drive Wheel Up
Walk Mode:
Brake Up
Drive Wheel Down
Stop Mode:
Brake Down
Drive Wheel Down

Fig. 16

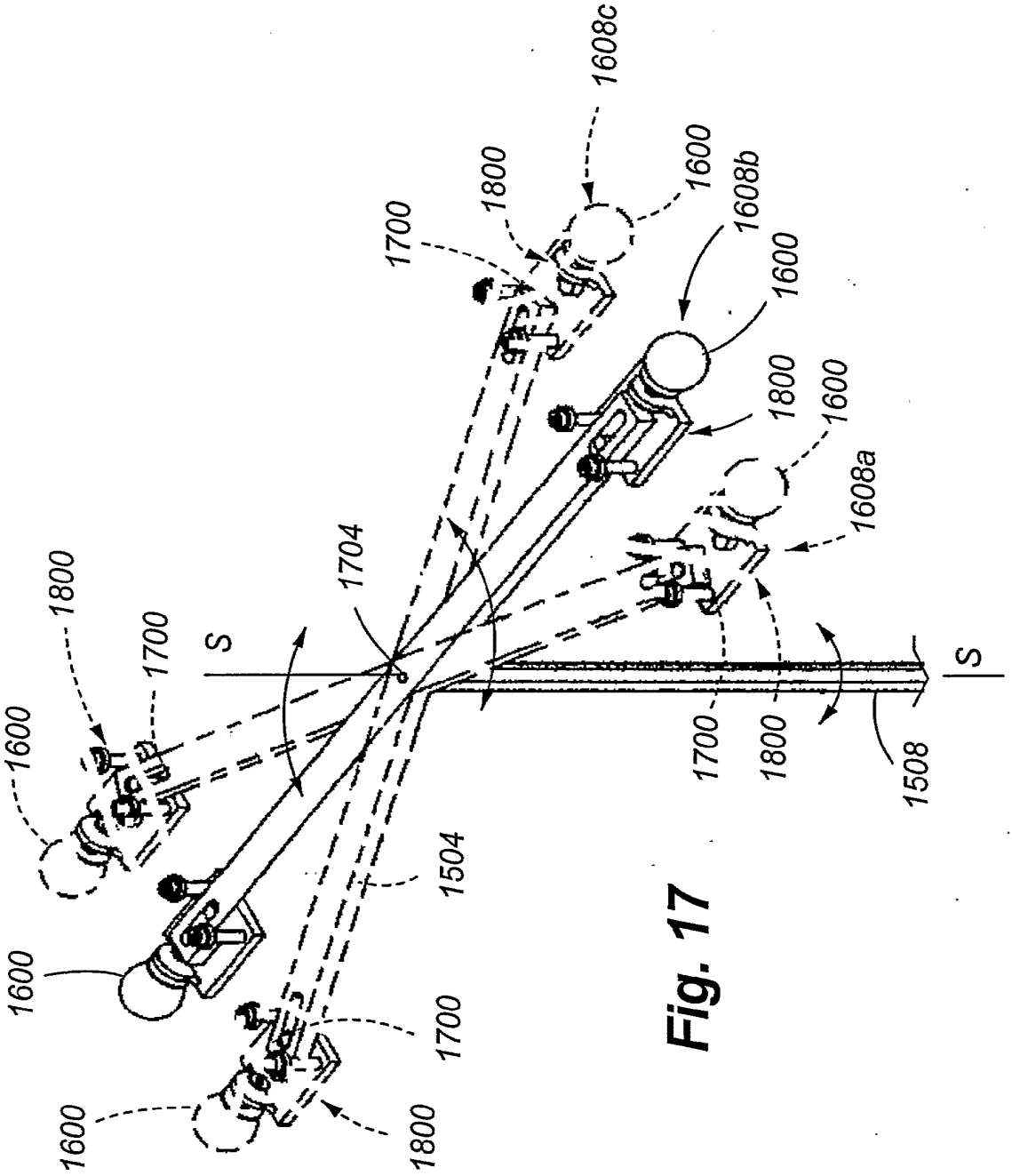
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Fig. 17

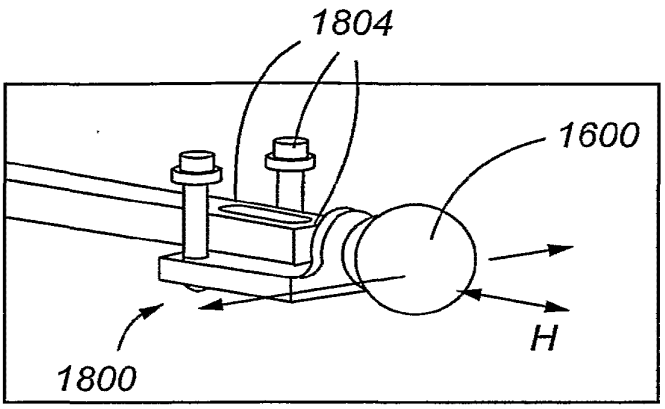
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Fig. 18

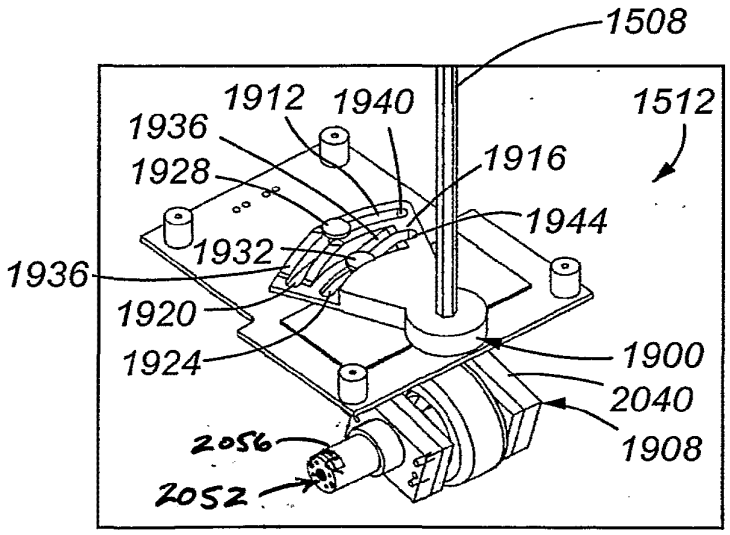
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Fig. 19

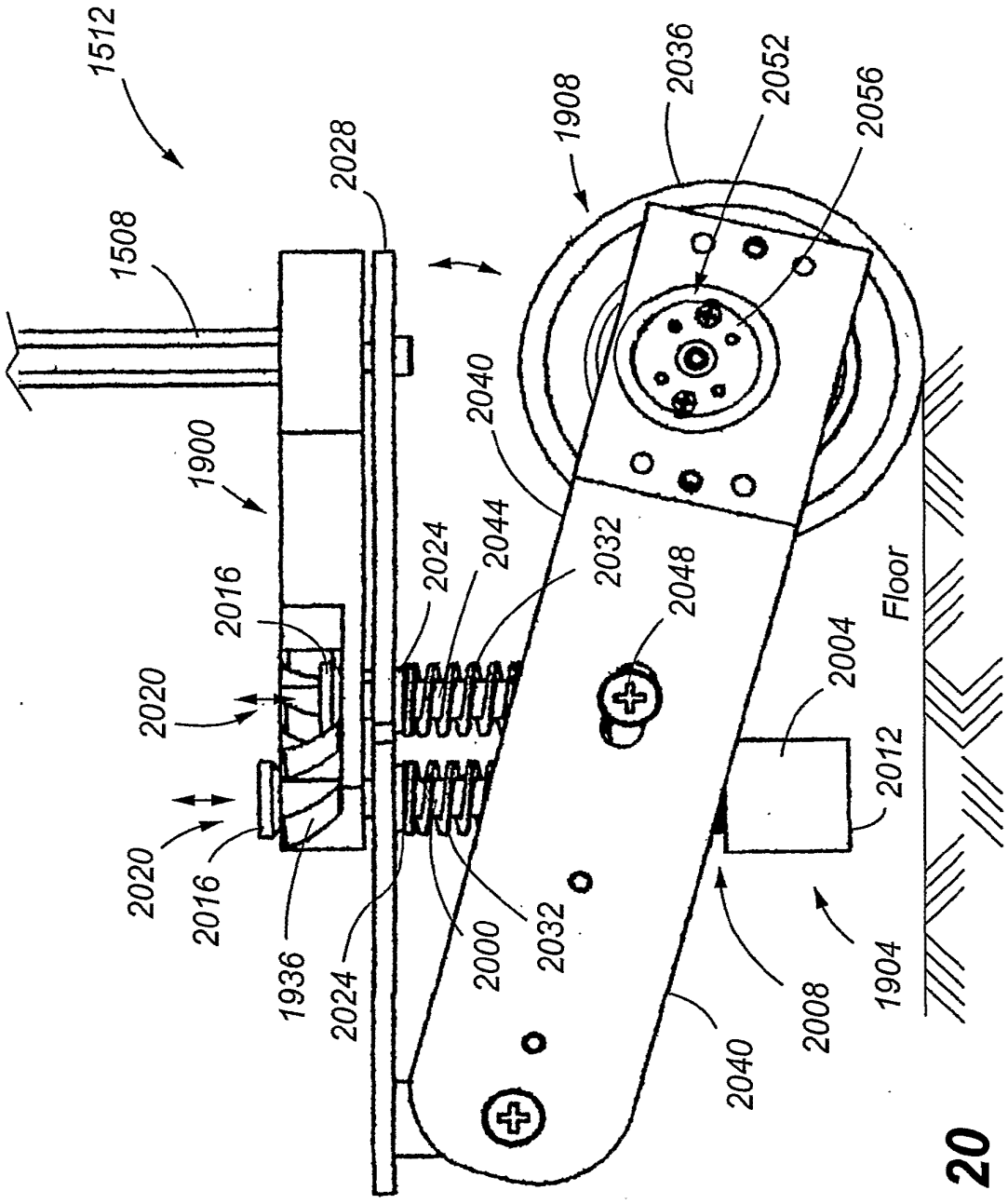
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Fig. 20

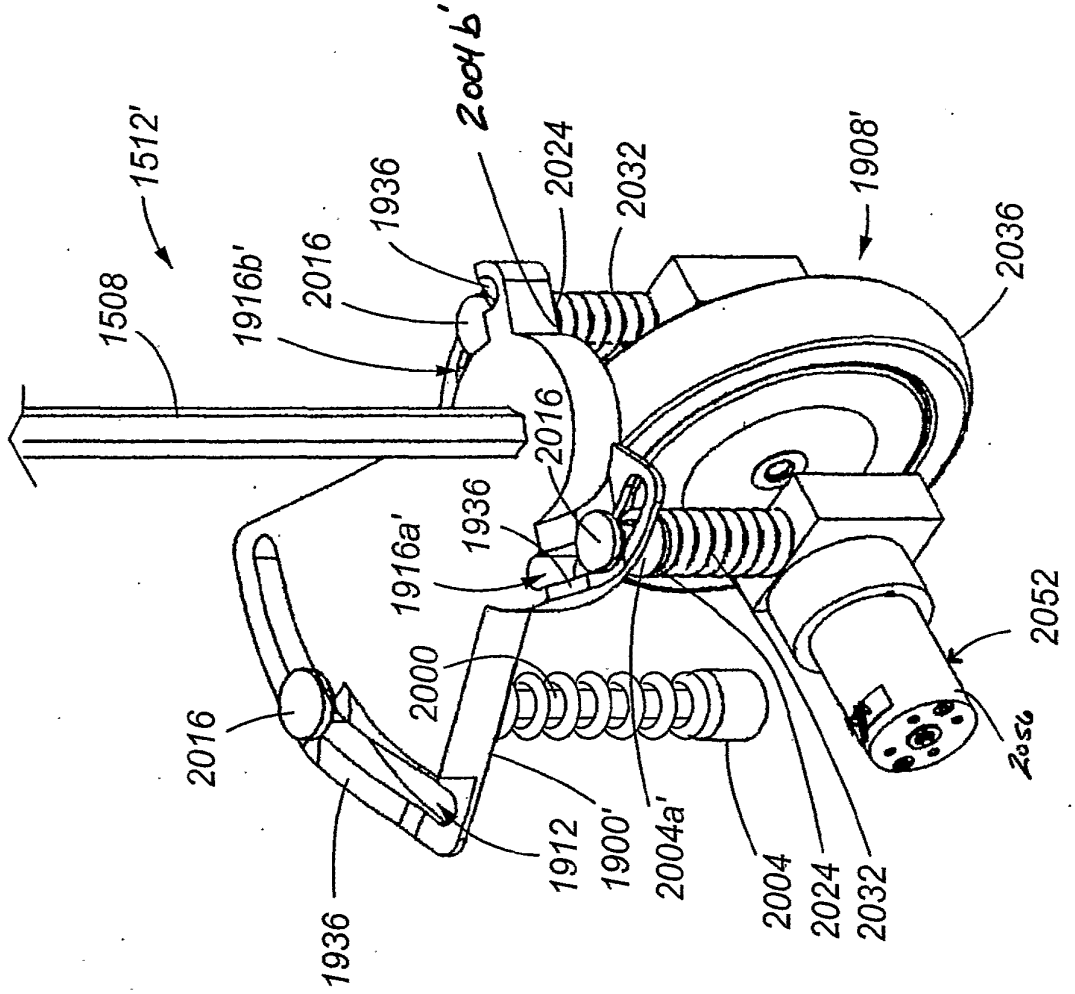
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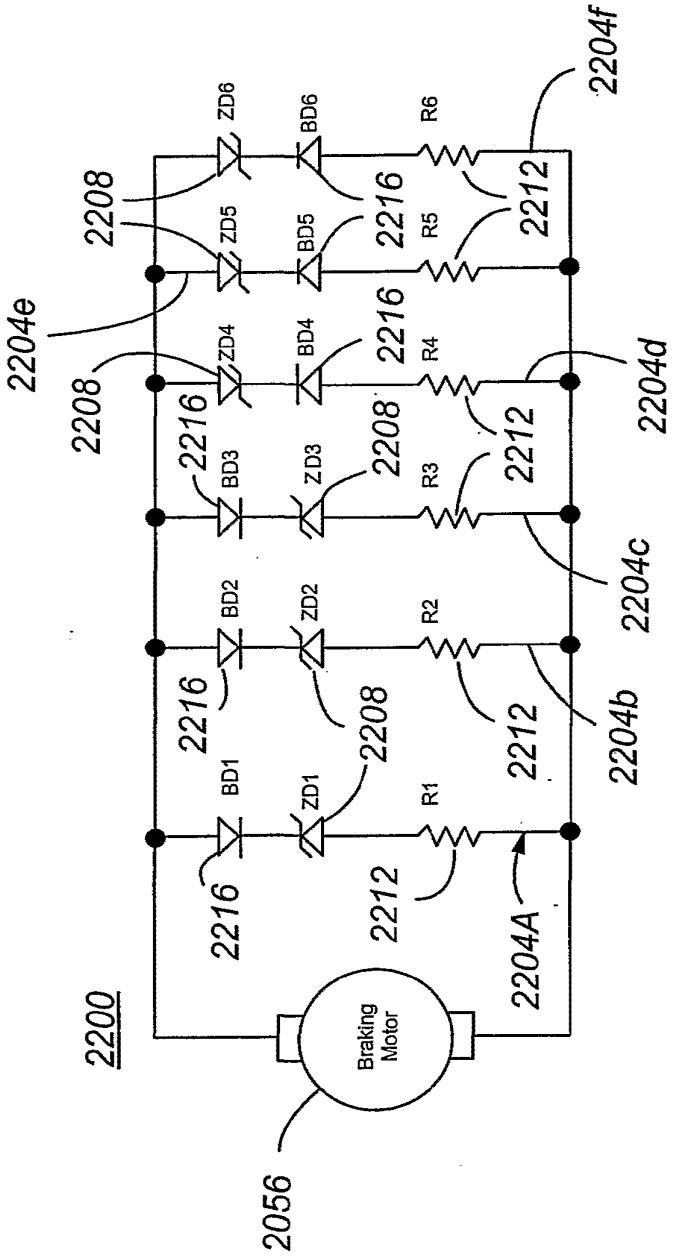
Fig. 21

Fig. 22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ZD4
ZD5
ZD6
R1
R2
R3
R4
R5
R6

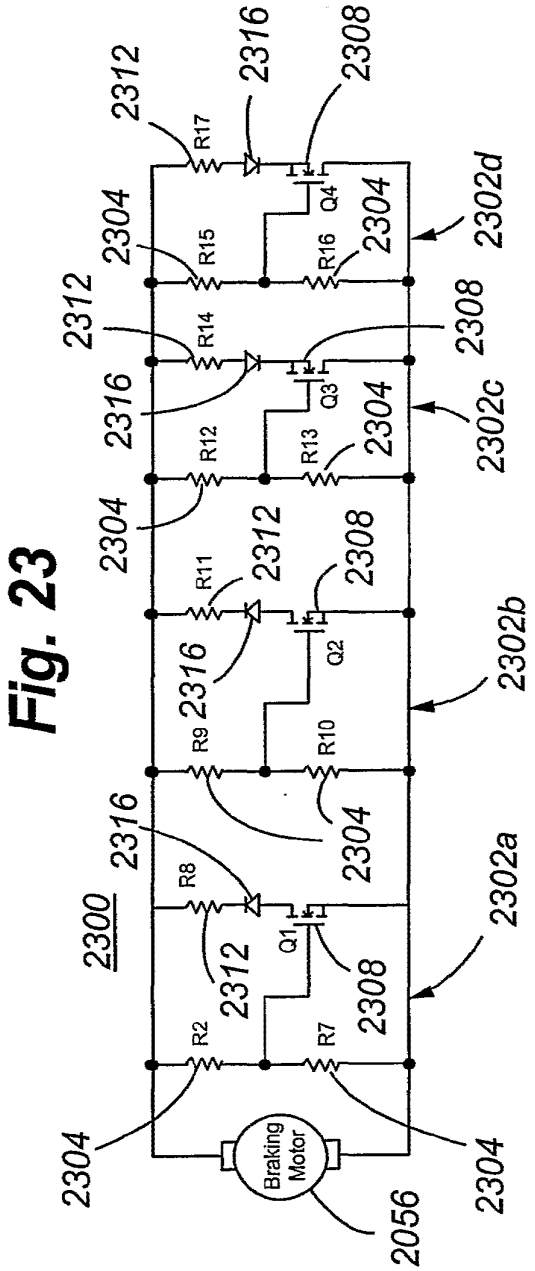

Fig. 23

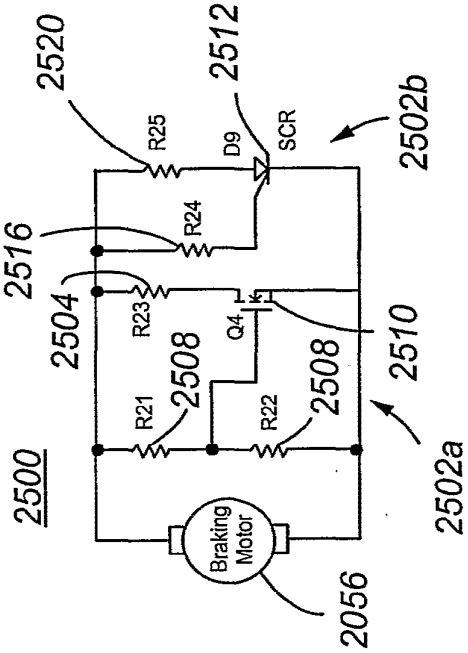

Fig. 25

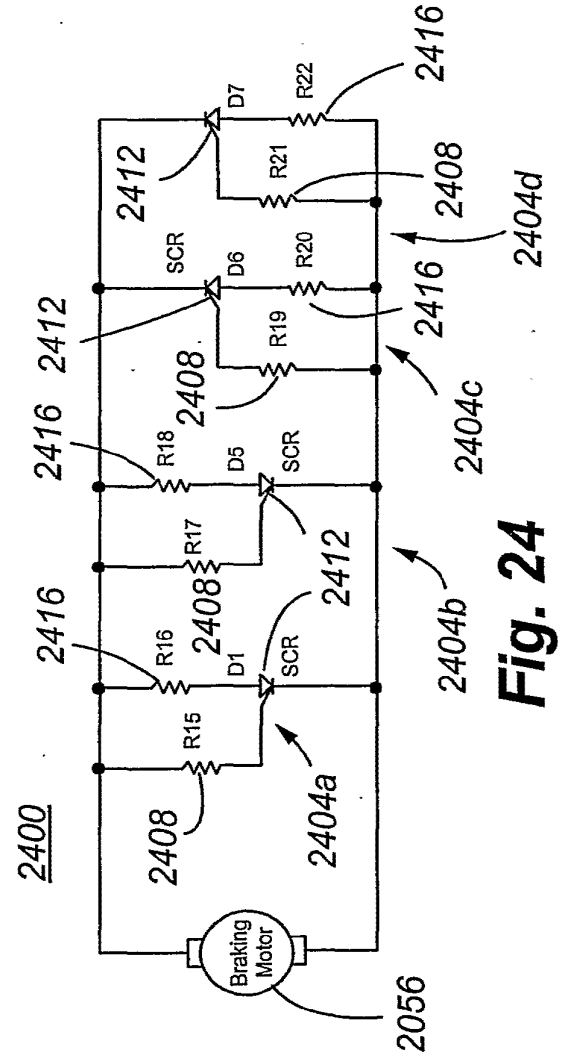

Fig. 24

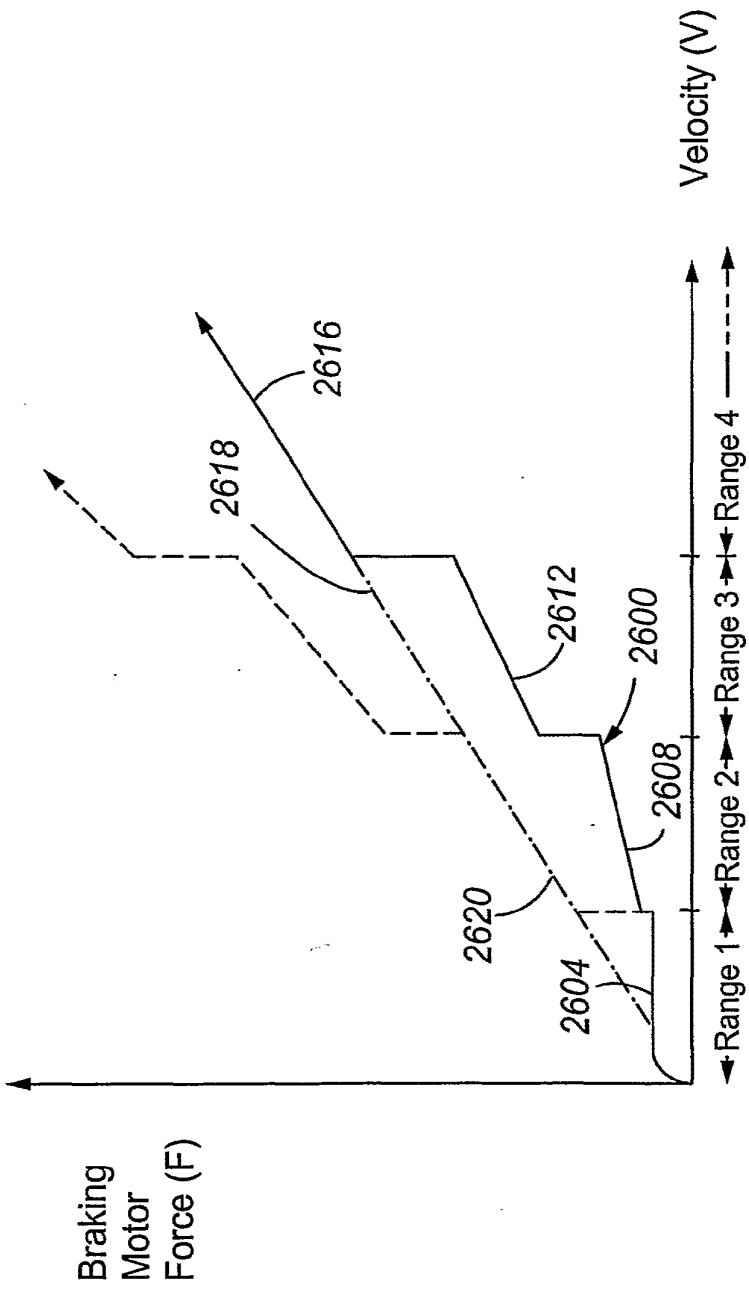
Braking Motor Force (F)
Velocity (V)
Range 1
Range 2
Range 3
Range 4
2604
2620
2608
2600
2612
2618
2616

Fig. 26

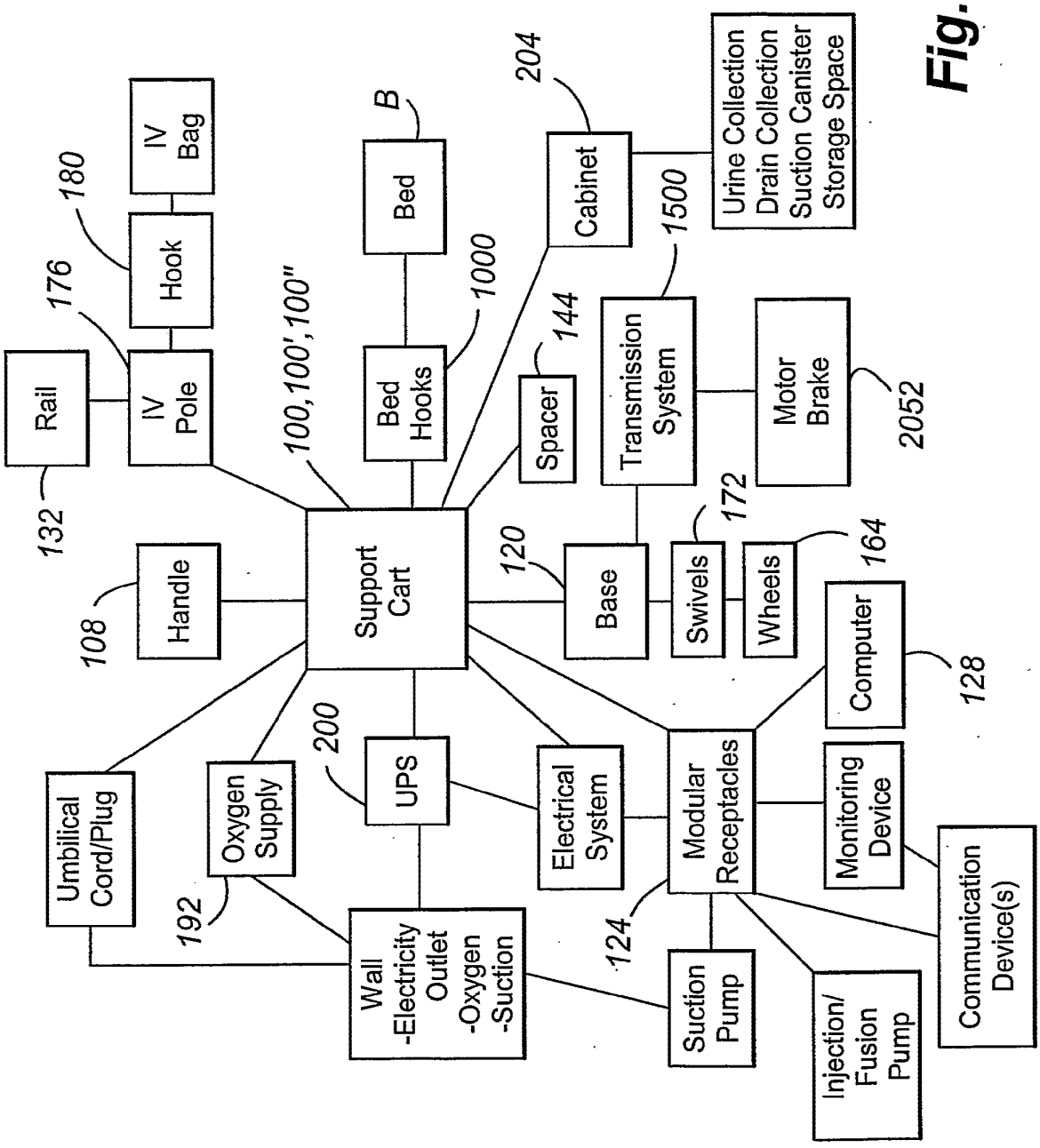
Support Cart
100,100',100"
Handle
108
IV Pole
176
Rail
132
Hook
180
IV Bag
Bed
B
Bed Hooks
1000
Cabinet
204
Urine Collection
Drain Collection
Suction Canister
Storage Space
1500
Spacer
144
Transmission System
Motor Brake
2052
Base
120
Swivels
172
Wheels
164
Computer
128
Modular Receptacles
124
Electrical System
UPS
200
Oxygen Supply
192
Umbilical Cord/Plug
Wall -Electricity Outlet -Oxygen -Suction
Suction Pump
Injection/ Fusion Pump
Monitoring Device
Communication Device(s)

Fig. 27

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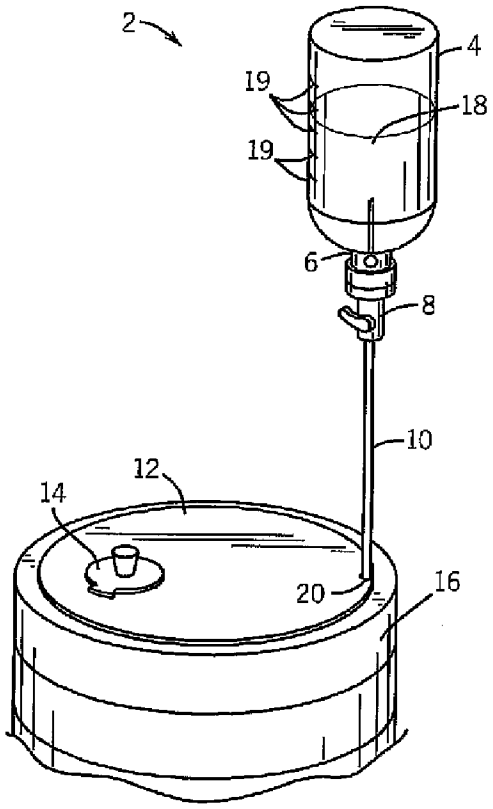
[Continued on next page]

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



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

WO 2007/016170 A1

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

FIELD OF THE INVENTION

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

BACKGROUND

[0002] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0003] Nuclear medicine is a branch of health science that utilizes radioactive material for diagnostic and therapeutic purposes by injecting a patient with a small dose of the radioactive material, which concentrates in certain organs or biological regions of the patient. Radioactive materials typically used for nuclear medicine include Technetium-99m, Indium-113m, and Strontium-87m among others. Some radioactive materials naturally concentrate toward a particular tissue; for example, iodine concentrates toward the thyroid. However, radioactive materials are often combined with a tagging or organ-seeking agent, which targets the radioactive material for the desired organ or biologic region of the patient. These radioactive materials alone or in combination with a tagging agent are typically defined as radiopharmaceuticals in the field of nuclear medicine. At relatively lower doses of the radiopharmaceutical, a radiation imaging system (e.g., a gamma camera) can provide an image of the organ or biological region that collects the radiopharmaceutical. Irregularities in the image are often indicative of a pathologic condition, such as cancer. Higher doses of the radiopharmaceutical may be used to deliver a therapeutic dose of radiation directly to the pathologic tissue, such as cancer cells.

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

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

SUMMARY

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

[0006] Certain aspects commensurate in scope with the originally claimed invention are set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief summary of certain forms the invention might take and that these aspects are not intended to limit the scope of the invention. Indeed, the invention may encompass a variety of aspects that may not be set forth below.

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

[0013] FIG. 1 is a perspective view of an exemplary embodiment of a generator product including a visually accessible eluant supply bottle, a vented spike, a stop cock, tubing, a shielded lid, a shielded lid plug, and a shielded container;

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0023] One or more exemplary embodiments of the present invention are described below. In an effort to provide a concise description of these embodiments, some features of an actual implementation may not be described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions may be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Such a development effort would be a routine

undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[0038] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

CLAIMS:

1. A system, comprising:

a radioactivity shielded container;

a radioisotope generator disposed within the radioactivity shielded container; and

an elution supply mechanism comprising:

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

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

an eluant visualization portal.

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

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

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

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

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

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

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

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

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

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

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

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

14. A system, comprising:

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

a radioisotope generator disposed within the receptacle; and

an eluant supply mechanism comprising:

an eluant supply container;

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

an eluant measurement device coupled to the eluant supply mechanism.

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

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

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

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

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

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

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

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

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

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

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

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

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

eluting radioactive material from the radioisotope generator.

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

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

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

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

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

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

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

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

34. A system, comprising:

a radiation shielded lid comprising an aperture; and

an eluant supply mechanism comprising:

an eluant supply container;

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

an eluant measurement feature.

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

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

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

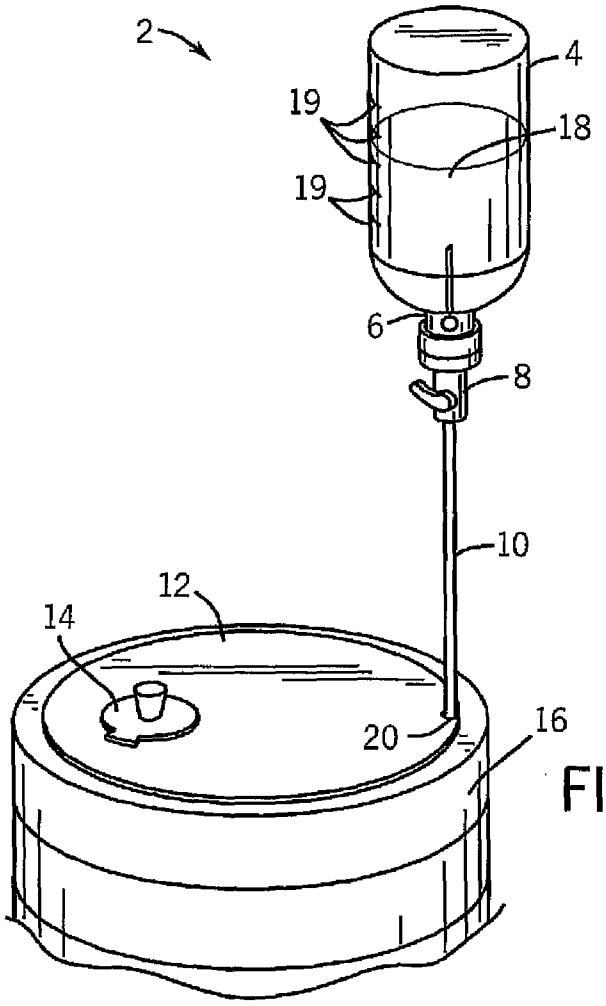

FIG. 1

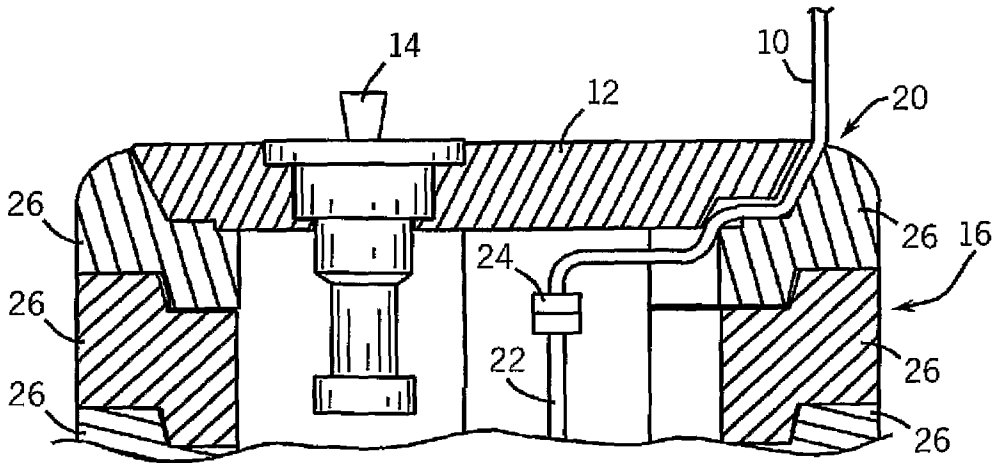

FIG. 2

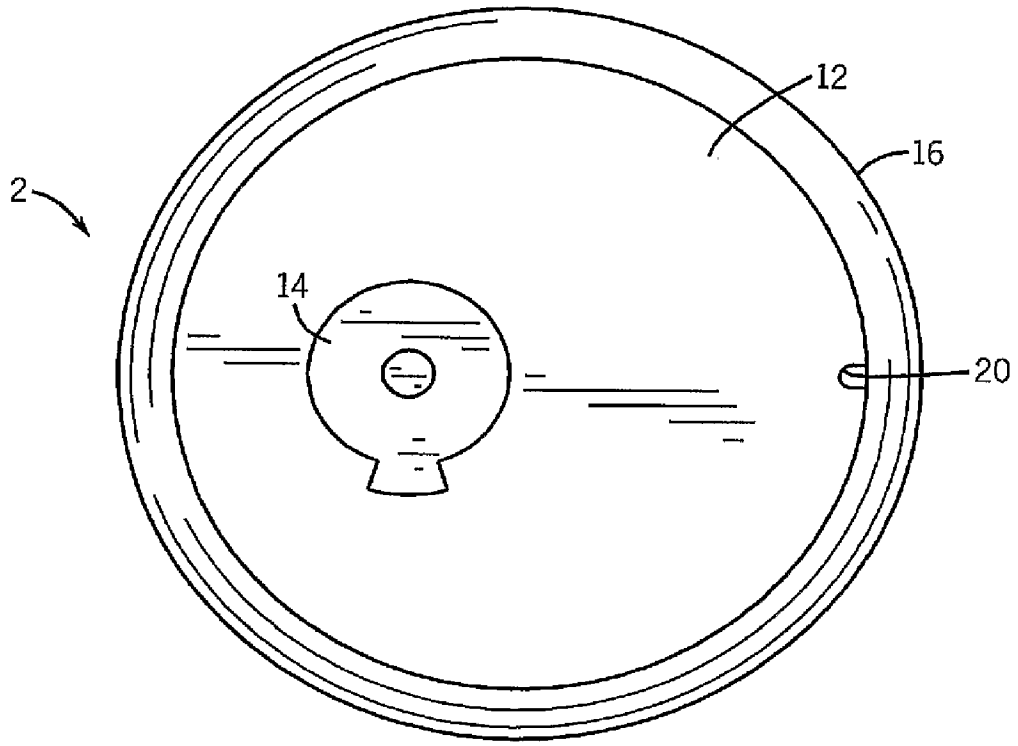

FIG. 3

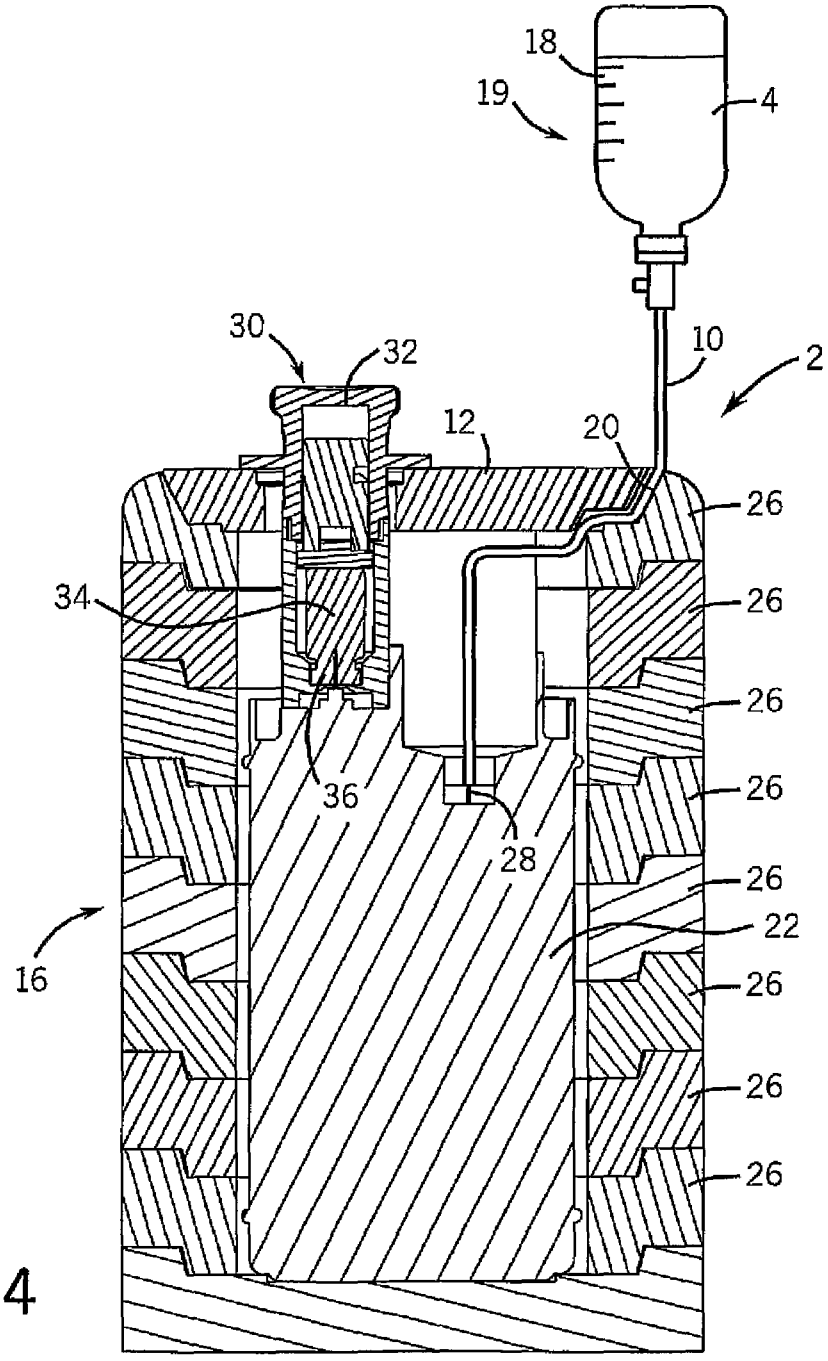

FIG. 4

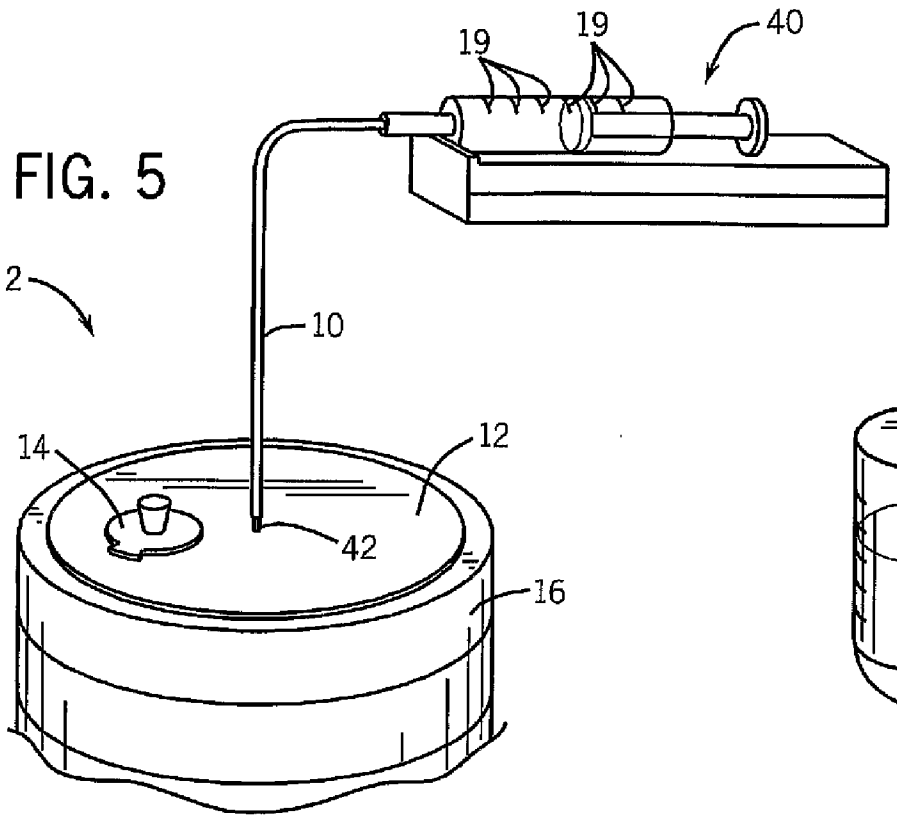

FIG. 5

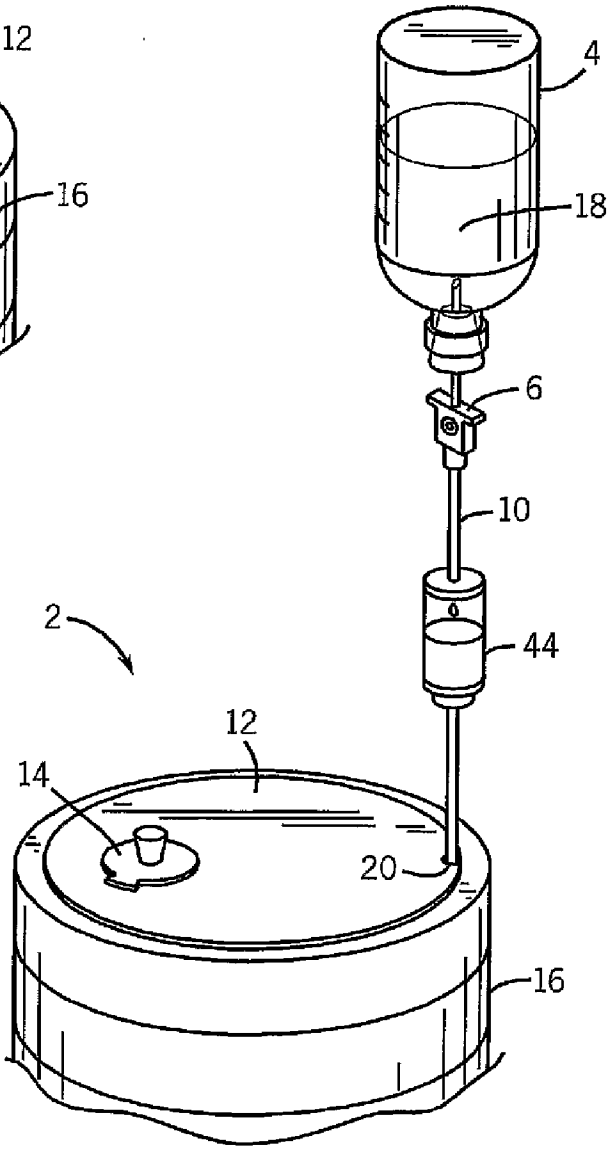

FIG. 6

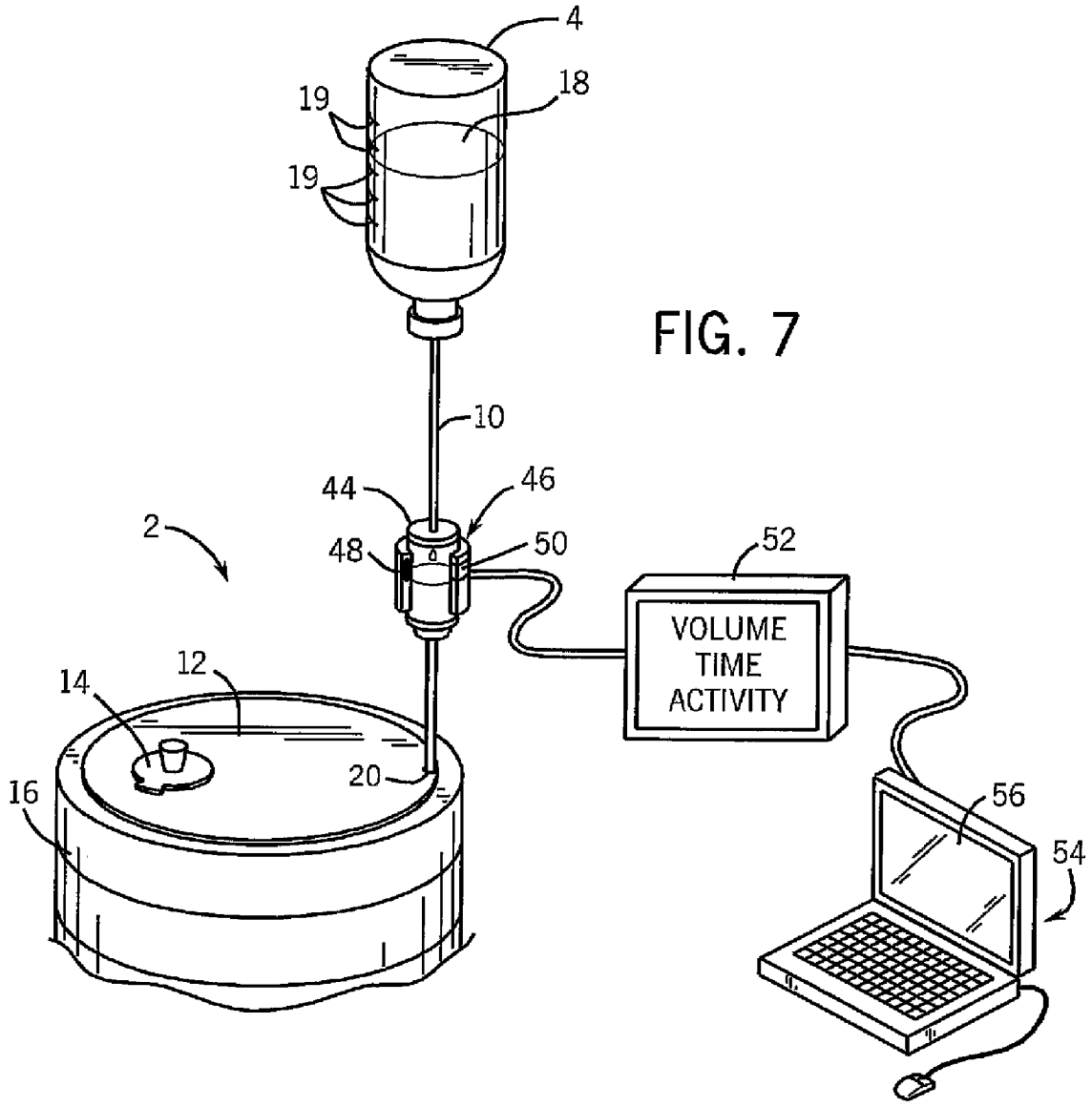
4
18
19
19
10
44
46
2
48
50
52
VOLUME
TIME
ACTIVITY
14
12
16
20
56
54

FIG. 7

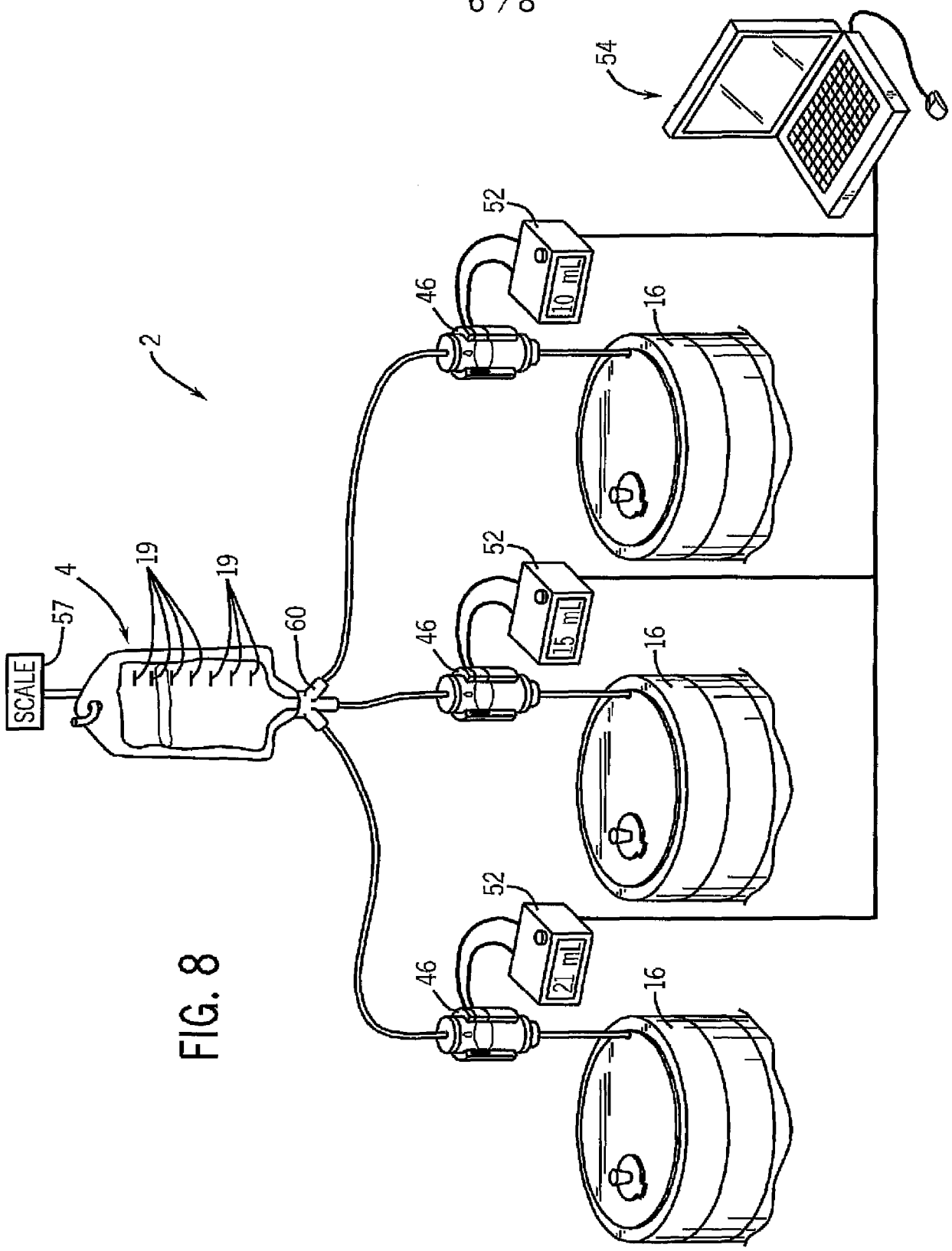

FIG. 8

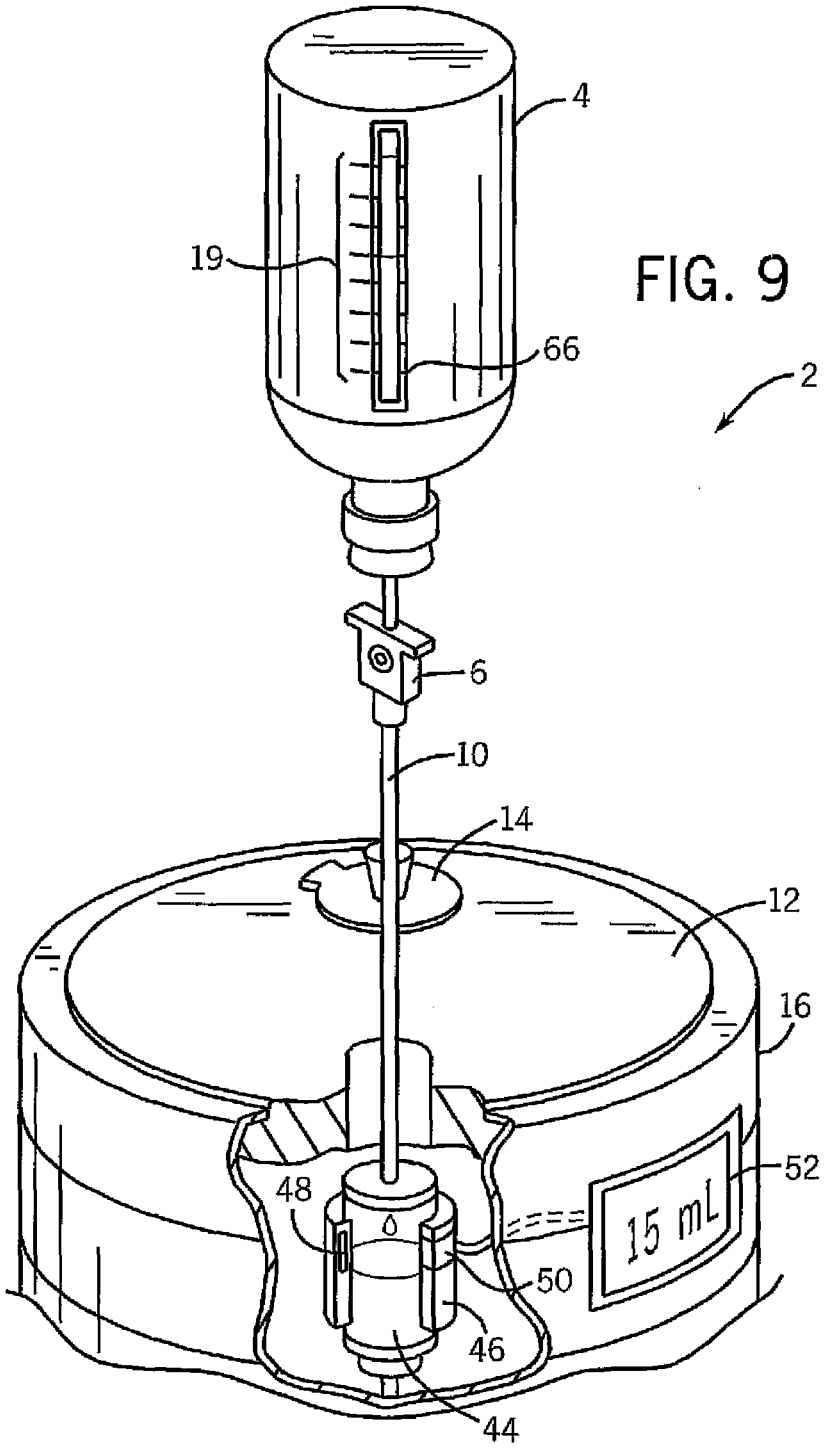

FIG. 9

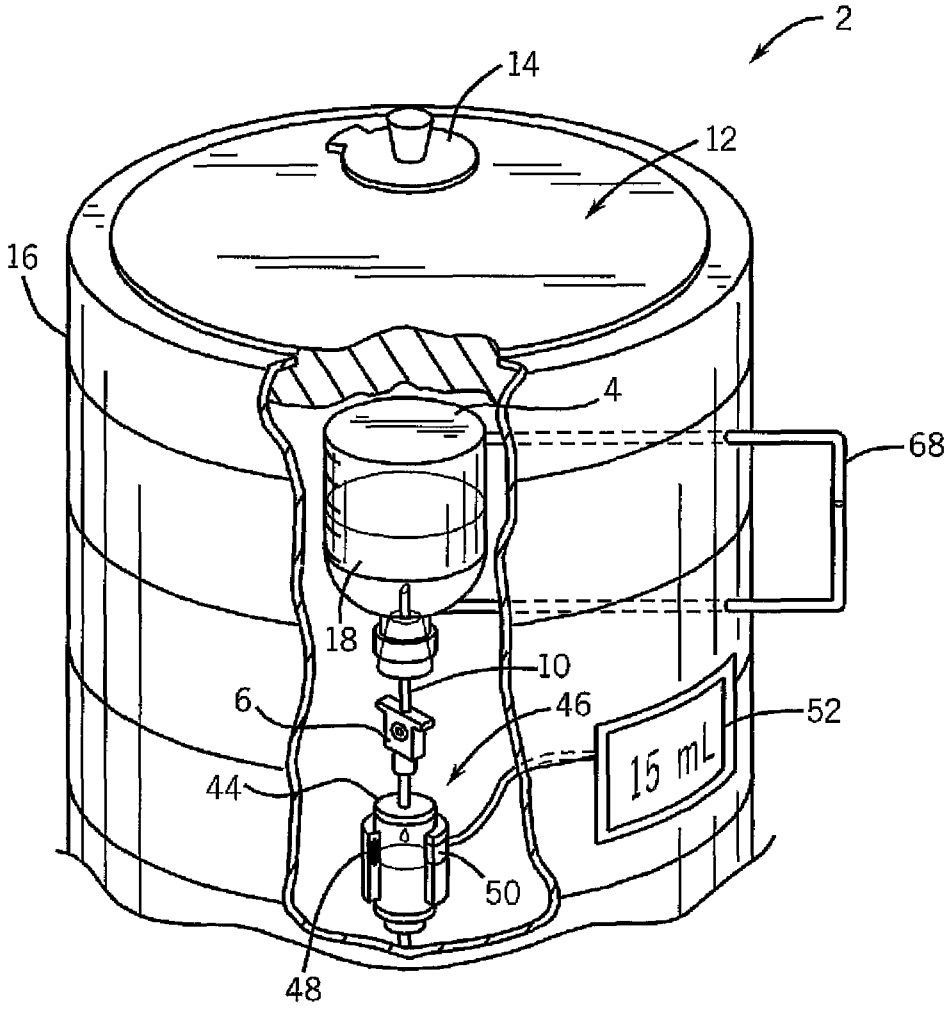

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/029055

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

-/--

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

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

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

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/029055

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/029055

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

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

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

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

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

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

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

see additional sheet

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

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

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

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

Remark on Protest

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

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

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

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

   A measurement device within the shielded container.

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

   Calculation of a future elution time based on a metric.

---

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

   Weiging the eluant with a scale.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/029055

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

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(19) World Intellectual Property Organization
International Bureau

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(10) International Publication Number
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G21G 4/08 (2006.01) *B65B 3/00* (2006.01)

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

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

(25) Filing Language: English

(26) Publication Language: English

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

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

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

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

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

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

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

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

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

WO 2007/030249 A2

RADIOISOTOPE GENERATION SYSTEM HAVING PARTIAL ELUTION CAPABILITY

FIELD OF THE INVENTION

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

BACKGROUND

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

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

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

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

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

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

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

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

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

SUMMARY

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

Corresponding reference characters indicate corresponding parts throughout the drawings.

DETAILED DESCRITPTION OF ILLUSTRATED EMBODIMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS:

What is claimed is

1. A radioisotope generation system comprising:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

monitoring the dispensing; and

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

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

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

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

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

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

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

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

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

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

26. A radioisotope generation system comprising:

a radioisotope generator operable to dispense eluate;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

46. A radioisotope generation system comprising:

a radioisotope generator for dispensing radioactive eluate; and

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

a signaling device communicatively connected with the sensor.

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

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

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

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

51. A method of dispensing a radioactive eluate comprising:

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

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

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

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

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

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

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

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

FIG. 1

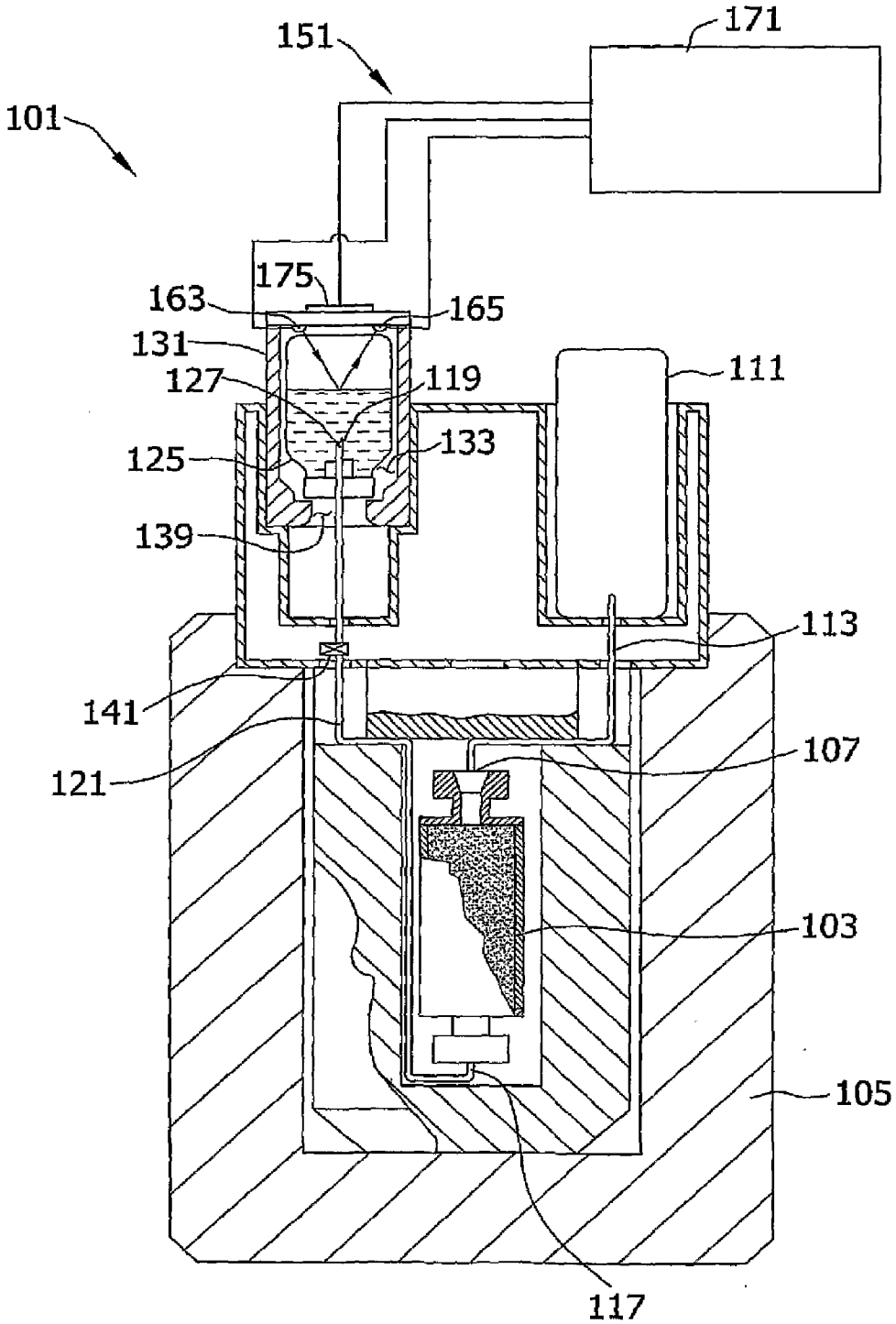
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FIG. 2

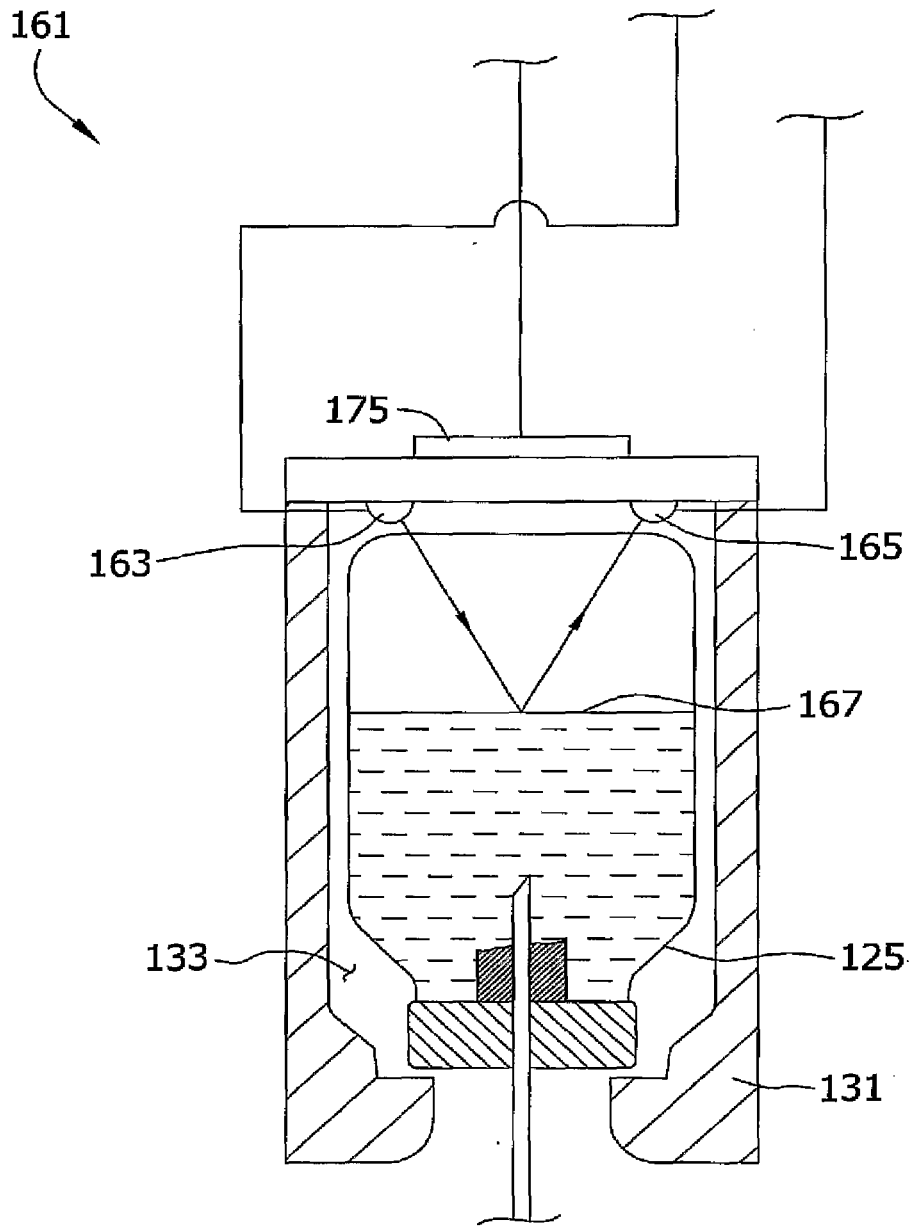

FIG. 3

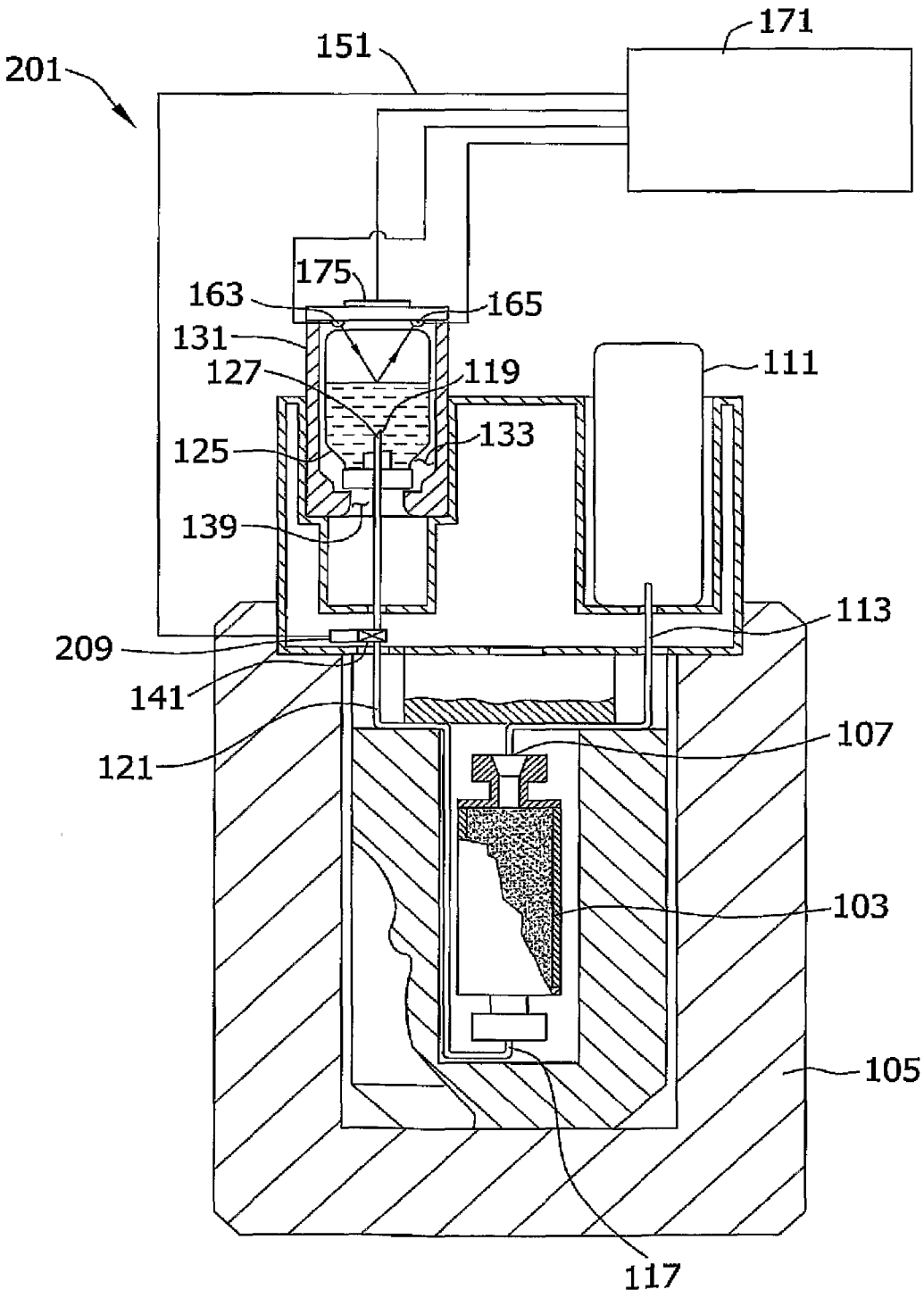
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FIG. 4

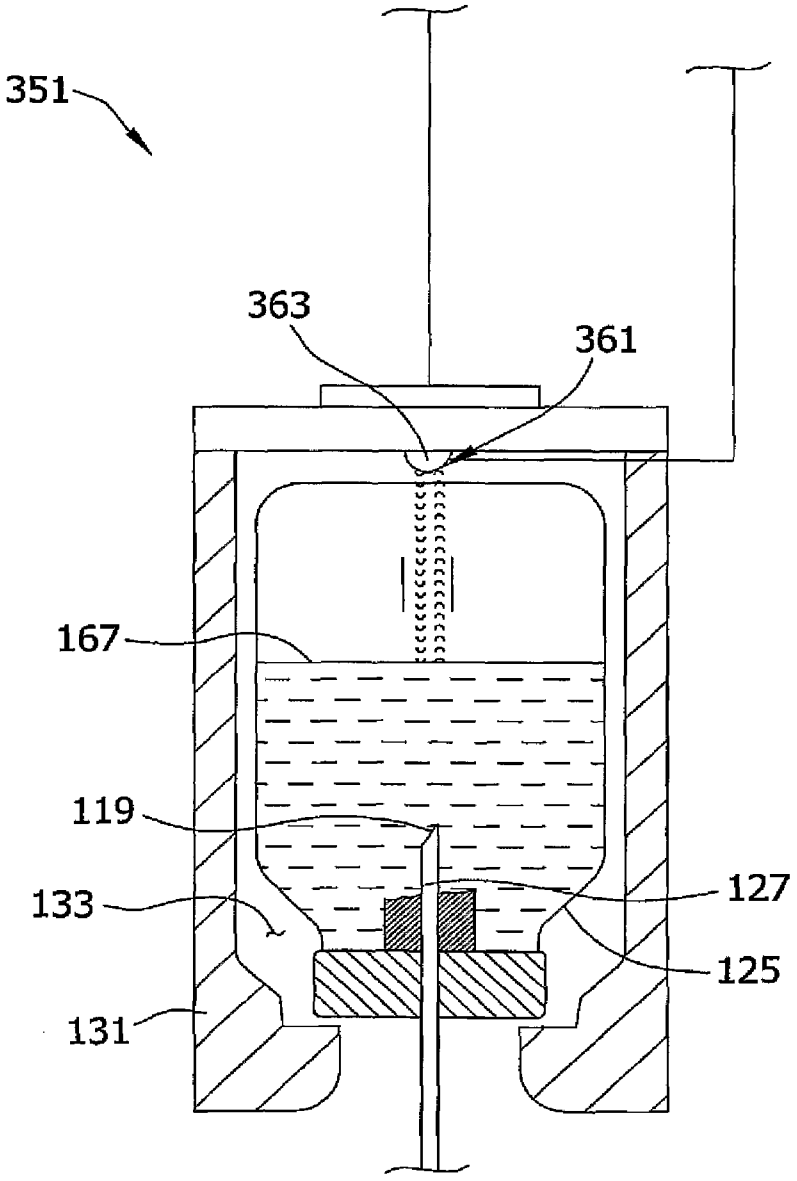

FIG. 5

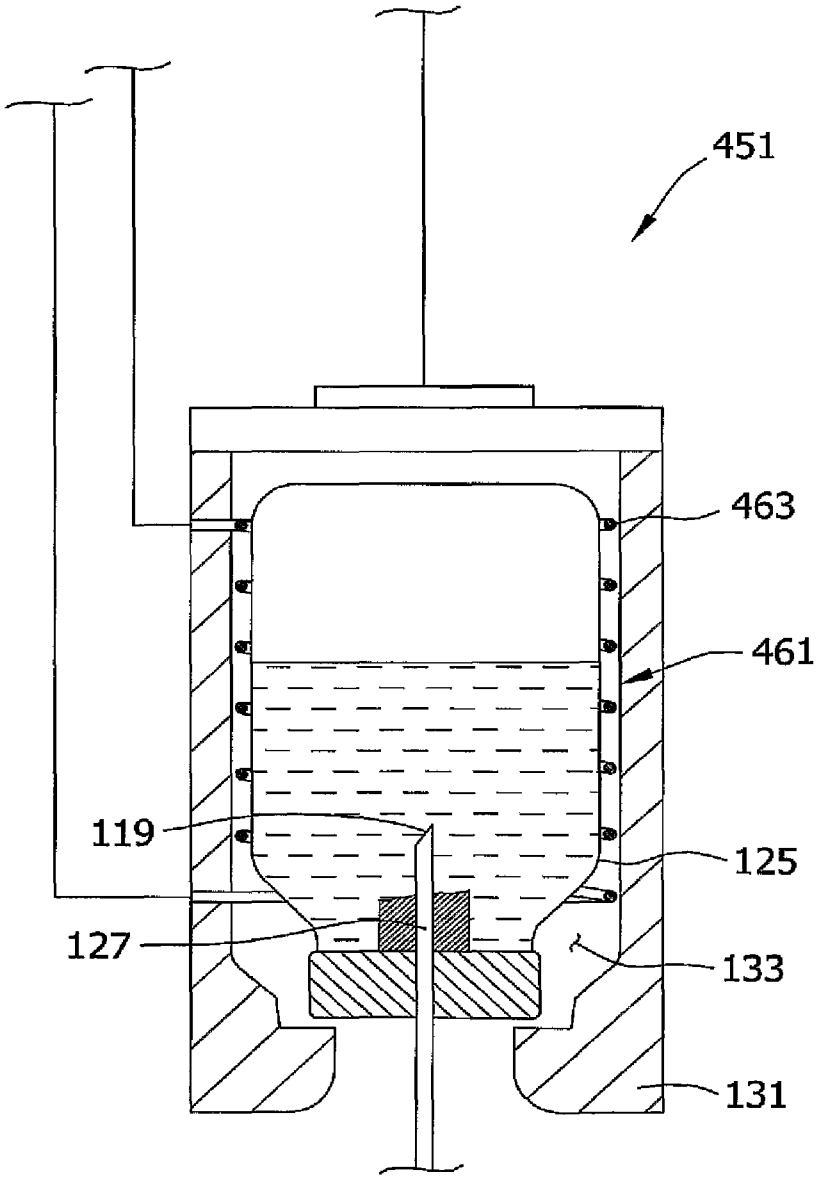

FIG. 6

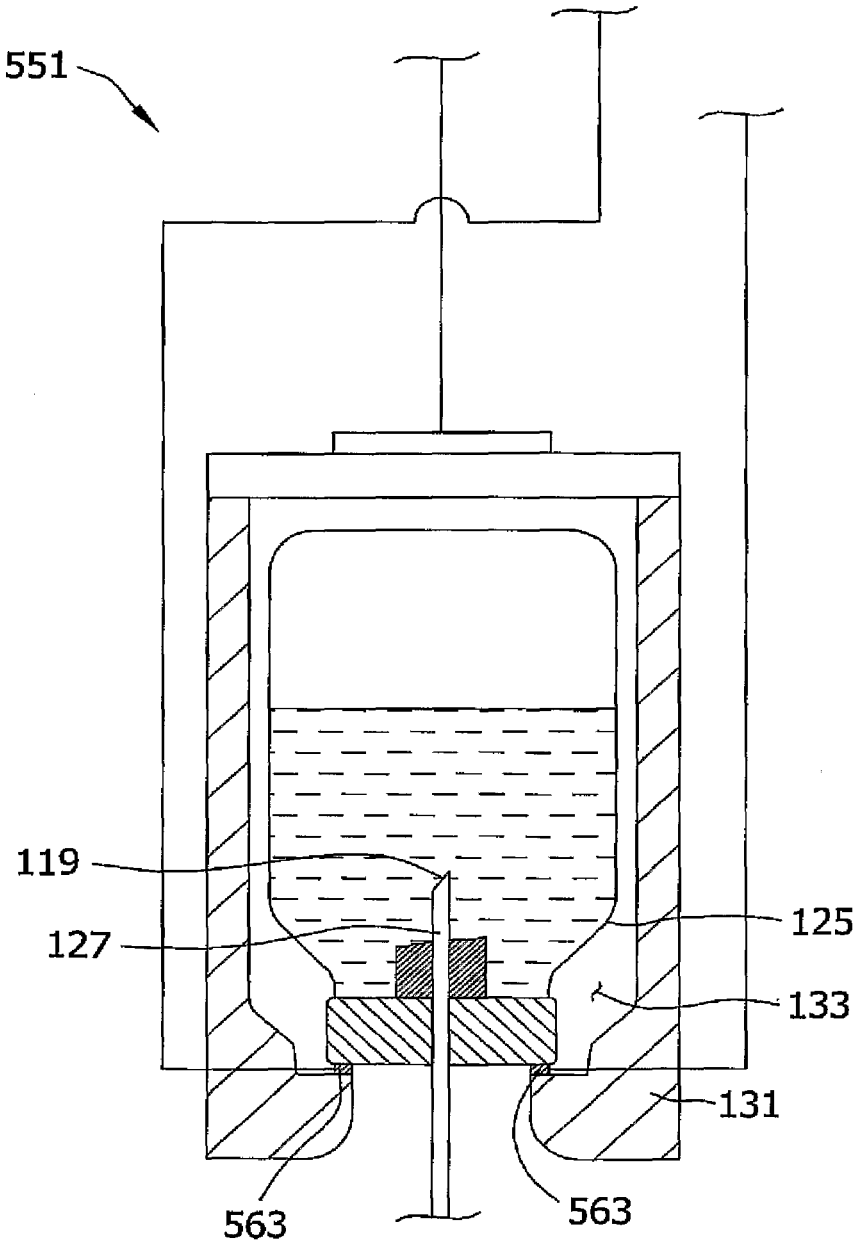

FIG. 7

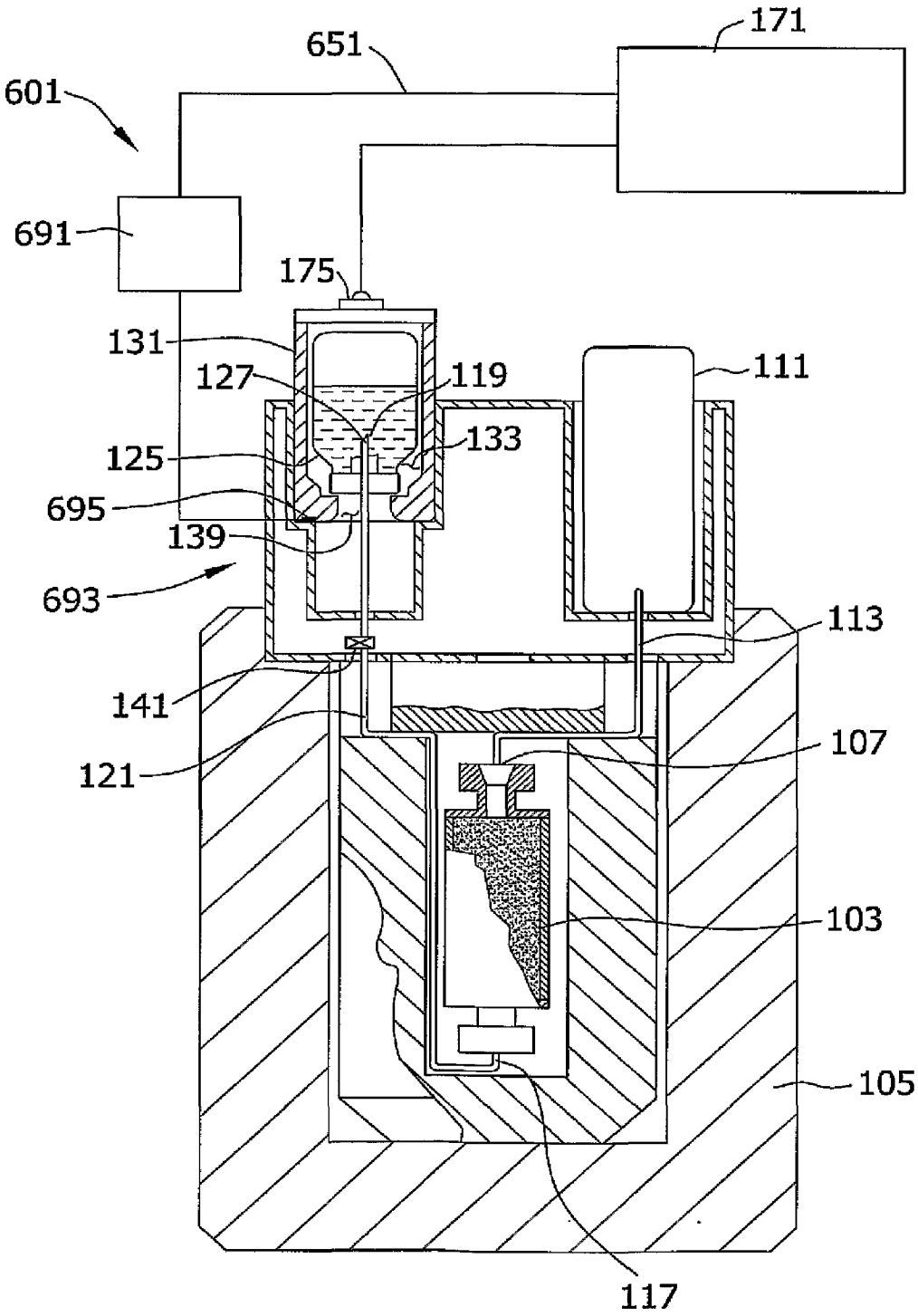
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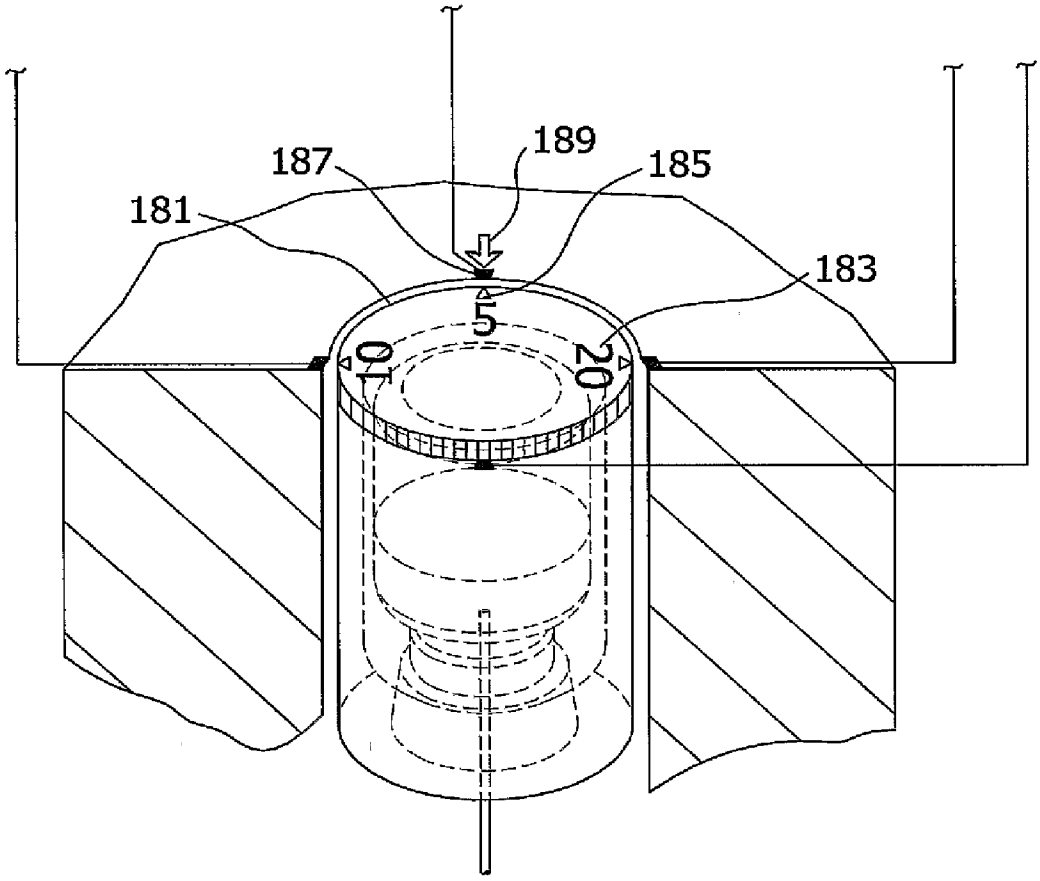
FIG. 8



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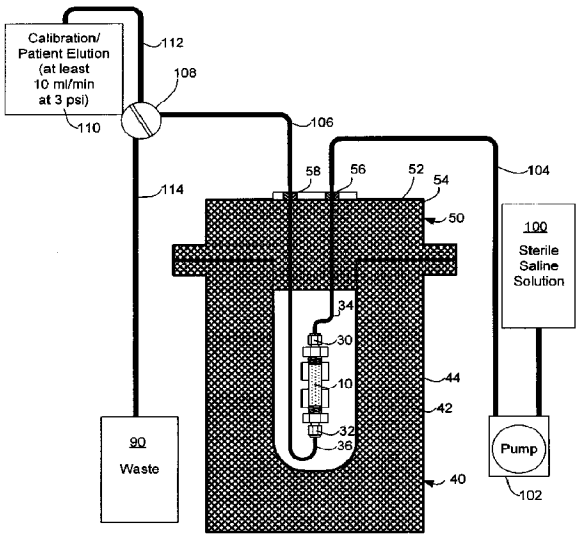
(54) **Title:** A RUBIDIUM GENERATOR FOR CARDIAC PERFUSION IMAGING AND METHOD OF MAKING AND MAINTAINING SAME



(57) **Abstract:** An $^{82}Sr/^{82}Rb$ generator column is made using a fluid impervious cylindrical container having a cover for closing the container in a fluid tight seal, and further having an inlet for connection of a conduit for delivering a fluid into the container and an outlet for connection of a conduit for conducting the fluid from the container. An ion exchange material fills the container, the ion exchange material being compacted within the container to a density that permits the ion exchange material to be eluted at a rate of at least 5 ml/min at a fluid pressure of 1.5 pounds per square inch (10 kPa). The generator column can be repeatedly recharged with ^{82}Sr. The generator column is compatible with either three-dimensional or two-dimensional positron emission tomography systems.

WO 2007/071022 A1

A RUBIDIUM GENERATOR FOR CARDIAC PERFUSION IMAGING AND METHOD OF MAKING AND MAINTAINING SAME

TECHNICAL FIELD

The present application relates in general to nuclear medicine and, in particular, to a rubidium generator for cardiac perfusion imaging and method of making and maintaining same.

BACKGROUND OF THE INVENTION

As is well known in the art, ^{82}Rb is used as a positron emission tomography (PET) tracer for measurement of myocardial perfusion (blood flow) in a non-invasive manner.

Recent improvements in PET technology have introduced 3-dimensional positron emission tomography (3D PET). Although 3D PET technology may permit more efficient diagnosis and prognosis in patients with suspected coronary artery disease, the sensitivity of 3D PET requires very accurate control of the delivery of ^{82}Rb activity to a patient being assessed.

As is well understood in the art, ^{82}Rb for myocardial perfusion imaging is produced using a strontium-rubidium ($^{82}Sr/^{82}Rb$) generator which is eluted using a sterile saline solution (0.9% Sodium Chloride Injection) to produce an ^{82}Rb eluate ([^{82}Rb] Rubidium Chloride Injection) that is injected into the patient during the PET imaging. Due to the above-noted sensitivity of 3D PET it is desirable to deliver the ^{82}Rb elution to the patient as far away from the patient's heart as can be practically achieved. This

is best accomplished by using a small vein in the patient's hand, for example, as the ^{82}Rb elution injection site. Doing so, however, requires a low pressure, low flow rate elution and precision flow control.

There therefore exists a need for an ^{82}Rb generator that enables low pressure elution and facilitates precision flow control of patient elution injections.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a rubidium generator column that enables low pressure elution and facilitates precision flow control of patient elutions.

The invention therefore provides a method of preparing an $^{82}Sr/^{82}Rb$ generator column for low pressure elution, comprising: filling the generator column with an ion exchange material that tightly binds ^{82}Sr but not ^{82}Rb, and compacting the ion exchange material to a density that permits fluid solutions to be pumped through the generator column at a rate of at least 5 ml/min at a fluid pressure of 1.5 pounds per square inch (10 kPa); conditioning the ion exchange material; and loading the generator column with a solution of ^{82}Sr.

The invention further provides an $^{82}Sr/^{82}Rb$ generator column, comprising: a fluid impervious cylindrical container having a cover for closing the container in a fluid tight seal, and further having an inlet for connection of a conduit for delivering a fluid into the container and an outlet for connection of a conduit for conducting the fluid from the container; and an ion exchange material filling the container, the ion exchange

material being compacted within the container to a density that permits the ion exchange material to be eluted at a rate of at least 5 ml/min at a fluid pressure of 1.5 pounds per square inch (10 kPa).

BRIEF DESCRIPTION OF THE DRAWINGS

Further features and advantages of the present invention will become apparent from the following detailed description, taken in combination with the appended drawings, in which:

Fig. 1 is a schematic diagram illustrating the packing of a generator column in accordance with the invention;

Fig. 2 is a schematic diagram of the generator column shown in Fig. 1 suspended in a shielding body and being loaded with ^{82}Sr;

Fig. 3 is a schematic diagram of the generator column shown in Fig. 1 configured for calibration and patient elutions;

Fig. 4 is a flowchart illustrating the method in accordance with the invention for making the generator columns shown in Figs. 1-3; and

Fig. 5 is a flowchart illustrating principle steps in the use of the generator column shown in Fig. 3.

It will be noted that throughout the appended drawings, like features are identified by like reference numerals.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides an $^{82}Sr/^{82}Rb$ generator column for use in positron emission tomography cardiac perfusion imaging. In accordance with the invention, the generator column is filled with an ion exchange material that tightly binds ^{82}Sr but not ^{82}Rb. The ion exchange material is compacted to a density that permits fluid solutions to be pumped through the generator column at a rate of at least 5 ml/min at a fluid pressure of 1.5 pounds per square inch (10 kPa). After the generator column is packed with the ion exchange material, it is conditioned with a source of excess sodium cations and loaded with a solution of ^{82}Sr. The generator column in accordance with the invention enables low pressure injections using a peristaltic pump and facilitates precision flow control of patient elutions. Advantageously, the generator column in accordance with the invention can also be reloaded with ^{82}Sr a plurality of times. This has distinct advantages. First, residue ^{82}Sr remaining in the column from a previous load is not wasted. Second, the expense of building and conditioning the generator column is distributed over a plurality of ^{82}Sr loads, so the overall cost of using ^{82}Rb for cardiac perfusion imaging is reduced.

Fig. 1 illustrates the packing of an ^{82}Rb generator column 10 using a method in accordance with the invention. As is known in the art, the generator column 10 is constructed from stainless steel hardware components that are commercially available. In the embodiment shown in Fig. 1, a pair of SWAGELOK® reducing adaptors with nuts and ferrules 12, 14 are connected to opposite ends of a stainless tubing 16 that is packed with an ion exchange material 18. In one embodiment of the invention, the ion exchange material 18 is an α-hydrous tin dioxide (

$SnO_2.xH_2O$, where x equals 1-2) wetted with a NH_4OH/NH_4Cl buffer (pH 10).

A 25 micron filter 24 closes a bottom of the cylinder 16 at an outlet end thereof. Likewise, a 25 micron filter 22 closes an inlet end of the cylinder 16 after the cylinder 16 is packed with the ion exchange material 18. A feature of the invention is that, unlike prior art generator columns in which the ion exchange material is tightly packed so that high pressure elution is required, the ion exchange material 18 is packed only to a density that permits fluid solutions to be pumped through the generator column at a rate of at least 5 ml/min at a fluid pressure of 1.5 pounds per square inch (10 kPa). As shown in Fig. 1, a simple and practical way of accomplishing the required packing of the ion exchange material 18 is to repeatedly strike a side of the generator column 10 with an instrument 26, such as a laboratory wrench, with a force that exerts about 0.1 Joule. Experience has shown that between 50 and 100 strikes are required to achieve the required density of the ion exchange material 18.

After packing of the generator column 10 is complete, a funnel 20 that was used to introduce the ion exchange material 18 into the cylinder 16 is removed and the ion exchange material is leveled with the top of the cylinder 16. The ion exchange material packed into the generator column 10 has a density of not more than 3 g/cm^3 in the packed state. The filter 22 is then placed on top of cylinder 16 and the SWAGELOK adapter, nut and ferrule 12 is secured to the top of the cylinder in a manner well known in the art. As will be understood by those skilled in the art, the generator column 10 in accordance with the invention is constructed under sterile conditions using

sterile components and may be pressure tested for leaks after assembly.

Fig. 2 is a cross-sectional view of the generator column 10 suspended in a shielding body 40. The shielding body 40 is made from a dense shielding material 42, such as lead, tungsten or depleted uranium optionally encased in a stainless steel shell 44. The shielding body 42 includes a shielding lid 50 having apertures through which extend an inlet line 34 and outlet line 36. The inlet line 34 is connected to an inlet end 30 of the generator column 10. The outlet line 36 is connected to an outlet end 32 of the generator column 10. The inlet and outlet lines are connected to external tubing lines 60, 62 using Luer fittings 56 and 58. The shielding lid 50 is likewise constructed of a shielding material 52 such as lead, tungsten or depleted uranium encased in a stainless steel shell 54.

After the generator column 10 is packed with ion exchange material 18, as explained above with reference to Fig. 1, the generator column 10 must be loaded with ^{82}Sr before patient elutions can begin. As schematically illustrated in Fig. 2, in one embodiment a syringe pump 80 is used to deliver ^{82}Sr from a supply 70 through an inlet tube 60 to the generator column 10. The ^{82}Sr is bound by the ion exchange material 18 in the generator column 10. Waste fluid is evacuated through the outlet tube 36 and outlet line 62 to a shielded waste container 90, in a manner known in the art.

Fig. 3 is a schematic diagram of the generator column 10 configured for daily use as an ^{82}Rb source for cardiac perfusion imaging. A source of sterile saline solution 100 is connected to a saline supply tube 104. The sterile

saline solution 100 is pumped through the saline supply tube 104 by a pump 102. In one embodiment of the invention, the pump 102 is a peristaltic pump. In accordance with an alternate embodiment, the pump 102 is the syringe pump 80 shown in Fig. 2.

