

divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from generator into waste bottle 23, until activity detector 25 detects the desired activity of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21.

- [34] With further reference to Figure 1D, it may be appreciated that shielding assembly 200 encloses those portions of circuit 300 from which radioactive radiation may emanate, with the exception of that portion of patient line 305p, which must extend out from shielding assembly 200 in order to be coupled to the patient for injection, or in order to be coupled to shielded sample vials, as will be described below. Thus, technical personnel, who operate system 10, are protected from radiation by shielding assembly 200, except at those times when an infusion is taking place, or when quality control tests require collection of eluate into sample vials. During infusions and quality control test sample collection, all technical personnel are typically in another room, or otherwise distanced from system 10, in order to avoid exposure to radiation during the

infusion, and, according to some preferred embodiments of the present invention, system 10 includes at least one means for informing technical personnel that an infusion is about to take place or is taking place. With reference back to Figures 1A and 1C, system 10 is shown including a light projector 100, mounted on post 142. According to the illustrated embodiment, projector 100, projects a light signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23, and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system, including in the control room.

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

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

- [36] Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc..., into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example, deposited therein during infusion procedures.
- [37] Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly

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

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

further illustrates optional thumb screws 290, one securing lid 223 to sidewall 203 and another securing door 221 to sidewall 201, or other means for securing the doors, which are known to those skilled in the art, may be incorporated. Each sidewall 201, 203, 205 and the corresponding lid/door 223, 221, 225, 227 thereof may be individually cast from 3% antimony lead, or from other known shielding materials, and then assembled together according to methods known to those skilled in the art.

- [39] According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a latch component 191 is provided to hold each of doors 221, 225 in an opened position, thereby, preventing doors 221, 225 from falling closed, which could pinch/crush fingers of technical personnel and/or tubing lines of circuit 300, when in the midst of a maintenance procedure. Figure 2B is a perspective view of framework 19 of the cabinet structure of system 10, according to some embodiments, to which latch component 191 is mounted; Figure 2B includes an enlarged detailed view of latch component 191, according to some embodiments. Figure 2B illustrates latch component 191 including a first pin 193, corresponding to door 225, and a second pin 195, corresponding to door 221; each pin 193, 195 includes a lever end 193A, 193B, respectively, and a holding end 193B, 195B, respectively. An edge of each door 221, 225, upon opening of doors 221, 225, may push past the holding end 195B, 193B of the corresponding pin 195, 193, in a first direction, per arrow F, and then may rest against a respective side S95 and S93 of each end 195B, 193B, until the corresponding lever end 195A, 193A is rotated in a counter-clockwise direction, per arrow cc, thereby moving the corresponding holding end 193B, 195B to make way for the closing of doors 221, 225. Doors 221, 225 being held by latch component 191 in an open position may be seen in Figure 3A.
- [40] With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from

being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225. The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

- [41] Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.
- [42] Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can

facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover.

- [43] Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305 passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.
- [44] Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together, according to alternate embodiments, mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.
- [45] According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple

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

- [46] As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

- [47] With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.
- [48] Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.
- [49] Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A

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

- [50] According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format.
- [51] Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on.
- [52] Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or

571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a storage medium (i.e. disk) reader, a scanner, a barcode reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc...).

[53] If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag, which leads computer 17 to prompt the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume, via screen 574, as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished.

[54] In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous

day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied.

- [55] In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate is being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.
- [56] Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in

conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82® that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

- [57] Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. In conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).
- [58] Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.
- [59] Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user

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

- [60] After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough

test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

- [61] With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.
- [62] With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously

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

- [63] With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the

user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

- [64] With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with a option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

- [65] Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary of the infusion, which includes the patient identification number and pertinent system parameters, may be downloaded onto a computer readable storage device to be transferred to one or more remote computers and/or automatically transferred thereto, via wireless communication or a cable connection. The one or more remote computers may be included, for example, in a hospital information system, and/or an inventory system, and/or a billing system, and/or in a medical imaging system. With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data.
- [66] Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline purge, as procedures for saline purging should be readily apparent to those skilled in the art, with reference to the schematic of infusion circuit 300 shown in Figure 1D. A saline purge of circuit 300 is desired to assure that all the air is removed from circuit 300 when a new generator and/or a new complete or partial tubing set is installed. An air purge of the tubing lines of circuit 300 may be performed after removing reservoir 15, by-passing generator 21, by connecting tubing line 304 to tubing line 305, and coupling patient line 305p to a vial, for example, as is directed by the computer interface, in screens 983 and 984 shown in Figure 10. The air purge is desirable for blowing out the tubing lines, thereby removing all remaining eluant and eluate, prior to installing a

new generator and/or prior to transporting system 10 from one site to another. If generator 21 is not depleted and will be used in system 10 at the new site, it is important to by-pass the generator prior to purging the tubing lines of circuit 300 with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

- [67] According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.
- [68] The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator.

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

We claim:

1. A cabinet structure for an infusion system, the structure comprising:
a platform on which the infusion system is mounted; and
a shell surrounding an interior space of the structure, the interior space containing at least a portion of the infusion system;
wherein the shell comprises a first upper opening into the interior space, a second upper opening into the interior space and an access panel;
the access panel mates with the second upper opening and is removable therefrom;
the first upper opening is sized to provide access to a waste bottle of the infusion system within the interior space; and
the second upper opening is sized and oriented to allow a lowering of a radioisotope generator, for the system, into the interior space, and a lifting of the generator out from the interior space, the second upper opening being located at an elevation, with respect to a lowermost portion of the cabinet structure, which is lower than an elevation, with respect to the lowermost portion of the cabinet structure, of the first upper opening.
2. The structure of claim 1, further comprising a wheel element mounted to the platform to provide mobility for the system.
3. The structure of claim 2, further comprising a mechanism to reversibly lock a rotation of the wheel element.
4. The structure of claim 2, wherein:
the wheel element comprises a first wheel mounted in proximity to a first end of the platform and second wheel mounted in proximity to a second end of the platform, the second end being opposite the first end; and
the first wheel is mounted to swivel with respect to the platform.
5. The structure of claim 4, further comprising a foot activated pedal for reversibly locking a rotation of at least one of the first and second wheels.

6. The structure of claim 1, further comprising a post extending upward from an upper outer surface of the shell, the post for mounting at least one of: a tray, a computer of the system and an eluant reservoir of the system.
7. The structure of claim 1, further comprising a removable bin, the bin mating with a contoured portion of an upper outer surface of the shell.
8. The structure of claim 7, wherein the access panel comprises the contoured portion of the shell, such that access to the access panel is provided by removing the bin away from the contoured portion of the upper outer surface of the shell.
9. The structure of claim 7, wherein the bin includes a plurality of receptacles.
10. The structure of claim 7, wherein the bin includes a handle for removing the bin away from the contoured portion of the upper outer surface of the shell.
11. The structure of claim 1, wherein the elevation of the first upper opening is greater than approximately 24 inches.
12. The structure of claim 1, wherein the elevation of the second upper opening is greater than approximately 12 inches.
13. The structure of claim 1, wherein the second upper opening further provides access to a portion of an infusion tubing circuit of the system within the interior space.
14. The structure of claim 1, wherein the access panel includes a security lock.

15. The structure of claim 1, wherein:
 - the shell further includes at least one additional opening; and
 - each of the at least one additional opening provides a passageway for a single tubing line of an infusion tubing circuit of the system to pass through the shell.

16. The structure of claim 15, wherein each of the at least one additional opening includes a grommet-type seal.

17. The structure of claim 1, wherein the shell further comprises at least one external recess sized to hold a shielded vial.

18. A cabinet structure for an infusion system, the structure comprising:
 - a platform on which the infusion system is mounted; and
 - a shell surrounding an interior space of the structure, the interior space containing at least a portion of the infusion system;wherein the shell comprises an upper surface, an upper opening into the interior space, and an access panel, the access panel mating with the upper opening and being removable therefrom;
 - the upper opening is sized and oriented to allow a lowering of a radioisotope generator, for the system, into the interior space, and a lifting of the generator out from the interior space, the upper opening being located at an elevation, with respect to a lowermost portion of the cabinet structure, which is substantially lower than an elevation, with respect to the lowermost portion of the cabinet structure, of an uppermost portion of the upper surface.

19. The structure of claim 18, wherein the elevation of the upper opening is between approximately 12 inches and approximately 24 inches, in order to facilitate an ergonomic stance for a user to lower and lift the generator into and out from the interior space.

20. The structure of claim 18, further comprising a handle for moving the system from one location to another, the handle extending from the shell in proximity to the upper surface thereof.
21. The structure of claim 18, further comprising:
a wheel element mounted to the platform, the wheel element including a first wheel mounted in proximity to a first end of the platform and a second wheel mounted to swivel, with respect to the platform, in proximity to the second end of the platform, the second end being opposite the first end; and
a handle for moving the structure on the wheel element, the handle extending from the shell in proximity to the first end of the platform and in proximity to the upper surface of the shell.
22. The structure of claim 18, wherein the elevation of the uppermost portion of the upper surface is greater than approximately 24 inches, and the elevation of the upper opening is less than approximately 24 inches.
23. A cabinet structure for an infusion system, the structure comprising:
a platform on which the infusion system is mounted; and
a shell surrounding an interior space of the structure and including an upper surface in which at least one opening and an external recess is formed;
wherein the interior space contains at least a portion of the infusion system;
the at least one opening provides a passageway for a tubing line of the infusion system to extend out from the interior space; and
the external recess is sized to contain a spill from the infusion system.
24. The cabinet structure of claim 23, further comprising:
a post extending upward from the upper surface of the shell, the post adapted to hold an eluant reservoir of the infusion system; and
wherein the external recess is located in proximity to the post.

25. The cabinet structure of claim 23, wherein the at least one opening includes a grommet-type seal.
26. The cabinet structure of claim 23, wherein the at least one opening comprises a pair of openings and each of the pair of openings is sized to provide a passageway for a single tubing line of the infusion system.
27. A cabinet structure for an infusion system, the structure comprising:
a platform on which the infusion system is mounted;
a shell surrounding an interior space of the structure; and
a plurality of external receptacles;
wherein the interior space contains at least a portion of the infusion system; and
the plurality of external receptacles are sized to hold articles pertaining to operation of the infusion system.
28. The cabinet structure of claim 27, wherein:
the shell includes an upper surface, the upper surface including a contoured portion;
and
the plurality of external receptacles are formed in removable bin which mates with the contoured portion of the upper surface.
29. The cabinet structure of claim 28, wherein the removable bin includes a handle for removing the bin away from the contoured portion of the upper surface.
30. The cabinet structure of claim 28, wherein the contoured portion of the upper surface is separable from a remainder of the shell to provide access into the interior space surrounded by the shell.
31. The cabinet structure of claim 27, wherein the shell includes an upper surface and the plurality of external receptacles are formed as recesses in the upper surface.

32. The cabinet structure of claim 27, wherein the articles include a shielded vial for collecting samples from the infusion system.

33. The cabinet structure of claim 27, wherein the articles include technical documentation.

ABSTRACT

A cabinet structure for an infusion system includes a platform, on which the system is mounted, and a shell surrounding an interior space, which contains at least a portion of the system. The shell preferably includes an opening that is sized and oriented to allow a lowering of a radioisotope generator, for the system, into the interior space, and a lifting of the generator out from the interior space. The shell may further include another opening, located at a higher elevation than the aforementioned opening, in order to provide access to a waste bottle of the infusion system.

4365663_1.DOC

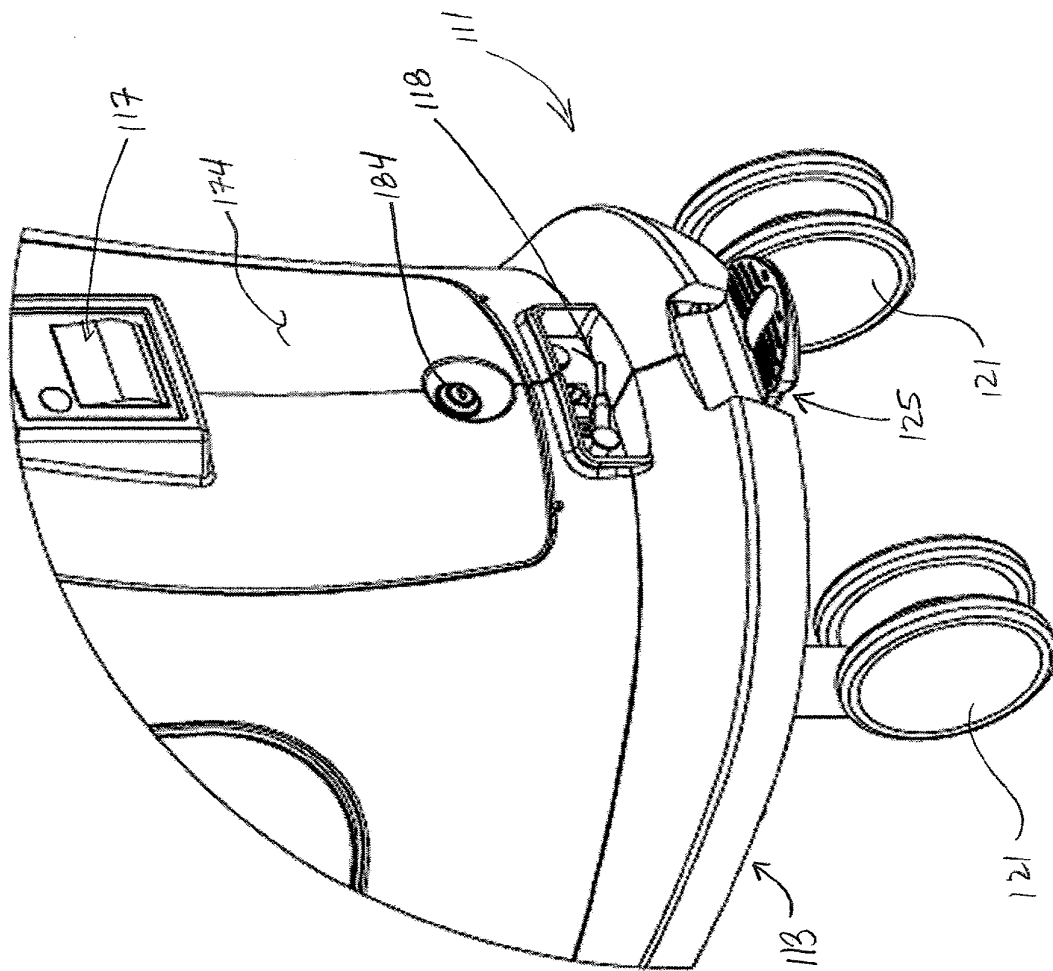


FIGURE 1B

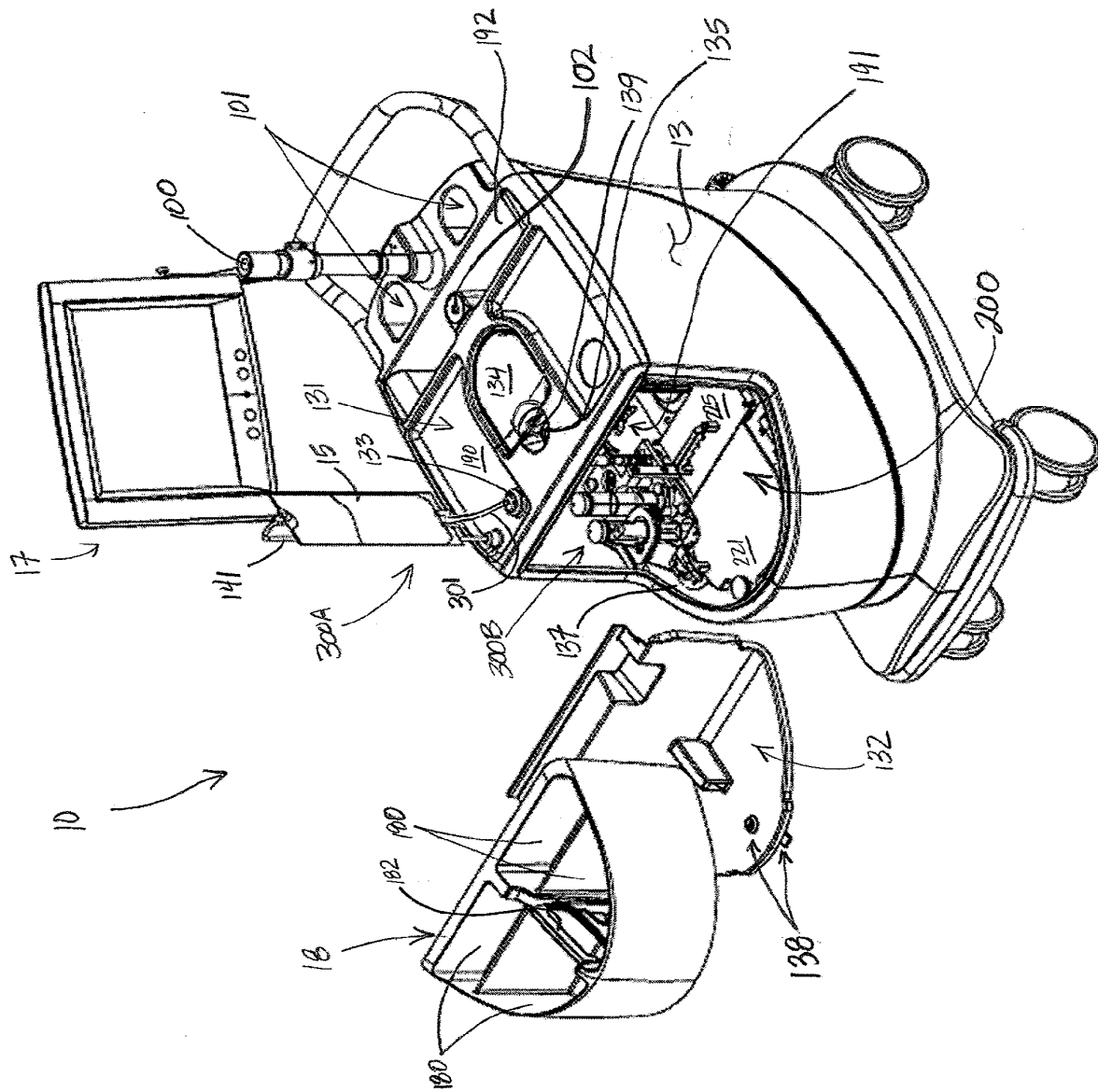


FIGURE 1C

300

300A

300B

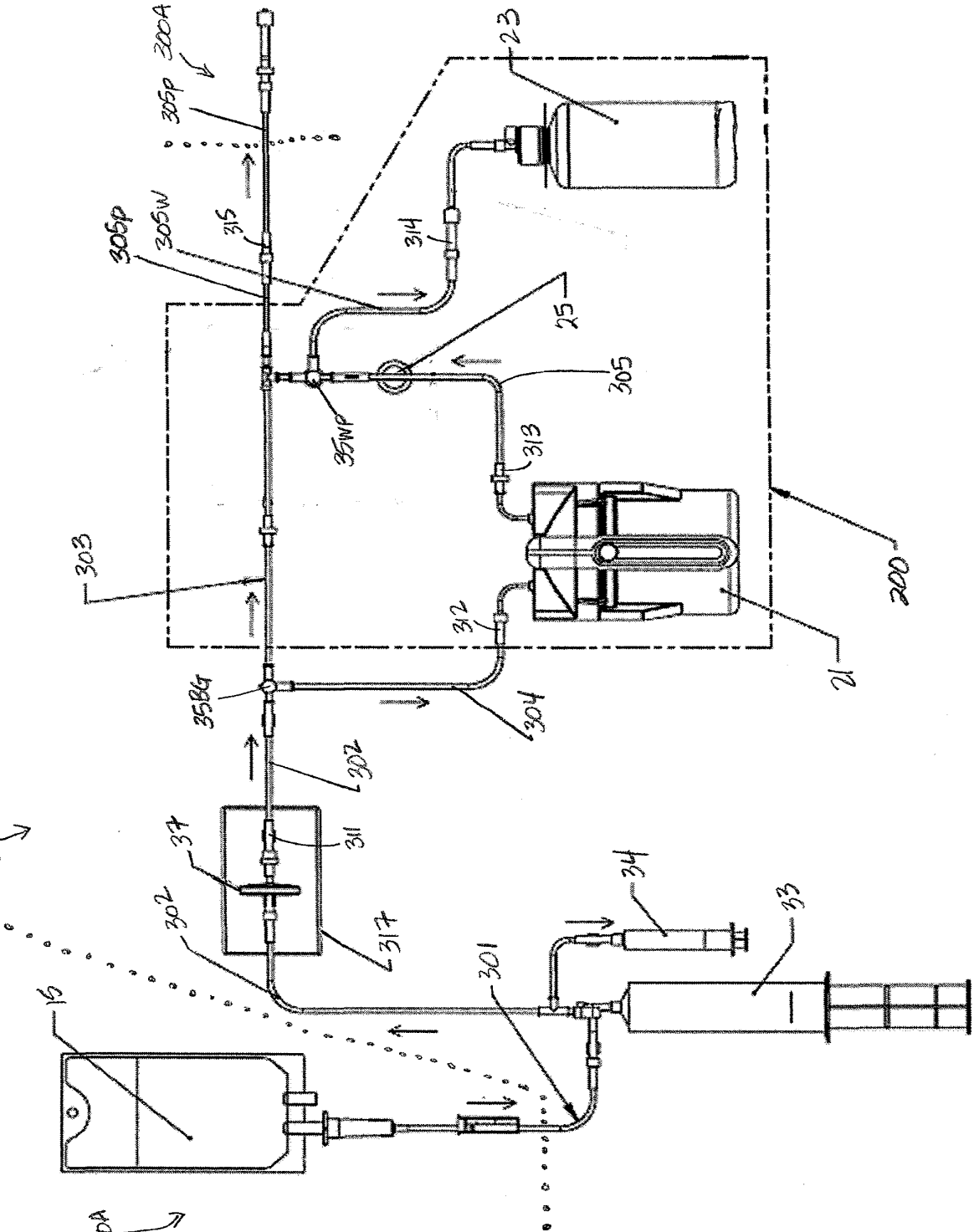


FIGURE 1D

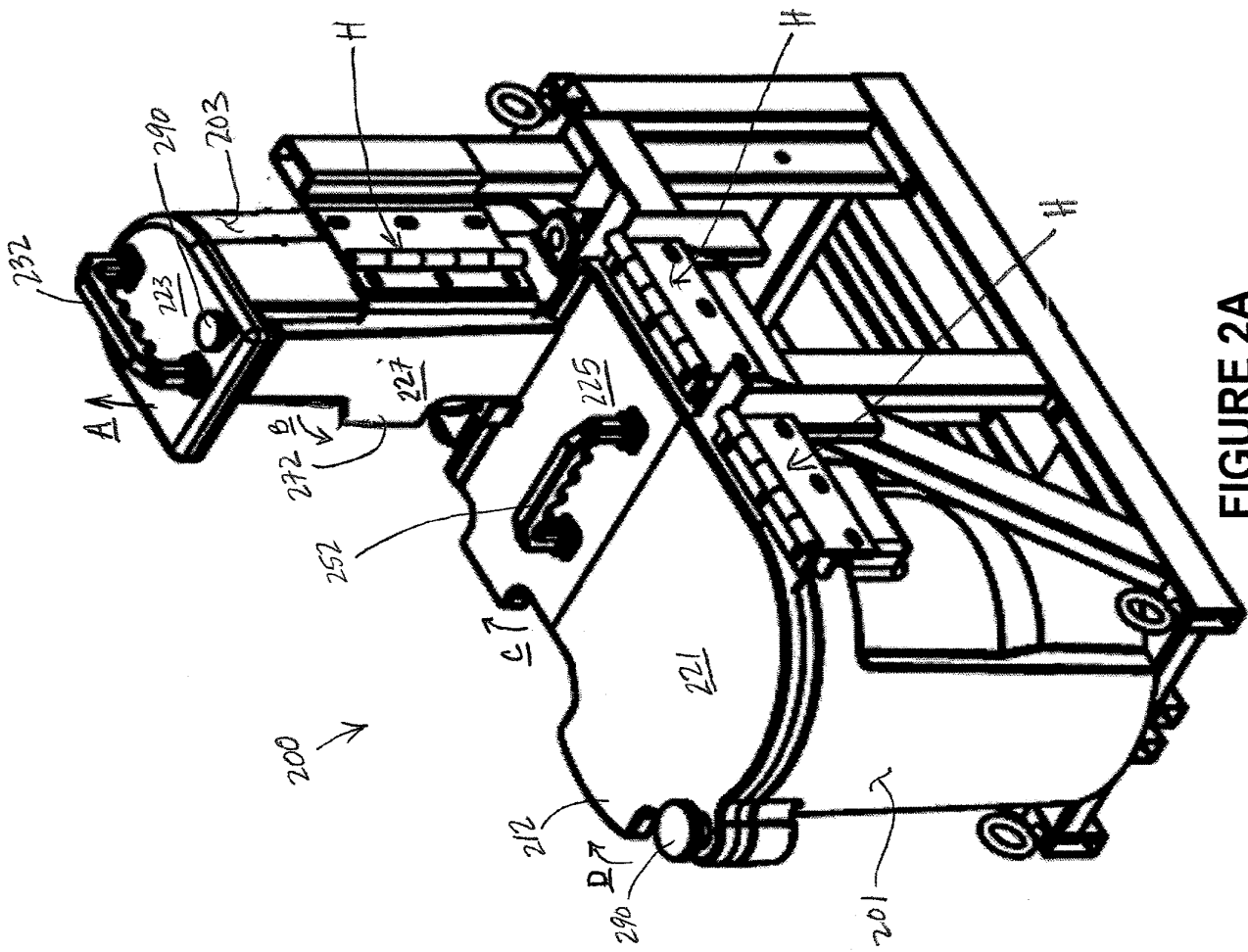


FIGURE 2A

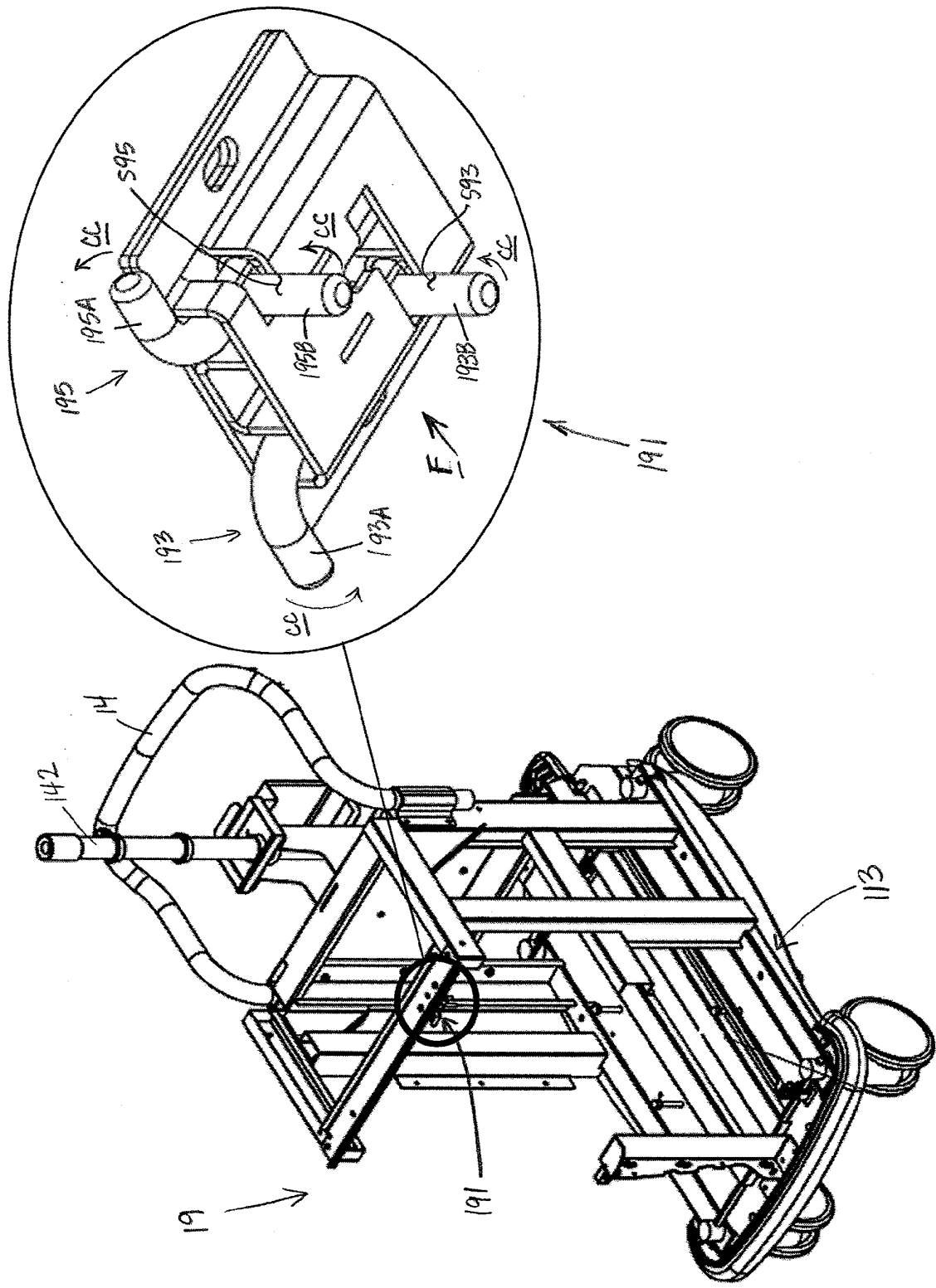


FIGURE 2B

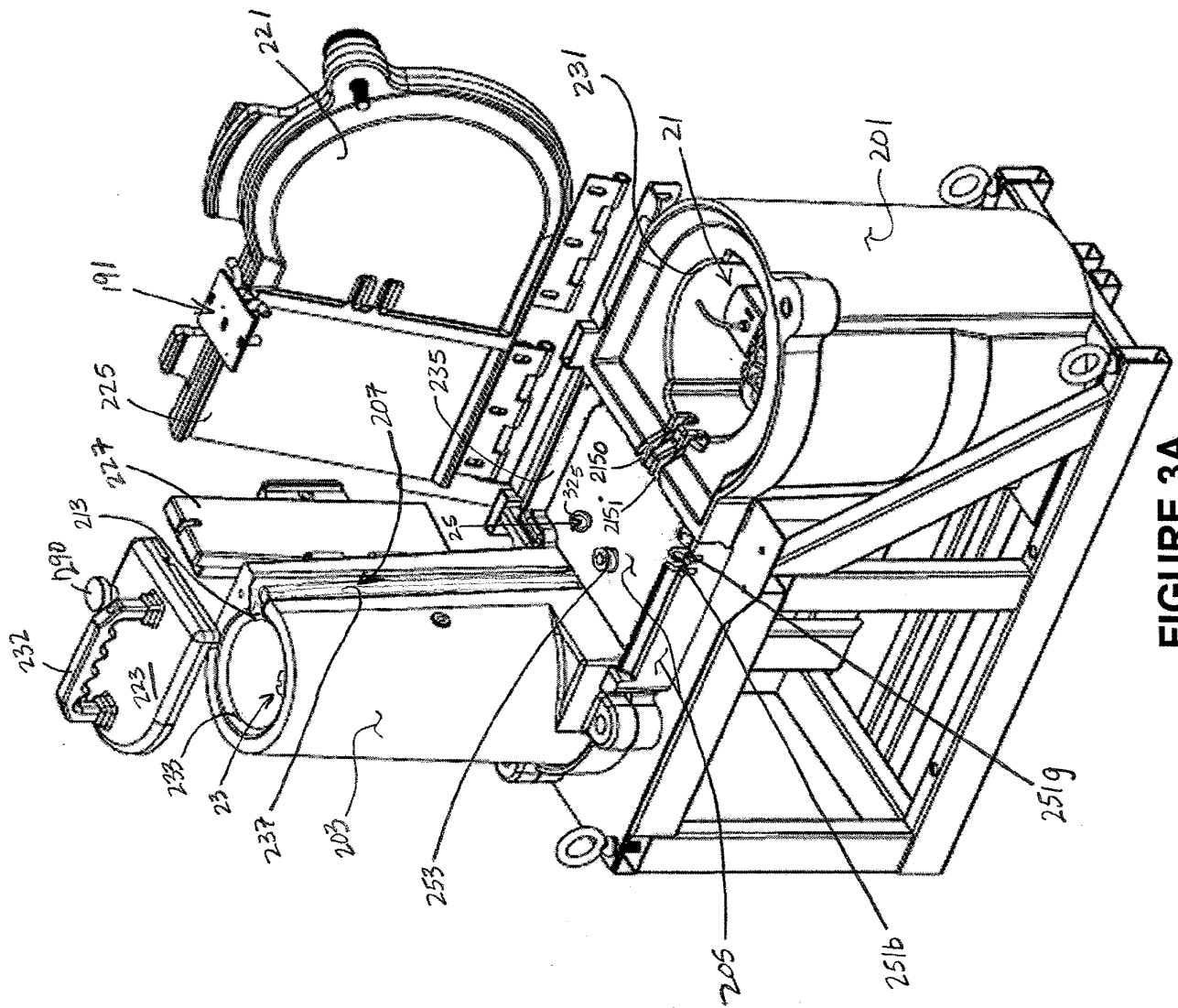


FIGURE 3A

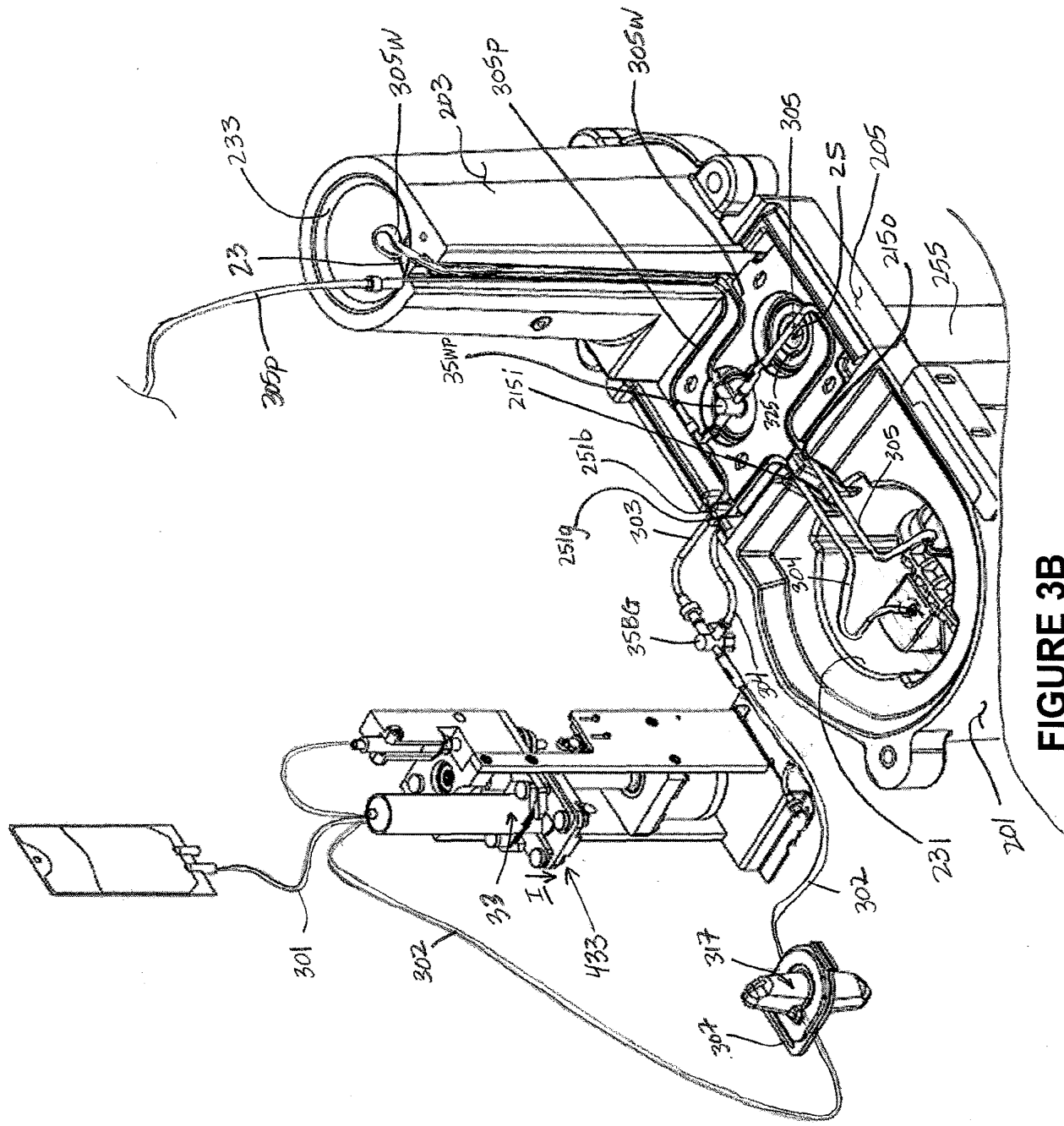


FIGURE 3B

470

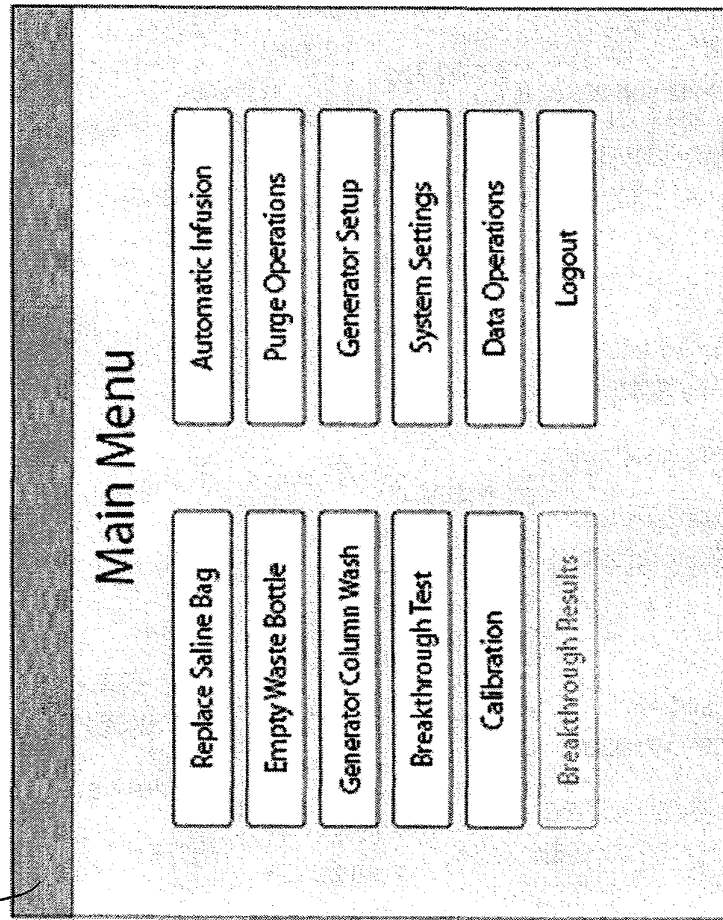


FIGURE 4

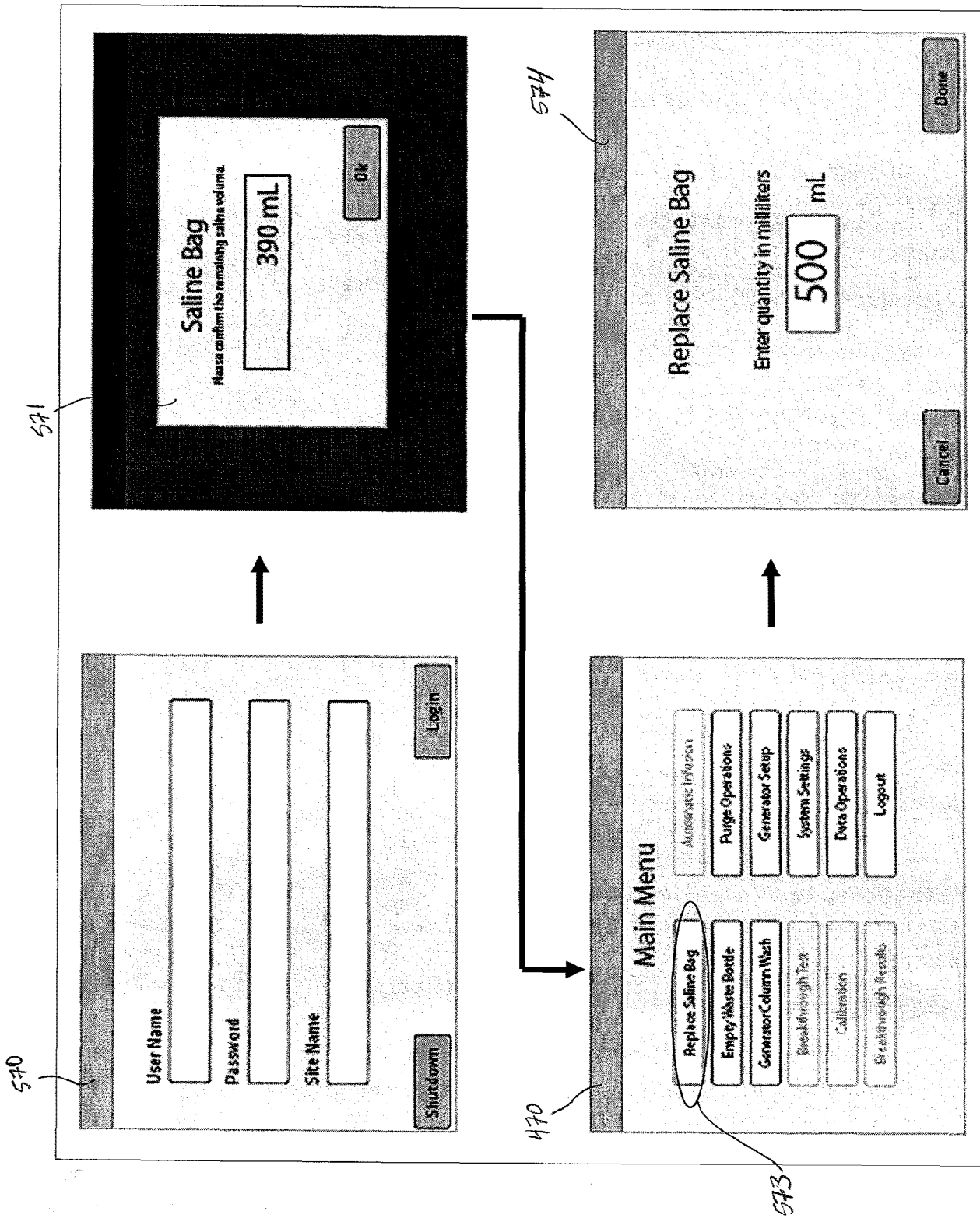


FIGURE 5A

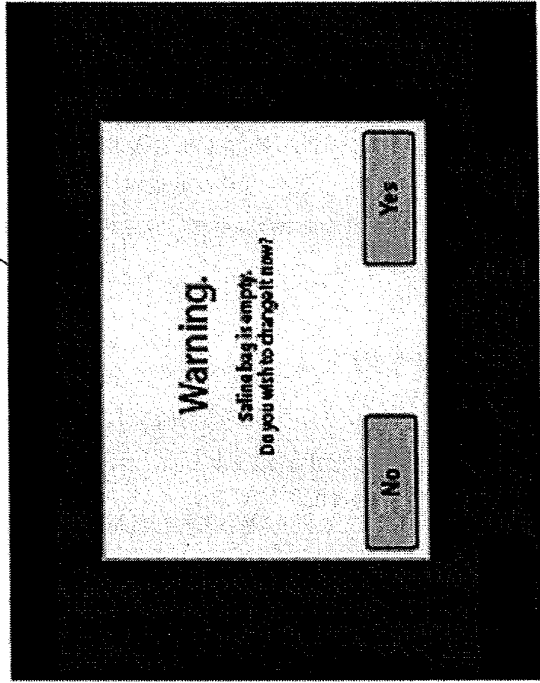
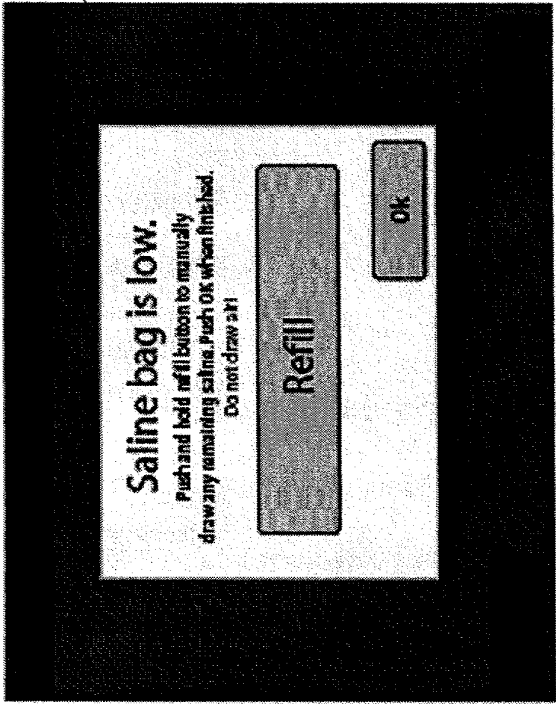


FIGURE 5B

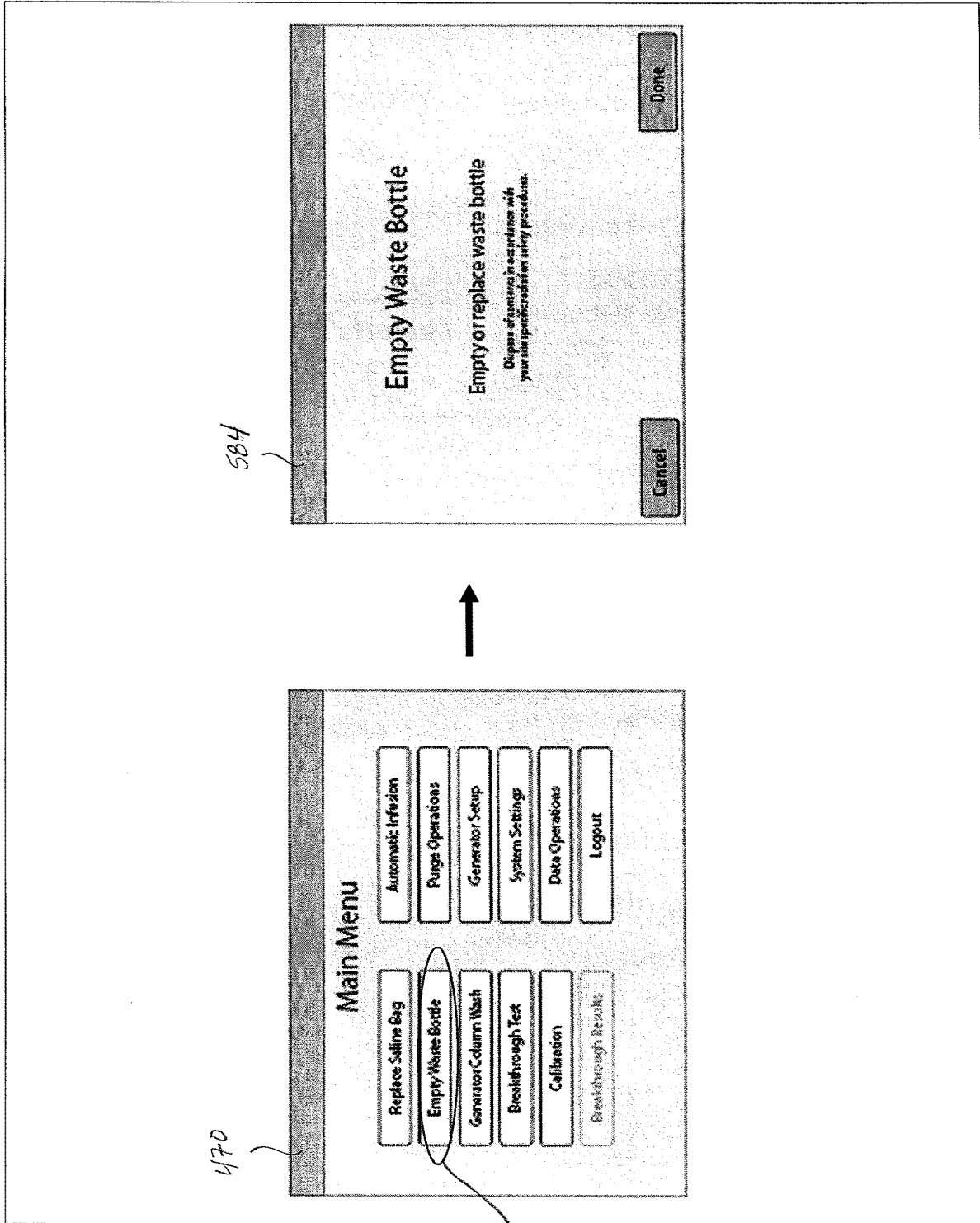
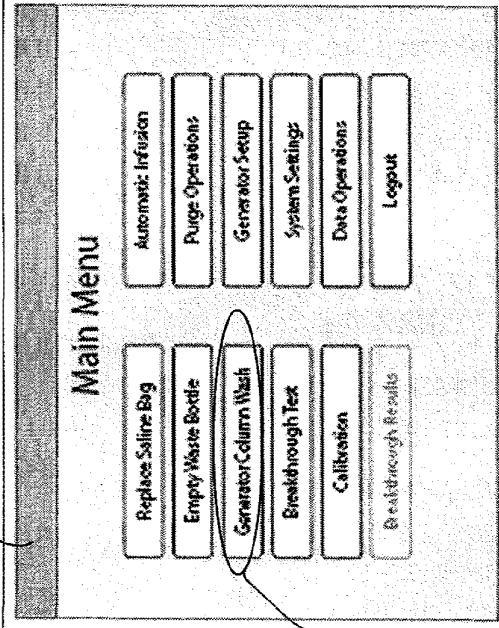


