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(54) **AIR TRAP FOR A MEDICAL INFUSION DEVICE**

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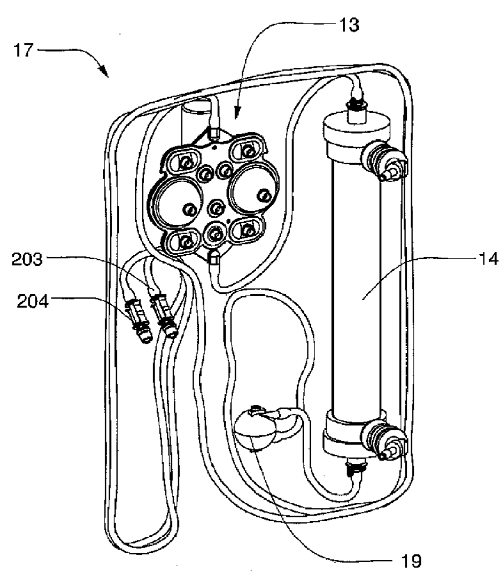
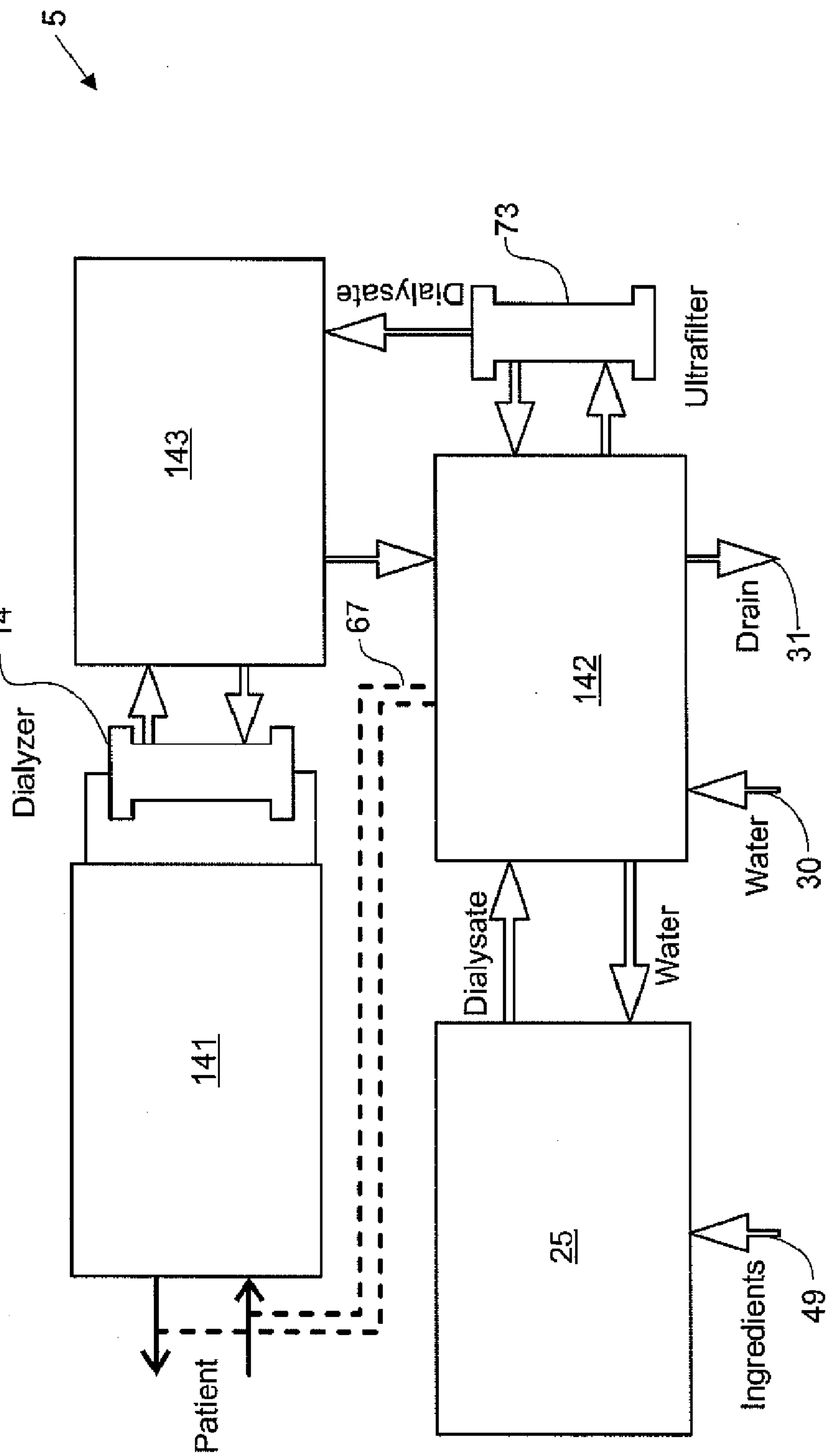
(57) **ABSTRACT**

An air trap for a blood circuit and method for removing air from blood in a dialysis unit. The air trap may include a blood inlet supply line, a blood outlet supply line, and a container having an approximately spherical internal wall, an inlet at a top end of the container connected to the blood inlet supply line, and an outlet at a bottom end of the container connected to the blood outlet supply line. The inlet may be offset from a vertical axis of the approximately spherical internal wall such that blood entering the container is directed to flow in a spiral-like path. The inlet port may be arranged to introduce blood into the container in a direction that is approximately tangential to the approximately spherical inner wall of the container and/or in a direction that is approximately perpendicular to the vertical axis of the container.

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Dialysate
Ultrafilter
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Drain
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Water
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Dialysate
Water
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Ingredients
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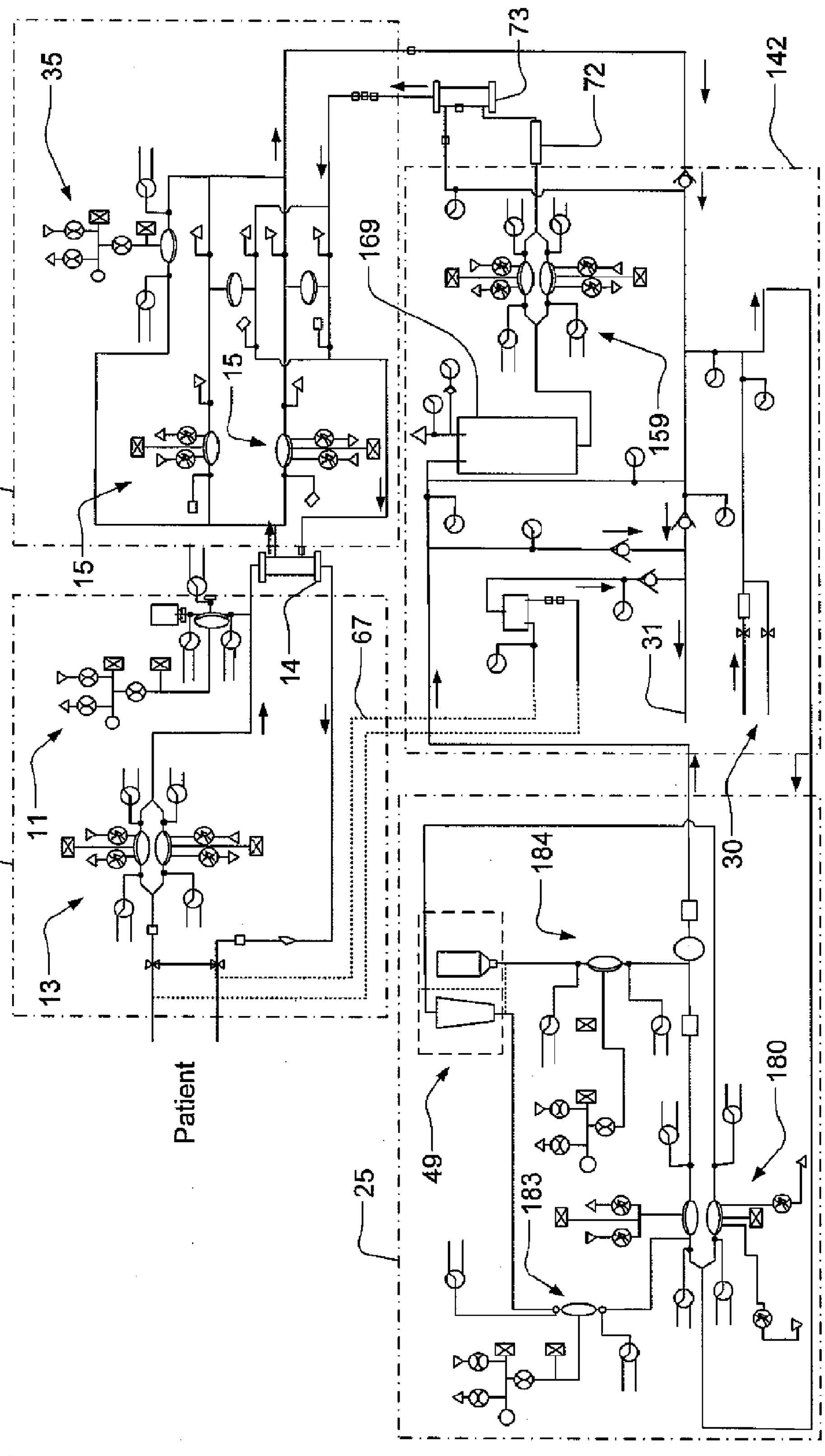
Patient

FIG. 1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Patient

FIG. 2

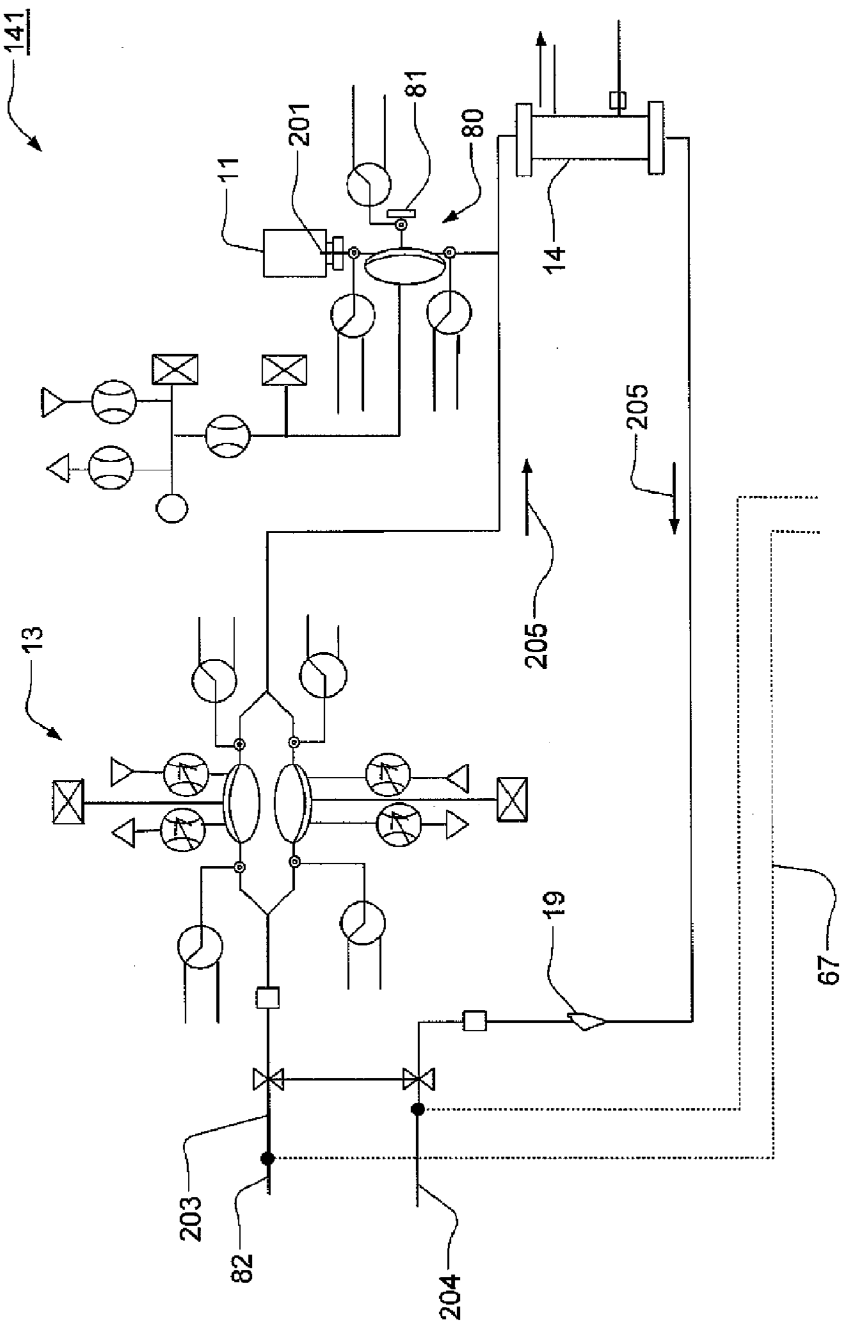

FIG. 3

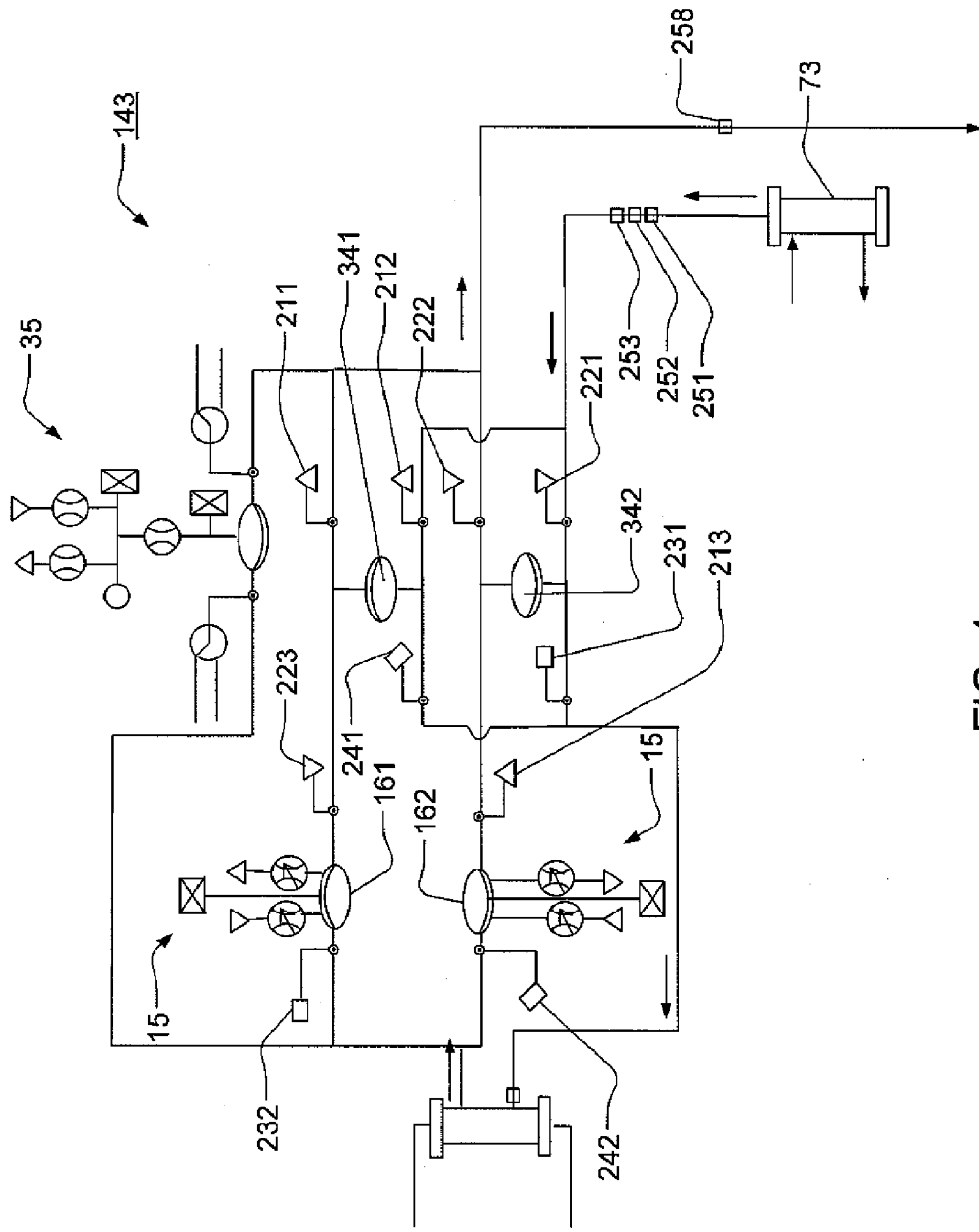
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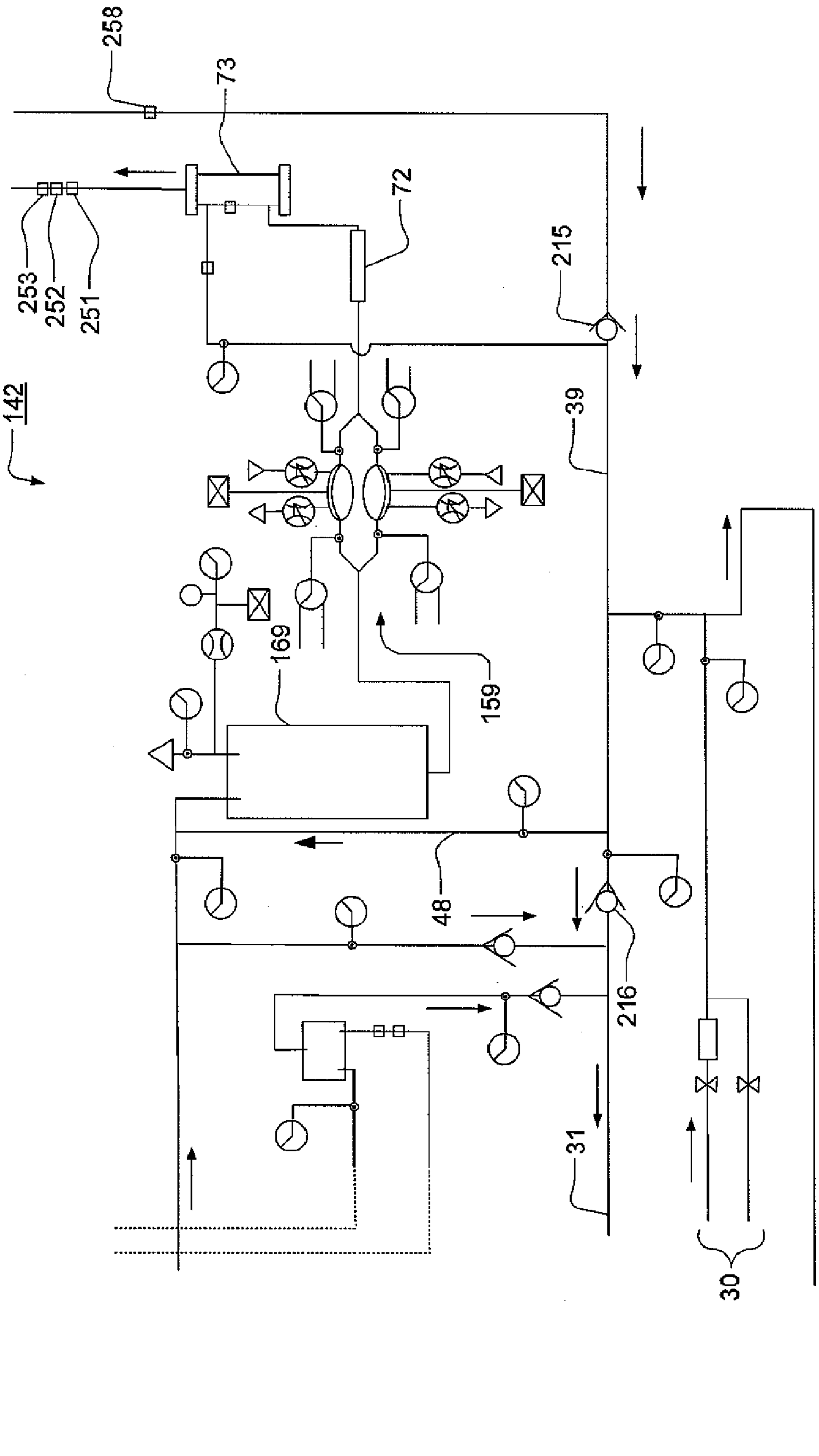
FIG. 4



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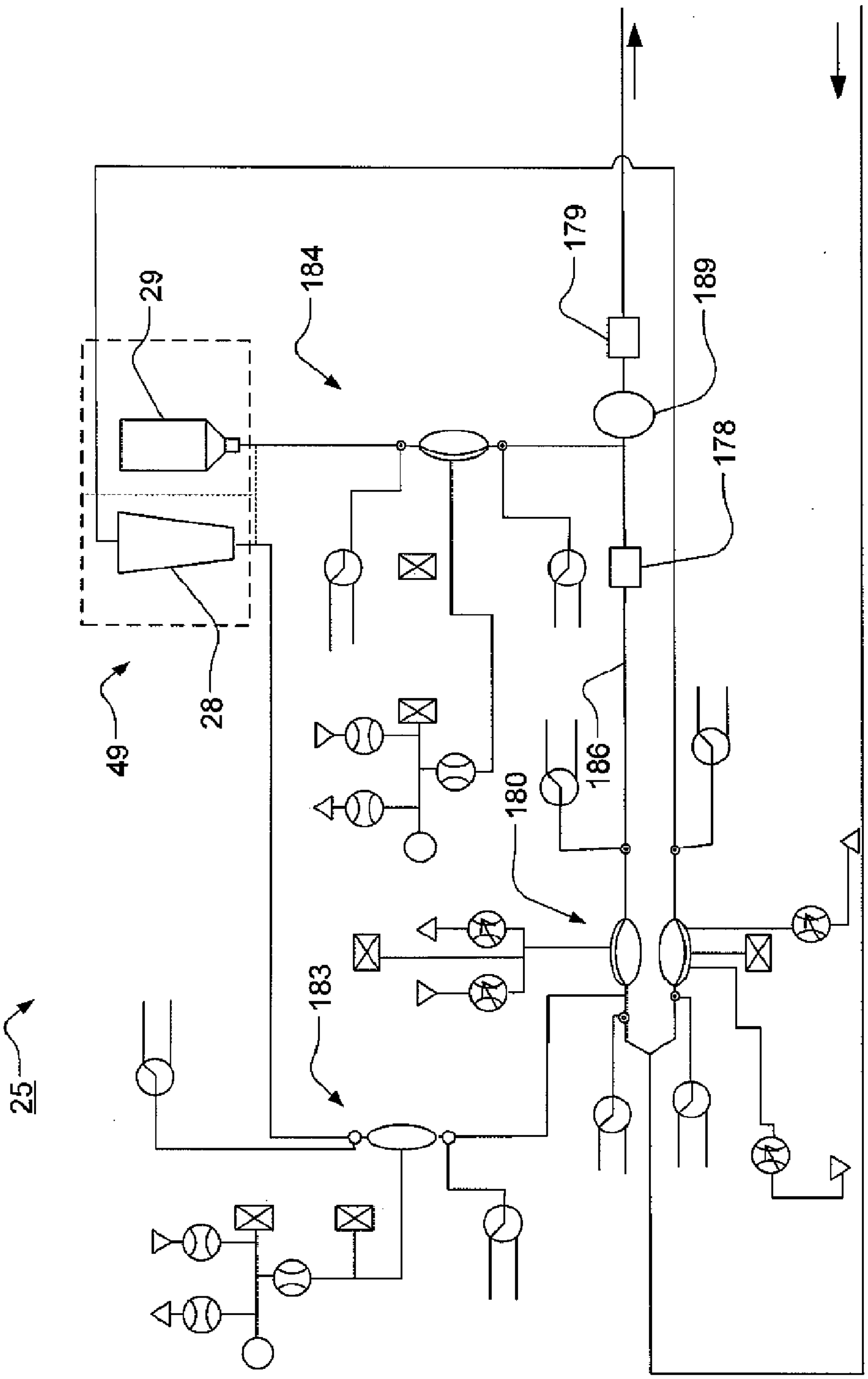