As understood by those skilled in the art, the pump 102 is controlled by a control algorithm that regulates a flow rate and volume of the sterile saline solution 100 pumped through the generator column 10 via the inlet tube 104 to provide an ^{82}Rb eluate via an outlet tube 106 connected to a controlled valve 108. The valve 108 directs the eluate through a delivery line 112 for a calibration elution or a patient elution 110, or to a shielded waste container 90. As is further understood by those skilled in the art, control of the system shown in Fig. 3 is complex and not all of the fluid paths and control mechanisms are depicted because elution control is not a subject of this invention.

Fig. 4 is a flowchart illustrating principle steps in constructing the generator column 10 in accordance with the invention. The process begins by preparing the ion exchange material and packing the generator column as explained above with reference to Fig. 1 (step 200). The generator column is then conditioned by saturating the ion exchange material 18 with sodium cations. In one embodiment, this is accomplished by passing 120 ml of 2 M NaCl through the column at a flow rate of 0.5 ml/minute followed by waiting for a period of 12 hours. 500 ml of sterile saline solution is then passed through the column at a flow rate of 10 ml/minute. A nondestructive pH test is performed (step 202) by testing a pH of the initial sterile saline solution passed through the column. This

nondestructive pH test prolongs the life of the generator column 10.

If it is determined (step 204) that the pH of the generator column 10 is not alkaline, the generator column 10 is defective and it is disposed of (step 224). If the saline solution is determined in step 204 to be alkaline, the generator column is loaded with ^{82}Sr (step 206) in a manner well known in the art using the equipment briefly described above with reference to Fig. 3. After the ^{82}Sr is loaded into the generator column 10, the generator column 10 is flushed with 1.0 L of sterile saline solution to clear traces of tin dioxide and any radionuclide impurities. The generator column is then eluted with sterile saline solution and the eluate is tested for: trace metals; sterility; radionuclide purity; pyrogens; and pH (step 208). If all of those tests are passed (step 210) the generator column 10 is ready for use (step 212). If any one of the tests fails, ^{82}Sr is optionally recovered from the generator column 10 (step 222) and the generator column 10 is disposed of (step 224).

During generator use, daily testing is performed for the purpose of patient safety and quality control, as will be described in detail with reference to Fig. 5. As long as all daily tests are passed, the generator column can continue to be used for patient elutions. As understood by those skilled in the art, one of the daily tests is a measure of ^{82}Rb yield. If it is determined in step 214 that one of the daily tests failed, it is further determined whether a reload of the generator column 10 is permitted (step 216). Reloading is permitted if the daily test failed due insufficient ^{82}Rb yield only. If the daily test failed for some other reason the generator column 10

cannot be further used, and the ^{82}Sr is optionally recovered (step 222) before the generator column is disposed of (step 224), as described above. If an ^{82}Sr reload is permitted, it is determined in step 218 whether the number of ^{82}Sr reloads of the generator column 10 has exceeded a predetermined reload limit. A generator column in accordance with the invention can be loaded with ^{82}Sr at least three times before any significant ^{82}Sr breakthrough occurs. If it determined in step 218 that the reload limit has been reached, certain jurisdictions require that the generator column be flushed and the eluate tested for: trace metals; sterility; radionuclide purity; pyrogens; and pH. If it is determined in step 218 that the reload limit has not been reached, the process branches back to step 206 and the generator column is reloaded with ^{82}Sr and steps 208-218 are repeated.

Fig. 5 is a flowchart illustrating principle steps involved in the daily use of the generator column 10 in accordance with the invention. Prior to each day's use of the generator column 10, the generator column 10 is flushed with 50 ml of sterile saline solution (step 300) in order to remove any strontium breakthrough from the generator column 10 into the waste vessel 90. The operator then waits for a predetermined period of time (step 302) before performing a calibration elution (step 304). As is well understood by those skilled in the art, under stable conditions the generator column maintains a $^{82}Sr/^{82}Rb$ equilibrium which is achieved after about 10 minutes. Consequently, the predetermined wait before a calibration elution is performed is at least 10 minutes. After the required wait, the generator column is eluted with about 15 ml of sterile saline solution at a constant flow rate of about 15 ml/minute. The calibration eluate is tested (step

306) for ^{82}Rb yield and ^{82}Sr breakthrough. In step 308 it is determined whether the ^{82}Rb yield is above a predetermined radioactivity limit. As is understood by those skilled in the art, the half life of ^{82}Rb is very short (i.e. 76 seconds). Consequently, in one embodiment the ^{82}Rb yield is measured using a positron counter during the elution, in a manner well known in the art.

In step 310, it is determined whether the ^{82}Sr, ^{85}Sr breakthrough is less than a predetermined breakthrough limit. As is also understood by those skilled in the art, all jurisdictions define a threshold for permissible levels of ^{82}Sr, ^{85}Sr breakthrough. As is further understood by those skilled in the art, the strontium breakthrough is readily determined by testing the radioactivity of the elution after about 20 minutes has elapsed, at which time the amount of residual ^{82}Rb is insignificant and does not distort the test results.

Before daily use begins, a cumulative volume of all fluids flushed and eluted through the generator column 10 is computed. Since the generator column 10 in accordance with the invention is repeatedly reloaded with ^{82}Sr, each generator column is identified by a unique identifier, in one embodiment a serial number. If the user of a generator column 10 does not have the facility to reload the generator column 10, the user must return the generator column 10 to the manufacturer, along with a cumulative total of fluid flushed and eluted through the column during that use. Likewise, when a reloaded column is supplied to a user, a cumulative volume of fluid used to flush and elute the column during all prior reload(s) and use(s) is provided to the user. Control software used to control a volume of fluid used during generator column 10 flushes and

elutions accepts the cumulative volume and stores it. The control software then recomputes the cumulative volume after each subsequent flush or elution of the generator column 10. That computed cumulative volume is compared (step 312) to a predefined volume limit. In accordance with one embodiment of the invention, empirical data has shown that 10 to 30 litres of sterile saline solution 100 can be pumped through the generator column 10 before significant ^{82}Sr breakthrough is experienced, so the volume limit may be set between 10 and 30 litres.

If each of the tests 308-312 is successfully passed, patient elutions (step 314) may be performed in a manner well known in the art. After each elution, it is necessary to wait a predetermined period of time, about 5 to 10 minutes, (step 316) to permit ^{82}Rb to regenerate. After each elution, the cumulative volume is recomputed by adding to the cumulative volume a volume of fluid pumped through the generator column 10 during the patient elution. Then it is determined whether the control system date has changed, i.e. a new day has begun (step 318). If not, the cumulative volume is compared to the predetermined volume limit. If the volume limit has been exceeded, the generator column is disposed of (step 324).

If it is determined in step 318 that the control system date has changed, the generator column 10 must be flushed and re-tested per steps 300-312, as described above. If those tests determine that the ^{82}Rb yield is less than a predetermined limit (step 308) then it is determined in step 320 whether the reload limit has been exceeded and if not the generator column 10 is returned for reload and pre-use testing (step 322). Otherwise, the generator column is disposed of (step 324). It should be

noted that if any of tests 308-312 fail, the generator column 10 may be returned to the manufacturer who determines whether the generator column 10 can be reloaded (step 320) and disposes of the generator column 10 (step 324) if it cannot be reloaded.

The generator column 10 in accordance with the invention reduces the expense of cardiac perfusion imaging while ensuring compatibility with 3D PET imaging systems by enabling low pressure, low flow rate elutions that can be precisely flow controlled. Research has conclusively established that the generator column 10 in accordance with the invention remains sterile and pyrogen-free for a period of at least six months when used in accordance with the procedures and limits described above.

Although the invention has been explained with reference to 3D PET imaging systems, it should be understood that the generator column 10 is equally compatible with 2D PET imaging systems and provides the same advantages of low cost, precise flow control, low pressure and low flow elution and a long service life.

The embodiment(s) of the invention described above is(are) intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

Claims:

1. A method of preparing a $^{82}Sr/^{82}Rb$ generator column for low pressure elution, comprising:

filling the generator column with an ion exchange material that tightly binds ^{82}Sr but not ^{82}Rb, and compacting the ion exchange material to a density that permits at least 5 ml/min of fluid solution to be pumped through the generator column at a fluid pressure of 1.5 pounds per square inch (10 kPa);

conditioning the ion exchange material; and

loading the generator column with a solution of ^{82}Sr.

2. The method as claimed in claim 1 wherein compacting the ion exchange material comprises compacting the ion exchange material to a density of not more than 3 g/cm^3.

3. The method as claimed in claim 2 wherein compacting the ion exchange material comprises repeatedly striking the generator column with a controlled force.

4. The method as claimed in claim 2 wherein repeatedly striking the generator column comprises repeatedly delivering a controlled force that transfers about 0.1 Joule to the generator column.

5. The method as claimed in claim 3 further comprising repeatedly striking the generator column to deliver the controlled force between 50 and 100 times in order to compact the ion exchange material.

6. The method as claimed in claim 1 wherein conditioning the ion exchange material comprises eluting the material with a source of sodium ions and subsequently flushing the column with a sterile saline solution.

7. The method as claimed in claim 6 further comprising measuring a pH of the sterile saline solution after the generator column has been eluted with the source of sodium ions.

8. The method as claimed in claim 1 further comprising eluting the generator column with a predetermined volume of sterile saline solution and testing the eluate to: determine whether the eluate is free of trace metals; determine whether the eluate is free of radionuclide impurities; measure a pH of the eluate; determine whether the eluate is sterile; and determine whether the eluate is free of pyrogens.

9. The method as claimed in claim 1 further comprising reloading the generator column with ^{82}Sr after the ^{82}Sr has depleted to an extent that an elution of the generator column with the saline solution yields an ^{82}Rb activity that is below a predetermined limit, until a total number of reloads reaches a predetermined radioactivity limit.

10. The method as claimed in claim 1 further comprising, on a daily basis, flushing the generator column with a predetermined volume of sterile saline solution to remove any ^{82}Sr or ^{85}Sr breakthrough.

11. The method as claimed in claim 10 further comprising waiting a predetermined period of time after the flushing, and eluting the generator column with a predetermined volume of sterile saline solution at a constant flow rate to obtain a calibration eluate of ^{82}Rb activity.

12. The method as claimed in claim 11 further comprising measuring a total ^{82}Rb activity of the calibration eluate during the elution for activity calibration.

13. The method as claimed in claim 11 further comprising measuring a radiation activity level of the calibration eluate after a predetermined period of time has elapsed to determine whether a concentration of ^{82}Sr or ^{85}Sr in the test eluate is below a predetermined breakthrough limit.

14. The method as claimed in claim 11 further comprising:

waiting a predetermined period of time after obtaining the calibration eluate, and eluting the generator column with a sterile saline solution to obtain a patient eluate of ^{82}Rb activity; and

computing for each generator column after each flush or elution, a cumulative volume of sterile saline flushed and eluted through the generator column, and disposing of the generator column when the cumulative volume exceeds a predetermined volume limit.

15. An $^{82}Sr/^{82}Rb$ generator column, comprising:

a fluid impervious cylindrical container having a cover for closing the container in a fluid tight

seal, and further having an inlet for connection of a conduit for delivering a fluid into the container and an outlet for connection of a conduit for conducting the fluid from the container; and

an ion exchange material filling the container, the ion exchange material being compacted within the container to a density that permits the ion exchange material to be eluted at a flow rate of at least 5 ml/min at fluid pressure of 1.5 pounds per square inch (10 kPa).

16. The $^{82}Sr/^{82}Rb$ generator column as claimed in claim 15 wherein the ion exchange material comprises α-hydrous tin dioxide.

17. The $^{82}Sr/^{82}Rb$ generator column as claimed in claim 16 wherein a total volume of the α-hydrous tin dioxide in the generator column is about 1.5 cm^3.

18. The $^{82}Sr/^{82}Rb$ generator column as claimed in claim 17 wherein the α-hydrous tin dioxide has a density of about 3 g/cm^3.

19. The $^{82}Sr/^{82}Rb$ generator column as claimed in claim 15 further comprising a particle filter at each of the inlet and the outlet.

20. The $^{82}Sr/^{82}Rb$ generator column as claimed in claim 15 further comprising a peristaltic or syringe pump for flushing and eluting the generator column.

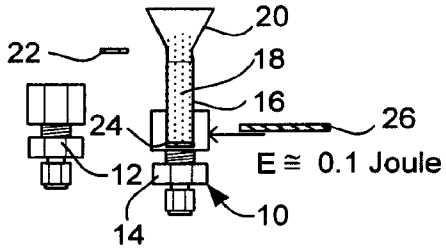

20
22
18
16
24
26
E ≅ 0.1 Joule
12
10
14

FIG. 1

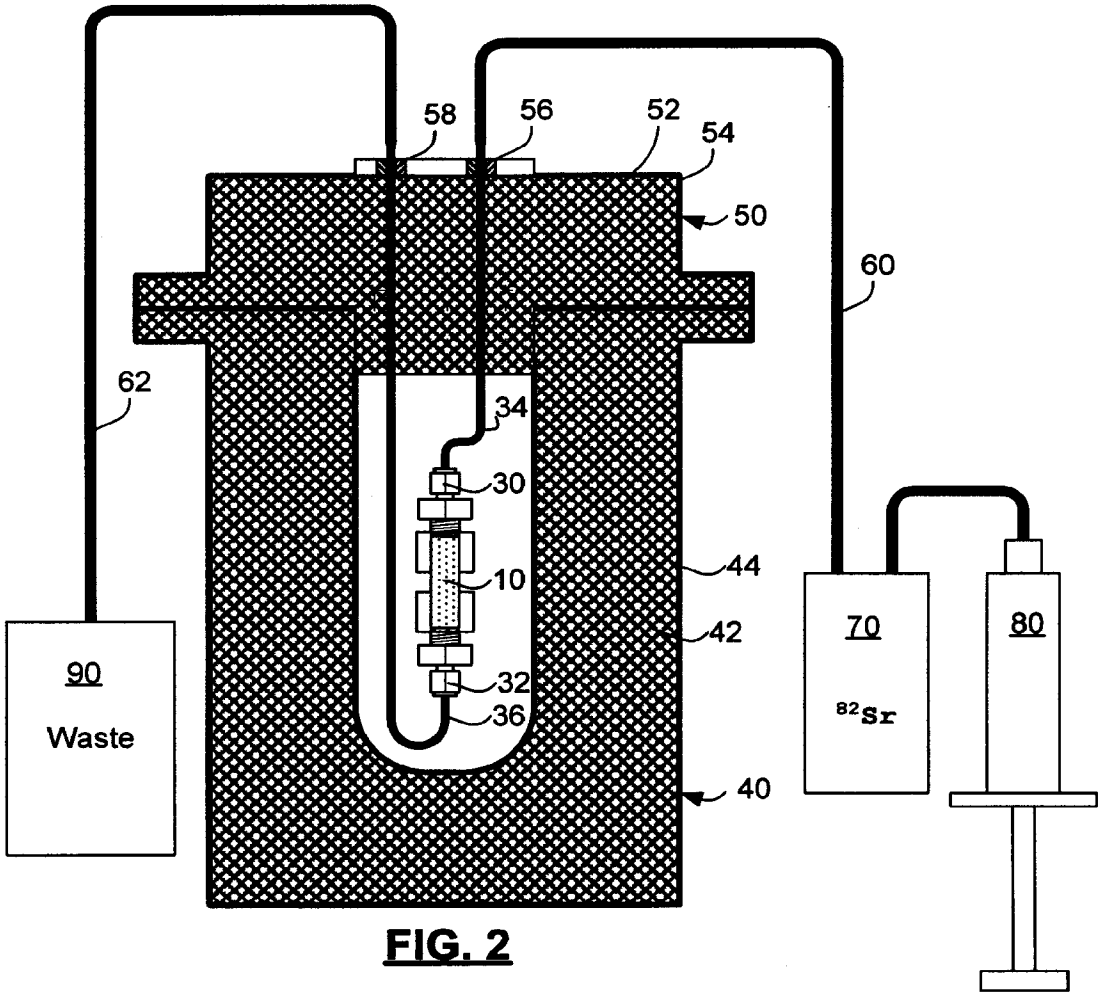

58
56
52
54
50
60
62
34
30
10
44
42
90
Waste
70
82Sr
80
32
36
40

FIG. 2

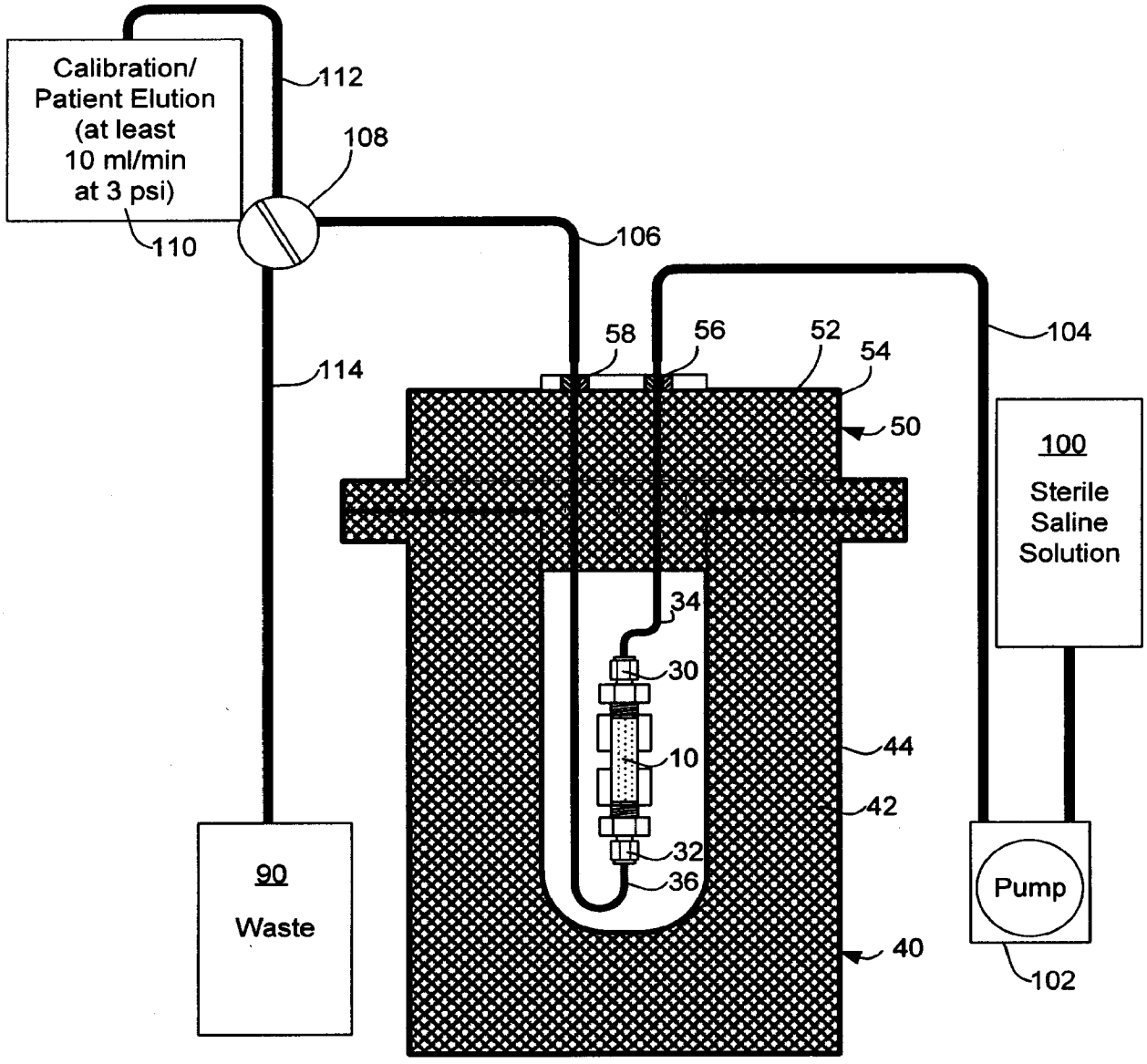

Calibration/
Patient Elution
(at least
10 ml/min
at 3 psi)
110
112
108
106
114
58
56
52
54
104
50
100
Sterile
Saline
Solution
34
30
10
44
42
32
36
90
Waste
Pump
40
102

FIG. 3

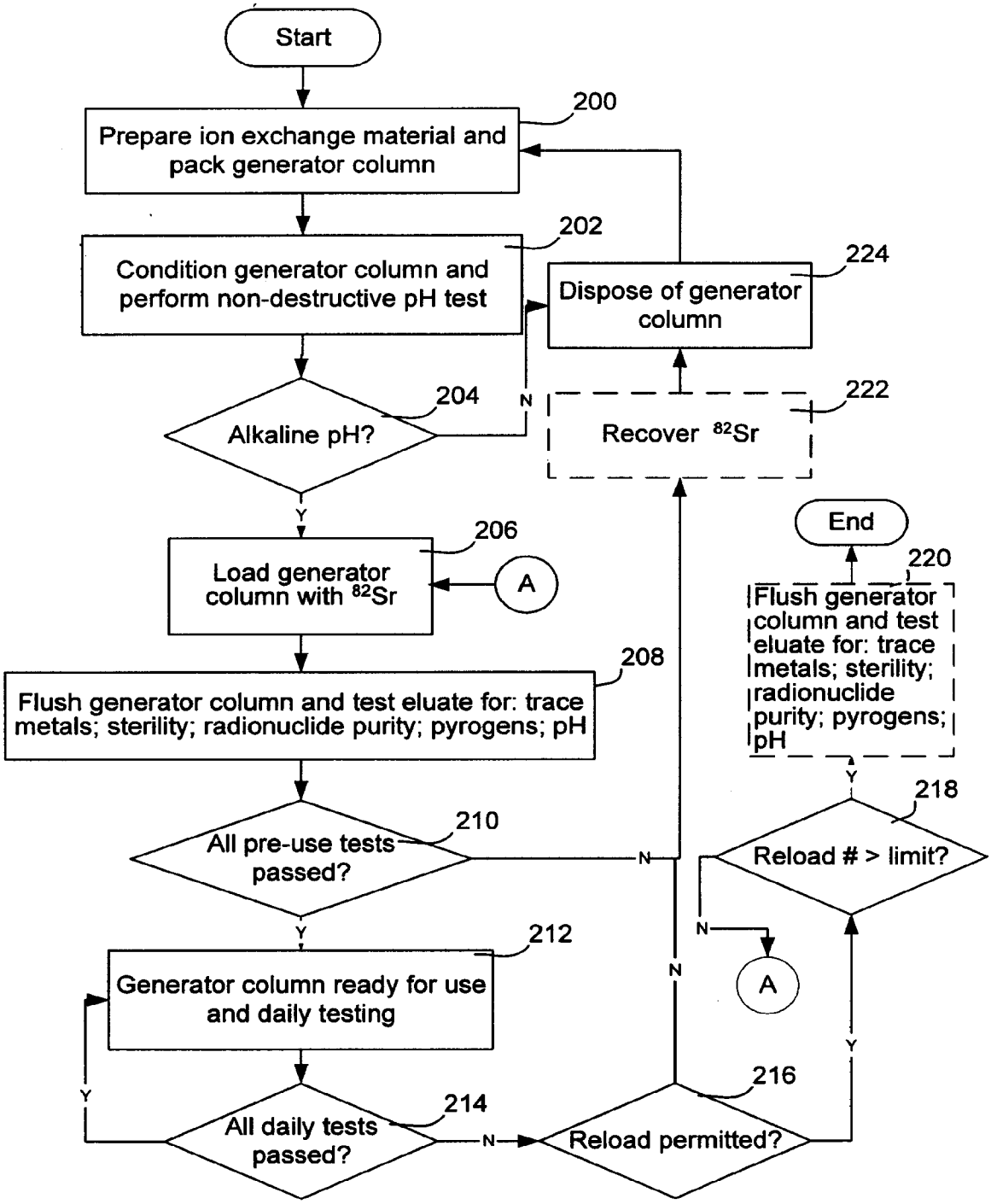

Start
200
Prepare ion exchange material and pack generator column
202
Condition generator column and perform non-destructive pH test
224
Dispose of generator column
204
Alkaline pH?
N
222
Recover ^{82}Sr
Y
End
206
Load generator column with ^{82}Sr
A
220
Flush generator column and test eluate for: trace metals; sterility; radionuclide purity; pyrogens; pH
208
Flush generator column and test eluate for: trace metals; sterility; radionuclide purity; pyrogens; pH
Y
218
210
All pre-use tests passed?
N
Reload # > limit?
Y
212
N
A
Generator column ready for use and daily testing
N
Y
216
Y
214
All daily tests passed?
N
Reload permitted?

FIG. 4

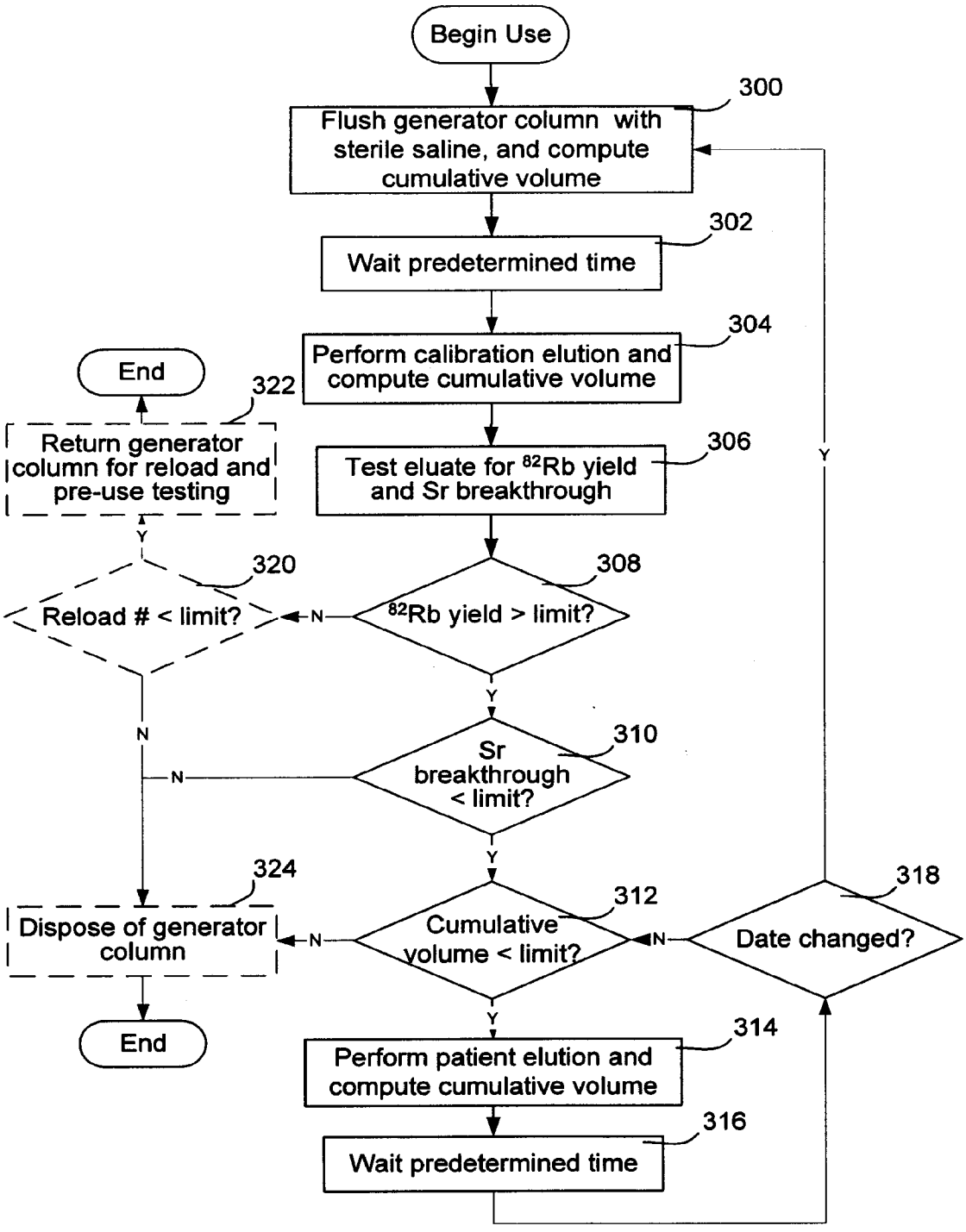

Begin Use
300
Flush generator column with sterile saline, and compute cumulative volume
302
Wait predetermined time
304
Perform calibration elution and compute cumulative volume
306
Test eluate for 82Rb yield and Sr breakthrough
308
82Rb yield > limit?
N
320
Reload # < limit?
322
Return generator column for reload and pre-use testing
End
Y
N
310
Sr breakthrough < limit?
N
Y
312
Cumulative volume < limit?
N
318
Date changed?
Y
324
Dispose of generator column
End
314
Perform patient elution and compute cumulative volume
316
Wait predetermined time
Y

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2006/002043

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***B01D 15/42*** (2006.01) , ***B01J 20/34*** (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: ***B01D 15/42*** (2006.01) , ***B01J 20/34*** (2006.01) , B01D 15/20 (2006.01) , B01J 20/28 (2006.01) , A61K 51/00 (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)
Canadian Patents Database, Delphion, Knovel, Scopus, Internet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ALVAREZ-DIAZ, Teresa M. et al., Manufacture of strontium-82/rubidium-82 generators and quality control of rubidium-82 chloride for myocardial perfusion	1-20
Y	imaging in patients using positron emission tomography, Applied Radiation and Isotopes, vol. 50, no. 6, 1999, pp. 1015-1023 * Whole document *	1-2, 15-20 3-5 6-14
Y	YANO, Y, et al., Rubidium-82 Generators for Imaging Studies, The Journal of Nuclear Medicine, vol. 18, no. 1, 1977, pp. 46-50 * p. 47, col. 1, lines 9-12 *	1-2, 15-20
Y	US 4175037 A (BENNEY, C. H. et al.) 20 November 1979 (20-11-1979) * col. 1, line 64 - col. 2, line 42 *	3-5
Y	US 3935884 A (HAZELTON) 3 February 1976 (03-02-1976) * col. 1, lines 8-11 *	3-5

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

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"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
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"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)	17 April 2007 (17-04-2007)

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	Pierre Cuerrier 819- 997-4379

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2006/002043

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2845136 A (ROBINSON) 29 July 1958 (29-07-1958) * col. 1, lines 57-63 *	3-5
Y	US 3164980 A (LOYD) 12 January 1965 (12-01-1965) * col. 3, lines 7-9 *	3-5
Y	SCOTT, . P. W. (editor), Gas Chromatography, Proceedings of the third symposium organized by the Society of Analytical Chemistry and the Gas Chromatography Discussion Group of the Hydrocarbon Research Group of the Institute of Petroleum, held at the Assembly Rooms, Edimburgh, 8-10 June 1960, pp. 240-241	3-5
Y	Bracco Diagnostics, CardioGen-82® Rubidium Rb 82 Generator, USA, May 2000 * Whole document *	6-14
Y	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 * Whole document *	6-14
A	Rousseau, Ronald W., Handbook of Separation Process Technology, John Wiley & Sons, 1987, pp. 717-718 * chapter 13.3-2 *	1-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/CA2006/002043

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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		AU3859578 A	07-02-1980
		CA1115551 A1	05-01-1982
		CH637843 A5	31-08-1983
		DE2838086 A1	18-10-1979
		FR2422426 A1	09-11-1979
		GB1597338 A	03-09-1981
		JP54134695 A	19-10-1979
		NL7808498 A	12-10-1979
		SE7809128 A	11-10-1979
US3935884	03-02-1976	NONE	
US2845136	29-07-1958	NONE	
US3164980	12-01-1965	NONE	

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PCT/CA2007/000295

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26 February 2007 (26.02.2007)

(25) Filing Language: English

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(30) Priority Data:
11/372,149 10 March 2006 (10.03.2006) US

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

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

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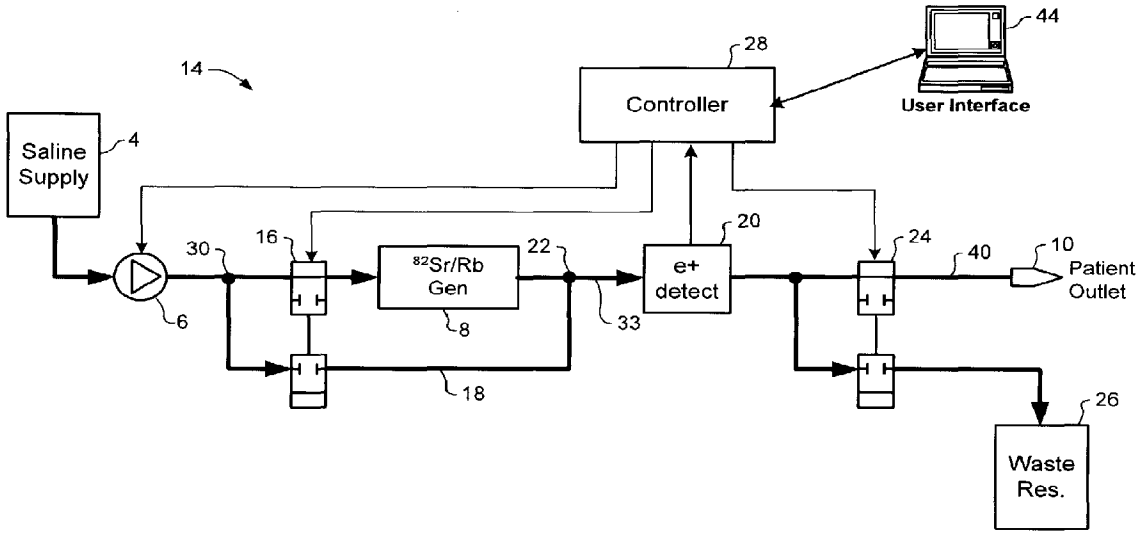
— *with international search report*

[Continued on next page]

(54) **Title:** RUBIDIUM ELUTION SYSTEM CONTROL



(57) **Abstract:** 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. During each elution run, a plurality of successive concentration parameter values are obtained at predetermined intervals. Each concentration parameter value is indicative of a respective instantaneous activity concentration of the active saline solution. Respective error values between each concentration parameter value and a target activity concentration value of the elution run are computed. Error data based on a plurality of the computed error values is accumulated. Between successive elution runs, at least one performance parameter of the elution system is adjusted based on the accumulated error data.

WO 2007/104133 A1

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

RUBIDIUM ELUTION SYSTEM CONTROL

FIELD OF THE INVENTION

The present application relates in general to nuclear medicine and, in particular, to a rubidium elution control system.

BACKGROUND OF THE INVENTION

As is well known in the art, Rubidium (^{82}Rb) is used as a positron emission tomography (PET) tracer for non-invasive measurement of myocardial perfusion (blood flow).

Recent improvements in PET technology have introduced 3-dimensional positron emission tomography (3D PET). Although 3D PET technology may permit more efficient diagnosis and prognosis in patients with suspected coronary artery disease, the sensitivity of 3D PET requires very accurate control of the delivery of ^{82}Rb activity to a patient being assessed.

FIGs. 1 and 2 illustrate a conventional rubidium elution system used for myocardial perfusion imaging. As may be seen in FIG. 1, the elution system comprises a reservoir of sterile saline solution (e.g. 0.9% Sodium Chloride Injection), a pump, and a strontium-rubidium ($^{82}Sr/^{82}Rb$) generator. In operation, the pump causes the saline solution to flow from the reservoir 4 and through the generator 8 to elute the ^{82}Rb. The active solution output from the generator 8 is then supplied to a patient (not shown) via a patient outlet 10.

When the system 2 is not in use, the amount of ^{82}Rb within the generator 8 accumulates until a balance is reached between the rate of ^{82}Rb production (that is, ^{82}Sr

decay) and the rate of ^{82}Rb decay. As a result, the ^{82}Rb activity level in the active saline emerging from the generator 8 tends to follow a "bolus" profile 12 shown by the solid line in FIG. 2a. In particular, at the start of an ^{82}Rb elution "run", the activity level rises rapidly and peaks, as accumulated ^{82}Rb is flushed out of the generator 8. Thereafter, the activity level drops back to a substantially constant value. The maximum activity level A_{MAX} (bolus peak) obtained during the run is dependent on the amount of accumulated ^{82}Rb in the generator 8, and thus is generally a function of the system's recent usage history, principally: the current ^{82}Rb production rate; the amount of accumulated ^{82}Rb (if any) remaining at the end of the previous elution run; and the idle time since the previous run. The generally constant level of the bolus tail is dependent on the rate of ^{82}Rb production and the saline flow rate produced by the pump 6.

As is well known in the art, ^{82}Rb is generated by radioactive decay of the ^{82}Sr, and thus the rate of ^{82}Rb production at any particular time is a function of the mass of remaining ^{82}Sr. As will be appreciated, this value will diminish (exponentially) through the useful life of the generator 8. The result is a family of bolus curves, illustrated by the dashed lines of FIG. 2a, mapping the change in elution system performance over the useful life of the generator 8.

Because of the high activity level of ^{82}Rb possible in the generator 8, it is desirable to limit the total activity dosage delivered to the patient during any given elution run. The total elution time required to reach this maximum permissible dose (for any given flow rate) will therefore vary over the life of the ^{82}Sr charge in the

generator 8, as may be seen in FIG. 2b, where the total activity dose, represented by the area under each curve, is equal in both cases.

A limitation of this approach, particularly for 3D PET imaging, is that the delivery of a high activity rate over a short period of time tends to degrade image quality. Low activity rates supplied over a relatively extended period are preferred. As a result, the user is required to estimate the saline flow rate that will obtain the best possible image quality, given the age of the generator and its recent usage history, both of which will affect the bolus peak and tail levels. This estimate must be continuously adjusted throughout the life of the generator 8, as the ^{82}Sr decays.

Accordingly, techniques for controlling an ^{82}Rb elution system that enable a desired activity level to be supplied over a desired period of time, independently of a state of the $^{82}Sr/^{82}Rb$ generator, remain highly desirable.

SUMMARY OF THE INVENTION

Accordingly, an object of the present invention is to provide techniques for controlling an ^{82}Rb elution system.

The present invention therefore provides 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. During each elution run, a plurality of successive concentration parameter values are obtained at

predetermined intervals. Each concentration parameter value is indicative of a respective instantaneous activity concentration of the active saline solution. Respective error values between each concentration parameter value and a target activity concentration value of the elution run are computed. Error data based on a plurality of the computed error values is accumulated. Between successive elution runs, at least one performance parameter of the elution system is adjusted based on the accumulated error data.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features and advantages of the present invention will become apparent from the following detailed description, taken in combination with the appended drawings, in which:

FIG. 1 is a block diagram schematically illustrating principal elements of a conventional Rubidium elution system;

FIGs 2a and 2b are graphs illustrating representative performance of the elution system of FIG. 1;

FIG. 3 is a block diagram schematically illustrating principal elements of a Rubidium elution system in accordance with an embodiment of the present invention;

FIG. 4 illustrates a pinch-type valve arrangement usable in the elution system of FIG. 3;

FIG. 5 schematically illustrates a positron detector usable in the elution system of FIG. 3;

Figs. 6a-6d schematically illustrate respective operating states of the Rubidium elution system of FIG. 3;

FIGs. 7a-7c schematically illustrate a first algorithm for controlling the Rubidium elution system of FIG. 3; and

FIGs. 8a-8c schematically illustrate a second algorithm for controlling the Rubidium elution system of FIG. 3;.

It will be noted that throughout the appended drawings, like features are identified by like reference numerals.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a Rubidium (^{82}Rb) elution and control system in which the ^{82}Rb activity rate delivered to a patient can be controlled substantially independently of the condition of the ^{82}Sr/^{82}Rb generator. Representative embodiments are described below with reference to FIGs. 3-8.

In the embodiment of FIG. 3, the elution system comprises reservoir 4 of sterile saline solution (e.g. 0.9% Sodium Chloride Injection); a pump 6 for drawing saline from the reservoir 4 at a desired flow rate; a generator valve 16 for proportioning the saline flow between a strontium-rubidium (^{82}Sr/^{82}Rb) generator 8 and a bypass line 18 which circumvents the generator 8; a positron detector 20 located downstream of the merge point 22 at which the generator and bypass flows merge; and a patient valve 24 for controlling supply of active saline to a patient outlet 10 and a waste reservoir 26. A controller 28 is connected to the pump 6, positron detector 20 and valves 16 and 24 to control the elution system 14 in accordance with a desired control algorithm, as will be described in greater detail below.

If desired, the strontium-rubidium ($^{82}Sr/^{82}Rb$) generator 8 may be constructed in accordance with Applicant's co-pending United States Patent Application No. 11/312,368 entitled A Rubidium Generator For Cardiac Perfusion Imaging And Method Of Making And Maintaining Same, filed December 21, 2005. In such cases, the pump 6 may be a low-pressure pump such as a peristaltic pump. However, other types of generator may be used. Similarly, other types of pump may be used, provided only that the pump selected is appropriate for medical applications and is capable of maintaining a desired saline flow rate through the generator.

The generator and patient valves 16, 24 may be constructed in a variety of ways. In principal, the generator valve may be provided as any suitable valve 16 arrangement capable of proportioning saline flow between the generator 8 and the bypass line 18. If desired, the generator valve may be integrated with the branch point 30 at which the saline flow is divided. Alternatively, the generator valve 16 may be positioned downstream of the branch point 30, as shown in FIG. 3. In embodiments in which flexible (e.g. Silicon) tubing is used to convey the saline flow, the generator valve 16 may be provided as one or more conventional "pinch" valves of the type illustrated in FIG. 4. The use of pinch valves is beneficial in that it enables saline flow to be controlled in a readily repeatable manner, and without direct contact between the saline solution and components of the valve. Factors associated with the design of the patient valve 24 are substantially the same as those discussed above for the generator valve 16, with the exception that the saline flow through the patient valve 24 is (or must be assumed to be) carrying radioactive ^{82}Rb. Accordingly, while any suitable

valve design may be selected for the patient valve 24, it is particularly beneficial to avoid direct contact between the active saline solution and valve components. For this reason, pinch valves are preferred for the patient valve 24.

As may be seen in FIG. 5, the positron detector 20 may conveniently be provided as a scintillator 32 disposed immediately adjacent to a feed-line 33 carrying the active saline solution; a photon counter 34 optically coupled to the scintillator 32; and a radiation shield 36 surrounding the scintillator 32 and photon counter 34. The scintillator 32 may be provided by a length of fluorescent optical fiber, which absorbs Beta (e+) radiation generated by ^{82}Rb decay to produce a photon. The photon counter 34 (which may, for example be an H7155 detector manufactured by Hamamatsu) detects incident photons, and generates a detection signal 38 corresponding to each detected photon. The shielding 36, which may be constructed of lead (Pb), serves to shield the scintillator 32 and photon counter 34 from ambient Gamma and Beta radiation. In some embodiments, the radiation shield 36 is approximately ½ inch thick in the vicinity of the scintillation fiber 32, and may extend (in both directions) at least 5-times the feed-line 33 outer diameter from the scintillation fiber 32. This arrangement effectively suppresses ingress of ambient Gamma and Beta radiation along the channel through which the feed-line 33 passes. As a result, spurious photons are suppressed, and the rate at which photons are counted by the photon counter 34 will be proportional to the ^{82}Rb activity concentration of the active saline solution adjacent to the scintillator 32. In the illustrated embodiments, the number of photons detected within a predetermined period of time is counted (e.g. by

the controller 28), and the count value C_{det} is used as an activity parameter which is proportional to the ^{82}Rb activity concentration. If desired, a proportionality constant K between the activity parameter C_{det} and the ^{82}Rb activity concentration can be empirically determined.

In operation, the pump 6 and valves 16, 24 can be controlled to route saline solution through the system 14 in accordance with various modes of operation, as may be seen in FIGs. 6a-6d. Thus, for example, in a "Bypass-to-waste" mode of the system illustrated in FIG. 6a, the generator and patient valves 16, 24 are positioned to route the entire saline flow through the bypass line 18, and into the waste reservoir 26. This mode of operation is suitable for initializing the system 14 immediately prior to beginning an elution run.

FIG. 6b illustrates a "patient line flush" mode of the system 14, in which the generator and patient valves 16, 24 are positioned to route the saline flow through the bypass line 18 and out through the patient outlet 10. This mode of operation may be used prior to an elution run to prime (that is, expel air from) the patient line 40 in preparation for insertion of the patient outlet into, for example, a vein of a patient. At the end of an elution run, this mode may also be used to flush any ^{82}Rb activity remaining within the patient line 40 into the patient, thereby ensuring that the patient receives the entire activity dose required for the PET imaging.

FIG. 6c illustrates a "waiting for threshold" mode of the system 14, in which the generator and patient valves 16, 24 are positioned to route the saline flow through the generator 8, and into the waste reservoir 26. This mode of operation is suitable during the beginning an elution run,

while the ^{82}Rb concentration is increasing from zero, but has not yet reached desired levels. Flushing this leading portion of the ^{82}Rb bolus 12 to the waste reservoir 26 avoids exposing the patient to unnecessary ^{82}Rb activity and allows the total activity dosage delivered to the patient to be closely controlled.

FIG. 6d illustrates an "elution" mode of the system 14, in which the generator valve 16 is actively controlled via a control loop 42 from the positron detector 20 to proportion saline flow through both the generator 8 and the bypass line 18. The generator 8 and bypass saline flows are then recombined (at 22) downstream of the generator 8 to produce an active saline solution having a desired ^{82}Rb activity concentration. The patient valve 24 is positioned to direct the active saline solution to the patient outlet 10.

In the foregoing description, each operating mode is described in terms of the associated steps in performing an elution run to support PET imaging of a patient. However, it will be appreciated that this context is not essential. Thus, for example, one or more of the above operating modes may be used to facilitate calibration of the system, in which case the patient outlet 10 would be connected to a conventional dose calibrator (not shown), rather than a patient.

As will be appreciated from the foregoing discussion, each of the operating modes of the elution system is controlled by the controller unit 28 operating under software control. As a result, it is possible to implement a wide variety of automated processes, as required. Thus, for example, elution runs can be fully automated, based on user-entered target parameters, which allows the user to

avoid unnecessary radiation exposure. Similarly, it is possible to automate desired system calibration and ^{82}Sr break-through detection protocols, which ensures consistency as well as limiting radiation exposure of users. A further benefit of software-based elution system control is that data logs from each elution run can be easily maintained, which assists not only system diagnostics, but can also be used to ensure that the elution parameters (e.g. elution concentration and duration) specified for PET imaging have been satisfied.

As described above, in the "elution" mode of operation (FIG. 6d), the generator valve 16 is actively controlled via a control loop 42 from the positron detector 20 to proportion saline flow through both the generator 8 and the bypass line 18. Recombining the corresponding generator and bypass saline flows downstream of the generator 8 produces an active saline solution having a desired ^{82}Rb activity concentration. Preferably, the control loop 42 is implemented using suitable software executing in the controller 28. Representative algorithms for implementing the control loop 42 are described below with reference to FIGs. 7 and 8.

In the embodiment of FIG. 7, the controller 28 implements a threshold-based control algorithm, in which the generator valve 16 is controlled by comparison of measured activity concentration to a desired activity concentration. If the measured concentration is higher than the desired concentration, the generator valve 16 directs saline flow to the bypass line 18 rather than the generator 8, and vice versa.

In general, the elution run is designed to generate a target ^{82}Rb activity concentration which follows a desired

function in time $C_M(t)$. In the embodiment of FIG. 7, $C_M(t)$ is a square-wave function having a predetermined constant activity concentration C_M and duration (t_2-t_1), as may be seen by the dotted line of FIG. 7b. These parameters may be provided by explicit user input using the user interface 44 (Fig. 3), or calculated from other user-input parameters, such as a total activity dosage and saline flow rate. As will be appreciated, the target activity profile $C_M(t)$ need not be a square-wave function, other profiles may be used, such as a ramp function, if desired.

In some embodiments, the target activity profile $C_M(t)$ may define the desired ^{82}Rb activity concentration at the patient outlet 10. In such cases, an adjusted target profile $C'_M(t)$ may be computed based on the selected flow rate and patient supply line length, to account for expected ^{82}Rb decay (and thus loss of activity) in the patient supply line 40 between the positron detector 20 and the patient outlet 10. This arrangement is advantageous in that it allows a user to specify an amount of activity (either activity concentration or total dose) delivered to the patient, and the control loop 42 will operate to match this specification, taking into account the ^{82}Rb decay within the system 14.

FIG. 7a is a flow chart illustrating a representative threshold-based valve control algorithm which may be used in the embodiment of FIG. 7. For ease of illustration, the flow-chart of FIG. 7a only illustrates the control loop. Process steps and threshold, related to transitioning between various modes of operation are not shown.

In preparation for an elution run, a user enters target parameters for the elution. These parameters may include any three of: total activity dose, target activity

concentration, elution duration, and saline flow rate. From the entered parameters, the remaining parameter can be calculated, and, if desired, an adjusted target profile $C'_M(t)$ obtained (step S2).

At the start of the elution run, the controller 28 opens the generator valve 16 (at time t_0 in FIG. 7b) to place the elution system 14 into the "Waiting for Threshold" mode. During this period, the activity level detected by the positron detector will begin to ramp up following the leading edge of the 'natural' bolus curve 12 (Fig. 2a). During this period, the patient valve 24 remains closed, so that any activity eluted from the generator 8 is passed to the waste reservoir 26. When the detected activity concentration C_{det} exceeds the target value C_M, the controller 28 opens the patient valve 24 (at time t_1 in FIG. 7b), and shifts to the "elution" mode of operation.

During the elution mode, the controller 28 iteratively obtains an updated concentration parameter C_{det} (at S4), which indicates the instantaneous activity concentration at the positron detector. The concentration parameter C_{det} is then compared to the desired concentration C_M. If C_{det} is below the desired concentration C_M (at S6), the generator valve 16 is opened (at S8) so that saline flows through the generator 8 to elute ^{82}Rb activity. If C_{det} is above the desired concentration C_M (at S10), the generator valve 16 is closed (at S12) so that saline flows through the bypass line 18. As may be seen in FIG. 7b, due to delay in response, the result of this operation is a saw-tooth activity concentration profile 46 centered on the target concentration C_M (or C'_M). At the end of the elution run (time t_2 in FIG. 7b), the controller 28 closes the

generator valve 16 and places the elution system 14 into the "Patient line Flush" mode, which terminates elution of ^{82}Rb activity from the generator 8 and flushes any remaining ^{82}Rb activity within the patient line 40 into the patient.

FIG. 7c illustrates the activity concentration profile delivered to the patient as a result of the above-described process. As may be seen from FIG. 7c, no ^{82}Rb activity is delivered to the patient during the "Waiting for Threshold" mode (t_0-t_1). During the "elution" mode (t_1-t_2, the activity concentration 46 follows a saw-tooth pattern centered on the target concentration C_M (or C'_M). Finally, in "Patient line Flush" mode (following t_2) the activity concentration drops rapidly as ^{82}Rb elution is terminated and residual activity is flushed from the patient supply line 40.

As will be appreciated, the accuracy with which the delivered activity concentration follows the target profile $C_M(t)$ is largely dependent on the line volume between the merge point 22 and the positron detector 20. In some cases relatively large excursions from the target profile $C_M(t)$ are acceptable. However the control loop response is such that the difference cannot be reduced past a certain limit. As a result, the "error" between the target profile $C_M(t)$ and the delivered concentration profile 46 (Fig. 7c) cannot be eliminated in the embodiment of FIG. 7. A pulse-width modulation technique which overcomes this limitation is described below with reference to FIG. 8.

The embodiment of FIG. 8 differs from that of FIG. 7 primarily in the manner in which the generator valve 16 is controlled. In the embodiment of FIG. 7, the generator valve 16 is opened or closed based on a comparison between

the detected activity concentration C_{det} and desired activity concentration. By contrast, in the embodiment of FIG. 8, the generator valve is opened and closed continuously at a predetermined frequency. Any desired frequency may be used, depending primarily on the physical properties of the generator valve 16. In some embodiments, a frequency of between 1 and 10 Hz (e.g. 5 Hz) may be used. In order to control the proportioning of saline flow between the generator 8 and the bypass line 18, the duty cycle of the valve 16 is varied. Thus, for example, a duty cycle of "0" may have the effect of directing the entire saline flow through the bypass line 18, and a duty cycle of "100" directs the entire saline flow through the generator 8. A duty cycle between these limits divides the saline flow between the generator 8 and bypass line 18 in accordance with the duty cycle value. The precision with which the saline flow can be divided between the generator 8 and bypass line 18 will be determined by a minimum adjustment step size, which can be a programmable value.

As described above, the amount of ^{82}Rb eluted from the generator 8, for any given flow rate, will depend on the recent usage history of the elution system 14, and the instantaneous production rate of ^{82}Rb within the generator 8. Accordingly, it is possible to improve the accuracy of the elution system 14 by implementing a predictive control algorithm, in which models of the valve 16 and generator performance are used to predict the amount of ^{82}Rb activity that will be eluted from the generator 8 for a given duty cycle setting.

In particular, the generator performance can be modeled to predict the amount of ^{82}Rb activity that will be eluted from the generator for a given flow rate, as will be

described in greater detail below. In some embodiments, a dose calibrator (not shown) is used to measure the generator performance in terms of, for example, ^{82}Rb activity concentration vs. eluted volume. This data can be used to predict eluted ^{82}Rb activity concentration for any given saline flow rate.

In addition, the generator valve response can be modeled to enable a prediction of the flow rate through the generator for any given total saline flow rate (as determined by the pump control setting) and valve duty cycle. In some embodiments, the valve response may be modeled in terms of respective parameters defining upper and lower duty cycle limits Π_{max} and Π_{min}, and a flow ratio vs. duty cycle slope L between the upper and lower limits. With this arrangement, the upper duty cycle limit Π_{max} represents the value beyond which all of the flow is considered to be directed into the generator 8. Conversely, the lower duty cycle limit Π_{min} represents the value below which all of the flow is considered to be directed into the bypass line 18. The flow ratio vs. duty cycle slope L defines the change in the ratio between the respective flows through the generator 8 and the bypass line 18 for duty cycle values lying between the upper and lower limits.

In cases where the valve response is non linear, it may be advantageous to replace the flow ratio vs. duty cycle slope parameter L with one or more parameters defining a mathematical valve response curve.

At the start of the elution run, the controller 28 opens the generator valve 16 (at time t_0 in FIG. 8b) to place the elution system into the "Waiting for Threshold" mode. During this period, the activity level detected by

the positron detector 20 will begin to ramp up following the leading edge of the 'natural' bolus curve 12 (Fig. 2a). During this period, the patient valve 24 remains closed, so that any activity eluted from the generator is passed to the waste reservoir 26. When the detected activity concentration reaches the target concentration C_M (or adjusted target C'_M, as applicable), the controller 28 opens the patient valve 24 (at time t_1 in FIG. 8b), and shifts to the "elution" mode of operation.

During the elution mode, the controller 28 implements a predictive control algorithm in which previously stored generator performance data is used (at S14) to estimate a flow ratio that will yield the target activity concentration C_M (or C'_M) at the positron detector 20, for the selected flow rate of the elution run. This estimated (predicted) flow ratio is then used to control the duty cycle of the generator valve 16. The controller 28 then obtains an updated concentration parameter C_{det} (at S16), which indicates the instantaneous activity concentration at the positron detector 20. The concentration parameter C_{det} is then compared to the target concentration C_M (or C'_M) to obtain an error function ΔC (at S18). Based on the value of the error function ΔC, the duty cycle of the generator valve 16 is adjusted. If $\Delta C<0$ (step S20), the duty cycle is increased (at S22) so that proportionally more saline flows through the generator 8 to elute more ^{82}Rb activity. If $\Delta C>0$ (step S24), the duty cycle is decreased (at S26) so that proportionally more saline flows through the bypass line 18. If neither condition is satisfied the duty cycle is maintained at its current status (S28). As may be seen in FIG. 8b, the result of this operation is a low-error concentration profile 48 that closely matches the target concentration C_M (or C'_M). At the end of the elution run

(time t_2 in FIG. 8b), the controller 28 closes the generator valve 16 (that is, reduces the duty cycle to "0") and places the elution system 14 into the "Patient line Flush" mode, which terminates elution of ^{82}Rb activity from the generator 8 and flushes any remaining ^{82}Rb activity within the patient line 40 into the patient.

FIG. 8c illustrates the activity concentration profile 48 delivered to the patient as a result of the above-described process. As may be seen from FIG. 8c, no ^{82}Rb activity is delivered to the patient during the "Waiting for Threshold" mode (t_0-t_1). During the "elution" mode (t_1-t_2), the activity concentration closely follows the target concentration C_M (or C'_M). Finally, in "Patient line Flush" mode (following t_2) the activity concentration drops rapidly as ^{82}Rb elution is terminated and residual activity is flushed from the patient supply line 40.

In practice, the above-described predictive control algorithm has been found to produce an ^{82}Rb activity concentration that closely matches the desired target profile $C_M(t)$, except during the first few seconds of the elution, where significant prediction errors may occur. In cases where all of the activity from the generator must be eluted to reach the requested total dosage, this error must be tolerated. However, in other cases it is possible to eliminate the error by delaying the start of the "elution" mode of operation. Thus, for example, during the "waiting for threshold", mode, the detected activity level C_{det} can be monitored and compared to a threshold (e.g. 90% of the target concentration C_M). When the threshold level is reached, the generator valve control loop 42 begins operating as described above with reference to FIGs. 8a and 8b, but the patient valve 24 remains closed so that active

solution continues to be routed to the waste reservoir 26. After a predetermined delay, the patient valve 24 opens to begin supplying active saline solution to the patient outlet 10. The duration of the delay may be calculated based on the relative activity of the elution. For example, in elutions in which the target activity concentration C_M is less than 10% of the maximum concentration that the generator 8 can produce, a delay of about 10 seconds may be used. Conversely, for elutions in which the target activity concentration C_M is more than about 70% of the maximum concentration that the generator 8 can produce, no delay may be required. For elutions in which the target activity concentration lies between these two limits, an intermediate delay may be calculated.

As described above, the predictive control algorithm uses stored generator performance data to model the generator performance and thereby enable prediction of a valve flow ratio (or, equivalently duty cycle) that will yield the target activity concentration C_M (or C'_M) at the positron detector 20. One way of obtaining the generator performance data is to calibrate the elution system 14 by performing a predefined elution run with the patient outlet 10 connected to a conventional dose calibrator (e.g. a Capintec CRC-15). Such a calibration elution run enables the dose calibrator to be used to measure the generator performance in terms of, for example, ^{82}Rb activity concentration vs. eluted volume. This data can be used to predict eluted ^{82}Rb activity concentration, for any given saline flow rate, with an accuracy that that will gradually decline with time elapsed since the calibration run. Repeating the calibration run at regular intervals (e.g. once per day) allows the generator performance data to be updated to track changes in the generator performance as

the generator 8 ages, and thereby enable accurate flow ratio prediction between successive calibration runs. If desired, calibration elutions can be scheduled to run automatically, for example as part of a daily protocol, which ensures system accuracy and at the same time limiting the potential for human error.

Preferably, calibration elution runs are performed at the same flow rate (e.g. 15ml/min), and over the same duration (e.g. 1 minute). This enables the known half-life of the ^{82}Rb (76 seconds) to be used to predict the decay time of activity detected by the dose calibrator. A difference between the predicted and actual decay times indicates breakthrough of ^{82}Sr. Accordingly, ^{82}Sr breakthrough can be automatically detected as part of a scheduled system calibration protocol, by sampling the activity level in the dose calibrator at regular intervals throughout the duration of each calibration elution run, and for a predetermined period following completion of the calibration run. The resulting calibration data tracks the activity level within the dose calibrator, as both a function of time and active saline solution volume. Calibration data collected during the elution enables prediction of the ^{82}Rb decay curve after the elution has stopped. Comparison between this predicted decay curve and the calibration data collected after the elution enables detection of ^{82}Sr breakthrough.

The calibration data collected during the elution can also be used to calculate the proportionality constant K between the activity parameter C_{det} and the ^{82}Rb activity concentration. In particular, the instantaneous activity detected by the dose calibrator during the calibration elution is the convolution of the activity concentration

and the well known ^{82}Rb decay curve. Since the saline volumetric flow rate is known, the calibration data collected during the elution can be used to calculate the actual activity concentration of the active saline solution entering the dose calibrator, and thus the proportionality constant K.

In the foregoing description, the predictive control algorithm uses stored generator performance data to predict a valve duty cycle that will yield the target activity concentration C_M (or C'_M) at the positron detector, and this estimate is used to control the generator valve 16. An error ΔC between the detected concentration parameter C_{det} the target activity concentration C_M is then calculated and used to adjust the flow ratio (duty cycle) of the generator valve 16. This error may also be used as data input for a self-tuning algorithm for updating the generator valve response parameters. This functionality is useful for ensuring accuracy of the predictive control algorithm, as well as compensating valve performance changes due, for example, to component aging and wear.

In some embodiments, the self-tuning algorithm uses error data accumulated over a number of elution runs. Thus, for example, during each elution run, desired flow ratios can be calculated (e.g. based on the saline flow rate, target activity concentration C_M and stored generator performance data) and error function ΔC values stored as a function of desired flow ratio. Accumulation of error value vs. flow ratio data over a number of elution runs can then be processed to obtain a slope error ΔL. This error value can then be used to incrementally adjust the flow ratio vs. duty cycle slope parameter L of the value so as to drive the slope error ΔL toward zero.

The upper duty cycle limit Π_{max} may be adjusted based on error data accumulated during elutions in which the predicted activity concentration from the generator cannot satisfy the desired target value C_M. This situation can occur during elution runs conducted toward the end of the useful life of the generator 8, when the ^{82}Rb production rates are at their lowest. When the predicted activity concentration from the generator 8 is less than the desired target value C_M, the predictive control algorithm will operate to set the duty cycle at its upper limit value Π_{max}. In this condition, if the measured concentration parameter C_{det} is less than the target value C_M, the error function value ΔC will be a non-zero value, and the corrective loop (FIG. 8a) will attempt to further increase the duty cycle. If no further increase in the concentration parameter C_{det} occurs (as indicated by a change in the function value ΔC), then the upper limit value Π_{max} may be reduced by a predetermined step size (e.g. 10^{-5}). On the other hand, if operation of the corrective loop does produce an increase in the detected concentration C_{det}, the slope of the error data can be used to increase the upper limit value Π_{max}.

If desired, a similar approach can be used to correct for hysteresis of the valve 16. Hysteresis refers to a system behaving differently depending on the direction of change of an input parameter, usually involving a delayed response. In the case of a bi-state pinch valve of the type illustrated in Fig. 4 the opening and closing latencies may differ. This valve hysteresis manifests itself in the threshold-based elution control algorithm described above with reference to FIG. 7, and appears as a difference between a predicted elution duration (required to achieve a desired eluted activity dose) and the actual elution duration required to obtain that dose.

Accordingly, by monitoring the actual elution time for "total activity dose"-type elution runs, it is possible to calculate a hysteresis factor H, which can be applied to the threshold set point (i.e. the target activity concentration C_M) to compensate the valve hysteresis.

In the foregoing embodiments, the generator valve is controlled as a bi-state valve, which is either "on" to direct all of the saline solution flow into the generator 8; or "off" to direct all of the saline solution flow into the bypass line 18. In the embodiment of FIG. 7, the generator valve 16 is controlled in precisely this manner, in response to a threshold comparison. In the embodiment of FIG. 8, the valve 16 is cycled continuously at a predetermined frequency (e.g. 5Hz) and the duty cycle adjusted to emulate a continuously (or step-wise) variable proportioning valve. Both of these methods of valve control are particularly suited to embodiments in which the valve of FIG. 4, for example, is controlled by a solenoid and a spring. However, it will be appreciated that a continuously variable valve could be used, if desired. For example, the position of the valve of FIG. 4 could be controlled by a servo-motor, in which case accurate proportioning of saline flow between the generator and bypass lines could be obtained without cycling the valve between "on" and "off" states. Clearly, use of different generator valve control techniques would imply corresponding differences in the valve control signal and response parameters. However, based on the teachings provided herein, it is considered that all such modifications will be well within the purview of those of ordinary skill in the art, and therefore are contemplated within the scope of the present invention.

The embodiment(s) of the invention described above is(are) intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

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.

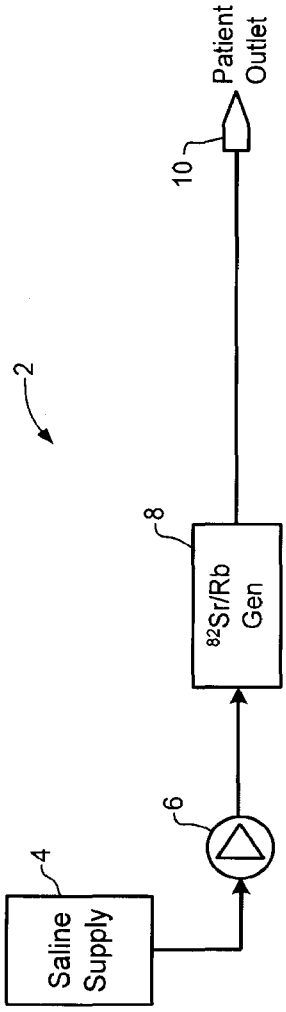


Figure 1a
(Prior Art)

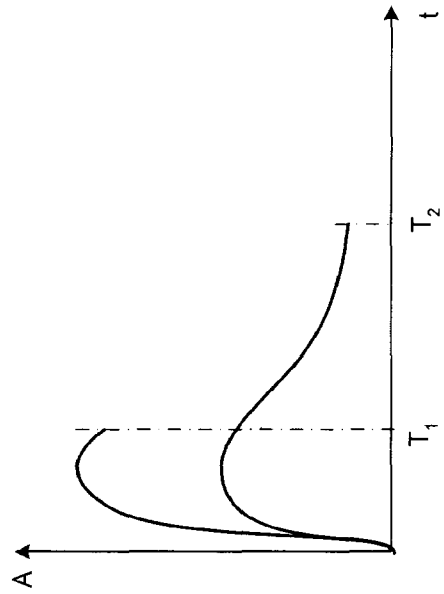


Figure 2b
(Prior Art)

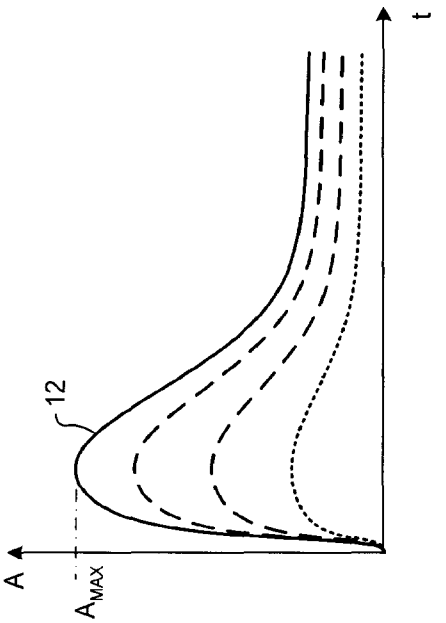


Figure 2a
(Prior Art)

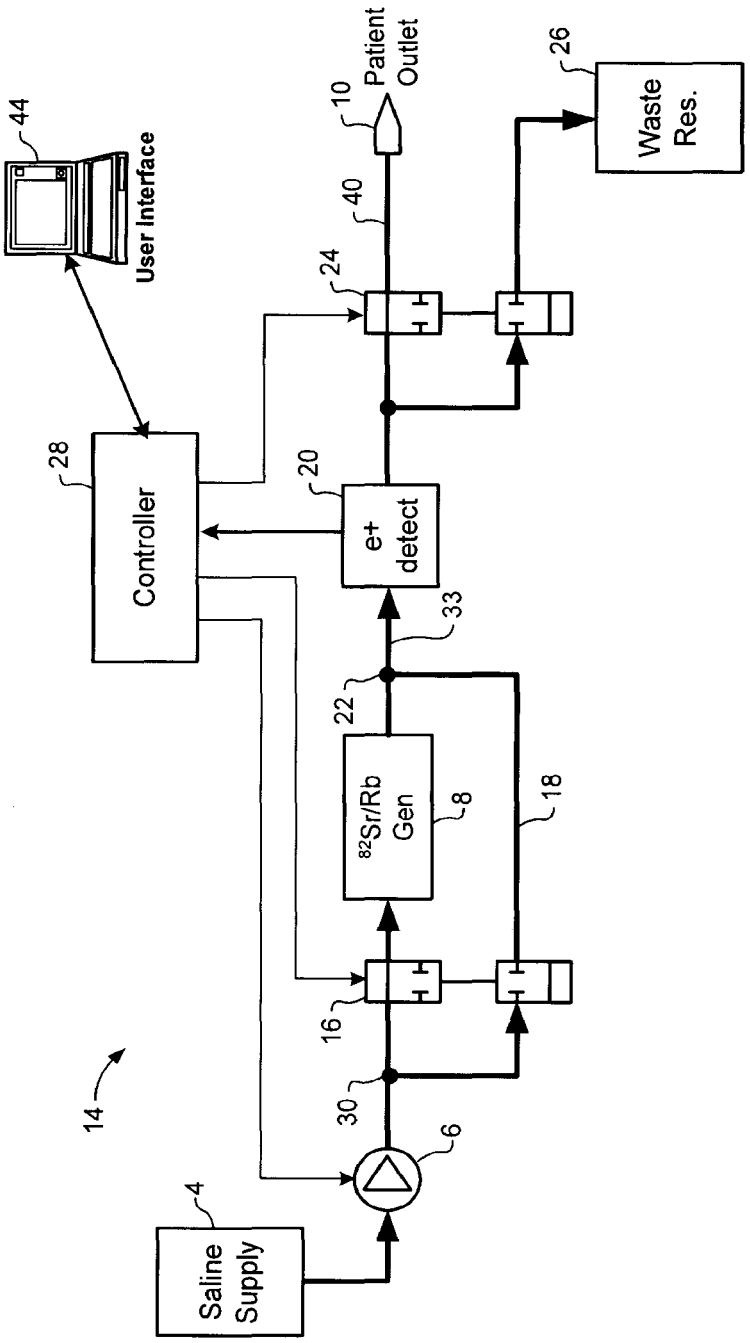

User Interface
44
Patient Outlet
10
Waste Res.
26
40
24
28
Controller
20
e+ detect
33
22
^{82}Sr/Rb Gen
8
18
16
30
6
14
4
Saline Supply

Figure 3

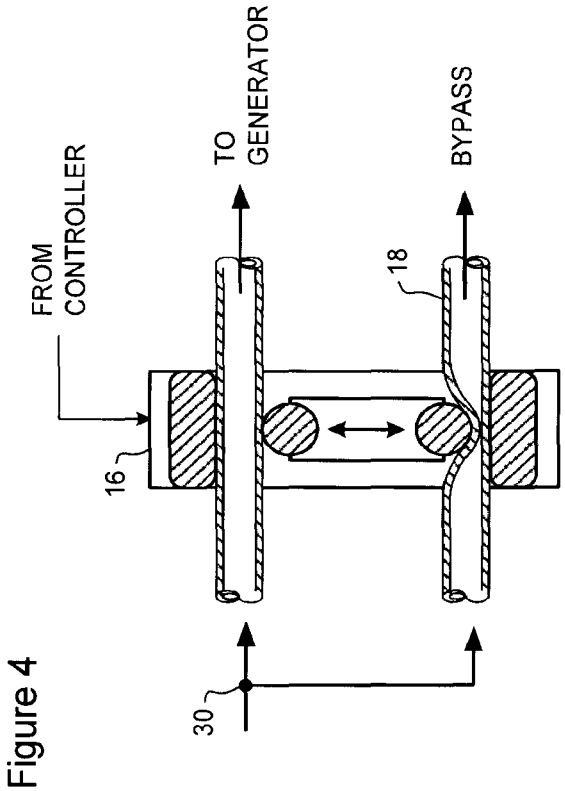


Figure 4

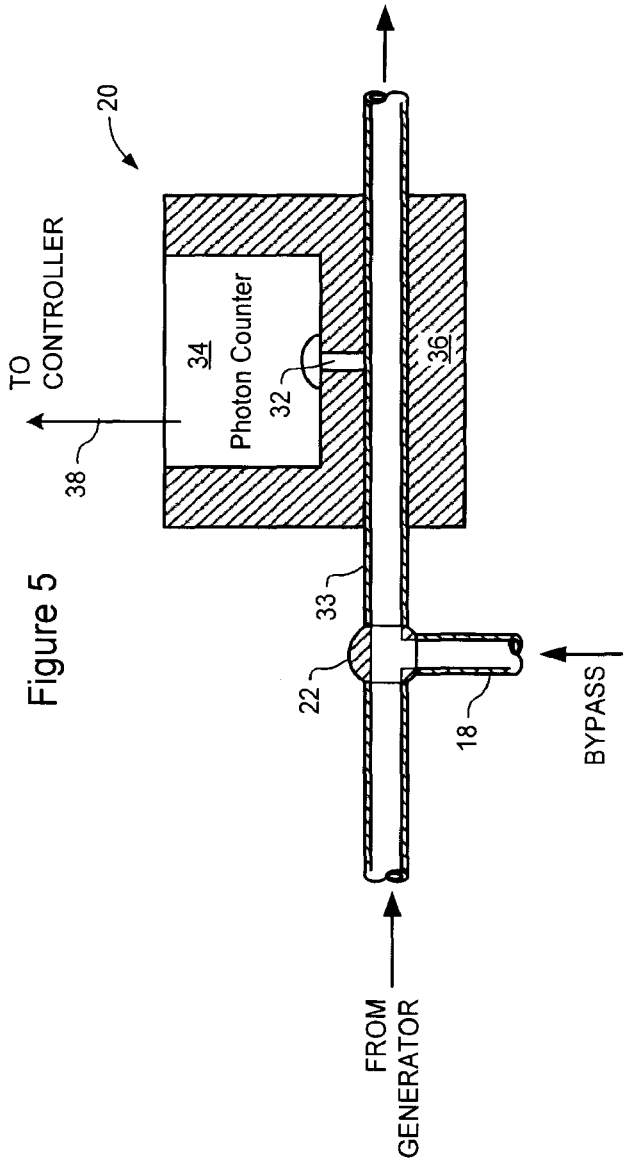


Figure 5

Figure 6a

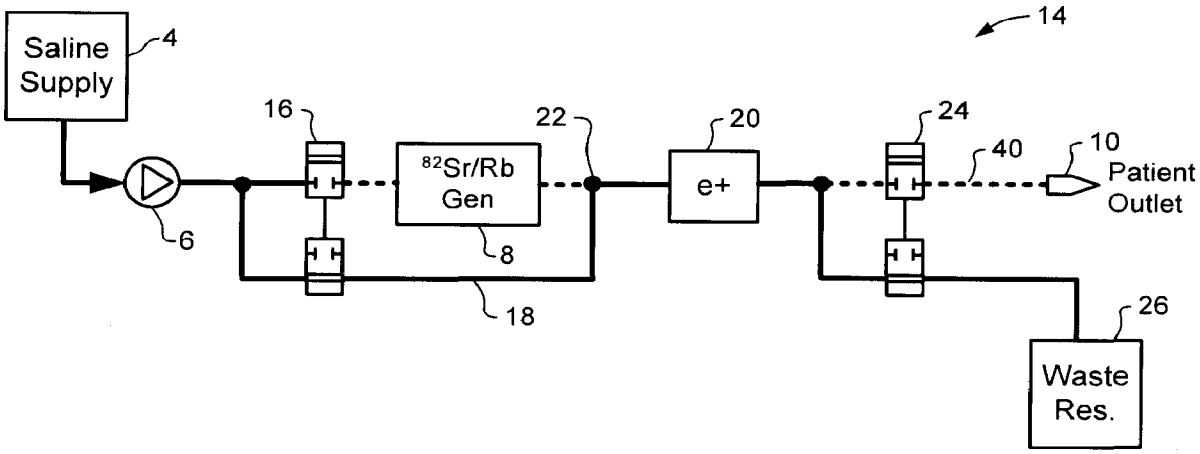


Figure 6b

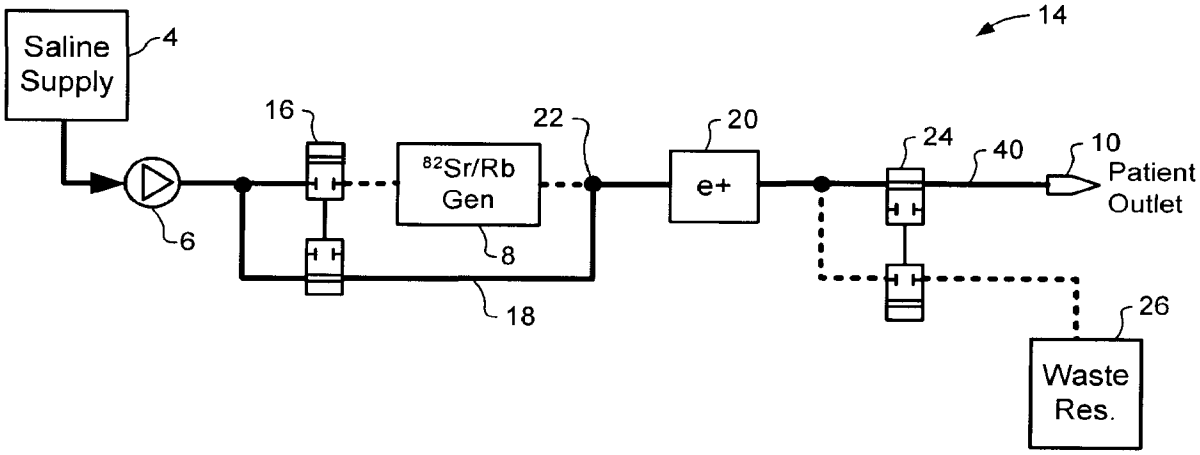


Figure 6c

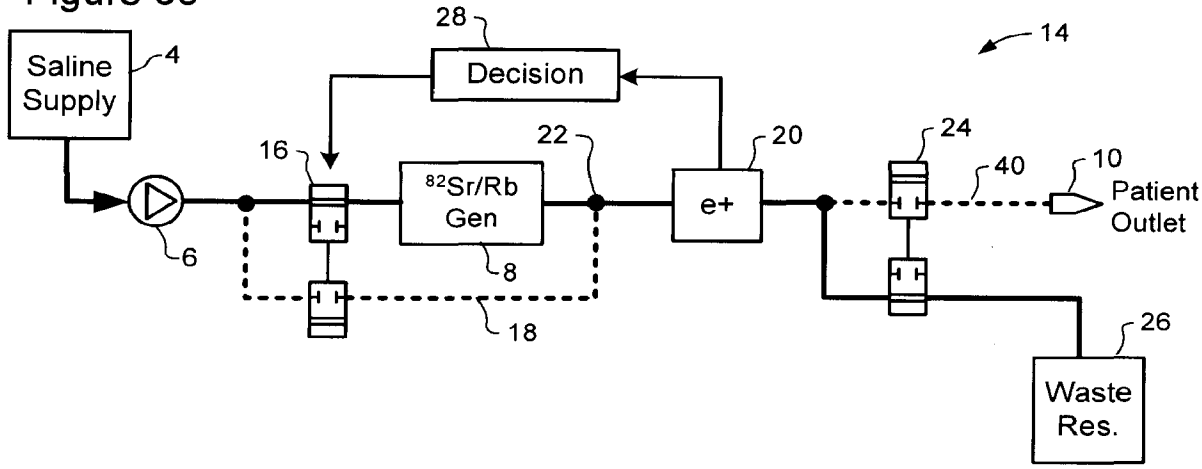


Figure 6d

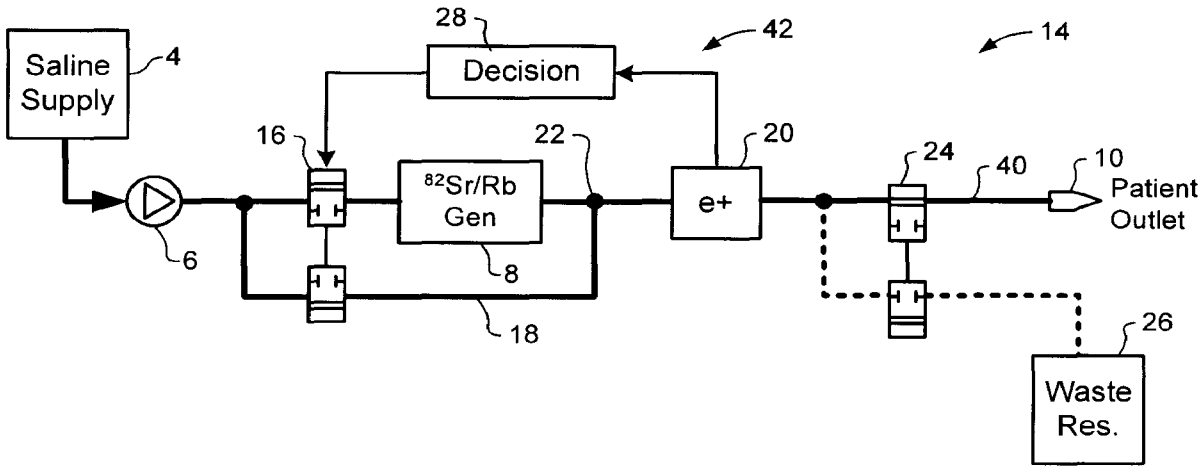

Saline Supply
4
28
Decision
42
14
16
22
20
24
40
10
Patient Outlet
^{82}Sr/Rb Gen
e+
6
8
18
26
Waste Res.

Figure 7a

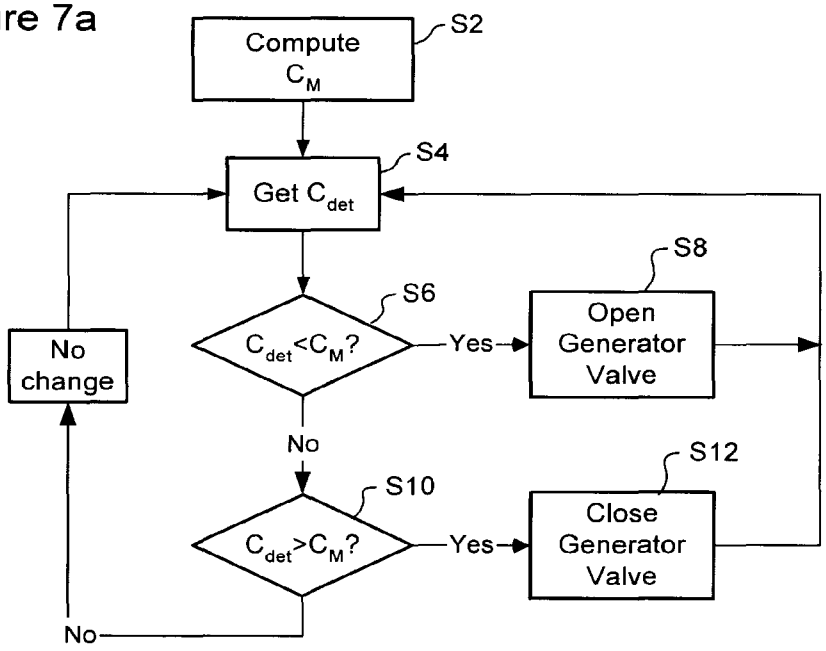


Figure 7b

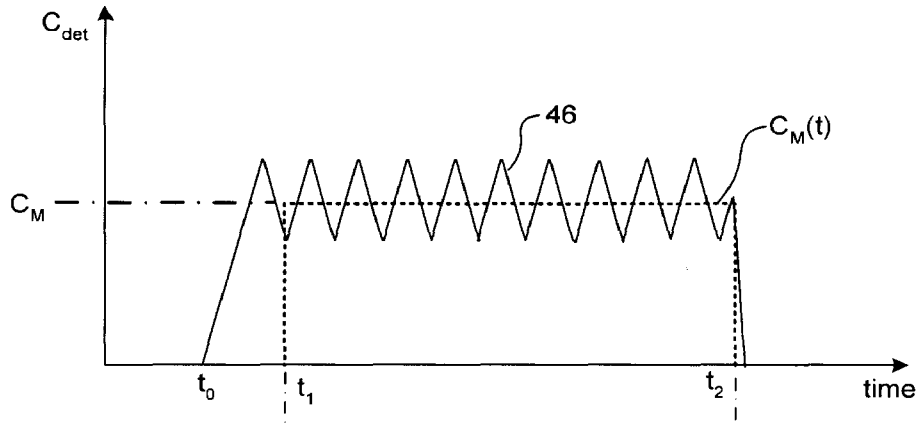


Figure 7c

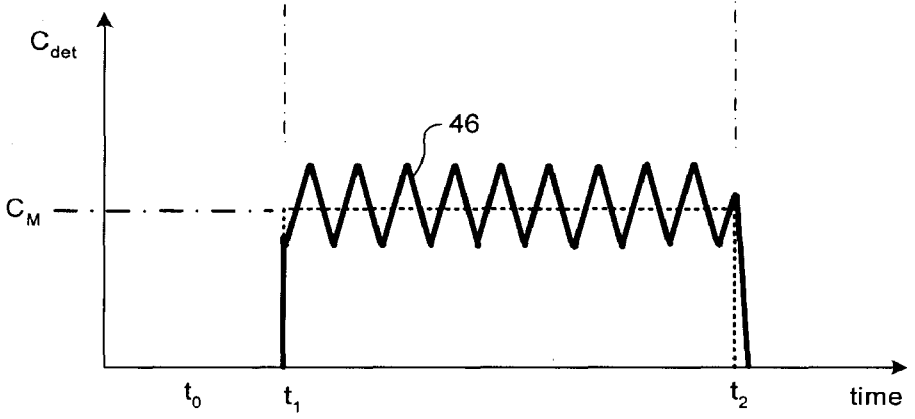


Figure 8a

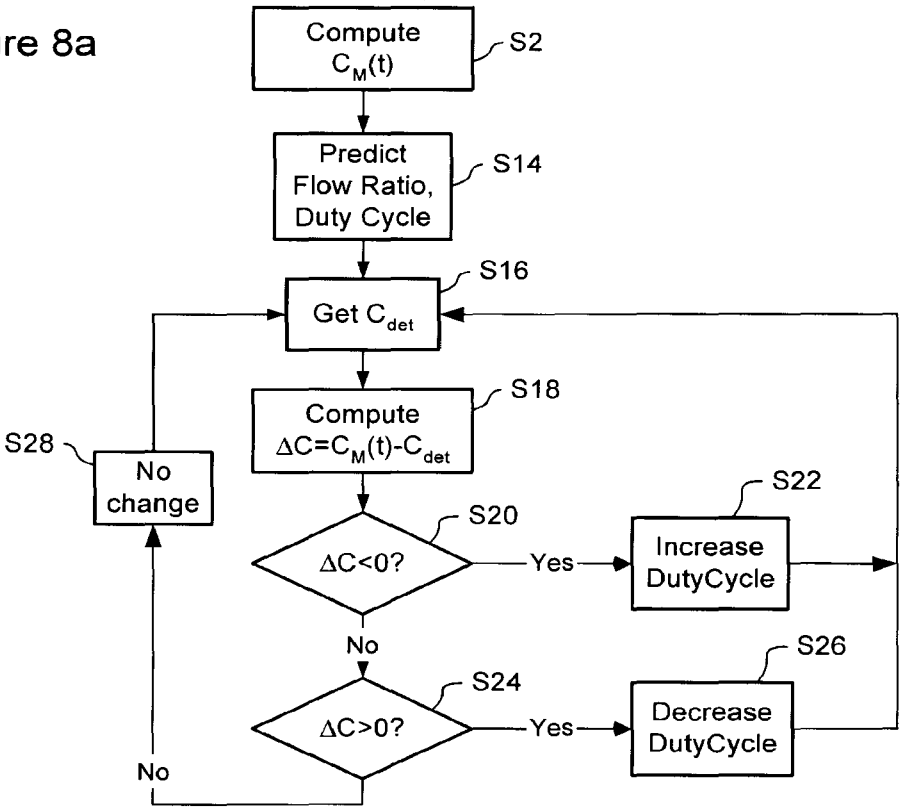


Figure 8b

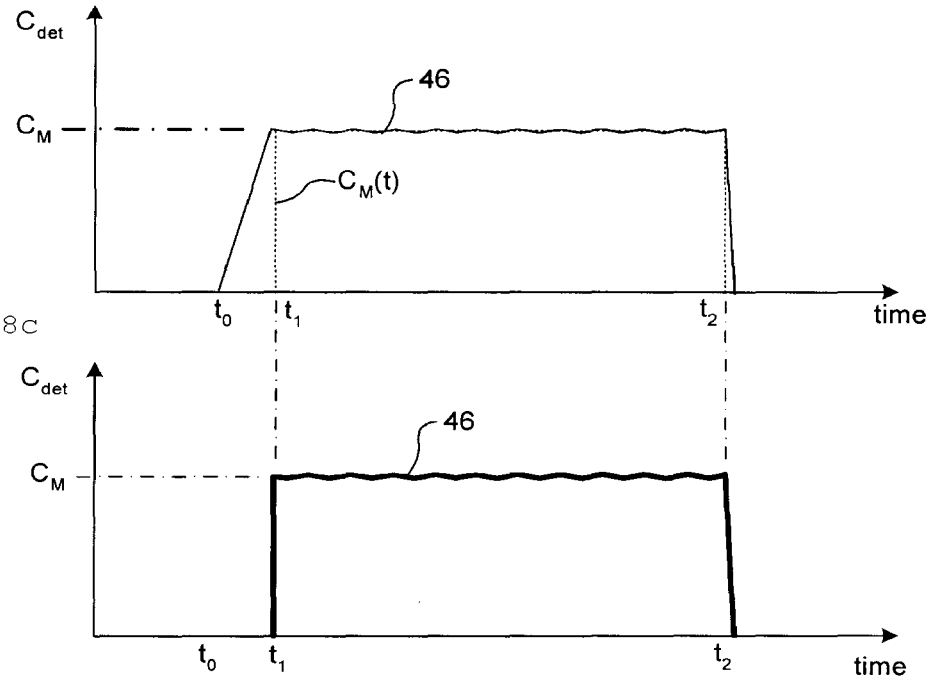


Figure 8c

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/000295

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents :
"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 Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Valérie Dubé 819- 934-4261

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/000295

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

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

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

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

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

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

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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

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	

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

(19) World Intellectual Property Organization
International Bureau

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

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(10) International Publication Number
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(51) International Patent Classification: Not classified

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PCT/US2006/033442

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(25) Filing Language: English

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

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

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

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

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

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

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

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

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

WO 2007/149108 A2

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

FIELD OF THE INVENTION

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

BACKGROUND

[0002] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0003] Nuclear medicine utilizes radioactive material for diagnostic and therapeutic purposes by injecting a patient with a small dose of the radioactive material, which concentrates in certain organs or biological regions of the patient. Radioactive materials typically used for nuclear medicine include Technetium-99m, Indium-113m, and Strontium-87m among others. Some radioactive materials naturally concentrate toward a particular tissue, for example, iodine concentrates toward the thyroid. However, radioactive materials are often combined with a tagging or organ-seeking agent, which targets the radioactive material for the desired organ or biologic region of the patient. These radioactive materials alone or in combination with a tagging agent may be to as radiopharmaceuticals in the field of nuclear medicine. At relatively lower doses of the radiopharmaceutical, a radiation imaging system (e.g., a gamma camera) provides an image of the organ or biological region that collects the radiopharmaceutical. Irregularities in the image are often indicative of a pathologic condition, such as cancer. Higher doses of the radiopharmaceutical may be used to deliver a therapeutic dose of radiation directly to the pathologic tissue, such as cancer cells.

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

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

SUMMARY

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

[0006] Certain aspects commensurate in scope with the originally claimed invention are set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief summary of certain forms the invention might take and that these aspects are not intended to limit the scope of the invention. Indeed, the invention may encompass a variety of features and aspects that may not be set forth below.

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE FIGURES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0030] One or more specific embodiments of the present invention will be described below. In an effort to provide a concise description of these embodiments, all features of an actual implementation may not be described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[0051] FIG. 16 is a flowchart illustrating an exemplary nuclear medicine process utilizing the radioactive isotope produced by the elution system 10 illustrated with reference to FIGS. 1-15. As illustrated, the process 104 begins by providing a radioactive isotope for nuclear medicine at block 106. For example, block 106 may include eluting technetium-99m from the radioisotope generator 18 illustrated and described in detail above. At block 108, the process 104 proceeds by providing a

tagging agent (e.g., an epitope or other appropriate biological directing moiety) adapted to target the radioisotope for a specific portion, e.g., an organ, of a patient. At block 110, the process 104 then proceeds by combining the radioactive isotope with the tagging agent to provide a radiopharmaceutical for nuclear medicine. In certain embodiments, the radioactive isotope may have natural tendencies to concentrate toward a particular organ or tissue and, thus, the radioactive isotope may be characterized as a radiopharmaceutical without adding any supplemental tagging agent. At block 112, the process 104 then may proceed by extracting one or more doses of the radiopharmaceutical into a syringe or another container, such as a container suitable for administering the radiopharmaceutical to a patient in a nuclear medicine facility or hospital. At block 114, the process 104 proceeds by injecting or generally administering a dose of the radiopharmaceutical into a patient. After a pre-selected time, the process 104 proceeds by detecting/imaging the radiopharmaceutical tagged to the patient's organ or tissue (block 116). For example, block 116 may include using a gamma camera or other radiographic imaging device to detect the radiopharmaceutical disposed on or in or bound to tissue of a brain, a heart, a liver, a tumor, a cancerous tissue, or various other organs or diseased tissue.

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

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

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

[0054] When introducing elements of the present invention or various embodiments thereof, the articles "a", "an", "the", and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including", and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements. Moreover, the use of "top", "bottom", "above", "below" and variations of these terms is made for convenience, but does not require any particular orientation of the components.

[0055] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the figures and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

CLAIMS:

1. A radiopharmaceutical system, comprising:

a radioisotope generator assembly, comprising:

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

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

an eluate extraction mechanism, comprising:

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

a radiation shielded housing disposed outside the radiation shield; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. An eluate extraction mechanism, comprising:

a radiation shielded housing;

an eluate conduit having a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing;

a hollow injection needle fluidly coupled to the opposite end of the eluate conduit; and

a plunger coupled to the radiation shielded housing movably through a guide structure, wherein the plunger is coupled to the hollow injection needle inside the radiation shielded housing.

16. The eluate extraction mechanism of claim 15, wherein the hollow injection needle comprises a release mechanism.

17. The eluate extraction mechanism of claim 15, wherein the plunger has a path of travel including a connected position and a disconnected position between the hollow injection needle and an eluate container disposed inside the radiation shielded housing.

18. The eluate extraction mechanism of claim 17, wherein the eluate container is disposed removably inside the radiation shielded housing adjacent a door.

19. The eluate extraction mechanism of claim 17, wherein the eluate container is disposed inside an eluate container shield comprising a radiation shielding material, wherein the eluate container shield comprises a viewing window and the eluate container comprises a transparent or translucent material.

20. The eluate extraction mechanism of claim 15, wherein the eluate extraction mechanism comprises a generator alignment portion protruding from a base of the radiation shielded housing.

21. An eluate extraction mechanism, comprising:

a radiation shielded housing comprising a door;

a shielded eluate collection assembly disposed removably inside the radiation shielded housing adjacent the door;

an eluate conduit having a radioisotope generator end disposed outside the radiation shielded housing and an opposite end disposed inside the radiation shielded housing; and

a hollow needle fluidly coupled to the opposite end of the eluate conduit, wherein the hollow needle includes a connected position and a disconnected position relative to the shielded eluate collection assembly.

22. The eluate extraction mechanism of claim 21, comprising an actuator disposed through the radiation shielded housing and coupled to the hollow needle.

23. The eluate extraction mechanism of claim 21, wherein the shielded eluate collection assembly comprises an eluate container disposed inside an eluate container shield comprising a radiation shielding material, wherein the eluate container shield comprises a viewing window and the eluate container comprises a transparent or translucent material.

24. The eluate extraction mechanism of claim 21, wherein the eluate extraction mechanism comprises a generator alignment portion protruding from a base of the radiation shielded housing.

25. A method of using a radiopharmaceutical system, the method comprising:

supplying an eluant into a radioisotope generator;

eluting a radioisotope in the radioisotope generator;

receiving an eluate at an output of the radioisotope generator; and

flowing the eluate from the output along an eluate conduit to a hollow needle that is removably inserted into an eluate container via a plunger.

26. The method of claim 25, wherein flowing comprises transferring the eluate through a radiation shield disposed about the radioisotope generator and directly into a radiation shielded housing disposed outside the radiation shield, wherein the radiation shielded housing is disposed about the eluate container, the hollow needle, and at least a portion of the plunger.

27. The method of claim 25, comprising maintaining a continuous connection between the output and the eluate conduit during connections and disconnections between the hollow needle and the eluate container.

28. The method of claim 25, comprising enabling selective viewing of the eluate within the eluate container via a window.

29. The method of claim 25, comprising enabling selective access to the eluate container via a door.

30. The method of claim 25, comprising guiding the plunger along a path of movement between an engaged position and a disengaged position with the eluate container.