FIGURE 5C

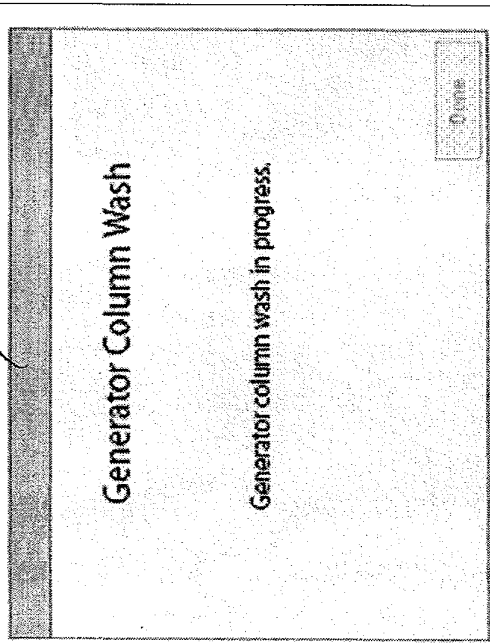
470



675



676



677

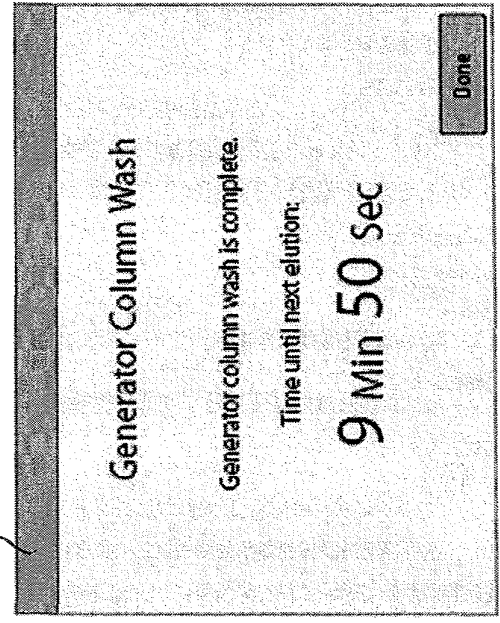


FIGURE 6

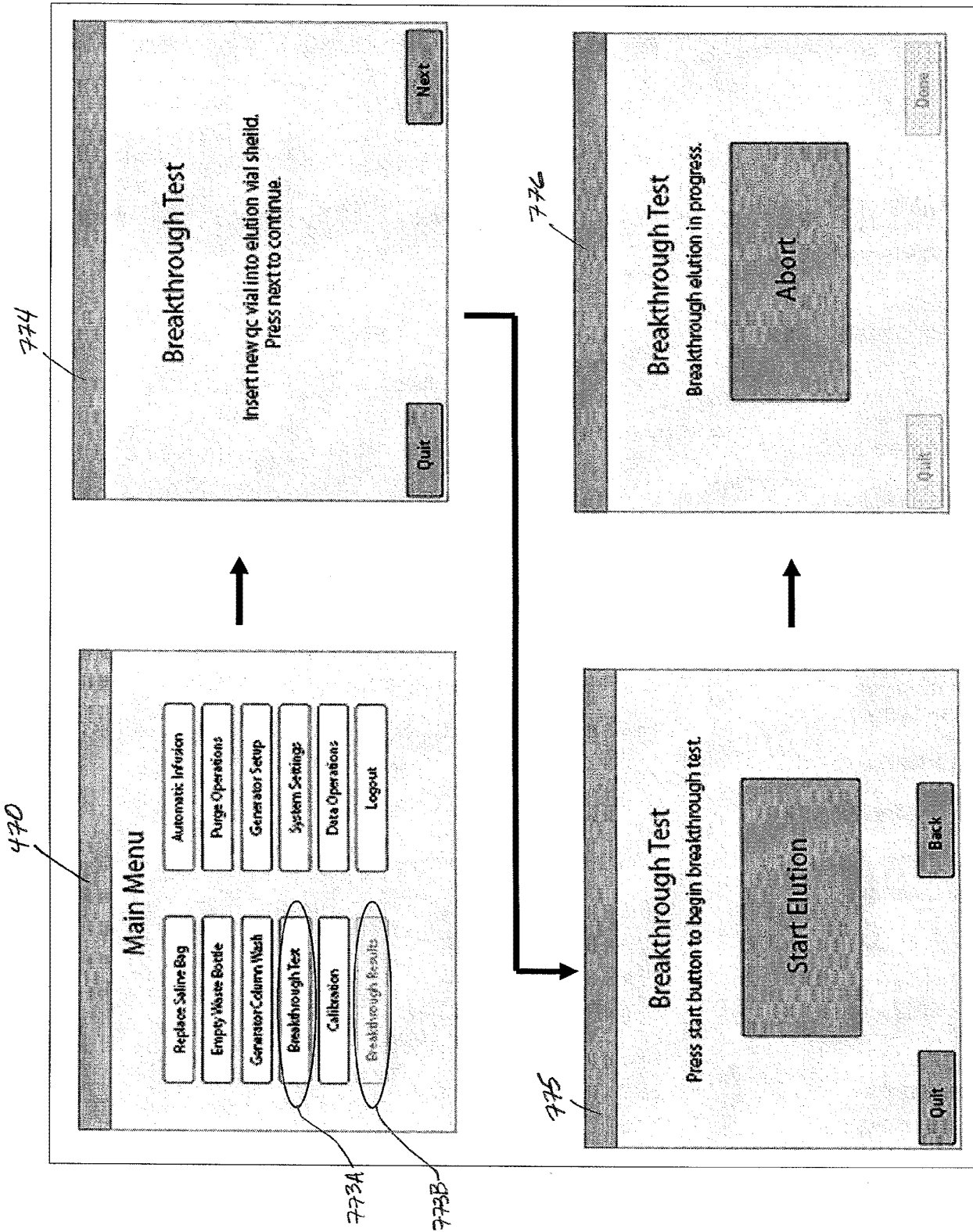


FIGURE 7A

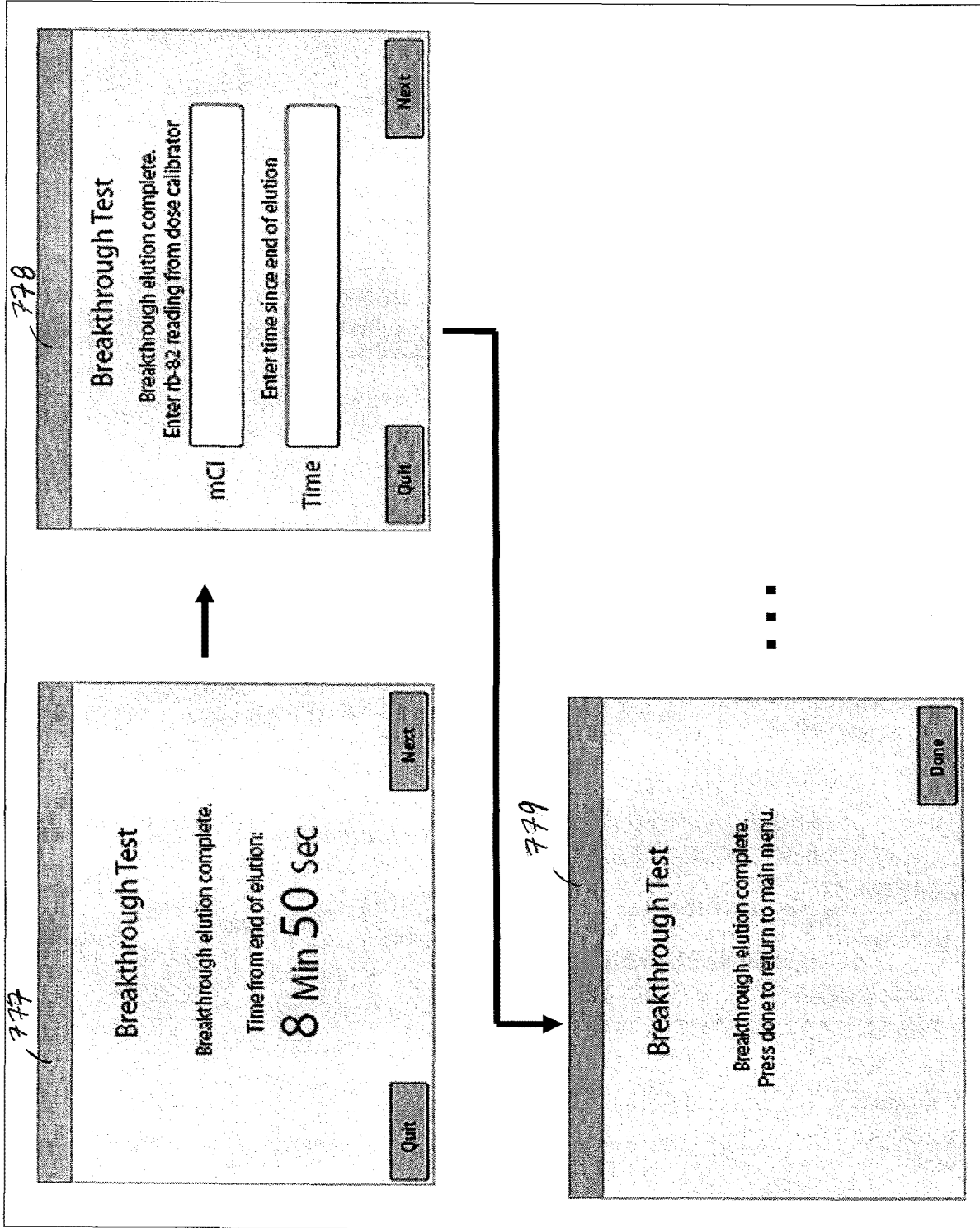


FIGURE 7B

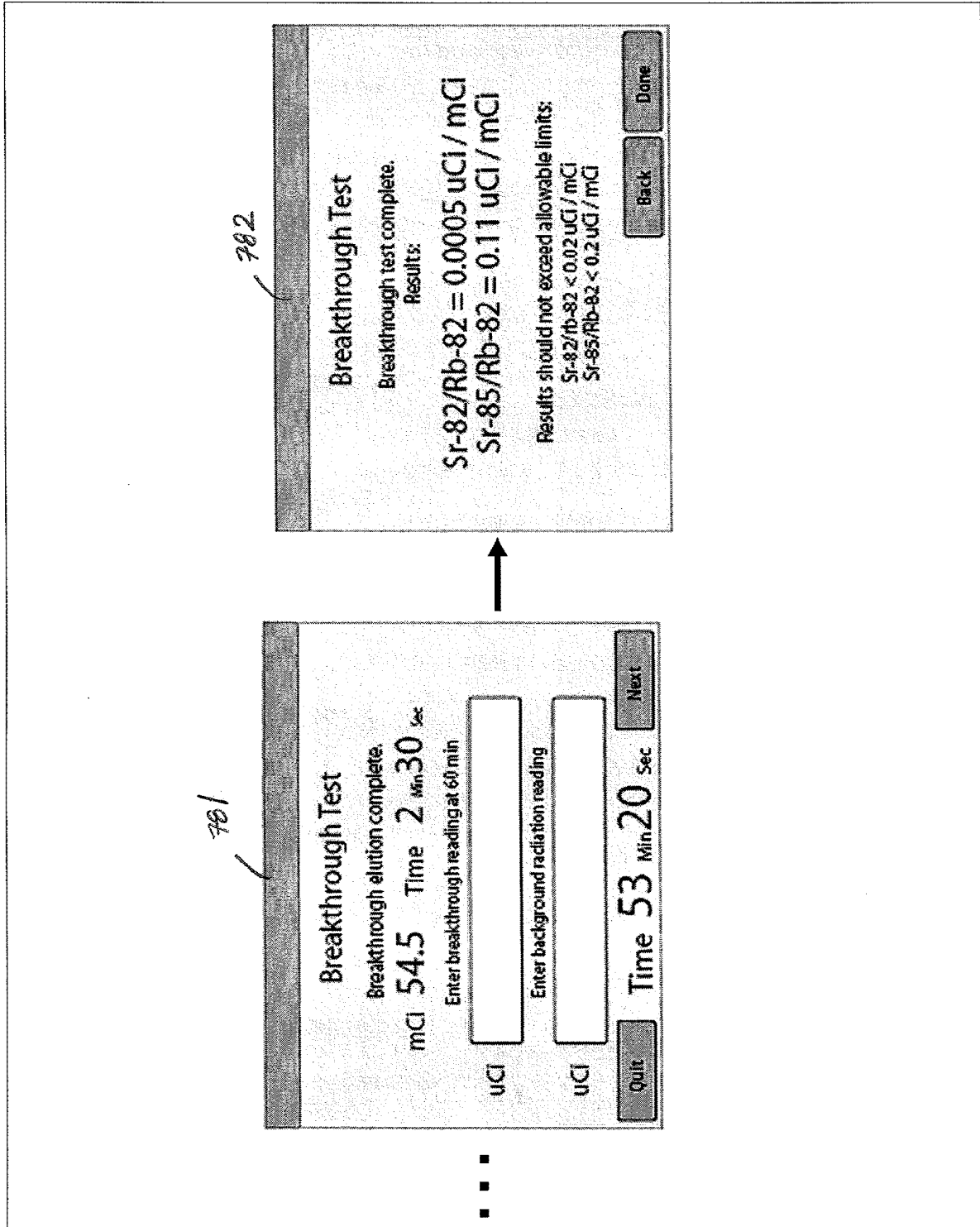


FIGURE 7C

470

Main Menu

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



874

Infusion System Calibration

Insert new qc vial into elution vial shield.
Press next to continue.

Quit Back Next

875

Infusion System Calibration

Patient Dose: 60 mCi

Patient Volume: 50 mL

Flow Rate: 50 mL/min (DEFAULT)

Dose Rate Threshold: 1.0 mCi/sec (DEFAULT)

Elution Volume: 99 mL (DEFAULT)

Quit Next



876

Infusion System Calibration

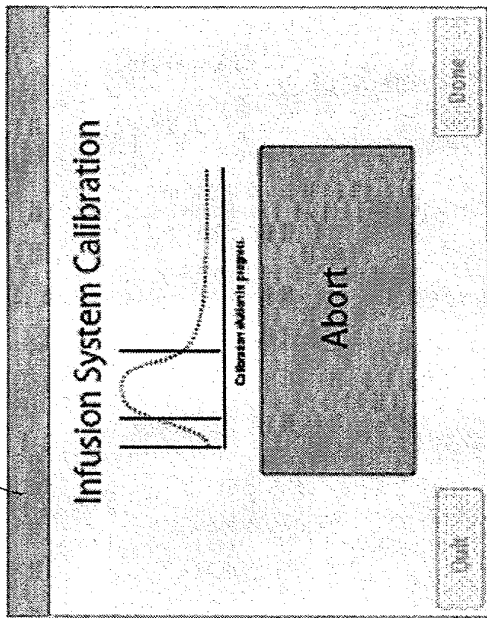
Press start button to begin calibration.

Start

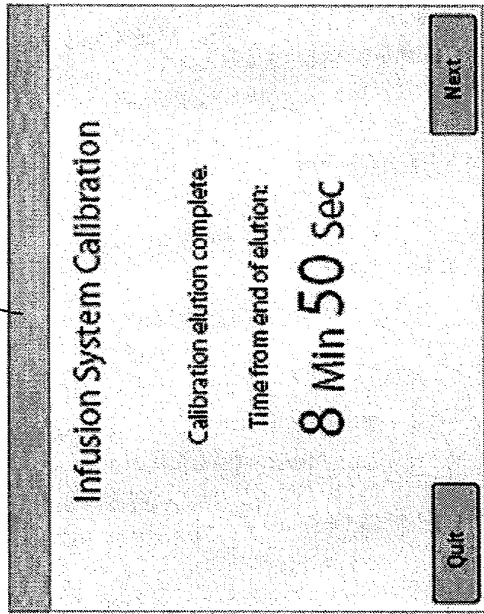
Quit Back

FIGURE 8A

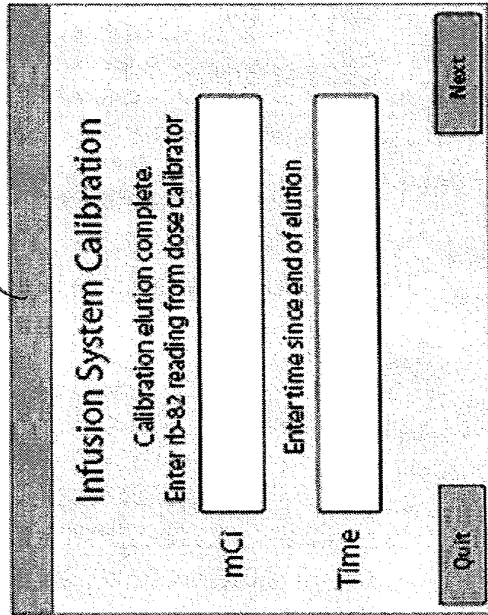
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878



879



880

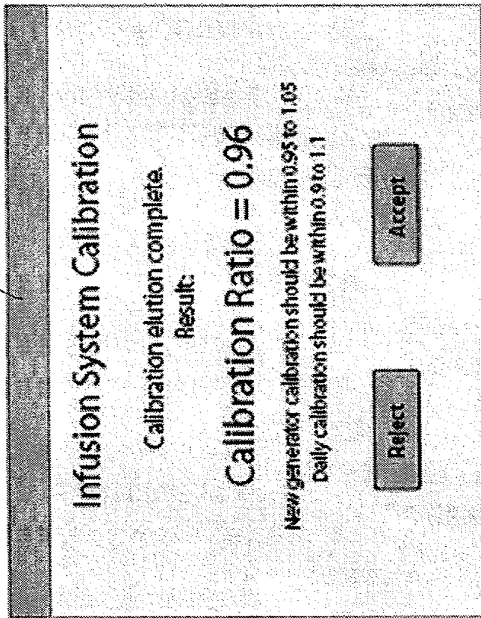


FIGURE 8B

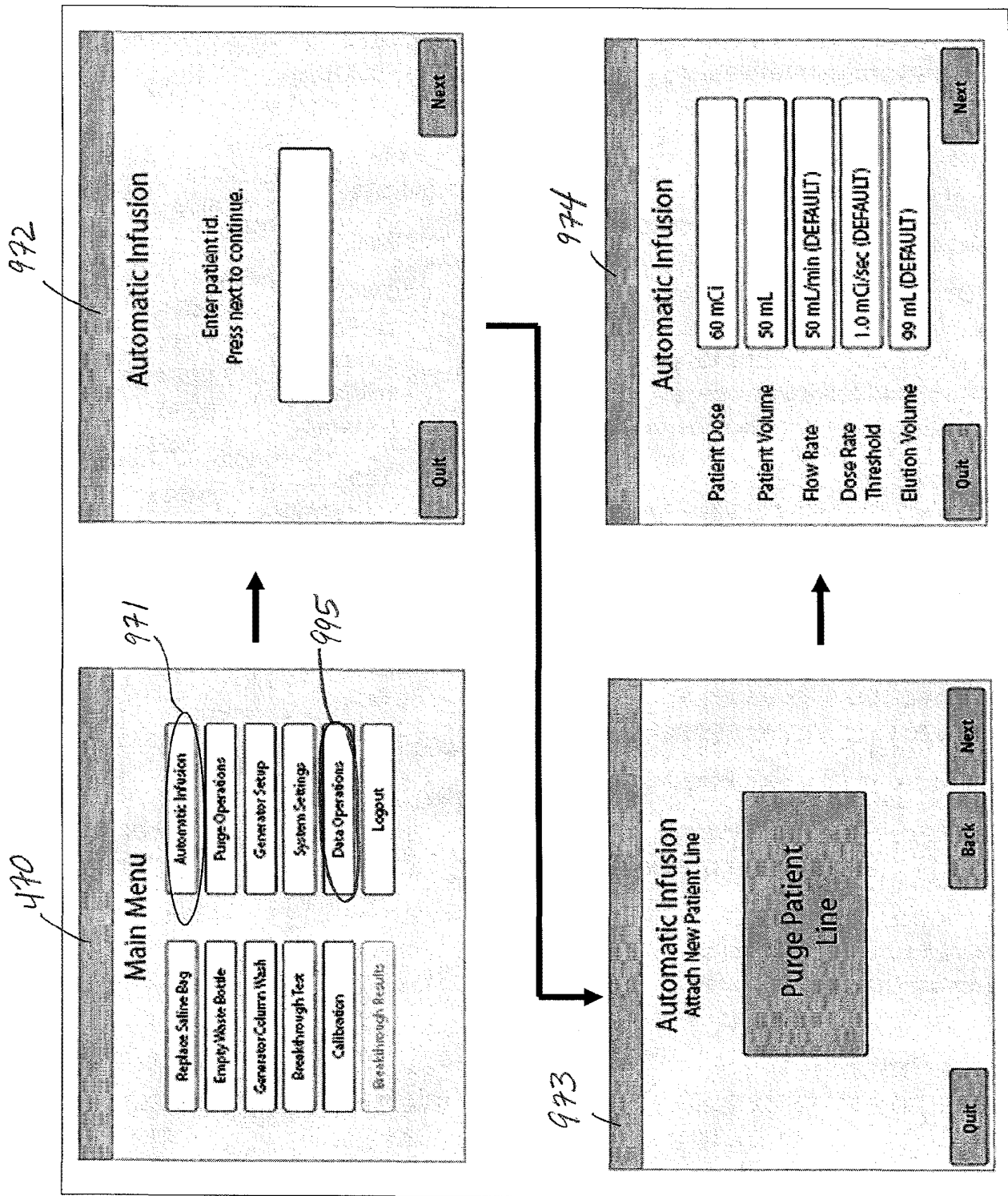


FIGURE 9A

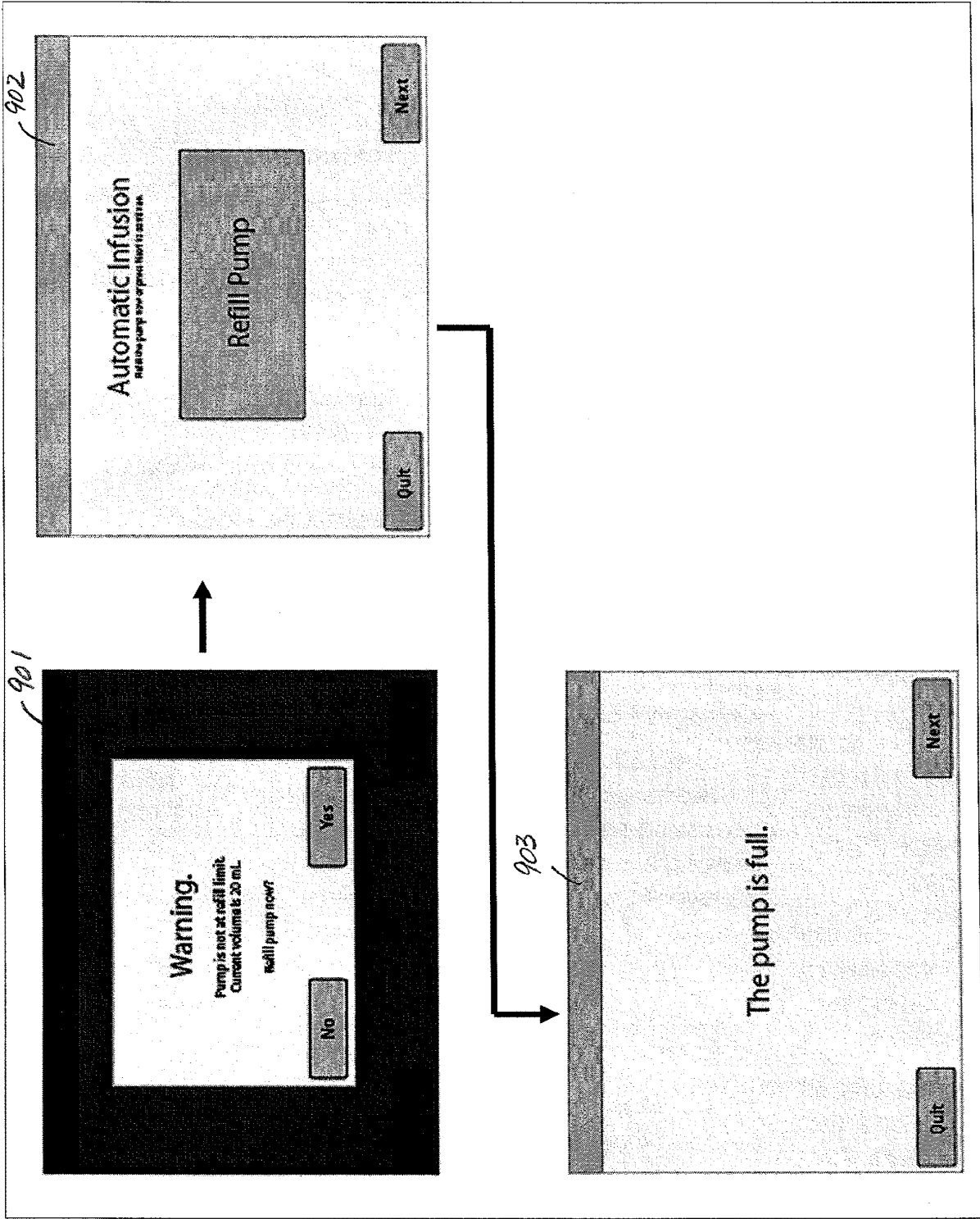


FIGURE 9B

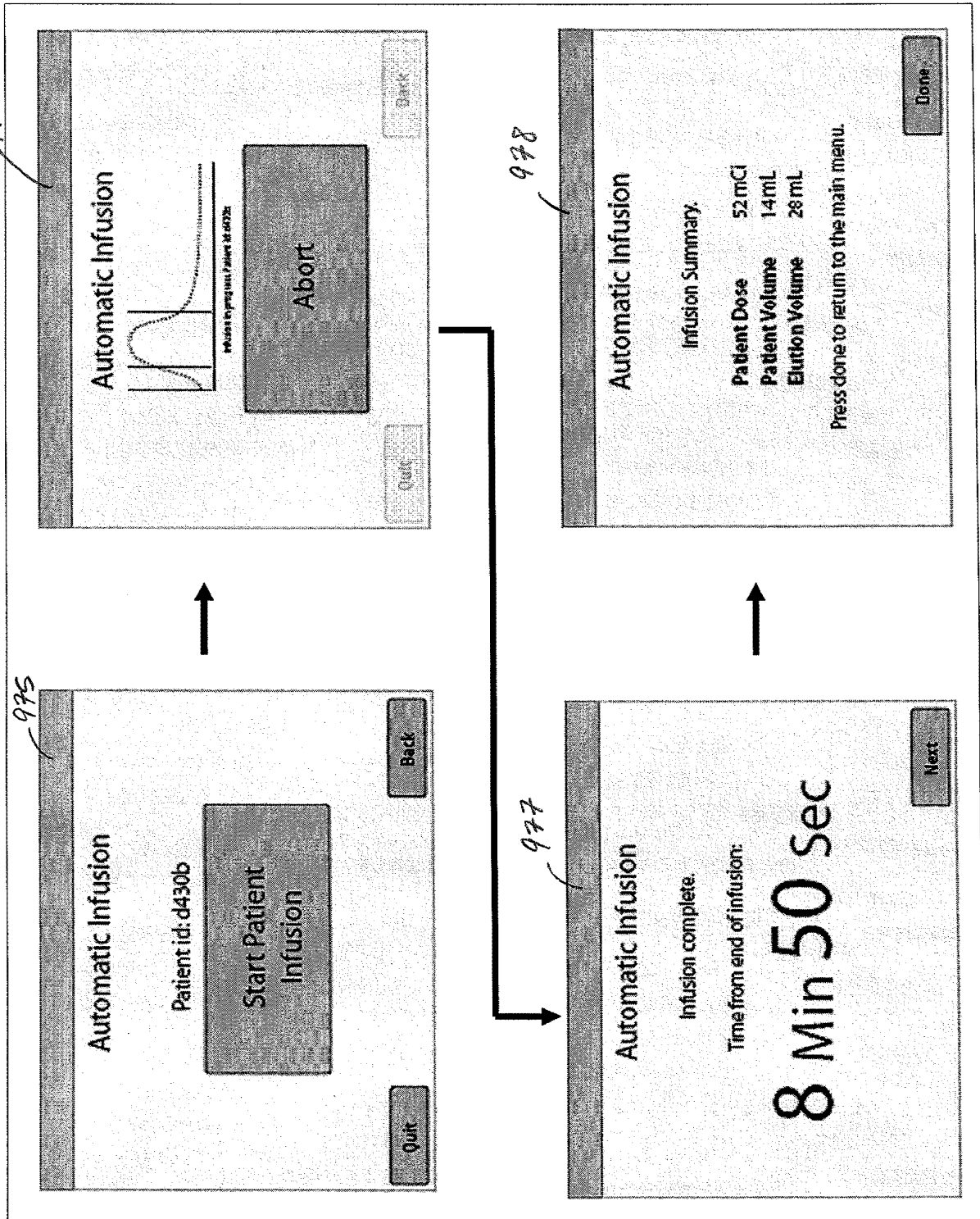


FIGURE 9C

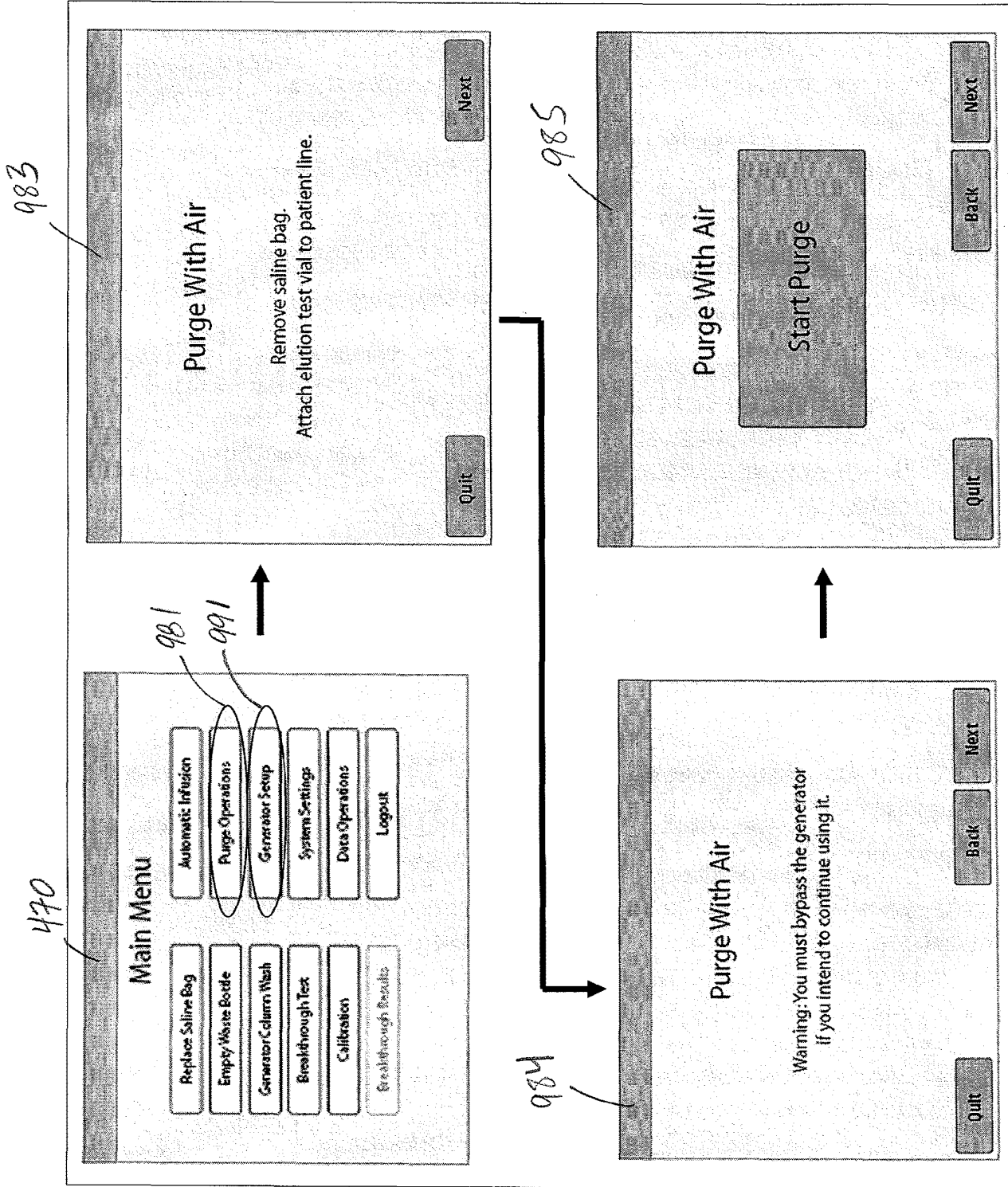


FIGURE 10

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| | | | |
|---|---|------------------------|-----------|
| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.8 |
| | | Application Number | |
| Title of Invention | CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS | | |
| The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application. | | | |

Secrecy Order 37 CFR 5.2

Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

| | | | | | |
|---|-------------------|---|--------------------|--|---|
| Applicant 1 | | | | | Remove |
| Applicant Authority | | <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name | Suffix | |
| | Charles | | Quirico | | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | | |
| City | | State/Province | | Country of Residenceⁱ | |
| Citizenship under 37 CFR 1.41(b)ⁱ | | | | | |
| Mailing Address of Applicant: | | | | | |
| Address 1 | | | | | |
| Address 2 | | | | | |
| City | | State/Province | | | |
| Postal Code | | Countryⁱ | | | |
| Applicant 2 | | | | | Remove |
| Applicant Authority | | <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name | Suffix | |
| | Ernest | | Balestracci | | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | | |
| City | | State/Province | | Country of Residenceⁱ | |
| Citizenship under 37 CFR 1.41(b)ⁱ | | | | | |
| Mailing Address of Applicant: | | | | | |
| Address 1 | | | | | |
| Address 2 | | | | | |
| City | | State/Province | | | |
| Postal Code | | Countryⁱ | | | |
| Applicant 3 | | | | | Remove |
| Applicant Authority | | <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name | Suffix | |
| | Jake | | Childs | | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | | |
| City | | State/Province | | Country of Residenceⁱ | |

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|---|---|------------------------|-----------|
| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.8 |
| | | Application Number | |
| Title of Invention | CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS | | |

| | | | |
|---|------------|--|---|
| Citizenship under 37 CFR 1.41(b) i | | | |
| Mailing Address of Applicant: | | | |
| Address 1 | | | |
| Address 2 | | | |
| City | | State/Province | |
| Postal Code | | Country ⁱ | |
| Applicant 4 | | | <input type="button" value="Remove"/> |
| Applicant Authority <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name |
| | Pete | | Madson |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | |
| City | | State/Province | Country of Residence ⁱ |
| Citizenship under 37 CFR 1.41(b) i | | | |
| Mailing Address of Applicant: | | | |
| Address 1 | | | |
| Address 2 | | | |
| City | | State/Province | |
| Postal Code | | Country ⁱ | |
| Applicant 5 | | | <input type="button" value="Remove"/> |
| Applicant Authority <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name |
| | Dan | | Clements |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | |
| City | | State/Province | Country of Residence ⁱ |
| Citizenship under 37 CFR 1.41(b) i | | | |
| Mailing Address of Applicant: | | | |
| Address 1 | | | |
| Address 2 | | | |
| City | | State/Province | |
| Postal Code | | Country ⁱ | |
| All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. <input type="button" value="Add"/> | | | |

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| Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a). | |
| <input type="checkbox"/> An Address is being provided for the correspondence information of this application. | |
| Customer Number | 22859 |

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|---|---|--|---|
| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.8 |
| | | Application Number | |
| Title of Invention | CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS | | |
| Email Address | | <input type="button" value="Add Email"/> | <input type="button" value="Remove Email"/> |

Application Information:

| | | | |
|---|---|---|--------------------------|
| Title of the Invention | CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS | | |
| Attorney Docket Number | 56782.1.8 | Small Entity Status Claimed | <input type="checkbox"/> |
| Application Type | Nonprovisional | | |
| Subject Matter | Utility | | |
| Suggested Class (if any) | | Sub Class (if any) | |
| Suggested Technology Center (if any) | | | |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.8 |
| | | Application Number | |
| Title of Invention | CABINET STRUCTURE CONFIGURATIONS FOR INFUSION SYSTEMS | | |

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

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| Application Number | Country ⁱ | Parent Filing Date (YYYY-MM-DD) | Priority Claimed |
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| | | | | |
|--|--------------------------|----------------|-------|---------------------------------------|
| Assignee 1 | | | | <input type="button" value="Remove"/> |
| If the Assignee is an Organization check here. <input checked="" type="checkbox"/> | | | | |
| Organization Name | Bracco Diagnostics, Inc. | | | |
| Mailing Address Information: | | | | |
| Address 1 | 107 College Road East | | | |
| Address 2 | | | | |
| City | Princeton | State/Province | NJ | |
| Country ⁱ | US | Postal Code | 08540 | |
| Phone Number | | Fax Number | | |
| Email Address | | | | |
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Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

| | | | | |
|------------------|------------------------|-----------|-------------------|---------------------|
| Signature | /Charles D. Segelbaum/ | | Date (YYYY-MM-DD) | 2008-06-11 |
| First Name | Charles D. | Last Name | Segelbaum | Registration Number |
| | | | | 42138 |

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| EFS ID: | 3440941 |
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| Confirmation Number: | 7402 |
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| 1 | | 56782_1_8_Application.pdf | 180243 3691df61092370152f58ed47ce47fe72663e5331 | yes | 34 |
| Multipart Description/PDF files in .zip description | | | | | |
| | | Document Description | Start | End | |
| | | Specification | 1 | 27 | |
| | | Claims | 28 | 33 | |
| | | Abstract | 34 | 34 | |
| Warnings: | | | | | |
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| 2 | Drawings-only black and white line drawings | 56782_1_5_6_7_8_Drawing s.pdf | 3090157 51f728353556654064c53570776bc61a122bc41f | no | 23 |
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Document made available under the Patent Cooperation Treaty (PCT)

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International filing date: 11 June 2009 (11.06.2009)

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INFUSION SYSTEM CONFIGURATIONS

RELATED APPLICATIONS

- [01] The present application is related to the following commonly assigned utility patent applications, all of which are filed concurrently herewith and all of which are hereby incorporated by reference in their entireties: Practitioner Docket No. 56782.1.5, entitled: SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS; Practitioner Docket No. 56782.1.7, entitled: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE; and Practitioner Docket No. 56782.1.8, entitled: CABINET STRUCTURES SUPPORTING INFUSION SYSTEMS.

TECHNICAL FIELD

- [02] The present invention pertains to configurations of systems that generate and infuse radiopharmaceuticals, and, more particularly, to the routing of infusion circuit tubing lines.

BACKGROUND

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

[04] Whether the half-life of a particular radioactive isotope, employed by a radiopharmaceutical, is relatively short or long, a patient undergoing a nuclear imaging procedure is not typically exposed to a significant amount of radiation. However those personnel, whose job it is to set up and maintain radiopharmaceutical infusion systems, and to administer doses therefrom, are subject to more frequent and prolonged exposures to radiation. Therefore, shielding assemblies, which provide a radiation barrier to protect these personnel from excessive exposure to radiation sources, are an important component of radiopharmaceutical generators and infusion systems. These shielding assemblies are typically formed with lead sidewalls, the bulk and weight of which can pose difficulties for the personnel who regularly set up disposable tubing lines for the infusion circuit of the infusion system. These lines should be routed into and out from compartments of the shielding assembly without kinking or crushing the lines. Thus, there is a need for new infusion system configurations and assemblies that facilitate this task.

BRIEF DESCRIPTION OF THE DRAWINGS

- [05] The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.
- [06] Figure 1A is a first perspective view of an infusion system, according to some embodiments of the present invention.
- [07] Figure 1B is another perspective view of a portion of a cabinet structure of the system shown in Figure 1A, according to some embodiments.
- [08] Figure 1C is a second perspective view of the system shown in Figure 1A, according to some embodiments.
- [09] Figure 1D is a schematic of an infusion circuit, according to some embodiments of the present invention.

- [10] Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A-C, according to some embodiments of the present invention.
- [11] Figure 2B is a perspective view of a framework of the system, according to some embodiments, with an enlarged detailed view of a component of the system, according to some embodiments.
- [12] Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.
- [13] Figure 3B is a perspective view of the infusion circuit, shown in Figure 1C, configured and routed, according to some embodiments.
- [14] Figure 3C is a perspective view of a disposable infusion circuit subassembly, according to some embodiments.
- [15] Figure 3D is a frame for the subassembly shown in Figure 3C, according to some embodiments.
- [16] Figure 4 is a main menu screen shot from an interface of a computer, which may be included in systems of the present invention, according to some embodiments.
- [17] Figure 5A is a schematic showing a first group of successive screen shots from the computer interface, according to some embodiments.
- [18] Figure 5B is a pair of screen shots from the computer interface, which provide indications related to eluant volume levels in a reservoir of the system, according to some embodiments.
- [19] Figure 5C is a schematic showing a second group of successive screen shots from the computer interface, according to some embodiments.
- [20] Figure 6 is a schematic showing a third group of successive screen shots from the computer interface, according to some embodiments.
- [21] Figures 7A-C are schematics showing a fourth group of successive screen shots from the computer interface, according to some embodiments.
- [22] Figures 8A-B are schematics showing a fifth group of successive screen shots from the computer interface, according to some embodiments.

- [23] Figures 9A-C are schematics showing a sixth group of successive screen shots from the computer interface, according to some embodiments.
- [24] Figure 10 is a schematic showing a seventh group of successive screen shots from the computer interface, according to some embodiments.

DETAILED DESCRIPTION

- [25] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.
- [26] Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surrounds an interior space in which a portion of infusion system 10 is contained (-seen in Figure 1C). Shell may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13, and a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may included, for example, a keyboard, a series of control buttons or levers, a

barcode reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions. Operation of system 10, which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

- [27] Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one location for another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.
- [28] Figure 1B is a perspective view of a portion of system 10, on a side 111 of the cabinet structure, which is in proximity to wheels 121. Figure 1B illustrates a lever or pedal 125, which is located for activation by a foot of the person, who grasps handle 14 to maneuver system 10. In a neutral position, pedal 125 allows wheels 121, 122 to rotate, and, if embodied as casters, to swivel freely. Pedal 125 may be depressed to a first position which prevents a swiveling of wheels 122, according to those embodiments in which wheels 122 are casters, and may be further depressed to brake wheels 121, 122 from rolling and swiveling, upon reaching a desired location. Figure 1B further illustrates a rear access panel 174, for example, providing access to circuit boards of the aforementioned controller contained within the interior space surrounded shell 13, an optional lock 184, to secure panel 174, a power jack 118, for connecting system 10 to a power source, and a printer 117 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include one or more additional

connectors, or ports (not shown), which allow system 10 to be coupled to, for communication with, other devices used for nuclear imaging procedures.

- [29] Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective view of system 10, wherein a removable access panel 132 is shown as a contoured portion of upper surface 131, which, when exposed, by lifting away a bin 18, that mates therewith, may be removed from another opening 137 formed in upper surface 131. Figure 1C also provides a better view of another panel 134 which may be lifted away from opening 139. According to the illustrated embodiment, openings 139 and 137 provide a user of system 10 with independent access to separate portions of infusion system 10, which are contained within shell 13, for example, to set up and maintain system 10; and openings 133 and 135 provide passageways for tubing lines to pass through shell 13. Figure 1C further illustrates an optional switch 102, which in case of an emergency, may be activated to abort function of system 10. With reference to Figures 1A and 1C, it may be appreciated that an arrangement of features formed in upper surface 131 of shell 13, in conjunction with bin 18, tray 16 and computer 17, provide a relatively ergonomic and organized work area for technical personnel who operate system 10.
- [30] Turning now to Figure 1D, a schematic of an infusion circuit 300, which may be incorporated by system 10, is shown. Figure 1D illustrates circuit 300 generally divided into a first part 300A, which includes components mounted outside shell 13, and a second part 300B, which includes components mounted within the interior space surrounded by shell 13. (Parts 300A and 300B are delineated by dotted lines in Figure 1D.) Figure 1D further illustrates second part 300B of circuit 300 including a portion contained within a shielding assembly 200, which is designated schematically as a dashed line. Some embodiments of shielding assembly 200 will be described in greater detail, in conjunction with Figures 2A-B and 3A-B, below.

[31] According to the illustrated embodiment, circuit 300 includes an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34, for monitoring pumping pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity detector 25, for measuring the activity of the eluate discharged from generator 21, in order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance. Figure 1D illustrates an eluant tubing line 301 coupled to reservoir 15 and to pump 33, and, with reference to Figures 1A-B, it may be appreciated that opening 133 provides the passageway for tubing line 301 to enter the interior space surrounded by shell 13. According to some preferred embodiments, opening 133 includes a grommet-type seal that prevents leakage of eluant, which may spill from reservoir 15, into the interior space through opening 133, while allowing a user to assemble tubing line 301 through opening 133. Likewise opening 135, which provides a passageway for patient line 305p, may include a grommet-type seal.

- [32] Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from generator into waste bottle 23, until activity detector 25 detects the desired activity of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21.
- [33] With further reference to Figure 1D, it may be appreciated that shielding assembly 200 encloses those portions of circuit 300 from which radioactive radiation may emanate, with the exception of that portion of patient line 305p, which must extend out from shielding assembly 200 in order to be coupled to the patient for injection, or in order to be coupled to shielded sample vials, as will be described below. Thus, technical personnel, who operate system 10, are protected from radiation by shielding assembly 200, except at those times when

an infusion is taking place, or when quality control tests require collection of eluate into sample vials. During infusions and quality control test sample collection, all technical personnel are typically in another room, or otherwise distanced from system 10, in order to avoid exposure to radiation during the infusion, and, according to some preferred embodiments of the present invention, system 10 includes at least one means for informing technical personnel that an infusion is about to take place or is taking place. With reference back to Figures 1A and 1C, system 10 is shown including a light projector 100, mounted on post 142. According to the illustrated embodiment, projector 100, projects a light signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23, and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system, including in the control room.

- [34] When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a threshold to be safe. Opening 139 is preferably located at an elevation of

between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional maintenance procedures, such as changing out generator 21 and/or other components of circuit 300, as will be described below.

- [35] Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc..., into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example, deposited therein during infusion procedures.

- [36] Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. According to the illustrated embodiment, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed by a sidewall 203 of shielding assembly 200 to contain waste bottle 23, as previously described. When panel 132 is separated from shell 13, and door 221 opened, generator 21 may be lifted out from an opening 231 (Figure 3A) which mates with door 221 of sidewall 201. A weight of generator 21, which includes its own shielding, may be between approximately 23 and approximately 25 pounds, thus, according to some preferred embodiments of the present invention, the elevation of each of openings 137 and 231, with respect to the lowermost portion of the cabinet structure, is between approximately 1 foot and approximately 2 feet, in order to facilitate an ergonomic stance for technical personnel to lift generator 21 out from the compartment. According to an exemplary embodiment, when shielding assembly 200 is contained in the cabinet structure of Figure 1A, openings 137 and 231 are located at an elevation of approximately 12 inches, with respect to the lower surface of platform 113, or at an elevation of approximately 19 inches, with respect to the ground surface upon which wheels 121, 122 rest. Figure 1C further illustrates access panel 132 including a security lock 138, which mates with a framework 19 of system 10, shown in Figure 2B, in order to limit access to generator 21.
- [37] Figures 1C and 2A further illustrate a lid or a door 225 of another sidewall 205 (Figure 3A) of shielding assembly 200, which encloses another compartment that is accessible through opening 137 of shell 13, and which is located adjacent the compartment enclosed by sidewall 201. Each of doors 221, 225 are shown being attached by a corresponding hinge H, and another door 227 is shown

attached to sidewall 203 by another hinge H. Figure 2A illustrates each of lid 223 and doors 221, 225, 227 including a handle 232, 212, 252 and 272, respectively, for moving lid 223 and doors 221, 225, 227, in order to provide access to the corresponding compartments, which can be seen in Figures 3A-B. Figure 2A further illustrates optional thumb screws 290, one securing lid 223 to sidewall 203 and another securing door 221 to sidewall 201, or other means for securing the doors, which are known to those skilled in the art, may be incorporated. Each sidewall 201, 203, 205 and the corresponding lid/door 223, 221, 225, 227 thereof may be individually cast from 3% antimony lead, or from other known shielding materials, and then assembled together according to methods known to those skilled in the art.

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

- [39] With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225. The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.
- [40] Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.
- [41] Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle

23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover.

- [42] Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305 passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.
- [43] Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together, according to alternate embodiments,

mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.

- [44] According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w, respectively, extending from second side 392 of frame 39. Although ends 406, 407 are shown extending upward from tray 39a, as they would within shielding assembly 200, it should be appreciated that the tubing lines of circuit 300 are preferably flexible and would drop down under their own weight rather than extending upward, as shown, if not supported. Referring back to Figure 1D, in conjunction with Figure 3C, it can be seen that fittings are provided for coupling subassembly 390 into circuit 300: a first fitting 311 couples the section of eluant line 302 to filter 37; a second fitting 312 couples eluant line 304 to an inlet port of generator 21; a third fitting 313, which may incorporate a check valve, couples eluate line 305 to an outlet port of generator 21; a fourth fitting 314 couples waste line 305w to waste bottle 23; and a fifth fitting 315 couples patient line 305p to an extension thereof, which extends outside shell 13 (designated by the dotted line). Each of the fittings 311, 312, 313, 314, 315 may be of the Luer type, or any other suitable type that is known to those skilled in the art.
- [45] As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing

line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

- [46] With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.
- [47] Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.
- [48] Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only

displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17 away from radioactive radiation.

- [49] According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format.
- [50] Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on.

- [51] Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a storage medium (i.e. disk) reader, a scanner, a barcode reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc...).
- [52] If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag, which leads computer 17 to prompt the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume, via screen 574, as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished.
- [53] In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu

470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied.

- [54] In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate is being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.
- [55] Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is

displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments.

According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82® that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

- [56] Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. In conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).
- [57] Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example,

the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

- [58] Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.
- [59] After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is

instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

- [60] With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.
- [61] With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process

when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration elution process. When the user transfers the vial containing the sample of eluate into the dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 878. With further reference to Figure 8B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 879, which includes data entry fields for the activity measure and the time, with respect to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data is input by the user, as described above, computer calculates a calibration coefficient, or ratio, and presents the ratio on a screen 880. According to Figure 8B, screen 880 further provides an indication of a desirable range for the calibration ratio and presents an option for the user to reject the calculated ratio, in which case, the user may instruct computer 17 to recalculate the ratio.

- [62] With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a

patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

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

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

- [64] Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary of the infusion, which includes the patient identification number and pertinent system parameters, may be downloaded onto a computer readable storage device to be transferred to one or more remote computers and/or automatically transferred thereto, via wireless communication or a cable connection. The one or more remote computers may be included, for example, in a hospital information system, and/or an inventory system, and/or a billing system, and/or in a medical imaging system. With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data.
- [65] Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline purge, as procedures for saline purging should be readily apparent to those skilled in the art, with reference to the schematic of infusion circuit 300 shown in Figure 1D. A saline purge of circuit 300 is desired to assure that all the air is removed from circuit 300 when a new generator and/or a new complete or partial tubing set is installed. An air purge of the tubing lines of

circuit 300 may be performed after removing reservoir 15, by-passing generator 21, by connecting tubing line 304 to tubing line 305, and coupling patient line 305p to a vial, for example, as is directed by the computer interface, in screens 983 and 984 shown in Figure 10. The air purge is desirable for blowing out the tubing lines, thereby removing all remaining eluant and eluate, prior to installing a new generator and/or prior to transporting system 10 from one site to another. If generator 21 is not depleted and will be used in system 10 at the new site, it is important to by-pass the generator prior to purging the tubing lines of circuit 300 with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

[66] According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

[67] The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for

guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator.

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

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| | | | |
|---|--------------------------------|------------------------|-----------|
| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.6 |
| | | Application Number | |
| Title of Invention | INFUSION SYSTEM CONFIGURATIONS | | |
| The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application. | | | |

Secrecy Order 37 CFR 5.2

Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

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| Applicant 1 | | | | | Remove |
| Applicant Authority | | <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name | Suffix | |
| | Charles | | Quirico | | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | | |
| City | | State/Province | | Country of Residenceⁱ | |
| Citizenship under 37 CFR 1.41(b)ⁱ | | | | | |
| Mailing Address of Applicant: | | | | | |
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| Address 2 | | | | | |
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| Postal Code | | Countryⁱ | | | |
| Applicant 2 | | | | | Remove |
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| Applicant 3 | | | | | Remove |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.6 | |
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| Title of Invention | INFUSION SYSTEM CONFIGURATIONS | | | |
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| Applicant 4 | | | | <input type="button" value="Remove"/> |
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| Applicant 6 | | | | <input type="button" value="Remove"/> |
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| Mailing Address of Applicant: | | | |
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| Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a). | |
| <input type="checkbox"/> An Address is being provided for the correspondence information of this application. | |
| Customer Number | 22859 |
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Application Information:

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| Attorney Docket Number | 56782.1.6 | Small Entity Status Claimed | <input type="checkbox"/> |
| Application Type | Nonprovisional | | |
| Subject Matter | Utility | | |
| Suggested Class (if any) | | Sub Class (if any) | |
| Suggested Technology Center (if any) | | | |
| Total Number of Drawing Sheets (if any) | 23 | Suggested Figure for Publication (if any) | |

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| <input type="checkbox"/> Request Early Publication (Fee required at time of Request 37 CFR 1.219) |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.6 |
| | | Application Number | |
| Title of Invention | INFUSION SYSTEM CONFIGURATIONS | | |

Domestic Benefit/National Stage Information:

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| This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification. | | | |
| Prior Application Status | | | <input type="button" value="Remove"/> |
| Application Number | Continuity Type | Prior Application Number | Filing Date (YYYY-MM-DD) |
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Foreign Priority Information:

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| This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a). | | | |
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Assignee Information:

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| Assignee 1 | | | <input type="button" value="Remove"/> |
| If the Assignee is an Organization check here. <input checked="" type="checkbox"/> | | | |
| Organization Name | Bracco Diagnostics, Inc. | | |
| Mailing Address Information: | | | |
| Address 1 | 107 College Road East | | |
| Address 2 | | | |
| City | Princeton | State/Province | NJ |
| Country ⁱ | US | Postal Code | 08540 |
| Phone Number | | Fax Number | |
| Email Address | | | |
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Signature:

| | | | |
|--|------------------------|-------------------|------------|
| A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature. | | | |
| Signature | /Charles D. Segelbaum/ | Date (YYYY-MM-DD) | 2008-06-11 |

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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.6 | | |
| | | Application Number | | | |
| Title of Invention | INFUSION SYSTEM CONFIGURATIONS | | | | |
| First Name | Charles D. | Last Name | Segelbaum | Registration Number | 42138 |

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

Infusion system configurations and assemblies facilitate routing of infusion circuit tubing lines. Tubing lines are routed into and out from compartments of a shielding assembly for the infusion system, at locations which prevent kinking and/or crushing of the lines, and/or provide for ease in assembling the circuit. A plurality of the lines may be held together by a support frame to form a disposable infusion circuit subassembly, that can further facilitate routing of the lines.

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We claim:

1. An infusion system comprising:
 - a cabinet structure including a shell defining an interior space thereof;
 - an eluant source;
 - a shielding assembly located within the interior space of the cabinet structure, the shielding assembly including a sidewall defining a plurality of compartments and providing a barrier to radioactive radiation for the compartments, the shielding assembly further including a corresponding plurality of doors, each door, when open, providing access to the corresponding compartment via an opening in the sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;
 - a radioisotope generator contained within a first compartment of the plurality of compartments of the shielding assembly;
 - an eluant line coupled to the eluant source and to the generator, the eluant line extending from the eluant source to the generator, through the shielding assembly, at a first location between the sidewall and a first door of the plurality of doors, which corresponds to the first compartment;
 - an eluate line coupled to the generator and extending out from the first compartment and into a second compartment of the plurality of compartments of the shielding assembly, at a second location between the sidewall and both the first door and a second door of the plurality of doors, which corresponds to the second compartment, the second compartment being located immediately adjacent the first compartment;
 - a patient line coupled to the eluate line, within the second compartment, the patient line extending out from the second compartment at a third location between the sidewall and the second door, and out from the interior space through an opening in the shell of the cabinet structure.

2. The system of claim 1, wherein:
 - the eluant source comprises a reservoir and a pump;
 - the reservoir is mounted to the cabinet structure outside the interior space defined by the shell and the pump is mounted within the interior space;
 - the eluant line includes a first segment coupled to the reservoir and to the pump and a second segment coupled to the pump and to the generator; and
 - the first segment of the eluant line extends from the reservoir to the pump through another opening in the shell of the cabinet structure.

3. The system of claim 2, wherein at least one of the openings in the shell of the cabinet structure includes a grommet-type seal surrounding the corresponding line that extends therethrough.

