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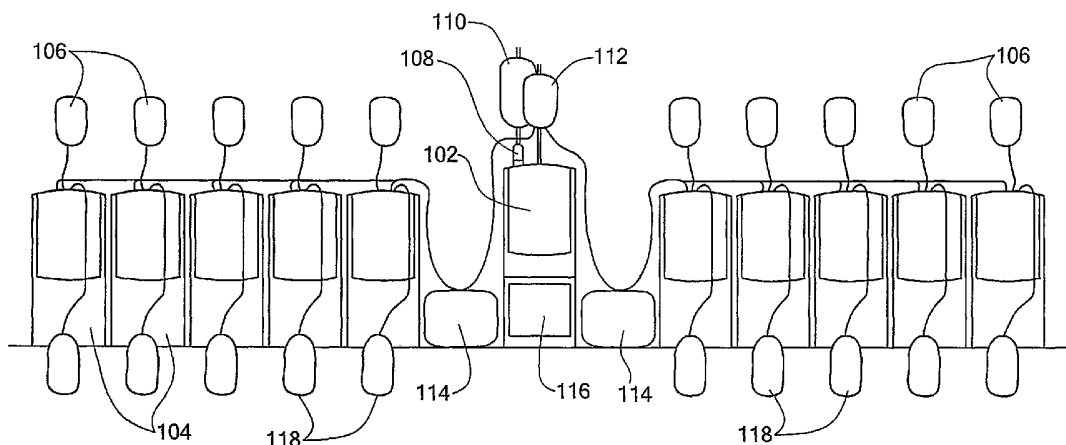
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[Continued on next page]

(54) Title: SYSTEM, DEVICE, AND METHOD FOR MIXING A SUBSTANCE WITH A LIQUID



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(57) Abstract: A system, device, and method for mixing a substance with a liquid pumps the liquid into a container of the substance to produce a solution. The container may be part of a container assembly including a port assembly for coupling with the container to produce an inlet and/or and outlet port for the container. The container assembly may be received within a receiving chamber for causing the coupling. The solution may be permitted to flow out of the outlet port when the solution rises within the container to a level of the outlet port so that the substance is partially diluted before flowing out of the outlet port.

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SYSTEM, DEVICE, AND METHOD FOR MIXING A SUBSTANCE WITH A LIQUID

5 FIELD OF THE INVENTION

The present invention relates generally to pumping liquids, and more particularly to mixing a substance with a liquid.

10 BACKGROUND OF THE INVENTION

Millions of people receive blood transfusions each year. Although helpful in many cases, blood transfusions have associated risks. Among
15 others, there is a risk that microorganisms capable of causing disease (i.e., pathogens) could pass from the donor blood to the ultimate blood recipient. For example, untreated blood used in a blood transfusion could have pathogens causing the West Nile Virus, or AIDS. It thus is critical for the public health to ensure that transfused blood is substantially free of
20 pathogens.

The medical community has responded to this need by developing various techniques for removing known and unknown pathogens from donated blood. One technique involves mixing precise amounts of a diluted anti-pathogen compound with blood. Some time after mixing, a rinsing
25 process removes the anti-pathogen compound from the blood. One complexity with this process, however, is the fact that the diluted anti-pathogen compound has a very short shelf life (e.g., on the order of about four hours). Accordingly, the diluted anti-pathogen compound must be produced a relatively short time before it is mixed with blood.

30 The anti-pathogen compound is not easy to handle before it is diluted. To the contrary, it has a very high pH (e.g., on the order of 11.0 or higher) and thus, is highly caustic and toxic. Mere contact with the undiluted solution can melt plastic, or burn flesh. Because of these undesirable properties, the undiluted solution typically is manually diluted by highly trained laboratory
35 technicians that necessarily must be protected from direct contact with it.

Consequently, laboratory technicians often are required to wear relatively impermeable protective gear while diluting the solution behind a chemical laminar flowhood. Such a process, however, is inherently slow, imprecise, and costly due to the multitude of safety requirements. Moreover, even with
5 safeguards, diluting the undiluted solution still poses a risk to the laboratory technician.

SUMMARY OF THE INVENTION

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Embodiments of the present invention provide for safely and efficiently mixing a substance with a liquid.

In accordance with one aspect of the invention, the substance is contained in a container assembly having a sealed container that contains the
15 substance. The container assembly is joined with a port assembly within a receiving chamber. The port assembly provides at least an inlet to the container, and typically also an outlet from the container. A liquid is added to the container through the inlet to produce a solution of substance and liquid. Continued ingress of liquid may cause the solution to flow out of the
20 container through the outlet.

In accordance with other aspect of the invention, the substance is a caustic substance that is provided in a primary container having a bottom and a top, with the caustic substance filling the primary container from the bottom to a given point between the bottom and the top. An outlet is provided in the
25 primary container, such that the outlet is between the given point and the top. A predetermined amount of liquid is added to the primary container to produce a combined caustic substance and liquid solution that rises at least to the level of the outlet. At least some of the solution is permitted to flow from the primary container through the outlet after the solution rises to the outlet.

30 In connection with developing a mixing system for treating blood with diluted anti-pathogen, a new apparatus for use in a fluid processing system having a pump was invented. In accordance with one aspect of the invention, the apparatus includes a pump cassette for use with the pump. The pump

cassette includes at least one pump chamber and a first port in selective fluid communication with the at least one pump chamber. A spiking assembly includes at least one hollow spike having a piercing end for piercing a first container. The at least one hollow spike includes a first spike in fluid
5 communication with the first port of the pump cassette.

In accordance with related embodiments of the invention, first tubing may be coupled at one end to the first port of the pump cassette and at another end to a non-piercing end of the first spike so as to provide a first fluid path between the first port and the first spike. The first port may be a
10 fluid outlet port, wherein the first spike provides a fluid inlet to the first container. Alternatively, the first port may be a fluid inlet port, wherein the first spike provides a fluid outlet from the first container.

In accordance with further related embodiments of the invention, the spiking assembly includes a housing. The housing may include two
15 substantially identical halves that are joined together. The spiking assembly may further include a spike holder captured by the housing, the spike holder engaging the at least one spike. The spike holder may be overmolded onto the at least one spike. The overmolded spike holder may include, for each spike, a tubing barb proximate to the non-piercing end of the spike for
20 coupling a tube to the spike. The housing may include at least one element for engaging each tube about the tubing barb so as to secure the tubes within the housing. The spiking assembly may include a spike guard disposed within the housing and overlaying the piercing end of the at least one spike. The spike guard may include a grommet capable of being pierced by the at
25 least one spike, and that may function as a fluid seal when in contact with the first container. The spike guard may include at least one tab for engaging one or more slots in the housing to prevent movement of the spike guard, the at least one tab capable of being disengaged from the one or more slots to allow movement of the spike guard towards the at least one spike such that the at
30 least one spike can pierce the grommet. The housing may include at least one element for engaging a container holder. The at least one element may

include a surface forming an undercut for engaging at least one corresponding feature on the container holder.

In accordance with still further related embodiments of the invention, the at least one spike includes a second spike. Second tubing may be coupled
5 at one end to a non-piercing end of the second spike, and at another end to a second container, so as to provide a second fluid path between the second spike and the second container. A filter may be coupled between the second spike and the fluid receptacle along the second fluid path.

In accordance with other related embodiments of the invention, the
10 pump cassette may include a second port in selective fluid communication with the at least one pump chamber. Third tubing may be coupled at one end to the second port, the third tubing providing a third fluid path between the second port and a third container. A third spike may be coupled to another end of the third tubing for piercing the third container. The at least one pump
15 chamber may include two pump chambers, wherein fluid can be pumped from one port into one pump chamber while fluid is pumped from the other pump chamber out the other port. The pump cassette may be pneumatically controlled by the pump.

In accordance with another aspect of the invention, an apparatus for
20 piercing a container includes a housing. A spike holder is captured by the housing. The spike holder engages at least one hollow spike having a piercing end for piercing the container. A spike guard is disposed within the housing and overlays the piercing end of the at least one spike.

In accordance with related embodiments of the invention, the spike
25 guard may include a grommet capable of being pierced by the at least one spike. The grommet may function as a fluid seal when in contact with the container. The at least one hollow spike includes a first spike for providing a fluid inlet to the container. The housing may include two substantially identical halves that are joined together. The spike holder may be
30 overmolded onto the at least one spike. The overmolded spike holder may include, for each spike, a tubing barb proximate to the non-piercing end of the spike for coupling a tube to the spike. The housing may include at least one

element for engaging each tube about the tubing barb so as to secure the tubes within the housing. The spike guard may include at least one tab for engaging one or more slots in the housing to prevent movement of the spike guard, the at least one tab capable of being disengaged from the one or more slots to allow movement of the spike guard towards the at least one spike such that the at least one spike can pierce the grommet. The housing may include at least one element for engaging a container holder. The at least one element may include a surface forming an undercut for engaging at least one corresponding feature on the container holder. The at least one spike may include a second spike for providing an outlet from the container.

In accordance with another aspect of the invention, a kit includes a pump cassette for use with a pump. The pump cassette includes at least one pump chamber and a first port in selective fluid communication with the at least one pump chamber. The kit further includes a spiking assembly that includes at least one hollow spike having a piercing end for piercing a first container. First tubing is also provided in the kit for connecting at one end to the fluid outlet port of the pump cassette and at another end to a non-piercing end of a first spike for providing a first fluid path between the first port and the first spike.

In accordance with related embodiments of the invention, the at least one spike further includes a second spike. The kit may further include a second container and second tubing. One end of the second tubing may be connected to a non-piercing end of the second spike, while another end may be connected to the second container for providing a second fluid path between the second spike and the second container. A filter may be provided that can be connected between the second spike and the second container along the second fluid path. The kit may further include third tubing, which can be connected at one end to a fluid inlet port of the pump cassette. A third spike may be coupled to another end of the third tubing for piercing a third container.

In accordance with still another aspect of the invention, a method for attaching tubing to one or more spikes of a spiking assembly is presented.

The method includes overmolding a spike holder over a portion of each of the spikes such that each spike maintains a substantially fixed position within the spike holder and at least one barb is formed proximate to each spike. A tube is attached to each spike, each tube installed over one of the barbs.

5 In accordance with related embodiments of the invention, the tubing may be captured within a housing. The housing includes at least one element for engaging the tubing about the barbs so as to secure the tubes within the housing.

 In accordance with one aspect of the invention, a system for pumping
10 fluid using a pump cassette is presented. The system includes a control assembly for operating the pump cassette. A force assembly has a movable member capable of applying force to the pump cassette, to press the pump cassette against the control assembly.

 In accordance with related embodiments of the invention, the movable
15 member includes an expandable member that is capable of expanding, such as a bladder. Expansion of the expandable member presses the pump cassette against the control assembly. The force member may include a door, the movable member coupled to the door. The force member may include a back plate and a frame, with the movable member positioned between the back
20 plate and the frame. The system may include a pneumatic circuit for controlling the movable member. The movable member may be coupled to a piston assembly which is capable of contacting the pump cassette.

 In accordance with further related embodiments of the invention, the system may include a cassette receptacle for receiving the pump cassette. The
25 force assembly may be movably coupled to the control assembly to allow access to the cassette receptacle. For example, the force assembly may be pivotally coupled to the control assembly, or may move in a linear fashion away from the control assembly. The cassette receptacle may be movably coupled to the force assembly and/or control assembly to allow further
30 accessibility.

 In still further related embodiments of the invention, the control assembly includes a bezel and a bezel gasket. The bezel gasket includes a

membrane capable of being displaced to operate the pump cassette. The control assembly may include a rigid and/or fixed plate to which the bezel is attached.

In accordance with another aspect of the invention, a method of
5 pumping fluid using a pump cassette is presented. The method involves providing the pump cassette and providing a control assembly capable of operating the pump cassette. The pump cassette is inserted into a cassette receptacle. A movable member is moved against at least one of the cassette
10 receptacle and pump cassette to press the pump cassette against the control assembly.

In accordance with related embodiments of the invention, the movable member is capable of expanding. Moving of the movable member includes expanding the movable member to press the pump cassette against the control assembly. Expanding the movable member may be performed
15 pneumatically. The method may further include pumping at least one fluid through the pump cassette. In various embodiments, at least two fluids are mixed together within the pump cassette. Inserting the pump cassette into the receptacle may include opening a door on the control assembly to gain access to the cassette receptacle, the movable member attached to the door.

20 In accordance with another embodiment of the invention, a system for pumping fluid using a pump cassette includes means for operating the pump cassette. The system also includes operating means for applying force to the pump cassette to press the pump cassette against the operating means.

In accordance with related embodiments of the invention, the means
25 for applying force to the pump cassette includes an expandable member, such as a bladder, that is capable of expanding to press the pump cassette against the operating means. The operating means may include a bezel and a bezel gasket capable of being displaced to operate the pump cassette. The system may include a pump cassette receptacle for receiving the pump cassette. The
30 means for applying force to the pump cassette may be movably coupled to the operating, to allow access to the cassette receptacle.

In accordance with one aspect of the invention, a door locking system includes an assembly having a first engagement surface. A door is coupled to the assembly. The door includes a latch member having a second engagement surface for engaging the first engagement surface. A movable member is capable of generating a force against at least one of the assembly and the door to press together and substantially prevent disengagement of the first engagement surface and the second engagement surface.

In accordance with related embodiments of the invention, the first engagement surface forms an undercut, and the second engagement surface forms a projection for engaging the undercut. The latch member may include a post extending from the door, the post including the second engagement surface. The latch member may include a handle for operating the latch. The handle may be capable of pivoting to control alignment of the second engagement surface. When the first engagement surface is engaged with the second engagement surface, the movable member generating force against the one of the door and the assembly may prevent the handle from pivoting. The movable member may be capable of generating a continuous force against the at least one of the assembly and the door. The movable member may be coupled to one of the door and the assembly and/or positioned between the door and a surface of the assembly. The movable member may contact the at least one of the assembly and the door. An element may be positioned between the movable member and the at least one of the assembly and the door, such as a pump cassette, wherein the movable member contacts the element when generating the force.

In accordance with further related embodiments of the invention, the movable member is an expandable member, such as a bladder. A pneumatic circuit may control the movable member.

In accordance with still further related embodiments of the invention, the assembly includes a control element for operating a pump cassette. The control element may include a bezel and a bezel gasket that includes a membrane capable of being displaced so as to operate the pump cassette. A pneumatic control circuit may be utilized to displace the membrane.

A cassette receptacle may be movably coupled to one of the door and the assembly, the cassette receptacle capable of receiving the pump cassette. The movable member may be capable of pressing the cassette against the control element.

5 In accordance with another aspect of the invention, a door locking system includes an assembly having a first engagement means. A door attached to the assembly includes a second engagement means for engaging the first engagement means. The system further includes movable means for generating a force against at least one of the assembly and the door to press
10 together and substantially prevent disengagement of the first engagement means and the second engagement means.

 In accordance with another aspect of the invention, a method for locking a door is presented. The method includes providing an assembly that includes a first engagement surface. The assembly is coupled to a door, the
15 door including a latch member having a second engagement surface for engaging said first engagement surface. The method further includes moving a movable member against at least one of the door and the assembly to press together and substantially prevent disengagement of the first engagement surface and the second engagement surface.

20 In accordance with related embodiments of the invention, the first engagement surface forms an undercut. The second engagement surface may have a projection for engaging the undercut.

 In accordance with further related embodiments of the invention, a handle may be controlled to operate the latch member. Prior to moving the
25 movable member against the one of the door and the assembly, the door may be closed and the handle moved such that the second engagement surface of the latch member is aligned to engage the first engaging surface. Opening the door may include moving the movable member away from the one of the door and the assembly. The handle can then be moved such that the second
30 engagement surface is in non-alignment to engage the first engaging surface, allowing the door to be opened.

In accordance with still further related embodiments of the invention, moving the movable member against one of the assembly and the door includes expanding an expandable member, such as a bladder. The bladder may be pneumatically operated. A cassette receptacle may be attached to one of the door and the assembly. A pump cassette may be inserted into the cassette receptacle. The assembly may include a membrane capable of being displaced. The membrane may be pneumatically displaced to operate the pump cassette. The movable member may be moved against one of the pump cassette and the cassette receptacle to press the pump cassette against the membrane.

In accordance with other related embodiments of the invention, moving the movable member may include placing the movable member in contact with the at least one of the assembly and the door. An element may be placed between the at least one of the assembly and the door, such that the movable member contacts the element, such as a pump cassette, generating the force on the at least one of the assembly and the door.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings:

FIG. 1A shows an exemplary blood processing system 100 having a compounder in accordance with an embodiment of the present invention;

FIG. 1B shows an exemplary wiring diagram for one embodiment of the blood processing system shown in FIG. 1A;

FIG. 1C shows an exemplary wiring diagram for another embodiment of the blood processing system shown in FIG. 1A;

FIG. 2A shows an exemplary vial assembly in accordance with an embodiment of the present invention;

FIG. 2B shows a perspective view of the vial receptacle in accordance with an embodiment of the present invention;

FIG. 3A shows an exemplary compounder disposable set in accordance with an embodiment of the present invention;

FIG. 3B shows a front view of the compounder pump cassette in accordance with an embodiment of the present invention;

FIG. 3C shows a rear view of the compounder pump cassette in accordance with an embodiment of the present invention;

5 FIG. 3D shows a cross-sectional view of the spike receptacle in accordance with an embodiment of the present invention;

FIG. 3E shows a side view of a spike receptacle housing section in accordance with an embodiment of the present invention;

10 FIG. 3F shows a top view of a spike receptacle guard in accordance with an embodiment of the present invention;

FIG. 3G shows an exploded perspective view of the spike receptacle in accordance with an embodiment of the present invention;

FIG. 3H shows a cut-out perspective view of the spike receptacle in accordance with an embodiment of the present invention;

15 FIG. 3I shows a cross-sectional view of an exemplary spike having two fluid channels in accordance with an embodiment of the present invention;

FIG. 4 shows a conceptual block diagram of the compounder in accordance with an embodiment of the present invention;

20 FIG. 5A is an architectural flow diagram showing the relationship between the pneumatic control assembly and the other assemblies in accordance with an embodiment of the present invention;

FIG. 5B shows an exemplary embodiment of the pneumatic control assembly in accordance with an embodiment of the present invention;

25 FIG. 5C shows an exemplary embodiment of the air pump in accordance with an embodiment of the present invention;

FIG. 6A shows an exploded view of an exemplary front plate assembly in accordance with an embodiment of the present invention;

FIG. 6B shows a perspective front view of an exemplary bezel in accordance with an embodiment of the present invention;

30 FIG. 6C shows a plan view of the bezel of FIG. 6B;

FIG. 6D shows a side view of the bezel of FIG. 6B;

FIG. 6E shows an end view of the bezel of FIG. 6B;

FIG. 6F shows a perspective rear view of the bezel of FIG. 6B;

FIG. 6G shows a perspective front view of the bezel of FIG. 6B with the ribs machined away;

FIG. 6H shows a perspective front view of a bezel gasket for use with
5 the bezel of FIG. 6B;

FIG. 6I shows a perspective rear view of the bezel gasket of FIG. 6H;

FIG. 6J shows an exploded view of a bezel assembly including a rib insert for adding ribs to a bezel in accordance with an embodiment of the present invention;

10 FIG. 7A shows an exploded view of the door assembly in accordance with an embodiment of the present invention;

FIG. 7B shows a front perspective view of the door assembly shown in FIG. 7A in accordance with an embodiment of the present invention;

FIG. 7C shows a rear perspective view of the door assembly shown in
15 FIG. 7A in accordance with an embodiment of the present invention, in which the cassette receptacle is in a retracted position;

FIG. 7D shows a rear perspective view of the door assembly shown in FIG. 7A in accordance with an embodiment of the present invention, in which the cassette receptacle is in an open position;

20 FIG. 7E shows a first engagement surface having an undercut, in accordance with one embodiment of the invention;

FIG. 7F shows a cross-sectional view of an exemplary door lock system with the door in contact with an occluder blade and the latch member in an unlatched position, in accordance with an embodiment of the present
25 invention;

FIG. 7G shows a cross-sectional view of an exemplary door lock system with the door rotated inward sufficiently to overcome the occluder springs and the latch member in an unlatched position, in accordance with an embodiment of the present invention;

30 FIG. 7H shows a cross-sectional view of an exemplary door lock system with the door fully closed and the latch member in a latched position, in accordance with an embodiment of the present invention;

FIG. 7I is a process flow diagram describing a process for locking a door, in accordance with one embodiment of the invention;

FIG. 8A shows a cross-sectional view of an occluder assembly in accordance with an embodiment of the present invention;

5 FIG. 8B shows a side perspective view of the occluder assembly shown in FIG. 8A in accordance with an embodiment of the present invention;

FIG. 8C shows an exploded view of the occluder assembly shown in FIG. 8A in accordance with an embodiment of the present invention;

10 FIG. 9A shows an exemplary vial spike assembly in accordance with an embodiment of the present invention;

FIG. 9B is a schematic diagram showing the vial spike assembly shown in FIG. 9A prepared for insertion of the vial assembly and the spike receptacle in accordance with an embodiment of the present invention;

15 FIG. 9C is a schematic diagram showing the vial spike assembly shown in FIG. 9A with the vial assembly and spike receptacle inserted into the cylinder and the cover in an open position in accordance with an embodiment of the present invention;

20 FIG. 9D is a schematic diagram showing the vial spike assembly shown in FIG. 9A with the vial assembly and spike receptacle inserted into the cylinder and the cover in a closed position in accordance with an embodiment of the present invention;

FIG. 9E shows a cross-sectional view of the vial spike assembly with the vial assembly and spike receptacle locked and loaded and ready for spiking, in accordance with an embodiment of the present invention;

25 FIG. 9F shows a cross-sectional view of the vial spike assembly after spiking is completed, in accordance with an embodiment of the present invention;

FIG. 10 shows an exploded view of the vial spike assembly shown in FIG. 9A in accordance with an embodiment of the present invention;

30 FIG. 11 shows an exemplary spiking mechanism in which the vial is inverted and the spikes enter the vial from below, in accordance with an alternative embodiment of the present invention;

FIG. 12 shows a process flow diagram describing the compounding and blood treatment process in accordance with an embodiment of the present invention;

FIGs. 13A-B show a process flow diagram showing additional details of the compounding process shown in FIG. 12 in accordance with an
5 embodiment of the present invention;

FIG. 14 shows a process flow diagram describing the compounder dry CIT process shown in FIGs. 12 and 13 in accordance with an embodiment of the present invention;

10 FIG. 15 shows a process flow diagram describing the compounder buffer solution priming process shown in FIGs. 12 and 13 in accordance with an embodiment of the present invention;

FIG. 16 shows a process flow diagram describing the compounder wet CIT process shown in FIGs. 12 and 13 in accordance with an embodiment of
15 the present invention;

FIG. 17 shows a process flow diagram describing the process for manual compounder teardown in accordance with an embodiment of the present invention;

FIG. 18 shows a process flow diagram describing the compounder volumetric calibration process in accordance with an embodiment of the
20 present invention; and

FIG. 19 shows a logic flow diagram showing exemplary logic for mixing a substance with a liquid in accordance with an embodiment of the present invention.

25

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Embodiments of the present invention provide for safely and efficiently mixing a substance with a liquid. For convenience, this mixing
30 process may be referred to hereinafter as "compounding," and an apparatus that performs such compounding may be referred to hereinafter as a "compounder" or "compounder pump."

In certain embodiments of the present invention, the substance is contained in a container assembly having a sealed container that contains the substance. The container assembly is joined with a port assembly within a receiving chamber. The port assembly provides at least an inlet to the container, and typically also an outlet from the container. A liquid is added to the container through the inlet to produce a solution of substance and liquid. Continued ingress of liquid may cause the solution to flow out of the container through the outlet.

FIG. 19 is a logic flow diagram showing exemplary logic 1900 for mixing a substance with a liquid in accordance with an embodiment of the present invention. Beginning in block 1902, a container having a substance contained therein is provided, in block 1904. A predetermined quantity of a liquid is added to the container to produce a solution, in block 1906. The solution is permitted to flow from an outlet of the container to a receptacle when the solution rises within the container to a level of the outlet, in block 1908. Typically, liquid continues to be added to the container so that the resulting solution in the receptacle reaches has a predetermined concentration of substance to liquid. The logic ends in block 1999.

In certain embodiments of the present invention, the substance is a caustic substance that is provided in a primary container having a bottom and a top, with the caustic substance filling the primary container from the bottom to a given point between the bottom and the top. An outlet is provided in the primary container, such that the outlet is between the given point and the top. A predetermined amount of liquid is added to the primary container to produce a combined caustic substance and liquid solution that rises at least to the level of the outlet. At least some of the solution is permitted to flow from the primary container through the outlet after the solution rises to the outlet.

In exemplary embodiments of the present invention, the substance to be mixed with the liquid is a caustic anti-pathogen compound known as PEN110(TM) or INACTINE(TM), which is an organic solvent with a pH over 11 that is distributed by V.I. Technologies, Inc. of Watertown, Massachusetts. Such an anti-pathogen compound can be used to reduce pathogens in a

substance such as blood. One problem with such an anti-pathogen compound is that it typically cannot be added directly to the blood (or other substance) targeted for pathogen reduction. Therefore, the anti-pathogen compound is preferably mixed with a buffer solution, such as sodium phosphate, to form a working solution that then can be added to the blood or other substance to reduce pathogens in the blood. Because of the caustic nature of the anti-pathogen compound, the anti-pathogen compound should not come into contact with certain materials, such as plastic tubing commonly used to carry fluids in pump mechanisms. Therefore, in exemplary embodiments of the present invention, mixing is preferably accomplished by pumping the buffer solution into an anti-pathogen compound container through an inlet in order to form a partially diluted solution of anti-pathogen compound and buffer solution. The continued ingress of buffer solution to the anti-pathogen compound container through the inlet causes further dilution and also causes the partially diluted solution to flow out of the anti-pathogen compound container through an outlet to a working solution container. By partially diluting the anti-pathogen compound within the anti-pathogen compound container, the undiluted anti-pathogen compound does not come into contact with anything outside of the anti-pathogen compound container, including human operators, the pump mechanism (including tubing from the anti-pathogen compound container to the working solution container), and the external environment in general. The anti-pathogen compound is typically diluted to a predetermined concentration (e.g., 1 part anti-pathogen compound to 99 parts buffer solution), within predetermined tolerances. The anti-pathogen compound container is preferably sealed following dilution to allow for safe disposal of the anti-pathogen compound container.

SYSTEM OVERVIEW

FIG. 1A shows an exemplary blood processing system 100 having a compounder in accordance with an embodiment of the present invention.

Among other things, the blood processing system 100 includes a single compounder pump 102 and ten essentially identical blood pumps 104 organized as two banks of five blood pumps each. The compounder pump 102 pumps buffer solution from a buffer solution container 110 into a vial of anti-pathogen compound 108. The mixture, referred to as a working solution, is pumped into a working solution container 112. Each of the blood pumps 104 mixes working solution from the working solution container 112 with red blood cell concentrate (RBCC) 106 to form an incubation solution that is pumped into an incubation bag 118. The incubation solution is typically allowed to incubate for some period of time, after which it is rinsed to remove the anti-pathogen compound to produce a pathogen reduced blood product. The blood processing system 100 typically also includes two sterile docks 114 that are used by the operator to splice together plastic tubing as necessary for various blood processing operations. The blood processing system 100 is controlled through a user interface 116.

FIG. 1B shows an exemplary wiring diagram for one embodiment of the blood processing system 100. The compounder pump 102 and the blood pumps 104 are typically powered from a common 12-Volt external power supply 126, and are controlled by an external process controller 120. The process controller 120 includes the user interface 116, a computer 122, and a serial port concentrator 124. The compounder pump 102 and the blood pumps 104 are in communication with the process controller 120 through the serial port concentrator 124, for example, over RS-232 communication links. The blood processing system 100 typically includes a tubing sealer 130 for sealing plastic tubing as necessary for various blood processing operations. The blood processing system 100 typically includes an uninterruptible power supply (UPS) 128 for maintaining electrical power to the 12-Volt power supply, the process controller, and other components in the event of a primary power loss.

FIG. 1C shows an exemplary wiring diagram for another embodiment of the blood processing system 100. The blood processing system 100 may include a printer in communication with the process controller for printing

out reports. The blood processing system 100 may include a card reader 134 in communication with the process controller for card-based operator identification. The blood processing system 100 may include a wireless bar code scanner base station 138 in communication with the process controller
5 for receiving bar code information scanned using a wireless bar code scanner 136. Bar codes are typically used to track the various solution containers and the pumps on which those containers were processed.

The process controller 120 coordinates the actions of the compounder pump 102, the blood pumps 104, and the operator throughout the various
10 mixing operations. The process controller 120 initiates high level embedded commands within the pumps to move and mix the fluids. The process controller 120 instructs the operator through the setup and teardown of each process through the user interface 116. The user interface 116 is also used to inform the operator of any anomalies that may occur during mixing
15 operations.

When the blood processing system 100 is operating from the uninterruptible power supply 128 and at other appropriate times, the process controller 120 will prevent compounding and other pump operations from starting, although the pumps will generally be allowed to complete any
20 ongoing operations. Furthermore, if the process controller fails, the pumps have internal logic for safely completing or terminating any ongoing operations.

VIAL ASSEMBLY

25

The anti-pathogen compound is typically provided as a container assembly including a sealed anti-pathogen compound container (typically a sealed glass vial partially filled with anti-pathogen compound) within a protective holder. The protective holder is designed to prevent breakage of
30 the sealed anti-pathogen compound container in case the container assembly is dropped or otherwise mishandled, within predetermined limits. For convenience, the anti-pathogen compound container may be referred to

hereinafter a "vial," the protective holder may be referred to hereinafter as a "vial receptacle," and the container assembly may be referred to hereinafter as a "vial assembly."

FIG. 2A shows an exemplary vial assembly 200 in accordance with an embodiment of the present invention. The vial assembly 200 includes a vial 210 within a vial receptacle 206. The vial 210 is sealed with a polypropylene screw-on vial cap 208 including a Teflon-faced silicone septum 202 that is capable of being pierced by the spikes of a spike receptacle, as discussed below. The vial receptacle 206 includes a vial containment rib 212 for holding the vial 210 within the vial receptacle 206. The vial receptacle 206 also includes one or more rows of spike receptacle engagement teeth 204 that are undercut for engaging a corresponding vial receptacle locking feature on the spike receptacle so that the spike receptacle cannot be easily removed from the vial receptacle 206 after the vial 210 is spiked, as discussed below. Multiple rows of spike receptacle engagement teeth 204 are typically included to accommodate vial height tolerances so that spiking and locking can be accomplished with various vial heights. The vial receptacle 206 also includes switch engagement features 214 that are essentially protruding rings that operate various switches in a spiking cylinder, as discussed below.

FIG. 2B shows a perspective view of the vial receptacle 206 in accordance with an embodiment of the present invention. The top portion of the vial receptacle 206 incorporating the spike receptacle engagement teeth 204 is preferably divided into four tabs 220, 222, 224, and 226. The tabs are able to deflect inward during spiking so as to facilitate engagement with the vial receptacle locking feature on the spike receptacle, as discussed below. Each tab includes multiple rows of spike receptacle engagement teeth. The teeth on each pair of opposing tabs are essentially aligned, although the teeth on adjacent pairs of tabs are staggered by approximately half the height of a tooth. Among other things, this staggering of the spike receptacle engagement teeth 204 provides twice the number of engagement locations without having to reduce the size of the teeth.

COMPOUNDER DISPOSABLES

In order to create the inlet and outlet for diluting the anti-pathogen compound in the vial 210 as discussed above, the septum 202 is preferably
5 pierced by a port assembly having two hollow spikes, one acting as the inlet and the other acting as the outlet. For convenience, this piercing operation may be referred to hereinafter as "spiking," and the port assembly may be referred to hereinafter as a "spike receptacle." The outlet spike is connected through plastic tubing to the working solution container. The inlet spike is
10 connected through plastic tubing to the output port of a pump cassette. The pump cassette also has an inlet port that can be connected through plastic tubing to a buffer solution container. The pump cassette is installed in the compounder and serves as an interface between the compounder, the vial 210, and the buffer solution container for pumping buffer solution from the buffer
15 solution container to the vial 210, as discussed below.

In order to dilute the anti-pathogen compound, the buffer solution is typically drawn from the buffer solution container through the inlet port into a chamber of the pump cassette and is then pumped from the pump cassette chamber through the outlet port to the inlet spike and into the vial. In
20 exemplary embodiments of the present invention, the spiking operation and the pumping operations (including drawing the buffer solution from the buffer solution container and pumping the buffer solution to the inlet spike) are controlled pneumatically, as discussed below.

In a typical embodiment of the present invention, the pump cassette,
25 the spike receptacle, the working solution container, and various plastic tubes connected thereto form a compounder disposable set. The compounder disposable set is used for a single compounding operation and is then discarded.

FIG. 3A shows an exemplary compounder disposable set 300 in
30 accordance with an embodiment of the present invention. The compounder disposable set 300 includes a pump cassette 306 including an inlet port 305, and outlet port 308, and a vent 307. The inlet port 305 is connected to one end

of a plastic tube 304 having, on its other end, a buffer bag spike 302 for piercing a buffer solution container. The outlet port 308 is connected to one end of a plastic tube 309, the other end of which is connected to an inlet spike 312 of a spike receptacle 310. An outlet spike 314 of the spike receptacle 310 is connected to a tube 318 that leads through a filter 320 to a working solution container 322. A tubing clamp 316 is used to crimp the tubes 309 and 316 near the spike receptacle 310 after the compounding operation is complete.

FIG. 3B shows a front view of the compounder pump cassette 306 in greater detail. The pump cassette 306 is essentially a rigid core including formations and sealing ribs 340 constituting various pumping chambers, fluid valves, and fluid pathways (channels). The rigid core is covered on each side by a flexible membrane. The flexible membranes seal against the core and isolate the compounder pump 102 from fluids within the cassette. The pump cassette 306 is designed to interface with the compounder pump 102 in only one direction. For example, the pump cassette 306 typically includes an asymmetric feature (such as the placement of tubing) that prevents the compounder door from closing if the pump cassette 306 is inserted incorrectly.

The pump cassette 306 includes the outlet port 308, the vent port 307, and the inlet port 305. The pump cassette 306 also includes two pumping chambers 333 and 334 that are used to draw buffer solution from the buffer solution container through the inlet port 305 and pump the buffer solution to the vial 210 through the outlet port 308.

FIG. 3C shows a rear view of the compounder pump cassette 306. In addition to the inlet port 305, the vent port 307, the outlet port 308, and the pump chambers 333 and 334, the pump cassette 306 includes various "volcano" valves 324, 326, 328, 330, 332, 336, and 338 that are used to open and close various fluid pathways within the pump cassette 306. The volcano valves and the pumping chambers are preferably operated pneumatically from the rear side of the pump cassette 306, as discussed below. The valve 324 is used to control pumping through the vent port, for example, to allow air to be pumped from the pump chambers 333 and 334 out the vent port 307.

The valves 326 and 332 are used for priming the pump chambers 334 and 333, respectively. The valves 328 and 336 are used to control pumping of buffer solution through the inlet port 305 into the pump chambers 334 and 333, respectively. The valves 330 and 338 are used to control pumping of buffer
5 solution through the outlet port 308 from the pump chambers 334 and 333, respectively.

FIG. 3D shows a cross-sectional view of the spike receptacle 310 in greater detail. The spike receptacle 310 includes a housing 344 that holds spikes 354 and a guard 360, and is designed to mate with the vial receptacle
10 206 during spiking, as discussed below. The housing 344 is preferably made up of two identical halves that, when joined together, are held together by ribs on each side that align with and are engaged by slots on the other side.