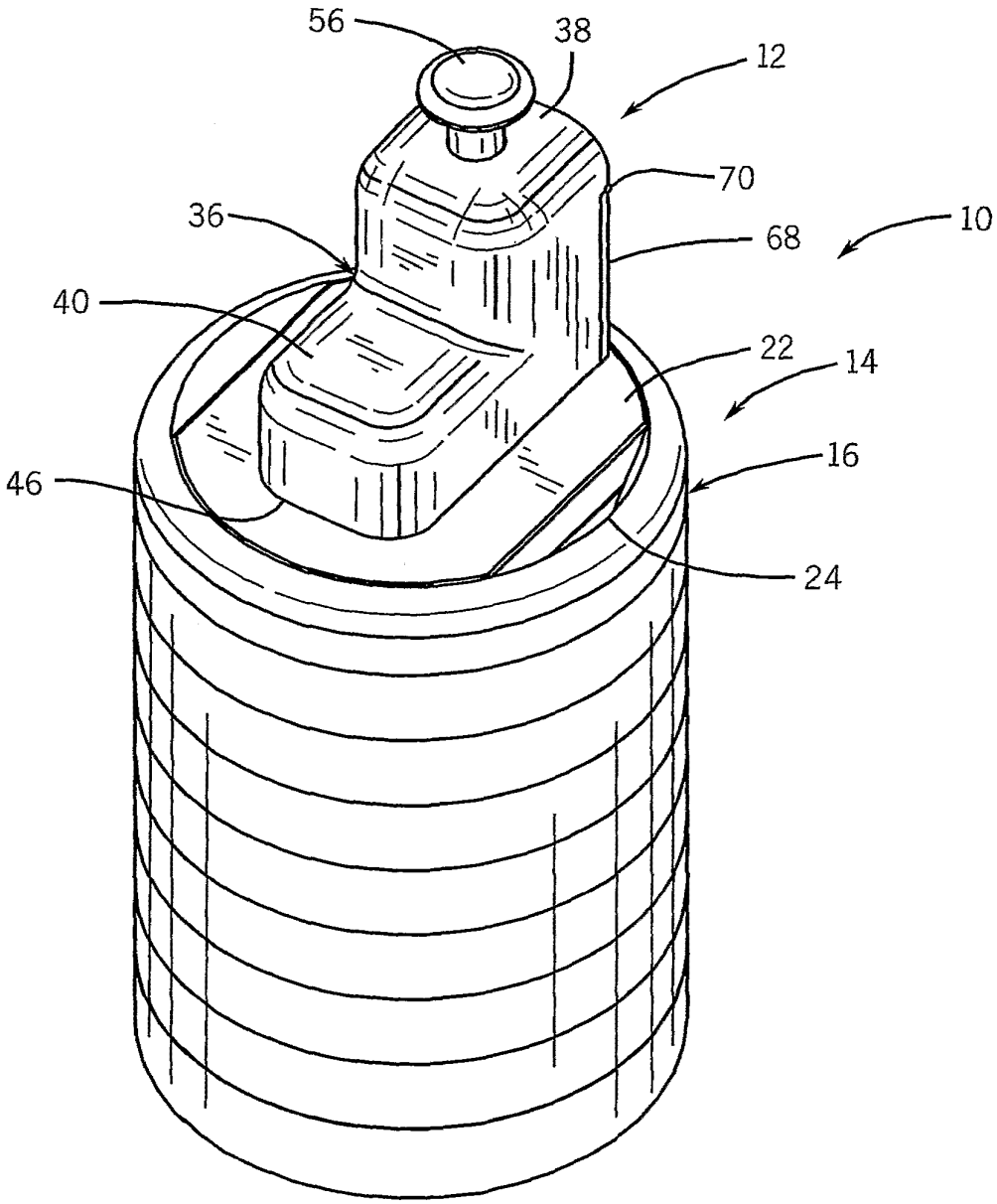

FIG. 1

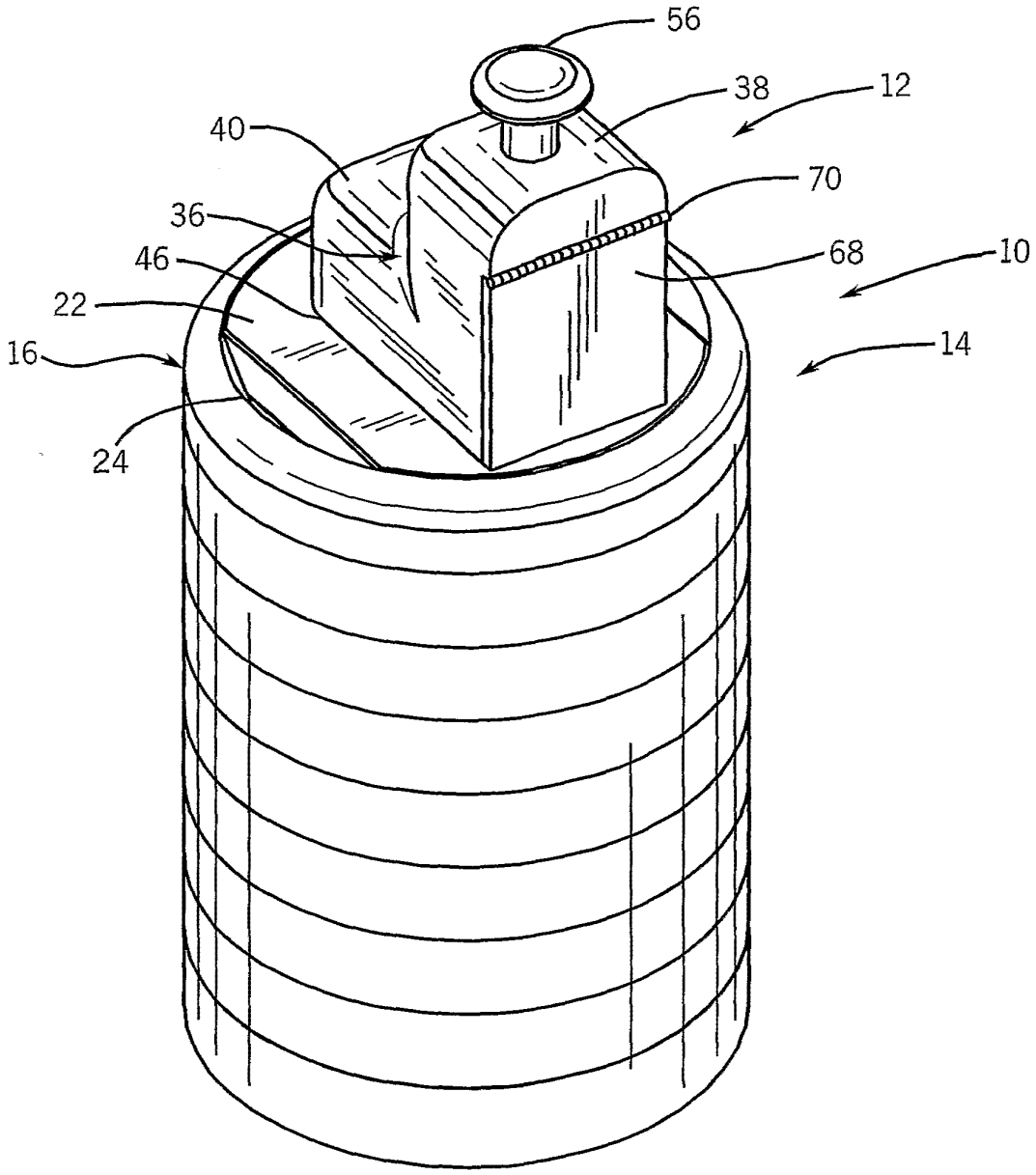

FIG. 2

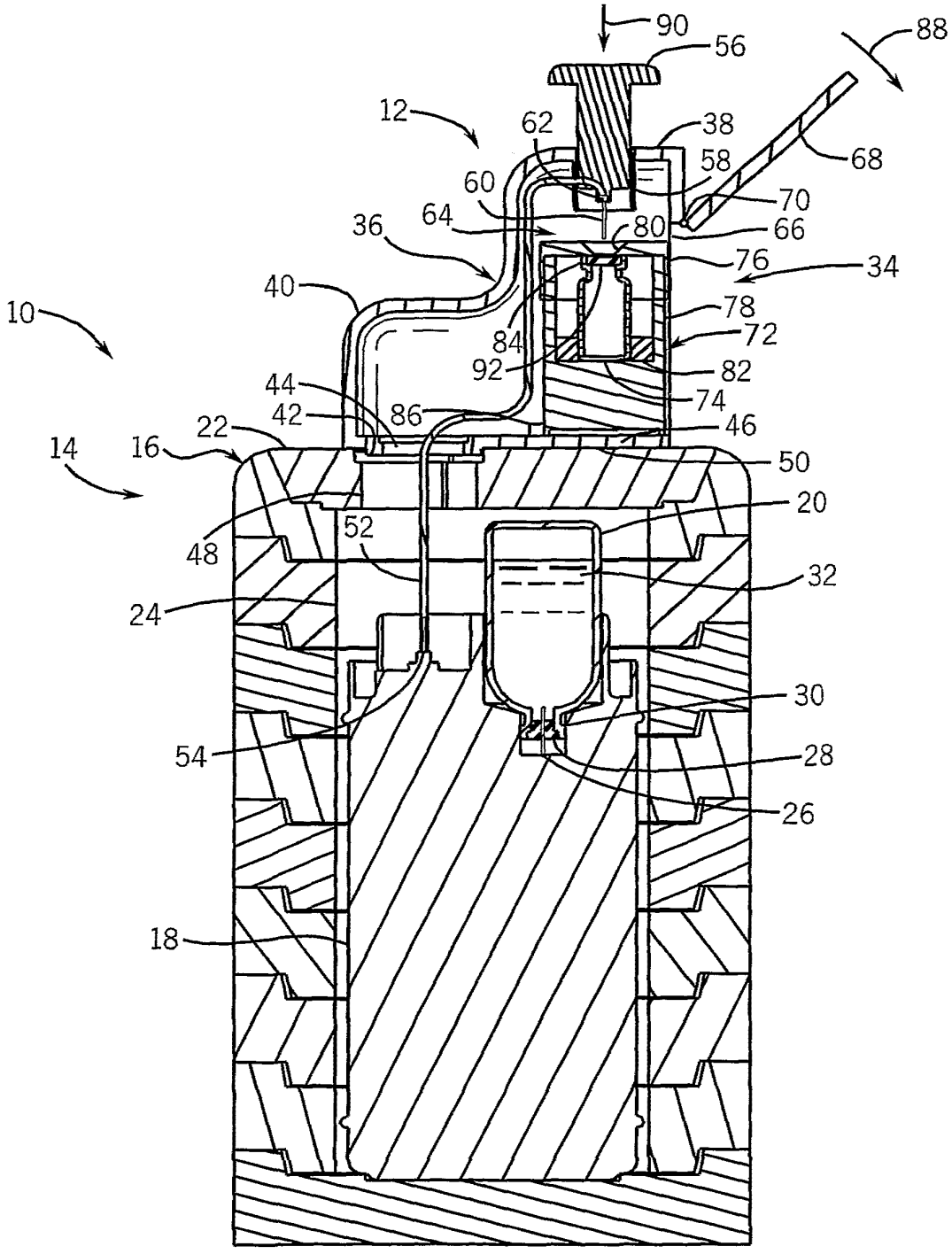
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FIG. 3

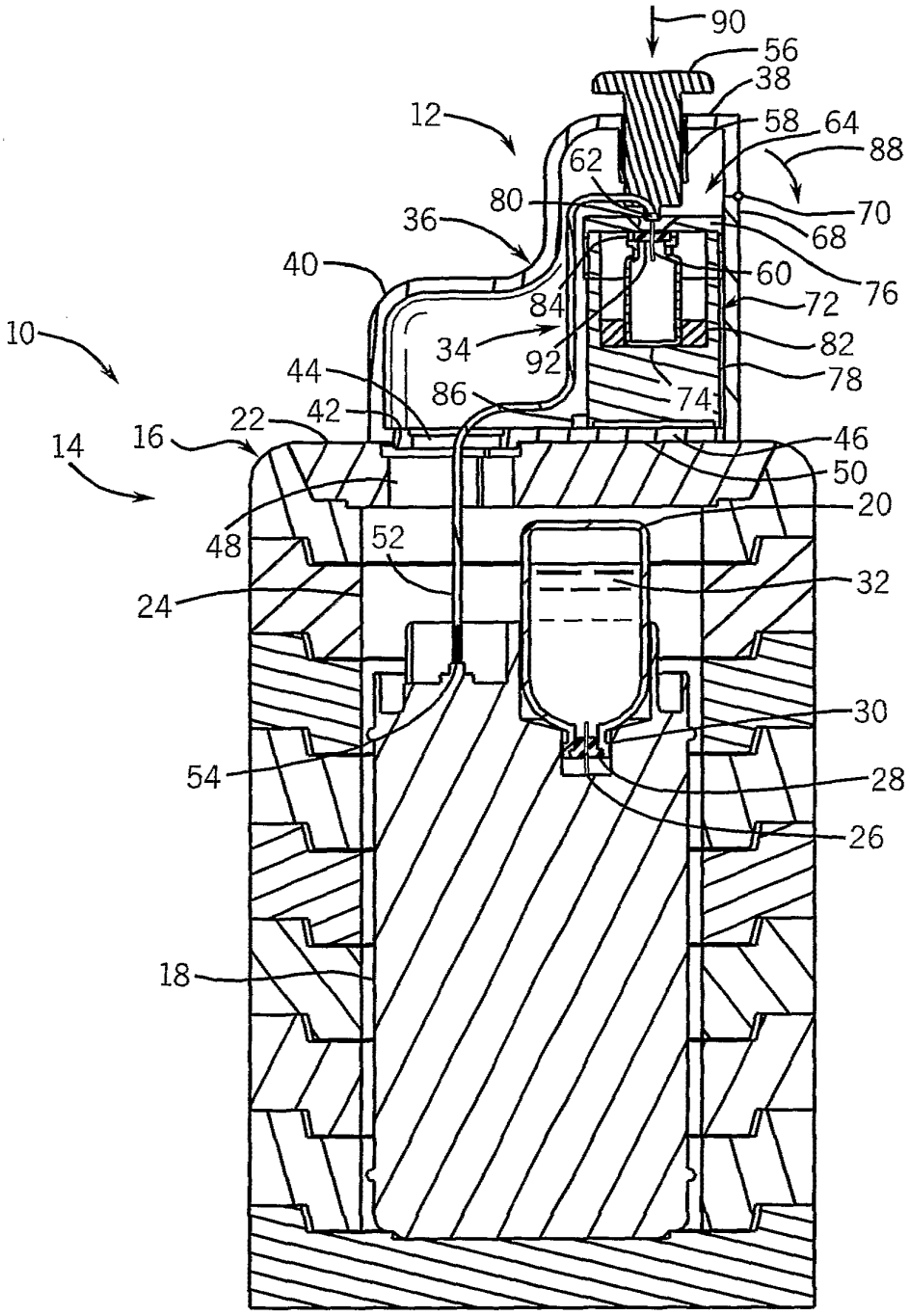
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FIG. 4

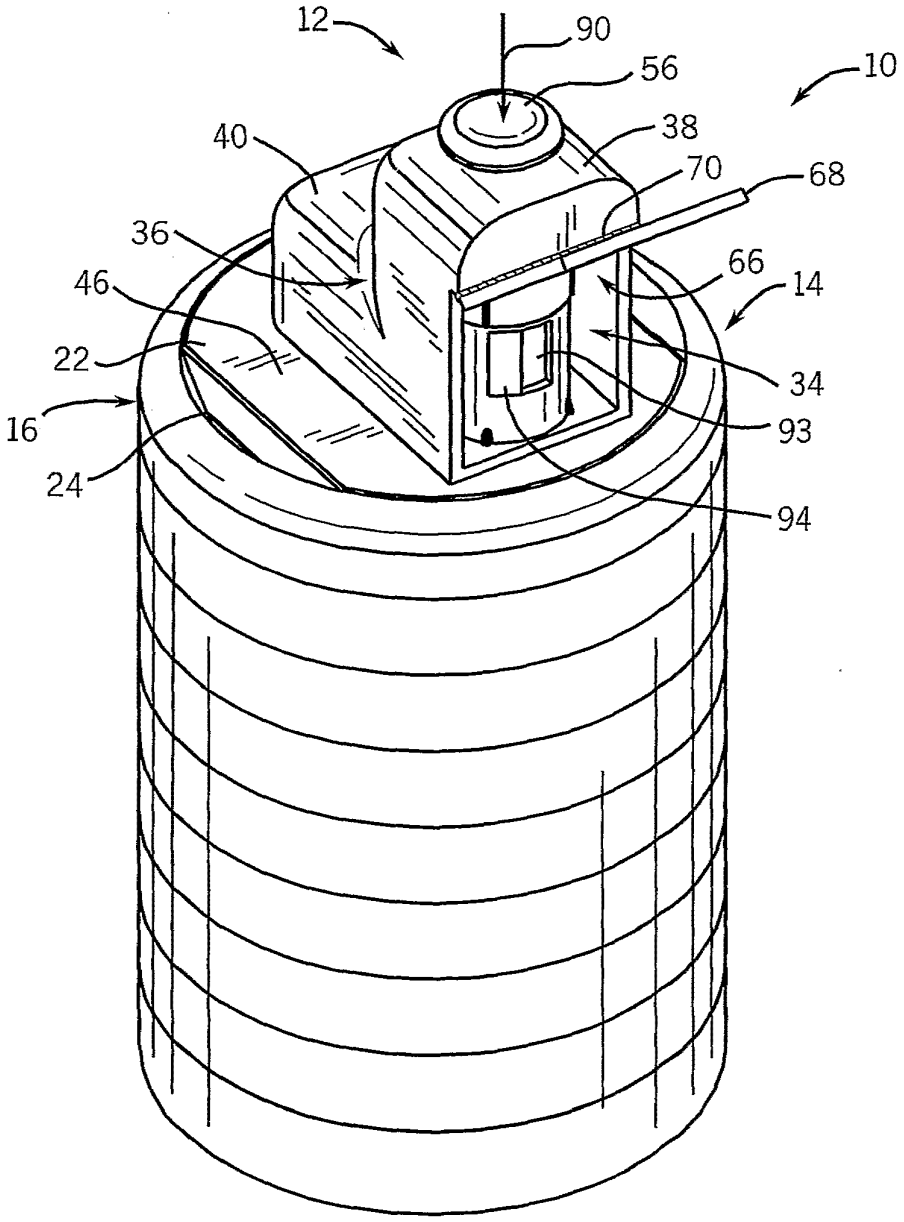

FIG. 5

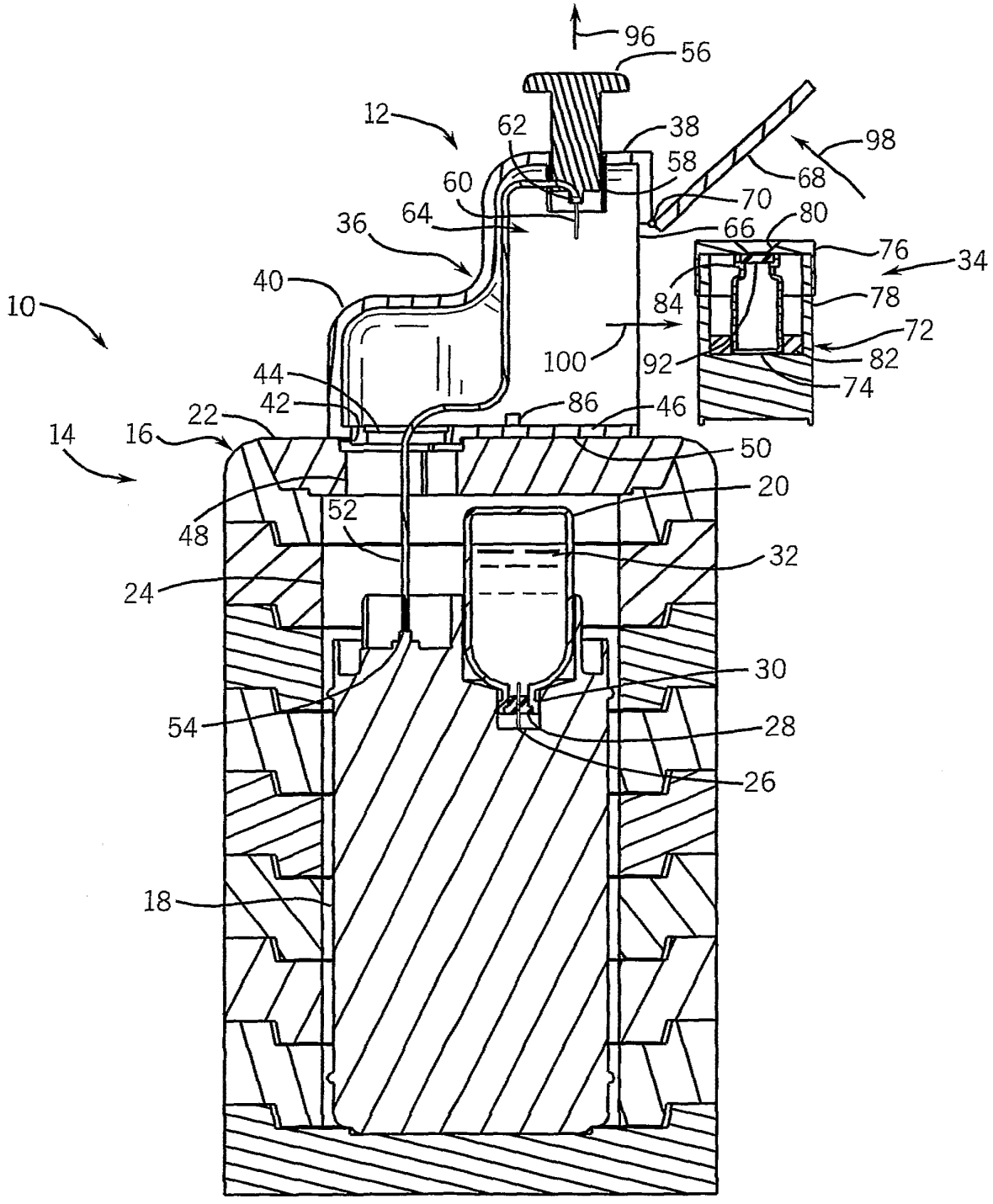
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FIG. 6

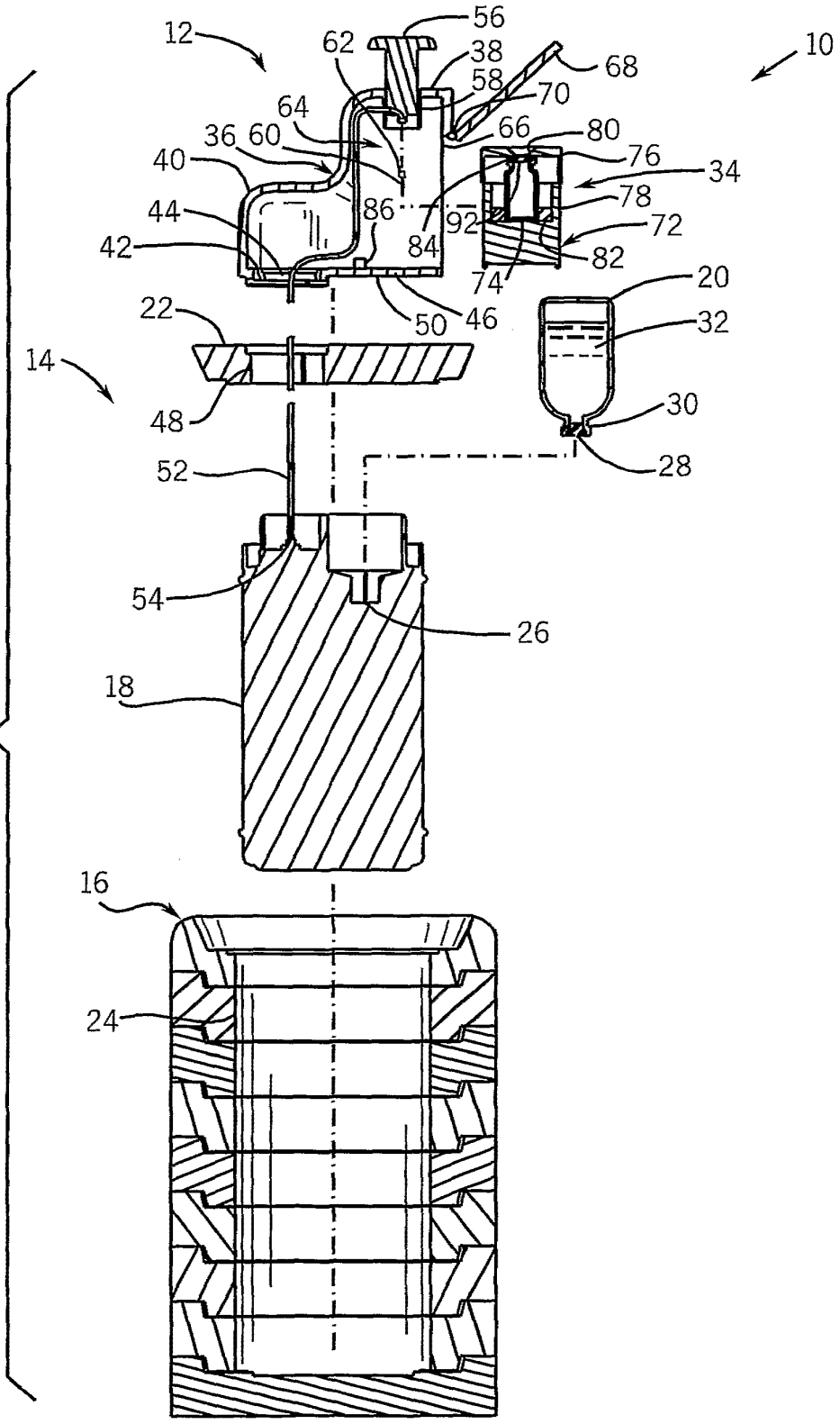
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FIG. 7

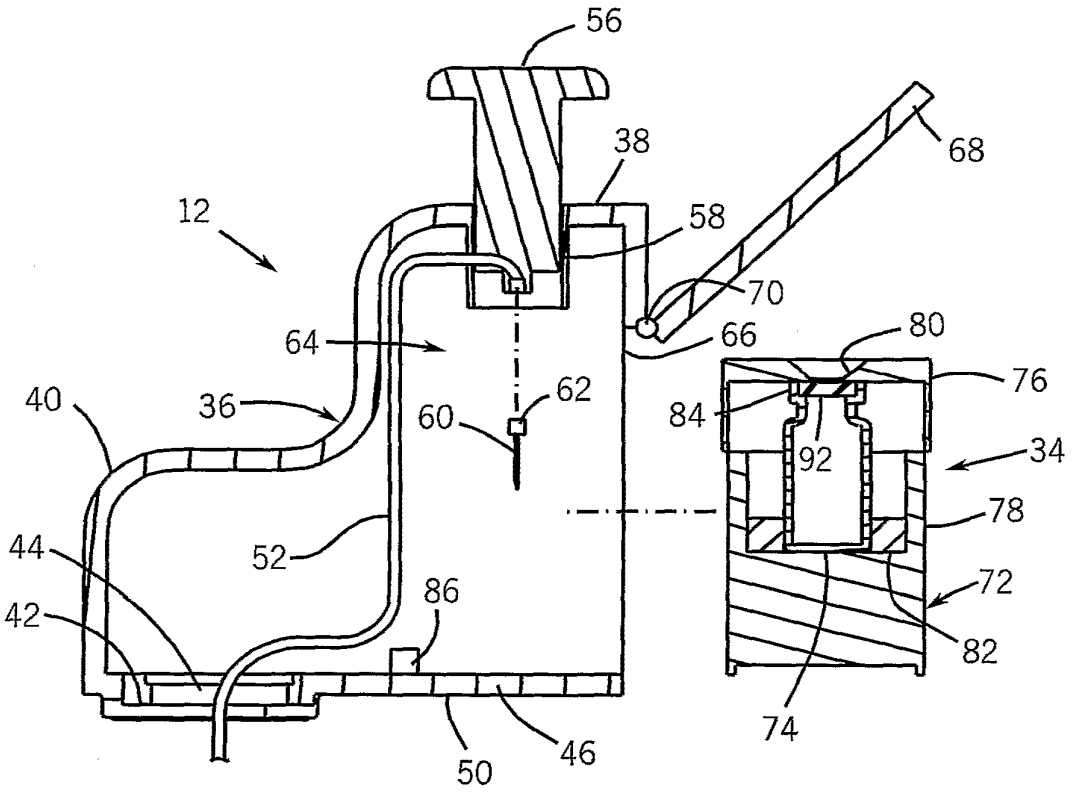
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FIG. 8

FIG. 9

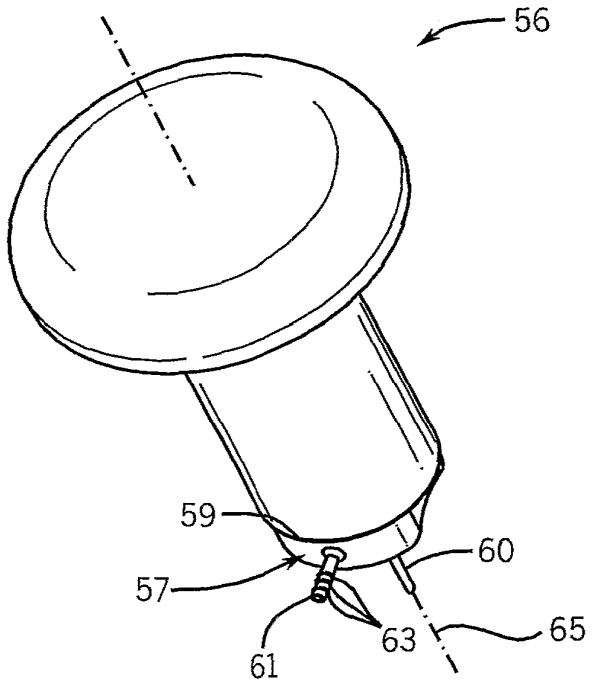
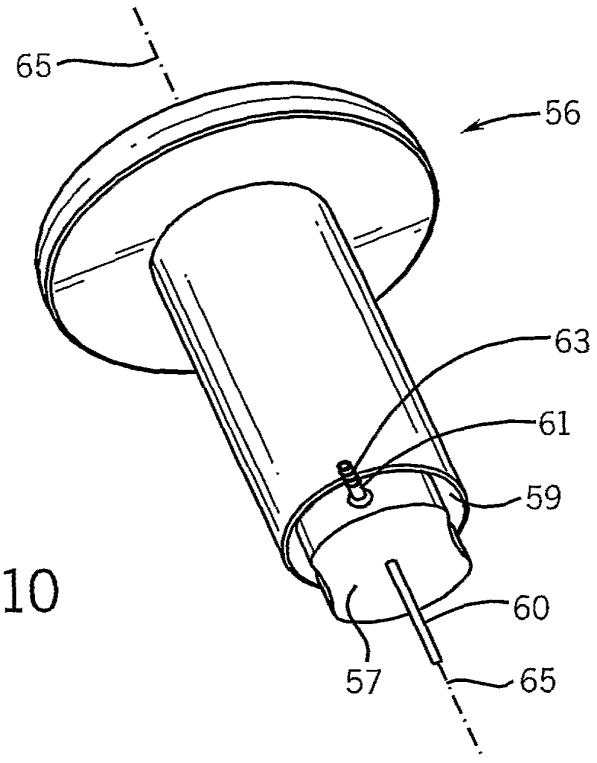


FIG. 10



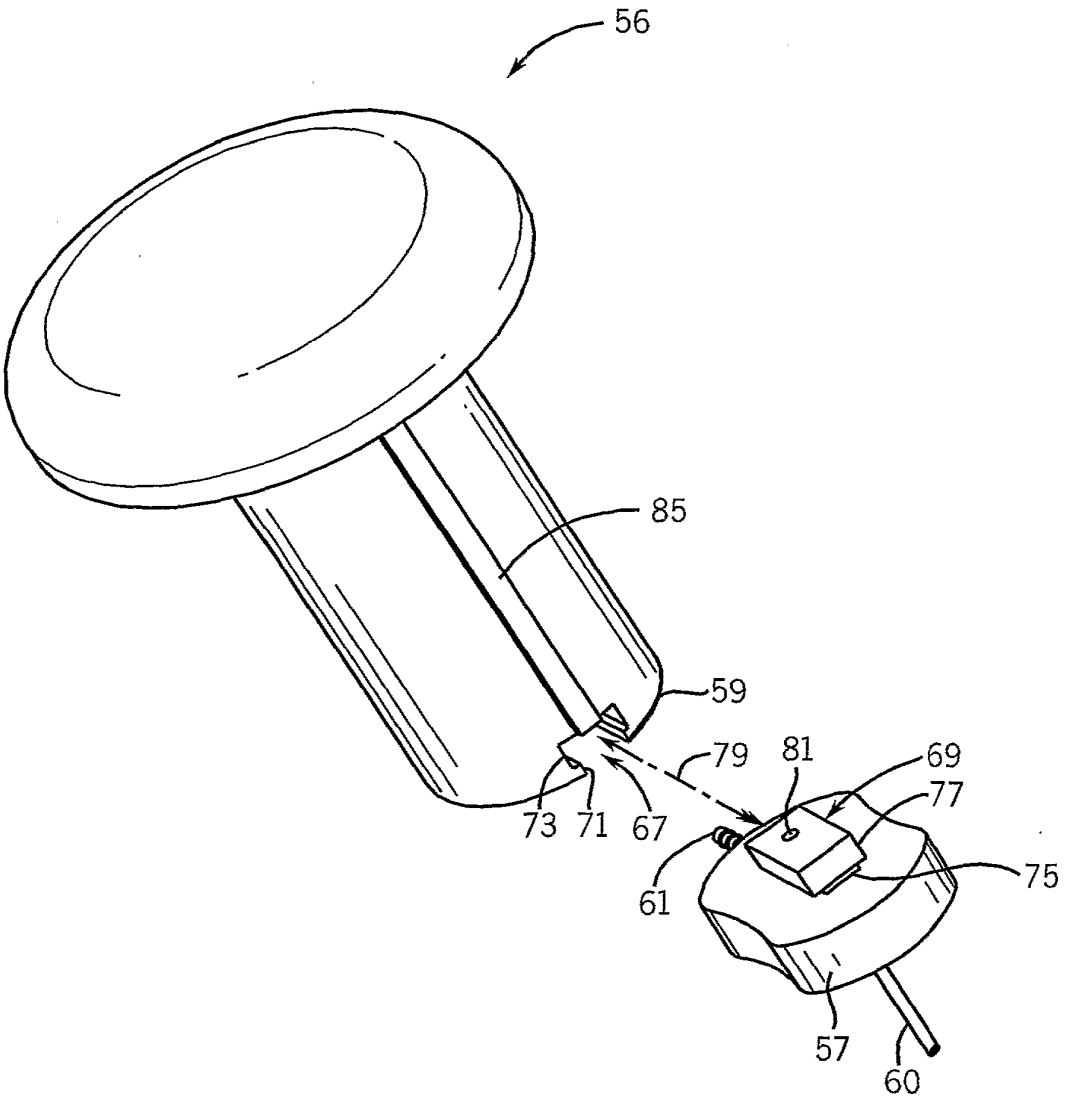


FIG. 11

FIG. 12

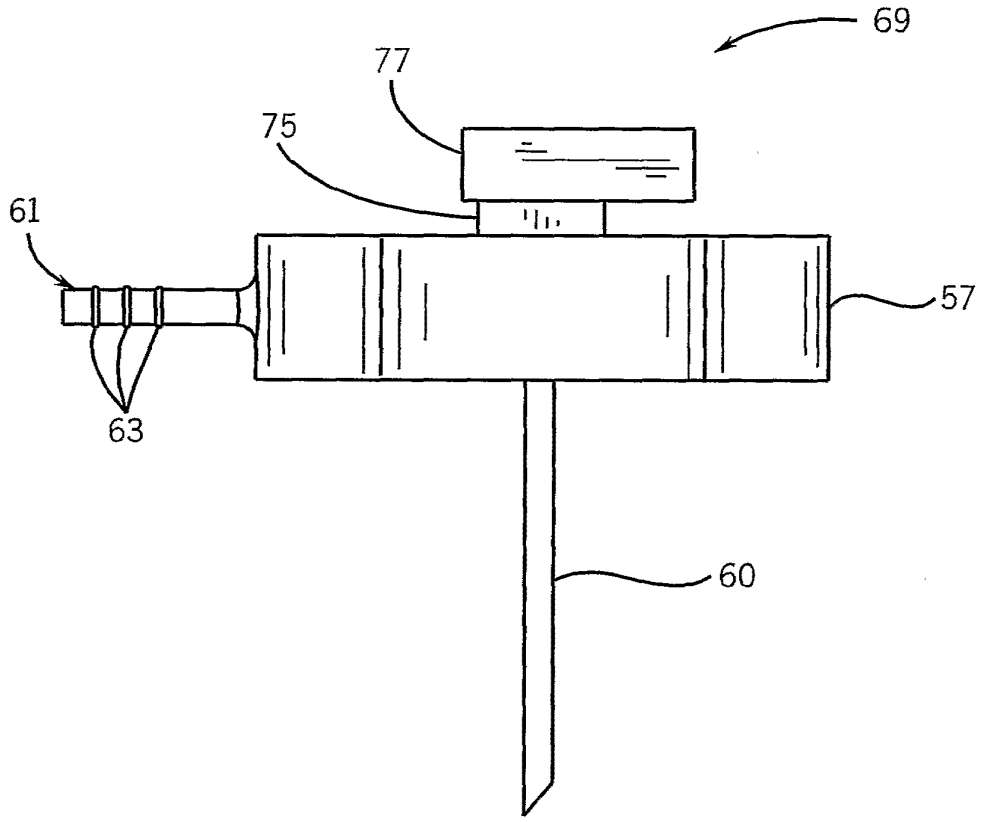


FIG. 13

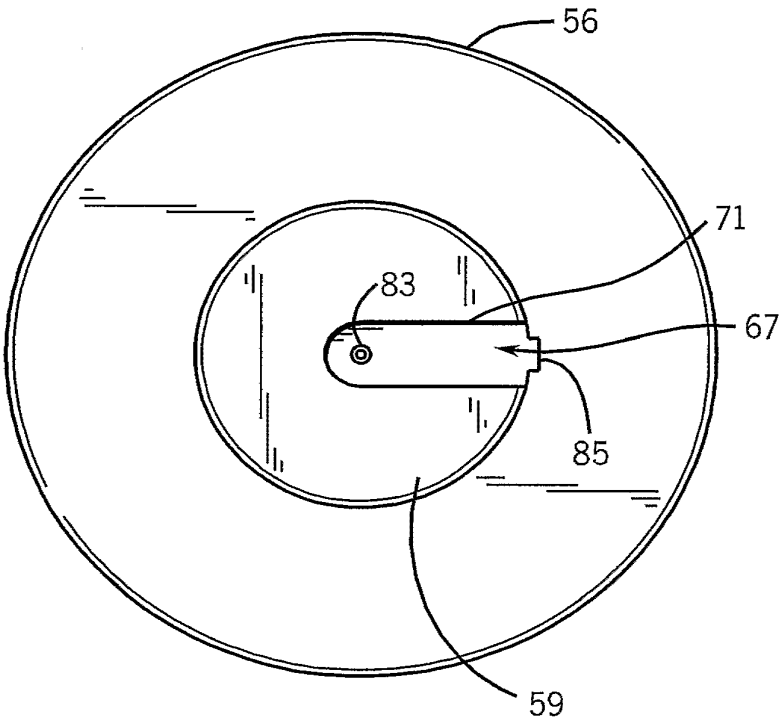
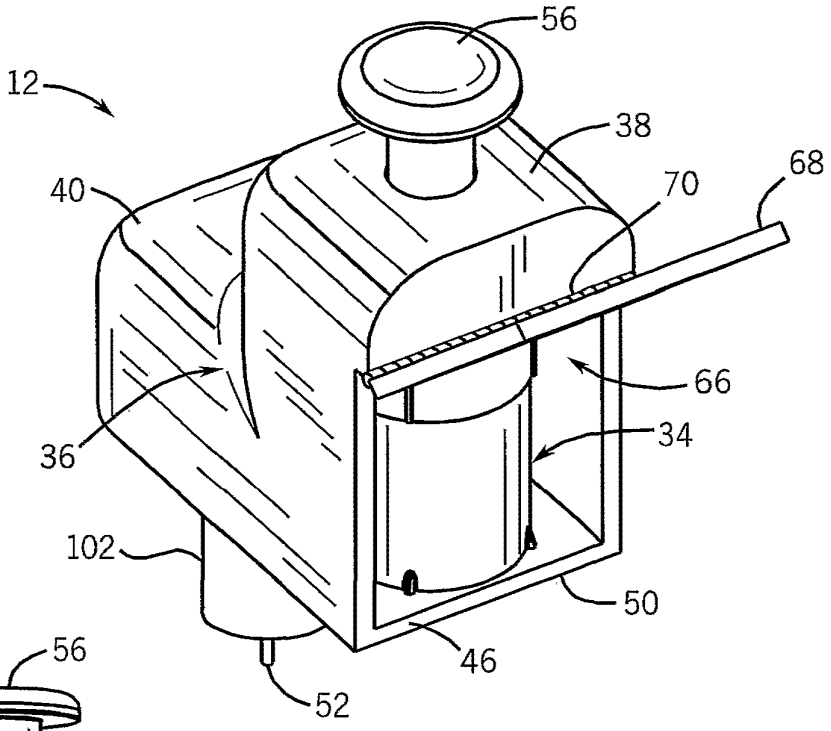


FIG. 14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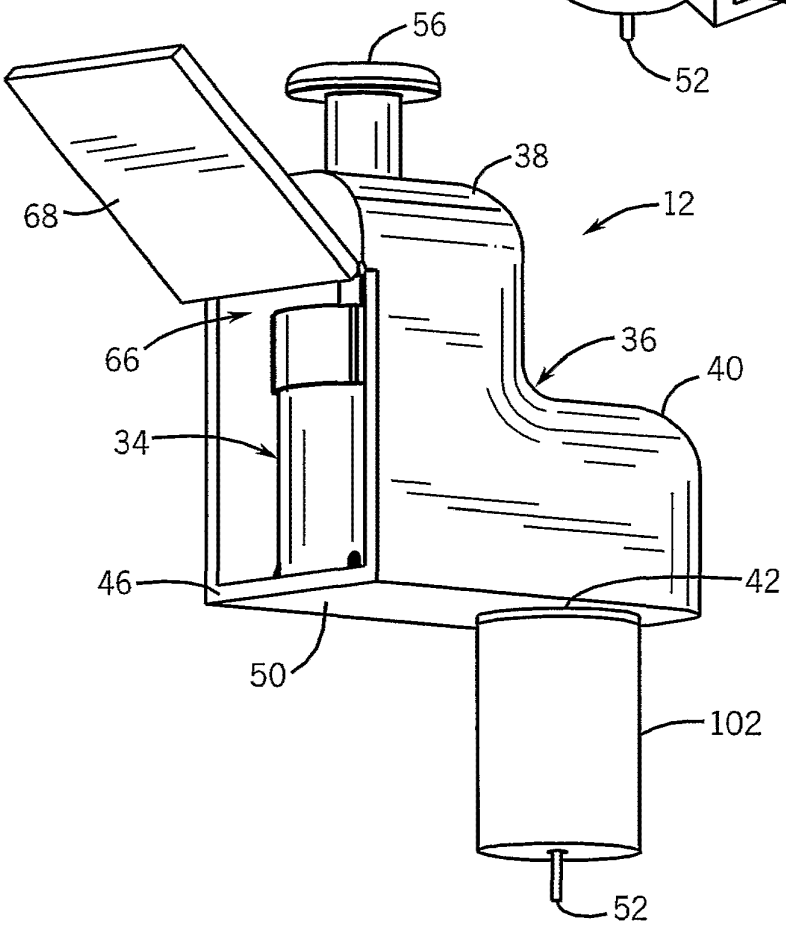
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FIG. 15

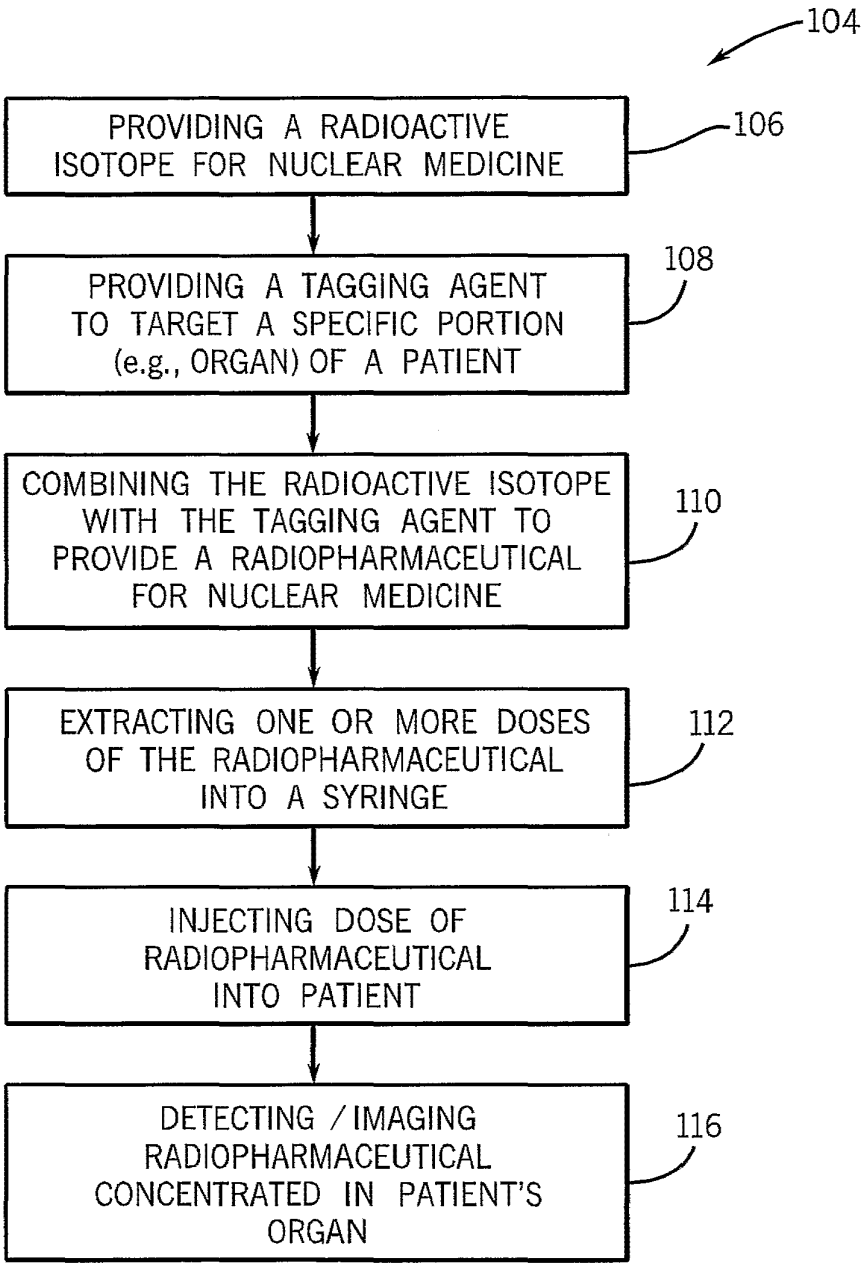
104
PROVIDING A RADIOACTIVE ISOTOPE FOR NUCLEAR MEDICINE
106
PROVIDING A TAGGING AGENT TO TARGET A SPECIFIC PORTION (e.g., ORGAN) OF A PATIENT
108
COMBINING THE RADIOACTIVE ISOTOPE WITH THE TAGGING AGENT TO PROVIDE A RADIOPHARMACEUTICAL FOR NUCLEAR MEDICINE
110
EXTRACTING ONE OR MORE DOSES OF THE RADIOPHARMACEUTICAL INTO A SYRINGE
112
INJECTING DOSE OF RADIOPHARMACEUTICAL INTO PATIENT
114
DETECTING / IMAGING RADIOPHARMACEUTICAL CONCENTRATED IN PATIENT'S ORGAN
116

FIG. 16

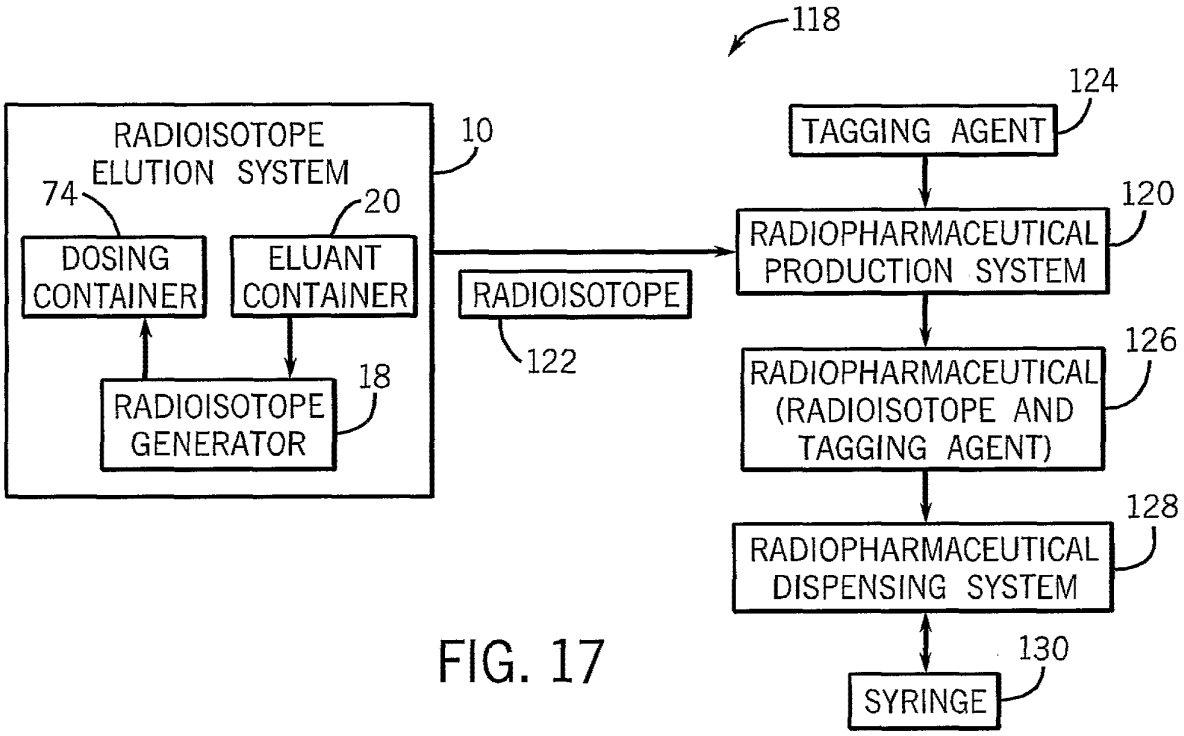
118
RADIOISOTOPE ELUTION SYSTEM
10
74
20
DOSING CONTAINER
ELUANT CONTAINER
RADIOISOTOPE GENERATOR
18
RADIOISOTOPE
122
TAGGING AGENT
124
RADIOPHARMACEUTICAL PRODUCTION SYSTEM
120
RADIOPHARMACEUTICAL (RADIOISOTOPE AND TAGGING AGENT)
126
RADIOPHARMACEUTICAL DISPENSING SYSTEM
128
SYRINGE
130

FIG. 17

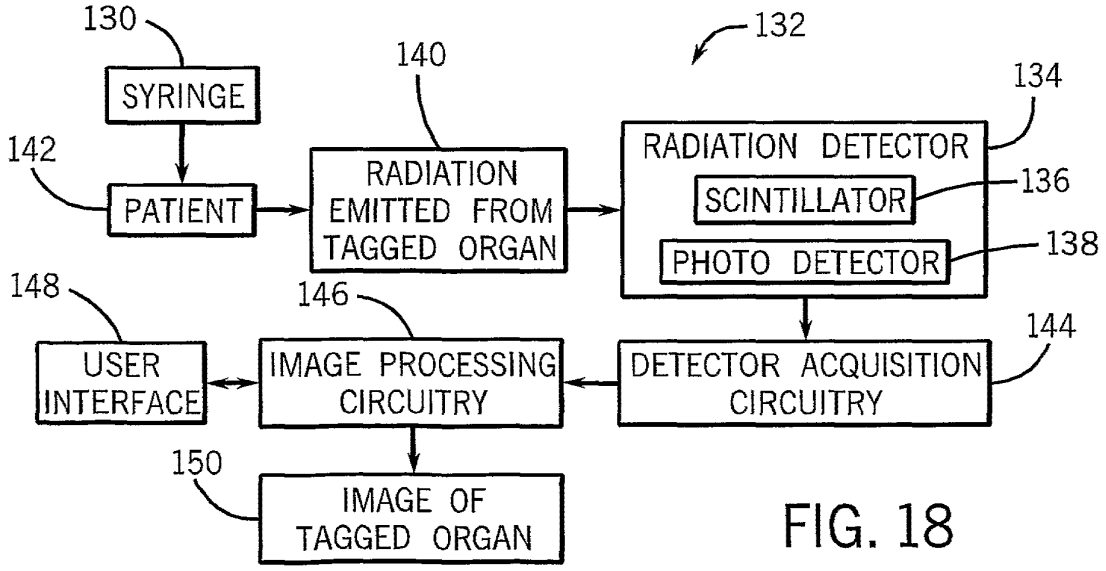
130
SYRINGE
142
PATIENT
140
RADIATION EMITTED FROM TAGGED ORGAN
132
134
RADIATION DETECTOR
SCINTILLATOR
136
PHOTO DETECTOR
138
148
USER INTERFACE
146
IMAGE PROCESSING CIRCUITRY
DETECTOR ACQUISITION CIRCUITRY
144
150
IMAGE OF TAGGED ORGAN

FIG. 18

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) → ^{82}Rb ($t_{1/2}$ = 75 seconds) and ^{68}Ge ($t_{1/2}$ = 271 days) → ^{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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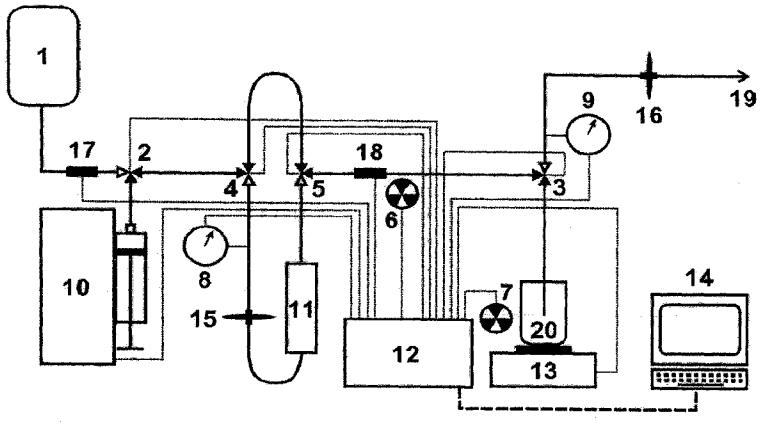
[продолжение на следующей странице]

(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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(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

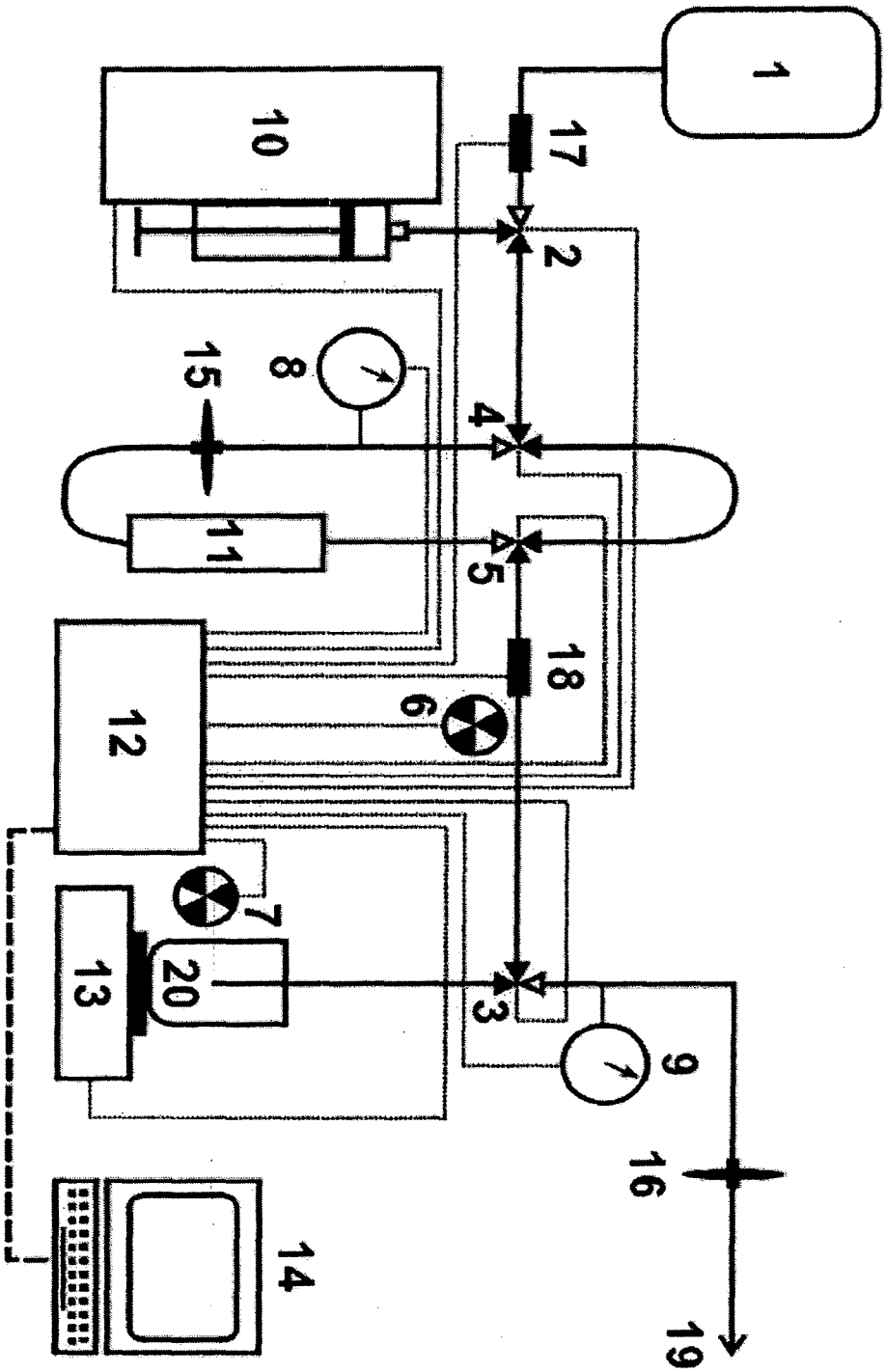
средство контроля веса отходов, выполненного в виде датчика усилия, а в отверстии

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

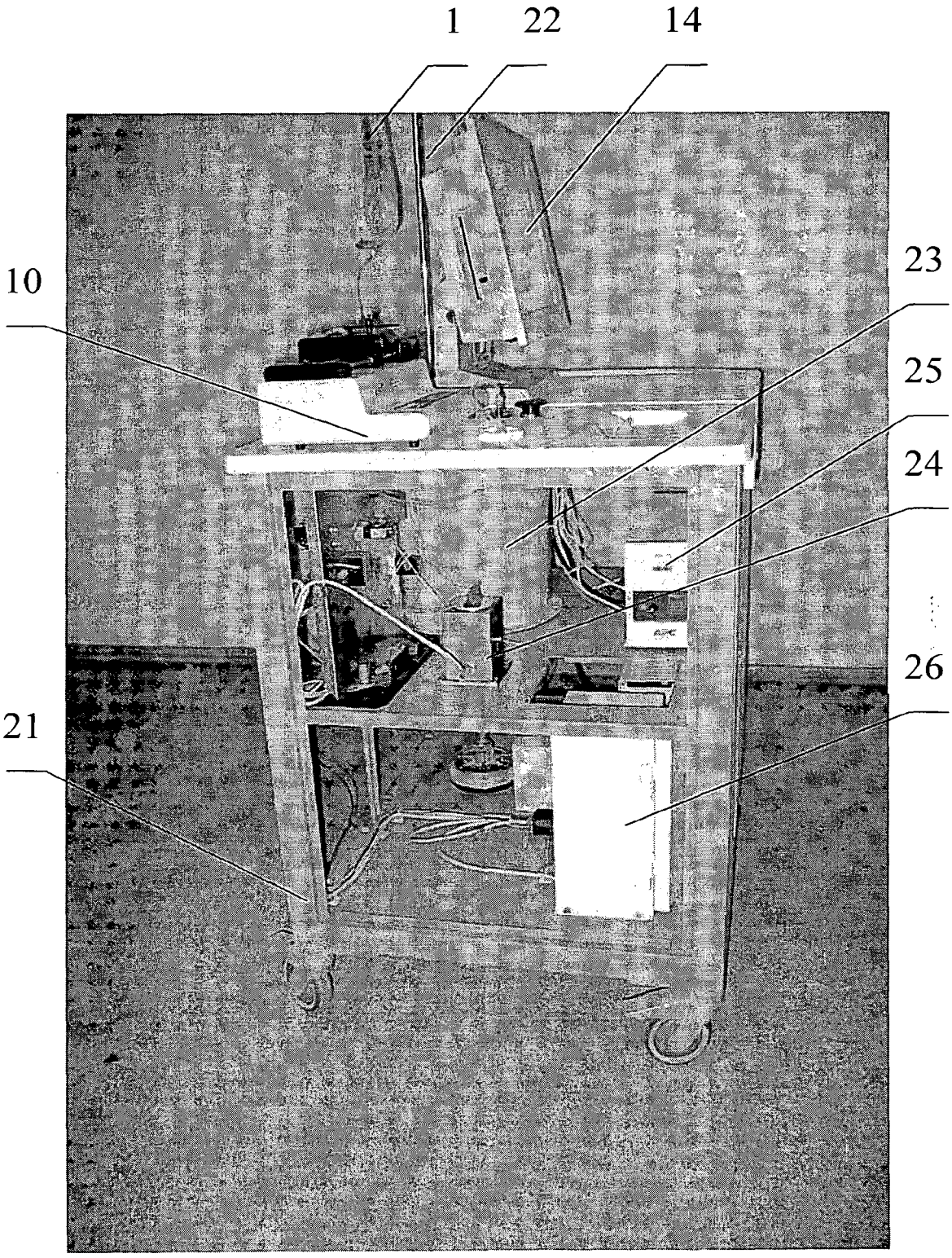
5. Система по п.1, отличающаяся тем, что стронций – рубидиевый генератор имеет радиационную защиту, включающую внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

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

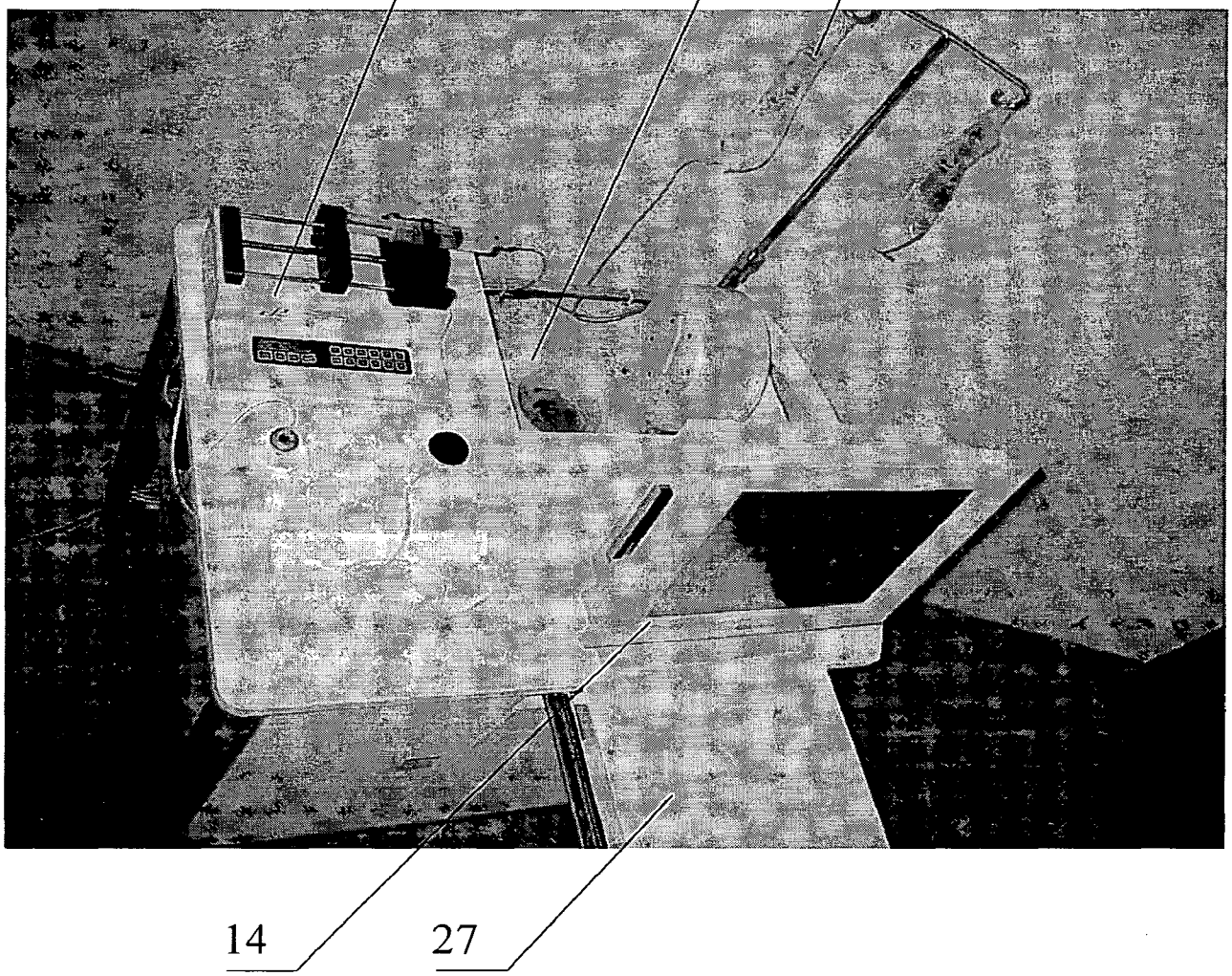
7. Система по п.6, отличающаяся тем, что корпус снабжен сдвигающейся столешницей.



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

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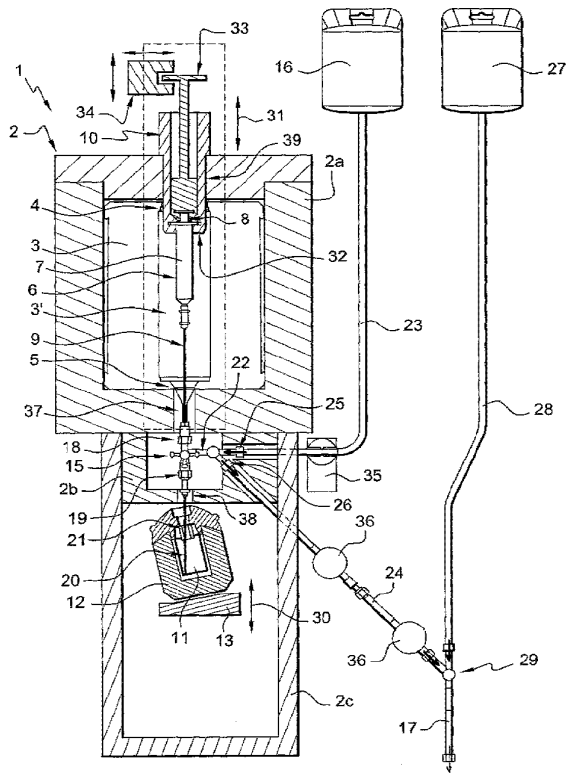
[Suite sur la page suivante]

(54) Title: MEDICAL UNIT FOR THE COLLECTION, CALIBRATION, DILUTION AND/OR INJECTION OF AN INJECTABLE RADIOACTIVE PRODUCT

(54) Titre : UNITE MEDICALE POUR LE PRELEVEMENT, LE CALIBRAGE, LA DILUTION ET/OU L'INJECTION D'UN PRODUIT RADIOACTIF INJECTABLE



(57) Abstract: The medical unit according to the invention comprises a shielded enclosure (2) that accommodates means (13) for supporting a container (12) comprising a source or a generator of radioactive product (11), means (10) for supporting a syringe (6), a device of the activity meter type (3), and a system of conduits (9, 23, 24) joined to at least one valve (15). The syringe support (10), the valve (15) and the radioactive source support (13) are arranged vertically relative to one another, each facing downwards, said syringe support (10) being designed to support said syringe (6) with its plunger (8) oriented upwards. The valve (15) and the syringe plunger (8) can be manoeuvred for performing the operations of collection, dilution and injection.

(57) Abrégé : L'unité médicale selon l'invention comporte une enceinte blindée (2) dans laquelle sont logés : des moyens (13) support d'un conteneur (12) comprenant une source ou un générateur de produit radioactif (11); des moyens (10) pour le support d'une seringue (6); un dispositif de type activimètre (3); et un système de conduites (9, 23, 24) associé à au moins une vanne (15). Le support de seringue (10), la vanne (15) et le support de source radioactive (13) sont agencés verticalement les uns par rapport aux autres, respectivement du haut vers le bas, ledit support de seringue (10) étant agencé pour supporter ladite seringue (6) avec son piston (8) orienté vers le haut. La vanne (15) et le piston de seringue (8) sont manoeuvrables pour assurer les opérations de prélèvement, de dilution et d'injection.

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UNITE MEDICALE POUR LE PRELEVEMENT, LE CALIBRAGE, LA DILUTION ET/OU L'INJECTION D'UN PRODUIT RADIOACTIF INJECTABLE

La présente invention concerne le domaine général de la médecine nucléaire. Elle concerne plus particulièrement une unité médicale employée pour le prélèvement, le calibrage, la dilution et/ou l'injection d'une substance radioactive destinée à être injectée à un patient.

Certaines substances radioactives sont particulièrement utiles dans le domaine médical, par exemple dans les procédures d'imagerie, à titre d'agents de contraste, ou comme agents thérapeutiques.

Pour limiter les doses de radiations reçues par le patient et par le personnel chargé des manipulations, on utilise des radioéléments de courtes demi-vies à usage médical, c'est-à-dire que le niveau de radiation émis par ces produits radioactifs décroît rapidement avec le temps.

Mais de tels produits radioactifs à courte demi-vie rendent problématique l'administration d'une dose appropriée au patient. Le dosage correspondant doit en effet être très précis ; il doit tenir compte du temps nécessaire pour la préparation de la dose à injecter, et aussi du temps susceptible de séparer le moment de la préparation de la dose de produit et le moment de l'injection proprement dite de cette dose au patient.

En outre, malgré le type de produits mis en œuvre (courte demi-vie), une autre contrainte à prendre en compte concerne la radioprotection du personnel médical chargé de préparer la dose radioactive et de l'injecter au patient. Cette radioprotection doit aussi être effective pour le patient.

De manière classique, les doses à injecter sont prélevées dans une seringue munie d'un blindage approprié, placée elle-même dans une enceinte blindée équipée de moyens de mesure et de contrôle appropriés, permettant de prélever dans la seringue la dose de produit radioactif recherchée. Ensuite, un opérateur récupère la seringue blindée et il se rend auprès du patient pour réaliser l'injection.

Cependant, cette manière d'opérer n'offre pas une sécurité optimale, tant sur le plan de la radioprotection pour l'opérateur que sur le plan de la précision de la dose injectée au patient.

Le document US-6 767 319 décrit un matériel de calibrage et d'injection de produit radioactif visant à limiter l'exposition du personnel à la substance radioactive et aussi optimiser la sécurité du patient.

L'installation correspondante comprend trois enceintes radioprotectrices indépendantes, contenant respectivement :

- des moyens pour le support d'une source en produit radioactif injectable,
- des moyens pour le support d'une seringue, qui sont équipés de moyens pour la manœuvre automatique de son piston, et qui sont associés à un dispositif de type activimètre pour la mesure en temps réel de l'activité radio-isotopique émise par le produit contenu dans la seringue, et
- un système de vannes.

Ce système de vannes est raccordé hydrauliquement, par le biais de tubulures, à l'enceinte contenant la source mère radioactive, à l'enceinte contenant la seringue, à une source de sérum physiologique et à un cathéter d'injection destiné à être connecté au patient.

Ce matériel comprend encore des moyens destinés à piloter le système de vannes et les moyens de manœuvre du piston de seringue, cela de manière adaptée pour assurer, dans un premier temps, le prélèvement d'une dose de produit radioactif et/ou de sérum physiologique au sein de la seringue, et dans un second temps l'éjection au travers du cathéter d'injection, du produit radioactif et/ou du sérum physiologique préalablement prélevés. La dose de produit radioactif est mesurée par le dispositif activimètre au cours du prélèvement dans la seringue.

Dans ce matériel, les tubulures reliant l'enceinte contenant le système de vannes et celles contenant la seringue ou la source radioactive, ne sont pas protégées et sont source d'émissions radioactives dans l'environnement.

De plus, du fait de sa structure, le matériel correspondant est encombrant. En outre, la complexité du réseau de tubulures entraîne la présence de volumes morts importants.

La présente invention propose une unité médicale originale de calibration et d'injection de produits radioactifs, très compacte, permettant le prélèvement, la mesure et l'injection des produits avec une grande précision, en toute sécurité, et avec des volumes morts réduits.

Cette unité médicale est du type comprenant :

- des moyens pour le support d'un conteneur en matériau radioprotecteur dans lequel est logée une source ou un générateur de produit radioactif injectable,
- des moyens pour le support d'une seringue équipée d'un piston,
- un dispositif de type activimètre pour la mesure en temps réel de l'activité radio-isotopique émise par le contenu de ladite seringue, et

- un système de conduites associé à au moins une vanne pour le raccordement hydraulique de ladite source radioactive, de ladite seringue, d'une source de sérum physiologique et d'un cathéter d'injection destiné à être connecté au patient,

ladite vanne et ledit piston de seringue étant manœuvrables pour assurer, d'une part, une aspiration dudit produit radioactif ou dudit sérum physiologique au sein de ladite seringue, et d'autre part, une éjection dudit produit radioactif, dudit sérum physiologique ou d'un mélange de ces deux produits, préalablement aspirés au sein de ladite seringue, cela au travers dudit cathéter d'injection, la dose de produit radioactif prélevée et injectée par ladite seringue étant mesurée par ledit activimètre.

Conformément à l'invention, l'unité médicale comporte encore une enceinte blindée réalisée en au moins un matériau radioprotecteur, dans laquelle sont logés le support de source radioactive, au moins une partie des moyens support de la seringue, l'activimètre, la vanne, et au moins une partie du système de conduites.

De plus, le support de seringue, la vanne et le support de source radioactive sont agencés verticalement les uns par rapport aux autres, respectivement du haut vers le bas, le support de seringue étant agencé pour porter la seringue verticalement avec son piston orienté vers le haut.

Cet agencement particulier permet à la seringue de prélèvement/injection et à la source de produit radioactif d'être très proches de la vanne, pour obtenir un ensemble très compact, avec des volumes morts minimisés.

Selon une caractéristique de réalisation, la vanne consiste en une vanne trois voies comprenant :

- une voie supérieure, destinée à être raccordée à la seringue de prélèvement et d'injection,
- une voie inférieure, destinée à être raccordée à la source de produit radioactif injectable, et
- une voie latérale, destinée à être raccordée à une première conduite connectée à la source de sérum physiologique et à une seconde conduite connectée au cathéter d'injection, lesdites conduites étant équipées chacune d'un clapet anti-retour convenablement orienté.

Dans ce cas, l'activimètre a avantageusement une forme générale tubulaire délimitant un puits central, d'axe vertical, destiné à contenir la seringue, ledit activimètre étant muni de deux ouvertures, l'une supérieure et l'autre inférieure, cette dernière étant orientée en regard de la vanne trois voies et du support de la source radioactive.

Pour réduire les volumes morts dans les conduits de ce matériel, la voie supérieure de la vanne, destinée à être raccordée à la seringue, comporte avantageusement un opercule hermétique destiné à être percé par l'aiguille équipant ladite seringue montée sur son support ; de même, la voie inférieure de la vanne, destinée à être raccordée à la source de produit radioactif est avantageusement prolongée par une aiguille destinée à percer un opercule obturant le flacon contenant ladite source radioactive.

Encore selon une caractéristique de réalisation de l'invention, les supports de source radioactive et de seringue sont portés chacun par des moyens assurant leur(s) déplacement(s) selon un axe vertical ou sensiblement vertical, cela entre deux positions :

- une première position, dans laquelle un opérateur peut charger la source radioactive et la seringue sur leurs supports respectifs, ou à l'inverse les décharger, et
- une seconde position dans laquelle la source radioactive et la seringue sont raccordées à la vanne.

Selon cette caractéristique, les moyens de déplacement du support de seringue permettent avantageusement son cheminement verticalement au travers d'un orifice ménagé dans l'enceinte blindée, entre :

- une position supérieure de chargement/déchargement, dans laquelle ledit support se situe au moins partiellement hors de ladite enceinte, et
- une position inférieure de raccordement, dans laquelle la seringue se positionne au sein du logement central de l'activimètre et est raccordée à la vanne.

De plus, le support de source radioactive chemine avantageusement au sein de l'enceinte blindée entre ses positions de chargement/déchargement et de raccordement ; cette enceinte est encore munie d'une trappe frontale pour permettre l'accès d'un opérateur au support de source radioactive au moins dans sa position de chargement/déchargement.

Encore selon une autre caractéristique, l'unité médicale comprend des moyens de commande informatiques et/ou électroniques aptes à piloter la vanne et les moyens de manœuvre du piston de seringue, cela de manière à mettre en œuvre les opérations de prélèvement et d'éjection par la seringue. De même, les moyens de commande informatiques/électroniques pilotent également éventuellement les moyens de déplacement du support de seringue et du support de source radioactive.

Dans ce cas, les moyens de manœuvre du piston de la seringue sont avantageusement de type motoréducteur débrayable, contrôlés par les moyens

informatiques/électroniques, pour assurer, d'une part, le prélèvement automatique d'une dose déterminée de produit radioactif au sein de la seringue et, d'autre part, pour assurer l'injection de cette dose au patient, soit automatiquement, soit manuellement. L'opérateur peut en effet, s'il le souhaite, débrayer les moyens motoréducteurs et contrôler manuellement l'injection de la dose radioactive au patient.

Selon toujours une forme de réalisation intéressante, l'enceinte se compose de trois sous-enceintes alignées verticalement les unes par rapport aux autres, à savoir :

- une sous-enceinte supérieure contenant la seringue et l'activimètre,
- une sous-enceinte intermédiaire contenant la vanne, et
- une sous-enceinte inférieure contenant la source de produit radioactif.

Ces sous-enceintes sont raccordées deux à deux par des ouvertures traversantes au travers desquelles passent certaines des conduites de raccordement hydraulique.

Pour optimiser encore le traitement des données des médicales, les moyens de commande informatiques/électroniques sont pourvus d'une connectique pour l'envoi et/ou la réception de données, en particulier pour les échanges avec un serveur informatique.

L'unité médicale selon l'invention peut être rendue mobile. Pour cela, elle est montée sur des roues avantageusement motorisées ; elle intègre éventuellement un système de géolocalisation, par exemple de type GPS.

L'invention sera encore illustrée, sans être aucunement limitée, par la description suivante d'un mode de réalisation particulier, donné uniquement à titre d'exemple et représenté sur les dessins annexés dans lesquels :

- la figure 1 est une représentation schématique, en coupe, d'une unité médicale conforme à l'invention ;
- la figure 2 est une vue en perspective de la structure externe d'une forme de réalisation possible de l'unité médicale illustrée figure 1.

Tel que représenté sur la figure 1, l'unité médicale 1 conforme à l'invention comprend une enceinte blindée 2 réalisée en matériau radioprotecteur dans laquelle on trouve un dispositif 3 pour la mesure en temps réel de l'activité radio-isotopique (activimètre de type ACAD (marque déposée)), de forme générale cylindrique d'axe vertical, muni d'une ouverture supérieure 4 et d'une ouverture inférieure 5.

Une seringue classique 6, comprenant un corps 7, un piston 8 et une aiguille 9, est installée dans le puits de mesure 3' de l'activimètre 3 (connectée à une unité de traitement appropriée) ; cette seringue 6 est montée verticalement sur un support

supérieur 10, son piston 8 étant orienté vers le haut, et donc son aiguille 9 étant orientée vers le bas.

Une source ou générateur 11 de produit radioactif est placé sous l'activimètre 3, en regard de son ouverture inférieure 5. Cette source de produit radioactif 11 est contenue dans un flacon conditionné dans un conteneur blindé 12 réalisé en matériau radioprotecteur. Le conteneur blindé 12 est logé dans l'enceinte blindée 2, posé sur un support 13.

Une vanne trois voies motorisée 15, logée dans l'enceinte blindée 2 entre la seringue 6 et le flacon de source radioactive 11, assure une connexion hydraulique appropriée entre ladite seringue 6, ledit flacon de source radioactive 11, une poche de sérum physiologique 16 (extérieure à l'enceinte blindée 2) et un cathéter 17 d'injection au patient (également extérieur à l'enceinte blindée 2). Cette vanne 15 est localisée en regard de l'ouverture inférieure 5 de l'activimètre 3, et en regard de la source radioactive 11.

La voie supérieure 18 de cette vanne trois voies 15 comporte un opercule hermétique destiné à être percé par l'aiguille 9 de la seringue 6. La voie inférieure 19 de la vanne 15 se prolonge par une aiguille 20 destinée à percer l'opercule hermétique 21 qui obture le flacon de source radioactive 11. La voie latérale 22 de la vanne 15 est connectée, par un raccordement en Y, à une tubulure 23 aboutissant à la poche de sérum physiologique 16, et à une tubulure 24 aboutissant au cathéter d'injection 17.
La tubulure 23 est équipée d'un clapet anti-retour 25 empêchant un retour de liquide en direction de la poche de sérum physiologique 16. La tubulure 24 est également équipée d'un clapet anti-retour 26 imposant le passage de liquide en direction du patient.

Sur la figure 1, on remarque que le cathéter 17 est également en communication avec une seconde poche 27 de sérum physiologique, par le biais d'une tubulure 28 et d'un raccordement en Y 29.

La vanne trois voies 15 a deux positions principales : - une première mettant en communication ses voies supérieure 18 et inférieure 19 (permettant la mise en communication de la seringue 6 avec la source de produit radioactif 11 pour assurer le prélèvement d'une dose de produit radioactif dans le corps de seringue 7), et - une seconde position, mettant en communication la voie supérieure 18 et la voie latérale 22 (soit pour aspirer du sérum physiologique venant de la poche 16 dans le corps de seringue 7, lors d'une opération d'aspiration par la seringue 6, soit pour éjecter le

liquide contenu dans le corps de seringue 7 dans le cathéter d'injection 17, par une manœuvre de vidange du corps de seringue 7).

Une troisième position possible de la vanne 15 consiste à mettre en communication la source de radioéléments 11 et les tubulures 23 et 24, cela pour casser la dépression du flacon de source radioactive 11 en autorisant l'aspiration du sérum physiologique provenant de la poche 16.

La vanne trois voies 15 est montée fixe à l'intérieur de l'enceinte 2 sur l'axe vertical ou sensiblement sur l'axe vertical passant par la seringue 6 et la source 11 de produit radioactif.

Le support 13 de la source de produit radioactif 11 est mobile verticalement, conformément à la flèche d'orientation 30, sous l'action de moyens mécaniques appropriés (non représentés) actionnés manuellement (ou au pied), ou par des moyens moteurs (également non représentés) de manière à permettre l'intégration de l'aiguille 20 dans le flacon de source radioactive 11, ou le retrait de cette aiguille 20 dudit flacon.

L'opérateur manœuvre le support mobile 13 dans cette dernière position « extraite » lorsqu'il souhaite changer la source de produit radioactif.

D'autre part, le support 10 de la seringue 6 est également mobile verticalement, conformément à la flèche d'orientation 31, sous l'action de moyens mécaniques appropriés (non représentés) actionnés manuellement ou par des moyens moteurs (également non représentés), de manière à permettre l'intégration de l'aiguille 9 de la seringue 6 dans la vanne trois voies 15, ou l'extraction de la seringue 6 au-dessus de l'activimètre 3 et hors du conteneur blindé 2, pour réaliser les opérations de mise en place et de retrait de la seringue 6.

Le support 10 de la seringue 6 est également structuré pour permettre une manœuvre du piston 8 de la seringue depuis l'extérieur du conteneur blindé 2, alors que ladite seringue 6 est centrée dans le puits de mesure 3' de l'activimètre 3.

Pour cela, le support 10 comporte une partie cylindrique 32 en prise avec la partie arrière du corps de seringue 7, et une partie centrale 33, en forme de piston coulissant dans la partie cylindrique 32, en prise avec la partie arrière du piston de seringue 8.

Lorsque le corps de seringue 7 est en position dans le puits de mesure 3' de l'activimètre 3, l'extrémité supérieure du piston coulissant 33 est accessible depuis l'extérieur de l'enceinte blindée 2. Cette extrémité supérieure de piston 33 est associée à une motorisation débrayable 34 qui, une fois embrayée, permet l'actionnement

automatique du piston de seringue 8 et qui, lorsqu'elle est débrayée, permet l'actionnement manuel de ce piston 8.

Cette particularité offre à l'opérateur un choix de gestion, automatique ou manuelle, du prélèvement de produit radioactif par la seringue 6 et/ou de l'éjection du produit dans le cathéter 17.

Sur la figure 1, on remarque encore la présence d'une électrovanne à pincement 35, positionnée sur la tubulure 23 de la poche de sérum physiologique 16. Cette électrovanne 35 a pour fonction d'empêcher la circulation intempestive de sérum physiologique au travers de la tubulure 23, avant la connexion du cathéter d'injection 17 au patient.

Sur la tubulure 24 d'alimentation du cathéter 17, on remarque aussi la présence de deux moyens anti-bulles/antibactérien 36 qui se présentent, par exemple, sous la forme de filtres, garantissant la stérilité du processus d'injection.

Toujours sur la figure 1, on remarque que l'enceinte blindée 2 se présente sous la forme de trois sous-ensembles blindés :

- un premier ensemble 2a intègre l'activimètre 3 et une partie du support de seringue 10,
- un second ensemble 2b cloisonne la vanne trois voies motorisée 15, et
- un troisième ensemble 2c cloisonne le support mobile 13 avec son conteneur blindé 12.

Les trois sous-enceintes 2a, 2b et 2c sont superposées ; la connexion entre la seringue 6 et la vanne 15 s'effectue au travers d'une ouverture 37 ménagée entre lesdits sous-ensembles 2a et 2b. La connexion entre la vanne 15 et la source de produit radioactif 11 est réalisée au travers d'une ouverture 38 ménagée entre les sous-ensembles 2b et 2c.

Le support 10 de la seringue 6 est réalisé en matériau radioprotecteur. Ses dimensions sont ajustées au mieux dans une ouverture 39 ménagée dans la partie supérieure du sous-ensemble 2a, pour obtenir une continuité de blindage en position abaissée (c'est-à-dire lorsque la seringue 6 est centrée dans le puits de mesure 3' de l'activimètre 3).

L'enceinte blindée 2 comporte encore des ouvertures appropriées pour le passage des tubulures 23 et 24 reliées, respectivement, à la poche de sérum physiologique 16 et au cathéter 17.

Les principales étapes mises en œuvre au sein de l'unité médicale 1, pour la préparation d'une dose déterminée de produit radioactif, puis son injection au patient, sont détaillées ci-dessous.

Tout d'abord, la dose de produit radioactif à injecter au patient est préparée au sein de la seringue 6.

Pour cela, la seringue 6 (avec son piston 8 en position basse) et la source de produit radioactif 11 sont connectées à la vanne trois voies 15 ; ensuite, cette vanne 15 est pilotée de sorte que ses voies supérieure 18 et inférieure 19 soient raccordées hydrauliquement, permettant la mise en communication respectivement de l'aiguille de seringue 9 avec la source 11 de produit radioactif.

Le piston de seringue 8 est ensuite manœuvré, vers le haut, pour aspirer la dose voulue de produit radioactif dans le corps de seringue 7, qui est mesurée en temps réel par l'activimètre 3. Cette dose est notamment fonction du poids du patient.

La dose préparée au sein de la seringue peut ensuite être administrée au patient.

A cet effet, la vanne 15 est à nouveau pilotée, cela de sorte que ses voies supérieure 18 et latérale 22 soient respectivement en communication avec l'aiguille de seringue 9, et avec les tubulures 23 et 24 (connectées à la poche 16 de sérum physiologique et au cathéter d'injection 17).

Avant la phase d'injection proprement dite, le piston de seringue 8 peut, si nécessaire, être piloté (vers le haut) pour aspirer un volume complémentaire de sérum physiologique provenant de la poche 16 ; ce volume de sérum permet de diluer le produit radioactif, et aussi d'obtenir un volume d'injection suffisant.

La seringue 6 est ensuite vidangée par le déplacement adapté du piston de seringue 8 (vers le bas). Le produit radioactif, éventuellement dilué par le volume complémentaire de sérum physiologique, chemine alors au travers de la tubulure 24 où il est filtré par les dispositifs 36, puis le long du cathéter d'injection 17 jusqu'au patient.

Suite à cette phase d'injection, l'opérateur peut éventuellement mettre en œuvre une phase complémentaire de rinçage du corps de seringue 7, de la vanne 15, et des conduites aval 17 et 24, avec un volume adapté de sérum physiologique pour assurer l'administration au patient de la totalité de la dose radioactive souhaitée.

A cet effet, le piston de seringue 8 est manœuvré successivement en aspiration (vers le haut) pour prélever un volume déterminé de sérum physiologique en provenance de la poche 16, puis manœuvré en éjection (vers le bas) pour éjecter ce volume au travers de la conduite 24 et du cathéter d'éjection 17.

Lorsque l'opérateur souhaite remplacer la seringue 6 ou la source de produit radioactif 11, il lui suffit de manœuvrer leurs structures supports respectives 10 et 13.
A titre indicatif, la seringue 6 et la vanne 15 avec ses différentes conduites peuvent être remplacées suite à chaque injection. La seringue 6, d'une part, et la vanne 15 avec son aiguille 20, ses tubulures 23, 24, la poche de sérum physiologique 16 et le cathéter 17, d'autre part, constituent un ensemble stérile à usage unique, remplaçable très facilement après chaque utilisation.

Les différents cycles précités de prélèvement, de dilution et d'injection de ce matériel sont gérés par des moyens de commande électroniques/informatiques de type automate programmable, aptes à piloter automatiquement les moyens de manœuvre 34 du piston de seringue 8 et la vanne trois voies 15, de manière appropriée.
L'ensemble de ces cycles peut être totalement automatisé. En fonction des besoins, ou des souhaits de l'utilisateur, l'injection de la dose radioactive au patient peut aussi être réalisée manuellement grâce aux moyens débrayables du motoréducteur 34.

Une forme particulièrement intéressante de l'unité médicale illustrée schématiquement sur la figure 1, est représentée sur la figure 2.

Sur cette figure 2, l'enceinte blindée 2 qui intègre l'ensemble du matériel fonctionnel décrit ci-dessus, est montée sur un châssis équipé de quatre roues 40. De préférence, certaines au moins des roues 40 sont associées à une motorisation, constituant une simple assistance aux déplacements, ou assurant elle-même le déplacement autonome de l'unité mobile, pilotée à distance par un boîtier à manette adapté.

L'unité mobile 1 peut aussi intégrer un système de géolocalisation, par exemple de type GPS, pour connaître en permanence son positionnement à distance dans un bâtiment.

Dans la partie inférieure de l'enceinte 2, on remarque la présence d'une trappe blindée 41 donnant accès à l'intérieur de la sous-enceinte 2c, pour le chargement ou le déchargement sur son support 13 du conteneur blindé 12 renfermant la source de produit radioactif 11 (en particulier lorsque ce support 13 est en position basse de chargement/déchargement).

Dans la partie supérieure, on remarque le support de seringue 10, la poche de sérum physiologique 16 accrochée à un support 42, ainsi qu'un tableau 43 de commande et de visualisation, à écran tactile, intégrant l'automate programmable de gestion des cycles, ou en relation directe avec celui-ci (par exemple déporté au sein du châssis de l'unité). Ce tableau de commande, de dialogue et de visualisation 43

permet d'effectuer les opérations de calibration (mesure d'activité), et la visualisation en temps réel des diverses phases de préparation du transfert (dilution ...) et d'injection du produit radioactif.

Les moyens de commande électroniques/informatiques correspondants sont équipés d'une connectique 44 pour l'envoi et/ou la réception de données, en particulier pour réaliser certains échanges avec un serveur informatique situé à proximité ou à distance (par exemple par l'intermédiaire d'un réseau intranet ou du réseau internet), notamment pour réaliser une télémaintenance à distance et collecter certaines données concernant le patient (nécessaires notamment à la détermination de la dose de radioéléments qui doit lui être administrée).

Le châssis de l'unité 1 porte également des moyens propres d'énergie, par exemple de type batteries rechargeables, assurant l'alimentation électrique notamment des roues motorisées 40 et des moyens de commande électroniques/informatiques.

Cette unité mobile blindée 1 constitue une unité autonome permettant la calibration et l'injection de tous produits radioactifs (en particulier de FDG). Elle est très compacte du fait de la superposition de l'activimètre, de la vanne trois voies et de la source de produit radioactif sur le même axe vertical ou sensiblement sur le même axe vertical, et du fait de la superposition des sous-enceintes 2a, 2b et 2c. Cette unité permet un prélèvement, une mesure et une injection en toute sécurité.

- REVENDICATIONS -

1.- Unité médicale pour le prélèvement, le calibrage, la dilution et/ou l'injection d'un produit radioactif, injectable à un patient, laquelle unité (1) comprend au moins :

- des moyens (13) pour le support d'un conteneur (12) en matériau radioprotecteur dans lequel est logée une source ou un générateur de produit radioactif injectable (11),
- des moyens (10) pour le support d'une seringue (6) équipée d'un piston (8),
- un dispositif (3) de type activimètre pour la mesure en temps réel de l'activité radio-isotopique émise par le contenu de ladite seringue (6), et
- un système de conduites (9, 20, 23, 24) associé à au moins une vanne (15) pour le raccordement hydraulique de ladite source radioactive (11), de ladite seringue (6), d'une source de sérum physiologique (16) et d'un cathéter d'injection (17) destiné à être connecté au patient,

ladite vanne (15) et ledit piston de seringue (8) étant manœuvrables pour assurer, d'une part, une aspiration dudit produit radioactif (11) ou dudit sérum physiologique (16) au sein de ladite seringue (6), et d'autre part, une éjection dudit produit radioactif (11), dudit sérum physiologique ou d'un mélange de ces deux produits, préalablement aspiré(s) au sein de ladite seringue (6), cela au travers dudit cathéter d'injection (17), la dose de produit radioactif prélevée et injectée par ladite seringue (6) étant mesurée par ledit activimètre (3),

caractérisée en ce qu'elle comporte une enceinte blindée (2) réalisée en au moins un matériau radioprotecteur, dans laquelle sont logés ledit support (13) de source radioactive (11), au moins une partie des moyens supports (10) de la seringue (6), ledit activimètre (3), ladite vanne (15) et au moins une partie dudit système de conduites (9, 20, 23, 24), et en ce que ledit support de seringue (10), ladite vanne (15) et ledit support (13) de source radioactive (11) sont agencés verticalement les uns par rapport aux autres, respectivement du haut vers le bas, ledit support de seringue (10) étant agencé pour porter ladite seringue (6) avec son piston (8) orienté vers le haut.

2.- Unité médicale selon la revendication 1, caractérisée en ce que la vanne (15) consiste en une vanne trois voies comprenant :

- une voie supérieure (18), destinée à être raccordée à la seringue (6) de prélèvement et d'injection,
- une voie inférieure (19), destinée à être raccordée à la source de produit radioactif injectable (11), et
- une voie latérale (22), destinée à être raccordée à une première conduite (23) connectée à la source de sérum physiologique (16) et à une seconde conduite (24)

connectée au cathéter d'injection (17), lesdites conduites (23, 24) étant équipées chacune d'un clapet anti-retour (25, 26) convenablement orienté.

3.- Unité médicale selon la revendication 2, caractérisée en ce que l'activimètre (3) a une forme générale tubulaire délimitant un puits central (3') d'axe vertical, destiné à contenir la seringue (6), ledit activimètre (3) étant muni de deux ouvertures, l'une supérieure (4) et l'autre inférieure (5), cette dernière étant orientée en regard de la vanne trois voies (15) et du support (13) de la source radioactive (11).

4.- Unité médicale selon l'une quelconque des revendications 2 ou 3, caractérisée en ce que la voie supérieure (18) de la vanne (15), destinée à être raccordée à la seringue (6), comporte un opercule hermétique destiné à être percé par l'aiguille (9) équipant ladite seringue (6).

5.- Unité médicale selon l'une quelconque des revendications 2 à 4, caractérisée en ce que la voie inférieure (19) de la vanne (15), destinée à être raccordée à la source de produit radioactif injectable (11), est prolongée par une aiguille (20) destinée à percer un opercule (21) obturant le flacon contenant ladite source radioactive (11).

6.- Unité médicale selon l'une quelconque des revendications 1 à 5, caractérisée en ce que les supports (13, 10) de source radioactive (11) et de seringue (6) sont portés chacun par des moyens assurant leur(s) déplacement(s) selon un axe vertical ou sensiblement vertical, cela entre deux positions :

- une première position, dans laquelle un opérateur peut charger la source radioactive (11) et la seringue (6) sur leurs supports respectifs (13, 10), ou à l'inverse les décharger, et
- une seconde position dans laquelle la source radioactive (11) et la seringue (6) sont raccordées à la vanne (15).

7.- Unité médicale selon la revendication 6, caractérisée en ce que les moyens de déplacement du support de seringue (10) permettent son cheminement verticalement au travers d'un orifice (39) ménagé dans l'enceinte blindée (2), entre :

- une position supérieure de chargement/déchargement, dans laquelle ledit support (10) se situe au moins partiellement hors de ladite enceinte (2), et
- une position inférieure de raccordement, dans laquelle la seringue (6) se positionne au sein du puits central (3') de l'activimètre (3) et est raccordée à la vanne (15).

8.- Unité médicale selon l'une quelconque des revendications 6 ou 7, caractérisée en ce que le support (13) de source radioactive (11) chemine au sein de l'enceinte blindée (2) entre ses positions de chargement/déchargement et de

raccordement, ladite enceinte (2) étant encore munie d'une trappe (41) frontale pour permettre l'accès d'un opérateur audit support (13) de source radioactive (11) au moins dans sa position de chargement/déchargement.

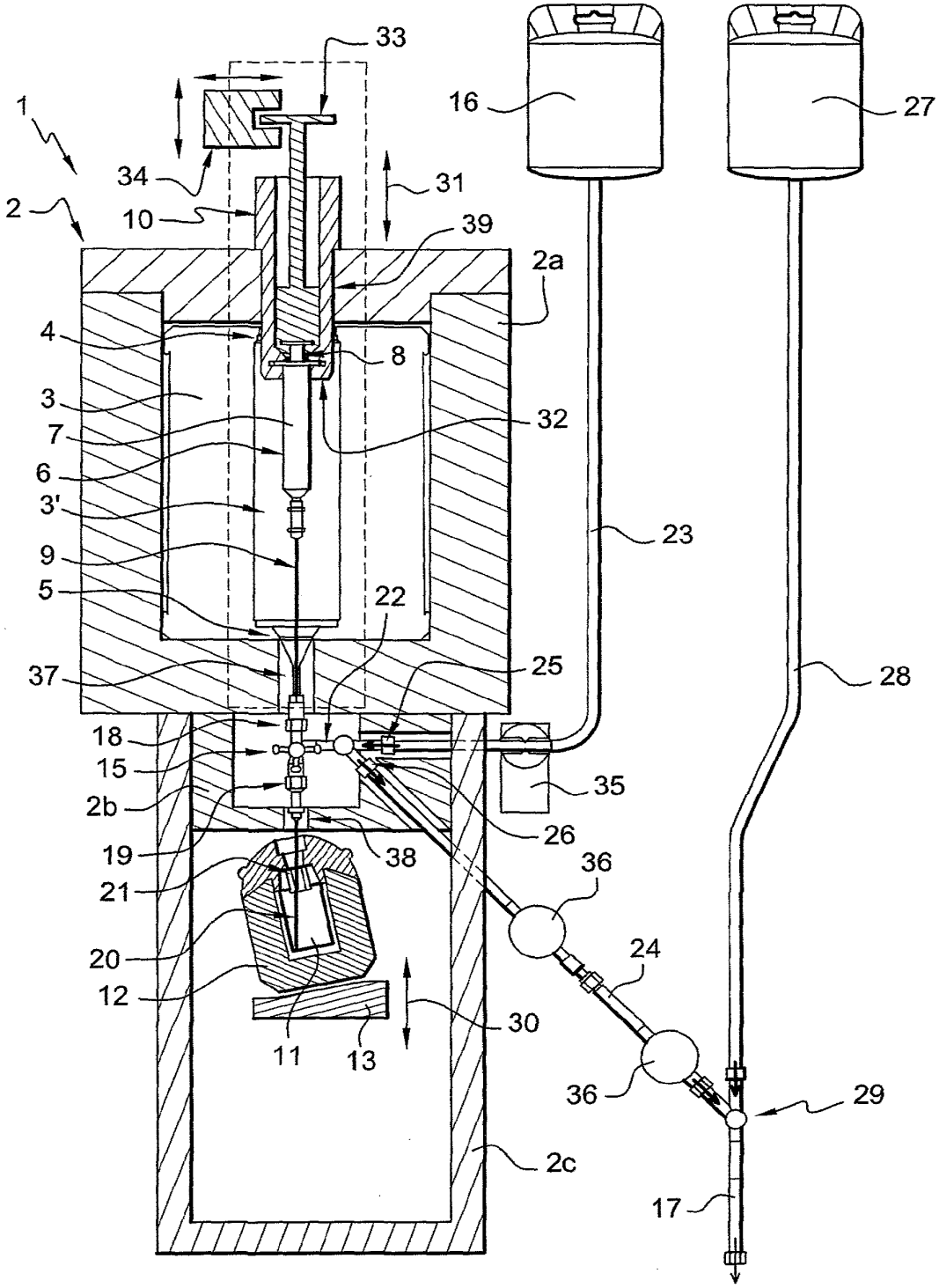
9.- Unité médicale selon l'une quelconque des revendications 1 à 8, caractérisée en ce qu'elle comprend encore des moyens de commande informatiques et/ou électroniques aptes à piloter la vanne (15) et les moyens (33, 34) de manœuvre du piston de seringue (8), cela de manière à mettre en œuvre les opérations de prélèvement et d'éjection par ladite seringue (6), lesquels moyens de commande informatiques/électroniques pilotent également éventuellement les moyens de déplacement du support de seringue (10) et du support de source radioactive (13).