4. The system of claim 1, further comprising:
 - a bypass flush line coupled to the eluant source and coupled to the patient line, within the second compartment;
 - wherein the flush line extends from the eluant source to the patient line, through the shielding assembly at a fourth location between the sidewall and the second door.

5. The system of claim 1, wherein the eluant line includes a filter, the filter being mounted within the interior space of the cabinet structure.

6. The system of claim 1, further comprising:
 - a filter holder mounted within the interior space of the cabinet structure; and
 - wherein the eluant line includes a filter, the filter being housed in the holder.

7. The system of claim 1, further comprising:
 - a waste bottle contained within a third compartment of the plurality of compartments of the shielding assembly; and
 - a waste line coupled to the eluate line, within the second compartment, and coupled to the waste bottle, within the third compartment;wherein the waste line extends out from the second compartment at the third location.

8. The system of claim 7, wherein the waste line extends into the third compartment at a fourth location, the fourth location being between the sidewall and a third door of the plurality of doors, which corresponds to the third compartment.

9. The system of claim 7, wherein:
 - the plurality of compartments of the shielding assembly further includes a fourth compartment located immediately adjacent the second compartment and the third compartment;
 - the waste line extends from the second compartment directly into the fourth compartment at the third location, the third location also being between the sidewall and a fourth door of the plurality of doors, which corresponds to the fourth compartment; and
 - the waste line extends from the fourth compartment directly into the third compartment at a fourth location, the fourth location being between the sidewall and a third door of the plurality of doors, which corresponds to the third compartment.

10. The system of claim 9, further comprising a retaining member mounted within the fourth compartment to hold the waste line in place within the fourth compartment.

11. The system of claim 9, wherein:
 - the patient line extends from the second compartment directly into the fourth compartment at the third location; and
 - the patient line extends out from the fourth compartment at a fifth location, the fifth location being between the sidewall and the fourth door.

12. The system of claim 11, further comprising a retaining member mounted within the fourth compartment to hold the waste line and the patient line in place within the fourth compartment.

13. The system of claim 1, wherein:
 - the plurality of compartments of the shielding assembly further includes a third compartment located immediately adjacent the second compartment;
 - the patient line extends from the second compartment directly into the third compartment at the third location, the third location also being between the sidewall and a third door of the plurality of doors, which corresponds to the third compartment; and
 - the patient line extends out from the third compartment at a fourth location, the fourth location being between the sidewall and the third door.

14. The system of claim 13, further comprising a retaining member mounted within the third compartment to hold the patient line in place within the third compartment.

15. The system of claim 1, wherein the opening in the shell of the cabinet structure includes a grommet-type seal surrounding the patient line extending therethrough.

16. A shielding assembly for an infusion system, the shielding assembly comprising:
 - a sidewall defining a plurality of compartments and providing a radioactive radiation barrier for the compartments;
 - a first passageway formed in an upper surface of a first portion of the sidewall, the first portion of the sidewall defining a first compartment of the plurality of compartments, the first compartment being sized to contain a radioisotope generator of the infusion system, and the first passageway being sized to accommodate routing of an eluate line from the generator;
 - a second passageway formed along a second portion of the sidewall, the second portion of the sidewall extending upward relative to the first portion of the sidewall and defining a second compartment of the plurality of compartments, the second compartment being sized to accommodate a waste bottle of the infusion system and the second compartment being located on a side of the second portion of the sidewall that is opposite the second passageway, and the second passageway being sized to accommodate routing of at least one extension of the eluate line from the generator.

17. The shielding assembly of claim 16, wherein the upper surface of the first portion of the sidewall extends about a perimeter of an opening into the first compartment.

18. The shielding assembly of claim 16, wherein the second passageway extends to an upper surface of the second portion of the sidewall, the upper surface of the second portion extending about a perimeter of an opening into the second compartment.

19. The shielding assembly of claim 16, further comprising a retaining member mounted within the second passageway to hold the at least one extension of the eluate line in place within the second passageway.

20. The shielding assembly of claim 16, further comprising:
a third compartment defined by a third portion of the sidewall, the third compartment extending between the first passageway and the second passageway and being sized to hold a portion of an infusion circuit of the infusion system;
wherein the portion of the infusion circuit includes the eluate line, a patient line and a waste line, the patient line and the waste line being coupled to the eluate line within the third compartment; and
the at least one extension of the eluate line includes the patient line and the waste line.
21. The shielding assembly of claim 20, further comprising a third passageway formed in an edge of the third compartment, the third passageway being sized to accommodate routing of an eluant line from an eluant source of the infusion system.
22. The shielding assembly of claim 21, further comprising a fourth passageway formed in the upper surface of the first portion of the sidewall and extending alongside the first passageway, the fourth passageway being sized to accommodate routing of the eluant line to the generator.
23. The shielding assembly of claim 16, further comprising a third passageway formed in the upper surface of the first portion of the sidewall, the third passageway being sized to accommodate routing of an eluant line from an eluant source of the infusion system to the generator.
24. The shielding assembly of claim 23, wherein the third passageway extends alongside the first passageway

25. A shielding assembly for an infusion system, the shielding assembly comprising:
a sidewall defining plurality of compartments and providing a radioactive radiation barrier for the compartments;
a first passageway formed in an upper surface of a first portion of the sidewall, the first portion of the sidewall defining a first compartment of the plurality of compartments, the first compartment being sized to contain a radioisotope generator of the infusion system, and the first passageway being sized to accommodate routing of an eluate line from the generator; and
a second compartment defined by a second portion of the sidewall, the second compartment being sized to hold a portion of an infusion circuit of the infusion system and extending immediately adjacent to the first passageway, and the infusion circuit being an extension of the eluate line from the generator.
26. The shielding assembly of claim 25, further comprising a second passageway formed in an edge of the second compartment, the second passageway being sized to accommodate routing of an eluant line from an eluant source of the infusion system.
27. The shielding assembly of claim 26, further comprising a third passageway formed in the upper surface of the first portion of the sidewall and extending alongside the first passageway, the third passageway being sized to accommodate routing of the eluant line to the generator.
28. The shielding assembly of claim 25, further comprising a second passageway formed in the upper surface of the first portion of the sidewall, the second passageway being sized to accommodate routing of an eluant line from an eluant source of the infusion system to the generator.

29. A disposable infusion circuit subassembly for an infusion system, the assembly comprising:

- an eluate line;
- a patient line;
- a waste line;
- a valve member coupling the patient line and the waste line to the eluate line; and
- a support frame including a perimeter edge, the support frame holding the valve member and a portion of each of: the eluate line, the patient line and the waste line in approximately fixed relation with respect to the perimeter edge;

wherein the perimeter edge of the support frame is sized to fit within a compartment of a shielding assembly of the infusion system; and

an end of each of the eluate line, the patient line and the waste line extends out from the perimeter edge.

30. The subassembly of claim 29, wherein the end of the eluate line extends out from a first side of the perimeter edge of the support frame, and the end of each of the patient line and the waste line extends out from a second side of the perimeter edge, the second side being opposite the first side.

31. The subassembly of claim 29, further comprising:

- an eluant line; and

wherein the support frame further holds a portion of the eluant line in approximately fixed relation with respect to the perimeter edge of the support frame;

opposing ends of the eluant line extend out from the perimeter edge; and

the portion of the eluant line extends between the opposing ends of the eluant line.

32. The subassembly of claim 31, wherein
the end of the eluate line extends out from a first side of the perimeter edge of the support frame, and the end of each of the patient line and the waste line extends out from a second side of the perimeter edge, the second side being opposite the first side;
a first of the opposing ends of the eluant line extends out from a third side of the perimeter edge, the third side extending between the first side and the second side; and
a second of the opposing ends of the eluant line extends out from the first side of the perimeter edge.
33. The subassembly of claim 29, further comprising:
a bypass line coupled to the patient line; and
wherein the support frame further holds a portion of the bypass line in approximately fixed relation with respect to the perimeter edge of the support frame; and
an end of the bypass line extends out from the perimeter edge.
34. The subassembly of claim 33, wherein:
the end of the eluate line extends out from a first side of the perimeter edge of the support frame, and the end of each of the patient line and the waste line extends out from a second side of the perimeter edge, the second side being opposite the first side; and
the end of the bypass line extends out from a third side of the perimeter edge, the third side extending between the first side and the second side.
35. The subassembly of claim 29, wherein the support frame exposes and orients the valve member for interlocking with a valve actuator receptacle within the compartment of the shielding assembly.
36. The subassembly of claim 29, wherein the support frame is formed from at least one thermoformed plastic sheet.

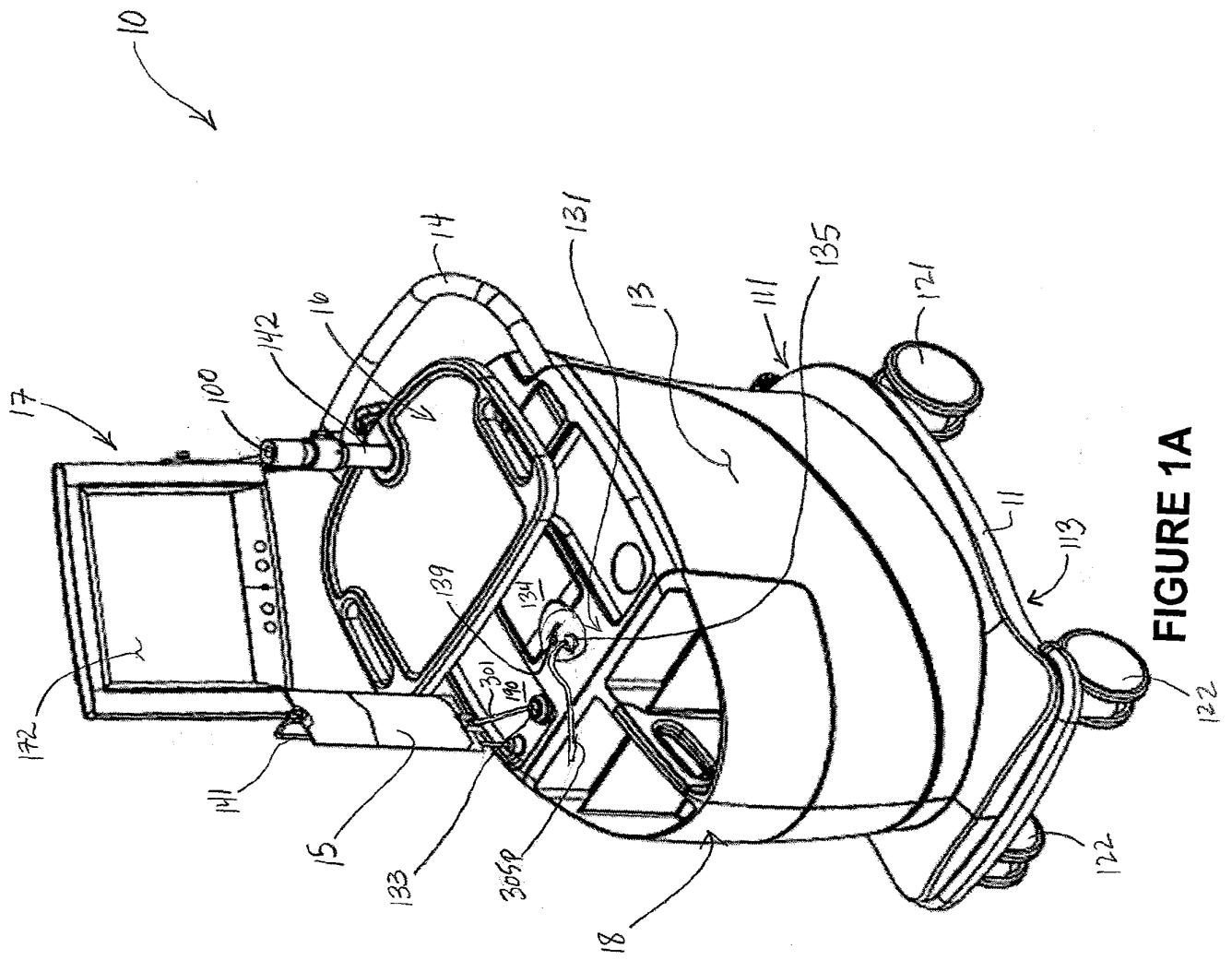


FIGURE 1A

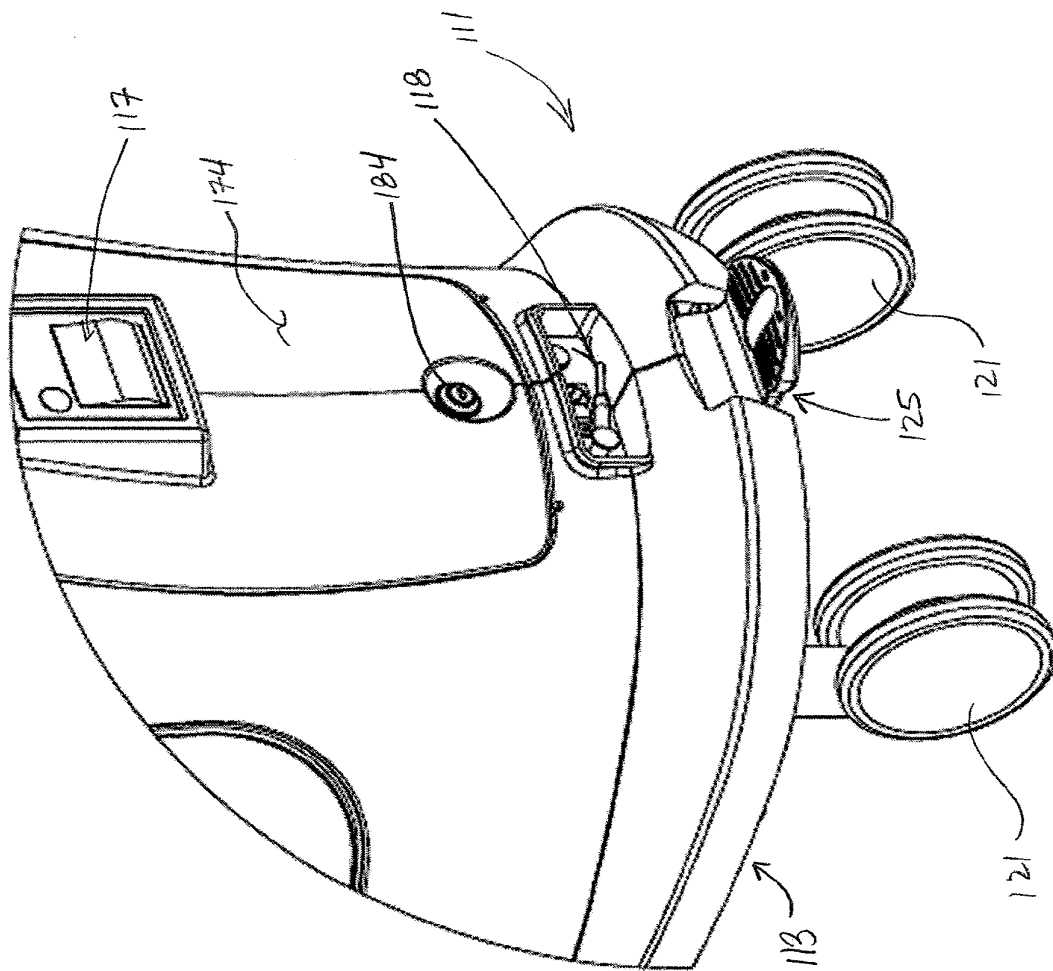


FIGURE 1B

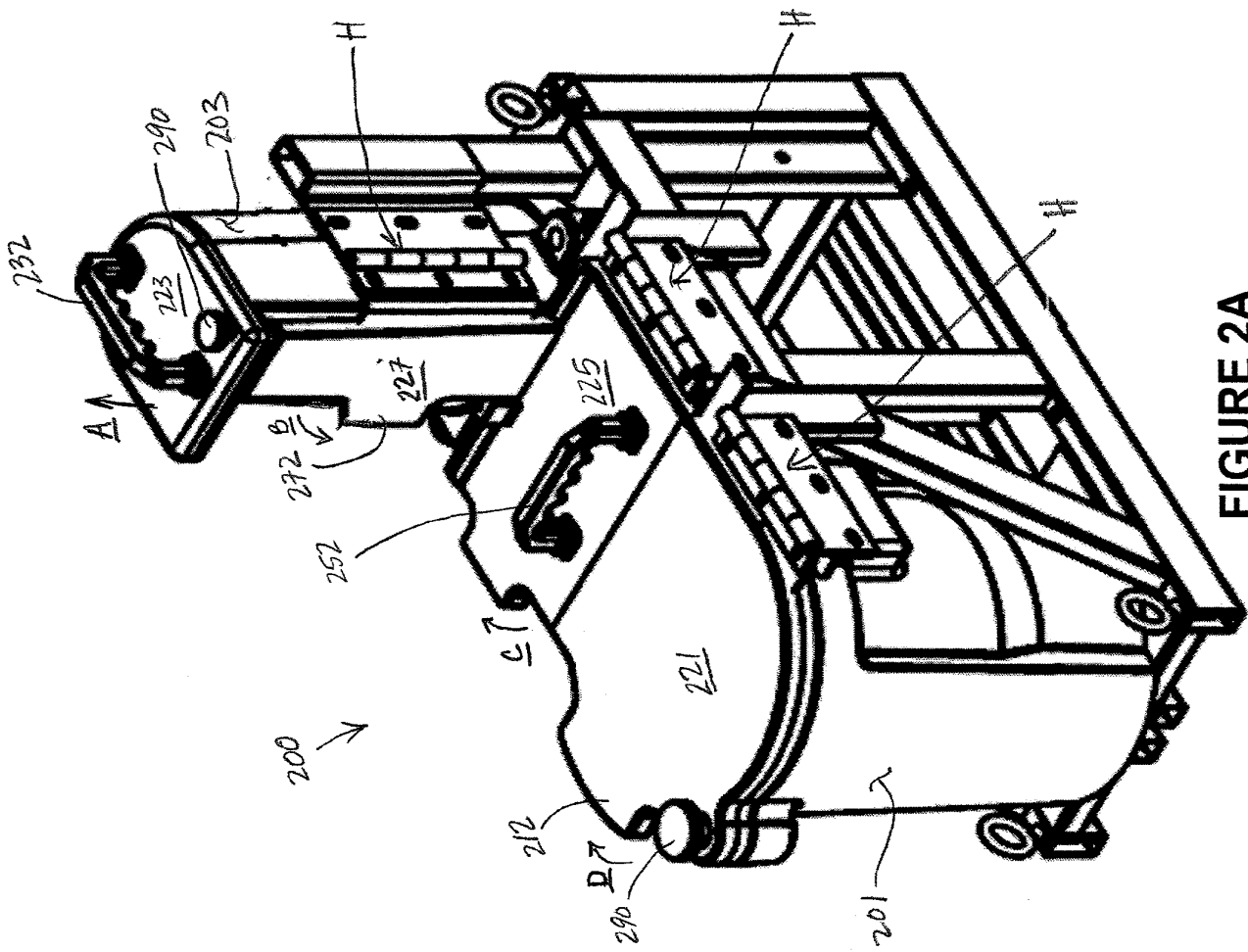


FIGURE 2A

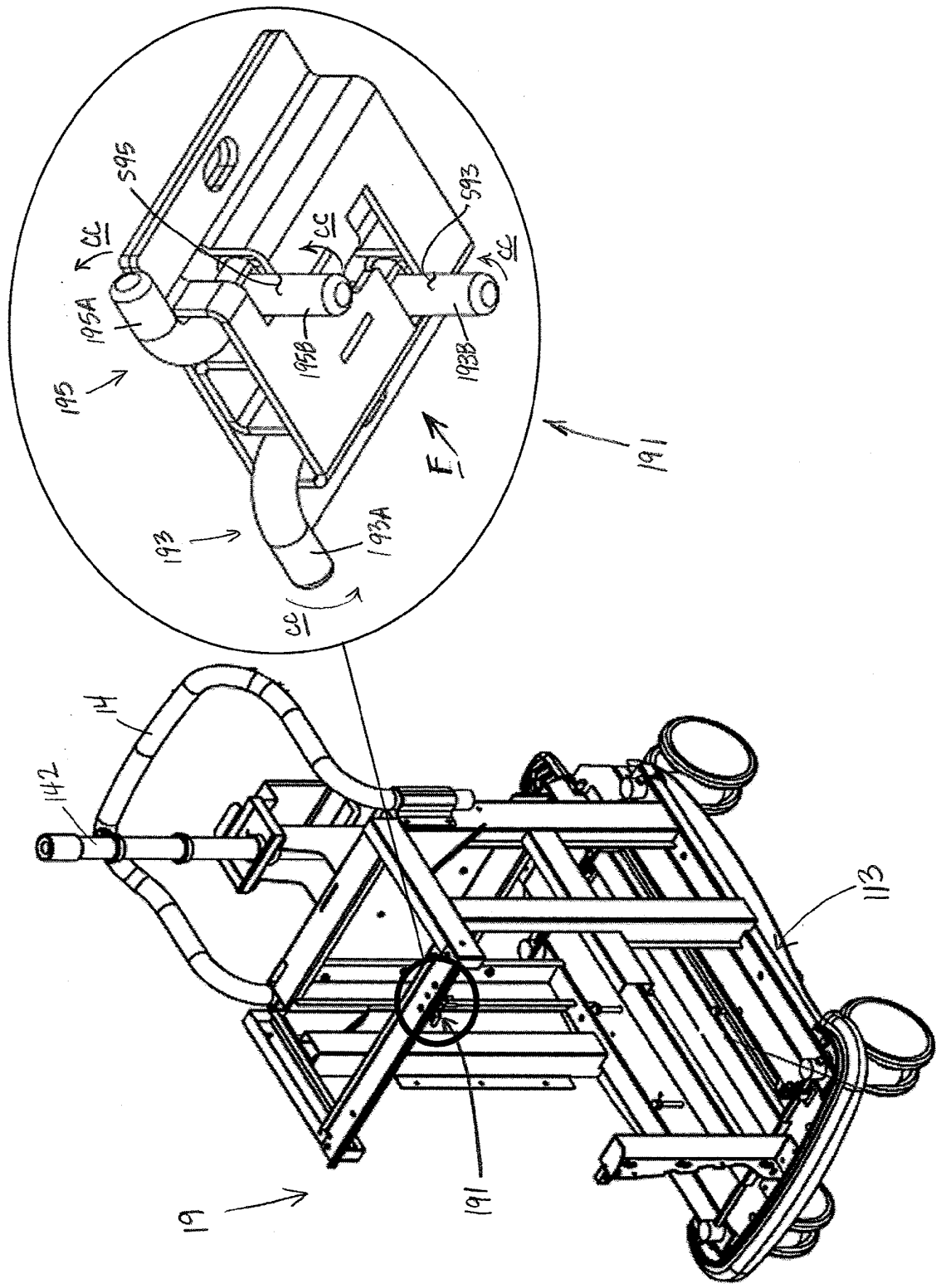


FIGURE 2B

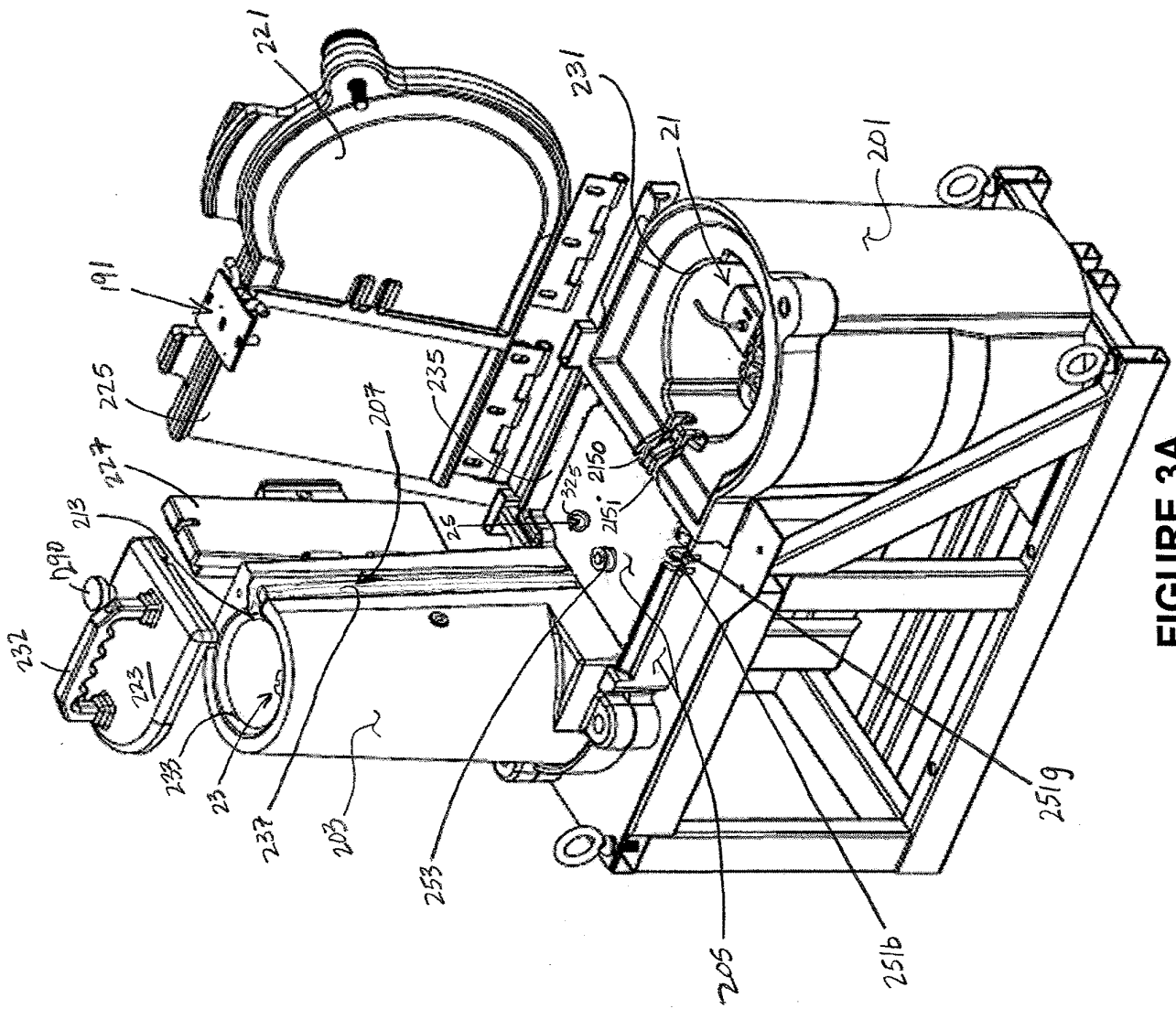


FIGURE 3A

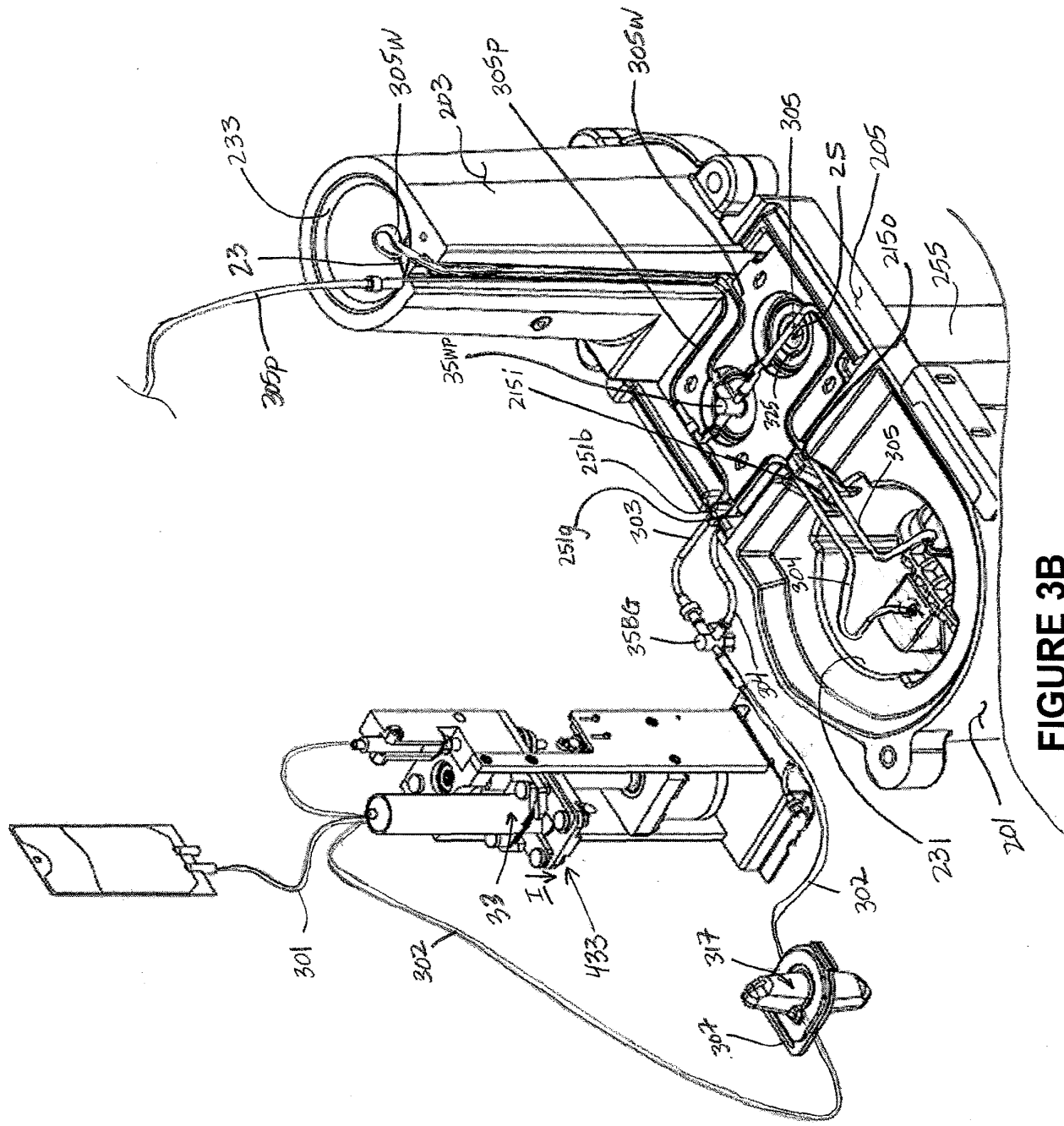


FIGURE 3B

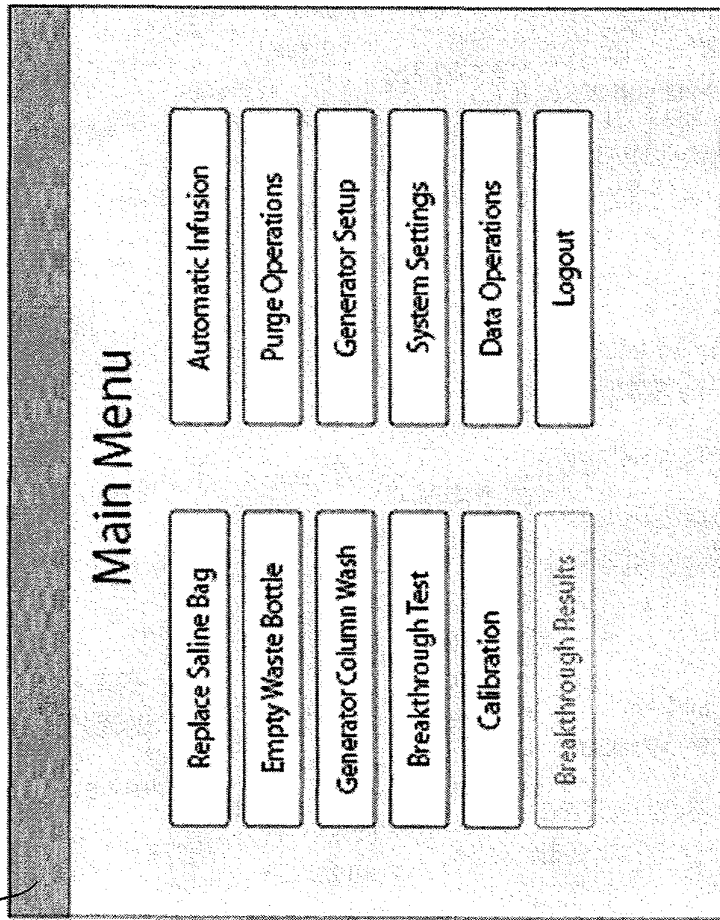


FIGURE 4

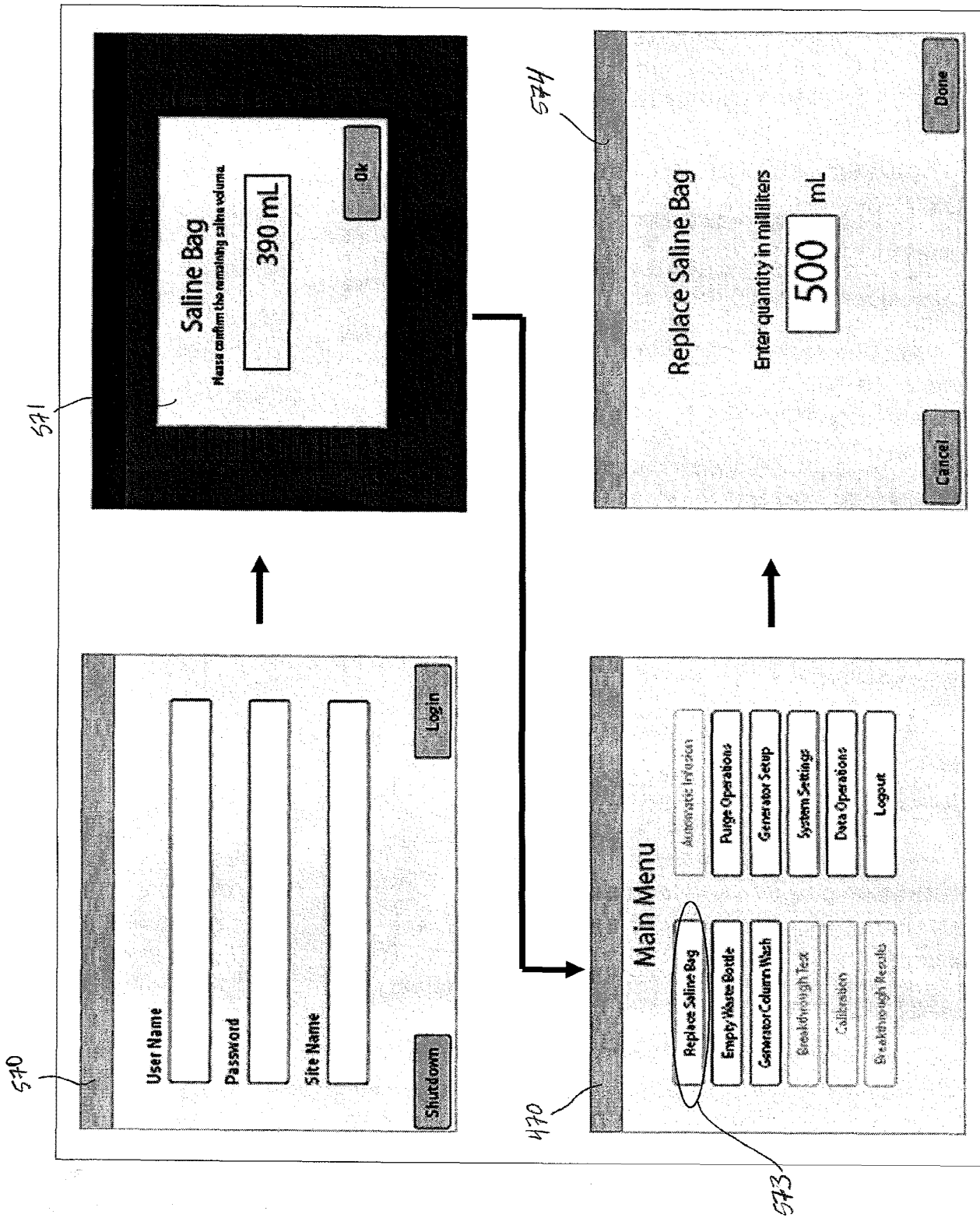


FIGURE 5A

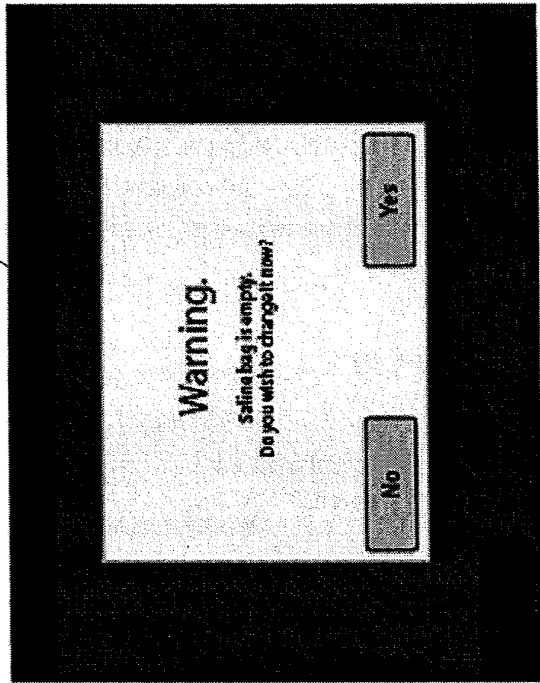
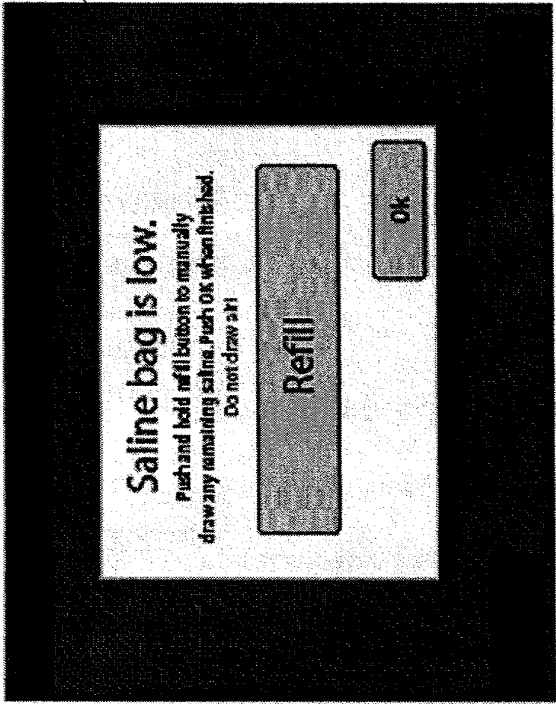


FIGURE 5B

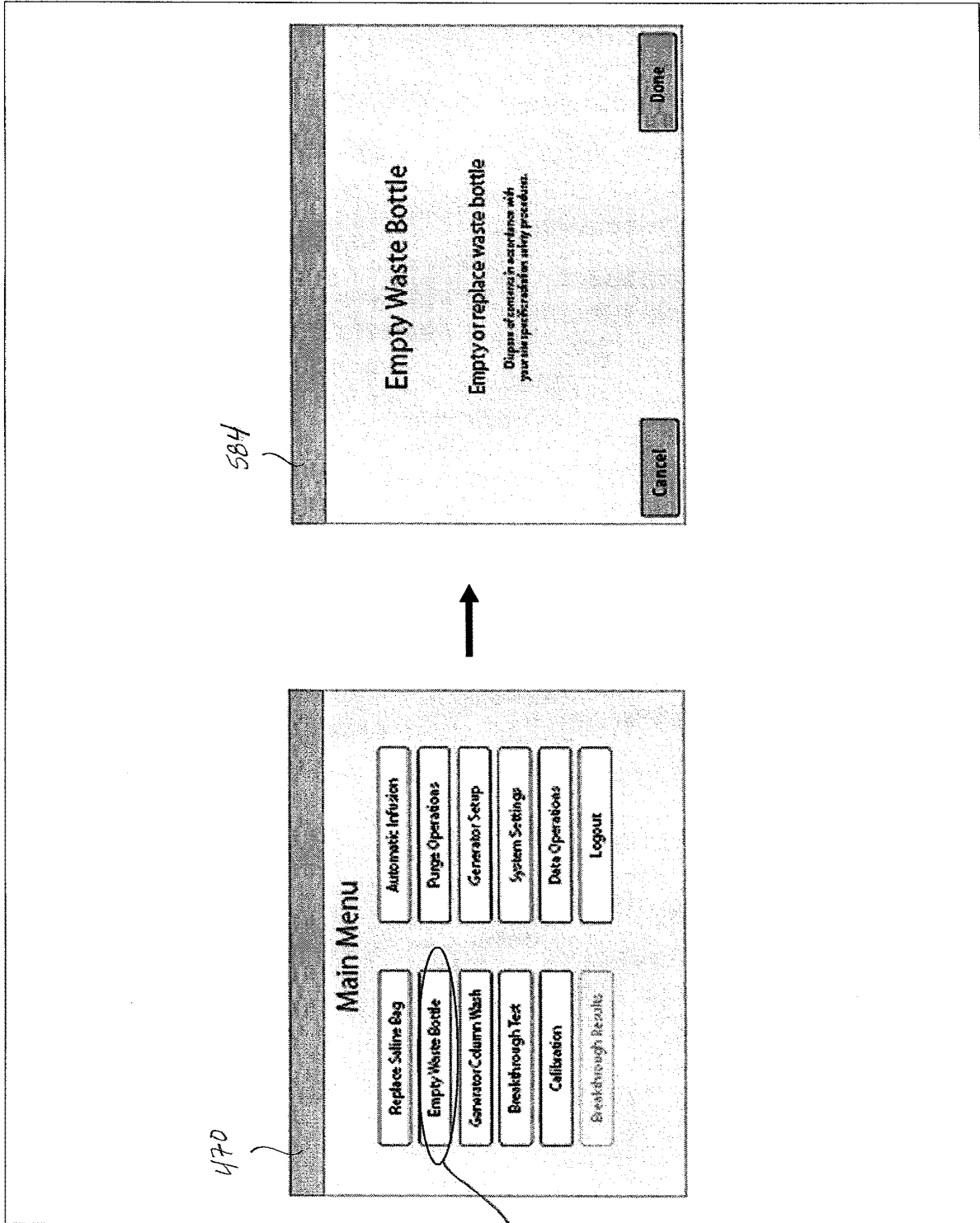
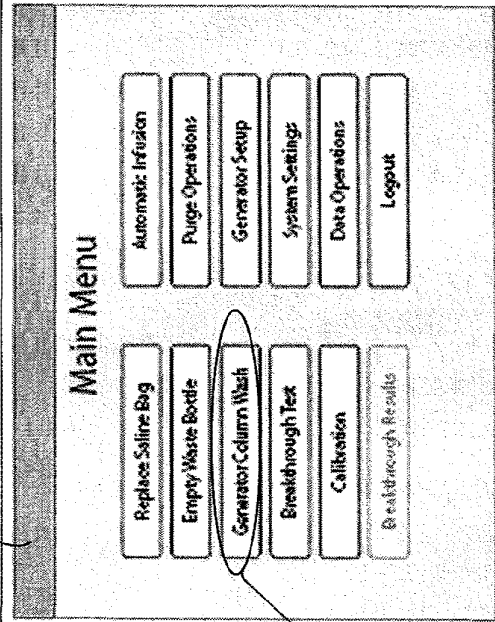


FIGURE 5C

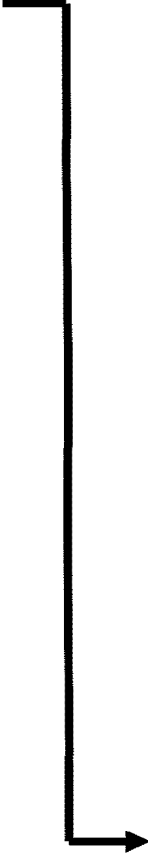
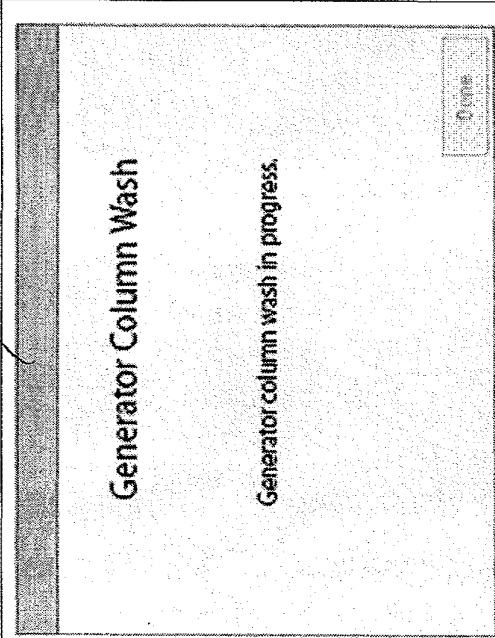
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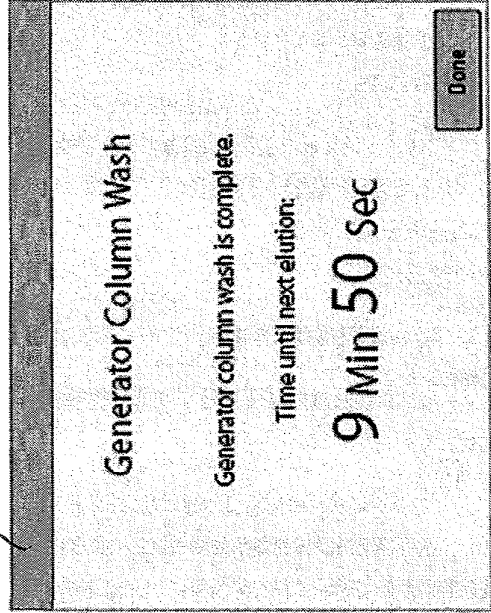


FIGURE 6

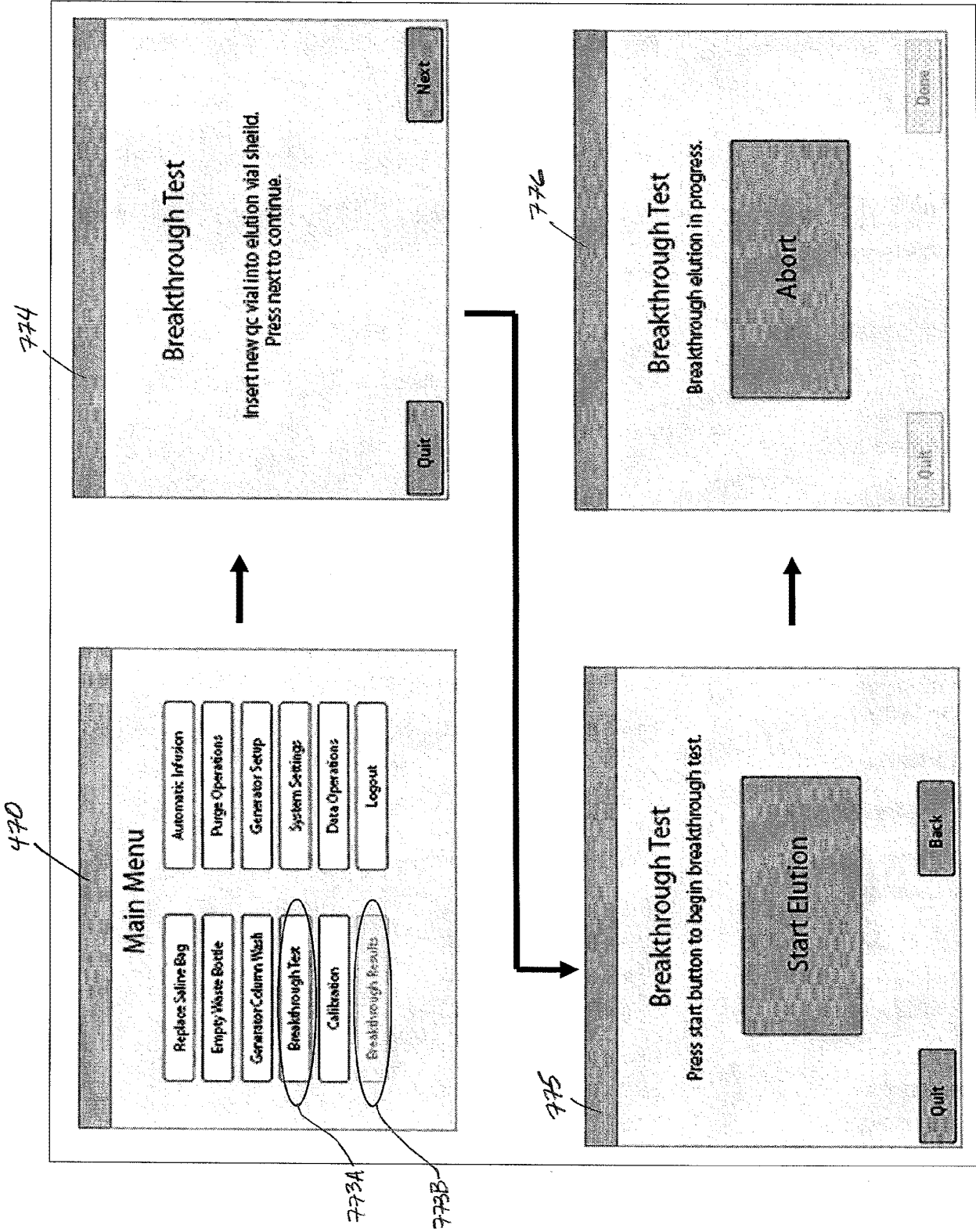


FIGURE 7A

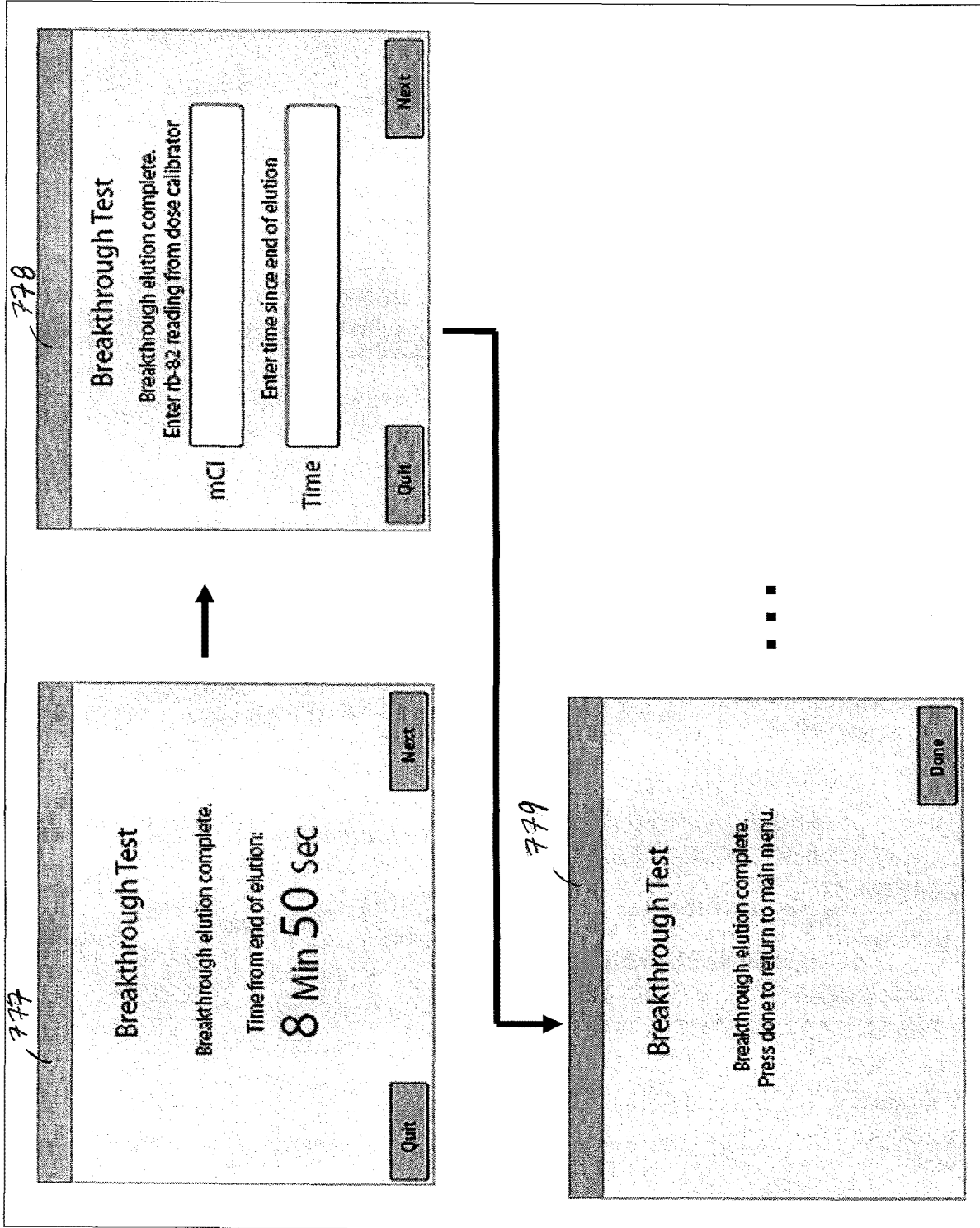


FIGURE 7B

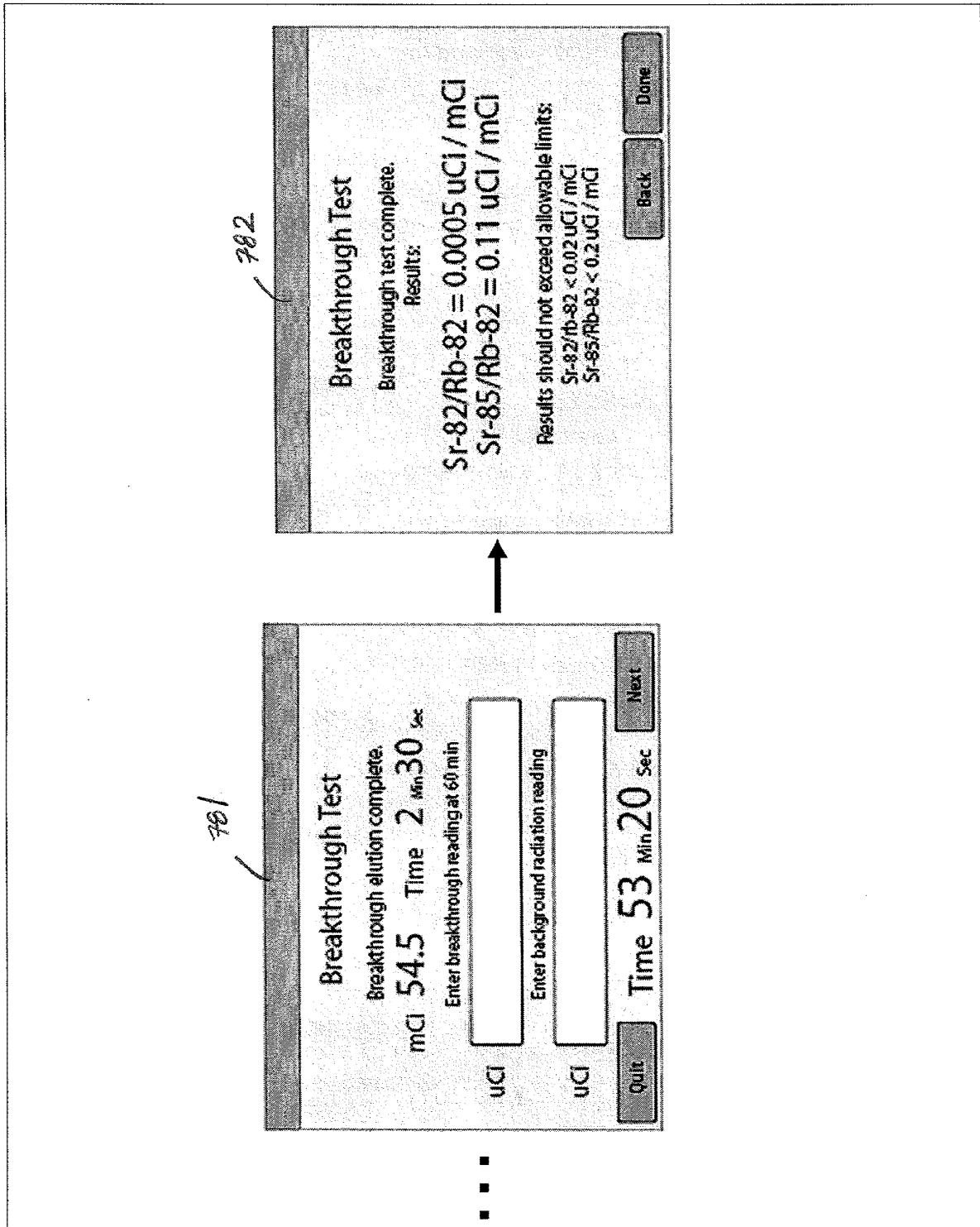


FIGURE 7C

874

Infusion System Calibration

Insert new qc vial into elution vial shield.
Press next to continue.