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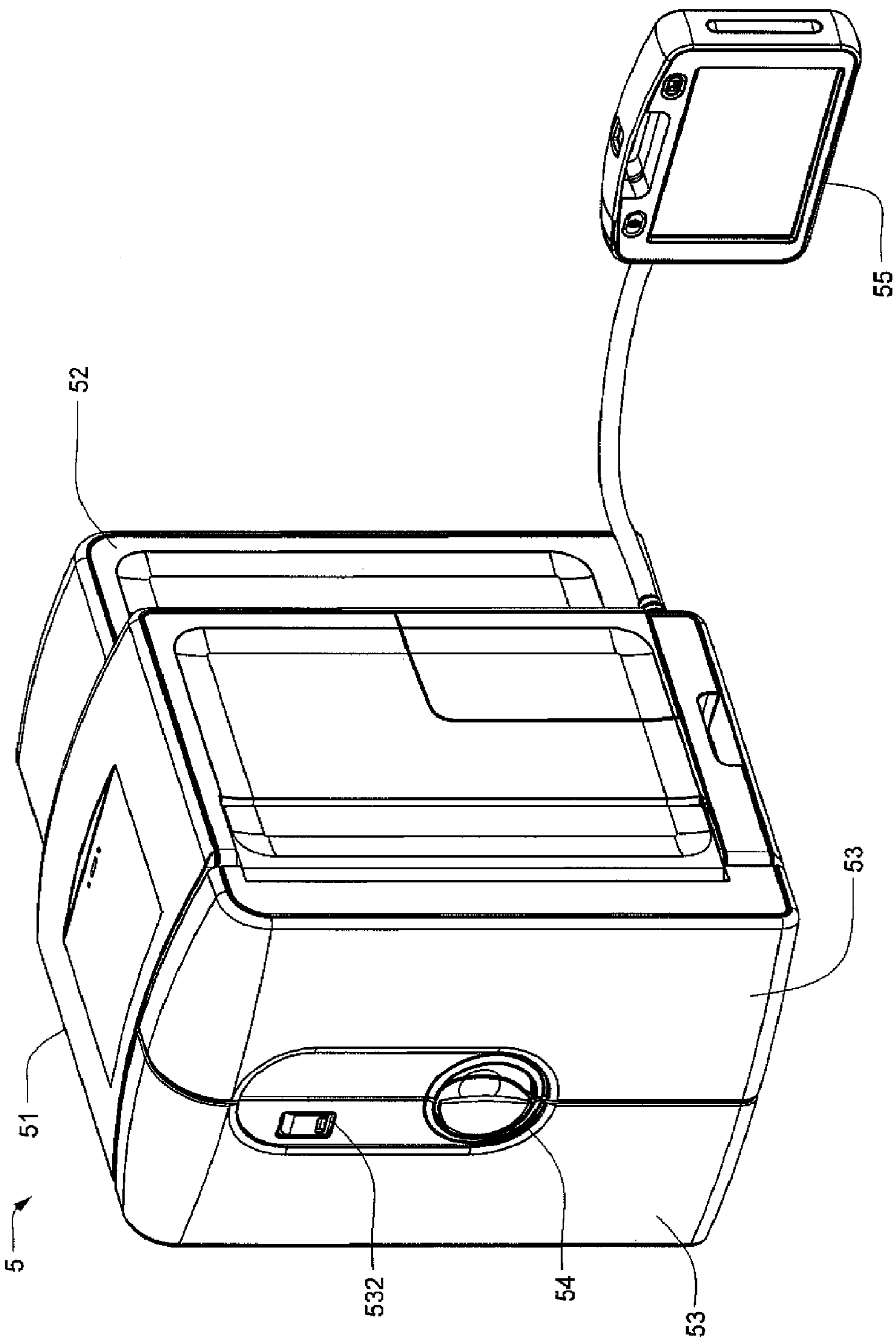

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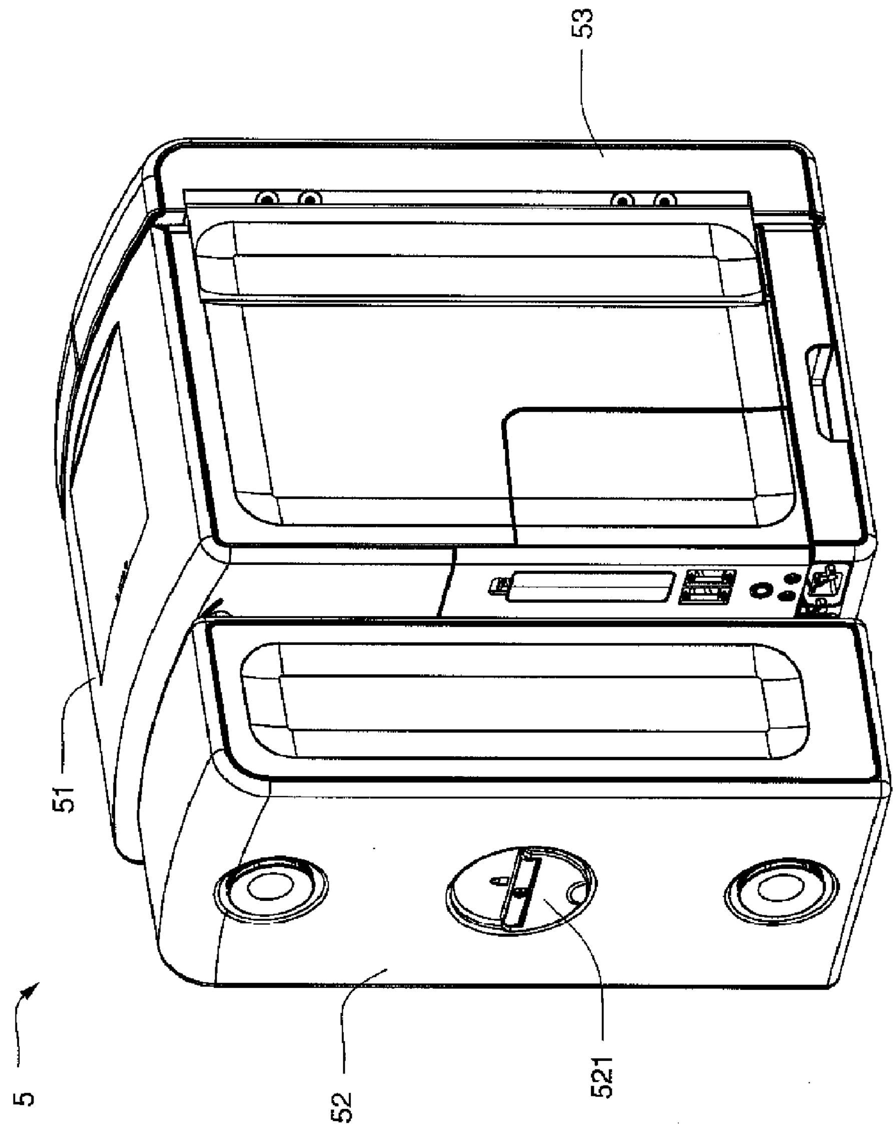
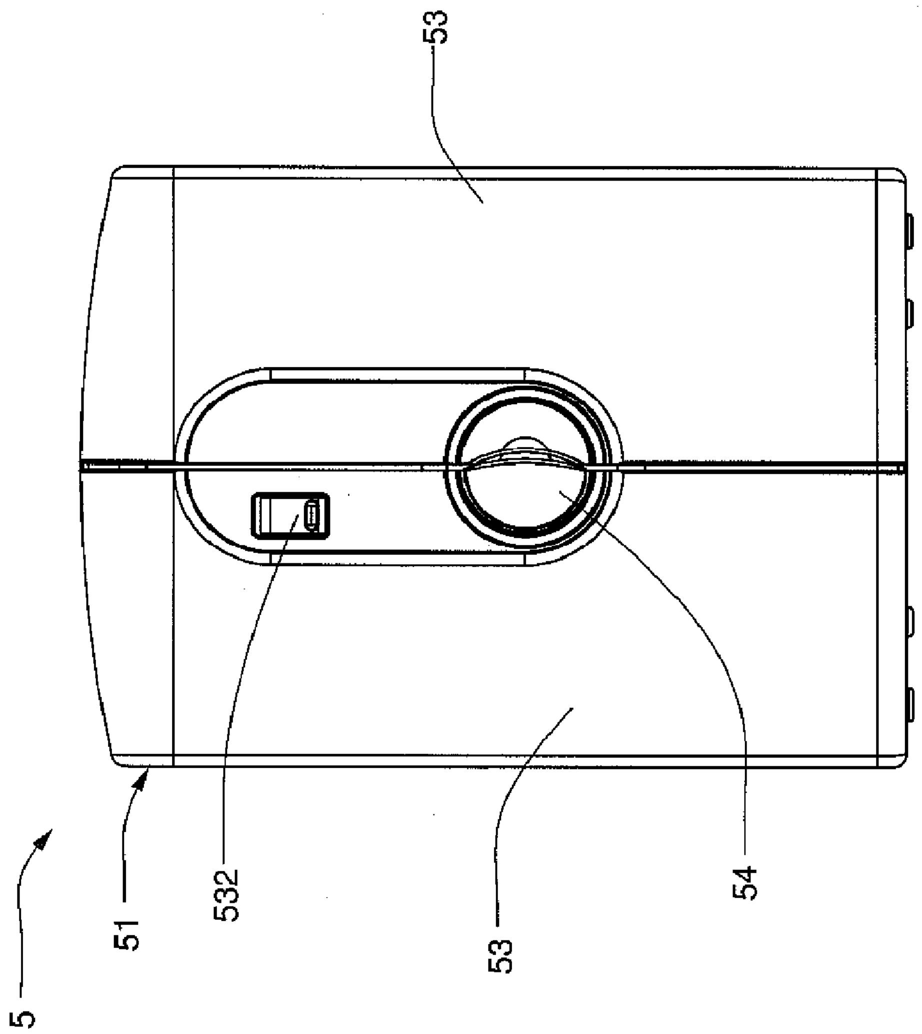


FIG. 8



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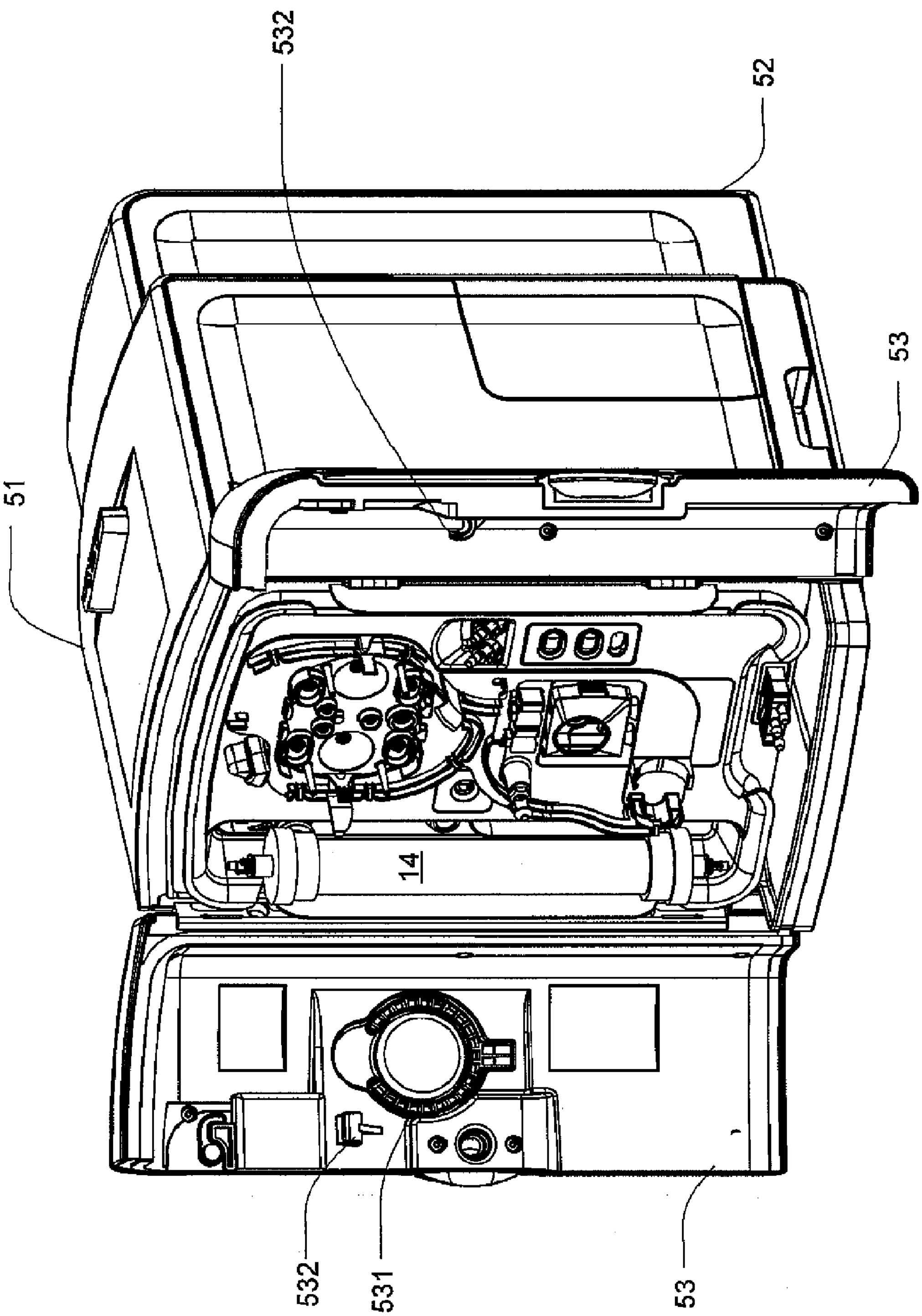

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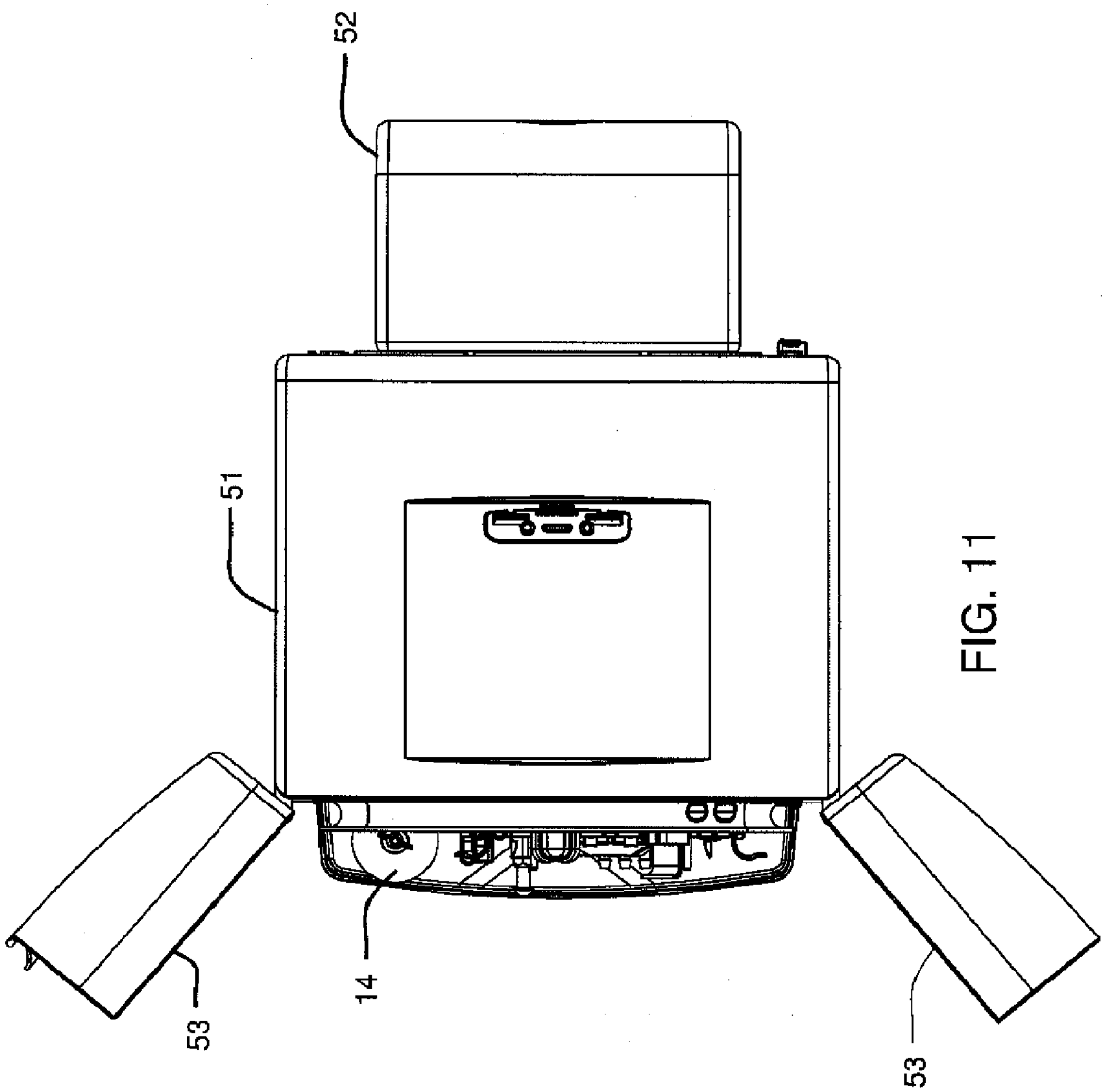

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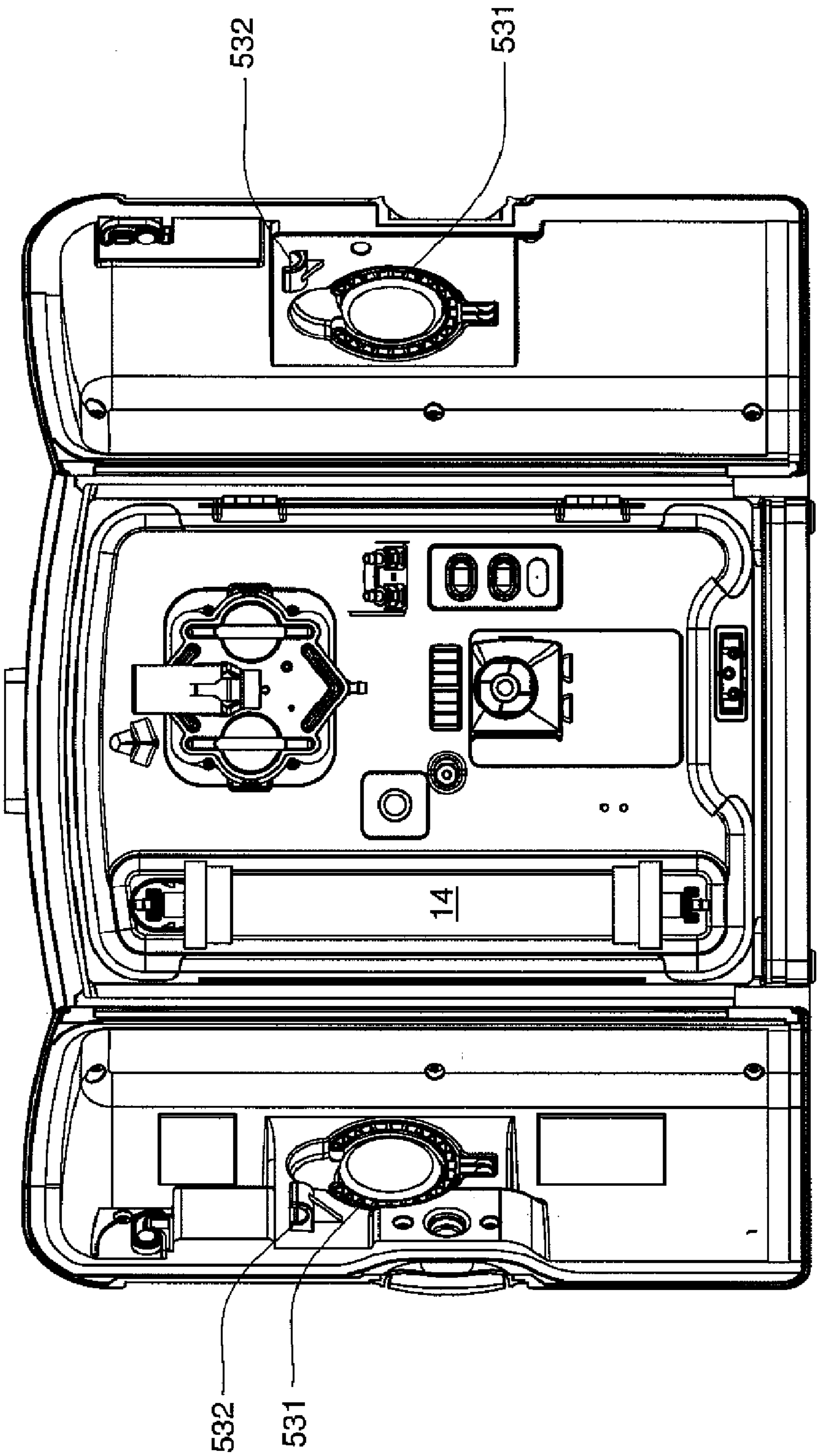
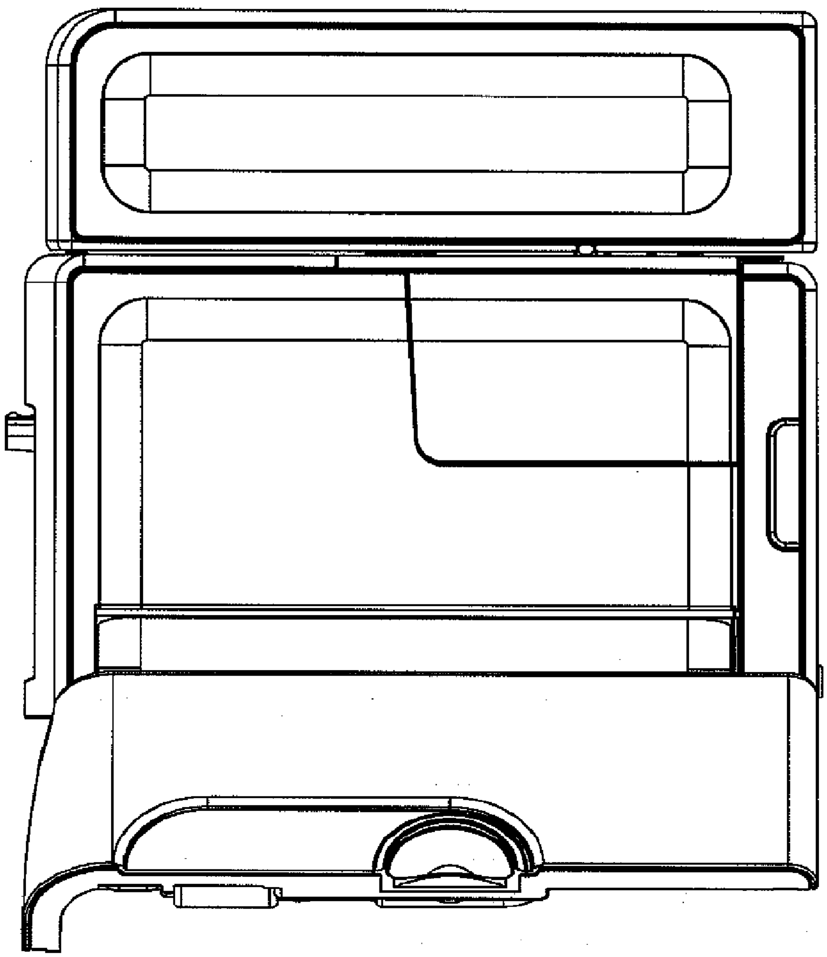