10.- Unité médicale selon la revendication 9, caractérisée en ce que les moyens de manœuvre du piston (8) de la seringue (6) sont de type motoréducteurs débrayables (34), contrôlés par les moyens de commande informatiques/électroniques, pour assurer, d'une part, le prélèvement automatique d'une dose déterminée de produit radioactif au sein de ladite seringue (6), et d'autre part, pour assurer l'injection de cette dose au patient, soit automatiquement, soit manuellement.

11.- Unité médicale selon l'une quelconque des revendications 1 à 10, caractérisée en ce que l'enceinte (2) se compose de trois sous-enceintes (2a, 2b, 2c) alignées verticalement les unes par rapport aux autres, à savoir - une sous-enceinte supérieure (2a) contenant la seringue (6) et l'activimètre (3), - une sous-enceinte intermédiaire (2b) contenant la vanne (15), et - une sous-enceinte inférieure (2c) contenant la source de produit radioactif (11), lesquelles sous-enceintes (2a, 2b, 2c) sont raccordées deux à deux par des ouvertures traversantes (37, 38) au travers desquelles passent certaines des conduites (9, 20) de raccordement hydraulique.

12.- Unité médicale selon l'une quelconque des revendications 1 à 11, caractérisée en ce que les moyens de commande informatiques/électroniques sont pourvus d'une connectique (44) pour l'envoi et/ou la réception de données, en particulier pour les échanges avec un serveur informatique.

13.- Unité médicale selon l'une quelconque des revendications 1 à 12, caractérisée en ce qu'elle est montée sur des roues (40) pour la rendre mobile, et en ce qu'elle intègre éventuellement un système de géolocalisation, par exemple de type GPS.


1
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25
28
18
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2c
17

Fig. 1

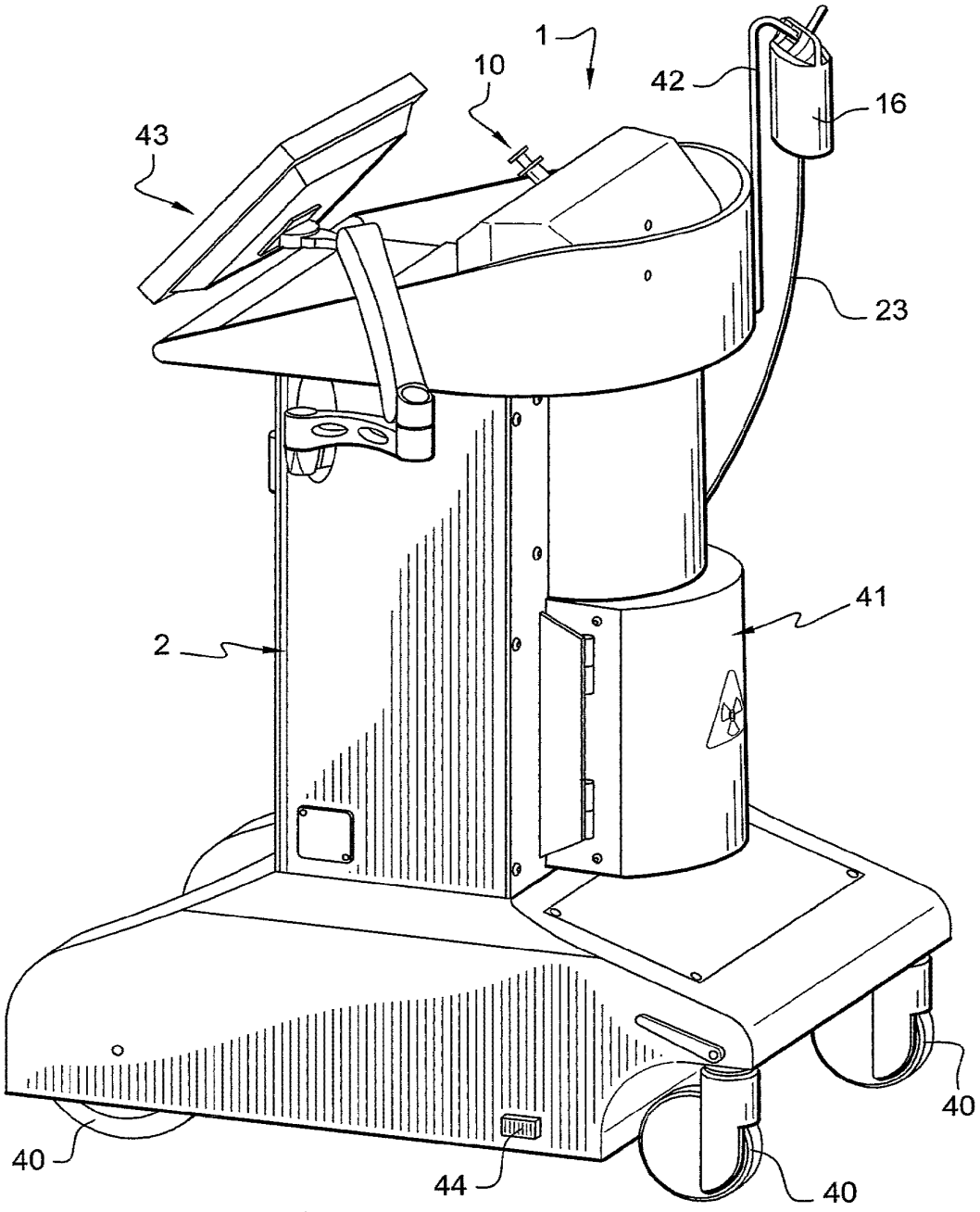

Fig. 2

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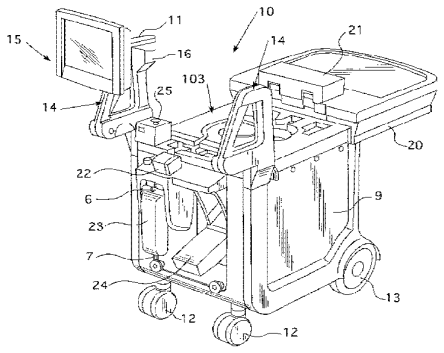

(57) Abstract: A fluid path set for a fluid delivery system includes a tube coil that is designed to optimally position one or more volumes of a pharmaceutical within an ionization chamber to optimally measure and prepare a pharmaceutical dose for administration to a patient. The tube coil may be maintained in a desired dimensional geometry by means of a core structure around which the tube coil is positioned. Novel developments in radiopharmaceutical administration methods and systems include, but are not limited to, the configuration and layout of a fluid path set for use in a fluid delivery system, arrangements for piercing and drawing fluid from a pharmaceutical container (such as a vial), arrangements for optimizing the positioning of a tube coil within an ionization chamber, a handling system for transporting vial shields that maintain an operator's hand and fingers at a safe distance from a pharmaceutical vial, a method for calibrating a radiopharmaceutical delivery system in which the difference between the expected and measured activities of two radioisotopes are used to calculate an estimated error in the measured activity of a third radioisotope and a vial access system that ensures an optimal draw of fluid from a radiopharmaceutical container.

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RADIOPHARMACEUTICAL ADMINISTRATION METHODS, FLUID DELIVERY SYSTEMS AND COMPONENTS THEREOF

BACKGROUND OF THE INVENTION

[1] The present invention relates to methods, systems and components thereof for delivering pharmaceutical substances to patients for imaging procedures and, more particularly, for delivering radiopharmaceuticals to patients for positron emission tomography (PET) or single-photon emission computerized tomography (SPECT) procedures.

[2] PET and SPECT are noninvasive, three-dimensional, imaging procedures that provide information regarding physiological and biochemical processes in patients. PET and SPECT images of, for example, the brain or another organ, are produced by injecting the patient with a dose of a radiopharmaceutical (using, for example, fluid delivery systems such as those disclosed in U.S. Patent No. 6,767,319, JP Publication Nos. 2000-350783 and 2002-306609 and PCT Publication Nos. WO 2004/091688, WO 2006/007750 and 2004/004787, the disclosures of which are incorporated herein by reference) and then creating an image based on the radiation emitted by the radiopharmaceutical. The radiopharmaceutical generally includes a radioactive substance, such as a radioisotope, that can be absorbed by certain cells in the brain or other organs, concentrating it there.

[3] Radioisotopes, especially those with short half-lives, can be relatively safely administered to patients in the form of a labeled substrate, ligand, drug, antibody, neurotransmitter or other compound or molecule that is normally processed or used by the body (for example, glucose). The radioisotope acts as a tracer of specific physiological or biological processes. For example, fluorodeoxyglucose (FDG) is a normal molecule of glucose, the basic energy fuel of cells, to which is attached a radioisotope or radioactive fluor (i.e., F-18). The F-18 radioisotope is produced in a cyclotron equipped with a unit to synthesize the FDG molecule.

[4] Cells (for example, in the brain) that are more active in a given period of time after an injection of FDG will absorb more FDG because they have a higher metabolism and require more energy. The F-18 radioisotope in the FDG molecule experiences a radioactive decay, emitting a positron. When a positron collides with an electron, annihilation occurs, liberating a burst of energy in the form of two beams of gamma rays in opposite directions. The PET scanner detects the emitted gamma rays to compile a three dimensional image.

[5] To allow for cell uptake of the radiopharmaceutical, the patient typically rests for a period of time (45-90 minutes for FDG) after the radiopharmaceutical is injected. After sufficient time for cell uptake has elapsed, the patient is typically placed on a movable bed that slides into the PET (or SPECT or other suitable) scanner. The PET scanner includes several rings of radiation detectors. Each detector emits a brief pulse of light every time it is struck with a gamma ray coming from the radioisotope within the patient's body. The pulse of light is amplified, by for example a photomultiplier, and the information is sent to the computer for forming images of the patient.

[6] To minimize the radiation dose to patients, radiopharmaceuticals containing radioisotopes, such as Flourine-18, Technetium-99, Carbon-11, Copper-64, Gallium-67, Iodine-123, Nitrogen-13, Oxygen-15, Rubidium-82, Thallium-201, Chromium-51, Iodine-131, Iodine-151, Iridium-192, Phosphorus-32, Samarium-153, and Yttrium-90, having relatively short half-lives are typically used for PET and SPECT imaging procedures and other radio-therapies. F-18, for example, has a half-life of 109.7 minutes.

[7] Because of its short half-life, the radioactivity level of the radioisotope will quickly decrease after it is manufactured in a cyclotron or a reactor. Consequently, the elapsed time (and corresponding decrease in radioactivity level of the radioisotope) after synthesis of the radiopharmaceutical must be factored into calculating the volume of radiopharmaceutical required to be injected into the patient to deliver the desired radioactivity dose. If the time delay after synthesis is long in relation to the radioisotope's half-life or if the calculated volume of radiopharmaceutical to be injected into the patient is insufficient to deliver the desired radioactivity dose, the delivered radioactivity dose may be too low to provide diagnostic-quality images, resulting in wasted time and effort and exposing the patient and medical personnel to unnecessary radiation.

[8] Further, long-term radiation exposure to technologists and other personnel working in the scanner room can pose a significant health risk. Although the half-life of the radiopharmaceutical is rather short and the applied dosages are considered an acceptable risk to the patient, under current procedures administering personnel are exposed each time they work with the radiopharmaceuticals and other contaminated materials, such as tubing and syringes, used to inject the radiopharmaceuticals into patients. Constant and repeated exposure over an extended period of time can be harmful.

[9] A number of techniques are used to reduce radiation exposure to medical personnel, including minimizing the time of exposure of personnel, maintaining distance between personnel and the source of radiation and shielding personnel from the source of radiation. In general, the radiopharmaceuticals are typically delivered to a nuclear medicine hospital suite or other medical facility from a radiopharmaceutical synthesis facility (within or outside the hospital or medical facility) equipped with a cyclotron in, for example, a lead-shielded container (often called a "PIG"). Often, the radiopharmaceutical is manually drawn from such containers into a shielded syringe. See, for example, U.S. Pat. No. 5,927,351, disclosing a drawing station for handling radiopharmaceuticals for use in syringes. Remote injection mechanisms can also be used to maintain distance between the operator and the radiopharmaceutical. See, for example, U.S. Pat. No. 5,514,071, disclosing an apparatus for remotely administering radioactive material from a lead encapsulated syringe. Nevertheless, these current procedures and systems still result in unnecessary and repeated exposure of technicians and other medical personnel to radiation.

[10] It has long been recognized as very desirable to develop devices, systems, components and methods for calculating and delivering accurate and effective doses of radiopharmaceuticals to patients, while reducing the exposure of administering or other medical personnel to such hazardous pharmaceuticals.

SUMMARY OF THE INVENTION

[11] The present invention broadly contemplates and provides devices, systems, components and methods for accurately calculating or delivering effective doses of pharmaceuticals to patients.

[12] In a first aspect, the invention provides a fluid path set including a tube coil that is designed to optimally position one or more volumes of a pharmaceutical within an ionization chamber to optimally measure and prepare a pharmaceutical dose for administration to a patient. The tube coil may be maintained in a desired dimensional geometry by means of a core structure around which the tube coil is positioned or coiled.

[13] The fluid path set includes a medical fluid component comprising a first tubing section for connection to a source of a medical fluid, a pharmaceutical component comprising a second tubing section for connection to a source of a pharmaceutical, a coil assembly component comprising a tube coil having a height of approximately 1.53 inches, a diameter of approximately 1.95 inches and a volume capacity of

approximately 12.5 ml, and a connector comprising a first port for connecting the first tubing section of the medical fluid component, a second port for connecting the second tubing section of the pharmaceutical component and a third port for connecting the tube coil of the coil assembly component.

[14] In a second aspect, the present invention provides a vial access system for inserting a cannula into a pharmaceutical container, such as a vial. The vial access system includes structures that shields the operator from exposure to hazardous pharmaceuticals, such as radiopharmaceuticals, and is designed with an inclined bottom surface to tilt the pharmaceutical container from the horizontal and thereby allow the cannula to optimally extract the pharmaceutical from the container.

[15] The vial access system includes a base portion comprising a substantially horizontal lower surface and a sloped upper surface adapted to support a vial comprising a bottom wall and a substantially cylindrical wall connected thereto. The sloped upper surface is adapted to ensure that a residual volume of fluid in the vial gathers in an area defined at least partially by a portion of the junction between the bottom wall and the cylindrical wall of the vial.

[16] In a third aspect, the present invention provides a vented cannula for insertion into a pharmaceutical container, such as a vial. The vented cannula may be used in the vial access system of the present invention or may be fluidly connected to a shielded syringe to provide an alternate fluid delivery system.

[17] The vented cannula includes a main hub comprising two opposed lateral sides and defining a fluid port and a vent, a fluid draw needle in connection with the fluid port and adapted to be placed within the container, a vent needle in connection with the vent and adapted to be placed within the container; and two resilient arms connected to the opposed lateral sides of the main hub. Each of the two arms includes a top edge and a hook member formed thereon and extending outwardly therefrom.

[18] In a fourth aspect, the present invention provides a fluid delivery system having a retractable shielded cover to shield operators of the system from the fluid path components and the pharmaceutical contained therein. In another aspect, the fluid path components and the pharmaceutical may be disposed in a slidable drawer that may be removed from the shielded system to allow access thereto.

[19] The fluid delivery system includes a housing having an upper surface defining a plurality of recessed portions for accommodating one or more components of a fluid path set, a cover movably connected to the housing and a locking mechanism

associated with the cover. The cover is adapted to move between a first position that exposes the upper surface and a second position that overlies the upper surface, and the locking mechanism is adapted to lock the cover in the second position.

[20] In another aspect, the fluid delivery system includes a syringe comprising a body defining a discharge outlet and a plunger movably disposed within the body, a connector comprising a valve member and defining first, second and third ports, a first tubing segment connected between the discharge outlet of the syringe and the first port of the connector, a cannula defining a fluid port, a second tubing segment connected between the fluid port of the cannula and the second port of the connector, a third tubing segment comprising a first end connected to the third port of the connector and a second end comprising a second connector, and a per-patient tubing set comprising a first end that is adapted to be connected to the second connector on the second end of the third tubing segment and a patient end that is adapted to be connected to venous access device in a patient.

[21] In a fifth aspect, the present invention provides a method of priming the fluid path components of the fluid delivery system to remove air therefrom and to prepare the system to administer a pharmaceutical dose to a patient.

[22] A method of priming at least a portion of a fluid path set in a fluid delivery system includes: (1) placing a tubing section of the fluid path set in fluid connection with a source of a radiopharmaceutical; (2) placing a portion of the tubing section within a dose calibrator of the fluid delivery system; (3) pumping a volume of the radiopharmaceutical through the tubing section; (4) monitoring the dose calibrator to determine if a measured activity level is substantially equal to or above a predetermined activity level; and (5) if the measured activity level is substantially equal to or above the predetermined activity level, then concluding that the tubing section of the fluid path set has been primed.

[23] In a sixth aspect, the present invention provides a carrying system for connecting to and transporting a vial shield (containing a pharmaceutical vial). The carrying system may be used to transport the vial shield to and place the vial shield within the fluid delivery system of the present invention. In another aspect, the carrying system may be used to position the vial shield within the vial access device of the present invention.

[24] The vial shield carrying system includes a collar unit adapted to removably engage a flange on the vial shield and a handle unit adapted to engage the collar unit. The collar unit defines two elongated slots formed in a top surface thereof, each of the

slots including a pin disposed therein and extending between two opposing walls thereof. The handle unit includes a handle connected to a U-shaped cross piece that defines two, downwardly extending arms having hook members formed therein. The open ends of the hook members are formed on opposite ends of the arms and are adapted to engage the pins in the slots of the collar unit through rotation of the handle.

[25] In a seventh aspect, the present invention provides a system and a method for calibrating a radiopharmaceutical delivery system in which the difference between the expected (based on decay from the initial activity) and measured activities of two radioisotopes are used to calculate an estimated error in the measured activity of a third radioisotope. In response to a difference between the expected and measured activity of the first or the second radioisotope, the gain of the ionization chamber is adjusted to eliminate or reduce the error for that radioisotope. When the estimated error of the third radioisotope falls within an acceptable range, the activity of the third radioisotope is measured to check that the actual error between the expected and measured activity of the third radioisotope is substantially similar to the estimated error.

[26] Preferably, the energy levels of the first, second and third radioisotopes are less than, greater than, and relatively close to, respectively, the energy level of the radioisotope to be delivered by the system to the patient. In addition, the operator may take consecutive measurements of the first and second radioisotopes (i.e., in an iterative fashion) and adjust the gain of the ionization chamber in response thereto, before measuring the activity of the third radioisotope and comparing it against the estimated error of the third radioisotope.

[27] A method of calibrating includes (1) measuring an activity level of a first radioisotope in an ionization chamber of the fluid delivery system, the first radioisotope having an energy level less than that of the radioisotope to be delivered to the patient; (2) comparing the measured activity level of the first radioisotope to an expected activity level of the first radioisotope; (3) adjusting the gain of the ionization chamber to compensate for the difference, if any, between the measured activity and the expected activity of the first radioisotope; (4) measuring an activity level of a second radioisotope in the ionization chamber of the fluid delivery system, the second radioisotope having an energy level similar to or greater than that of the radioisotope to be delivered to the patient; (5) comparing the measured activity level of the second radioisotope to an expected activity level of the second radioisotope; (6) adjusting the gain of the ionization chamber to compensate for the difference, if

any, between the measured activity and the expected activity of the second radioisotope; and (7) calculating an estimated error in a measured activity of a third radioisotope based on the differences, if any, between the measured activity and the expected activity of the first radioisotope and the measured activity and the expected activity of the second radioisotope.

[28] Broadly contemplated herein are improvements in radiopharmaceutical administration methods and systems. These inventions include, but are not limited to, the configuration and layout of a fluid path set for use in a fluid delivery system, arrangements for piercing and drawing fluid from a radiopharmaceutical container (such as a vial), arrangements for optimizing the positioning of a tube coil within an ionization chamber, a handle / carrying system for transporting vial shields or "pigs" that keeps an operator's hand and fingers at a safe distance from a vial access cap, and a vial access system that ensures an optimal draw of fluid from a radiopharmaceutical container.

[29] The novel features which are considered characteristic of the present invention are set forth herebelow. The invention itself, however, both as to its construction and its method of operation, together with additional objects and advantages thereof, will be best understood from the following description of the specific embodiments when read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[30] For the present invention to be clearly understood and readily practiced, the present invention will be described in conjunction with the following figures, wherein like reference characters designate the same or similar elements, which figures are incorporated into and constitute a part of the specification.

[31] Fig. 1A is a perspective view of a fluid delivery system of the present invention.

[32] Fig. 1B is another perspective view of the fluid delivery system of Fig. 1A with the shielded cover thereof in a retracted position.

[33] Fig. 1C is a top plan view of the fluid delivery system shown in Figs. 1A and 1B with various fluid path components positioned therein.

[34] Fig. 1D is a cross-sectional view taken along line 1D-1D of Fig. 1A.

[35] Fig. 1E is a cross-sectional view taken along line 1E-1E of Fig. 1A.

[36] Fig. 2A is a schematic illustration of the multi-patient fluid path set and components thereof of the present invention.

[37] Fig. 2B is an exploded view showing the multi-patient fluid path set shown in Fig. 2A connected to a fluid source and disposed above the fluid delivery system shown in Figs. 1A-1E.

[38] Fig. 2C is a perspective view of an alternate embodiment of the multi-patient fluid path set of the present invention.

[39] Fig. 3A is an elevational view of a preferred embodiment of a coil assembly of the present invention.

[40] Fig. 3B is a partial cross-sectional view of Fig. 3A.

[41] Fig. 3C is a plan view (in partial cross-section) taken along line 3C-3C of Fig. 3A.

[42] Fig. 3D is a cross-sectional view taken along line 3D-3D of Fig. 3A.

[43] Fig. 3E is a perspective view of the core element of the coil assembly shown in Fig. 3A.

[44] Fig. 3F is an enlarged view of Fig. 1D showing the coil assembly in the ionization chamber of the fluid delivery system.

[45] Fig. 4A is an elevational view of preferred embodiments of a vial shield carrying system and a vial access system of the present invention.

[46] Fig. 4B is a perspective view showing the vial shield, the vial shield carrying system and the vial access system of Fig. 4A.

[47] Fig. 4C is an elevational view of a pharmaceutical vial that may be used in the fluid delivery system of the present invention.

[48] Figs. 5A-5D are various views of an alternate embodiment of a vial shield carrying system of the present invention.

[49] Fig. 6A is a bottom perspective view of a preferred embodiment of a vial access system of the present invention.

[50] Fig. 6B is a top perspective view of the vial access system shown in Fig. 6A.

[51] Fig. 6C is an exploded, perspective view of a preferred embodiment of the vented cannula of the multi-patient fluid path set of the present invention oriented to be connected to the cap of the vial access system shown in Figs. 6A-6B.

[52] Fig. 6D is a perspective view (similar to Fig. 4B) showing the vial access system and the vial-carrying shield disposed in a well of the fluid delivery system, and the vented cannula connected to the cap of the vial access system and in position to be lowered and inserted through the septum cap of the vial shield into the radiopharmaceutical vial.

[53] Fig. 6E is another perspective view (similar to Fig. 6D) showing the cap of the vial access system lowered into position and the vented cannula thereby inserted into the pharmaceutical vial.

[54] Fig. 6F is an enlarged view of Fig. 1E showing the vial access system and the vented cannula of the present invention.

[55] Fig. 6G is a perspective view of the vented cannula shown in Fig. 6C.

[56] Fig. 6H is an elevational view of the vented cannula shown in Fig. 6G.

[57] Fig. 6I is a left-side view of the vented cannula shown in Fig. 6H.

[58] Fig. 6J is a right-side view of the vented cannula shown in Fig. 6H.

[59] Fig. 7 shows a main screen of a graphical user interface of the present invention.

[60] Figs. 8, 9, 10, 11, 12A, 12B, 13, 14, 15, 16A, 16B, 17, 18, 19, 20, 21 and 22 are various depictions of a graphical user interface for use in system preparation tasks.

[61] Figs. 23, 24A-F, 25A, 25B, 26A, 26B, 27A, 27B, 28A, 28B, 29, 30A, 30B, 31, 32A and 32B are various depictions of a graphical user interface for use in patient treatment tasks.

[62] Figs. 33A-C, 34A and 34B are various depictions of a graphical user interface for use in injection history/recall operations or tasks.

[63] Figs. 35, 36, 37, 38, 39A, 39B, 40, 41, 42, 43, 44A-D, 45A-D and 46 are various depictions of a graphical user interface for use in system configuration tasks.

[64] Fig. 47A is a perspective view of the vented cannula shown in Figs. 6C and 6G-6J being utilized as part of a first alternate fluid delivery system.

[65] Fig. 47B is another perspective view showing the first alternate fluid delivery system of Fig. 47A.

[66] Fig. 47C is an elevational view of the first alternate fluid delivery system of Figs. 47A and 47B.

[67] Fig. 48 is a perspective view of the vented cannula shown in Figs. 6C and 6G-6J being utilized as part of a second alternate fluid delivery system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[68] As used herein, the term "pharmaceutical" refers to any substance or drug to be injected or otherwise delivered into the body (either human or animal) in a medical procedure and includes, but is not limited to, substances used in imaging procedures (for example, contrast media) and therapeutic substances. A number of such pharmaceutical substances pose a danger to both the patient and the personnel administering the substance if not handled and/or injected properly. Examples of hazardous pharmaceuticals include, but are not limited to, radiopharmaceuticals, biological pharmaceuticals, chemotherapeutic pharmaceuticals and gene therapeutic pharmaceuticals.

[69] Turning now to the drawings, Figs. 1A-1E show a preferred embodiment of the administration, injector or fluid delivery system 10 of the present invention. The fluid delivery 10 is preferably a cart-like apparatus 9 having wheels 13 and/or casters 12 for allowing the system to be movable. One or more of the wheels 13 may be lockable to prevent the system 10 from moving once it is in position. The system 10 also preferably includes one or more handles 14 for allowing an operator to move or position the system 10. Alternately, the fluid delivery system 10 may be a stand-alone or fixed-position apparatus.

[70] The fluid delivery system 10 includes a display or graphical user interface (GUI) 15 for programming and operating the system 10. The GUI display 15 is preferably attached to one of the handles 14 (as shown) of the system 10. The display 15 may be a color display and incorporate touch-screen capability, as known in the art, for ease of use. The display 15 may be fixed, but is preferably pivotally connected to the fluid delivery system 10 (as shown), by means of a movable arm 11 that is pivotally connected to a joint 16. Further, the display 15 may be tilted or swiveled with respect to the arm 11 to allow for optimal positioning of the display 15 by an operator.

[71] The fluid delivery system 10 preferably includes a retractable lid or cover 20 having a primary handle including a latch release 1 (see Figs. 1D and 1E) and a secondary handle 21. The lid 20 preferably covers an upper surface 103 that defines a number of recessed portions, such as wells and troughs, into which a vial or container (see 902 in Fig. 4C) of a pharmaceutical or a radiopharmaceutical (discussed in more detail below) and various components of a multi-patient fluid path set (hereinafter MPDS; discussed in more detail below) may be positioned during an injection procedure. A locking mechanism, such as a combination or a key lock (not shown), may be used to lock the lid 20 in a closed position to, for example, prevent use or access of the system 10 by unauthorized personnel. In another embodiment, the locking mechanism may be a software-implemented lock, such as a password-protected access point, that is accessible through the display 15 and is adapted to lock the cover in a closed position and/or to prevent unauthorized personnel from accessing or operating the system 10.

[72] The lid 20 is slidable or retractable (by, for example, using primary handle and latch release 1) with respect to the cart 9 to allow for insertion and removal of the vial or container 902 and MPDS from the fluid delivery system 10. The lid 20, upper surface 103 and various other portions of the cart 9 preferably include suitable radioactive shielding (such as lead) for minimizing potential radiation exposure from the radiopharmaceutical to the operator. In this manner, the radiopharmaceutical vial 902 and the components of the MPDS can lie below the plane of surface 103, whereupon the surface 103 or one or more portions thereof can be covered by the lid 20 during use to limit radiation exposure to the operator or other medical personnel. Further, instead of a retractable lid 20, surface 103 itself could be disposed on a portion of the injector apparatus 10 (e.g., a drawer-type mechanism) that slidably displaces with respect to a remainder of the injector apparatus 10.

[73] As further shown in Figs. 1A, 1B and 1D, the fluid delivery system 10 includes a pumping mechanism, such as a peristaltic pump 22, a removable/replaceable source of medical fluid 23 (such as saline), a printer 24 and an interrupt button 25. The peristaltic pump 22 is shown in a closed position in Fig. 1A, but may be opened (see Figs. 1B, 1C and 2B) to receive a length of tubing 27(see Figs. 1C and 2) in fluid connection with the source of medical fluid 23 to inject the fluid into a patient (discussed in more detail below). While a peristaltic pump 22 is currently preferred, any suitable type of pumping mechanism, such as a piston-driven syringe pump, gear pump, rotary pump or in-line pump, may be used.

[74] The printer 24 may be used to generate records of the injection and/or imaging procedures performed on patients, for inclusion in patients' medical records or for billing or inventory purposes. The printer 24 may be pivotally connected to the system 10 (see Fig. 1B) to allow an operator to load paper or labels into the printer 24.

[75] The interrupt button 25 allows an operator to quickly and easily pause or abort an injection procedure in the event of, for example, patient discomfort or an emergency, without having to resort to the GUI display 15 (which also can be manipulated to pause or abort an injection procedure). The interrupt button 25 may be connected to LEDs and/or a printed circuit board to provide visual and/or auditory alarms when the interrupt button 25 has been activated.

[76] Turning to Figs. 1C-1E, 2A and 2B, additional features and components of the fluid delivery system 10, including the upper surface 103, the MPDS 200, a vial access device 600 and a single-patient fluid path set 700 (hereinafter SPDS), will be discussed.

[77] As shown in Fig. 1C, the upper surface 103 generally defines wells and recesses or troughs into which various components of the MPDS are situated. Specifically, a first recess or trough 107 accommodates a first tubing section 204 of the MPDS 200 and a tubing holder 150 for holding the tubing section 204 and preventing it from getting kinked or tangled with, for example, the SPDS 700. The first tubing section 204 may also include the tubing length 27 that is placed within the peristaltic pump 22 and is in fluid connection with the medical fluid source 23.

[78] The first trough 107 leads into a second recess or trough 113 that accommodates a second pumping mechanism 180, such as a peristaltic pump, and a T-connector 205 (preferably including check valves 214, 215) of the MPDS 200. As shown in Fig. 1C, the second trough 113 also leads to a first well 111 that accommodates a vial access device 600 and a radiopharmaceutical vial or container 902 disposed in a vial shield or PIG 554 (discussed in more detail below) and to a second well 121 that accommodates a dose calibrator or ionization chamber 160 for the fluid delivery system 10. As shown in Figs. 1D and 3F, the ionization chamber 160 preferably accommodates a coil assembly 400 of the MPDS 200 (discussed in more detail below).

[79] A third recess or trough 125 extends from the second well 121 to a third well 127 and further along the surface 103 of the fluid delivery system 10. The trough 125 accommodates a T-connector 222 of the MPDS 200, two pinch valves 170, 172, an

air detector 174 and a mount or retainer 176 for holding the connector end 228 of the MPDS 200. The pinch valves are preferably powered and controlled by the fluid delivery system 10, but alternately could be manually-operated. In another alternate embodiment, the pinch valves 170, 172 and the T-connector 222 of the MPDS 200 may be replaced with a manual or automated 3-way stopcock.

[80] The third well 127 accommodates a waste receptacle or bag 224 for receiving medical fluid and/or pharmaceutical that is discarded during, for example, a priming procedure (discussed in more detail below) to prepare the system 10 for an injection procedure.

[81] As shown in Fig. 1C, the SPDS 700 includes a length of tubing (preferably coiled, as shown) having a first end 702 that is attachable to the connector end 228 of the MPDS 200 and a patient end 704 having a luer connector that is attachable to, for example, a catheter (not shown) placed in a venous structure of a patient. As discussed in more detail below, the MPDS 200 may be used for multiple patients but the SPDS 700 is intended to be used on a per-patient basis and discarded after use with a single patient to prevent, for example, cross-contamination between patients.

[82] As can be appreciated after reviewing Fig. 1A-1E, the secondary handle 21 of lid 20 overlies the tubing holder 150 and the mount 176 when the lid 20 and handle 21 are closed to cover the MPDS 200. The secondary handle 21 may be flipped open (from the closed position shown in Fig. 1A) without retracting the cover 20 to allow an operator to connect the SPDS 700 to the MPDS 200(as discussed in more detail below). As best shown in Fig. 1C, the SPDS 700 may be placed under the secondary handle 21 when it is closed.

[83] The fluid delivery system 10 further includes a system controller 5 (see Figs. 1D and 1E) in communication with the various components thereof, including the GUI 15, the pumps 22, 180, the dose calibrator or ionization chamber 160, the stop button 25, the air detector 176, the printer 24 and the motors 30, 31 (see Fig. 3F) for pinch valves 170, 172, respectively, for controlling the operation of the system 10. The system controller 5 is preferably a single-board computer, including a CPU having a main memory.

[84] As can be appreciated, the wells and troughs formed in the upper surface 103 can be sized, configured or arranged as suitable for the length, design or configuration of the MPDS 200 or other components thereof, including the radiopharmaceutical vial 902, vial shield 554, vial access device 600, ionization chamber 160, waste receptacle 224, etc.

[85] It should be understood that Fig. 1C in no way is intended to convey dimensions or relative dimensions of the aforementioned recessed portions or MPDS components; instead, Fig. 1C conveys general positional relationships of such recessed portions with respect to one another.

[86] It should further be understood and appreciated that the recessed portions shown and described with respect to Fig. 1C are preferably encased throughout with suitable radioactive shielding to further minimize exposure to an operator.

[87] Turning now to Figs. 2A and 2B, a preferred embodiment of the MPDS 200 and components thereof will be discussed. In addition, specific details of the coil assembly 400 employed in the MPDS 200 are shown and described with respect to Figs. 3A-3F and Fig. 1D.

[88] By way of a general overview, the MPDS 200 in accordance with at least one presently preferred embodiment of the present invention allows for FDG (or other radiopharmaceutical) to be drawn from a bulk radiopharmaceutical vial 902 and placed into a coil assembly 400 that allows an ionization chamber 160 to measure the amount of activity in the coil assembly 400. Once the system prepares a dose having the desired activity level, the fluid delivery system 10 will deliver the FDG dose to the patient (through the SPDS 700).

[89] Generally, the MPDS 200 can be considered in terms of four components: (1) a medical fluid or saline component; (2) an FDG or pharmaceutical component; (3) a coil assembly component; and (4) a waste component. The saline component preferably draws saline out of a bulk source 23 (e.g., via peristaltic pump 22). This is then used to prime the MPDS (i.e., remove air therefrom), position FDG in the coil assembly 400 in the ionization chamber 160, and then deliver the dose to the patient.

[90] The FDG component preferably serves to draw FDG out of a bulk radiopharmaceutical vial 902 (e.g., via peristaltic pump 180) and place the same into the fluid path to the ionization chamber 160.

[91] The coil assembly component preferably is employed to position the radiopharmaceutical to allow its radioactivity level to be optimally measured by the ionization chamber 160. Through the arrangement of the coil assembly 400 (as discussed in more detail below), the radiopharmaceutical can be optimally oriented and located within the "linear region" of the ionization chamber 160 to more accurately measure its activity level and prepare an optimal dose for injection into a patient.

[92] The waste component preferably holds the saline fluid and/or radiopharmaceutical that are discarded during the prime and dose preparation procedures, which are conducted to prepare the fluid path and the pharmaceutical dose for injection into a patient.

[93] Fig. 2A schematically illustrates the MPDS 200 in accordance with a preferred embodiment of the present invention. The MPDS shown in Fig. 2A may preferably be pre-connected as shown and may originally be stored in a sterile packet or container for use in an injector apparatus, such as fluid delivery system 10, when desired. For a non-restrictive and illustrative appreciation of a manner in which MPDS 200 can be incorporated in an injector apparatus, simultaneous reference may be made to Figs. 1A-1E and 2B (and the discussion thereof hereinabove).

[94] Primary components of MPDS 200 include, as shown, a spike 202 for connecting the MPDS to the medical fluid or saline source 23, a vented cannula 208 for connecting with a source of FDG or other radiopharmaceutical, a coil assembly 400, a T-connector 205 with check valves 214, 215 for fluidly connecting the saline source 23, the radiopharmaceutical source and the coil assembly 400, a waste bag 224, a connector end 228, and a T-connector 222 for fluidly connecting the coil assembly 400, the waste bag 224 and the connector end 228.

[95] In general, MPDS 200 and fluid delivery system 10 are configured for priming (i.e., purging air from) the MPDS 200, delivering pharmaceutical (e.g., FDG) to a patient, and providing a saline flush, while minimizing or eliminating exposure of administering or operating personnel to the detrimental effects of the pharmaceutical and minimizing or eliminating creation of contaminated waste. Moreover, MPDS 200 and other elements of the present invention also facilitate safe delivery of the pharmaceutical to multiple destinations (for example, dose delivery to a series of patients).

[96] A T-connector 205 and check valves 214, 215 preferably accommodate a first tubing section 204 that is in fluid connection with spike 202 and a second tubing section 210 in fluid connection with cannula 208. The check valves 214, 215 may be integrally formed with the T-connector 205 or may be separate components, or they could be combined into a single dual check valve. The check valves 214, 215 prevent saline from being pumped by peristaltic pump 22 into second tubing section 210 and the pharmaceutical from being pumped by peristaltic pump 180 into the first tubing section 204.

[97] A third tubing section 216 thence preferably leads to coil assembly 400 (including tube coil 444), and a fourth tubing section 220 preferably leads from the coil assembly 400 to the T-connector 222. As described below, in a preferred embodiment the tube coil 444 is formed from a tubing section 217 that has dimensions different from those of the third tubing section 216 and the fourth tubing section 220. In an alternate embodiment, the third tubing section 216, the tube coil 444 and the fourth tubing section 220 are formed from the same length of tubing.

[98] A fifth tubing section 226 leads from the T-connector 222 to the waste receptacle 224 and a sixth tubing section 230 leads from the T-connector 222 to the connector end 228. As shown above in Fig. 1C, the connector end 228 mates with the first end 702 of the SPDS 700 for delivery of a pharmaceutical to a patient.

[99] In a preferred embodiment, the connector end 228 is a swabable luer valve (Part No. 245204024 provided by Halkey-Roberts Corporation of St. Petersburg, FL) that is biased to close or seal off the connector end 228 of the MPDS 200 when the SPDS 700 is not connected thereto. The swabable luer valve prevents the MPDS 200 from being contaminated and allows an operator to swab or clean (by, for example, an alcohol wipe) the connector end 228 prior to connecting an SPDS 7000 thereto. Alternately, however, the connector end 228 may be a standard luer connector as known in the art.

[100] As schematically shown in Fig. 2A, the tubing length 27 of the first tubing section 204 can be placed within pump 22 (indicated by dotted lines) to pump saline or other medical fluid from source 23 and a portion of the second tubing section 210 can be placed within pump 180 (indicated by dotted lines) to pump a radiopharmaceutical from a radiopharmaceutical source.

[101] Absolute and relative dimensions of the components shown in Fig. 2A, including tubing, may be chosen to best suit the applications at hand. Preferably, the first tubing section 204 is approximately 56.75 inches in length, has an outer diameter (OD) of approximately 0.188 inches and an inner diameter (ID) of approximately 0.062 inches and has a 45 durometer, the third tubing section 216 is approximately 15 inches in length, has an OD of approximately 0.163 inches and an ID of approximately 0.062 inches and has a 60 durometer, the fourth tubing section 220 is approximately 12 inches in length, has an OD of approximately 0.163 inches and an ID of approximately 0.062 inches and has a 60 durometer, and the fifth tubing section 226 and the sixth tubing section 230 are each approximately 5 inches in length, have an OD of approximately 0.163 inches and an ID of approximately 0.062 inches and have a 60 durometer. The second tubing section 210 is approximately

8.75 inches in length and is formed of microbore tubing having an OD of about 0.094 inches and an ID of about 0.032 inches and a 45 durometer. The tubing in tube coil 444 preferably is approximately 41 inches in length, has an OD of about 0.218 inches and an ID of about 0.156 inches and an 80 durometer.

[102] Preferably, the microbore tubing of second tubing section 210 is formed of, for example, silicone, C-Flex, or silicone-like PVC material. Essentially, the use of microbore tubing in second tubing section 210 improves volume accuracy and thereby improves measured activity accuracy (i.e., of pharmaceutical delivered to the patient) and reduces radiopharmaceutical waste.

[103] By way of tubing material for the other tubing sections 204, 216, 220, 226, 230 and tube coil 444, essentially any suitable polymeric material, including standard PVC or pump tubing, may be employed.

[104] In an alternate embodiment of the MPDS 200' shown in Fig. 2C, a conventional manifold 228' or stopcock may be substituted for the connector end 228 of the MPDS 200 (all other components of the MPDS 200' may be identical or similar to those shown in Fig. 2A and are denoted in Fig. 2C by prime notations). As shown in Fig. 2C, the manifold 228' includes three outlet ports (preferably including swabable valves) to which respective first ends 702' of the SPDSs 700' are connected. By connecting the respective patient ends 704 of the SPDSs 700' to, for example, catheters placed in patients, pharmaceutical doses can be delivered sequentially or concurrently to three separate patients. While the manifold 228' shown in Fig. 2C includes three ports for connection to three SPDSs 700', two, four, five or any suitable number of ports may be included in manifold 228' for connection with a like number of SPDSs 700'.

[105] Referring again to Figs. 1A-2B, the placement of the MPDS 200 in the fluid delivery system 10 and the connection of the SPDS will now be discussed. To set up the system 10 at, for example, the beginning of the day, the operator lifts the secondary handle 21, grasps the primary handle and latch release 1 and retracts the lid 20 to reveal the upper surface 103 of the system 10. If a used MPDS 200 is present in the system 10, the operator will remove and discard it.

[106] A new MPDS 200 may be removed from its (typically sterile) packaging and placed in the system 10 as shown in Fig. 1C. This includes placing the waste receptacle 224 into well 127, placing coil assembly 400 into ionization chamber 160, placing second tubing section 210 into operative connection with pump 180, placing the tubing length 27 of the first tubing section 204 into operative connection with pump

22 and tubing holder 150, placing vented cannula 208 into fluid connection with radiopharmaceutical source or vial 902 located in well 111, placing fifth tubing section 226 in operative connection with pinch valve 170, and placing sixth tubing section 230 in operative connection with pinch valve 172, air detector 174 and mount 176. A saline source 23 may be hung on hook 6 (see Figs. 1A, 1B and 2B) or otherwise mounted on fluid delivery system 10, and spike 202 is inserted into port 7 (see Figs. 1A, 1B and 2B) of source 23 to fluidly connect the MPDS 200 to the source 23. Of course, this installation procedure does not need to completed in the order described above, but may be completed in any suitable order consistent with the description or drawings hereof.

[107] After the MPDS 200 is installed and preferably primed (as discussed below), the first end 702 of the SPDS 700 is connected to the connector end 228 of the MPDS 200 and the SPDS 700 is preferably primed to provide a wet connection at the patient end 704 of the SPDS 700, which is then connected to a catheter (not shown) located in a patient. The SPDS 700 is preferably a coiled tubing formed of standard PVC, approximately 60 inches in length and having an OD of approximately 0.100 inches and an ID of approximately 0.060 inches and a 90 durometer.

[108] As shown in Figs. 2A and 2B, the MPDS 200 includes a coil assembly 400. In the broadest sense, coil assembly 400 may include a section of tubing (including portions of third and fourth tubing sections 216, 220) that is simply gathered (in a coiled or an uncoiled, amorphous fashion) and placed inside ionization chamber 160.

[109] As shown in Figs. 3A-3F, however, a preferred embodiment of coil assembly 400 includes a (preferably thermoformed) core element or structure 446 that is preferably configured for allowing a tubing section 217 to be wrapped thereupon and to assume the coiled tube section indicated at 444. As such, the coiled tube section or tube coil 444 is preferably formed on the core element 446 to facilitate optimal positioning of the tube coil 444 within the ionization chamber 160.

[110] To facilitate positioning of the tube coil 444, the core element 446 preferably includes a tube channel 410 defined by shoulders 412, 414 (see Fig. 3B) that retain tube coil 444 therebetween to hold the tube coil 444 in position and to prevent tube kinking. Further, the upper surface 420 of core element 446 defines an inlet channel or groove 422 and an outlet channel or groove 424 to accommodate third tubing section 216 and fourth tubing section 220, respectively.

[111] In an alternate embodiment, the core element 446 could include a coiled tube channel (not shown) formed therealong to further guide and retain the tubing segments or turns that form tube coil 444 between shoulders 412, 414.

[112] The core element 446 preferably is self-centering when inserted into the sleeve 162 of the ionization chamber 160 of the fluid delivery system 10 to thereby facilitate optimal performance (see Fig. 3F). This may be achieved either through structural features of the coil assembly 400, the structure of core element 446 itself, or a combination thereof when used with the sleeve 162 of the ionization chamber 160.

[113] As best shown in Fig. 3E, the core element 446 is preferably formed by folding two elements (450, 452) together along an integral hinge 455. Suitable form-locking mechanisms can be molded onto the core element 446 to facilitate clasping of the elements 450, 452 together.

[114] Figs. 1C, 1D and 3F show coil assembly 400 positioned concentrically in the sleeve 162 of the ionization chamber 160. The core element 446 and the tube coil 444 are sized and dimensioned so that the coil assembly 400 is optimally positioned within the "linear region" of the ionization chamber 160 so that the ionization chamber 160 can accurately determine the activity level of one or more volumes of radiopharmaceutical that is located within the tube coil 444. The "linear region" of an ionization chamber is the region in which activity level measurements are repeatable and predictable. For the preferred ionization chamber (Model IK-102 Short Ionization Chamber provided by Veenstra Instruments) used in system 10, the "linear region" is located within a window of 5 mm to 65 mm measured from the base or bottom wall 160a of the ionization chamber 160 (see Fig. 3F).

[115] In a preferred embodiment, the tube coil 444 is comprised of approximately 7 turns (see Figs. 3A and 3B) formed from a length of tubing that is approximately 41.0 inches. As shown in Fig. 3B, the height H of the tube coil 444 is approximately 1.53 inches and the diameter D of the tube coil 444 is approximately 1.95 inches. The tube coil 444 is preferably formed from a tube having an OD of 0.218 inches and an ID of 0.156 inches. Further, based on the length and ID of the tubing, the tube coil 444 preferably has a volume capacity of approximately 12.5 ml.

[116] As discussed heretofore, a source, container or vial 902 (see Fig. 4C) of a pharmaceutical or radiopharmaceutical is placed into the fluid delivery system 10 (e.g., in well 111 formed in upper surface 103) to prepare and perform an injection procedure. A radiopharmaceutical container or vial 902 is typically placed in a conventional vial shield or PIG 554 for transport by personnel.

[117] Turning now to Figs. 4A and 4B, preferred embodiments of a vial shield carrying device or system 500 and a vial access system 600 of the present invention are shown. Vial access system 600 is removably disposed within well 111 of fluid delivery system 10 and operates to hold vial shield 554 and to access the contents of the vial 902 contained therein. (Vial access system 600 will be described in more detail below with reference to Figs. 6A-6J.

[118] As best shown in Fig. 4A, the vial shield 544 (containing a radiopharmaceutical vial 902) includes a flange 504 formed along a top end thereof and a removable septum cap 562 that is securely and removably engaged with the vial shield 544 (e.g., via threading) to allow insertion and removal of the vial 902 therefrom.

[119] As shown in Figs. 4A and 4B, the carrying system 500 includes a collar unit 502 that removably engages the flange 504 formed on the vial shield 554. The collar 502 may be formed in two pieces 506, 508 that are pivotally connected together (e.g., at one end thereof) to allow the collar 502 to engage and disengage the flange 504.

[120] The collar 502 includes two elongated slots 510 formed in a top surface therein. As best shown in Fig. 4B, the slots 510 each include a pin 512 disposed therein and extending between two opposing walls 514 thereof.

[121] The carrying system 500 further includes a handle unit 520 that engages with the collar unit 502 and the septum cap 562 to allow the vial shield 554 (and vial 902) to be carried and installed in the fluid delivery system 10. The handle unit 520 includes a handle 556 that is rigidly connected to a generally U-shaped cross piece 564a. The cross-piece 564a defines two, downwardly extending arms 530 having slots 532 formed thereon.

[122] The slots 523 each form a slight hook on the ends thereof and are adapted to engage and retain a second cross piece 564b that supports a plunger 566 having a generally frustoconical shape that mates with a generally frustoconical recess of the septum cap 562 (see Fig. 4B).

[123] The second cross piece 564b is also generally U-shaped and defines two downwardly extending arms 534 having hooks 536 formed therein. The open ends of the hooks 536 are formed on opposite ends of the arms 534 and are adapted to accept and retain the pins 512 in slots 510 of collar 502. The slots 510 are sized to provide sufficient clearance for the arms 534 to be inserted thereinto (in a downward direction) and for the hooks 536 to engage pins 512 (through rotation of handle 556).

[124] The plunger 566 is connected to the second cross piece 564b by means of a connector (such as a screw 540) and a spring 538. The plunger 566 is biased by spring 538 to ensure a tight fit between the plunger 566 and the septum cap 562.

[125] To engage and carry the vial shield 554, the collar 502 is connected to the flange 504 of the vial shield 554 as described above. The handle unit 520 is then moved into proximity to the vial shield 554 (by an operator grasping the handle 556 and moving the unit 520 into position) and the arms 534 are lowered into the slots 510 of the collar 502. At substantially the same time, the plunger 566 is engaged with the septum cap 562, with the spring 538 insuring a tight fit between the two. The operator then turns the handle unit 520 in a clockwise direction (see Arrow A in Fig. 4A) to seat the pins 512 in slots 510 into the hooks 536 of arms 534.

[126] The operator then lifts the combined vial shield 554 and vial carrying system 500 (by moving the handle unit 520 in an upward direction) and transports it to, for example, the fluid delivery system 10. The operator then lowers the vial shield 554 into the vial access system 600 disposed in well 111 (see Fig. 4A) and rotates the handle unit 520 in a counter-clockwise direction to disengage the hooks 536 from the pins 512. The operator then lifts the handle 556 in an upward direction to remove the arms 534 from the slots 510 and the plunger 566 from the septum cap 562, thereby leaving the vial shield 554 (with septum cap 562 and collar 502) in vial access device 600 in well 111 (see Fig. 4B).

[127] In a preferred embodiment, the plunger 566 includes radioactive shielding (such as lead) to shield the operator from radiation that would otherwise leak through or be emitted from the septum of the septum cap 562. Together with the vial shield 554 and the septum cap 562, the plunger 556 of the vial carrying system 500 shields the operator from the radiation emitted by the radiopharmaceutical and prevents unnecessary radiation exposure. Further by extending the handle 556 from the vial shield 554, the distance between the two functions to also lessen any possible radiation exposure to the operator.

[128] An alternate embodiment of the carrying system is shown in Figs. 5A-5D. As with the preferred embodiment described above with respect to Figs. 4A and 4B, the carrying system 1500 helps minimize operator exposure to radiation. Dimensions shown in Fig. 5A are for illustrative and non-restrictive purposes; here they are given in inches. As with Figs. 4A and 4B, generally contemplated here is an integral carrying system 1500 that enables the vial shield 1554 to be carried and placed in the fluid delivery system 10 with minimal operator finger/hand radiation exposure

because the design of the carrying system 1500 increases the distance from the vial 902 contained within the vial shield 1554.

[129] Shown in Figs. 5A and 5C is a vial shield 1554 with a plunger 1566 of the carrying/installation handle system 1500 engaged with the septum cap 1562 of the vial shield 1544. The septum cap 1562 engages securely with the vial shield 1554 (e.g., via threading) to provide suitable radioactive shielding.

[130] As shown in Figs. 5A-5D, a crosspiece 1564a with a central aperture is rigidly connected to handle 1556 and is preferably configured to slidably accommodate an extension tube 1558. At a free end of extension tube 1558, the plunger 1566 is preferably disposed to engage with septum cap 1562. Though this engagement may be embodied in essentially any suitable way, here plunger 1566 has a generally frustoconical shape that engages with a generally frustoconical recess of septum cap 1562.

[131] As further shown in Figs. 5A and 5B (and as can be better appreciated by the perspective views in Figs. 5C and 5D), handle 1556 preferably terminates in a ring 1564b that is configured for engaging with structural features of cap 1562 (to be described more fully below).

[132] As shown in Fig. 5B, plunger 1566 may be hingedly or pivotably connected to extension tube 1558 via a hinge or pivot connection 1568, which provides freedom of motion to allow the plunger 1566 to mate with the septum cap 1562 without the operator having to otherwise place her hand and fingers directly above the septum cap 1562 before it is covered by the plunger 1566 (thereby reducing the possibility of radiation exposure to the operator).

[133] While Figs. 5A-5C show handle 1556 in a retracted position, i.e., maximally displaced away from plunger 1566, Fig. 5D shows in perspective view a different stage of the engagement of handle 1556 with vial shield 1554. As such, Figs. 5A-5C shows handle 1556 maximally retracted from plunger 1566 (and, by extension, cap 1562), while Fig. 5D shows handle 1556 in a "fully engaged" configuration with respect to cap 1562.

[134] Preferably, plunger 1566 will initially mate with cap 1562. Thence, handle 1556 is preferably moved towards cap 1562 (conceptually progressing from Fig. 5B to 5D) such that slots 1570 on ring 1564b fit over and capture posts 1572 (through clockwise rotation of handle 1556) on cap 1562. The handle 1556 may then be lifted to carry and deposit the vial shield 1554 in the well 111, as described above.

The carrying system 1500 is disengaged from the vial shield 1554 through counter-clockwise rotation of the handle 1556 to disengage the capture posts 1572 from the slots 1570 on the ring 1564b. Of course, after the contents of the vial 902 are depleted, the carrying system 1500 can be attached to the vial shield 1554 as described above to remove the vial shield 1554 and the vial 902 from the fluid delivery system 10.

[135] As discussed above with respect to Figs. 4A-4B, the fluid delivery system 10 includes a vial access system 600 that is removably disposed within well 111 of fluid delivery system 10 and is adapted to hold vial shield 554, 1554 and to provide access to the contents of the vial 902 within vial shield 554, 1554.

[136] Because vials (such as vial 902 described herein) typically come in various sizes, such as 10 ml, 15 ml, 20 ml and 30 ml, the fluid delivery system 10 of the present invention is intended to accommodate various vial sizes. To do so, the fluid delivery system 10 may include one or more vial shields and vial access systems (varying primarily in size in relation to the preferred embodiment of the vial shields 554, 1554 and vial access system 600 disclosed and described herein) that are specifically sized to accommodate known vial sizes. In a preferred embodiment, three vial shields and vial access systems 600 are provided with the fluid delivery system 10, and the well 111 is configured and designed to accept each of the vial access systems 600. However, the fluid delivery system 10 can be provided with one, four, five or any suitable number of vial shields and vial access systems depending on evolving needs or changes in the size or shape of the vials. Thus, depending on the size of the vial used at a clinical site or for a particular procedure, an operator of the fluid delivery system 10 can select the appropriate vial shield and vial access system and place it in the well 111 of the fluid delivery system to enable a fluid injection procedure.

[137] Preferred embodiments of the vial access system 600 and the vented cannula 208 of the MPDS 200 are described below in relation to Figs. 6A-6J (and with reference to Figs. 4A and 4B). Generally, as best shown in Figs. 6A, 6B and 6F, the vial access system 600 includes a base portion 670 that preferably includes a sloped surface 672, the function of which will be more fully appreciated herebelow. Two (preferably removable and extendable) support members or pins 674 are provided to support and retain a vial shield 554 (i.e., enclosing a vial 902; see Fig. 4C) when it is placed on the sloped surface 672 (e.g., after being carried and disposed there using the vial shield carrying systems 500, 1500 discussed above).

[138] As shown, the vial access system 600 further includes a vertical support arm 676 that is disposed within a housing 678. A cap member 684 and a handle member 682 are connected to an upper end of the vertical support arm 676. The vertical support arm 676 is preferably slidably and rotationally displaceable with respect to the housing 678. That is, the arm 676 may slide and rotate with respect to the housing 678 (see e.g., Figs. 4B and 6D) to allow the vial shield 554 to be readily inserted and removed therefrom and to lower the vented cannula 208 into the vial 902 contained within the vial shield 554 (as discussed in more detail below).

[139] The handle 682 is used by an operator or technician to insert and remove the vial access system 600 from the well 111 of the fluid delivery system 10. The handle 682 is preferably connected to the vertical support arm 676 via a suitable pivot connection (such as a hinge or bolt connection) 680 to permit movement of the handle 682 between an extended, carrying position (see Fig. 6D) for carrying the vial access system 600 and a horizontal or operating position (see Figs. 6B and 6E) in which the handle 682 rests on top of the cap 684 (e.g., when the vial access system 600 is disposed in the well 111), thereby allowing the cover 20 of the fluid delivery system 10 to be closed.

[140] The cap 684 is preferably rigidly connected to the vertical support arm 676 via an arm 650 (see Figs. 6A and 6D), but it may be pivotally connected to the vertical support arm 676 via, for example, a pivot connection (not shown) or adjustably connected to the vertical support arm 676 via, for example, a slot (not shown) formed in the arm 650. As best shown in Figs. 6E and 6F, when the cap 684 is lowered (by sliding the vertical support arm 676 within the housing 678) to insert the cannula 208 into the vial 902 within the vial shield 554, and the handle 682 is pivoted to a horizontal position atop the cap 684, the cap 684 and the handle 682 (and thus the remainder of the vial access system 600) lies below or flush with the upper surface 103 of the fluid delivery system 10, thereby allowing the cover 20 to close over the upper surface 103 of the fluid delivery system 10 and the MPDS 200 installed therein. The cap 684 preferably includes or is formed with radioactive shielding material (e.g., lead) to minimize radiation exposure to personnel from the FDG or other radioactive solution contained within the vial 902 in the vial shield 554.

[141] As best shown in Figs. 6A and 6C, the underside of cap 684 includes a mounting mechanism 686 for accepting the cannula 208 (or other suitable type of spike, cannula or needle) for piercing the septum of a vial 902 or other pharmaceutical container in the vial shield 554. The mounting mechanism 686 preferably includes

two arms 687 that define a groove or slot 688 therebetween. Each of the arms 687 includes a tab member 690 extending downwardly therefrom.

[142] The vented cannula 208, in accordance with a preferred embodiment of the present invention, may be employed for spiking a pharmaceutical source (such as the radiopharmaceutical vial 902 discussed above) and preferably includes a main hub 332 to which are connected (or integrally formed) two, resilient spring arms 350. The spring arms 350 and the main hub 332 cooperate to define two U-shaped channels 352 on lateral sides of the main hub 332.

[143] As shown in Figs. 6C and 6G-6J, each of the spring arms 350 includes a flange or hook member 370 formed thereon and extending outwardly therefrom. The hook members 370 each defines an inclined surface or edge 372 formed thereon.

[144] The vented cannula 208 further includes a ledge or flange 338 that is connected to or integrally formed with the main hub 332 and is disposed in a horizontal plane above the two spring arms 350. The ledge 338 and the top edges of the spring arms 350 cooperate to define horizontal grooves or slots 360 therebetween for accommodating the arms 687 of the mounting mechanism 686 on the cap 684 of the vial access system 600.

[145] To connect the cannula 208 to the mounting mechanism 686 on the cap 684, the main hub 332 of the cannula 208 is aligned with the slot 688 of the mounting mechanism 686 and the arms 687 of the mounting mechanism 686 are aligned with the grooves 360 defined between the spring arms 350 and the top ledge 338 of the main hub 332. Once the structural elements of the cannula 208 and the mounting mechanism 686 are aligned, the cannula 208 is inserted into the mounting mechanism 686 until the hook members 370 of the spring arms 350 engage the front edges 691 of the tab members 690. Upon further insertion of the cannula 208, the front edges 691 of the tab members 690 engage and ride along the inclined surfaces 372 of the hook members 370, thereby moving the spring arms 350 in an inward direction (i.e., toward the vertical axis of cannula 208). This inward movement of the hook members 370 allows them to clear the front edges 691 of the tab members 690 and ride along the inner sides 693 thereof until the hook members 370 clear the tab members 690 and move or snap back into their original position to engage the rear edges 692 of the tab members 690. At this point, the cannula 208 is fully inserted into and retained by the mounting mechanism 686. To remove the cannula 208 from the mounting mechanism 686 (e.g., when the MPDS 200 is removed from the fluid delivery system 10), the operator pinches the hook members 370 together (i.e., moves them toward the vertical axis of the cannula 208) until they clear the

rear edges 692 of the tab members 690, and then slides the cannula 208 out of engagement with the mounting mechanism 686.

[146] Referring again to Figs. 6C and 6G-6J, the vented cannula 208 includes a longer, fluid draw needle 340 in fluid connection with the second tubing section 210 of the MPDS 200 via a fluid port 384 and a shorter, vent needle 342 in fluid connection with a vent 334. As known in the art, the vent 334 may include a suitable filter for filtering the ambient air that is drawn into the vial 902 to allow fluid to be drawn therefrom.

[147] The description now turns to the preferred operation and use of the vial access system 600 and the vented cannula 208 of the present invention. When a vial shield 554 (holding a pharmaceutical vial 902) is to be placed in the vial access system 600, the vertical support arm 676 is raised to an extended position and rotated (see Figs. 2B and 4A) to move the cap 684 out of its normal position above the sloped surface 672. The vial shield 554 is then inserted into the well 111 and placed on the sloped surface 672 (see Fig. 6F). The support pins 674 engage the vial shield 554 to hold it in position on the sloped surface 672.

[148] After the vial shield 554 is inserted into the vial access system 600 (see Fig. 4B), the vented cannula 208 of the MPDS 200 is inserted into the mounting mechanism 686 on the cap 684 and the cap 684 is rotated back into position (e.g., by turning the handle 682) above the septum cap 562 of the vial shield 554 (see Fig. 6D). Then the cap 684 is lowered (e.g., by using the handle 682 to urge the vertical support arm 676 into the housing 678) to insert the fluid draw needle 340 and the vent needle 342 of the cannula 208 through the septum of the septum cap 562 and into the pharmaceutical vial 902 (see Fig. 6F). The handle 682 is then rotated to lie in a substantially horizontal orientation on or above the cap 684 (see Figs. 1C and 6E), thereby allowing the cover 20 of the fluid delivery system 10 to be closed. While the preferred method of operating the vial access system 600 and the vented cannula 208 is provided above, the method and steps can be conducted in any suitable order or arrangement to achieve the desired results.

[149] As best shown in Fig. 6F, the support surface 672 is preferably configured such that when a vial is pierced by the fluid draw and vent needles 340, 342 of the cannula 208, the bottom end of the fluid draw needle 340 will be placed at or near the location where the cylindrical wall of the vial meets the bottom (floor) of the vial. Thus, to the extent that some vials may not have a completely flat bottom or floor (e.g., may have a rounded bump with a maximum height at the central longitudinal axis of the vial), the fluid draw needle 340 will be in a position to maximally draw

fluid from the vial as it collects at the junction of the vial's bottom and cylindrical wall (i.e., to avoid waste of the pharmaceutical). Or, even in a flat-bottomed vial, such an orientation of the vial will help ensure that fluid maximally gathers and is drawn in a closely defined area.

[150] As discussed above, the dimensions of the vial access system(s) 600 provided with the fluid delivery system 10 can preferably be chosen in accordance with dimensions of the vial shields and vials to be employed, to ensure that as much fluid from the vial is drawn as possible. By way of a non-restrictive example, the sloped surface 672 could be sloped at an angle of about 10-13 degrees with respect to the horizontal.

[151] Instead of being incorporated into and as part of the MPDS 200 for use with the fluid delivery system 10, the vented cannula 208 of the present invention may be used in other fluid delivery systems, including ones that use shielded syringes (see e.g., U.S. Patent Nos. 5,927,351 and 5,514,071, the contents of which are incorporated herein by reference), for injecting pharmaceuticals or other medical fluids into patients.

[152] As shown in Figs. 47A-C, the vented cannula 208 may be used with a hand-held syringe 380 (preferably held within a conventional lead-shielded container (not shown for ease of illustration)) having a discharge outlet 386 and a plunger 381 slidably disposed therein. The fluid draw needle 340 of the cannula 208 is in fluid connection with the shielded syringe 380 by means of a tube 383 connected between the discharge outlet 386 of the syringe 380 and the fluid port 384 of the cannula 208. The tube 383 preferably includes a connector 387, such as a standard luer connector, for removably connecting the tube 383 to the shielded syringe 380. The other end of the tube 383 may be non-removably attached to the fluid port 384 of the cannula 208 by use of, for example, an adhesive. Alternately, the tube 383 may include a connector (not shown) for removable connection to the fluid port 384 or may be press fit and held by friction forces onto the fluid port 384.

[153] The tube 383 may be fashioned in any length or diameter suitable for the application. In use, the fluid draw and vent needles 340, 342 of the cannula 208 are inserted into a vial (not shown) containing a pharmaceutical or other fluid. The plunger 381 is retracted (moved away from the discharge outlet 386 of the syringe 380) to aspirate fluid from the vial into the syringe 380. The connector 387 is disconnected from the shielded syringe 380 and the syringe 380 is then connected, generally via an intermediate tubing (not shown), to a catheter disposed in a patient.

The plunger 381 is then advanced (moved toward the discharge outlet 386) to inject fluid into the patient.

[154] As shown in Fig. 48, the vented cannula 208 may also be utilized as part of a second alternate fluid delivery system 399 including a shielded (not shown for ease of illustration), hand-held syringe 380' having a discharge outlet 386' and a plunger 381' slidably disposed therein. In addition to like elements shown in Figs 47A-C, the system 399 includes first, second and third tubing segments 390, 391, 392 that are connected via a T-connector 393 having an integral stopcock 394. The third tubing segment 392 also preferably includes a swabable valve 395 to which the first end 702 of the SPDS 700 described above could be connected. Instead of a swabable valve 395, it is contemplated that a conventional luer connector could be used for suitable applications.

[155] After the vented cannula 208 is placed in a pharmaceutical source (not shown), the stopcock 394 is actuated to open the fluid path between the vented cannula 208 and the syringe 380' and to close the path to the third tubing segment 392. The plunger is then retracted to aspirate fluid into the syringe 380' from the pharmaceutical source. The stopcock 394 is then actuated to open the fluid path between the syringe 380' and the third tubing segment 392 and to close the path to the second tubing segment 391. The first end 702 of the SPDS 700 is then preferably connected to the swabable valve or luer connector 395, and the plunger 381' is advanced to pump fluid to the patient end 704 of the SPDS 700 (e.g., to purge air from the tubing and to thereby provide a wet connection between the patient end 704 of the SPDS 700 and the catheter (not shown) in a patient). The patient end 704 is then connected to the catheter and the plunger 381' is advanced again to pump or deliver fluid through the SPDS 700 to the patient.

[156] After the fluid is delivered to the patient, the SPDS 700 is disconnected from the patient and the valve or luer connector 395 and is discarded. If another injection is to be performed, a new SPDS 700 can be connected to the valve or connector 395 and the system 399 can be primed to again provide a wet connection at the patient end 704 of the SPDS 700.

[157] The disclosure now turns to the operation of the fluid delivery system 10 and its various components. As known in the art, in injection procedures and other fluid delivery operations in which pharmaceuticals are delivered to a patient, air is purged from the fluid path by pumping an amount of the pharmaceutical and/or a diluent, such as saline, through the fluid path to the end of a tubing set (e.g., MPDS 200 or SPDS 700) before connecting the tubing set to a catheter in the patient. Such an air

purging or "priming" procedure is standard practice to prevent the occurrence of an air embolism in a patient, which can cause serious injury or death. Further, the dimensions (e.g., length and ID) of the SPDS 700 and the various tubing sections of the MPDS 200 (provided above) are necessary for accurate priming, activity measurement and delivery of the pharmaceutical to the patient because the system 10 relies on those dimensions to accurately determine and monitor the volume of pharmaceutical and saline that is required for those various operations.

[158] Referring again to Figs. 1C and 2A, once the MPDS 200 is installed in the fluid delivery system 10, the spike 202 is placed in fluid connection with the saline source 23 and the cannula 208 is inserted into the vial 902 and placed in fluid connection with the pharmaceutical therein, the MPDS 200 is primed to remove air therefrom.

[159] In a preferred method of priming the MPDS 200, the pump 22 is activated to draw saline out of source 23 and to move the saline through first tubing section 204, check valve 215, T-connector 205 and into third tubing section 216. The pump 180 is then activated to draw a small amount of pharmaceutical out of vial 902 and to move the pharmaceutical through second tubing section 210, check valve 214, T-connector 205 and into third tubing section 216. The pump 23 is then activated again to draw additional saline from saline source 23 to thereby move the volume of pharmaceutical present in third tubing section 216 into the tube coil 444 of coil assembly 400 located in the dose calibrator 160.

[160] To ensure that the second tubing section 210 is primed, the dose calibrator 160 is monitored to measure the level of radioactivity in the coil 444. If the dose calibrator measures no activity (or an activity level below a predetermined, baseline activity level), then the second tubing section 210 has not been appropriately primed and the priming process described above needs to be reinitiated by the operator. If the dose calibrator measures any activity level (or an activity level above the predetermined, baseline activity level), then the system 10 concludes that the second tubing section 210 has been correctly primed.

[161] After the second tubing section 210 is primed, the motor 30 is activated to open the pinch valve 170 and thereby open the fluid path from the fourth tubing section 220 through the T-connector 222 and the fifth tubing section 226 to the waste receptacle 224, the motor 31 is activated to close the pinch valve 172 and thereby close the fluid path along the sixth tubing section 230, and pump 22 is activated again to move the saline and the pharmaceutical in tube coil 444 through fourth tubing section 220, T-connector 222, fifth tubing section 226 and into waste receptacle 224.

[162] Subsequently, the first end 702 of the SPDS 700 is connected to the connector end 228 of the MPDS 200. The motor 30 is activated to close the pinch valve 170 (and thereby close the fluid path from the fourth tubing section 220 through the T-connector 222 and the fifth tubing section 226 to the waste receptacle 224), the motor 31 is activated to open the pinch valve 172 (and thereby open the fluid path along the sixth tubing section 230), and the pump 22 is activated again to move the saline through the T-connector 222 and the sixth tubing section 230 to the patient end 704 of the SPDS 700. At this point, the entire length of the MPDS 200 and the SPDS 700 is primed and the patient end 704 of the SPDS 700 can be connected to the catheter or other venous access device placed in a patient.

[163] In an alternate embodiment, after the pharmaceutical is moved into the waste receptacle 224, the remainder of the MPDS 200 is primed prior to the SPDS 700 being connected to connector end 228 of the MPDS 200. (This alternate priming method may be accomplished if the connector end 228 of the MPDS 200 is not the preferred swabable luer valve but rather is, for example, a standard luer connector or another connector that is not biased to a closed position when disconnected from the first end 702 of the SPDS 700.) Then, the first end 702 of the SPDS 700 is connected to the connector end 228 of the MPDS 200 and the SPDS 200 is primed to provide a wet connection at the patient end 704 of the SPDS 700.

[164] To accomplish this alternate priming method, the motor 30 is activated to close the pinch valve 170 (and thereby close the fluid path from the fourth tubing section 220 through the T-connector 222 and the fifth tubing section 226 to the waste receptacle 224), the motor 31 is activated to open the pinch valve 172 (and thereby open the fluid path along the sixth tubing section 230), and the pump 22 is activated again to move the saline through the T-connector 222 and the sixth tubing section 230 to the connector end 228 of the MPDS 200. Then, after the first end 702 of the SPDS 700 is connected to the connector end 228 of the MPDS 200, the pump 22 is activated again to move saline through the SPDS 700 to the patient end 704 thereof.

[165] After the MPDS 200 and the SPDS 700 are primed and the patient end 704 of the SPDS 700 is connected to the patient, the system 10 is ready for an injection procedure. While preferred and alternate methods of priming the MPDS 200 and the SPDS 200 are described above, other methods or steps may be employed or the steps above may be rearranged in any suitable manner to purge air from the MPDS 200 and the SPDS 700.

[166] In an alternate embodiment of the MPDS 200, the T-connector 205 and the check valves 214, 215 can be replaced with an automated, motor-driven stopcock. T-connector 222 also can be replaced with an automated stopcock as well.

[167] The disclosure now turns to embodiments of the present invention, as illustrated in Figures 7-46, that could conceivably be employed in programming and operating a fluid delivery system as broadly contemplated herein.

[168] Shown schematically in Figures 7-46 are various incarnations of a touch screen arrangement 1000 displayed on a graphical user interface, such as GUI 15, that could be employed with the fluid delivery system 10. As a non-restrictive example, such a touch screen arrangement could be utilized in conjunction with a system controller 5 and/or computer of any of a variety of fluid delivery systems as broadly contemplated herein.

[169] In order to clearly and unambiguously communicate to an operator the current status of the system 10, a graphical user interface with easily legible symbols and icons, including exceedingly user-friendly data entry mechanisms, is broadly contemplated. An operator will thus be able to intuitively understand and undertake various tasks for operating system 10.

[170] While a touch screen arrangement is contemplated in connection with Figures 7-46, it is to be understood that other types of data entry arrangements are conceivable that would achieve an equivalent purpose. For example, soft or hard key entry could be used, as well as trackball arrangements, mouse arrangements, or a cursor control touch pad (remote from the screen).

[171] The touch screen arrangement 1000 shown in Figures 7-46 can preferably be employed for four categories of tasks, namely: (1) system preparation, (2) patient treatment, (3) injection history (i.e., obtaining information regarding previous treatments) and (4) system configuration. Preferably, a touch screen arrangement 1000 will be flexibly and selectably manipulable to accommodate and undertake any and all of these tasks as desired.

System Preparation

[172] The "system preparation" category includes a number of tasks that are preferably performed in the following order to prepare the system 10 for a fluid injection or delivery procedure: (1) disposing of a used MPDS 200 and vial 902 from, for example, the previous day or previous use of the system 10 (if still present in the system 10); (2) conducting a quality control check or "daily QC" of the system 10;

(3) installing a new pharmaceutical vial 902 and a new MPDS 200 in the system 10; and (4) priming the MPDS 200 to remove air therefrom. While the above order is the preferred one for preparing the system 10, the tasks may be performed in any suitable manner and order for the intended application.

[173] Fig. 7 conveys a "main" screen visible on touch screen arrangement 1000, which may be an initial screen presented to an operator when the system 10 is initially activated.

[174] As such, and as shown in Fig. 7, touch screen arrangement 1000 preferably generally depicts at a very high level the fluid path (e.g., MPDS 200 and SPDS 700) of the fluid delivery system 10. It can be appreciated that touch screen 1000 can easily be "mapped" (i.e., provide a one-to-one correspondence) to major components of the MPDS 200, the SPDS 700 and other components of the system 10 such as that discussed and illustrated herein with respect to Figs. 1A-6J, but that level of detail is generally not required for programming and use of the system 10.

[175] As shown in Fig. 7, the touch screen shows a saline field 1002 (here in the stylized shape of an IV bag), a pharmaceutical or FDG field 1004 (here in the stylized shape of a vial) and an ionization chamber graphic 1010. A tubing graphic 1008, as shown, encompasses a three-way junction with branches leading, respectively, to saline field 1002, FDG field 1004 and ionization chamber graphic 1010. As shown, the tubing graphic 1008 is coiled inside the ionization chamber graphic 1010 to indicate the tube coil 444 described above.

[176] Touch screen arrangement 1000 in Fig. 7 shows the system 10 as being in an "idle" state. As such, no fluid is shown as being disposed in or moving through tubing graphic 1008 and ionization chamber graphic 1010. Further, saline and FDG fields 1002, 1004 in Fig. 7 both convey an "empty" status, to indicate that the system 10 has not yet been provided with information regarding the presence and/or amount of fluid in the saline source 23 and the vial 902.

[177] Indicated at 1006 is a touch field showing desired activity (currently displayed as 15.0 mCi) for an injection procedure to be performed. When the system 10 is activated, the desired activity field 1006 preferably displays a default activity value that can be pre-programmed into the system 10 or pre-set by the operator. Alternately, the desired activity field 1006 can default to the last activity level that was programmed into the system 10. Further, a display (read-only) system preparation field 1020 includes an associated "setup" button 1022a that, when activated, permits system preparation tasks to be performed.

[178] Indicated at 1012, 1014, 1016 and 1018, respectively, in Fig. 7 are circular status icons that provide quick and easy reference to different aspects of system status and, as such, will highlight when an aspect of system status is "on" or "active" or provide status information on the system 10. Thus, icons 1012-1018 from left to right, respectively, convey information on the following system aspects: activity present 1012, fluid motion / injection status 1014, check for air / priming status 1016, and system battery status 1018.

[179] The system battery (not shown) provides power to the system controller 5 and to the ionization chamber 160 (to maintain the ionization chamber at its normal operating state) in the event that the system 10 is disconnected from an AC power source. The system battery is charged while the system 10 is connected to an AC power source.

[180] Fig. 7 also shows four rectangular touch fields 1020-1023 along the bottom thereof. Reset button 1020 is activated to reset or clear information, such as case identification information, desired activity level, etc., from the treatment screens (as described in more detail below). Configuration button 1021 is activated to access the configuration screens for the system 10 (as described in more detail below). Records or Injection History button 1022 is activated to access information regarding prior injection procedures (as described in more detail below). Help button 1023 is activated to access searchable text, FAQs or other information that might be provided about the use and operation of the system 10.

[181] When the setup button 1022a is activated, the touch screen changes to that shown in Fig. 8. and "summary" 1030, "setup guide" 1032 and "daily QC" (quality control) 1034 touch fields preferably appear and the "summary" touch field 1030 is activated, prompting the appearance of a summary display 1038. As shown, summary display 1038 provides FDG and saline fields 1040, 1044, respectively, as well as MPDS tubing field 1048 and waste field 1050.

[182] In the saline field 1044, a "replace" button 1046 can be activated by the user to inform the system 10 that the saline source 23 has been replaced and to allow the user to input the volume of the saline source into the system 10 (see Fig. 13). After the saline volume is input via pop-up screen 1110 including keypad 1114 in Fig. 13, the saline volume is displayed as shown in Fig. 11. In a preferred embodiment, the saline source 23 is replaced at the same time that a new vial 902 is placed into the system 10.

[183] As part of the FDG field 1040 in Fig. 8, there are shown a number of informational displays (shown here as blank) regarding assay information that can be input by a

user into the system 10. An edit button 1042 can be activated by the user to facilitate the entry of such information. When the edit button 1042 is activated, the display shown in Fig. 10 appears. The user can then input the noted assay information (typically provided on the pharmaceutical vial 902) into the system 10. Specifically, a lot number can be entered into field 1072, while the activity and volume of, for example, FDG or other radiopharmaceutical in the vial can be entered into touch fields 1080 and 1082, respectively. In a manner well known to those of ordinary skill in the art, the activation of any of these fields can prompt a numerical keypad pop-up to assist in data entry, or data can be entered in essentially any other suitable manner (e.g., directly via a physical keyboard).

[184] Further, the assay date of the radiopharmaceutical in the vial is entered in field 1074 via a calendar button 1074a (which prompts the appearance of a pop-up calendar in known manner), or a simplified entry touch field 1074 which selectively permits the entry of a day such as "today" or "yesterday" (which is useful for radiopharmaceuticals, such as FDG, that have very short half-lives).

[185] The assay time is entered into touch field 1076 (via a pop-up time field or keyboard/keypad entry) and an AM/PM toggle field 1076a. Other functional buttons are present, such as "clear all" 1078, "cancel" 1084 and "OK" 1086 buttons, to facilitate entry, deletion and/or acceptance of inputted values of the requested assay information. When the OK button 1086 is activated to accept the assay information shown in Fig. 10, the display shown in Fig. 11 appears.

[186] Finally, as shown in both Figs. 8 and 11, information regarding the amount of radioactivity present in the MPDS tubing 200 is displayed at area 1048, while a waste field 1050 is preferably provided to graphically display the quantity of fluid and the activity level in the waste receptacle 224. Further, an "OK" button 1036 is activated to notify the system 10 that the system preparation tasks have been completed.

[187] Fig. 9 illustrates the display screen that is shown when the "setup guide" touch field 1032 shown in Fig. 8 is activated. As shown, setup guide 1032 prompts the appearance of a setup screen 1053 to assist an operator in physically preparing the system 10 for a procedure. Setup screen 1053 preferably includes four tabs 1054, 1056, 1058, 1060), which each, respectively, assist an operator in a different aspect of system setup (here, FDG removal, saline source installation, FDG installation, and MPDS installation, respectively).

[188] Fig. 9 also shows that FDG tab 1058 has been activated, prompting the appearance of display 1062. Up and down arrows 1066, 1068 preferably permit an operator to go through numbered procedure steps 1-4 as shown to install FDG vial 902 into the system 10, and a graphical image 1064 of the fluid delivery system 10 preferably graphically relates each of the numbered procedure steps. Here, for instance, "step 1" is shown graphically for the unlocking and opening of the cart. After the FDG vial 902 is installed in the system 10, status icon 1012a is highlighted (see Fig. 11) because activity is now present in the system 10.

[189] After the FDG vial 902, the saline source 23 and the MPDS 200 have been installed using, for example, the display shown in Fig. 9, and the FDG assay information and the saline volume information have been provided to the system (as shown in Fig. 11), the "purge air" button 1052 shown in Fig. 11 can be activated to prime the MPDS 200. When purge air button 1052 is activated, the "Prime MPDS" query prompt 1100 shown in Fig. 12A is displayed. When the "Yes" button 1101 in Fig. 12A is activated, the MPDS priming operation described in detail above is performed by the system 10 and a "Priming MPDS" status display 1102 is shown (see Fig. 12B) to indicate the status and completion of the MPDS priming operation to the user.

[190] After the MPDS 200 is primed by the system 10, a volume of fluid (i.e., a mixture of saline and a pharmaceutical (e.g., FDG)) is present in the waste receptacle 224 (as described in detail above). The outcome of the MPDS priming operation and the current status of the system 10 is displayed to the user, as shown in Fig. 14.

[191] As Fig. 14 shows, and as compared to the pre-MPDS priming system status shown in Fig. 11, the waste receptacle 224 contains 20 ml of waste (i.e., saline and pharmaceutical) and has an activity level of 15 mCi, the MPDS tubing has an activity level of 2 mCi, the saline source 23 contains 485 ml of saline (compared to 500 ml in Fig. 11) and the vial 902 contains 15 ml of FDG and has an activity level of 374 mCi (compared to 30 ml and an activity level of 700 mCi in Fig. 11).

[192] As shown in Fig. 14, the "Activity" (i.e., 700.0 mCi) listed in the Assay Information section of display 1038 is the amount of radioactivity provided by the radiopharmaceutical at the time it was assayed. The "Total Activity" (i.e., 415 mCi) shown next to the FDG display 1040 is the amount of radioactivity currently provided by the radiopharmaceutical present in the vial 902. The difference (i.e., 285 mCi) between the "Activity" and the "Total Activity" is calculated from the decay rate of the radioisotope and the elapsed time since the radiopharmaceutical was assayed. The activity level (i.e., 374 mCi) displayed within the FDG display

1040 is the 'extractable activity'; that is, the amount of activity that can be extracted from the vial 902. The "extractable activity" is less than the "total activity" because there is a small volume of radiopharmaceutical (e.g., approximately 1-2 ml) that cannot be extracted from pharmaceutical vials or containers and becomes discarded waste.

[193] Preferably prior to installing and priming the MPDS 200, the operator or other personnel should perform a quality control check on the fluid delivery system 10. In a preferred embodiment, the quality control check is performed daily, for example at the beginning of a work day, to ensure that the fluid delivery system 10 is in good working order. The quality control check is initiated by activating the "Daily QC" field or button 1034, as shown in Fig. 15. When activated, the "daily QC" touch field 1034 prompts the appearance of a QC display 1120 to assist an operator in performing a quality control check. A menu of checks to be performed preferably appears via the following touch fields: zero check (1122), bias adjustment (1124), background check (1126), constancy/accuracy test (1128) and ionization chamber battery (i.e., high voltage) measurement check (1130). In addition, the QC display 1120 provides a warning prompt 1121 to the operator that no activity (i.e., no radiopharmaceutical) should be inside the ionization chamber 160 when the quality control check is conducted.

[194] To the left of each touch field, preferably, is a "check box" or "pass/fail" indicator that preferably indicates one of the following four states, as appropriate: highlighted (if the corresponding touch field 1122-1130 is activated) to indicate an active test or check; not highlighted and blank to indicate an unexecuted test or check; checked with a checkmark to indicate a successful test or check; and an "X" to indicate a failed test or check.

[195] The QC display 1120 also includes a "Previous Test" button 1132 and a "Start" button 1134. The Previous Test button 1132 is activated to display the results of the previous quality control check of the system 10. When the Start button 1134 is activated, the tests or checks displayed in the QC display 1120 are initiated. Preferably, the checks are conducted in the order presented (i.e., from top to bottom) but they may be performed in any suitable order.

[196] Upon activating the Start button 1134, the "Zero Check" test 1122 is initiated. As shown in Fig. 16A, when the Zero Check test is initiated, the system 10 creates a pop-up 1136 that queries the operator as to whether there is activity (i.e., a radiopharmaceutical) inside of the ionization chamber 160 of the fluid delivery system 10. If the operator activates the "No" touch button 1137 in pop-up 1136,

system 10 "zeros out" the ionization chamber by automatically adjusting internal parameters so that the output from the ionization chamber indicates no activity. This check primarily accounts for environmental background radiation. When the check is completed, the system 10 displays a checkmark (see Fig. 16B) in the Zero Check display 1122.

[197] As shown in Fig. 17, the quality control check continues on to the Bias Adjustment check, which is similar to the Zero Check above but makes finer adjustments to internal biasing parameters to offset the effects of minor current fluctuations due to noise within the circuitry of the ionization chamber. The fine adjustments are made to ensure consistent activity readings from one measurement to the next. Fig. 17 shows a checkmark in the Bias Adjustment display 1124, thereby indicating that the system 10 has successfully adjusted the bias setting.

[198] Fig. 17 further shows that the Background Check is in progress. As such, field 1126 is highlighted and a progress bar 1126a indicates the degree of progress (here, 20%). The Background Check basically completes the ionization chamber "zeroing" steps conducted during the Zero and Bias Adjustment checks. The system 10 takes several readings (e.g., 10) from the ionization chamber and captures the average of those readings for display to the user. This allows the user to determine whether the ionization chamber has been sufficiently zeroed out.

[199] The next system check is the "Constancy/Accuracy" test, which is used to monitor the performance of the ionization chamber by measuring the same check source at intervals over a long period of time. The check source (e.g., Cs-137) is placed in the ionization chamber and the measured activity is compared to the expected activity based on the original assay information (decayed for time) of the check source. This ensures that the ionization chamber is providing accurate readings. The measured activity is also compared to previous readings of the same check source (decayed for time) by the ionization chamber. This ensures that the readings provided by the ionization chamber are consistent over time.

[200] When the system 10 initiates the "Constancy / Accuracy" test, a pop-up 1140 is generated (see Fig. 18) to prompt the operator to place a suitable pharmaceutical (in this example, Cs-137) in the ionization chamber 160 and to input information about the radiopharmaceutical (see data fields in pop-up 1140) into the system 10. In a preferred embodiment, the pop-up 1140 automatically includes the radiopharmaceutical information from the most recent "Constancy/Accuracy" test, and the operator activates the "Edit" button 1144 to input new and accurate

information when necessary. In an alternate embodiment the data fields in pop-up 1140 could be left blank for filling by the operator.

[201] After the pharmaceutical is placed in the ionization chamber 160 and the data fields in pop-up 1140 are complete and accurate, the operator activates the "OK" button 1146 to initiate the "Constancy/Accuracy" test. The "Constancy/Accuracy" display bar 1128 preferably includes a test progress bar (not shown) similar to bar 1126a in Fig. 17 that indicates the degree of progress to the operator. If the operator wishes to bypass the Constancy/Accuracy" test, she may activate the "Skip" button 1142 to bypass the test and proceed to the "Battery Measurement" test (discussed below with respect to Fig. 20). Once the "Constancy/Accuracy" test is completed, another pop-up 1148 is generated by the system 10 (see Fig. 19) to prompt the operator to remove the pharmaceutical from the ionization chamber 160. After the operator activates the "OK" button 1149 in pop-up 1148 to inform the system 10 that the radiopharmaceutical has been removed from the ionization chamber 160, the system 10 then initiates the ionization chamber "Battery Measurement" check.

[202] As shown in Fig. 20, the four previous system checks (see displays 1122-1128) are indicated by checkmarks as having been successfully completed. The ionization chamber "Battery Measurement" check measures the voltage output provided by a battery pack internal to the ionization chamber to ensure that the voltage output is sufficient to produce accurate readings from the ionization chamber. The ionization chamber "Battery Measurement" check is shown as being 84% completed by progress bar 1130a.

[203] After the "Battery Measurement" check is completed, the system 10 generates a "Summary" display screen 1150, as shown in Fig. 21, with specific results for all of the checks. If the "Constancy/Accuracy" test was bypassed by the operator (by activating Skip button 1142 in Fig. 18), the system 10 generates "Summary" display 1150a shown in Fig. 22, which indicates that the "Constancy/Accuracy" test was skipped.

[204] Screen 1150 also includes a print button 1152 that is activated to, for example, print out the test results (via printer 24 of system 10) for the system's maintenance file. In addition, the Summary display 1150 includes a New Test button 1154, which is activated by the operator to initiate a new series of quality control checks. When the New Test button is activated, the display 1120 shown in Fig. 15 is generated and the quality control check is conducted again by the system 10.

Patient Treatment

[205] The "Patient Treatment" category of tasks is described below in relation to Figs. 23-32B. The "Patient Treatment" category includes a number of tasks that are preferably performed in the following order to administer or inject a radiopharmaceutical into a patient: (1) setting the desired activity level to be delivered to the patient; (2) inputting patient and/or case identification information into the system 10; (3) connecting the first end 702 of the SPDS 700 to the connector end 228 of the MPDS 200; (4) priming the SPDS 700 to remove air therefrom; (5) connecting the patient end 704 of the SPDS 700 to the patient; (6) conducting a test injection to ensure the integrity of the fluid path to the patient; (7) preparing the radiopharmaceutical dose to be administered or injected into the patient; (8) measuring the activity level of the radiopharmaceutical dose in the dose calibrator 160 to ensure that it is equal or substantially equal to the desired activity level to be delivered to the patient; (9) discarding the radiopharmaceutical dose if, for example, the patient is experiencing discomfort or the measured activity level is not equal or substantially equal to the desired activity level; and (10) administering or injecting the radiopharmaceutical dose to the patient if the measured activity level is equal or substantially equal to the desired activity level. While the above order is the preferred one for the "Patient Treatment" tasks, the tasks may be performed in any suitable manner and order for the intended application.

[206] After the operator prepares the system 10 for a fluid delivery procedure by, for example, completing the steps set forth above in the "System Preparation" tasks, the system 10 generates the display 1000 shown in Fig. 23 which indicates in the upper left hand side thereof that the "System is ready." The saline field 1002 indicates that 500 ml of saline is available and the FDG field 1004 indicates that 700 mCi of FDG are available, as shown.

[207] As further shown in Fig. 23, the Desired Activity field 1006 indicates that 15.0 mCi is the current desired activity level. This 15.0 mCi activity level is preferably an operator-defined, default setting in the system 10, but also could be the desired activity level that was programmed for the last injection procedure.

[208] The desired activity level is preferably set by the operator in one of two ways: (1) manual input; or (2) a calculation based on patient weight. If the operator wants to set the desired activity level by manual input rather than by patient weight, the operator activates the "No" button 1202a in display 1006. In response thereto, the system 10 generates the display and keypad 1204 shown in Fig. 24A. The operator uses the keypad 1204 to input the desired activity level.

[209] If instead the operator wants to set the desired activity level based on patient weight, the operator activates the "Yes" button 1202b in Fig. 23. Upon activation of the "Yes" button 1202b, the system 10 generates the display 1000 and pop-up 1205 shown in Fig. 24B, which prompts the operator to "Enter patient weight" (displayed in pounds or kilograms in data field 1003) using pop-up 1205. Further, the operator can select the formula to be used in calculating the weight-based activity level by activating formula touch field 1011. When formula touch field 1011 is activated, the pop-up table 1013 shown in Fig. 24C is displayed and the operator is prompted to "Select formula." In a preferred embodiment the operator can select up to five operator-defined formulas. For example, as shown in Fig. 24C, the operator can select among three predefined formulas: (1) Standard (0.1 mCi/lb.); (2) Melanoma (0.13 mCi/lb.); and (3) Pediatric (0.07 mCi/lb.). However, the system 10 can include more than pre-set or predefined weight-based formulas. For example, the system 10 can also include formulas based on other patient parameters, such as glucose-level or cardiac output, or scanner parameters, such as acquisition time or crystal type.

[210] Once the formula is selected, the desired activity level is calculated using the formula and the patient's weight. The desired activity level (e.g., 13.5 mCi), the patient's weight (e.g., 135 lb.) and the formula (e.g., 0.1 mCi/lb.) are displayed in field 1006 and the screen display 100 indicates that the "System is ready", as shown in Fig. 24D.

[211] In addition, as displayed in display and keypad 1204 shown in Fig. 24A, in a preferred embodiment the system 10 includes pre-defined minimum and maximum activity levels that define the operating range (i.e., 5-25 mCi) of the system 10. The operating range of the system 10 cannot be altered by the operator, and the system 10 preferably will not accept a desired activity level (whether manually input or calculated based on patient weight or other patient or scanner parameter) that falls outside of the system's operating range. In a preferred embodiment, the system will default to the maximum or the minimum activity level (i.e., 25 mCi or 5 mCi) if the operator attempts to input or the system calculates a desired activity level that is greater than the maximum activity level or less than the minimum activity level, respectively.

[212] Furthermore, if desired for safety or medical practice or preference reasons, the operator preferably can define her own minimum and maximum desired activity levels for the system, as long as they fall within the operating range of the system 10. For example, the operator can define a minimum desired activity level of 10.0

mCi and a maximum desired activity level of 17.5 mCi for the system 10 because those two parameters fall within the 5-25 mCi operating range of the system 10. In such a case, as shown in Fig 24E, even though the operator inputted a patient weight of 5 lb. and chose a formula of 0.1 mCi/lb. (which would result in a calculated desired activity level of 0.5 mCi), the system 10 sets the desired activity level to the minimum desired activity level of 10.0 mCi. When the system 10 uses the minimum desired activity level instead of a manually input activity level or a calculated weight-based activity level, the system 10 indicates that to the operator by using, for example, the downward arrow icon 1006a shown in display field 1006 of Fig. 24E.

[213] Likewise, as shown in Fig. 24F, even though the operator inputted a patient weight of 999 lb. and chose a formula of 0.1 mCi/lb. (which would result in a calculated desired activity level of 99.9 mCi), the system 10 set the desired activity level to the maximum desired activity level of 17.5 mCi. When the system 10 uses the maximum desired activity level instead of a manually input activity level or a calculated weight-based activity level, the system 10 indicates that to the operator by using, for example, the upward arrow icon 1006b shown in display field 1006 of Fig. 24F.

[214] After the desired activity level is programmed or set by the system 10, preferably the operator inputs case information including patient identification and injection site information into the system 10, as shown in Figs. 25A and 25B. When the operator activates the Edit button 1208 in the Case ID field 1206 (see e.g., Fig. 23), the "Case Information" pop-up display 1217 shown in Fig. 25A appears. The display 1217 includes an "Identification" field 1217a and a keypad 1217j for inputting a patent or other identification number in field 1217a. In addition, the display 1217 includes a number of "Injection Site" touch buttons 1217b-1217i for identifying and recording in the system 10 the site on the patient at which the radiopharmaceutical will be administered or injected, including 'Left Antecubital' 1217b, 'Right Antecubital' 1217c, 'Left Hand' 1217d, 'Right Hand' 1217e, 'Left Foot' 1217f, 'Right Foot' 1217g, 'Access Port' 1217h and 'Other' 1217i.

[215] Once the Identification and Injection Site information is input into the system 10, the information is displayed in the Case ID field 1206, as shown in Fig. 25B. Further, as shown in Fig. 25B, after the requisite information is input into the system 10 and displayed in the Case ID field 1206, a Patient Preparation field 1210 including a Prime touch button 1212 is generated and displayed for the operator.

[216] Before the Prime button is 1212 is activated, the first end 702 of the SPDS 700 should be attached to the connector end 228 of the MPDS 200, as discussed in detail

above. When the SPDS 700 is connected to the MPDS 700, the operator can activate the prime button 1212 to cause the system 10 to prime the SPDS 700 to remove air therefrom.

[217] As shown in Fig. 26A, after the Prime button 1212 is activated the system 10 indicates that the system is "Priming" the SPDS 700 and generates a progress bar 1213 (which indicates in Fig. 26A that the priming operation is 17% completed). Further, the system 10 highlights the fluid path field 1008 and the coil field 1010 in display 1000 to indicate that saline is being pumped from saline source 23 (indicated by saline field 1002) through the MPDS 200 and the SPDS 700 to prime the SPDS 700. After the SPDS priming operation is completed, the system 10 generates a prompt display 1215, as shown in Fig. 26B, that queries the operator as to whether all air has been expelled or purged from the SPDS 700. If the "Yes" button 1215a is activated, the SPDS priming operation is completed and the system 10 is ready to conduct a test injection and/or to prepare the pharmaceutical dose for injection into the patient, as discussed in more detail below. If, on the other hand, the "No" button 1215b is activated, the SPDS priming operation is preferably conducted again.

[218] After the SPDS priming operation is completed, the patient end 704 of the SDPS 700 is connected to the patient (as described above) and the Patient Preparation display field 1210 on the touch screen 1000 includes a "Test Inject" button 1212a, as shown in Fig. 28A. If the operator desires to conduct a test injection to, for example, ensure the integrity of the fluid path along the MPDS 700, the SPDS 200 and the patient's vasculature, the operator activates the "Test Injection" button 1212a and the system 10 pumps saline from the saline source 23 through the MPDS 200 and the SPDS 700 to the patient. Concurrently, the system 10 generates the display shown in Fig. 27A to inform the operator that the system 10 is "Test Injecting" and highlights the fluid path display 1008 from the saline source icon 1002 to the ionization chamber display 1010. The display 1000 also includes a progress bar 1213a to indicate the degree of progress made (here 45%) in completing the test injection procedure.