Quit Back Next

470

Main Menu

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

873

875

Infusion System Calibration

Patient Dose 60 mCi
 Patient Volume 50 mL
 Flow Rate 50 mL/min (DEFAULT)
 Dose Rate Threshold 1.0 mCi/sec (DEFAULT)
 Elution Volume 99 mL (DEFAULT)

Quit Next

876

Infusion System Calibration

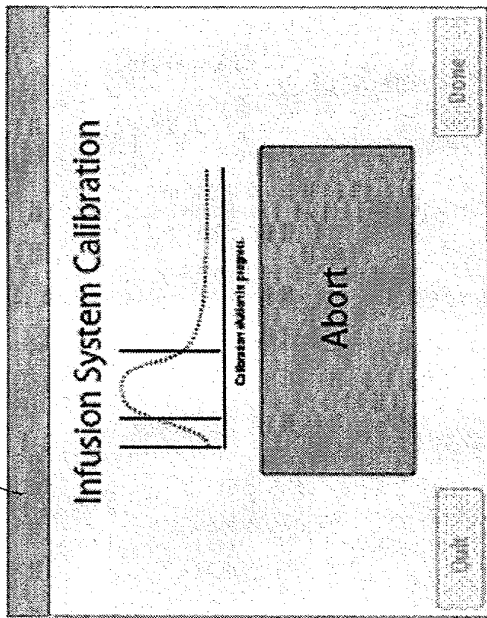
Press start button to begin calibration.

Start

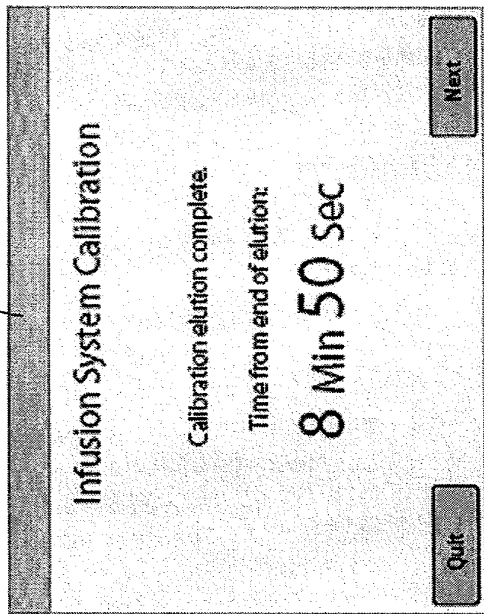
Quit Back

FIGURE 8A

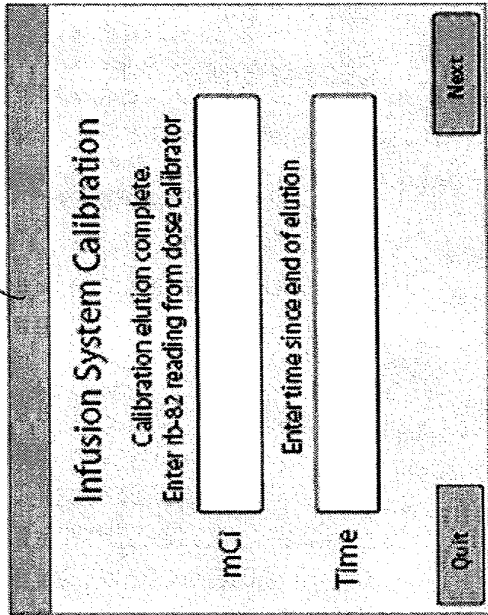
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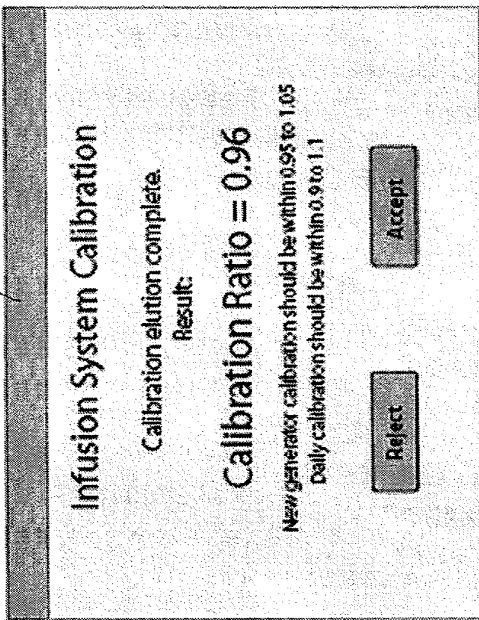


FIGURE 8B

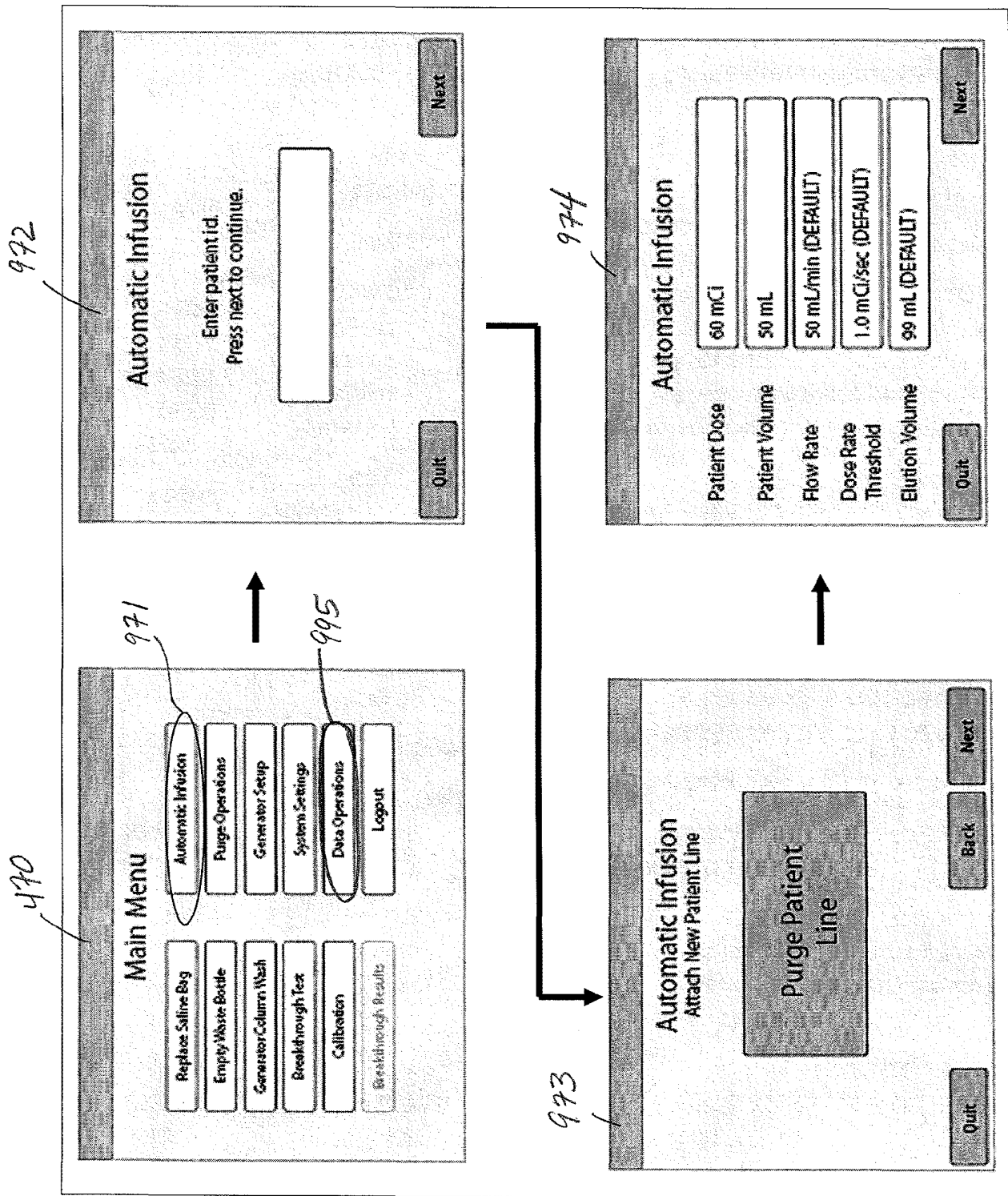


FIGURE 9A

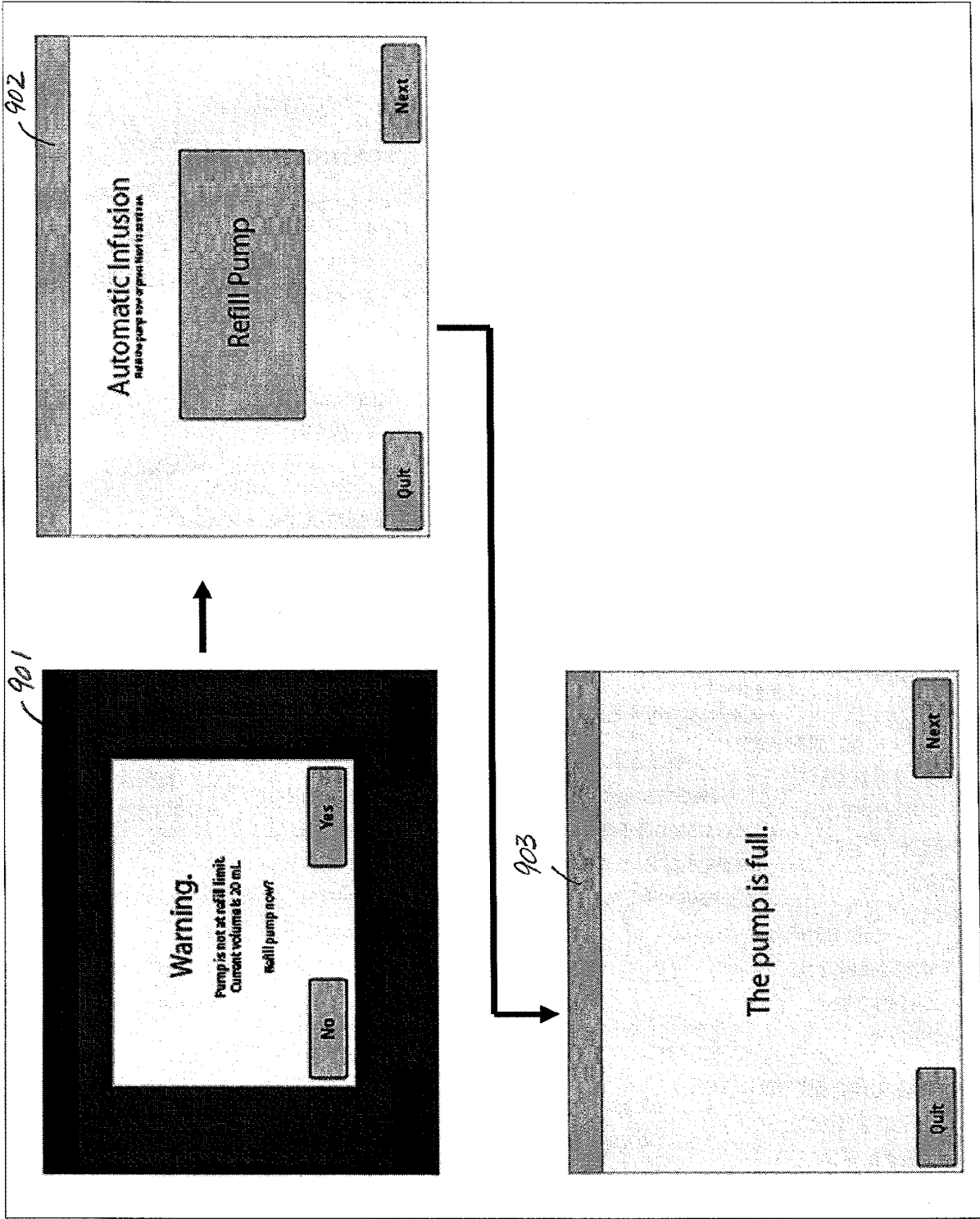


FIGURE 9B

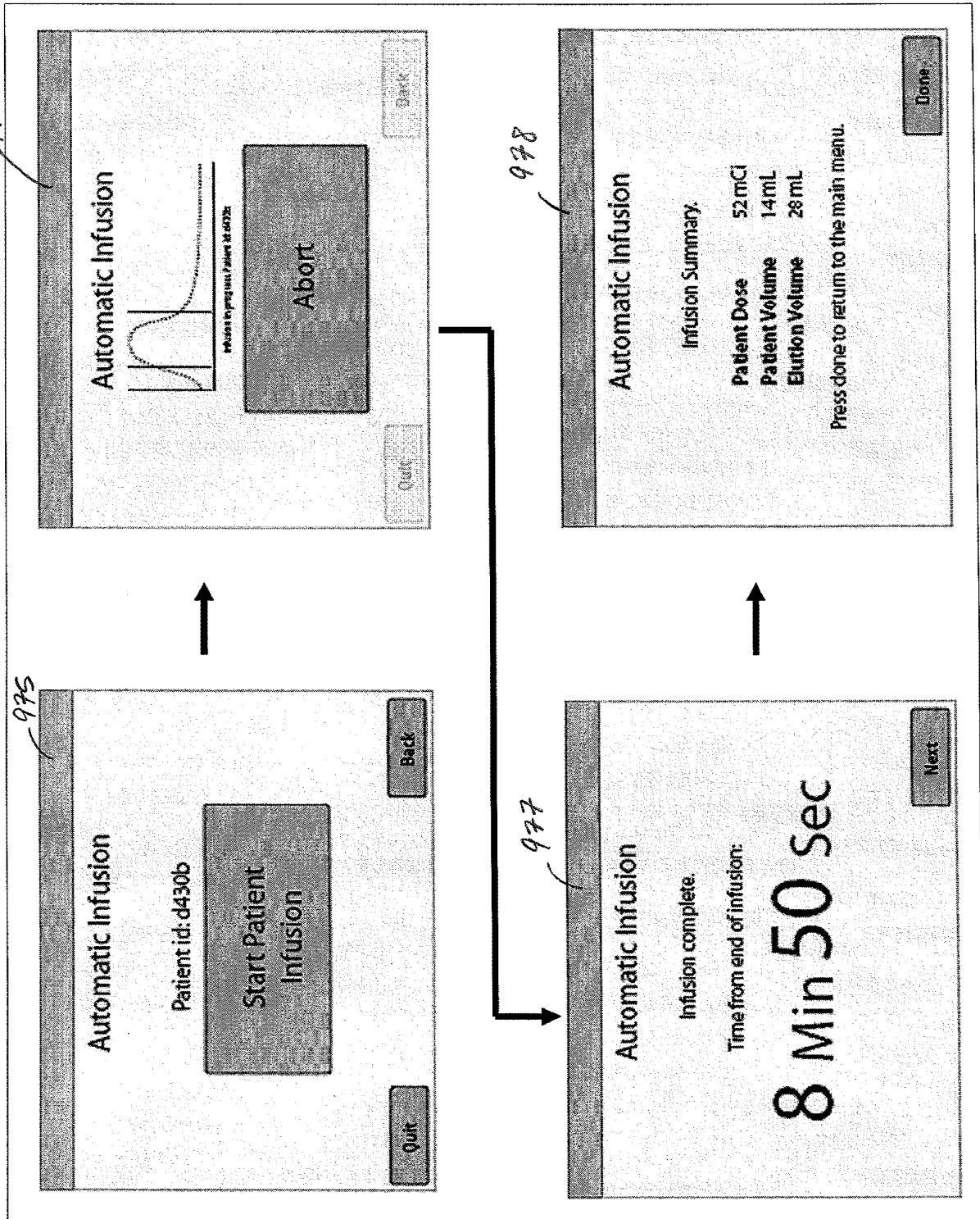


FIGURE 9C

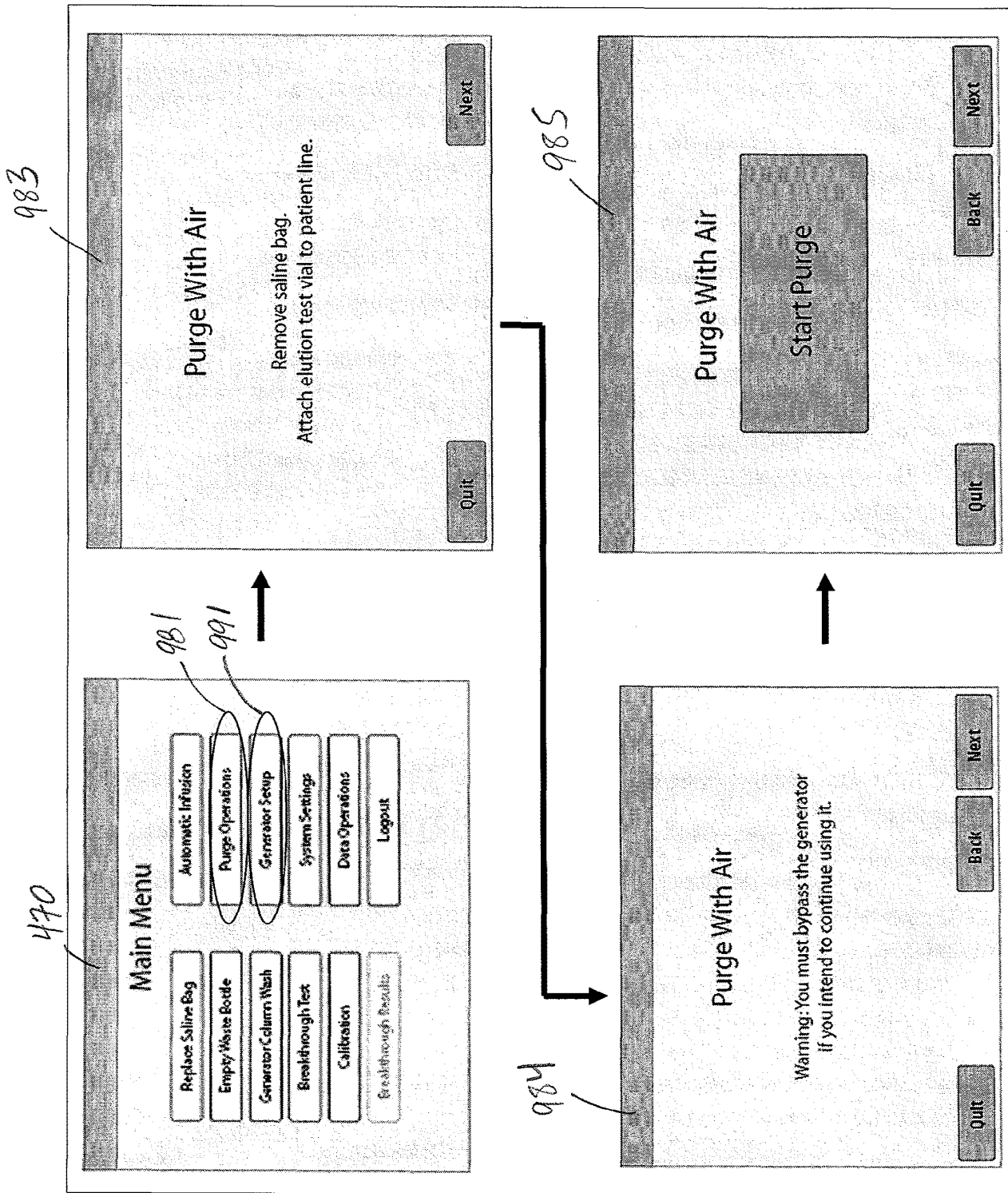


FIGURE 10

Electronic Acknowledgement Receipt

| | |
|---|--------------------------------|
| EFS ID: | 3440373 |
| Application Number: | 12137363 |
| International Application Number: | |
| Confirmation Number: | 7372 |
| Title of Invention: | INFUSION SYSTEM CONFIGURATIONS |
| First Named Inventor/Applicant Name: | Charles Quirico |
| Customer Number: | 22859 |
| Filer: | Charles D. Segelbaum |
| Filer Authorized By: | |
| Attorney Docket Number: | 56782.1.6 |
| Receipt Date: | 11-JUN-2008 |
| Filing Date: | |
| Time Stamp: | 18:17:12 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

| | |
|--|-------------|
| Submitted with Payment | yes |
| Payment Type | Credit Card |
| Payment was successfully received in RAM | \$2040 |
| RAM confirmation Number | 3781 |
| Deposit Account | |
| Authorized User | |

File Listing:

| Document Number | Document Description | File Name | File Size(Bytes) /Message Digest | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|-----------|----------------------------------|------------------|------------------|
|-----------------|----------------------|-----------|----------------------------------|------------------|------------------|

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|-------------------------------------|--|--|---|------------|----|
| 1 | Application Data Sheet | 56782_1_6_ApplicationData Sheet.pdf | 1284273 <small>b7e40ce86833c8fd11966abe84efa6714 684b80</small> | no | 6 |
| Warnings: | | | | | |
| Information: | | | | | |
| 2 | | 56782_1_6_Application.pdf | 190633 <small>6f212722655f71babe87e0285a80ab21 502541d9</small> | yes | 37 |
| | Multipart Description/PDF files in .zip description | | | | |
| | Document Description | | Start | End | |
| | Specification | | 1 | 27 | |
| | Claims | | 28 | 36 | |
| | Abstract | | 37 | 37 | |
| Warnings: | | | | | |
| Information: | | | | | |
| 3 | Drawings-only black and white line drawings | 56782_1_5_6_7_8_Drawing s.pdf | 3090157 <small>511728353556654064c53570776bc61a 122bc41f</small> | no | 23 |
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| Information: | | | | | |
| 4 | Fee Worksheet (PTO-06) | fee-info.pdf | 8523 <small>4403cd10203f809d59976199ddd5c2a06 1dd25565</small> | no | 2 |
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| Information: | | | | | |
| Total Files Size (in bytes): | | | 4573586 | | |

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US2009/047031

International filing date: 11 June 2009 (11.06.2009)

Document type: Certified copy of priority document

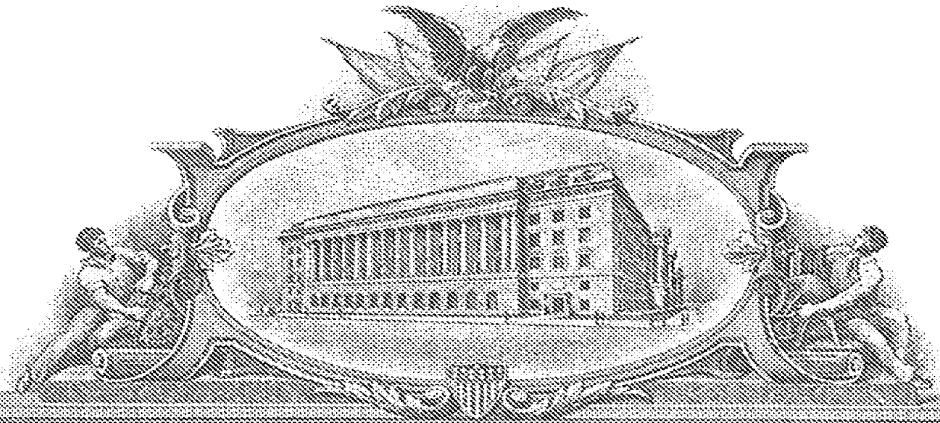
Document details: Country/Office: US
Number: 12/137,363
Filing date: 11 June 2008 (11.06.2008)

Date of receipt at the International Bureau: 01 July 2009 (01.07.2009)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



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September 12, 2009

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**APPLICATION NUMBER: 12/137,356
FILING DATE: June 11, 2008
RELATED PCT APPLICATION NUMBER: PCT/US09/47031**

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US12/137,356



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SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS

RELATED APPLICATIONS

- [01] The present application is related to the following commonly assigned utility patent applications, all of which are filed concurrently herewith and all of which are hereby incorporated by reference in their entireties: Practitioner Docket No. 56782.1.6, entitled: INFUSION SYSTEM CONFIGURATIONS; Practitioner Docket No. 56782.1.7, entitled: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION; and Practitioner Docket No. 56782.1.8, entitled: CABINET STRUCTURES SUPPORTING INFUSION SYSTEMS.

TECHNICAL FIELD

- [02] The present invention pertains to systems that generate and infuse radiopharmaceuticals, and, more particularly, to shielding assemblies thereof.

BACKGROUND

- [03] Nuclear medicine employs radioactive material for therapy and diagnostic imaging. Positron emission tomography (PET) is one type of diagnostic imaging, which utilizes doses of radiopharmaceutical, for example, generated by elution within a radioisotope generator that are injected, or infused into a patient. The infused dose of radiopharmaceutical is absorbed by cells of a target organ, of the patient, and emits radiation, which is detected by a PET scanner, in order to generate an image of the organ. An example of a radioactive isotope, which may be used for PET, is Rubidium-82 (produced by the decay of Strontium-82); and an example of a radioisotope generator, which yields a saline solution of Rubidium-82, via elution, is the CardioGen-82® available from Bracco Diagnostics Inc. (Princeton, NJ).
- [04] Whether the half-life of a particular radioactive isotope, employed by a radiopharmaceutical, is relatively short or long, a patient undergoing a nuclear imaging procedure is not typically exposed to a significant amount of radiation.

However those personnel, whose job it is to set up and maintain radiopharmaceutical infusion systems, and to administer doses therefrom, are subject to more frequent exposures to radiation. Therefore, shielding assemblies, which provide a radiation barrier to protect these personnel from excessive exposure to radiation sources, are an important component of radiopharmaceutical generators and infusion systems. These shielding assemblies are typically formed with lead sidewalls, the bulk and weight of which can pose difficulties for the personnel who regularly set up, maintain and use the systems. Thus, there is a need for improved shielding assemblies employed by systems that generate and infuse radiopharmaceuticals.

BRIEF DESCRIPTION OF THE DRAWINGS

- [05] The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.
- [06] Figure 1A is a first perspective view of an infusion system, according to some embodiments of the present invention.
- [07] Figure 1B is another perspective view of a portion of a cabinet structure of the system shown in Figure 1A, according to some embodiments.
- [08] Figure 1C is a second perspective view of the system shown in Figure 1A, according to some embodiments.
- [09] Figure 1D is a schematic of an infusion circuit, according to some embodiments of the present invention.
- [10] Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A-C, according to some embodiments of the present invention.

- [11] Figure 2B is a perspective view of a framework of the system, according to some embodiments, with an enlarged detailed view of a component of the system, according to some embodiments.
- [12] Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.
- [13] Figure 3B is a perspective view of the infusion circuit, shown in Figure 1C, configured and routed, according to some embodiments.
- [14] Figure 3C is a perspective view of a disposable infusion circuit subassembly, according to some embodiments.
- [15] Figure 3D is a frame for the subassembly shown in Figure 3C, according to some embodiments.
- [16] Figure 4 is a main menu screen shot from an interface of a computer, which may be included in systems of the present invention, according to some embodiments.
- [17] Figure 5A is a schematic showing a first group of successive screen shots from the computer interface, according to some embodiments.
- [18] Figure 5B is a pair of screen shots from the computer interface, which provide indications related to eluant volume levels in a reservoir of the system, according to some embodiments.
- [19] Figure 5C is a schematic showing a second group of successive screen shots from the computer interface, according to some embodiments.
- [20] Figure 6 is a schematic showing a third group of successive screen shots from the computer interface, according to some embodiments.
- [21] Figures 7A-C are schematics showing a fourth group of successive screen shots from the computer interface, according to some embodiments.
- [22] Figures 8A-B are schematics showing a fifth group of successive screen shots from the computer interface, according to some embodiments.
- [23] Figures 9A-C are schematics showing a sixth group of successive screen shots from the computer interface, according to some embodiments.
- [24] Figure 10 is a schematic showing a seventh group of successive screen shots from the computer interface, according to some embodiments.

DETAILED DESCRIPTION

- [25] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.
- [26] Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surrounds an interior space in which a portion of infusion system 10 is contained (-seen in Figure 1C). Shell may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13, and a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may included, for example, a keyboard, a series of control buttons or levers, a barcode reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional

embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions. Operation of system 10, which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

- [27] Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one location for another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.
- [28] Figure 1B is a perspective view of a portion of system 10, on a side 111 of the cabinet structure, which is in proximity to wheels 121. Figure 1B illustrates a lever or pedal 125, which is located for activation by a foot of the person, who grasps handle 14 to maneuver system 10. In a neutral position, pedal 125 allows wheels 121, 122 to rotate, and, if embodied as casters, to swivel freely. Pedal 125 may be depressed to a first position which prevents a swiveling of wheels 122, according to those embodiments in which wheels 122 are casters, and may be further depressed to brake wheels 121, 122 from rolling and swiveling, upon reaching a desired location. Figure 1B further illustrates a rear access panel 174, for example, providing access to circuit boards of the aforementioned controller contained within the interior space surrounded shell 13, an optional lock 184, to secure panel 174, a power jack 118, for connecting system 10 to a power source, and a printer 117 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include one or more additional connectors, or ports (not shown), which allow system 10 to be coupled to, for communication with, other devices used for nuclear imaging procedures.
- [29] Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective view of system 10, wherein a removable access panel 132 is shown

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

- [30] Turning now to Figure 1D, a schematic of an infusion circuit 300, which may be incorporated by system 10, is shown. Figure 1D illustrates circuit 300 generally divided into a first part 300A, which includes components mounted outside shell 13, and a second part 300B, which includes components mounted within the interior space surrounded by shell 13. (Parts 300A and 300B are delineated by dotted lines in Figure 1D.) Figure 1D further illustrates second part 300B of circuit 300 including a portion contained within a shielding assembly 200, which is designated schematically as a dashed line. Some embodiments of shielding assembly 200 will be described in greater detail, in conjunction with Figures 2A-B and 3A-B, below.
- [31] According to the illustrated embodiment, circuit 300 includes an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34, for monitoring pumping pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for

example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity detector 25, for measuring the activity of the eluate discharged from generator 21, in order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance. Figure 1D illustrates an eluant tubing line 301 coupled to reservoir 15 and to pump 33, and, with reference to Figures 1A-B, it may be appreciated that opening 133 provides the passageway for tubing line 301 to enter the interior space surrounded by shell 13. According to some preferred embodiments, opening 133 includes a grommet-type seal that prevents leakage of eluant, which may spill from reservoir 15, into the interior space through opening 133, while allowing a user to assemble tubing line 301 through opening 133. Likewise opening 135, which provides a passageway for patient line 305p, may include a grommet-type seal.

- [32] Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a

dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from generator into waste bottle 23, until activity detector 25 detects the desired activity of the eluate, at which time the feedback from activity detector 25 causes the controller to direct the corresponding servo-motor to re-set valve 35WP for diverting the flow of eluate into patient line 305p. According to some embodiments, once a prescribed volume of the eluate has passed through patient line 305p, the controller directs the corresponding servomotor to re-set divergence valve 35BG for diverting the flow of eluant through by-pass line 303 and into patient line 305p in order to flush, or push any eluate remaining in patient line 305p into the patient. According to some embodiments, the controller may also direct the corresponding servomotor to re-set divergence valve 35WP back toward waste bottle 23, prior to the flush through by-pass line 303, in order to prevent back flow of eluant, through line 305, toward generator 21.

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

signal upward, for maximum visibility, when pump 33 is pumping eluant and elution is taking place within generator 21, or at all times when pump 33 is pumping eluant. According to some embodiments, the light signal flashes on and off when the eluate is being diverted from generator 21 into waste bottle 23, and the light signal shines steadily when the eluate is being diverted through patient line 305p, or visa versa. According to other embodiments, a projector 100 shines a light having a first color, to indicate that eluate is being diverted to waste bottle 23, and then shines a light having a second, different color, to indicate that eluate is being directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system, including in the control room.

- [34] When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a threshold to be safe. Opening 139 is preferably located at an elevation of between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional maintenance procedures,

such as changing out generator 21 and/or other components of circuit 300, as will be described below.

- [35] Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. Additional receptacles 180 are shown formed in bin 18, on either side of a handle 182, which facilitates removal of bin 18 away from shell 13. Technical personnel may, thus, conveniently transport bin 18 to a storage area for a collection of supplies, for example, sharps, gloves, tubing lines, etc..., into one or more receptacles 180 thereof, and/or to a waste container where separate receptacles 180 of bin 18 may be emptied of waste, such as packaging for the aforementioned supplies, for example, deposited therein during infusion procedures.
- [36] Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. According to the illustrated embodiment, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed by a

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

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

materials, and then assembled together according to methods known to those skilled in the art.

- [38] According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a latch component 191 is provided to hold each of doors 221, 225 in an opened position, thereby, preventing doors 221, 225 from falling closed, which could pinch/crush fingers of technical personnel and/or tubing lines of circuit 300, when in the midst of a maintenance procedure. Figure 2B is a perspective view of framework 19 of the cabinet structure of system 10, according to some embodiments, to which latch component 191 is mounted; Figure 2B includes an enlarged detailed view of latch component 191, according to some embodiments. Figure 2B illustrates latch component 191 including a first pin 193, corresponding to door 225, and a second pin 195, corresponding to door 221; each pin 193, 195 includes a lever end 193A, 193B, respectively, and a holding end 193B, 195B, respectively. An edge of each door 221, 225, upon opening of doors 221, 225, may push past the holding end 195B, 193B of the corresponding pin 195, 193, in a first direction, per arrow F, and then may rest against a respective side S95 and S93 of each end 195B, 193B, until the corresponding lever end 195A, 193A is rotated in a counter-clockwise direction, per arrow cc, thereby moving the corresponding holding end 193B, 195B to make way for the closing of doors 221, 225. Doors 221, 225 being held by latch component 191 in an open position may be seen in Figure 3A.
- [39] With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21

is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225. The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

- [40] Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.
- [41] Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover.

- [42] Figure 3A further illustrates sidewall 205 including a valve actuator receptacle 253, into which divergence valve 35WP is mounted, to be controlled by one of the servomotors (not shown) of system 10, and an opening 325 for activity detector 25. Activity detector 25 is mounted in a shielded well 255 that extends downward from opening 325 (shown in Figure 3B), and, with reference to Figure 3B, tubing line 305 passes over opening 325 so that detector 25 can detect an activity of the eluate, which passes therethrough. According to some embodiments, the positioning, within the compartment enclosed by sidewall 205, of the components of the portion of infusion circuit 300 which are shown routed therein, is facilitated by providing the components mounted in a frame 39 as a disposable subassembly 390, an embodiment of which is illustrated by Figures 3C-D.
- [43] Figure 3C is a perspective view of subassembly 390, and Figure 3D is a perspective view of frame 39. According to the embodiment illustrated by Figure 3D, frame 39 is formed from mating trays 39A, 39B, for example, formed from a thermoformed plastic, which fit together to capture, therebetween, and hold, in fixed relation to a perimeter edge of frame 39, divergence valve 35WP and portions of eluant tubing line 304, by-pass tubing line 303, eluate tubing line 305, waste line 305w and patient line 305p. Figure 3C illustrates the perimeter edge divided into a first side 391, a second side 392, opposite first side 391, a third side 393, extending between first and second sides 391, 392, and a fourth side 394, opposite third side 393. Although Figure 3D shows trays 39A, 39B individually formed for fitting together, according to alternate embodiments, mating trays of frame 39 may be parts of a continuous sheet of plastic folded over on itself.
- [44] According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and 407 of patient line 305p and waste line 305w,

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

[45] As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

[46] With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is

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

- [47] Figure 3B further illustrates a filter holder 317 that is mounted alongside an interior surface of shell 13 to hold filter 37 (Figure 1D) of tubing line 302. Filter holder 317, like frame 39 for subassembly 390, may be formed from a thermoformed plastic sheet; holder 317 may have a clam-shell structure to enclose filter 37 in an interior space, yet allow tubing line 302, on either side of filter 37, to extend out from the interior space, in between opposing sides of the clam-shell structure. Holder 317 is shown including an appendage 307 for hanging holder 317 from a structure (not shown) inside shell 13.
- [48] Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which

radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17 away from radioactive radiation.

- [49] According to some preferred embodiments, computer 17 is pre-programmed to guide the user, via monitor 172, through procedures necessary to maintain system 10, to perform quality control tests on system 10, and to operate system 10 for patient infusions, as well as to interact with the user, via the touch-screen capability of monitor 172, according to preferred embodiments, in order to track volumes of eluant and eluate contained within system 10, to track a time from completion of each elution performed by system 10, to calculate one or more system parameters for the quality control tests, and to perform various data operations. It should be understood that screen shots shown in Figures 4-9C are exemplary in nature and are presented to provide an outline of some methods of the present invention in which computer 17 facilitates the aforementioned procedures, without limiting the scope of the invention to any particular computer interface format.
- [50] Figure 4 is a screen shot of a main menu 470, which is presented by computer 17 on monitor 172, according to some embodiments. Main menu 470 includes a listing of each computer-facilitated operation that may be selected by the user, once the user has logged on.
- [51] Figure 5A is a schematic showing a series of screen shots which includes a log in screen 570. After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. According to some embodiments, when the user touch-selects the data entry fields of screen 570 or 571, or of any of the other screens presented herein, below, a virtual keyboard is displayed for touch-select data entry into the selected data entry field; alternately, computer 17 may be augmented with another type of device for user data entry, examples of which include, without limitation, a peripheral keyboard device, a

storage medium (i.e. disk) reader, a scanner, a barcode reader (or other reader of encoded information), a hand control (i.e. mouse, joy stick, etc...).

[52] If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag, which leads computer 17 to prompt the user to enter a quantity of saline contained by the new saline bag, via a screen 574. Thus, computer 17 uses either the confirmed eluant/saline volume, via screen 571, or the newly entered eluant/saline volume, via screen 574, as a baseline from which to track depletion of reservoir volume, via activations of pump 33, in the operation of system 10. With reference to Figure 5B, during the operation of system 10, when computer 17 detects that the eluant reservoir/saline bag has been depleted to a predetermined volume threshold, computer 17 warns the user, via a screen 577. If the user has disregarded screen 577 and continues to deplete the saline bag, computer 17 detects when the saline bag is empty and provides indication of the same to the user, via a screen 578. To replenish the reservoir/saline bag, the user may either refill the reservoir/bag or replace the empty reservoir/bag with a full reservoir/bag. According to some embodiments, system 10 automatically precludes any further operation of the system until the reservoir is replenished.

[53] In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via

presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied.

- [54] In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate is being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.
- [55] Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82® that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

- [56] Once the appropriate amount of time has lapsed, after the elution process of generator column wash, a first quality control test may be performed. With reference to Figure 7A, the user may select, from main menu 470, an item 773A, which directs computer 17 to begin a sequence for breakthrough testing. In conjunction with the selection of item 773A, the user attaches a needle to an end of patient line 305p and inserts the needle into to a test vial, for the collection of an eluate sample therefrom, and, according to Figure 7A, computer 17 presents a screen 774, which instructs the user to insert the test vial into a vial shield, which may be held in recess 101 of shell 13 (Figure 1C).
- [57] Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.
- [58] Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777. With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a

screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

- [59] After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable limits; the screen may

further direct the user to contact the generator supplier, for example, to order a replacement generator.

- [60] With reference to Figure 8A, during the aforementioned 60 minute time period, while waiting to complete the breakthrough testing, the user may perform calibration by selecting item 873 from main menu 470. Upon selection of item 873, computer 17 presents a screen 874, which instructs the user to insert a new test vial into an elution vial shield. In addition to placing the vial in the shield, the user, preferably, replaces patient line 305p with a new patient line, and then attaches a needle to the end of the new patient line for insertion into the test vial, in order to collect an eluate sample therefrom. After performing these steps, the user may move to screen 875, wherein a plurality of data entry fields are presented; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary. Once the user confirms entry of desired parameters for the calibration, the user may enter a command, via interaction with a subsequent screen 876, to start the calibration elution.
- [61] With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration

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

- [62] With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen 974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

- [63] With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with a option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type of light signal, for example, the more rapidly flashing light, previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.
- [64] Printer 117 (Figure 1B) may be activated to print out a hard copy of the infusion summary, on which the patient identification number and pertinent system parameters are also printed, for reference. Alternatively, or in addition, according to some embodiments, the summary of the infusion, which includes the patient

identification number and pertinent system parameters, may be downloaded onto a computer readable storage device to be transferred to one or more remote computers and/or automatically transferred thereto, via wireless communication or a cable connection. The one or more remote computers may be included, for example, in a hospital information system, and/or an inventory system, and/or a billing system, and/or in a medical imaging system. With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data.

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

with air, so that air is not blown across the generator, since air through generator 21 may compromise both the function and the aseptic nature of generator 21.

- [66] According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.
- [67] The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup. When the user selects item 991, computer 17 may present an option for guidance in removing an old, depleted, generator and a set of tubing lines, prior to installing the new generator, or an option to just be guided in the installation of the new generator.
- [68] In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

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|---|---|------------------------|-----------|
| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.5 |
| | | Application Number | |
| Title of Invention | SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS | | |
| The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application. | | | |

Secrecy Order 37 CFR 5.2

Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

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|---|-------------------|---|--------------------|--|---|
| Applicant 1 | | | | | Remove |
| Applicant Authority | | <input checked="" type="radio"/> Inventor | | <input type="radio"/> Legal Representative under 35 U.S.C. 117 | <input type="radio"/> Party of Interest under 35 U.S.C. 118 |
| Prefix | Given Name | Middle Name | Family Name | Suffix | |
| | Charles | | Quirico | | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | | |
| City | | State/Province | | Country of Residenceⁱ | |
| Citizenship under 37 CFR 1.41(b)ⁱ | | | | | |
| Mailing Address of Applicant: | | | | | |
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| Address 2 | | | | | |
| City | | State/Province | | | |
| Postal Code | | Countryⁱ | | | |
| Applicant 2 | | | | | Remove |
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| Applicant 3 | | | | | Remove |
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| | Dan | D. | Darst | | |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.5 | |
| | | Application Number | | |
| Title of Invention | SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS | | | |
| Citizenship under 37 CFR 1.41(b) i | | | | |
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| City | | | State/Province | |
| Postal Code | | | Country ⁱ | |
| Applicant 4 | | | | <input type="button" value="Remove"/> |
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| | Eric | J. | Krause | |
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| Applicant 5 | | | | <input type="button" value="Remove"/> |
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| Applicant 6 | | | | <input type="button" value="Remove"/> |
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| | Jake | | Childs | |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.5 |
| | | Application Number | |
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| Mailing Address of Applicant: | | | | |
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| Applicant 7 | | | | <input type="button" value="Remove"/> |
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| City | | State/Province | | |
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| Applicant 8 | | | | <input type="button" value="Remove"/> |
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| | Dan | | Clements | |
| Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service | | | | |
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| Citizenship under 37 CFR 1.41(b)ⁱ | | | | |
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| All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. | | | | |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.5 |
| | | Application Number | |
| Title of Invention | SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS | | |

Application Information:

| | | | |
|---|---|---|--------------------------|
| Title of the Invention | SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS | | |
| Attorney Docket Number | 56782.1.5 | Small Entity Status Claimed | <input type="checkbox"/> |
| Application Type | Nonprovisional | | |
| Subject Matter | Utility | | |
| Suggested Class (if any) | | Sub Class (if any) | |
| Suggested Technology Center (if any) | | | |
| Total Number of Drawing Sheets (if any) | 23 | Suggested Figure for Publication (if any) | |

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| <input type="checkbox"/> | Request Early Publication (Fee required at time of Request 37 CFR 1.219) |
| <input type="checkbox"/> | Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing. |

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| Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing. | | | |
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Domestic Benefit/National Stage Information:

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| This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification. | | | |
| Prior Application Status | | | <input type="button" value="Remove"/> |
| Application Number | Continuity Type | Prior Application Number | Filing Date (YYYY-MM-DD) |
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| Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button. | | | <input type="button" value="Add"/> |

Foreign Priority Information:

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| This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a). |
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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | 56782.1.5 | |
| | | Application Number | | |
| Title of Invention | SHIELDING ASSEMBLIES FOR INFUSION SYSTEMS | | | |
| | | | | <input type="button" value="Remove"/> |
| Application Number | Country ⁱ | Parent Filing Date (YYYY-MM-DD) | Priority Claimed | |
| | | | <input type="radio"/> Yes <input checked="" type="radio"/> No | |
| Additional Foreign Priority Data may be generated within this form by selecting the Add button. | | | | <input type="button" value="Add"/> |

Assignee Information:

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| | | | <input type="button" value="Remove"/> |
| Assignee 1 | | | |
| If the Assignee is an Organization check here. <input checked="" type="checkbox"/> | | | |
| Organization Name | Bracco Diagnostics, Inc. | | |
| Mailing Address Information: | | | |
| Address 1 | 107 College Road East | | |
| Address 2 | | | |
| City | Princeton | State/Province | NJ |
| Country ⁱ | US | Postal Code | 08540 |
| Phone Number | | Fax Number | |
| Email Address | | | |
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Signature:

| | | | | | |
|--|------------------------|-----------|-------------------|---------------------|-------|
| A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature. | | | | | |
| Signature | /Charles D. Segelbaum/ | | Date (YYYY-MM-DD) | 2008-06-11 | |
| First Name | Charles D. | Last Name | Segelbaum | Registration Number | 42138 |