FIG. 12



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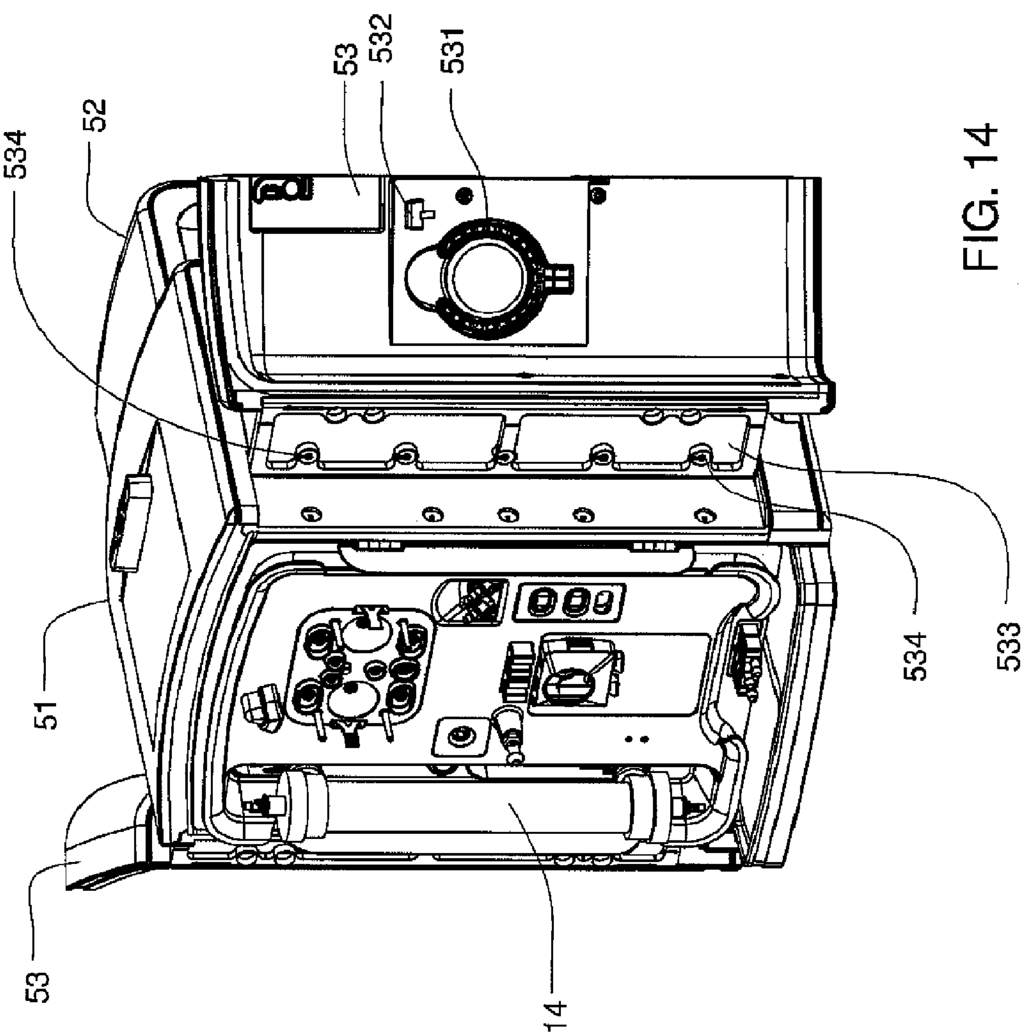

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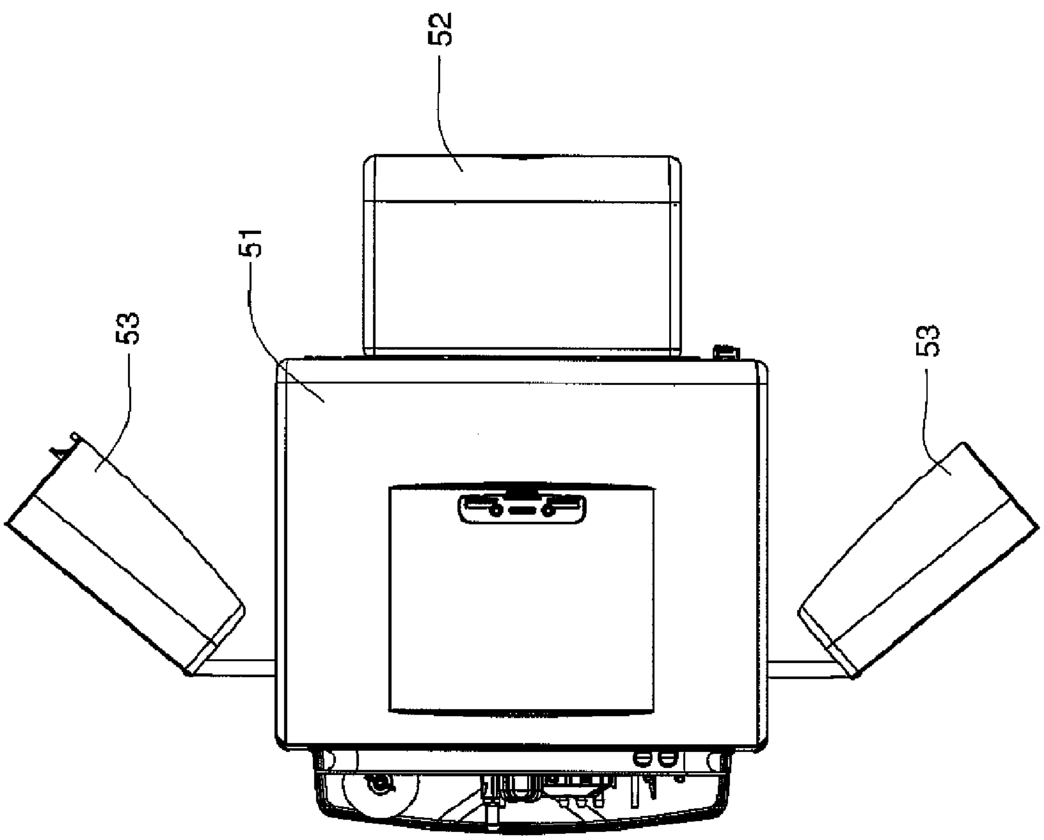

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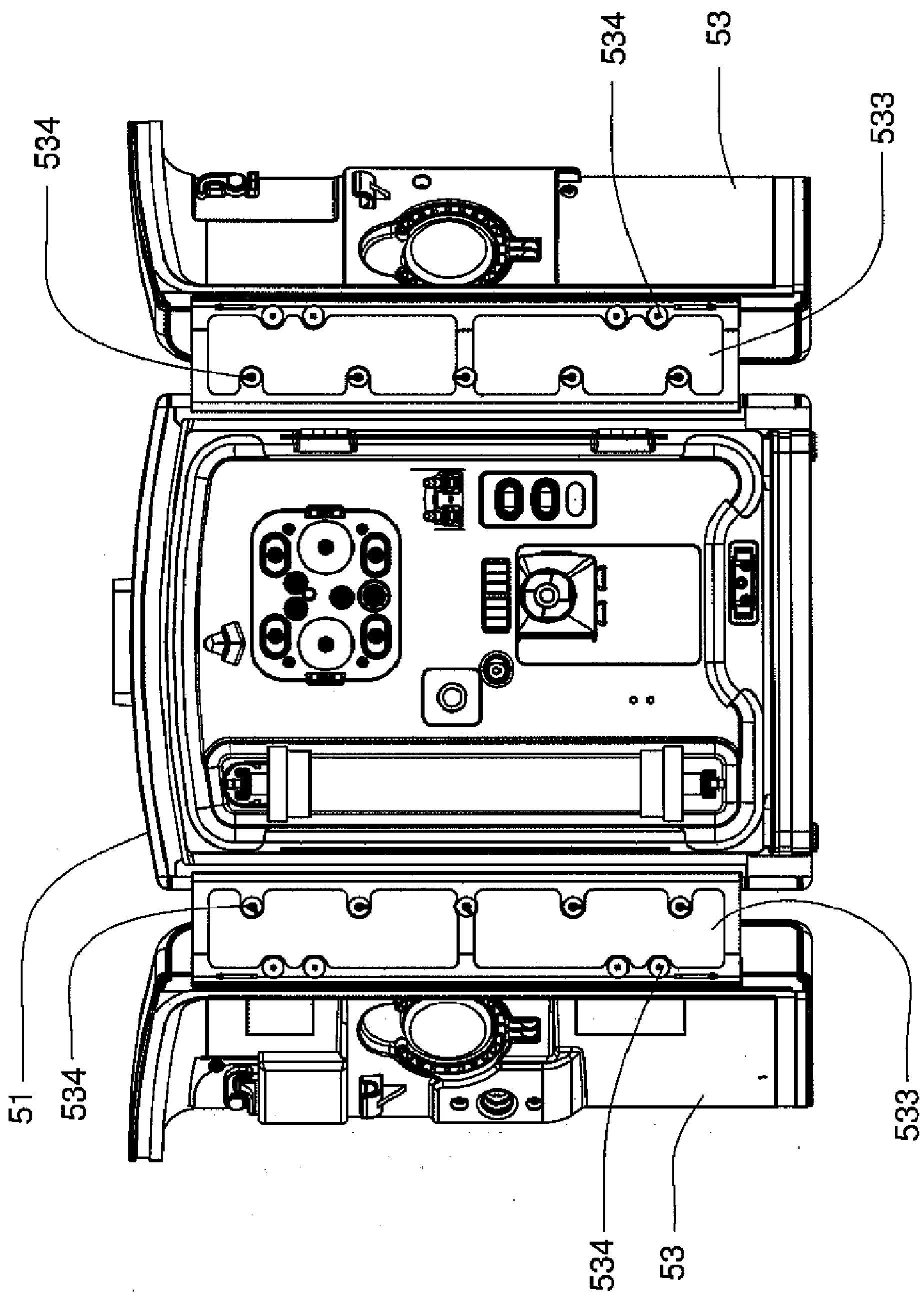

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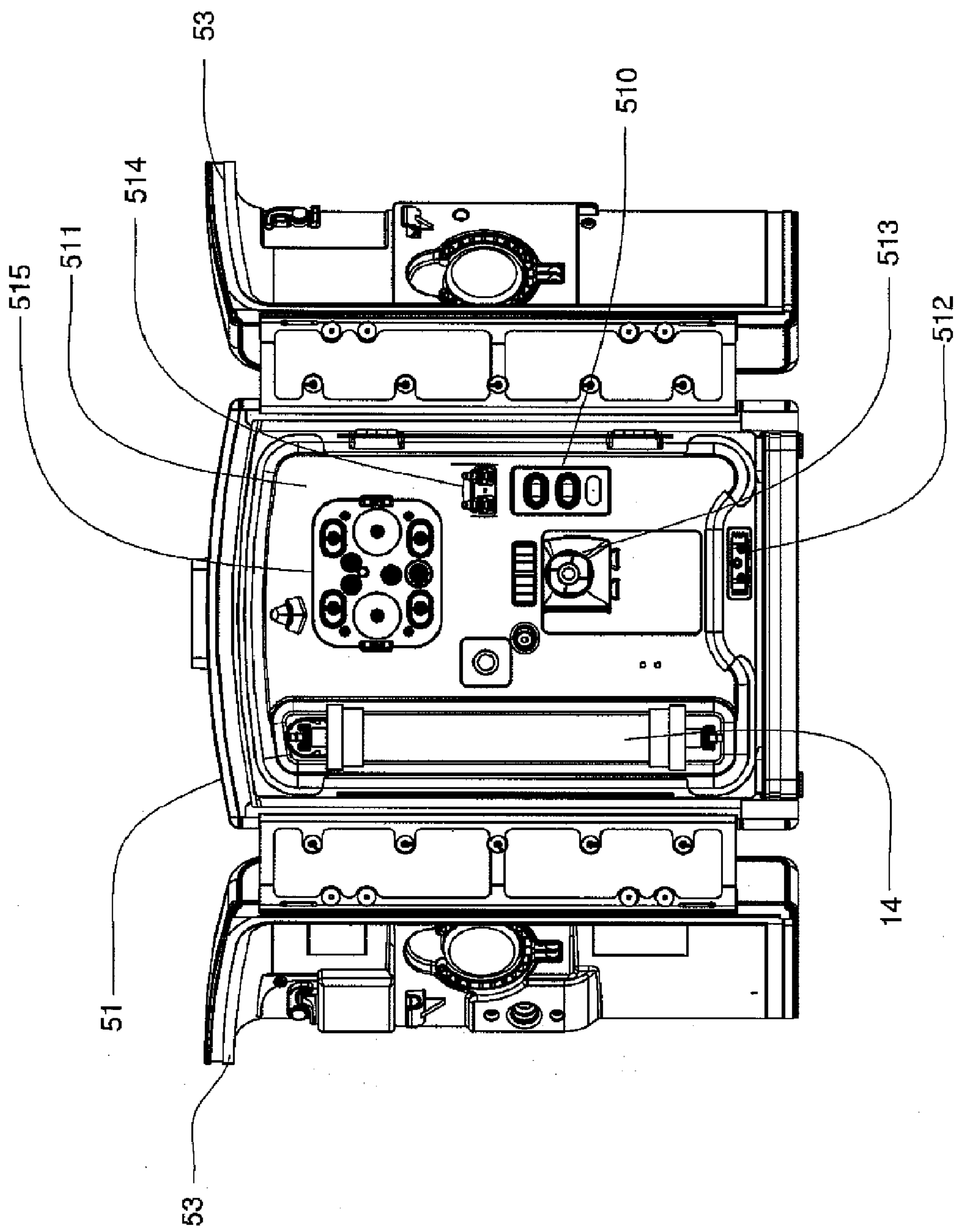
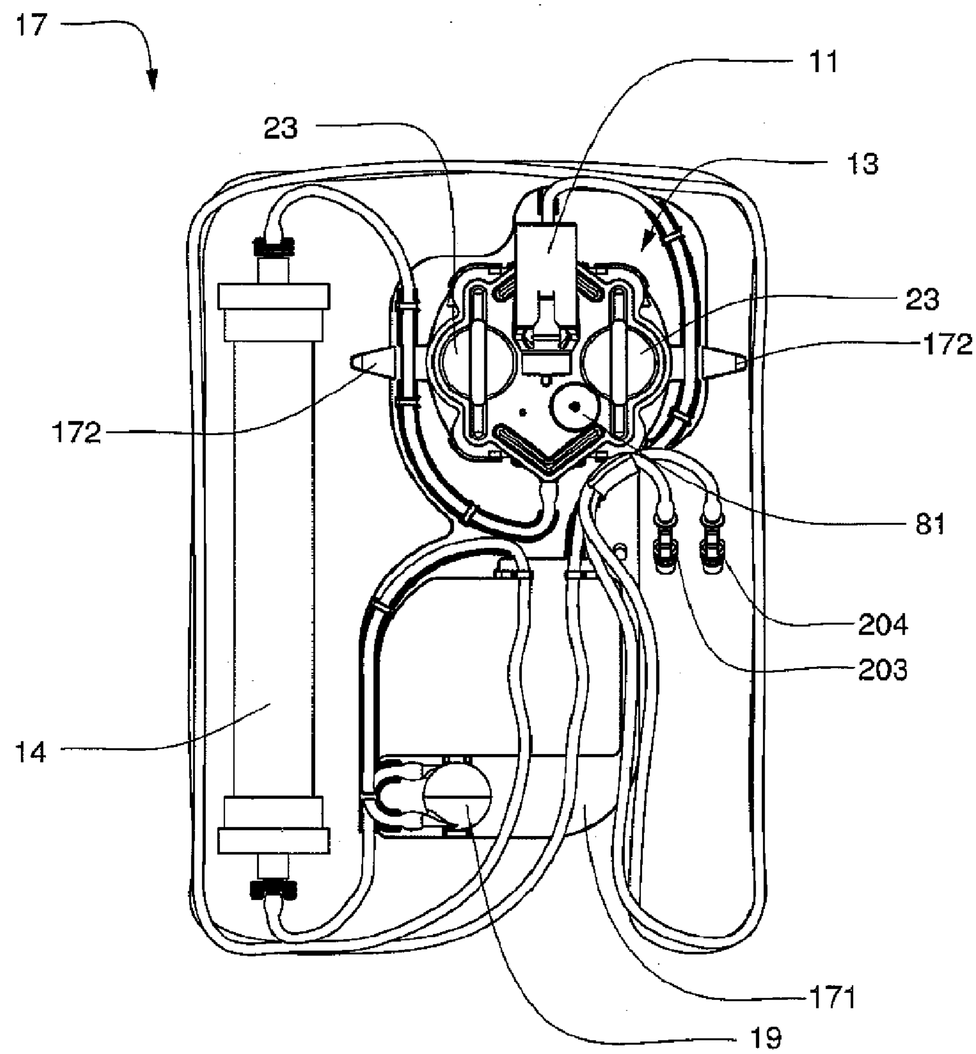


FIG. 17



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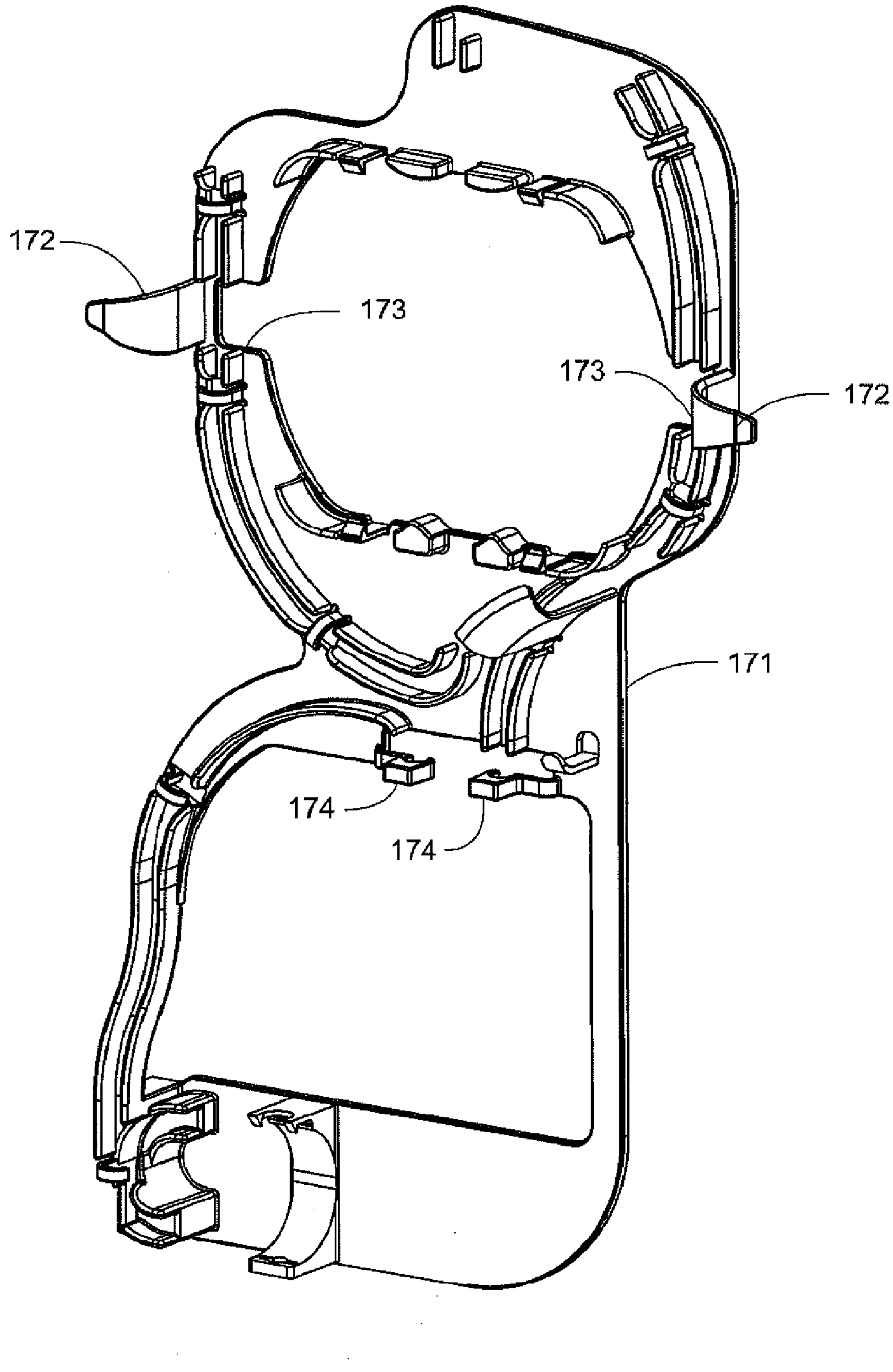
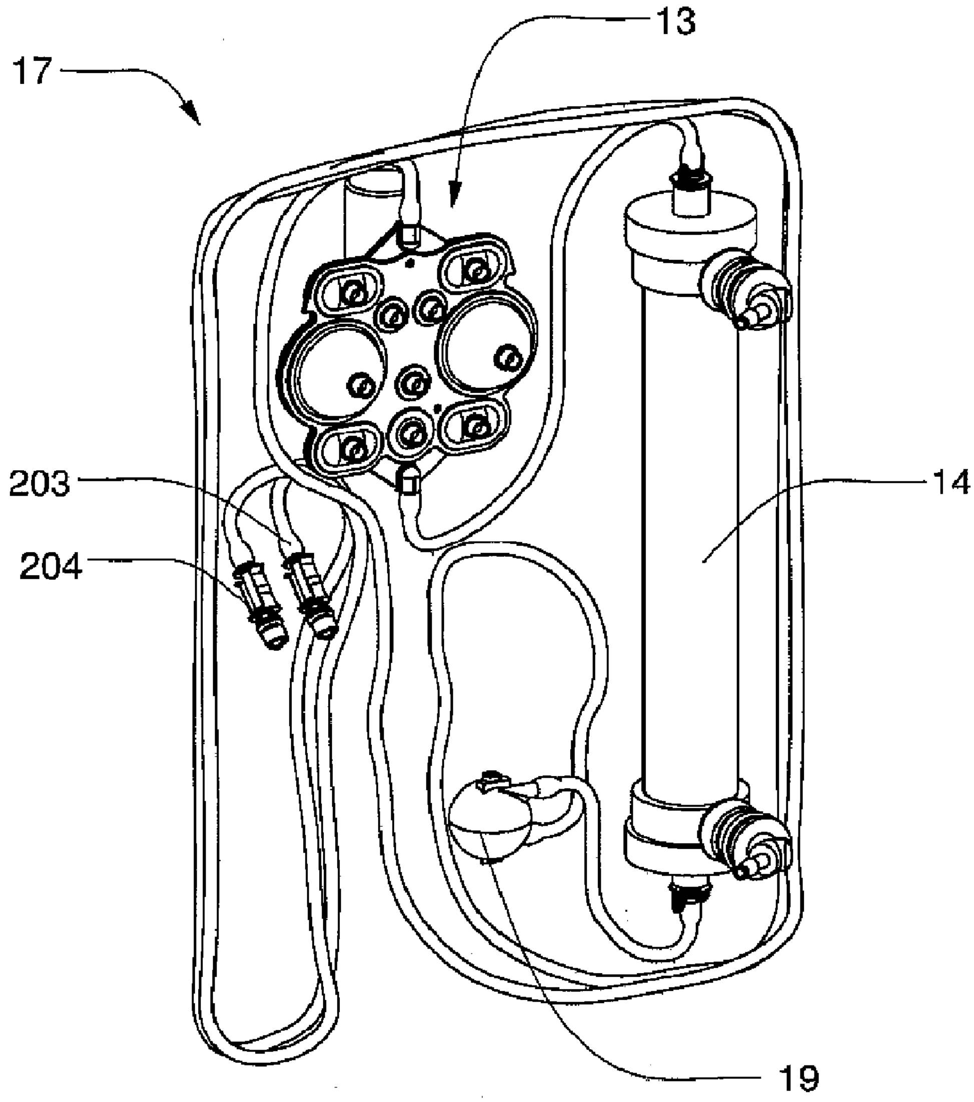


FIG. 19



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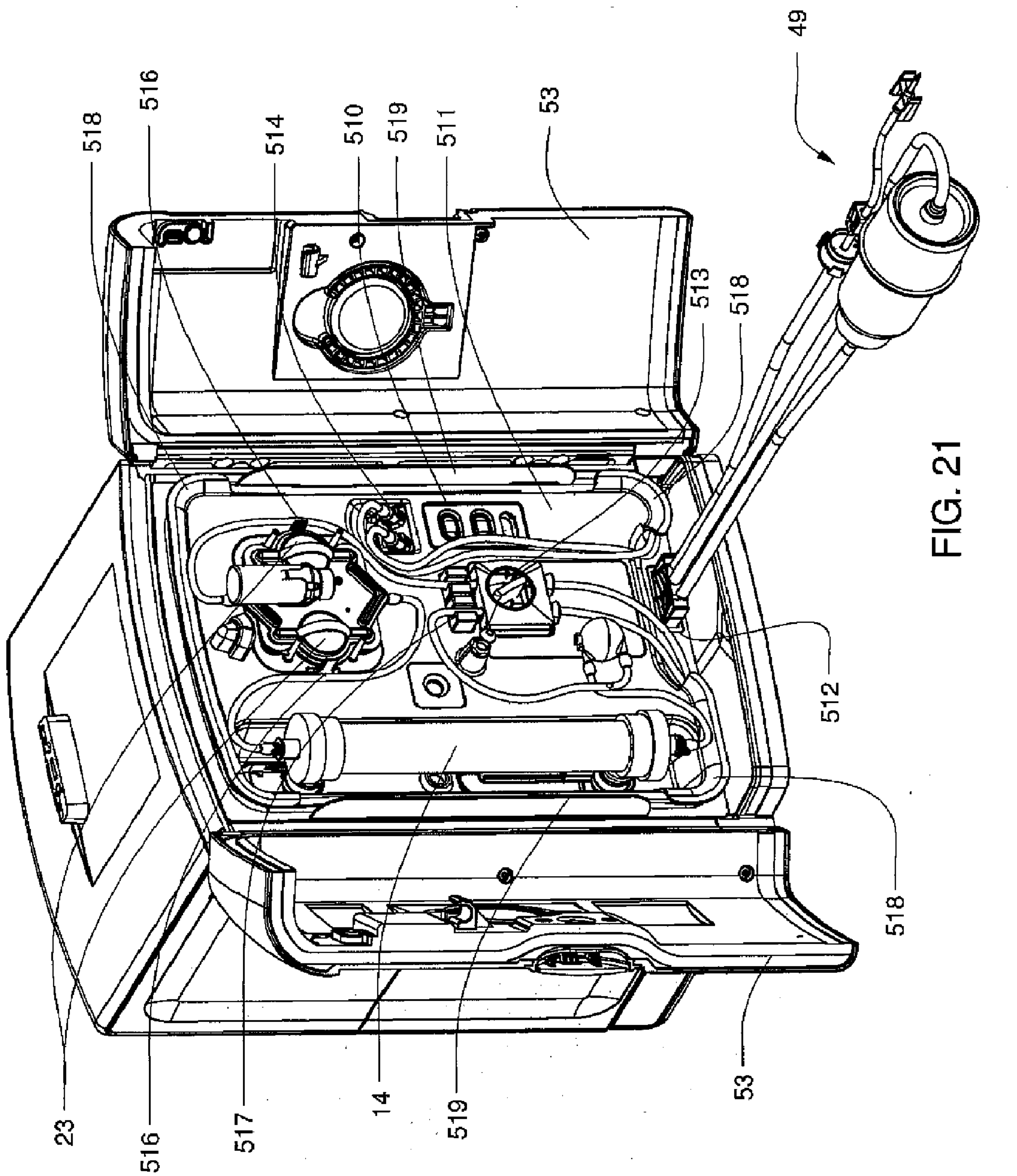