The spikes 354 are contained by a polycarbonate spike holder 352 that is preferably overmolded onto the two spikes 354. The overmolded spike
15 holder 352 includes tubing barbs 342. Tubing is attached to the spikes over the tubing barbs 342. The overmolded spike holder 352 helps maintain parallelism of the spikes 354, and provides a fluid-tight connection with the tubing.

The top portion of the housing 344 has an area that engages the
20 overmold's barb feature so as to capture the tubing within the housing 344. This creates a double-mechanical (as well as bonded) feature that permanently attaches the tubing to the spike. The spike housing 344 also features an undercut vial receptacle locking feature 348 that engages the spike receptacle engagement teeth 204 of the vial receptacle 206 to permanently
25 attach the spike receptacle 310 to the vial receptacle 206 after spiking, as discussed below. The spike housing 344 also includes a rim 398 that is slightly wider than the remainder of the housing 344. The rim 398 prevents the spike receptacle 310 from being fully inserted into the vial spike assembly 406. The rim 398 includes two orientation tabs 399 that are used to align the
30 spike receptacle 310 within the vial spike assembly 406.

The guard 360 protects the spikes 354 and protects the operator from the spikes 354. The guard 360 includes a center hole that is filled or covered

with an elastomeric (silicone) grommet 356. The guard 360 is designed to engage the vial cap 208, and has four release tabs 358 that hold it loosely in the housing 344. The release tabs 358 protrude out through slots in the housing 344, making it difficult to move the guard 360 when the tabs 358 are in place. When the assembly is placed into the vial spiking assembly, the fingers are pushed in by the inner wall of the spiking cylinder, releasing the guard 360 so that spiking can occur through the grommet 356, as discussed below. The grommet 356 also acts as a redundant seal between the vial cap 208 and the spike guard 360 in case fluid were to leak through the septum 202 around the spikes 354 during pumping.

The spike receptacle 310 includes a sensor feature 346 that is essentially a protruding ring near the top of the spike receptacle 310. The sensor feature 346 is designed to engage a switch in a locking mechanism of the vial spiking assembly, as discussed below.

FIG. 3E shows a side view of a spike receptacle housing section 344 in accordance with an embodiment of the present invention. Among other things, the housing section 344 includes the rim 398, which preferably extends around the outer periphery of the housing section 344, and the undercut vial receptacle locking feature 348, which preferably extends around the inner periphery of the housing section 344. The housing section 344 includes a center channel 397 with a slot 396 for engaging a tab 358 of the guard 360, and also includes a partial channel 395 with a partial slot 394 at each edge such that, when two housing sections 344 are joined, four channels with slots are formed (two central and two where the housing sections meet. When the guard tabs are positioned within the slots, the guard 360 is held substantially in place so as to cover the spikes. When the guard tabs are released from the slots during spiking, the guard 360 is able to slide upward along the channels to allow spiking to occur, and also to provide a redundant seal against the vial in case fluid leaks from around the spikes. The housing section 344 includes formations 393 for receiving and engaging the overmolded spike holder 352 with attached tubing so as to hold the spikes and associated tubing in place.

FIG. 3F shows a top view of the guard 360 in accordance with an embodiment of the present invention. The guard 360 includes four tabs 358 that are positioned within, and are engaged by, the channels and slots in the housing 344. The tabs 358 are pushed inward during spiking in order to
5 release the tabs from the slots in the housing 344.

FIG. 3G shows an exploded perspective view of the spike receptacle 310 in accordance with an embodiment of the present invention. The spike receptacle 310 includes two housing sections 344, guard 360, grommet 356, spikes 354 with overmolded spike holder 352, and associated tubing. The
10 tubing is pushed onto the overmolded spike holder 352 over the barbs. The grommet 356 is inserted into a hole in the guard 360 such that it is held in place by the guard 360 and covers the hole in the guard 360. As shown in FIG. 3H, the overmolded spike holder 352 with attached tubing fits into corresponding formations of the housing sections 344, and the tabs of the
15 guard 360 fit into the slots in the housing sections 344.

With reference again to FIG. 2B, during spiking, the spike receptacle 310 and the vial receptacle 206 are forced together such that the spike receptacle 310 becomes locked onto the vial receptacle 206 over the tabs 220, 222, 224, and 226. During spiking, the tabs deflect inward as needed to allow
20 the vial receptacle locking feature 348 to pass over successive rows of spike receptacle engagement teeth 204 until the vial receptacle 206 is seated as far onto the vial receptacle 206 as possible. The staggered teeth provide twice as many engagement points for the vial receptacle locking feature 348 compared to teeth that are not staggered.

25 While the spiking receptacle 310 preferably includes two hollow spikes for forming the inlet and outlet, it should be noted that the present invention is in no way limited to two spikes. A single spike having both an inlet channel and an outlet channel could be used. Alternatively, multiple inlet spikes and/or multiple outlet spikes could be used.

30 FIG. 3I shows a cross-sectional view of an exemplary spike having two fluid channels 381 and 382 in accordance with an embodiment of the present invention. In a typical embodiment of the invention, one of the fluid channels

would be used to provide an inlet to the vial, while the other fluid channel would be used to provide an outlet from the vial. Appropriate tubing connections would typically be provided to allow separate tubing to be connected to the two fluid channels.

5

COMPOUNDER

As discussed above, the compounder 102 creates a working solution of anti-pathogen compound and buffer solution. A disposable pump cassette 306 serves as an interface between the compounder 102, the vial 210, the buffer solution container, and the working solution container, so that no anti-pathogen compound, buffer solution, or working solution comes into actual contact with the components of the compounder 102. The compounder 102 preferably uses pneumatics to operate the pump cassette 306 as well as other components, as discussed below. Each compounding cycle of the compounder 102 typically makes a sufficient quantity of working solution for processing 30 RBCC containers by the ten blood pumps 104.

The compounder produces the working solution by pumping a quantity of buffer solution from the buffer solution container to the vial so as to mix with the anti-pathogen compound in the vial to produce working solution. Adding the buffer solution to the vial causes the level of the working solution to rise within the vial. When the working solution rises to the level of an outlet provided in the vial, the working solution is permitted to flow from the vial to the working solution container.

The compounder 102 preferably includes a library of generic pump control (N-Pump) functions. The N-Pump library functions are used to perform various generic pumping operations such as, for example, pumping fluid into a chamber of the pump cassette, pumping fluid out of a chamber of the pump cassette, measuring the amount of fluid pumped, performing air detection, and maintaining tank pressures. The compounder 102 preferably also includes a Fluid Logic Module (FLM) that contains higher level functions that employ the N-Pump library functions to implement compounder-specific

functions (such as specific logic for mixing the buffer solution with the anti-pathogen compound to produce the working solution).

The compounder 102 includes one master board connected to two pump boards that together perform the N-Pump and FLM functions. The master board communicates to each of the pump boards via a multi-drop RS-485 bus. Each pump board controls a single pump chamber of the pump cassette 306 and the valves on its board.

In the compounder 102, the pump chambers are synchronized to pump in series. Thus, as one chamber is filling with buffer solution, the other chamber will be delivering buffer solution to the vial. The pumping algorithm is typically terminated when the volume of buffer solution pumped is within one pump stroke of the target volume.

FIG. 4 shows a conceptual block diagram of the compounder 102 in accordance with an embodiment of the present invention. Among other things, the compounder 102 includes a door assembly 402, an occluder assembly 404, a vial spike assembly 406, a front plate assembly 408, a pneumatic control assembly 410, a power/communication interface 412 including connectors for the 12-Volt power supply and the RS-232 communication link to the process controller 120, and chassis components 414. Each of these assemblies will be discussed below.

PNEUMATIC CONTROL ASSEMBLY

The pneumatic control assembly 410 provides positive and negative air pressure for operating the various other pneumatically controlled components and also acts as the general controller for the compounder 102. FIG. 5A is an architectural flow diagram showing the relationship between the pneumatic control assembly 410 and the other assemblies in accordance with an embodiment of the present invention. In this figure, the pneumatic control assembly 410 is represented by master module 512, accumulator assembly 513, and two buffer pump modules 514 and 515. The air pump 511 is considered to be one of the chassis components 414. The air pump 511

generates high and low air pressure for the master module 512, which stores high and low air pressure in the accumulator assembly 513. The pneumatic control assembly 410 directs air pressure (positive and negative), from the DC air pump 411, to the various pneumatic mechanisms of the pump. The master module 512 pneumatically controls a bladder in the occluder assembly 404, a bladder in the door assembly 402, and a bladder in the vial spiking assembly 406, as discussed below. The master module 512 provides high and low air pressure to the buffer pump modules 514 and 515. Each buffer pump module 514 and 515 controls a single pump chamber of the pump cassette 306 through the front plate assembly 408 and the valves on its module.

FIG. 5B shows an exemplary embodiment of the pneumatic control assembly 410 in accordance with an embodiment of the present invention. Among other things, the pneumatic control assembly 410 includes manifold mounting bracket 502, a negative pressure accumulator (pressure bottle) 513a, a positive pressure accumulator (pressure bottle) 513b, a manual door vent mechanism 503, the Tank Management Module Assembly 512, the two Chamber Module Assemblies 514 and 515, and associated tubing and fittings.

The tank management module 512 includes an input/output (I/O) board, a CPU board, a valve-interface board, a pneumatic manifold system, pneumatic valves, pressure transducers 2-vent covers (mufflers), stand-offs, and associated tubing and fittings. The tank management module 512 is used to control the pressures in the accumulators 513, a bladder in the door assembly 402, a bladder in the occluder assembly 404, and a bladder in the vial spiking assembly 406. The I/O board contains electrical controls for controlling LEDs that provide status information to the operator and for controlling various sensors in the vial spiking assembly 406. The pressure transducers are used to monitor the pressures of the accumulators 513 and the bladder in the door assembly 402.

In the un-powered state, the pneumatic valve that controls flow to the bladder in the door assembly 402 preferably shuts closed. This prevents the door from being opened in the event of a loss of power.

In the un-powered state, the pneumatic valve that controls flow to the bladder in the occluder assembly 404 is preferably channeled to vent. This causes the occluder to occlude the tubing to prevent further flow of fluid through the tubing, as discussed below.

5 Each chamber module 514 and 515 includes a CPU board, a valve interface board, pneumatic manifold system, pneumatic valves (including a VSO (variable) valve), a VSX chamber (504 and 505 respectively), O-ring, copper mesh, vent cover (muffler), stand-offs, pressure transducers, and associated tubing and fittings. Each chamber module assembly controls the
10 pneumatics for one of the pumping chambers and its associated valves. The VSX chambers 504 and 505 act as reference volumes in order to measure the volume of fluid that is delivered with the FMS system. The pressure transducers are used to monitor the pressure of the VSX chamber, and of the pumping chamber. The positive pneumatic system contains a pressure relief
15 valve to prevent the air pump from pressurizing the positive system to greater than 16.0 psig.

In the un-powered state, all of the pneumatic valves preferably open the fluid valves to the positive pressure line. This ensures that the fluid valves are closed if there is a loss of power.

20 The compounder 102 typically includes three microprocessor systems, one on the tank management module 512 and one on each of the chamber modules 514 and 515. These three microprocessor systems monitor each other for normal operation. Each microprocessor system also monitors key internal processes and data for validity. If any of these monitors fail, a failsafe line
25 permits any of the three processors to stop pumping operations, close all of the fluid valves and occluder, and send an anomaly signal to the process controller. If the compounder 102 detects an anomaly with the commands received from the process controller (e.g., commands received out of sequence), then the compounder will stop fluid flow and send an anomaly
30 signal to the process controller.

FIG. 5C shows an exemplary embodiment of the air pump 511 in accordance with an embodiment of the present invention. The air pump 511

includes a pump motor 591 mounted to a pump plate 592 using double-sided tape 594 and two miniature nylon cable ties 595. Four ribbed isolator grommets 593 are inserted into corresponding openings in the pump plate 592.

5

FRONT PLATE ASSEMBLY

The front plate assembly 408 includes all necessary pneumatic pathways to interface to the disposable pump cassette 306. The front plate assembly 408 includes a bezel and a bezel gasket through which the pump cassette 306 is operated. During operation of the compounder 102, the pump cassette 306 is positioned in the door assembly 402 and is pressed against the front plate assembly 408 in alignment with the bezel and bezel gasket by a bladder in the door assembly 402, as discussed below. Air lines connected to the bezel from the pneumatic control assembly 410 are used to displace membranes of the bezel gasket to operate the various valves and chambers of the pump cassette 306.

FIG. 6A shows an exploded view of an exemplary front plate assembly 408 in accordance with an embodiment of the present invention. Among other things, the front plate assembly 408 includes a rigid front plate 602 to which are mounted a bezel 604, chamber foam 606, spacer 608, air-in-line sensor 610, bezel gasket 612, gasket retainer 614, hardware 616, dowel pins 618, and grommet 620. The bezel 604, chamber foam 606, and bezel gasket 612 are mounted to the front plate 602 by the gasket retainer 614 and associated hardware 616, forming a bezel assembly. This bezel assembly is used to control pumping and mixing of fluids using the pump cassette 306, as described below. The front plate 602 includes holes for allowing air tubes to pass between the rear of the bezel 604 and the pneumatic control assembly 410, which is typically situated behind the front plate 602. The front plate 602 also includes openings for occluder blades and for engaging a door latch mechanism, as described below. The air-in-line sensor 610 is positioned so as to align with and engage the inlet tube 304, and is used during processing to

detect air in the inlet tube 304 indicating that there is no more buffer solution to be processed. The bezel 604 is shown with ribs that are removed when used in the compounder.

FIG. 6B shows a view of the pumping side of an exemplary bezel 604 in accordance with an embodiment of the present invention. The bezel 604 is a rigid block. The block is preferably made as a molded polycarbonate/ABS unit. The bezel 604 includes a depression having a chamber wall up from which extend rib structures 636 that form an elevated contour above the pumping side of the rigid block. The bezel 604 is typically molded with the rib structures 636, for example, using a mold with integral rib formations or a "blank" mold (i.e., without integral rib formations) and a mold insert having rib formations. The depression has at least one and preferably two cavities 635 therein. The cavities 635 are in fluid communication with ports that connect to air lines out the back of the bezel. The rib structures 636 allow pneumatic pressure to be applied over the elevated contour.

The elevated contour of the ribs 636 limits the pump stroke volume, making the ribbed depression suitable for use in the blood processing unit, where finer control over pumping is generally required. The bezel gasket 612 fits over the pumping side of the rigid block sealing the air paths. As positive pressure is applied through one or more cavities into the depression beneath the ribs the gasket membrane 613 covering the ribs is forced away from the pumping side to push against the working solution chamber. When negative pressure is applied through the one or more cavities, the gasket membrane 613 is pulled against the elevated contour of the ribs pulling a small amount of working solution into the working solution chamber.

Referring with greater particularity to the rib structures 636 of the preferred embodiment, it is noted that the rib structures 636 are arranged so as to provide a symmetrical grid of air passages as shown in FIG. 6C. Moreover, the elevated contour may be in the shape of a mound that increases in height from a perimeter of the depression to a middle of the mound as seen in FIGS. 6D and 6E. The depression has two cavities 635 therein and the ribs 636 provide a plurality of air passages 642 between the two cavities. In the

particular arrangement, the ribs 636 leave a straight air passage 640 unobstructed at each of the two cavities, such that at each of the two cavities the respective straight air passage 640 connects the cavity to the plurality of air passages 642 between the two cavities. The ribs 636 and the air passages 642 formed thereby run parallel to the perimeter of the depression. In this case, the depression is oval shaped and the ribs are aligned with the perimeter. It is desirable for the arrangement of ribs to distribute the air pressure in a relatively even manner across the elevated contour to provide an evenly distributed pull and push against the working solution chamber.

10 The bezel 604 includes a second depression 644 with two cavities 635 for operating the other chamber of the pump cassette 306. This depression 644 lacks ribs. The bezel 604 further includes various valve cavities 639 for operating the various valves of the pump cassette 306.

FIG. 6F shows a view of the back side of the bezel 604 in accordance with an embodiment of the present invention. The bezel 604 includes ports 637 to which pneumatic tubing from the pneumatic control assembly 410 are connected. The ports are hollow tubular structures, in particular, solvent bondable tubing connections integrally molded with the rigid block. In this embodiment, each of the cavities 635, 639 is in fluid communication with a single port 637. The port may have an inner diameter larger in size than the cavity in fluid communication therewith. The integral ports 637 allow the pneumatic connections to be made without an added expense from threaded fittings or O-rings.

Unlike the blood pump 104, the compounder 102 requires a bezel with two full volume depressions. In accordance with an embodiment of the present invention, the bezel 604 is designed so that the single molded rigid block can also be used as the compounder bezel as shown in FIG. 6G. The depression 622 beneath the rib structures 636 has a chamber wall 624. Removal of the ribs leaves an open chamber defined by the chamber wall 624. The ribs may be removed from the molded bezel by precision machining, such as milling.

Although the ribs are preferably molded or otherwise integral to the bezel and are removable if needed, a ribbed bezel assembly can alternatively be formed by coupling a rib insert into a depression of the bezel. The rib insert would typically be configured substantially as shown and described above, but would be a separate component. The rib insert could be coupled into a depression of the bezel in any of a variety of ways. For example, the rib insert could be snapped into the depression, for example using tabs on the rib insert that are engaged by corresponding slots on the bezel, or the rib insert could be glued or otherwise attached to the bezel.

FIG. 6J shows an exploded view of a bezel assembly including a rib insert in accordance with an embodiment of the present invention. The bezel includes an open depression 698. The rib insert 698 is coupled to the bezel so as to fit within the depression 698. The rib insert 699 is typically shaped to match the contour of the depression, and the ribs typically extend above the surface of the bezel.

FIG. 6H shows a front view of an exemplary bezel gasket 612 in accordance with an embodiment of the present invention. The bezel gasket 612 fits over the front of the bezel 604 and acts as an interface between the bezel 604 and the pump cassette 306 for sealing the fluid paths of the bezel 604 and for actuating the chambers and valves of the pump cassette 306. The pump cassette 306 is pressed firmly against the front side of the bezel gasket 612 during processing in order to produce an air-tight seal between the bezel gasket 612 and the pump cassette 306. The bezel gasket 612 includes membranes 613 that correspond to the depressions and the valve cavities. If desired, chamber foam 606 may be inserted between the chamber membrane and the ribs or depressions in the bezel. The chamber foam 606 allows air to pass through it and serves to fill some space between the bezel and the membrane. Positive and negative air pressure produced through the bezel cavities operate on the bezel gasket membranes 613, which in turn operate on the chambers and valves of the pump cassette 202.

FIG. 6I shows a rear view of an exemplary bezel gasket 612 in accordance with an embodiment of the present invention. The rear side of the

bezel gasket 612 contacts the pumping side of the bezel 604, and is pressed firmly against the bezel 604 during blood processing in order to produce an air-tight seal.

5 DOOR ASSEMBLY

The door assembly 402 provides a means to load and align the disposable cassettes within the compounder 102. The door assembly 402 provides a force on the disposable cassette against the bezel components of the front plate assembly 408 in order to provide sealing of the cassette's fluid paths and valves. The door assembly 402 includes a special latch system that helps maintain the seal, and also helps prevent accidental opening of the door during processing, as described in greater detail below. The door assembly 402 also provides a surface for the occluders to function against.

15 FIG. 7A shows an exploded view of the door assembly 402 in accordance with an embodiment of the present invention. Among other things, the door assembly 402 includes a door cowl 701, a latch spring post 702, a door latch 703, a cassette receptacle 704, a back plate 705, a latch pin 706, a bladder 707 with an attached pneumatic circuit 730, a frame 708, a door pin 709, a door mounting bracket 710, a piston assembly 711 including a piston plate 731 and a piston cover 732, a human interface board assembly 712, double coated tape 713, a miniature cable tie 714, recessed bumpers 715, E-rings 722, cable tie mount 723, torsion springs 724 and 725, extension spring 726, a cassette orientation tab 799, and various screws 716, 717, 718, 719, 720, 25 and 721. The human interface board assembly 712 is mounted to the inside of the door cowl 701. The piston assembly 711 includes a rigid plate 731 having a protrusion that is covered by the piston cover 732. The bladder 707, double coated tape 713, and piston assembly 711 are sandwiched between the back plate 705 and the frame 708, which are mechanically coupled together to form a frame assembly 750. The door latch 703 is positioned so that a handle 30 portion is accessible from a front side of the door cowl 701. The frame assembly 750 is mounted to the inside of the door cowl 701 so that a latch

portion of the door latch 703 protrudes through the frame assembly 750 and the frame assembly 750 holds the door latch 703 in place. The cassette receptacle 704 is pivotally mounted to the frame 708 using the door mounting bracket 710, the door pin 709, and the E-rings 722. Recessed bumpers 715
5 reduce strain on the door if the door is opened too far or with excessive force. The torsion springs 724 and 725 aid the operator in closing the door, as the door has considerable weight due to the many components. The cassette orientation tab 799 prevents the door from being closed if the pump cassette is oriented incorrectly in the cassette receptacle 704.

10 The bladder 707 is coupled to, and controlled by, a pneumatic circuit 730 that provides positive and/or negative air pressure to the bladder 707. Positive pressure supplied to the bladder 707 causes the bladder 707 to expand in the direction of the frame 708. This, in turn, causes the entire piston assembly 711 to move toward the control assembly 408, such that the
15 piston cover 732 presses against the pump cassette 202 and/or cassette receptacle 704, thereby producing an outward force on the door 402 away from the control assembly 408. Alternatively, supplying negative pressure to the bladder 707 causes the piston assembly 711 to move away from the pump cassette 202 and/or cassette receptacle 704, thereby reducing the outward
20 force on the door 402 away from the control assembly 408.

The door assembly is designed to permit single-handed operation, specifically by pulling up on the handle. However, the door latch 703 is designed so that the door cannot be easily opened when the pump cassette is in place in the cassette receptacle 704 with the door closed and the bladder 707
25 is inflated. Specifically, the latch portions of the door latch 703 have undercuts that are engaged by recesses in the front plate assembly 408. When the pump cassette is in place in the cassette receptacle 704 with the door closed and the bladder 707 is inflated so as to push the pump cassette against the bezel components of the front plate assembly 408, a sufficient force is
30 generated between the door assembly 402 and the front plate assembly 408 to prevent the door handle from being easily lifted. This door locking mechanism is described in greater detail below.

FIG. 7B shows a front perspective view of the door assembly 402 in accordance with an embodiment of the present invention. The human interface board assembly 712 having LEDs and the handle portion of the door latch 703 are visible from the front of the door cowl 701. A portion of the cassette receptacle 704 and a portion of the pneumatic circuit 730 are also visible.

FIG. 7C shows a rear perspective view of the door assembly 402 in accordance with an embodiment of the present invention, in which the cassette receptacle 704 is in a retracted position. Visible at the rear of the door cowl 701 are the frame 708, the latch portion of the door latch 703, the cassette receptacle 704, the piston assembly 711, the door mounting bracket 710, the torsion springs 724 and 725, a portion of the human interface board assembly 712, and a portion of the pneumatic circuit 730.

FIG. 7D shows a rear perspective view of the door assembly 402 in accordance with an embodiment of the present invention, in which the cassette receptacle 704 is in an open position. Visible at the rear of the door cowl 701 are the frame 708, the latch portion of the door latch 703, the cassette receptacle 704, the piston assembly 711, the door mounting bracket 710, the torsion springs 724 and 725, a portion of the human interface board assembly 712, and a portion of the pneumatic circuit 730.

As shown in FIG. 7E, the front plate assembly 408 includes a latching structure 9220 for engaging the latch member 703. The latching structure 9220 has an undercut feature forming surfaces 9221 and 9222. Similarly, the latch member 703 has an undercut feature forming surfaces 9223 and 9224. In order to close the door, the door must be rotated inward past its locking position such that surface 9225 travels beyond surface 9222, at which point the latch member 703 can be rotated upward such that the surface 9223 travels above surface 9221. When the door 402 is closed, the latch member 703 is engaged by the latching structure 9220 such that the surface 9223 overlaps the surface 9221. Opposing forces are placed on the latch member 703 and the front plate assembly 408 such that the surfaces 9222 and 9224 are forced toward one another. With the latch member 703 so engaged, the surface 9221

prevents the latch member 703 from being rotated or otherwise displaced downward due to contact with the surface 9223 and therefore prevents disengagement of the latch member 703 from the latching structure 9220.

When the opposing forces are removed or overcome, the door 402 and latch member 703 can be pushed inward toward the front plate assembly 408 until the surface 9223 no longer overlaps the surface 9221 and the latch member 703 can be rotated or otherwise displaced downward to as to disengage the latch member 703 from the latching structure 9220.

As discussed above, the door must typically be rotated inward past its locking position in order to close and open the door. In order to lock the door when the door is closed, a force is applied by a movable member such that the latch member is locked against the latching structure. Among other things, the movable member prevents or otherwise restricts inward rotation of the door, making it difficult or impossible to open the door when it is locked.

As discussed below, the assembly 102 typically includes an occluder assembly for occluding one or more pliable plastic tubes coupled to the pump cassette. The occluder assembly is typically attached to the back of the front plate assembly 408, and includes one or more occluder blades that protrude through openings in the front plate assembly 408 and make contact with corresponding structures on the door assembly 402 when the door 402 is in a closed position. Each occluder blade is typically spring loaded and is pneumatically controlled to permit extension and retraction of the occluder blade. In exemplary embodiments of the invention, each occluder blade is held in an extended position by a flat spring and is retracted by inflating a bladder positioned under the spring so as to deflect, and thereby shorten the effective length of, the spring.

In typical embodiments of the invention, the occluder blades are positioned so that, when they are in an extended position, they make contact with the door 402 before the latch member 703 is engaged by the latching structure 9220. In order to close or open the door, the door 402 must be rotated inward toward the front plate assembly 408 beyond the extended position of the occluder blades. The occluder blades can be retracted to

facilitate closing and opening of the door. If, however, the occluder blades are not retracted (for example, due to a loss of power), then the door 402 must be rotated inward toward the front plate assembly 408 with a force sufficient to overcome the occluder springs and deflect the occluder blades inward in order to close or open the door.

FIG. 7F shows a cross-sectional view of an exemplary door lock system with the door 402 in contact with an occluder blade 814 and the latch member 703 in an unlatched position, in accordance with an embodiment of the present invention. The occluder blade 814 is a component of an occluder assembly 404 that is attached to a back side of the front plate assembly 408, with the occluder blade 814 protruding through a slot in the front plate assembly 408. The occluder blade 814, which is spring loaded, prevents the door 402 from closing and latching unless and until the door 402 is rotated inward with sufficient force to overcome the occluder spring.

FIG. 7G shows a cross-sectional view of an exemplary door lock system with the door 402 rotated inward sufficiently to overcome the occluder springs and the latch member 703 in an unlatched position, in accordance with an embodiment of the present invention. The occluder blade 814 is shown in its fully extended position so as to demonstrate the amount of door rotation needed to overcome the occluder springs.

FIG. 7H shows a cross-sectional view of an exemplary door lock system with the door fully closed and the latch member in a latched position, in accordance with an embodiment of the present invention. In this position, the latch member 703 is fully engaged by the latching structure 9220 of the front plate assembly 408, and the occluder blade 814 is deflected inward. In order to open the door 402 from this position, the door 402 must be rotated inward until the surface 9223 no longer overlaps the surface 9221, at which time the handle 742 can be lifted, causing the latch member 703 to rotate downward clear of the latching structure 9220.

FIG. 7I shows a process for locking the door 402, in accordance with an embodiment of the present invention. In block 8472, the assembly 104 including the front plate assembly 408 and the attached door assembly 402 is

provided. As shown in FIG. 7E, the front plate assembly 408 includes a latching structure 9220 having an undercut feature defining surfaces 9221 and 9222, and the door assembly 402 includes a latch member 703 including an undercut feature defining surfaces 9223 and 9224.

5 The process continues by checking if the door 402 is open, in block 8474. If the door 402 is open, the door 402 is closed in block 8476. As discussed above, the door 402 is preferably closed by rotating the door 402 inward toward the front plate assembly 408 with sufficient force to overcome the force of the occluders until the latching structure 9220 engages the latch
10 member 703 such that the surface 9223 overlaps the surface 9221. Closing the door 402 may be facilitated by rotating the latch member 703 downward (e.g., by pulling up on the handle 742) while rotating the door 402 inward. The latch member 703 is preferably spring loaded, allowing the latch member 703 to engage with the latching structure 9220 when the door 402 is rotate inward
15 sufficiently.

When the door 402 is closed (or if the door 402 was already closed), the process continues by moving a movable member against at least one of the door 402 and the front plate assembly 408, in block 8478. In exemplary embodiments of the invention, the movable member includes an inflatable
20 bladder that is situated in the door 402 and, when inflated, pushes the door 402 outward away from the front plate assembly 408. The movable member causes the surfaces 9222 and 9224 to be forced toward one another. With the latch member 703 so engaged, the surface 9221 prevents the latch member 703 from being rotated or otherwise displaced downward due to contact with the
25 surface 9223 and therefore prevents disengagement the latch member 703 from the latching structure 9220. Opening of the door 402 by accidental or inappropriate manipulation of the handle 742 is thus prevented.

OCCLUDER ASSEMBLY

30

The occluder assembly 404 is used to occlude various tubes as needed for testing, compounding, and protection in the event of a failure. The

occluder assembly 404 includes an occluder blade, an occluder spring, a two-piece sheet metal enclosure, an occluder bladder, guide bushings, connectors, spacers, shafts, and miscellaneous hardware. The occluder assembly 404 for the compounder 102 includes a single occluder blade. The
5 occluder assembly 404 includes a bladder that, when inflated, retracts the occluder, which enables fluid to pass through the tubing. In the event of a loss of pneumatics, the occluder assembly 404 defaults to the occluded position so as to prevent fluid from passing through the tubing. The occluder assembly 404 is mounted to the front plate assembly 408, and provides a
10 mounting point for the vial spike assembly 406.

FIG. 8A shows a cross-sectional view of an occluder assembly 404 in accordance with an embodiment of the present invention. Among other things, the occluder assembly 404 includes a housing 802, tubing 804 connected to a bladder 808, a spacer 806 coupled to the front of the housing
15 802, an occluder blade 814, an occluder spring 812, and an adjuster 810. The occluder spring 812 is essentially a flat spring. The occluder blade 814 is connected to the end of the occluder spring 812. When the bladder 808 is inflated, the occluder spring 812 is deflected downward at the middle so as to shorten the effective length of the occluder spring 812 and retract the occluder
20 blade 814. When the bladder 808 is deflated, the occluder spring 812 extends flat and therefore extends the occluder blade 814.

FIG. 8B shows a side perspective view of the occluder assembly 404 in accordance with an embodiment of the present invention. The housing 802, the tubing 804, the occluder blade 814, and various standoffs 816 are shown.

25 FIG. 8C shows an exploded view of the occluder assembly 404 in accordance with an embodiment of the present invention. The occluder assembly 404 includes an occluder blade 875, a shaft 874, a front bracket 872, a rear bracket 871, a mylar sheet 869, a spring 868, a shaft spacer 867, an occluder bladder 866, rear blocks 865, sliding blocks 864 and 861, four spike
30 standoffs 863, a rear shaft 862, an enclosure bottom 860, an enclosure top 859, double coated tape 858, three E-rings 852, and various hardware, 873, 857, 856, 855, 854, 853, and 851. The occluder blade 875 mounts to the front

bracket 872 via the shaft 874. The rear bracket 871 is mounted to the enclosure top 859 via shaft 862, blocks 865, spacer 867, and clamps 852. The rear bracket 871 is held in a substantially fixed position, although the rear bracket 871 is able to rotate about the shaft 862 as needed for operation of the occluders.

5 The front bracket 872 is mounted to the enclosure top 859 via shaft 874 and sliding blocks 861 and 864. The front bracket 872 is able to slide forward and backward along channels formed in the sliding blocks 861 and 864 as needed for operation of the occluders. Thus, the blocks 865 constrain the position of the occluder blade and act as bearing surfaces as the rear shaft rotates, and the

10 sliding blocks 861 and 864 act as bearing surfaces for the front shaft as the occluder blade is actuated and released. It should be noted that the present invention is not limited to the block-type bearings shown, but rather various types of bushings, bearings, fixed blocks, moving blocks, or any combination thereof could be used to permit rotation of the rear shaft and/or brackets and

15 translational movement of the front shaft. The occluder blade 875 can be manually retracted if necessary. The edge of the occluder blade 875 that engages the tubing is typically rounded so as not to cut or crease the tubing.

VIAL SPIKE ASSEMBLY

20

The vial spike assembly 406 is used to join the vial assembly 200 with the spike receptacle 310 so as to cause spiking of the vial. The vial spike assembly 406 is preferably positioned so as to protrude through the top of the compounder 102. This provides easy access to the vial spike assembly 406 for

25 inserting and removing the vial assembly 200 and spike receptacle 310 in support of compounding operations.

FIG. 9A shows an exemplary vial spike assembly 406 in accordance with an embodiment of the present invention. The vial spike assembly 406 includes a cylinder 912 for receiving the vial assembly 200 and the spike

30 receptacle 310, a base 914 for supporting the cylinder 912, a piston 904 operating within the cylinder and connected to a bladder plate 906 by a shaft 920, a bladder 918 for controlling movement of the piston 904 within the

cylinder 912 by operating on the bladder plate 906, three switches (sensors) for sensing the presence and position of the vial assembly 200 and spike receptacle 310 (one of which is shown as switch 908, and the other two located within the cylinder 912 and shown in later figures), a sensor cover 902, a spike
5 cover 910 acting as a locking mechanism and including switch 908 that is operated by the sensor feature 346 of the spike receptacle 310, a drain port 916, and associated plumbing and mounting hardware (not shown).

In order to perform spiking to allow for dilution of the anti-pathogen compound, the vial assembly 200 is first inserted into the cylinder 912.
10 Sensors in the cylinder 912 detect the presence of the vial assembly 200 within the cylinder 912 and also the position of the vial assembly 200 within the cylinder 912.

Once the vial assembly 200 is in place within the cylinder 912, the spike receptacle 310 is inserted into the cylinder 912. As the spike receptacle 310 is
15 installed in the cylinder 912, the fit between the spike receptacle housing 344 and the inner wall of the cylinder 912 causes the release tabs 358 on the spike guard 360 to move inward so as to release the guard 360. This enables the guard 360 to move easily. The spike cover 910 is then closed. The switch 908 in the cover 910 is engaged by the sensor feature 346 of the spike receptacle
20 310 and so detects the presence of the spike receptacle 310 and also closure of the cover 910.

FIG. 9B is a schematic diagram showing the vial spike assembly 406 prepared for insertion of the vial assembly 200 and the spike receptacle 310 in accordance with an embodiment of the present invention. The cylinder 912
25 and cover 910 are shown, with the cover 910 in an open position so that the vial assembly 200 and spike receptacle 310 can be inserted into the cylinder 912. The spike receptacle 310 includes orientation tabs 399 that align with orientation slots 922 in the cylinder 912.

FIG. 9C is a schematic diagram showing the vial spike assembly 406
30 with the vial assembly 200 and spike receptacle 310 inserted into the cylinder 912 and the cover 910 in an open position in accordance with an embodiment of the present invention. In this configuration, the sensors in the cylinder will

detect the presence of the vial assembly 200 within the cylinder 912 and will also detect that the vial assembly 200 is in a pre-spiking position within the cylinder 912. The switch 908 will not detect presence of the spike receptacle 310 within the cylinder 912, as the cover 910 is in the open position.

5 FIG. 9D is a schematic diagram showing the vial spike assembly 406 with the vial assembly 200 and spike receptacle 310 inserted into the cylinder 912 and the cover 910 in a closed position in accordance with an embodiment of the present invention. In this configuration, the switch 908 will indicate presence of the spike receptacle 310 within the cylinder 912 and closure of the
10 cover 910.