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

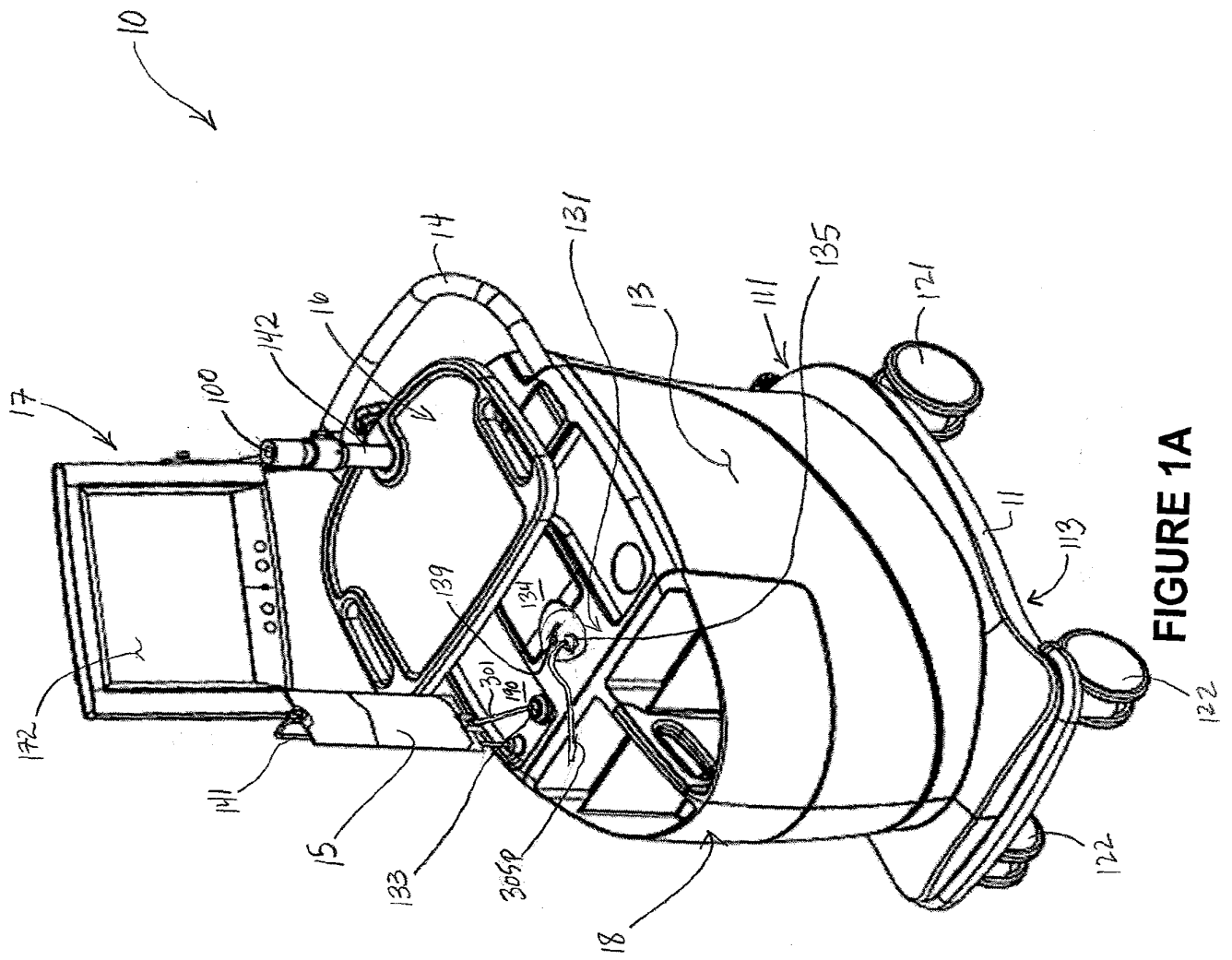


FIGURE 1A

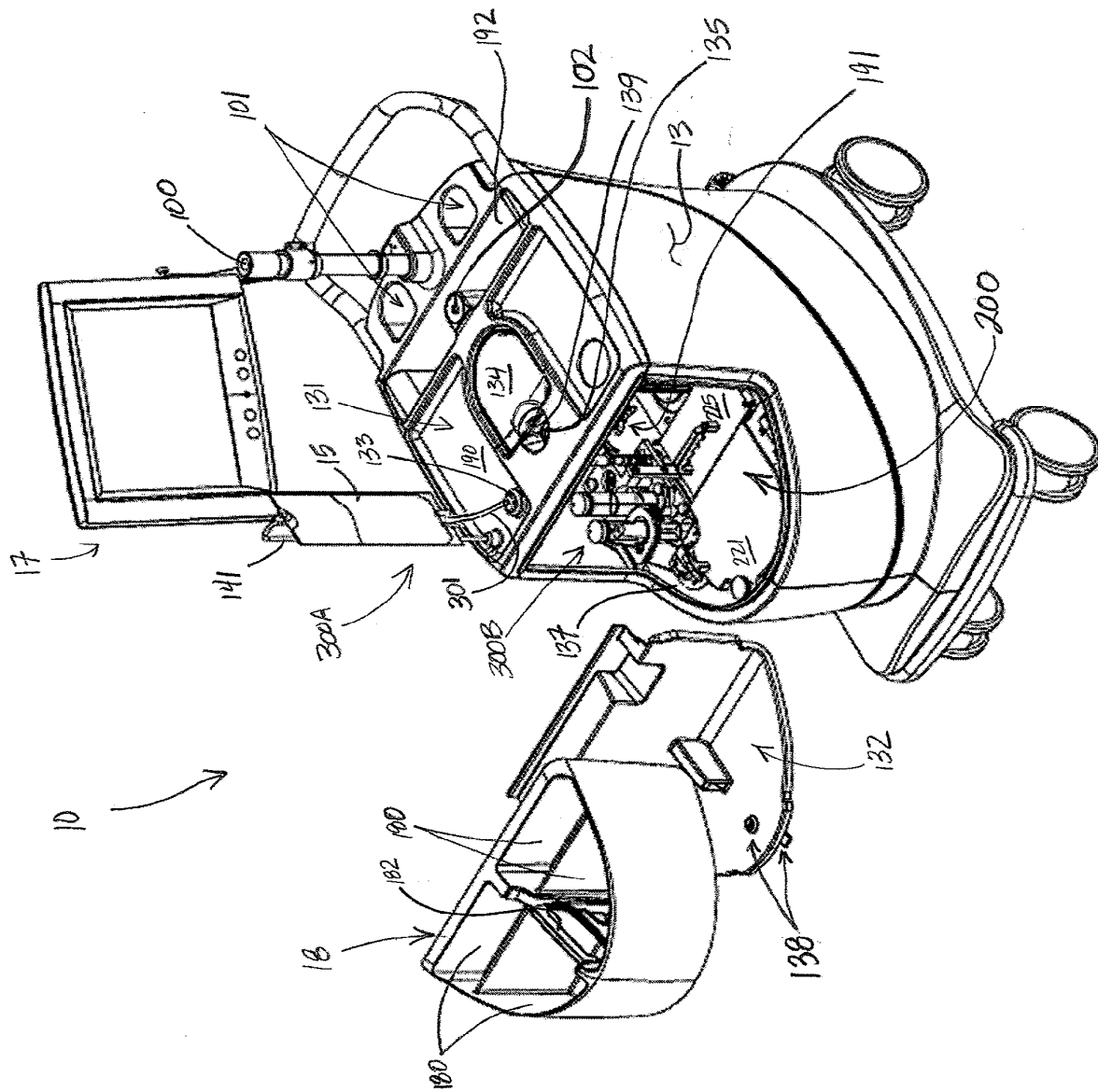


FIGURE 1C

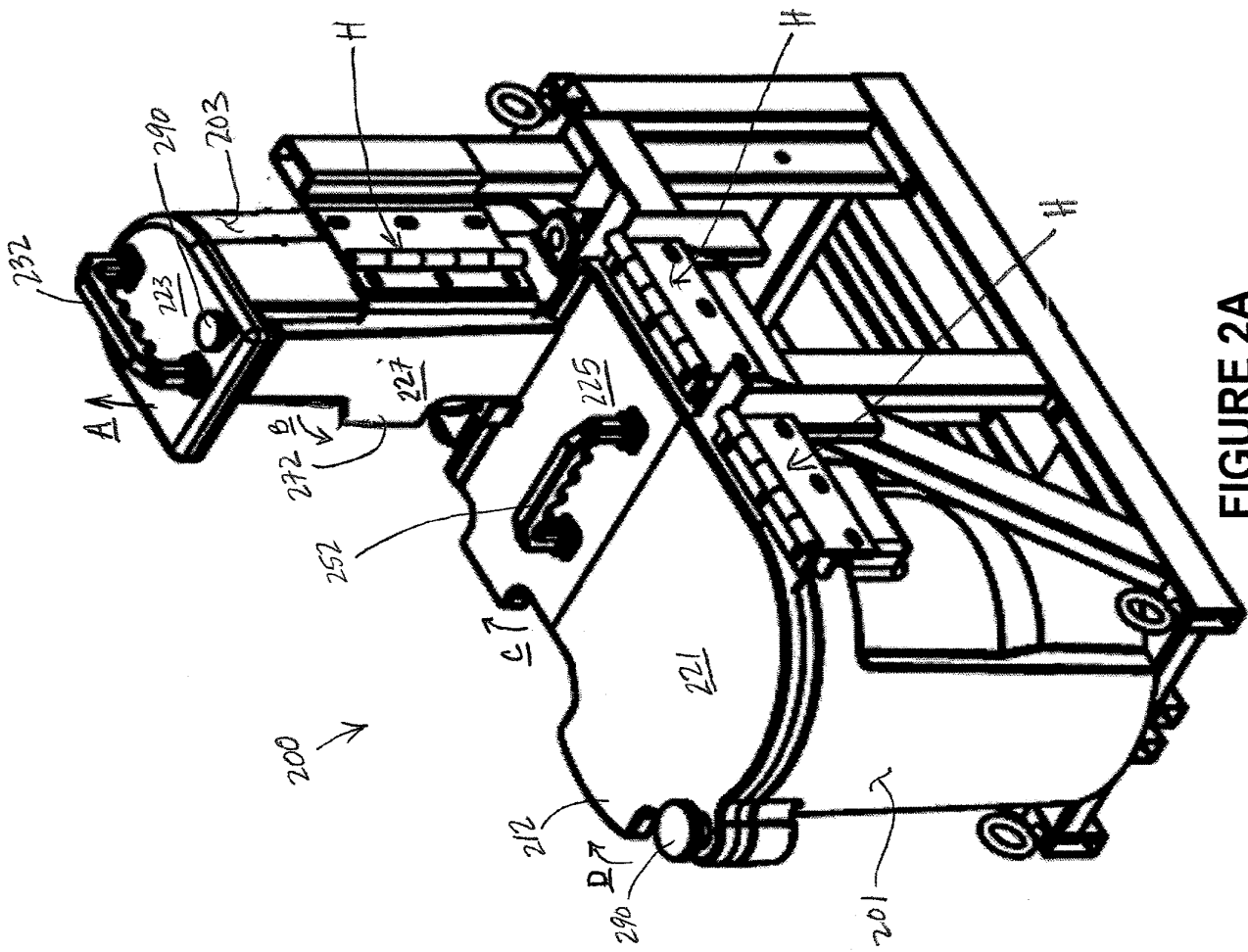


FIGURE 2A

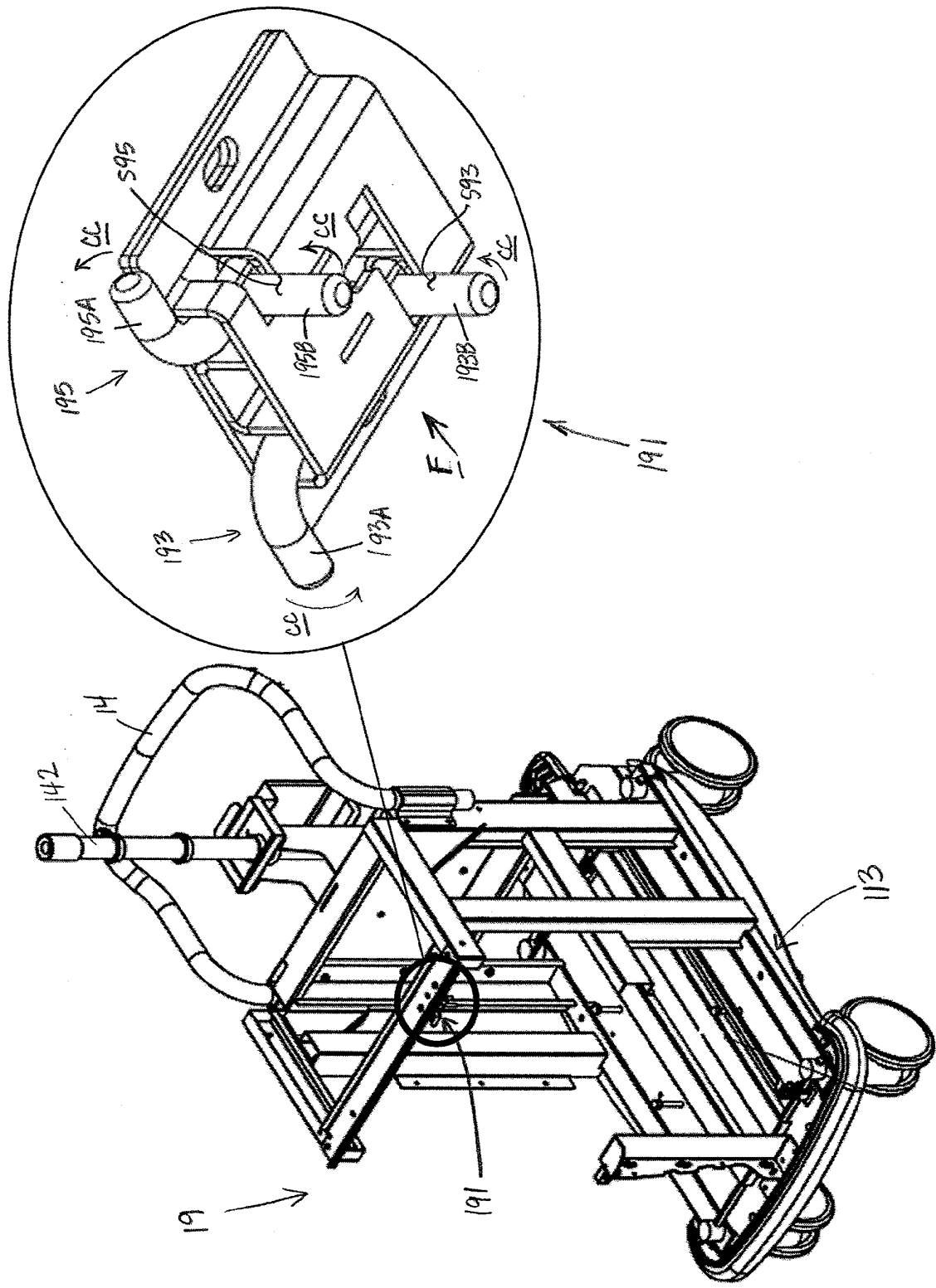


FIGURE 2B

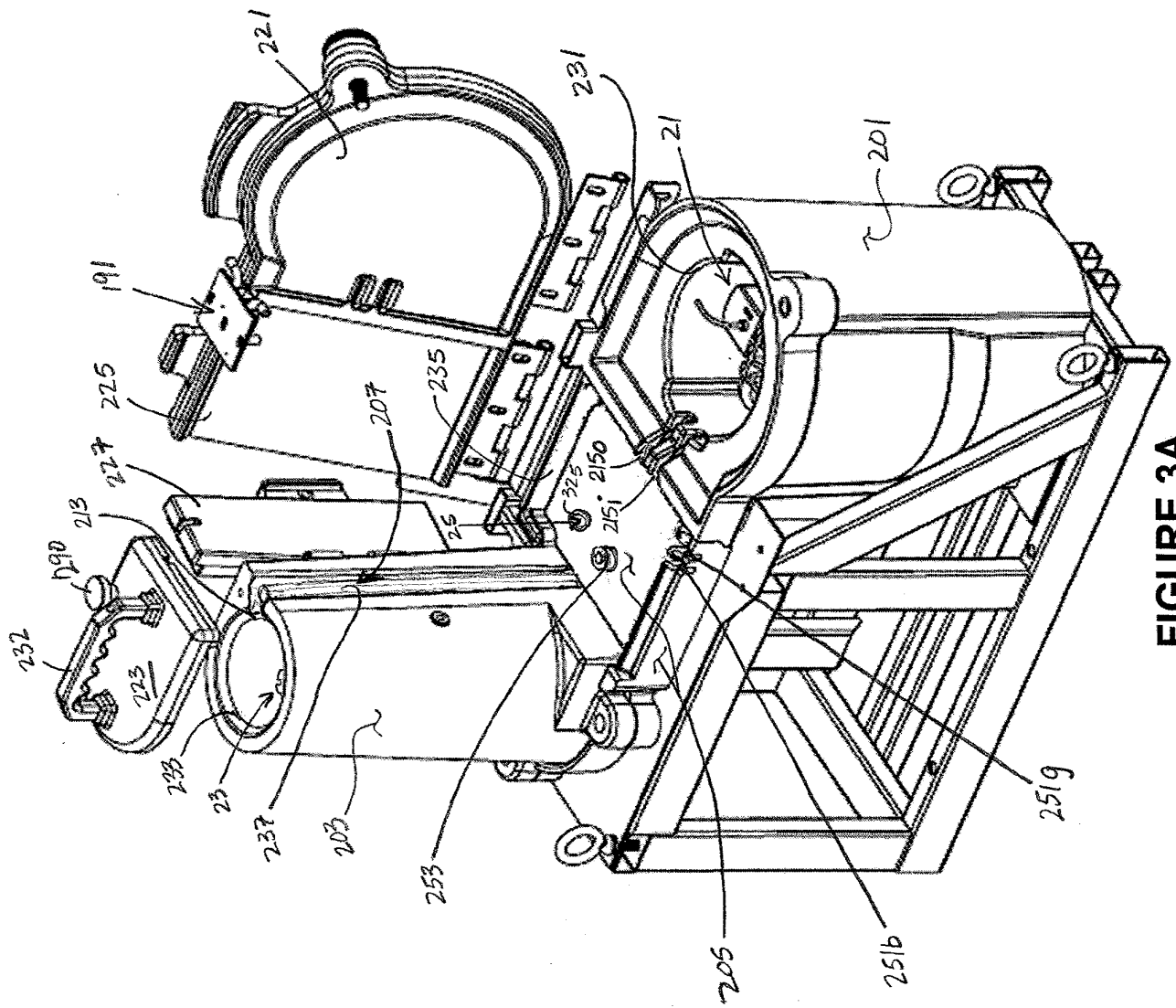


FIGURE 3A

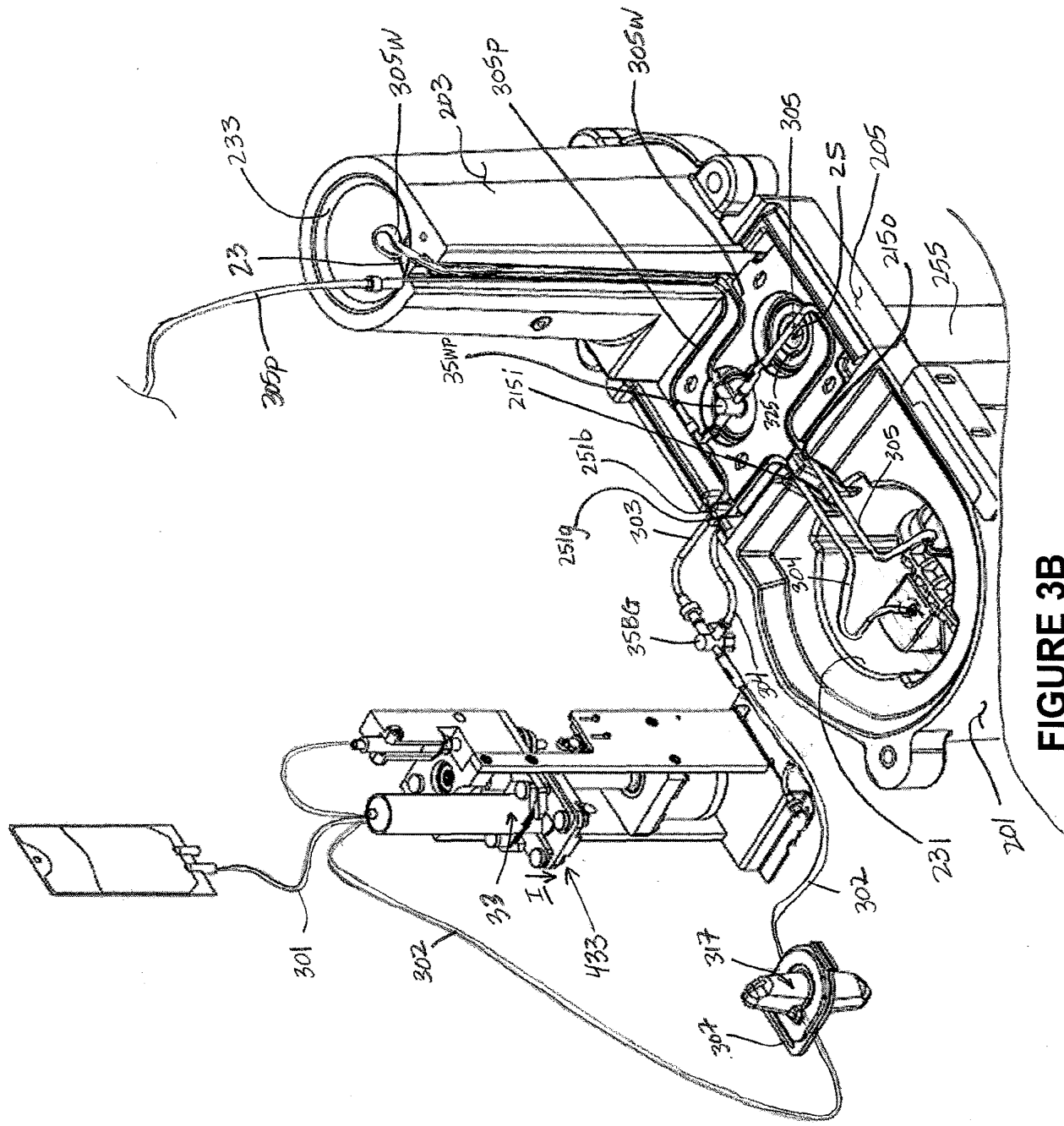


FIGURE 3B

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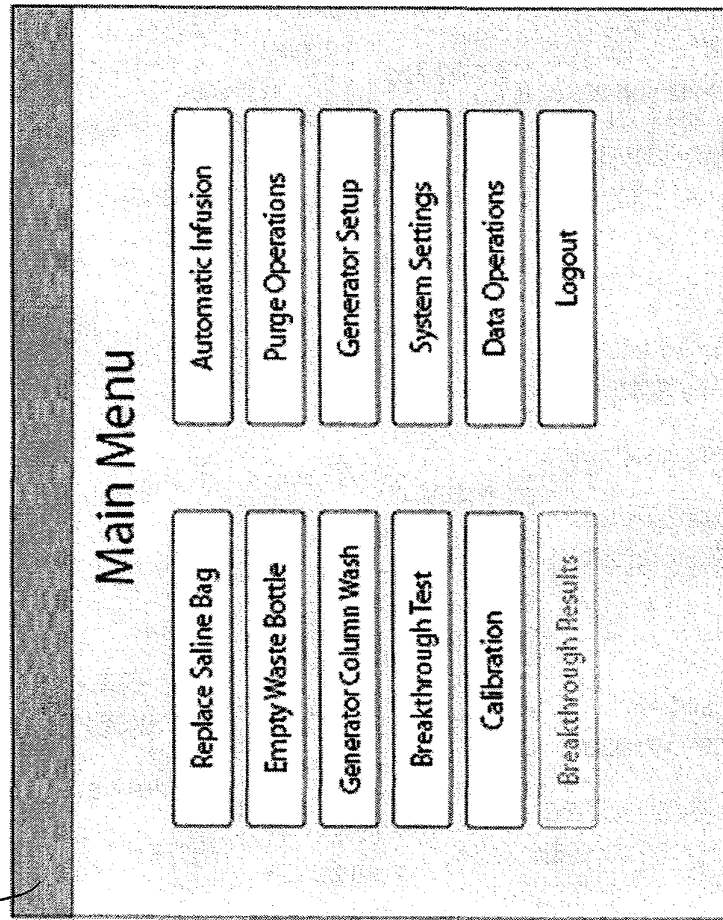


FIGURE 4

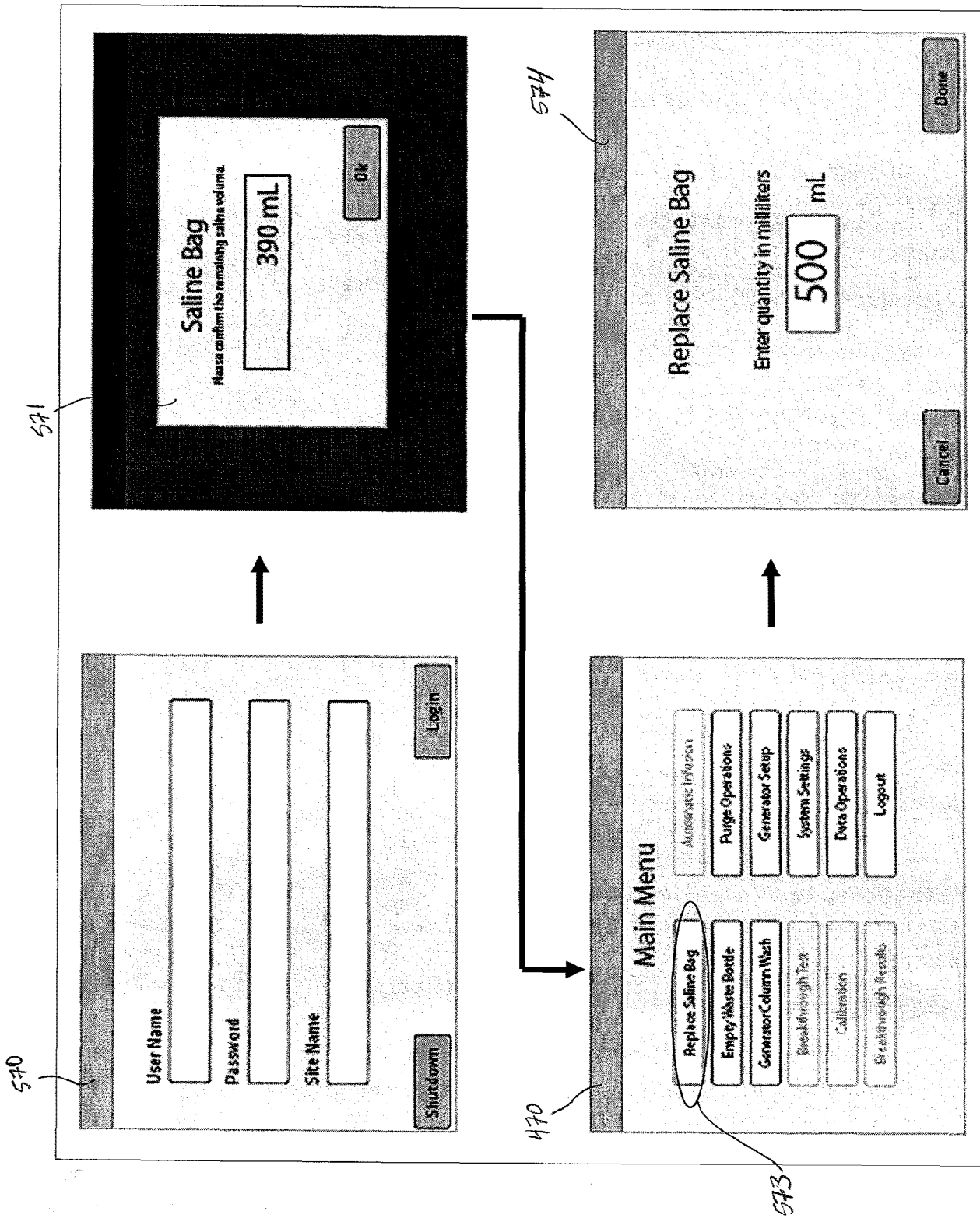


FIGURE 5A

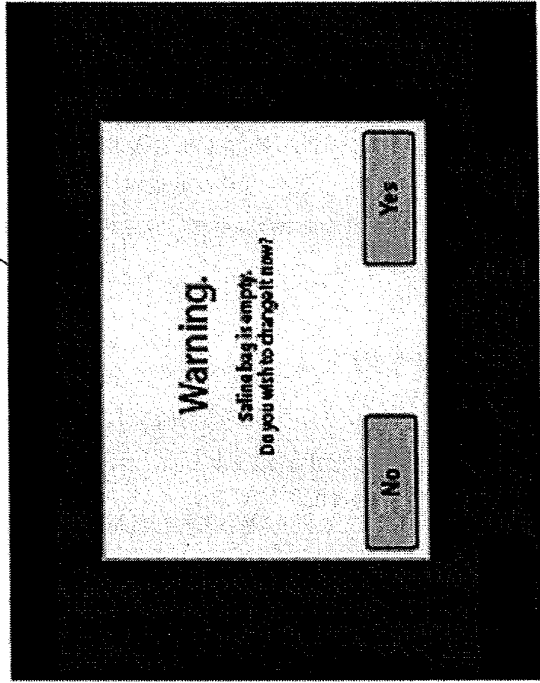
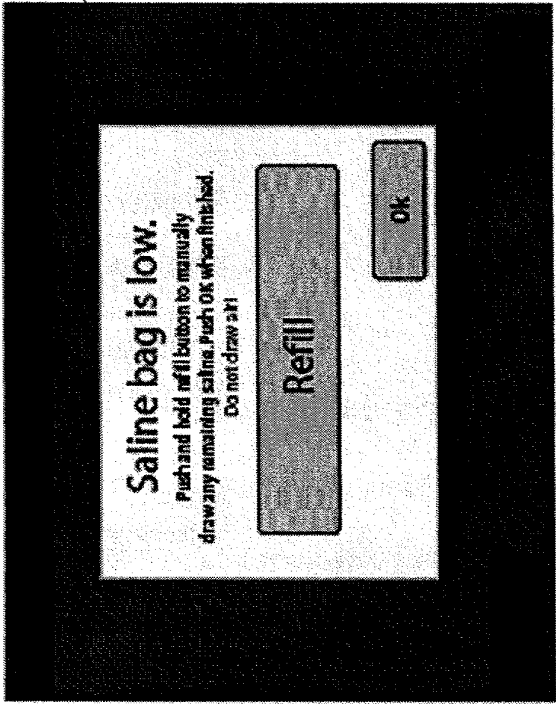


FIGURE 5B

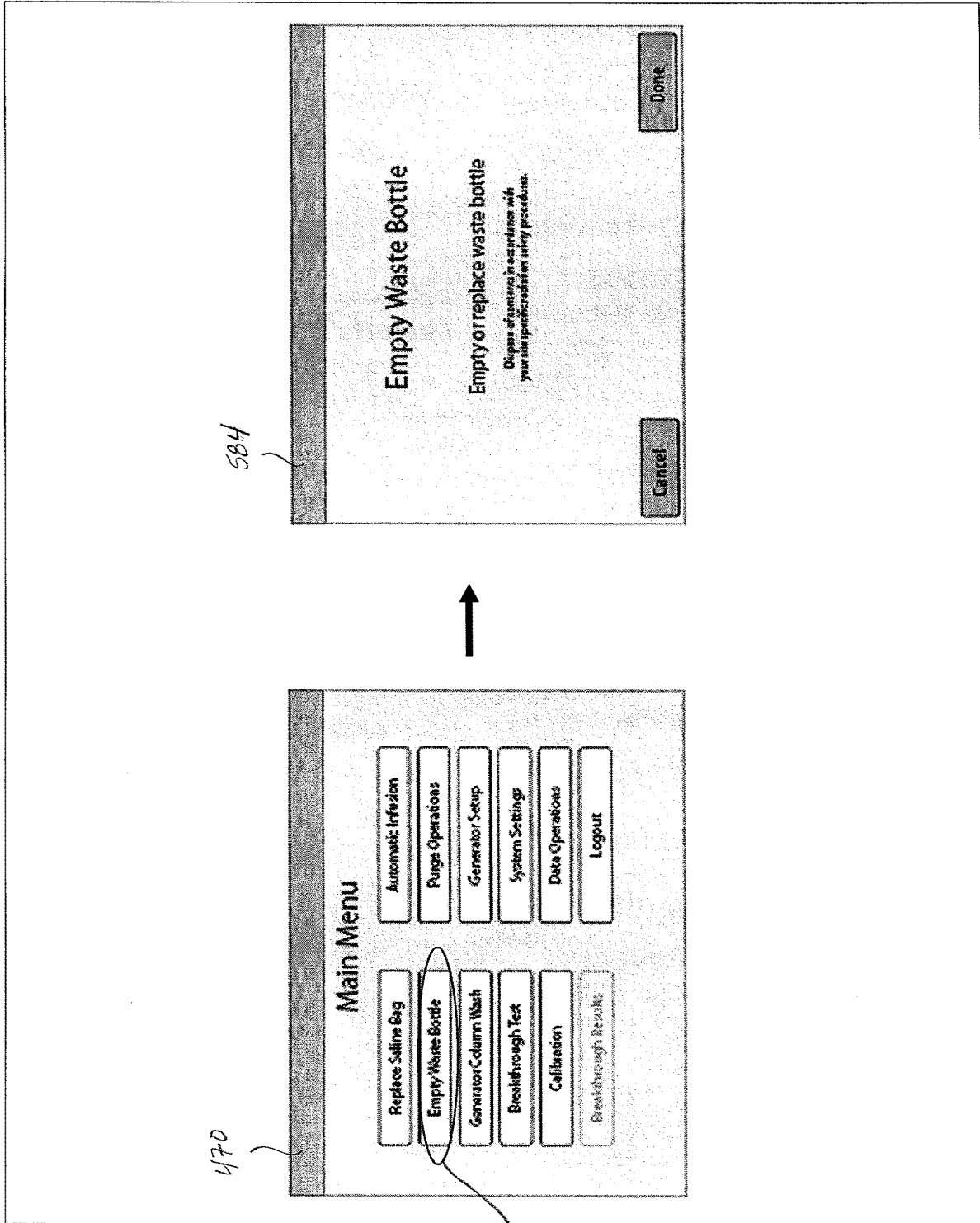
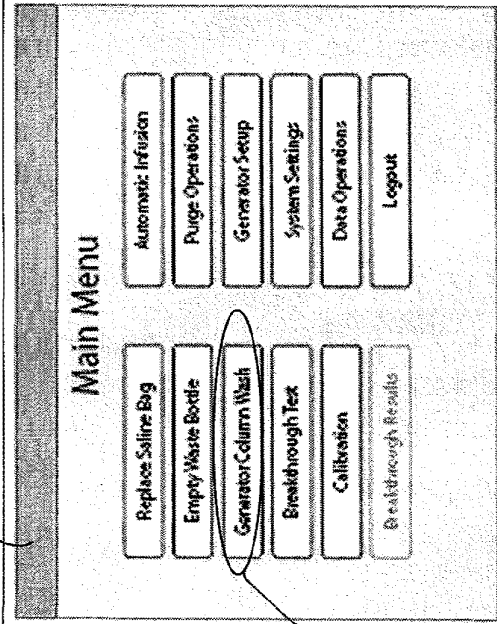


FIGURE 5C

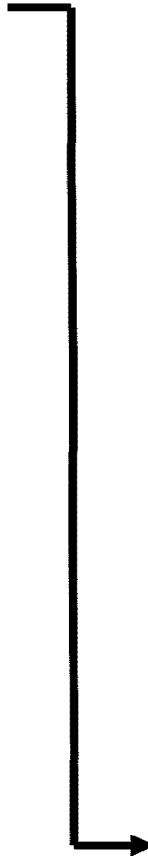
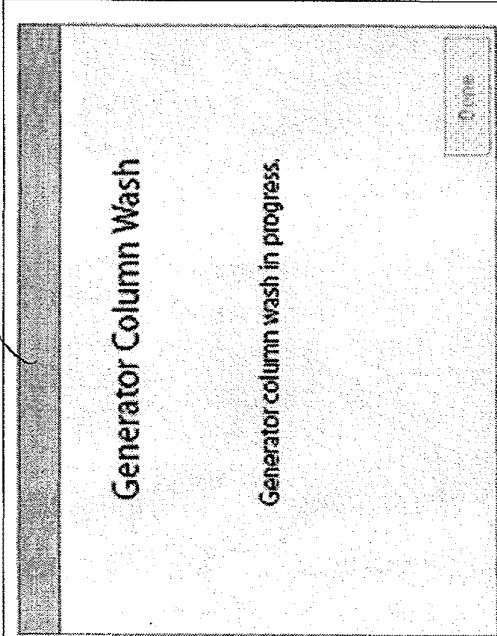
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675



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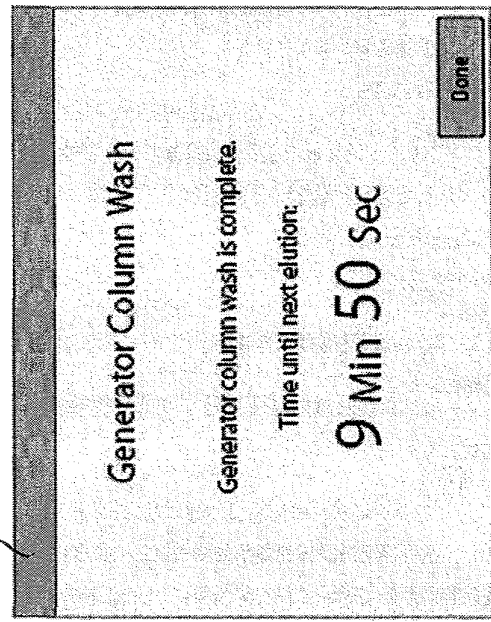


FIGURE 6

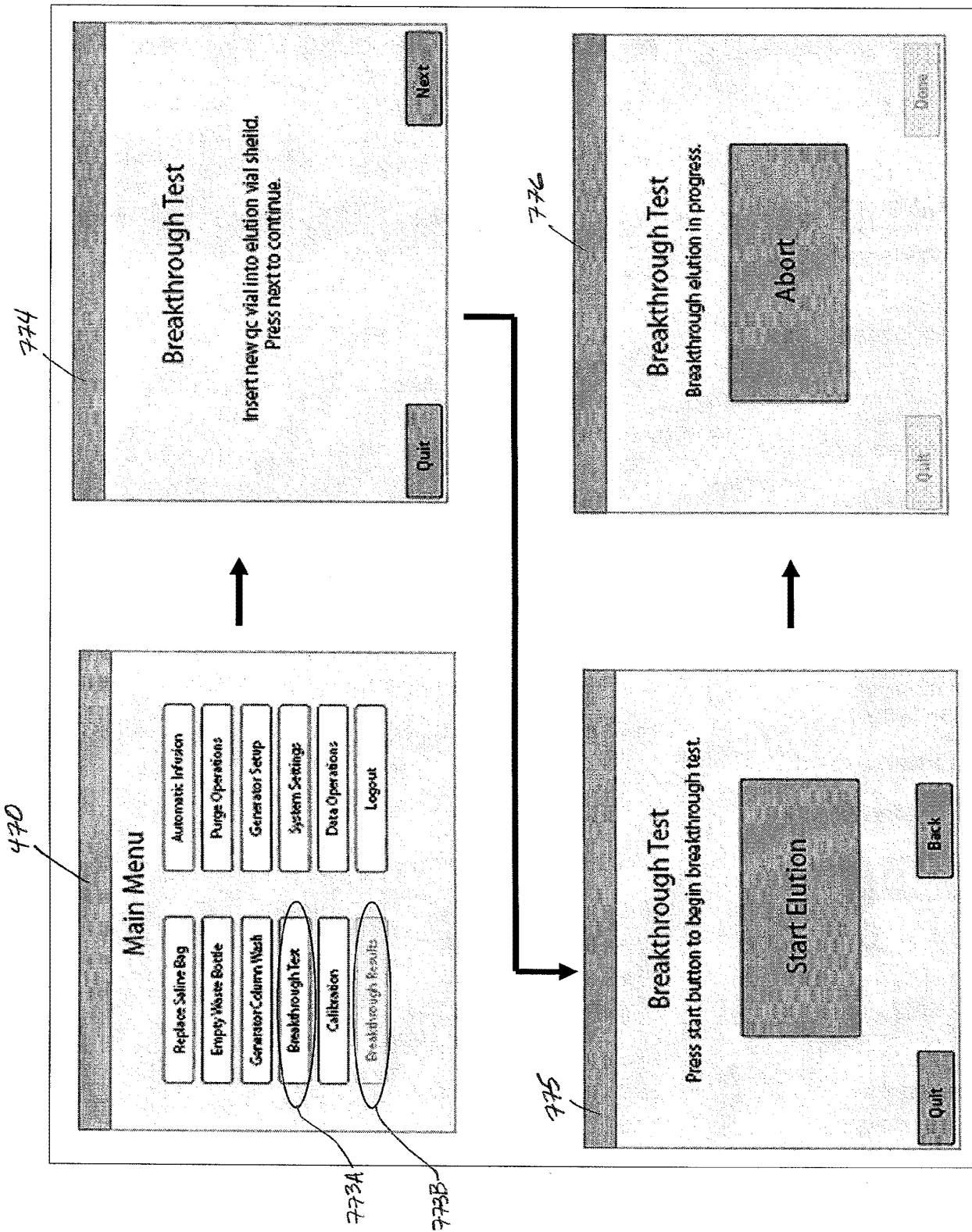


FIGURE 7A

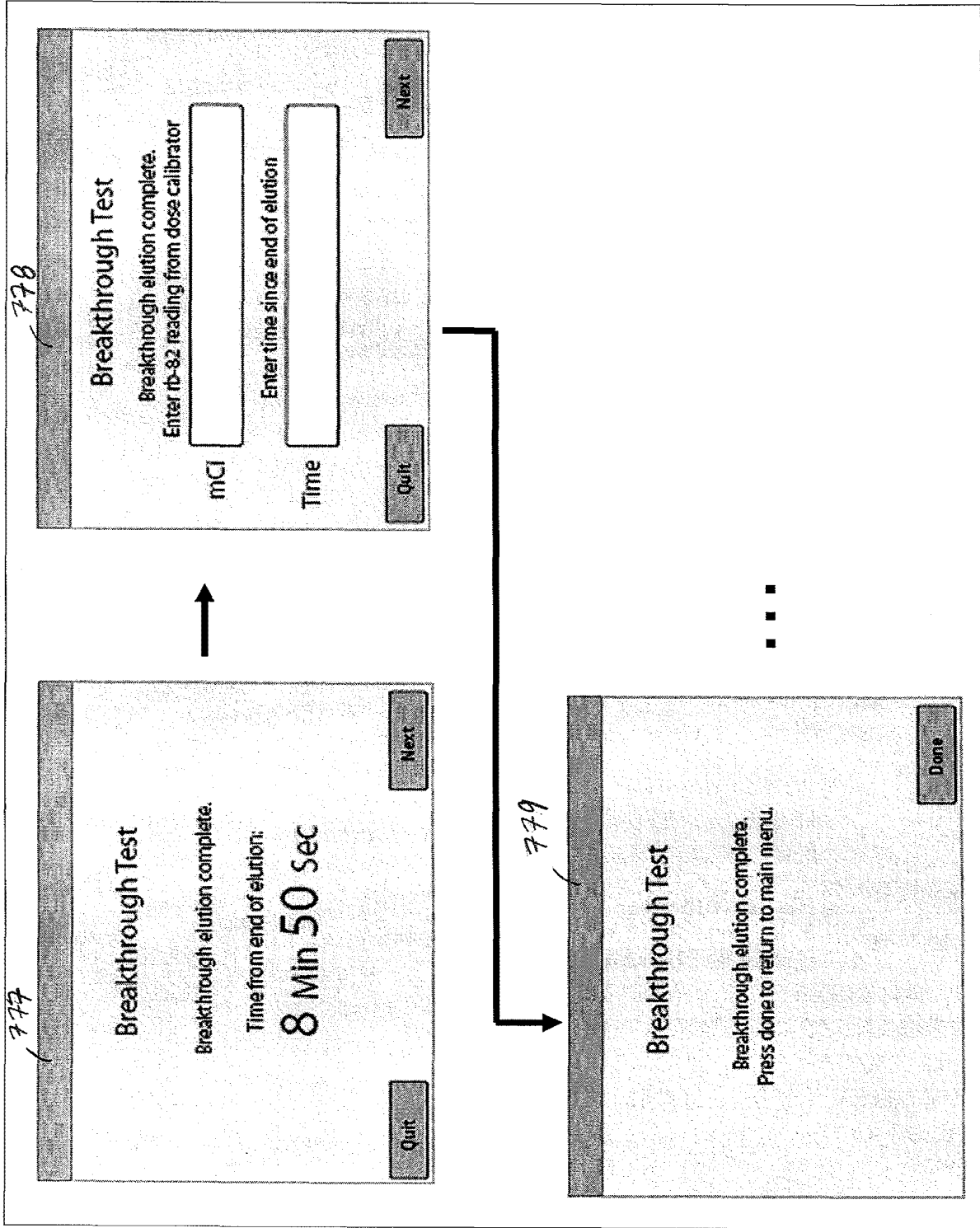


FIGURE 7B

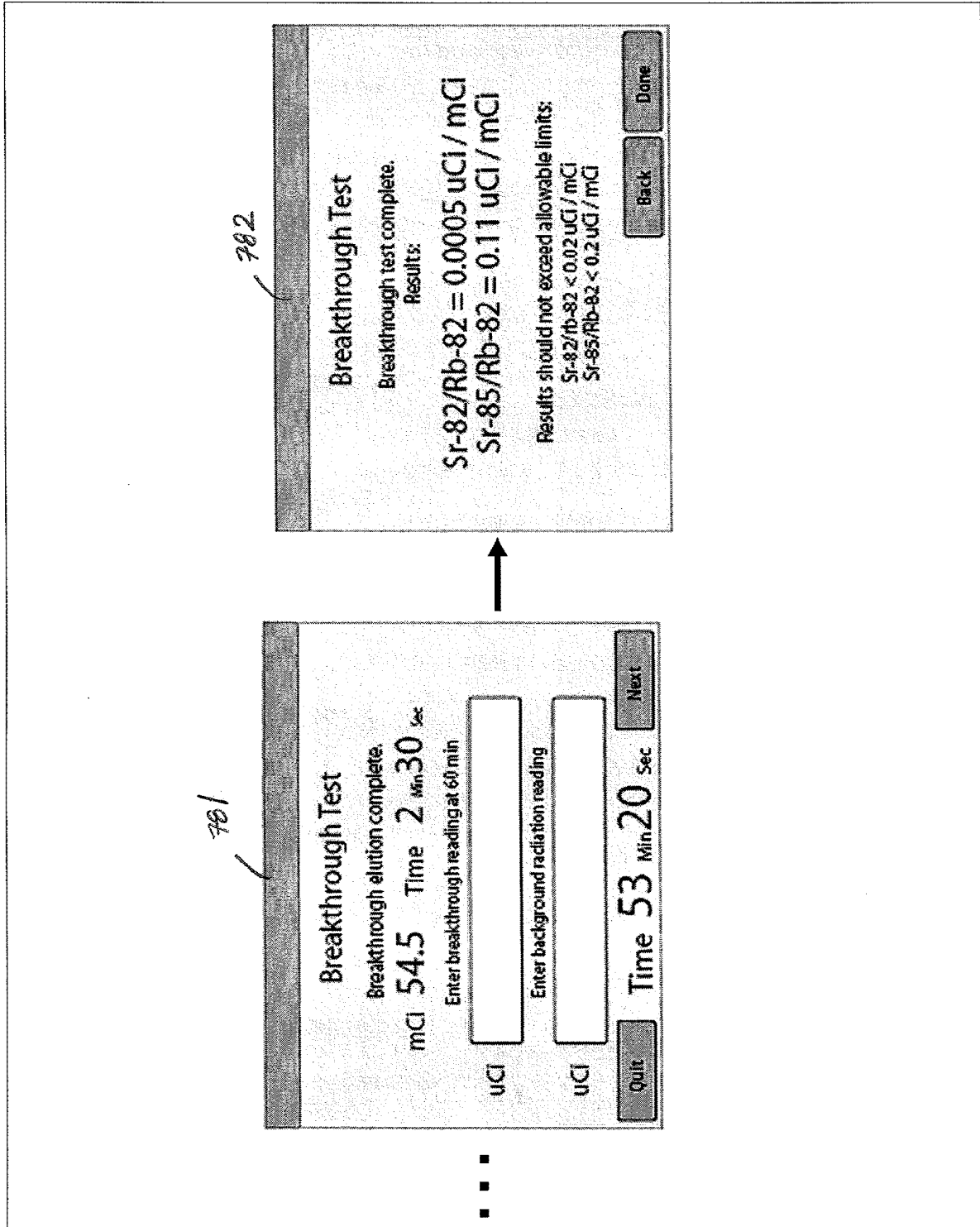


FIGURE 7C

470

Main Menu

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



874

Infusion System Calibration

Insert new qc vial into elution vial shield.
Press next to continue.

Quit Back Next

875

Infusion System Calibration

Patient Dose: 60 mCi

Patient Volume: 50 mL

Flow Rate: 50 mL/min (DEFAULT)

Dose Rate Threshold: 1.0 mCi/sec (DEFAULT)

Elution Volume: 99 mL (DEFAULT)

Quit Next



876

Infusion System Calibration

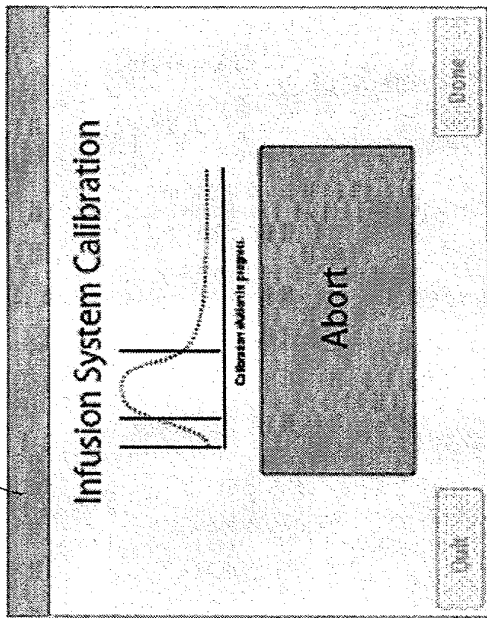
Press start button to begin calibration.

Start

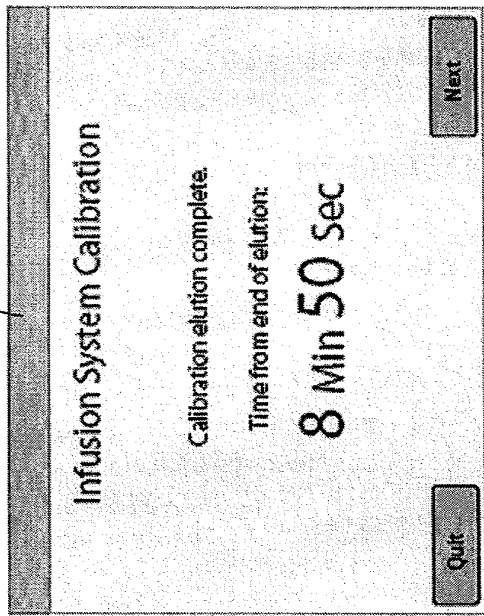
Quit Back

FIGURE 8A

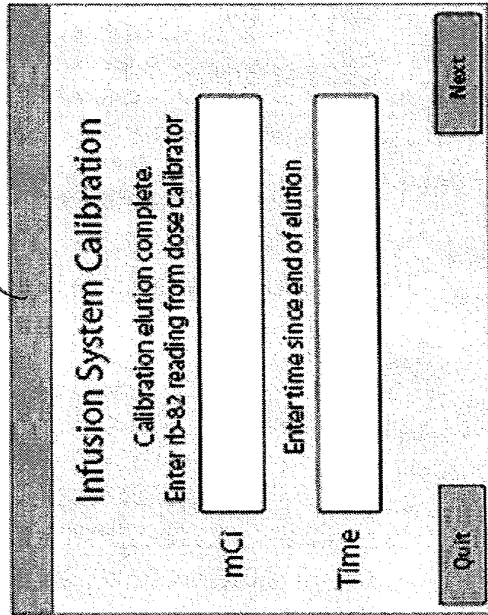
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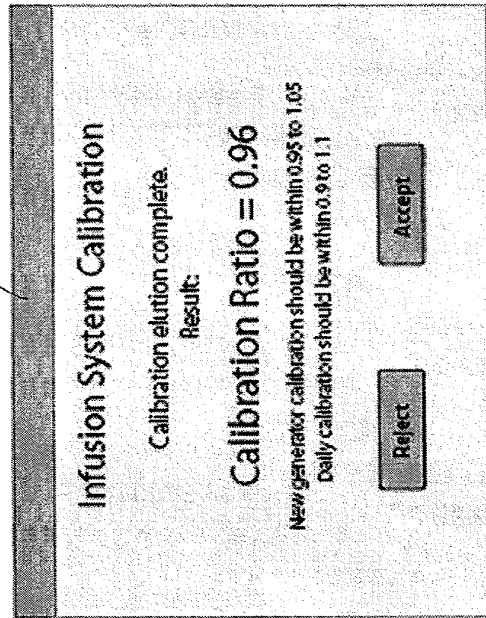


FIGURE 8B

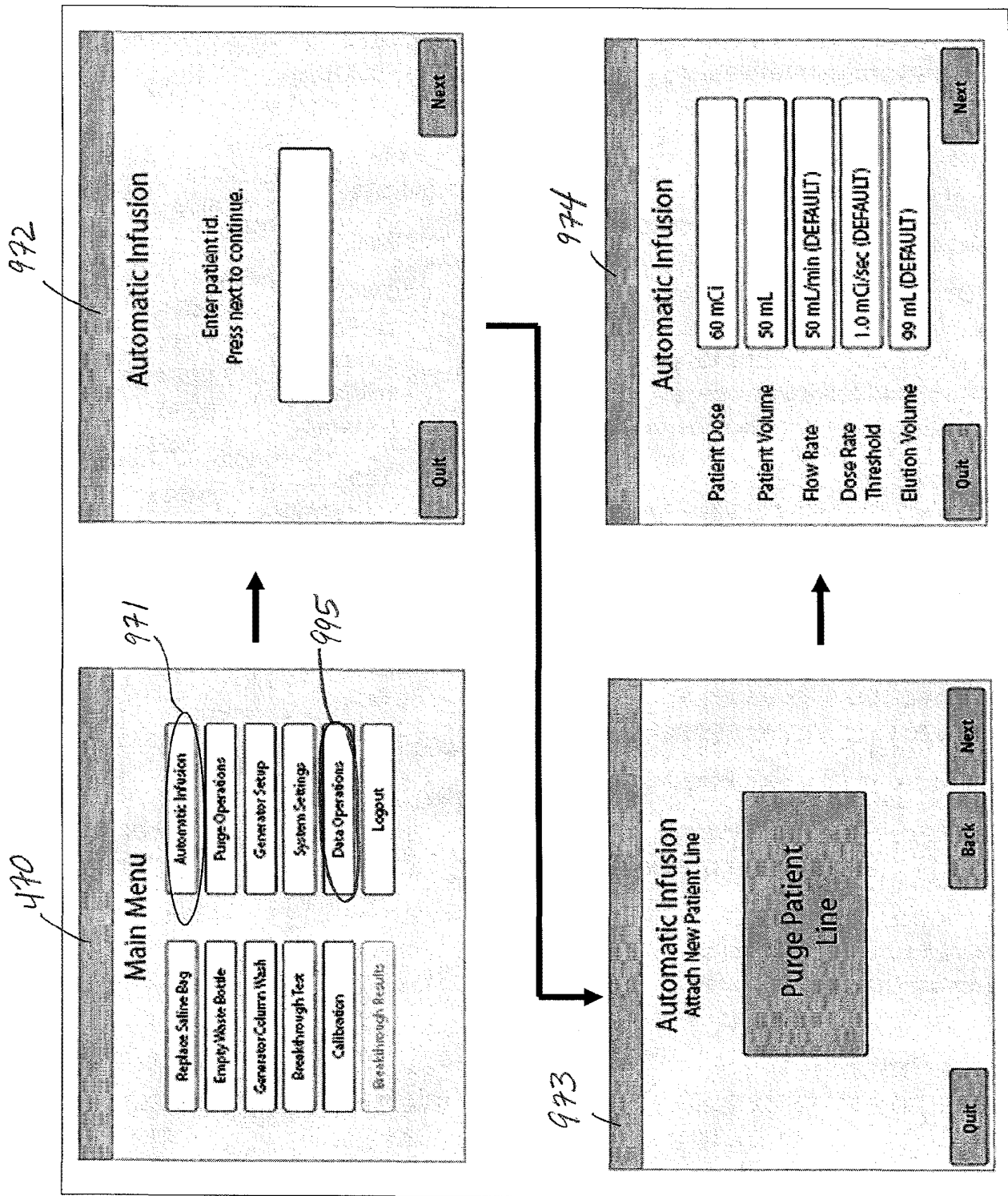


FIGURE 9A

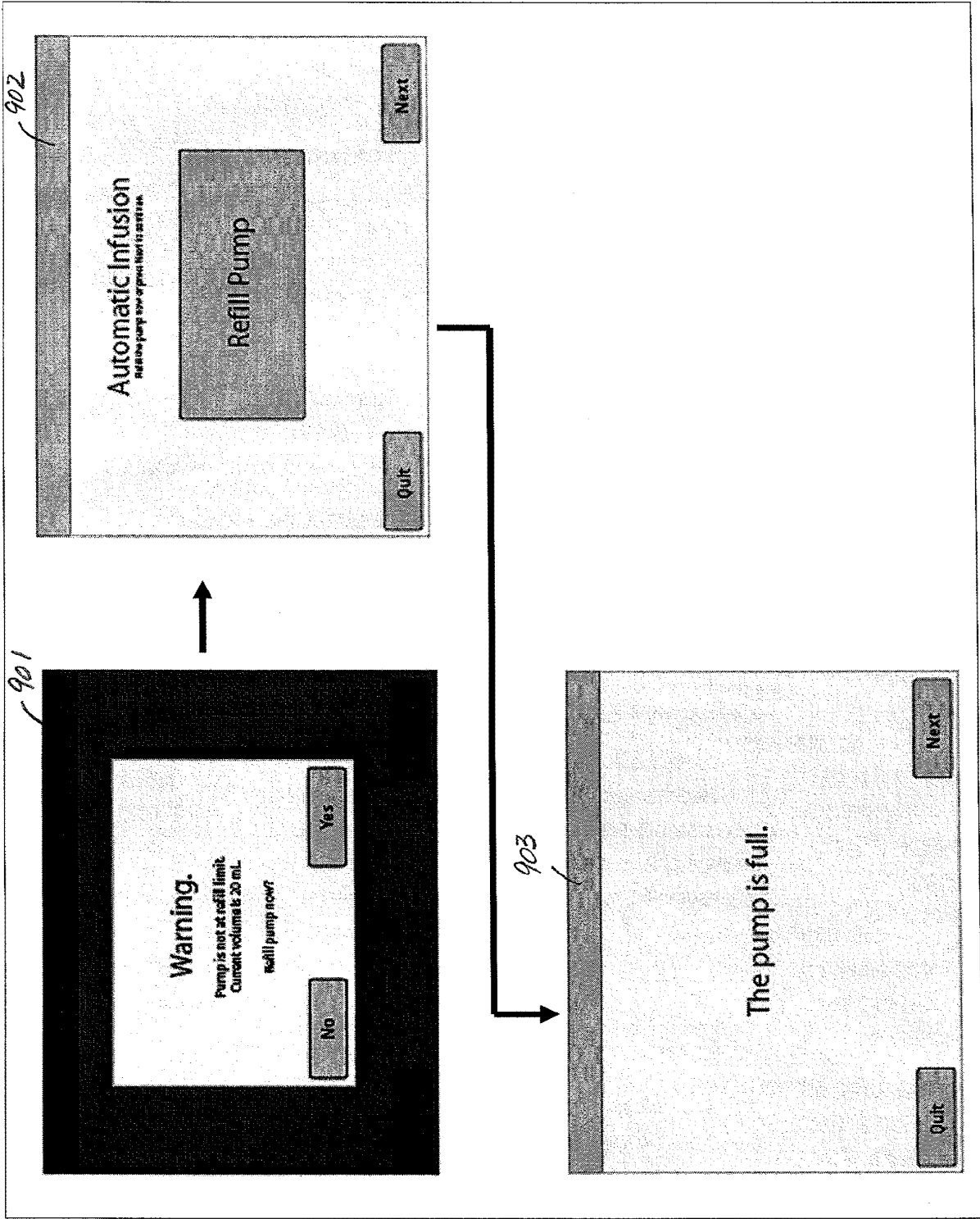


FIGURE 9B

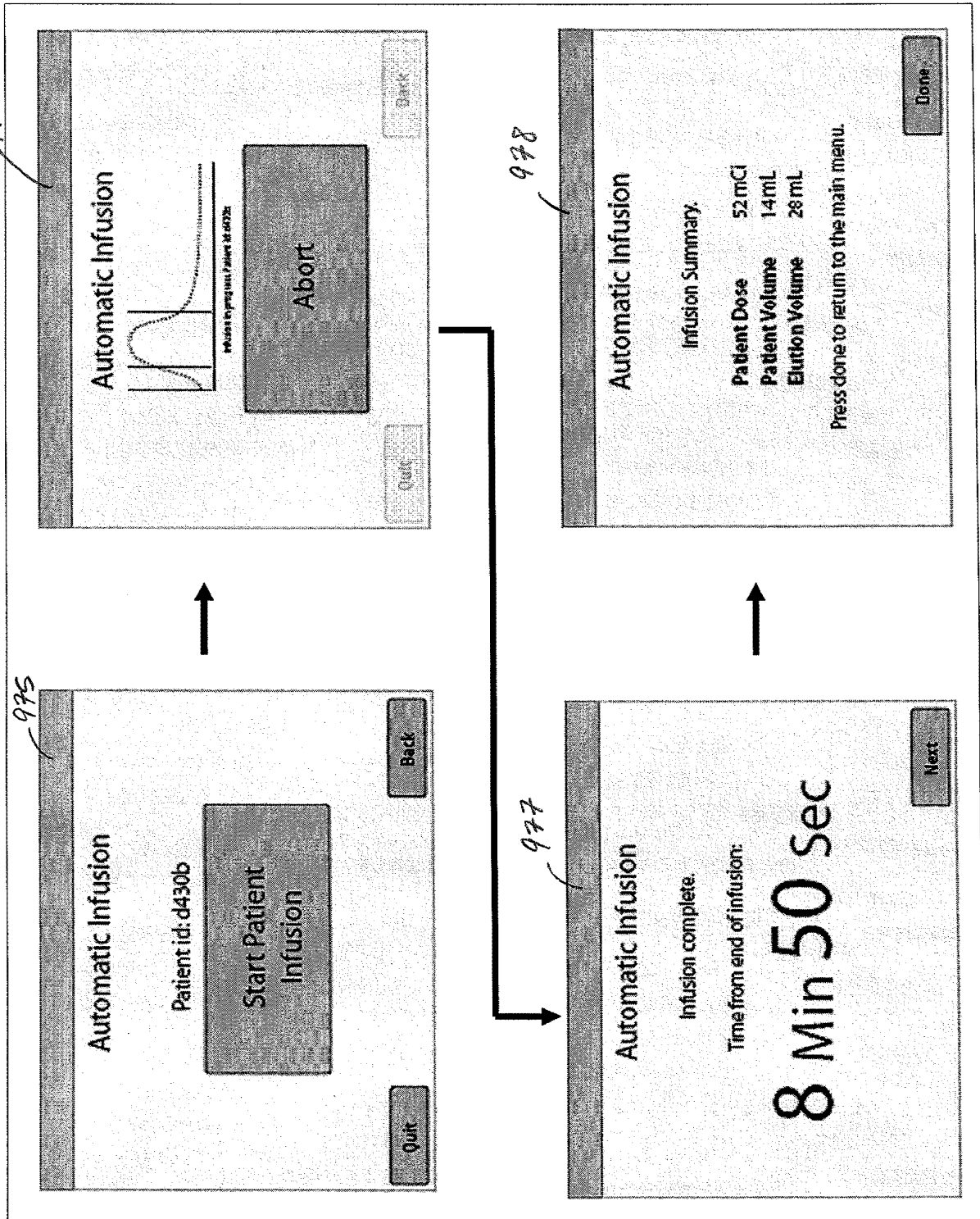


FIGURE 9C

983

Purge With Air

Remove saline bag.
Attach elution test vial to patient line.