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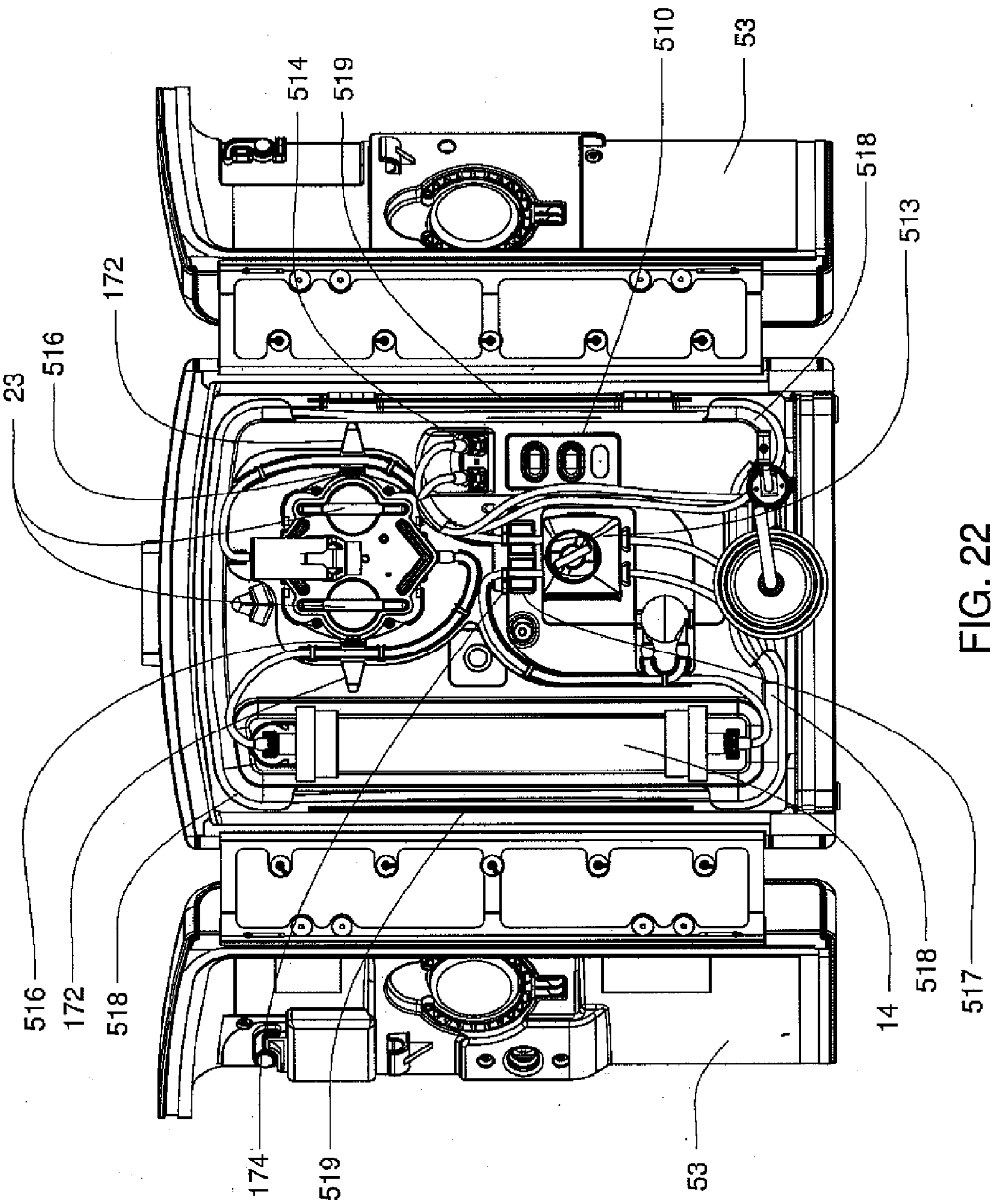
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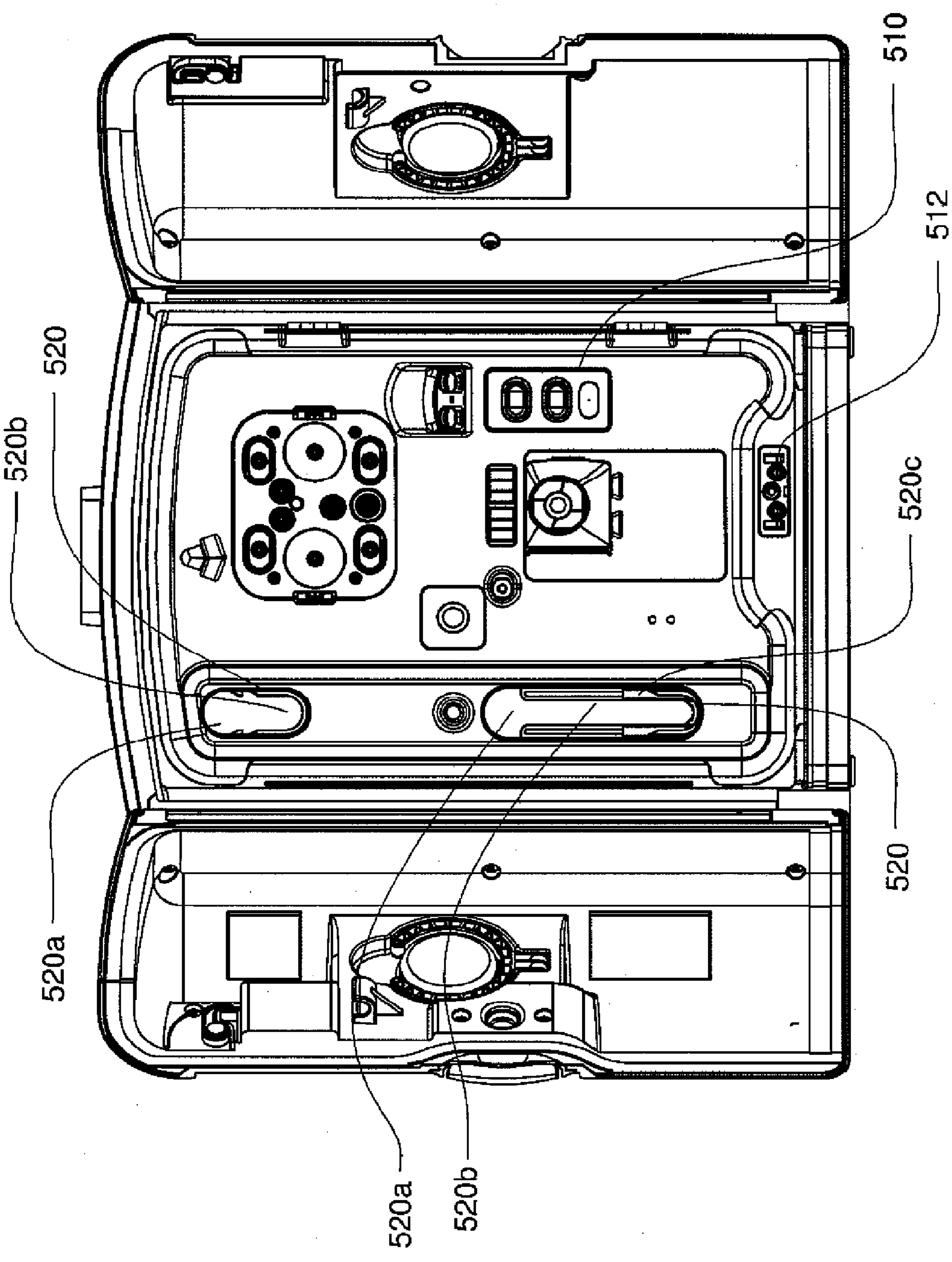
FIG. 22



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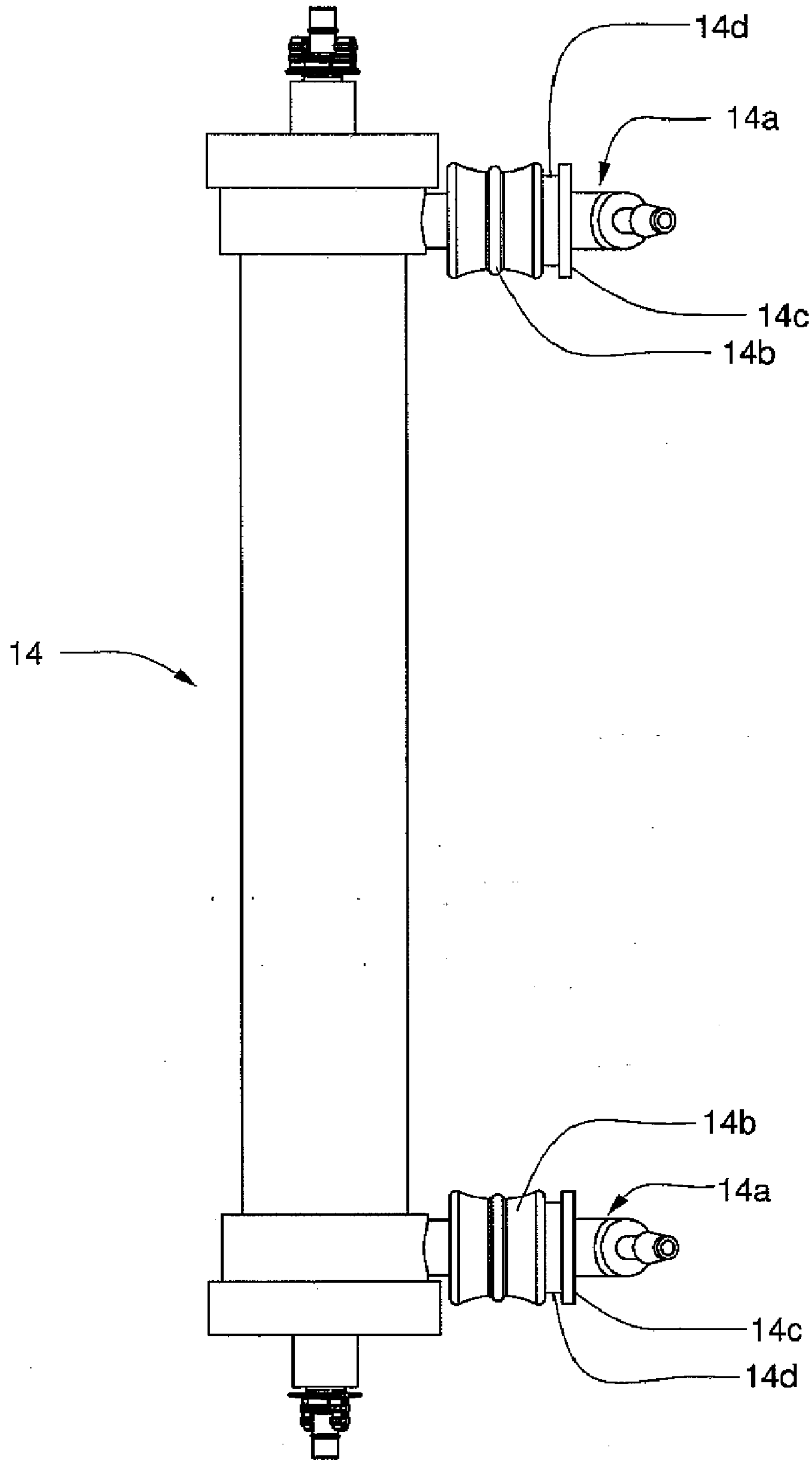

FIG. 24

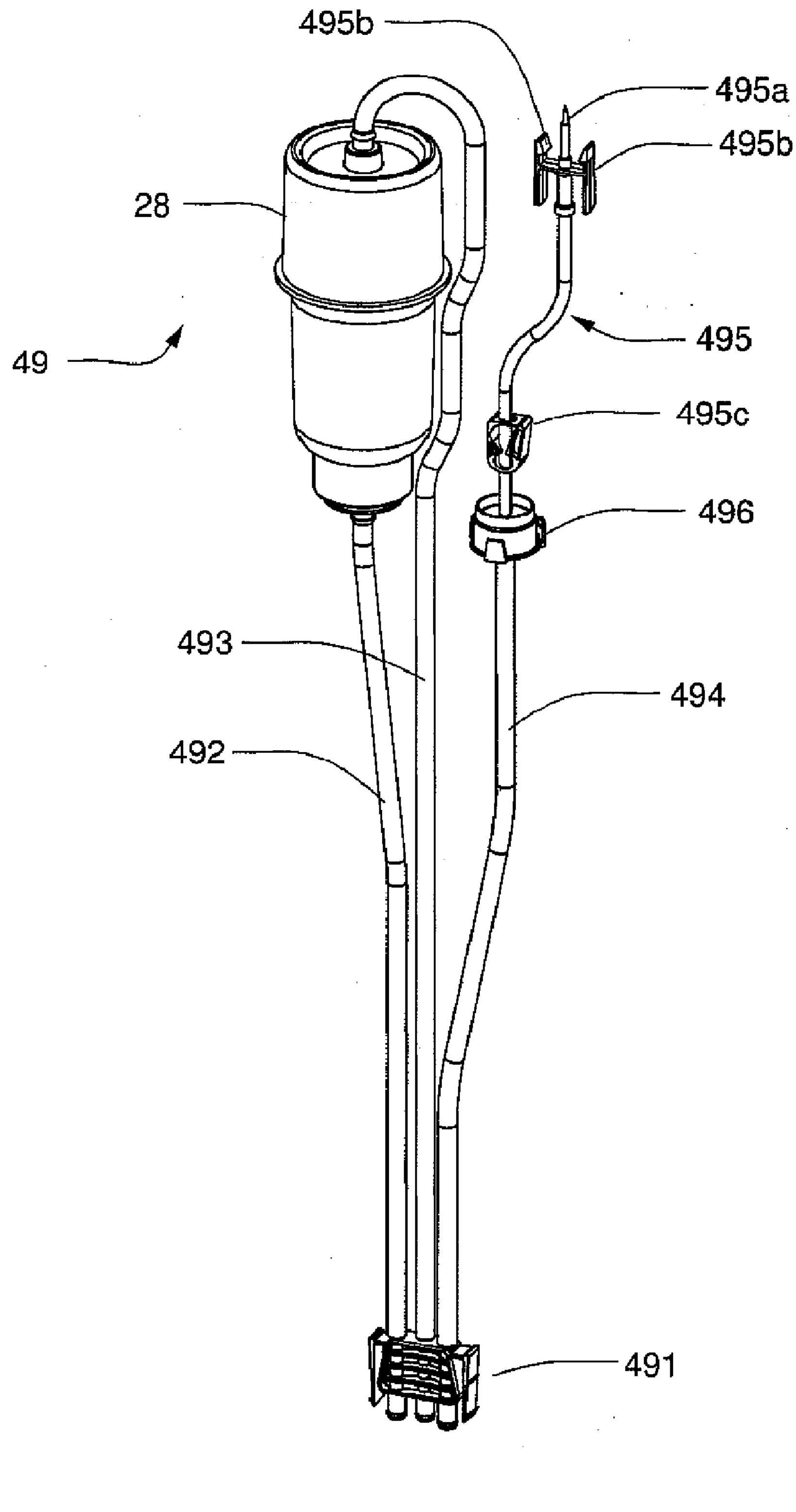

FIG. 25

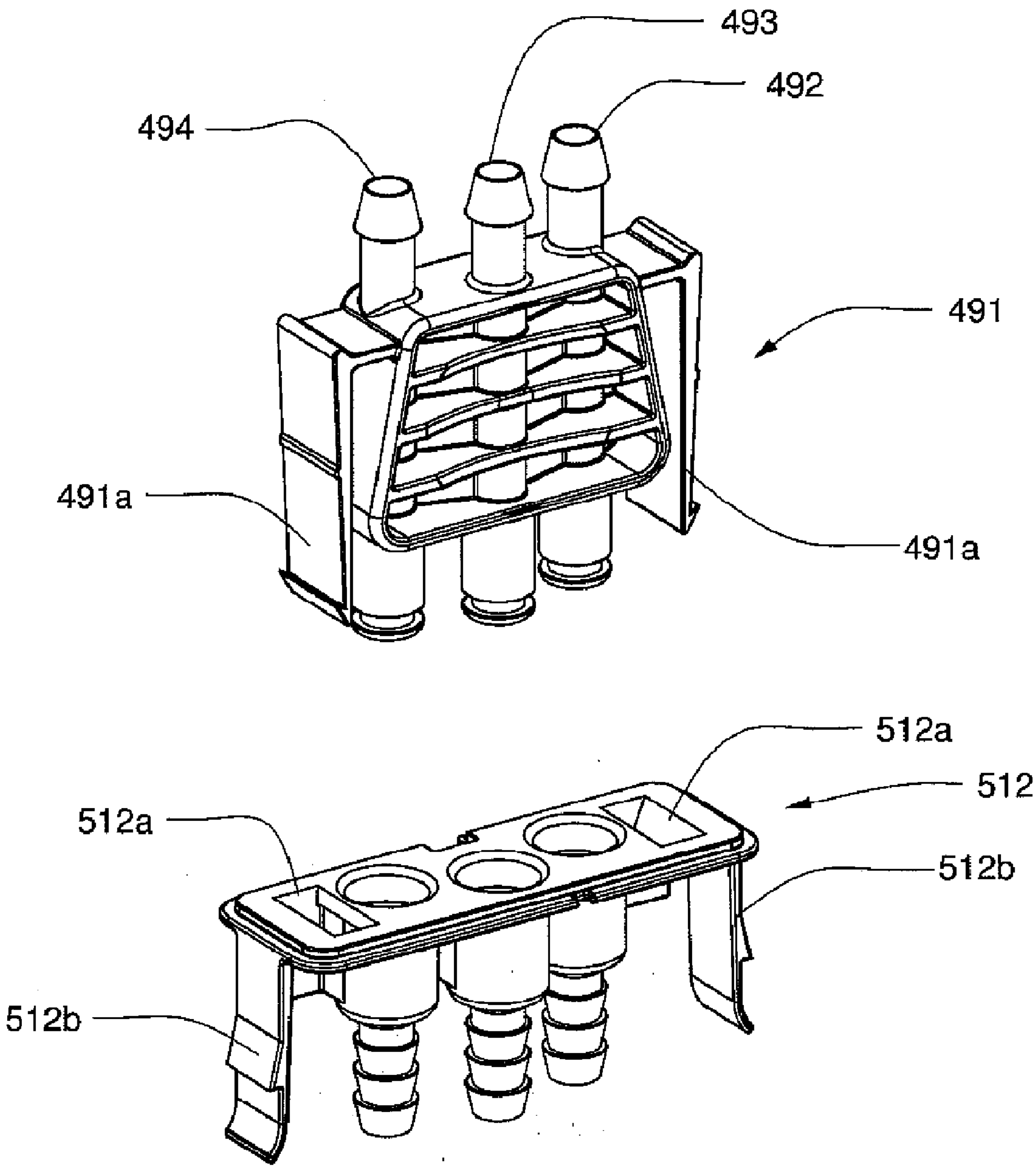

FIG. 26

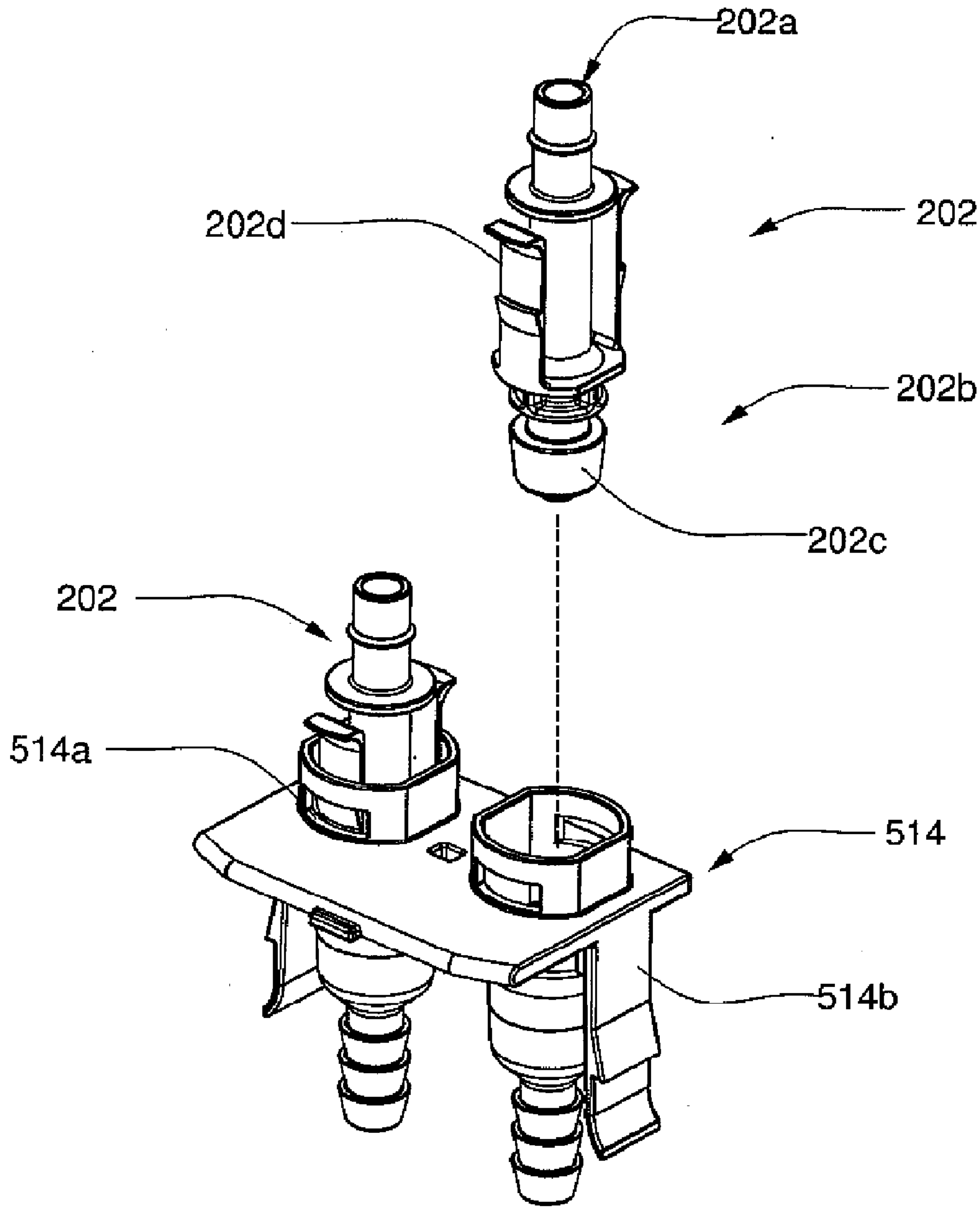

FIG. 27

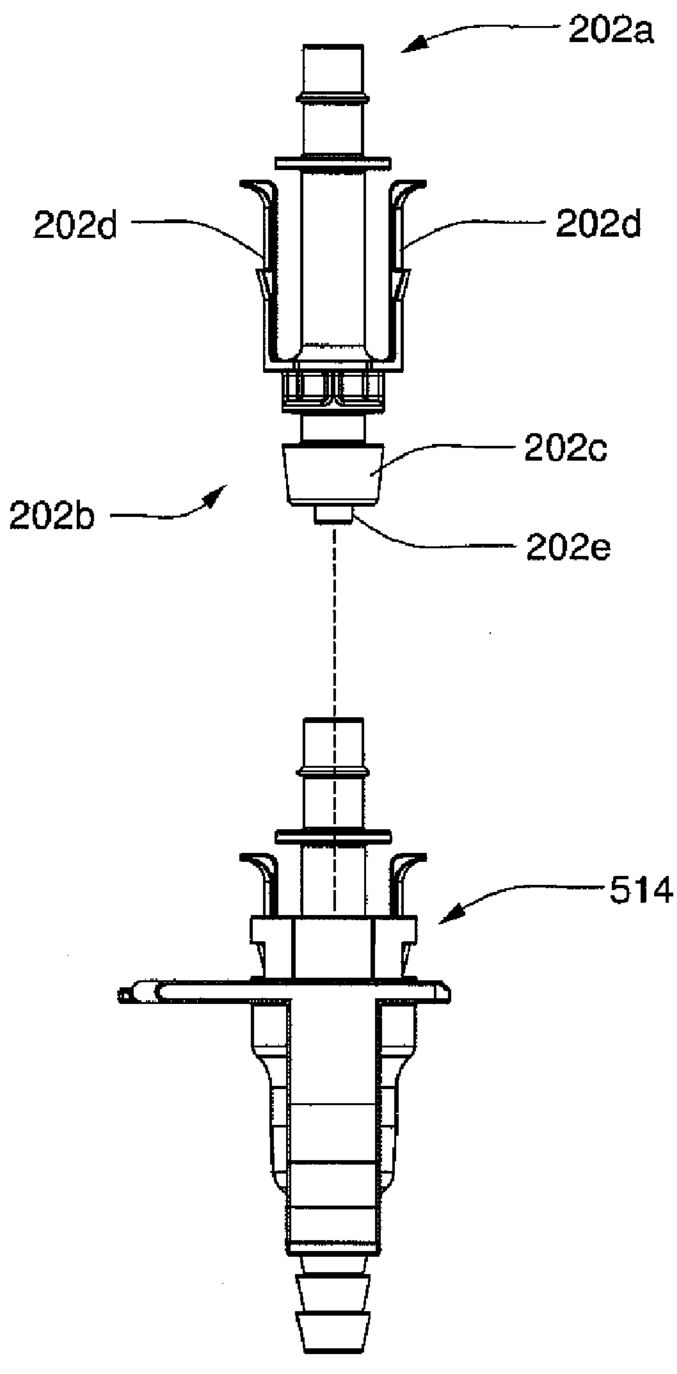

FIG. 28

AIR TRAP FOR A MEDICAL INFUSION DEVICE

FIELD OF INVENTION

[0001] The present invention generally relates to hemodialysis and similar dialysis systems, e.g., systems able to treat blood or other bodily fluids extracorporeally.