[219] If the operator needs to pause the test injection due to, for example, patient discomfort or incorrect positioning of the catheter in the patient, she can activate the "Pause" button 1212d in the Patient Preparation" display 1210 (see Fig. 27A) to pause the procedure. When the test injection procedure is paused, the system 10 generates the display shown in Fig. 27B, indicating that the test injection is "Paused" and providing a "Resume" button 1212b and a "Stop" button 1212c in the Patient Preparation display 1210. To resume or stop the test injection, the operator

can activate the corresponding "Resume" and "Stop" buttons, 1212b, 1212c, respectively.

[220] In addition to using the various "Pause" and "Stop" buttons provided by the GUI display 15, an operator can also depress the interrupt button 25 on the cabinet 9 of the system 10 to at any time pause or stop a procedure or operation being conducted by the system.

[221] After the test injection is completed or terminated the system 10 generates the display 1000 shown in Fig. 28A, which includes an FDG Dose display 1216 and a corresponding "Prepare" button 1218. After the operator activates the "Prepare" button 1218, the system 10 generates the display shown in Fig. 28B and begins to pump a volume of FDG (or other suitable pharmaceutical or radiopharmaceutical) from the vial 902 through the MPDS 200 to the tube coil 444 thereof disposed in the ionization chamber 160. As shown in Fig. 28B, to reflect this operation the display 1000 informs the operator that the system 10 is "Measuring Dose" and highlights the fluid path display 1008 from the FDG source display 1004 to the ionization chamber display 1010. The display also includes a progress bar 1214a that shows the system's progress (here 78%) in measuring the pharmaceutical dose.

[222] In a preferred embodiment, the system 10 prepares the pharmaceutical dose in accord with the methodology described in PCT Publication No. WO 2006/007750, in which the activity level of a first amount of a radioactive liquid is measured and used to calculate a second amount of the radioactive liquid that is required for the combined amounts to have a pre-determined level of radioactivity to be delivered to a patient. The contents of PCT Publication No. 2006/007750 are incorporated herein by reference. The dimensions of the coil assembly 400 and the core structure 446, including the height, diameter and volume of the tube coil 444, the length, number of turns, OD and ID of the tubing that forms the tube coil 444, and the dimensional location of the "linear region" of the Veenstra IK-102 ionization chamber, provided above are necessary to optimally and accurately prepare the pharmaceutical dose, whether in accord with the preferred methodology described in PCT Publication No. WO 2006/007750 or using another suitable dose preparation methodology.

[223] The stated tube coil 444 dimensions are necessary to optimally position within the "linear region" of ionization chamber: (1) the volume(s) of pharmaceutical required to deliver the desired activity level to the patient; and (2) the volume of saline necessary to position the total volume of pharmaceutical in the tube coil. The tube coil 444 could be formed from tubing having a larger ID than that stated above (i.e.,

0.156 inches), but larger IDs tend to allow the radiopharmaceutical to be diffused with the saline (which is used to 'place' or 'position' the radiopharmaceutical within the tube coil 444), which may result in the radiopharmaceutical volume or a portion thereof being positioned outside of the tube coil 444 and thus outside of the "linear region" of the ionization chamber (resulting in inaccurate activity level measurements and delivery). Likewise, the tube coil 44 could be formed from tubing having a smaller ID than 0.156 inches (which would possibly further decrease or prevent the diffusion of the radiopharmaceutical with the saline), but the dimensions of the tube coil 444 (e.g., length of tubing, coil tube height, number of turns) required to maintain a tube coil volume of 12.5 ml would result in the tube coil 444 extending beyond the "linear region" of the ionization chamber (resulting in inaccurate activity level measurements and delivery).

[224] Further, the core structure 446 operates to maintain the desired tube coil geometry (e.g., tube coil diameter and height) and to properly position the tube coil 444 axially and vertically within the sleeve 162 so that the tube coil 444 thereby resides within the "linear region" of the ionization chamber 160 (see e.g., Fig. 3F).

[225] With specific reference to the dose preparation methodology described in PCT Publication No. WO 2006/007750, the 12.5 ml volume of the tube coil 444 is designed to accommodate two volumes of a radiopharmaceutical from vial 902 separated by a volume of saline from source 23, regardless of whether the dose is prepared shortly after the radiopharmaceutical was assayed (when a small volume of the radiopharmaceutical is required to deliver a desired activity level) or after a significant amount of time has passed (e.g., in relation to the radioisotope's half-life) since the radiopharmaceutical was assayed (when a greater volume of the radiopharmaceutical is required to deliver the same desired activity level). As a specific example of the above, the 12.5 ml tube coil 444 is designed to accommodate: (1) two 1/16 ml volumes or "slugs" of a pharmaceutical (for a total volume of 1/8 ml) at a concentration of 40 mCi/ml (i.e., highest concentration that the system 10 is designed to handle), separated by a calculated volume of saline necessary to fill or substantially fill the remaining tube coil volume; and (2) two 1.5 ml "slugs" of a pharmaceutical (for a total volume of 3 ml) at a concentration of 1.67 mCi/ml (i.e., lowest concentration that the system 10 is designed to handle), separated by a calculated volume of saline necessary to fill or substantially fill the remaining tube coil volume.

[226] After the dose is pumped by the system 10 into the tube coil 444 disposed within the ionization chamber 160, the activity level of the dose is measured by the system 10.

The measured activity level is then displayed to the operator and the ionization chamber display 1010 is highlighted, as shown in Fig. 29. A new display field 1006a is generated by the system, showing the measured "Calibrated Activity" (here 13.5 mCi) of the prepared dose. Just below field 1006a is a "plus/minus" range indicator 1224. Range indicator 1224, as shown, includes a center circle 1224a, flanked on each side by 10 rectangles. Left and right arrows are also included, respectively, at the far left and far right of indicator 1224. Preferably, as shown in Fig. 29, center circle highlights when the measured "Calibrated Activity" level is the same as the previously programmed, desired activity level (which is the case in Fig. 29). Otherwise, if the measured activity level is greater or lesser than the desired activity level, corresponding rectangles or, in some cases, arrows will highlight to the right of the center circle 1224a (for measured activity > desired activity) or to the left of the center circle 1224a (for measured activity < desired activity) to visually indicate to the operator the difference between the measured and desired activity levels.

[227] In a preferred embodiment, each of the rectangles represents a default value of a 1% discrepancy in the desired to measured activity level, such that three rectangles to the right of the center circle 1224a would be highlighted if the measured activity level was 3% greater than the desired activity level of 13.5 mCi. If the measured activity exceeds the desired activity by more than 10%, then all the rectangles to the right of the center circle 1224a and the right arrow would highlight. Preferably, the extent of the rectangles in indicator 1224 will convey an acceptable range within which the measured activity may fall. Thus, such an acceptable range could be plus or minus ten percent or could be another range as deemed appropriate, with each rectangle representing one tenth of the positive or negative extent of that range. Alternately, however, the default value of each rectangular could be pre-set to another value (such as 0.1 mCi) or could be changed by the operator to another value more suitable for the intended application.

[228] In addition to displaying the measured activity level, as shown in Fig. 29 the display 1000 also generates a "Discard" button 1222 and an "Inject" button 1220 in the FDG Dose display 1216. If for example the measured activity is outside of a clinically acceptable range for the intended procedure, the operator can activate the "Discard" button 1222 to have the system 10 discard the measured dose (i.e., by pumping the dose to the waste receptacle 224, as discussed in detail above) and to prepare another dose for delivery to the patient. Specifically, when the "Discard" button 1222 is activated the system generates the dialog box 1231 shown in Fig. 30A, which queries the operator to confirm that the measured dose is to be discarded. If the

operator confirms that the measured dose is to be discarded by activating the "Yes" button 1231a, the system 10 generates the display shown in Fig. 30B, which indicates to the operator that the system is "Discarding" and creates a progress bar 1233 that indicates the status of the "discarding" operation (here 86% completed). The display 1000 also highlights the fluid path display 1008 from the saline source display 1002 to the ionization chamber display 1010 to indicate that the system 10 is pumping saline through the MPDS 200 to push the dose from the tube coil 444 to the waste receptacle 224 (as described above).

[229] If, on the other hand, the operator activates the "No" button 1231b in Fig. 30A to inform the system 10 that she does not want to discard the measured dose, the system 10 reverts to the display shown in Fig. 29 and the "Discard" button 1222 and the "Inject" button 1220 are again made available to prompt the operator to decide whether to discard or to inject the measured pharmaceutical dose.

[230] If the operator desires to inject the measured dose and thus activates the "Inject" button 1220 shown in Fig. 29, the system 10 generates the display shown in Fig. 31 which indicates to the operator that the system 10 is "Injecting" and, via progress bar 1223, that the injection operation (in Fig. 31) is 27% completed. The fluid path display 1008 between the saline source display 1002 and through the ionization chamber display 1010 to the arrow at the end of the fluid path display 1008 is highlighted to indicate that the system 10 is pumping saline from the saline source 23 to push the dose in the ionization chamber 160 through the remainder of the MPDS 200 and the SPDS 700 to the patient (as described above). Further, the system 10 generates a "Pause" button 1230 in FDG Dose display 1216. As with the test injection operation discussed above (see Fig. 27A), the operator can activate the "Pause" button 1230 or the interrupt button 25 to pause the injection procedure.

[231] After the "Pause" button 1221 is activated, the display shown in Fig. 32A is generated and displayed to the operator. The display shown in Fig. 32A informs the operator that the system 10 is "Paused" and includes a "Discard" button 1222a and a "Resume" button 1230a in the FDG Dose display 1216.

[232] If the injection needs to be terminated, the operator activates the "Discard" button 1222a and the system reverts to that shown and described above with respect to Figs. 30A and 30B to discard the dose into the waste receptacle 224. However, if the procedure can be resumed, the operator activates the "Resume" button 1230a in Fig. 32A and the injection procedure continues to deliver the measured dose to the patient.

[233] When the injection procedure is completed, a pop-up 1240 preferably appears as shown in Fig. 32B. This pop-up 1240, as shown, preferably contains information about the activity and volume of the dose (e.g., FDG) just delivered to the patient, the total fluid delivered (which would include saline) and other identifying information including, for example, the patient identification number, radiopharmaceutical lot number and patient injection site (as shown on the right of pop-up 1240). Activating the "OK" button 1242 causes pop-up 1240 to disappear and the system to revert to an "Idle" state (as shown in Fig. 7) or a "Ready" state (as shown in Fig. 23), while activating the "print" button 1244 prompts the injection information to be printed out by the printer 24 for patient, billing, inventory or other suitable records.

[234] Other capabilities and functions not expressly discussed hereinabove or shown in the drawings are of course conceivable in accordance with the embodiments of the present invention. For instance, if the extraction of a pharmaceutical dose (e.g., FDG) from a vial is interrupted for an unforeseeable reason and is not prompted by a desired "pause", the system could alert the operator to discard the dose (and in that connection present a button for the purpose).

Injection History

[235] The disclosure now turns to a discussion of the injection history operations or tasks that can be performed using the display 1000, as depicted in Figs. 33A-C, 34A and 34B.

[236] The injection history operations or tasks may be prompted by activating the Records / Injection History button 1022, which is displayed when the system 10 is in an "Idle" state (see e.g., Fig. 7) or a "Ready" state (see e.g., Figs. 23, 24D and 28A). Activation of Records button 1022 preferably prompts the appearance of the calendar display 1302 shown in Fig. 33A (here 'October 2006'). Highlighted touch fields within the calendar display 1302 preferably correspond to those dates of the displayed month (here 'October 2006' in field 1309) on which the system 10 was used to perform an injection procedure, while those other days of the displayed month in which the system 10 was not used are not highlighted. Arrow buttons to the left 1309a and right (not shown), respectively, of field 1309 preferably permit the operator to scroll through different months to access and retrieve injection history information.

[237] The calendar display 1302 also includes a "Print Summary" button 1304, a "Print Days" button 1306 and a "Done" button 1308. Activation of the "Print Summary"

button 1304 provides a high-level summary of the injection procedures conducted for the specified month (here 'October 2006'), similar to the injection procedure information displayed in Fig. 34A. The "Print Days" button 1306 preferably prompts the appearance of the display 1302a shown in Fig. 33B. The "Done" button 1308 can be activated once the operator has completed the necessary injection history retrieval operation or task, and the display 1000 then preferably reverts to the "Idle" state display (see e.g., Fig. 7) or the "Ready" state display (see e.g., Figs. 23, 24D and 28A) as appropriate.

[238] Referring now to Fig. 33B (prompted by activation of "Print Days" button 1306), the display 1302a includes an "All Days" touch field 1330 (which is activated in Fig. 33B) including a "Print" button 1334, and a "Range" touch field 1332. If the operator mistakenly activated the "Print Days" button 1309 on display 1302 (see Fig. 33A), she can activate the "Cancel" button 1336 to return to the display 1302 shown in Fig. 33A. If the operator wishes to print the injection history information for all the days in the selected month (here 'October 2006'), "Print" button 1334 can be activated and the printer 24 will print the injection history records for the days in which the system 10 performed injection procedures. If the operator instead wants to access injection history information for a range of days in the selected month, the operator can activate the "Range" touch field 1332, which prompts the appearance of the display 1302b shown in Fig. 33C.

[239] As shown in Fig. 33C, the display 1302b includes a "From" touch field 1332a and a "To" touch field 1332b which the operator activates to select the "From" and "To" dates in the selected month to establish the range of dates for which injection history information is to be accessed. Once the date range is selected, the "Print" button 1334 is activated to prompt the printer 24 to print the injection history information.

[240] Referring back to Fig. 33A, in addition to activating the "Print Summary" button 1304 or the "Print Days" button 1306, the operator is also able to activate any of the highlighted calendar buttons to access injection history information for that day of the selected month. For example, if the operator wanted to retrieve injection history information for 10 October 2006, the operator would activate the "10" button 1340 shown in Fig. 33A and the system 10 would generate the display 1310 (including selected date field 1310a) shown in Fig. 34A.

[241] As shown in Fig. 34A, a series of display fields 1312 includes information on the lot number, case ID, delivery time and delivered activity of a given injection procedure conducted on the selected day (here '10 October 2006 (Tuesday)'). Page up 1316 and page down 1318 arrow buttons are provided to allow the operator to scroll

through the procedures conducted on the selected day. Page left 1350 and page right 1351 arrow buttons are also provided to allow the operator to scroll through and select dates prior to or subsequent to the selected '10 October 2006' date displayed in date field 1310a. A "Month View" button 1320 can be activated to revert to a "month view" as shown in Fig. 33A, while the "Print Day" button 1306a can be activated to print the injection history details of all injection procedures on the day in question (i.e., the day currently being displayed). Further, "magnifying glass" touch fields 1314 are provided for each procedure and, upon activation, preferably prompts a detailed injection history display 1360 (see Fig. 34B) for the selected procedure.

[242] As shown in Fig. 34B, the detailed injection history display 1360 provides details on the specific pharmaceutical injected (here "FDG"), the date (10 October 2006) and time (09:15) of injection and the activity level (15.1 mCi) and volume (5 ml) of the injected pharmaceutical. Further, the display 1360 indicates the total volume (35.0 ml) of injected fluid (pharmaceutical and saline), the Patient Identification number, the Lot number of the pharmaceutical and the IV Injection Site on the patient. The "Print" button 1363 is activated to print the injection details and the "OK" button 1362 is activated to revert to the display 1310 shown in Fig. 34A.

System Configuration

[243] The disclosure now turns to a discussion of system configuration tasks, as depicted in Figures 35-46. The configuration tasks are undertaken to permit an operator to set various system preferences, including but not limited to preferences related to the following: (1) Language; (2) Date / Time display; (3) Units; (4) Audio; (5) FDG / Pharmaceutical dose preparation formulas; (6) Saline volumes; (7) Case Information display; (8) Printing; (9) Daily QC isotope reference information; (10) Linearity measurement tests; (11) Calibration tests; and (12) Field Service reminders.

[244] The system configuration tasks may be prompted by activating the Configuration button 1021, which is displayed when the system 10 is in an "Idle" state (see e.g., Fig. 7) or a "Ready" state (see e.g., Figs. 23, 24D and 28A). Activation of Configuration button 1021 preferably prompts the appearance of the "System", "Treatment" and "Maintenance" touch fields (1402, 1404 and 1406, respectively) shown in Fig. 35, each of which when activated prompts the appearance of a distinct tabbed menu display 1400a-c (as explained in more detail below). An "OK" button 1418 may be activated when the system configuration tasks are completed, while a "default" button" 1416 may be activated to reset the system 10 to the default configuration settings.

[245] As shown in Fig. 35, the "System" touch field 1402 is activated and the tabbed menu display 1400a is provided. On menu display 1400a, tabs for language, date/time, units and audio are provided (1408, 1410, 1412, and 1414, respectively), and language tab 1408 is activated to prompt a language menu 1420. Preferably, language menu 1420 will permit the selection of any of a number of languages to be used with the system 10 in accordance with operator or local preferences.

[246] Fig. 36 shows date/time tab 1410 activated to prompt a date/time display 1422. Via a calendar button 1422a, a current date can be set, while date format preferences (e.g., European vs. American, etc.) can be set via touch field 1422b. A time display field 1422c preferably shows the current time and a time edit button 1422d may be activated to set the time as well as to select a 12- or 24-hour time format.

[247] Fig. 37 shows units tab 1412 activated to prompt a display 1424. Display 1424 preferably permits, via buttons 1426a, 1426b, 1428a, 1428b, a choice of units for weight (lbs. vs. kg) and activity (Curies vs. Becquerels), respectively.

[248] Fig. 38 shows audio tab 1414 activated to prompt a display 1444. "High", "normal" and "low" audio volumes (e.g., for prompts or alarms) can be selected via buttons 1444a, 1444b and 1444c, respectively.

[249] Fig. 39A shows the treatment touch field 1404 activated, which generates a second tabbed menu display 1400b. On menu display 1400b, tabs for "FDG", "saline", "case" and "printing" are provided (1450, 1452, 1454, and 1456, respectively). In Fig. 39A, FDG tab 1450 is activated to prompt a display 1460. Preferably, display 1460 includes an entry field 1462 for entering a default desired activity level (which may then automatically appear in field 1006 of Fig. 7).

[250] The display 1460 further includes a weight-based dosing sub-menu 1460a that includes on/off buttons 1464a, 1464b and an "Edit Formulas" button 1466. If the operator would like the system 10 to default to a weight-based calculation for desired activity level, the operator activates the "On" button 1464a. If a default, weight-based calculation for desired activity level is not desired, the operator can select the "Off" button 1464b (as shown in Fig. 39A). Further, upon activation of the "Edit Formulas" button 1466, the system 10 generates the pop-up edit display 1470 shown in Fig. 39B to allow the operator to edit existing or add new formulas for calculating desired activity level based on, for example, patient weight.

[251] As shown in Fig. 39B, the edit display 1470 may include a column of five buttons 1476, each preferably corresponding to a predetermined formula for a procedure

type that, for instance, may commonly be repeated. Here, a "Melanoma" button 1476a is activated to then present a sub-display 1478 which can afford an editing of any or all of the following: name of the formula (via button 1478a), multiplier to be used in calculating weight-based desired activity level (via touch field 1478b), and minimum and maximum desired activity levels (via touch fields 1478c and 1478d, respectively). Also, the entire formula can be deleted (via button 1478e) from the set 1476, if desired. Further, the operator may enter new formulas into the system 10 by activating the "New Formula" buttons 1476b

[252] Fig. 40 shows Saline tab 1452 activated to prompt a display 1480. Display 1480 preferably contains touch fields 1482, 1484 and 1486, respectively, for pre-selecting a default saline bulk size (here 500 ml) for the saline source 23 (if, for example, the facility generally uses or will use the same bulk size of saline), an additional saline flush volume (e.g., to account for the additional tubing length if the SPDS 700 is connected to an IV instead of directly to a catheter in a patient) and a test inject volume (here 30 ml). The Default Bulk Size volume entered in 1482, for example, can be a quantity that initially appears to an operator at a time when saline is installed in the system 10, which can be changed or left alone as appropriate. Any data entry in touch fields 1482, 1484, 1486 can be accomplished, e.g., via a keypad 1488.

[253] Fig. 41 shows case tab 1454 activated to prompt a display 1490. Display 1490 preferably permits the operator to set a default preference (via on/off buttons 1492) as to whether Case ID information (i.e., for a given patient) can be edited as appropriate. Further, the display 1490 allows the operator to set a default injection site for the system 10 by activating one of the injection site buttons 1494 provided in display 1490. Of course, the default injection site location can be changed by the operator during the preparation steps for the fluid delivery procedure if the actual injection site is different from the default injection site.

[254] Fig. 42 shows printing tab 1456 activated to prompt a display 1502 which allows an operator to establish an automatic printing of record labels (e.g., as may be printed at the end of an injection procedure) and the quantity of record labels to be printed.

[255] Finally, Fig. 43A shows maintenance touch field 1406 activated, which generates a third tabbed menu display 1400c. On menu display 1400c, tabs for "Daily QC", "Linearity", "Calibration" and "Field Service" (1510, 1512, 1514, 1516, respectively) are provided. The maintenance tabs relate to general maintenance and calibration of the system 10.

[256] As shown in Fig. 43, Daily QC tab 1510 is activated to prompt a display 1518. Display 1518 allows the operator to input information related to the radioisotope to be used to conduct daily QC tests (described above) of the system 10. Specifically, Isotope touch field 1520 and Lot Number touch field 1522 permit the operator to input the specific radioisotope to be used (here Cs-137) and the lot number thereof, respectively. Further, the operator can input the time and date that the radioisotope was created (e.g., in a cyclotron or a reactor), as well as the activity level of the radioisotope when it was created, in the Time and Activity touch fields 1526, 1524, respectively. The Edit button 1526a can be activated to edit the previously entered time and date information.

[257] Fig. 44A shows linearity tab 1512 activated to prompt a display 1530. Display 1530 prompts the operator for information and assists in conducting a linearity measurement for the system 10, which should be conducted every quarter (as noted in display 1530). Linearity measurements are based on the known decay of radioisotopes and are conducted to ensure that the ionization chamber 160 in the system 10 is reliably measuring the activity level of a radioisotope placed therein. Specifically, during a linearity measurement the measured activity level of a radioisotope is compared to the known activity level of the radioisotope (based on its half-life decay) at selected intervals (e.g., every 15 minutes) over a period of time (e.g., 24 hours) to determine whether the measured activity level falls within an acceptable error range.

[258] When the linearity tab 1512 is activated, details from the most recent linearity measurement are shown in sub-display 1532, while a button 1534 can be activated to prompt the appearance of a related graph (of, for example, measured vs. known activity level over the measurement period). To conduct a new linearity measurement, button 1536 is activated, which preferably generates the display 1540 shown in Fig. 44B.

[259] As shown in Fig. 44B, isotope field 1542 may be activated to identify the radioisotope to be used for the linearity measurement (here F-18). While isotope field 1542 preferably conveys the reference isotope, the activity level of the radioisotope (e.g., at the time it was drawn) can be input into activity level field 1544. In addition, the reference date and time for the activity level (e.g., the date and time that the radioisotope was drawn) is input into touch fields 1546 and 1548, respectively, by using, for example, a calendar button 1546a and a AM/PM time button 1548a. Once the requisite radioisotope information is inputted into display 1540, the operator can activate the "Begin Measurement" button 1543 to start the

linearity measurement. Of course, the operator can activate the "Cancel" button 1541 to cancel the linearity measurement and return to the display 1530 shown in Fig. 44A

[260] After the "Begin Measurement" button 1543 is activated, the pop-up display 1545 shown in Fig. 44C is generated to prompt the operator to confirm that the reference radioisotope has been placed in the ionization chamber 160. If the operator activates the "Yes" button 1545a (as shown in Fig. 44C) to confirm that the F-18 radioisotope has been placed in the ionization chamber 160, the system 10 will begin the linearity measurement.

[261] If the operator activates the "No" button 1545b, the display reverts to the display 1540 shown in Fig. 44B, and the operator can then load the reference radioisotope source into the ionization chamber and once again activate the "Begin Measurement" button 1543 to start the linearity measurement.

[262] After the operator activates the "Yes" button 1545a, the display 1547 shown in Fig. 44D is generated. In addition to displaying the radioisotope in field 1542 and the maximum allowable error for the linearity measurement in field 1552, the display 1547 also shows the estimated time for completion of the linearity measurement (here "23:15:03" hours) and the measured activity (in field 1554), the calculated activity (in field 1558) and the current error (in percentage format) (in field 1556). The linearity measurement may be aborted via an "Abort" button 1560 and the results of the linearity measurement, including a graph of the results, may be printed by selecting a "Print" button (not shown).

[263] As shown in Fig. 45A, activation of calibration tab 1514 prompts the system 10 to generate a calibration display 1570, which shows the results of a previous ionization chamber calibration routine. Ionization chamber calibration routines are preferably conducted upon installation of the system 10 (at, for example, a medical facility) and approximately once a year thereafter to ensure that the ionization chamber 160 of the system 10 is properly calibrated to operate over the range of energies and activity levels of the radiopharmaceuticals for which the ionization chamber 160 is intended to be used. In a preferred calibration routine, the gain of the ionization chamber is increased or decreased to best fit or adjust the measured activity levels of two or three radioisotopes (preferably having energy levels different from (e.g., lower than and greater than) the energy levels of the radiopharmaceuticals to be used with the system 10) against their known activity levels.

[264] By way of a specific example, the system 10 is currently intended to be used to administer FDG (which contains the radioisotope F-18) to patients. The energy level of F-18 is 511 KeV. In a first preferred embodiment, three radioisotopes are used to calibrate the ionization chamber 160: (1) Co-57 (energy level of 122 KeV; less than that of F-18); (2) Co-60 (energy level of 1333 KeV; greater than that of F-18); and (3) Cs-137 (energy level of 662 KeV; relatively close to that of F-18). In a second preferred embodiment, two radioisotopes are used for the calibration routine: (1) Co-57; and (2) Cs-137.

[265] Returning to Fig. 45A, the calibration display 1570 includes a sub-display 1571 conveying previous calibration results for Co-57 (field 1571a), Co-60 (field 1571b) and Cs-137 (field 1571c), while a button 1574 can be activated to begin a new calibration routine. Previous results can also be printed, e.g., via a button 1572.

[266] Upon activating button 1574, a display 1573 is generated (see Fig. 45B) that prompts the operator to place the radioisotope source (here Co-57) in the ionization chamber 160. The display 1573 includes a sub-display 1573a that lists various information about the isotope, including the isotope's name, the lot number, the date and time that the isotope was drawn and the activity level of the isotope when it was drawn. Further, the display 1573 includes "Cancel" button 1573b, "Edit" button 1573c and "OK" button 1573d. The cancel button 1573b is activated to cancel the calibration routine, the edit button 1573c is activated to edit the isotope information provided in sub-display 1573a and the OK button 1573d is activated (as shown in Fig. 45B) to commence the calibration routine with respect to the noted radioisotope (here Co-57), as discussed in more detail below.

[267] If the edit button 1573c in display 1573 is activated, the edit source display 1576 shown in Fig. 45C appears. The operator can edit the isotope information in display 1576 by entering the isotope name in field 1580, the lot number in field 1582, the activity level (at isotope creation) in field 1584 and the reference time and date (of isotope creation) in field 1586 via edit button 1586a. After the isotope information is entered, the operator activates the OK button 1578 and the display 1000 reverts to the display 1573 shown in Fig. 45B. If the isotope information is now correct, the operator can activate the OK button 1573d in display 1573 to commence the calibration routine for the noted radioisotope (here Co-57).

[268] After the OK button 1573d is activated, a tabbed calibration display 1590, including touch tabs for Co-57 (tab 1592), Co-60 (tab 1594) and Cs-137 (tab 1596), appears (as shown in Fig. 45D) and shows the results of the calibration routine for the noted radioisotope (here Co-57). Specifically, the display 1590a for Co-57 tab 1592

shows the target or expected activity for Co-57 (in field 1598), the actual measured activity for the Co-57 placed in the ionization chamber 160 (in field 1600) and the error between the target and measured activity (in field 1602). To thereafter compensate for the error (here 1%), the low gain of the ionization chamber (displayed in field 1604) is adjusted by using the 'plus' and 'minus' buttons 1606, respectively. Further, as shown in Fig. 45D, based on the error for Co-57 the system 10 calculates an estimated error (here 1%) for Cs-137 and displays it in field 1612. Based on the target or expected activity for Cs-137 (entered by the operator and displayed in field 1608) and the estimated error, the estimated measured activity is calculated by the system 10 and displayed in field 1610.

[269] The calibration routine is continued by thereafter activating the tab 1594 for the Co-60 isotope and repeating the steps described above with respect to Figs. 45B-45D. To compensate for the error (not shown) between the expected activity and the measured activity for Co-60, the high gain of the ionization chamber is adjusted (in the same way as shown in Fig. 45D for Co-57). The system 10 then uses the error for Co-60 to revise the estimated error for Cs-137, which is then displayed in field 1612 for the operator.

[270] The operator may continue the process above (i.e., iteratively conducting Co-57 and Co-60 activity measurements and adjusting the low and high gain of the ionization chamber) until the estimated error for Cs-137 (whose energy level of 662 KeV is relatively close to the 511 KeV energy level of F-18) is within an acceptable range (e.g., 1%). At that time, the operator activates the tab 1596 for the Cs-137 isotope and places the Cs-137 source in the ionization chamber to confirm that the difference between the expected and measured activity of the Cs-137 isotope is substantially similar to or within an acceptable range from the estimated error displayed in field 1612. At this point the calibration routine is completed, and the results may be printed and/or stored for later accessing by system maintenance personnel. As shown, an "abort" button 1614 for terminating the calibration procedure is provided for the operator.

[271] Finally, Fig. 46 shows field service tab 1516 activated to prompt a display 1620 which can be used to pre-set one or more future reminder dates to undertake preventative maintenance for the system 10.

[272] It is to be appreciated that the systems, devices and methods of the present invention can be used in a very wide variety of drug delivery and therapeutic procedures. In general, the systems, devices and methods of the present invention are particularly suited for use in connection with any hazardous pharmaceutical or substance to be

injected into a patient (human or animal). Even pharmaceuticals, such as contrast agents or thrombolytic agents, that are not considered to be especially hazardous can be beneficially administered via systems broadly contemplated herein and provide hospital personnel additional protection against adverse effects.

[273] To the extent that systems of the present invention can be applicable to radiotherapy drugs or pharmaceuticals wherein the drug or pharmaceutical itself is radioactive, it is to be appreciated that, as clear to one skilled in the art, maintaining containment of radiotherapy pharmaceuticals promotes safety. If the drug or pharmaceutical is radioactive, the use of radiation absorbing or leaded shielding will help protect the operator and patient from unnecessary radiation. Containment of radiotherapy pharmaceutical is discussed in U.S. Patent Application Publication No. 2003-0004463, the contents of which are incorporated herein by reference.

[274] While procedures discussed herein in accordance with embodiments of the present invention have generally been described with respect to liquid drugs, it is to be understood that they can also apply to powdered drugs with either a liquid or gaseous vehicle, or gaseous drugs that are to be delivered to a recipient.

[275] If not otherwise stated herein, it may be assumed that all components and/or processes described heretofore may, if appropriate, be considered to be interchangeable with similar components and/or processes disclosed elsewhere in the specification, unless an express indication is made to the contrary.

[276] If not otherwise stated herein, any and all patents, patent publications, articles and other printed publications discussed or mentioned herein are hereby incorporated by reference as if set forth in their entirety herein.

[277] It should be appreciated that the apparatus, systems, components and methods of the present invention may be configured and conducted as appropriate for any context at hand. The embodiments described above are to be considered in all respects only as illustrative and not restrictive.

WHAT IS CLAIMED IS:

1. A fluid path set for use in a fluid delivery system, the fluid path set comprising:

a medical fluid component comprising a first tubing section for connection to a source of a medical fluid;

a pharmaceutical component comprising a second tubing section for connection to a source of a pharmaceutical;

a coil assembly component comprising a tube coil having a height of approximately 1.53 inches, a diameter of approximately 1.95 inches and a volume capacity of approximately 12.5 ml; and

a connector comprising a first port for connecting the first tubing section of the medical fluid component, a second port for connecting the second tubing section of the pharmaceutical component and a third port for connecting the tube coil of the coil assembly component.

2. The fluid path set of Claim 1 wherein the tube coil comprises a tubing section having an outer diameter of approximately 0.218 inches, an inner diameter of approximately 0.156 inches and a length of approximately 41 inches.

3. The fluid path set of Claim 2 wherein the tube coil is formed in a helical coil of approximately 7 turns of the tubing section.

4. The fluid path set of Claim 3 wherein the coil assembly further comprises a core structure around which the tube coil is formed, the core structure comprising an upper shoulder and a lower shoulder that define a tube channel therebetween, the upper and lower shoulders adapted to retain the tube coil therebetween within the tube channel.

5. The fluid path set of Claim 4 wherein the core structure further comprises an upper surface defining an inlet for accommodating a first end of the tubing section and an outlet for accommodating a second end of the tubing section.

6. The fluid path set of Claim 5 wherein the coil assembly component further comprises a third tubing section connected to the third port of the connector and the first end of the tubing section and a fourth tubing section connected to the second end of the tubing section.

7. The fluid path set of Claim 6, further comprising:

a waste component comprising a fifth tubing section in connection with a waste receptacle;

a sixth tubing section having a connector end that is adapted to be connected to a single-patient tubing set; and

a second connector comprising a first port for connecting the fourth tubing section of the coil assembly component, a second port for connecting the fifth tubing section of the waste component and a third port for connecting the sixth tubing section.

8. The fluid path set of Claim 7 wherein the connector end comprises a swabable luer valve that is biased to a closed position when the single-patient tubing set is not connected thereto.

9. The fluid path set of Claim 7 wherein the connector end comprises a manifold or a stopcock each having two or more outlet ports for connection to respective single-patient tubing sets.

10. The fluid path set of Claim 7 wherein the first tubing section is approximately 56.75 inches in length and has an outer diameter of approximately 0.188 inches, an inner diameter of approximately 0.062 inches and a durometer of 45, the second tubing section is approximately 8.75 inches in length and has an outer diameter of approximately 0.094 inches, an inner diameter of approximately 0.032 inches and a durometer of 45, the third tubing section is approximately 15 inches in length and has an outer diameter of approximately 0.163 inches, an inner diameter of approximately 0.062 inches and a durometer of 60, the fourth tubing section is approximately 12 inches in length and has an outer diameter of approximately 0.163 inches, an inner diameter of approximately 0.062 inches and a durometer of 60, and the fifth tubing section and the sixth tubing section are each approximately 5 inches in length and have an outer diameter of approximately 0.163 inches, an inner diameter of approximately 0.062 inches and a durometer of 60.

11. The fluid path set of Claim 1 wherein the first tubing section comprises a first check valve and a spike for connecting to the source of a medical fluid and the second tubing

section comprises a second check valve and a vented cannula for connecting to the source of a pharmaceutical.

12. The fluid path set of Claim 1 wherein the second tubing section comprises a vented cannula comprising:

a main hub comprising two opposed lateral sides and defining a fluid port and a vent;

a fluid draw needle in connection with the second tubing section through the fluid port and adapted to be placed within the source of a pharmaceutical;

a vent needle in connection with the vent and adapted to be placed within the source of a pharmaceutical; and

two resilient arms connected to the opposed lateral sides of the main hub, each of the two arms comprising a top edge and a hook member formed thereon and extending outwardly therefrom.

13. The fluid path set of Claim 12 wherein the fluid draw needle is longer than the vent needle.

14. The fluid path set of Claim 12 wherein the vent comprises a filter.

15. The fluid path set of Claim 12 wherein the main hub of the vented cannula further comprises a ledge extending therefrom in a horizontal plane above the two arms, the ledge and the top edges of the two arms cooperating to define horizontal slots therebetween.

16. The fluid path set of Claim 15 wherein the hook members extend outwardly from the arms in a plane substantially normal to the horizontal plane of the ledge.

17. The fluid path set of Claim 12 wherein the main hub and each of the arms cooperate to define substantially U-shaped grooves extending along the lateral sides of the main hub.

18. A vented cannula for drawing fluid from a container, the vented cannula comprising:

a main hub comprising two opposed lateral sides and defining a fluid port and a vent;

a fluid draw needle in connection with the fluid port and adapted to be placed within the container;

a vent needle in connection with the vent and adapted to be placed within the container; and

two resilient arms connected to the opposed lateral sides of the main hub, each of the two arms comprising a top edge and a hook member formed thereon and extending outwardly therefrom.

19. The vented cannula of Claim 18 wherein the fluid draw needle is longer than the vent needle.

20. The vented cannula of Claim 18 wherein the vent comprises a filter.

21. The vented cannula of Claim 18 wherein the main hub of the vented cannula further comprises a ledge extending therefrom in a horizontal plane above the two arms, the ledge and the top edges of the two arms cooperating to define horizontal slots therebetween.

22. The vented cannula of Claim 21 wherein the hook members extend outwardly from the arms in a plane substantially normal to the horizontal plane of the ledge.

23. The vented cannula of Claim 18 wherein the main hub and each of the arms cooperate to define substantially U-shaped grooves extending along the lateral sides of the main hub.

24. A method of calibrating a fluid delivery system for delivering a pharmaceutical containing a radioisotope to a patient, the method comprising:

measuring an activity level of a first radioisotope in an ionization chamber of the fluid delivery system, the first radioisotope having an energy level less than that of the radioisotope to be delivered to the patient;

comparing the measured activity level of the first radioisotope to an expected activity level of the first radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the measured activity and the expected activity of the first radioisotope;

measuring an activity level of a second radioisotope in the ionization chamber of the fluid delivery system, the second radioisotope having an energy level similar to or greater than that of the radioisotope to be delivered to the patient;

comparing the measured activity level of the second radioisotope to an expected activity level of the second radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the measured activity and the expected activity of the second radioisotope; and

calculating an estimated error in a measured activity of a third radioisotope based on the differences, if any, between the measured activity and the expected activity of the first radioisotope and the measured activity and the expected activity of the second radioisotope.

25. The method of Claim 24, further comprising:

comparing the estimated error in a measured activity of the third radioisotope to a predetermined acceptable error or error range;

if the estimated error is the same as or similar to the predetermined acceptable error or is within the predetermined acceptable error range, then measuring an activity level of the third radioisotope in the ionization chamber of the fluid delivery system;

calculating the difference, if any, between the measured activity level of the third radioisotope and an expected activity level of the third radioisotope to derive an actual error; and

determining whether the actual error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range.

26. The method of Claim 24 wherein the calculating step comprises:

calculating an initial estimated error in a measured activity of a third radioisotope based on the difference, if any, between the measured activity and the expected activity of the first radioisotope; and

calculating a revised estimated error in a measured activity of the third radioisotope based on the difference, if any, between the measured activity and the expected activity of the second radioisotope.

27. The method of Claim 26, further comprising:

comparing the revised estimated error in a measured activity of the third radioisotope to a predetermined acceptable error or error range;

if the revised estimated error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range, then measuring an activity level of the third radioisotope in the ionization chamber of the fluid delivery system;

calculating the difference, if any, between the measured activity level of the third radioisotope and an expected activity level of the third radioisotope to derive an actual error; and

determining whether the actual error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range.

28. The method of Claim 27, further comprising:

if the revised estimated error is not the same or similar to the predetermined acceptable error or is not within the predetermined acceptable error range, then remeasuring the activity level of the first radioisotope in the ionization chamber of the fluid delivery system;

comparing the remeasured activity level of the first radioisotope to the expected activity level of the first radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the remeasured activity and the expected activity of the first radioisotope;

calculating a second revised estimated error in a measured activity of the third radioisotope based on the difference, if any, between the remeasured activity and the expected activity of the first radioisotope;

remeasuring the activity level of the second radioisotope in the ionization chamber of the fluid delivery system;

comparing the remeasured activity level of the second radioisotope to the expected activity level of the second radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the remeasured activity and the expected activity of the second radioisotope; and

calculating a third revised estimated error in a measured activity of the third radioisotope based on the difference, if any, between the remeasured activity and the expected activity of the second radioisotope.

29. The method of Claim 28, further comprising:

comparing the third revised estimated error in a measured activity of the third radioisotope to a predetermined acceptable error or error range;

if the third revised estimated error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range, then measuring an activity level of the third radioisotope in the ionization chamber of the fluid delivery system;

calculating the difference, if any, between the measured activity level of the third radioisotope and an expected activity level of the third radioisotope to derive an actual error; and

determining whether the actual error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range.

30. The method of Claim 27, further comprising:

if the revised estimated error is not the same or similar to the predetermined acceptable error or is not within the predetermined acceptable error range, then remeasuring the activity level of the first radioisotope in the ionization chamber of the fluid delivery system;

comparing the remeasured activity level of the first radioisotope to the expected activity level of the first radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the remeasured activity and the expected activity of the first radioisotope;

calculating a second revised estimated error in a measured activity of the third radioisotope based on the difference, if any, between the remeasured activity and the expected activity of the first radioisotope;

comparing the second revised estimated error in a measured activity of the third radioisotope to a predetermined acceptable error or error range;

if the second revised estimated error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range, then measuring an activity level of the third radioisotope in the ionization chamber of the fluid delivery system;

calculating the difference, if any, between the measured activity level of the third radioisotope and an expected activity level of the third radioisotope to derive an actual error;

determining whether the actual error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range;

if the second revised estimated error is not the same or similar to the predetermined acceptable error or is not within the predetermined acceptable error range, then remeasuring the activity level of the second radioisotope in the ionization chamber of the fluid delivery system;

comparing the remeasured activity level of the second radioisotope to the expected activity level of the second radioisotope;

adjusting the gain of the ionization chamber to compensate for the difference, if any, between the remeasured activity and the expected activity of the second radioisotope; and

calculating a third revised estimated error in a measured activity of the third radioisotope based on the difference, if any, between the remeasured activity and the expected activity of the second radioisotope.

31. The method of Claim 30, further comprising:

comparing the third revised estimated error in a measured activity of the third radioisotope to a predetermined acceptable error or error range;

if the third revised estimated error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range, then measuring an activity level of the third radioisotope in the ionization chamber of the fluid delivery system;

calculating the difference, if any, between the measured activity level of the third radioisotope and an expected activity level of the third radioisotope to derive an actual error; and

determining whether the actual error is the same or similar to the predetermined acceptable error or is within the predetermined acceptable error range.

32. The method of Claim 24 wherein the radioisotope to be delivered to the patient is F-18.

33. The method of Claim 32 wherein the first radioisotope is Co-57, the second radioisotope is Co-60 and the third radioisotope is Cs-137.

34. The method of Claim 24 wherein the low gain of the ionization chamber is adjusted to compensate for the difference, if any, between the measured activity and the expected activity of the first radioisotope and the high gain of the ionization chamber is adjusted to compensate for the difference, if any, between the measured activity and the expected activity of the second radioisotope.

35. A vial access system comprising:

a base portion comprising a substantially horizontal lower surface and a sloped upper surface adapted to support a vial comprising a bottom wall and a substantially cylindrical wall connected thereto, the sloped upper surface adapted to ensure that a residual volume of fluid in the vial gathers in an area defined at least partially by a portion of the junction between the bottom wall and the cylindrical wall of the vial.

36. The vial access system of Claim 35, further comprising:

a housing extending vertically from the base portion;

a vertical support arm comprising an upper end, the vertical support arm movably disposed within the housing; and

a cap member connected to the upper end of the vertical support arm and adapted to overlie a septum of the vial.

37. The vial access system of Claim 36 wherein the cap member comprises a mounting mechanism disposed on an underside thereof, the mounting mechanism adapted to retain a cannula therein for insertion through the septum of the vial.

38. The vial access system of Claim 37 wherein the vertical support arm is slidably disposed within the housing to allow the cannula to be inserted into and removed from the vial.

39. The vial access system of Claim 38 wherein the vertical support arm is rotatably disposed within the housing to allow the cap member to be rotated into and out of a position that overlies the septum of the vial.

40. The vial access system of Claim 37 wherein the mounting mechanism comprises two arms that cooperate to define a slot therebetween, each of the two arms comprising a tab member extending downwardly therefrom, each of the tab members comprising a front edge and a rear edge.

41. The vial access system of Claim 36, further comprising a handle member pivotally connected to the upper end of the vertical support arm.

42. The vial access system of Claim 36 wherein the cap member includes or is formed from radioactive shielding material.

43. The vial access system of Claim 35, further comprising at least one support member connected to the base portion for retaining the vial on the sloped upper surface of the base portion.

44. The vial access system of Claim 43 wherein the at least one support member comprises two support pins that are connected to the sloped upper surface of the base portion.

45. The vial access system of Claim 35 wherein the vial is contained within a vial shield and the fluid is a radiopharmaceutical.

46. The vial access system of Claim 35 wherein the sloped upper surface is sloped at an angle of approximately 10-13 degrees with respect to a horizontal plane.

47. A method of priming at least a portion of a fluid path set in a fluid delivery system, the method comprising:

placing a tubing section of the fluid path set in fluid connection with a source of a radiopharmaceutical;

placing a portion of the tubing section within a dose calibrator of the fluid delivery system;

pumping a volume of the radiopharmaceutical through the tubing section;

monitoring the dose calibrator to determine if a measured activity level is substantially equal to or above a predetermined activity level; and

if the measured activity level is substantially equal to or above the predetermined activity level, then concluding that the tubing section of the fluid path set has been primed.

48. The method of Claim 47, further comprising:

if the measured activity level is zero or below the predetermined activity level, then concluding that the tubing section of the fluid path has not been primed; and

pumping a second volume of the radiopharmaceutical through the tubing section.

49. The method of Claim 47, further comprising:

placing a second tubing section in fluid connection with a source of medical fluid and the tubing section;

pumping a volume of the medical fluid through the second tubing section and at least a portion of the tubing section to move the volume of the radiopharmaceutical to the portion of the tubing section that is positioned within the dose calibrator.

50. The method of Claim 49, further comprising:

placing the tubing section in fluid connection with a waste receptacle;

pumping a second volume of the medical fluid through the second tubing section and at least a portion of the tubing section to move the volume of the radiopharmaceutical into the waste receptacle.

51. A fluid delivery system, comprising:

a housing having an upper surface defining a plurality of recessed portions for accommodating one or more components of a fluid path set;

a cover movably connected to the housing and adapted to move between a first position that exposes the upper surface and a second position that overlies the upper surface; and.

a locking mechanism associated with the cover and adapted to lock the cover in the second position.

52. The fluid delivery system of Claim 51 wherein the cover is slidably connected to the housing.

53. The fluid delivery system of Claim 51 wherein the first position allows an operator to insert or remove the one or more components of the fluid path set.

54. The fluid delivery system of Claim 51 wherein the plurality of recessed portions includes wells and troughs.

55. The fluid delivery system of Claim 51, further comprising:

one or more handles connected to the housing;

a plurality of wheels or casters connected to the housing; and

a display connected to the housing.

56. The fluid delivery system of Claim 51 wherein the cover and the upper surface comprises or is formed from a radioactive shielding material.

57. The fluid delivery system of Claim 51, further comprising:

a dose calibrator for measuring the radioactivity level of a radiopharmaceutical;

a pumping mechanism for pumping the radiopharmaceutical; and

a controller in communication with the dose calibrator and the pumping mechanism.

58. The fluid delivery system of Claim 51 wherein the locking mechanism comprises a mechanical lock that locks the cover to the housing in the second position.

59. The fluid delivery system of Claim 57 wherein the locking mechanism is a software-implemented lock that is in communication with the controller, the software implemented lock adapted to lock the cover to the housing in the second position.

60. The fluid delivery system of Claim 51, further comprising a printer associated with the housing.

61. A vial shield carrying system for carrying a vial shield containing a pharmaceutical vial, the vial shield carrying system comprising in combination:

a collar unit adapted to removably engage a flange on the vial shield, the collar unit defining two elongated slots formed in a top surface thereof, each of the slots including a pin disposed therein and extending between two opposing walls thereof; and

a handle unit adapted to engage the collar unit, the handle unit comprising a handle connected to a U-shaped cross piece defining two, downwardly extending arms having hook members formed therein, the open ends of the hook members formed on opposite ends of the arms and adapted to engage the pins in the slots of the collar unit through rotation of the handle.

62. The vial shield carrying system of Claim 61, further comprising a plunger connected to the U-shaped cross piece and adapted to mate with a septum cap of the vial shield when the handle unit engages the collar unit on the vial shield.

63. The vial shield carrying system of Claim 62, further comprising a spring disposed between the plunger and the U-shaped cross piece, the spring adapted to bias the plunger into engagement with the septum cap of the vial shield.

64. The vial shield carrying system of Claim 63 wherein the arms are lowered into the slots of the collar unit, the plunger is engaged with the septum cap of the vial shield and the handle is rotated in a clockwise direction to seat the pins of the collar unit in the hook members of the handle unit.

65. The vial shield carrying system of Claim 64 wherein the handle is rotated in a counter-clockwise direction to disengage the hook members of the handle unit from the pins of the collar unit.

66. The vial shield carrying system of Claim 62 wherein the plunger comprises or is formed from a radioactive shielding material.

67. The vial shield carrying system of Claim 61 wherein the collar unit comprises two members that are pivotally connected to allow the collar unit to engage and disengage the flange of the vial shield.

68. A fluid delivery system, comprising:

a syringe comprising a body defining a discharge outlet and a plunger movably disposed within the body;

a connector comprising a valve member and defining first, second and third ports;

a first tubing segment connected between the discharge outlet of the syringe and the first port of the connector;

a cannula defining a fluid port;

a second tubing segment connected between the fluid port of the cannula and the second port of the connector;

a third tubing segment comprising a first end connected to the third port of the connector and a second end comprising a second connector; and

a per-patient tubing set comprising a first end that is adapted to be connected to the second connector on the second end of the third tubing segment and a patient end that is adapted to be connected to venous access device in a patient.

69. The fluid delivery system of Claim 68 wherein the connector comprises a T-connector and the valve member comprises a stopcock.

70. The fluid delivery system of Claim 68 wherein the second connector comprises a swabable valve or a luer connector.

71. The fluid delivery system of Claim 68 wherein the syringe contains a radiopharmaceutical and is disposed within a lead-shielded container.

72. The fluid delivery system of Claim 68 wherein the syringe is a hand-held syringe.

73. The fluid delivery system of Claim 68 wherein the cannula further comprises:

a main hub comprising two opposed lateral sides and defining a vent;

a fluid draw needle in connection with the fluid port and adapted to be placed within a fluid container;

a vent needle in connection with the vent and adapted to be placed within the fluid container; and

two resilient arms connected to the opposed lateral sides of the main hub, each of the two arms comprising a top edge and a hook member formed thereon and extending outwardly therefrom.

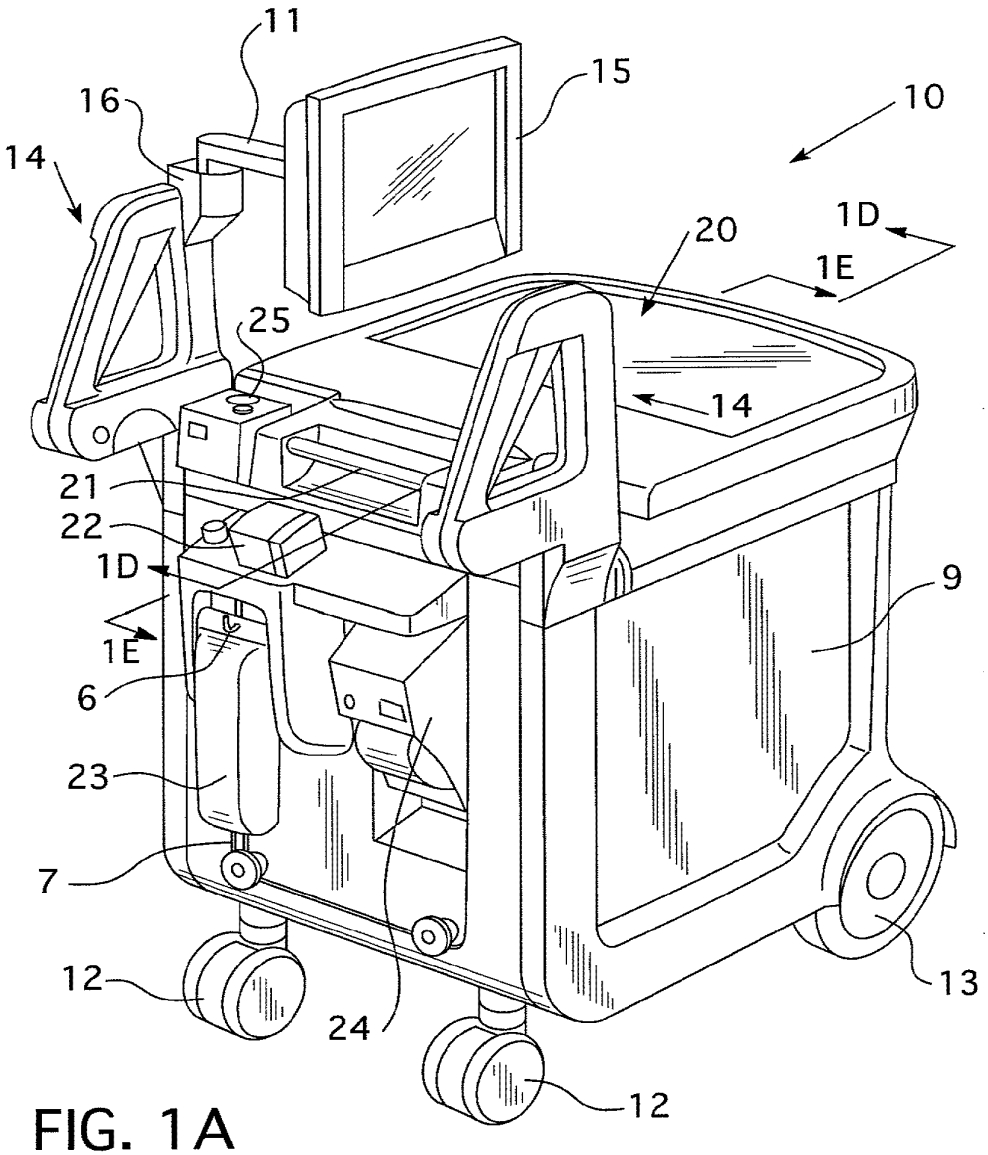

FIG. 1A

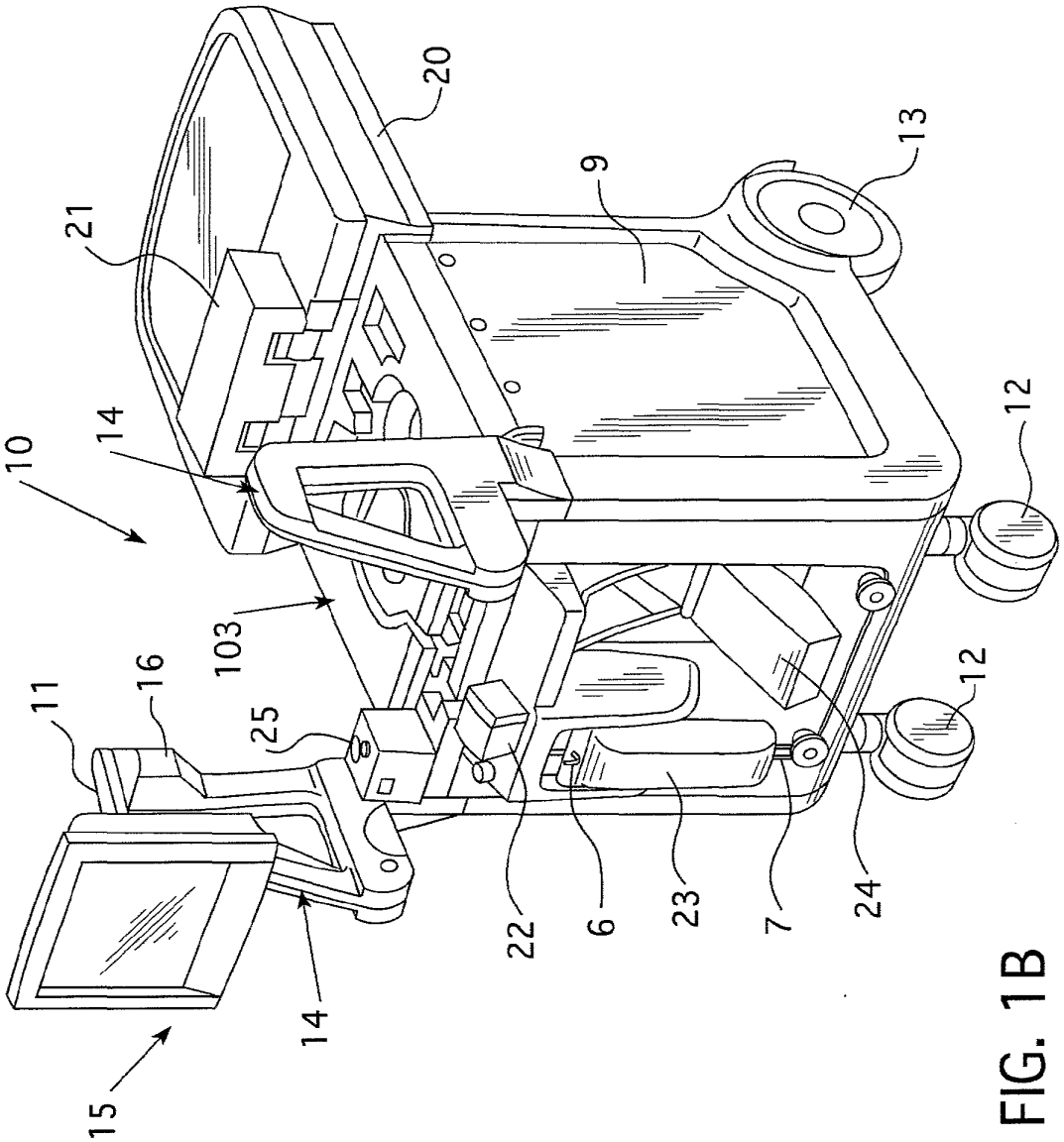

FIG. 1B

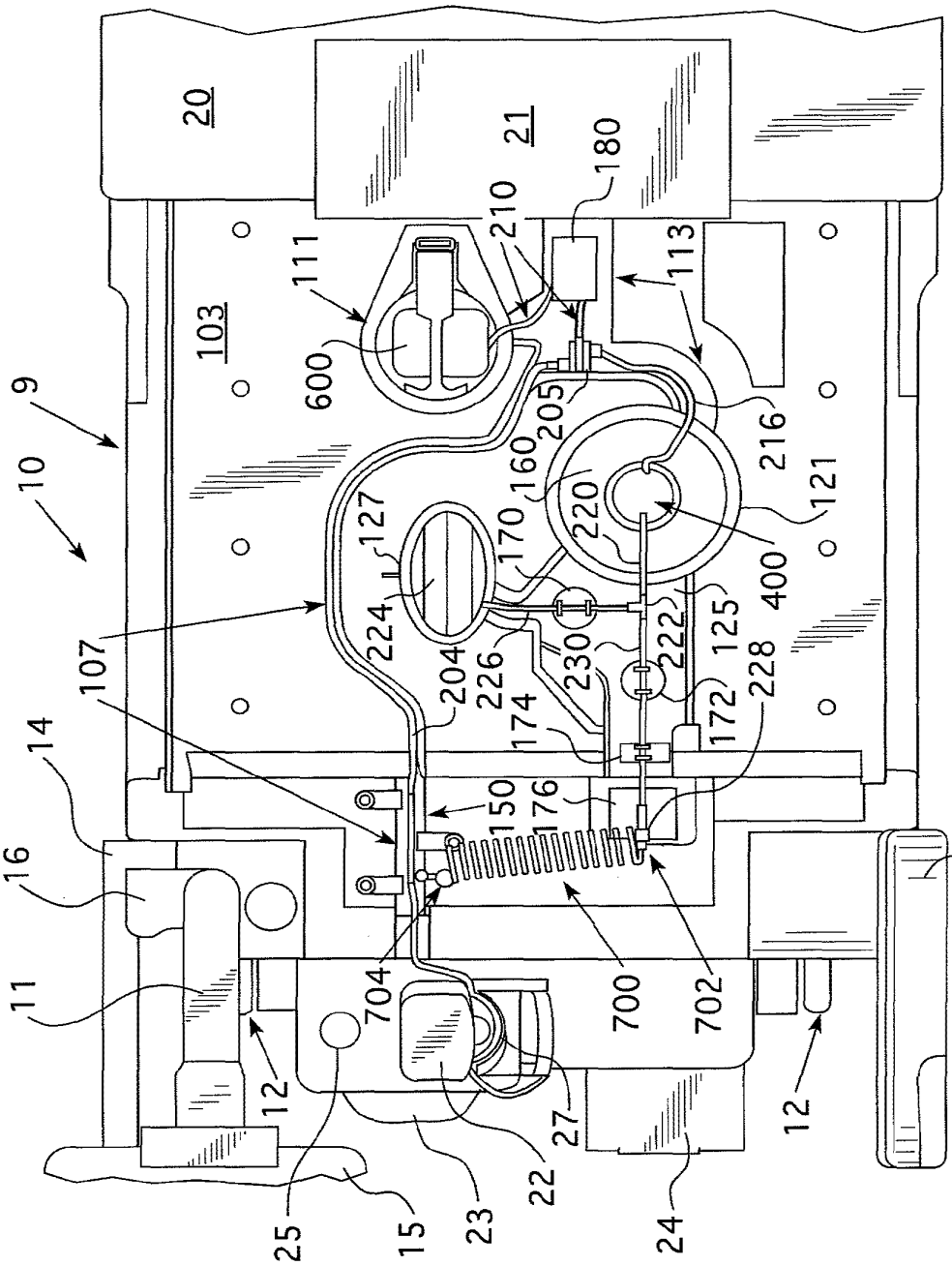
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FIG. 1C

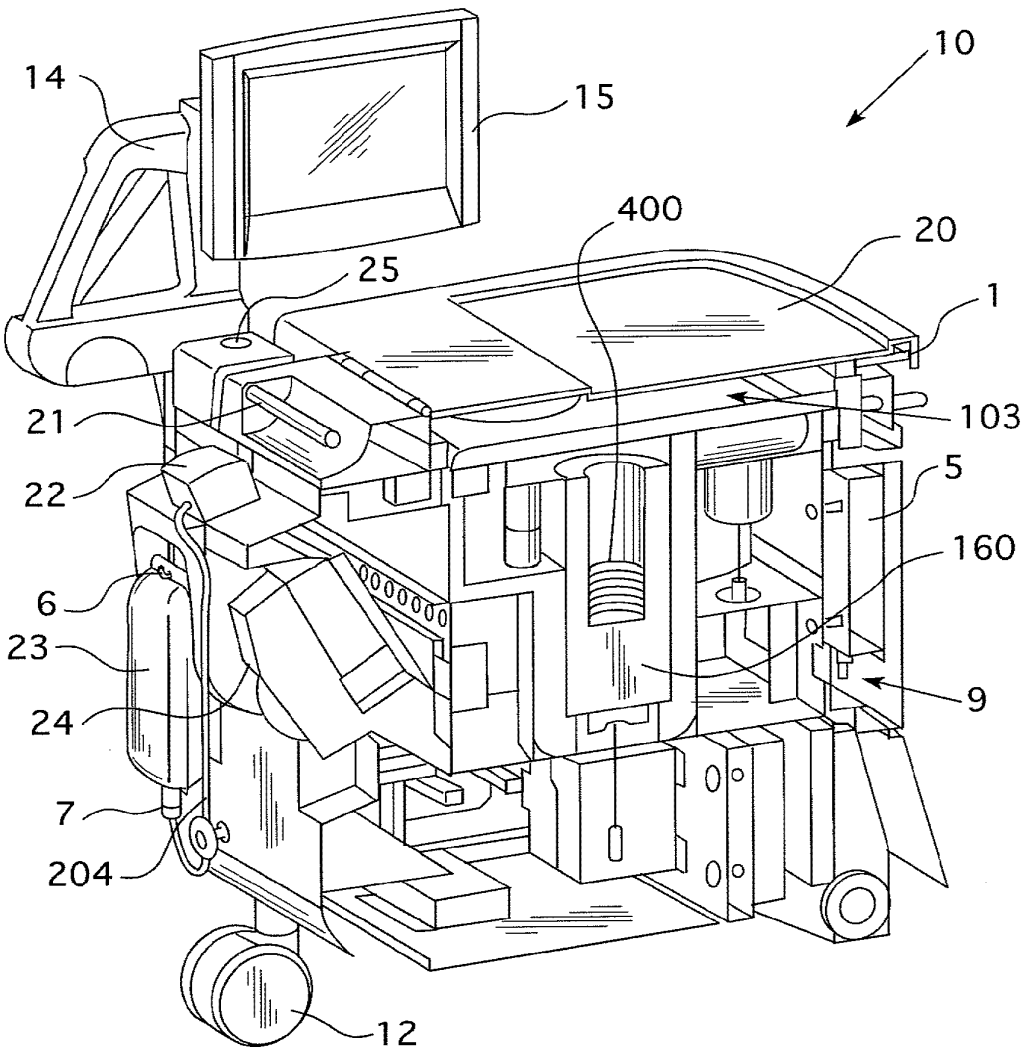

FIG. 1D

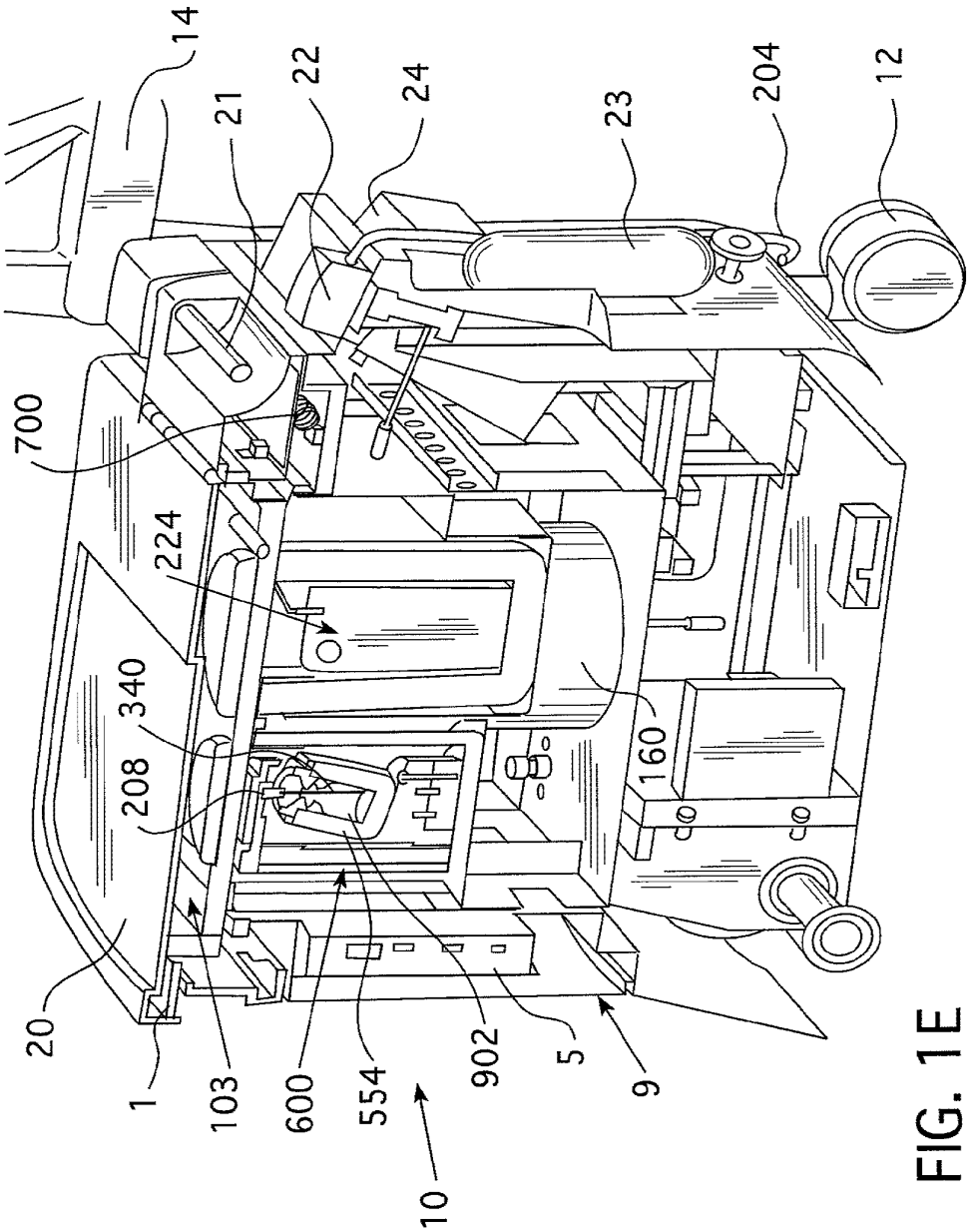

FIG. 1E

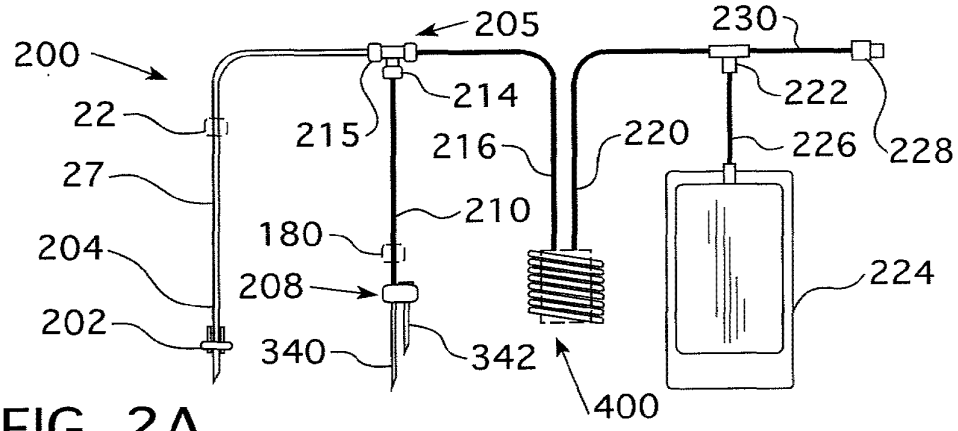
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FIG. 2A

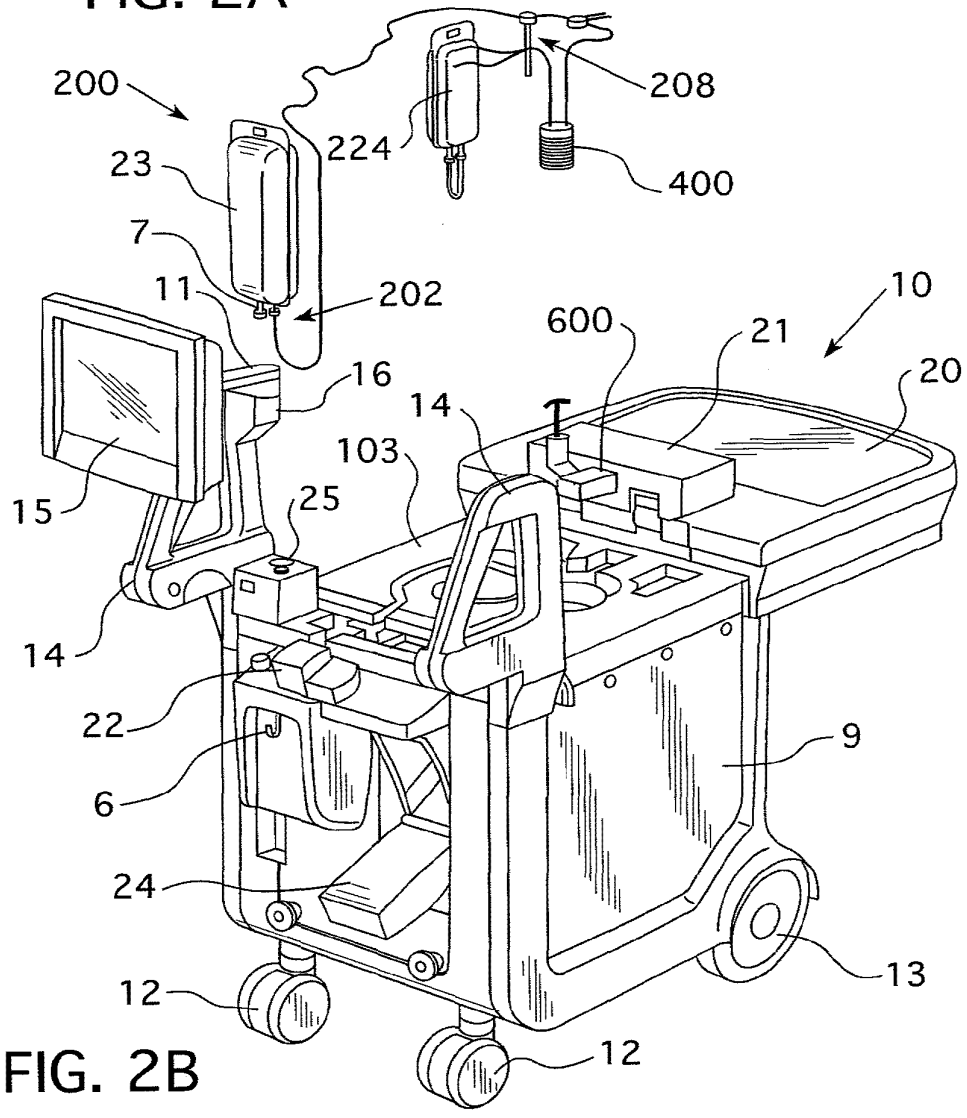
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FIG. 2B

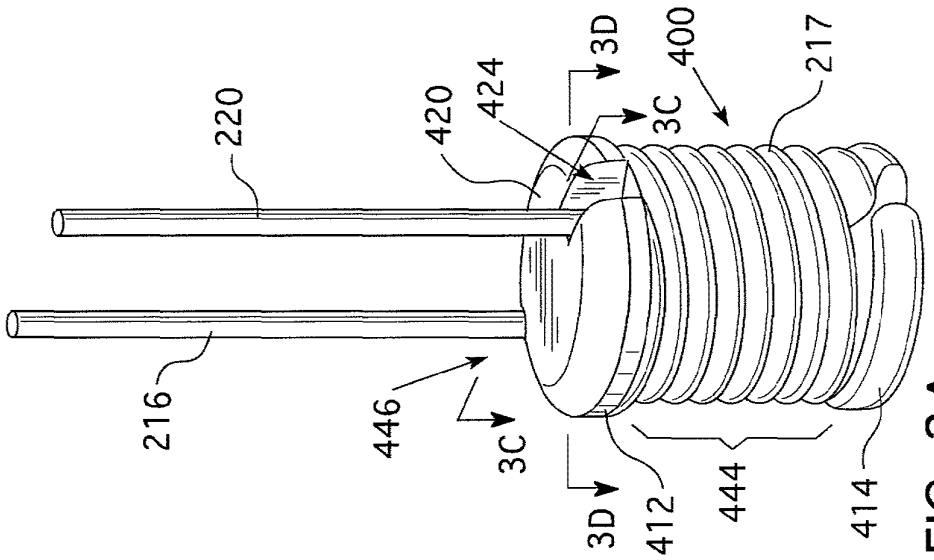
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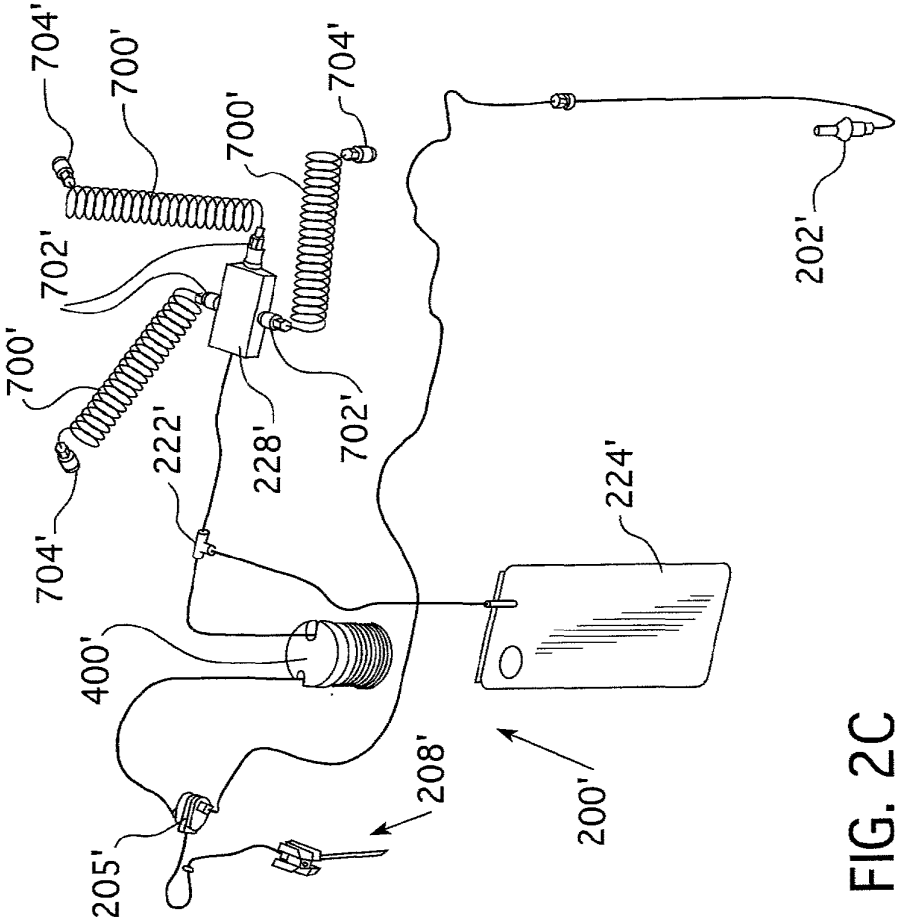
FIG. 3A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200'

FIG. 2C

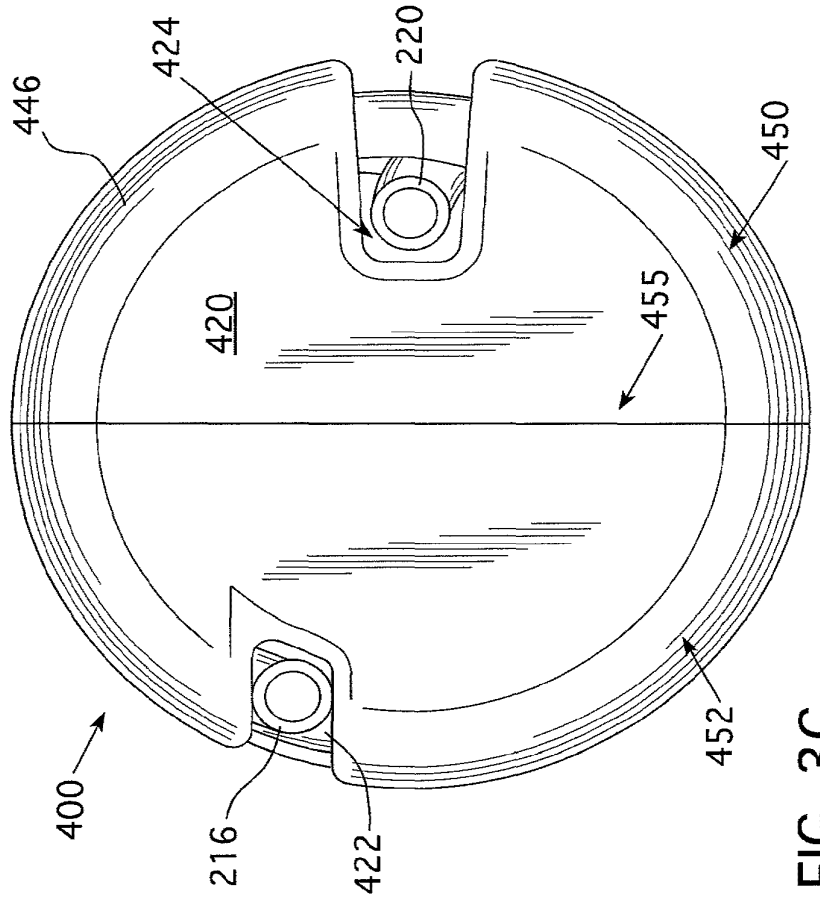
446
424
220
450
420
455
400
216
422
452

FIG. 3C

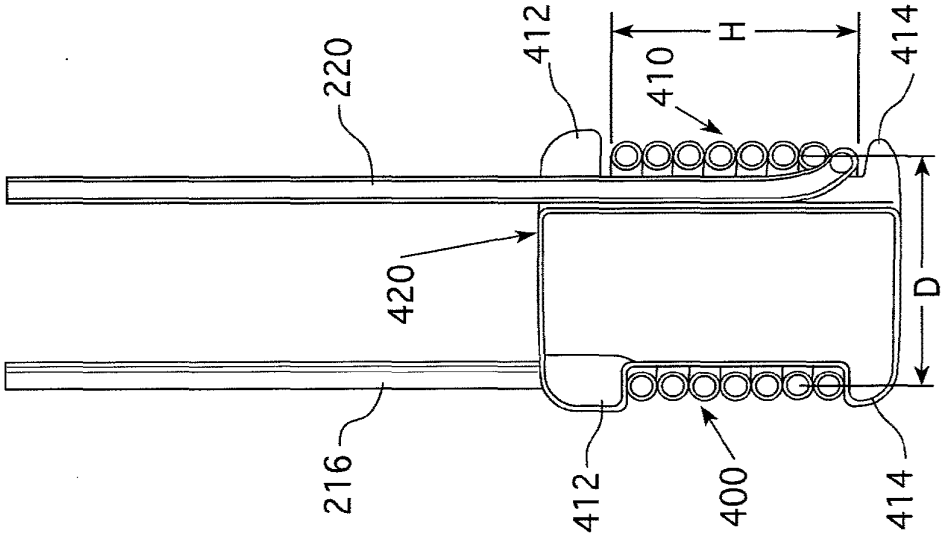
220
412
H
410
414
420
D
216
412
400
414

FIG. 3B

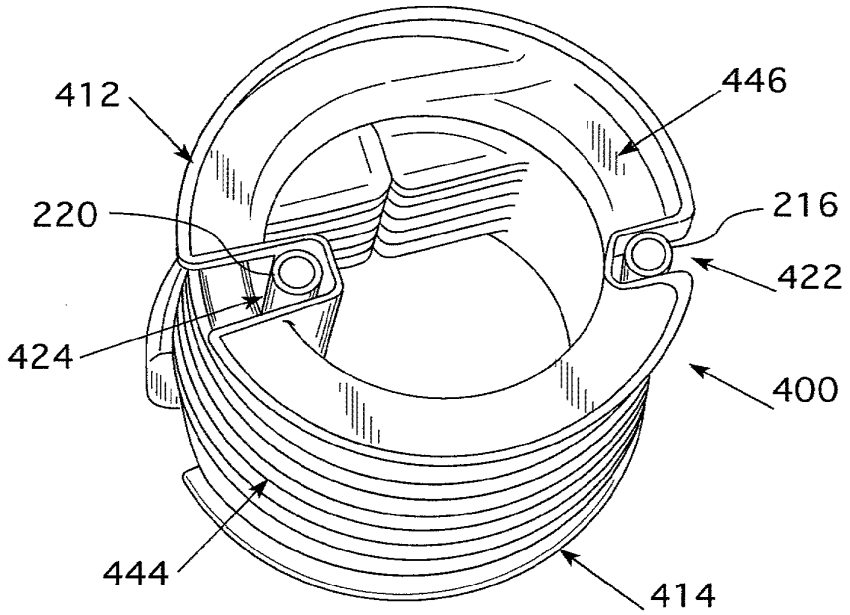
412
446
220
216
422
424
400
444
414

FIG. 3D

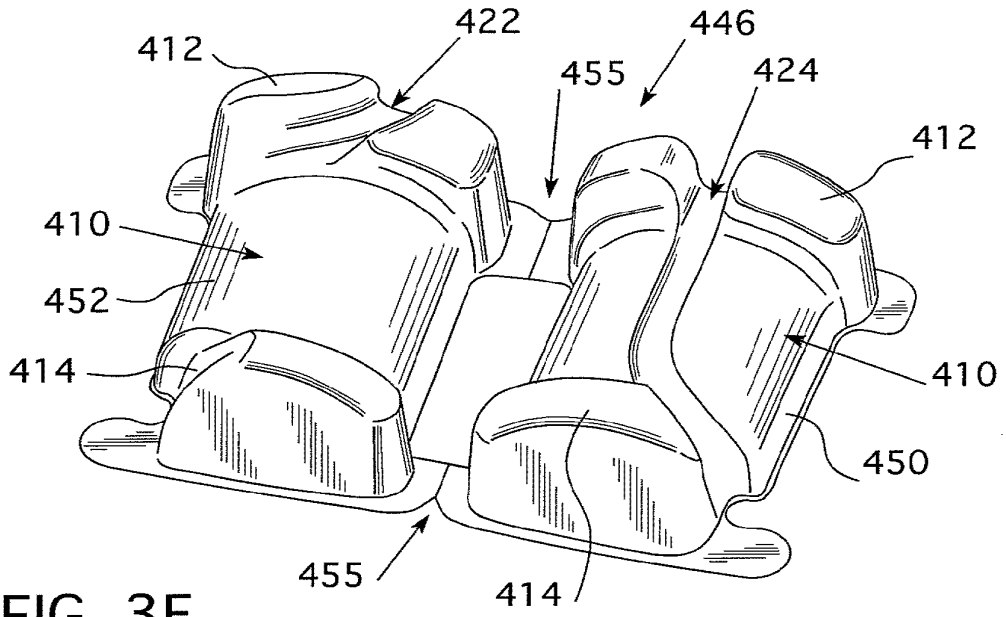
422
446
412
455
424
412
410
452
414
410
450
455
414

FIG. 3E

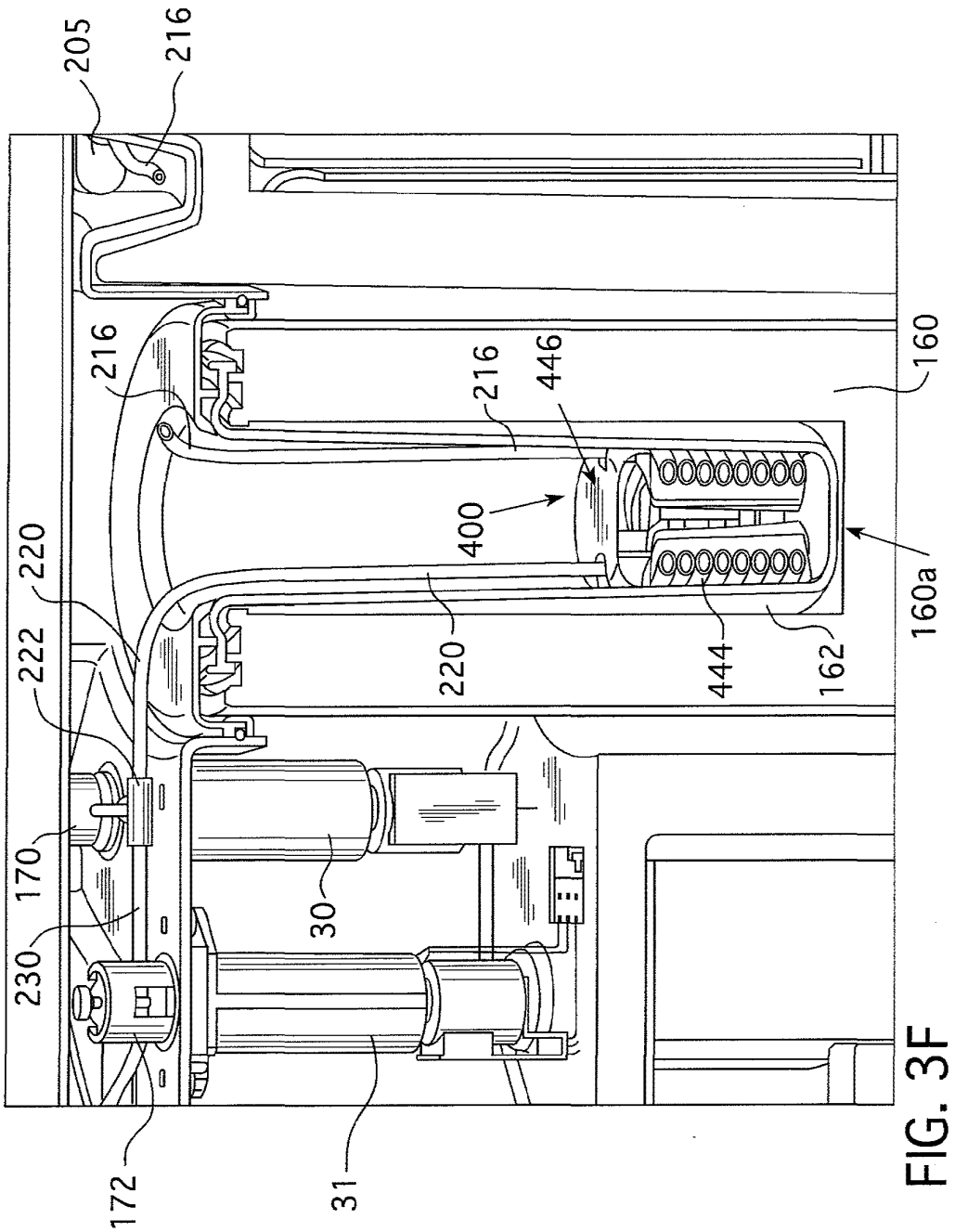
205
216
216
216
446
160
400
220
222
220
444
162
160a
170
230
30
172
31

FIG. 3F

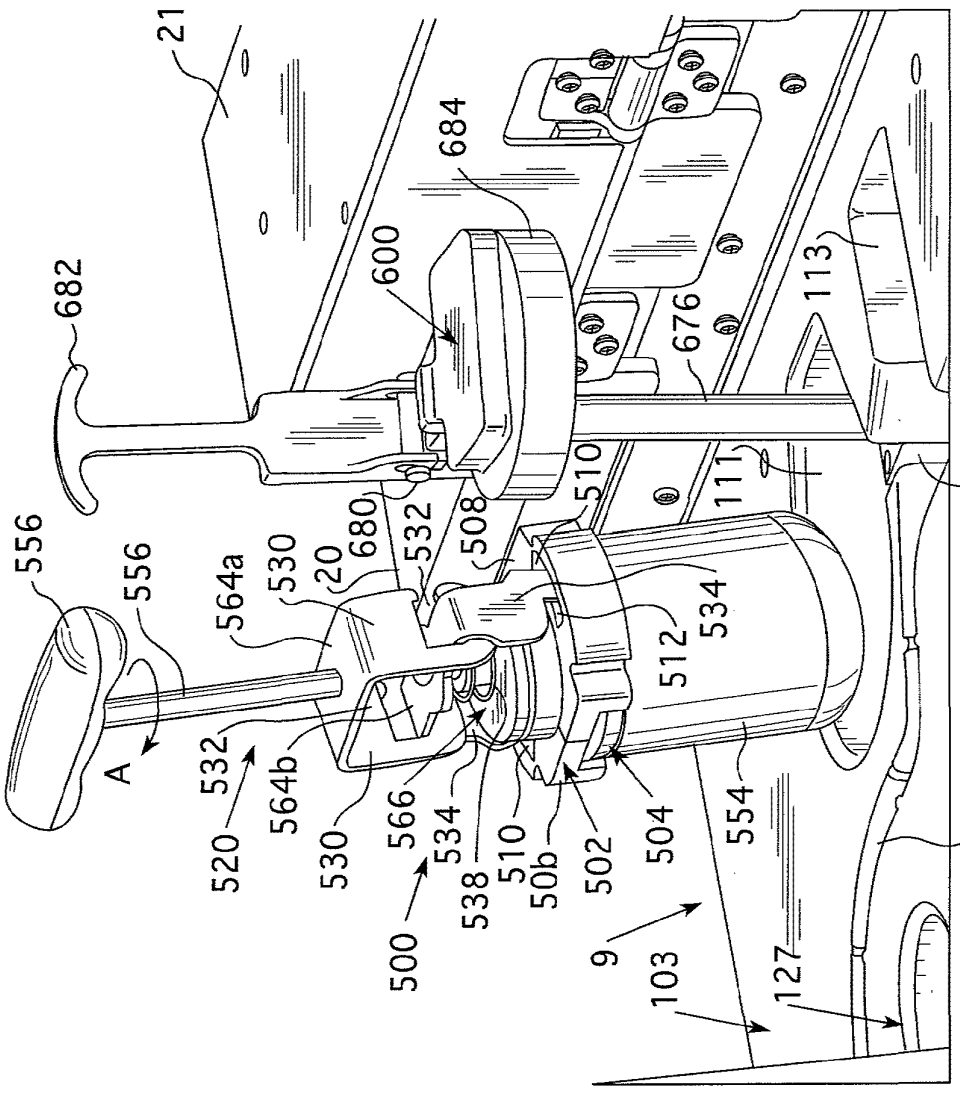
21
684
600
682
676
113
556
556
564a
530
20
680
532
508
510
111
678
534
512
A
532
564b
566
534
510
50b
502
504
554
107
520
530
500
538
9
103
127

FIG. 4A

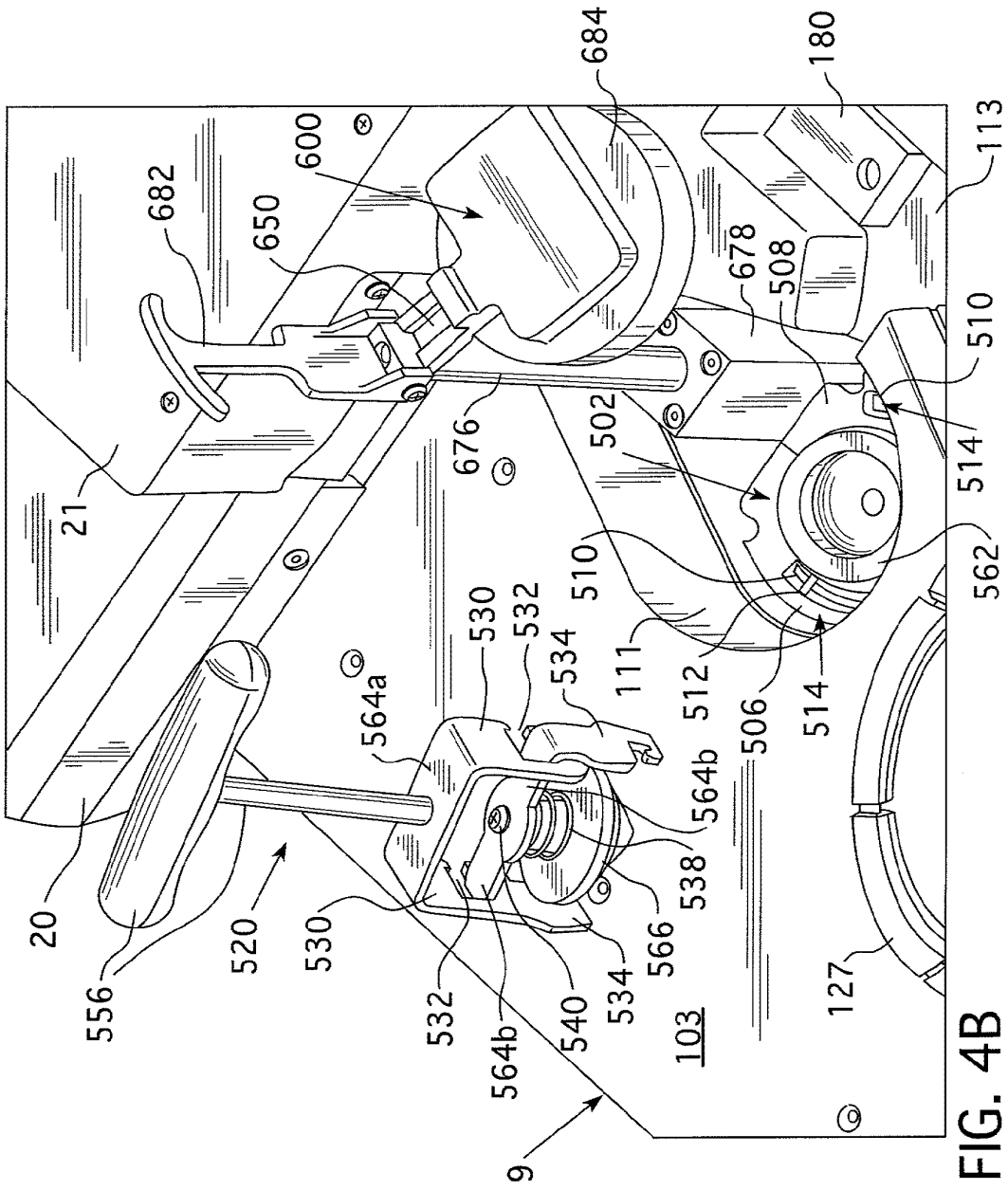
684
180
600
682
650
113
678
508
510
676
502
514
21
562
510
530
532
534
111
512
564a
506
514
564b
538
20
520
530
566
556
532
534
540
564b
103
127
9