Quit Next

985

Purge With Air

Start Purge

Quit Back Next

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Main Menu

Replace Saline Bag Automatic Infusion

Empty Waste Bottle **Purge Operations**

Generator/Column Wash **Generator Setup**

Breakthrough Test System Settings

Calibration Data Operations

Breakthrough Results Logout

981

991

984

Purge With Air

Warning: You must bypass the generator if you intend to continue using it.

Quit Back Next

FIGURE 10

We claim:

1. A shielding assembly for an infusion system, the shielding assembly being mounted within a cabinet structure, and the shielding assembly comprising:
 - a plurality of compartments having sidewalls providing barriers to radioactive radiation for the compartments;
 - a corresponding plurality of doors, each door, when open, providing access to the corresponding compartment via an opening in its sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;
 - a first compartment of the plurality of compartments enclosed by a first sidewall of the sidewalls and sized to contain a radioisotope generator of the infusion system, the first sidewall including a first sidewall opening oriented upward and aligned with a first upper opening through a shell of the cabinet structure, an upper surface of the shell being located at an elevation with respect to a lowermost portion of the cabinet structure substantially greater than the first sidewall opening and the first upper opening.

2. The shielding assembly of claim 1, wherein the lowermost portion of the cabinet structure is at approximately ground level, the first sidewall opening is at an elevation of between approximately 12 inches and approximately 24 inches with respect to the lowermost portion of the cabinet.

3. The shielding assembly of claim 2, wherein the upper surface of the shell is at an elevation of between approximately 24 inches and 36 inches with respect to the lowermost portion of the cabinet structure.

4. The shielding assembly of claim 1, further comprising a second compartment of the plurality of compartments enclosed by a second sidewall of the sidewalls and sized to contain a waste bottle of the infusion system, the second sidewall including a second sidewall opening oriented upward and aligned with a second upper opening through the shell of the cabinet structure, the second upper opening being an opening in the upper surface of the shell.

5. A shielding assembly for an infusion system, the shielding assembly being mounted within a cabinet structure, and the shielding assembly comprising:

- a first compartment sized to contain a radioisotope generator of the infusion system, the first compartment being enclosed by a first sidewall that forms a barrier to radioactive radiation, the first sidewall including an opening extending therethrough and a lid, the lid mating with the opening to alternately enclose the first compartment and provide access to the first compartment, via the opening, and the opening being oriented upward and located at a first elevation with respect to a lowermost portion of the cabinet structure;
- a second compartment sized to contain a portion of an infusion tubing circuit of the infusion system that is downstream of the generator, the second compartment being enclosed by a second sidewall that forms a barrier to radioactive radiation, the second sidewall including a base portion and a lid portion, the lid portion mating with the base portion to alternately enclose the second compartment and provide access to the second compartment; and
- a third compartment sized to contain a waste bottle of the infusion system, the third compartment being enclosed by a third sidewall that forms a barrier to radioactive radiation, the third sidewall including an opening, extending through the third sidewall, and a lid, the lid of the third sidewall mating with the opening of the third sidewall to alternately enclose the third compartment and provide access to the third compartment, via the opening of the third sidewall, the

opening of the third sidewall being oriented upward and located at a second elevation with respect to the lowermost portion of the cabinet structure, and the second elevation being greater than the first elevation of the opening of the first sidewall.

6. The shielding assembly of claim 5, wherein the opening of the first sidewall is aligned with a first upper opening through a shell of the cabinet structure and the opening of the third sidewall is aligned with a second upper opening through the shell of the cabinet structure, the second upper opening being located at a greater elevation with respect to the lowermost portion of the cabinet structure than the first upper opening.
7. The shielding assembly of claim 5, wherein an opening through a shell of the cabinet structure provides access to both the lid of the first sidewall and to the lid portion of the second sidewall.
8. The shielding assembly of claim 5, wherein the lowermost portion of the cabinet structure is at approximately ground level and the first elevation is between approximately 12 inches and approximately 24 inches.
9. The shielding assembly of claim 5, wherein the lowermost portion of the cabinet structure is at approximately ground level and the second elevation is between approximately 24 inches and approximately 36 inches.
10. The shielding assembly of claim 5, further comprising:
 - a fourth compartment sized to contain another portion of the infusion tubing circuit of the infusion system downstream from the generator, the fourth compartment being enclosed by a portion of the third sidewall and a door that forms a barrier to radioactive radiation, the door mating with the portion of the third sidewall to alternately enclose the fourth compartment and provide access to the fourth compartment; and

wherein the fourth compartment is immediately adjacent to the second compartment; the portion of the infusion tubing circuit contained in the second compartment includes an eluate line, extending from the generator, a patient line, being coupled to the eluate line, and a waste line, being coupled to the eluate line; and the other portion of the infusion tubing circuit contained in the fourth compartment includes an extension of the patient line, from the second compartment, and an extension of the waste line, from the second compartment.

11. The shielding assembly of claim 10, wherein the fourth compartment extends approximately vertically along the portion of the third sidewall, on an opposite side of the third sidewall from the third compartment.

12. The shielding assembly of claim 11, wherein the fourth compartment includes a retaining member to hold the extension of the patient line and the extension of the waste line in place within the fourth compartment.

13. The shielding assembly of claim 10, wherein the lid of the third sidewall, when mated with opening of the third sidewall, prevents the door of the fourth compartment from opening to provide access to the fourth compartment.

14. The shielding assembly of claim 13, wherein the door of the fourth compartment, when mated with the portion of the third sidewall, prevents the lid portion of the second sidewall from opening to provide access to the second compartment.

15. The shielding assembly of claim 14, wherein the lid portion of the second sidewall, when mated with the base portion of the second sidewall, prevents the lid of the first sidewall from opening to provide access to the first compartment.

16. The shielding assembly of claim 10, wherein the door of the fourth compartment, when mated with the portion of the third sidewall, prevents the lid portion of the second sidewall from opening to provide access to the second compartment.

17. The shielding assembly of claim 5, wherein the lid portion of the second sidewall, when mated with the base portion of the second sidewall, prevents the lid of the first sidewall from opening to provide access to the first compartment.

18. The shielding assembly of claim 5, wherein the lid of the first sidewall is hinged to open in an upward direction; and further comprising a latch component, mounted within the cabinet structure, to hold the lid of the first sidewall in an open position.

19. The shielding assembly of claim 5, wherein the lid portion of the second sidewall is hinged to open in an upward direction; and further comprising a latch component, mounted within the cabinet structure, to hold the lid portion of the second sidewall in an open position.

20. A method for setting up an infusion system, the method comprising:
opening a first door of a shielding assembly of the infusion system to access a first compartment of the assembly and to allow for a second door of the shielding assembly to be opened; and
opening the second door, after opening the first door, to access a second compartment of the shielding assembly, the second compartment being separate from, and outside of, the first compartment;
placing a radioisotope generator into the second compartment and connecting the generator to an infusion tubing circuit;
placing a portion of the infusion tubing circuit into the first compartment;
closing the second door to enclose the generator within the second compartment;
and
closing the first door, after closing the second door, to enclose the portion of the infusion tubing circuit within the first compartment.

21. The method of claim 20, further comprising unlocking and removing an access panel from a shell of a cabinet structure, which encloses the shielding assembly, to access the first door and the second door of the shielding assembly.
22. The method of claim 20, further comprising:
opening a third door, prior to opening the first door, to access a third compartment of the shielding assembly and to allow for the first door to be opened;
placing another portion of the infusion tubing circuit into the third compartment; and
closing the third door, after closing the first door, to enclose the other portion of the infusion tubing circuit within the third compartment.
23. The method of claim 22, further comprising unlocking and removing an access panel from a shell of a cabinet structure, which encloses the shielding assembly, to access the first door, the second door and the third door of the shielding assembly.
24. The method of claim 22, further comprising:
opening a fourth door, prior to opening the third door, to access a fourth compartment of the shielding assembly and to allow for the third door to be opened;
connecting a waste line of the infusion tubing circuit to a waste bottle;
placing the waste bottle into the fourth compartment; and
closing the fourth door, after closing the third door, to enclose the waste bottle within the fourth compartment.
25. The method of claim 20, further comprising securing at least one of the first and second doors in an open position.

26. A shielding assembly for an infusion system, the shielding assembly comprising a plurality of compartments and providing a radioactive radiation barrier for the compartments, the assembly further comprising:

- a first door to alternately enclose and provide access to a first compartment of the plurality of compartments, the first compartment sized to contain a radioisotope generator of the infusion system; and

- a second door to alternately enclose and provide access to a second compartment of the plurality of compartments, the second compartment being separate from, and outside of, the first compartment, the second compartment being sized to contain a portion of an infusion tubing circuit of the infusion system that is downstream of the generator, and the second door, when enclosing the second compartment, preventing the first door from opening to provide access to the first compartment.

27. The shielding assembly of claim 26, further comprising a third door to alternately enclose and provide access to a third compartment of the plurality of compartments, the third compartment sized to contain another portion of the infusion tubing circuit of the infusion system downstream from the generator, the third door, when enclosing the third compartment, preventing the second door from opening to provide access to the second compartment.

28. The shielding assembly of claim 27, further comprising a fourth door to alternately enclose and provide access to a fourth compartment of the plurality of compartments, the fourth compartment being sized to contain a waste bottle of the infusion system, the fourth door, when enclosing the fourth compartment, preventing the third door from opening to provide access to the third compartment.

29. The shielding assembly of claim 28, wherein the third compartment shares a sidewall with the fourth compartment and extends approximately vertically along the shared sidewall.

30. The shielding assembly of claim 29, wherein the third compartment includes a retaining member attached to the shared sidewall to hold the other portion of the infusion tubing circuit in place along the shared sidewall.

31. An infusion system comprising:

- a cabinet structure including a shell defining an interior space thereof, the shell including a first opening, a second opening and an access panel, the access panel mating with the second opening and being removable therefrom;
- a lock reversibly engaging the access panel to secure access to the interior space of the cabinet structure;
- an eluant source;
- a shielding assembly located within the interior space of the cabinet structure, the shielding assembly including a sidewall defining a plurality of compartments and providing a barrier to radioactive radiation for the compartments, the shielding assembly further including a corresponding plurality of doors, each door, when open, providing access to the corresponding compartment via an opening in the sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;
- a radioisotope generator contained within a first compartment of the plurality of compartments of the shielding assembly and being accessible through the second opening of the shell of the cabinet structure, when the access panel is unlocked, and when a first door of the plurality of doors, which corresponds to the first compartment, is open;
- an eluant line coupled to the eluant source and to the generator;
- an eluate line coupled to the generator; and
- a patient line coupled to the eluate line and extending out from the interior space of the cabinet structure through the first opening of the shell.

32. The assembly of claim 31, wherein the first door is hinged to open in an upward direction; and further comprising a latch component, mounted within the cabinet structure, to hold the first door in an open position.

33. The system of claim 31, further comprising:
a waste bottle contained within a second compartment of the plurality of compartments of the shielding assembly; and
a waste line coupled to the eluate line and to the waste bottle;
wherein the shell of the cabinet structure further includes a third opening; and
a second door of the plurality of doors, which corresponds to the second compartment, is aligned with the third opening of the shell, for access thereto, and is located at a higher elevation, with respect to a lowermost surface of the cabinet structure, than that of the second door.
34. The system of claim 31, further comprising:
a waste bottle contained within a second compartment of the plurality of compartments of the shielding assembly; and
a waste line coupled to the eluate line and to the waste bottle;
wherein a second door of the plurality of doors, which corresponds to the second compartment, when closed, prevents the first door from opening to provide access to the first compartment.
35. The system of claim 31, wherein:
the eluate line and at least a portion of the patient line are contained in a second compartment of the plurality of compartments of the shielding assembly; and
a second door of the plurality of doors, which corresponds to the second compartment, when closed, prevents the first door from opening to provide access to the first compartment.
36. The system of claim 35, wherein the second door is accessible only through the second opening of the shell of the cabinet structure, when the access panel is unlocked.

37. The system of claim 35, wherein the first door and the second door are both hinged to open in an upward direction; and further comprising at least one latch component, mounted within the cabinet structure, to hold the first door and the second door in an open position.

ABSTRACT

A shielding assembly for an infusion system includes a plurality of compartments and a door for each compartment, and provides a radioactive radiation barrier for the compartments. One of the compartments contains a radioisotope generator of the infusion system and another of the compartments may contain a waste bottle of the infusion system. An opening into each of the generator and waste bottle compartments may be oriented upward, and the opening into the latter may be at a higher elevation than the opening into the former, for example, to facilitate independent removal and replacement of each. A door of at least one of the compartments, other than the generator compartment, when closed, may prevent the door of the generator compartment from being opened. A cabinet structure for the infusion system may enclose the shielding assembly and secure the generator.

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(54) Title: INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

(57) Abstract: Methods for setting up, maintaining and operating a radiopharmaceutical infusion system, that includes a radioisotope generator, are facilitated by a computer of the system. The computer includes pre-programmed instructions and a computer interface, for interaction with a user of the system, for example, in order to track contained volumes of eluant and/or eluate, and/or to track time from completion of an elution performed by the system, and/or to calculate one or more system and/or injection parameters for quality control, and/or to perform purges of the system, and/or to facilitate diagnostic imaging.

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

RELATED APPLICATIONS

5 The present application claims priority to the following U.S. patent applications: U.S. patent application serial No. 12/137,356, filed June 11, 2008; U.S. patent application serial No. 12/137,363, filed June 11, 2008; U.S. patent application serial No. 12/137,364, filed June 11, 2008; and U.S. patent application serial No. 12/137,377, filed June 11, 2008.

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TECHNICAL FIELD

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

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BACKGROUND

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

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 Set up, maintenance and operational procedures for infusion systems that both generate and inject doses of radiopharmaceuticals are relatively involved in order to assure the safety and efficacy of each injected dose for the patient. Efficiency in carrying out these procedures is highly desirable for technical personnel, who work

with these systems on a routine basis and would like to avoid unnecessarily prolonged exposure to radioactive radiation. Thus there is a need for new system configurations that facilitate more efficient set up, maintenance and operation.

5 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

Figure 1E is a perspective view of exemplary sample vial shielding that may be employed in conjunction with the infusion system of Figure 1A.
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Figure 2A is a perspective view of a shielding assembly for an infusion system, such as that shown in Figures 1A-C, according to some embodiments of the present invention.

Figure 2B is a perspective view of a framework of the system, according to some embodiments, with an enlarged detailed view of a component of the system, according to some embodiments.
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Figure 3A is another perspective view of the shielding assembly shown in Figure 2A.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

30 The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary

embodiments. Utilizing the teaching provided herein, those skilled in the art will recognize that many of the examples have suitable alternatives that can be utilized.

Figure 1A is a first perspective view of an infusion system 10, according to some embodiments of the present invention, wherein system 10 is shown supported by a cabinet structure, which includes a platform 113 (seen better in Figure 2B) and a shell 13; shell 13 extends upward from a skirt 11, that surrounds platform 113, to surrounds an interior space in which a portion of infusion system 10 is contained (- seen in Figure 1C). Shell may be formed from panels of injection-molded polyurethane fitted together according to methods known to those skilled in the art. Figure 1A illustrates the cabinet structure of system 10 including a grip or handle 14, which extends laterally from shell 13, in proximity to an upper surface 131 thereof, and a post 142, which extends upward from shell 13, and to which a work surface, or tray 16 and a computer 17 are, preferably, attached, via an ergonomic, positionable mount. According to some embodiments, computer 17 is coupled to a controller of system 10, which is mounted within the interior space surrounded by shell 13; and, a monitor 172 of computer 17 not only displays indications of system operation for a user of system 10, but also serves as a device for user input (e.g. touch screen input). However, according to alternate embodiments, another type of user input device, known to those skilled in the art, may be employed by computer 17. Other types of user input devices may be included, for example, a keyboard, a series of control buttons or levers, a bar code reader (or other reader of encoded information), a scanner, a computer readable medium containing pertinent data, etc. The user input device may be mounted on the cabinet structure of system 10, as shown, or may be tethered thereto; alternatively the user input device may be remote from system 10, for example, located in a separate control room. According to some additional embodiments, another user input device, for example, in addition to a touch screen of computer 17, may be remote from system 10 and used to start and stop infusions, as well as to monitor system operation both during quality control infusions and during patient infusions. Operation of system 10, which is facilitated by computer 17, will be described below, in conjunction with Figures 4-9C.

Figure 1A further illustrates two pairs of wheels 121, 122, mounted to an underside of platform 113, to make system 10 mobile; handle 14 is shown located at an elevation suitable for a person to grasp in order to maneuver system 10, from one

location for another, upon pairs of wheels 121, 122. According to some preferred embodiments, one or both pairs of wheels 121, 122, are casters, allowing for rotation in a horizontal plane (swivel), in order to provide additional flexibility for maneuvering system 10 in relatively tight spaces.

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

 Figure 1B further illustrates: a rear access panel 174 of shell 13, for example, providing access to circuit boards of the aforementioned controller contained within the interior space that is surrounded by shell 13; an optional lock 184, to secure panel 174; a power jack 118, for connecting system 10 to a power source; and a printer 117
20 for providing documentation of each patient infusion carried out by system 10, and of system quality control test results. In some embodiments, system 10 may further include a power strip by which auxiliary equipment may be powered, and one or more additional electrical connectors, or ports (not shown), which are supported by platform 113 and may be integrated into shell 13, for example, in proximity to jack
25 118 or printer 117; these electrical connectors/ports allow system 10 to communicate with, other devices used for nuclear imaging procedures, for example, a PET scanner/camera, and/or for coupling to an intranet network, and/or to the internet, for example, to link up with software programs for various types of data analysis, and/or to link to computers of consulting clinicians/physicians, and/or to link into service
30 providers and/or component suppliers data bases for enhanced maintenance and inventory management.

 Figure 1A further illustrates upper surface 131 of shell 13 including several openings 133, 135, 139 formed therein. Figure 1C is a partially exploded perspective

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

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

According to the illustrated embodiment, circuit 300 includes: an eluant reservoir 15, for example, a bag, bottle or other container, containing saline as the eluant, which is shown hanging from a post, or hanger 141 above upper surface 131 of shell 13 in Figure 1A; a syringe pump 33, for pumping the eluant from reservoir 15, and a pressure syringe 34 (or other device or sensor), for monitoring pumping pressure; a filter 37, which may also serve as a bubble trap, for the pumped eluant; a radioisotope generator 21, through which the filtered eluant is pumped to create a radioactive eluate, for example an eluate carrying Rubidium-82 that is generated by the decay of Strontium-82, via elution, within a column of generator 21; and an activity detector 25, for measuring the activity of the eluate discharged from generator 21, in

order to provide feedback for directing the flow of the eluate, via a divergence valve 35WP, either to a waste bottle 23 or through a patient line 305p, for example, to inject a dose of the radiopharmaceutical eluate into a patient. With reference back to Figure 1A, patient line 305p is shown extending out from shell 13, through opening 135, to a distal end thereof, which, according to some embodiments, includes a filter. Patient line 305p may be coupled to another line that includes a patient injection needle (not shown). Alternatively, patient line 305p may be coupled to another line (not shown), which extends from a source of another active substance, for example, a stress agent; the other line is coupled to the line that includes the patient injection needle, in order to permit injection of the additional active substance.

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

Figure 1D further illustrates another eluant tubing line 302 coupled to pump 33 and a divergence valve 35BG, which may either direct pumped eluant through a tubing line 304, to generator 21, or direct the pumped eluant through a by-pass tubing line 303, directly to patient line 305p. Divergence valve 35BG, as well as divergence valve 35WP, which directs eluate from an eluate tubing line 305 either to a waste line 305w or to patient line 305p, may each be automatically operated by a corresponding servomotor (not shown), coupled to the controller (not shown) of system 10, which controller receives feedback from activity detector 25. When system 10 is operating for automatic infusion, to deliver a dose of radiopharmaceutical to a patient, for example, Rubidium-82 for diagnostic imaging, divergence valve 35BG is initially set to direct eluant to generator 21 and divergence valve 35WP is set to direct eluate from generator into waste bottle 23, until activity detector 25 detects the desired activity of

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

Although not shown in Figure 1D, a number of sensors, for example, to measure pressure and/or flow velocity, may be incorporated into circuit 300, according to some alternate embodiments, in order to monitor for flow anomalies, for example, related to occlusions/plugs in circuit 300 and/or leaks, and/or to provide feedback for control of an activity level of infused doses of radiopharmaceutical. Suitable sensors for any of the above purposes are known to those skilled in the art. Examples of flow meters that may be incorporated into circuit 300, include the Innova-Sonic® Model 205 Transit-Time Ultrasonic Liquid Flow Meter that employs digital signal processing

(available from Sierra Instruments, Inc.) and the Flocat LA10-C differential pressure flow meter. One example of a pressure sensor that may be employed to detect infusion circuit occlusions is the PRO / Pressure-Occlusion Detector (available from INTROTEK® of Edgewood, NY, a subsidiary of Magnetrol of Downers Grove, IL), which employs pulse-type ultrasound; this sensor detects subtle changes in positive and negative air pressure and produces a corresponding passive resistive output signal, which may be routed to the system controller and/or computer 17. On or more of this type of sensor may be incorporated into infusion circuit 300 by simply fitting the sensor around any of the tubing lines of infusion circuit 300; in fact, the PRO / Pressure-Occlusion Detector may be a suitable alternative to pressure syringe 34 of circuit 300. Other types of pressure sensors, for example, similar to those known in the art for blood pressure monitoring, may be employed in infusion circuit 300.

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

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

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

directed to patient line 305p for infusion. Light projector 100 may further project a more rapidly flashing light, for example, for approximately five seconds, once a peak bolus of radioactivity is detected in the eluate, to provide further information to technical personnel. Alternative means of informing technical personnel that an
5 infusion is taking place may also be incorporated by system 10, for example, including audible alarms or other types of visible or readable signals that are apparent at a distance from system, including in the control room.

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

20 When maintenance of system 10 requires the emptying waste bottle 23, relatively easy access to waste bottle 23 is provided through opening 139 in top surface 131 of shell 13. It should be noted that technical personnel are preferably trained to empty waste bottle 23 at times when the eluate, contained in waste bottle 23, has decayed sufficiently to ensure that the radioactivity thereof has fallen below a
25 threshold to be safe. Opening 139 is preferably located at an elevation of between approximately 2 feet and approximately 3 feet; for example, opening 139 may be at an elevation of approximately 24 inches, with respect to a lower surface of platform 113, or at an elevation of approximately 32 inches, with respect to a ground surface upon which wheels 121, 122 rest. According to the illustrated embodiment, opening 139 is
30 accessed by lifting panel 134; just within opening 139, a shielded lid or door 223 (Figure 2A) may be lifted away from a compartment of shielding assembly 200 that contains waste bottle 23. With further reference to Figure 1C, it may be appreciated that opening 137 provides access to other portions of circuit 300 for additional

maintenance procedures, such as changing out generator 21 and/or other components of circuit 300, as will be described below.

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

Figures 1A and 1C further illustrate a pair of relatively shallow external recesses 190, which are formed in upper surface 131 of shell 13, for example, in order to catch any spills from infusion system; one of recesses 190 is shown located in proximity to post, or hanger 141, which holds reservoir 15, and in proximity to
20 opening 133, through which tubing line 301 passes. Another recess 192 is shown formed in upper surface 131; a width and depth of recess 192 may accommodate storage of technical documentation associated with infusion system 10, for example, a technical manual and/or maintenance records, or printouts from printer 117 (Figure 1B). With reference to Figure 1C, upper surface 131 of shell 13 is shown to also
25 include additional recesses 101, which are each sized to hold a shielded test vial, which contains samples from infusion system 10, for example, for breakthrough testing and/or calibration, which will be described in greater detail, below. An exemplary test vial shield is shown in Figure 1E. The test vial shield of Figure 1E is preferably formed from Tungsten rather than lead, for example, to reduce exposure to
30 lead, for improved shielding, and to reduce the weight of the shield. Figure 1E illustrates the test vial shield including a handle to simplify manipulation thereof, but alternative configurations of test vial shields have no handle – for these a sling, or strap, may be employed for handling.

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

Figure 2A is a perspective view of shielding assembly 200, according to some embodiments of the present invention. With reference to Figures 1C and 2A, together, it may be appreciated that opening 137, in upper surface 131 of shell 13, provides access to a lid or door 221 of a sidewall 201 of shielding assembly 200, which sidewall 201 encloses a compartment sized to contain a radioisotope generator of system 10, for example, generator 21, previously introduced. It should be noted that, according to alternate embodiments, the compartment enclosed by sidewall 201 is large enough to hold more than one generator, for example, to increase system operating efficiency for relatively high volume operation. In some of these alternate embodiments, tubing lines 304 and 305 are each branched for parallel flow through the multiple generators, in which case divergence valves may be employed to alternate the flow through the generators, one at a time. In others of these alternate embodiments, the multiple generators are connected in series between tubing line 304 and tubing line 305. In addition, a reservoir for accumulating eluate may be included in circuit 300, downstream of the generators and upstream of divergence valve 35 WP, in conjunction with a second pump, in some cases. Embodiments including multiple generators and/or an eluate reservoir and second pump can be employed to better manage an activity level of each dose, or patient injection, for example, as described below, in conjunction with Figures 12A-B.

According to the embodiment illustrated in Figure 2A, opening 137 and door 221 are located at a lower elevation, for example, with respect to platform 113, than are opening 139 and lid 223, which provide access to the compartment being formed

by a sidewall 203 of shielding assembly 200 to contain waste bottle 23, as previously described. When panel 132 is separated from shell 13, and door 221 opened, generator 21 may be lifted out from an opening 231 (Figure 3A) which mates with door 221 of sidewall 201. A weight of generator 21, which includes its own shielding, may be
5 between approximately 23 and approximately 25 pounds, thus, according to some preferred embodiments of the present invention, the elevation of each of openings 137 and 231, with respect to the lowermost portion of the cabinet structure, is between approximately 1 foot and approximately 2 feet, in order to facilitate an ergonomic stance for technical personnel to lift generator 21 out from the compartment.

10 According to an exemplary embodiment, when shielding assembly 200 is contained in the cabinet structure of Figure 1A, openings 137 and 231 are located at an elevation of approximately 12 inches, with respect to the lower surface of platform 113, or at an elevation of approximately 19 inches, with respect to the ground surface upon which wheels 121, 122 rest. Figure 1C further illustrates access panel 132 including a
15 security lock 138, which mates with a framework 19 of system 10, shown in Figure 2B, in order to limit access to generator 21.

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

According to the illustrated embodiment, doors 221, 225 are hinged to open in an upward direction, per arrows D and C, and, with reference back to Figure 1C, a

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

With further reference to Figure 2A, according to some preferred embodiments of the present invention, an edge of door 225 overlaps door 221 to prevent door 221 from being opened, per arrow D, if door 225 is not opened, per arrow C; and an edge of door 227 overlaps an edge of door 225 to prevent door 225 from being opened if door 227 is not opened, per arrow B; and an edge of lid 223 overlaps door 227 to prevent door 227 from being opened if lid 223 is not opened, per arrow A. Thus, access to the compartment enclosed by sidewall 201 and containing generator 21 is only systematically allowed through a sequential opening of lid 223 and doors 227, 225, 221, since, when generator 21 is replaced it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225. The routing of these portions of circuit 300 will be described in conjunction with Figures 3A-C.

Figure 3A is another perspective view of shielding assembly 200, according to some embodiments of the present invention. In Figure 3A, lid 223 and doors 221, 225, and 227 are opened to provide a view into openings 233, 235 and 231 of sidewalls 203, 205 and 201, respectively, and into a passageway 207, which is formed in

sidewall 203, opposite the compartment, which contains waste bottle 23. Passageway 207 is shown extending vertically along sidewall 203 and having a grooved extension 213 formed in a perimeter surface of opening 233. An optional retaining member 237, for example, formed from an elongate strip of resilient plastic having a generally c-shape cross-section, is shown being mounted along a length of passageway 207 to hold lines 305w and 305p in place within passageway 207. Figure 3A further illustrates a pair of passageways 251b and 251g, which are formed as grooves in a portion of sidewall 205, and another pair of passageways 215i and 215o, which are formed as grooves in a portion of sidewall 201. A routing of portions of tubing circuit 300 (Figure 1D) through passageways 207, 251b, 251c, 215i and 215o is shown in Figure 3B.

Figure 3B illustrates tubing line 304 being routed through passageways 251g and 215i, eluate tubing line 305 being routed through passageway 215o, and both waste line 305w and patient line 305p being routed along passageway 207. Waste line 305w further extends through grooved extension 213 to waste bottle 23, and patient line 305p further extends outward from shielding assembly 200, for example, to extend out through opening 135 in upper surface 131 of shell 13 (Figure 1A). According to the illustrated embodiment, each passageway formed in shielding assembly 200, by being accessible along a length thereof, can facilitate a relatively easy routing of the corresponding tubing line therethrough, when the corresponding lid/door is open, and a depth of each passageway prevents pinching and/or crushing of the corresponding tubing line routed therethrough, when the corresponding lid/door is closed down thereover. With further reference to Figures 3A-B, it may be appreciated that the compartment formed by sidewall 201 may have a shape matching an exterior contour of generator 21, such that generator 21 is 'keyed' to the compartment, for example, to prevent installation of an improper generator into system 10, and/or to facilitate the proper orientation of generator 21 within the compartment for the proper routing of tubing lines. Alternately, or in addition, according to alternate embodiments, if system 10 includes a reader of encoded information in communication with computer 17, a unique identification and/or data associated with each generator may be provided, for example, in a bar code label or a radiofrequency identification (RFID) tag that is attached to each generator, so that the reader may transfer the information to computer 17, when a generator is installed, in order to either enable system operation or to

provide an indication to the user that an incorrect generator has been installed. Of course a user of system 10 may, alternately, manually enter information, that is provided on a generator label or marking, into computer 17, in order to either enable system 10, or to receive feedback from computer 17 that the incorrect generator is installed.

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

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

According to the illustrated embodiment, an end 404A, of eluant line 304, and an end 403, of by-pass line 303 extend from third side 393 of frame 39 to couple with divergence valve 35BG and an upstream section of eluant tubing line 302. Figure 3C further illustrates an opposite end 404B of eluant line extending from first side 391 of frame 39, alongside a similarly extending end 405 of eluate line 305, and ends 406 and

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

As previously mentioned, when generator 21 is replaced, it is typically desirable to also replace those portions of circuit 300 which are shielded behind lid 223 and doors 227, 225, and, in those instances wherein system 10 is moved to a new site each day, these portions may be replaced daily. Thus, according to the illustrated embodiment, these portions are conveniently held together by frame 39, as subassembly 390, in order to facilitate relatively speedy removal and replacement, while assuring a proper assembly orientation, via registration with features formed in sidewall 205 (Figure 3A), for example: registration of divergence valve 35WP with valve actuator receptacle 253, registration of tubing line ends 403 and 404A with passageways 251b and 251g, respectively, registration of tubing line ends 404B and 405 with passageways 215i and 215o, respectively, and registration of tubing line ends 406 and 407 with passageway 207.

With further reference to Figure 3B, other portions of tubing circuit 300 are shown. Figure 3B illustrates eluant tubing line 301 extending from reservoir 15, outside of shell 13 (Figure 1A), to syringe pump 33, which is mounted to an actuating platform 433. According to the illustrated embodiment, platform 433 is actuated by another servomotor (not shown) of system 10, which is controlled by the controller and computer 17 of system 10, to cause a plunger of pump 33 to move, per arrow I, so

as to draw in eluant, from reservoir 15, through tubing line 301, and then to cause the plunger to move in the opposite direction so as to pump the eluant, through tubing line 302, to either generator 21 or to by-pass line 303. Although the illustrated embodiment includes syringe pump 33, other suitable pumps, known to those skilled in the art, may be substituted for pump 33, in order to draw eluant from reservoir 15 and to pump the eluant throughout circuit 300. Although not shown, it should be appreciated that divergence valve 35BG is fitted into another valve actuating receptacle mounted within shell 13 and coupled to yet another servomotor (not shown) of system 10.

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

Turning now to Figures 4-9C details concerning computer-facilitated operation of system 10 will be described, according to some embodiments of the present invention. As previously mentioned, and with reference back to Figure 1A, computer 17 of system 10 includes monitor 172, which, preferably, not only displays indications of system operation to inform a user of system 10, but is also configured as a touch screen to receive input from the user. It should be understood that computer 17 is coupled to the controller of system 10, which may be mounted within the interior space surrounded by shell 13. Although Figure 1A shows computer 17 mounted to post 142 of system 10, for direct hardwiring to the controller of system 10, according to some alternate embodiments, computer 17 is coupled to the controller via a flexible lead that allows computer 17 to be positioned somewhat remotely from those portions of system 10, from which radioactive radiation may emanate; or, according to some other embodiments, computer 17 is wirelessly coupled, for example, via two-way telemetry, to the controller of system 10, for even greater flexibility in positioning computer 17, so that the operation of system 10 may be monitored and controlled remotely, away from radioactive radiation.

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

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

to some embodiments, computer 17 is pre-programmed to provide guidance in multiple languages.

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

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

After the user enters the appropriate information into data entry fields of log in screen 570, computer 17 presents a request for the user to confirm the volume of eluant that is within reservoir 15 (e.g. saline in saline bag), via a screen 571, and then brings up main menu 470. If the user determines that the volume of eluant/saline is insufficient, the user selects a menu item 573, to replace the saline bag. If system 10 includes an encoded information reader, such as a bar code or RFID tag reader, confirmation that the selected reservoir is proper, i.e. contains the proper saline solution, may be carried out by computer 17, prior to connecting the reservoir into circuit 300, by processing information read from a label/tag attached to the reservoir. Alternatively, or in addition, tubing line 301 of circuit 300 may be provided with a

connector which only mates with the proper type of reservoir 15. According to some embodiments, system 10 may further include an osmolarity or charge detector, which is located just downstream of reservoir 15 and is linked to computer 17, so that an error message may be presented on monitor 172 stating that the wrong osmolarity or charge is detected in the eluant supplied by reservoir, indicating an improper solution. One example of a charge detector that may be employed by system 10 is the SciCon™ Conductivity Sensor (available from SciLog, Inc. of Middleton, WI).

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

In addition to tracking the volume of eluant in reservoir 15, computer 17 also tracks a volume of the eluate which is discharged from generator 21 into waste bottle 23. With reference to Figure 5C, an item 583 is provided in main menu 470, to be selected by the user when the user empties waste bottle 23. When the user selects item 583, computer 17 presents a screen 584, by which the user may effectively command computer 17 to set a waste bottle level indicator to zero, once the user has emptied waste bottle 23. Typically, the user, when powering up system 10 for operation, each

day, will either empty waste bottle 23, or confirm that waste bottle 23 was emptied at the end of operation the previous day, and utilize screen 584 to set the waste bottle level indicator to zero. Thus, computer 17, can track the filling of waste bottle 23 via monitoring of the operation of pump 33 and divergence valve 35WP, and provide an indication to the user when waste bottle 23 needs to be emptied, for example, via presentation of screen 584, in order to warn the user that, unless emptied, the waste bottle will overflow. According to some embodiments, system 10 automatically precludes any further operation of the system until the waste bottle is emptied.

According to some alternative embodiments, a fluid level sensor may be coupled to waste bottle, for example, as mentioned above in conjunction with Figure 1D, in order to automatically detect when waste bottle is filled to a predetermined level and to provide, via computer 17, an indication to the user that waste bottle 23 needs to be emptied and/or to automatically preclude operation of system 10 until the waste bottle is emptied.

In addition to the above maintenance steps related to eluant and eluate volumes of system 10, the user of system 10 will typically perform quality control tests each day, prior to any patient infusions. With reference to Figure 6, according to preferred methods, prior to performing the quality control tests (outlined in conjunction with Figures 7A-C and 8A-B), the user may select an item 675 from main menu 470, in order to direct system 10 to wash the column of generator 21. During the generator column wash, which is performed by pumping a predetermined volume of eluant, for example, approximately 50 milliliters, through generator 21 and into waste bottle 23, computer 17 provides an indication, via a screen 676, that the wash is in progress. Also, during the generator column wash, the system may provide a signal to indicate that eluate is being diverted to waste bottle 23, for example, light projector 100 (Figure 1C) may project a flashing light signal, as previously described.

Figure 6 further illustrates a screen 677, which is presented by computer 17 upon completion of the column wash, and which provides an indication of a time lapse since the completion of the wash, in terms of a time countdown, until a subsequent elution process may be effectively carried out. While screen 677 is displayed, system 10 may be refilling, from reservoir 15, pump 33, which has a capacity of approximately 55 milliliters, according to some embodiments. According to some preferred embodiments of the present invention, computer 17 starts a timer once any

elution process is completed and informs the user of the time lapse, either in terms of the time countdown (screen 677), or in terms of a time from completion of the elution, for example, as will be described in conjunction with Figure 7B. According to an exemplary embodiment, wherein generator 21 is the CardioGen-82® that yields a saline solution of Rubidium-82, produced by the decay of Strontium-82, via the elution, a time required between two effective elution processes is approximately 10 minutes.

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

Figure 7A further illustrates a subsequent screen 775, by which computer 17 receives input, from the user, for system 10 to start the breakthrough elution, followed by a screen 776, which provides both an indication that the elution is in progress and an option for the user to abort the elution. As previously described, the system may provide a signal to indicate that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when the eluate is diverted from generator 21 through patient line 305p and into the test vial, for example, once activity detector 25 detects a dose rate of approximately 1.0 mCi/sec in the eluate discharged from generator 21. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate.

Upon completion of the elution process for breakthrough testing, computer 17 presents a screen 777, shown in Figure 7B, which, like screen 677, provides an indication of a time lapse since the completion of the elution, but now in terms of a time since completion of the breakthrough elution process. When the user transfers

the vial containing the sample of eluate into a dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 777.

With further reference to Figure 7B, once the user has received the activity measure from the dose calibrator, the user proceeds to a screen 778, which includes data entry fields for the activity measure and the time between that at which the dose calibrator measured the activity of the sample and that at which the elution was completed. The user may enter the data via the touch-screen interface of monitor 172, or via any of the other aforementioned devices for user data entry. According to some alternate embodiments, computer 17 may receive the data, electronically, from the dose calibrator, either via wireless communication or a cable connection.

After the data is entered by the user, computer 17 presents screen 779, from which the user moves back to main menu 470 to perform a system calibration, for example, as will be described in conjunction with Figures 8A-B, although the breakthrough testing is not completed. With reference back to Figure 7A, an item 773B is shown, somewhat faded, in main menu 470; item 773B may only be effectively selected following the completion of steps for item 773A, so as to perform a second stage of breakthrough testing. In the second stage, the breakthrough of the sample of eluate collected in the test vial for the breakthrough testing is measured, at a time of approximately 60 minutes from the completion of the elution that produced the sample. With reference to Figure 7C, after the user has selected item 773B from main menu 470, in order to direct computer 17 to provide breakthrough test results, a screen 781 is displayed. Screen 781 includes, for reference, the values previously entered by the user in screen 778, along with another pair of data entry fields into which the user is instructed to enter the breakthrough reading of the sample at 60 minutes and the background radiation reading, respectively. After the user enters this remaining information, as described above, computer 17 may calculate and then display, on a screen 782, the breakthrough test results. According to the illustrated embodiment, computer 17 also displays on screen 782 pre-programmed allowable limits for the results, so that the user may verify that the breakthrough test results are in compliance with acceptable limits, before moving on to a patient infusion. According to some embodiments, system 10 will not allow an infusion if the results exceed the acceptable limits, and may present a screen explaining that the results are outside the acceptable

limits; the screen may further direct the user to contact the generator supplier, for example, to order a replacement generator.

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

With reference to Figure 8B, after computer 17 starts the elution process, a screen 87 informs the user that the calibration elution is in progress and provides an option to abort the elution. As previously described, the system may provide an indication that elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line, and into the test vial. Another type of light signal, for example, the more rapidly flashing light, as previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. Upon completion of the elution process for calibration, computer 17 presents a screen 878, which provides an indication of a time lapse since the completion of the elution, in terms of a time since completion of the calibration elution process. When the user transfers the vial containing the sample of eluate into the dose calibrator, to measure the activity of the sample, the user may make a note of the time lapse indicated on screen 878. With further reference to Figure 8B, once the user has received the activity measure from the dose calibrator, the

user proceeds to a screen 879, which includes data entry fields for the activity measure and the time, with respect to the completion of elution, at which the dose calibrator measured the activity of the sample. Once the data is input by the user, as described above, computer calculates a calibration coefficient, or ratio, and presents the ratio on a screen 880. According to Figure 8B, screen 880 further provides an indication of a desirable range for the calibration ratio and presents an option for the user to reject the calculated ratio, in which case, the user may instruct computer 17 to recalculate the ratio.

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

With reference to Figure 9A, upon completion of the above-described quality control tests, the user may select an item 971, from main menu 470, in order to direct system 10 to begin a procedure for the generation and automatic infusion of a radiopharmaceutical into a patient. As previously described, system 10 infuses the patient with the radiopharmaceutical so that nuclear diagnostic imaging equipment, for example, a PET scanner, can create images of an organ of the patient, which absorbs the radiopharmaceutical, via detection of radioactive radiation therefrom. According to Figure 9A, upon selection of item 971, computer 17 presents a screen 972 which includes a data entry field for a patient identification number. This identification number that is entered by the user is retained by computer 17, in conjunction with the pertinent system parameters associated with the patient's infusion. After the user enters the patient identification number, computer 17 directs, per a screen 973, the user to attach a new patient line and to purge the patient line of air. A subsequent screen

974 presented by computer 17 includes data entry fields by which the user may establish parameters for the automatic infusion; all or some of the fields may be filled in with pre-programmed default parameters, which the user has an option to change, if necessary.

5 With reference to Figure 9B, if pump 33 does not contain enough eluant/saline for the patient infusion, computer 17 will present a warning, via a screen 901, which includes an option for the user to direct the refilling of pump 33, via a subsequent screen 902. Once pump 33 has been filled, computer 17 presents an indication to the user, via a screen 903. According to some embodiments, if the user does not re-fill
10 pump 33, yet attempts to proceed with an infusion, system 10 will preclude the infusion and present another screen, that communicates to the user that no infusion is possible, if the pump is not refilled, and asking the user to refill the pump, as in screen 901. When pump 33 contains a sufficient volume of eluant for the patient infusion, computer 17 presents a screen 975, which is shown in Figure 9C, and allows the user
15 to enter a command for system 10 to start the patient infusion. During the infusion, computer 17 provides the user with an indication that the infusion is in process and with a option for the user to abort the infusion, via a screen 976. As previously described, the system may provide an indication that an elution is in progress, for example, light projector 100 (Figure 1C) may project a flashing light signal during that
20 portion of the elution process when eluate is diverted from generator 21 through waste line 305w and into waste bottle 23, and then a steady light signal during that portion of the elution process when activity detector 25 has detected that a prescribed dose rate threshold is reached, for example, 1.0 mCi/sec, and the eluate is being diverted from generator 21, through the new patient line for infusion into the patient. Another type
25 of light signal, for example, the more rapidly flashing light, previously described, may be projected when a peak bolus of radioactivity is detected in the eluate. At the completion of the infusion, a screen 977 is displayed by computer 17 to inform the user of the completion of the infusion and a time since the completion. Computer 17 also displays a summary of the infusion, per screen 978.

30 With further reference to Figure 9C, screen 976 shows an exemplary activity profile (activity - mCi/sec, on y-axis, versus time - sec, on x-axis) for the infusion/injected dose (designated between the two vertical lines). Those skilled in the art will appreciate that the shape of this profile depends upon the infusion flow rate,

for a given volume of the dose, which flow rate is controlled, for example, by the speed at which pump 33 drives flow through the patient line, and upon the amount of Strontium-82 remaining in the generator. In the absence of flow rate control, activity profiles may change over the life of the generator. Furthermore, the peak bolus of radioactivity, particularly for injected doses from a relatively new generator, may exceed a saturation level of the imaging equipment, i.e. PET scanner. According to some preferred methods of the present invention, in order to maintain relatively consistent, and desirable/effective, activity profiles for patient injections, over the life of the generator, the operating speed of pump 33 may be varied (both over the course of a single injection and from injection to injection), according to feedback from activity detector 25. Such a method may be implemented via incorporation of another quality control test in which pump 33 is operated to drive flow through the generator at a constant rate, in order to collect, into computer, a plurality of activity measurements from activity detector 25; the plurality of measurements comprise a characteristic, or baseline activity profile from which the computer 17 may calculate an appropriate flow rate profile to control a speed of pump 33, in order to achieve the desirable/effective activity profile. In general, at the start of generator life, when Strontium-82 is plentiful, the pump is controlled to drive infusion flow at relatively lower rates, and, then, toward the end of generator life, when much of the Strontium-82 has been depleted, the pump is controlled to drive infusion flow at relatively higher rates. As was described above, in conjunction with Figure 1D, if a desired infusion/injection flow rate is relatively high, that is, high enough to create too much back pressure, via flow through the column of generator 21, by-pass line 303 may be employed by adjusting divergence valve 35BG to divert a flow of eluant therethrough after a sufficient volume has been pumped through generator at a lower flow rate. According to this method, once a dose of eluate, from generator 21, has flowed into patient line 305p, divergence valve 35BG is set to divert the flow of eluant through by-pass line 303, and then pump speed is increased to pump eluant at a higher flow rate in order to push the dose out from patient line 305p, for injection at the higher flow rate.

Consistency of activity profiles among injected doses can greatly facilitate the use of PET scanning for the quantification of flow, for example, in coronary perfusion studies. Alternative infusion circuit configurations, operable according to alternative methods, to achieve consistency of activity profiles among injected doses, as well as a

more uniform level of radioactivity across each individual dose, will be described below, in conjunction with Figures 12A-C.

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

With reference back to Figure 9A the user may select an item 995, from main menu 470, in order have system 10 perform data operations, such as, archiving a data
20 base of patient infusion information and quality control test results, transmitting patient infusion summary records to USB mass storage devices, and various types of data filtering, for example, according to date ranges and/or patient identification numbers, for example, to search for a particular set of data and/or to compile a summary report of related sets of data. Additionally, certain information, which is
25 collected by computer 17 over the course of system operation, and which defines system operation, may be transmitted to a local or remote computerized inventory system and/or to computers of technical support personnel, maintenance/service providers and/or suppliers of infusion circuit elements/components, thereby facilitating more efficient system operation and maintenance.