BACKGROUND

[0002] Many factors make hemodialysis inefficient, difficult, and expensive. These factors include the complexity of hemodialysis, the safety concerns related to hemodialysis, and the very large amount of dialysate needed for hemodialysis. Moreover, hemodialysis is typically performed in a dialysis center requiring skilled technicians. Therefore any increase in the ease and efficiency of the dialysis process could have an impact on treatment cost or patient outcome.

SUMMARY OF INVENTION

[0003] Aspects of the invention generally relate to hemodialysis and similar dialysis systems. Illustrative embodiments described herein involve, in some cases, interrelated products, alternative solutions to a particular problem, and/or a plurality of different uses of one or more systems and/or articles. Although the various systems and methods described herein are described in relation to hemodialysis, it should be understood that the various systems and method described herein are applicable to other dialysis systems and/or in any extracorporeal system able to treat blood or other bodily fluids, such as hemofiltration, hemodiafiltration, etc.

[0004] In one aspect of the invention, an enclosure for containing a portable hemodialysis unit is provided, where the hemodialysis unit includes suitable components for performing hemodialysis including a dialyzer, one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. The enclosure may include a housing that supports the components of the hemodialysis unit and has a front panel at which blood circuit connections and dialysate fluidic connections are located. For example, the front panel may support blood line connections for patient blood access, connections for a reagent supply, dialyzer connections for both blood flow and dialysate, etc. Thus, in one embodiment, an operator may complete all necessary fluid circuit connections for the blood circuit and reagent supply at the housing front panel. The enclosure may also include a pair of vertical, side-by-side doors hingedly mounted to the housing at opposite sides of the front panel so that the doors are movable between open and closed positions. With the doors in an open position, an operator may have access to the blood circuit connections and dialysate fluidic connections. Also, with the doors in the closed position, access to the patient access and dialysate fluidic connections may be blocked, and the doors may allow for the retention of heat in the housing suitable for disinfection during a disinfection cycle. For example, at least one of the doors may include a seal to resist air exchange between an interior and an exterior of housing when the doors are in the closed position to help retain heat and/or help resist entry of dust, dirt or other contaminants.

[0005] In one embodiment, each of the vertical, side-by-side doors is mounted to the housing via a hinge plate that is pivotally mounted to the door at a first end, and is pivotally mounted to the housing at a second end opposite the first end. Thus, the doors may be positionable at two open positions, e.g., a first open position in which blood circuit connections and dialysate fluidic connections are exposed and the hinge plate is adjacent the housing, and a second open position in which the hinge plate is positioned away from the housing. One or more retainer members may be included to maintain the doors in an open position relative to a corresponding hinge plate. For example, the retainer member may include at least one magnet attached to the door or the hinge plate that tends to keep the door in an open position relative to the hinge plate and the housing. Also, one or more retainer members may maintain the hinge plates in a closed position relative to the housing, e.g., in a position close to the housing, and/or maintain the hinge plates in an open position away from the housing.

[0006] In one embodiment, at least one of the doors may include a container holder that is movable between a folded position and an extended position in which the container holder is arranged to support a container, such as reagent supply container. In addition, or alternately, one or both of the doors may include a hook to support a control interface for the hemodialysis unit, such as a remote interface unit that is connected to the housing by a communication cable. These features may make use of the dialysis unit easier by supporting components in a convenient location.

[0007] In another embodiment, the front panel may include at least one flanged portion to support blood lines of a blood circuit assembly. For example, the front panel may include several flanged sections arranged at a periphery of the front panel, such as at lower corners and at a top edge of the front panel. Blood circuit lines that connect to a patient may be relatively long (e.g., up to 3-4 feet or more), and may be wrapped around the periphery of the front panel and retained in place by the flanged portions. The flanged portions may be arranged to support the blood lines and allow the doors to be moved to the closed position without contacting the blood lines, e.g., to avoid pinching of the blood lines at door hinge points.

[0008] In one embodiment, the blood circuit connections at the front panel include arterial and venous blood line connectors for the blood circuit, and the dialysate fluidic connections at the front panel include a connection point for a reagent supply, dialyzer dialysate connections, and a blood line connection point for connecting the arterial and venous blood lines to a directing circuit of the dialysis unit.

[0009] The hemodialysis unit may include a control interface that is connected to the housing by a flexible cable and that is arranged to allow a user to receive information from and provide information to the hemodialysis unit. In one embodiment, the enclosure may include a control interface mounting area at a top of the enclosure where the control interface is mountable. For example, the control interface may include a foldable leg or other support that permits the control interface to be stood in a near vertical orientation on the top of the housing.

[0010] In another embodiment, the enclosure may include an electronics section that is separated and insulated from a disinfection section that is heated to disinfect components of the hemodialysis unit. For example, the disinfection section may include all of the liquid circuit components, such as valves, pumps, conduits, etc., of the various portions of the dialysis unit. The electronics section may include motors, computers or other data processing devices, computer memory, and/or other temperature sensitive electronics or other components. By isolating the electronics section from the disinfection section (at least to some degree), components in the electronics section may be spared exposure to the heat or other environmental conditions in the disinfection section whether during a disinfection operation or otherwise.

[0011] In another aspect of the invention, a portable hemodialysis system may be arranged so that power for the fluid circuit pumps of a dialysis unit may be provided by a modular power unit, e.g., a unit that can be selectively connected to or disconnected from the dialysis unit. As a result, failure of a power unit need not necessarily disable the entire dialysis system. Instead, the power unit may be replaced with another power unit, allowing for treatment to continue. For example, a modular assembly for a portable hemodialysis system may include a dialysis unit, e.g., including a housing that contains suitable components for performing hemodialysis, such as a dialyzer, one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. The housing may have a front panel at which blood circuit connections and dialysate fluidic connections are located, e.g., where an operator may make patient blood access connections, connect a reagent supply, and/or connect a dialyzer. The modular assembly may also include a power unit having a housing that contains suitable components for providing operating power to the pumps of the dialysis unit. The power unit may be selectively connected to the dialysis unit and provide power to the dialysis unit for the pumps when connected to the dialysis unit, but may be incapable of providing power to the dialysis unit when disconnected from the dialysis unit. The power unit may be selectively connected to and disconnected from the dialysis unit by operation of a single handle, e.g., an operator may turn or otherwise operate a single handle to disconnect the power unit from the dialysis unit. In one embodiment, the dialysis unit and the power unit are sized and weighted to each be carried by hand by a human.

[0012] In one embodiment, the pumps of the dialysis unit are pneumatic pumps and the power unit provides pneumatic power to the dialysis unit. For example, the power unit may provide air pressure and/or vacuum to the dialysis unit to power the pumps. The power unit may include one or more air pressure pumps and/or air vacuum pumps, and the dialysis unit may include a plurality of valves to control application of pneumatic power to the pumps. To aid with use of the hemodialysis system in the home, the power unit and dialysis unit electrical power requirements may be provided by standard residential electrical power, e.g., approximately 110 V, 15 amp electrical power. The dialysis unit may provide electrical power to the power unit, and the power unit may use the electrical power to generate operating power for the pumps.

[0013] In another aspect of the invention, a blood circuit assembly for a dialysis unit may be arranged to allow the replacement of most or all blood circuit components in a single operation. For example, the blood circuit assembly may include an organizing tray, a pair of pneumatic pumps mounted to the organizing tray for circulating blood received from a patient through a circuit including a dialyzer unit and returned to the patient, an air trap mounted to the organizing tray arranged to remove air from blood circulating in the circuit, a pair of dialyzer connections arranged to connect to the inlet and outlet of a dialyzer unit, and a pair of blood line connectors, one inlet blood line connector for receiving blood from the patient and providing blood to the pneumatic pumps and the other outlet blood line connector for returning blood to the patient.

[0014] In one embodiment, an anticoagulant connection is provided for engaging with an anticoagulant source and providing anticoagulant into the blood circuit. For example, the anticoagulant connection may include a pump for pumping anticoagulant from the anticoagulant source, such as heparin from a vial of heparin, to the circuit. The anticoagulant connection may include a vial holder arranged to hold two or more differently sized vials, and a spike to pierce the vial. In one embodiment, the pair of pneumatic pumps, the anticoagulant connection, and the anticoagulant pump are part of a pump cassette.

[0015] In another embodiment, the blood circuit assembly may be selectively mounted to and removed from a dialysis unit. To aid in handling of the blood circuit assembly, the organizing tray may include a pair of handles arranged for gripping by a user. The organizing tray may also include openings adjacent each of the handles for receiving retaining tabs on a dialysis unit that engage with the blood circuit assembly and retain the blood circuit assembly on the dialysis unit.

[0016] In one embodiment, the inlet blood line connector is connected to an inlet for the pump cassette, an outlet for the pump cassette is connected to a dialyzer inlet connector, a dialyzer outlet connector is connected to an inlet of the air trap, and an outlet of the air trap is connected to the outlet blood line connector. The inlet of the air trap may be located above the outlet of the air trap when the blood circuit assembly is mounted to a dialysis unit, e.g., to aid in trapping of air circulating in the circuit during treatment. The blood line connectors may be arranged for a threaded luer-type connection to a patient access, as well as be arranged for a press-in type connection to the dialysis unit. Such an arrangement may make it easier for an operator to connect the blood line connectors to the dialysis unit after treatment (e.g., for later disinfection and/or priming of the blood circuit) while allowing the connectors to engage with standard luer-type connectors at a patient blood access.

[0017] In one embodiment, the organizing tray may include circuit tube engagement members having a hole or slot through which a respective circuit tube passes. The engagement members may engage with the respective circuit tube to allow the circuit tube to be pulled and stretched for engagement with an occluder of the dialysis unit. For example, the circuit tubes of the blood circuit assembly may include silicone tubing that has to be stretched (and thereby reduced in diameter) to engage with an occluder. The circuit tube engagement members may resist the pull of an operator on the tubes, allowing the tubes to be stretched and placed in engagement with the occluder.

[0018] In another aspect of the invention, a method for replacing a blood circuit assembly of a dialysis unit includes grasping a pair of handles on an organizing tray of a blood circuit assembly that is mounted to a dialysis unit, disengaging locking tabs of the dialysis unit from the blood circuit assembly to free the blood circuit assembly from the dialysis unit, and pulling on the handles on the organizing tray of the blood circuit assembly to remove the blood circuit assembly from the dialysis unit. Disengagement of the locking tabs may be performed by flexing the locking tabs away from each other such that each locking tab is moved toward a nearest one of the handles. After removal of the blood circuit assembly, a replacement blood circuit assembly may be provided, openings in the organizing tray of the replacement blood circuit assembly may be aligned with the locking tabs so that each locking tab is received into a respective opening, and the organizing tray may be pushed relative to the dialysis unit such that the locking tabs engage with the replacement blood circuit assembly to mount the replacement blood circuit assembly to the dialysis unit. Mounting the replacement blood circuit assembly may also involve connecting control ports on the dialysis unit to mating ports on the assembly so that fluid control signals may be provided for pumps and valves of the blood circuit assembly. Other blood circuit connections may be made, such as inlet and outlet connections for the dialyzer, and the blood line connectors may be connected to receive dialysate into the blood circuit.

[0019] In another aspect of the invention, an air trap for a blood circuit in a dialysis unit includes a blood inlet supply line, a blood outlet supply line, and a container having an approximately spherical internal wall, an inlet at a top end of the container connected to the blood inlet supply line, and an outlet at a bottom end of the container connected to the blood outlet supply line. The inlet may be offset from a vertical axis of the approximately spherical internal wall such that blood entering the container through the inlet is directed to flow in around the approximately spherical wall in a spiral-like path. Such flow in the container may help to remove air bubbles from the blood as it flows from the inlet to the outlet, with any removed air remaining near the top of the container. The inlet port may be arranged to introduce blood into the container in a direction that is approximately tangential to the approximately spherical inner wall of the container and/or in a direction that is approximately perpendicular to the vertical axis of the container.

[0020] In one embodiment, a self-sealing port may be located at a top of the container, e.g., in the form of a split septum that is arranged to permit introduction of fluid into, and withdrawal of liquid from, the container by inserting a needleless device through the split septum. The self-sealing port may be arranged to be self-cleaning when disinfection liquid is circulated through the container, e.g., the port may be suitably exposed to flowing disinfection liquid to remove debris and/or heat material on the port to achieve desired disinfection.

[0021] In another aspect of the invention, a tube securing arrangement of a blood circuit assembly includes a organizing tray that supports components of a blood circuit assembly and includes a pair of tube engagement members each having a hole, a pair of patient inlet and outlet lines arranged to connect with patient access points for receiving liquid from and/or providing liquid to the patient, and a pair of stops on the patient inlet and outlet lines, respectively. The patient inlet and outlet lines may each pass through a hole of a respective tube engagement member so that the stop engages with the tube engagement member. With this arrangement, the tube engagement members may resist pulling and stretching of the inlet and outlet lines when engaging the lines with an occluder. The tube engagement members may be flexible to allow a user to press inwardly on the engagement member and seat the respective inlet or outlet line in the occluder, yet resist downward pulling of the line.

[0022] In another aspect of the invention, a hemodialysis system includes a dialyzer mount arranged to support a plurality of differently sized and/or shaped dialyzer units and to accommodate different distances between dialysate connections on the dialyzer units. The dialyzer mount, which may be located on a front panel of the dialysis unit, may include a pair of flange portions that are each arranged to engage with a respective dialysate quick-connect fitting connected to a dialysate port of the dialyzer. Each flange portion may be arranged to engage with a groove on the quick connect fitting that is located between a portion of the base of the quick connect fitting and a slide element of the quick connect fitting. For example, the dialyzer mount may include a pair of keyhole features with each keyhole feature having an upper insertion area sized to receive a portion of the base of the quick-connect fitting inserted into the upper insertion area, and a lower flanged portion having a width that is smaller than an overall a width of the base of the quick-connect fitting and that engages with a groove on the quick connect fitting. The lower flanged portion may include a pair of opposite flanges that engage with the groove and allow the quick-connect fitting to slide along the flanges.

[0023] In one embodiment, the bottom keyhole feature may include an adjustable support that is moveable in a vertical direction. For example, the adjustable support may be movable along the opposed flanges. Thus, the adjustable support may be fixable in a plurality of different positions on the flanges to support the weight of the dialyzer. In one arrangement, the adjustable support includes a "U" shaped member and at least one thumb screw that may be tightened to fix the "U" shaped member in place.

[0024] In another aspect of the invention, a blood line connector for a blood circuit of a hemodialysis unit may have the ability to make two different types of fluid tight connections, e.g., a screw-type connection with a luer connector at a patient access and a press-in type connection with a dialysate circuit of the hemodialysis unit. For example, the blood line connector may include a tube connection end arranged to sealingly engage with a blood circuit tube, and a patient access connection end with a frustoconical member having an internally threaded portion arranged to engage with an externally threaded patient access, and a pair of locking arms extending rearwardly from the frustoconical member. The locking arms may each have a finger depression portion and a barbed portion, and may be arranged to engage with a mating connector on the dialysis unit at the barbed portions to lock the frustoconical member in sealing engagement with the mating connector when making a press-in type connection. The barbed portions may disengage from the mating connector when the finger depression portions are urged toward each other. In one embodiment, the patient access connection end may include a central tube extending from the center of the frustoconical member. The internally threaded portion of the frustoconical member and the central tube may be arranged to mate with a female luer-type patient access connector or any other suitable screw-type connection.

[0025] In another aspect of the invention, a method for operating a dialysis unit includes connecting blood line connectors of arterial and venous blood lines for a dialysis unit to patient access connectors in communication with a patient blood system. In one embodiment, the patient access connectors may require a corresponding blood line connector to establish a threaded engagement with the patient access connector, thereby forming a luer or screw-type connection between the blood line connectors and the patient access connectors. The dialysis unit may be operated to withdraw blood from a patient access connector and into an arterial blood line, subject the withdrawn blood to a dialysis process to produce treated blood, and return the treated blood to the patient via the venous blood line and the other patient access connector. Thereafter, the blood line connectors may be disconnected from the patient access connectors by unscrewing the blood line connectors from a corresponding patient access connector, and the blood line connectors may be connected to a directing circuit of the dialysis unit. The blood line connectors may be connected to the directing circuit by a press-in connection with a corresponding connection point on the dialysis unit, e.g., by pushing the blood line connectors into the connection points to establish the press-in connection.

[0026] In another aspect of the invention, a reagent supply arrangement for a hemodialysis system may be arranged to provide two or more reagent materials for use in preparing a dialysate and may include a connector arranged to help prevent the connection of a reagent material to the wrong port. For example, the reagent supply may include an E-prong connector having three parallel prongs with two outer prongs arranged in a common plane and a center prong arranged above the common plane, a first supply line for a first reagent connected in fluid communication with one of the outer prongs, a second supply line for a second reagent connected in fluid communication with the other of the outer prongs, a liquid line connected in fluid communication with the center prong, and a container for housing the first reagent having an inlet connected to the liquid line and an outlet connected to the first supply line for the first reagent. The E-prong connector may help prevent the improper connection of the first and second supply lines to the dialysis unit, e.g., because the central prong being located out of the plane of the two outer prongs ensure connection of the E-prong connector in only one way to the dialysis unit.

[0027] In one embodiment, the container includes a bicarbonate material suitable for use in generating a dialysate for the hemodialysis system. The liquid line may be a water supply line that provides water to the container, allowing the water to mix with the bicarbonate (which may be in powder or other solid form) and flow to the first supply line. The second supply line may be an acid supply line that includes a connector and provides acid material to the E-prong connector. The reagent supply may also include an acid bag spike that is removably engaged with the connector of the acid supply line. The acid bag spike may include a spike member and a pair of spring clips at an end of the acid bag spike opposite the connector of the acid supply line, allowing the acid bag spike to be fluidly connected with an acid bag or other acid source.

[0028] In another aspect of the invention, a method for operating a hemodialysis system includes providing a dialysis unit having an enclosure containing suitable components for performing hemodialysis including a dialyzer, one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. The enclosure may include a housing that supports the components and has a front panel at which blood circuit connections and dialysate fluidic connections are made. A reagent supply may be provided including an E-prong connector, a first supply line for a first reagent connected in fluid communication with one of the outer prongs, a second supply line for a second reagent connected in fluid communication with the other of the outer prongs, a liquid line connected in fluid communication with the center prong, and a container for housing the first reagent having an inlet connected to the liquid line and an outlet connected to the first supply line for the first reagent. The E-prong connector may be engaged with a connection point at the front panel of the dialysis unit, thereby allowing the dialysis unit to provide water to the liquid line of the reagent supply, and allowing the dialysis unit to receive the first and second reagents from the first and second supply lines.

[0029] Other advantages and novel features of the present invention will become apparent from the following detailed description of various non-limiting embodiments of the invention when considered in conjunction with the accompanying figures. In cases where the present specification and a document incorporated by reference include conflicting and/or inconsistent disclosure, the present specification shall control. If two or more documents incorporated by reference include conflicting and/or inconsistent disclosure with respect to each other, then the document having the later effective date shall control.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Aspects of the invention are described with reference to illustrative embodiments, which are described with reference to the drawings in which like numerals reference like elements, and wherein:

[0031] FIG. **1** is a schematic representation of fluid handling components of a hemodialysis system in an illustrative embodiment;

[0032] FIG. **2** shows a schematic fluid flow diagram for the dialysis system of FIG. **1**;

[0033] FIG. **3** is a schematic fluid flow diagram for the blood flow circuit of the FIG. **2** embodiment;

[0034] FIG. **4** is a schematic fluid flow diagram for the balancing circuit of the FIG. **2** embodiment;

[0035] FIG. **5** is a schematic fluid flow diagram for the directing circuit of the FIG. **2** embodiment;

[0036] FIG. **6** is a schematic fluid flow diagram for the mixing circuit of the FIG. **2** embodiment;

[0037] FIG. **7** is a right front perspective view of a hemodialysis system in an illustrative embodiment;

[0038] FIG. **8** is a left rear perspective view of the hemodialysis system of FIG. **7**;

[0039] FIG. **9** is a front view of the hemodialysis system of FIG. **7**;

[0040] FIG. **10** is a right front perspective view of the view of the hemodialysis system of FIG. **7** with the doors in a first open position;

[0041] FIG. **11** is a top view of the hemodialysis system of FIG. **10**;

[0042] FIG. **12** is a front view of the hemodialysis system of FIG. **10**;

[0043] FIG. **13** is a right side view of the hemodialysis system of FIG. **10**;

[0044] FIG. **14** is a right front perspective view of the view of the hemodialysis system of FIG. **7** with the doors in a second open position;

[0045] FIG. **15** is a top view of the hemodialysis system of FIG. **14**;

[0046] FIG. **16** is a front view of the hemodialysis system of FIG. **14**;

[0047] FIG. **17** is a front view of the hemodialysis system of FIG. **7** with the doors in an open position exposing a front panel of the system;

[0048] FIG. **18** is a front view of a blood circuit assembly for use with the system of FIG. **7**;

[0049] FIG. **19** right perspective view of a organizing tray for the blood circuit assembly of FIG. **18**;

[0050] FIG. **20** is a left rear perspective view of the blood circuit assembly of FIG. **18**;

[0051] FIG. **21** shows a left front perspective view of the front panel of the system of FIG. **7**;

[0052] FIG. **22** shows a front view of the front panel of the system of FIG. **7**;

[0053] FIG. **23** shows a front view of the front panel of the system of FIG. **7** with a pair of mounting features for the dialyzer;

[0054] FIG. **24** shows a side view of a dialyzer with quick-connect fittings attached to the dialysate inlet/outlet ports of the dialyzer;

[0055] FIG. **25** shows a right perspective view of a reagent supply for use with the system of FIG. **7**;

[0056] FIG. **26** shows a perspective view of an E-prong connector for the reagent supply of FIG. **25** and a corresponding connection point at the front panel of the hemodialysis system;

[0057] FIG. **27** shows a perspective view of a pair of blood line connectors for the blood circuit assembly and a corresponding connection point at the front panel of the hemodialysis system; and

[0058] FIG. **28** shows a side view of a blood line connector and connection point of FIG. **27**.

DETAILED DESCRIPTION

[0059] Various aspects of the invention are generally directed to new systems for hemodialysis and the like, such as hemofiltration systems, hemodiafiltration systems, plasmapheresis systems, etc. Accordingly, although the various systems and methods described herein are described in relation to hemodialysis, it should be understood that the various systems and method described herein are applicable to other dialysis systems and/or in any extracorporeal system able to treat blood or other bodily fluids, such as plasma.