FIG. 4B

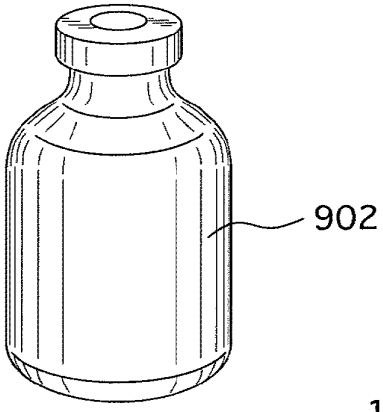

FIG. 4C

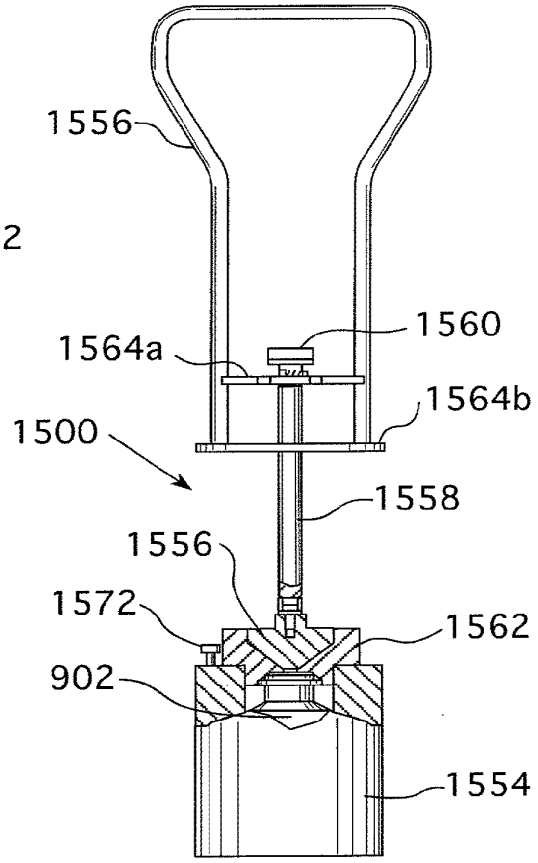

FIG. 5A

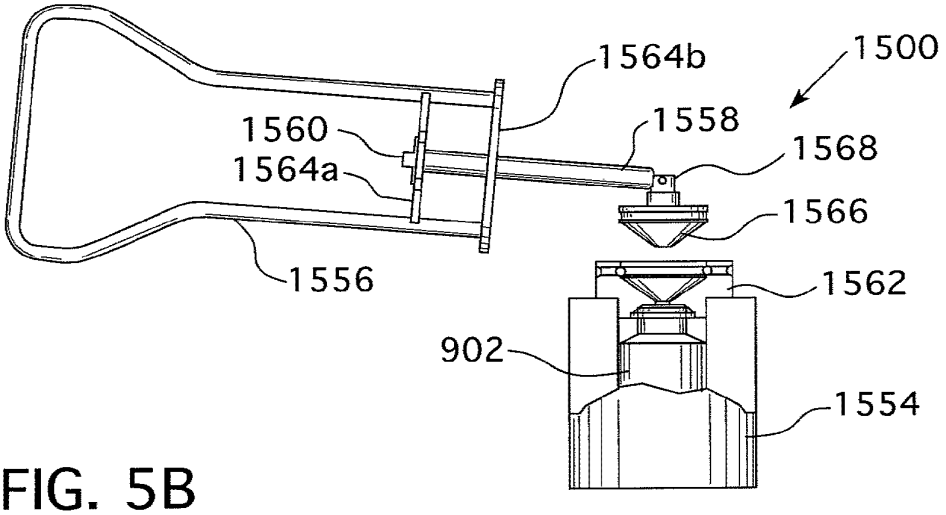

FIG. 5B

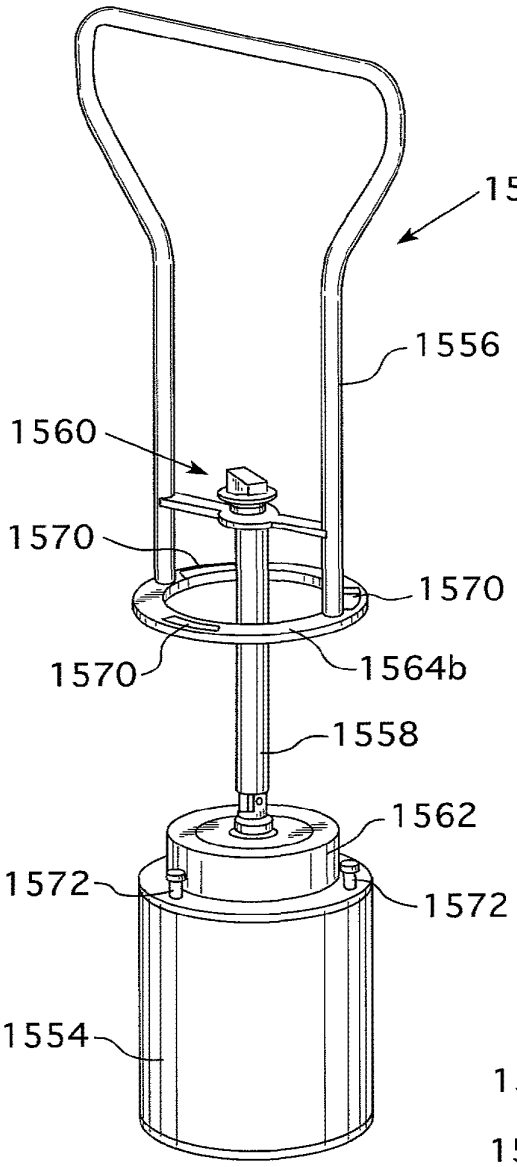
1500
1556
1560
1570
1570
1570
1564b
1558
1562
1572
1572
1554

FIG. 5C

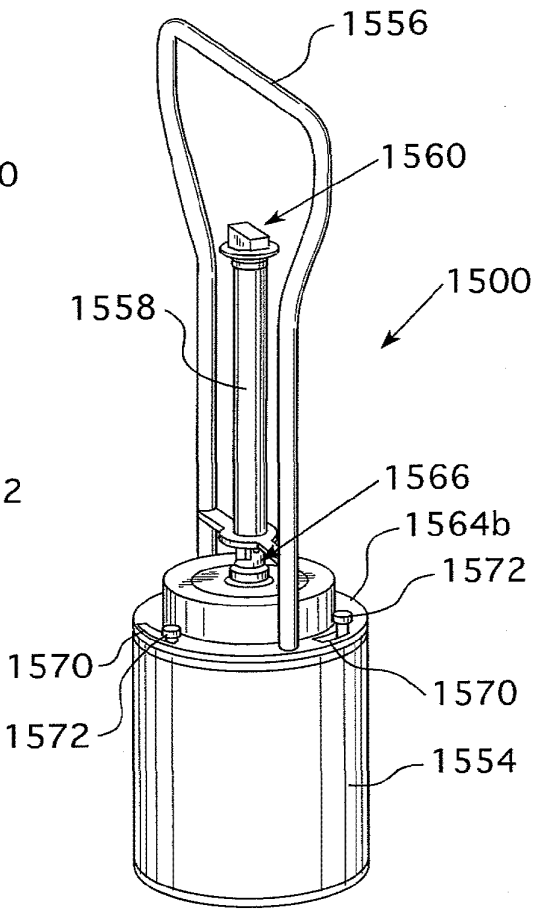
1556
1560
1500
1558
1566
1564b
1572
1570
1570
1572
1554

FIG. 5D

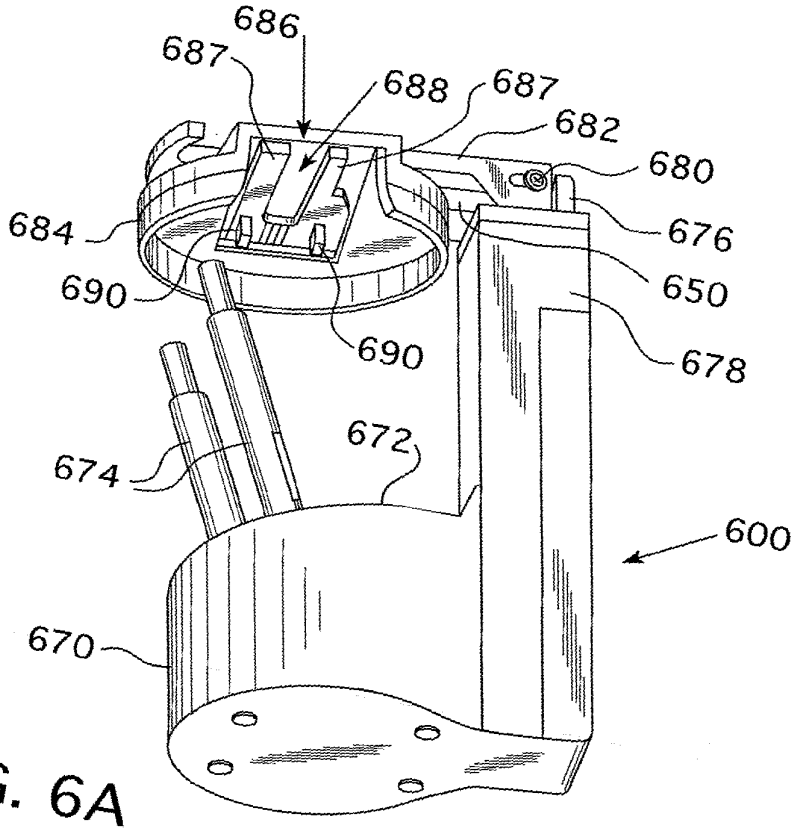
686
687
688
687
682
680
684
676
690
650
690
678
672
674
600
670

FIG. 6A

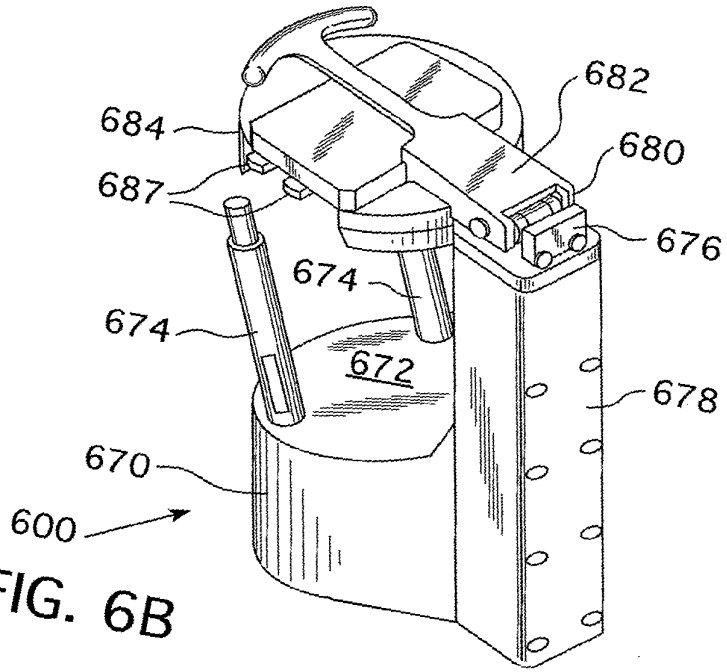
682
684
680
687
676
674
674
672
678
670
600

FIG. 6B

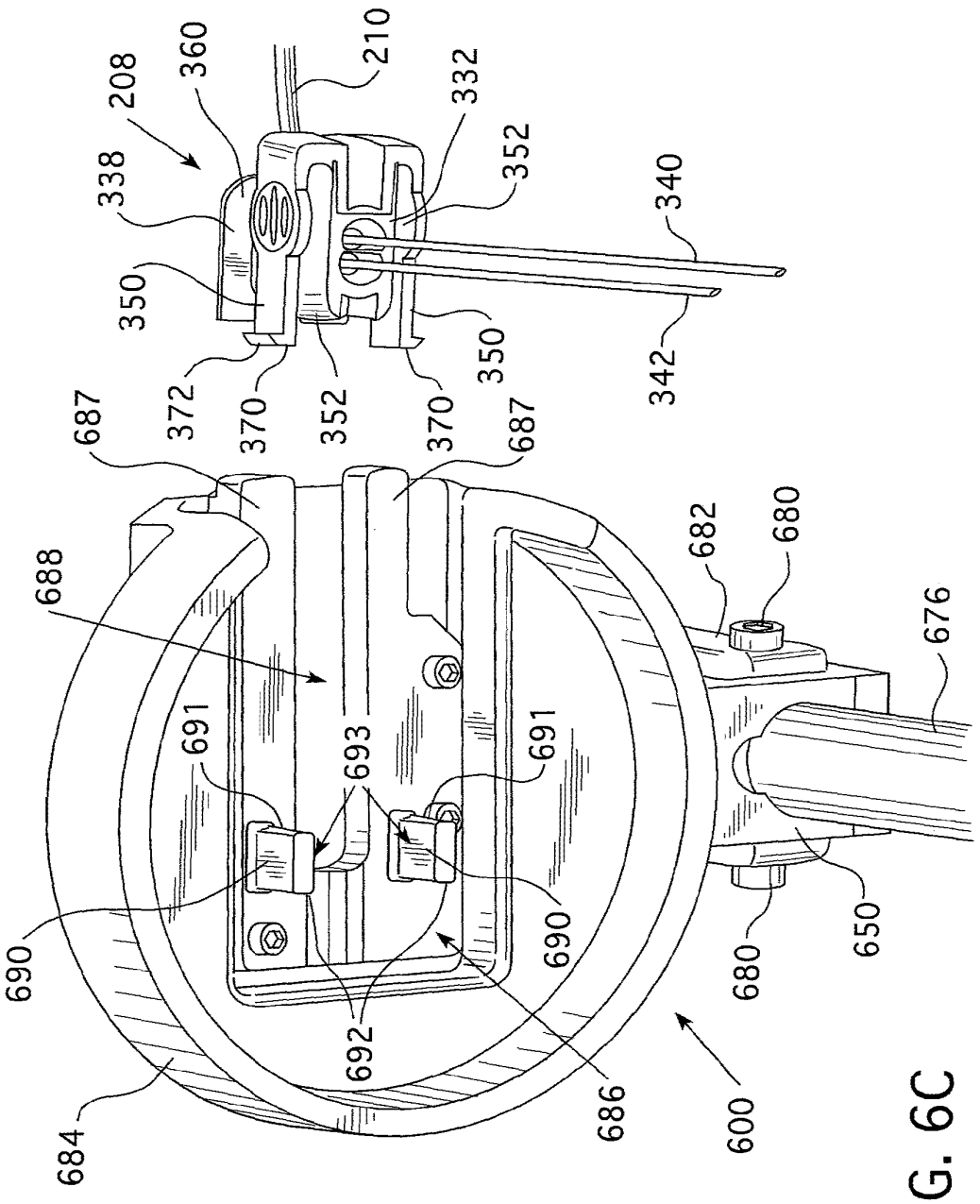
208
360
210
332
338
352
340
350
350
342
372
370
352
370
687
687
688
682
680
676
691
693
691
690
690
692
686
684
600
680
650

FIG. 6C

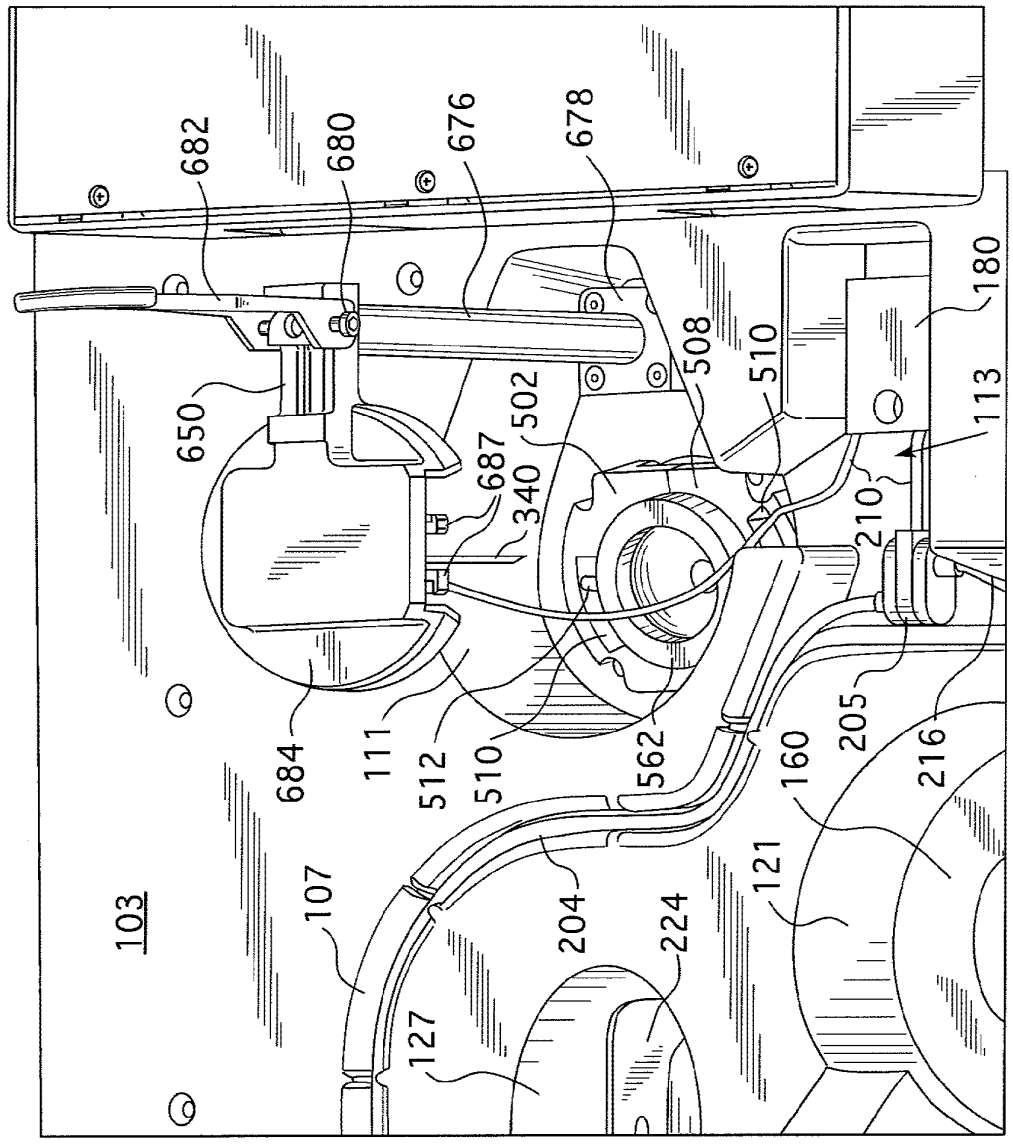
682
680
676
678
180
650
508
510
502
113
687
340
210
684
111
512
510
562
205
216
160
103
107
204
224
121
127

FIG. 6D

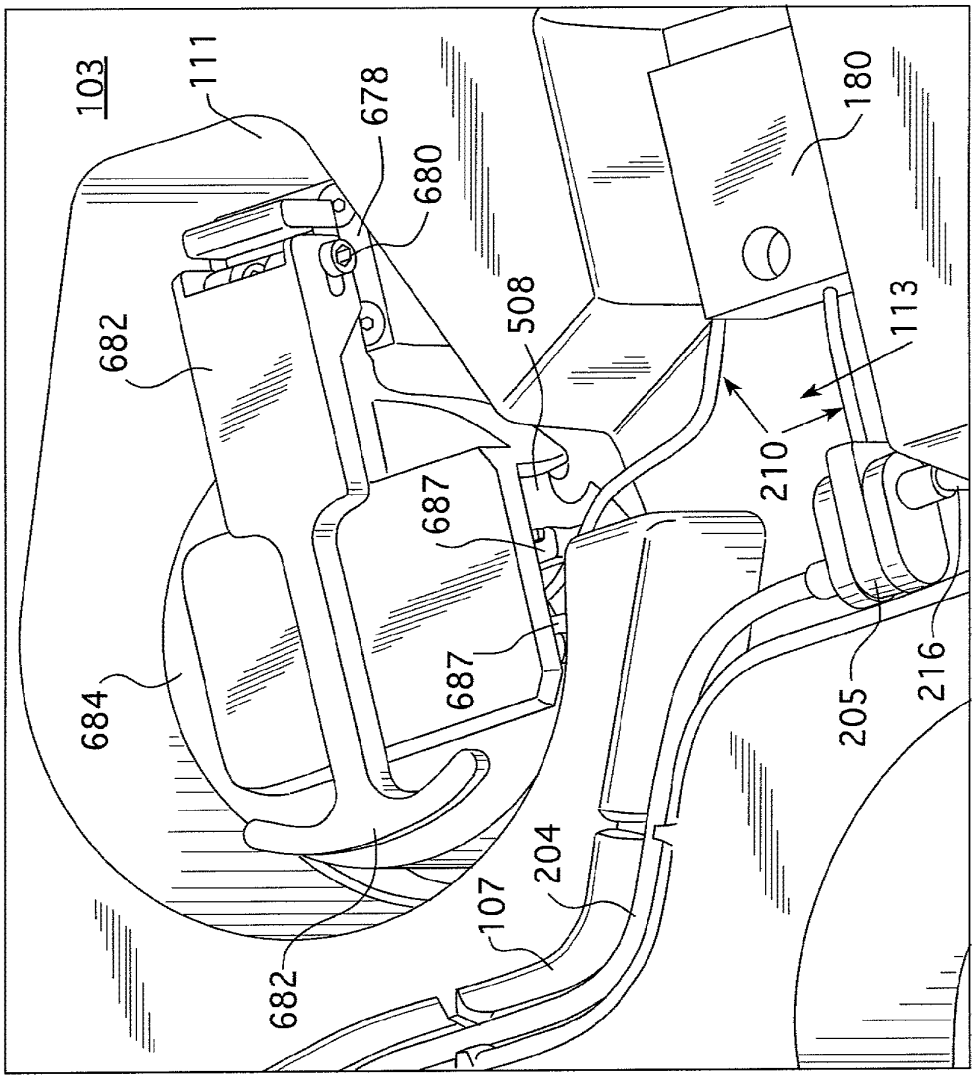
103
111
678
680
180
682
508
113
210
687
687
684
205
216
204
107
682

FIG. 6E

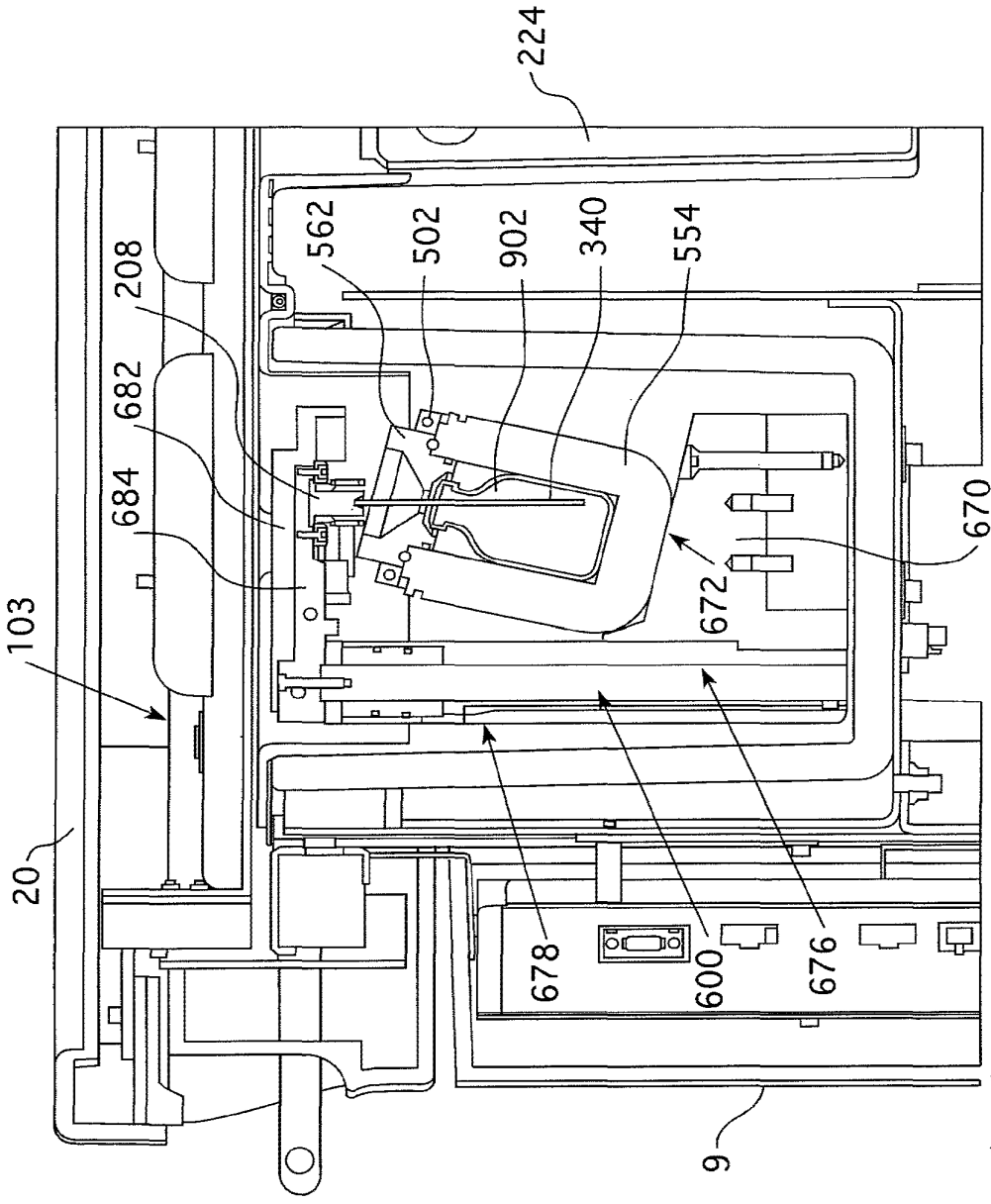

FIG. 6F

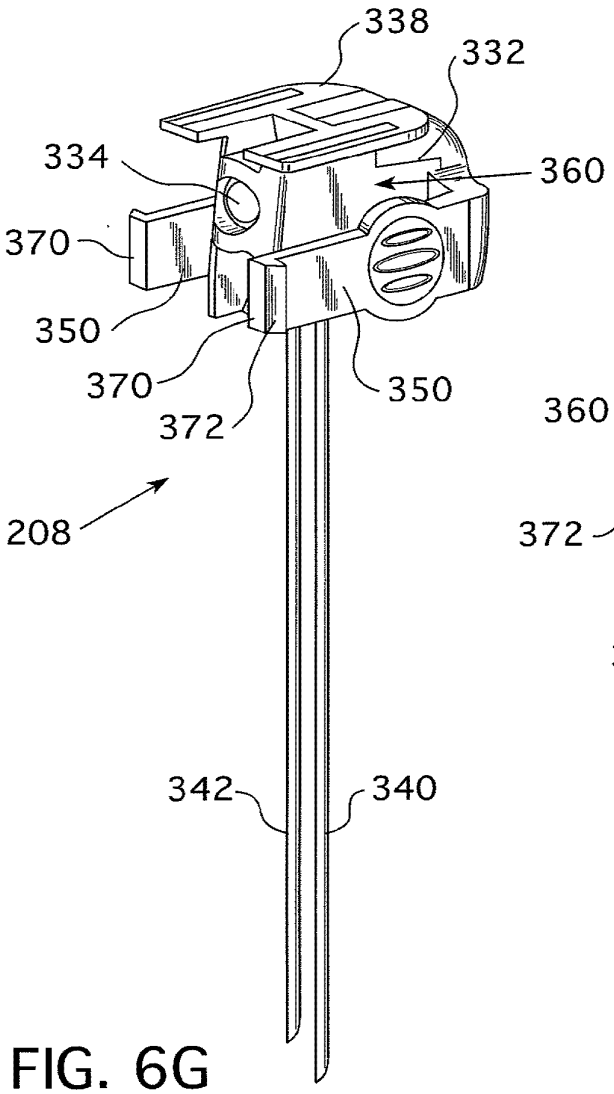
338
332
334
360
370
350
370
372
350
208
342
340

FIG. 6G

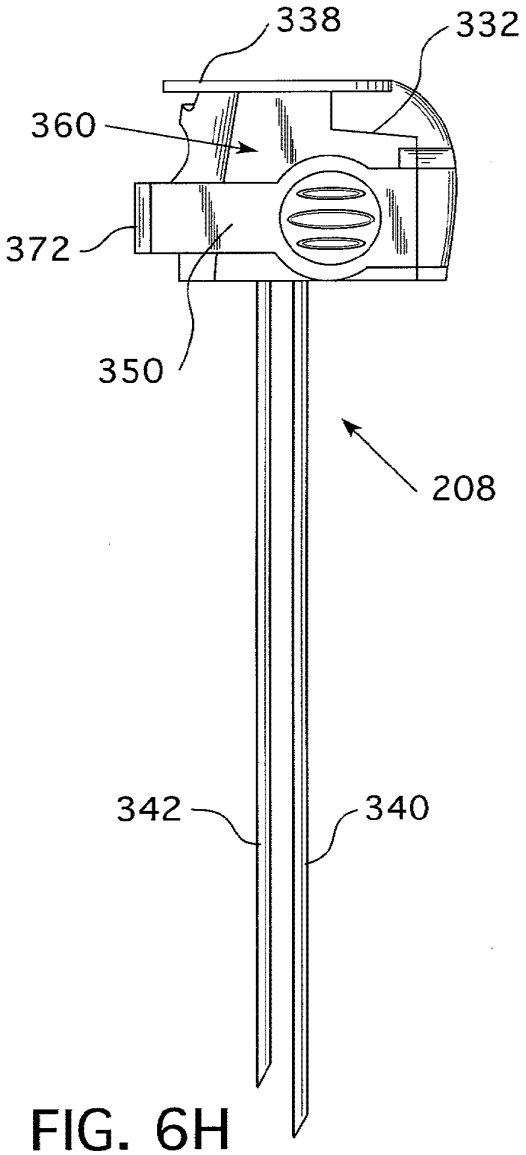
338
332
360
372
350
208
342
340

FIG. 6H

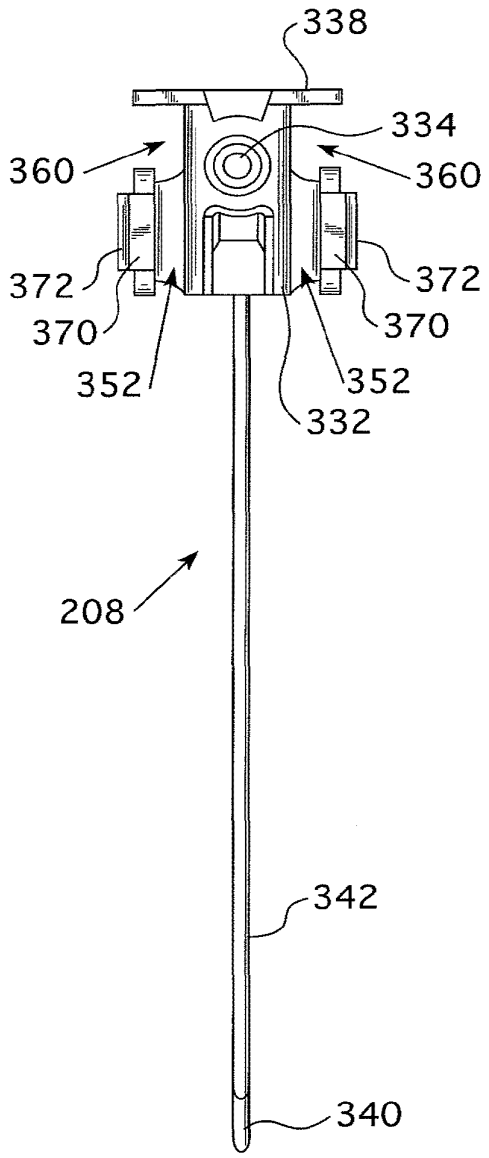
338
334
360
360
372
372
370
370
352
352
332
208
342
340

FIG. 6I

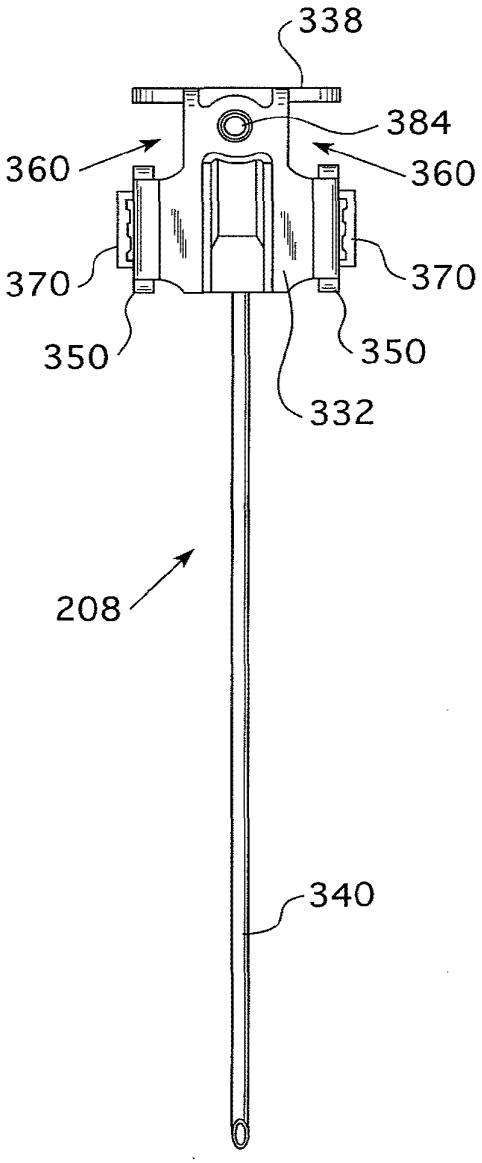
338
384
360
360
370
370
350
350
332
208
340

FIG. 6J

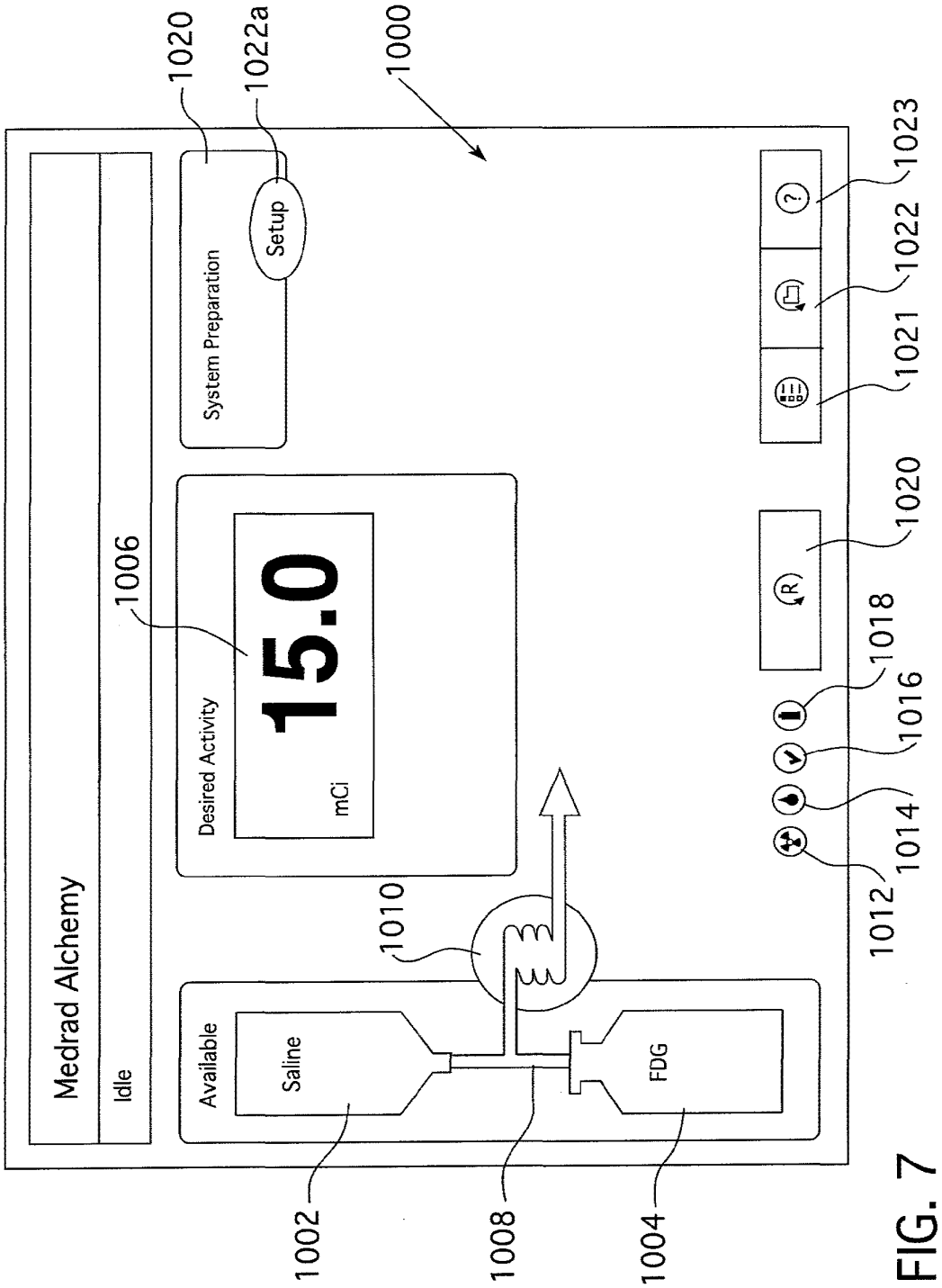
1020
1022a
1000
1023
1022
1021
1006
1020
1018
1016
1014
1012
1010
1002
1008
1004
Medrad Alchemy
Idle
System Preparation
Setup
Desired Activity
15.0
mCi
Available
Saline
FDG
R
?

FIG. 7

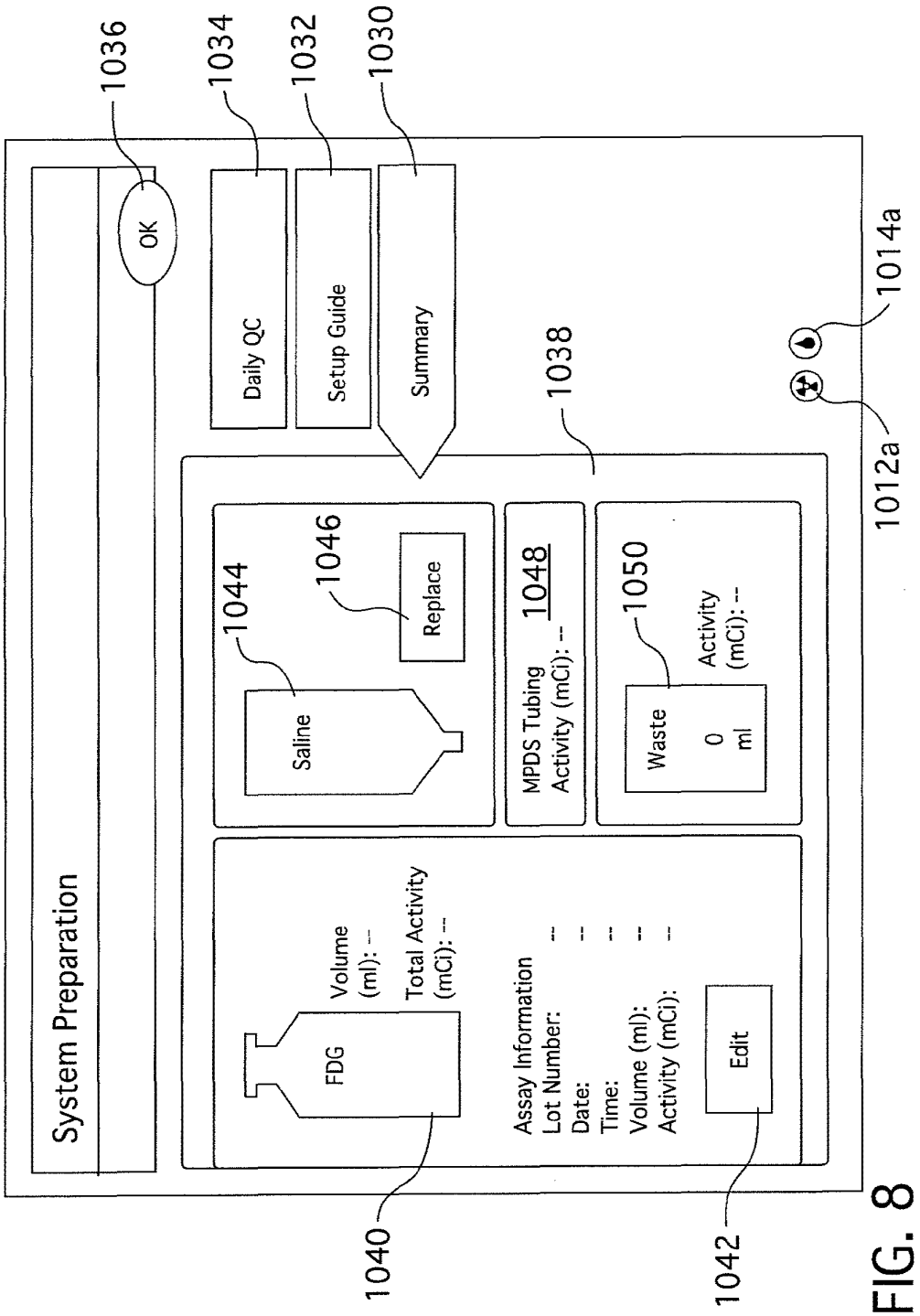
System Preparation
OK
Daily QC
Setup Guide
Summary
1036
1034
1032
1030
1038
1014a
1012a
Saline
1044
Replace
1046
MPDS Tubing
Activity (mCi): --
1048
Waste
0
ml
Activity
(mCi): --
1050
FDG
Volume
(ml): --
Total Activity
(mCi): --
Assay Information
Lot Number: --
Date: --
Time: --
Volume (ml): --
Activity (mCi): --
Edit
1040
1042

FIG. 8

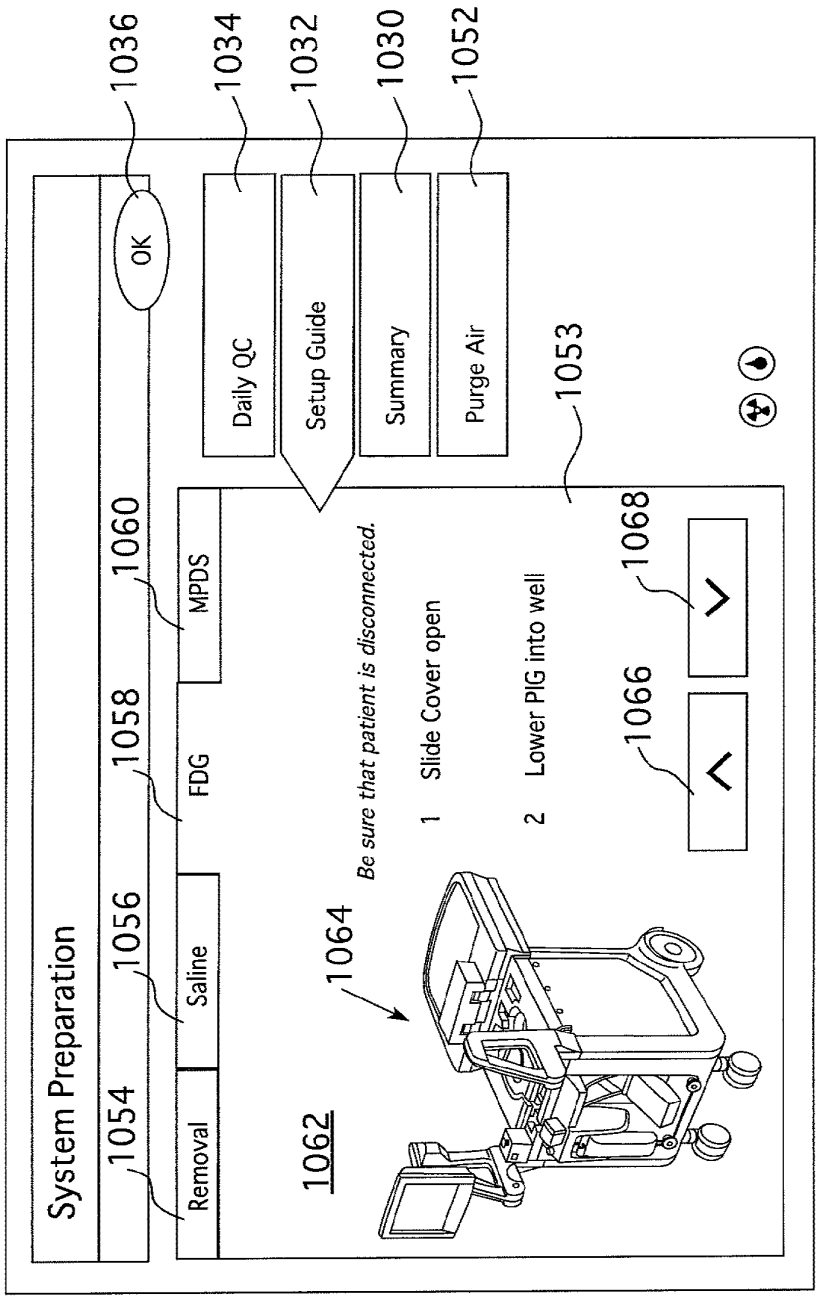
System Preparation
1054
Removal
1056
Saline
1058
FDG
1060
MPDS
OK
1036
Daily QC
1034
Setup Guide
1032
Summary
1030
Purge Air
1052
1053
Be sure that patient is disconnected.
1 Slide Cover open
2 Lower PIG into well
1062
1064
1066
1068

FIG. 9

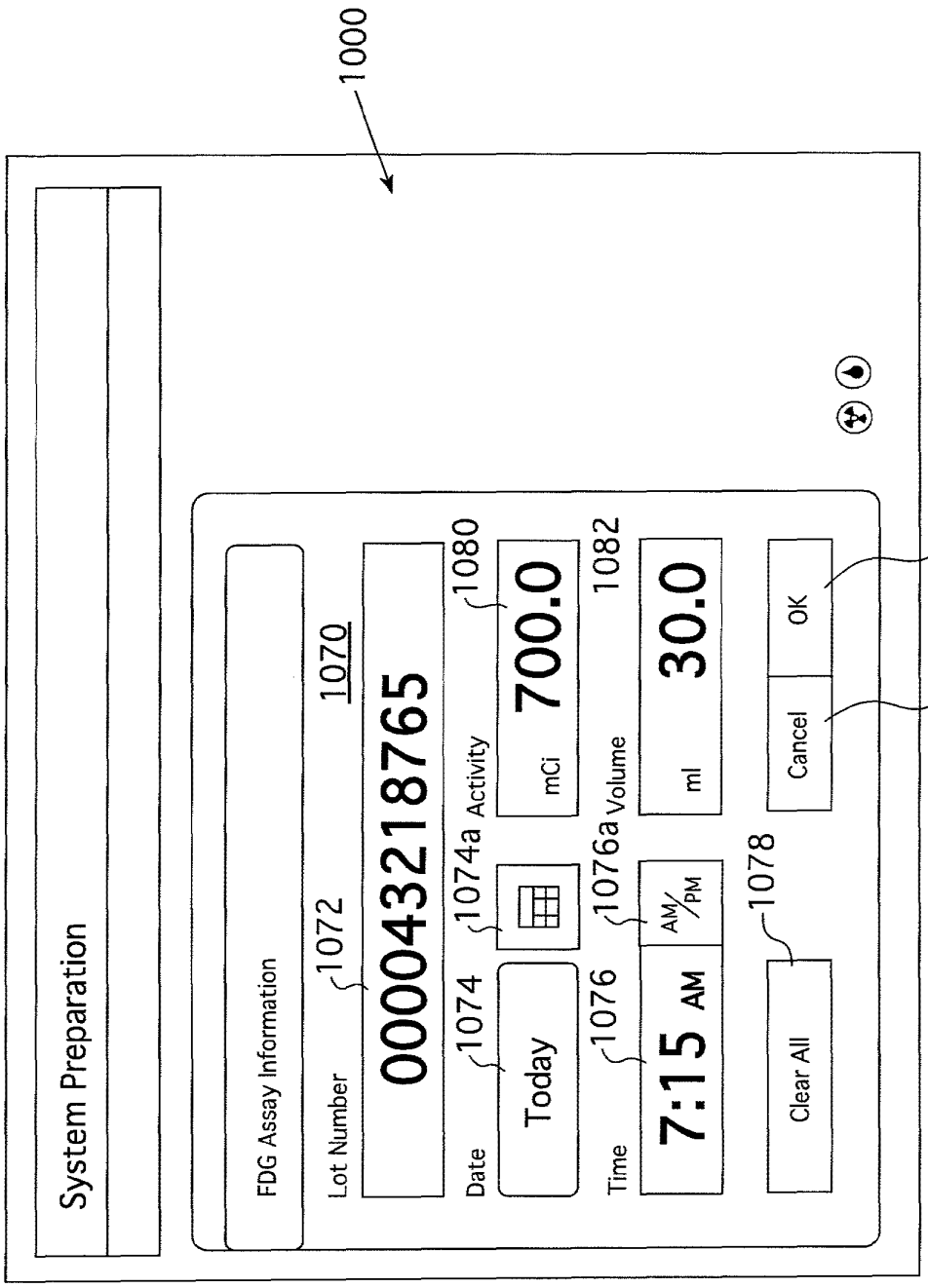
1000
System Preparation
FDG Assay Information
Lot Number
1072
1070
0000432187 65
Date
1074
Today
1074a
Activity
1080
700.0
mCi
Time
1076
7:15 AM
1076a
AM/PM
Volume
1082
30.0
ml
1078
Clear All
Cancel
OK
1086
1084

FIG. 10

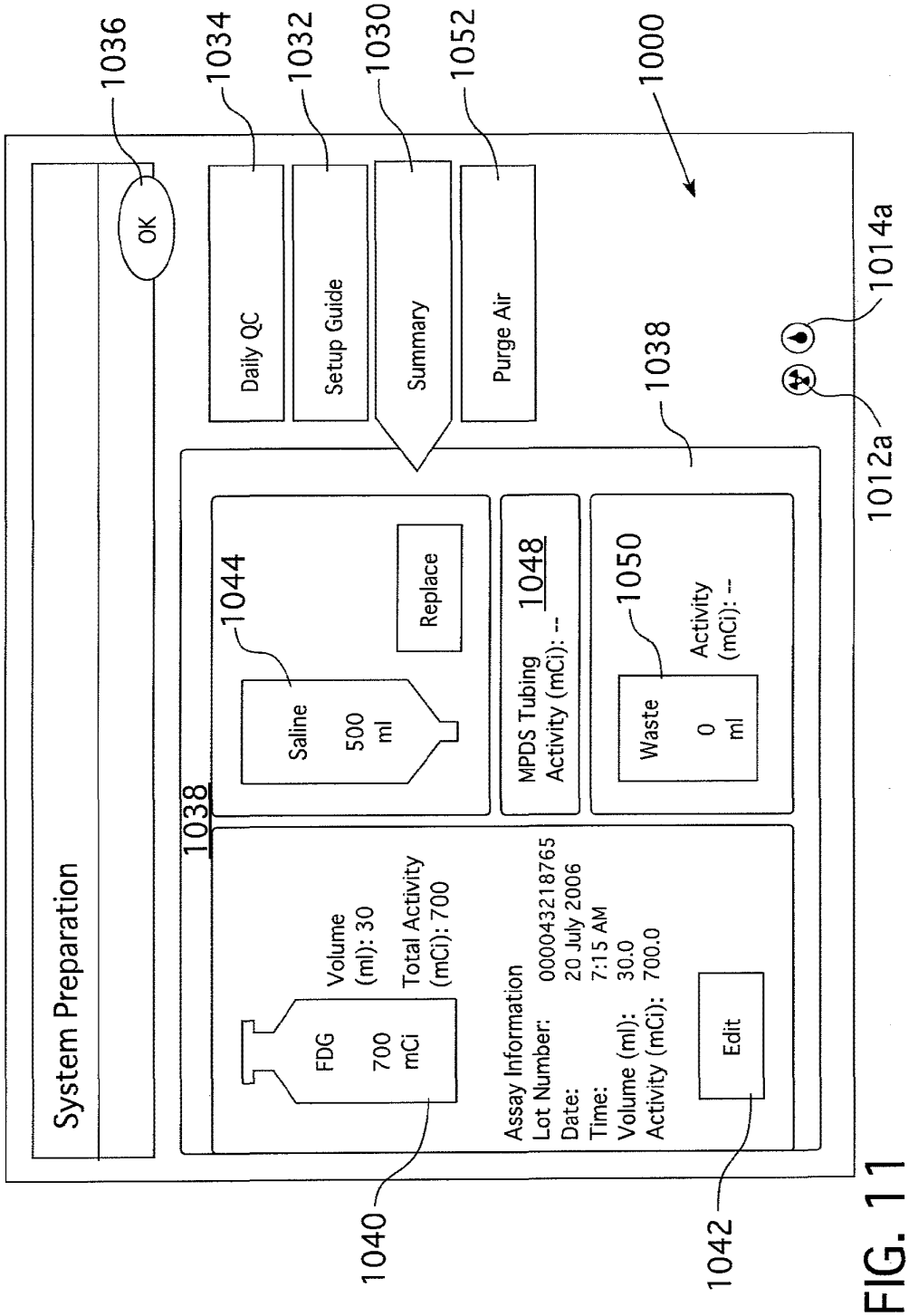
1036
1034
1032
1030
1052
1000
OK
Daily QC
Setup Guide
Summary
Purge Air
1038
1014a
1012a
1038
1044
Saline
500
ml
Replace
MPDS Tubing 1048
Activity (mCi): --
1050
Waste
0
ml
Activity
(mCi): --
System Preparation
FDG
700
mCi
Volume
(ml): 30
Total Activity
(mCi): 700
Assay Information
Lot Number: 000043218765
Date: 20 July 2006
Time: 7:15 AM
Volume (ml): 30.0
Activity (mCi): 700.0
Edit
1040
1042

FIG. 11

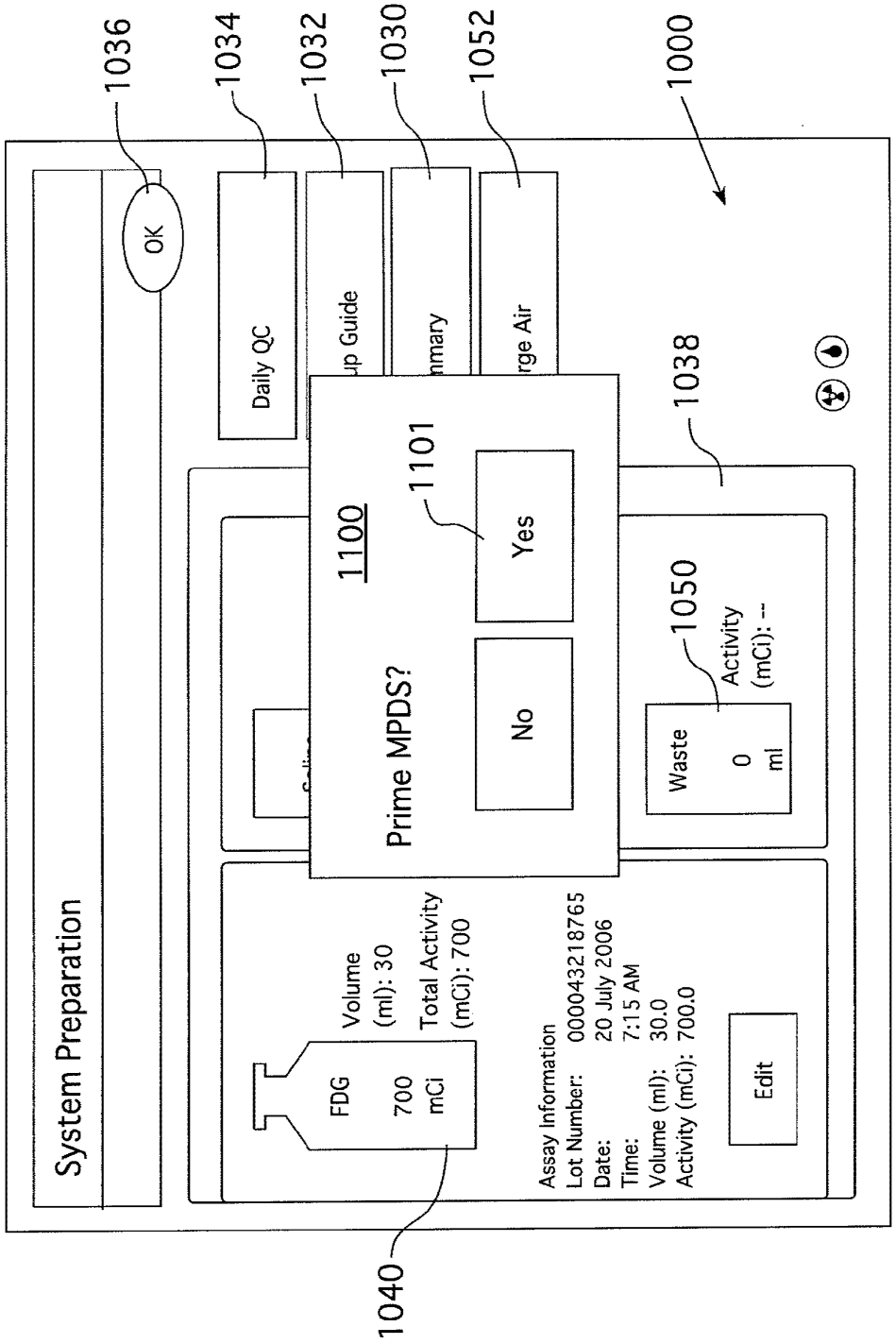
1036
1034
1032
1030
1052
1000
OK
Daily QC
up Guide
nmary
rge Air
1038
1100
1101
Yes
No
Prime MPDS?
1050
Waste
0
ml
Activity
(mCi): --
System Preparation
FDG
700
mCi
Volume
(ml): 30
Total Activity
(mCi): 700
Assay Information
Lot Number: 00004321876
Date: 20 July 2006
Time: 7:15 AM
Volume (ml): 30.0
Activity (mCi): 700.0
Edit
1040

FIG. 12A

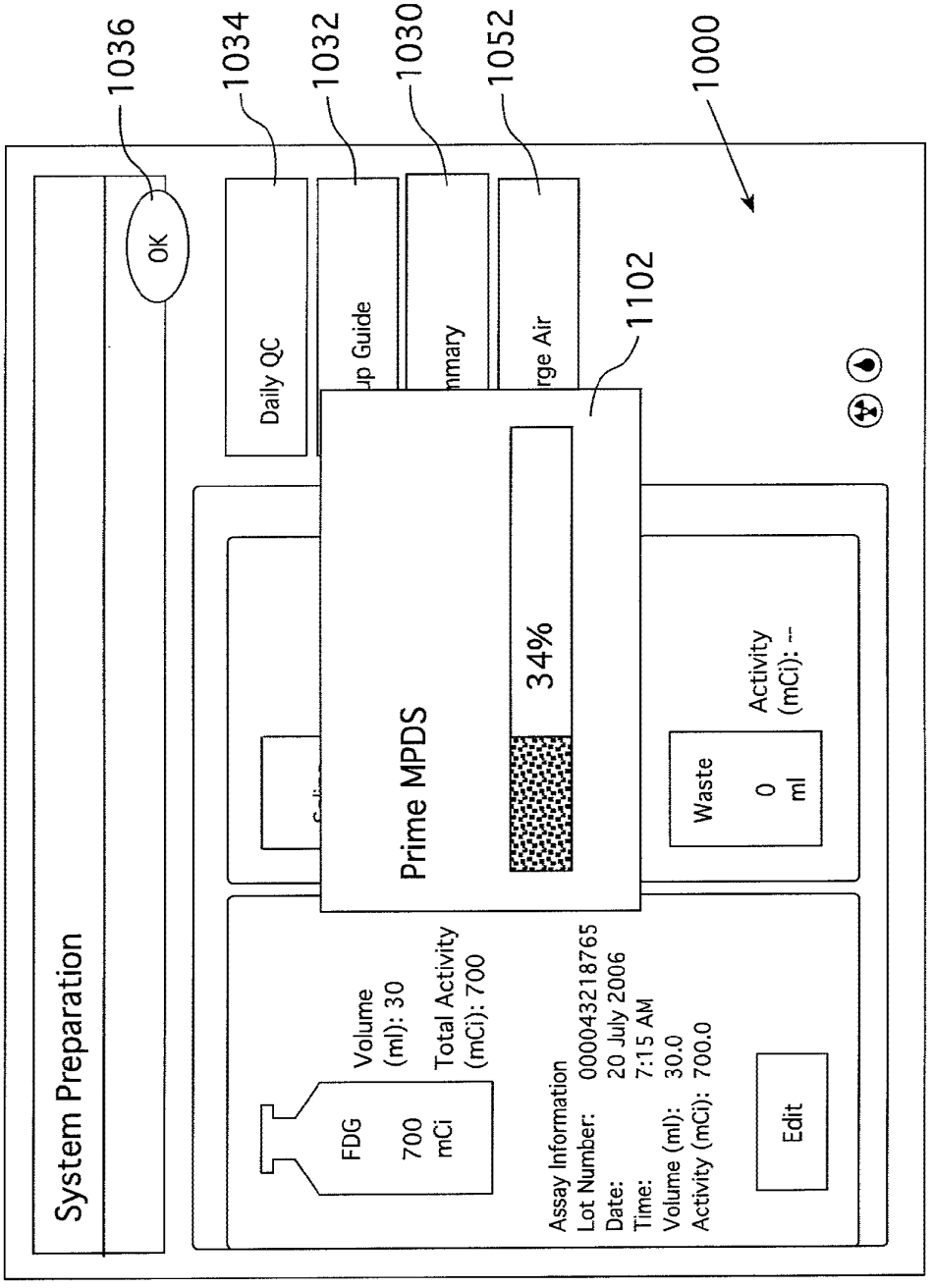
1036
1034
1032
1030
1052
1000
1102
OK
Daily QC
Prime MPDS
34%
System Preparation
FDG
700
mCi
Volume
(ml): 30
Total Activity
(mCi): 700
Assay Information
Lot Number: 00004321876
Date: 20 July 2006
Time: 7:15 AM
Volume (ml): 30.0
Activity (mCi): 700.0
Edit
Waste
0
ml
Activity
(mCi): --

FIG. 12B

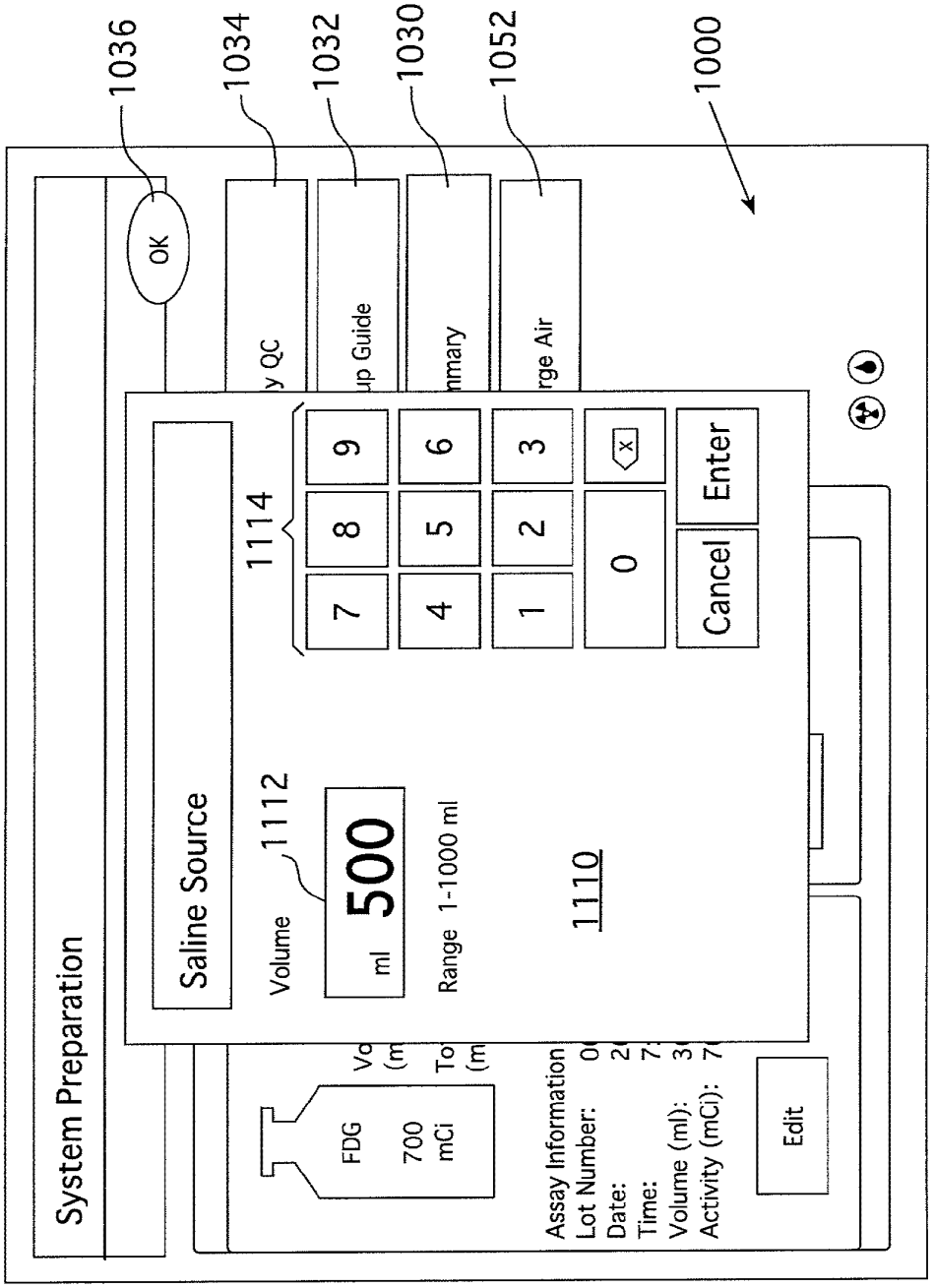
1036
1034
1032
1030
1052
1000
OK
y QC
up Guide
mmary
rge Air
System Preparation
Saline Source
1112
Volume
500
ml
Range 1-1000 ml
1114
7
8
9
4
5
6
1
2
3
0
Cancel
Enter
1110
FDG
700
mCi
Assay Information
Lot Number:
Date:
Time:
Volume (ml):
Activity (mCi):
Edit

FIG. 13

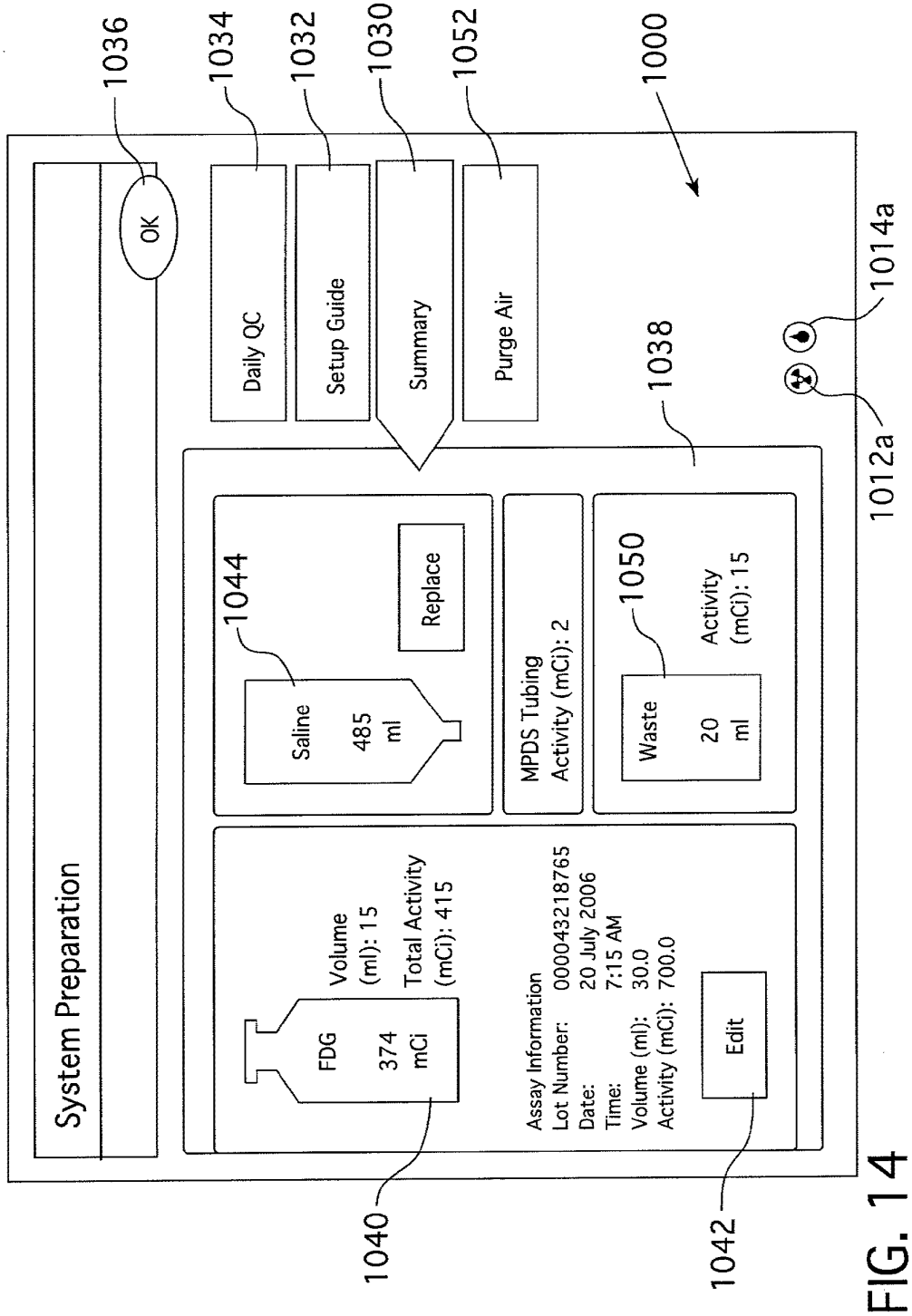
1036
1034
1032
1030
1052
1000
OK
Daily QC
Setup Guide
Summary
Purge Air
1014a
1012a
1038
System Preparation
1044
Saline
485
ml
Replace
MPDS Tubing
Activity (mCi): 2
1050
Waste
20
ml
Activity
(mCi): 15
FDG
374
mCi
Volume
(ml): 15
Total Activity
(mCi): 415
Assay Information
Lot Number: 000043218765
Date: 20 July 2006
Time: 7:15 AM
Volume (ml): 30.0
Activity (mCi): 700.0
Edit
1040
1042

FIG. 14

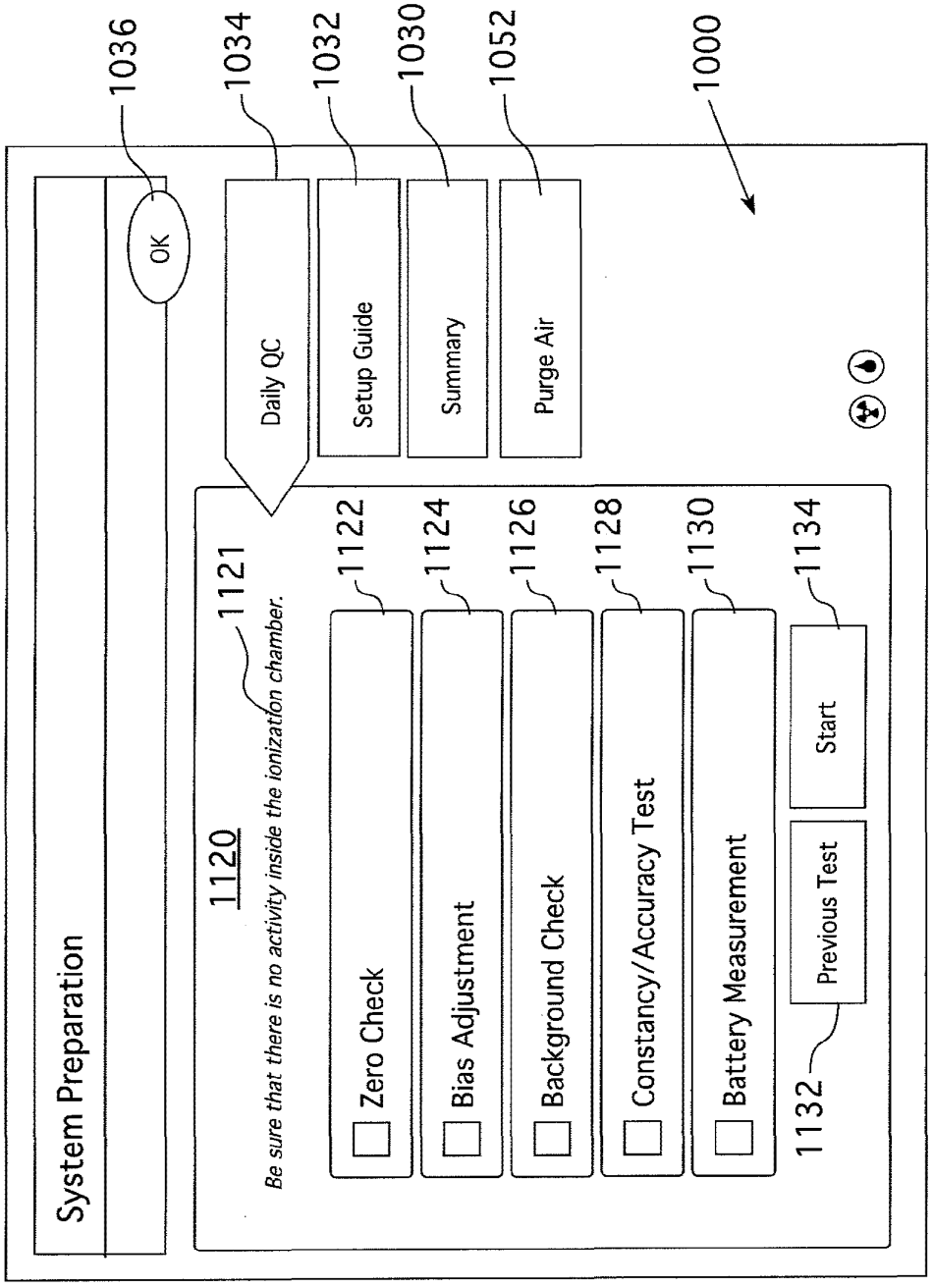
1036
1034
1032
1030
1052
1000
System Preparation
OK
Daily QC
Setup Guide
Summary
Purge Air
1120
1121
Be sure that there is no activity inside the ionization chamber.
1122
1124
1126
1128
1130
1134
Zero Check
Bias Adjustment
Background Check
Constancy/Accuracy Test
Battery Measurement
Start
Previous Test
1132

FIG. 15

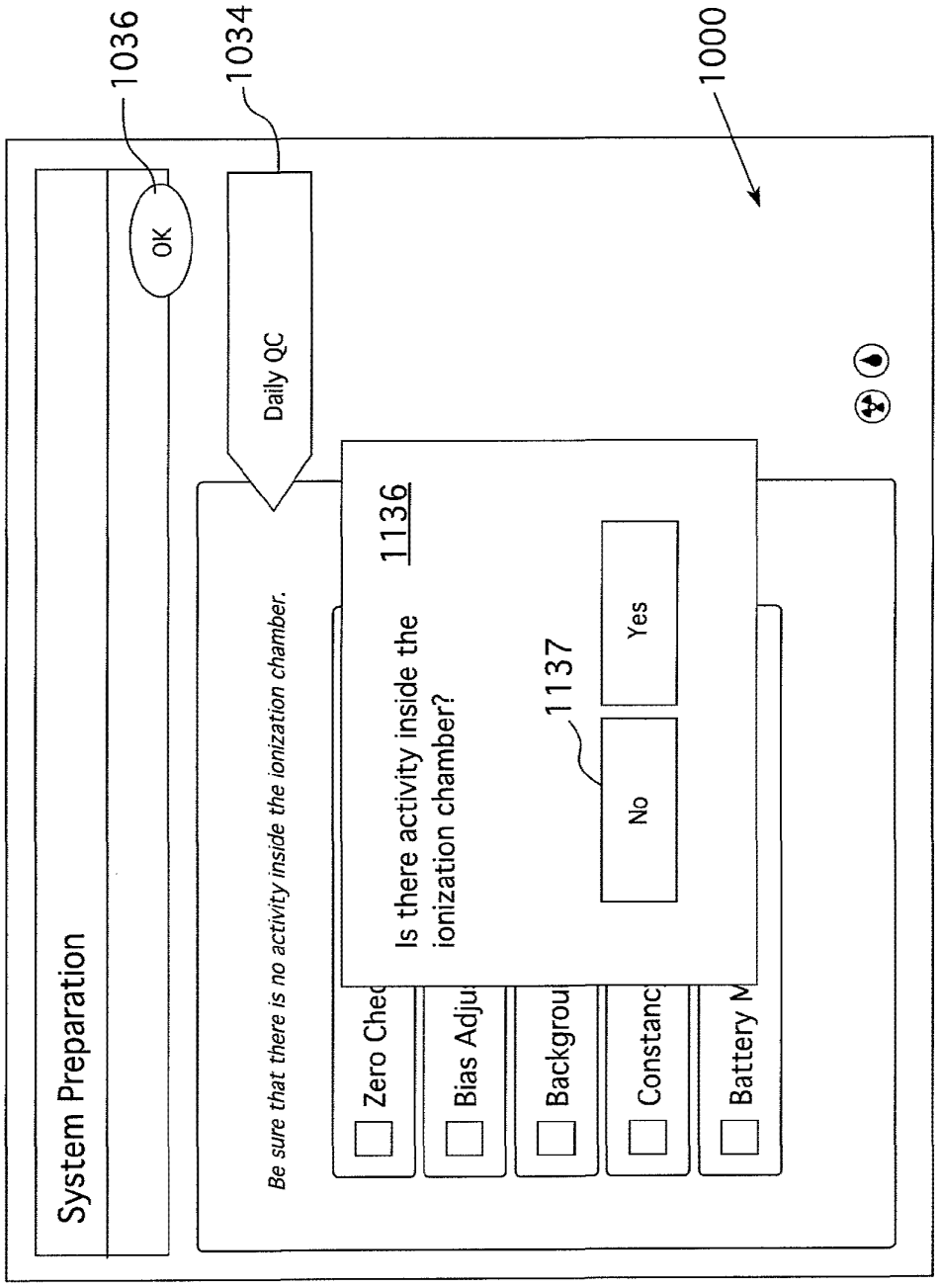
1036
1034
1000
OK
Daily QC
System Preparation
Be sure that there is no activity inside the ionization chamber.
Zero Chec
Bias Adju
Backgrou
Constanc
Battery M
Is there activity inside the ionization chamber?
1136
1137
No
Yes

FIG. 16A

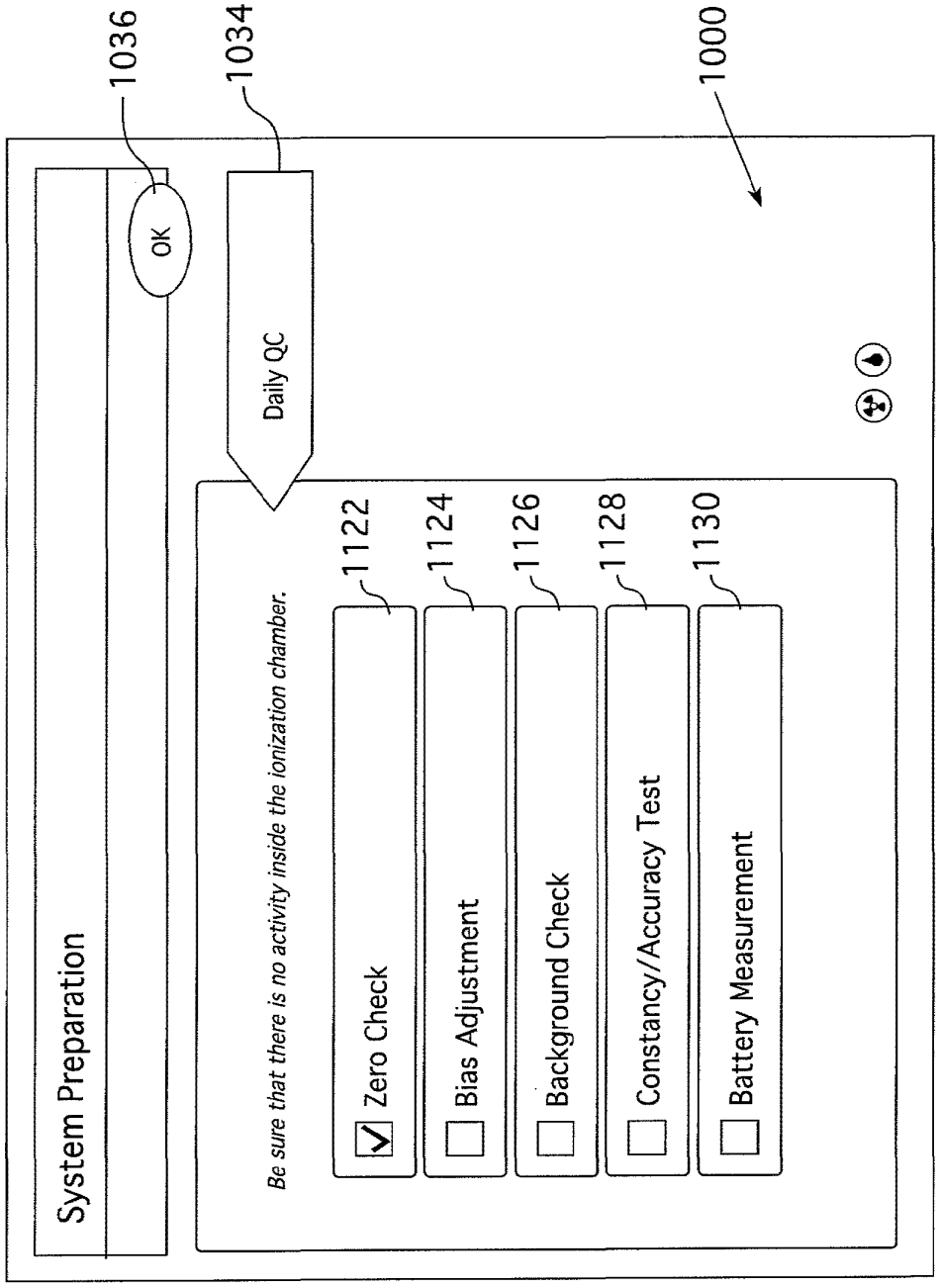
1036
1034
1000
OK
Daily QC
System Preparation
Be sure that there is no activity inside the ionization chamber.
1122
1124
1126
1128
1130
Zero Check
Bias Adjustment
Background Check
Constancy/Accuracy Test
Battery Measurement

FIG. 16B

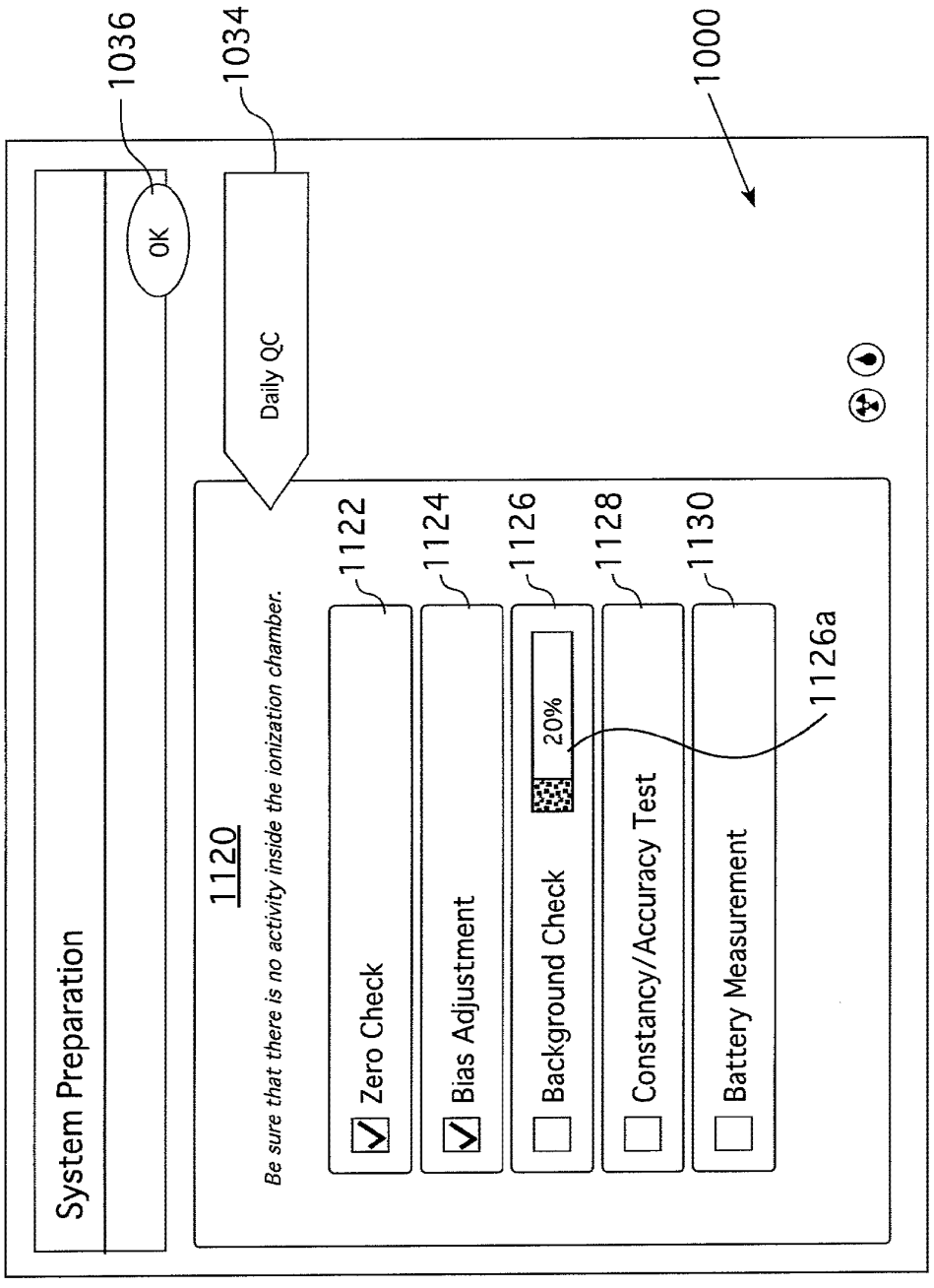
1036
1034
1000
OK
Daily QC
System Preparation
1120
Be sure that there is no activity inside the ionization chamber.
1122
1124
1126
1128
1130
Zero Check
Bias Adjustment
Background Check
20%
Constancy/Accuracy Test
Battery Measurement
1126a

FIG. 17

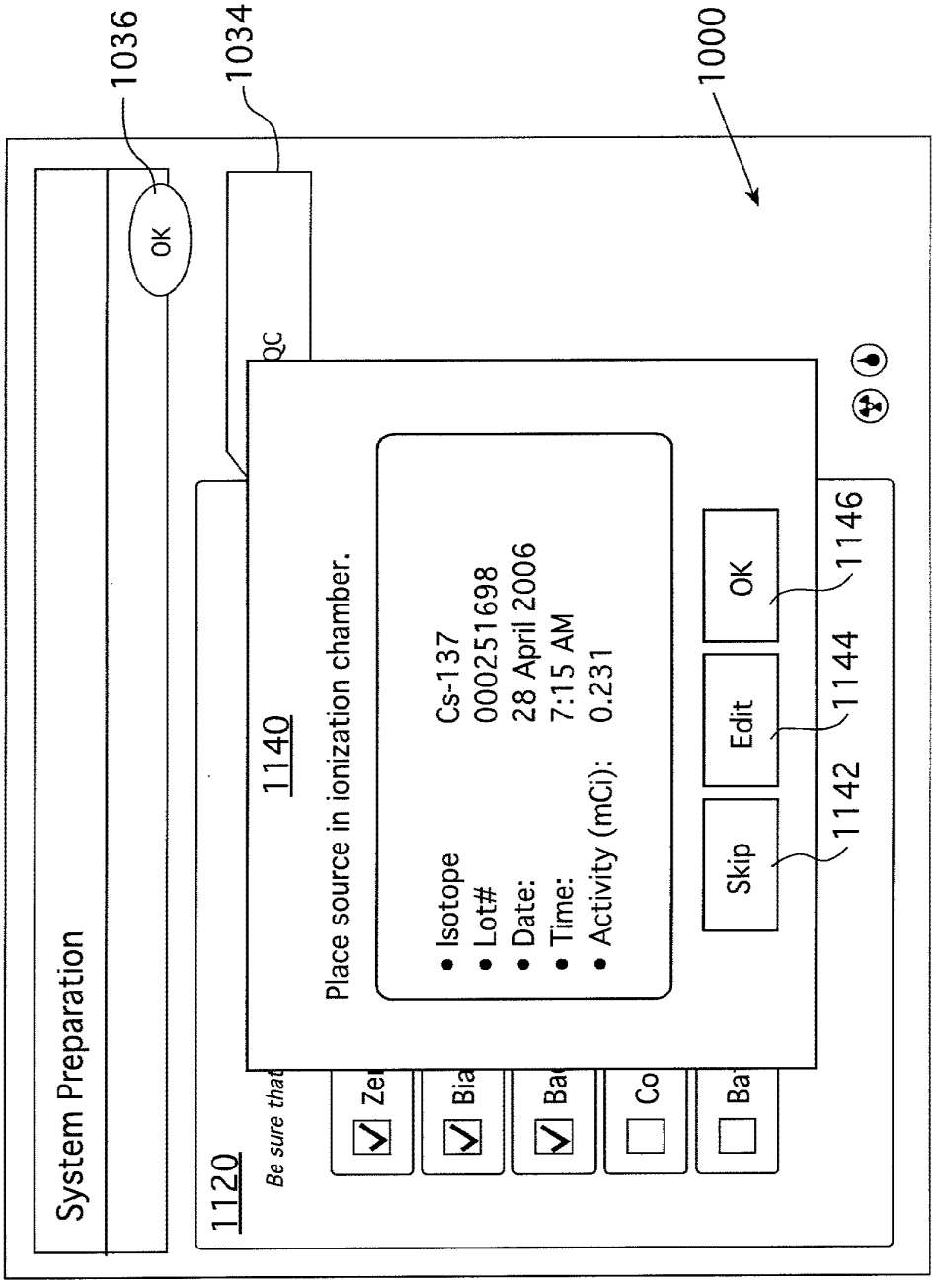
1036
1034
1000
System Preparation
OK
QC
1120
1140
Place source in ionization chamber.
• Isotope Cs-137
• Lot# 000251698
• Date: 28 April 2006
• Time: 7:15 AM
• Activity (mCi): 0.231
Skip
Edit
OK
1142
1144
1146

FIG. 18

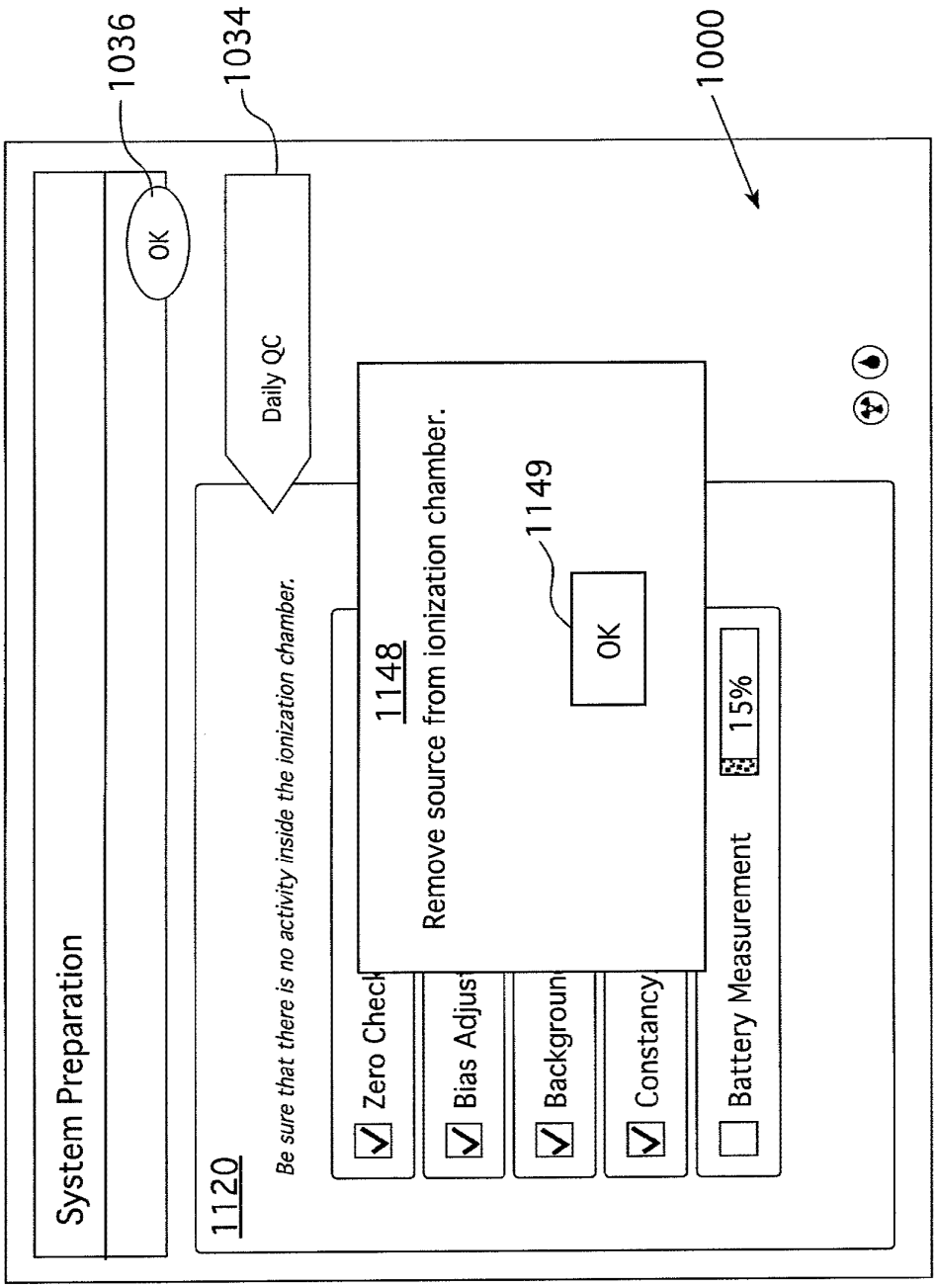
1036
1034
1000
System Preparation
OK
Daily QC
1120
Be sure that there is no activity inside the ionization chamber.
Zero Check
Bias Adjust
Background
Constancy
Battery Measurement
15%
1148
Remove source from ionization chamber.
1149
OK

FIG. 19

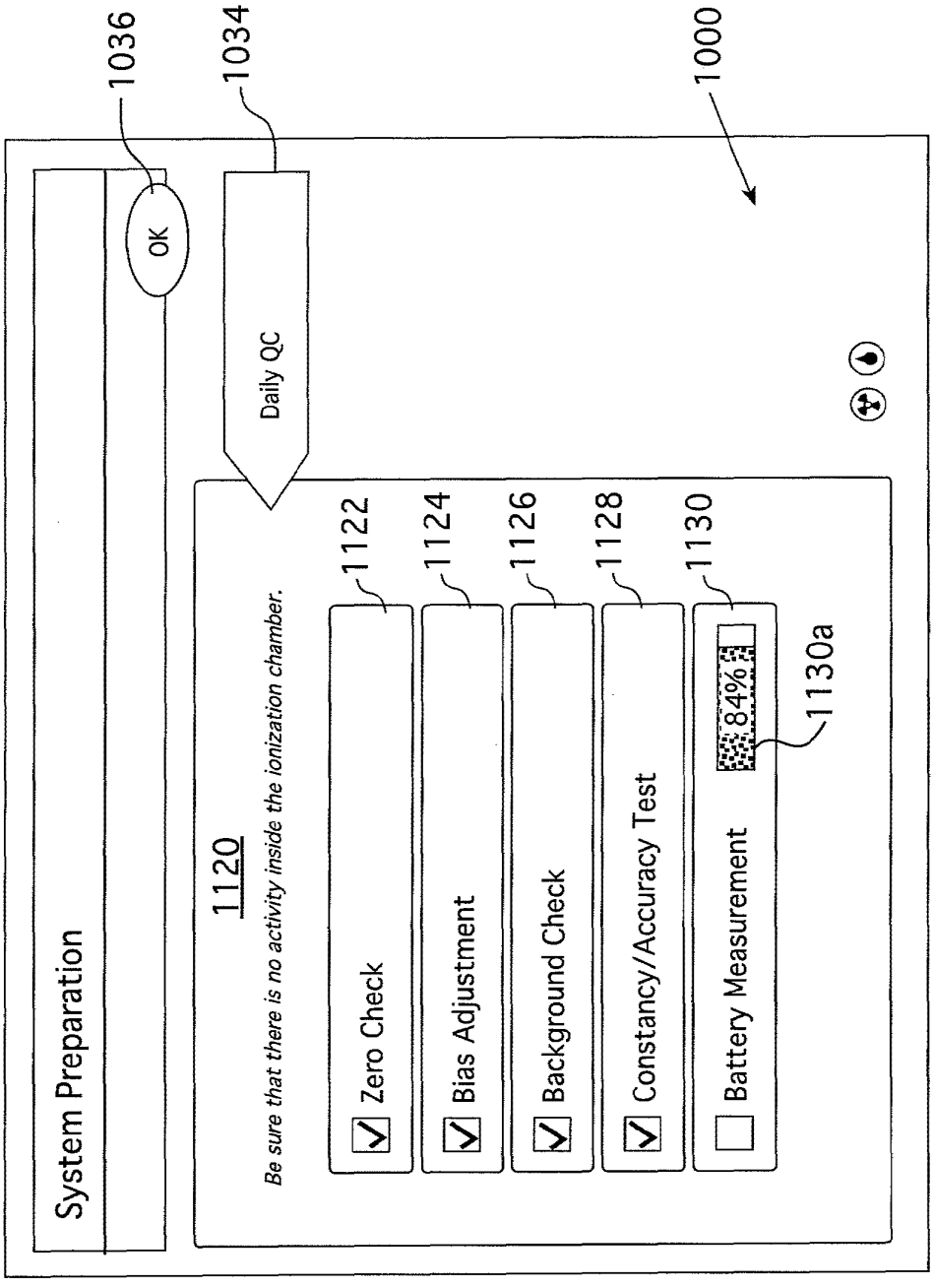
1036
1034
1000
OK
Daily QC
System Preparation
1120
Be sure that there is no activity inside the ionization chamber.
1122
1124
1126
1128
1130
Zero Check
Bias Adjustment
Background Check
Constancy/Accuracy Test
Battery Measurement
84%
1130a

FIG. 20

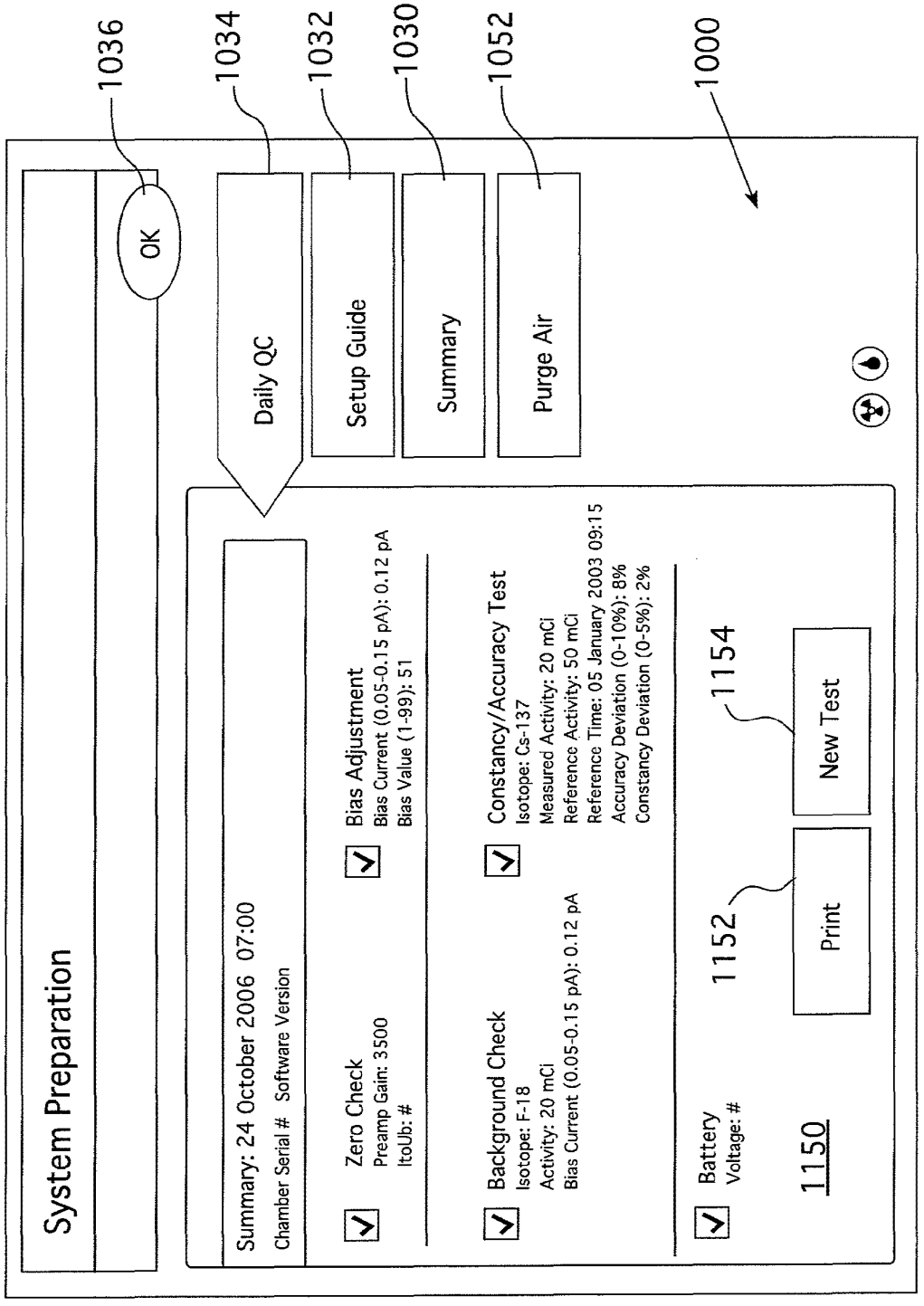
System Preparation
OK
1036
1034
1032
1030
1052
1000
Daily QC
Setup Guide
Summary
Purge Air
Summary: 24 October 2006 07:00
Chamber Serial # Software Version
Zero Check
Preamp Gain: 3500
ItoUb: #
Bias Adjustment
Bias Current (0.05-0.15 pA): 0.12 pA
Bias Value (1-99): 51
Background Check
Isotope: F-18
Activity: 20 mCi
Bias Current (0.05-0.15 pA): 0.12 pA
Constancy/Accuracy Test
Isotope: Cs-137
Measured Activity: 20 mCi
Reference Activity: 50 mCi
Reference Time: 05 January 2003 09:15
Accuracy Deviation (0-10%): 8%
Constancy Deviation (0-5%): 2%
Battery
Voltage: #
1150
1152
Print
1154
New Test