30 Turning now to Figure 10, an item 981 for computer-facilitated purging of the tubing lines of system 10 is shown included in main menu 470. When a user selects item 981, computer 17 guides the user to select either an air purge or a saline purge. The direction provided by computer 17 is not explicitly laid out herein, for a saline

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

According to preferred embodiments, once the user has followed the instructions presented in screens 983 and 984 and selects to start the air purge, for example, via screen 985, computer 17 directs the controller of system 10 to carry out a complete air purge, in which pump 33 and divergence valves 35BG and 35WP are automatically controlled. The automated air purge preferably includes the following steps, which may be best understood with reference to tubing circuit 300 in Figure 1D: pumping any remaining volume of eluant left in pump 33, through lines 302, 304, 305 and 305w, to waste bottle 23; refilling pump 33 with air and pumping the air through lines 302, 304, 305 and 305w, into waste bottle 23 (lines 304 and 305 have been previously connected directly to one another, in order to by-pass generator 21; if generator 21 is depleted and will be replaced with a new generator, pumping air through generator 21 may be acceptable); refilling pump 33 with air and then pumping a portion of the air through lines 302, 304, 305 and 305p, into the vial, and then a remaining portion of the air through lines 302, 304, 303 and 305p, into the vial. With reference to Figure 1D and the previous description of divergence valves 35BG, 35WP, it should be understood how divergence valves 35BG, 35WP are automatically controlled to carry out the above steps.

The purge operations, which are facilitated by selecting item 981 from main menu 470, may also be accessed via the selection of an item 991 for generator setup.

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

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

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

Figure 12A illustrates circuit 1300A including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, through which the

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

Figure 12B illustrates circuit 1300B including, like the previously described circuit 300, eluant reservoir 15, pump 33, radioisotope generator 21, activity detector 25, and waste bottle 23, as well as the two filters 37 and two pressure transducers 1334, as in circuit 1300A. In contrast to circuits 300 and 1300A, circuit 1300B further includes an eluate reservoir 1350, which is shown located downstream of generator 21, in between first and second segments 305A, 305B of the eluate tubing line. It should be noted that a pump is combined with reservoir 1350, for example, similar to syringe pump 33, such that, when a divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305A, the associated pump may be operated to draw in a volume of eluate, and, then, when divergence valve 1335IO is set to allow fluid communication between reservoir 1350 and tubing line segment 305B, the pump may be operated to push the volume of eluate out through tubing line segment 305B for a patient injection, when divergence valve 35WP is set to direct flow into patient line 305p. With reference back to Figures 3A-B, sidewall 205 of shielding assembly 200 may be enlarged to further enclose eluate reservoir 1350. For example, another shielded well, to house the eluate reservoir, may extend alongside well 255, in which activity detector 25 is described as being mounted. Furthermore, sidewall 205 may include another valve actuator receptacle for

divergence valve 1335IO, similar to receptacle 253, shown in Figure 3A for divergence valve 35WP.

Collection of discrete volumes of eluate, in reservoir 1350, may help to achieve a more uniform activity level over each injection, for example, like that of profile 5 1200B in Figure 12C, and, according to preferred methods, feedback from activity detector 25 may be used to control the pump associated with reservoir 1350, in order to vary injection flow rate and, thereby, maintain a relatively consistent activity level across multiple injections, and, when necessary, to vary injection flow rate over an individual injection to maintain the uniform activity level. Feedback from the 10 pressure transducer 1334, that is downstream from detector 25, and/or from a flow meter (not shown) of circuit 1300B may also be used to control the varying of injection flow rate.

With further reference to Figures 12A-B, it should be noted that alternative circuits may be configured to employ a combination of the methods described for 15 circuits 1300A and 1300B. Furthermore, some infusion circuits of the present invention may employ multiple generators 21, as mentioned above, in conjunction with Figure 2A, to help maintain the relatively uniform level of activity over each injection and the relatively consistent level of activity from injection to injection.

In the foregoing detailed description, the invention has been described with 20 reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

We claim:

1. An infusion system comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer; the infusion tubing circuit including an eluant line coupled to the pump and to the generator and an eluate line coupled to the generator and to the activity detector; and the computer being coupled to a user interface, to the pump and to the activity detector and being pre-programmed to receive input from a user of the system, via the user interface, to collect information, from the pump and the activity detector, and to provide output to the user, via the user interface, according to a method, the method comprising:
 - 10 activating the pump to pump a volume of eluant from the reservoir, through the eluant line and through the generator, in order to generate a sample or a dose of eluate in the eluate line, via an elution within the generator, the sample being intended for a quality control measurement, and the dose being intended for diagnostic imaging; providing an indication, via the computer interface, that the elution is completed, when
15 the pump has completed pumping the volume of eluant through the generator; and providing an indication, via the computer interface, of a time lapse since the elution was completed.
2. The infusion system of claim 1, wherein the pre-programmed method further
20 comprises:
 - repeating the sequence of the steps of claim 1) multiple times; and
 - counting elutions per unit time;
 - categorizing each counted elution as having been generated as a sample or a dose; and
 - maintaining a record of the counted and categorized elutions.
- 25 3. The infusion system of claim 2, wherein the pre-programmed method further comprises measuring an activity level of the eluate for each dose and sample and entering each measurement into the record.
- 30 4. The infusion system of claim 2 or 3, wherein the pre-programmed method further comprises compiling a report that contains the record, the report being formatted for printing and/or for electronic transfer to another system.

5. The infusion system of claim 1, wherein the pre-programmed method further comprises:

repeating the sequence of the steps of claim 1 multiple times;

maintaining a record of elutions that categorizes each elution as having been generated

5 a sample or a dose;

measuring an activity level of the eluate for each dose and sample and entering the measurement into the record;

calculating and tracking an amount of activity left in the generator after each elution, over a life of the generator; and

10 compiling a report that includes an amount of activity left in the generator after a final elution at an end of the life of the generator.

6. An infusion system comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a
15 computer; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, a by-pass line coupled to the eluant line, via a divergence valve, and to the patient line, the by-pass line accommodating flow of eluant to the patient line, when the divergence valve is set to direct the flow to by-pass the generator; and the
20 computer being coupled to the pump and to the activity detector and being pre-programmed to collect information, from the pump and the activity detector and to control the divergence valve and the pump according to a method, the method comprising:

activating the pump a first time to pump a portion of a volume of eluant from the

reservoir, through the eluant line and through the generator at a first flow rate, in

25 order to generate eluate in the eluate line, via an elution within the generator, and to push a dose of the eluate into the patient line;

setting the divergence valve to direct flow through the by-pass line, once the dose has been pushed into the patient line; and

activating the pump a second time to pump a second portion of the volume of eluant

30 from the reservoir, through the eluant line, through the by-pass line and into the patient line to inject the dose out from the patient line;

wherein the pump, when activated the second time, is controlled to pump the second portion of the volume of eluant at a second flow rate, the second flow rate being higher than the first flow rate, in order to increase a flow rate of the injection of the dose.

5

7. The system of claim 6, wherein the first flow rate is less than approximately 70mL/minute and the second flow rate is greater than approximately 70mL/minute.

10

8. A method for operating an infusion system, the system comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer including a computer interface, the infusion tubing circuit including an eluant line coupled to the pump and to the generator, a waste line coupled to the generator and to the waste bottle, and a patient line coupled to the generator, the method comprising:

15

entering, into the computer, via the computer interface, a command to activate the pump in order to generate an eluate from a portion of a volume of eluant pumped through the generator, via an elution within the generator;

receiving an indication, from the computer, via the computer interface, that the elution is completed, when the pump has completed pumping the portion of the volume of

20

eluant; and
receiving an indication, from the computer, via the computer interface, of time lapsed since the elution was completed.

9. The method of claim 8, further comprising:

25

entering, into the computer, via a computer interface, the volume of eluant contained in the reservoir, prior to the elution; and

receiving, from the computer interface, an indication of a volume of eluant in the reservoir, based upon tracking the portion of the volume of eluant that is pumped from the reservoir.

30

10. The method of claim 8, further comprising:

directing flow of the eluate through the patient line of the infusion tubing circuit to a first shielded test vial, in order to collect a first sample of the eluate during the elution;

5 measuring an activity of the first sample; and

transferring the measured activity of the first sample and a time between completion of the elution and the measuring of the activity to the computer, so that the computer may calculate a breakthrough of the generator.

10 11. The method of claim 10, further comprising:

selecting a breakthrough test procedure of the computer, via the computer interface, prior to entering the command to activate the pump; and

receiving instructions from the computer interface to couple the patient line to the first shielded test vial, after selecting the breakthrough test and prior to entering the

15 command to activate the pump.

12. The method of claim 10, further comprising:

exchanging the patient line of the infusion tubing circuit for a first new patient line, after collecting the first sample;

20 directing flow of the eluate through the first new patient line to a second shielded test vial;

repeating the steps of claim 8, after exchanging the patient line, wherein the pump is activated a second time and a second elution takes place, in order to fill the second vial with a second sample of the eluate from the first new patient line;

25 measuring an activity of the second sample; and

transferring the measured activity of the second sample and a time between completion of the second elution and the measuring of the activity of the second sample to the computer, so that the computer may calculate a calibration coefficient for the

infusion system based on the measured activity of the second sample and an

30 activity of the eluate detected, during the second elution, by the activity detector of the system.

13. The method of claim 12, further comprising:

selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump for the second time; and

5 receiving instructions from the computer interface to couple the first new patient line to the second shielded test vial, after selecting the calibration procedure and prior to entering the command to activate the pump for the second time.

14. The method of claim 12, further comprising:

exchanging the first new patient line of the infusion tubing circuit for a second new

10 patient line, after the computer calculates the calibration coefficient;

coupling the second new patient line to a patient;

repeating the steps of claim 8, after exchanging the first new patient line for the second new patient line, wherein the pump is activated a third time and a third elution takes place; and

15 directing flow of the eluate through the patient line, once an activity of the eluate, as detected by the activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate to the patient from the second patient line for diagnostic imaging.

20 15. The method of claim 14, further comprising receiving a report from the computer, upon completion of the third elution, the report including a patient identification number and at least one quantification related to the activity of the dose of the eluate.

16. The method of claim 8, further comprising:

25 directing flow of the eluate through the patient line to a shielded test vial in order to collect a sample of the eluate from the patient line during the elution;

measuring an activity of the sample; and

transferring the measured activity of the sample and a time between completion of the elution and the measuring of the activity to the computer, so that the computer may

30 calculate a calibration coefficient for the infusion system based on the measured activity and an activity of the eluate detected, during elution, by the activity detector of the system.

17. The method of claim 16, further comprising:

selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump; and

5 receiving instructions from the computer interface to couple the patient line to the shielded test vial, after selecting the calibration procedure and prior to entering the command to activate the pump.

18. The method of claim 8, further comprising:

coupling the patient line of the infusion tubing circuit to a patient;

10 directing flow of the eluate through the patient line, once an activity of the eluate, as detected by the activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate into the patient for diagnostic imaging; and

receiving a report from the computer, upon completion of the elution, the report including a patient identification number and at least one quantification related to
15 the activity of the dose of the eluate.

19. The method of claim 8, wherein the computer interface comprises a touch-activated display screen.

20 20. The method of claim 8, further comprising:

receiving an indication, from the system, that the eluate is being diverted, from the generator, through the waste line of the infusion tubing circuit, when the pump is activated;

25 receiving an indication, from the system, that the eluate is being diverted from the generator, through the patient line of the infusion tubing circuit, when the pump is activated;

21. The method of claim 20, wherein:

the system further comprises a light projector;

30 the indication that the eluate is being diverted through the waste line comprises a flashing light projection from the light projector; and

the indication that the eluate is being diverted through the patient line comprises a solid light projection from the light projector.

22. The method of claim 20, further comprising receiving an indication from the system that a peak bolus of radioactivity has been detected, in the eluate, by the activity detector.

5 23. The method of claim 22, wherein:

the system further comprises a light projector; and

the indication that the peak bolus of radioactivity has been detected comprises a flashing light from the light projector.

10 24. The method of claim 8, further comprising:

entering, into the computer, via the computer interface, a command to set a waste

bottle level indicator to zero, when the waste bottle is empty and prior to entering the command to activate the pump; and

receiving, from the computer, via the computer interface, an indication that the waste

15 bottle needs to be emptied, based upon the computer tracking a volume of the

eluate that is diverted, from the generator, through the waste line of the infusion tubing circuit.

25. The method of claim 8, further comprising:

20 coupling the patient line of the tubing circuit to the patient;

directing flow through the patient line, once an activity of the eluate, as detected by the

activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate into a coronary artery of the patient for diagnostic imaging;

collecting parameters defining an activity profile of the injected dose; and

25 transferring the parameters to another system for analysis.

26. The method of claim 8, wherein the system further comprises at least one sensor for detecting a leak in the tubing circuit, and further comprising receiving an indication, from the computer, via the computer interface, that a leak in the tubing circuit is detected and an
30 indication of a location of the leak.

27. The method of claim 8, wherein the pump is activated to pump the portion of the volume of eluant through the generator at a constant flow rate; and further comprising collecting, into the computer, a plurality of activity measurements of the eluate, over time, from the activity detector, while the pump is pumping, the collected plurality of activity measurements comprising a baseline activity profile, so that the computer may calculate a flow rate profile that corresponds to a desired activity profile, the flow rate profile for controlling a speed of the pump, upon a subsequent activation.
28. The method of claim 27, wherein the subsequent activation of the pump is for pumping another portion of the volume of eluant through the generator, to generate a dose of eluate, via another elution within the generator, for a patient injection.
29. The method of claim 27, wherein:
the subsequent activation of the pump follows a second activation of the pump;
the second activation of the pump is for pumping a second portion of the volume of eluant through the generator, to generate a dose of eluate, via another elution within the generator; and
the subsequent activation of the pump is for pumping a third portion of the volume of eluant through a tubing line that by-passes the generator at a higher flow rate than that achieved by the second activation of the pump, the third portion of the volume of eluant for injecting the dose of eluate into a patient.
30. A computer readable medium having computer executable instructions for executing a method for maintaining an infusion system, the method comprising:
tracking a portion of a volume of eluant that is pumped from a reservoir of the system and through a generator of the system, in order to generate, via elution, an eluate; providing an indication of the volume of eluant within the reservoir to a user of the system;
tracking a volume of the eluate that is diverted from the generator to a waste bottle of the system; and
providing an indication to the user that the waste bottle needs to be emptied.

31. The computer readable medium of claim 30, wherein the method further comprises receiving, from the user, a command to set a waste bottle level indicator to zero when the waste bottle is empty.

5 32. A computer readable medium having computer executable instructions for executing a method of calibrating an activity detector of an infusion system, the method comprising:
receiving a calibration command;
receiving calibration parameters relating to an elution process;
activating a pump of the infusion system to initiate the elution process, the elution
10 process producing a sample of an eluate;
tracking a time from the end of the elution process;
receiving from the activity detector of the infusion system an activity level detected
during the elution process;
receiving a measured activity level of the eluate sample obtained from a dose
15 calibrator;
receiving a time measured from the completion of the elution process to the
measurement of the activity level by the dose calibrator;
calculating a calibration coefficient for the infusion system based on the measured
activity level of the eluate sample and activity level detected during the elution
20 process; and
providing the calibration coefficient as an output.

33. A computer readable medium having computer executable instructions for executing a
method of conducting a breakthrough test of a radioisotope generator of an infusion
25 system, the method comprising:
receiving a breakthrough test command;
activating a pump of the infusion system to initiate an elution process, the elution
process using the generator to produce a sample of an eluate from a patient line;
tracking a time lapsed from the end of the elution process;
30 receiving a measured activity level of the eluate sample obtained from a dose
calibrator;
receiving a time measured from the completion of the elution process to the
measurement of the activity level by the dose calibrator;

calculating a breakthrough of the radioisotope generator based on the measured activity level and the time between completion of the elution process and the measuring of the activity level; and
providing the breakthrough of the generator as an output.

5

34. The computer readable medium of claim 33, wherein the method further comprises: receiving a second measured activity level of the eluate sample obtained from a dose calibrator, the second measured activity level being a measurement taken at predetermined time period after the completion of the elution process.

10

35. The computer readable medium of claim 33, wherein the predetermined time period is 60 minutes after completion of the elution process.

15

36. A method for purging a tubing circuit of an infusion system with air, the system comprising a pump coupled to the tubing circuit, a radioisotope generator, a waste bottle and a computer including a computer interface, the method comprising:

receiving instructions from the computer, via the computer interface, to disconnect the pump from an eluant reservoir of the system, and to by-pass the generator by disconnecting an eluant line and an eluate line, of the tubing circuit, from the generator, and connecting the eluant line to the eluate line; and

20

entering, into the computer, via the computer interface, a command to perform an air purge of the tubing circuit, the air purge being automated, via the computer, to perform purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit;

25

wherein a first valve, of the two divergence valves, is located between a first portion of the eluate line and two downstream portions of the eluate line, a first of the two downstream portions extending to a waste bottle of the system and a second of the two downstream portions extending to a vial outside the system;

a second valve, of the two divergence valves, is located between a first portion of the eluant line, extending from the pump, and two downstream portions of the eluant line, a first of the two downstream portions of the eluant line being connected to the first portion of the eluate line, and a second of the two downstream portions of the eluant line being connected to the second of the two downstream portions of the eluate line.

5

Fig. 1A

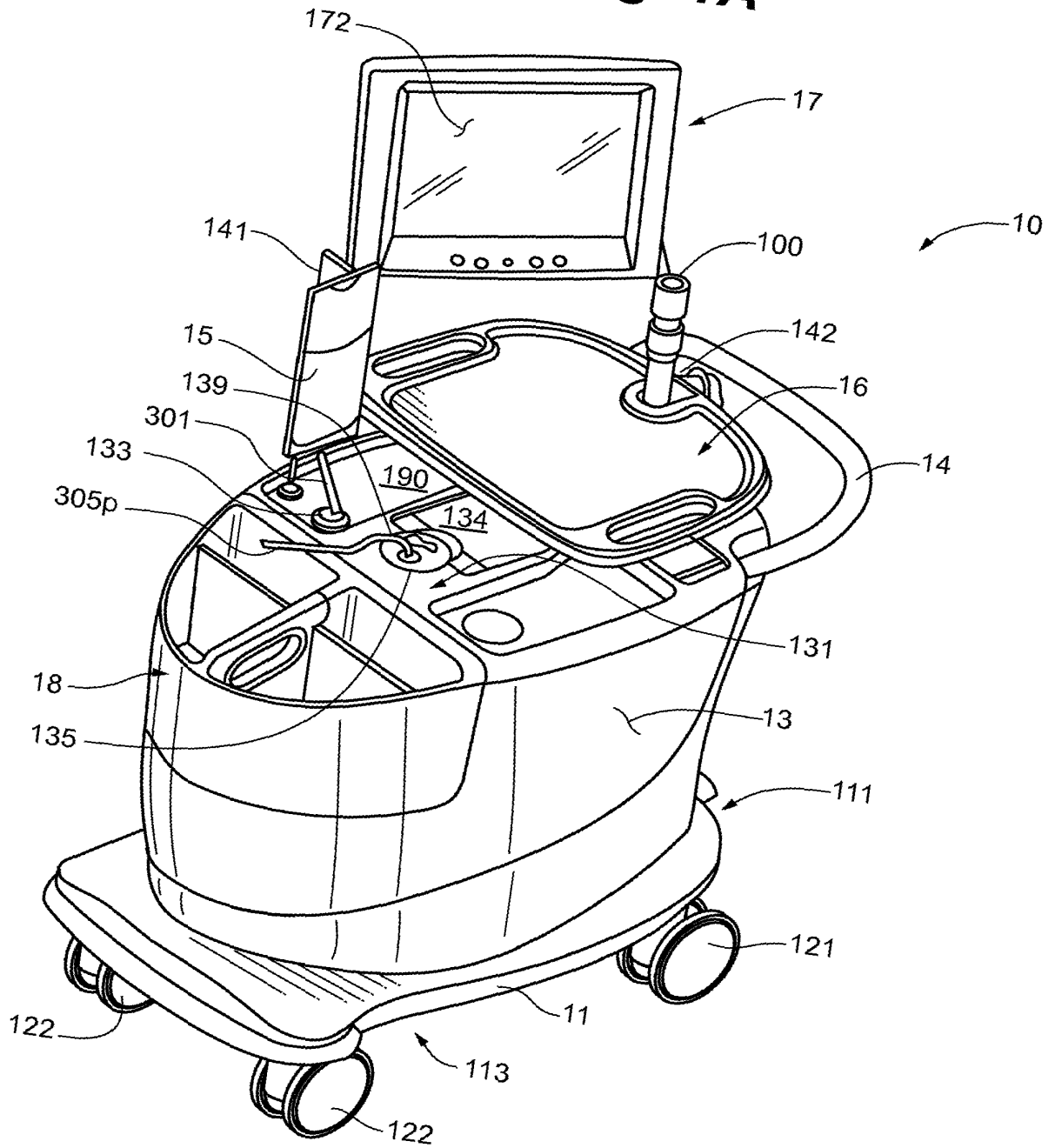


Fig. 1B

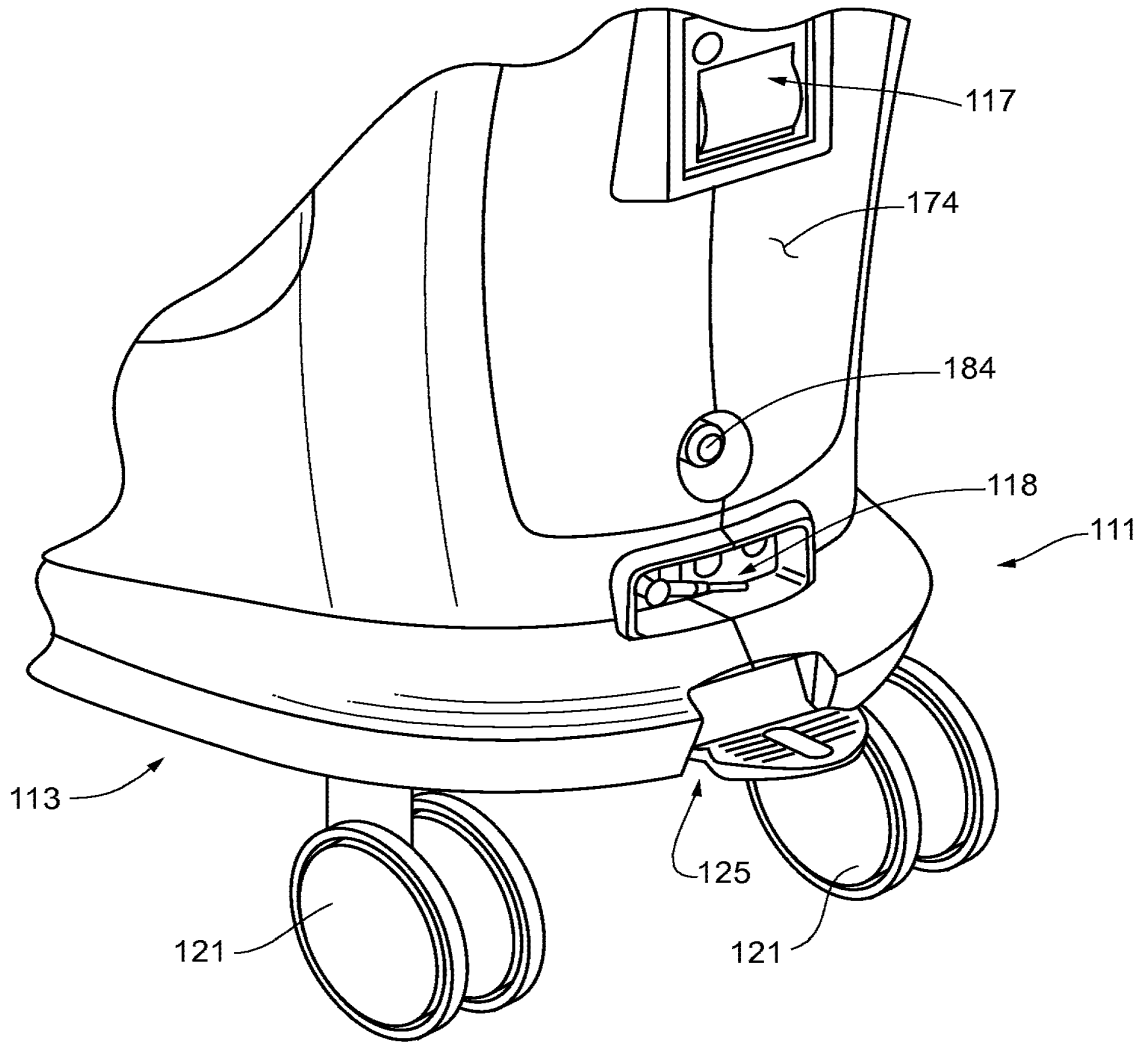
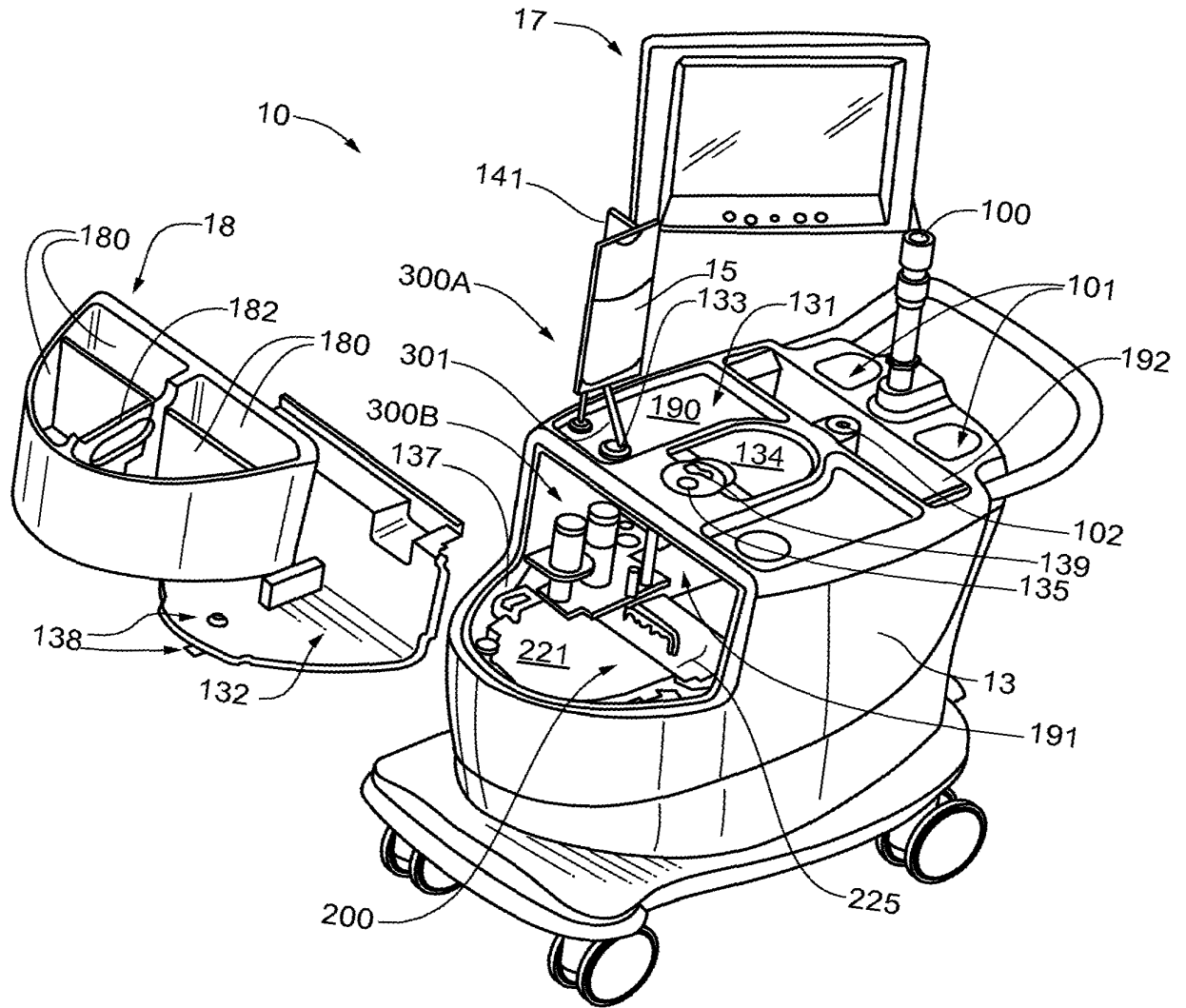


Fig. 1C



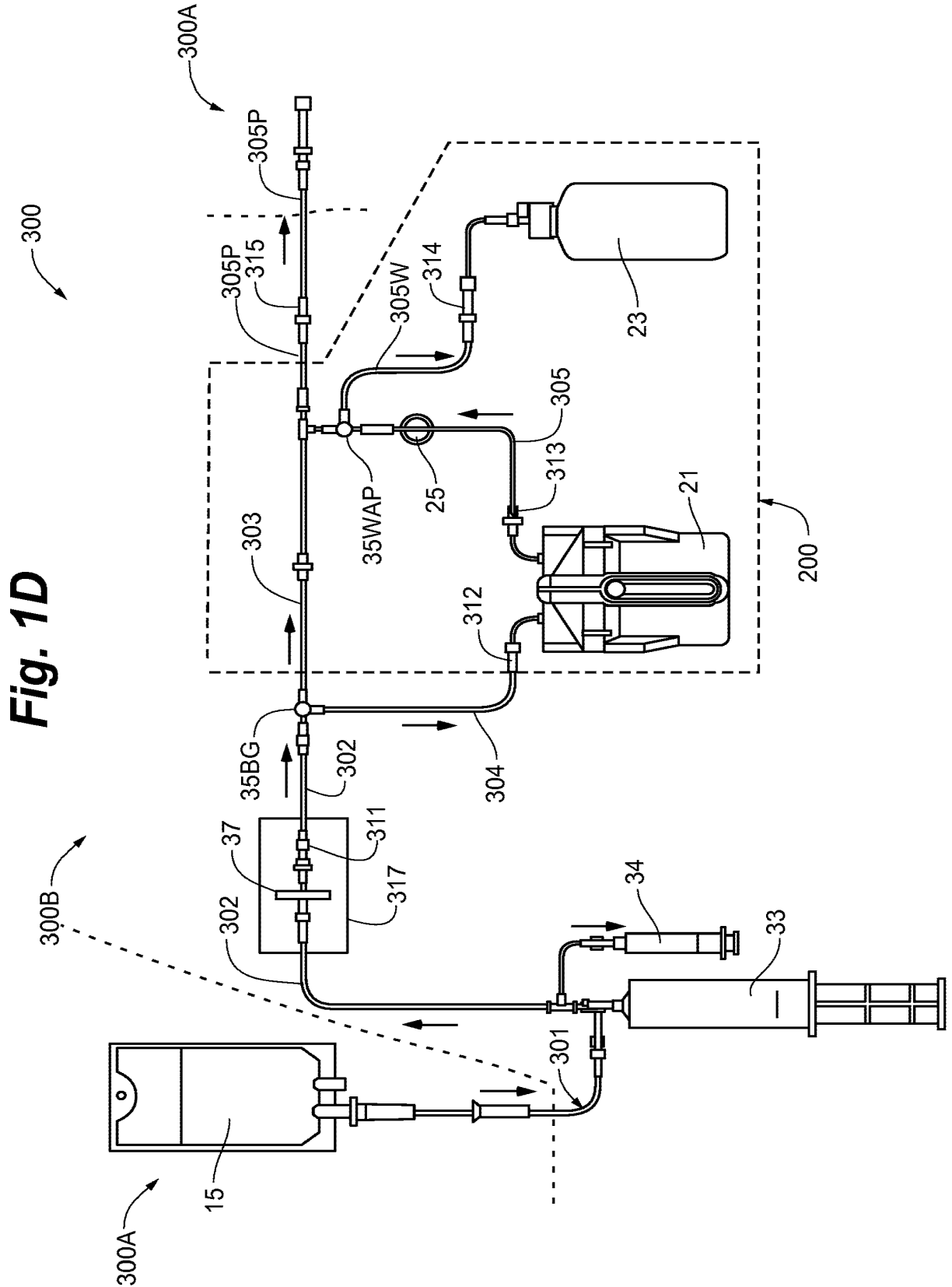
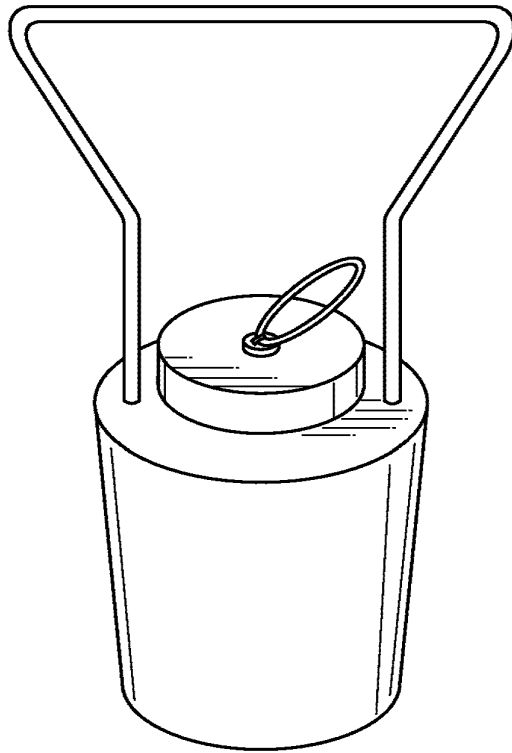


Fig. 1D

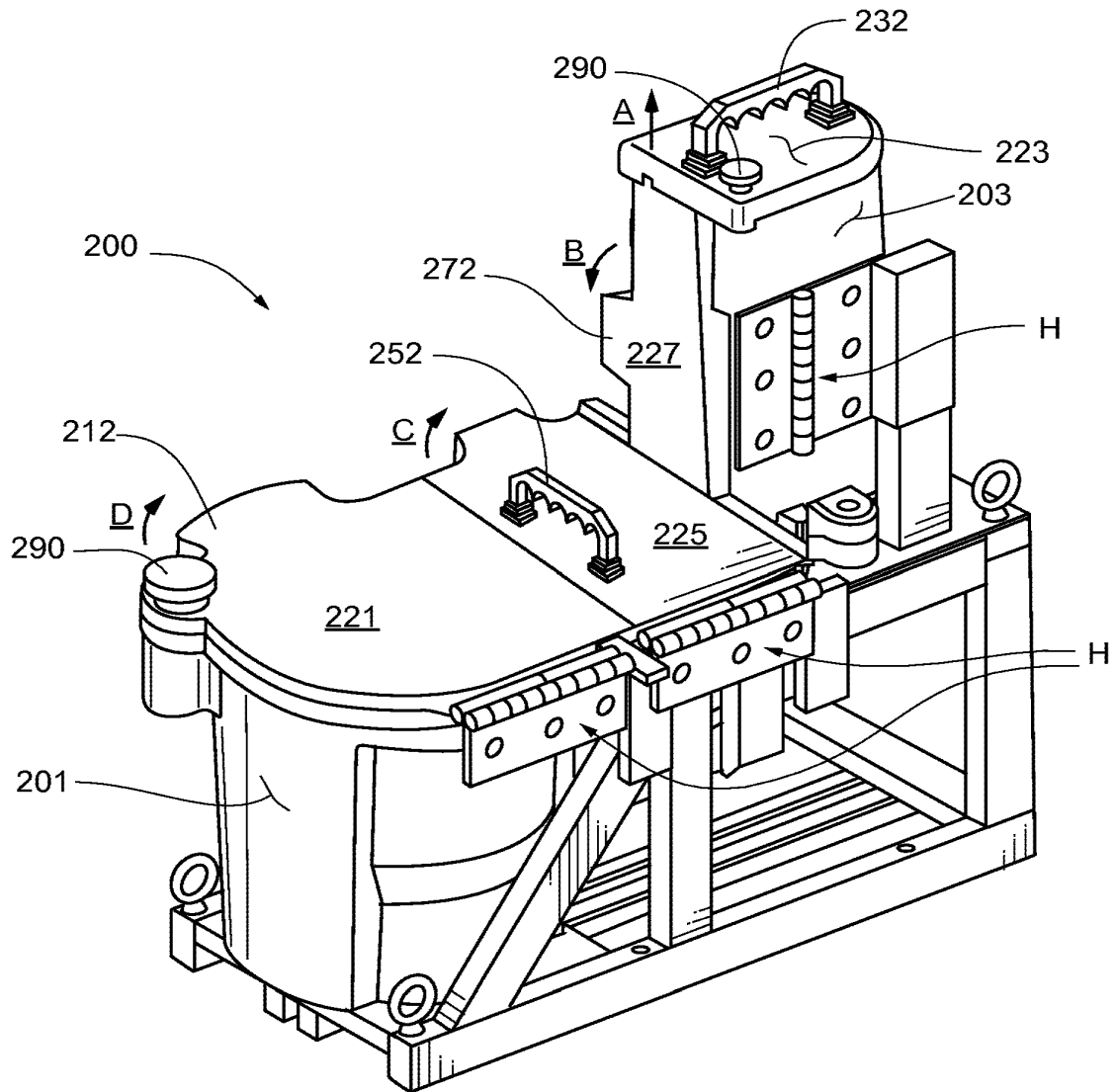
5/27

Fig. 1E



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Fig. 2A



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Fig. 2B-1

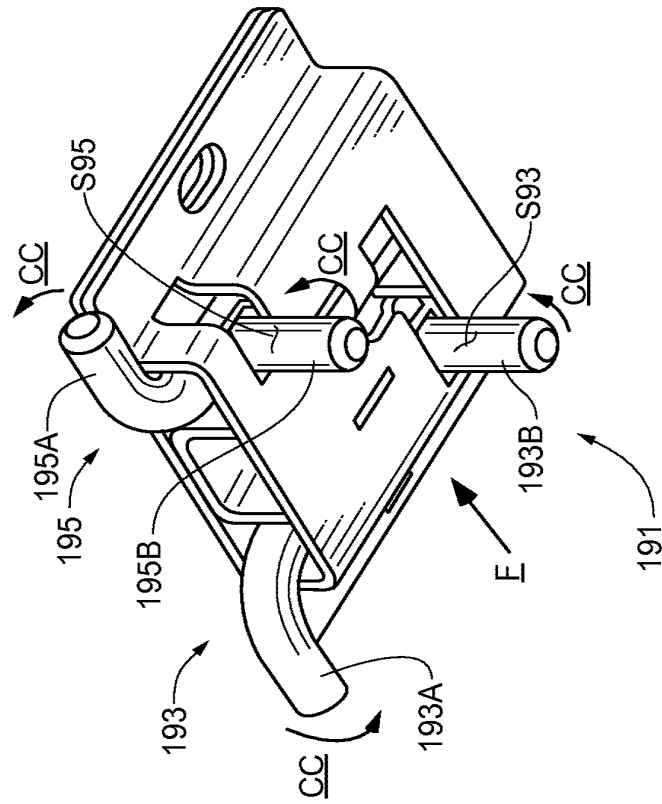
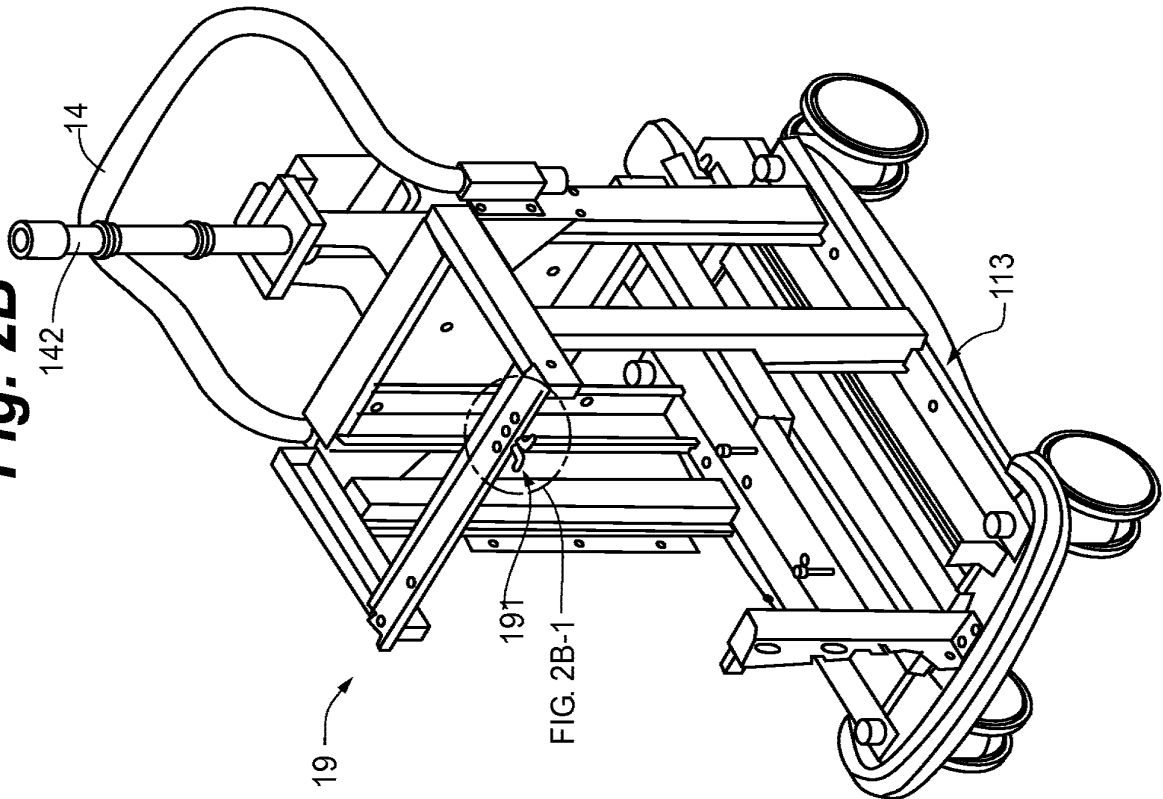


Fig. 2B



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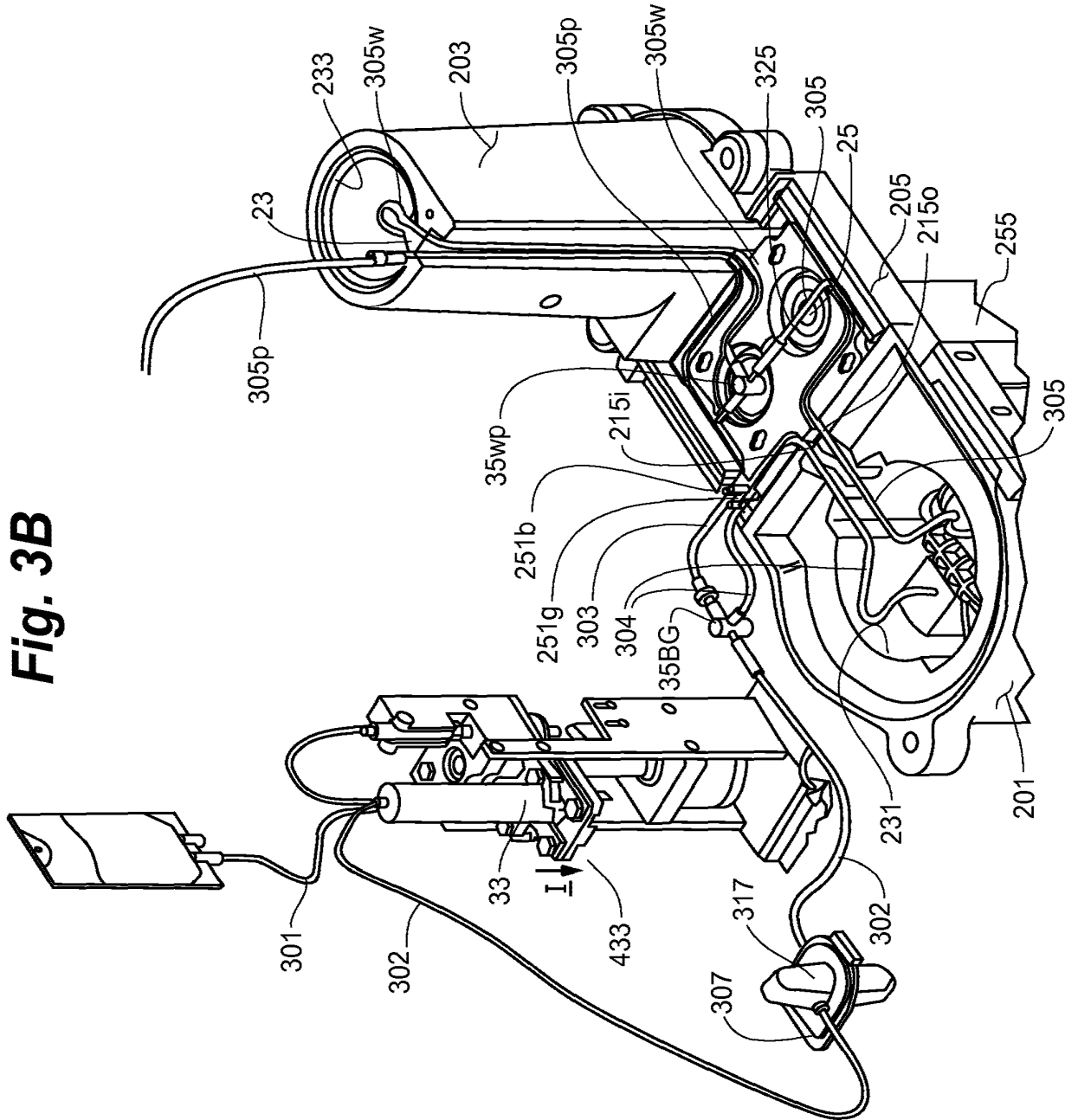
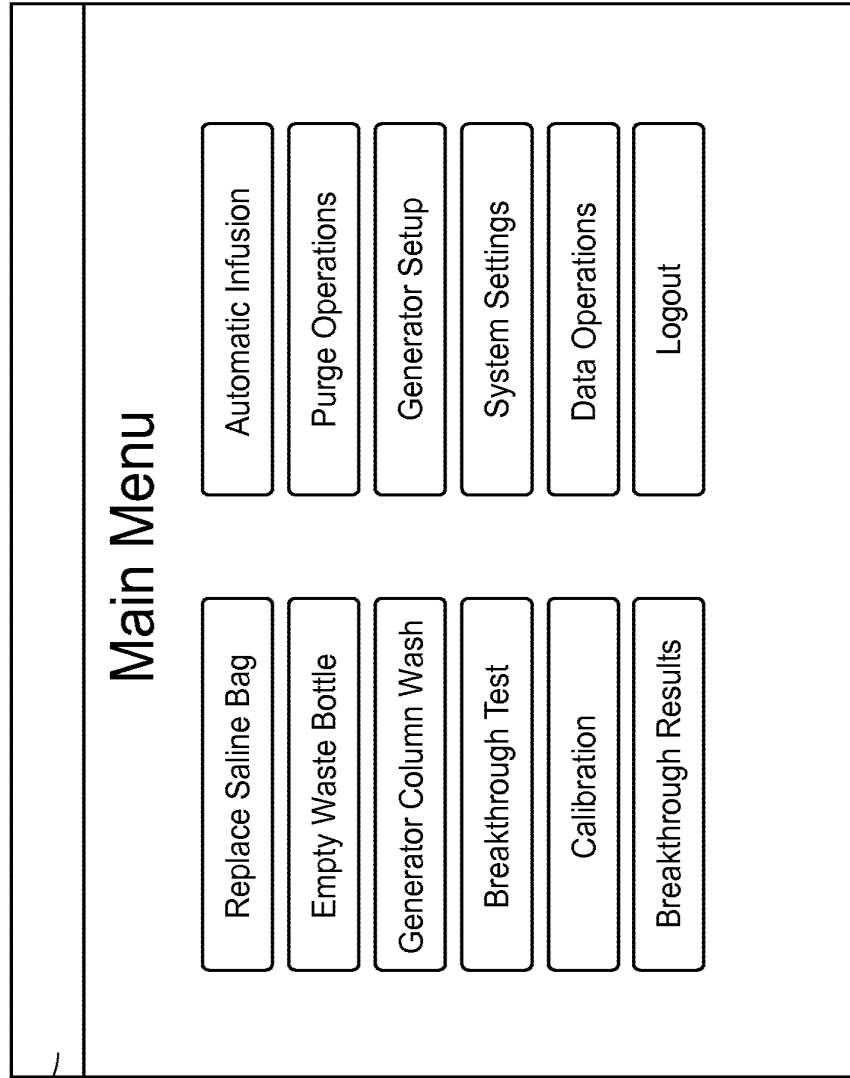


Fig. 3B

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Fig. 4



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Fig. 5A

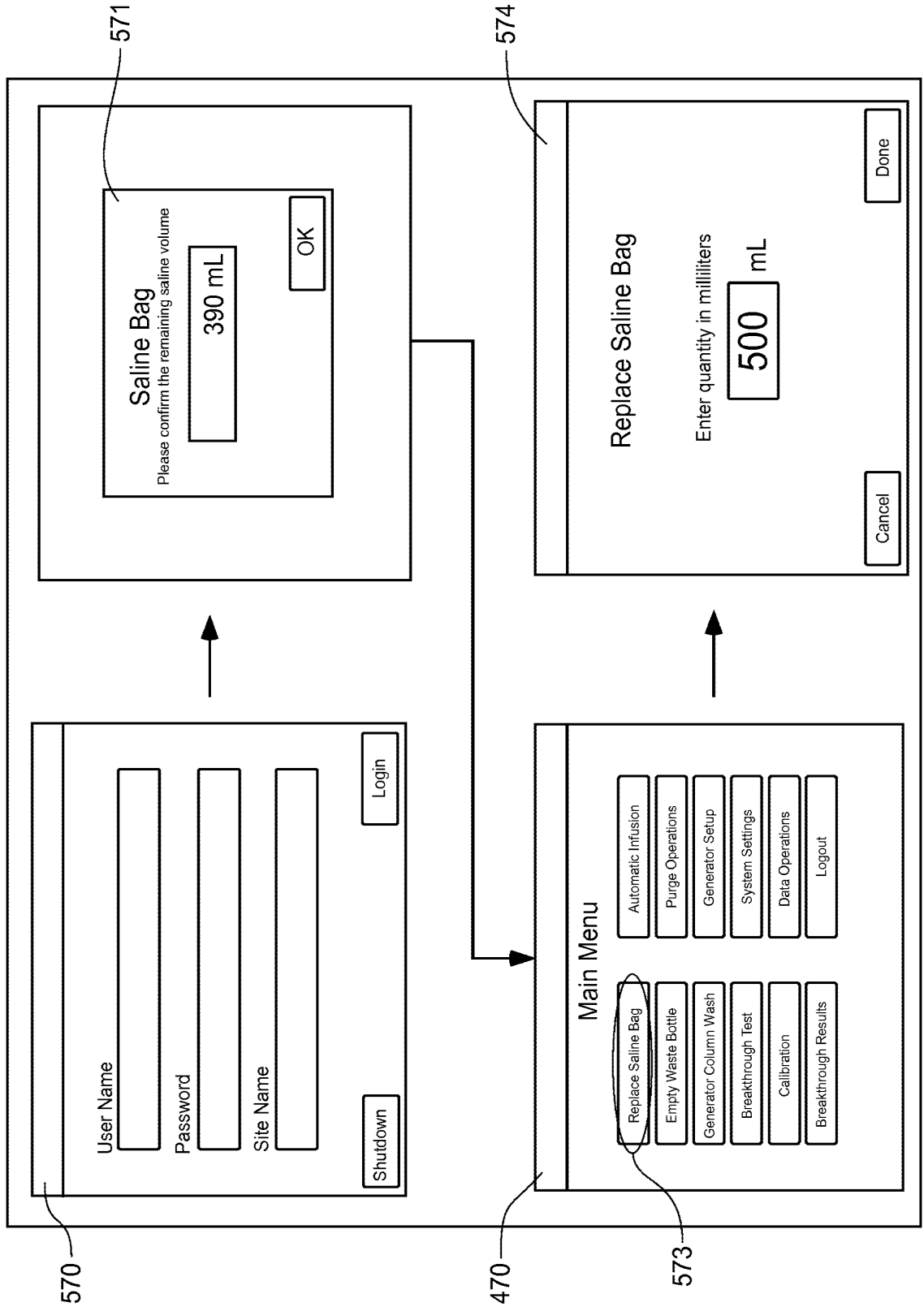
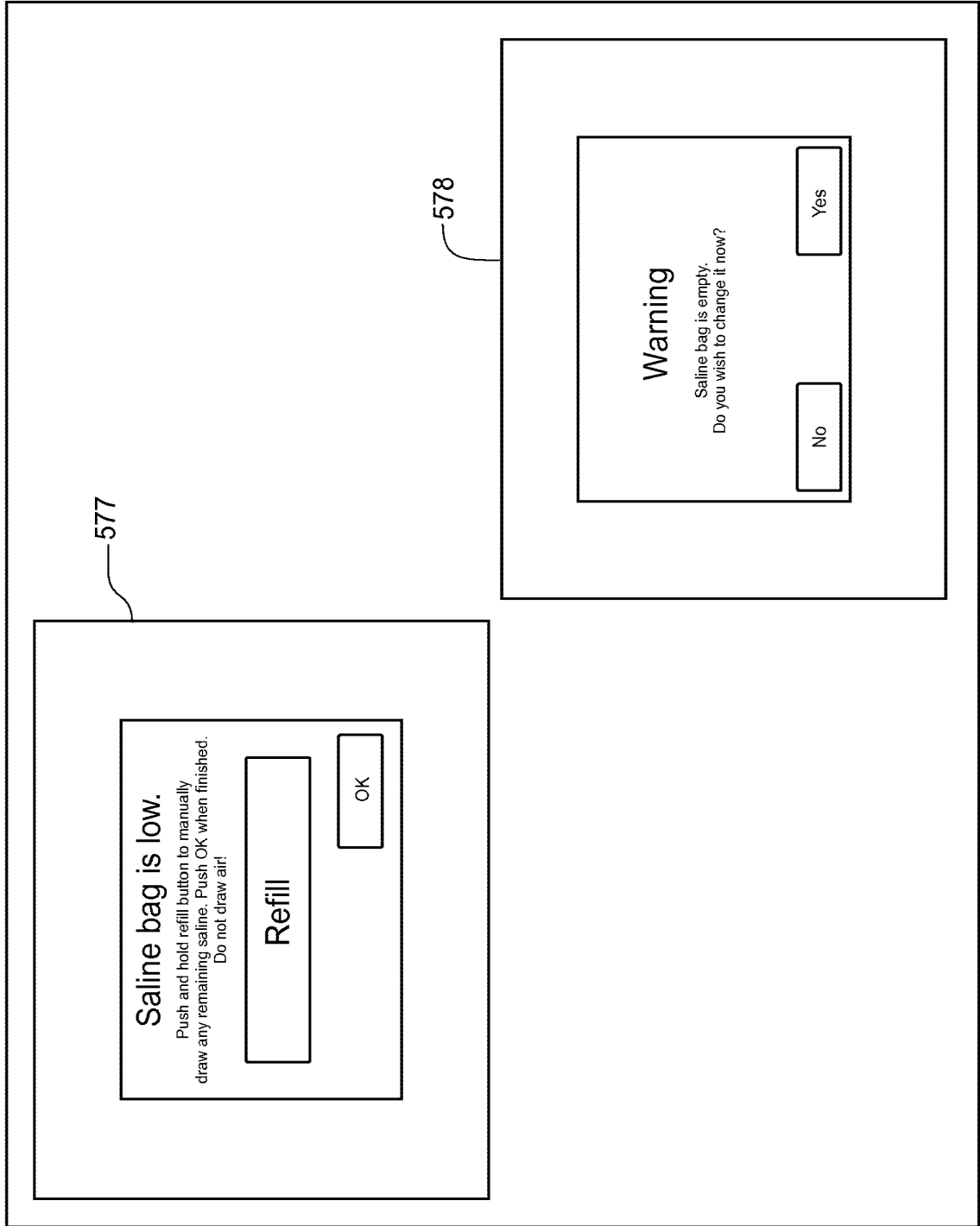
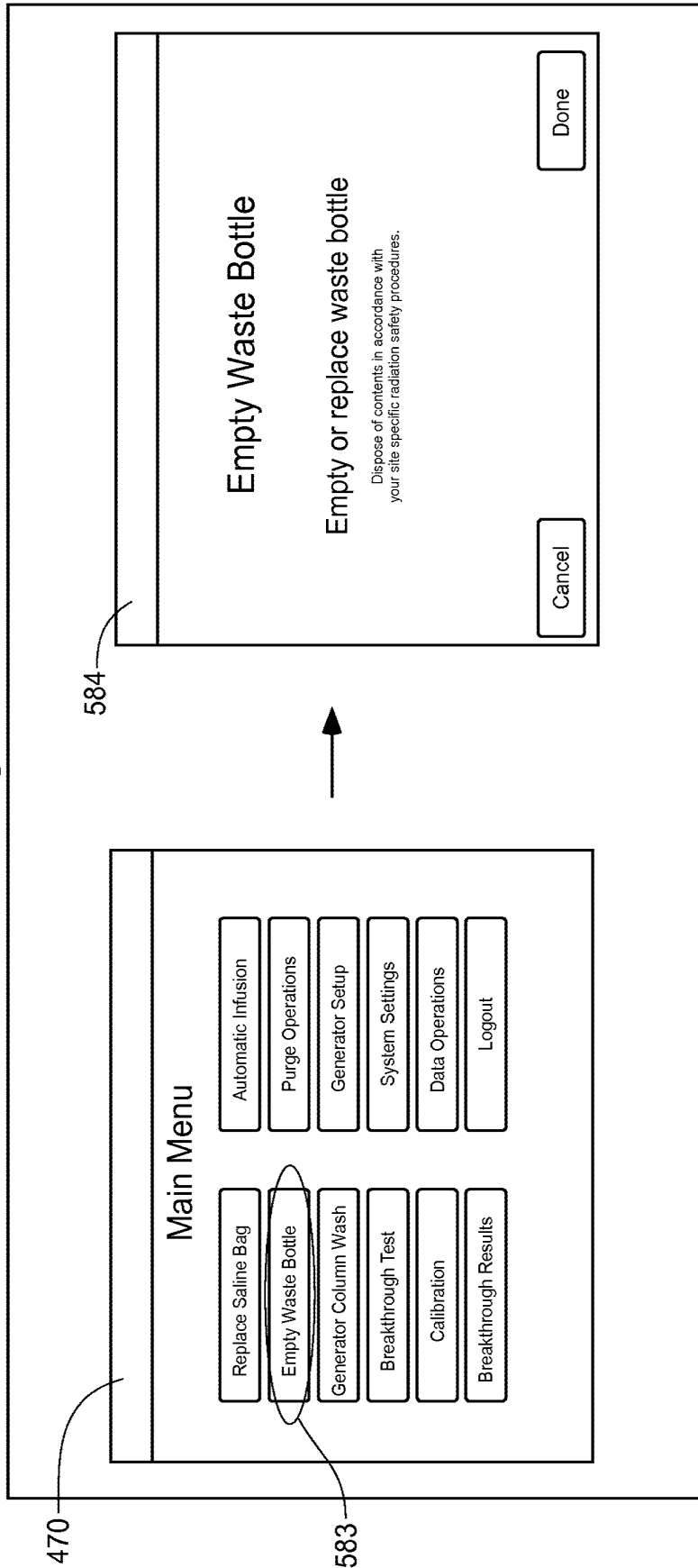