 FIG. 9E shows a cross-sectional view of the vial spike assembly 406 with the vial assembly 200 and spike receptacle 310 locked and loaded and ready for spiking, in accordance with an embodiment of the present invention. The vial receptacle 206 carrying the vial 210 with vial cap 208 and
15 vial septum 202 is positioned within the cylinder such that a vial loaded sensor 926 is actuated and a vial spiked sensor 924 is not actuated by the switch engagement features 214. The spike housing 344 is locked by cover 910 such that the spike guard 360 with grommet 356 is aligned with the vial cap 208. The bladder 918 is deflated so that the bladder plate 906, shaft 920,
20 and piston 904 are retracted.

 Once the vial assembly 200 and spike receptacle 310 are positioned and locked in place, the bladder 918 can be inflated to cause the bladder plate 906 to push the shaft 920 and piston 904 upward. This forces the vial assembly 200 upward into the spike receptacle 310, causing spiking of the vial. The
25 sensors in the cylinder 912 detect the movement of the vial assembly 200 and completion of the spiking operation. The sensors can also detect incomplete spiking, for example, insufficient movement of the vial assembly 200, in which case an anomaly signal is typically sent to the process controller 120.

 FIG. 9F shows a cross-sectional view of the vial spike assembly 406
30 after spiking is completed, in accordance with an embodiment of the present invention. The bladder 918 is inflated so that the bladder plate 906, shaft 920, and piston 904 have pushed the vial receptacle 206 carrying the vial 210 with

vial cap 208 and vial septum 202 up and into the spike housing 344, which is held in place by the cover 910. With the vial receptacle 206 in this position, the vial loaded sensor 926 is not actuated and the vial spiked sensor 924 is actuated by the switch engagement features 214. During the spiking operation, the spike guard 360 with grommet 356 was also pushed upward along with the vial receptacle 206, and the grommet 356 is pressed tightly against the vial cap 206 so as to provide a secondary seal for the spikes in case fluid were to leak through the septum 202 around the spikes 354 during pumping.

When the spiking operation is complete, the bladder 918 can be deflated. The vial assembly 200 and the spike receptacle 310 will be permanently connected, specifically by the engagement of the spike receptacle engagement teeth 204 on the vial receptacle 206 with the vial receptacle locking feature 348 of the spike receptacle 310. The vial assembly 200 and spike receptacle 310 can be removed from the cylinder by pull on the tubing that connects to the spike receptacle 310. As discussed above, the tubing is strongly attached to the spike receptacle 310 and so will not disengage from the spike receptacle 310.

FIG. 10 shows an exploded view of the vial spike assembly 406 in accordance with an embodiment of the present invention. Among other things, the vial spike assembly 406 includes a cylinder base 1001, a spike cylinder 912, a piston 904, a shaft 920, a bladder plate 906, a spike cover guide 1008, a spike cylinder base 1010, a bladder 918, a cover bracket 1012, a spike cover 910, an ultra-subminiature snap-action switch 908, a plate 1017, a sensor cover 1018, a plunger 1020, two snap-action enclosed switches 924 and 926, a dual sensor bracket 1022, a sensor channel 902, and assorted hardware (not numbered). The piston 904 is connected to the shaft 920 and is positioned within the spike cylinder 912. The cylinder base 1001 is attached to the bottom of the spike cylinder 912 and to the spike cylinder base 1010. The shaft 920 extends through the cylinder base 1001 and the spike cylinder base 1010 and is attached to the bladder plate 906, which in turn is attached to the bladder 918. The switches 924 and 926 are attached to the dual sensor bracket

1022 and are positioned within corresponding openings in the side of the spike cylinder 912. The sensor channel 902, cover bracket 1012, and spike cover guide 1008 are attached to the spike cylinder 912, with the sensor channel 902 covering the dual sensor bracket 1022. The switch 908 is attached
5 to the spike cover 910 using the plate 1017 and the sensor cover 1018. The spike cover 910 is rotatably coupled to the spike cover guide 1008.

It should be noted that the vial spike assembly 406 can be designed to cause spiking in different ways while remaining within the scope of the present invention. For example, in alternative embodiments of the invention,
10 the vial assembly 200 can be held stationary while the spike receptacle 310 is pushed onto the vial assembly 200 so as to cause spiking. Also, the orientation of the vial assembly 200 and the spike receptacle 310 can be reversed, such that the vial is inverted and the spikes enter the vial from below.

15 FIG. 11 shows an exemplary spiking mechanism in which the vial is inverted and the spikes enter the vial from below, in accordance with an alternative embodiment of the present invention. In this embodiment, the spikes are of different length, with the shorter spike 1102 acting as the inlet spike and the longer spike 1104 acting as the outlet spike. As buffer solution
20 is added to the vial through the inlet spike 1102, the anti-pathogen compound in the vial becomes partially diluted. When the vial fills with fluid past the hollow of the outlet spike 1104, the diluted solution flows out the outlet spike 1104 to the working solution container.

25 CHASSIS COMPONENTS

The chassis components 414 include various mechanical hardware components that are not considered part of the other assemblies. Among other things, the chassis components 414 include the DC air pump 511, , a
30 chassis base, a door sensor (and cable), mounting foot grommets, skins (housing), and associated hardware and fasteners. The housing includes a

mounting point, on the back of the unit, for the manual piston bladder (door) vent 503.

COMPOUNDING

5

As discussed above, the compounder 102 and the blood pumps 104 operate under control of the process controller 120. In exemplary embodiments of the present invention, introduction of the anti-pathogen compound into the RBCC is performed in two stages, a first stage in which
10 the anti-pathogen compound is mixed with buffer solution to a first concentration, and a second stage in which the working solution is mixed with the RBCC to a second concentration.

FIG. 12 shows a process flow diagram describing the compounding and blood treatment process in accordance with an embodiment of the
15 present invention. Rectangular blocks indicate commands sent to the pump by the process controller 120. Rounded blocks indicate instructions sent to the operator by the process control 120.

The process starts in block 1201. In block 1202, the process controller instructs the operator to load and scan a compounder disposable set. After
20 the compounder disposable set is loaded into the compounder, the process controller instructs the compounder to run a dry cassette integrity test (CIT) in block 1203. The compounder dry CIT is described in more detail with reference to FIG. 14 below. Assuming the dry CIT is acceptable, the process controller instructs the operator to hang, scan, and connect the buffer solution
25 bag so that the buffer solution bag is connected to the inlet port of the pump cassette, in block 1204. The process controller then instructs the compounder to prime the compounder disposable set, in block 1205. Compounder priming is described in more detail with reference to FIG. 15 below. The process controller then instructs the compounder to run a wet CIT, in block 1206. The
30 compounder wet CIT is described in more detail below with reference to FIG. 16. Assuming the wet CIT is acceptable, the process controller then instructs the operator to scan and load the vial assembly and spike receptacle into the

vial spike assembly, in block 1207. The process controller then instructs the compounder to spike the vial, in block 1208. Once spiking is completed, the process controller instructs the compounder to perform the compounding operation, in block 1209.

5 As discussed above, compounding involves drawing buffer solution from the buffer solution container and pumping the buffer solution to the vial to dilute the anti-pathogen compound and pump the working solution to the working solution container. The compounder measures the volume of buffer solution pumped to the vial so that the resulting working solution will have a
10 predetermined concentration of anti-pathogen compound, within predetermined limits. After compounding is complete, the vial will contain some amount of fluid including buffer solution and perhaps a very small amount of anti-pathogen compound.

15 After compounding is complete, the process controller coordinates "teardown" of the compounder for removal and disposal of the compounder disposable set from the compounder. Specifically, with reference again to FIG. 12, the process controller instructs the operator to heat seal the working solution line, in block 1235, and then agitate and invert the working solution
20 bag, in block 1214. The process controller then instructs the operator to heat seal the buffer solution line, in block 1227. The process controller then instructs the operator to clamp the lines leading to the vial, in block 1228. The process controller then instructs the compounder to release the compounder door, in block 1231, which is accomplished by deflating the bladder in the
25 door assembly. The process controller then instructs the compounder to release the bladder pressure on the vial spike (piston), in block 1232. The process controller then instructs the operator to remove the compounder disposables from the compounder 1233.

 After compounder "teardown" is complete, the process controller
30 coordinates the blood processing operations in which the RBCC is mixed with working solution by the blood pumps 104 in order to produce the incubation solutions. Specifically, the process controller instructs the operator to load

and scan a blood pump disposable set in a bank of blood pumps, in block 1210, and runs a blood pump dry cassette integrity test (CIT), in block 1212. The process controller then instructs the operator to connect the disposable set to the working solution line using the sterile dock, in block 1213, and to open
5 the break-away closure on the working solution line, in block 1215. The process controller then primes the blood pumps with working solution, in block 1216, and runs a blood pump wet CIT on each of the blood pumps, in block 1217. The process controller then instructs the operator to open the break-away closure on each of the RBCC lines, in block 1219, and then
10 operates each of the blood pumps to mix RBCC with working solution to produce incubation solution, in block 1219. When blood processing is complete, the process controller instructs the operator to heat seal each of the incubation bag lines, in block 1220, and also to heat seal the working solution line, in block 1221. The process controller then tests the heat seal on the
15 incubation bag lines, in block 1223, and then instructs each of the blood pumps to release the door (by deflating the door bladder), in block 1224. The process controller then instructs the operator to remove each of the incubation bags, in block 1225, and tear down the blood disposable set, in block 1226.

If there is enough working solution remaining for another blood
20 processing cycle, then the process may recycle to block 1210 to coordinate blood processing operations for another bank of blood pumps. If and when the working solution has expired or there is not enough working solution remaining for another blood processing cycle, then the process controller typically instructs the operator to remove the working solution bag, in block
25 1236. The process ends in block 1234.

FIGs. 13A-B show a process flow diagram showing additional details of the compounding process in accordance with an embodiment of the present invention. The process begins in block 1301. A determination is made whether the process controller has been on for more than 48 hours, in
30 block 1302. If so, then the process controller is restarted, in block 1303, which essentially ends this iteration of the process, in block 1304. If the process controller has not been on for more than 48 hourse, then the pump

configuration is checked, in block 1305. If the pump configuration is incorrect, then the process enters anomaly handling, in block 1306. If the pump configuration is correct, then a check is made as to whether the occluder is engaged, in block 1307. If the occluder is engaged, then the process controller instructs the compounder to unseal the door, in block 1308. The operator is then instructed to load the compounder cassette and hang the solution bags, in block 1309. When the door is confirmed to be closed, in block 1310, the process controller instructs the compounder to seal the door, in block 1311, which is done by inflating the bladder in the door assembly. If door sealing fails, then the process enters anomaly handling, in block 1312. If the door seals, then the process controller instructs the compounder to perform the dry CIT, in block 1313. If the dry CIT fails, then the process enters anomaly handling, in block 1314. If the dry CIT passes, then the process controller instructs the operator to connect the buffer solution line, in block 1315, and then instructs the compounder to prime, in block 1316. If priming fails, then the process enters anomaly handling, in block 1317. If priming is successful, then the process controller instructs the compounder to perform the wet CIT, in block 1318. If the wet CIT fails, then the process enters anomaly handling, in block 1319. If the wet CIT passes, then the process controller instructs the operator to load and lock the vial assembly and spike receptacle into the vial spike assembly, in block 1320. The process controller confirms that the vial assembly and spike receptacle are loaded and locked, in block 1321. If the vial assembly and spike receptacle cannot be loaded and locked, then the process enters anomaly handling, in block 1322. Upon confirmation that the vial assembly and spike receptacle are loaded and locked, then the process controller instructs the compounder to perform the spiking operation, in block 1323. If spiking fails, then the process enters anomaly handling, in block 1324. If spiking is successful, then the process controller instructs the compounder to perform the compounding operation, in block 1325. If the compounding operation fails, then the process enters anomaly handling, in block 1326. Upon successful completion of the compounding operation, the process controller instructs the operator to heat

seal the buffer solution line, in block 1327, and perform other operations (such as clamping the lines leading to the spike receptacle). The process controller instructs the operator to invert the working solution bag, in block 1328. The process ends in block 1329.

5 FIG. 14 shows a process flow diagram describing the compounder dry CIT process in accordance with an embodiment of the present invention. The dry CIT process begins in block 1401. The positive pneumatic system is first isolated from the cassette and a baseline leak rate for the positive assembly is obtained, specifically by closing the occluder, in block 1402, opening all fluid
10 valves and vial spike valve and closing the variable valves, in block 1403, measuring the positive tank leak rate, in block 1404, venting the vial spike bladder if the positive tank leak rate is less than a predetermined threshold, and generating an error signal if the positive tank leak rate is greater than or equal to the predetermined threshold, in block 1405.

15 Then, the negative pneumatic system is isolated from the cassette and a baseline leak rate for the negative assembly is obtained, specifically by closing all fluid valves, in block 1407, measuring the positive tank leak rate, in block 1408, and generating an error signal if the negative tank leak rate is greater than or equal to a predetermined threshold, in block 1409.

20 Then, the process tests the cassette sheeting of the valves outside of the volcano valves, specifically by opening the occluder, in block 1410, measuring the positive tank leak rate, in block 1411, and generating an error signal if the positive tank leak rate is greater than or equal to a predetermined threshold, in block 1412.

25 Then, the process tests the cassette sheeting at the center of the volcano valves, specifically by opening valves 1A1 and 2A1 and all fluid valves, in block 1413, measuring the positive and negative tank leak rates, in block 1414, and generating an error signal if the positive or negative tank leak rate is greater than or equal to a predetermined threshold, in block 1415.

30 Then, the process verifies calibration of the positive transducers, specifically by isolating the positive transducers and connecting the positive transducers together, in block 1416, measuring the positive tank leak rate, in

block 1417, generating an error signal if the positive tank leak rate is greater than or equal to a predetermined threshold, in block 1418, determining whether all positive transducers agree to within a predetermined threshold, in block 1419, and generating an error signal if the positive transducers do not agree to within a predetermined threshold, in block 1420.

Then, the process verifies calibration of the negative transducers, specifically by isolating the negative transducers and connecting the negative transducers together, in block 1421, measuring the negative tank leak rate, in block 1422, generating an error signal if the negative tank leak rate is greater than or equal to a predetermined threshold, in block 1423, determining whether all negative transducers agree to within a predetermined threshold, in block 1424, and generating an error signal if the negative transducers do not agree to within a predetermined threshold, in block 1425.

Finally, the process tests integrity of the fluid valve leading to the vent filter, specifically by filling the chamber, in block 1426, pressurizing the chamber, in block 1427, measuring the chamber leak rate, in block 1428, and generating an error signal if the chamber leak rate is greater than or equal a predetermined threshold, in block 1429. The dry CIT process ends in block 1430.

FIG. 15 shows a process flow diagram describing the compounder buffer solution priming process in accordance with an embodiment of the present invention. The priming process begins in block 1501. The process first puts the chambers to the buffer bag through prime valves, in block 1502, and attempts to draw buffer solution from the buffer bag, in block 1503. If there is no flow, then an error signal is generated, in block 1507. Assuming there is flow, the process then gets the chambers from the buffer bag through buffer in valves, in block 1504, and attempts to draw buffer solution from the buffer bag, in block 1505. If there is no flow, then an error signal is generated in block 1507. If there is flow, then the process puts the chambers to the buffer bag through prime valves, in block 1506, and attempts to draw buffer solution from the buffer bag, in block 1508. If there is no flow, then an error signal is generated, in block 1507. If there is flow, then the process checks for

air in the chamber, in block 1509. If there is no air in the chamber, then the priming completes successfully in block 1525. If there is air in the chamber during this first pass, then this is considered an error condition, in block 1510, but the process recycles to block 1504 for a second pass. If, during the second
5 pass, air is still detected in the chamber in block 1509, then an error signal is generated, in block 1511.

FIG. 16 shows a process flow diagram describing the compounder wet CIT process in accordance with an embodiment of the present invention. The wet CIT process begins in block 1601, and involves three passes of blocks 1602
10 through 1619. In each pass, the occluder is retracted, in block 1602, and various measurements are performed on both chambers, in block 1603. If the measurements are outside of a predetermined threshold (NO in block 1604), then an error signal is generated, in block 1605. Otherwise, a chamber filling operation is performed, in block 1606. During the first pass, both chambers
15 are filled; during the second pass, only one chamber is filled; during the third pass, only the other chamber is filled. After the chamber filling operation, various measurements are performed on the chambers, in block 1607. If the measurements are outside of a predetermined threshold (NO in block 1608), then an error signal is generated, in block 1609. At this point, the occluder is
20 left retracted during the first pass, but is closed during the second and third passes, in blocks 1610 and 1611. The required fluid valves are then opened, in block 1612, tank pressure is applied to the chambers for a predetermined amount of time, in block 1613, and various measurements are performed on the chambers, in block 1614. If the measurements are outside of a
25 predetermined threshold (NO in block 1615), then an error signal is generated in block 1616. Otherwise, the process determines whether the volume displaced is within some threshold, in block 1617. If not, then an error signal is generated, in block 1618. After all three passes are complete, the occluder is disengaged, in block 1620, and both chambers are purged to the buffer
30 solution bag, in block 1621. The process ends in block 1622.

MANUAL TEARDOWN

During normal compounder teardown, the compounder receives commands from the process controller to release pressure against the pump door so that the door can be opened by the operator. The pressure against the door comes from both the door piston bladder and the tubing occluder. While the door piston bladder is pressurized and the tubing occluder is engaged, it is virtually impossible for the operator to open the pump door and remove the pump cassette. If communication between the process controller and the compounder is lost, then the operator will need to relieve this pressure manually in order to remove the cassette. Among other things, this involves the operator pressing the manual door release valve on the back of the pump to deflate the bladder in the door assembly. The operator may also manually retract the occluder if necessary.

FIG. 17 shows a process flow diagram describing the process for manual compounder teardown in accordance with an embodiment of the present invention. The process begins in block 1701. The operator is instructed to heat seal the buffer solution line and close the clamps on the lines leading to the spike receptacle, in block 1702. The operator then presses the manual door release valve on the back of the pump to deflate the bladder in the door assembly, in block 1703. The operator then manually retracts the occluder if necessary to allow opening of the door, in block 1704. The operator then removes the compounder disposables, in block 1705. A close-case file is created indicating the failure, in block 1706. The process ends in block 1707.

VOLUMETRIC CALIBRATION CHECK

The compounder is typically checked for calibration periodically to verify its ability to accurately measure volumes of pumped fluids. In exemplary embodiments of the invention, this calibration check is done by running test measurements with two different test cassettes having different but known chamber volumes.

FIG. 18 shows a process flow diagram describing the volumetric calibration check process in accordance with an embodiment of the present invention. The process begins in block 1801. The operator is instructed to scan a bar code on the compounder in block 1802 in order to test the
5 compounder. The operator is then instructed to load the first test cassette, in block 1803. Upon confirmation that the door is closed, in block 1804, the door is sealed, in block 1805. If the door fails to seal properly, then the process enters anomaly handling, in block 1806. If the door seals properly, a dry CIT is run, in block 1807. If the dry CIT fails, then the process enters anomaly
10 handling, in block 1808. If the dry CIT passes, then a volume calibration test is run to measure the volume of the chambers, in block 1809. If the difference between the measured volume and the known volume of the first cassette is greater than or equal to some predetermined threshold, then the process enters anomaly handling, in block 1810. Otherwise, the door is released, in
15 block 1811, and the operator is instructed to load the second test cassette, in block 1812. Upon confirmation that the door is closed, in block 1813, the door is sealed, in block 1814. If the door fails to seal properly, then the process enters anomaly handling, in block 1815. If the door seals properly, a dry CIT is run, in block 1816. If the dry CIT fails, then the process enters anomaly
20 handling, in block 1817. If the dry CIT passes, then a volume calibration test is run to measure the volume of the chambers, in block 1818. If the difference between the measured volume and the known volume of the second cassette is greater than or equal to some predetermined threshold, then the process enters anomaly handling, in block 1819. Otherwise, a test pass determination
25 is made, in block 1820, and a report is printed, in block 1821. The door is released, in block 1822, and the operator is instructed to remove the second test cassette, in block 1823. The process ends in block 1824.

It should also be noted that the flow diagrams are used herein to demonstrate various aspects of the invention, and should not be construed to
30 limit the present invention to any particular flow or implementation. In some cases, certain process steps can be omitted or performed in a different order

than shown without changing the overall results or otherwise departing from the true scope of the invention.

The present invention may be embodied in other specific forms without departing from the true scope of the invention. The described
5 embodiments are to be considered in all respects only as illustrative and not restrictive.

What is claimed is:

1. A method of mixing a caustic substance with a liquid, the method comprising:
 - 5 providing a primary container having the caustic substance, the primary container having a bottom and a top, the caustic substance filling the primary container from the bottom to a given point between the bottom and top, the primary container having an outlet between the given point and the top of the primary container;
 - 10 adding a predetermined amount of the liquid to the primary container to produce a combined caustic substance and liquid, the combined caustic substance and liquid rising to the outlet after the liquid is added; and
permitting at least a portion of the combined caustic substance and liquid to flow from the primary container through the outlet after the
15 combined caustic substance and liquid rises to the outlet.
2. The method as defined by claim 1 further comprising coupling the outlet to a final container, the portion of the combined caustic substance and liquid flowing from the primary container to the final container via the outlet.
20
3. The method as defined by claim 2 further comprising disconnecting the final container from the primary container, the liquid remaining in the final container having a concentration of caustic substance that is a function of the amount of liquid added to the primary container, the concentration being
25 sufficient for blood processing.
4. The method as defined by claim 1 wherein after the liquid is added to the container, the concentration of caustic substance varies within the primary container.
30
5. The method as defined by claim 1 wherein the liquid is a diluting solution.

6. The method as defined by claim 5 wherein the liquid is a buffer solution.
- 5 7. The method as defined by claim 1 wherein the orientation of the primary container remains stable as the liquid is added to the primary container.
8. The method as defined by claim 1 wherein the primary container has a
10 septum to sealingly contain the caustic substance.
9. The method as defined by claim 8 wherein the primary container has a top surface that is formed by the septum, providing including coupling a tube through the septum to produce the outlet.
- 15 10. The method as defined by claim 8 wherein providing comprises piercing a spike assembly through the septum in the primary container, the spike assembly having at least one spike forming an inlet for receiving the liquid and an outlet.
- 20 11. The method as defined by claim 1 wherein the primary container includes an inlet, further wherein adding includes adding the liquid to the primary container through the inlet.
- 25 12. The method as defined by claim 1 wherein the caustic substance has a pH that is greater than about 11.0.
13. The method as defined by claim 1 wherein the combined caustic substance and liquid rise to the outlet while the liquid is being added.
- 30

14. The method as defined by claim 1 wherein the primary container is produced from materials capable of withstanding substantially immediate corrosion by the caustic substance.
- 5 15. The method as defined by claim 1 wherein the caustic substance is an anti-pathogen compound.
16. A system for mixing a caustic substance with a liquid, the system comprising:
- 10 a primary container for containing the caustic substance, the primary container having a bottom and a top, the caustic substance filling the primary container from the bottom to a given point between the bottom and top, the primary container having an outlet between the given point and the top of the primary container;
- 15 a liquid controller operatively coupled with the primary container, the liquid controller being capable of adding a predetermined amount of the liquid to the primary container to produce a combined caustic substance and liquid, the liquid controller being capable of causing the combined caustic substance and liquid to rise to the outlet after the liquid is added,
- 20 at least a portion of the combined caustic substance and liquid flowing from the primary container through the outlet after the combined caustic substance and liquid rises to the outlet.
17. The system as defined by claim 16 further comprising a final container
- 25 capable of coupling with the outlet, the portion of the combined caustic substance and liquid being capable of flowing from the primary container to the final container via the outlet when the final container is coupled with the outlet.
- 30 18. The system as defined by claim 16 wherein the liquid is a diluting solution.

19. The system as defined by claim 16 wherein the primary container has a septum to sealingly contain the caustic substance.

20. The system as defined by claim 19 wherein the primary container has a top surface that is formed by the septum, the system further including a tube coupled through the septum to produce the outlet.

21. The system as defined by claim 19 further including a spike assembly capable of piercing through the septum in the primary container, the spike assembly having at least one spike forming an inlet for receiving the liquid and an outlet after piercing the septum.

22. The system as defined by claim 16 wherein the primary container includes an inlet for receiving the liquid.

23. The system as defined by claim 16 wherein the caustic substance has a pH that is greater than about 11.0.

24. The system as defined by claim 16 wherein the primary container is produced from materials capable of withstanding substantially immediate significant corrosion by the caustic substance.

25. The system as defined by claim 16 wherein the caustic substance is an anti-pathogen compound.

26. An apparatus for mixing a substance with a liquid, the substance being contained in a container assembly having a sealed container that contains the substance, the container assembly also having a port assembly to permit substance to flow from the sealed container when coupled, the apparatus comprising:

a receiving chamber for receiving the container assembly;

a container assembly controller operatively coupled with the receiving chamber, the container assembly controller controlling coupling of the container and the port assembly; and

5 a liquid controller operatively coupled with the receiving chamber, the liquid controller controlling the flow of the liquid into the container to produce a combined substance and liquid.

27. The apparatus as defined by claim 26 wherein the liquid controller controls flow of the liquid to also control the flow of combined substance and
10 liquid from the container.

28. The apparatus as defined by claim 26 wherein the container assembly controller mechanically moves at least a portion of the container assembly to couple the container with the port assembly.
15

29. The apparatus as defined by claim 26 wherein the container assembly controller includes logic for detecting the relative locations of the container and the port assembly.

20 30. The apparatus as defined by claim 26 wherein the receiving chamber has a cover capable of being in either one of an open position and a closed position, the cover securing the container assembly within the receiving chamber when in the closed position, the container assembly controller having logic for detecting if the cover is in the closed position.

25 31. The apparatus as defined by claim 30 wherein the container assembly controller permits the container to couple with the port assembly after detecting that the cover is in the closed position.

30 32. The apparatus as defined by claim 30 further including a cover lock that prevents the cover from being moved from the closed position while the liquid is being received by the container.

33. The apparatus as defined by claim 26 further including a pneumatically controlled member within the receiving chamber, the pneumatically controlled member capable of contributing to the coupling of
5 the container assembly in response to commands from the container assembly controller.

34. The apparatus as defined by claim 26 wherein the liquid controller includes logic that stores a value representing a predetermined amount of
10 liquid to be received by the container assembly.

35. The apparatus as defined by claim 26 further comprising a housing containing at least one of the container assembly controller and the liquid controller.
15

36. The apparatus as defined by claim 26 wherein the receiving chamber at least partially extends outwardly from the housing.

37. The apparatus as defined by claim 26 further comprising a sensor
20 within the receiving chamber for detecting the location of the container within the receiving chamber.

38. The apparatus as defined by claim 26 wherein the receiving chamber is configured to contain the container assembly in a single orientation.
25

39. The apparatus as defined by claim 26 further comprising a set of valves controlled by the liquid controller to control the flow of liquid into the container.

30 40. The apparatus as defined by claim 26 further comprising a cassette used by the liquid controller to measure the volume of the liquid to be directed to the container.

41. The apparatus as defined by claim 26 wherein the substance is a caustic solution.

5 42. The apparatus as defined by claim 26 wherein the substance is an anti-pathogen compound.

43. The apparatus as defined by claim 26, wherein the container assembly includes a container receptacle for holding the container and locking with the
10 port assembly.

44. The apparatus as defined by claim 43, wherein the container receptacle includes a first locking feature that interfaces with a corresponding second locking feature of the port assembly.

15 45. The apparatus as defined by claim 44, wherein the first locking feature comprises a plurality of port assembly engagement teeth, and wherein the port assembly comprises a corresponding locking feature that engages the plurality of port assembly engagement teeth.

20 46. The apparatus as defined by claim 45, wherein the container receptacle includes a plurality of tabs, each tab having port assembly engagement teeth, wherein the port assembly engagement teeth on adjacent tabs are staggered relative to one another.

25 47. The apparatus as defined by claim 46, wherein the port assembly engagement teeth are staggered by approximately half the height of a tooth.

48. The apparatus defined by claim 43, wherein the container receptacle
30 comprises at least one raised switch engagement feature on an outer surface of the container receptacle for operating a sensor within the receiving chamber.

49. An apparatus for mixing a substance with a liquid, the substance being contained in a container assembly having a sealed container that contains the substance, the container assembly also having a port assembly to permit
5 substance to flow from the sealed container when coupled, the apparatus comprising:

means for receiving the container assembly;

coupling means for controlling coupling of the container and the port assembly; and

10 flow means for controlling the flow of the liquid into the container to produce a combined substance and liquid.

50. The apparatus as defined by claim 49 wherein the flow means controls flow of the liquid to also control the flow of combined substance and liquid
15 from the container.

51. The apparatus as defined by claim 49 wherein the coupling means includes means for mechanically moving at least a portion of the container assembly to couple the container with the port assembly.

20

52. The apparatus as defined by claim 49 wherein the coupling means includes means for detecting the relative locations of the container and the port assembly.

25 53. The apparatus as defined by claim 49 wherein the receiving means has a cover capable of being in either one of an open position and a closed position, the cover securing the container assembly within the receiving means when in the closed position, the coupling means having means for detecting if the cover is in the closed position.

30

54. The apparatus as defined by claim 53 wherein the coupling means permits the container to couple with the port assembly after detecting that the cover is in the closed position.
- 5 55. The apparatus as defined by claim 53 further including a cover lock that prevents the cover from being moved from the closed position while the liquid is being received by the container.
56. The apparatus as defined by claim 49 further including a
10 pneumatically controlled means within the receiving means, the pneumatically controlled means capable of contributing to the coupling of the container assembly in response to commands from the coupling means.
57. The apparatus as defined by claim 49 wherein the flow means includes
15 means for storing a value representing a predetermined amount of liquid to be received by the container assembly.
58. The apparatus as defined by claim 49 further comprising a housing containing at least one of the coupling means and the flow means.
20
59. The apparatus as defined by claim 49 wherein the receiving means at least partially extends outwardly from the housing.
60. The apparatus as defined by claim 49 further comprising a means for
25 detecting the location of the container within the receiving means.
61. The apparatus as defined by claim 49 wherein the receiving means is configured to contain the container assembly in a single orientation.
- 30 62. The apparatus as defined by claim 49 further comprising a set of valves controlled by the flow means to control the flow of liquid into the container.

63. The apparatus as defined by claim 49 further comprising a means for measuring the volume of the liquid to be directed to the container, the measuring means being used by the flow means.

5 64. The apparatus as defined by claim 49 wherein the substance is a caustic substance.

65. The apparatus as defined by claim 49 wherein the substance is an anti-pathogen compound.

10

66. Apparatus for use in a fluid processing system having a pump, the apparatus comprising:

a pump cassette for use with the pump, the pump cassette including at least one pump chamber and a first port in selective fluid communication
15 with the at least one pump chamber; and

a mechanically operated spiking assembly including at least one hollow spike having a piercing end for piercing a first container, the at least one hollow spike including a first spike in fluid communication with the first port of the pump cassette.

20

67. Apparatus according to claim 66, further comprising:

first tubing coupled at one end to the first port of the pump cassette and at another end to a non-piercing end of the first spike so as to provide a first fluid path between the first port and the first spike.

25

68. Apparatus according to claim 66, wherein the first port is a fluid outlet port, and wherein the first spike provides a fluid inlet to the first container.

69. Apparatus according to claim 66, wherein the first port is a fluid inlet
30 port, and wherein the first spike provides a fluid outlet from the first container.

70. Apparatus according to claim 66, wherein the spiking assembly includes a housing.

71. Apparatus according to claim 70, wherein the housing comprises two substantially identical halves that are joined together.

72. Apparatus according to claim 70, wherein the spiking assembly further includes a spike holder captured by the housing, the spike holder engaging the at least one spike.

10

73. Apparatus according to claim 72, wherein the spike holder is overmolded onto the at least one spike.

74. Apparatus according to claim 73, wherein the overmolded spike holder includes, for each spike, a tubing barb proximate to the non-piercing end of the spike for coupling a tube to the spike.

15

75. Apparatus according to claim 74, wherein the housing includes at least one element for engaging each tube about the tubing barb so as to secure the tubes within the housing.

20

76. Apparatus according to claim 70, wherein the spiking assembly includes a spike guard disposed within the housing and overlaying the piercing end of the at least one spike.

25

77. Apparatus according to claim 76, wherein the spike guard includes a grommet capable of being pierced by the at least one spike.

78. Apparatus according to claim 77, wherein the grommet functions as a fluid seal when in contact with the first container.

30

79. Apparatus according to claim 76, wherein the spike guard includes at least one tab for engaging one or more slots in the housing to prevent movement of the spike guard, the at least one tab capable of being disengaged from the one or more slots to allow movement of the spike guard towards the
5 at least one spike such that the at least one spike can pierce the grommet.

80. Apparatus according to claim 70, wherein the housing includes at least one element for engaging a container holder.

10 81. Apparatus according to claim 80, wherein the at least one element includes a surface forming an undercut for engaging at least one corresponding feature on the container holder.

82. Apparatus according to claim 66, wherein the at least one spike
15 includes a second spike.

83. Apparatus according to claim 82, further comprising:
a second container; and
second tubing coupled at one end to a non-piercing end of the second
20 spike and at another end to the second container so as to provide a second fluid path between the second spike and the second container.

84. Apparatus according to claim 83, further comprising:
a filter coupled between the second spike and the fluid receptacle along
25 the second fluid path.

85. Apparatus according to claim 66, wherein the pump cassette includes a second port in selective fluid communication with the at least one pump chamber.
30

86. Apparatus according to claim 85, further comprising:

third tubing coupled at one end to the second port, the third tubing providing a third fluid path between the second port and a third container.

87. Apparatus according to claim 86, further comprising:

5 a third spike coupled to another end of the third tubing for piercing the third container.

88. Apparatus according to claim 85, wherein the at least one pump chamber includes two pump chambers, and wherein fluid can be pumped
10 from one port into one pump chamber while fluid is pumped from the other pump chamber out the other port.

89. Apparatus according to claim 66, wherein the pump cassette is pneumatically controlled by the pump.

15

90. Apparatus for use in a fluid processing system having a pump, the apparatus comprising:

a pump cassette for use with the pump, the pump cassette including at least one pump chamber and a first port in selective fluid communication
20 with the at least one pump chamber; and

a spiking assembly including a plurality of hollow spikes, each having a piercing end for piercing a first container, the plurality hollow spikes including a first spike in fluid communication with the first port of the pump cassette.

25

91. Apparatus according to claim 90, further comprising:

first tubing coupled at one end to the first port of the pump cassette and at another end to a non-piercing end of the first spike so as to provide a first fluid path between the first port and the first spike.

30

92. Apparatus according to claim 90, wherein the first port is a fluid outlet port, and wherein the first spike provides a fluid inlet to the first container.

93. Apparatus according to claim 90, wherein the first port is a fluid inlet port, and wherein the first spike provides a fluid outlet from the first container.

5

94. Apparatus according to claim 90, wherein the spiking assembly includes a housing.

95. Apparatus according to claim 94, wherein the housing comprises two substantially identical halves that are joined together.

10

96. Apparatus according to claim 94, wherein the spiking assembly further includes a spike holder captured by the housing, the spike holder engaging the at least one spike.

15

97. Apparatus according to claim 96, wherein the spike holder is overmolded onto the plurality of spikes.

98. Apparatus according to claim 97, wherein the overmolded spike holder includes, for each spike, a tubing barb proximate to the non-piercing end of the spike for coupling a tube to the spike.

20

99. Apparatus according to claim 98, wherein the housing includes at least one element for engaging each tube about the tubing barb so as to secure the tubes within the housing.

25

100. Apparatus according to claim 94, wherein the spiking assembly includes a spike guard disposed within the housing and overlaying the piercing end of the plurality of spikes.

30

101. Apparatus according to claim 100, wherein the spike guard includes a grommet capable of being pierced by the plurality of spikes.

102. Apparatus according to claim 101, wherein the grommet functions as a fluid seal when in contact with the first container.