FIG. 21

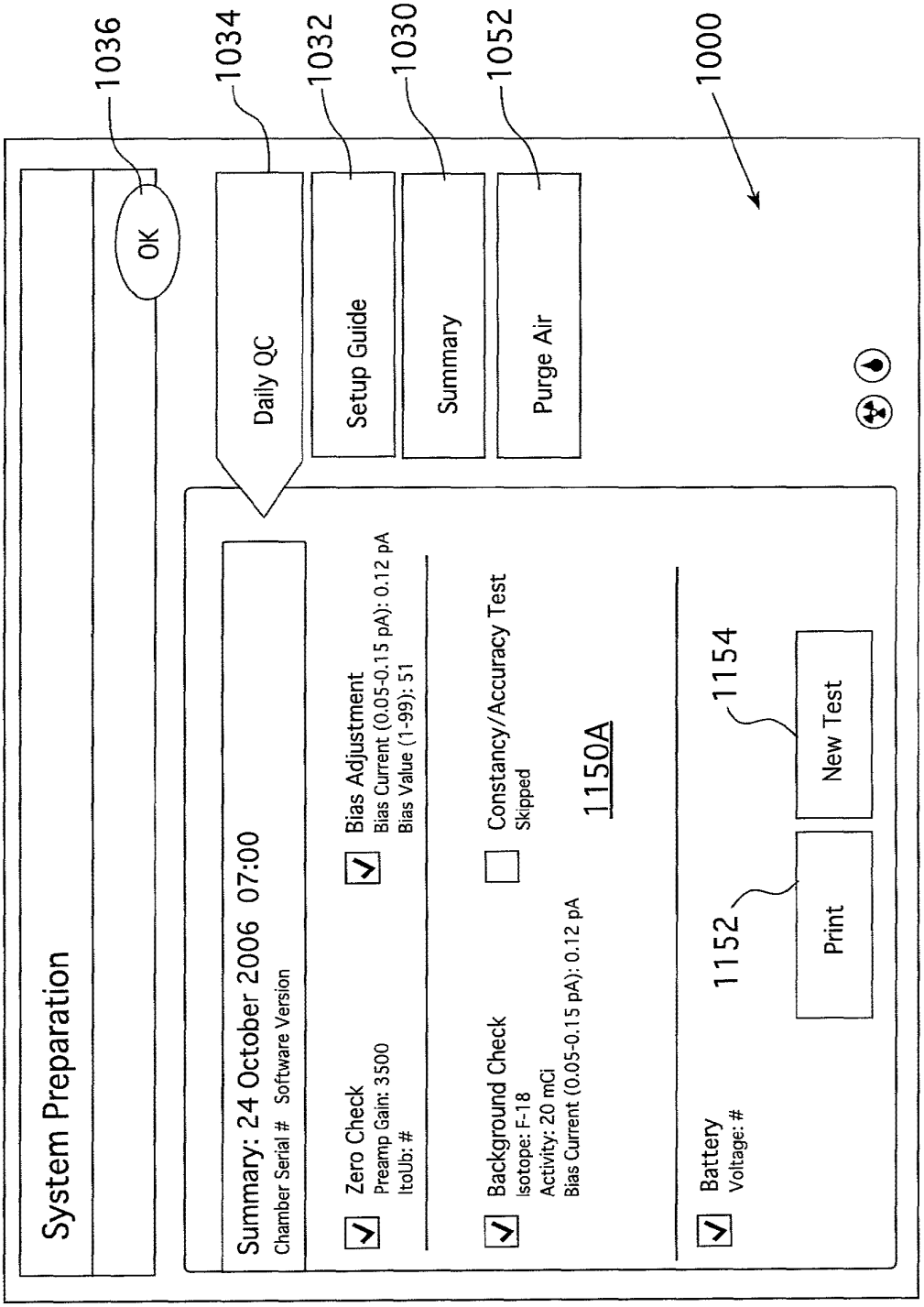
System Preparation
OK
1036
1034
1032
1030
1052
1000
Daily QC
Setup Guide
Summary
Purge Air
Summary: 24 October 2006 07:00
Chamber Serial # Software Version
Zero Check
Preamp Gain: 3500
ItoUb: #
Bias Adjustment
Bias Current (0.05-0.15 pA): 0.12 pA
Bias Value (1-99): 51
Background Check
Isotope: F-18
Activity: 20 mCi
Bias Current (0.05-0.15 pA): 0.12 pA
Constancy/Accuracy Test
Skipped
1150A
Battery
Voltage: #
1152
Print
1154
New Test

FIG. 22

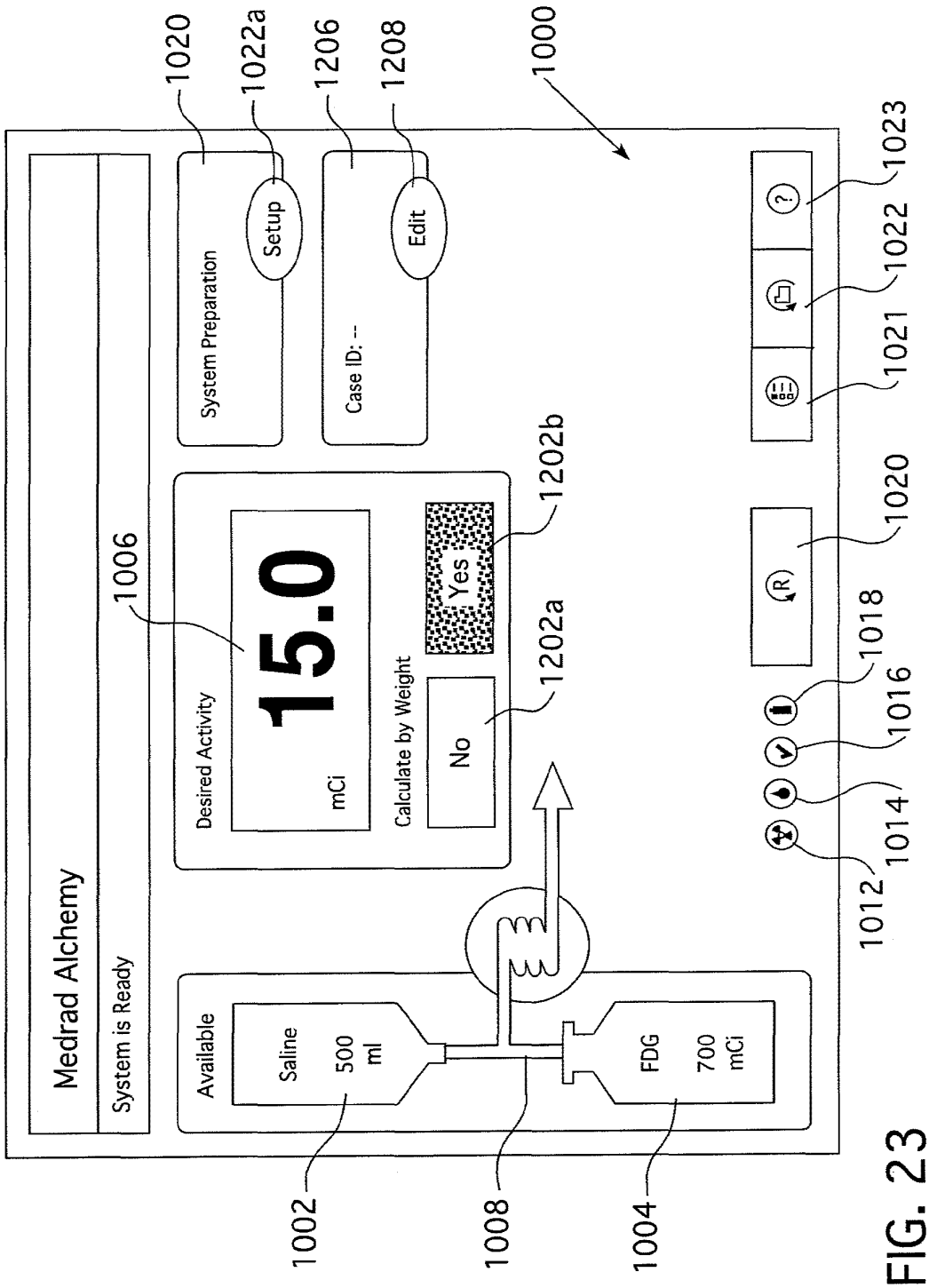
Medrad Alchemy
System is Ready
Available
Saline
500 ml
FDG
700 mCi
Desired Activity
15.0
mCi
Calculate by Weight
No
Yes
System Preparation
Setup
Case ID: --
Edit
1000
1002
1004
1006
1008
1012
1014
1016
1018
1020
1021
1022
1023
1202a
1202b
1206
1208

FIG. 23

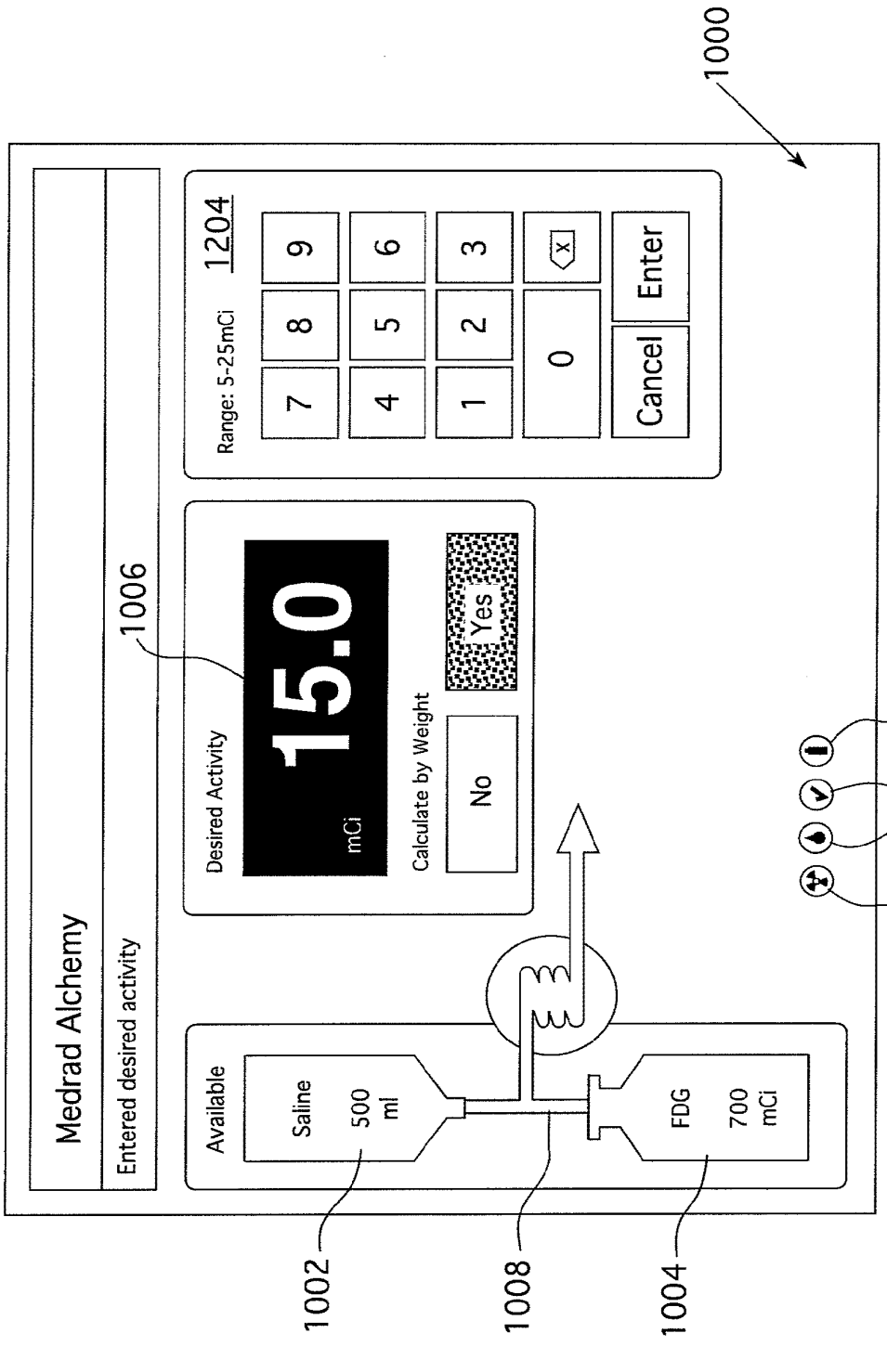
1000
Medrad Alchemy
Entered desired activity
1006
Desired Activity
15.0
mCi
Calculate by Weight
No
Yes
Range: 5-25mCi
1204
7
8
9
4
5
6
1
2
3
0
X
Cancel
Enter
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004
1018
1016
1014
1012

FIG. 24A

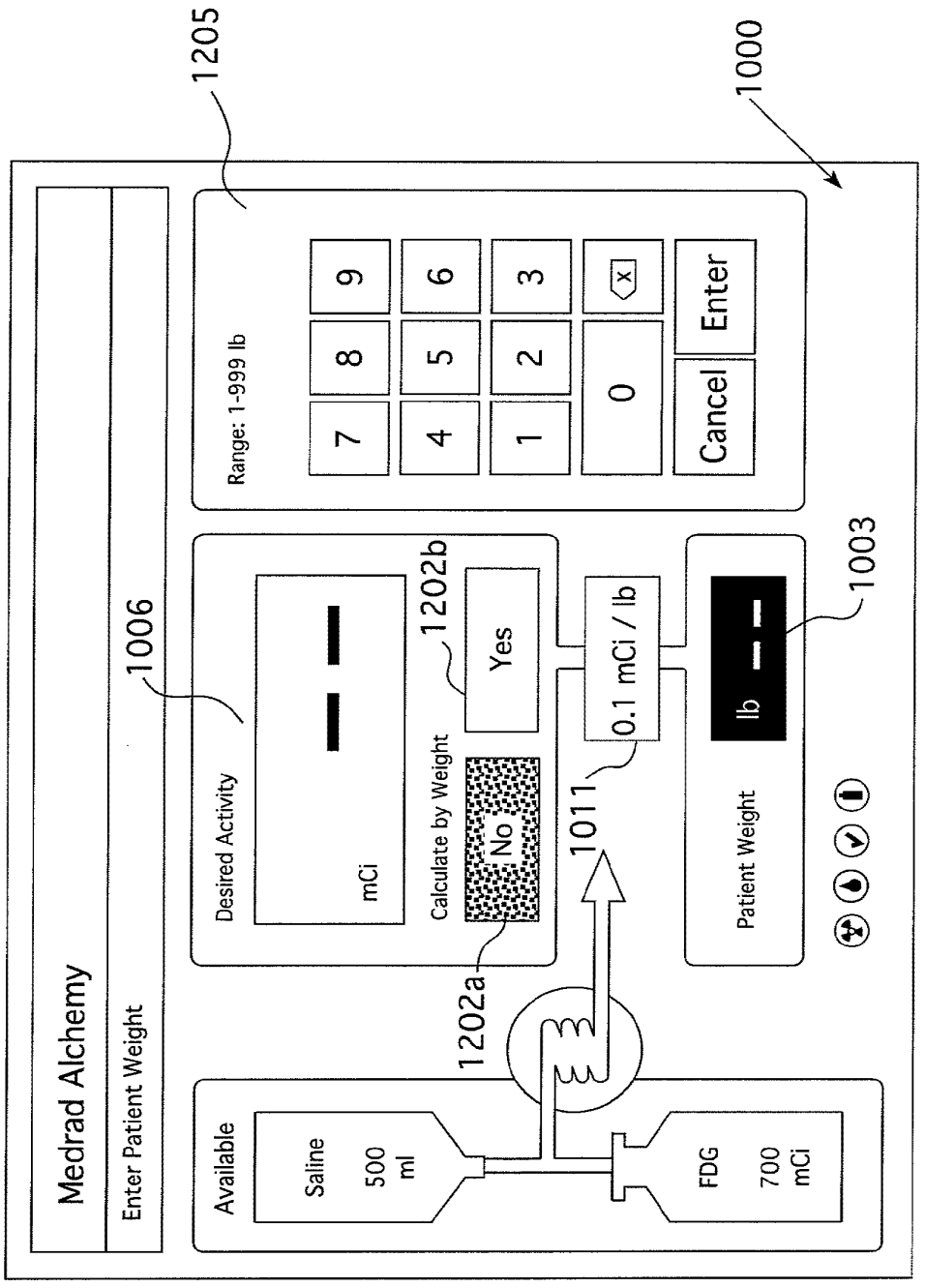
1205
1000
Medrad Alchemy
Enter Patient Weight
1006
Range: 1-999 lb
7
8
9
4
5
6
1
2
3
0
x
Cancel
Enter
Desired Activity
mCi
Calculate by Weight
No
Yes
1202b
1202a
1011
0.1 mCi / lb
Patient Weight
lb
1003
Available
Saline
500
ml
FDG
700
mCi

FIG. 24B

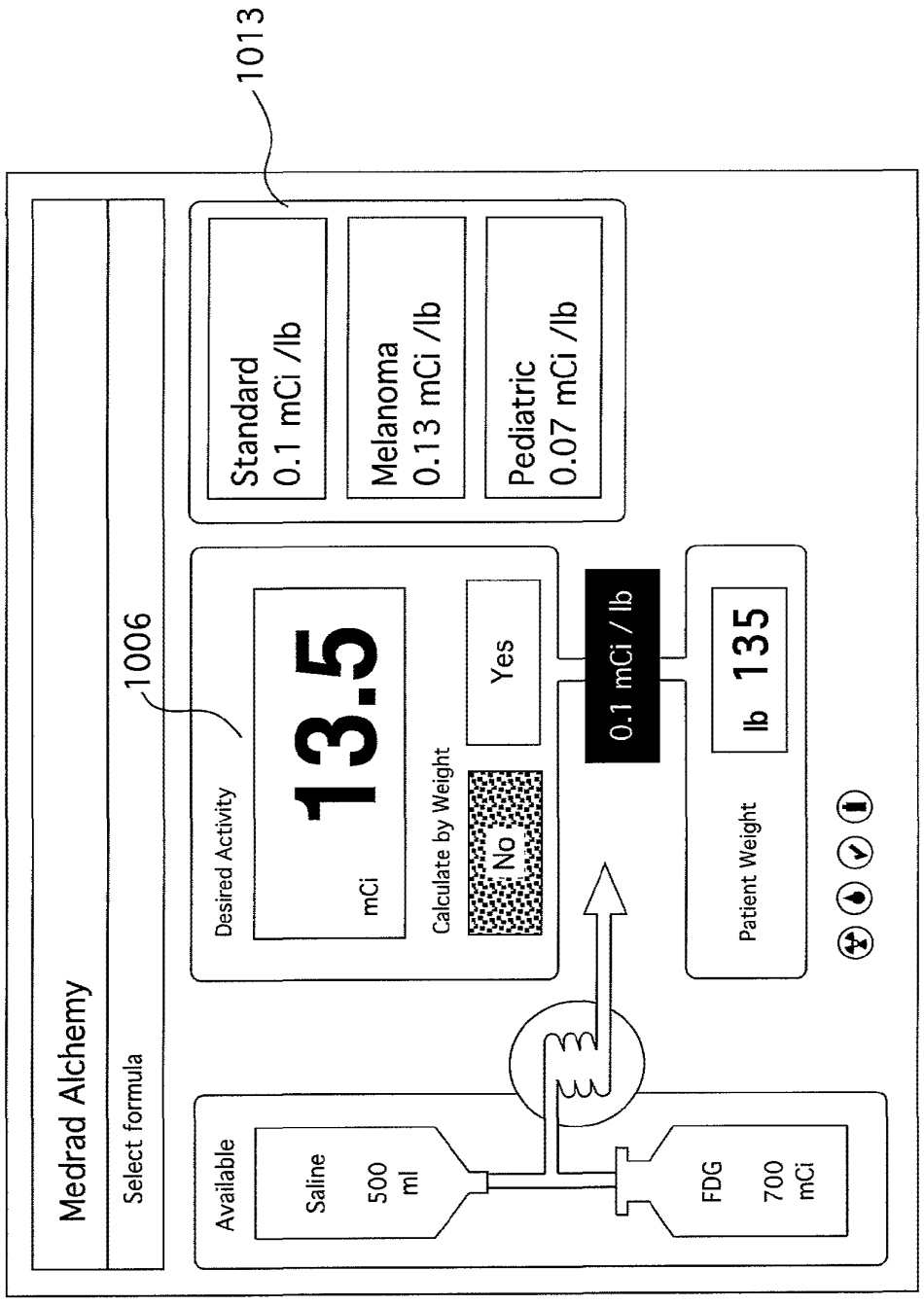
1013
Medrad Alchemy
Select formula
1006
Standard
0.1 mCi /lb
Melanoma
0.13 mCi /lb
Pediatric
0.07 mCi /lb
Desired Activity
13.5
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb 135
Available
Saline
500
ml
FDG
700
mCi

FIG. 24C

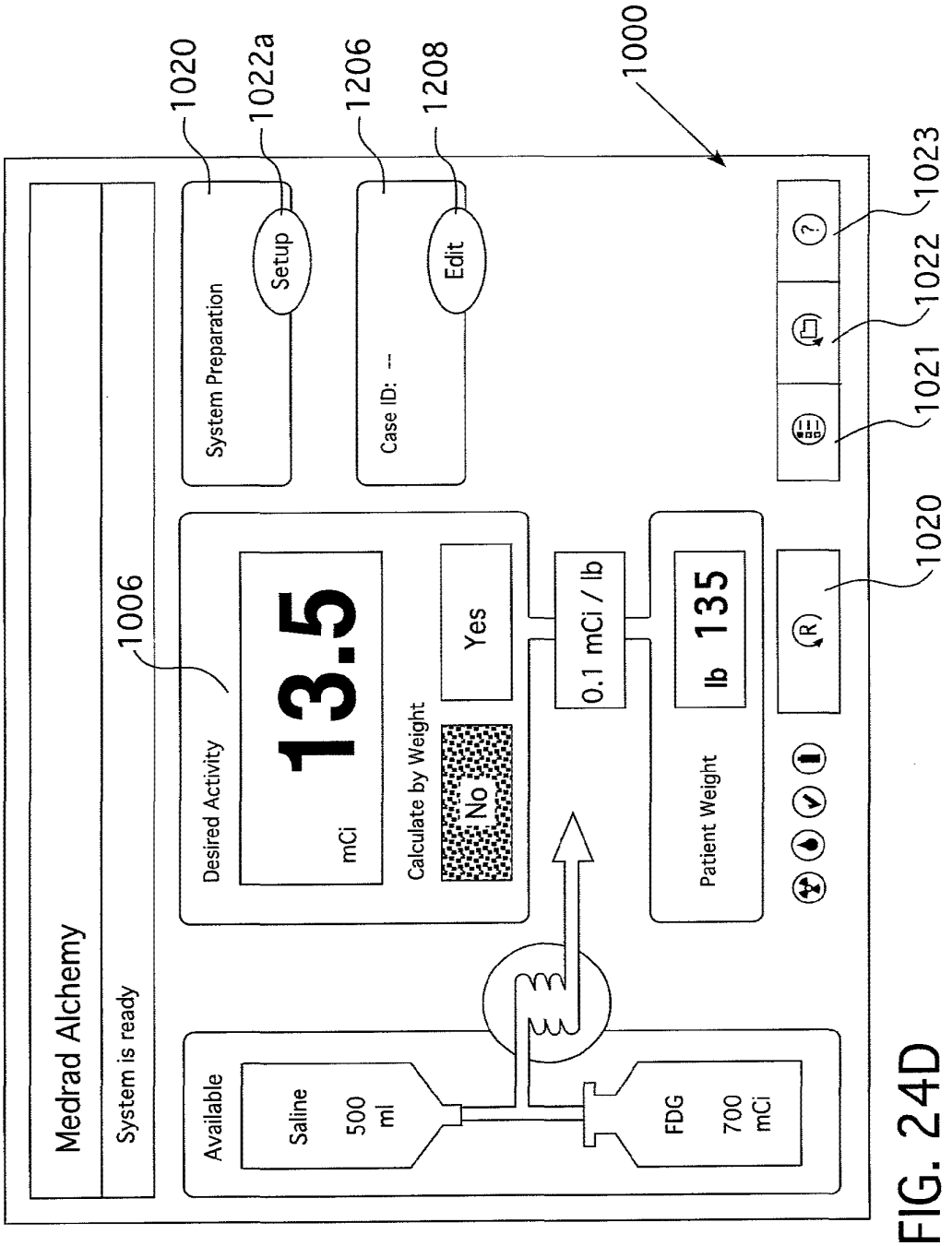
1000
1020
1022a
1206
1208
1023
1022
1021
1020
1006
Medrad Alchemy
System is ready
System Preparation
Setup
Case ID: --
Edit
Desired Activity
13.5
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb 135
R
Available
Saline
500
ml
FDG
700
mCi

FIG. 24D

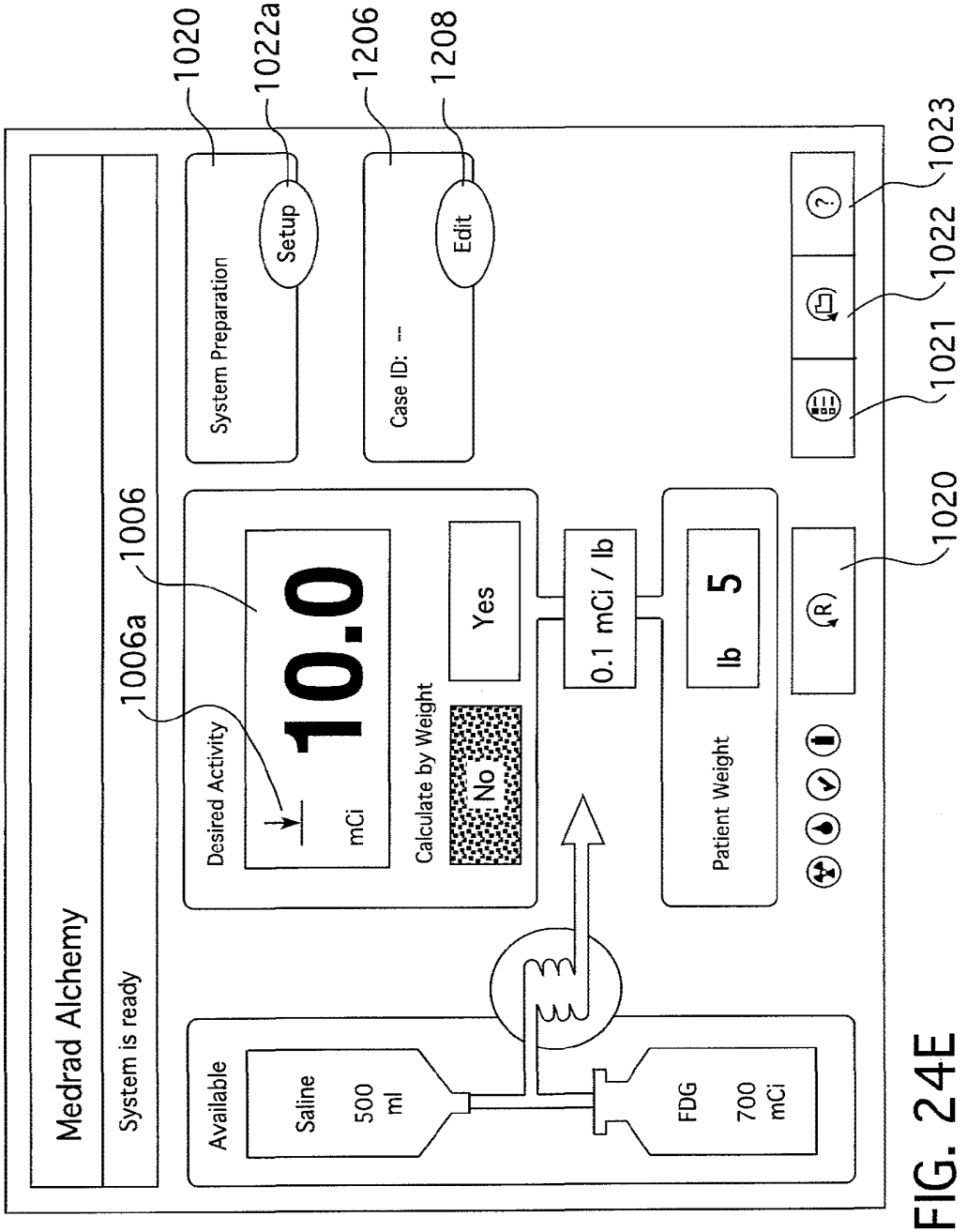
Medrad Alchemy
System is ready
1006
1006a
Desired Activity
10.0
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb
5
1020
1022a
System Preparation
Setup
1206
1208
Case ID: --
Edit
1021
1022
1023
Available
Saline
500
ml
FDG
700
mCi

FIG. 24E

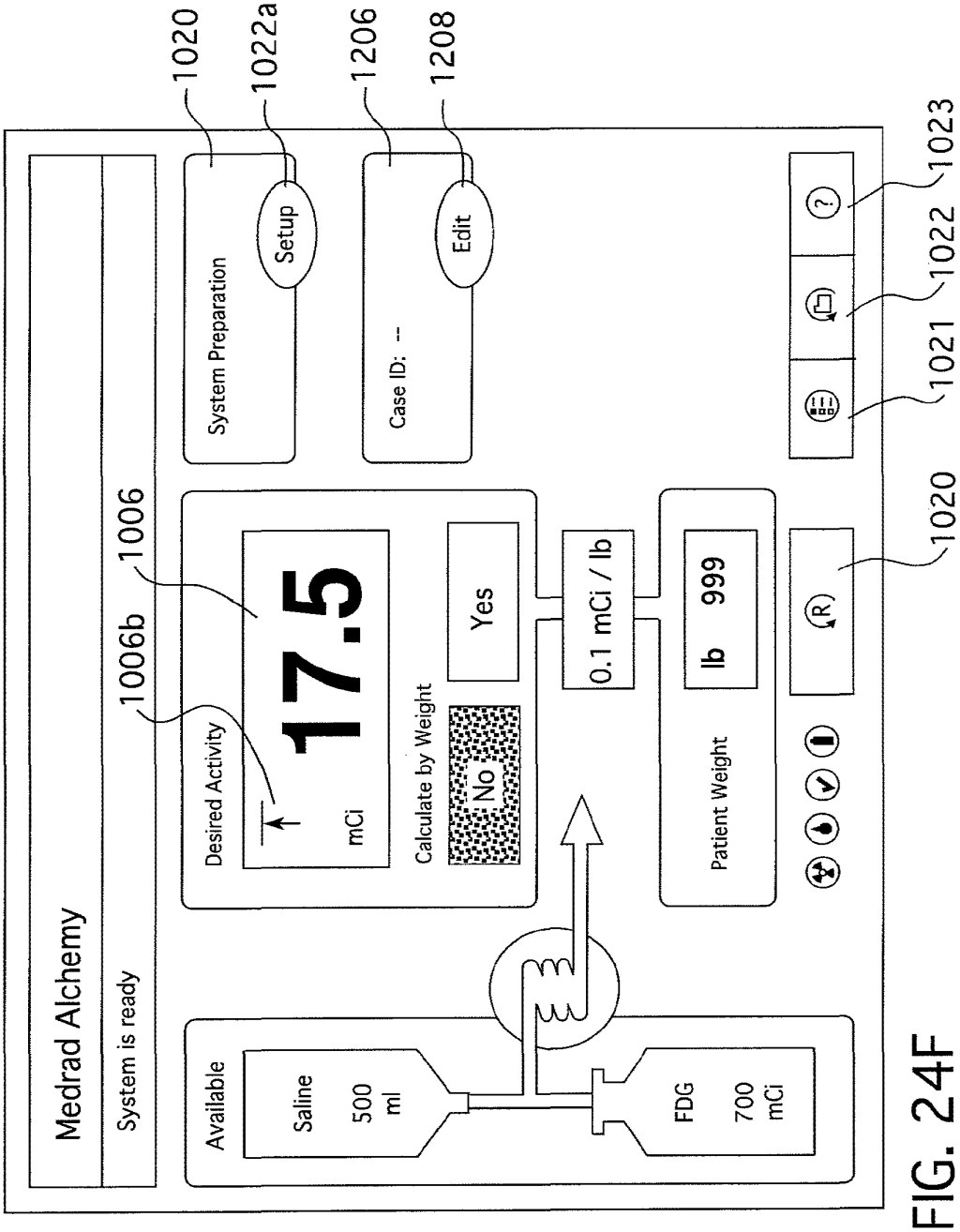
Medrad Alchemy
System is ready
1006
1006b
Desired Activity
17.5
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb 999
1020
1022a
System Preparation
Setup
1206
1208
Case ID: --
Edit
1023
1022
1021
1020
Available
Saline
500
ml
FDG
700
mCi

FIG. 24F

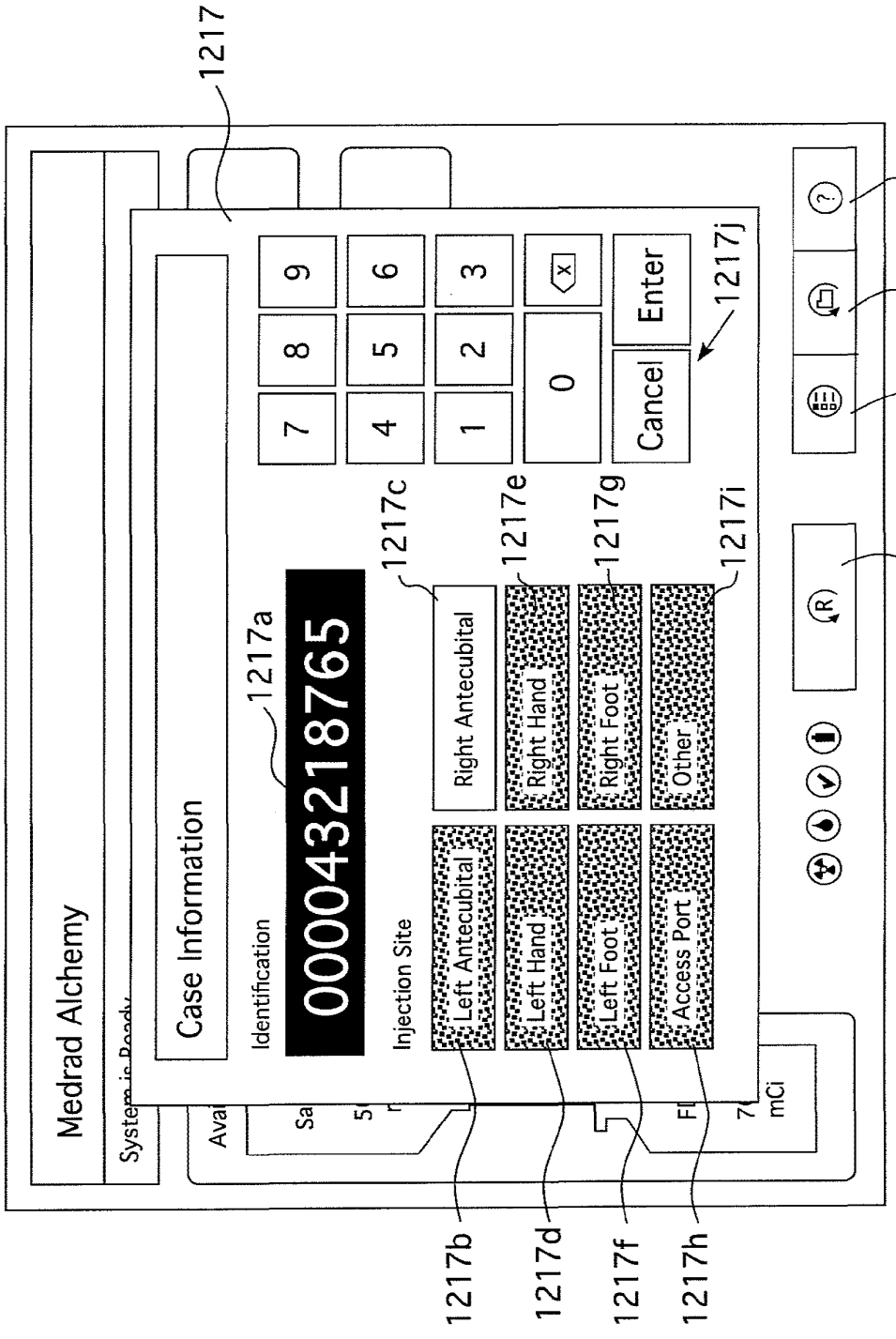
1217
Medrad Alchemy
Case Information
Identification
1217a
0000432187 65
Injection Site
1217c
Right Antecubital
1217e
Right Hand
1217g
Right Foot
1217i
Other
Left Antecubital
Left Hand
Left Foot
Access Port
1217b
1217d
1217f
1217h
7
8
9
4
5
6
1
2
3
0
Cancel
Enter
1217j
1020
1021
1022
1023
mCi

FIG. 25A

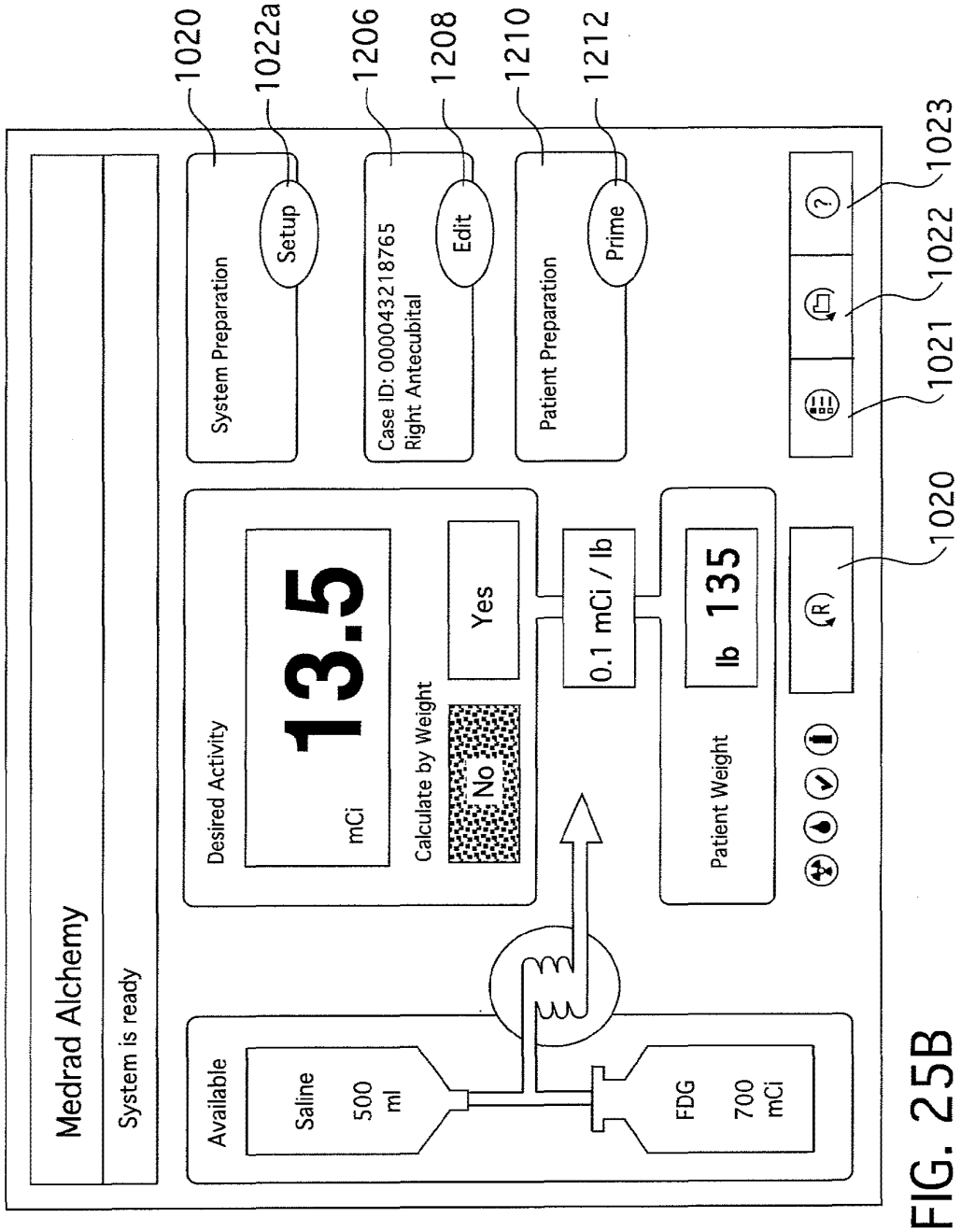
1020
1022a
1206
1208
1210
1212
Medrad Alchemy
System is ready
System Preparation
Setup
Case ID: 00004321876S
Right Antecubital
Edit
Patient Preparation
Prime
1023
1022
1021
1020
Desired Activity
13.5
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb 135
Available
Saline
500
ml
FDG
700
mCi

FIG. 25B

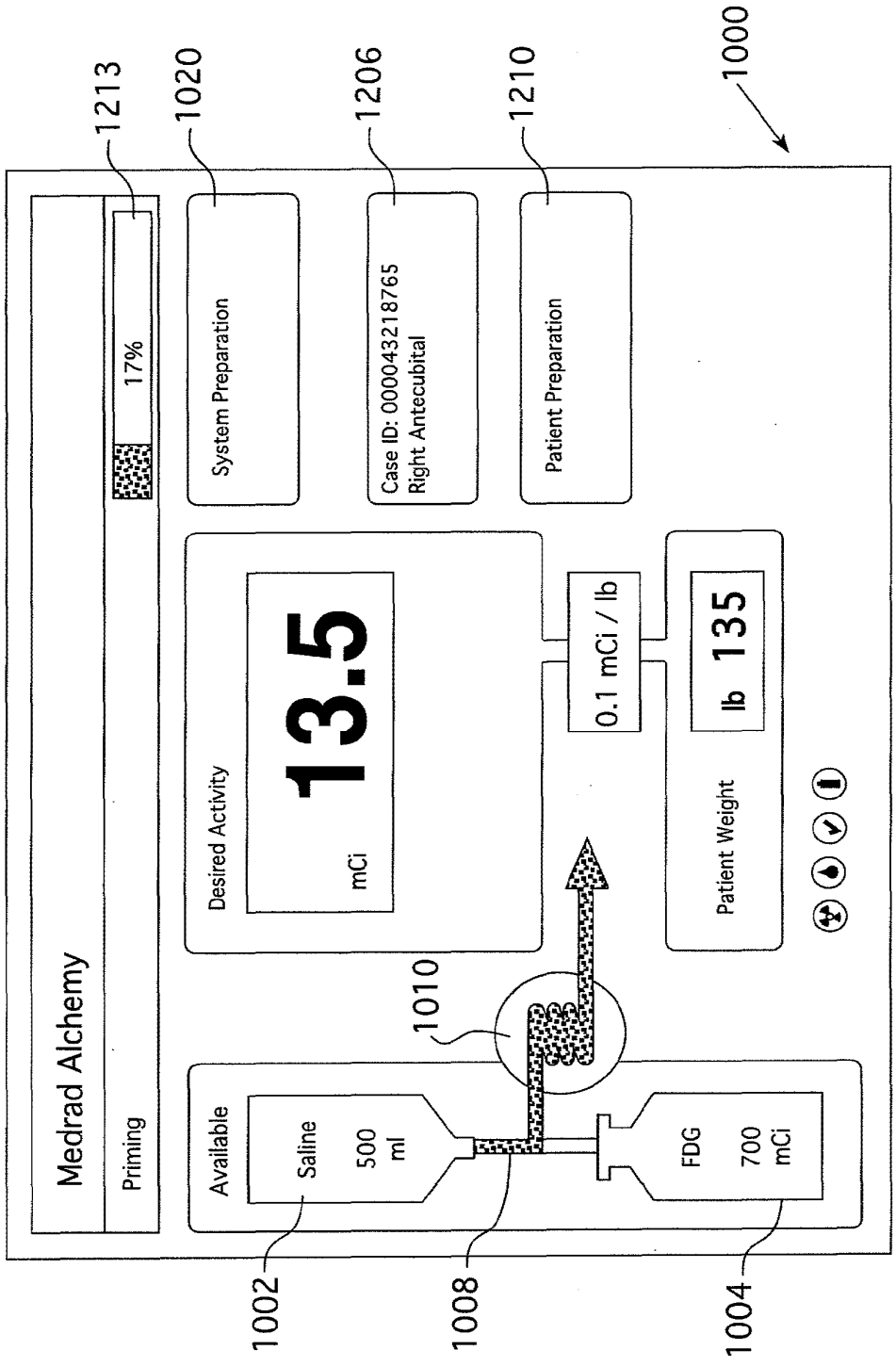
1213
1020
1206
1210
1000
Medrad Alchemy
Priming
17%
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
Desired Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004

FIG. 26A

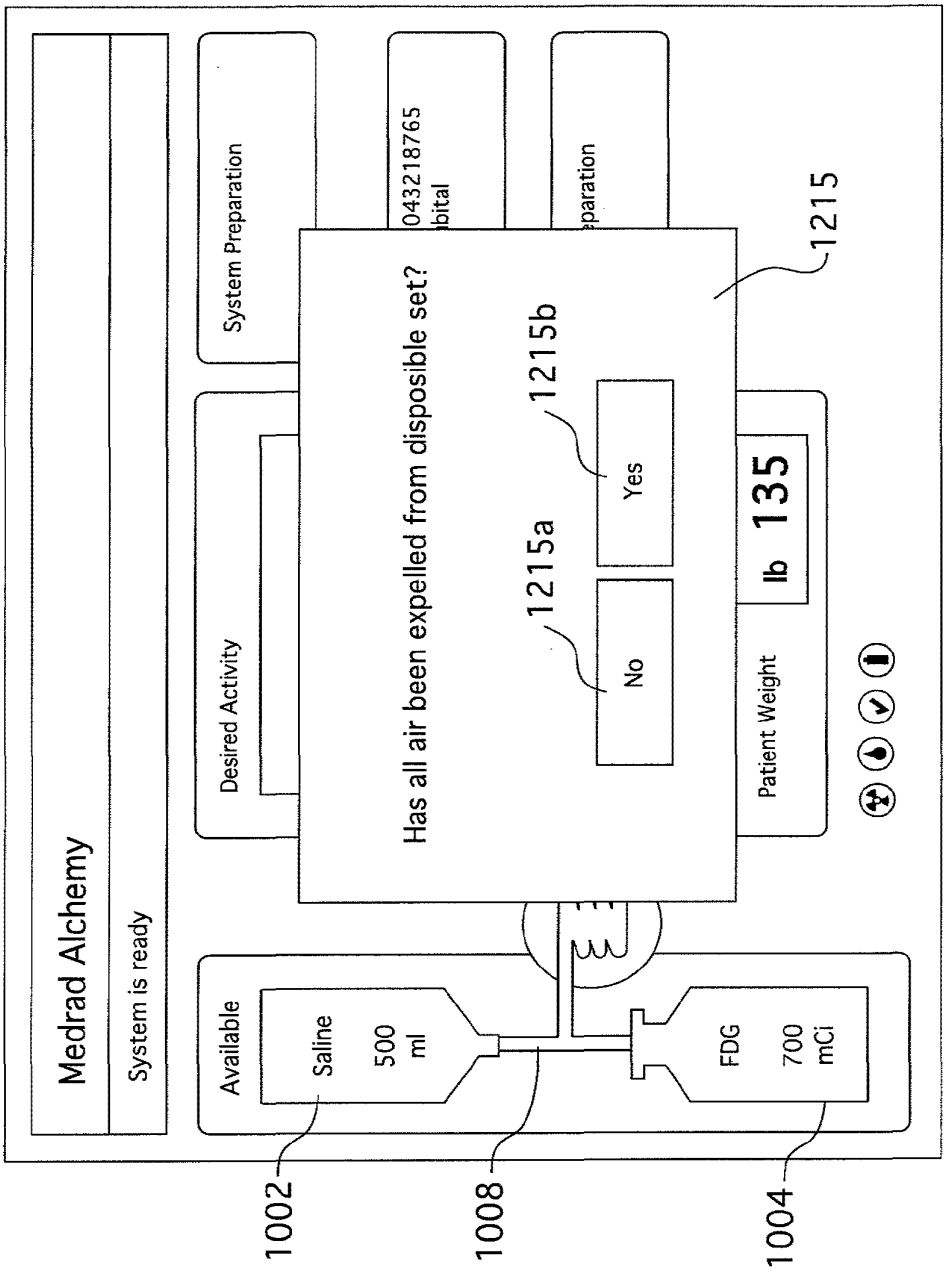
Medrad Alchemy
System is ready
System Preparation
Desired Activity
Has all air been expelled from disposible set?
1215
1215a
1215b
No
Yes
Patient Weight
lb 135
Available
Saline
500 ml
FDG
700 mCi
1002
1008
1004

FIG. 26B

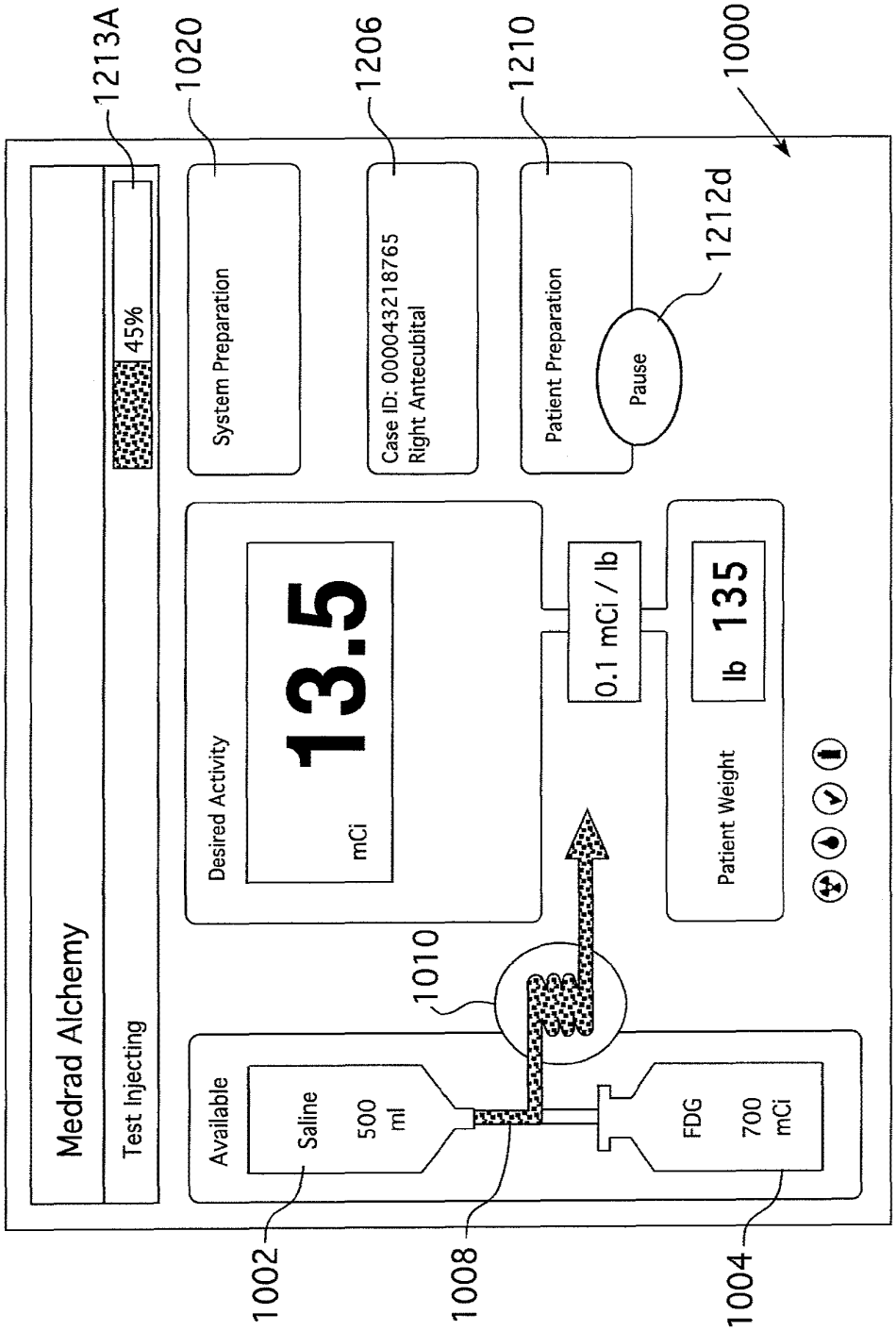
1213A
1020
1206
1210
1000
Medrad Alchemy
Test Injecting
45%
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
Pause
1212d
Desired Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004

FIG. 27A

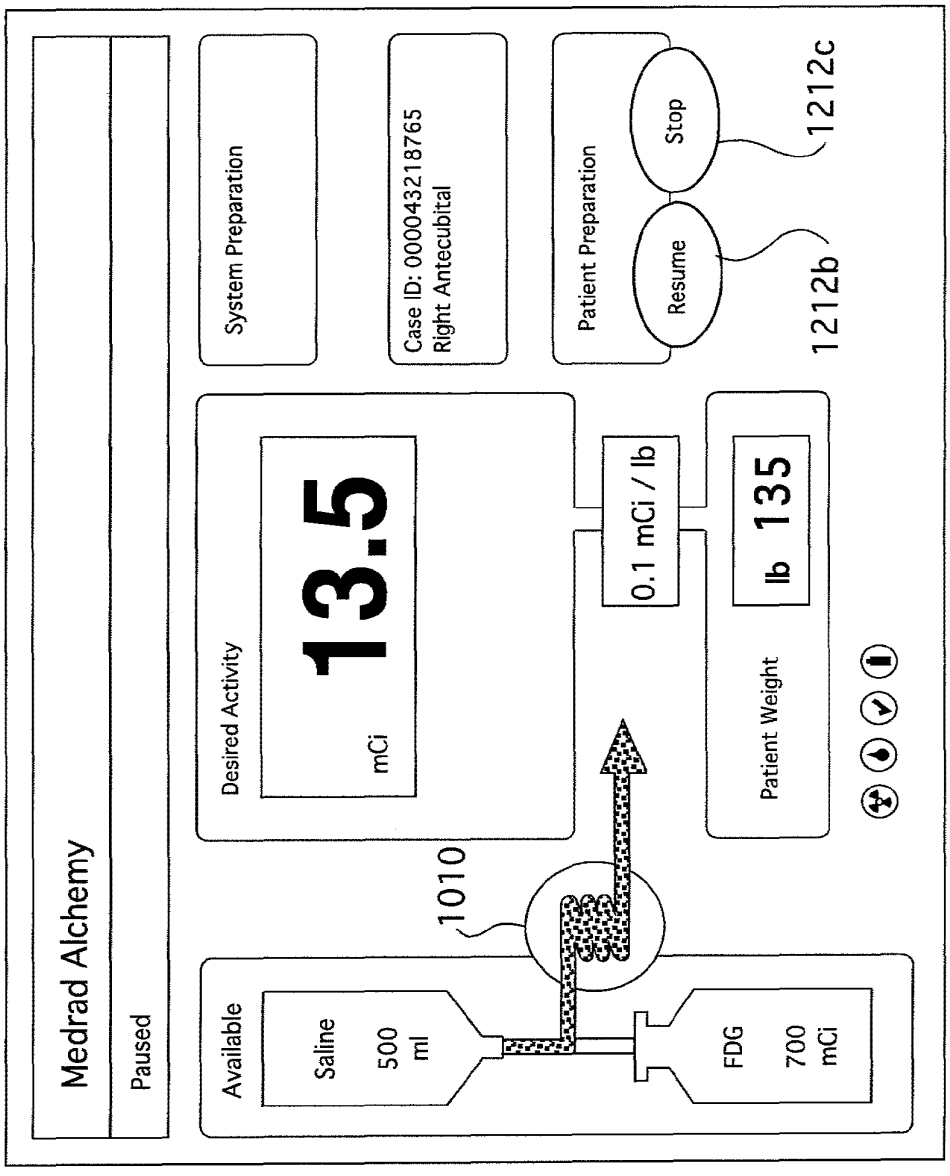
Medrad Alchemy
Paused
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
Stop
Resume
1212c
1212b
Desired Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi

FIG. 27B

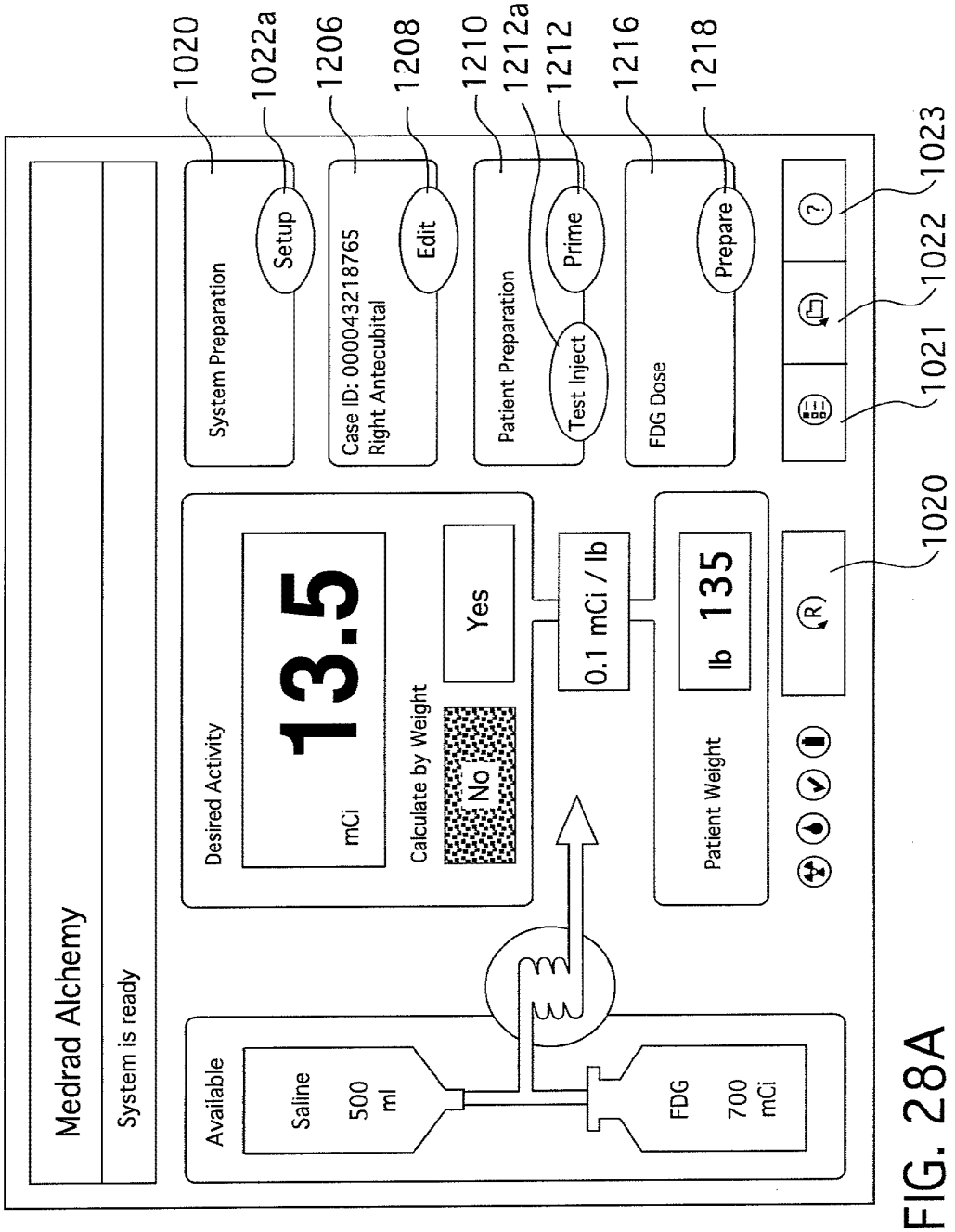
Medrad Alchemy
System is ready
Available
Saline
500
ml
FDG
700
mCi
Desired Activity
13.5
mCi
Calculate by Weight
No
Yes
0.1 mCi / lb
Patient Weight
lb 135
System Preparation
Setup
Case ID: 000043218765
Right Antecubital
Edit
Patient Preparation
Prime
Test Inject
FDG Dose
Prepare
1020
1022a
1206
1208
1210
1212a
1212
1216
1218
1020
1021
1022
1023

FIG. 28A

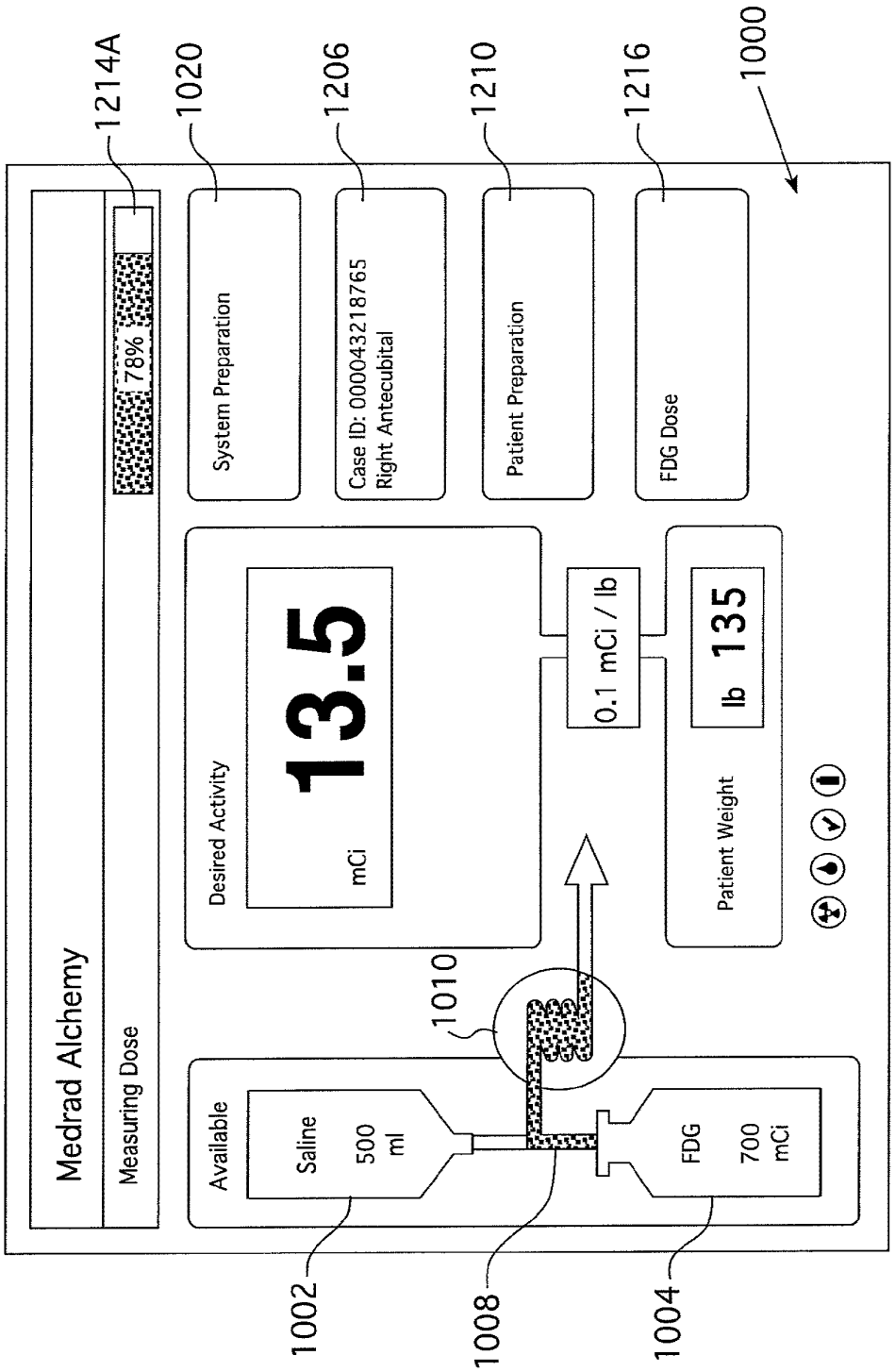
1214A
1020
1206
1210
1216
1000
Medrad Alchemy
Measuring Dose
78%
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
FDG Dose
Desired Activity
13.5
mCi
0.1 mCi / lb
lb 135
Patient Weight
1010
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004

FIG. 28B

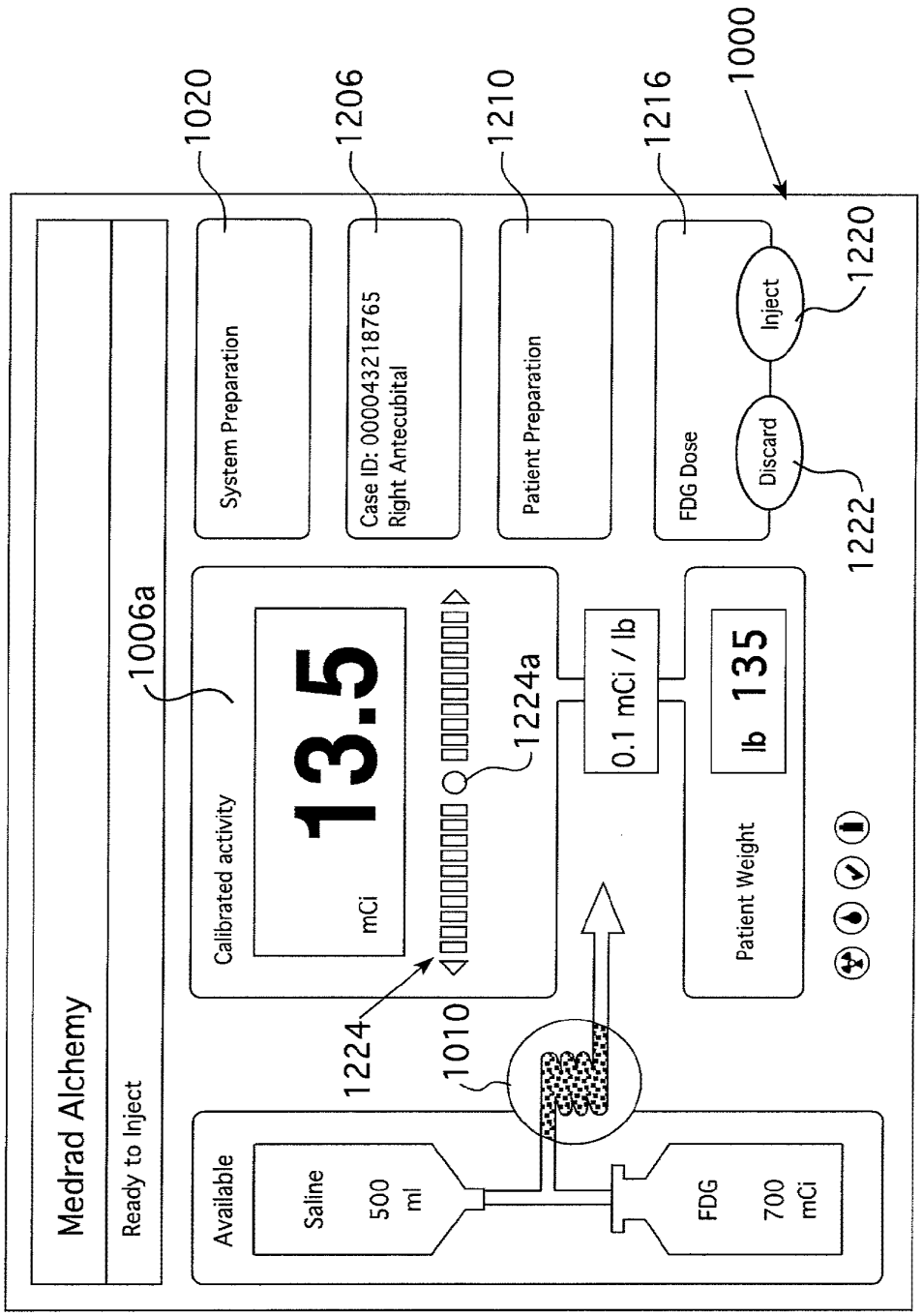
Medrad Alchemy
Ready to Inject
1006a
1020
System Preparation
1206
Case ID: 000043218765
Right Antecubital
1210
Patient Preparation
1216
FDG Dose
Discard
Inject
1220
1222
1000
Calibrated activity
13.5
mCi
1224a
1224
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi

FIG. 29

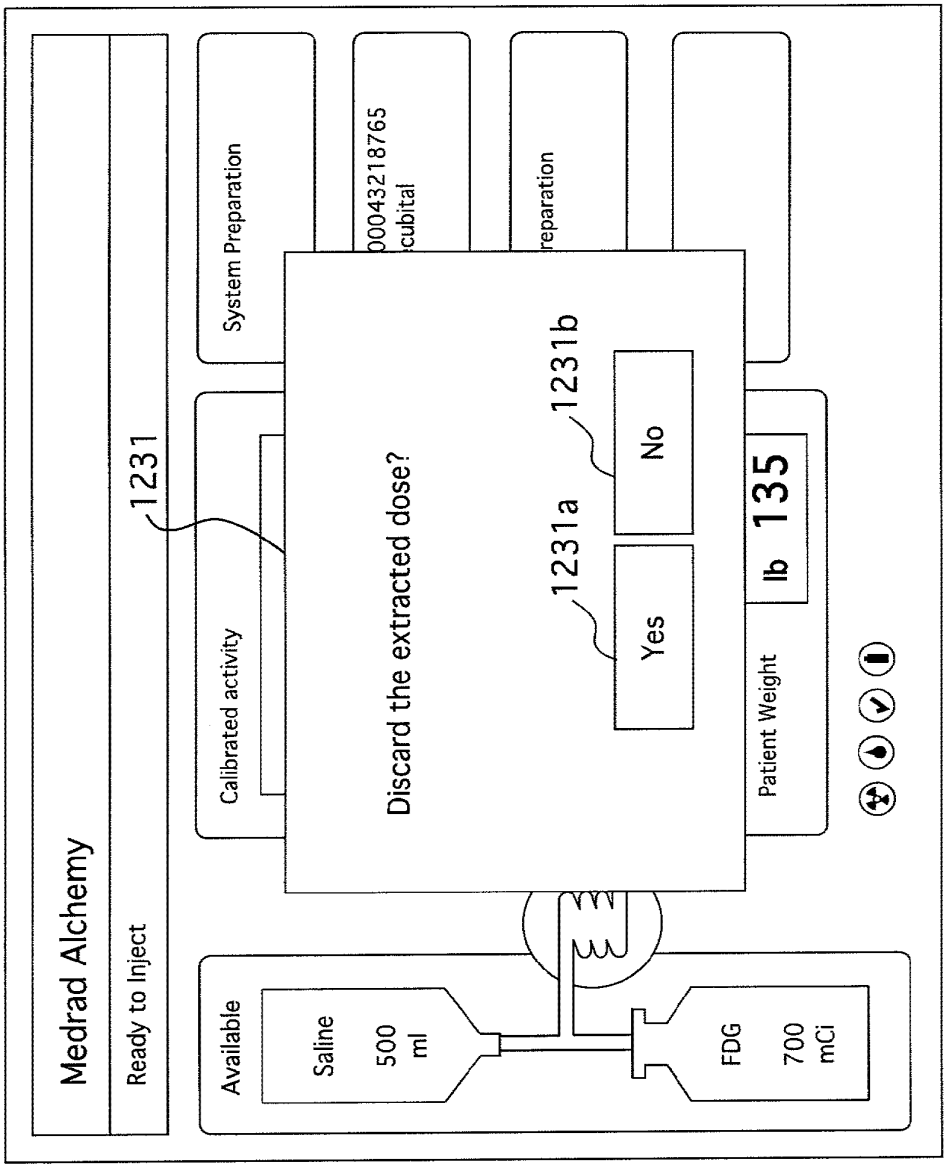
Medrad Alchemy
Ready to Inject
1231
System Preparation
Calibrated activity
Discard the extracted dose?
1231a
Yes
1231b
No
Patient Weight
lb 135
Available
Saline
500 ml
FDG
700 mCi

FIG. 30A

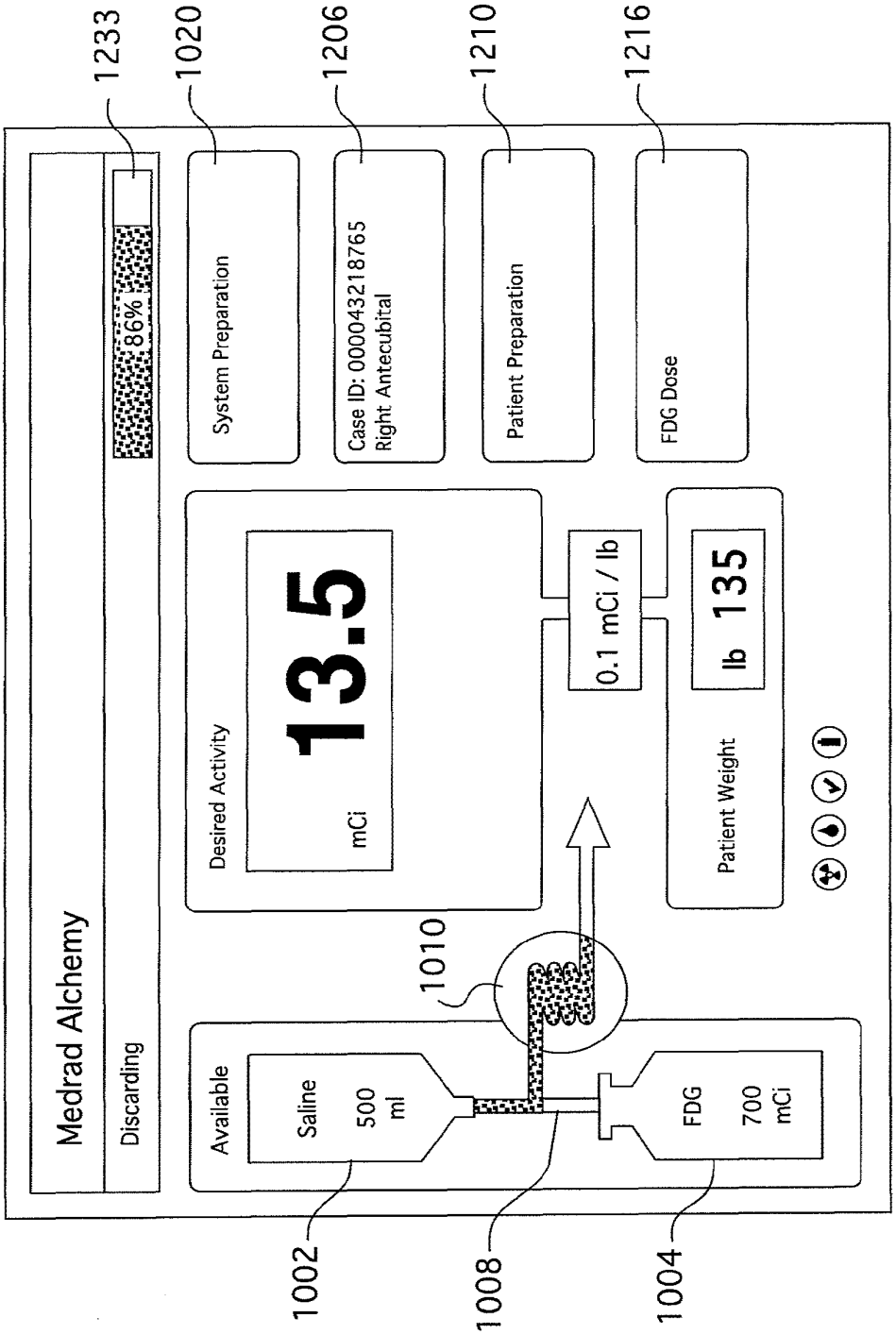
1233
1020
1206
1210
1216
Medrad Alchemy
Discarding
86%
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
FDG Dose
Desired Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004

FIG. 30B

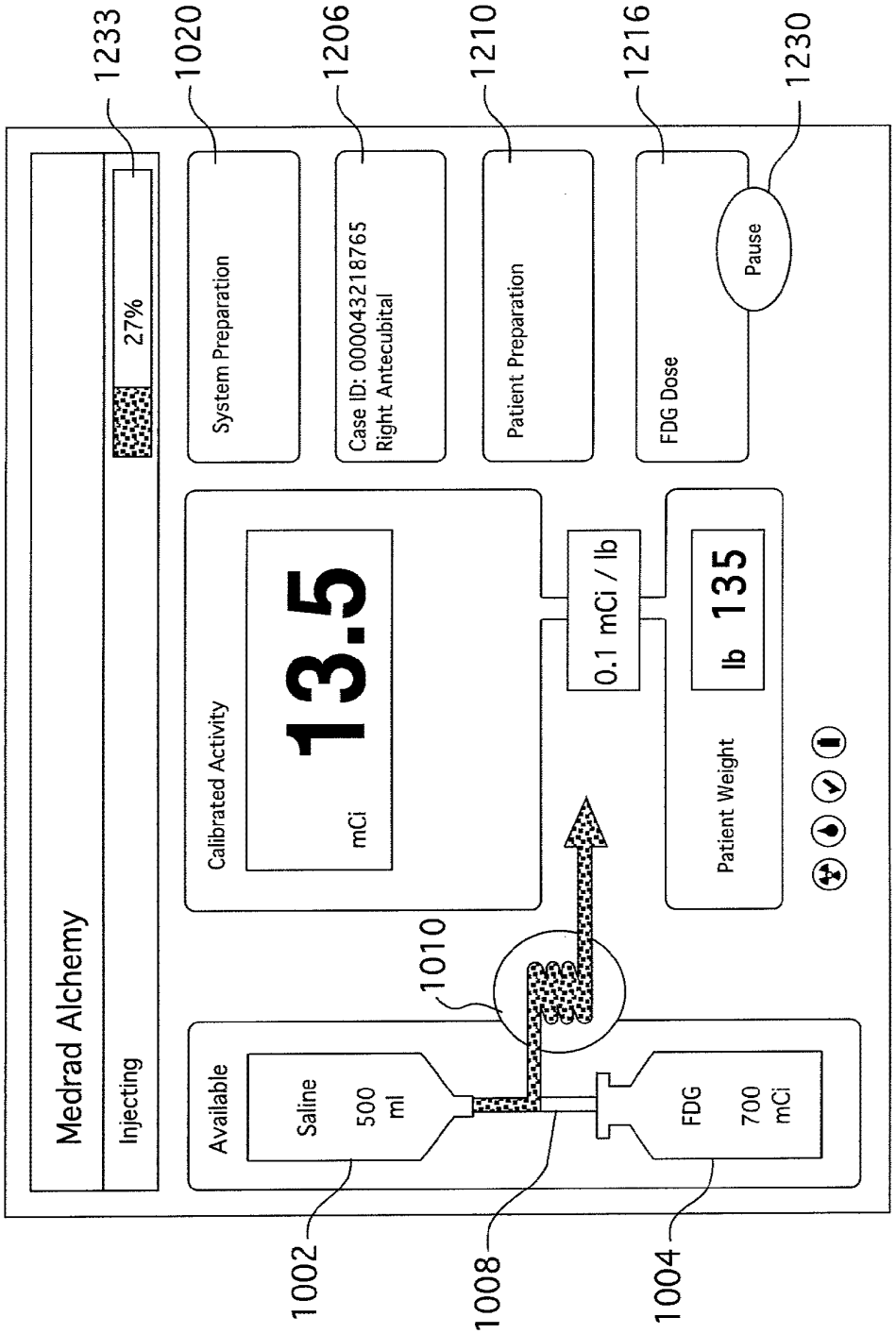
1233
1020
1206
1210
1216
1230
Medrad Alchemy
Injecting
27%
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
FDG Dose
Pause
Calibrated Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
1010
Available
Saline
500
ml
FDG
700
mCi
1002
1008
1004

FIG. 31

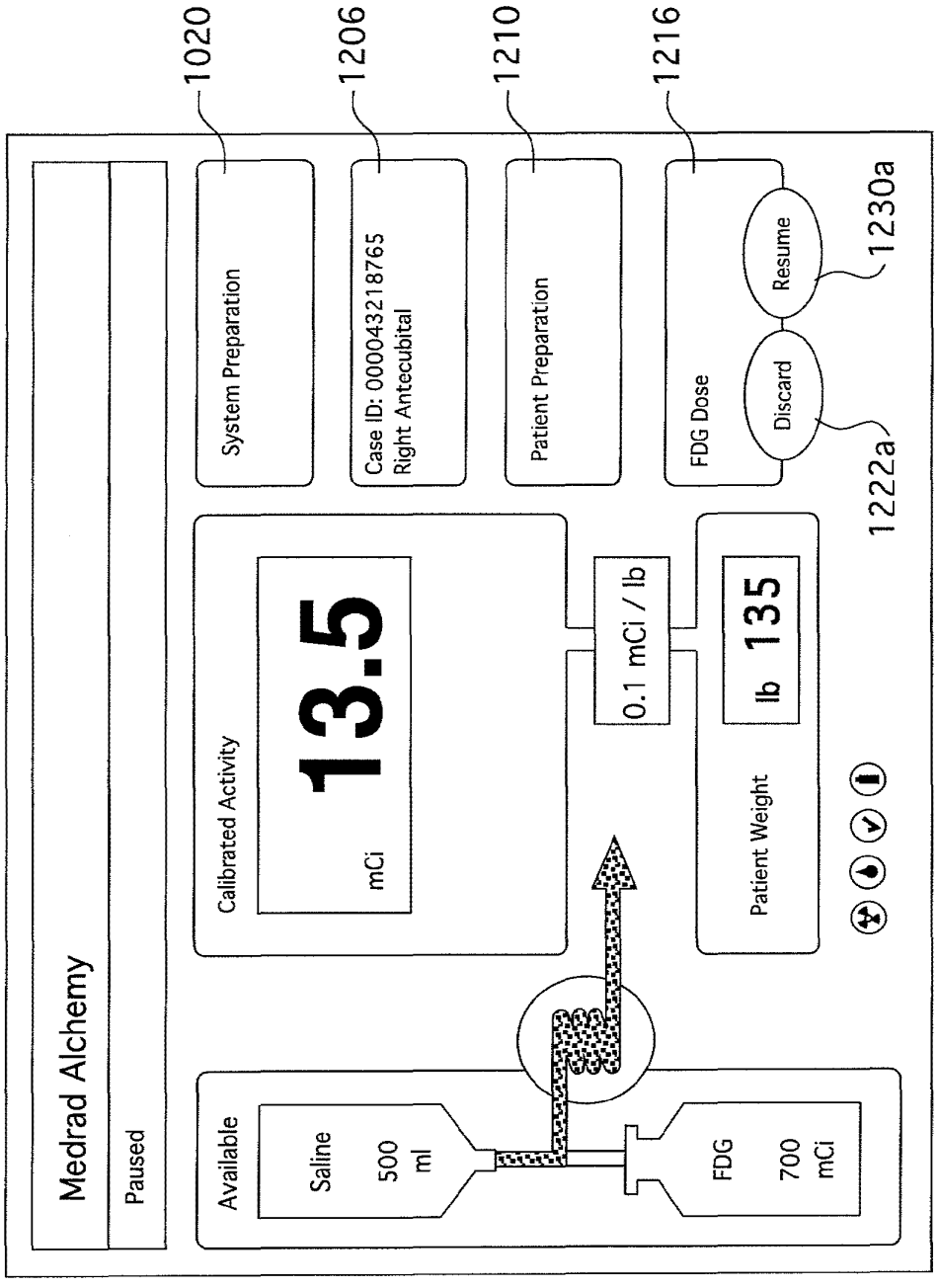
1020
1206
1210
1216
Medrad Alchemy
Paused
System Preparation
Case ID: 000043218765
Right Antecubital
Patient Preparation
FDG Dose
Resume
Discard
1230a
1222a
Calibrated Activity
13.5
mCi
0.1 mCi / lb
Patient Weight
lb 135
Available
Saline
500
ml
FDG
700
mCi

FIG. 32A

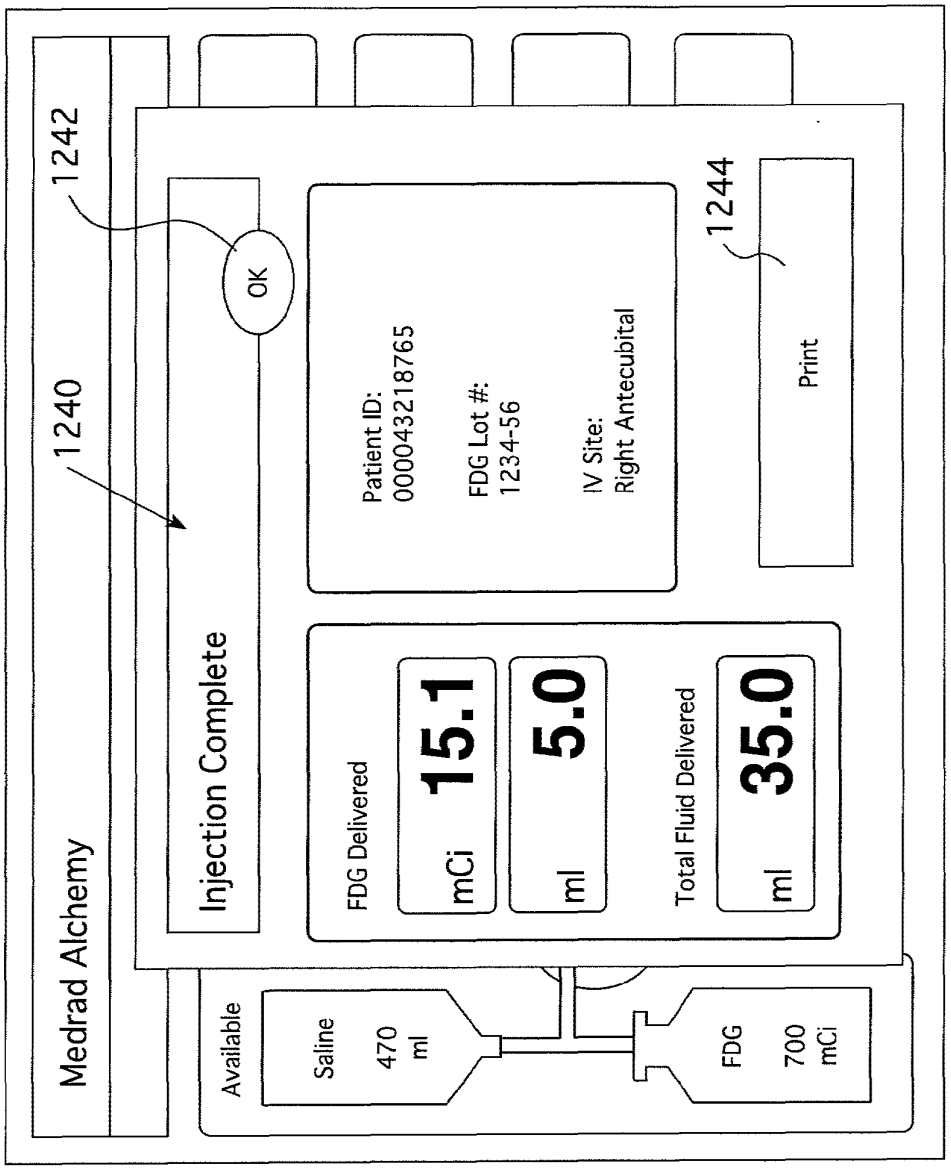
Medrad Alchemy
1240
1242
Injection Complete
OK
Patient ID:
0000043218765
FDG Lot #:
1234-56
IV Site:
Right Antecubital
1244
Print
FDG Delivered
15.1
mCi
5.0
ml
Total Fluid Delivered
35.0
ml
Available
Saline
470
ml
FDG
700
mCi

FIG. 32B

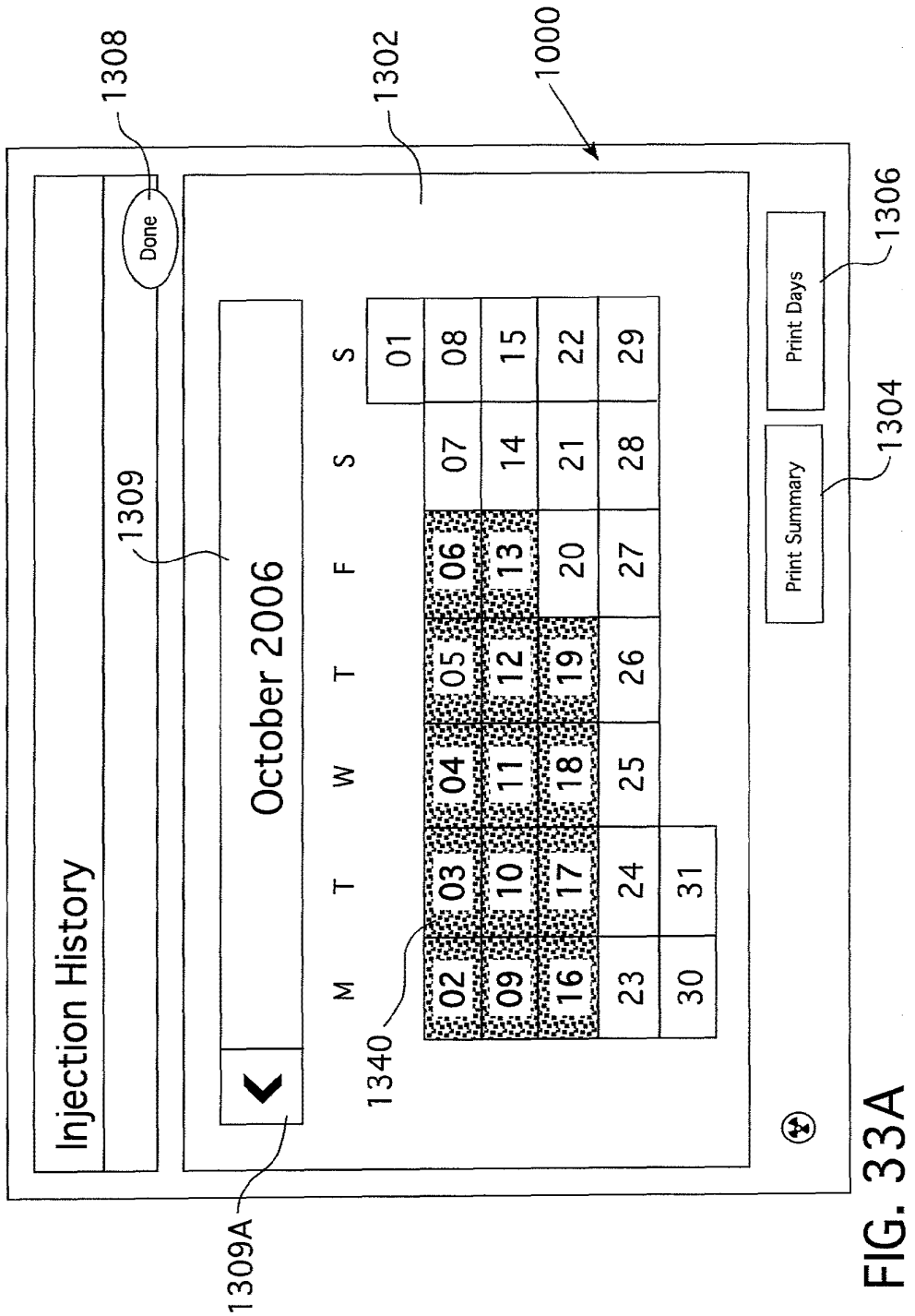
1308
1302
1000
Done
Injection History
1309
October 2006
M T W T F S S
01
02 03 04 05 06 07 08
09 10 11 12 13 14 15
16 17 18 19 20 21 22
23 24 25 26 27 28 29
30 31
1340
Print Days
1306
Print Summary
1304
1309A

FIG. 33A

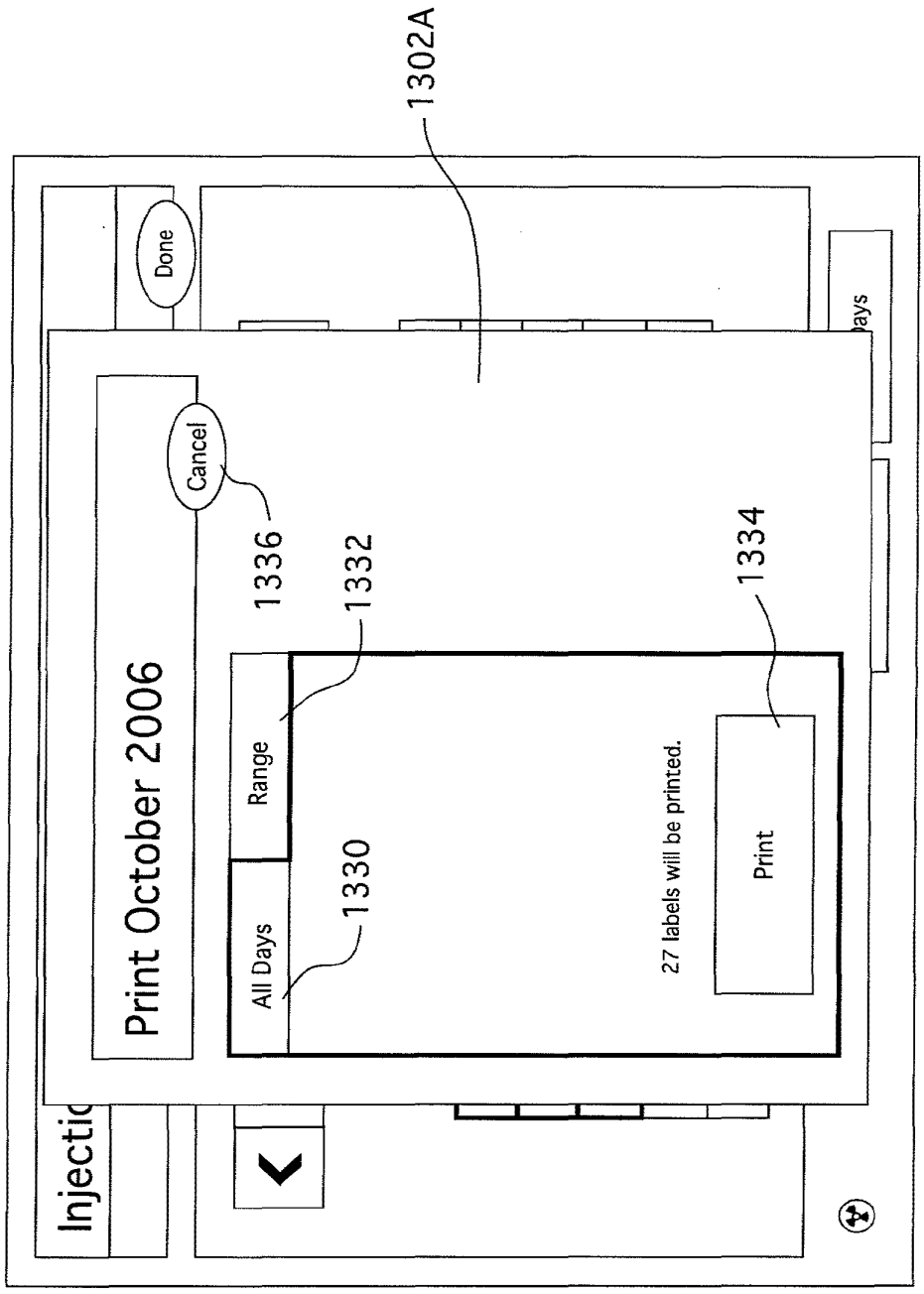
1302A
Done
Cancel
1336
1332
1334
Print October 2006
Range
All Days
1330
27 labels will be printed.
Print

FIG. 33B

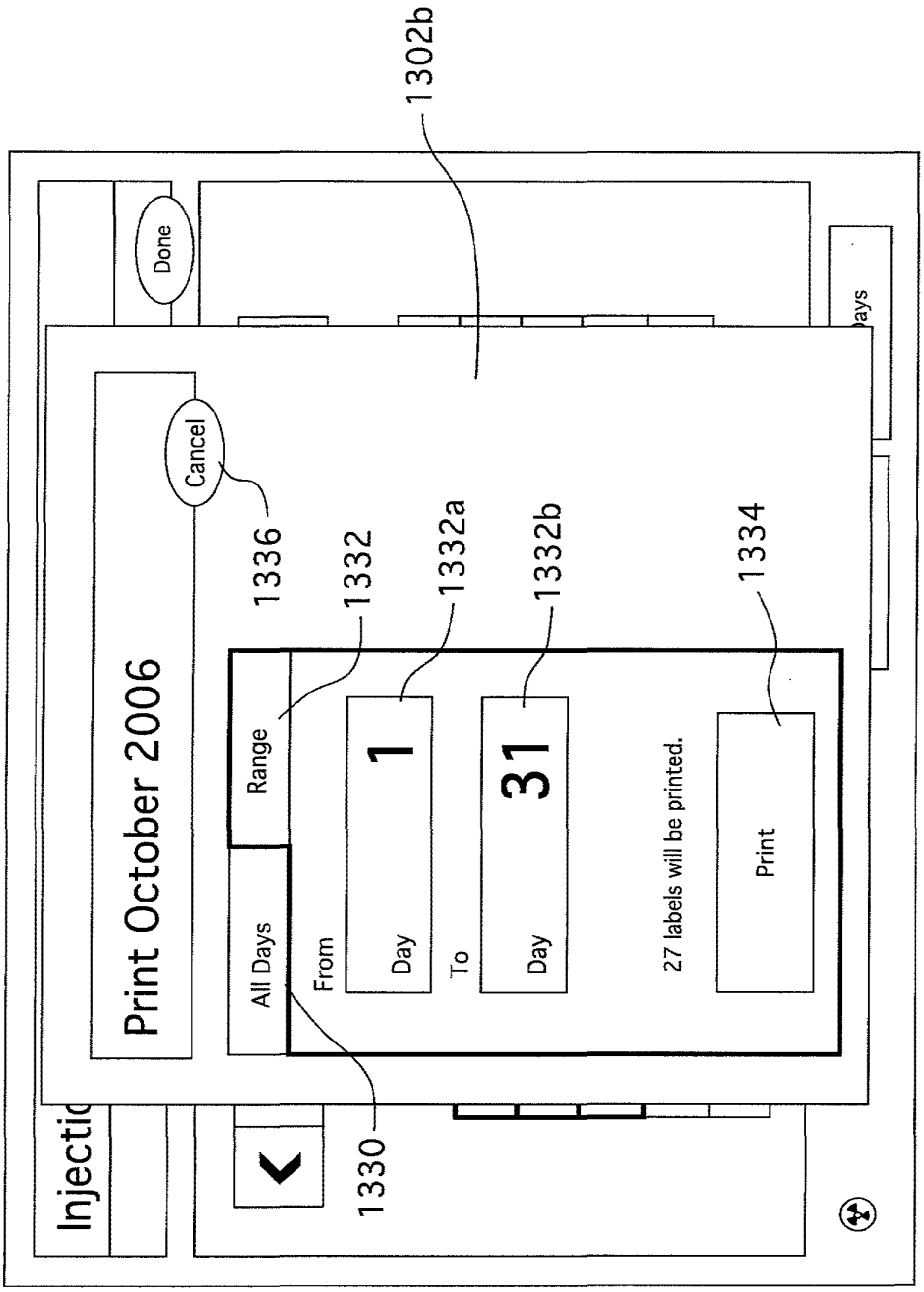
1302b
Done
Cancel
1336
1332
1332a
1332b
1334
Print October 2006
Range
All Days
From
1
Day
To
31
Day
27 labels will be printed.
Print
1330
Injecti