Fig. 5B



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Fig. 5C



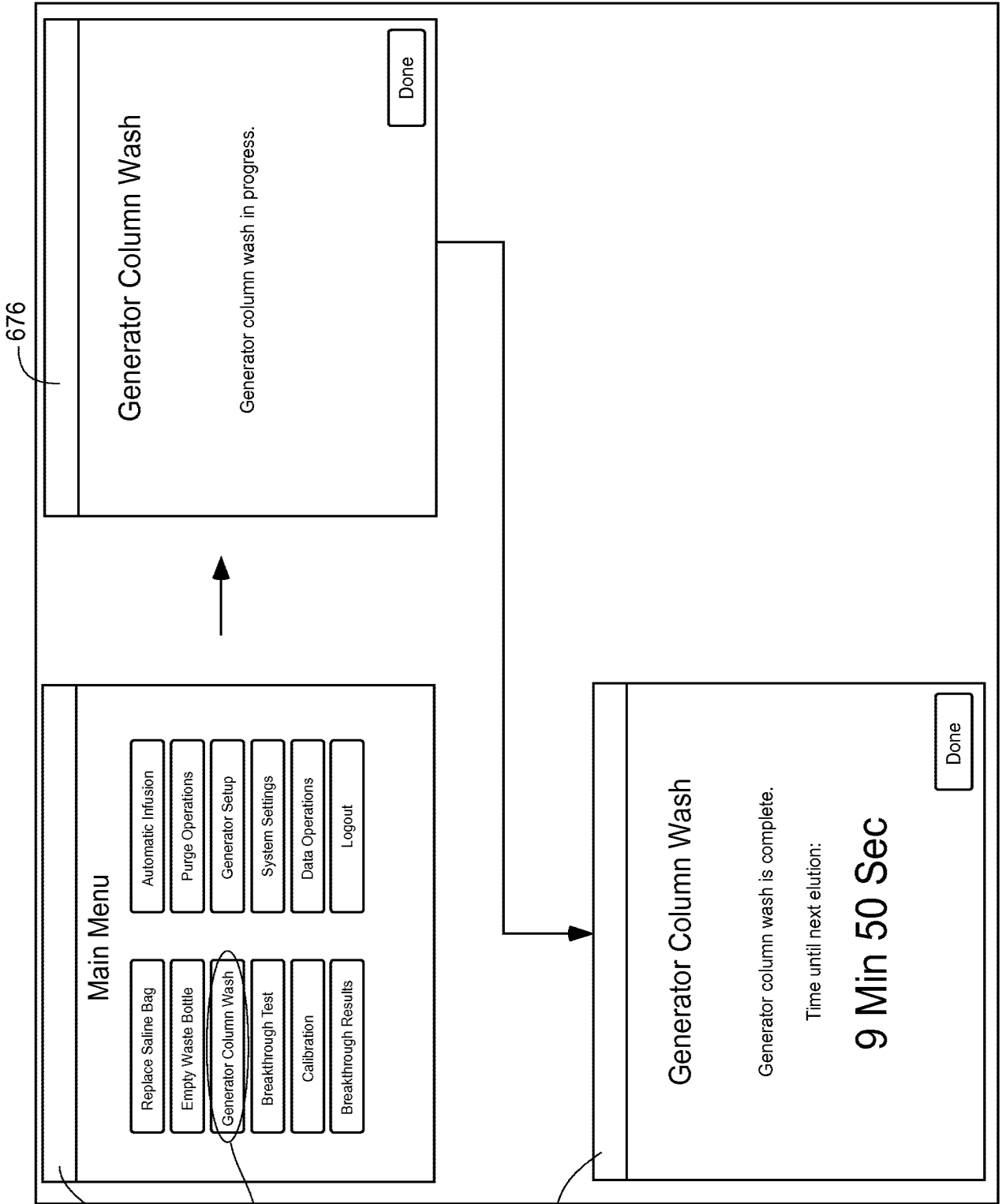


Fig. 6

Fig. 7A

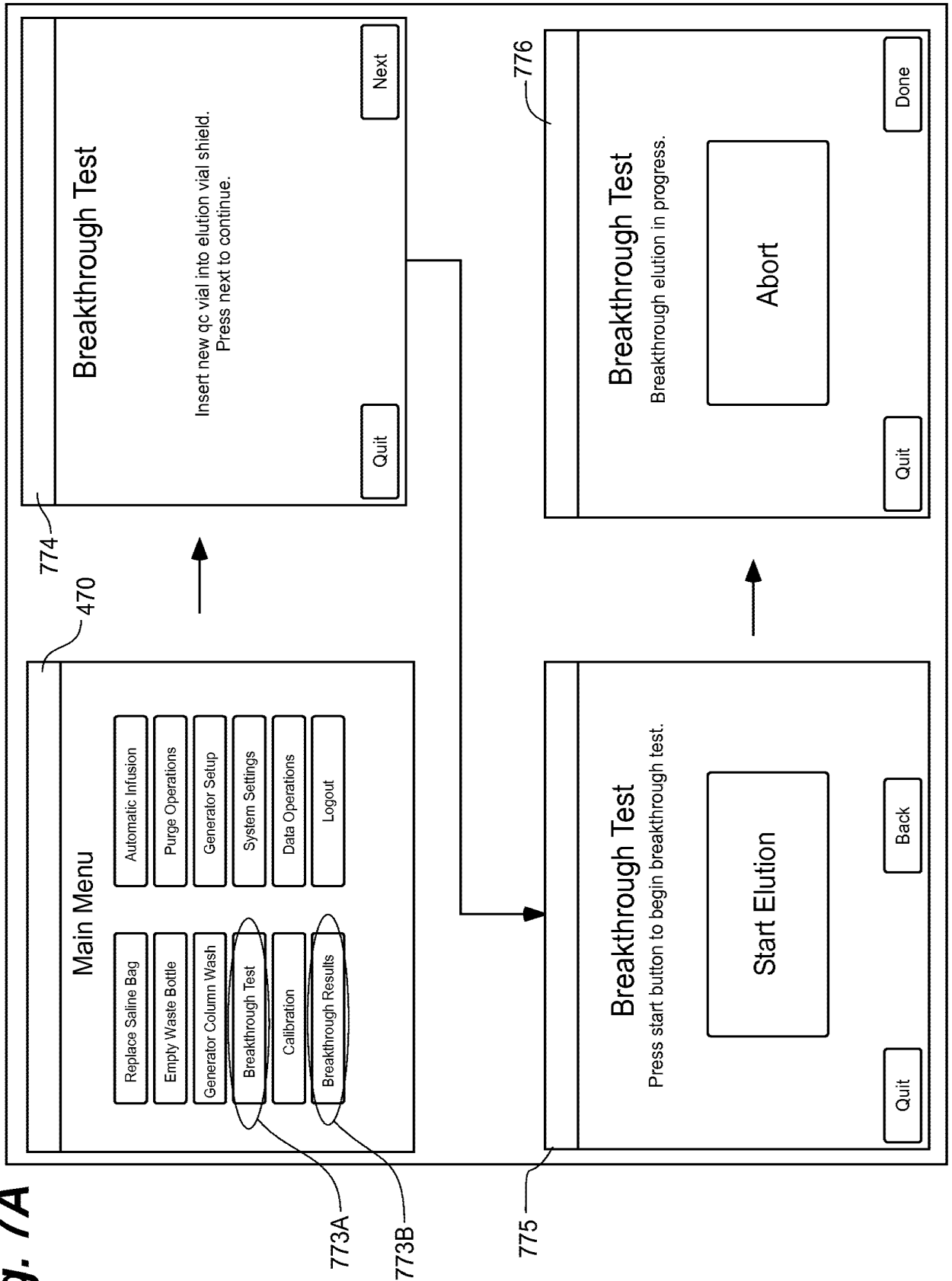


Fig. 7B

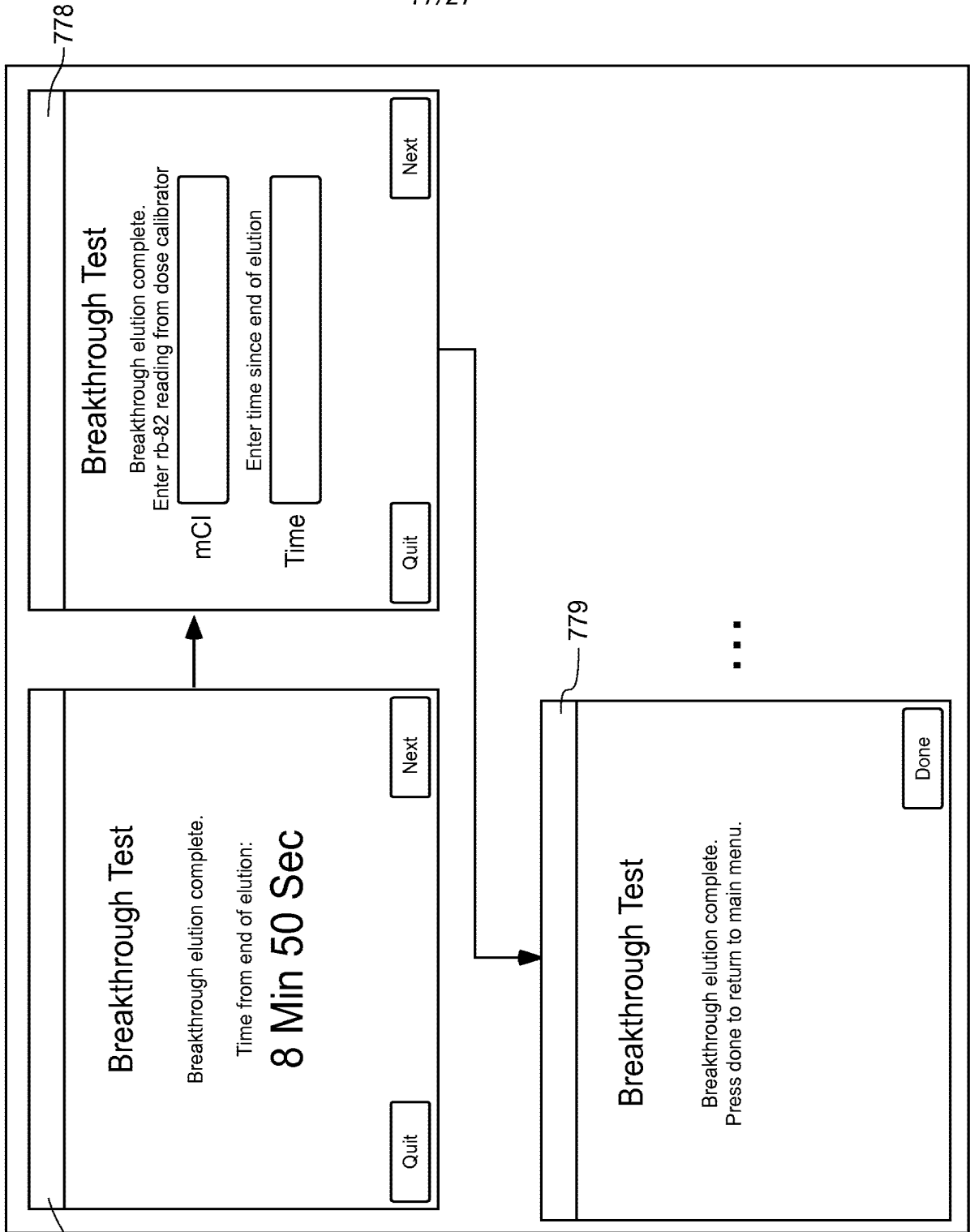
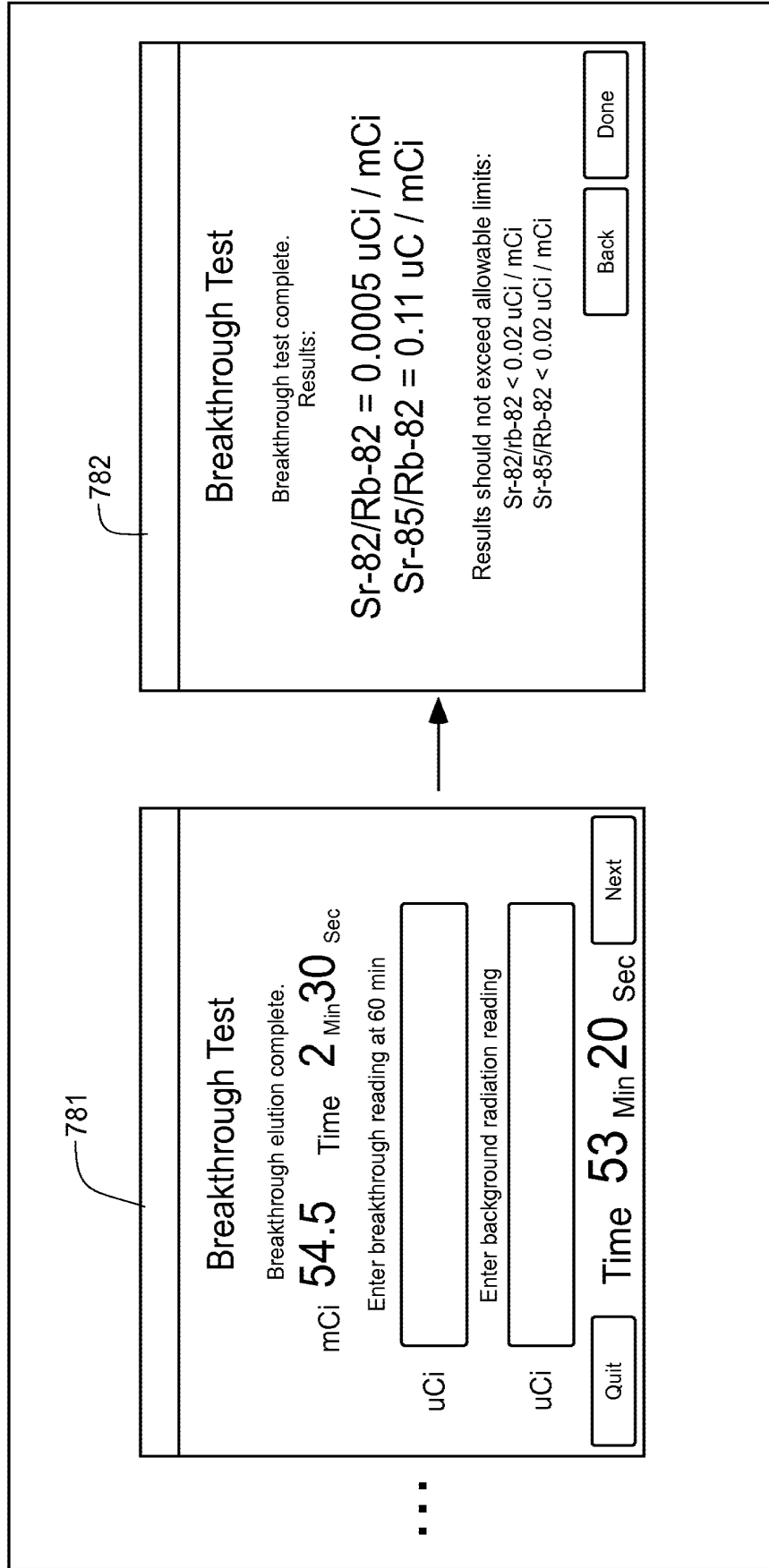


Fig. 7C



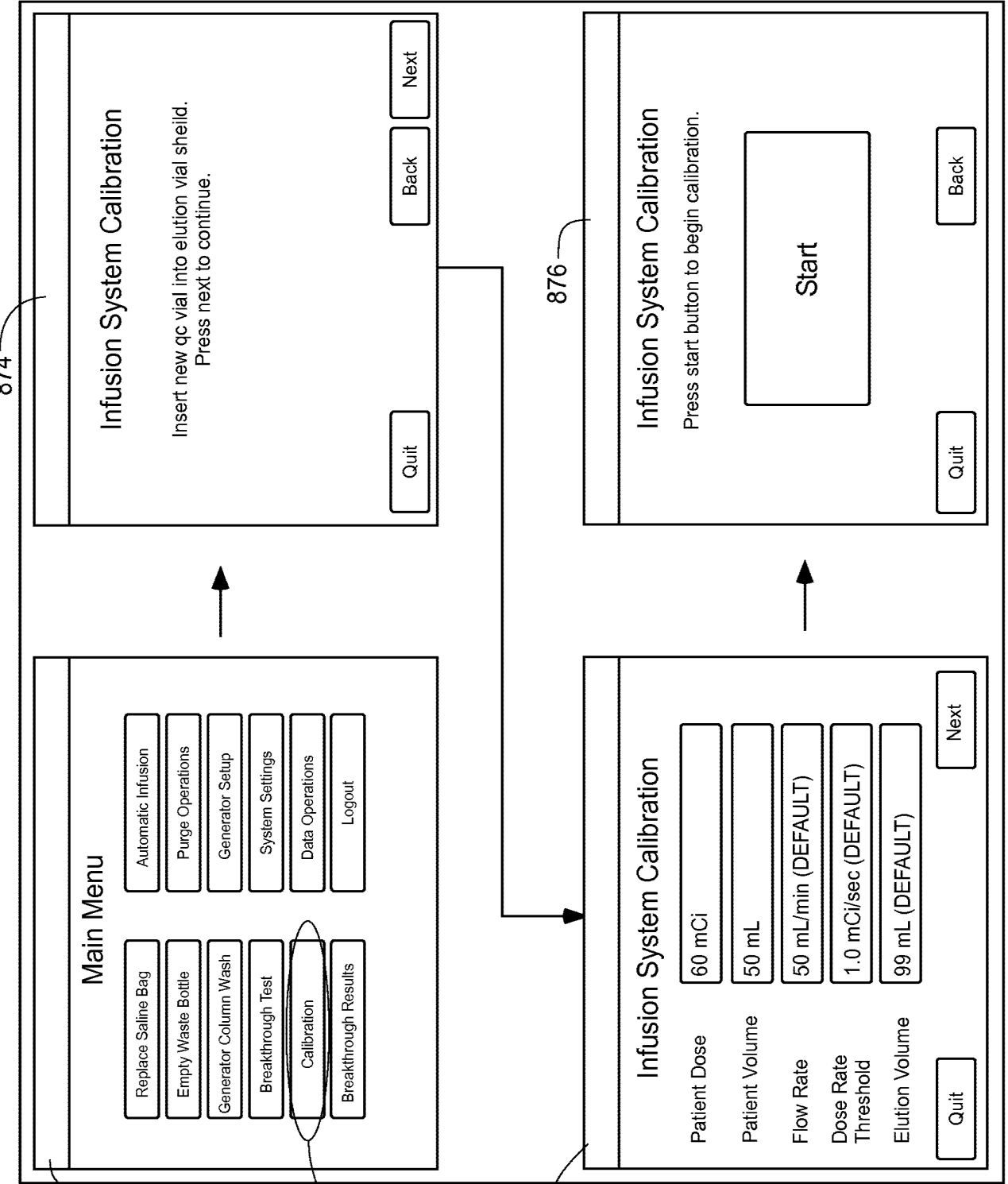


Fig. 8A

Fig. 8B

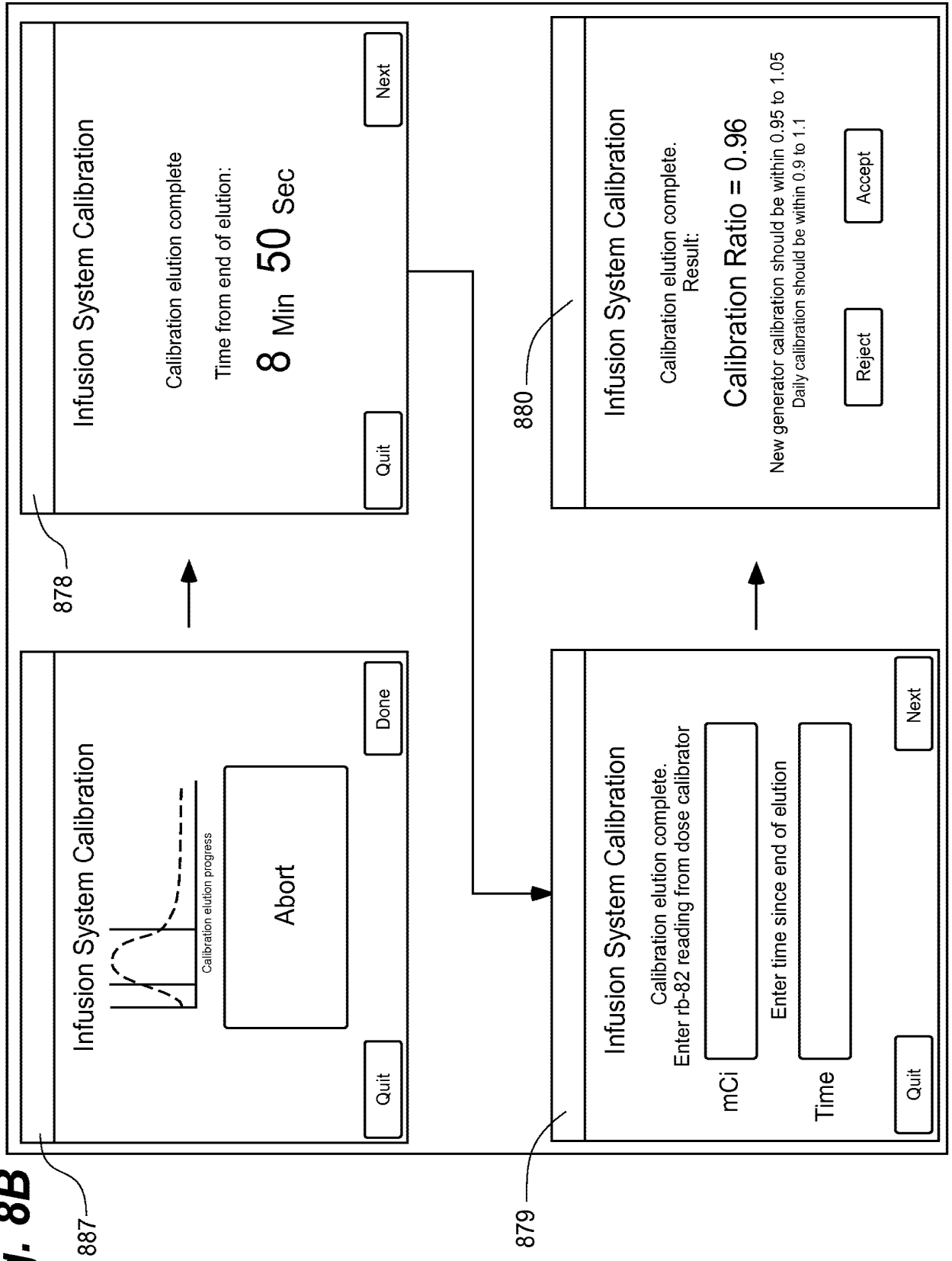


Fig. 9A

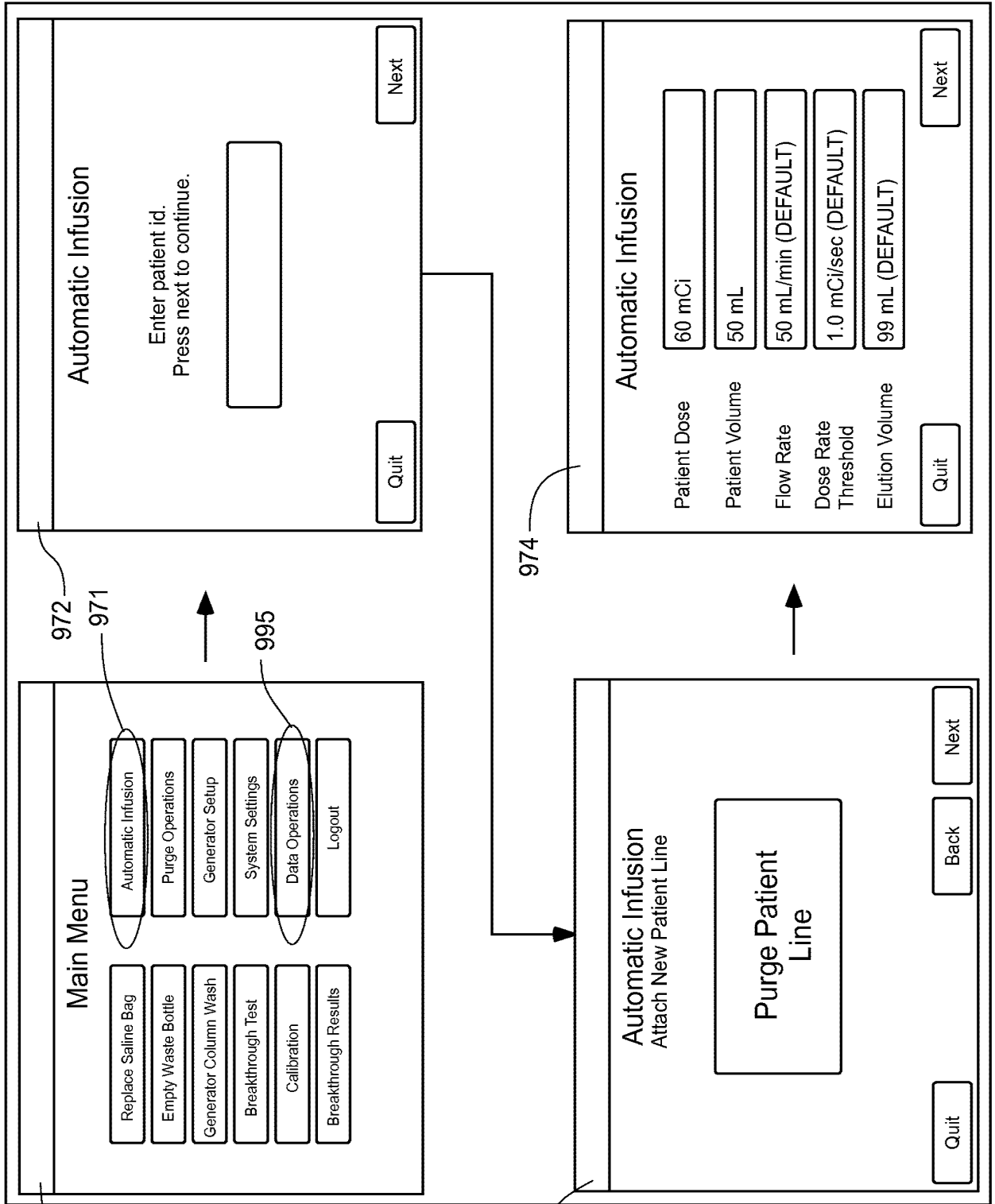
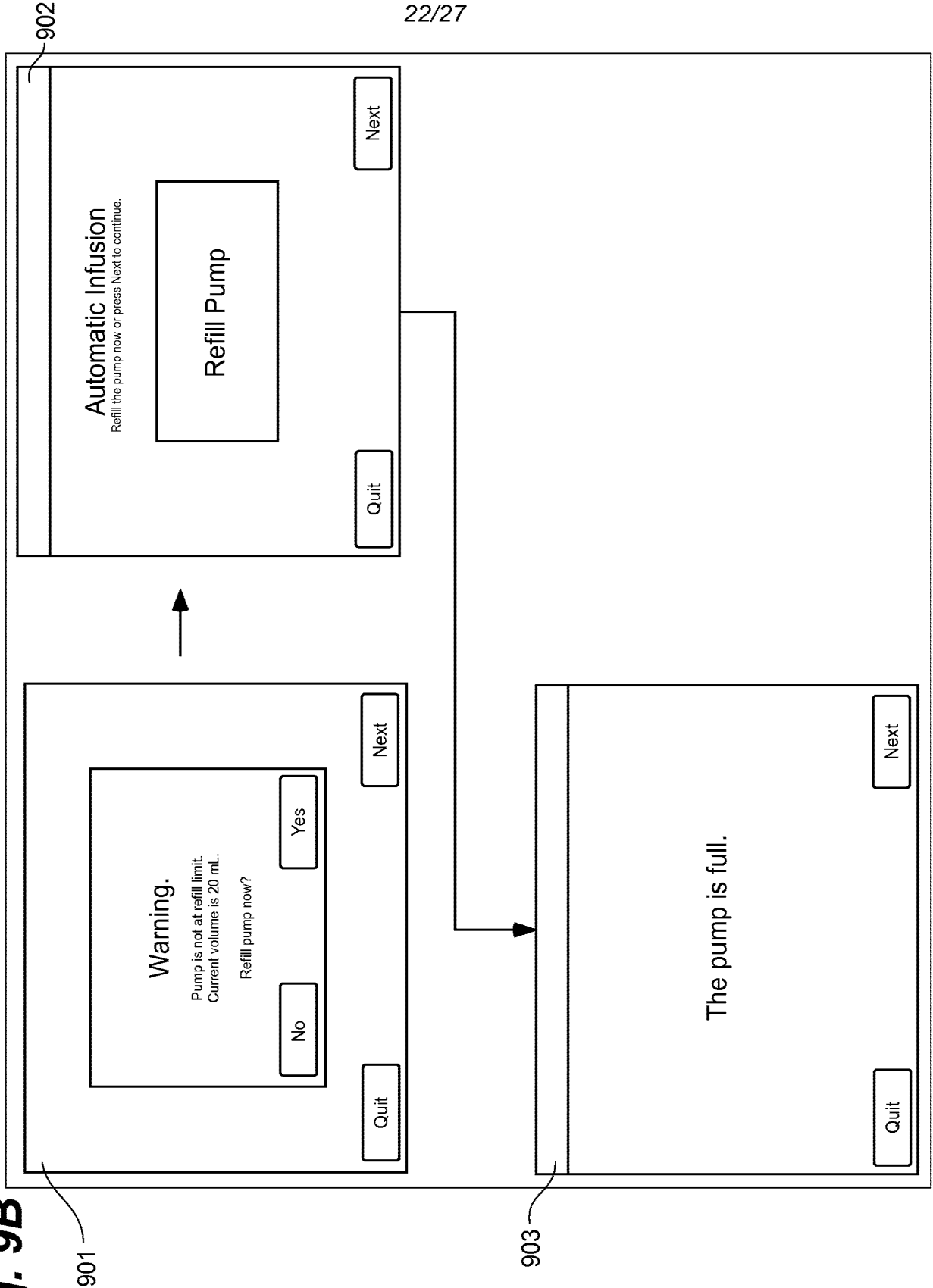


Fig. 9B



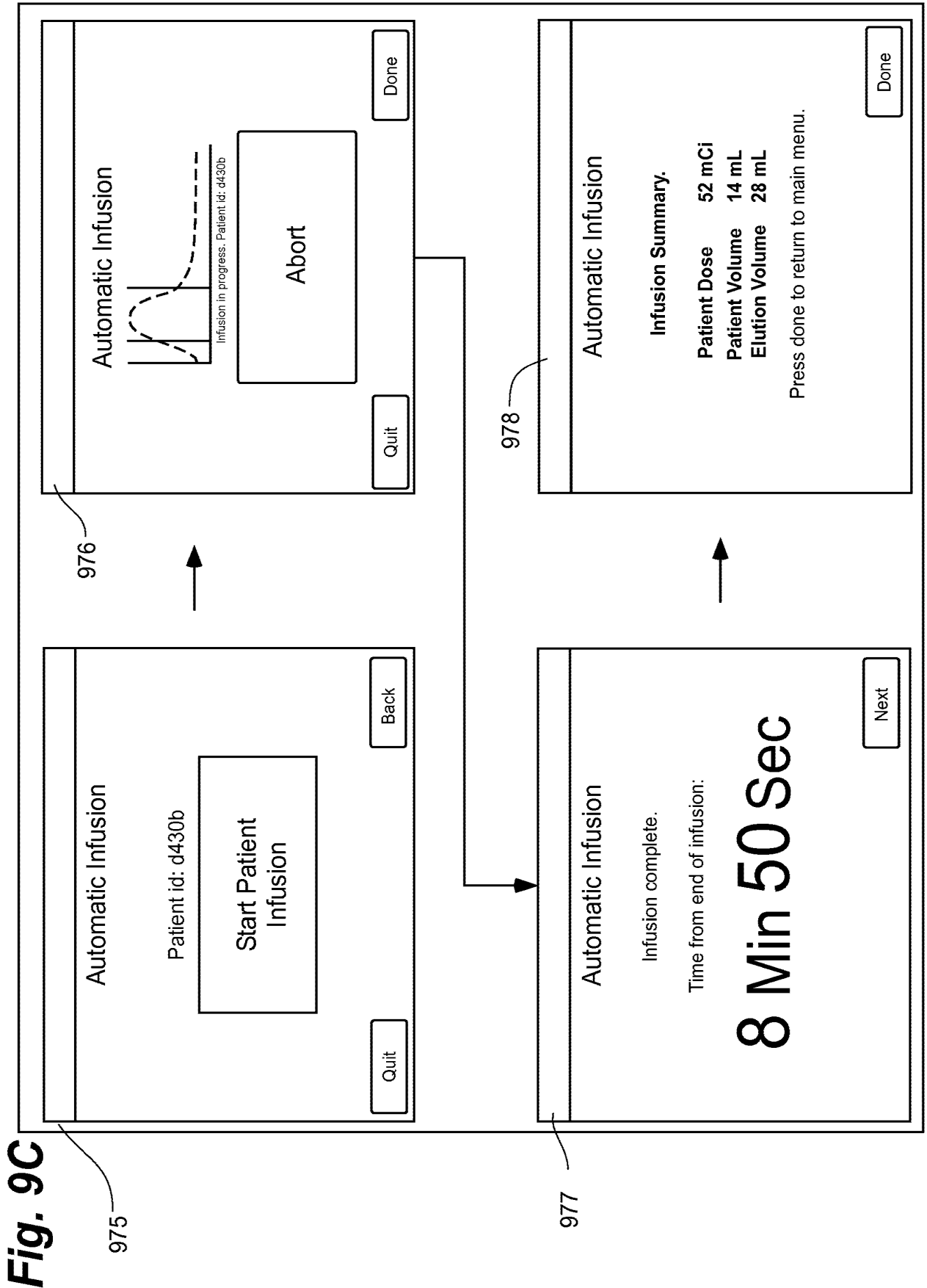


Fig. 9C

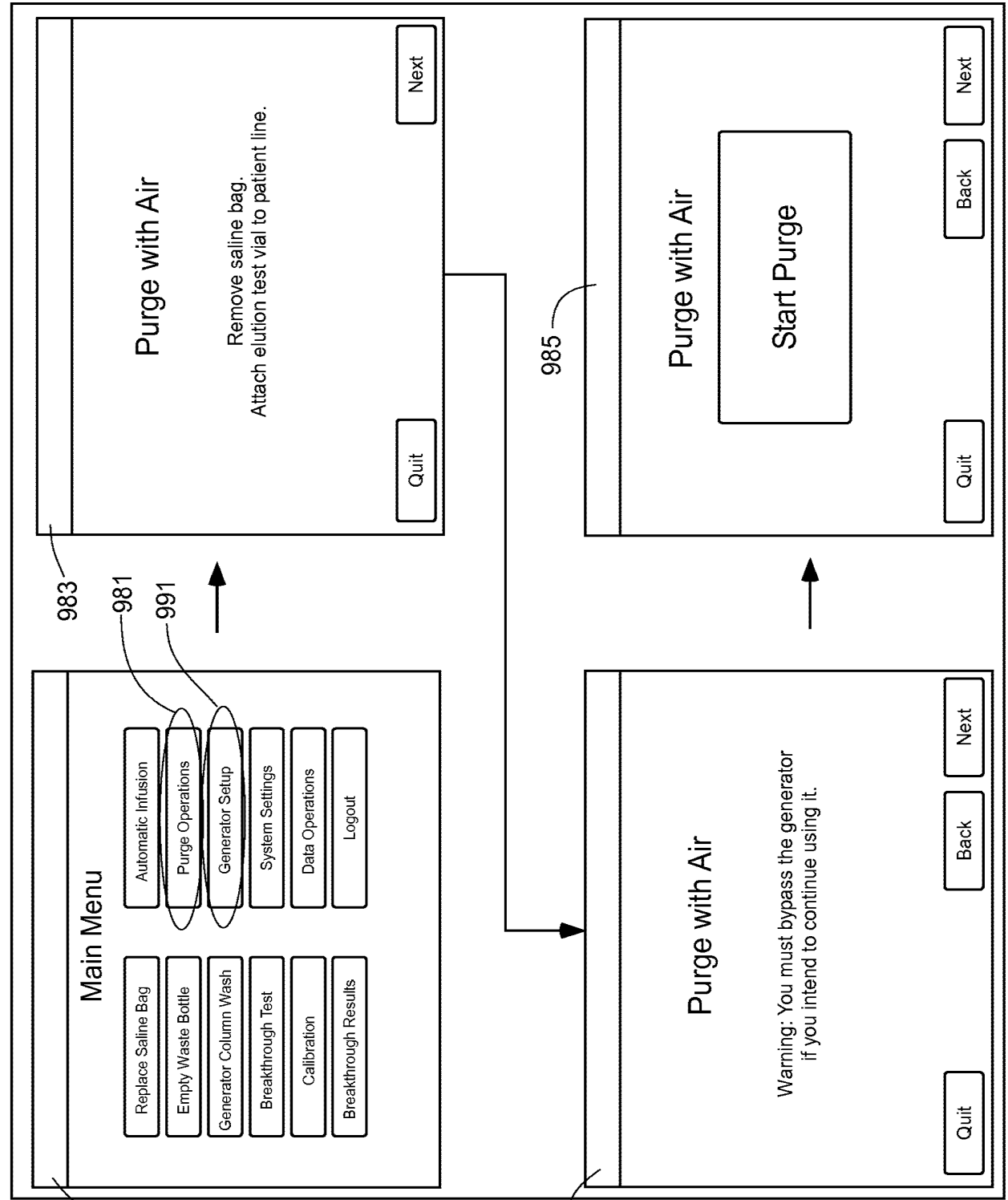


Fig. 10

Fig. 11

| | |
|--|--|
| CARADIOGEN-82 GENERATOR MONTHLY RECEIPT/RETURN WORKSHEET | |
| GENERATOR RECEIPT | |
| DATE OF DELIVERY: | 11/9/2008 |
| DATE OF CALIBRATION: | 11/10/2008 |
| LOT NUMBER: | |
| Sr-82 ACTIVITY: | 100 mCi |
| TOTAL ACTIVITY: | 256 mCi |
| Sr-85 ACTIVITY: | 156 mCi |
| GENERATOR RETURN | |
| DATE OF RETURN: | 12/27/2008 |
| DAYS SINCE CALIBRATION DATE: | 47 |
| Sr-82 RETURN CALCULATIONS | |
| INITIAL Sr-82 ACTIVITY: | 100 mCi |
| DECAY FACTOR: | 0.2718 |
| REMAINING Sr-82 IN mCi: | 27.18 mCi |
| REMAINING Sr-82 IN GBq: | 1.01 GBq |
| Sr-85 RETURN CALCULATIONS | |
| INITIAL Sr-85 ACTIVITY: | 156 mCi |
| DECAY FACTOR: | 0.6011 |
| REMAINING Sr-85 IN mCi: | 93.77 mCi |
| REMAINING Sr-85 IN GBq: | 3.47 GBq |
| RECEIPT SURVEY | |
| SURFACE: | 10.0 mrem/hr (MUST BE < 50 mrem/hr) |
| 1 METER: | 0.6 mrem/hr (MUST BE < 1 mrem/hr) |
| SURFACE WIPE: | 1599 dpm (MUST BE < 2200 dpm/100 cm ²) |
| RETURN SURVEY | |
| SURFACE: | 5.6 mrem/hr (MUST BE < 50 mrem/hr) |
| 1 METER: | 0.2 mrem/hr (MUST BE < 1 mrem/hr) |
| SURFACE WIPE: | 1278 dpm (MUST BE < 2200 dpm/100 cm ²) |
| SUMMARY | |
| TOTAL Sr-82/Sr-85 ACTIVITY: | 120.95 mCi |
| TOTAL Sr-82/Sr-85 ACTIVITY: | 4.48 GBq |
| TRANSPORT INDEX: | 0.2 |

Fig. 12A

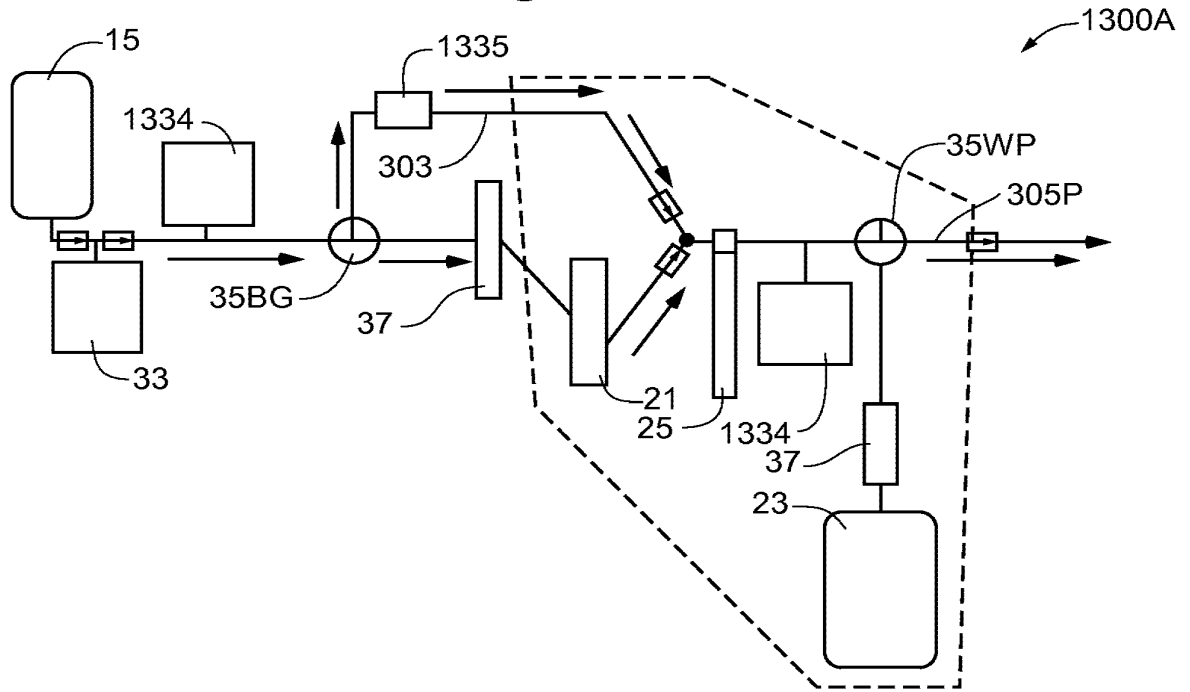


Fig. 12B

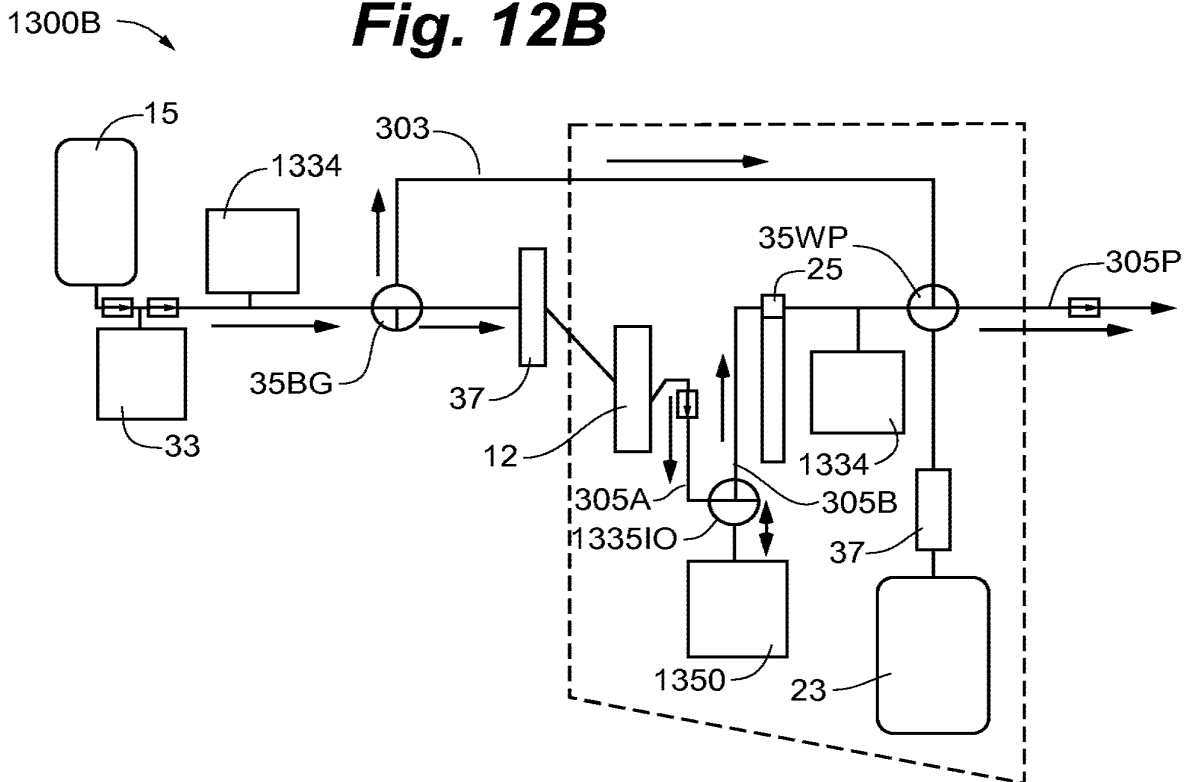
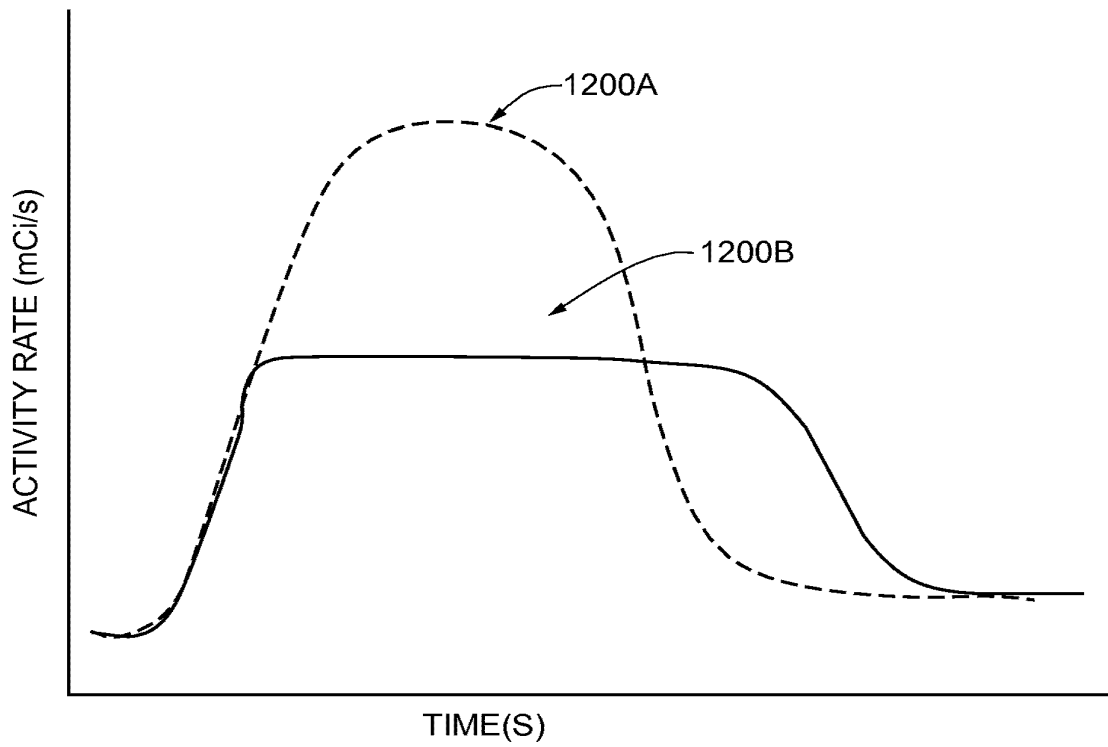


Fig. 12C





— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
6 May 2010