[0060] As discussed below, a hemodialysis system typically includes a blood flow path and a dialysate flow path. It should be noted that within such flow paths, the flow of fluid is not necessarily linear, and there may be any number of "branches" within the flow path that a fluid can flow from an inlet of the flow path to an outlet of the flow path. Examples of such branching are discussed in detail below. In the blood flow path, blood is drawn from a patient, and is passed through a dialyzer, before being returned to the patient. The blood is treated by the dialyzer, and waste molecules (e.g., urea, creatinine, etc.) and water are passed from the blood, through a semi-permeable membrane in the dialyzer, into a dialysate solution that passes through the dialyzer by the dialysate flow path. In various embodiments, blood may be drawn from the patient from two lines (e.g., an arterial line and a venous line, i.e., "dual needle" flow), or in some cases, blood may be drawn from the patient and returned through the same or catheter needle (e.g., the two lines or lumens may both be present within the same needle, i.e., a form of "dual lumen" flow). In still other embodiments, a "Y" site or "T" site is used, where blood is drawn from the patient and returned to the patient through one patient connection having two branches (one being the fluid path for the drawn blood, the second the fluid path for the return blood, i.e., a form of "single needle" flow). The patient may be any subject in need of hemodialysis or similar treatments, including non-human subjects, such as dogs, cats, monkeys, and the like, as well as humans.

[0061] In the dialysate flow path, fresh dialysate is prepared and is passed through the dialyzer to treat the blood from the blood flow path. The dialysate may also be equalized for blood treatment within the dialyzer (i.e., the pressure between the dialysate and the blood are equalized), often exactly, or in some embodiments, at least within about 1% or about 2% of the pressure of the blood. In some cases, it may be desirable to maintain a greater pressure difference (either positive or negative) between the blood flow path and dialysate flow path. After passing through the dialyzer, the used dialysate, containing waste molecules (as discussed below), is discarded in some fashion. The dialysate in some cases may be re-circulated in a "multi-pass" arrangement, which may be beneficial in capturing larger molecules having low mobility across the dialyzer. In some cases, the dialysate is heated prior to treatment of the blood within the dialyzer using an appropriate heater, such as an electrical resistive heater. The dialysate may also be filtered to remove contaminants, infectious organisms, debris, and the like, for instance, using an ultrafilter. The ultrafilter may have a pore size chosen to prevent species such as these from passing therethrough. For instance, the pore size may be less than about 0.3 micrometers, less than about 0.2 micrometers, less than about 0.1 micrometers, or less than about 0.05 micrometers, etc. The dialysate is used to draw waste molecules (e.g., urea, creatinine, ions such as potassium, phosphate, etc.) and water from the blood into the dialysate through osmosis or convective transport, and dialysate solutions are well-known to those of ordinary skill in the art.

[0062] The dialysate typically contains various ions such as sodium, chloride, bicarbonate, potassium and calcium that are similar in concentration to that of normal blood. In some cases, the bicarbonate, may be at a concentration somewhat higher than found in normal blood. Typically, the dialysate is prepared by mixing water from a water supply with one or more ingredients: an "acid" (which may contain various species such as acetic acid, dextrose, NaCl, CaCl, KCl, MgCl, etc.), sodium bicarbonate ($NaHCO_3$), and/or sodium chloride (NaCl). The preparation of dialysate, including using the appropriate concentrations of salts, osmolarity, pH, and the like, is well-known to those of ordinary skill in the art. As discussed in detail below, the dialysate need not be prepared at the same rate that the dialysate is used to treat the blood. For instance, the dialysate can be made concurrently or prior to dialysis, and stored within a dialysate storage vessel or the like.

[0063] Within the dialyzer, the dialysate and the blood typically are separated by a semi-permeable membrane. Typically, the semipermeable membrane is formed from a polymer such as cellulose, polyarylethersulfone, polyamide, polyvinylpyrrolidone, polycarbonate, polyacrylonitrile, or the like, which allows the transport of ions or small molecules (e.g., urea, water, etc.), but does not allow bulk transport or convection during treatment of the blood. In some cases (such as high-flux dialyzers), even larger molecules, such as beta-2-microglobulin, may pass through the membrane. In some cases, for example, ions and molecules may pass through the dialyzer by convective flow if a hydrostatic pressure difference exists across the semi-permeable membrane.

[0064] It should be noted that, as used herein, "fluid" means anything having fluidic properties, including but not limited to, gases such as air, and liquids such as water, aqueous solution, blood, dialysate, etc.

[0065] FIG. 1 shows a schematic block diagram of fluid circuitry for a hemodialysis system that incorporates various aspects of the invention. In this illustrative embodiment, the dialysis system 5 includes a blood flow circuit 141 that draws blood from a patient, passes the blood through a dialyzer 14, and returns the treated blood to the patient. A balancing circuit or an internal dialysate circuit 143 receives dialysate from an ultrafilter 73, passes the dialysate through the dialyzer 14, and receives used dialysate from the dialyzer 14. A directing circuit or an external dialysate circuit 142 provides fresh dialysate to the ultrafilter 73, and receives used dialysate from the internal dialysate circuit 143 (which may be directed to a drain 31). The directing circuit 142 can also receive water from a water supply 30 and pass it to a mixing circuit 25. The mixing circuit 25 forms dialysate using water from the directing circuit 142 and reagent ingredients 49, such as citric acid, salt and a bicarbonate, that may be received from a renewable source. The mixing circuit 25 may prepare dialysate, for example, on an as-needed basis, during and/or in advance of dialysis. New dialysate prepared by the mixing circuit 25 may be provided to the directing circuit 142, which may provide the dialysate to the ultrafilter 73, as described above. The directing circuit 142 may include a heater to heat the dialysate to a suitable temperature and/or to heat fluid in the system for disinfection. Conduits 67 (shown in dotted line) may be connected between the blood flow circuit 141 and the directing circuit 142, e.g., for disinfection of the hemodialysis system.

[0066] FIG. 2 is a schematic diagram showing a more detailed circuit arrangement for the dialysis system 5 shown in FIG. 1. It should be understood, of course, that FIG. 2 is only one possible embodiment of the general hemodialysis system of FIG. 1, and in other embodiments, other fluid circuits, modules, flow paths, layouts, etc. are possible. Examples of such systems are discussed in more detail below, and also can be found in the following, each of which is incorporated herein by reference: U.S. application Ser. No. 12/072,908, filed Feb. 27, 2008, U.S. Provisional Application 60/903,582, filed Feb. 27, 2007, U.S. Provisional Application 60/904,024, filed Feb. 27, 2007, U.S. patent application Ser. No. 11/871,680, filed Oct. 12, 2007, U.S. patent application Ser. No. 11/871,712, filed Oct. 12, 2007, U.S. patent application Ser. No. 11/871,787, filed Oct. 12, 2007, U.S. patent application Ser. No. 11/871,793, filed Oct. 12, 2007, or U.S. patent application Ser. No. 11/871,803, filed Oct. 12, 2007.

[0067] The blood flow circuit 141 includes an anticoagulant supply 11 and a blood flow pump 13 which pumps blood from a patient through a dialyzer 14 and returns the blood to the patient. The anticoagulant supply 11, although shown in the path of blood flowing towards the dialyzer, may be instead located in another suitable location. e.g., any location upstream or downstream from blood flow pump 13. The balancing circuit 143 includes two dialysate pumps 15, which pump dialysate into the dialyzer 14, and a bypass pump 35. The flow of blood through the blood flow circuit 141 in some cases, is synchronized with the flow of dialysate in the dialysate flow path. In an embodiment, the flow of dialysate into and out of the dialyzer 14 and the balancing circuit 143 is balanced volumewise using balancing chambers in the balancing circuit 143. The directing circuit 142 includes a dialysate pump 159, which pumps dialysate from a dialysate tank 169 through a heater 72 and/or the ultrafilter 73 to the balancing circuit 143. The directing circuit 142 also receives waste fluid from balancing circuit 143 and directs it to a drain 31. In some cases, the blood flow circuit 141 can be connected via conduits 67 to the directing circuit 142, e.g., for disinfection, as discussed below. Dialysate in the dialysate tank 169 is provided by the mixing circuit 25, which produces the dialysate using water from a water supply 30 provided via the directing circuit 142 and dialysate ingredients 49 (e.g., bicarbonate and acid). A series of mixing pumps 180, 183, 184 are used to mix the various components and produce the dialysate.

[0068] FIG. 3 shows a close-up view of the blood flow circuit 141 in this illustrative embodiment. Under normal operation, blood flows from a patient through arterial line 203 via blood flow pump 13 to the dialyzer 14 (the direction of flow during normal dialysis is indicated by arrows 205; in some modes of operation, however, the flow may be in different directions, as discussed below). Optionally, an anticoagulant may be introduced into the blood via anticoagulant pump 80 from an anticoagulant supply. After passing through dialyzer 14 and undergoing dialysis, the blood returns to the patient through venous line 204, optionally passing through an air trap and/or a blood sample port 19. The pump 13 may include, for instance, pumps 23 that are actuated by a control fluid.

[0069] For example, in one embodiment, the blood flow pump 13 may comprise two (or more) pod pumps 23. Each pod pump, in this particular example, may include a rigid chamber with a flexible diaphragm or membrane dividing each chamber into a pumping compartment and control compartment. There may be four entry/exit valves for these compartments, two for the pumping compartment and two for the control compartment. The valves for the control compartment of the chambers may be two-way proportional valves, one connected to a first control fluid source (e.g., a high pressure air source), and the other connected to a second control fluid source (e.g., a low pressure air source) or a vacuum source. The fluid valves can be opened and closed to direct fluid flow when the pod pumps 23 are operating. Non-limiting examples of pod pumps are described in U.S. Provisional Application 60/792,073, filed Apr. 14, 2006, or in U.S. patent application Ser. No. 11/787,212, filed Apr. 13, 2007, each incorporated herein by reference. If more than one pod pump is present, the pod pumps may be operated in any suitable fashion, e.g., synchronously, asynchronously, in-phase, out-of-phase, etc. For instance, in some embodiments, the two-pump pumps can be cycled out of phase to affect the pumping cycle, e.g., one pump chamber fills while the second pump chamber empties. A phase relationship anywhere between 0° (the pod pumps fill and empty in unison) and 180° (one pod pump fills as the other empties) can be selected in order to impart any desired pumping cycle. A phase relationship of 180° may yield continuous flow into and out of the set of pod pumps. This is useful, for instance, when continuous flow is desired, e.g., for use with dual needle or dual lumen catheter flow. Setting a phase relationship of 0°, however, may be useful in some cases for single needle/single lumen flow or in other cases. In a 0° relationship, the pod pumps will first fill from the needle, then deliver blood through the blood flow path and back to the patient using the same needle. In addition, running at phases between 0° and 180° can be used in some cases, to achieve a push/pull relationship (hemodiafiltration or continuous back flush) across the dialyzer.

[0070] An anticoagulant (e.g., heparin, or any other suitable anticoagulant) may be contained within a vial 11 (or other anticoagulant supply, such as a tube or a bag), and blood flow circuit 141 may include a spike 201 (which, in one embodiment, is a needle) that can pierce the seal of the vial. The spike **201** may be formed from plastic, stainless steel, or another suitable material, and may be a sterilizable material in some cases, e.g., the material may be able to withstand sufficiently high temperatures and/or radiation so as to sterilize the material.

[0071] An anticoagulant pump **80**, which can act as a metering chamber in some cases, can be used to control the flow of anticoagulant into the blood circuit. The anticoagulant pump **80** may be a pod pump or a membrane-based metering pump, and/or may be actuated by a control fluid, such as air. For example, the anticoagulant pump **80** may include a rigid chamber with a flexible diaphragm dividing the chamber into a pumping compartment and a control compartment. One valve for the control compartment of the chamber may be connected to a first control fluid source (e.g., a high pressure air source), and the other valve connected to a second control fluid source (e.g., a low pressure air source) or a vacuum source. Valves for the pumping compartment of the chamber can be opened and closed in coordination with the control compartment, thus controlling the flow of anticoagulant into the blood. In one set of embodiments, air provided through a filter **81** may also be introduced into the blood flow path by the anticoagulant pump **80**, e.g., to provide air into the vial **11** after or before anticoagulant is withdrawn from the vial.

[0072] Fluid Management System ("FMS") measurements may be used to measure the volume of fluid pumped through a pump chamber during a stroke of the membrane, or to detect air in the pumping chamber. FMS methods are described in U.S. Pat. Nos. 4,808,161; 4,826,482; 4,976,162; 5,088,515; and 5,350,357, which are hereby incorporated herein by reference in their entireties. In one illustrative embodiment, the volume of liquid delivered by an anticoagulant pump, a dialysate pump, or other membrane-based fluid pump is determined using an FMS algorithm in which changes in chamber pressure are used to calculate a volume measurement at the end of a fill stroke and at the end of a delivery stroke. The difference between the computed volumes at the end of fill and delivery strokes may be used to determine the actual stroke volume. This actual stroke volume can be compared to an expected stroke volume for the particular sized chamber. If the actual and expected volumes are significantly different, the stroke has not properly completed and an error message can be generated.

[0073] The blood flow circuit **141** may also include an air trap **19** to remove air bubbles that may be present within the blood flow path. In some cases, the air trap **19** is able to separate any air that may be present from the blood due to gravity, and/or may include a port for sampling blood.

[0074] FIG. **4** shows a close-up view of the balancing circuit **143** in the FIG. **2** embodiment. In the balancing circuit **143**, dialysate flows from the optional ultrafilter **73** into a dialysate pump **15**. In this embodiment, the dialysate pump **15** includes two pod pumps **161**, **162**, two balancing chambers **341**, **342**, and a pump **35** for bypassing the balancing chambers **341**, **342**. The balancing chambers **341**, **342** may be constructed such that they are formed from a rigid chamber with a flexible diaphragm dividing the chamber into two separate fluid compartments, so that entry of fluid into one compartment can be used to force fluid out of the other compartment and vice versa. Non-limiting examples of pumps that can be used as pod pumps and/or balancing chambers are described in U.S. Provisional Application 60/792,073, filed Apr. 14, 2006, or in U.S. patent application Ser. No. 11/787,212, filed Apr. 13, 2007.

[0075] In one embodiment, balancing of flow in the internal dialysate circuit works as follows. A set of pneumatically operated valves **211**, **212**, **213**, **241**, **242** has its operation synchronized and controlled together, where valves **211**, **212**, **213** are ganged and valves **241** and **242** are ganged, and a second set of pneumatically operated valves **221**, **222**, **223**, **231**, **232** similarly have its operation synchronized and controlled together, where valves **221**, **222**, **223** are ganged, and valves **231** and **232** are ganged. At a first point of time, the first set of valves **211**, **212**, **213**, **241**, **242** is opened while the second set of valves **221**, **222**, **223**, **231**, **232** is closed. Fresh dialysate flows into balancing chamber **341** while used dialysate flows from dialyzer **14** into pod pump **161**. Fresh dialysate does not flow into balancing chamber **342** since valve **221** is closed. As fresh dialysate flows into balancing chamber **341**, used dialysate within balancing chamber **341** is forced out and exits balancing circuit **143** (the used dialysate cannot enter pod pump **161** since valve **223** is closed). Simultaneously, pod pump **162** forces used dialysate present within the pod pump into balancing chamber **342** (through valve **213**, which is open; valves **242** and **222** are closed, ensuring that the used dialysate flows into balancing chamber **342**). This causes fresh dialysate contained within balancing chamber **342** to exit the balancing circuit **143** into dialyzer **14**. Also, pod pump **161** draws in used dialysate from dialyzer **14** into pod pump **161**.

[0076] Once pod pump **161** and balancing chamber **341** have filled with dialysate, the first set of valves **211**, **212**, **213**, **241**, **242** is closed and the second set of valves **221**, **222**, **223**, **231**, **232** is opened. Fresh dialysate flows into balancing chamber **342** instead of balancing chamber **341**, as valve **212** is closed while valve **221** is now open. As fresh dialysate flows into balancing chamber **342**, used dialysate within the chamber is forced out and exits balancing circuit, since valve **213** is now closed. Also, pod pump **162** now draws used dialysate from the dialyzer into the pod pump, while used dialysate is prevented from flowing into pod pump **161** as valve **232** is now closed and valve **222** is now open. Pod pump **161** forces used dialysate contained within the pod pump (from the previous step) into balancing chamber **341**, since valves **232** and **211** are closed and valve **223** is open. This causes fresh dialysate contained within balancing chamber **341** to be directed into the dialyzer **14** (since valve **241** is now open while valve **212** is now closed). At the end of this step, pod pump **162** and balancing chamber **342** have filled with dialysate. This puts the state of the system back into the configuration at the beginning of this description, and the cycle is thus able to repeat, ensuring a constant flow of dialysate to and from the dialyzer **14**. In an embodiment, the fluid (e.g. pneumatic) pressures on the control side of the balancing chamber valves are monitored to ensure they are functioning (e.g., opening and closing) properly.

[0077] As a specific example, a vacuum (e.g., 4 p.s.i. of vacuum) can be applied to the port for the first set of valves, causing those valves to open, while positive pressure (e.g., 20 p.s.i. of air pressure) is applied to the second set of valves, causing those valves to close (or vice versa). The pod pumps each urge dialysate into one of the volumes in one of the balancing chambers **341**, **342**. By forcing dialysate into a volume of a balancing chamber, an equal amount of dialysate is squeezed by the diaphragm out of the other volume in the balancing chamber. In each balancing chamber, one volume is occupied by fresh dialysate heading towards the dialyzer and the other volume is occupied by used dialysate heading from the dialyzer. Thus, the volumes of dialysate entering and leaving the dialyzer are kept substantially equal.

[0078] The bypass pump **35** can direct the flow of dialysate from the dialyzer **14** through balancing circuit **143** without passing through either of pod pumps **161** or **162**. In this embodiment, the bypass pump **35** is a pod pump, similar to those described above, with a rigid chamber and a flexible diaphragm dividing each chamber into a fluid compartment and a control compartment. This pump may be the same or different from the other pod pumps and/or metering pumps described above. When control fluid is used to actuate the bypass pump **35**, the additional drop in pressure on the exiting (spent) dialysate side of the dialyzer causes additional ultrafiltration of fluid from the blood in the dialyzer. This may cause a net efflux of fluid from the patient's blood, through the dialyzer, and ultimately to drain. Such a bypass may be useful, for example, in reducing the amount of fluid a patient has, which is often increased due to the patient's inability to excrete excess fluid (primarily water) through the kidneys. As shown in FIG. **4**, the bypass pump **35** may be controlled by a control fluid (e.g., air), irrespective of the operation of pod pumps **161** and **162**. This configuration may allow for easier control of net fluid removal from a patient, without having to operate the inside dialysate pumps either out of balance or out of phase with the blood pumps in order to achieve such fluid withdrawal from the patient.

[0079] To achieve balanced flow across the dialyzer, the blood flow pump, the pumps of the balancing circuit, and the pumps of the directing circuit (discussed below) may be operated to work together to ensure that flow into the dialyzer is generally equal to flow out of the dialyzer. If ultrafiltration is required, the ultrafiltration pump (if one is present) may be run independently of some or all of the other blood and/or dialysate pumps to achieve the desired ultrafiltration rate.

[0080] To prevent outgassing of the dialysate, the pumps of the balancing circuit may be kept at pressures above atmospheric pressure. In contrast, however, the blood flow pump and the directing circuit pumps use pressures below atmosphere to pull the diaphragm towards the chamber wall to complete a fill stroke. Because of the potential of fluid transfer across the semi-permeable membrane of the dialyzer and because the pumps of the balancing circuit run at positive pressures, the balancing circuit pumps may be able to use information from the blood flow pump(s) in order to synchronize the delivery strokes of the balancing circuit chambers to the dialyzer with the delivery strokes of the blood pumps.

[0081] In one set of embodiments, when running in such a balanced mode, if there is no delivery pressure from the blood flow pump, the balancing circuit pump diaphragm will push fluid across the dialyzer into the blood and the alternate pod of the balancing circuit will not completely fill. For this reason, the blood flow pump reports when it is actively delivering a stroke. When the blood flow pump is delivering a stroke the inside dialysate pump operates. When the blood flow pump is not delivering blood, the valves that control the flow from the dialyzer to the inside dialysate pumps (and other balancing valves ganged together with these valves, as previously discussed) may be closed to prevent any fluid transfer from occurring from the dialysate side to the blood side. During the time the blood flow pump is not delivering, the inside dialysate pumps are effectively frozen, and the inside dialysate pump delivery stroke resumes once the blood flow pump starts delivering again. The inside dialysate pump fill pressure can be set to a minimal positive value to ensure that the pump operates above atmosphere at minimal impedance. Also, the inside dialysate pump delivery pressure can be set to the blood flow pump pressure to generally match pressures on either side of the dialyzer, minimizing flow across the dialyzer during delivery strokes of the inside dialysate pump.

[0082] In another embodiment, the inside dialysate pump delivers dialysate to the dialyzer at a pressure slightly above the pressure at which blood is delivered to the dialyzer. This ensures that a full balance chamber of clean dialysate gets delivered to the dialyzer. On the return side, the inside dialysate pump can fill with spent dialysate from the dialyzer at a slightly lower pressure than the outlet pressure on the blood side of the dialyzer, ensuring that the receiving dialysate pump chamber can fill. This in turn ensures that there is enough dialysate available to complete a full stroke in the balancing chamber. Flows across the semi-permeable membrane caused by these differential pressures will tend to cancel each other; and the pumping algorithm otherwise attempts to match the average pressures on the dialysate and blood sides of the dialyzer.

[0083] It is generally beneficial to keep the blood flow as continuous as possible during therapy, as stagnant blood flow can result in blood clots. In addition, when the delivery flow rate on the blood flow pump is discontinuous, the balancing pump may pause its stroke more frequently, which can result in discontinuous and/or low dialysate flow rates. However, the flow through the blood flow pump can be discontinuous for various reasons. For instance, pressure may be limited within the blood flow pump, e.g., to +600 mmHg and/or −350 mmHg to provide safe pumping pressures for the patient. For instance, during dual needle flow, the two pod pumps of the blood flow pump can be programmed to run 180° out of phase with one another. If there were no limits on pressure, this phasing could always be achieved. However to provide safe blood flow for the patient these pressures are limited. If the impedance is high on the fill stroke (due to a small needle, very viscous blood, poor patient access, etc.), the negative pressure limit may be reached and the fill flow rate will be slower then the desired fill flow rate. Thus the delivery stroke must wait for the previous fill stroke to finish, resulting in a pause in the delivery flow rate of the blood flow pump. Similarly, during single needle flow, the blood flow pump may be run at 0° phase, where the two blood flow pump pod pumps are simultaneously emptied and filled. When both pod pumps are filled, the volumes of the two pod pumps are delivered. In an embodiment, the sequence of activation causes a first pod pump and then a second pod pump to fill, followed by the first pod pump emptying and then the second pod pump emptying. Thus the flow in single needle or single lumen arrangement may be discontinuous.

[0084] One method to control the pressure saturation limits would be to limit the desired flow rate to the slowest of the fill and deliver strokes. Although this would result in slower blood delivery flow rates, the flow rate would still be known and would be more continuous, which would allow for more accurate and continuous dialysate flow rates. Another method to make the blood flow rate more continuous in single needle operation would be to use maximum pressures to fill the pods so the fill time would be minimized. The desired deliver time could then be set to be the total desired stroke time minus the time that the fill stroke took. However, the less continuous the blood flow, the more the dialysate flow rate may have to be adjusted upward during blood delivery to the dialyzer to make up for the time that the dialysate pump is stopped when the blood flow pump is filling. If this is done with the correct timing, an average dialysate flow rate taken over several strokes can still match the desired dialysate flow rate.

[0085] FIG. **5** shows a close up of the directing circuit **142** in the FIG. **2** embodiment. In this embodiment, the directing circuit **142** can provide dialysate from a dialysate tank **169** via a dialysate pump **159** to a heater **72** and the ultrafilter **73**. The heater **72** may be used to warm the dialysate to body temperature, and/or a temperature such that the blood in the blood flow circuit is heated by the dialysate, and the blood returning to the patient is at body temperature or higher. In some cases, the heater **72** may be connected to a control system such that dialysate that is incorrectly heated (i.e., the dialysate is too hot or too cold) may be recycled (e.g., back to the dialysate tank **169**) or sent to drain instead of being passed to the dialyzer. The heater **72** may also be used, in some embodiments, for disinfection or sterilization purposes. For instance, water may be passed through the hemodialysis system and heated using the heater such that the water is heated to a temperature able to cause disinfection or sterilization to occur, e.g., temperatures of at least about 70° C., at least about 80° C., at least about 90° C., at least about 100° C., at least about 110° C., etc.