5 103. Apparatus according to claim 100, wherein the spike guard includes at least one tab for engaging one or more slots in the housing to prevent movement of the spike guard, the at least one tab capable of being disengaged from the one or more slots to allow movement of the spike guard towards the plurality of spikes such that the plurality of spikes can pierce the grommet.

10

104. Apparatus according to claim 94, wherein the housing includes at least one element for engaging a container holder.

105. Apparatus according to claim 104, wherein the at least one element
15 includes a surface forming an undercut for engaging at least one corresponding feature on the container holder.

106. Apparatus according to claim 90, wherein the plurality of spikes includes a second spike.

20

107. Apparatus according to claim 106, further comprising:
a second container; and
second tubing coupled at one end to a non-piercing end of the second
spike and at another end to the second container so as to provide a second
25 fluid path between the second spike and the second container.

108. Apparatus according to claim 107, further comprising:
a filter coupled between the second spike and the fluid receptacle along
the second fluid path.

30

109. Apparatus according to claim 90, wherein the pump cassette includes a second port in selective fluid communication with the at least one pump chamber.
- 5 110. Apparatus according to claim 109, further comprising:
third tubing coupled at one end to the second port, the third tubing providing a third fluid path between the second port and a third container.
111. Apparatus according to claim 110, further comprising:
10 a third spike coupled to another end of the third tubing for piercing the third container.
112. Apparatus according to claim 109, wherein the at least one pump chamber includes two pump chambers, and wherein fluid can be pumped
15 from one port into one pump chamber while fluid is pumped from the other pump chamber out the other port.
113. Apparatus according to claim 90, wherein the pump cassette is pneumatically controlled by the pump.
20
114. Apparatus for piercing a container, the apparatus comprising:
a housing;
a spike holder captured by the housing, the spike holder engaging at least one hollow spike having a piercing end for piercing the container; and
25 a spike guard disposed within the housing and overlaying the piercing end of the at least one spike.
115. Apparatus according to claim 114, wherein the spike guard includes a grommet capable of being pierced by the at least one spike
30
116. Apparatus according to claim 115, wherein the grommet functions as a fluid seal when in contact with the container.

117. Apparatus according to claim 114, wherein the at least one hollow spike includes a first spike for providing a fluid inlet to the container.
- 5 118. Apparatus according to claim 114, wherein the housing comprises two substantially identical halves that are joined together.
119. Apparatus according to claim 114, wherein the spike holder is overmolded onto the at least one spike.
- 10 120. Apparatus according to claim 119, wherein the overmolded spike holder includes, for each spike, a tubing barb proximate to the non-piercing end of the spike for coupling a tube to the spike.
- 15 121. Apparatus according to claim 120, wherein the housing includes at least one element for engaging each tube about the tubing barb so as to secure the tubes within the housing.
122. Apparatus according to claim 114, wherein the spike guard includes at least one tab for engaging one or more slots in the housing to prevent movement of the spike guard, the at least one tab capable of being disengaged from the one or more slots to allow movement of the spike guard towards the at least one spike such that the at least one spike can pierce the grommet.
- 20 123. Apparatus according to claim 114, wherein the housing includes at least one element for engaging a container holder.
124. Apparatus according to claim 123, wherein the at least one element includes a surface forming an undercut for engaging at least one corresponding feature on the container holder.
- 30

125. Apparatus according to claim 114, wherein the at least one spike includes a second spike for providing an outlet from the container.

126. A kit comprising:

5 a pump cassette for use with a pump, the pump cassette including at least one pump chamber and a first port in selective fluid communication with the at least one pump chamber;

a spiking assembly including at least one hollow spike having a piercing end for piercing a first container; and

10 first tubing for connection at one end to the fluid outlet port of the pump cassette and at another end to a non-piercing end of a first spike for providing a first fluid path between the first port and the first spike.

127. A kit according to claim 127, wherein the at least one spike further
15 includes a second spike.

128. A kit according to claim 127, further comprising:

a second container; and

20 second tubing for connection at one end to a non-piercing end of the second spike and at another end to the second container for providing a second fluid path between the second spike and the second container.

129. A kit according to claim 128, further comprising:

25 a filter for connection between the second spike and the second container along the second fluid path.

130. A kit according to claim 126, further comprising:

third tubing for connection at one end to a fluid inlet port of the pump cassette.

30

131. A kit according to claim 130, further comprising:

a third spike coupled to another end of the third tubing for piercing a third container.

132. A method for attaching tubing to one or more spikes of a spiking assembly, the method comprising:
- overmolding a spike holder over a portion of each of the spikes such that each spike maintains a substantially fixed position within the spike holder and at least one barb is formed proximate to each spike; and attaching a tube to each spike, each tube installed over one of the barbs.

10

133. A method according to claim 132, further comprising:
- capturing the tubing within a housing, wherein the housing includes at least one element for engaging the tubing about the barbs so as to secure the tubes within the housing.

15

134. Apparatus for use in a fluid processing system having a pump, the apparatus comprising:
- a pump cassette for use with the pump, the pump cassette including at least one pump chamber and a first port in selective fluid communication with the at least one pump chamber; and
- a spiking assembly including a spike, the spike having at least two fluid channels, at least one of the fluid channels in fluid communication with the first port of the pump cassette.

20

135. A system for pumping fluid using a pump cassette, the system comprising:
- a control assembly for operating the pump cassette, and
- a force assembly having a movable member capable of applying force to the pump cassette to press the pump cassette against the control assembly.

25

30

136. The system according to claim 135, wherein the movable member includes an expandable member capable of expanding to press the pump cassette against the control assembly.

- 5 137. The system according to claim 136, wherein the expandable member is a bladder.

138. The system according to claim 135, wherein the force assembly includes a door, the movable member attached to the door.

10

139. The system according to claim 135, wherein the force assembly includes a back plate and a frame, the movable member positioned between the back plate and the frame.

- 15 140. The system according to claim 135, further comprising a pneumatic circuit for controlling the movable member.

141. The system according to claim 135, wherein the movable member is coupled to a piston assembly, the piston assembly capable of contacting the
20 pump cassette.

142. The system according to claim 135, further including a cassette receptacle for receiving the pump cassette.

- 25 143. The system according to claim 142, wherein the force assembly is movably coupled to the control assembly to allow access to the cassette receptacle.

144. The system according to claim 142, wherein the cassette receptacle is
30 movably coupled to the force assembly.

145. The system according to claim 142, wherein the cassette receptacle is movably coupled to the control assembly.

146. The system according to claim 135, wherein the control assembly
5 includes:

a bezel; and

a bezel gasket including a membrane capable of being displaced to operate the pump cassette.

10 147. The system according to claim 146, further including a pneumatic control circuit for displacing the membrane.

148. The system according to claim 146, wherein the control assembly includes a rigid plate to which the bezel is attached.

15

149. A method of pumping fluid using a pump cassette comprising:
providing the pump cassette;
providing a control assembly capable of operating the pump cassette;
inserting the pump cassette into a cassette receptacle;
20 moving a movable member against at least one of the cassette receptacle and the pump cassette to press the pump cassette against the control assembly.

150. The method according to claim 149, wherein the movable member is
25 capable of expanding, and wherein moving the movable member against at least one of the cassette receptacle and the pump cassette includes:
expanding the movable member to press the pump cassette against the control assembly.

30 151. The method according to claim 150, wherein expanding the movable member includes pneumatically operating the expandable member.

152. The method according to claim 149, further including pumping at least one fluid through the pump cassette.
153. The method according to claim 149, wherein the control assembly includes a membrane capable of being displaced, and wherein said pumping includes:
pneumatically displacing the membrane to operate the pump cassette.
154. The method according to claim 149, wherein inserting the pump cassette into the cassette receptacle includes:
opening a door coupled to the control assembly to gain access to the cassette receptacle, the movable member attached to the door.
155. A system for pumping fluid using a pump cassette, the system comprising:
means for operating the pump cassette; and
movable means for applying force to the pump cassette to press the pump cassette against the operating means.
156. The system according to claim 155, wherein the means for applying force to the pump cassette includes an expandable member capable of expanding to press the pump cassette against the operating means.
157. The system according to claim 156, wherein the means for applying force to the pump cassette includes a door, the expandable member coupled to the door.
158. The system according to claim 156, wherein the expandable member is a bladder.
159. The system according to claim 155, wherein the operating means includes:

a bezel; and

a bezel gasket including a membrane capable of being displaced
operate the pump cassette.

5 160. The system according to claim 155, further comprising a cassette
receptacle for receiving the pump cassette.

161. The system according to claim 160, wherein the means for applying
force

10 to the pump cassette is movably coupled to the operating means, to allow
access to the cassette receptacle.

162. A door locking system comprising:

an assembly including a latching structure having a first engagement
15 surface and a first overlap surface;

a door movably coupled to the assembly, the door including a latch
member having a second engagement surface and a second overlap surface,
the door having a closed position in which the first engagement surface at
least partially contacts the second engagement surface and the first overlap
20 surface at least partially overlaps the second overlap surface, the second
engagement surface required to move beyond the first engagement surface in
order to close and open the door; and

a movable member capable of generating a force against at least one of
the assembly and the door to press together and substantially prevent
25 disengagement of the first engagement surface and the second engagement
surface.

163. The door locking system according to claim 162, wherein the first
engagement surface forms an undercut.

30

164. The door locking system according to claim 163, wherein the second
engagement surface forms a projection for engaging the undercut.

165. The door locking system according to claim 162, wherein the latch member includes a post extending from the door, the post including the second engagement surface.
- 5 166. The door locking system according to claim 162, wherein the latch member includes a handle for operating the latch, the handle capable of pivoting to control alignment of the second engagement surface.
- 10 167. The door locking system according to claim 166, wherein the handle is substantially incapable of pivoting when the first engagement surface is engaged with the second engagement surface and the movable member is generating force against one of the door and the assembly.
- 15 168. The door locking system according to claim 162, wherein the movable member is capable of generating a continuous force against the at least one of the assembly and the door.
169. The door locking system according to claim 162, wherein the movable member is coupled to one of the door and the assembly.
- 20 170. The door locking system according to claim 162, wherein the movable member is positioned between the door and a surface of the assembly.
- 25 171. The door locking system according to claim 162, wherein the movable member is an expandable member.
172. The door locking system according to claim 171, wherein the expandable member is a bladder.
- 30 173. The door locking system according to claim 162, further including a pneumatic circuit for controlling the movable member.

174. The door locking system according to claim 162, wherein the assembly includes a control element for operating a pump cassette.

5 175. The door locking system according to claim 174, wherein the control element includes:

a bezel; and

a bezel gasket including a membrane capable of being displaced so as to operate the pump cassette.

10

176. The door locking system according to claim 175, further including a pneumatic control circuit for displacing the membrane.

177. The door locking system according to claim 174, further including a cassette receptacle movably coupled to one of the door and the assembly, the
15 cassette receptacle capable of receiving the pump cassette.

178. The door locking system according to claim 177, wherein the movable member is capable of pressing the cassette against the control element.

20

179. The door locking system according to claim 162, wherein the movable member contacts the at least one of the assembly and the door.

180. The door locking system according to claim 162, further comprising
25 an element positioned between the movable member and the at least one of the assembly and the door, wherein the movable member contacts the element when generating the force.

181. The door locking system according to claim 180, wherein the element
30 is a pump cassette.

182. A door locking system comprising:

an assembly having a first engagement means;
a door coupled to the assembly, the door including a second
engagement means for engaging the first engagement means; and
movable means for generating a force against at least one of the
5 assembly and the door to press together and substantially prevent
disengagement of the first engagement surface and the second engagement
surface.

183. The door locking system according to claim 182, wherein the first
10 engagement means includes a surface forming an undercut, and the second
engagement means forms a projection for engaging the undercut.

184. The door locking system according to claim 182, further including a
handle attached to the second engagement means.

15 185. The door locking system according to claim 182, wherein the movable
means includes an expandable member.

186. The door locking system according to claim 185, wherein the
20 expandable member is a bladder.

187. The door locking mechanism according to claim 182, further including
a pneumatic circuit for controlling the moving member.

25 188. The door locking system according to claim 182, wherein the
assembly includes control means for operating a pump cassette.

189. The door locking system according to claim 188, wherein the control
means includes:
30 a bezel; and
a bezel gasket including a membrane capable of being displaced so as
to operate the pump cassette.

190. The door locking system according to claim 189, further including a pneumatic control circuit for displacing the membrane.

5 191. The door locking system according to claim 179, where the movable means is positioned between the door and the assembly.

192. The door locking system according to claim 182, wherein the movable means is capable of contacting and pressing against the at least one of the
10 assembly and the door.

193. The door locking system according to claim 182, further comprising an element positioned between the movable means and the at least one of the assembly and the door, wherein the movable member contacts the element
15 when generating the force.

194. The door locking system according to claim 193, wherein the element is a pump cassette.

20 195. A door locking method comprising:
providing an assembly including a latching structure having a first engagement surface and a first overlap surface, the assembly coupled to a door, the door including a latch member having a second engagement surface and a second overlap surface, the door having a closed position in which the
25 first engagement surface at least partially contacts the second engagement surface and the first overlap surface at least partially overlaps the second overlap surface, the second engagement surface required to move beyond the first engagement surface in order to close and open the door; and
moving a movable member to generate a force against at least one of
30 the door and the assembly to press together and substantially prevent disengagement of the first engagement surface and the second engagement surface.

196. The door locking method according to claim 195, wherein the first engagement surface forms an undercut and the second engagement surface forms a projection for engaging the undercut.

5

197. The door locking method according to claim 195, further comprising controlling a handle to operate the latch member.

198. The door locking method according to claim 197, wherein prior to
10 moving the movable member the method further comprising:
closing the door; and
moving the handle such that the second engagement surface of the latch member is aligned to engage the first engaging surface.

15 199. The door locking method according to claim 197, further comprising:
moving the movable member away from the one of the door and the assembly;
moving the handle such that the second engagement surface is in non-alignment to engage the first engaging surface; and
20 opening the door.

200. The door locking method according to claim 195, wherein moving the movable member against one of the assembly and the door includes expanding an expandable member.

25

201. The door locking method according to claim 200 wherein the expandable member is a bladder, and expanding the expandable member includes pneumatically operating the bladder.

30 202. The door locking method according to claim 195, wherein a cassette receptacle is attached to one of the door and the assembly, the method further comprising:

inserting a pump cassette into the cassette receptacle.

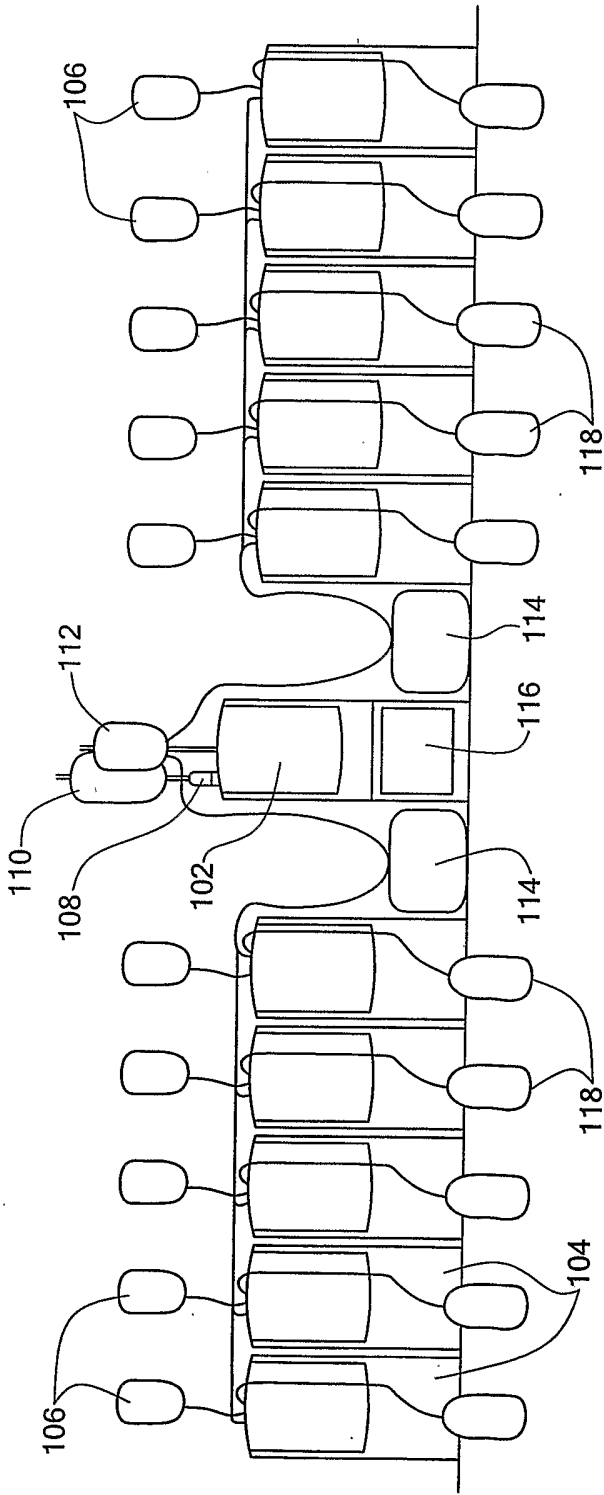
203. The door locking method according to claim 202, wherein the assembly includes a membrane capable of being displaced, the method
5 further comprising pneumatically displacing the membrane to operate the pump cassette.

204. The door locking method according to claim 202, wherein moving the movable member includes moving the movable member against one of the
10 pump cassette and the cassette receptacle to press the pump cassette against the membrane.

205. The door locking method according to claim 195, wherein moving the movable member includes placing the movable member in contact with the at
15 least one of the assembly and the door.

206. The door locking method according to claim 195, wherein moving the movable member includes placing the movable member in contact with an element positioned between the at least one of the assembly and the door,
20 such that a force is generated on the at least one of the assembly and the door.

207. The door locking method according to claim 206, wherein the element is a pump cassette.



100

FIG. 1A

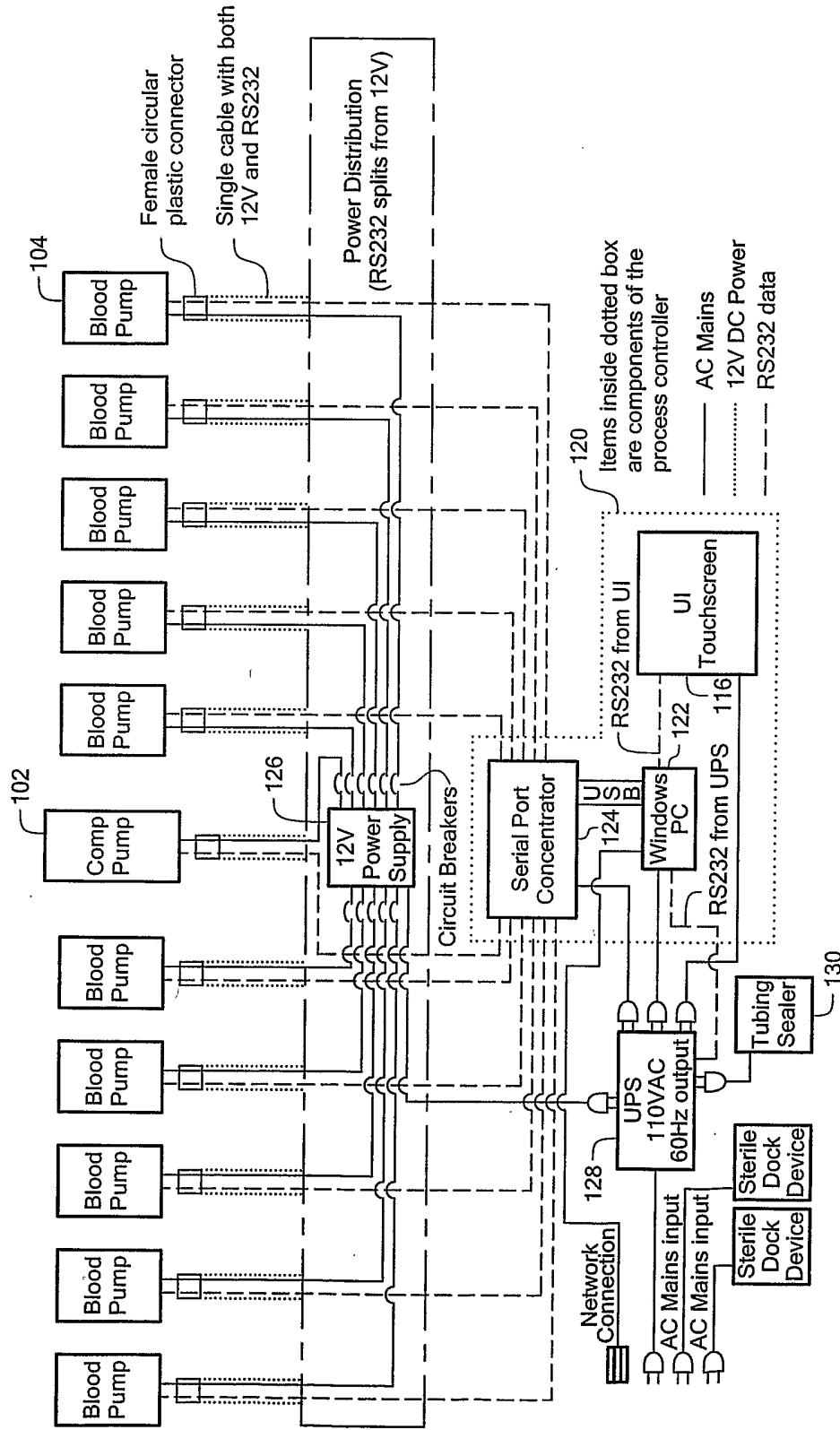


FIG. 1B

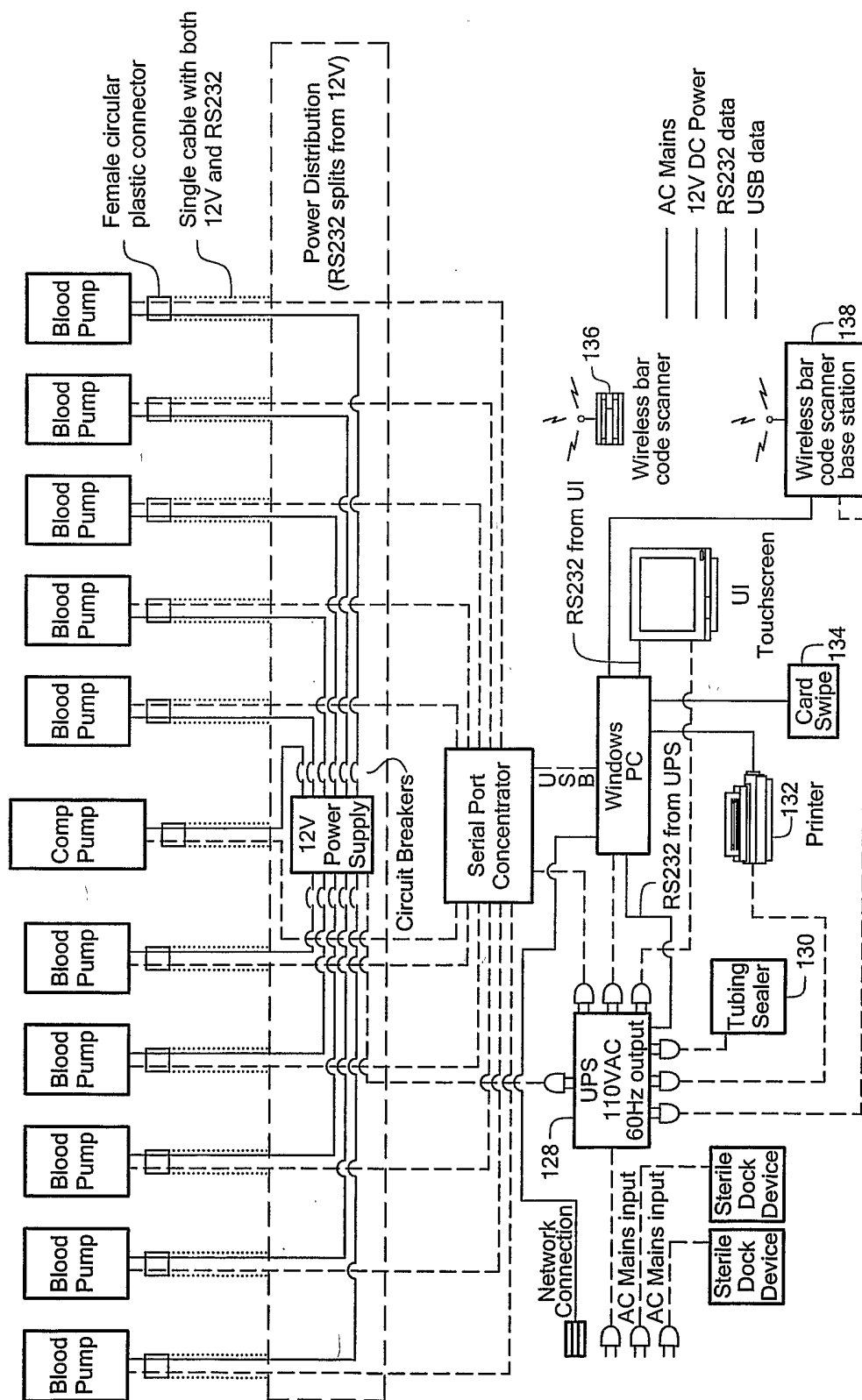
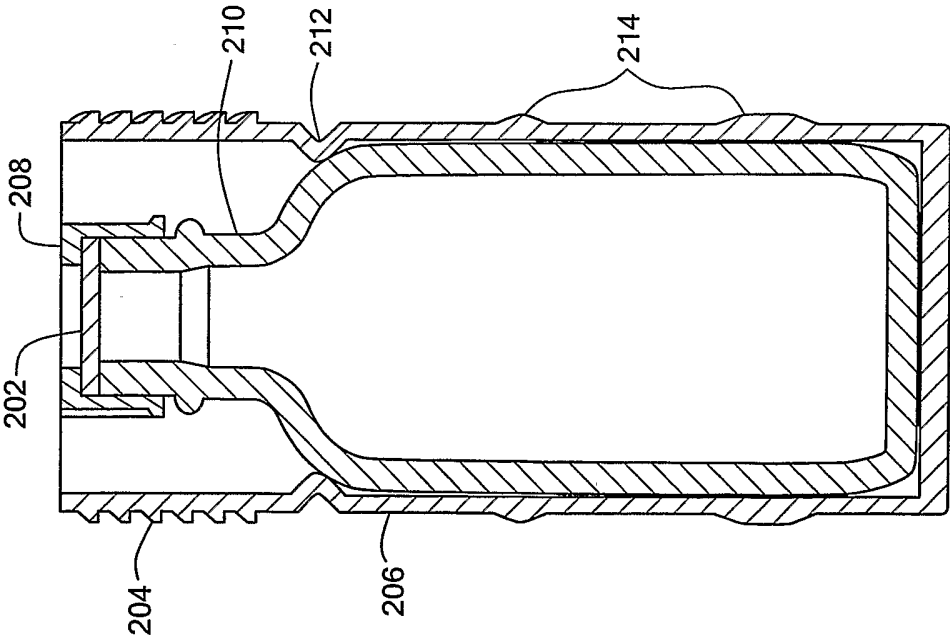
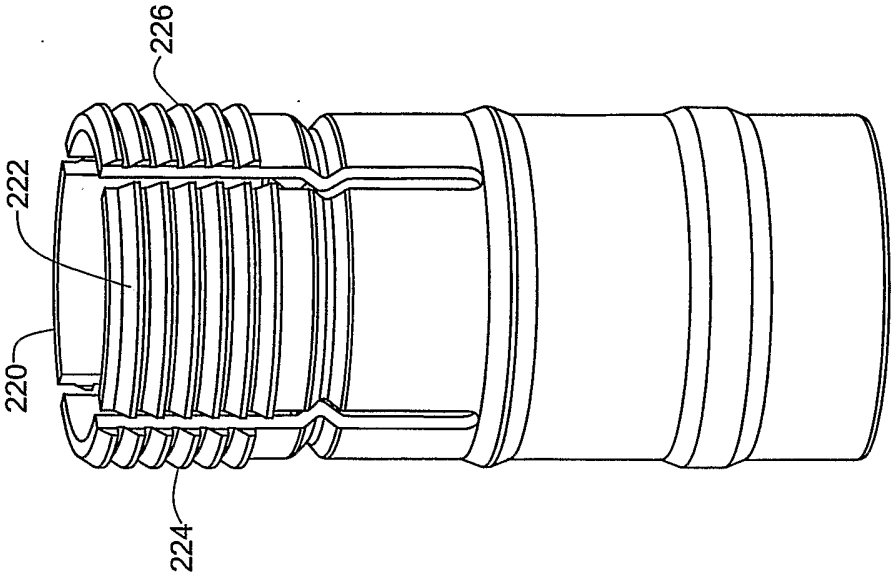