FIG. 33C

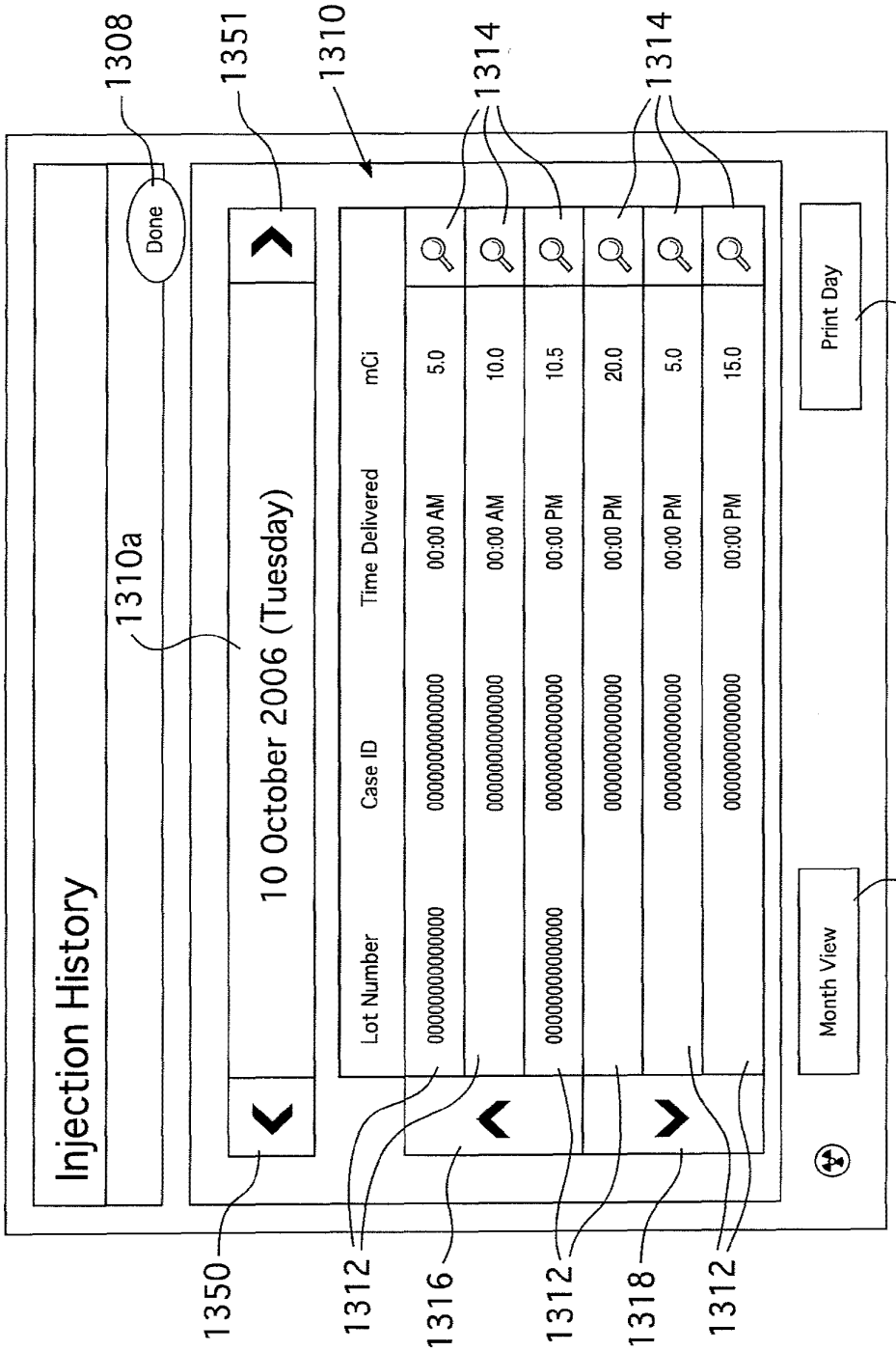
Injection History
Done
1308
1310a
1351
1310
10 October 2006 (Tuesday)
1314
1314
Lot Number
Case ID
Time Delivered
mCi
0000000000000
0000000000000
00:00 AM
5.0
0000000000000
0000000000000
00:00 AM
10.0
0000000000000
0000000000000
00:00 PM
10.5
0000000000000
0000000000000
00:00 PM
20.0
0000000000000
0000000000000
00:00 PM
5.0
0000000000000
0000000000000
00:00 PM
15.0
Print Day
1306a
Month View
1320
1350
1312
1316
1312
1318
1312

FIG. 34A

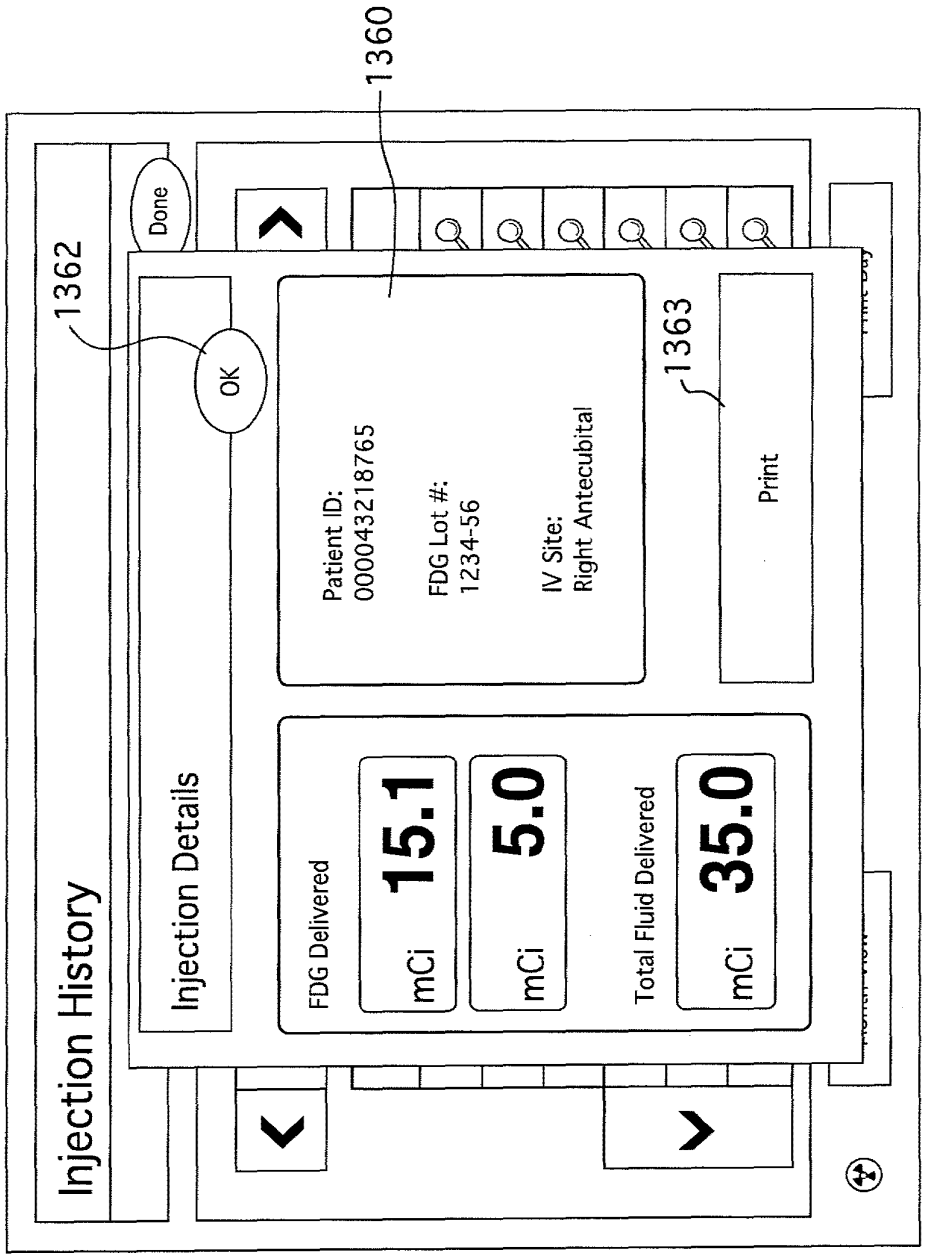
Injection History
1362
Done
OK
Injection Details
1360
Patient ID:
000043218765
FDG Lot #:
1234-56
IV Site:
Right Antecubital
1363
Print
FDG Delivered
15.1
mCi
5.0
mCi
Total Fluid Delivered
35.0
mCi

FIG. 34B

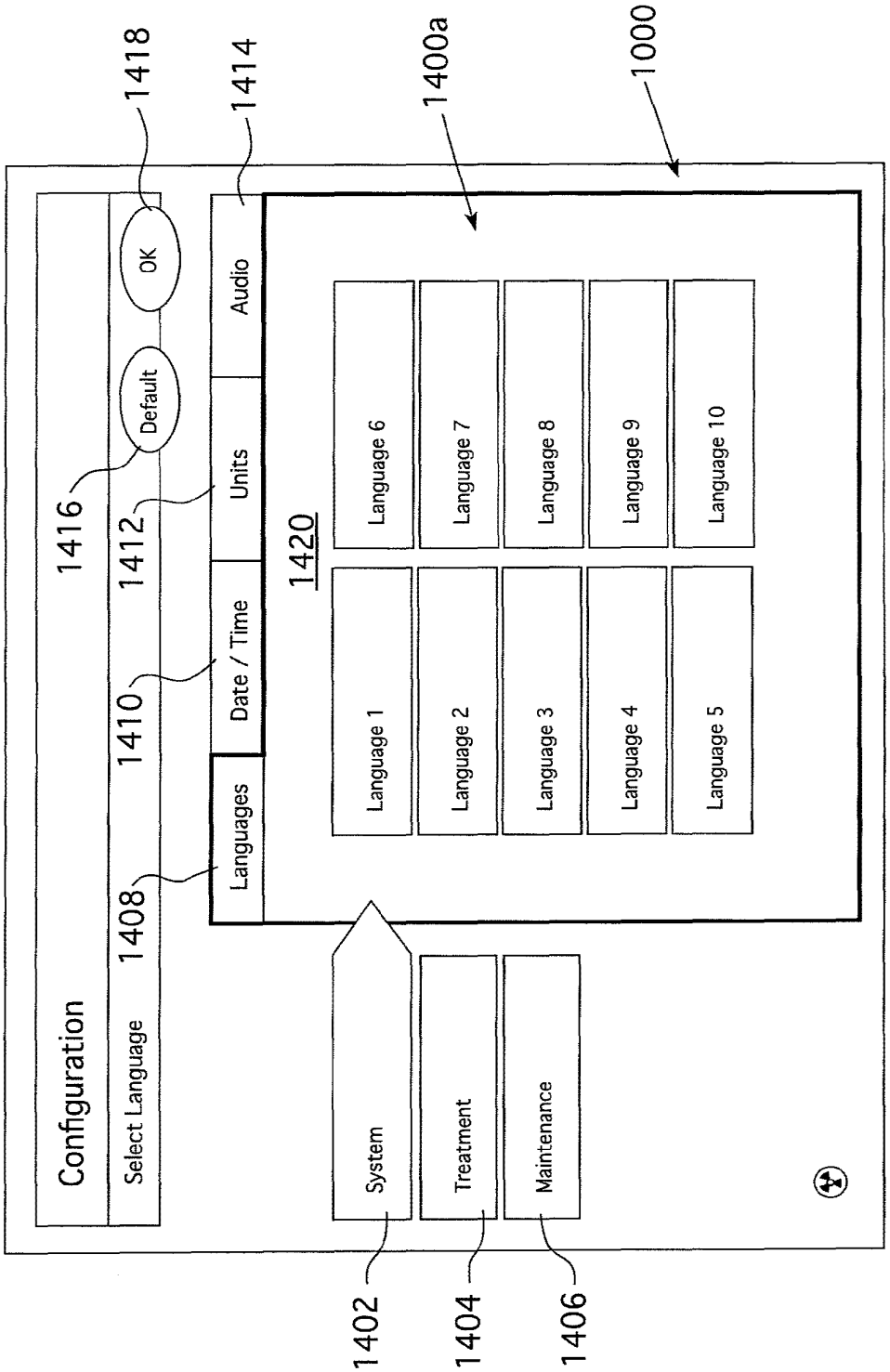
1000
1400a
1418
1414
1416
1412
1410
1408
1420
Configuration
Select Language
Languages
Date / Time
Units
Audio
OK
Default
Language 1
Language 2
Language 3
Language 4
Language 5
Language 6
Language 7
Language 8
Language 9
Language 10
System
Treatment
Maintenance
1402
1404
1406

FIG. 35

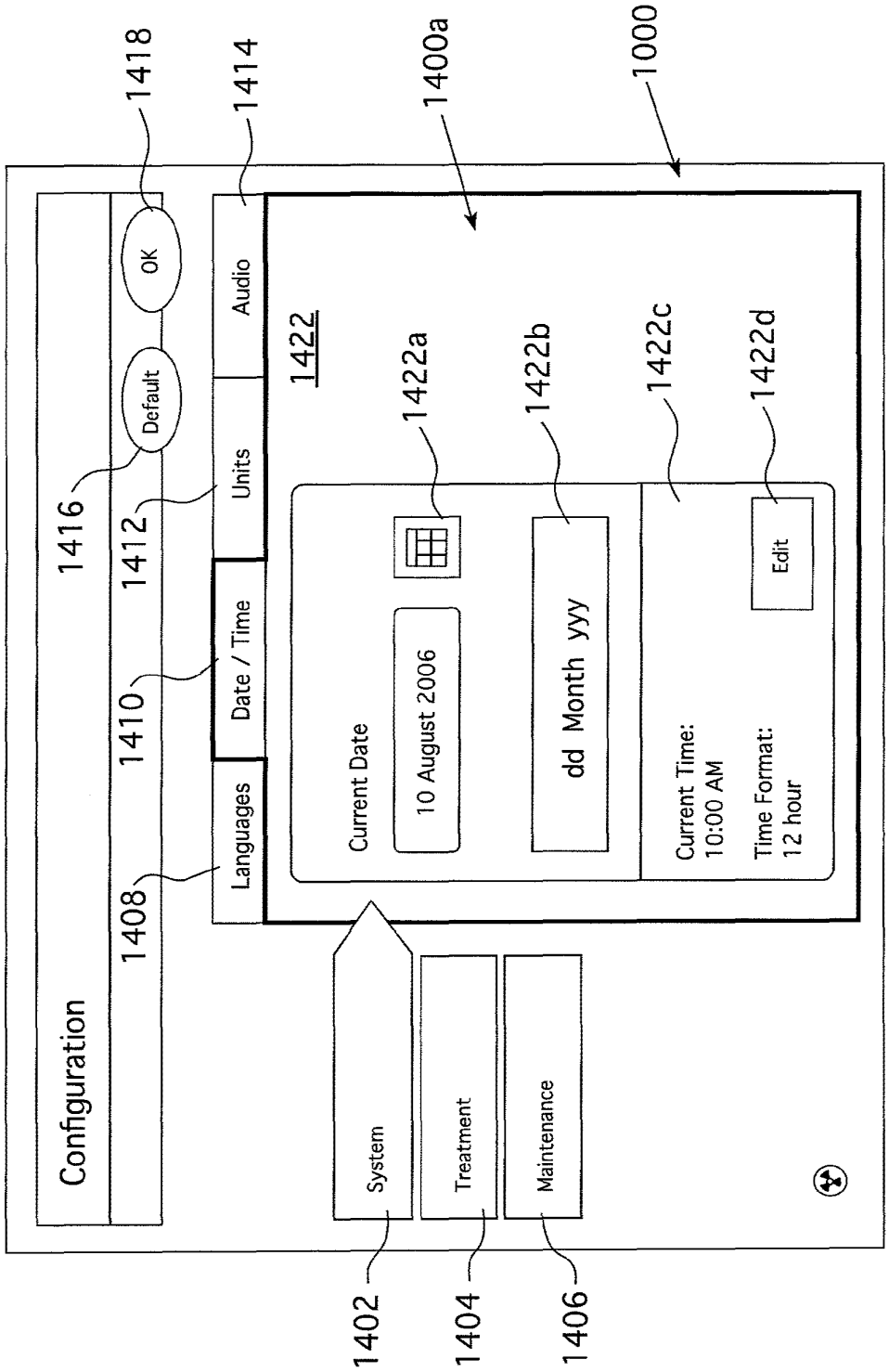
1000
1400a
1414
1418
Configuration
1408
1410
1412
1416
Languages
Date / Time
Units
Audio
Default
OK
1422
1422a
1422b
1422c
1422d
Current Date
10 August 2006
dd Month yyy
Current Time:
10:00 AM
Time Format:
12 hour
Edit
System
Treatment
Maintenance
1402
1404
1406

FIG. 36

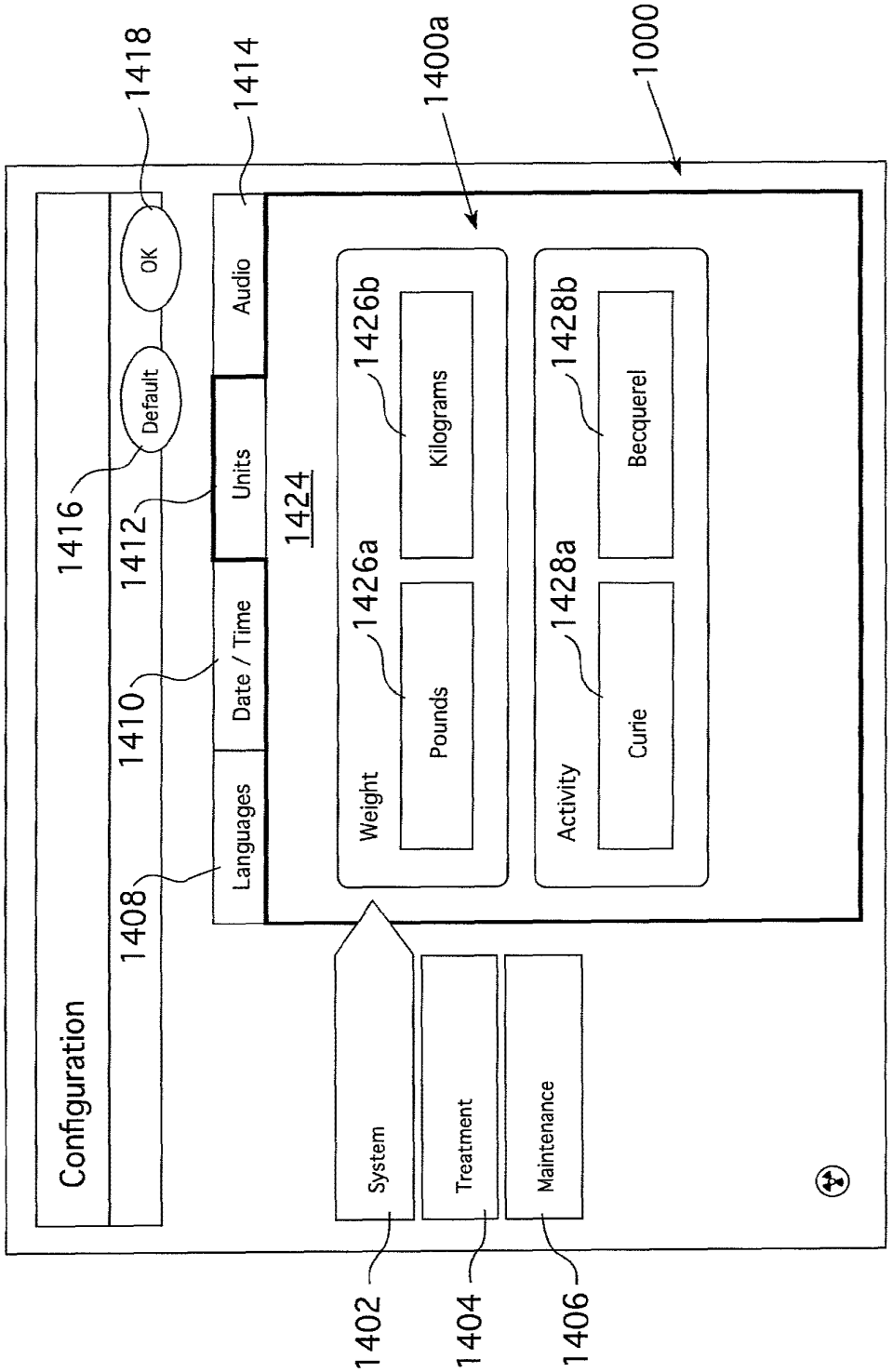
1000
1400a
1414
1418
Configuration
OK
Default
Audio
Units
Date / Time
Languages
1424
1426b
Kilograms
1426a
Pounds
Weight
1428b
Becquerel
1428a
Curie
Activity
System
Treatment
Maintenance
1402
1404
1406
1408
1410
1412
1416

FIG. 37

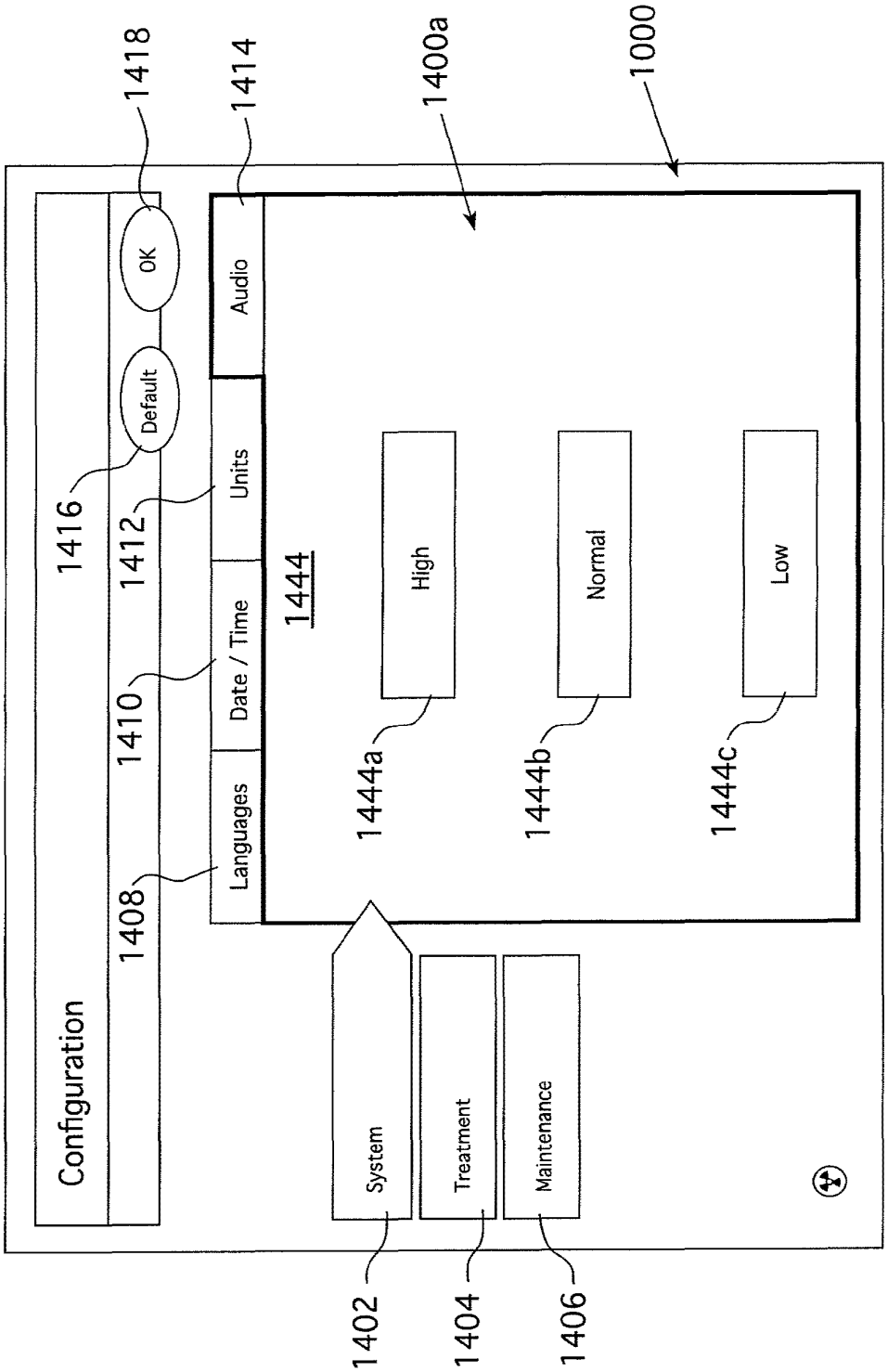
1418
1414
1400a
1000
OK
Audio
Default
Units
1416
1412
1444
High
Normal
Low
Date / Time
1410
1444a
1444b
1444c
Languages
1408
Configuration
System
Treatment
Maintenance
1402
1404
1406

FIG. 38

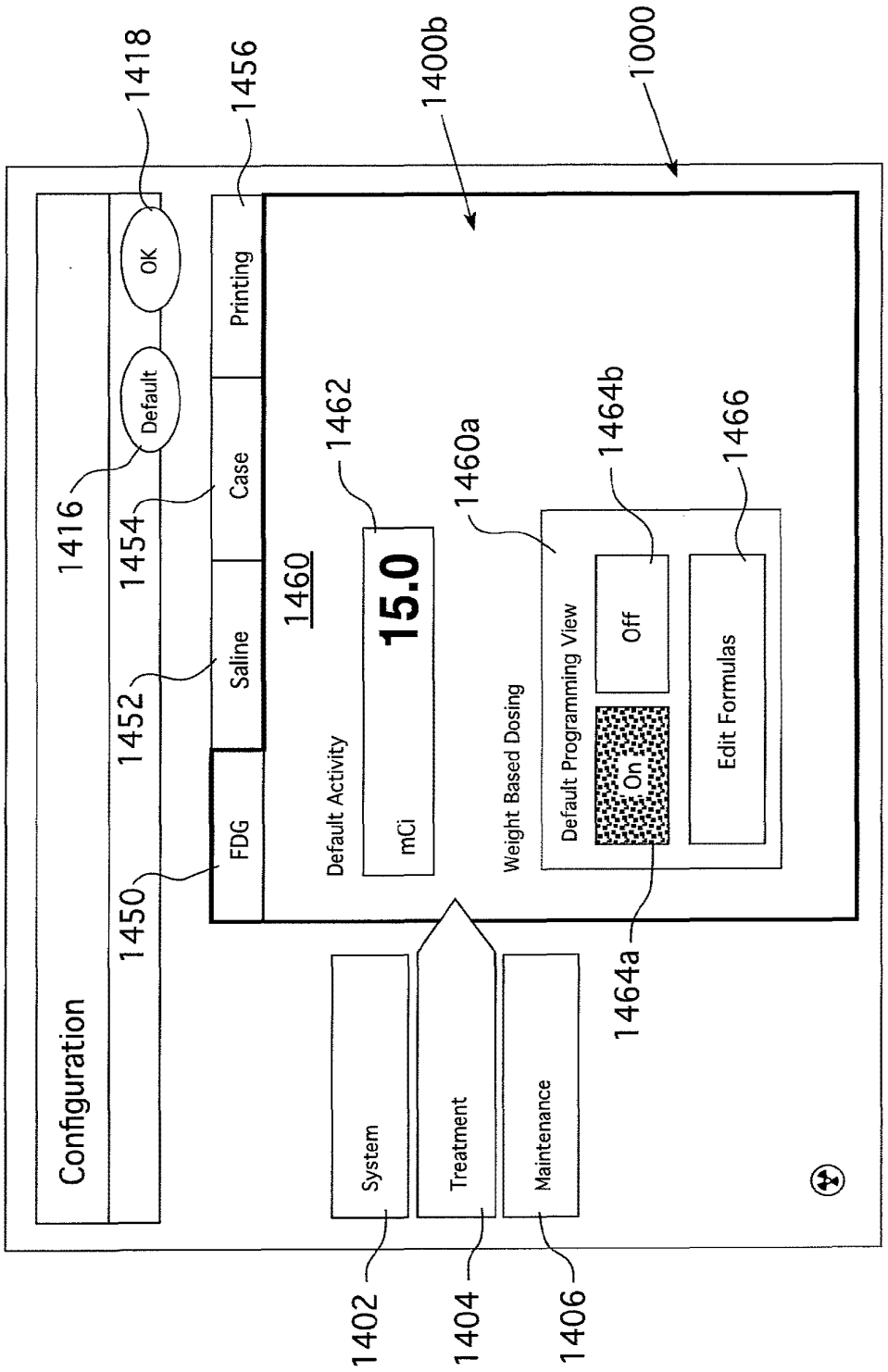
1000
1400b
1418
1456
OK
Default
Printing
Case
Saline
FDG
1416
1454
1452
1450
1460
1462
1460a
1464b
1466
Default Activity
15.0
mCi
Weight Based Dosing
Default Programming View
Off
On
Edit Formulas
1464a
Configuration
System
Treatment
Maintenance
1402
1404
1406

FIG. 39A

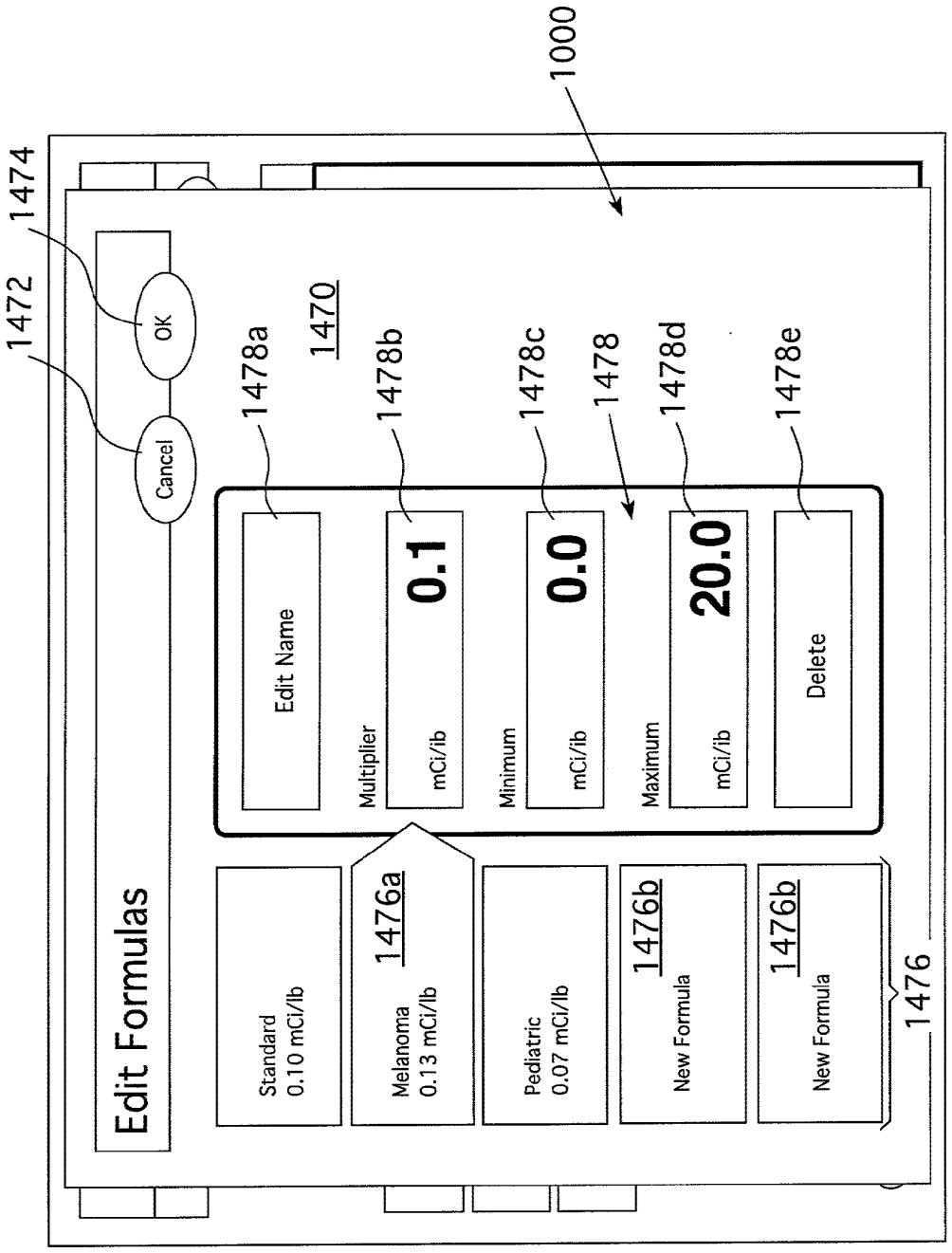
1000
1474
1472
OK
Cancel
Edit Formulas
1478a
1470
1478b
1478c
1478
1478d
1478e
Edit Name
Multiplier
0.1
mCi/lb
Minimum
0.0
mCi/lb
Maximum
20.0
mCi/lb
Delete
Standard
0.10 mCi/lb
1476a
Melanoma
0.13 mCi/lb
Pediatric
0.07 mCi/lb
1476b
New Formula
1476b
New Formula
1476

FIG. 39B

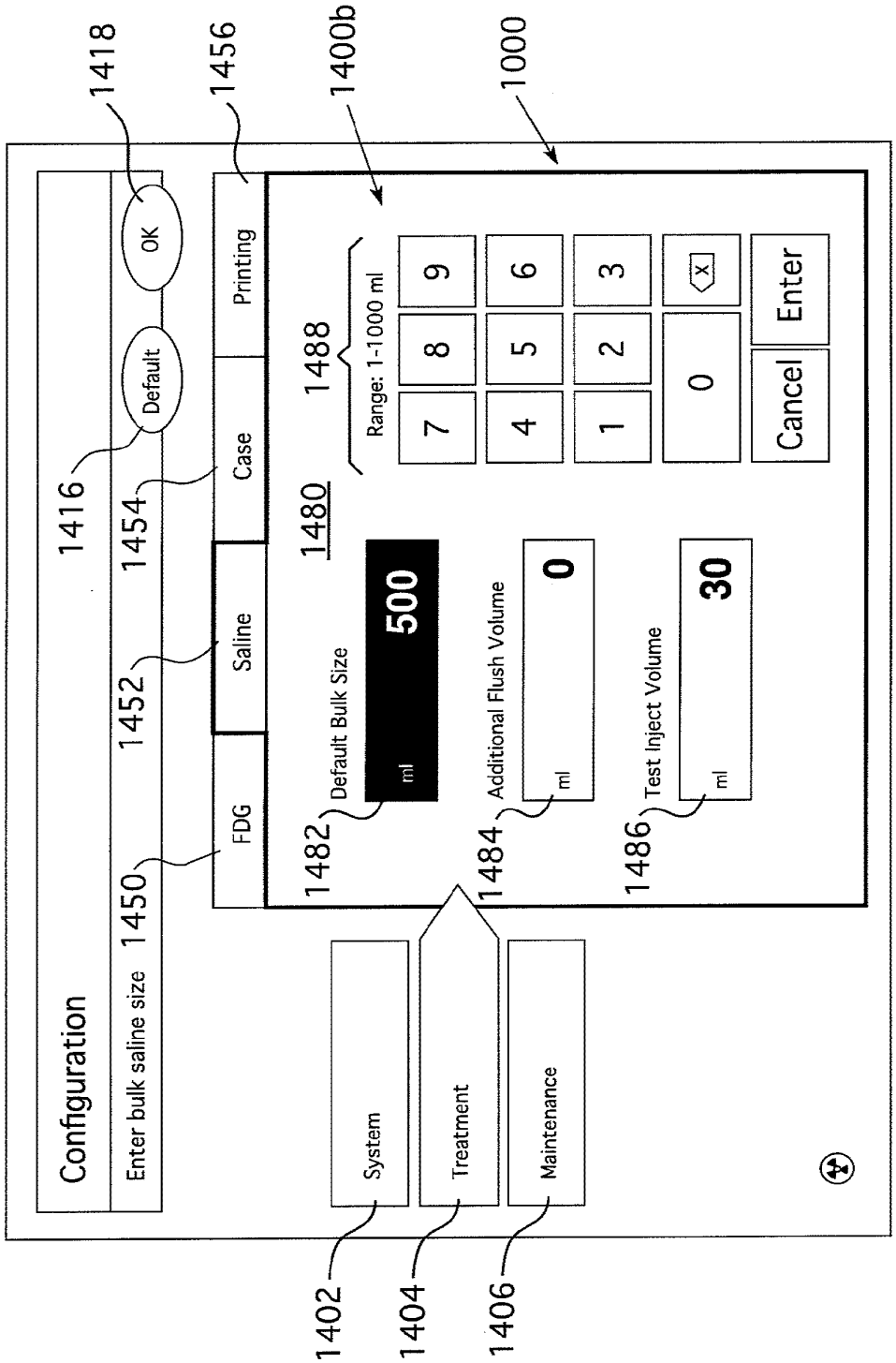
1418
1456
1400b
1000
OK
Default
Printing
Case
Saline
FDG
1416
1454
1452
1450
Configuration
Enter bulk saline size
1480
1488
Range: 1-1000 ml
7 8 9
4 5 6
1 2 3
0 X
Cancel Enter
Default Bulk Size
500
ml
1482
Additional Flush Volume
0
ml
1484
Test Inject Volume
30
ml
1486
System
Treatment
Maintenance
1402
1404
1406

FIG. 40

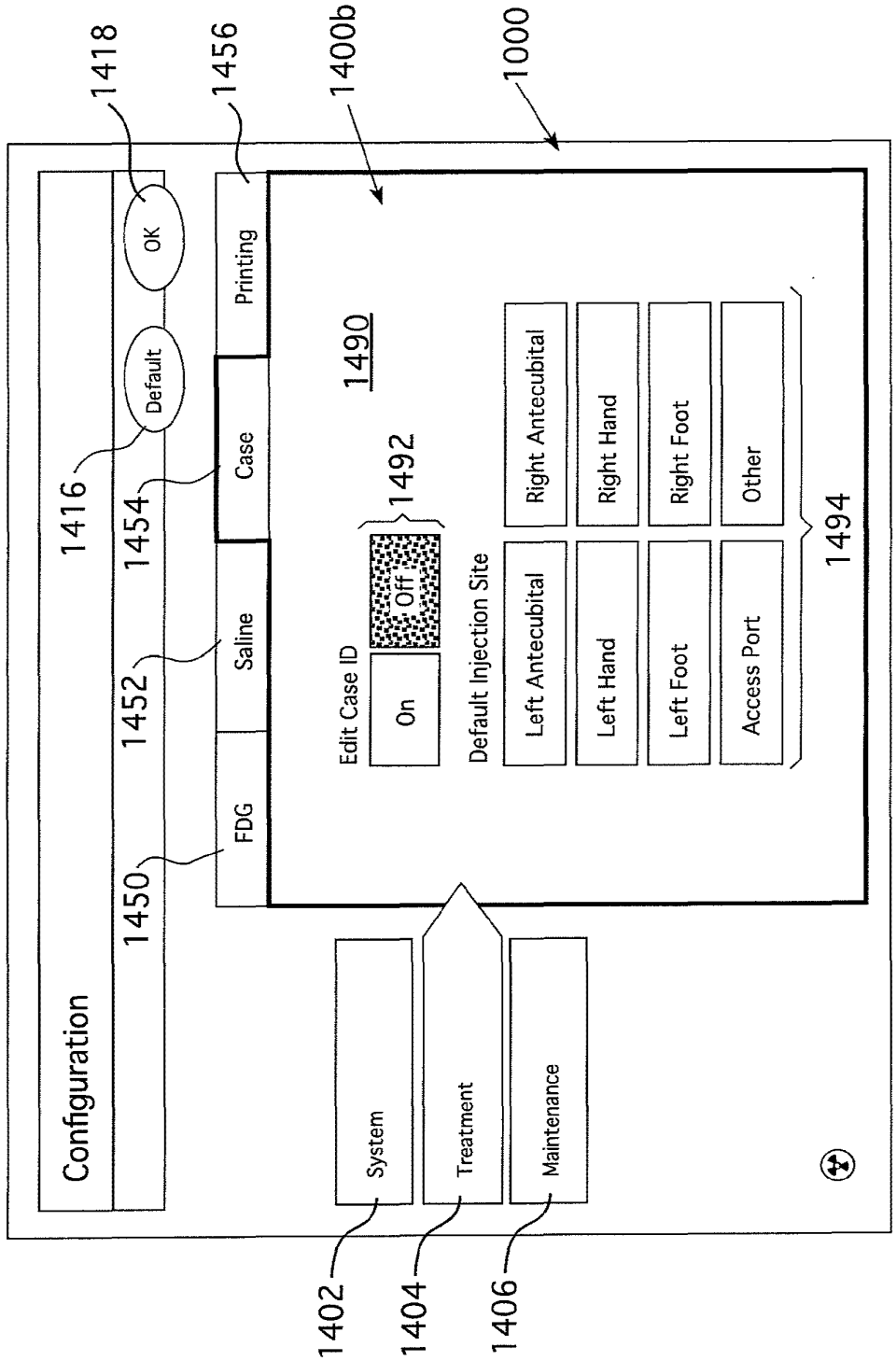
1418
1456
1400b
1000
OK
Default
Printing
Case
Saline
FDG
1416
1454
1452
1450
Configuration
1490
1492
Edit Case ID
On
Off
Default Injection Site
Left Antecubital
Left Hand
Left Foot
Access Port
Right Antecubital
Right Hand
Right Foot
Other
1494
System
Treatment
Maintenance
1402
1404
1406

FIG. 41

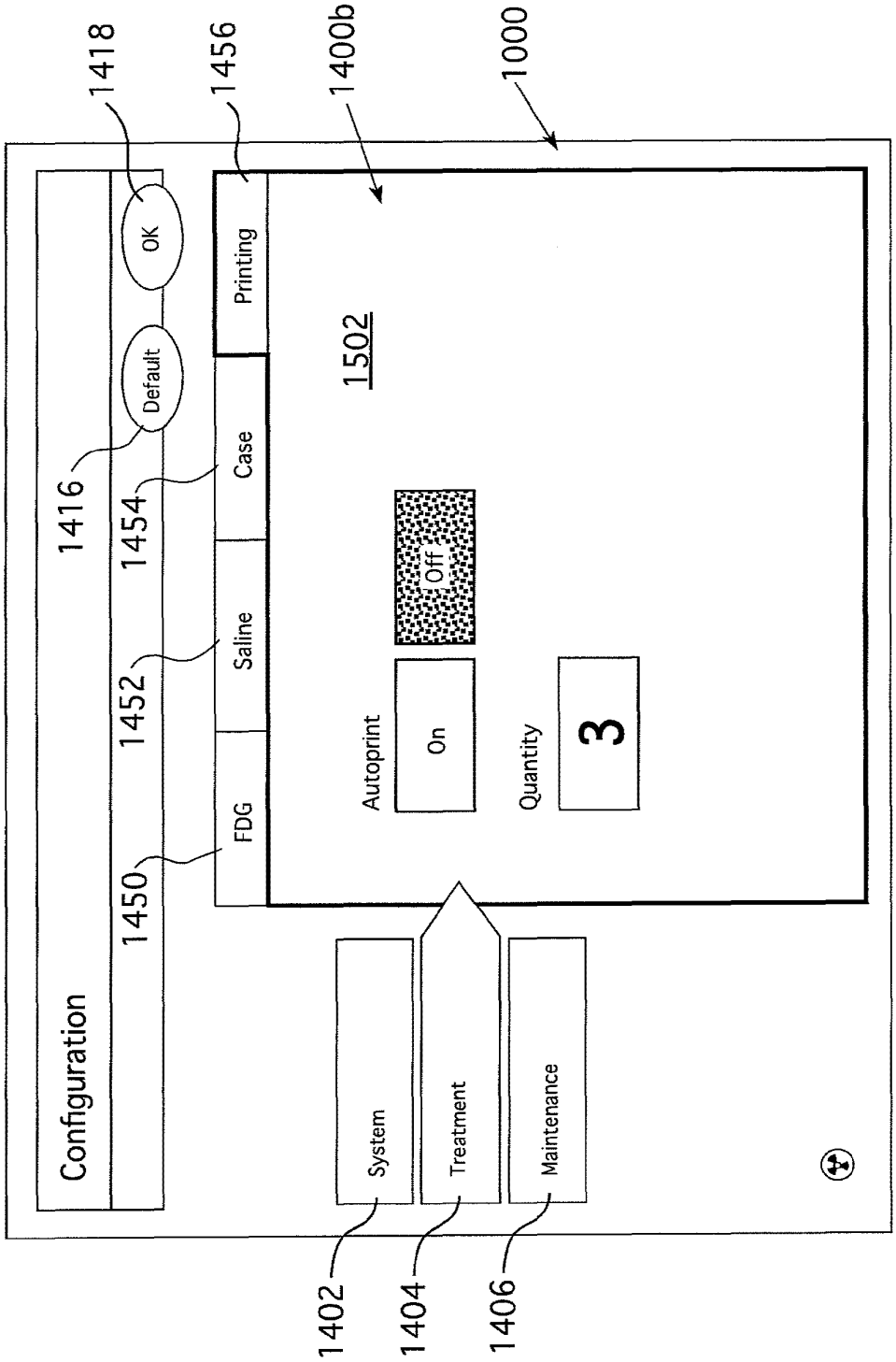
1418
1456
1400b
1000
OK
Default
Printing
1502
1416
1454
Case
Saline
1452
Off
Autoprint
On
Quantity
3
FDG
1450
Configuration
System
Treatment
Maintenance
1402
1404
1406

FIG. 42

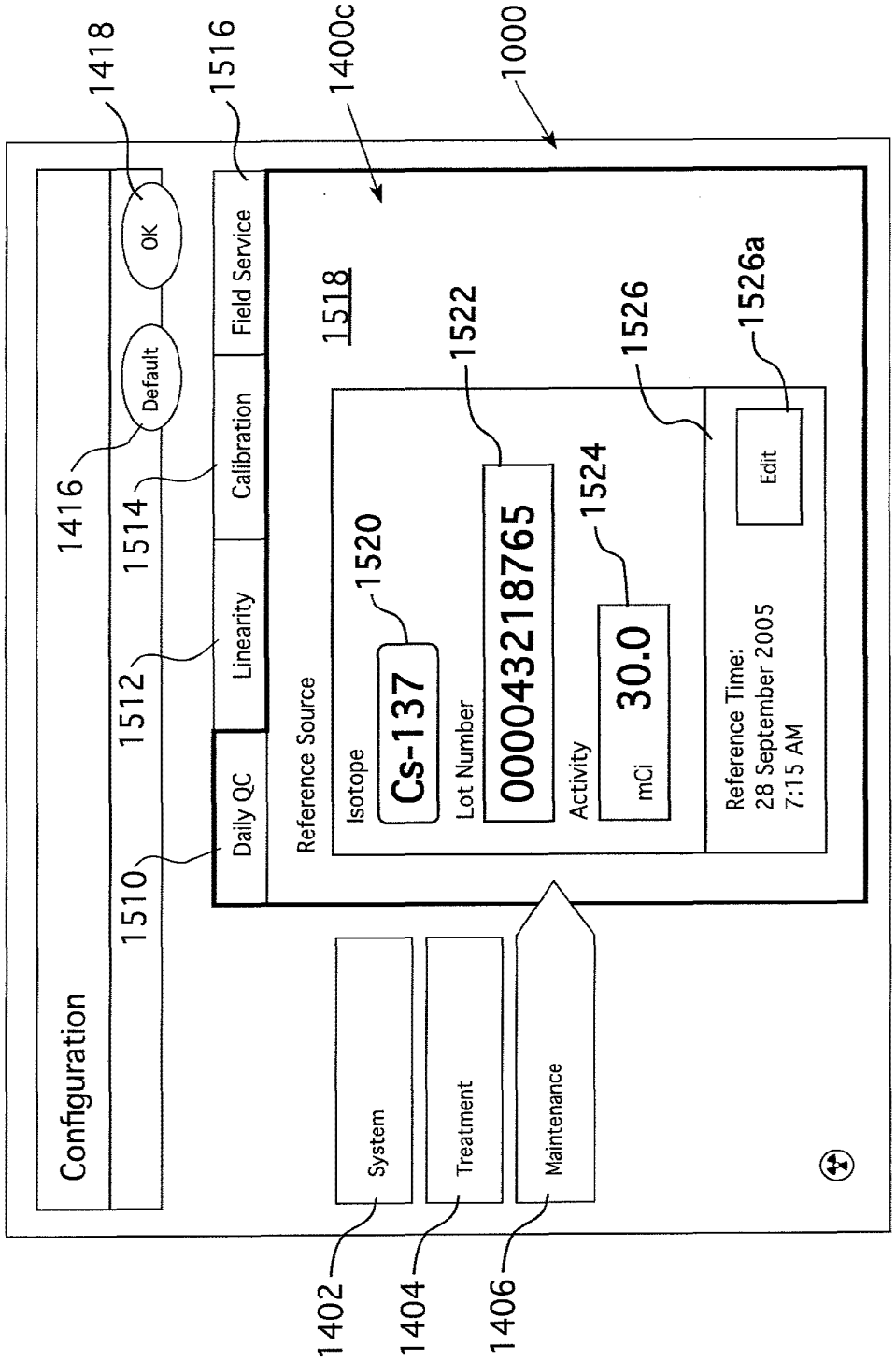
1418
1516
1400c
1000
OK
Default
Field Service
Calibration
Linearity
Daily QC
1416
1514
1512
1510
Configuration
1518
1522
1526
1526a
Reference Source
Isotope
Cs-137
1520
Lot Number
000043218765
Activity
30.0
mCi
1524
Edit
Reference Time:
28 September 2005
7:15 AM
System
Treatment
Maintenance
1402
1404
1406

FIG. 43

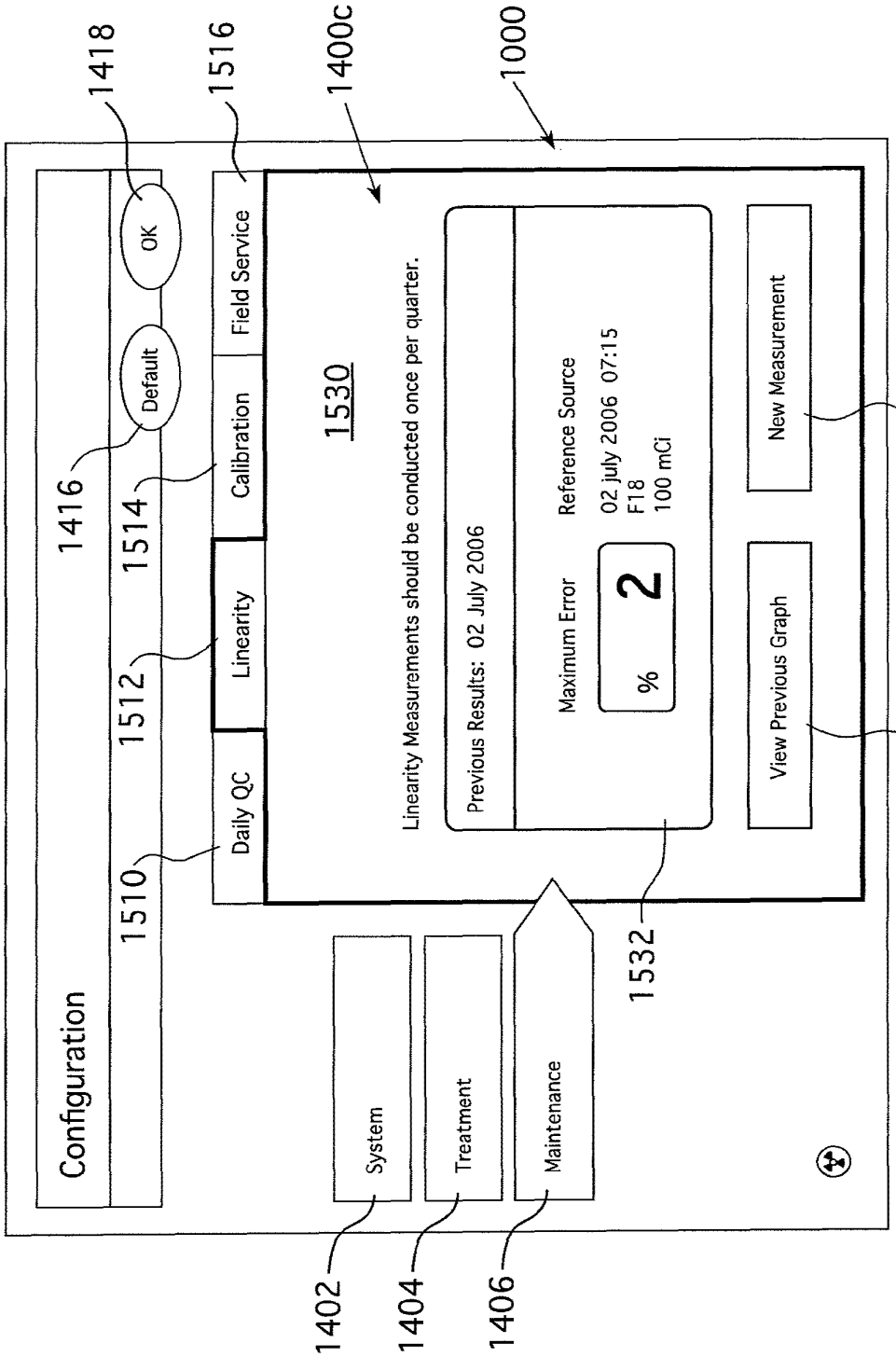
1418
1516
1400c
1000
OK
Field Service
Default
Calibration
1530
1416
1514
Linearity
1512
Daily QC
1510
Linearity Measurements should be conducted once per quarter.
Previous Results: 02 July 2006
Maximum Error
2
%
Reference Source
02 july 2006 07:15
F18
100 mCi
New Measurement
1536
View Previous Graph
1534
1532
Configuration
System
Treatment
Maintenance
1402
1404
1406

FIG. 44A

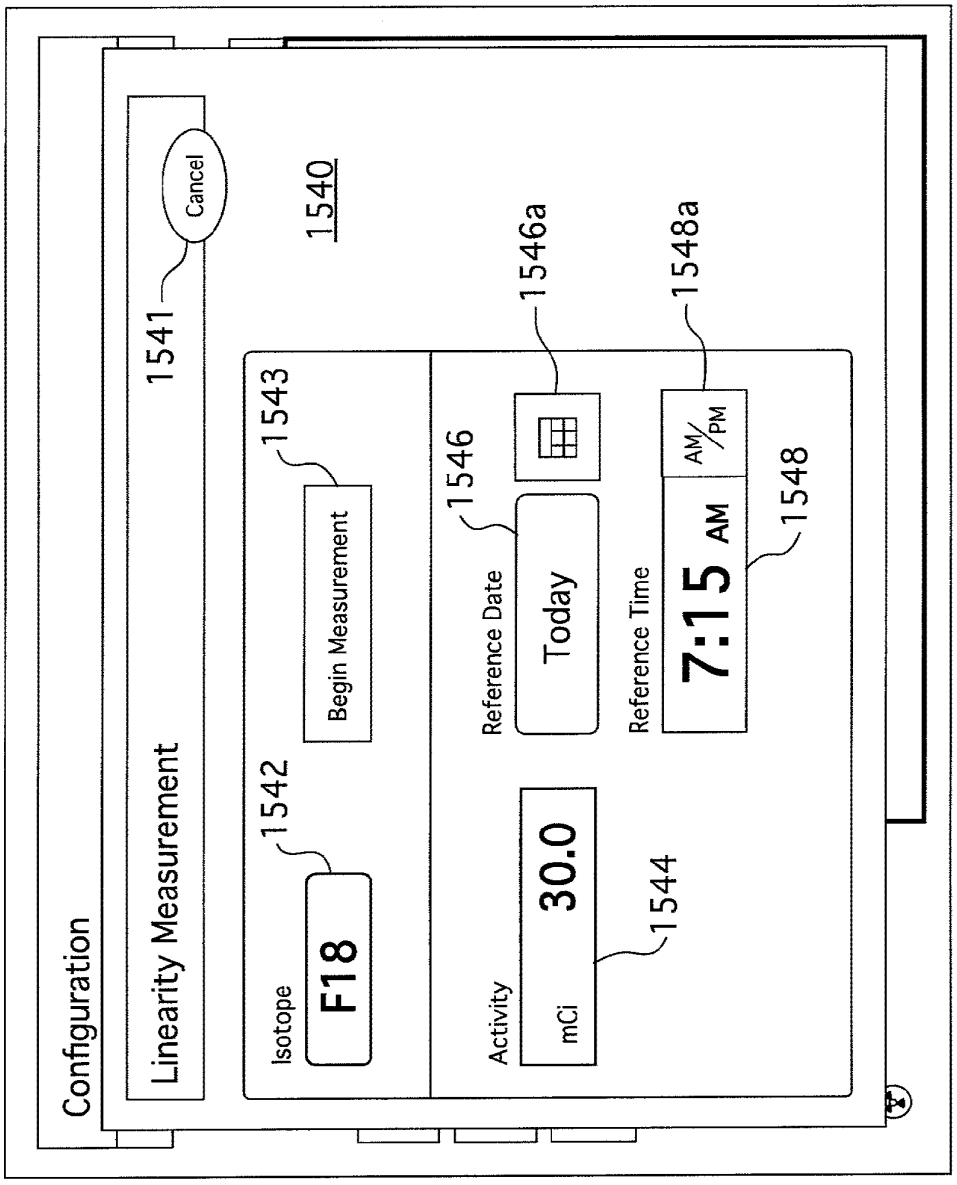
Configuration
Linearity Measurement
Cancel
1541
1540
1542
Isotope
F18
1543
Begin Measurement
1546
Reference Date
Today
1546a
1548
Reference Time
7:15 AM
AM/PM
1548a
Activity
30.0
mCi
1544

FIG. 44B

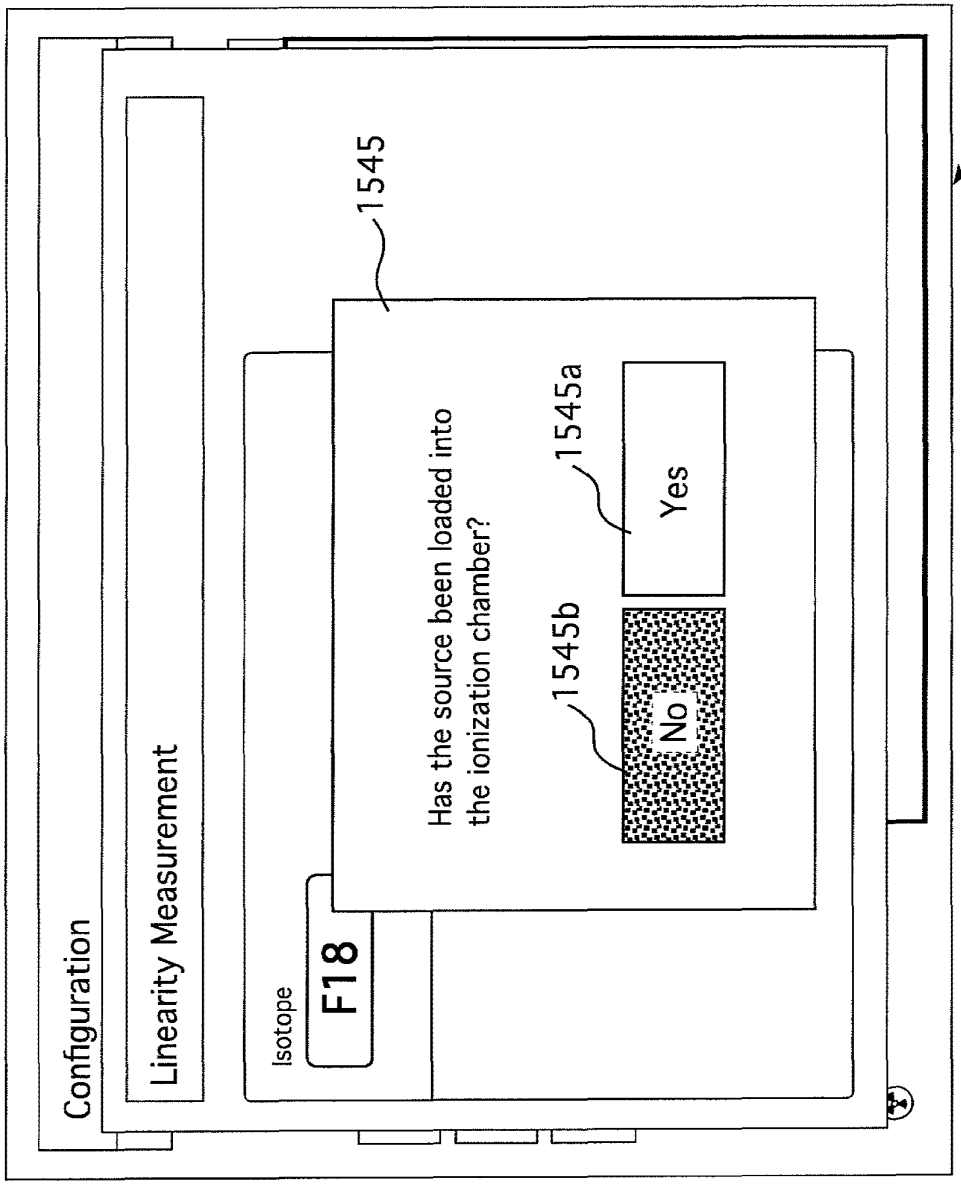
1000
Configuration
Linearity Measurement
Isotope
F18
1545
Has the source been loaded into the ionization chamber?
1545a
Yes
1545b
No

FIG. 44C

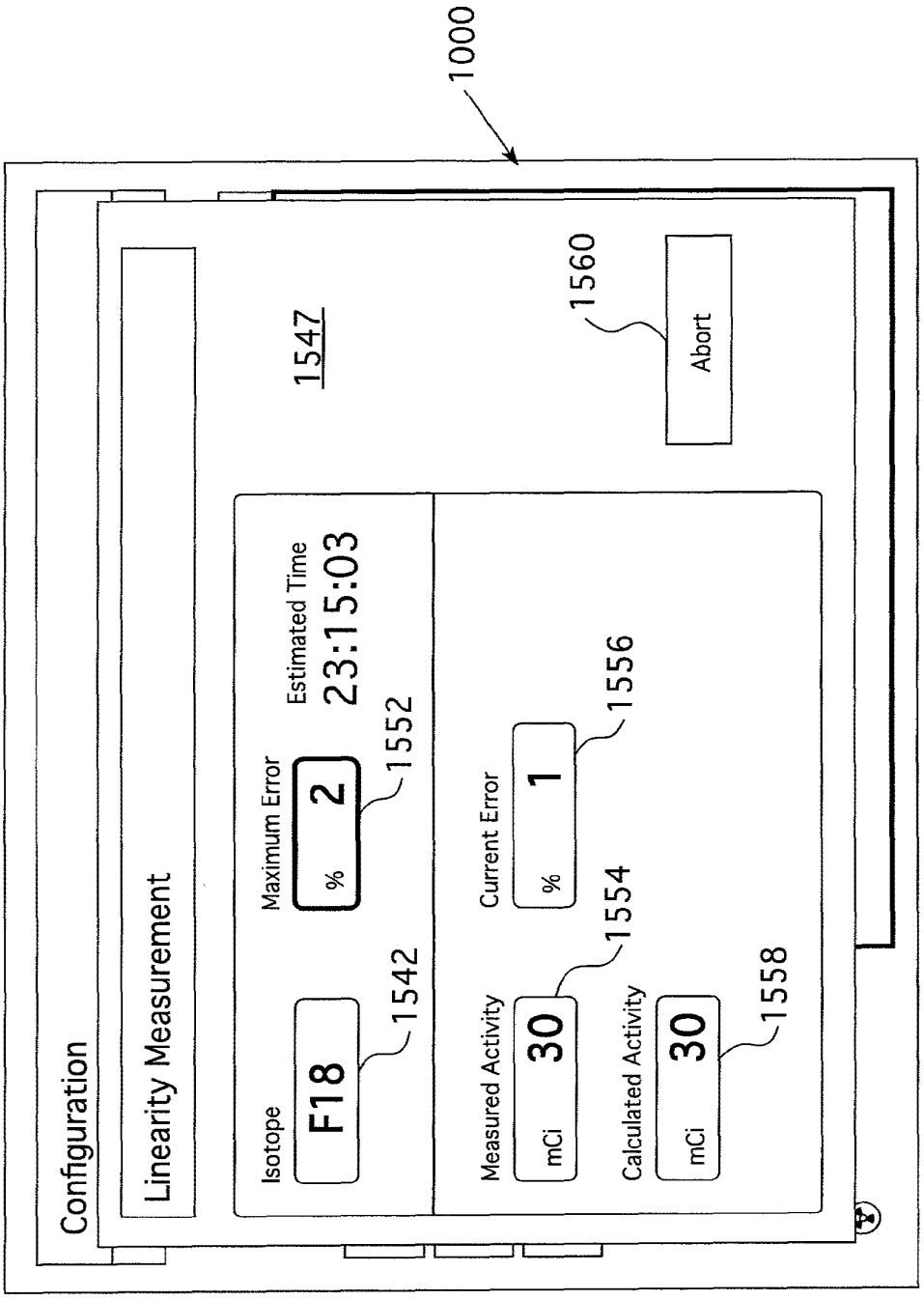
1000
Configuration
Linearity Measurement
1547
1560
Abort
Isotope
F18
1542
Maximum Error
%
2
1552
Estimated Time
23:15:03
Measured Activity
mCi
30
1554
Current Error
%
1
1556
Calculated Activity
mCi
30
1558

FIG. 44D

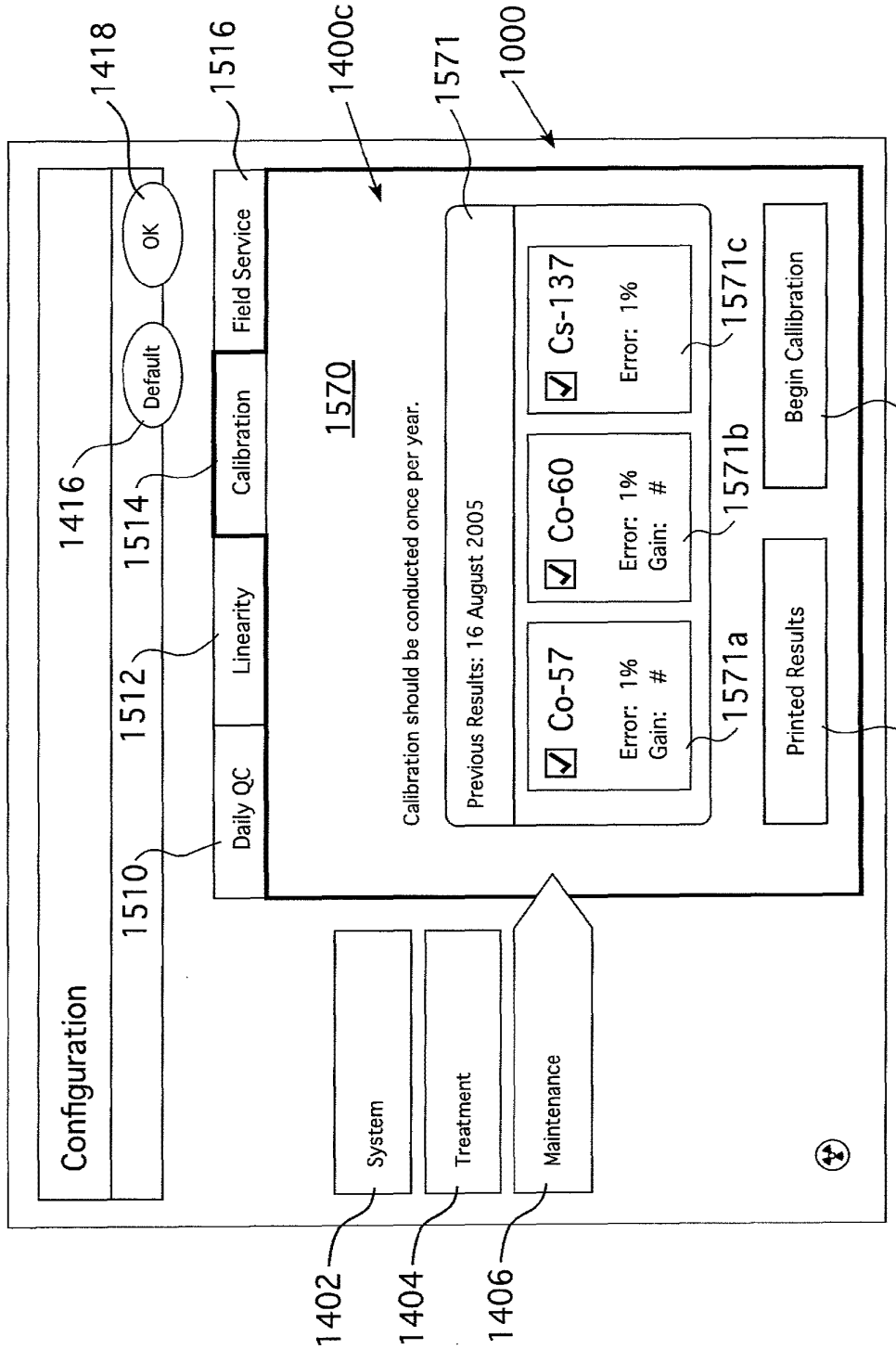
1000
1400c
1571
1516
1418
1570
Configuration
1510
1512
1514
1416
Daily QC
Linearity
Calibration
Field Service
OK
Default
Calibration should be conducted once per year.
Previous Results: 16 August 2005
Co-57
Error: 1%
Gain: #
Co-60
Error: 1%
Gain: #
Cs-137
Error: 1%
1571a
1571b
1571c
Printed Results
Begin Calibration
1572
1574
System
Treatment
Maintenance
1402
1404
1406

FIG. 45A

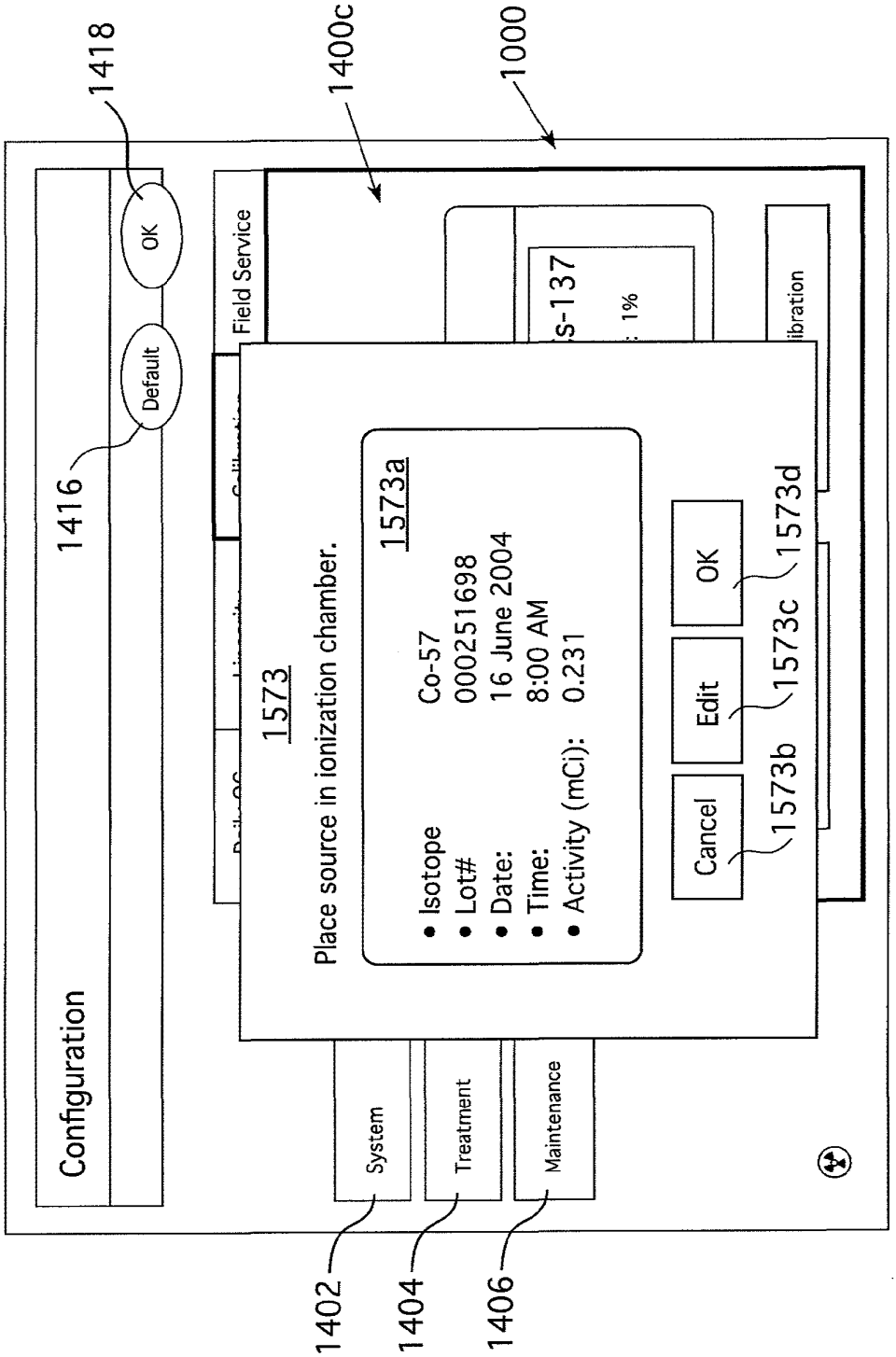
1418
1400c
1000
1416
OK
Default
Configuration
Field Service
1573
Place source in ionization chamber.
1573a
• Isotope Co-57
• Lot# 00251698
• Date: 16 June 2004
• Time: 8:00 AM
• Activity (mCi): 0.231
Cancel
Edit
OK
1573b
1573c
1573d
System
Treatment
Maintenance
1402
1404
1406

FIG. 45B

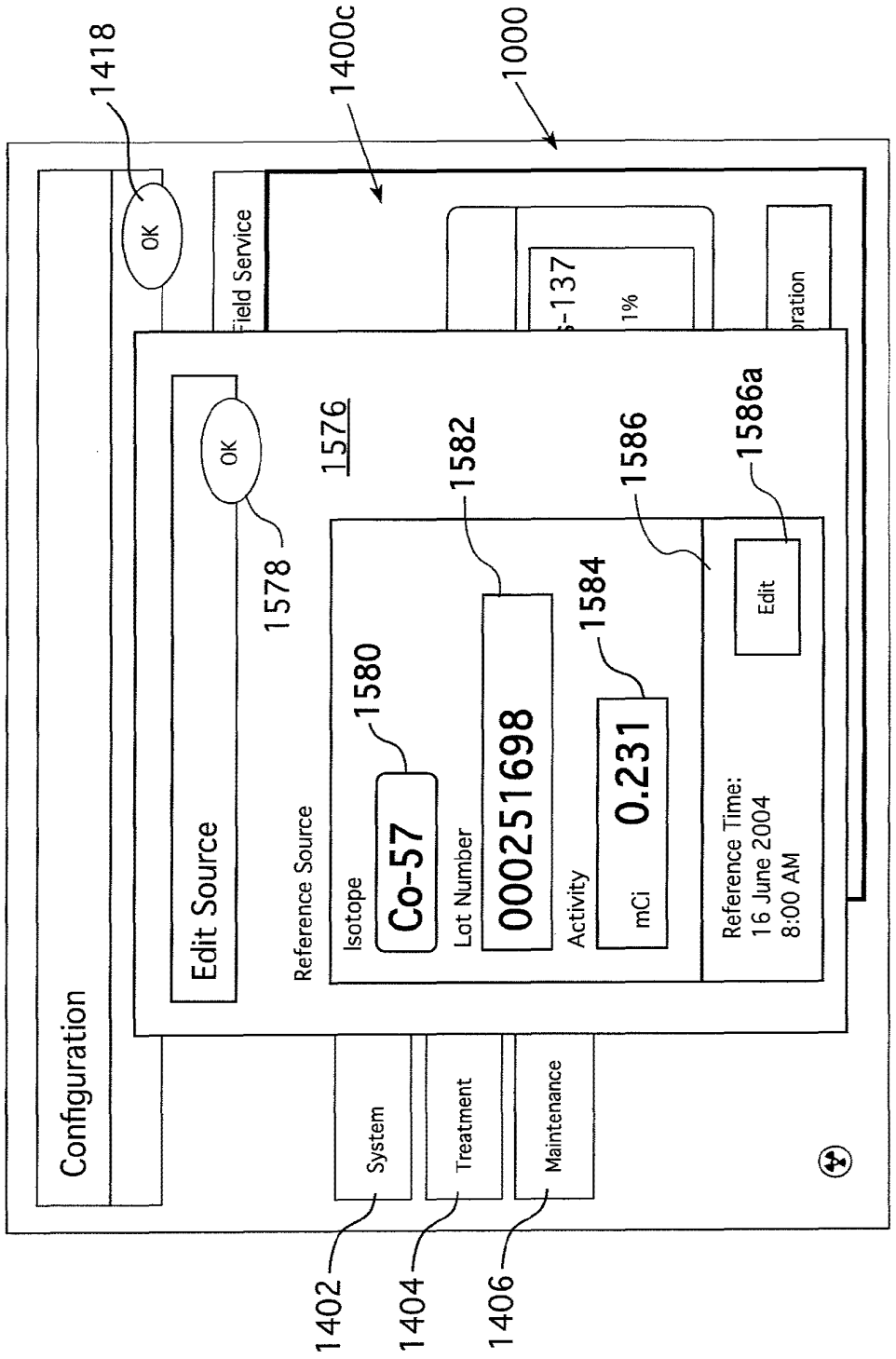
1418
1400c
1000
OK
Field Service
Configuration
Edit Source
OK
1578
1576
1582
1586
1586a
Reference Source
Isotope
Co-57
1580
Lot Number
000251698
Activity
mCi
0.231
1584
Edit
Reference Time:
16 June 2004
8:00 AM
System
Treatment
Maintenance
1402
1404
1406

FIG. 45C

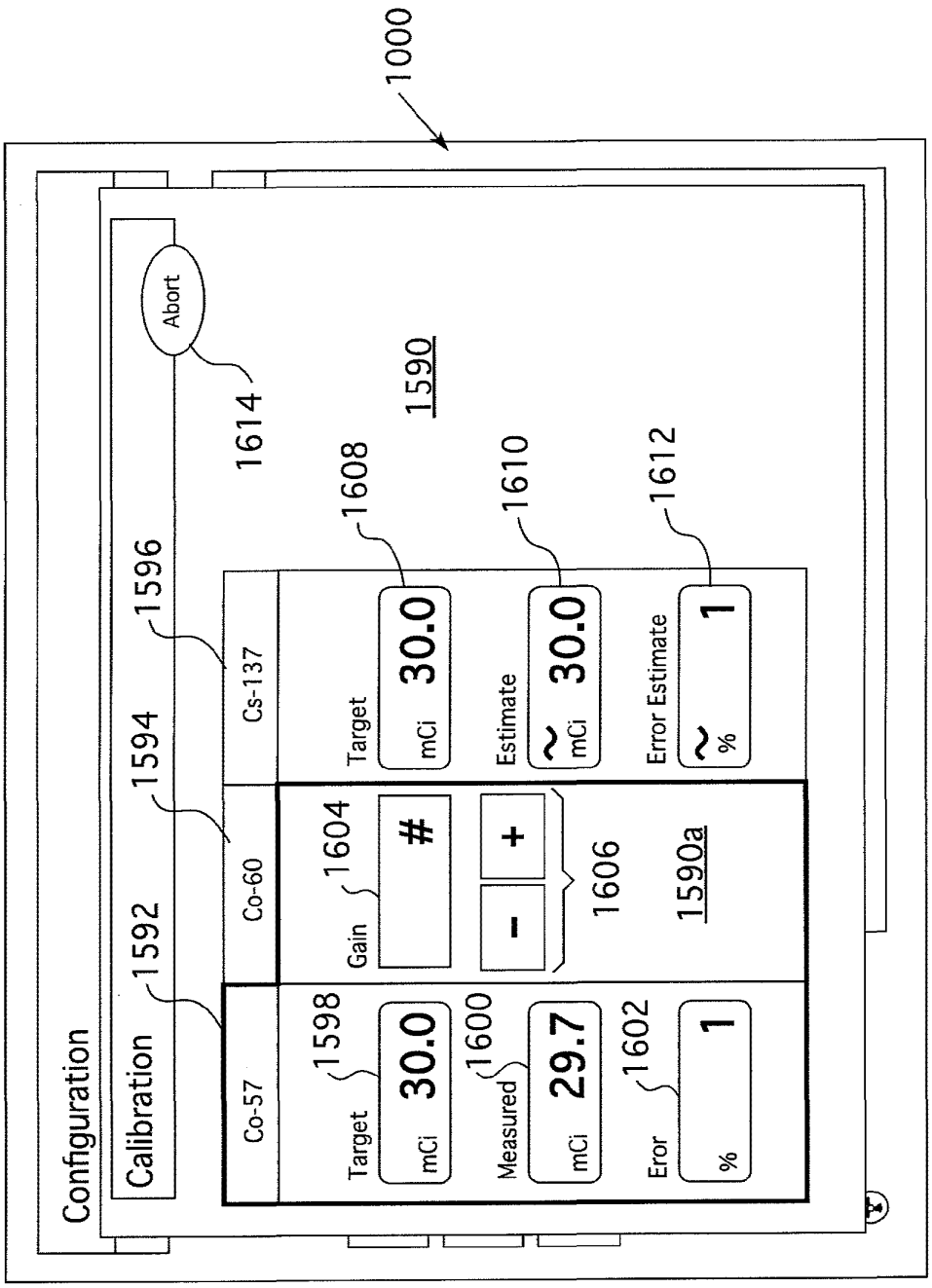
1000
Configuration
Calibration
1592
1594
1596
Co-57
Co-60
Cs-137
Abort
1614
1590
1608
1610
1612
Target
30.0
mCi
Estimate
~ 30.0
mCi
Error Estimate
~ 1
%
Gain
1604
#
1606
1590a
1598
Target
30.0
mCi
1600
Measured
29.7
mCi
1602
Eror
1
%

FIG. 45D

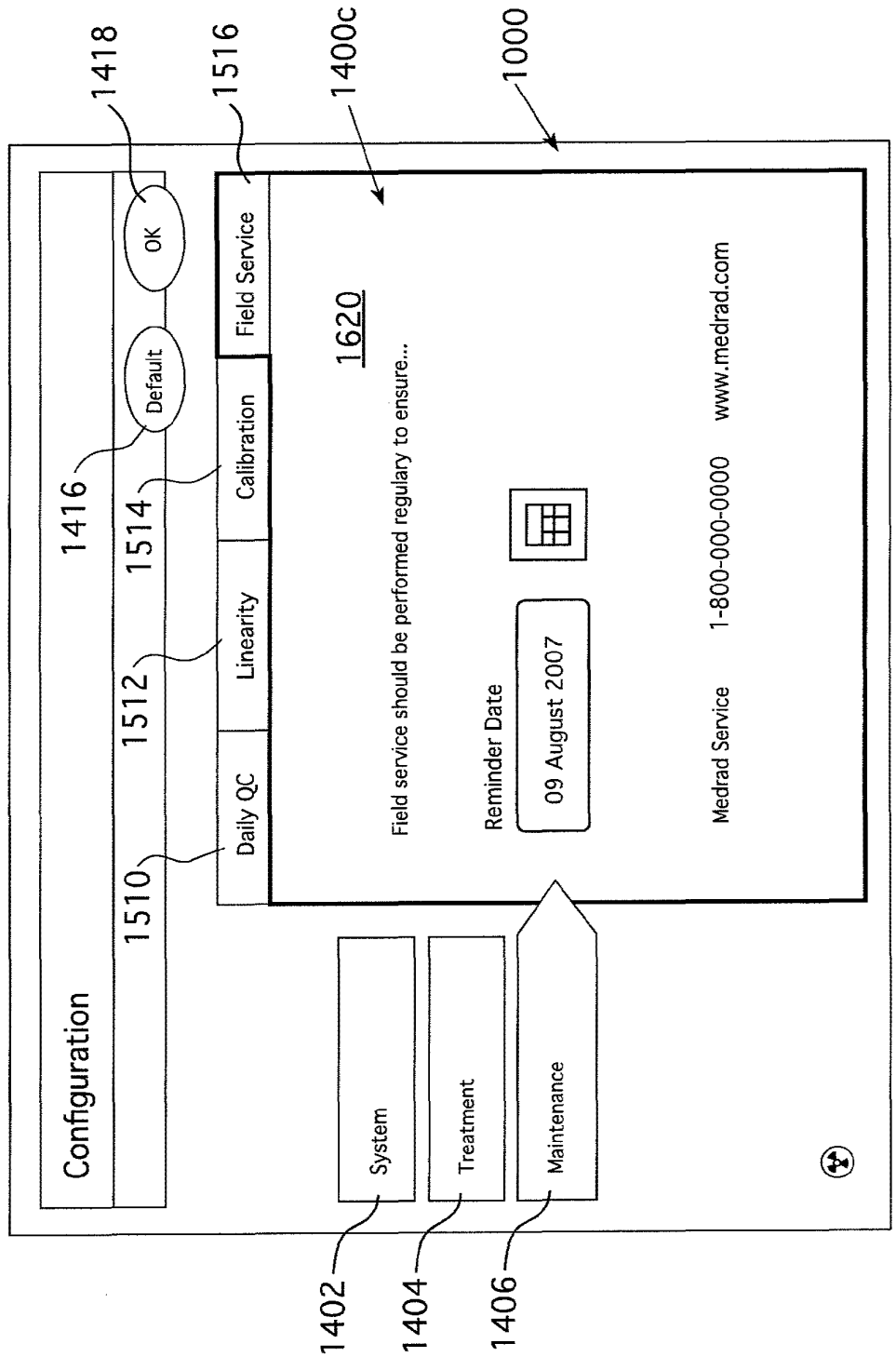
1418
1516
1400c
1000
OK
Default
Field Service
Calibration
Linearity
Daily QC
1416
1514
1512
1510
Configuration
1620
Field service should be performed regulary to ensure...
Reminder Date
09 August 2007
Medrad Service
1-800-000-0000
www.medrad.com
System
Treatment
Maintenance
1402
1404
1406

FIG. 46

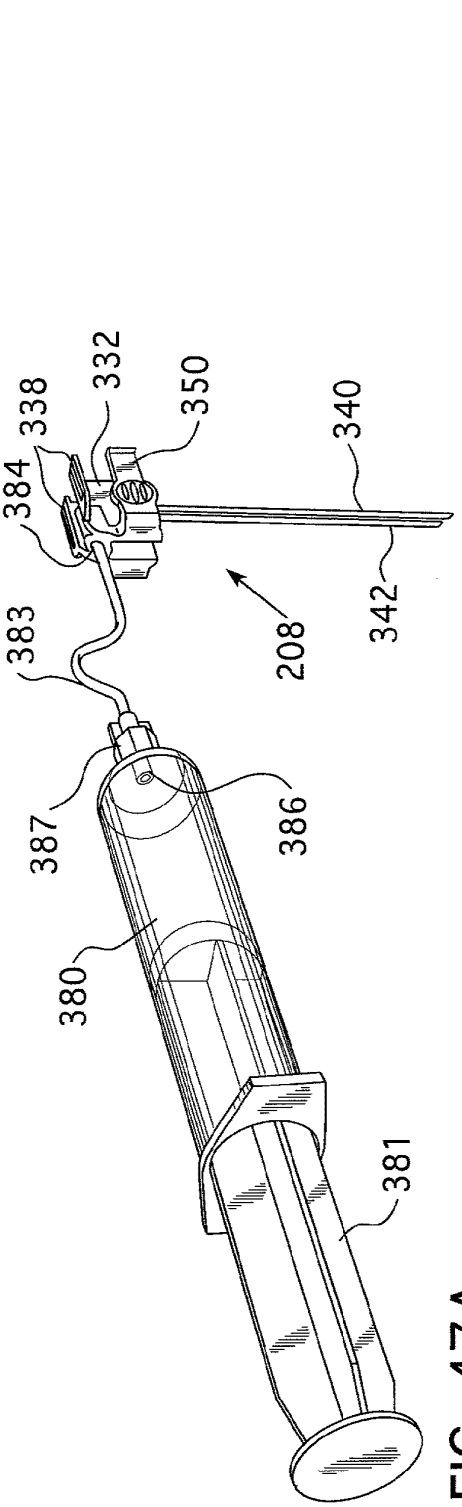

FIG. 47A

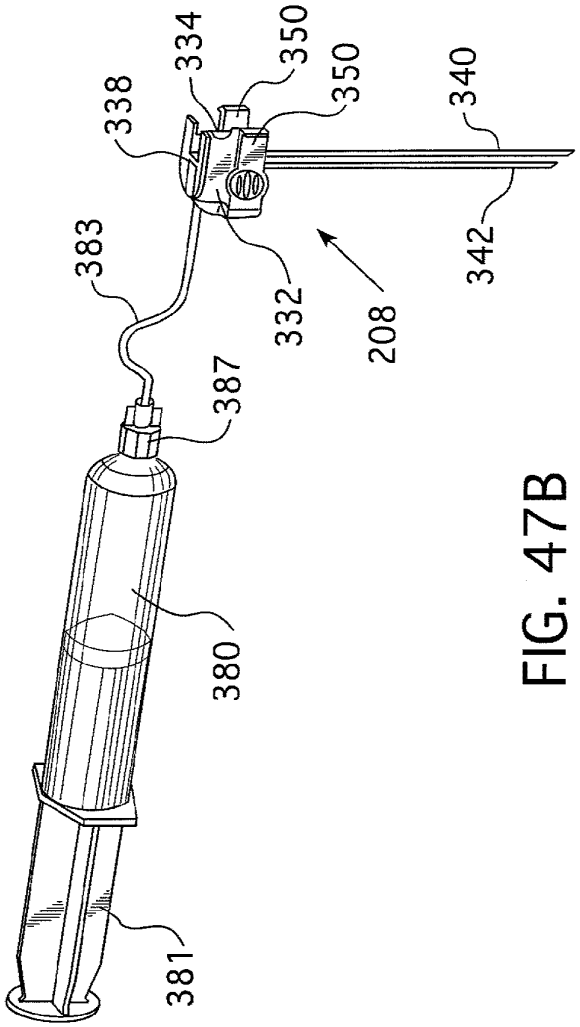

FIG. 47B

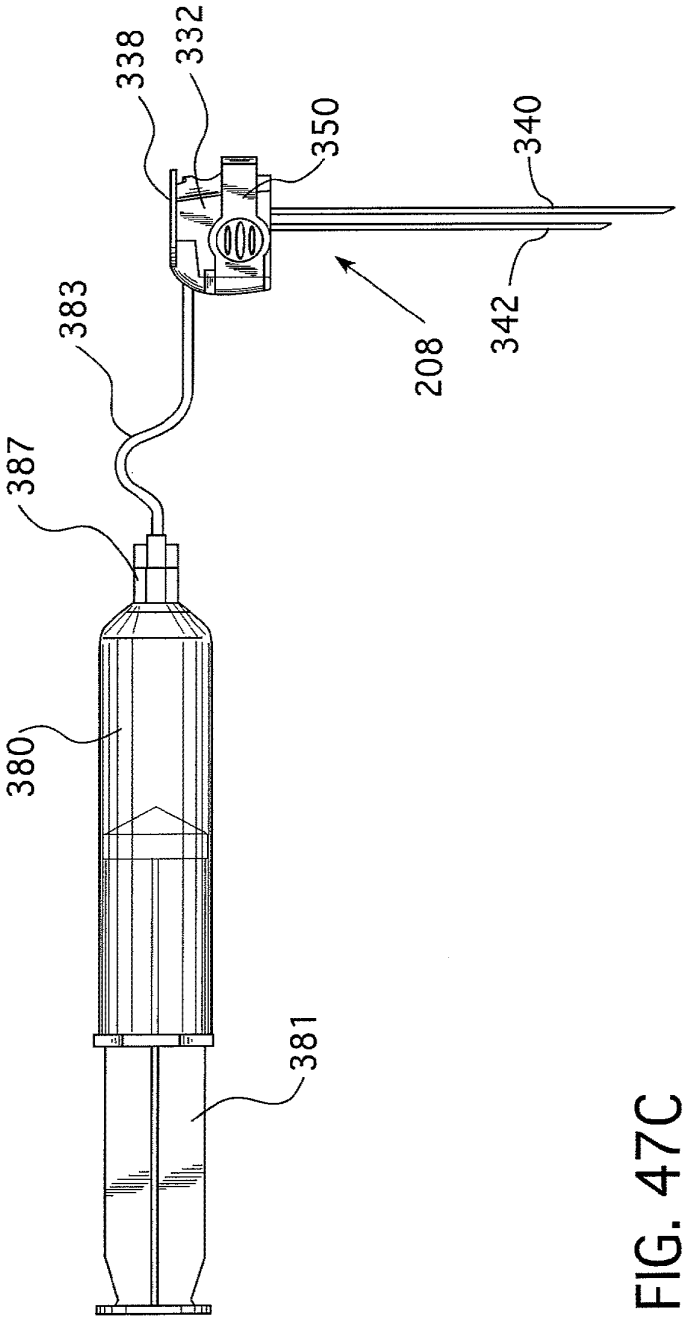

FIG. 47C

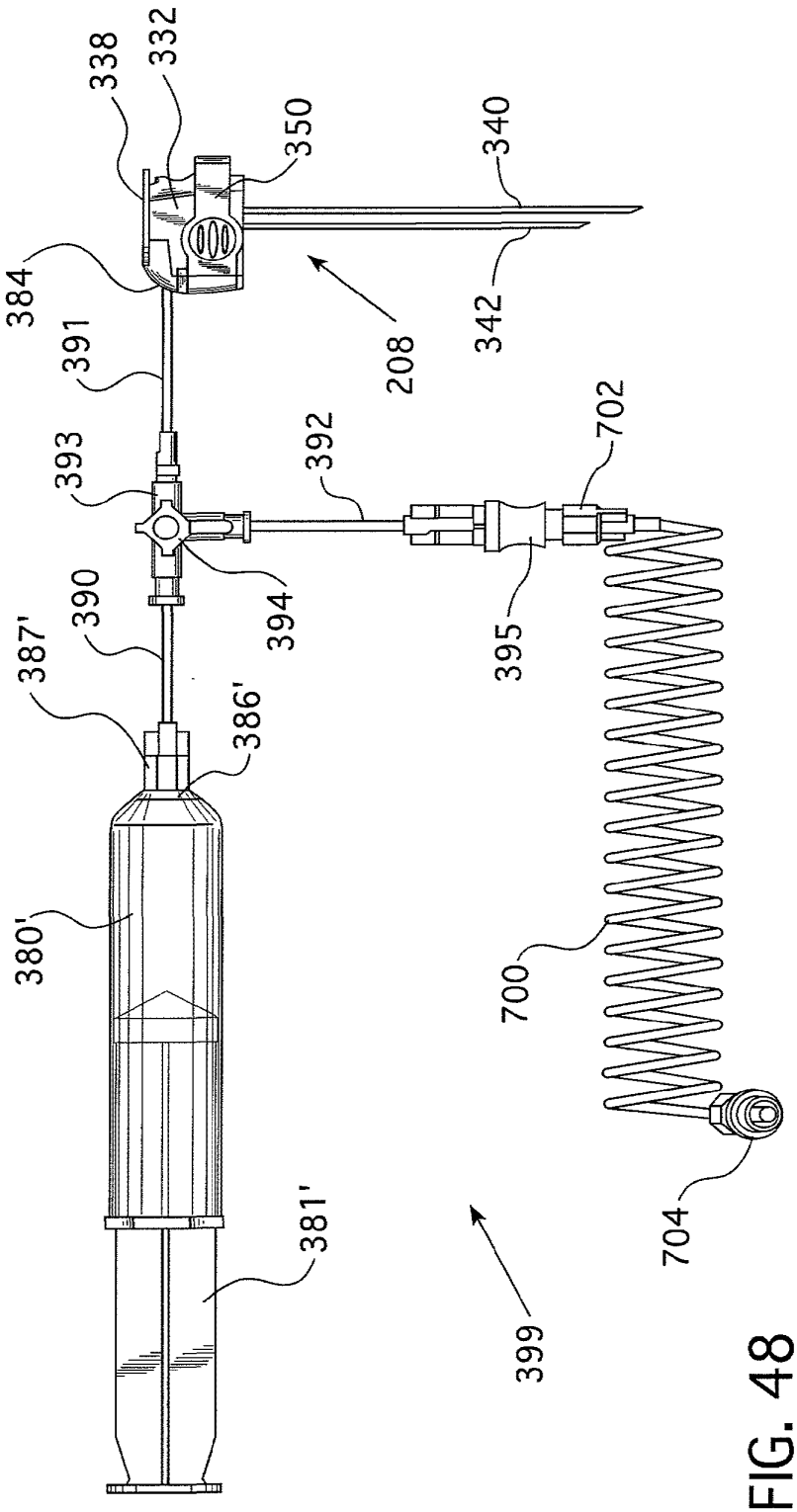
338
332
350
340
384
342
391
208
393
392
702
390
394
395
387'
386'
380'
700
381'
704
399

FIG. 48

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Office européen des brevets

(11) Publication number: **0 102 121**
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(12) # EUROPEAN PATENT APPLICATION

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

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

EP 0 102 121 A1

Croydon Printing Company Ltd.

Shielding device for a reservoir comprising a radioactive material.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

present must be as small as possible.

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

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

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

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

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

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

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

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

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

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

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

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

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

and Luer connections, are produced under laminar flow conditions.

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

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

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

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

The examination may be repeated any desirable number of times.

CLAIMS:

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

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

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

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

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

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

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