[0086] The flow of dialysate through the directing circuit **142** may be controlled (at least in part) by operation of the dialysate pump **159**. In addition, the dialysate pump **159** may control flow through the balancing circuit **143**. For instance, as discussed above, fresh dialysate from the directing circuit **142** flows into balancing chambers **341** and **342** of balancing circuit **143**. The dialysate pump **159** may be used as a driving force to cause the fresh dialysate to flow into these balancing chambers. In one set of embodiments, dialysate pump **159** includes a pod pump, e.g., similar to those described above.

[0087] The dialysate may also be filtered to remove contaminants, infectious organisms, pathogens, pyrogens, debris, and the like, for instance, using an ultrafilter **73**. The ultrafilter **73** may be positioned in any suitable location in the dialysate flow path, for instance, between the directing circuit and the balancing circuit, e.g., as shown, and/or the ultrafilter **73** may be incorporated into the directing circuit or the balancing circuit. If an ultrafilter is used, its pore size may be chosen to prevent species such as these from passing through the filter.

[0088] In some cases, the ultrafilter **73** may be operated such that waste from the filter (e.g., the retentate stream) is passed to a waste stream, such as waste line **39** in FIG. **5**. In some cases, the amount of dialysate flowing into the retentate stream may be controlled. For instance, if the retentate is too cold (i.e., heater **72** is not working, or heater **72** is not heating the dialysate to a sufficient temperature, the entire dialysate stream (or at least a portion of the dialysate) may be diverted to waste line **39**, and optionally, recycled to dialysate tank **169** using line **48**. Flow from the filter **73** may also be monitored for several reasons, e.g., using temperature sensors (e.g., sensors **251** and **252**), conductivity sensors (for confirming dialysate concentration, e.g., sensor **253**), or the like. An example of such sensors is discussed below; further non-limiting examples can be seen in a U.S. patent application Ser. No. 12/038,474, filed Feb. 27, 2008.

[0089] The ultrafilter and the dialyzer may provide redundant screening methods for the removal of contaminants, infectious organisms, pathogens, pyrogens, debris, and the like. Accordingly, any contaminant would have to pass through both the ultrafilter and the dialyzer before reaching a patient's blood. Even in the event that either the ultrafilter or dialyzer integrity fails, the other may still be able to maintain dialysate sterility and prevent contaminants from reaching the patient's blood.

[0090] The directing circuit **142** may also be able to route used dialysate coming from a balancing circuit to a drain, e.g., through waste line **39** to drain **31**. The drain may be, for example, a municipal drain or a separate container for containing the waste (e.g., used dialysate) to be properly disposed of. In some cases, one or more check or "one-way" valves (e.g., check valves **215** and **216**) may be used to control flow of waste from the directing circuit **142** and from the system **5**. Also, in certain instances, a blood leak sensor (e.g., sensor **258**) may be used to determine if blood is leaking through the dialyzer **14** into the dialysate flow path. In addition, a liquid sensor can be positioned in a collection pan at the bottom of the hemodialysis unit to indicate leakage of either blood or dialysate, or both, from any of the fluid circuits.

[0091] The directing circuit **142** may receive water from a water supply **30**, e.g., from a container of water such as a bag, and/or from a device able to produce water, e.g., a reverse osmosis device. In some cases, the water entering the system is set at a certain purity, e.g., having ion concentrations below certain values. The water entering into the directing circuit **142** may be passed on to various locations, e.g., to a mixing circuit **25** for producing fresh dialysate and/or to waste line **39**. In some cases, valves to the drain **31** and various recycle lines are opened, and conduits **67** may be connected between directing circuit **142** and blood flow circuit **141**, such that water is able to flow continuously around the system. If heater **72** is also activated, the water passing through the system will be continuously heated, e.g., to a temperature sufficient to disinfect the system.

[0092] FIG. **6** shows a close-up view of the mixing circuit **25** in the illustrative embodiment of FIG. **2**. Water from the directing circuit **142** flows into the mixing circuit **25** due to action of a pump **180**. In this embodiment, the pump **180** includes one or more pod pumps, similar to those described above. In some cases, a portion of the water is directed to reagent ingredients **49**, e.g., for use in transporting the ingredients, such as the bicarbonate **28**, through the mixing circuit **25**. In some cases, sodium chloride and/or the sodium bicarbonate **28** may be provided in a powdered or granular form, which is mixed with water provided by the pump **180**. Bicarbonate from bicarbonate source **28** is delivered via bicarbonate pump **183** to a mixing line **186**, which also receives water from the directing circuit **142**. Acid from an acid source **29** (which may be in a liquid form) is also pumped via an acid pump **184** to the mixing line **186**. The ingredients **49** (water, bicarbonate, acid, NaCl, etc.) are mixed in mixing chamber **189** to produce dialysate, which then flows out of mixing circuit **25** to the directing circuit **142**. Conductivity sensors **178** and **179** are positioned along mixing line **186** to ensure that as each ingredient is added to the mixing line, it is added at proper concentrations. The volumes delivered by the water pump **180** and/or the other pumps may be directly related to the conductivity measurements, so the volumetric measurements may be used as a cross-check on the composition of the dialysate that is produced. This may ensure that the dialysate composition remains safe even if a conductivity measurement becomes inaccurate during a therapy.

[0093] FIG. 7 shows a perspective view of a hemodialysis system 5 that incorporates various aspects of the invention. In accordance with one aspect of the invention, the system 5 includes a dialysis unit 51 and a power unit module 52 that are shown joined together. In this embodiment, the dialysis unit 51 has a housing that contains suitable components for performing hemodialysis, such as a dialyzer, one or more pumps to circulate blood through the dialyzer, a source of dialysate, and one or more pumps to circulate the dialysate through the dialyzer. For example, the dialysis unit 51 may include the mixing circuit 25, blood flow circuit 141, the balancing circuit 143 and the directing circuit 142 as described above. The dialysis unit 51 may also include all blood circuit connections and dialysate fluidic connections needed for operation of the system 5. Patient access and other connections may be revealed by opening side-by-side vertical doors 53 via a handle 54 at a front side of the dialysis unit 51 housing. In this embodiment, the dialysis unit 51 includes a control interface 55 (attached to the housing by a flexible cable in this embodiment) that a user may use to control operation of the dialysis unit 51. The control interface 55 may include a display screen with a touch sensitive overlay to allow touch control and interaction with a graphical user interface presented on the screen. The control interface 55 may also include other features, such as push buttons, a speaker, a microphone for receiving voice commands, a digital camera, and so on. The back side of the control interface 55 may include a retractable "kick-stand" (not shown) that allows the control interface 55 to be positioned on top of the dialysis unit 51 housing. Deploying the retractable "kick-stand" permits the control interface 55 to be placed in a near-vertical position to allow proper viewing of the display screen.

[0094] The power unit 52 housing may contain suitable components for providing operating power to the dialysis unit 51, e.g., pneumatic pressure/vacuum to power the pumps, valves and other components of the dialysis unit 51. "Pneumatic," as used herein, means using air or other gas to move a flexible diaphragm or other member. (It should be noted that air is used by way of example only, and in other embodiments, other control fluids, such as nitrogen (N_2), CO_2, water, an oil, etc., may be used). As discussed above, the pumps and valves of the dialysis unit 51 may operate on pneumatic power, and thus the power unit 52 may provide one or more pneumatic sources for use by the dialysis unit 51. In this way, the dialysis unit 51 need not necessarily be arranged to generate and/or store the necessary pneumatic power needed, but instead may rely on the power unit module 52. The power unit 52 may include one or more pneumatic pumps to generate desired air pressure and/or vacuum, one or more accumulators or other devices to store pneumatic power, valves, conduits and/or other devices to control flow of pneumatic power in the power unit 52, as well as a controller having suitable components, such as a programmed general purpose data processor, memory, sensors (e.g., to detect pressure, temperature, etc.), relays, actuators, and so on.

[0095] In one embodiment, the pneumatic power (e.g., air under suitable pressure/vacuum) may be supplied by the power unit 52 to the dialysis unit 51 via one or more supply tanks or other pressure sources. For instance, if two tanks are used in the power unit 52, one supply tank may be a positive pressure reservoir, and in one embodiment, has a set point of 750 mmHg (gauge pressure) (1 mmHg is about 133.3 pascals). The other supply tank can be a vacuum or negative pressure reservoir, and in one embodiment, has a set point of −450 mmHg (gauge pressure). This pressure difference may be used, for instance, between the supply tanks and the required pod pump pressure to allow for accurate control of the variable valves to the pod pumps. The supply pressure limits can be set based on maximum pressures that can be set for the patient blood flow pump plus some margin to provide enough of a pressure difference for control of the variable valves. Thus, in some cases, the two tanks may be used to supply pressures and control fluids for all of the dialysis unit 51 functions.

[0096] In one embodiment, the power unit 52 may include two independent compressors to service the supply tanks. Pressure in the tanks can be controlled using any suitable technique, for instance, with a simple "bang-bang" controller (a controller that exists in two states, i.e., in an on or open state, and an off or closed state), or with more sophisticated control mechanisms, depending on the embodiment. As an example of a bang-bang controller, for the positive tank, if the actual pressure is less than a set point, the compressor servicing the positive tank is turned on. If the actual pressure is greater than a set point, the compressor servicing the positive tank is turned off. The same logic may be applied to the vacuum tank and control of the vacuum compressor with the exception that the sign of the set point term is reversed. If the pressure tanks are not being regulated, the compressor is turned off and the valves are closed.

[0097] Tighter control of the pressure tanks can be achieved by reducing the size of the hysteresis band, however this may result in higher cycling frequencies of the compressor. If very tight control of these reservoirs is required, the bang-bang controller could be replaced with a proportional-integral-derivative ("PID") controller and using pulse width modulation ("PWM") signals on the compressors. Other methods of control are also possible.

[0098] Other pressure sources may be used in other embodiments, and in some cases, more than one positive pressure source and/or more than one negative pressure source may be used. For instance, more than one positive pressure source may be used that provides different positive pressures (e.g., 1000 mmHg and 700 mmHg), which may be used to minimize leakage. For example, high positive pressure can be used to control valves, whereas lower positive pressures can be used to control pumps. This limits the amount of pressure that can potentially be sent to the dialyzer or to the patient, and helps to keep actuation of the pumps from overcoming the pressures applied to adjacent valves. A non-limiting example of a negative pressure is −400 mmHg. In some cases, the negative pressure source may be a vacuum pump, while the positive pressure pump may be an air compressor.

[0099] Moreover, the power unit 52 may be selectively connectable to the dialysis unit 51, e.g., to allow different power units 52 to be interchanged. For example, the dialysis unit 51 may be arranged to work with different types of power units 52, such as power units 52 that use electrical power to generate the pneumatic power supply, as well as power units 52 that use stored pneumatic power (e.g., pressurized air stored in one or more high pressure tanks). Thus, a power unit 52 may be interchanged for another unit 52, in case of failure or other requirements. For example, it may be desired to use the system 5 in an area where noise generation is unacceptable, such as when nearby people are sleeping. In this case, it may be desirable to use a power unit 52 that uses stored pneumatic power, rather than a unit 52 that generates pneumatic power by running pumps or other noise generating equipment. As shown in FIG. **8**, the power unit **52** may be disconnected from the dialysis unit **51** by manipulating a handle **521**. For example, turning the handle **521** may unlock the power unit **52** from the dialysis unit **51**, disengaging not only mechanical connections between the housings, but also power and/or communications connections between the two. An interface (not shown) between the dialysis unit **51** and the power unit **52** may permit the units to exchange pneumatic power (from the power unit **52** to the dialysis unit **51**) as well as electrical power, control communications, and other. The dialysis unit **51** may have connection points for electrical power (e.g., standard 115V, 15 amp power found in most home power outlets), external communication (such as Ethernet, or any other suitable connection suitable for communication), a water supply, and so on. The dialysis unit **51** may provide electrical power or other connections to the power unit **52**, if desired.

[0100] The dialysis unit **51** may include a controller to control flow of control fluid for various components of the system **5**, as well as perform other desired functions. In some cases, the control fluid may be held at different pressures within the various tubes or conduits. For instance, some of the control fluid may be held at positive pressure (i.e., greater than atmospheric pressure), while some of the control fluid may be held at negative pressures (less than atmospheric pressure). In addition, in certain embodiments, the controller may have components that are kept separate from the various liquid circuits. This configuration has a number of advantages. For example, in one embodiment, the liquid circuits in the dialysis unit **51** may be heated to disinfection temperatures and/or exposed to relatively high temperatures or other harsh conditions (e.g., radiation) to effect disinfection, while electronic components of the controller may not be exposed to such harsh conditions, and may even be kept separate by an insulating wall (e.g., a "firewall") or the like. That is, the dialysis unit housing may have two or more compartments, e.g., one compartment with electronic and other components that may be sensitive to heat or other conditions, and another compartment with liquid circuit components that are heated or otherwise treated for disinfection.

[0101] Thus, in some embodiments, the system **5** may include a "cold" section (which is not heated), and a "hot" section, portions of which may be heated, e.g., for disinfection purposes. The cold section may be insulated from the hot section through insulation. In one embodiment, the insulation may be molded foam insulation, but in other embodiments can be any type of insulation, including but not limited to a spray insulation, an air space, insulation cut from sheets, etc. In one embodiment, the cold section includes a circulation system, e.g., a fan and/or a grid to allow air to flow in and out of the cold box. In some cases, the insulation may be extended to cover access points to the "hot" section, e.g., doors, ports, gaskets, and the like. For instance, when the "hot" section is sealed, the insulation may completely surround the "hot" section in some cases.

[0102] Non-limiting examples of components that may be present within the "cold" section include power supplies, electronics, power cables, pneumatic controls, or the like. In some cases, at least some of the fluids going to and from the "hot" section may pass through the "cold" section; however, in other cases, the fluids may pass to the "hot" section without passing through the "cold" section.

[0103] Non-limiting examples of components that may be present within the "hot" section include cassettes (if present), fluid lines, temperature and conductivity sensors, blood leak sensors, heaters, other sensors, switches, emergency lights, or the like. In some cases, some electrical components may also be included in the "hot" section. These include, but are not limited to, a heater. In one embodiment, the heater can be used to heat the hot box itself, in addition to fluid. In some embodiments, the heater **72** heats the entire "hot" section to reach a desired temperature.

[0104] In accordance with an aspect of the invention, the dialysis unit **51** housing may include vertical side-by-side doors that can be opened to expose all mechanical interface points for blood flow circuitry and connections for dialysate circuitry, i.e., all connection points for patient blood connections and acid/bicarbonate connections, that must be made by a user to use the dialysis unit **51**. FIG. **9** shows a front view of the dialysis unit **51** with the vertical side-by-side doors **53** in a closed state. In this arrangement, the doors **53** may block access to connection points for patient blood connections and acid/bicarbonate connections as well as seal the interior of the unit housing so as to allow heat retention suitable for disinfection. The seal provided by the doors **53** may be hermetic, preventing or substantially resisting any air exchange between the housing interior and an exterior environment, or may be of a somewhat lesser quality yet still allow for disinfection.

[0105] In this embodiment, the doors **53** are connected to the dialysis unit **51** housing by a dual hinge arrangement such that the doors **53** can be opened to two different states of opening. FIGS. **10-13** show the doors **53** in a first state of opening. In this state, the doors **53** expose all user-made connections for the blood circuit connections and for the dialyzer circuitry, including the dialyzer **14** itself and for reagent materials, such as consumable acid/bicarbonate materials. This position also exposes several other features, such as holders **531** for an acid/bicarbonate container (not shown) and hooks **532** that may be used to hold any suitable item, such as the control interface **55**, which may be hung by its handle on one of the hooks **532**. (See also FIG. **7** which shows a hook **532** on the front of the left door **53** which may be folded out to receive the control interface **55** or other item.) The holders **531** in this embodiment may be folded down from their position shown in the figures (i.e., folded up and into recesses in the doors **53**) so as to extend horizontally from the doors **53**. The holders **531** have a "C" shaped receiving section to receive and hold an acid/bicarbonate container, but of course could be shaped or otherwise arranged in any suitable way.

[0106] FIGS. **14-16** show the doors **53** in a second state of opening in which a hinge plate **533** for each door **53** is pivoted outward and away from the dialysis unit housing **51**. The hinge plates **533**, which in this embodiment extend vertically along almost the entire height of the dialysis unit housing **51**, are pivotally attached to the doors **53** at a first, outer end, and are pivotally attached at a second inner end to the dialysis unit housing **51**. (Of course, it should be understood that the hinge plates **533** could be arranged and/or positioned differently, e.g., at the top and bottom of the doors **53** as is found in many refrigerator door arrangements, each plates **533** may include two or more portions that are vertically separated from each other, etc.) Magnets **534** attached to the hinge plates **533** may interact with corresponding magnets (or other suitable components, such as a steel elements) attached to the dialysis unit housing **51** so as to attract the hinge plates **533** toward the dialysis unit housing **51**, thus tending to keep the hinge plates **533** in the position shown in FIGS. **10-13**. (Of course, the magnets **534** could be positioned on the unit housing, and the hinge plates **533** could have suitable elements (such as pieces of steel) that are attracted to the magnets **534**.) The doors **53** in this embodiment also include magnets attached near the hinge plates **533** so that when the doors **53** are opened to the first state as shown in FIGS. **10-13**, the magnets interact with corresponding magnets in the hinge plates **533** to help keep the doors **53** in an open position relative to the hinge plate **533**. These magnets will also help maintain the relative position of the doors **53** and the hinge plates **533** when the hinge plates **533** are opened to the second state shown in FIGS. **13-16**.

[0107] Although magnets are used in this illustrative embodiment as part of a retainer member to help the doors **53** and/or hinge plates **533** stay in a particular state of opening or closing, other arrangements for a retainer member are possible. For example, the hinge connection between the doors **53** and the hinge plates **533** and/or the connection between the hinge plates **533** and the housing **51** may include a detent arrangement that serves to resiliently hold the door **53** or hinge plate **533** in a particular position relative to the other part (the hinge plate or housing, respectively). In another embodiment, one or more springs may be used to help maintain the doors **53** in an open position relative to the hinge plates **533**. In yet another embodiment, the hinge plates **533** may have a friction or interference fit with a portion of the housing **51** that tends to maintain the hinge plates **533** in the closed position (adjacent the housing). Accordingly, a retainer member that functions to help maintain a door **53** in a particular position relative to its hinge plate **533**, and/or that functions to help maintain a hinge plate **533** in a particular position relative to the housing **51**, may take any one of a number of possible arrangements.

[0108] In accordance with another aspect of the invention, opening of the doors to the dialysis unit housing may reveal all of the user-made connections for blood circuit connections and dialysate fluidic connections needed for operation of the system **5**. For example, as shown in FIG. **17**, with the doors **53** in an open position (either the first or second state of opening) a front panel **511** of the dialysis unit **51** may be exposed. In this embodiment, the front panel **511** carries several items or connection points that must be accessed by a user. For example, the dialyzer **14**, which must be periodically replaced, is mounted to the front panel **511**. The dialyzer **14** must be connected not only to the blood flow circuit **141**, but also the balancing circuit **143**. Also, a connection point **512** for an acid/bicarbonate source **49** is located at a lower end of the front panel **511**. It is at this connection point **512** that a user may connect a source of consumable reagent ingredients **49** used by the dialysis unit **51** in making dialysate. An occluder **513** is also mounted on the front panel **511**. The occluder **513** receives tubes of the blood flow circuit and controls the open/closed state of the tubes based on system operation. The function of the occluder **513** is discussed in more detail in U.S. application Ser. No. 12/198,947, filed Aug. 27, 2008 (under Attorney Docket Number D0570.70020US00 (G28)) and below. In short, the occluder **513** allows flow through the arterial and venous lines of the blood flow circuit unless there is a system problem, such as a leak, pump failure, overpressure situation, etc. In such case, the occluder **513** automatically closes the blood lines to prevent all flow to or from the patient. Also exposed on the front panel **511** are blood line connection points **514** for connecting the arterial and venous blood lines **203**, **204** of the blood flow circuit **141** with the directing circuit **142** (as explained above with reference to FIGS. **2** and **3**, the blood flow circuit **141** may be connected to the directing circuit **142**). This connection is normally made at the end of treatment to allow the system to clean and disinfect the blood flow circuit **141**. The front panel **511** also has a set of control ports **515** that mate with corresponding control ports on the blood pump portion of the blood flow circuit **141**. The control ports **515** provide controlled levels of air pressure and/or vacuum to control the open/closed state of valves and to power the pumps of the blood flow circuit **141**.

[0109] Also exposed on the front panel **511** is a user control panel **510**. The user control panel **510** includes one or more buttons permitting the user to bypass the graphical user interface on control interface **55**, providing an alternate method to control certain functions (e.g., critical functions) during hemodialysis. This may be important, for example, if the control interface **55** should ever fail during a dialysis treatment session. Non-limiting examples of critical functions can include a "stop dialysis" or "pause dialysis" command and an "infuse dialysate solution" command.

[0110] FIG. **17** does not show the arterial and venous lines **203**, **204** for the blood flow circuit **141** because in this embodiment and in accordance with another aspect of the invention, the blood flow circuit **141** is formed as a blood circuit assembly that is removable from the front panel **511** of the dialysis unit **51**, and the blood circuit assembly is not mounted on the front panel **511** in FIG. **17**. FIG. **18** shows a front view of the blood circuit assembly **17** in this embodiment along with the dialyzer **14**. The blood circuit assembly **17** includes various components discussed above, for example with reference to FIG. **3**, that are mounted to a blood circuit organizing tray **171**. The arterial and venous lines **203** and **204** (e.g., including lengths of flexible silicone tubing) are terminated with blood line connectors that, in one aspect of the invention, are arranged to provide a plug-in or press-in connection with the blood line connection points **514** as well as provide a screw-type connection used with standard patient access points (e.g., luer type patient access connectors). The arterial line **203** leads to an inlet at the top of the blood pump **13**, which includes two pod pumps **23**, valves and other components for controlling blood flow. Associated with the blood pump **13** are an air filter **81**, an anticoagulant pump **80** (not shown), and an anticoagulant supply **11** (such as a vial of heparin). (Details regarding the blood pump **13** in this illustrative embodiment may be found in U.S. patent application Ser. No. 11/871,680, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,712, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,787, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,793, filed Oct. 12, 2007, entitled "Pumping Cassette"; and U.S. patent application Ser. No. 11/871,803, filed Oct. 12, 2007, entitled "Cassette System Integrated Apparatus.") Blood output from the blood pump **13** (the outlet is located at a bottom of the pump **13**) flows to an inlet of the dialyzer **14** (at the top of the dialyzer **14**), and out of the dialyzer (the dialyzer blood outlet is located at the bottom of the dialyzer **14**) to the inlet of the air trap **19**. The outlet of the air trap **19** is connected to the venous blood line **204**. Connections to the inlet and outlet blood ports of the dialyzer **14** are made with typical screw-type connections.

[0111] In accordance with another aspect of the invention, the air trap **19** is placed in the blood flow path after the blood exits the dialyzer and before it is returned to the patient. In an embodiment, air trap **19** can have a spherical or spheroid-shape container (i.e., a container having an approximately spherical inner wall), and have its inlet port located near the top and offset from the vertical axis of the container, and an outlet at a bottom of the container. (The vertical axis of the container is arranged in a vertical direction passing through the top and bottom "poles" of the approximately spherical container.) With the inlet port offset from the vertical axis (in this case set back toward the tray **171**), blood is introduced into the container in a direction that is approximately perpendicular to the vertical axis of the container and that is approximately tangential to the spherical inner wall of the container. The curved shape of the inside wall of the trap can thus direct the blood to circulate along the inside wall as the blood gravitates to the bottom of the container (e.g., in a spiral like fashion), facilitating the removal of air bubbles from the blood. Air present in the blood exiting the outlet of the dialyzer **14** will enter at the top of the air trap **19** and remain at the top of the container as blood flows out the outlet at the bottom and to the venous blood line **204**. By locating the inlet port near the top of trap **19**, it is also possible to circulate blood through the trap with minimal or no air present within the container (as a "run-full" air trap. The ability to avoid an air-blood interface for routine circulation of blood in the trap can be advantageous. Placing the inlet port at or near the top of the container also allows most or all of the air present in the trap to be removed from the trap by reversing the flow of fluid through the blood tubing (i.e. from the bottom to the top of the trap **19**, exiting through the inlet port of the trap **19**).

[0112] In an embodiment, a self-sealing port, such as a self-sealing stopper with a split septum or membrane, or another arrangement, is located at the top of the trap, allowing the withdrawal of air from the container (e.g., by syringe). The blood-side surface of the self-sealing membrane can be situated nearly flush with the top of the interior of the trap, in order to facilitate cleaning of the self-sealing port during disinfection, e.g., by reversing flow through the air trap using a dialysate or other cleaning fluid. Also, the inlet, outlet and internal wall of the container and the self-sealing port may be arranged to substantially eliminate stagnation regions, i.e., allow for few or no regions where blood can stagnate or clot. The self-sealing port can also serve as a blood sampling site, and/or to allow the introduction of liquids, drugs or other compounds into the blood circuit. A sealed rubber-type stopper can be used if access with a needle is contemplated. Using a self-sealing stopper with split septum permits sampling and fluid delivery using a needleless system.