FIG. 1C



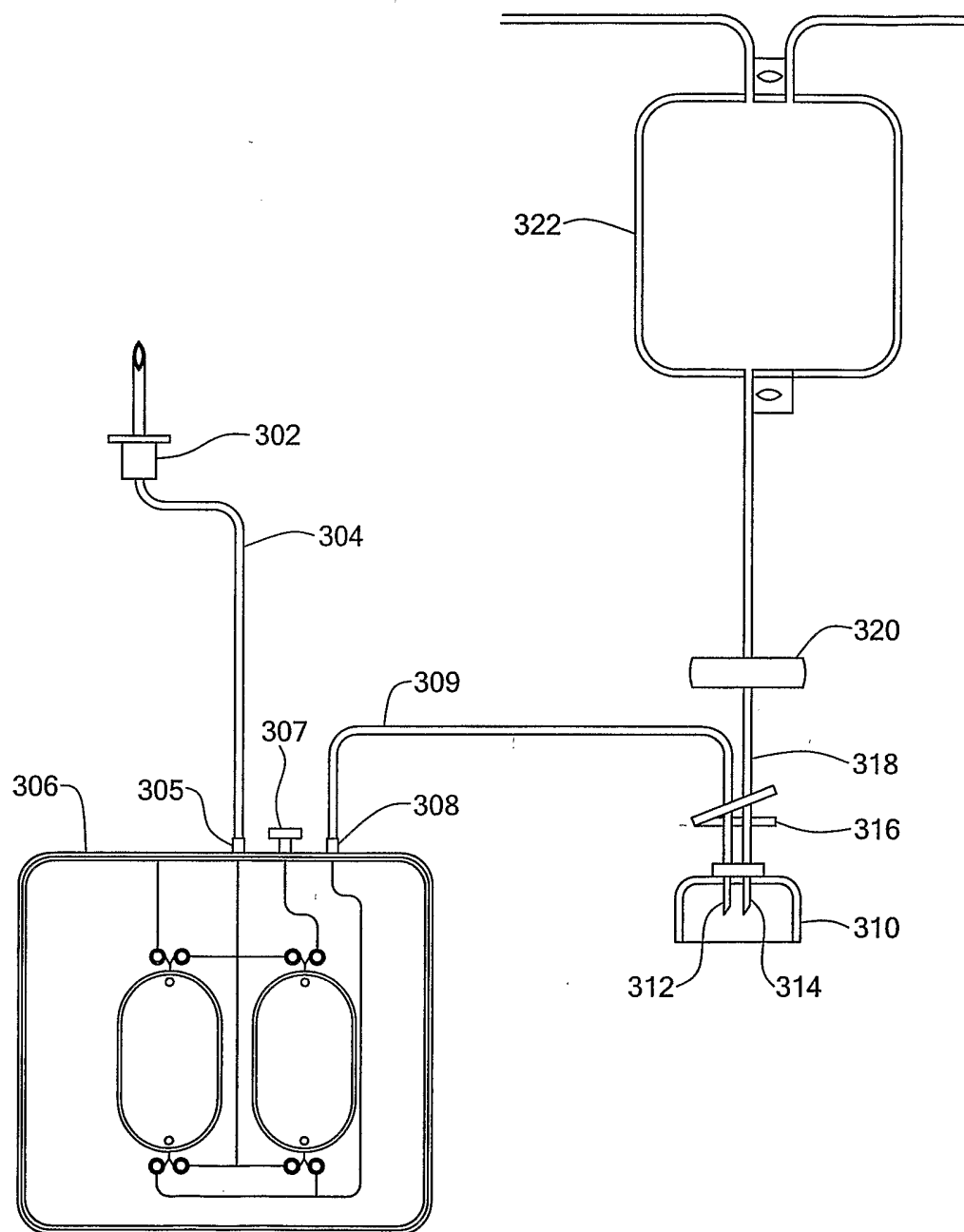
200

FIG. 2A



206

FIG. 2B



300
FIG. 3A

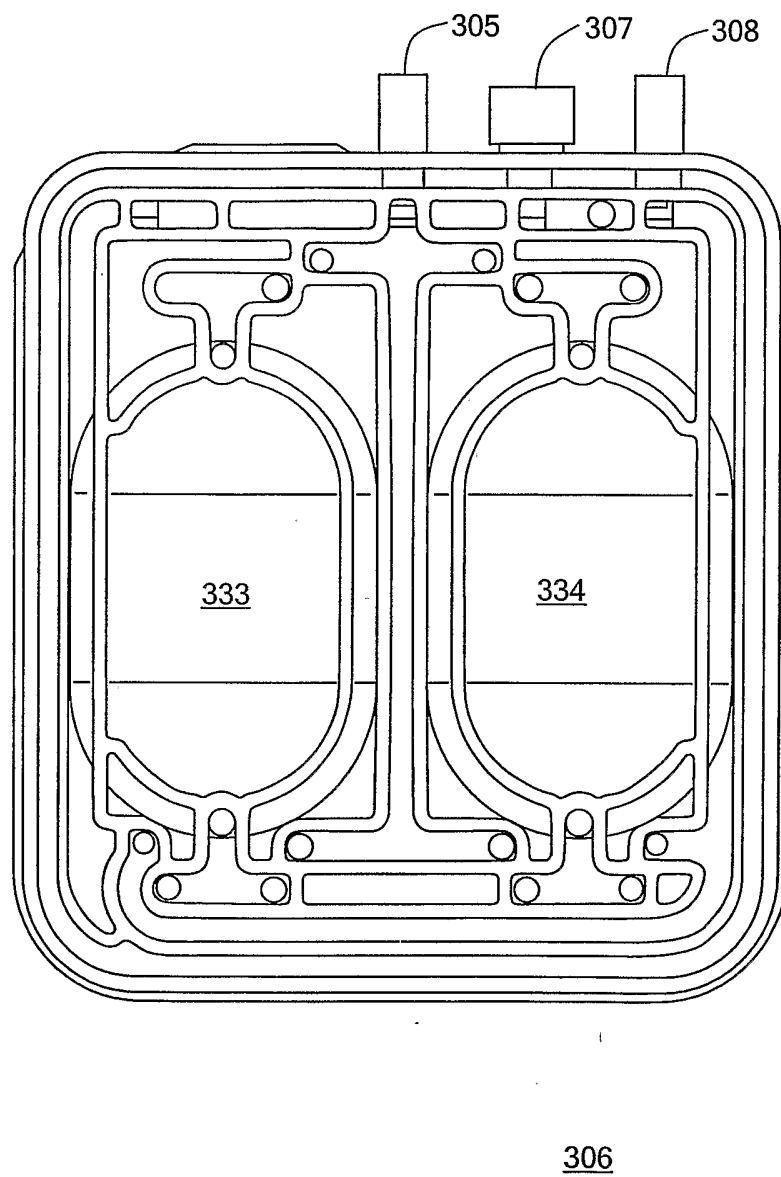


FIG. 3B

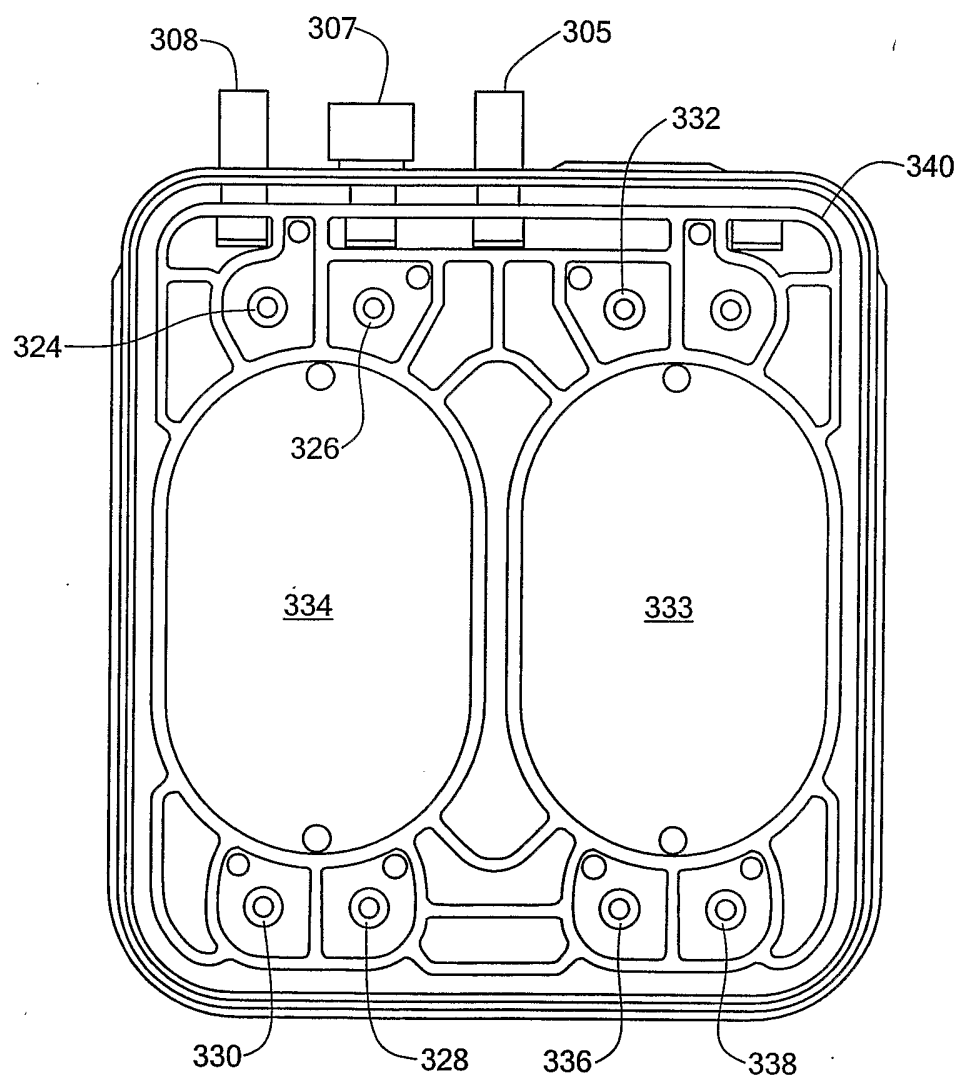
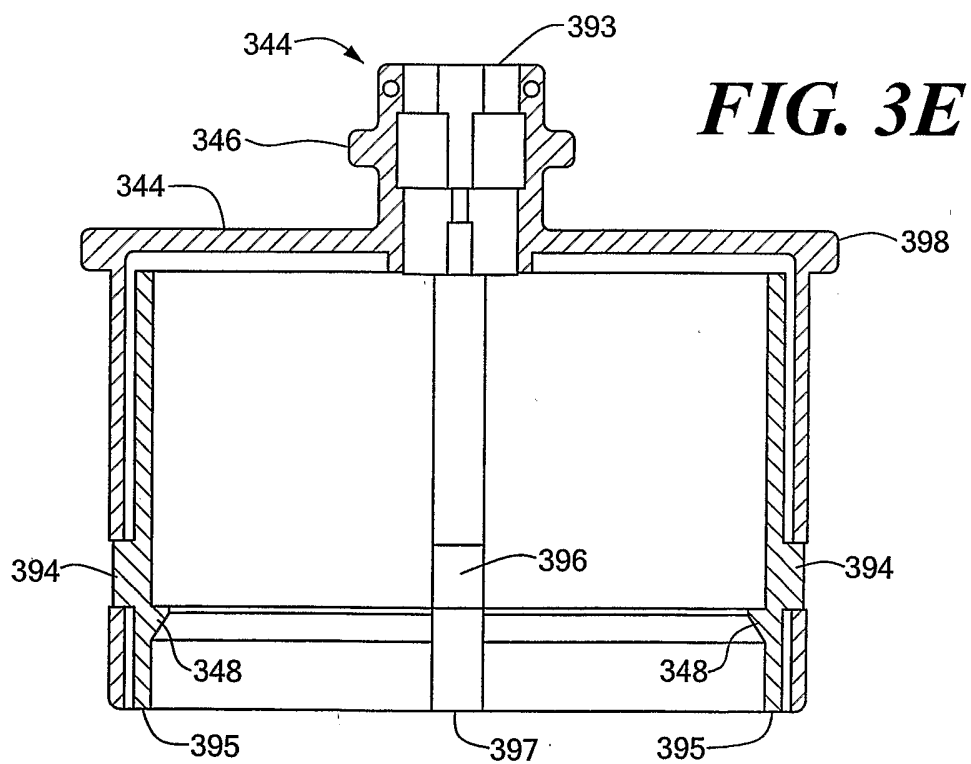
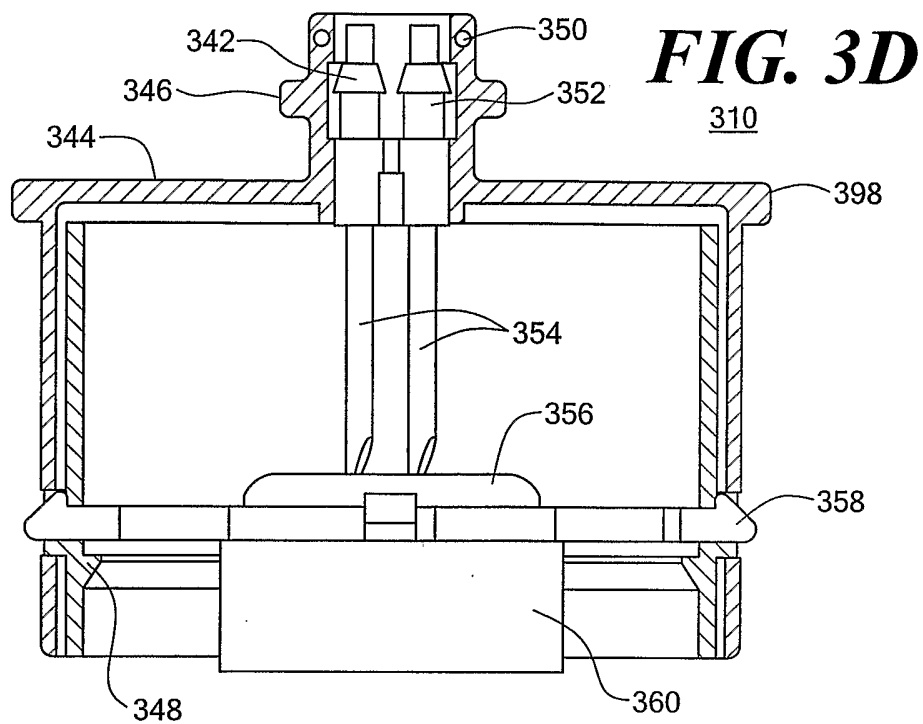


FIG. 3C ³⁰⁶



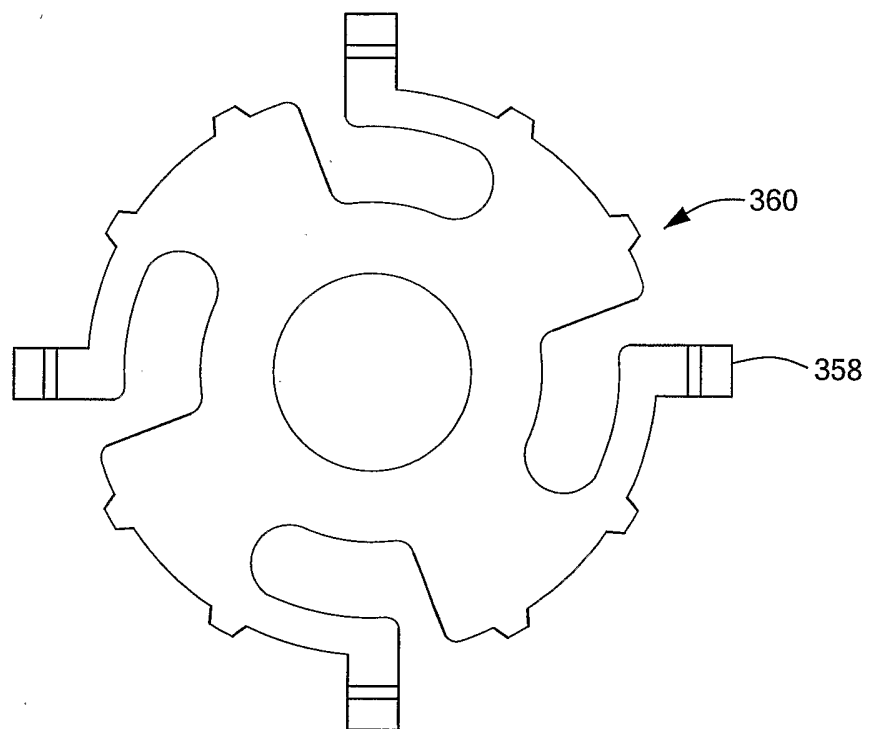
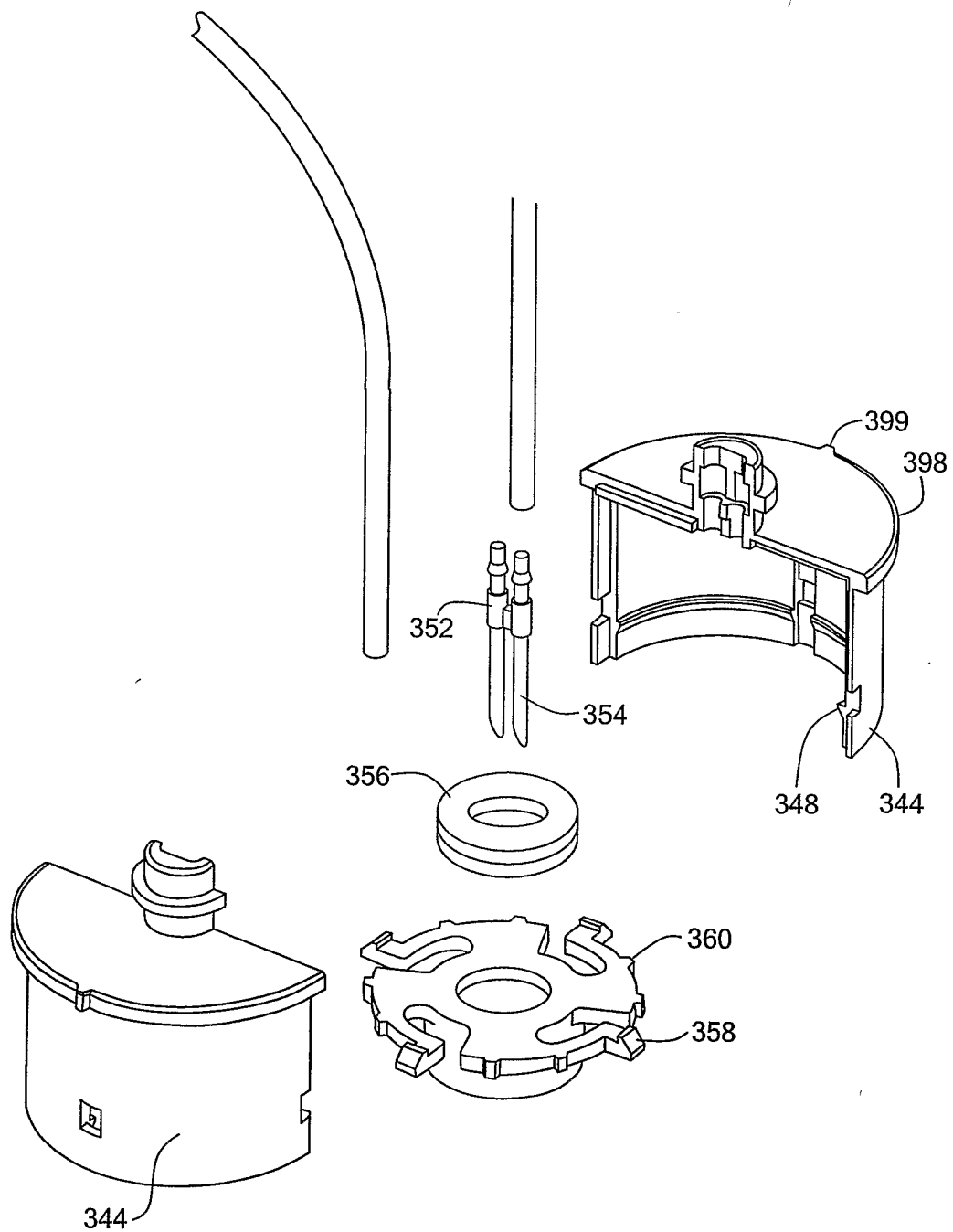


FIG. 3F

**FIG. 3G**

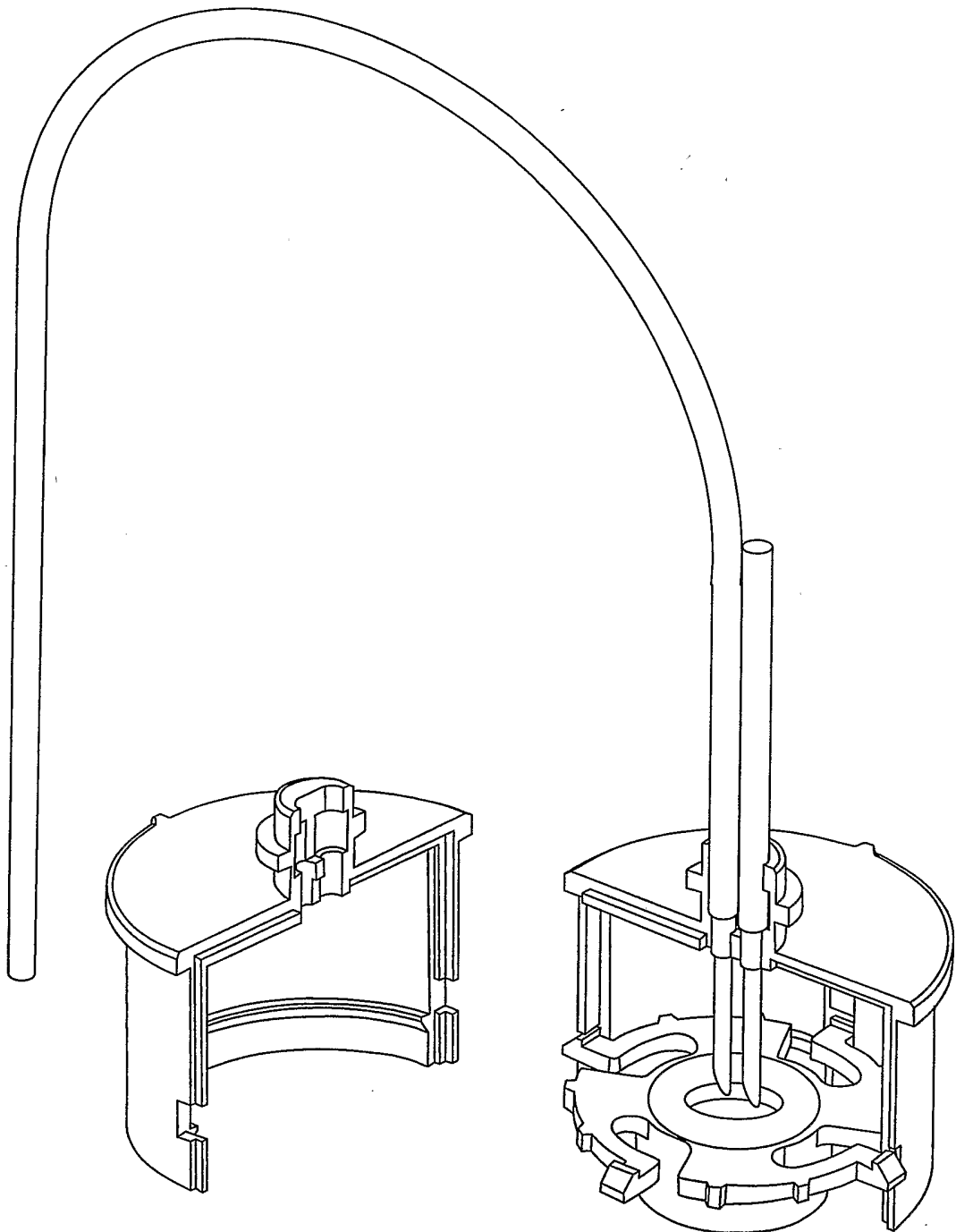
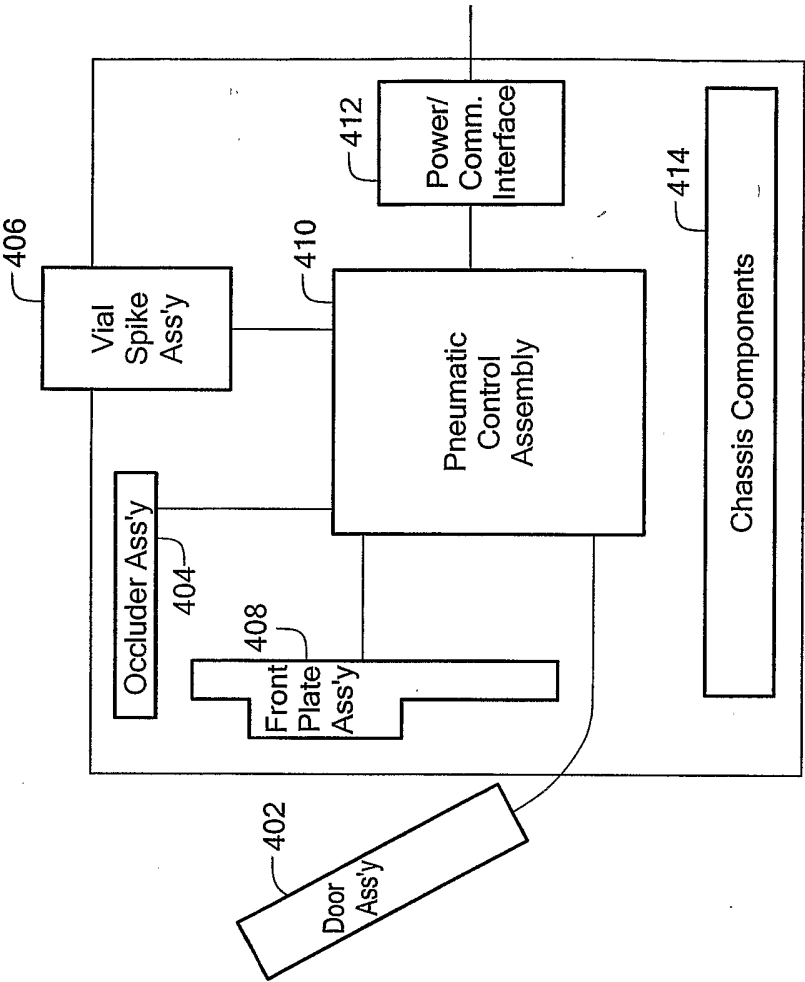


FIG. 3H



102

FIG. 4

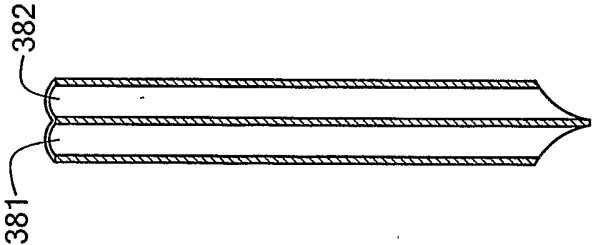
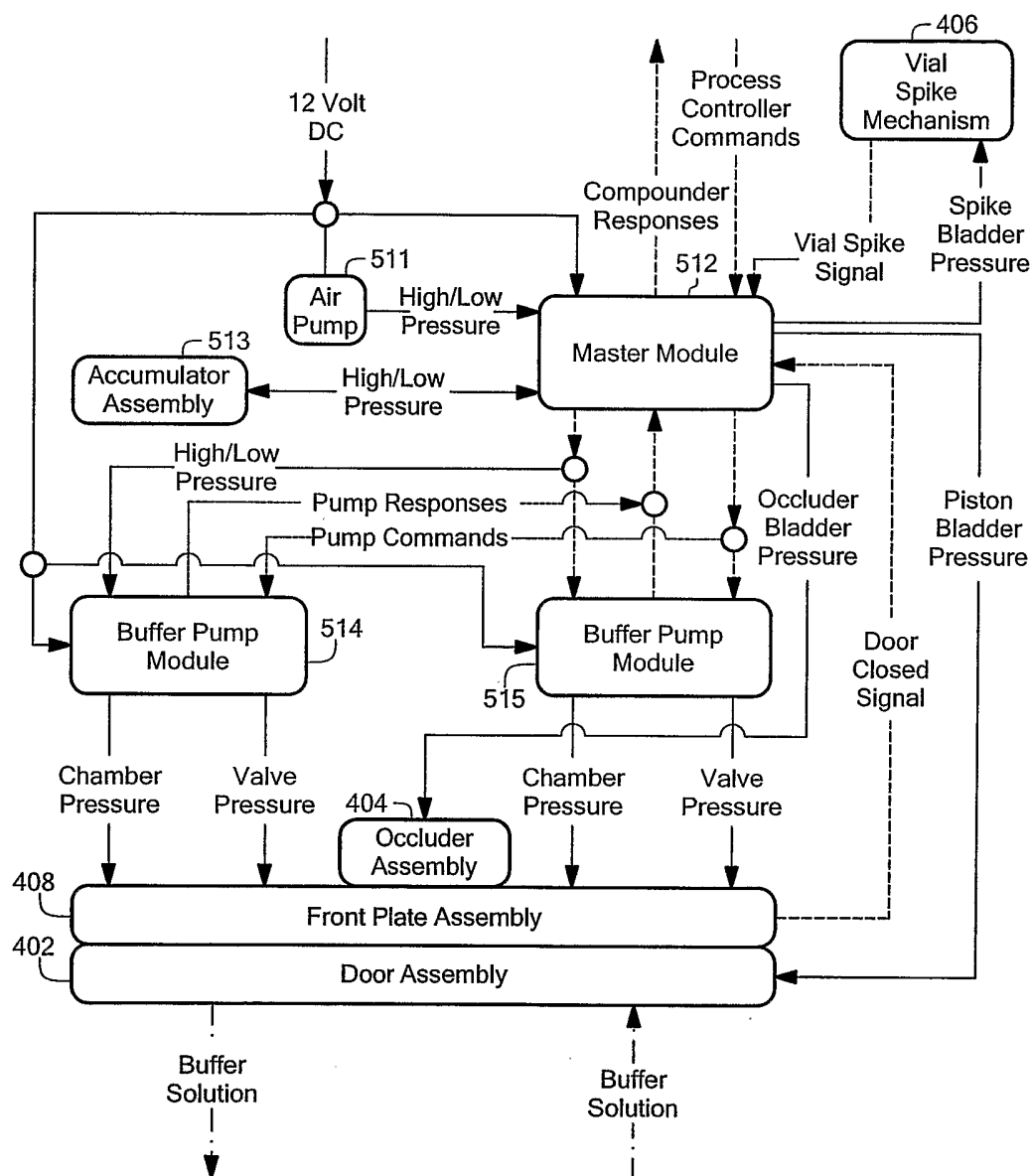


FIG. 31



Compounder Pump Architectural Flow Diagram

FIG. 5A

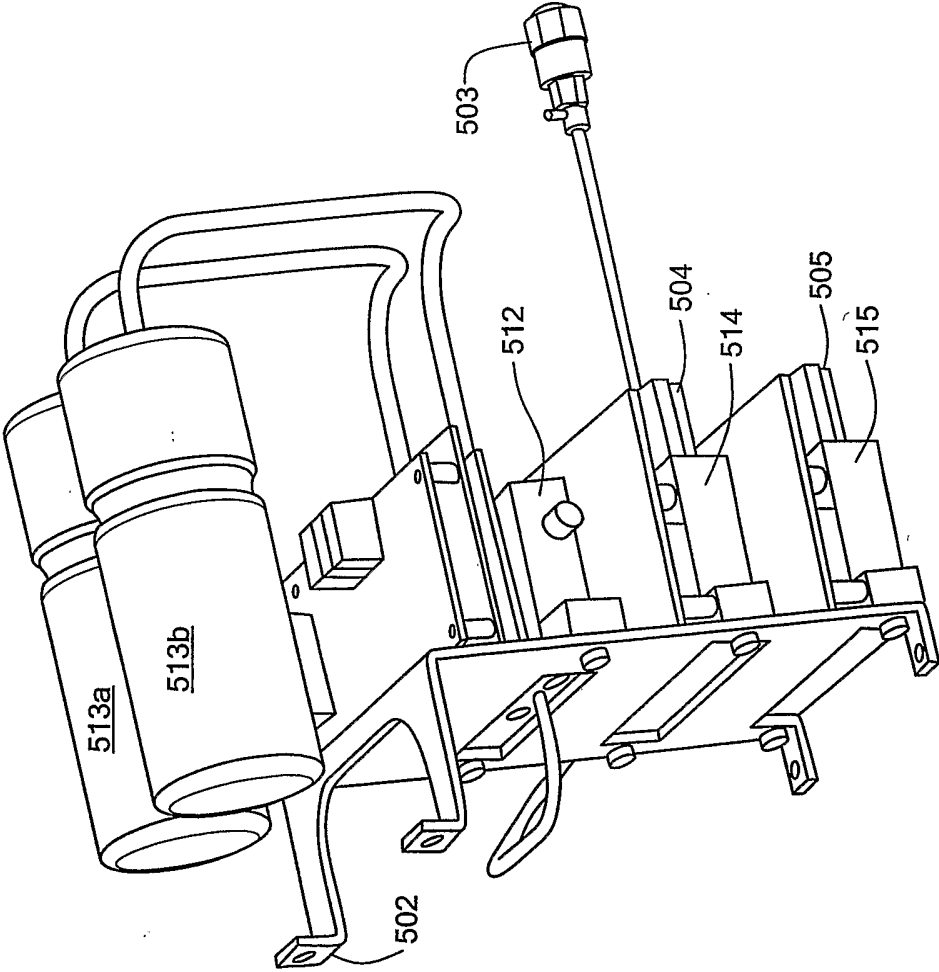
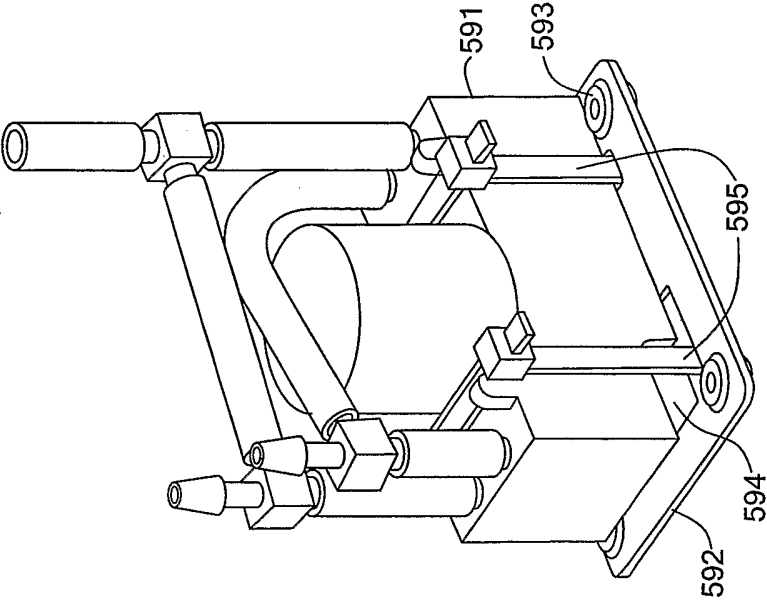


FIG. 5B



511

FIG. 5C

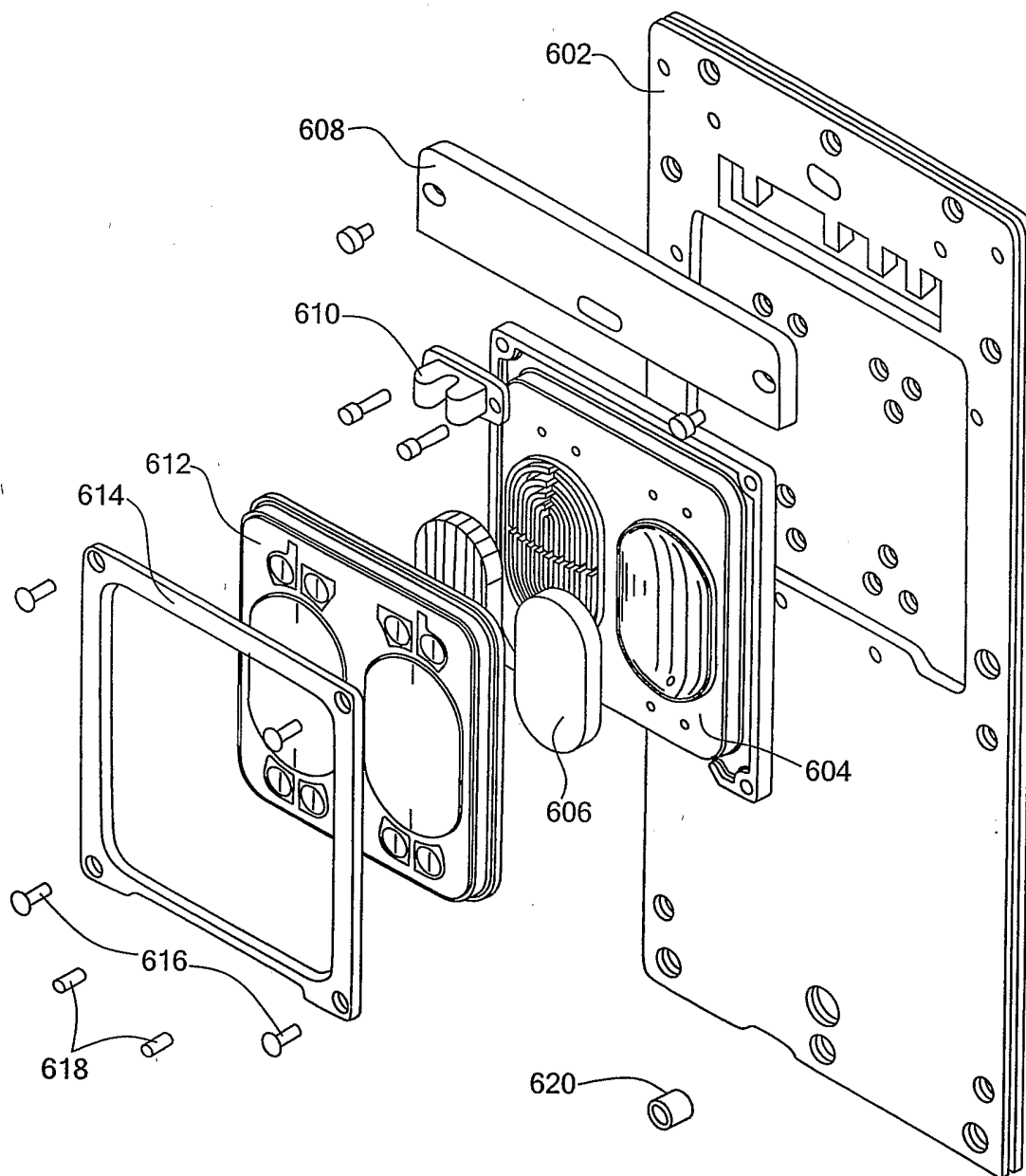
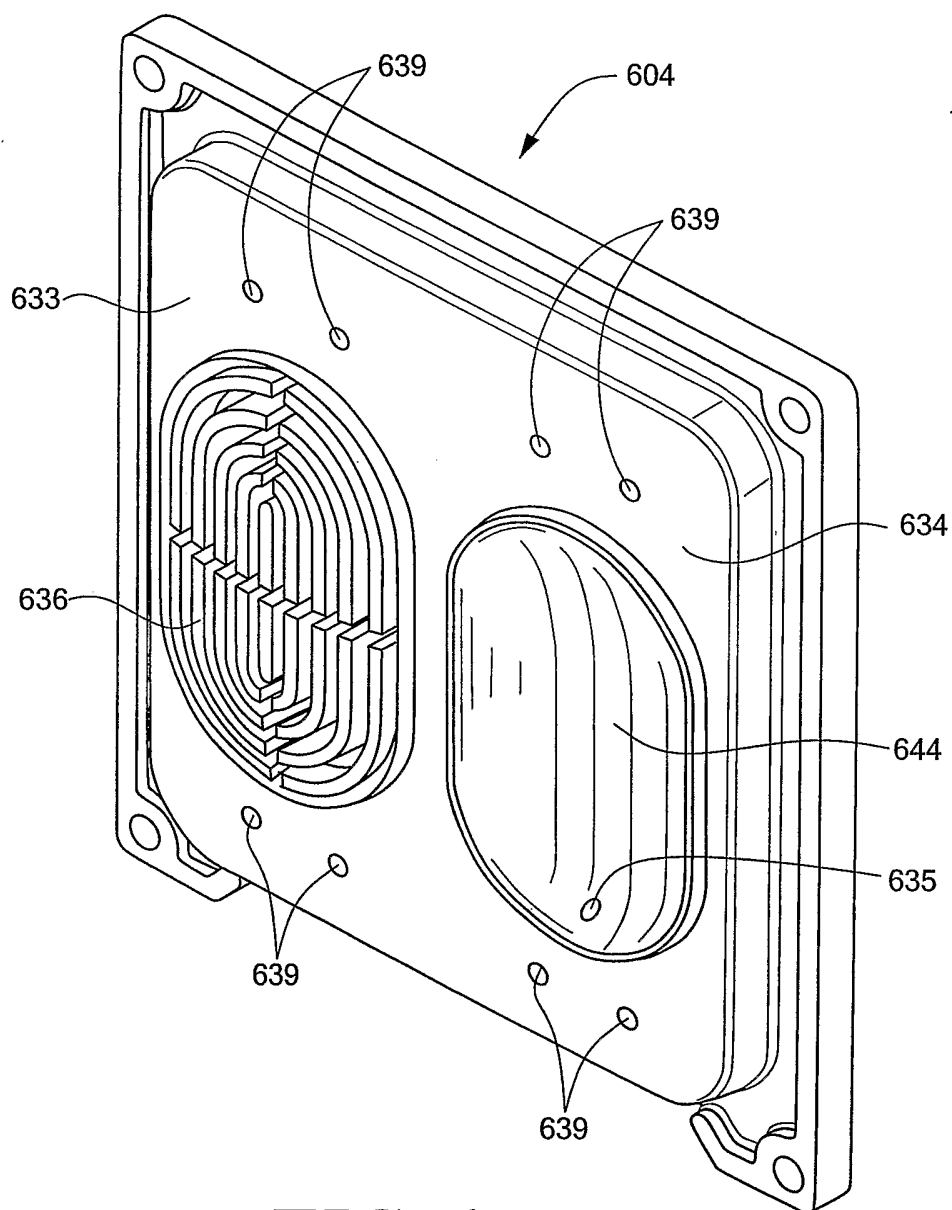


FIG. 6A 408

**FIG. 6B**

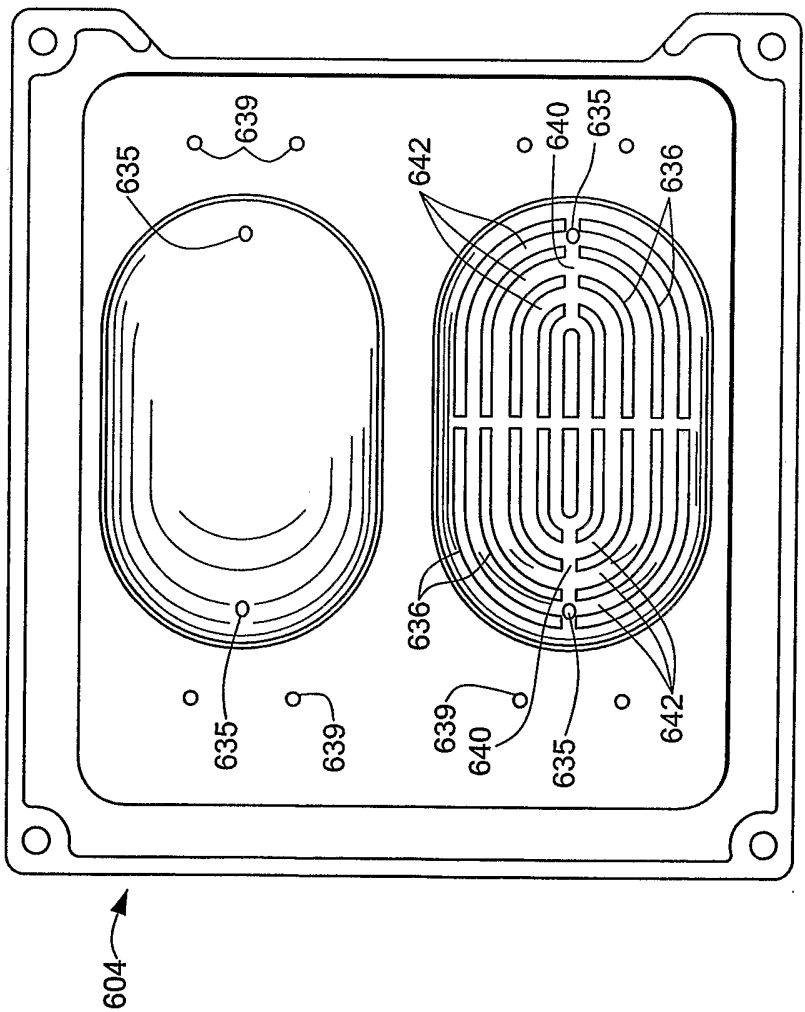


FIG. 6C

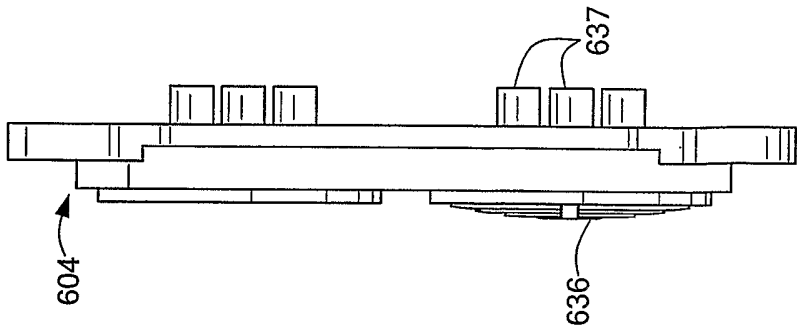


FIG. 6E

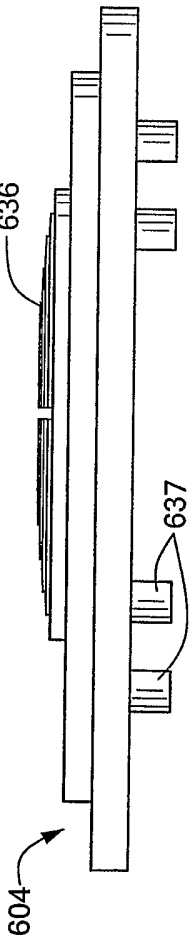


FIG. 6D

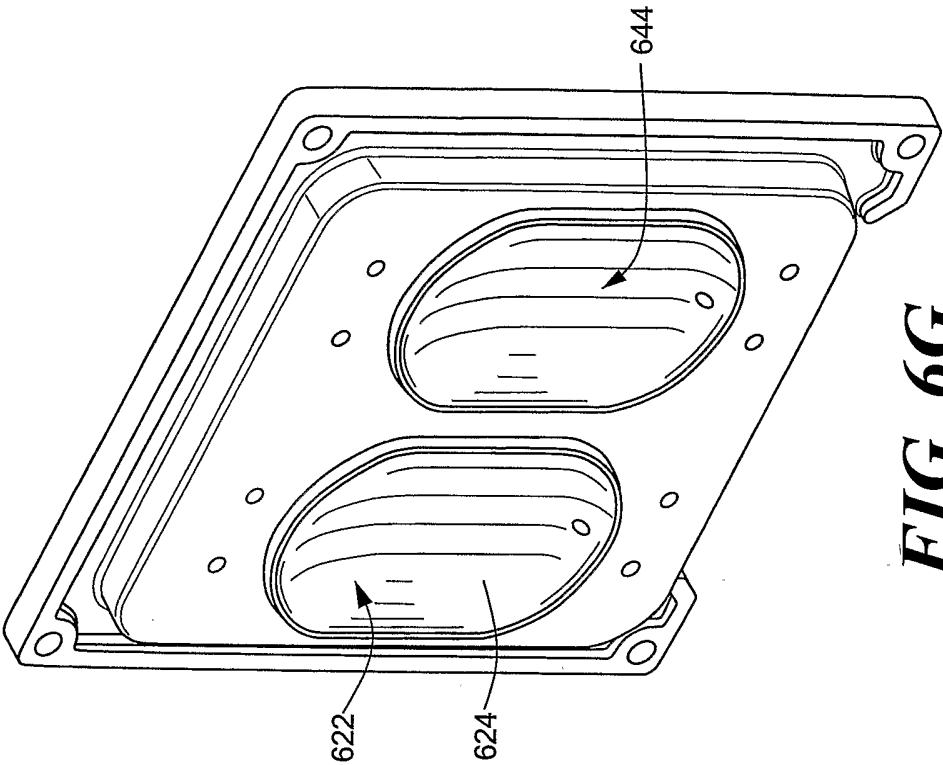


FIG. 6G

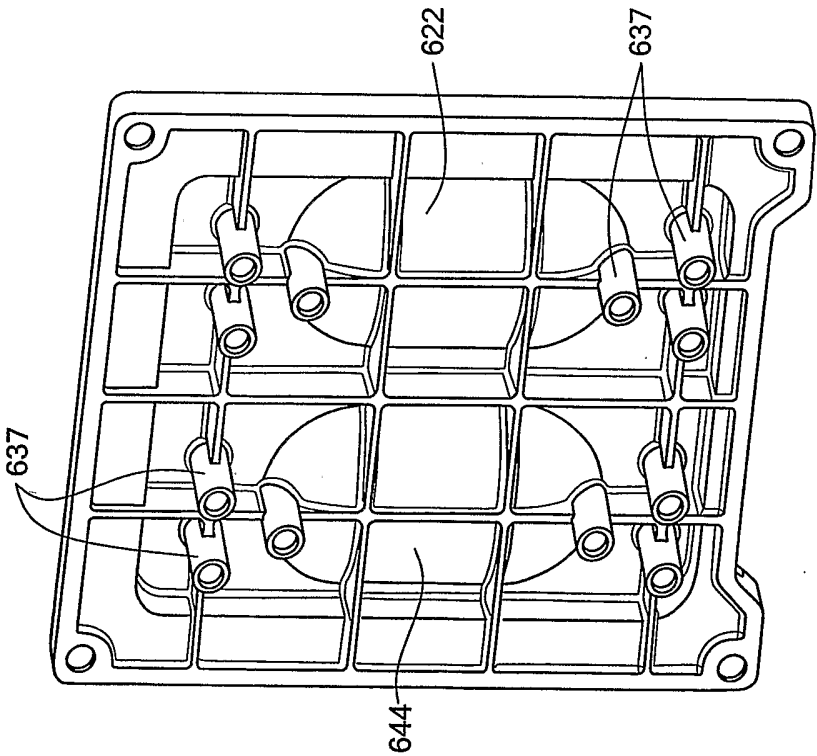


FIG. 6F

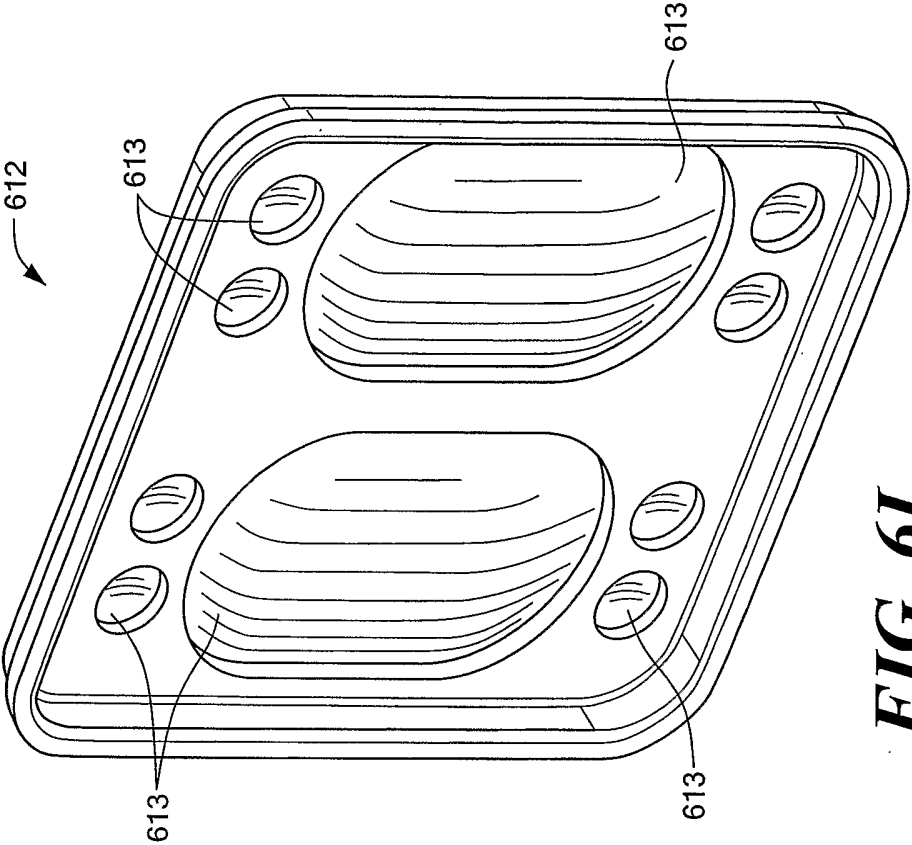


FIG. 6I

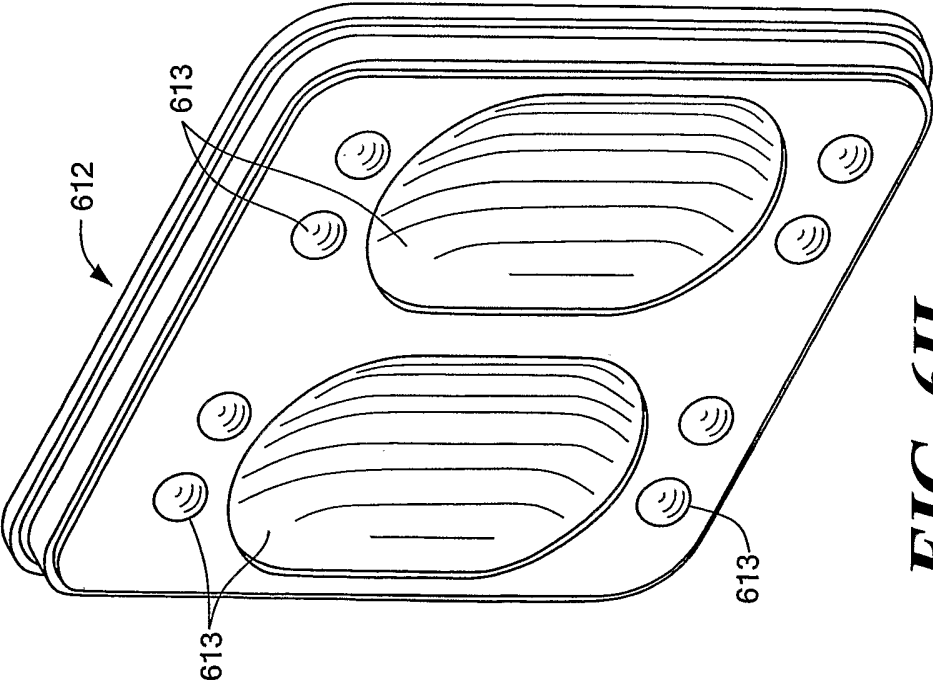


FIG. 6H

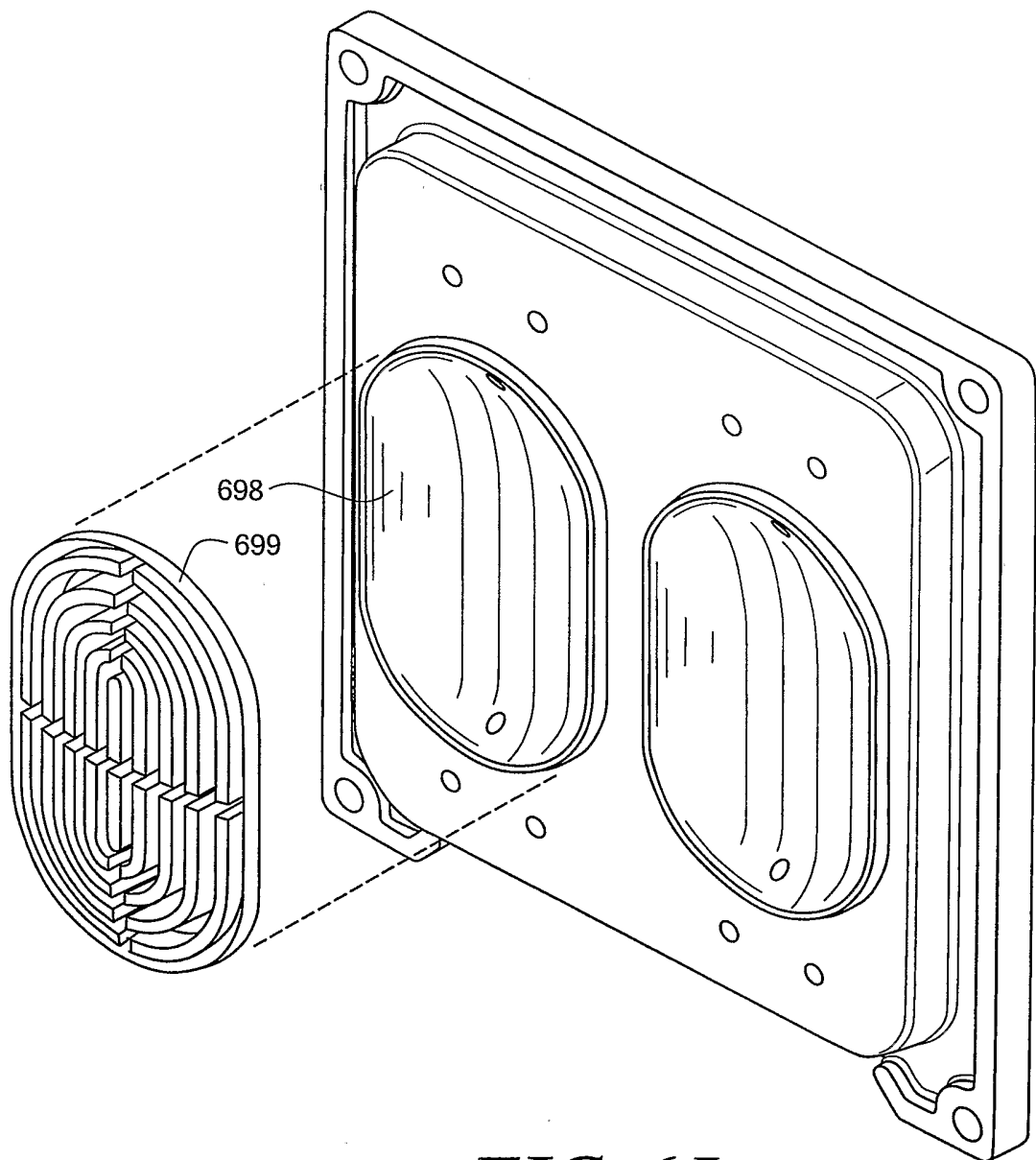
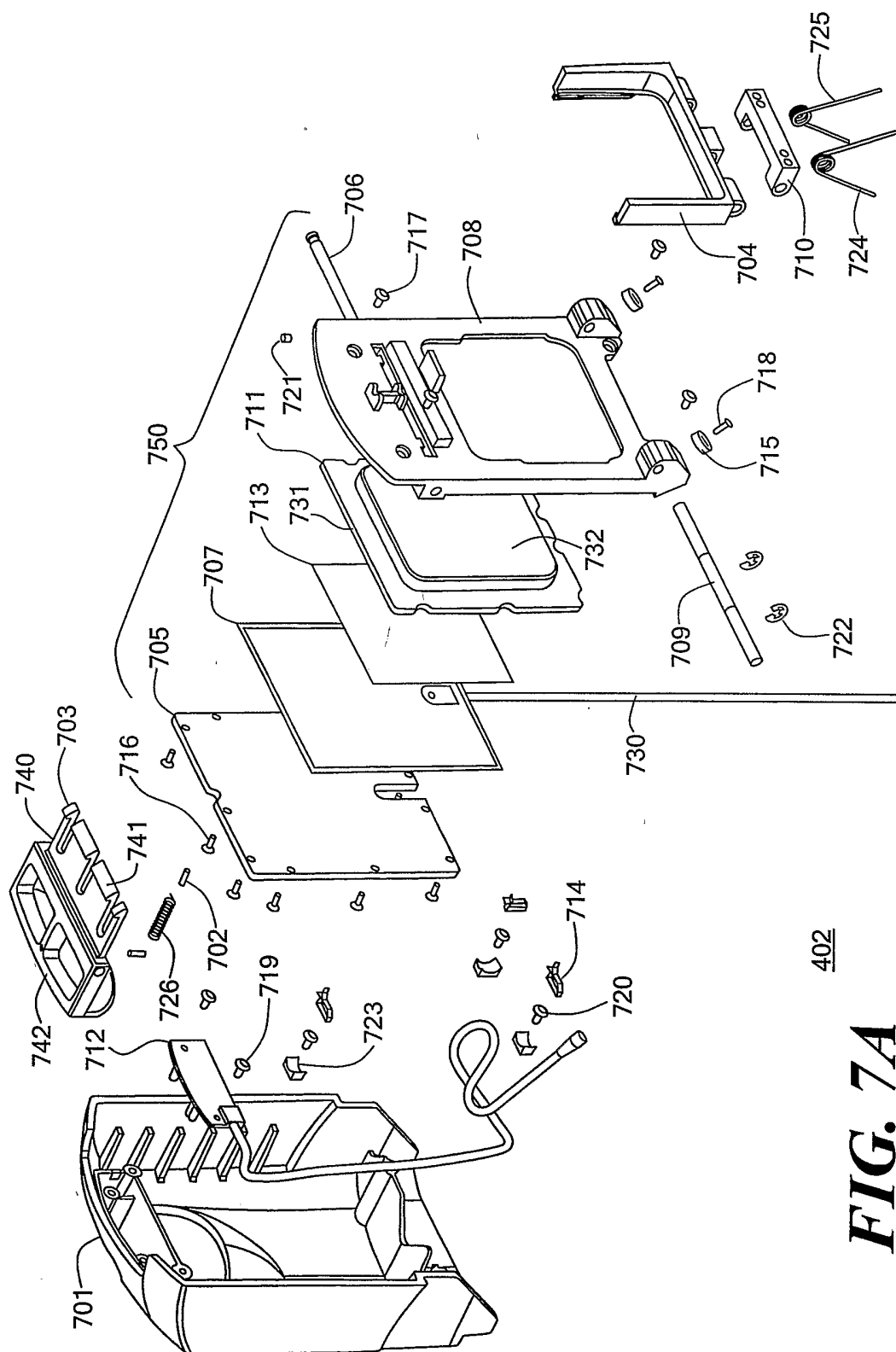


FIG. 6J



402

FIG. 7A

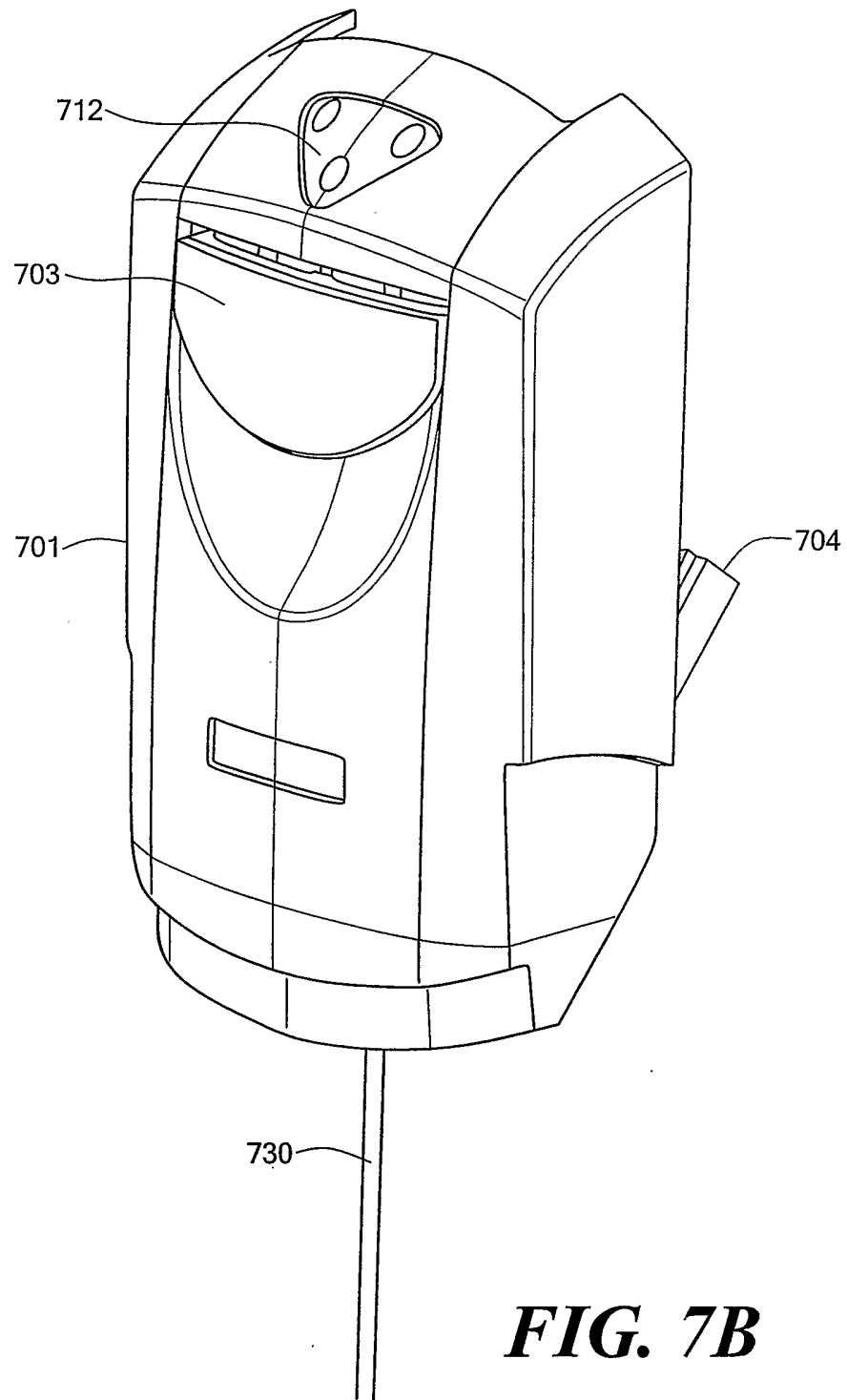
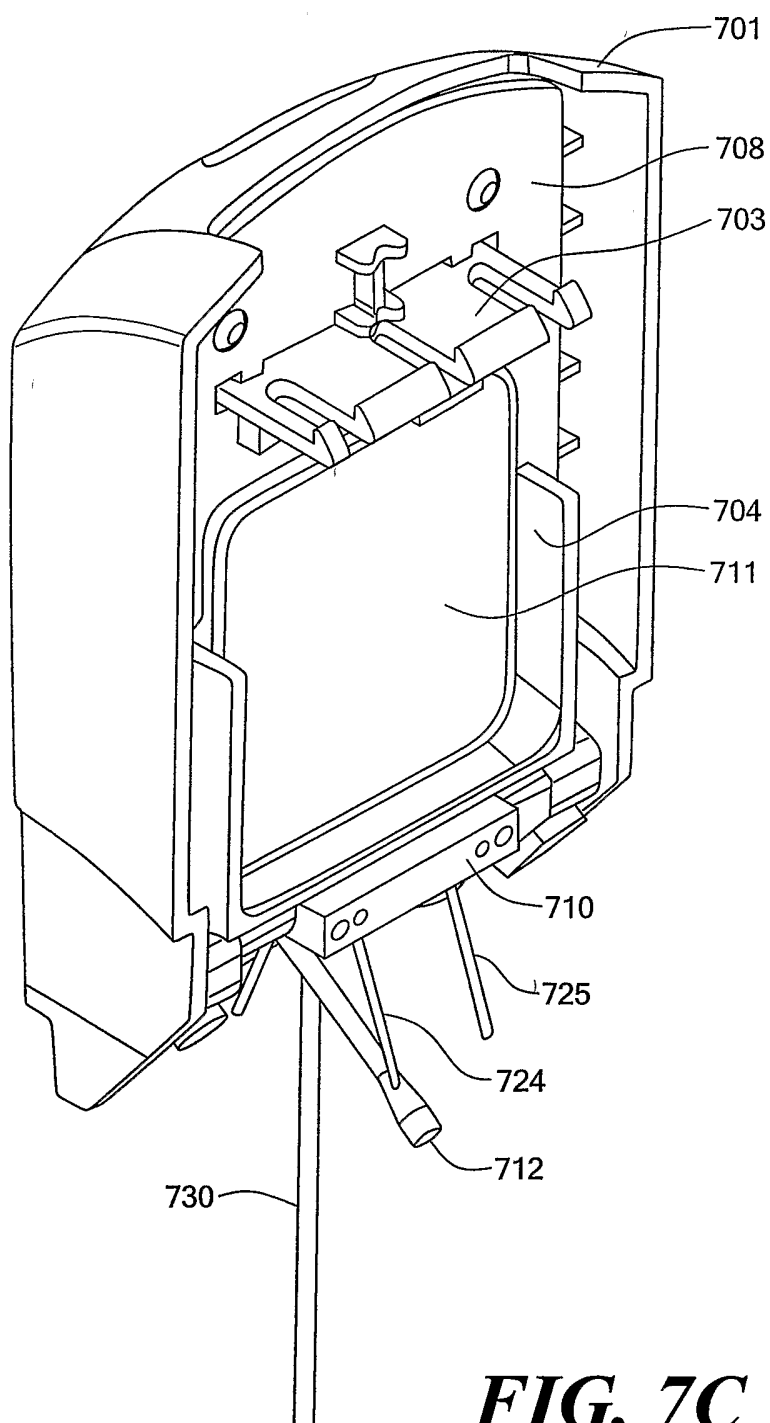
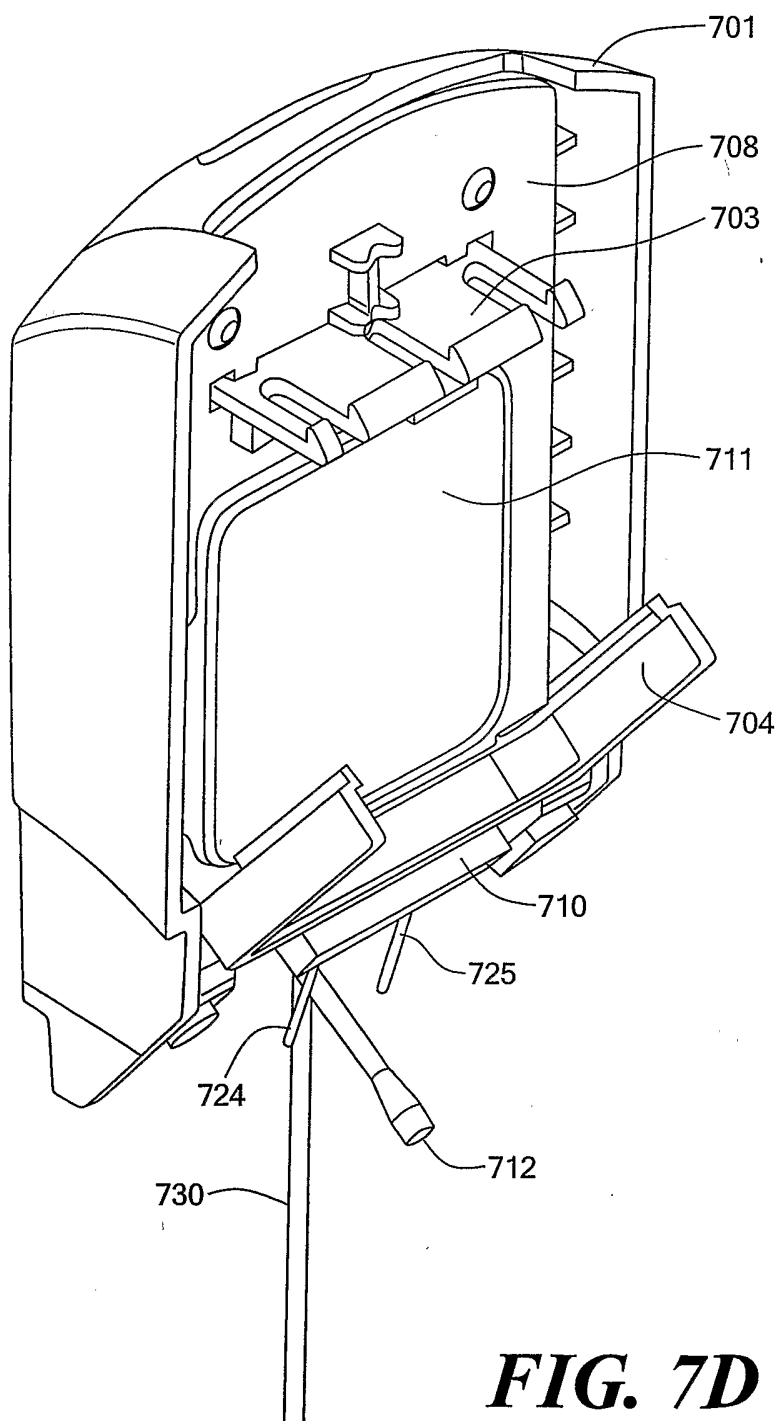
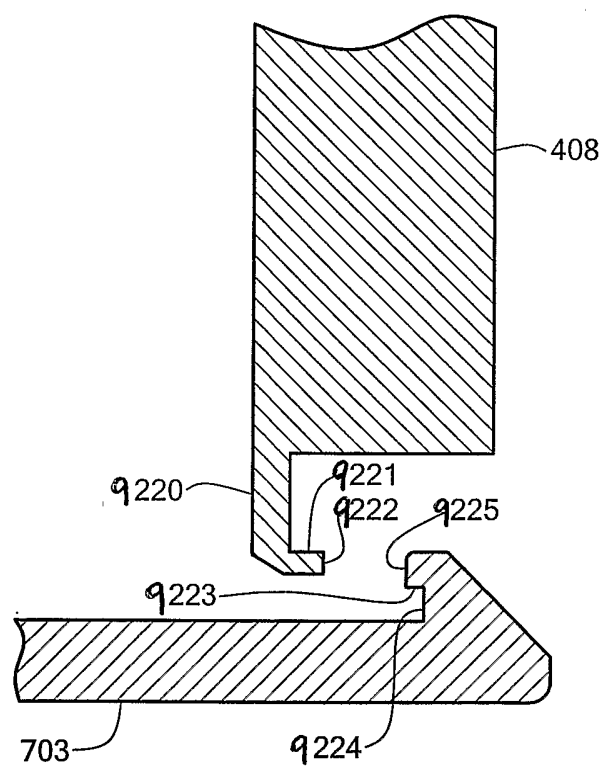


FIG. 7B

**FIG. 7C**

**FIG. 7D**

**FIG. 7E**

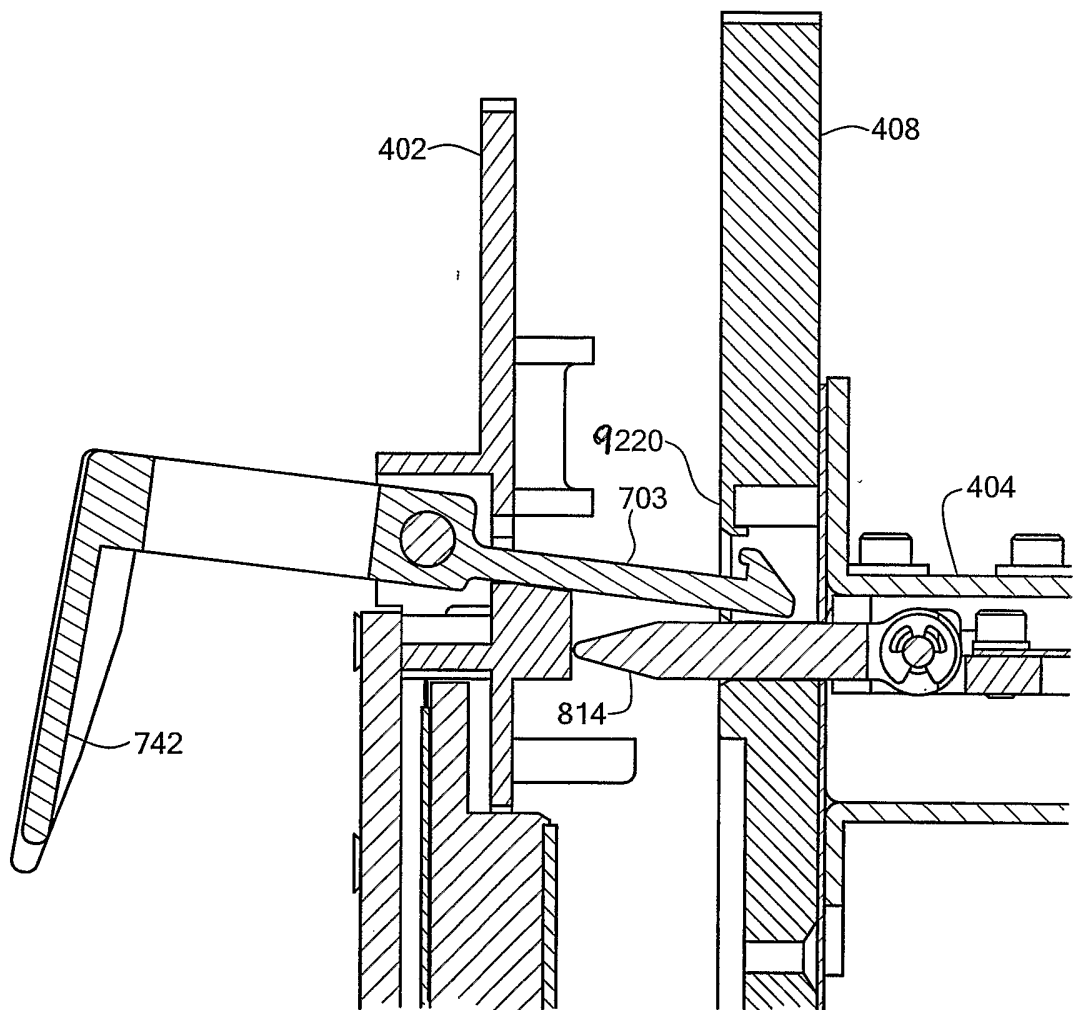


FIG. 7F

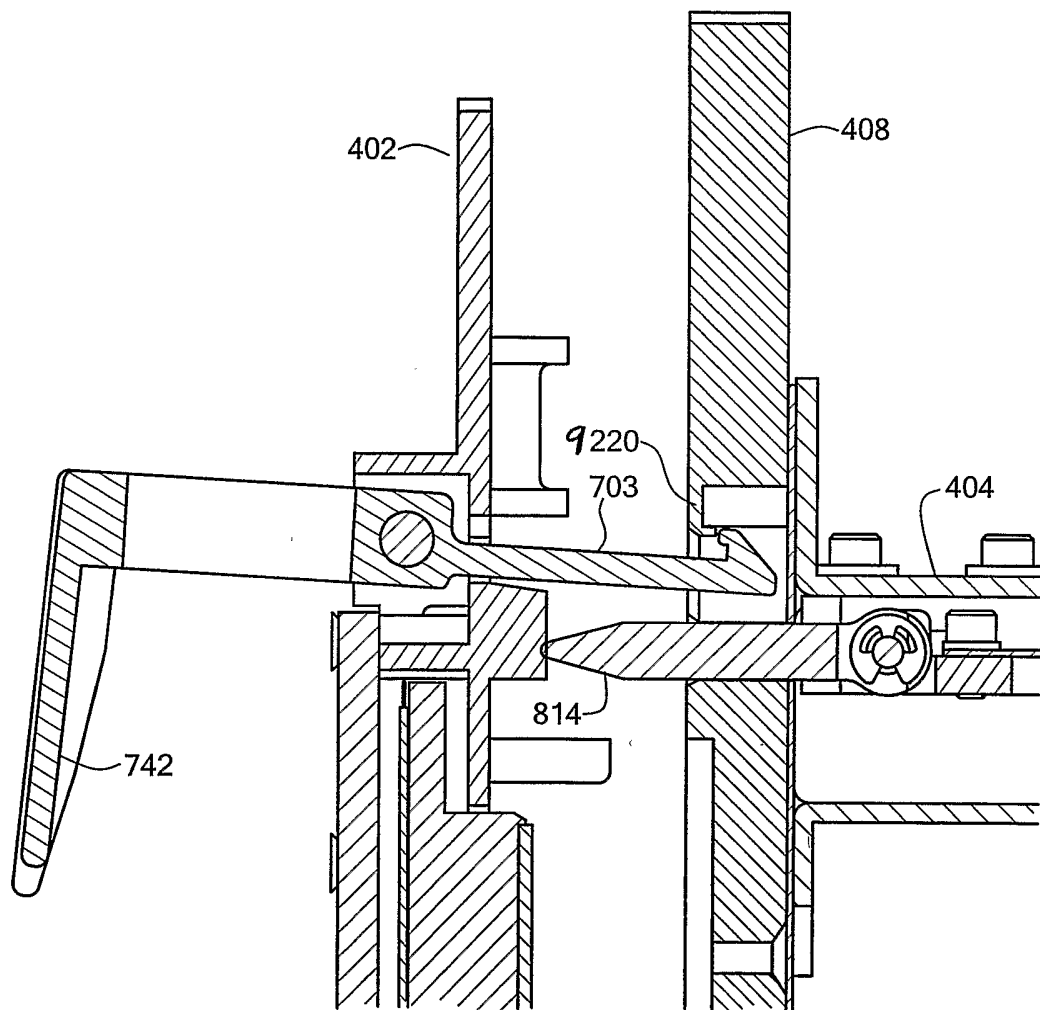


FIG. 76

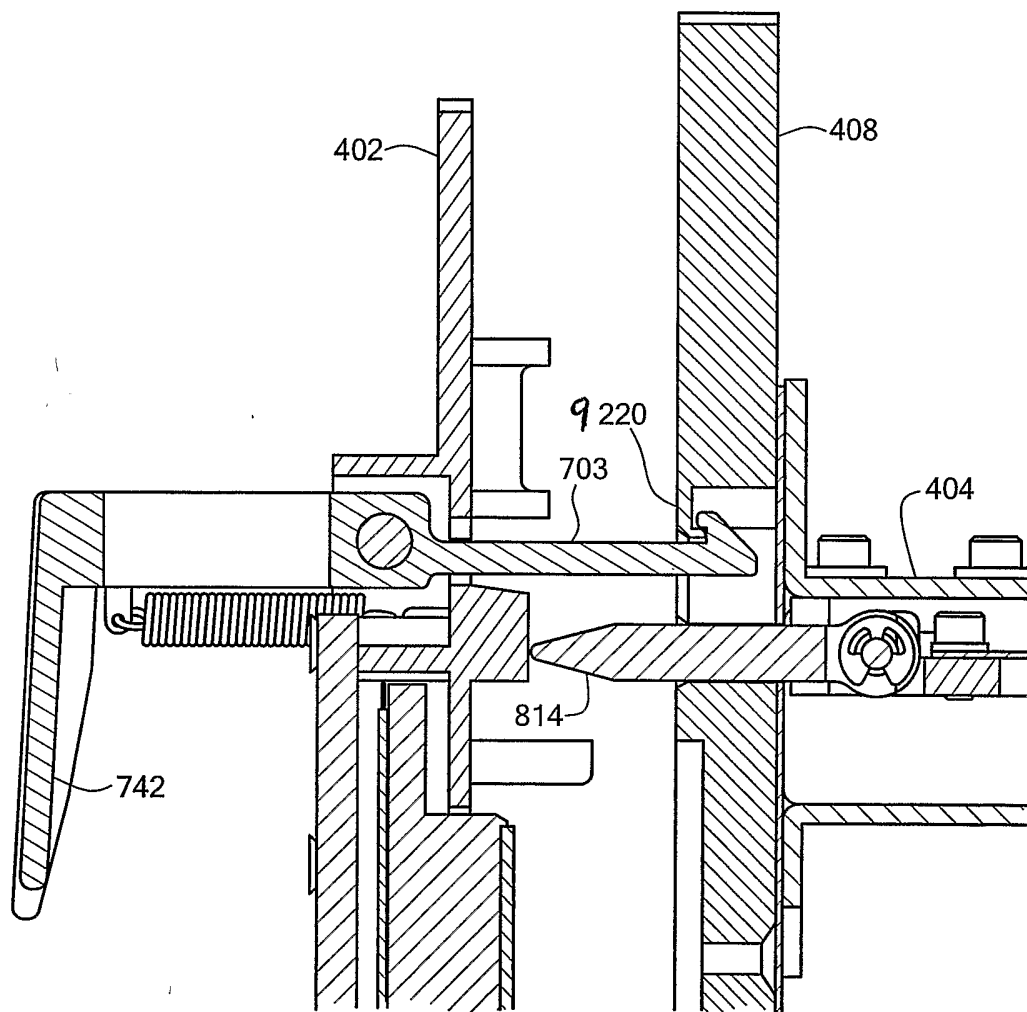
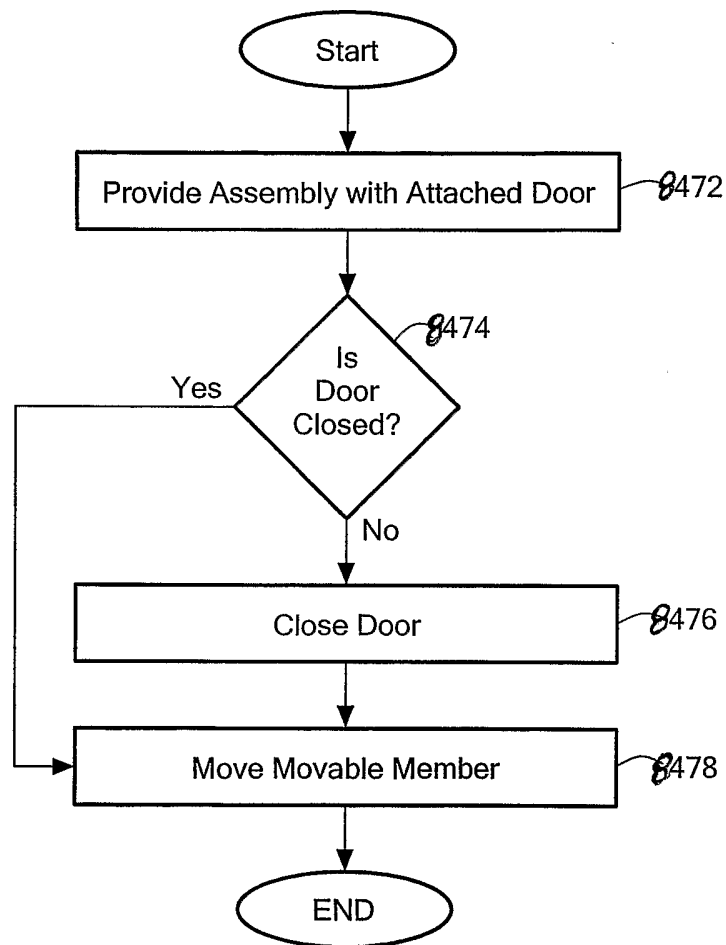
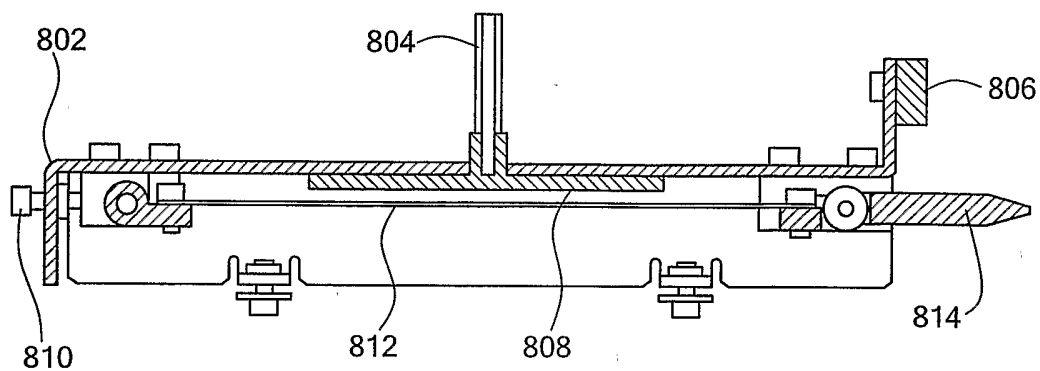
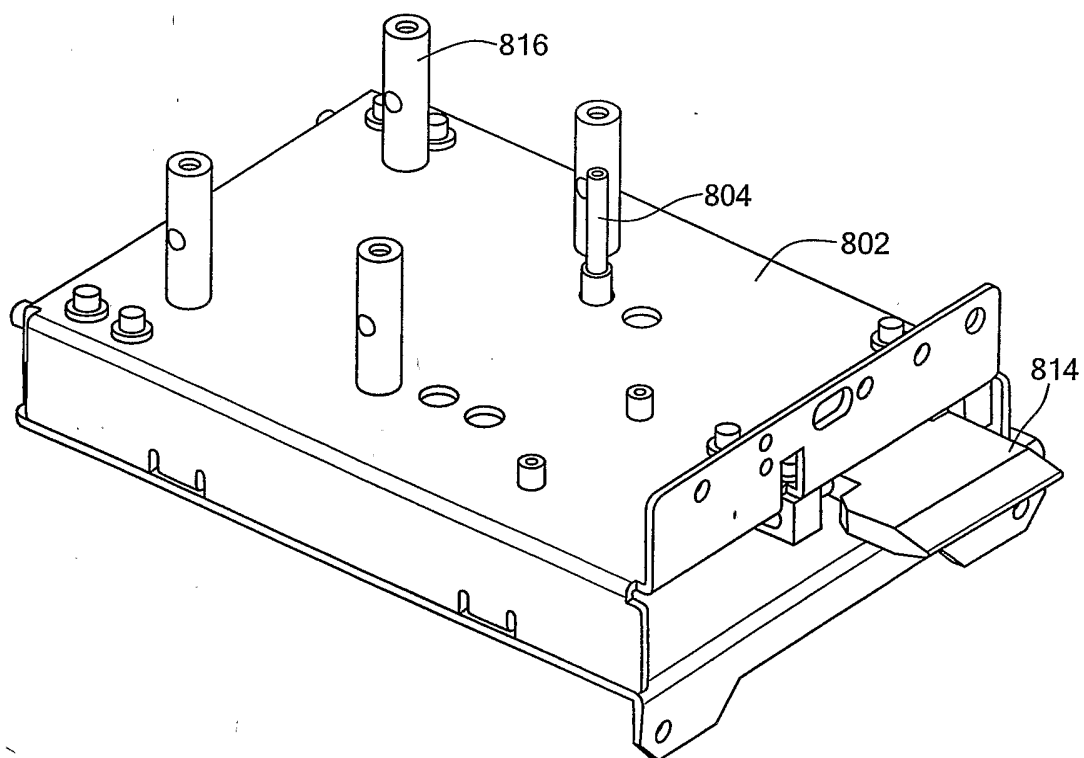


FIG. 7H

**FIG. 71**

**FIG. 8A****FIG. 8B**

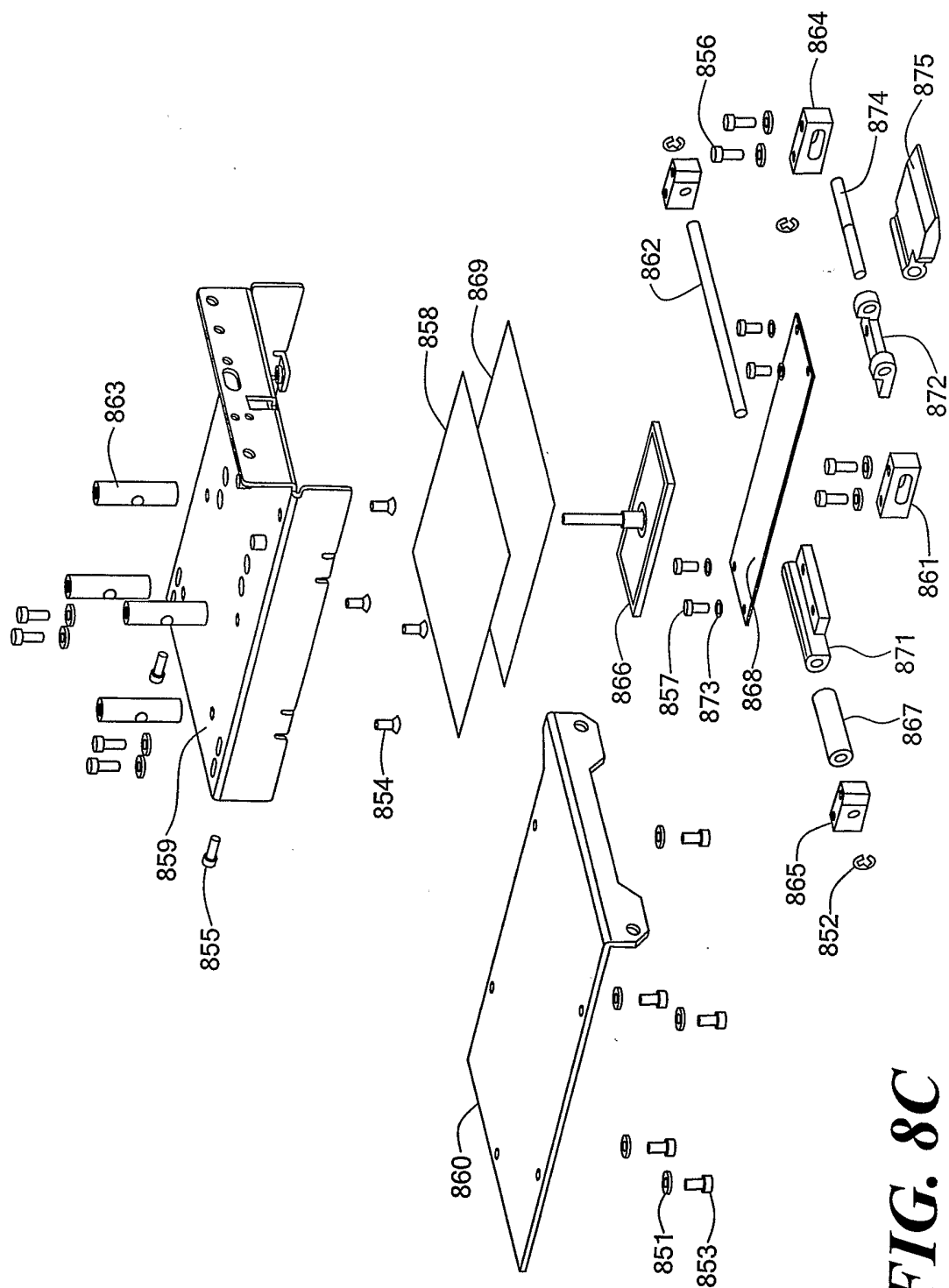


FIG. 8C

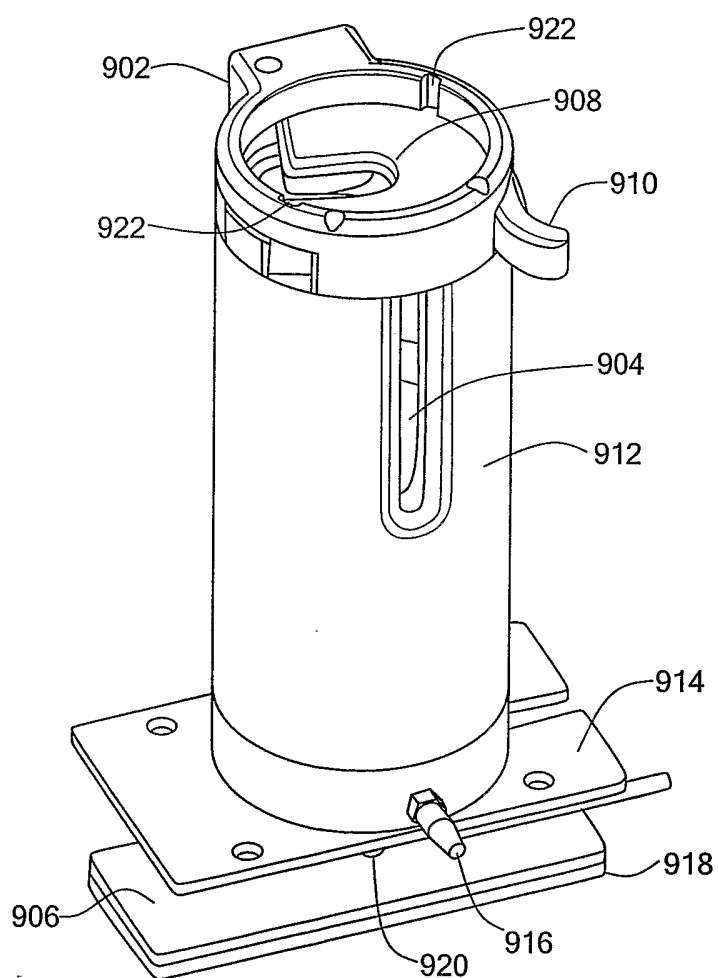


FIG. 9A ⁴⁰⁶

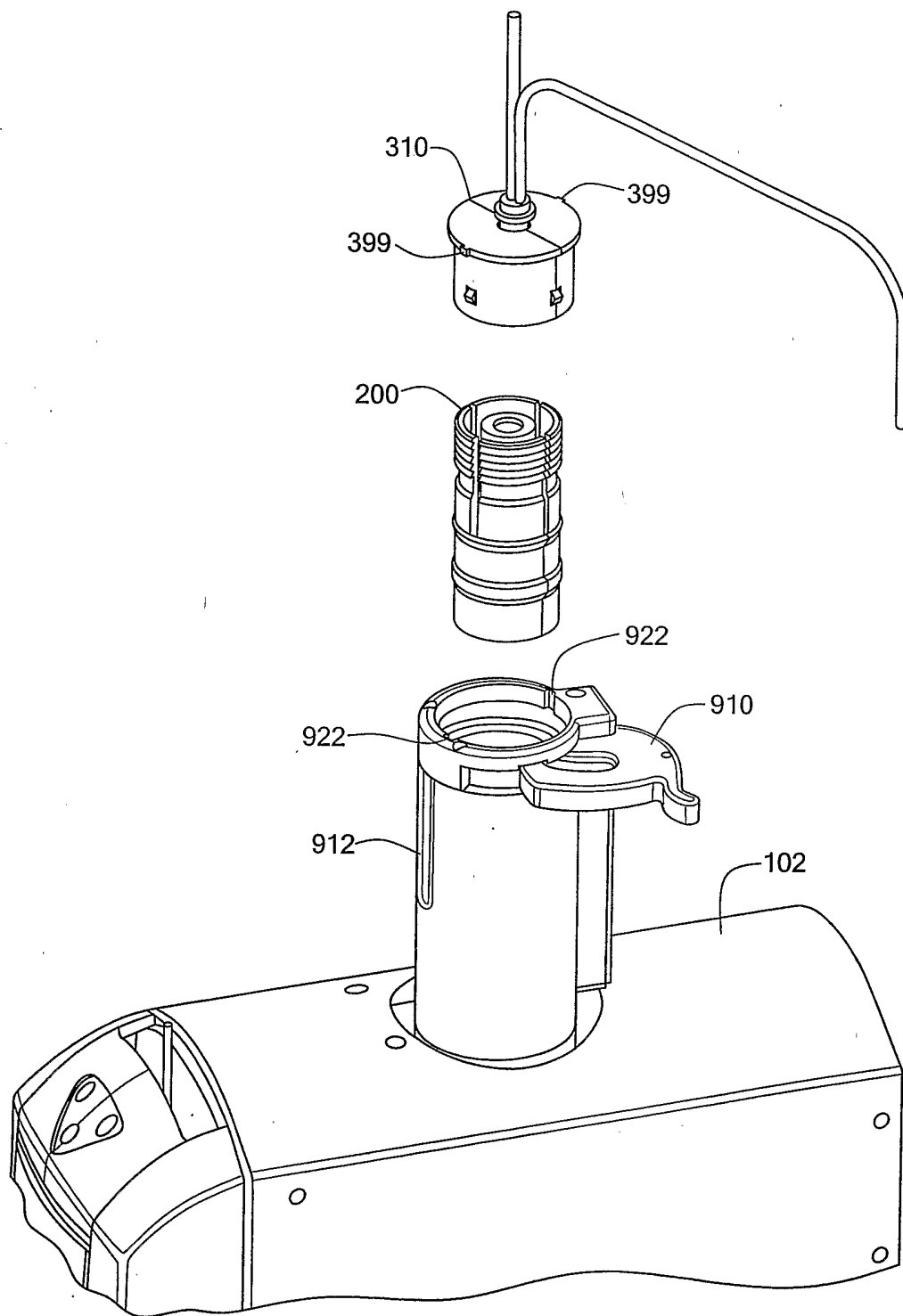
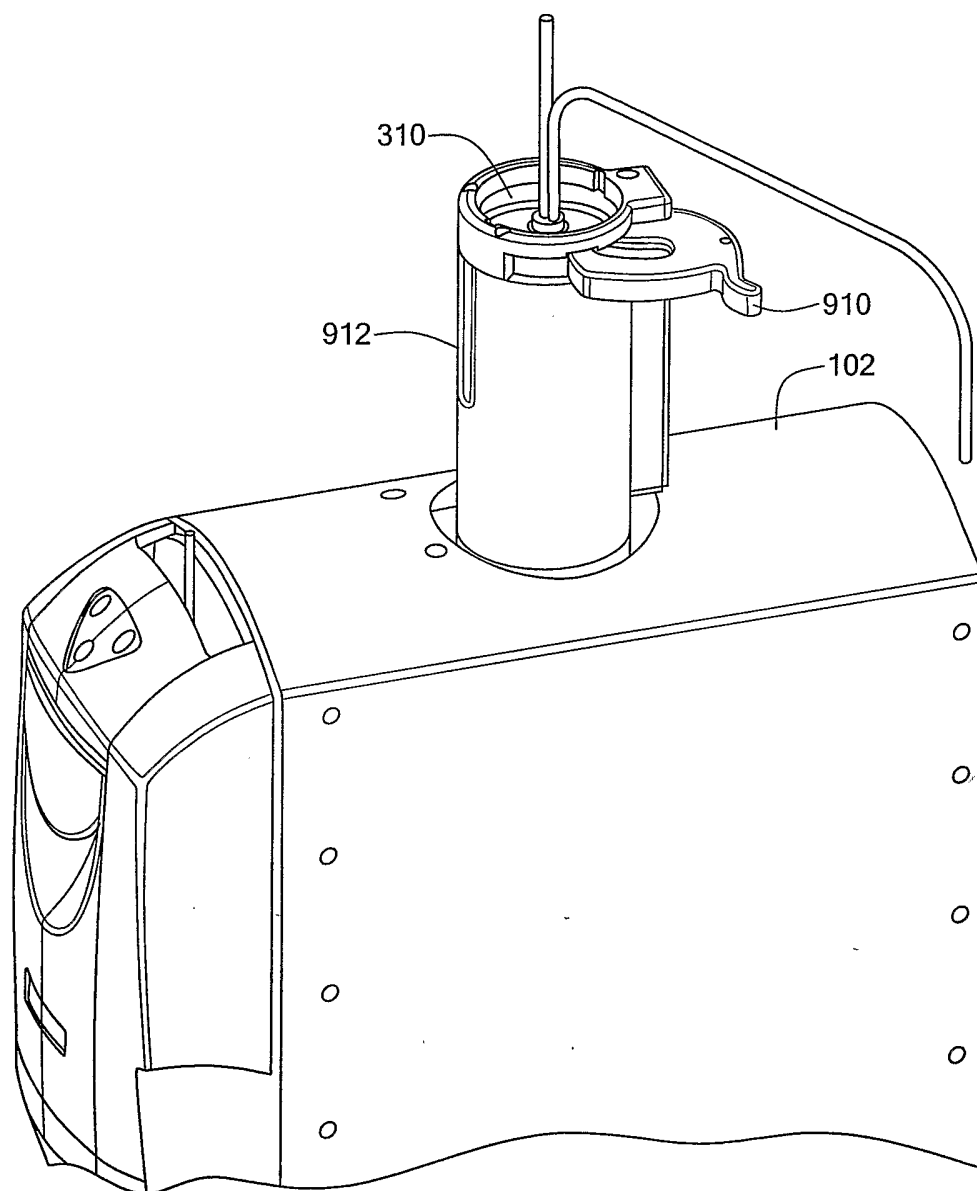
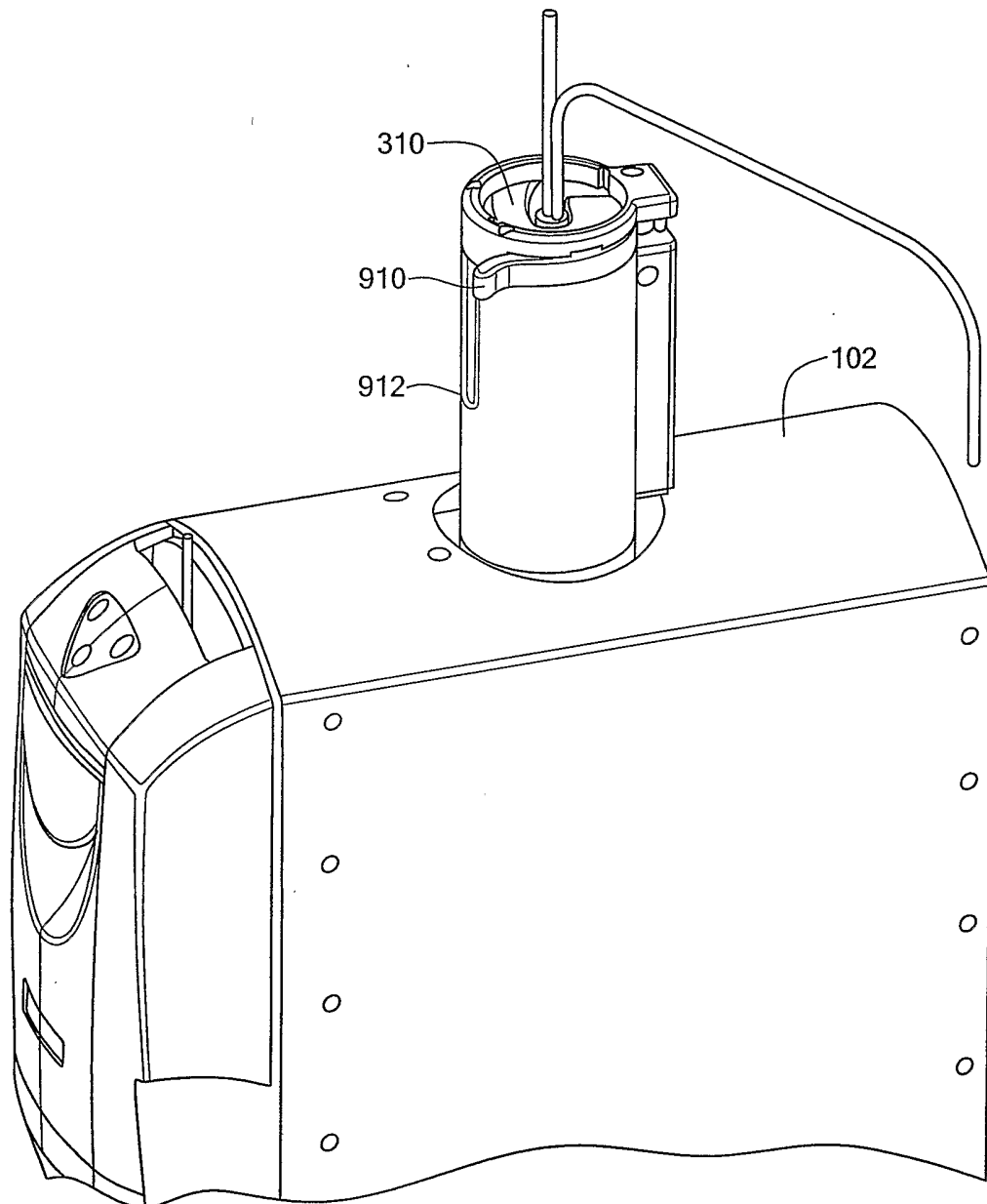


FIG. 9B

***FIG. 9C***

**FIG. 9D**

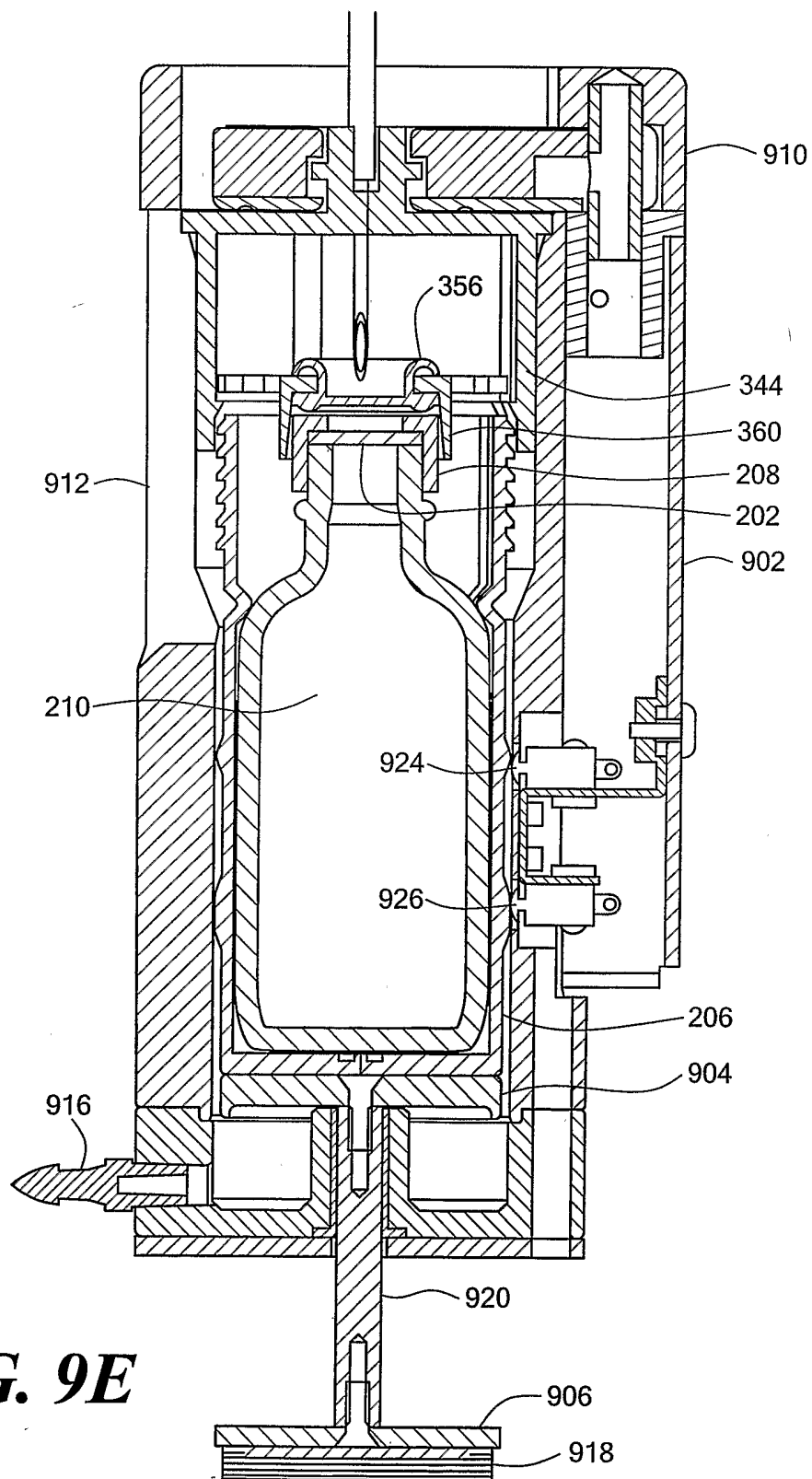
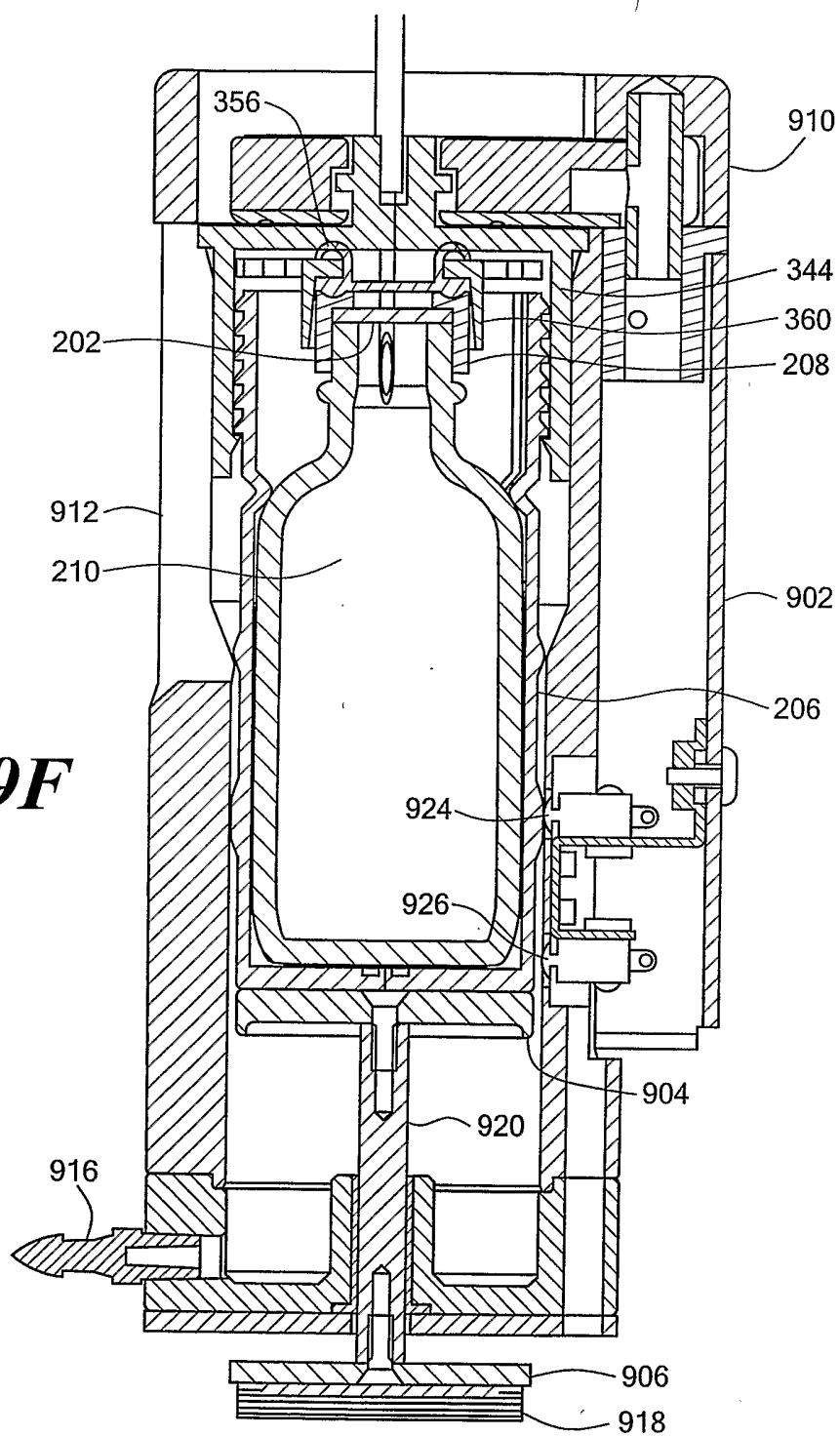
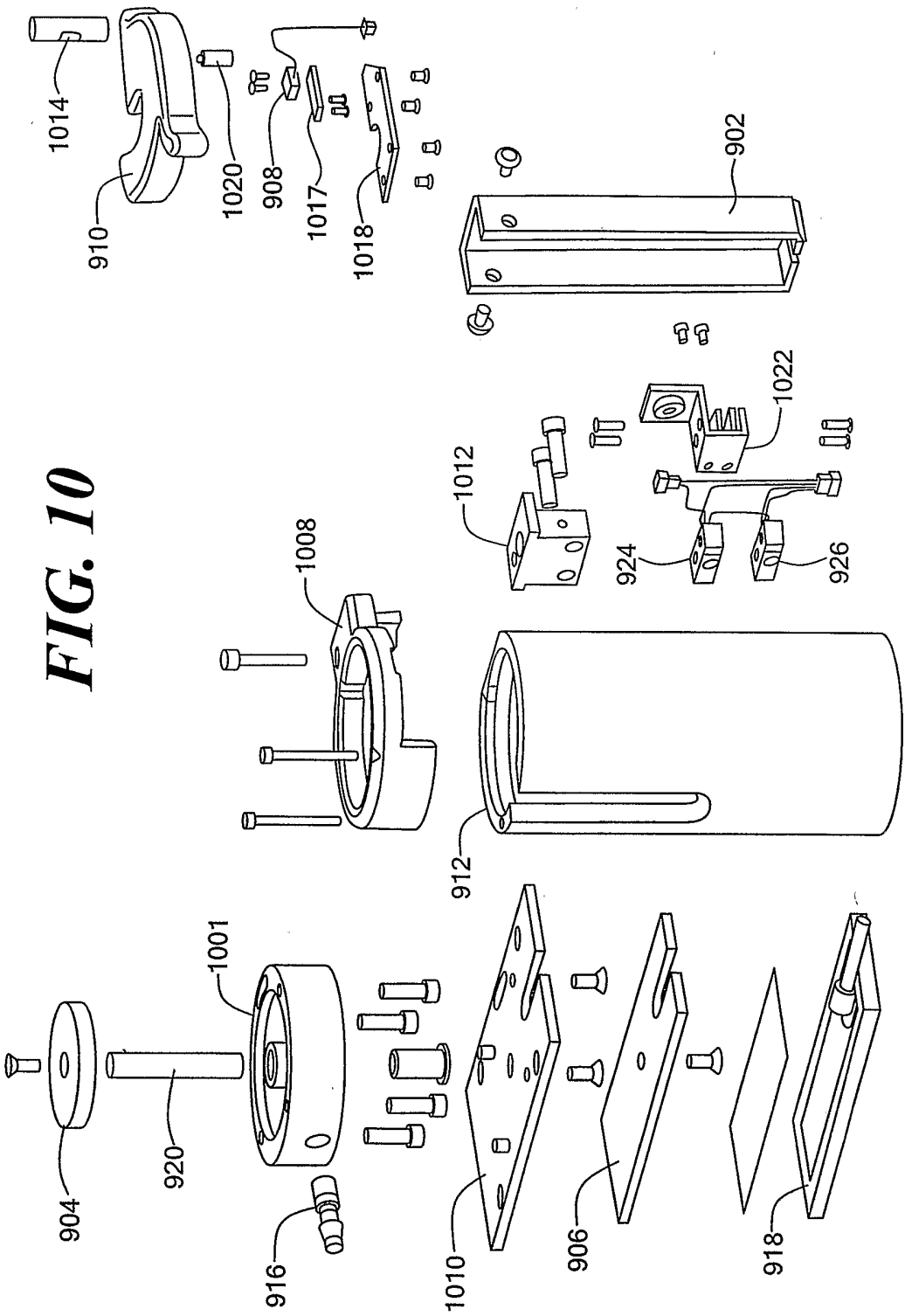
**FIG. 9E**

FIG. 9F



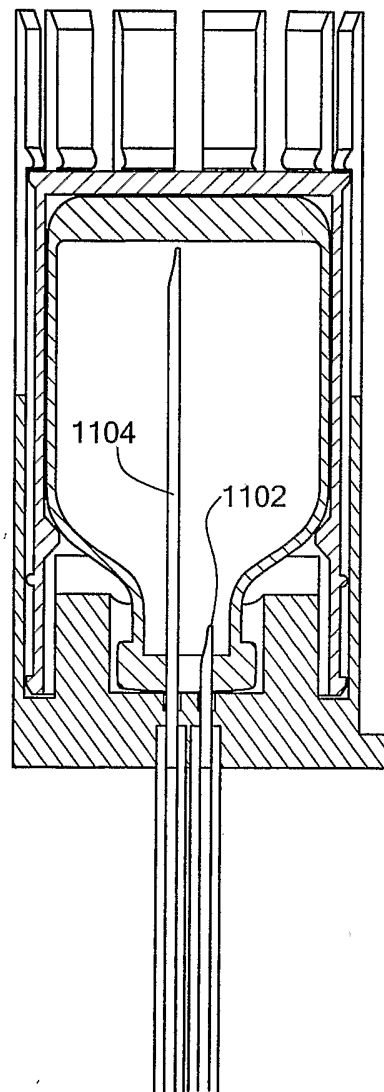


FIG. 11

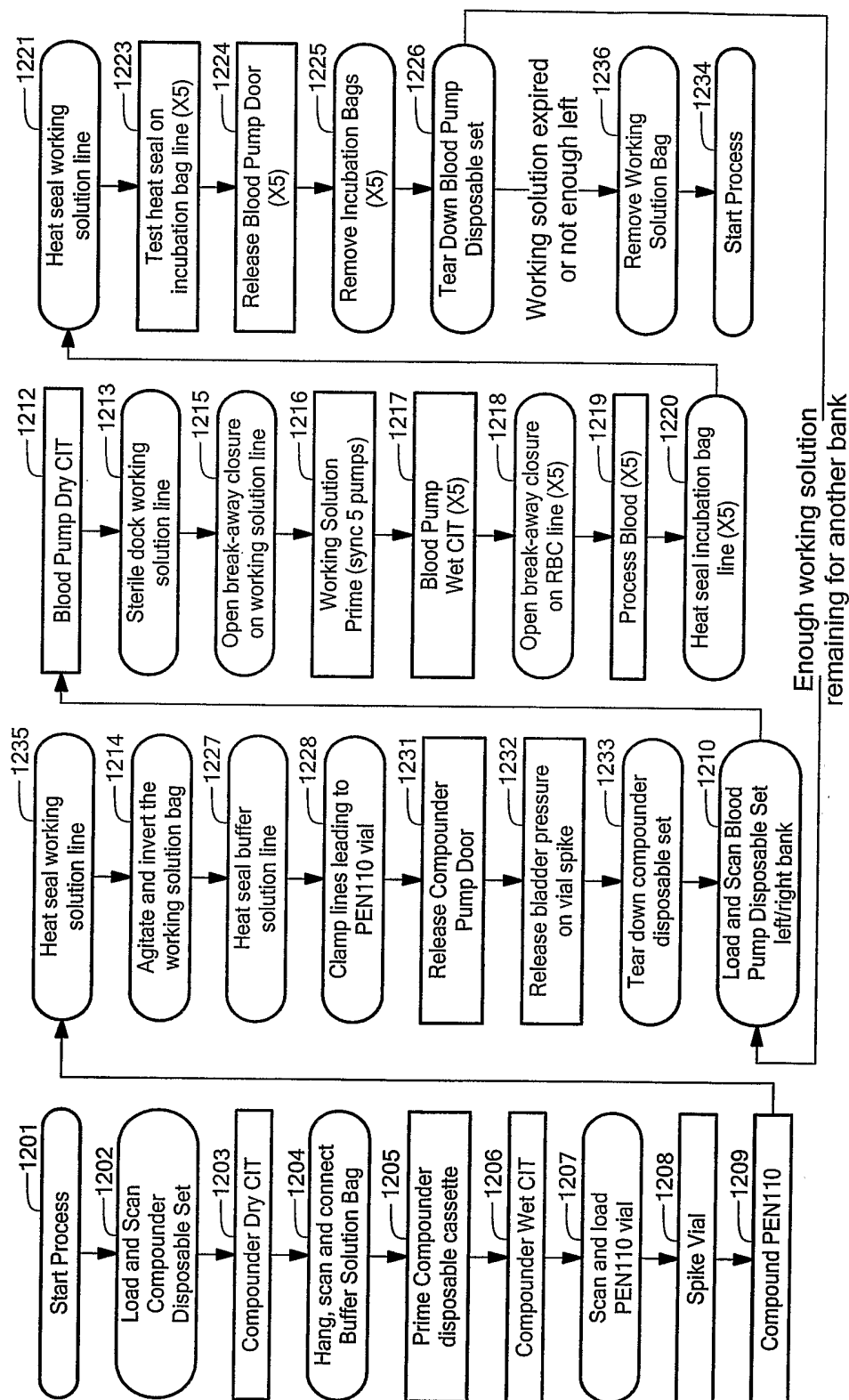
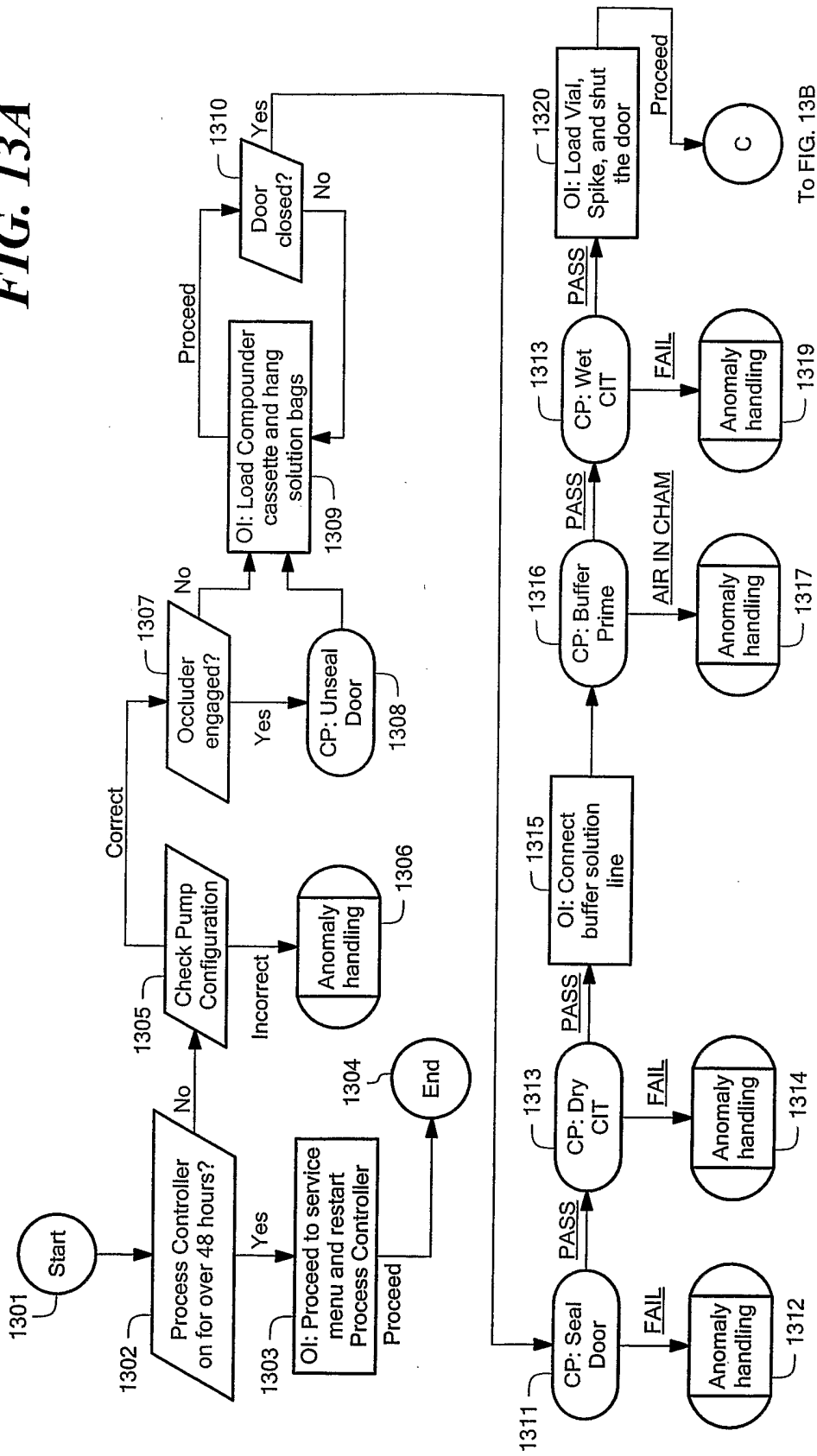


FIG. 12

FIG. 13A



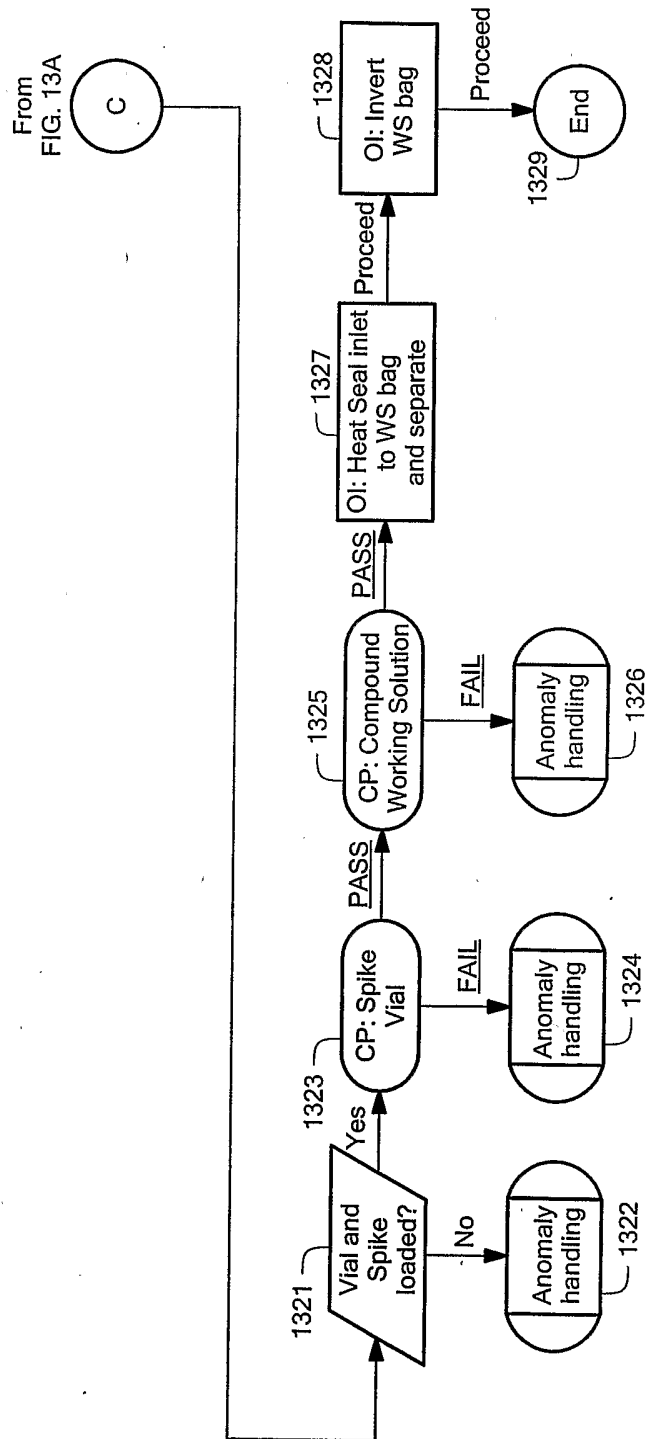


FIG. 13B

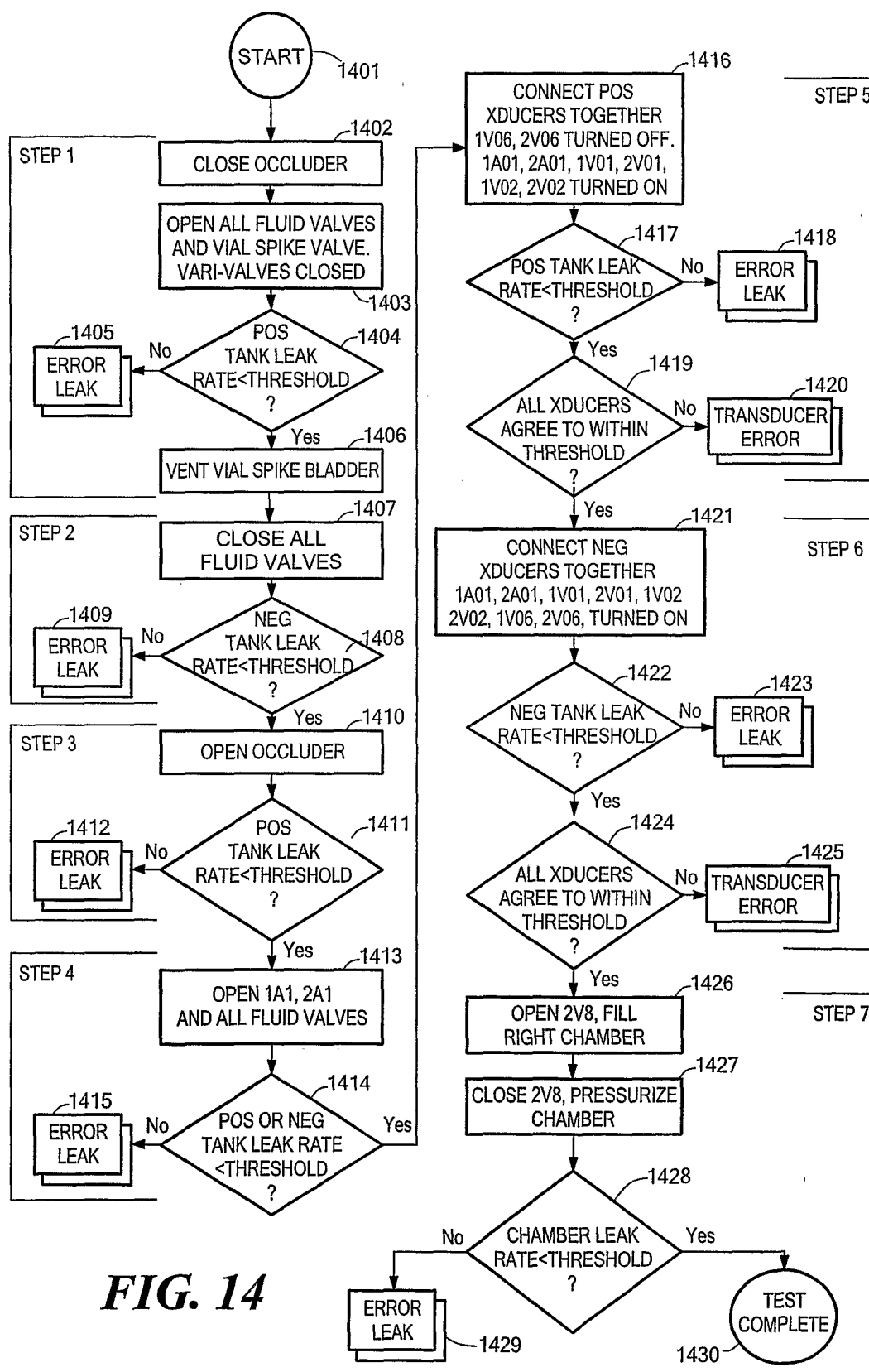
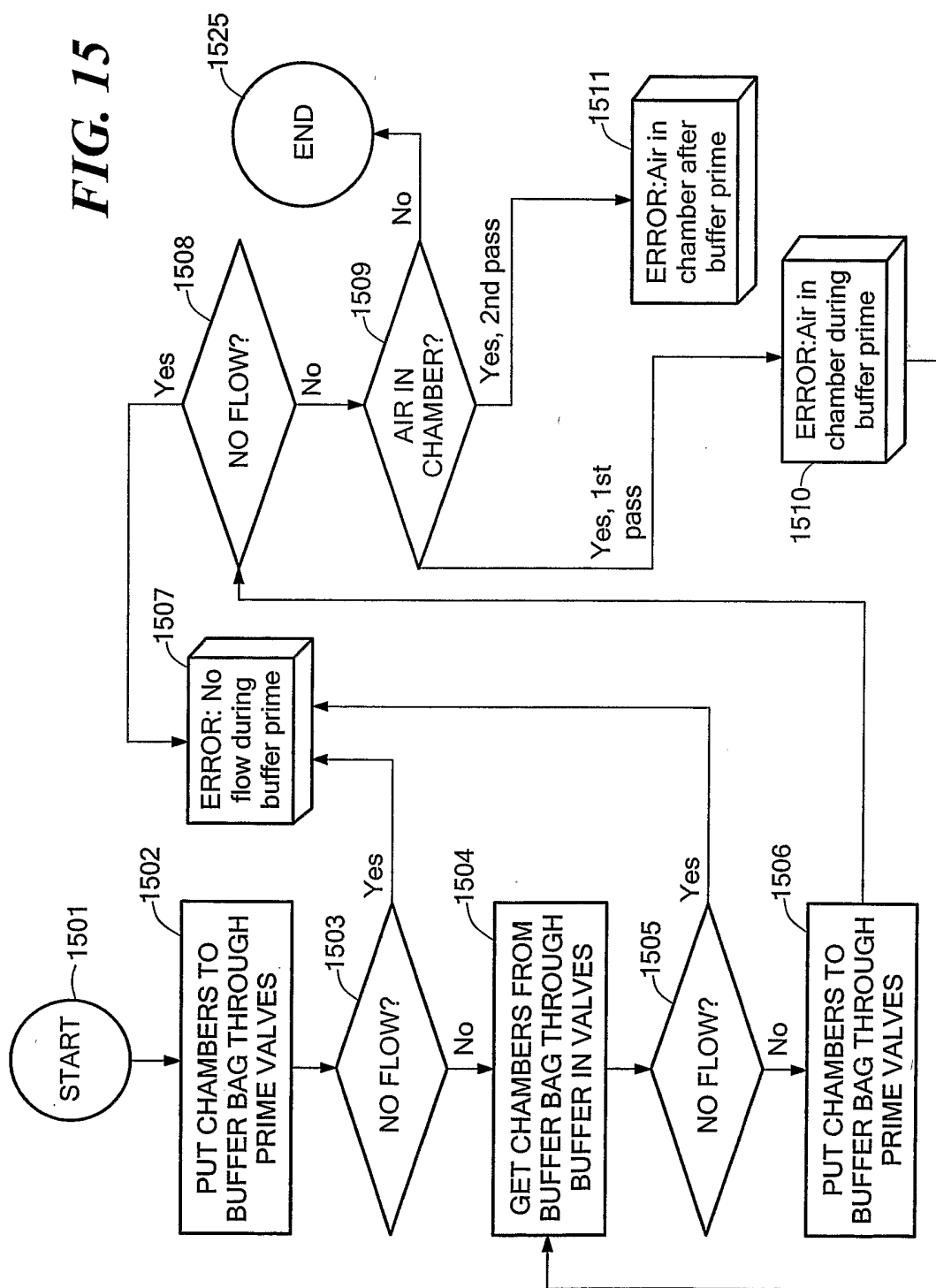


FIG. 15



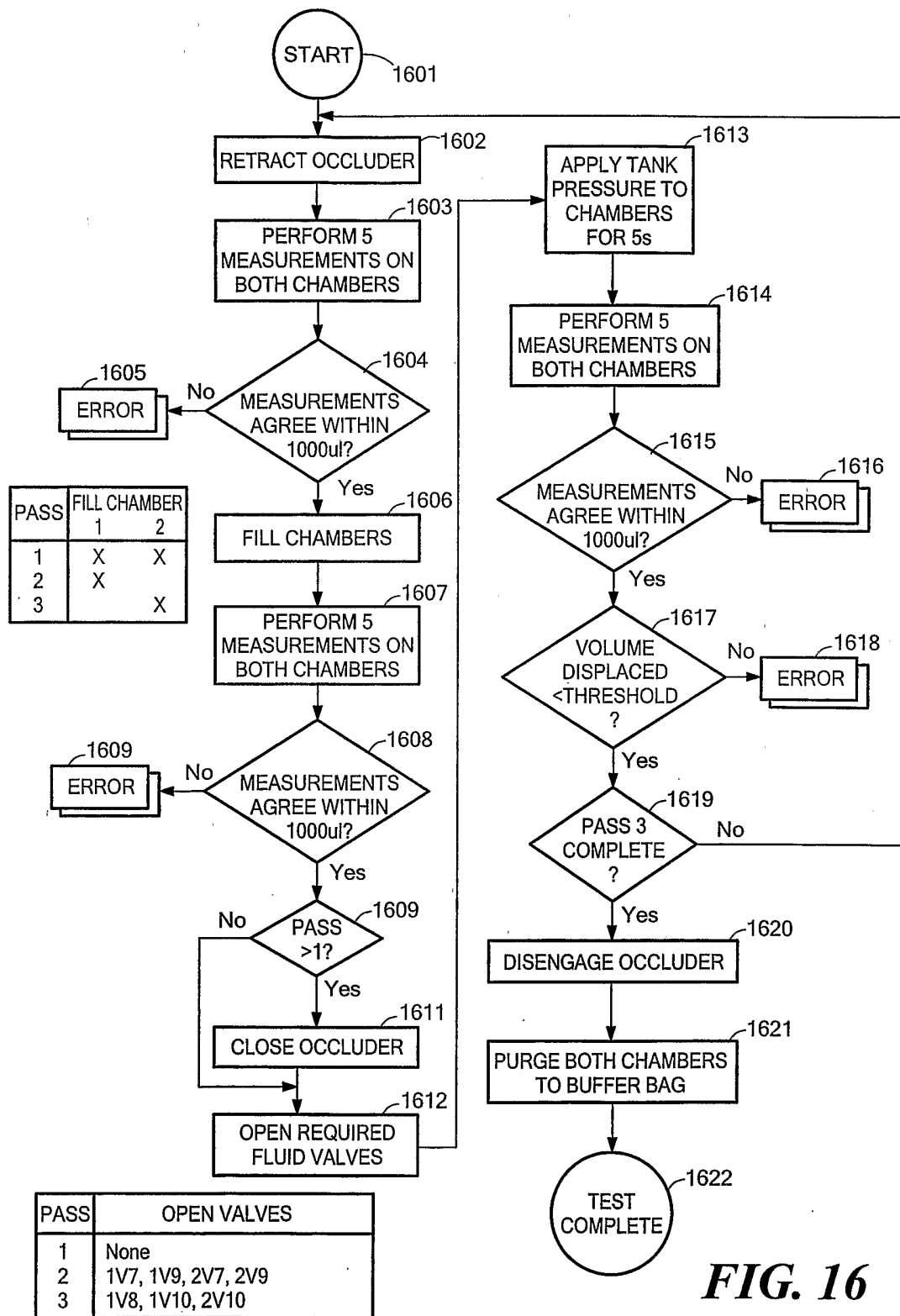
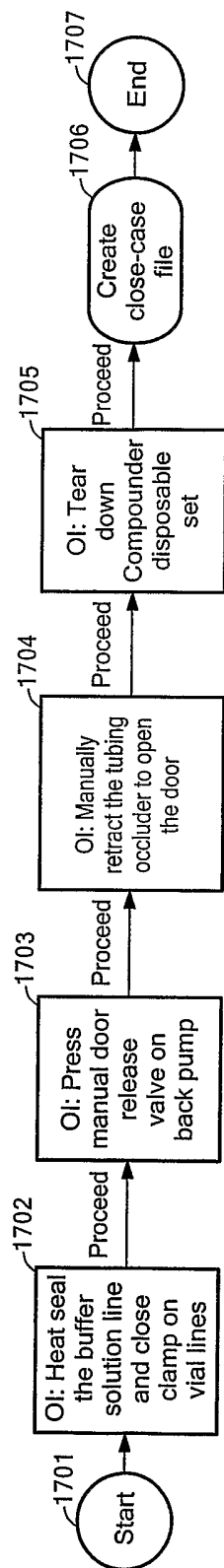
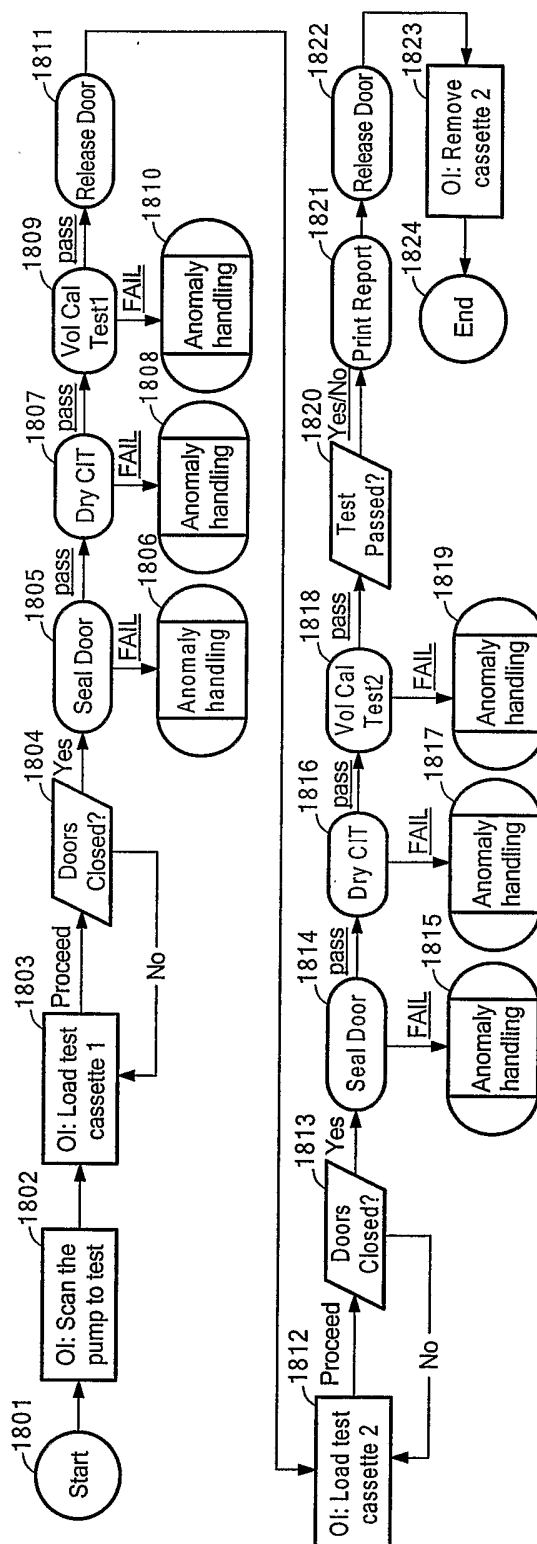
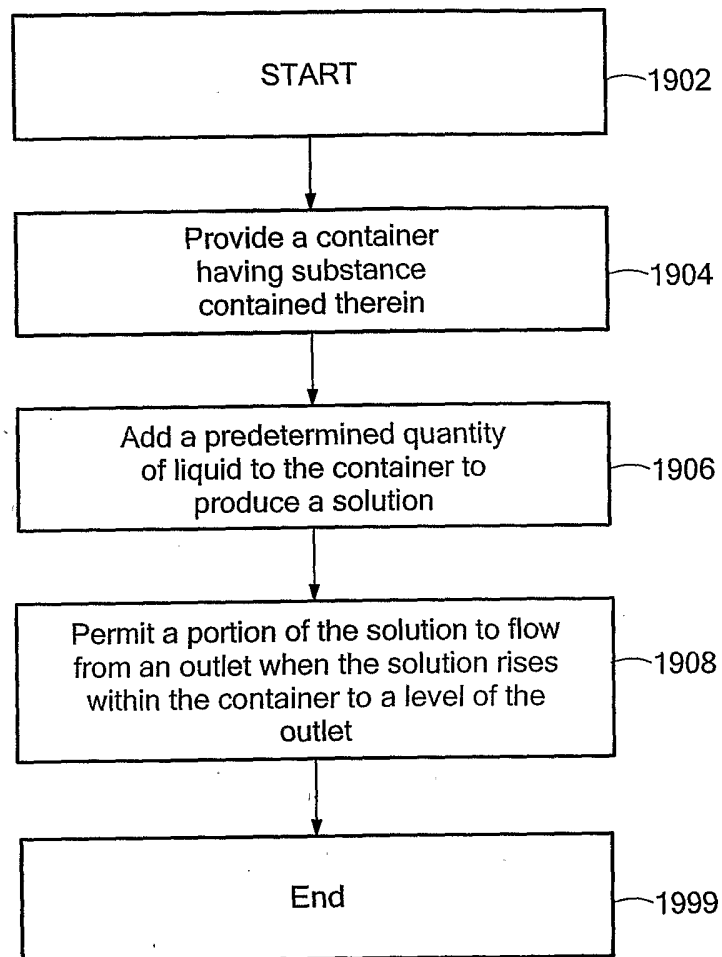


FIG. 16

**FIG. 17**

**FIG. 18**

**FIG. 19**1900