[0113] FIG. **19** shows the organizing tray **171** for the blood circuit assembly **17** without the various blood circuit assembly **17** components mounted. In accordance with one aspect of the invention, the organizing tray **171** includes handles **172** (in this embodiment, finger pulls) that a user can grip when mounting/dismounting the blood circuit assembly **17** to the front panel **511**. Inward of the handles **172** are openings **173** that allow spring tabs on the front panel **511** to pass through and engage with the organizing tray **171** and/or the blood pump **13** cassette to hold the blood circuit assembly **17** in place on the front panel **511**. In accordance with another aspect of the invention, the organizing tray **171** includes blood line engagement members **174** that each have a C-shaped recess or other hole through which a corresponding blood line **203**, **204** passes. (In this context, a "hole" includes a recess like that shown in FIG. **19**, a throughbore that has a continuous wall, e.g., as may be made by a drill, or other suitable opening.) As described in more detail below, the blood line engagement members **174** are used when mounting the blood lines **203**, **204** in the occluder **513**. In short, when mounting the blood lines **203**, **204** in the occluder **513**, the blood lines **203**, **204** must be pulled and stretched downwardly (so as to reduce the outside diameter of the line) while being pushed horizontally into slots for the occluder **513**. The blood line engagement members **174** function to both resist downward pulling on the blood lines **203**, **204** (e.g., each line **203**, **204** may include a stop ring above the respective engagement member **174** that cannot be pulled through the recess in the engagement member **174**) as well as permit the user to press inwardly on the engagement member **174** to seat the lines **203**, **204** in the occluder slots. The engagement members **174** are formed integrally with the organizing tray **171** so that a "living hinge" or relatively flexible portion of the organizing tray is positioned between the engagement member **174** and the main body of the organizing tray **171**. This arrangement allows the engagement members **174** to be pushed inwardly relative to the organizing tray **171** as the connection portion between the engagement members **174** and the organizing tray main body flexes.

[0114] FIG. **20** shows a rear view of the blood circuit assembly **17** with the organizing tray **171** removed. This view shows the rear side of the blood pump **13** section with control ports exposed. These control ports mate with corresponding ports **515** on the front panel **511** (see FIG. **17**) so that pneumatic control (e.g., suitable air pressure or vacuum) can be applied to the pumps and valves to control their operation and flow through the blood circuit assembly **17**. FIG. **20** also shows the offset of the inlet port of the air trap **19**, i.e., the inlet port at the top of the air trap **19** is arranged to the rear of the vertical axis of the generally spherical container portion of the air trap **19**.

[0115] FIG. **21** shows a perspective view of the front panel **511** of the dialysis unit **51** with the blood circuit assembly **17** mounted to the front panel **511** without the organizing tray **171**. (Normally, the blood circuit assembly **17** would include the organizing tray **171**, but the tray **171** is not shown in the example so as to more clearly show components at the front panel **511**.) On opposite sides of the blood pump **13** cassette, the front panel **511** has spring tabs **516** that extend forwardly and resiliently engage with the blood pump cassette and/or the organizing tray **171** to retain the blood circuit assembly **17** in place. The tabs **516** may include a barb or other feature to help retain the blood circuit assembly **17** in place. The spring tabs **516** may be flexed outwardly to release their hold on the blood circuit assembly **17**, allowing its removal. However, in the absence of an outwardly directed force on the spring tabs **516**, the tabs **516** will remain engaged with the blood circuit assembly **17**. FIG. **22** shows a front view of the front panel **511** with the organizing tray **171** of the blood circuit assembly **17** included. To remove the blood circuit assembly **17** from the front panel **511**, a user may place index fingers behind the handles **172** while simultaneously placing thumbs on the inner side of the spring tabs **516** (the sides nearest the blood pumps **23**) and flexing the spring tabs **516** outwardly and away from the pumps **23**. This causes the spring tabs **516** to release the blood circuit assembly **17**, e.g., disengagement of barbs on the tabs **516** from the blood pump **13** and/or the organizing tray **171**. Of course, to remove the blood circuit assembly **17**, other connections must be removed, including connections to the dialyzer **14** and the blood line connection points **514**, as well as removal of the lines **203**, **204** from the occluder **513**. When mounting the blood circuit assembly **17** to the front panel **511**, the organizing tray **171** may be grasped at the handles **172** and properly aligned, e.g., so that the spring tabs **516** are aligned to pass through the openings **173** and the control ports of the blood pump **13** cassette are aligned with the corresponding ports **515** on the front panel **511**. The blood circuit assembly **17** may then be simply pushed into place, so that the spring tabs **516** engage with the organizing tray **171** and/or the blood pump cassette. Other connections can then be made, such as connections to the dialyzer **14**, mounting of the blood lines **203**, **204** with the occluder **513**, etc.

[0116] FIG. **21** also shows the slots **517** that hold the blood lines **203**, **204** for leading into the occluder **513**. The slots **517** define a channel that is slightly smaller than the outside diameter of the blood lines **203**, **204** so that the lines **203**, **204** tend to remain in the slots **517** after placement in the slots. This helps to ensure proper association of the lines with the occluder **513**. Once the blood circuit assembly **17** is mounted on the spring tabs **516**, the user may then engage the blood lines **203**, **204** with the slots **517** by stretching the lines **203**, **204** downward (with the engagement members **174** on the organizing tray **171** engaging the stop ring or other feature on the respective line **203**, **204** and resisting the downward pull) and pushing the lines **203**, **204** into a corresponding slot. The lines **203**, **204** can be pushed into place by pressing inwardly on the engagement members **174**, which as described above, are flexible and bend inwardly relative to the organizing tray **171**. The lines **203**, **204** can then be routed through the occluder **513**.

[0117] In accordance with another aspect of the invention, the front panel **511** includes a blood line wrap feature around the periphery of the front panel **511**. In this illustrative embodiment, the front panel **511** includes flanged portions **518** along the top edge and at lower corners of the front panel **511**. This allows a user to wrap the blood lines **203**, **204** around the periphery of the front panel **511** by placing the lines **203**, **204** in a channel defined by the flanged portions **518**. The lines **203**, **204** may be wrapped in a clockwise direction, starting from a point near the bottom of the dialyzer **14**, and ending at a point near the lower right corner of the front panel **511**. The blood lines **203**, **204** may then be connected at the blood line connection points **514**, e.g., to allow disinfecting fluid to be circulated through the blood lines **203**, **204**. As a result, the blood lines **203**, **204** can be neatly retained on the front panel **511**, allowing easy access to other components on the front panel **511** and allowing the user to close the doors **53** with minimal concern for pinching the blood lines **203**, **204** between the doors **53** and the dialyzer unit housing **51**. Alternatively, the blood lines **203**, **204** may be first connected at the blood line connection points **514**, and then wrapped in a clockwise direction, starting from a point near the bottom of the dialyzer **14**, and ending at a point near the lower right corner of the front panel **511**. This ensures that the blood lines are properly distributed along the flanged portions **518** to reach the connection points **514**. Vertical fences **519** may also be provided along the left and right sides of the front panel **511** to help keep the blood lines **203**, **204** in a desired position and away from the hinge plates **533** and other possible pinch points.

[0118] In accordance with another aspect of the invention, the front panel **511** of the dialysis unit **51** (or other suitable component) may be arranged to accommodate a variety of differently sized and/or shaped dialyzer units **14**. Different patients, and in some cases even the same patient over time, may be prescribed different dialyzers so as to provide different treatment conditions. Thus, the dialysis unit **51** is preferably arranged to operate with multiple different types of dialyzers **14**. In many cases, different dialyzers **14** have different dimensions, such as the overall diameter and/or length of the dialyzer unit. In this illustrative embodiment as shown in FIG. **23**, the front panel **511** includes a dialyzer mount with a pair of "keyhole" features **520** that are arranged to engage with a respective dialysate quick-connect fitting on the dialyzer **14**. Each keyhole feature **520** includes an upper insertion area **520***a* sized to receive a portion of the quick-connect fitting and a lower flanged portion **520***b* that has a width that is smaller than an overall diameter of the quick-connect fitting and that engages with a grooved area of the quick-connect fitting. So as to aid in understanding of these features, FIG. **24** shows a dialyzer **14** with quick connect fittings **14***a* attached at dialysate inlet and outlet ports of the dialyzer **14**. (Blood inlet and outlet ports are located at the extreme top and bottom of the dialyzer **14** shown in FIG. **24**.) The quick connect fittings **14***a* shown are of a standard type, and most, if not all, dialyzers **14** have dialysate inlet/outlet ports that are arranged to engage with the standard quick connect fittings **14***a*. The quick connect fittings **14***a* each include a slide element **14***b* that is moved to the right (as shown in FIG. **24**) relative to a base **14***c* to allow the fitting **14***a* to be engaged with a dialysate port on the dialyzer **14**. When the slide element **14***b* is moved to allow the fitting **14***a* to be attached to the dialyzer **14**, a groove **14***d* is closed. However, once the fitting **14***a* is properly seated on the inlet/outlet port of the dialyzer **14**, the slide element **14***b* may be released, allowing a spring (not shown) to move the slide to the left as shown in FIG. **24**, reestablishing the groove **14***d* to the condition shown in FIG. **24**. Thus, when the quick connect fitting **14***a* is properly engaged with the dialyzer **14**, the groove **14***d* will be present as shown in FIG. **24**.

[0119] To mount the dialyzer **14** to the keyhole features **520**, the quick connect fittings **14***a* may be partially inserted into the upper insertion area **520***a* of the top and bottom keyhole features, respectively, so that the groove **14***d* of each fitting **14***a* is aligned with a flange of the lower flanged portion **520***b* of the keyhole features **520**. (Note that the upper insertion area **520** of the bottom keyhole feature **520** may be made longer than that shown in FIG. **23** to allow the accommodation of a wider range of dialyzer lengths.) With the grooves **14***d* aligned with the flanges, the dialyzer **14** may be lowered so that the quick connect fittings **14***a* are fully received into the lower flanged portions **520***b* of the keyhole features **520**.

[0120] In accordance with another aspect of the invention, one or both of the keyhole features **520** may be adjustable so that the weight of the dialyzer **14** is shared by both lower flanged portions **520***b* of the keyhole features **520**. For example, in this illustrative embodiment, the bottom keyhole feature **520** has part of the lower flanged portion **520***b* adjustable in vertical position relative to the top keyhole feature **520**. In this way, the portion of the lower flanged portion **520***b* may be adjusted in vertical position so that, with the top quick connect fitting **14***a* supported by the flanged portion **520***b* of the top keyhole feature **520**, the movable portion of the flanged portion **520***b* of the bottom keyhole feature can be moved, e.g., upwardly, so that the bottom quick connect fitting **14***a* is also supported by the flanged portion **520***b*. Thus, the weight of the dialyzer **14** can be shared by both keyhole features **520**. The flanged portion **520***b* may be made adjustable in any suitable way. In this embodiment, the flanged portion **520***b* has a "U" shaped member **520***c* that is vertically slidable along the vertical flanges and can be fixed in place by tightening a set of thumb screws. The "U" shaped member **520***c* may engage the quick connect fitting **14***a* so that the "U" shaped member **520***c* supports the weight (at least in part) of the dialyzer **14**.

[0121] Although in the embodiment above, the dialyzer **14** is supported by keyhole features in the front panel **511**, a support arrangement for the dialyzer may be configured in other ways. For example, the upper insertion area **520***a* is not necessarily required. Instead, only flange portions (e.g., in the shape of a "U" shaped flange having opposed flange portions) may be provided to engage the dialyzer quick connect fittings. The flange portions may be offset from the front surface of the front panel **511** to provide clearance for the fitting and allow the flange portions to engage with the grooves of the quick connect fittings. Also, the flange portions need not be provided in a vertical orientation as shown, but instead may be oriented at an angle to the vertical, e.g., in a horizontal arrangement. The flange portions may have a detent, catch, or other feature to help maintain the dialyzer in place as well.

[0122] In accordance with another aspect of the invention, a bicarbonate, acid and/or other reagent supply device may be selectively associated with the dialysis unit. As described above, the dialysis unit **51** requires a supply of certain chemicals to generate dialysate and/or other materials needed for system operation. FIG. **25** shows a reagent supply **49** used to provide acid, bicarbonate and/or other materials to the dialysis unit **52**. (FIG. **21** shows the reagent supply **49** attached to the acid/bicarbonate connection point **512** on the front panel **511**.) The reagent supply **49** in this illustrative embodiment includes an E-prong connector **491** that is arranged to mate with the acid/bicarbonate connection point **512**. As with other connections made by the user at the front panel **511**, e.g., including the blood line connections at the connection point **514**, the mating connectors may be color coded or otherwise marked to help ensure proper connections are made. For example, the E-prong connector **491** and the acid/bicarbonate connection point **512** may be colored orange, while the arterial line **203** and its mating connection at the connection point **514** may be colored red, and the venous line **204** and its mating connection at the connection point **514** are colored blue. Leading from the E-prong connector **491** are a bicarbonate supply line **492**, a water supply line **493** and an acid supply line **494**. (See FIG. **6** and the accompanying description regarding the function of these lines.) The water supply line **493** provides water to a bicarbonate supply **28** (which in this embodiment is a 750 g Altracart Bicarbonate cartridge (#500750A) sold by Baxter International Inc. that includes a powdered bicarbonate material, but may be any suitable supply), which provides bicarbonate to the dialysis unit **51** via the bicarbonate supply line **492**. In this embodiment, the acid supply line **494** leads to an acid bag spike **495**, which may be used to pierce and draw a suitable acid from a IV-type bag or other container. In this embodiment, the acid bag spike **495** includes a spike member **495***a* and a pair of spring clips **495***b*. The spring clips **495***b* are joined together at center portions by a connecting bar such that the spring clips **495***b* and the connecting bar form an "H" shape and allow the spring clips **495***b* to be pivoted relative to each other when proximal ends of the spring clips **495***b* are squeezed toward each other. The spring clips **495***b* may be arranged to engage with a connector element on an acid bag (or other acid supply, not shown) so that the spike member **495***a* remains engaged with the bag until a user disengages the clips **495***b*. For example, distal ends of the clips **495***b* may include barbs that engage with the acid supply, and the clips may be disengaged from the acid supply by squeezing proximal ends of the clips **495***b* together to disengage the barb elements at the distal ends of the clips **495***b* from the acid supply. The acid bag spike **495** may also include a valve **495***c* (in this case, a pinch clamp) to open/close the line of the acid bag spike **495**. In accordance with one aspect of the invention, the acid bag spike **495** may be replaced (disconnected from the acid supply line **494** at a cap connector **496**) with another component, such as an acid jug straw (not shown) or other arrangement. When used with a jug straw, the cap connector **496** may be engaged with an acid jug opening such that the cap connector **496** covers the opening, like a cap. Alternatively, the jug straw can terminate in a spike, which then has the ability to penetrate a self-sealing (e.g. rubber) membrane covering the opening of the acid jug. Thus, different types of components may be attached to the acid supply line **494** depending on the acid supply arrangement (such as a jug, bottle, bag, or other).

[0123] FIG. **26** shows a close up view of the E-prong connector **491** and the corresponding connection point **512** at the front panel **511**. The E-prong connector **491** has three parallel prongs (corresponding to the bicarbonate and acid supply lines **492** and **494** and the water supply line **493**) that that engage with corresponding receiving holes in the connection point **512**. The E-prong connector **491** and receiving holes in the connection point **512** are arranged so that a center lumen (the water supply line **493**) is arranged above, or otherwise out of, a common plane of the two outer lumens (the bicarbonate and acid supply lines **492** and **494**). In this way, it is ensured that the bicarbonate and acid supply lines **492** and **494** are properly connected since the E-prong connector **491** cannot be engaged with the connection point **512** unless appropriately oriented. The E-prong connector **491** includes a pair of spring tabs **491***a* that can be engaged with corresponding slots **512***a* in the connection point **512**, e.g., when the prongs are properly seated in receiving holes of the connection point **512**. With the tabs **491***a* engaged in the slots **512***a*, the E-prong connector **491** cannot be easily removed from the connection point **512**, helping reduce the likelihood of an accidental disconnection. The E-prong connector **491** may be disconnected by pressing the tabs **491***a* toward each other so that barbs at the distal ends of the tabs **491***a* disengage from the slots **512***a*. The connection point **512** has similar spring tabs **512***b* which allow the connection point **512** to be connected to and disconnected from the front panel **511**.

[0124] In accordance with another aspect of the invention, a disinfect connector (not shown) engages with connection point **512** for use during a disinfection procedure. The disinfect connector has three parallel prongs having a similar orientation as the E-prong connector **491**, so that the prongs may engage with the receiving holes in connection point **512**. The channels in the prongs of the disinfect connector terminate within a common chamber within the disinfect connector. Thus, during a disinfect procedure, the bicarbonate flow line, acid flow line and water flow line are all interconnected, permitting disinfection of each of these flow lines during the disinfect procedure. (This is shown as a dashed inverted "T" line at **49** in FIG. **6**).

[0125] In accordance with another aspect of the invention, the blood lines **203**, **204** are equipped with a connector that enables two types of connections to be made. One type of connection is a plug-in or press-in connection by which the connector can be pushed into a receiving lumen and a leakfree connection made without requiring rotation of the connector or the receiving lumen. A second type of connection is a screw-type connection by which a leakfree connection can be made by a threaded engagement of the connector with a complementary element. For example, FIGS. **27** and **28** show a perspective view and a side view of a blood line connector **202** that is used with the blood lines **203**, **204** and that can engage with the blood line connection point **514** on the front panel **511**. The connector **202** includes a tube connection end **202***a* that connects to the corresponding blood line **203**, **204**, and a patient access connection end **202***b* that is arranged to connect to both a patient access as well as the connection point **514** to establish a leakfree connection. At the patient access connection end **202***b*, the connector **202** includes a frustoconical member **202***c* that has an internally threaded portion arranged to engage with an externally threaded patient access. For example, the frustoconical member **202***c* may be part of a male-type luer connector that includes the central tube **202***e* extending from the center of the frustoconical member **202***c*. When making the luer connection, the tube **202***e* may extend into a female luer connector at the patient access and the threaded portion on the interior of the frustoconical member **202***c* may engage with a thread on the female luer connector of the patient access (whether arterial or venous). Such luer connections are standard when connecting blood lines to a patient access. However, the connector **202** may also be engaged with the connection point **514** by simply pushing the patient access connection end **202***b* into a receiving hole of the connection point **514**. When making this connection, the exterior of the frustoconical member **202***c* may engage with a suitable seat, or other surface or element in the connection point **514** (such as a valve seat, O-ring, or other) so that a seal is formed between the frustoconical member **202***c* and the connection point **514**. The central tube **202***e* may also, or instead, be used to engage with the connection point **514** to establish a suitable seal. Locking arms **202***d* that extend rearwardly from the frustoconical member **202***c* may engage with holes **514***a* in the connection point **514** (e.g., barbed portions on the arms **202***d* may engage with the holes **514***a*) to help maintain the connector **202** in the receiving hole of the connection point **514**. The connector **202** may be released by pressing the arms **202***d* toward each other (e.g., by pressing on finger depression portions at the distal ends of the arms **202***d*), thereby disengaging the barbs from the holes **514***a*, and withdrawing the connector **202**. Note that the connection point **514** may include spring tabs **514***b* to allow the connection point **514** to be selectively engaged/disengaged at the front panel **511**. The connectors **202** may be made in any suitable way, such as by molding of plastic as a single unitary part.

[0126] The following are each incorporated herein by reference in their entireties: U.S. Provisional Patent Application Ser. No. 60/903,582, filed Feb. 27, 2007, entitled "Hemodialysis System and Methods"; U.S. Provisional Patent Application Ser. No. 60/904,024, filed Feb. 27, 2007, entitled "Hemodialysis System and Methods"; U.S. patent application Ser. No. 11/787,213, filed Apr. 13, 2007, entitled "Heat Exchange Systems, Devices and Methods"; U.S. patent application Ser. No. 11/787,212, filed Apr. 13, 2007, entitled "Fluid Pumping Systems, Devices and Methods"; U.S. patent application Ser. No. 11/787,112, filed Apr. 13, 2007, entitled "Thermal and Conductivity Sensing Systems, Devices and Methods"; U.S. patent application Ser. No. 11/871,680, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,712, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,787, filed Oct. 12, 2007, entitled "Pumping Cassette"; U.S. patent application Ser. No. 11/871,793, filed Oct. 12, 2007, entitled "Pumping Cassette"; and U.S. patent application Ser. No. 11/871,803, filed Oct. 12, 2007, entitled "Cassette System Integrated Apparatus." In addition, the following are incorporated by reference in their entireties: U.S. Pat. No. 4,808,161, issued Feb. 28, 1989, entitled "Pressure-Measurement Flow Control System"; U.S. Pat. No. 4,826,482, issued May 2, 1989, entitled "Enhanced Pressure Measurement Flow Control System"; U.S. Pat. No. 4,976,162, issued Dec. 11, 1990, entitled "Enhanced Pressure Measurement Flow Control System"; U.S. Pat. No. 5,088,515, issued Feb. 18, 1992, entitled "Valve System with Removable Fluid Interface"; and U.S. Pat. No. 5,350,357, issued Sep. 27, 1994, entitled "Peritoneal Dialysis Systems Employing a Liquid Distribution and Pumping Cassette that Emulates Gravity Flow." Also incorporated herein by reference are a U.S. patent application entitled "Sensor Apparatus Systems, Devices and Methods," filed on even date herewith (Docket No. F63, now Ser. No. 12/038,474), and a U.S. patent application entitled "Cassette System Integrated Apparatus," filed on even date herewith (Docket No. F62).

[0127] While several embodiments of the present invention have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and/or structures for performing the functions and/or obtaining the results and/or one or more of the advantages described herein, and each of such variations and/or modifications is deemed to be within the scope of the present invention. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present invention is/are used. Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claims and equivalents thereto, the invention may be practiced otherwise than as specifically described and claimed.

[0128] The indefinite articles "a" and "an," as used herein in the specification and in the claims, unless clearly indicated to the contrary, should be understood to mean "at least one."

What is claimed is:

1. An air trap for a blood circuit in a dialysis unit, comprising:

a blood inlet supply line;

a blood outlet supply line; and

a container having an approximately spherical internal wall, an inlet at a top end of the container connected to the blood inlet supply line, and an outlet at a bottom end of the container connected to the blood outlet supply line, the inlet being offset from a vertical axis of the approximately spherical internal wall such that blood entering the container through the inlet is directed to flow in around the approximately spherical wall in a spiral-like path;

wherein when blood is supplied to the container via the blood inlet supply line and blood in the container is removed from the container via the blood outlet supply line, air in the blood entering the container remains in the container.

2. The air trap of claim **1**, wherein the container is formed by an approximately spherical shell.

3. The air trap of claim **1**, wherein the blood circuit includes a dialyzer and the air trap receives blood via the blood inlet supply line from the dialyzer.

4. The air trap of claim **1**, further comprising:

a self-sealing port located at a top of the container.

5. The air trap of claim **4**, wherein the self-sealing port is formed by a split septum.

6. The air trap of claim **4**, wherein the split septum is arranged to permit introduction of fluid into, and withdrawal of liquid from, the container by inserting a needleless device through the split septum.

7. The air trap of claim **4**, wherein the self-sealing port is arranged to be self-cleaning when disinfection liquid is circulated through the container.

8. The air trap of claim **7**, wherein an inner surface of the self-sealing port is approximately flush with the internal wall of the container at a top of the container.

9. The air trap of claim **8**, wherein the self-sealing port is cleaned by introducing liquid into the container via the blood outlet supply line and removing liquid from the container via the blood inlet supply line.

10. The air trap of claim **1**, wherein the inlet port is arranged to receive air in the container when liquid is introduced into the container via the outlet port during a priming operation.

11. The air trap of claim **1**, wherein the inlet port is arranged to introduce blood into the container in a direction that is approximately tangential to the approximately spherical inner wall of the container.

12. The air trap of claim **1**, wherein the inlet port is arranged to introduce blood into the container in a direction that is approximately perpendicular to the vertical axis of the container.

13. A method for removing air from a flow of blood in a dialysis unit, comprising:

introducing blood into an upper portion of an approximately spherical container;

causing the blood to flow in a spiral-like path in the container; and

removing the blood from a lower portion of the approximately spherical container.

14. The method of claim **13**, wherein the step of introducing comprises:

introducing blood into the container in a direction that is approximately tangential to an approximately spherical inner wall of the container.

15. The method of claim **13**, wherein the step of introducing comprises:

introducing blood into the container in a direction that is approximately perpendicular to the vertical axis of the container.

16. An air trap for a blood circuit in a dialysis unit, comprising:

a blood inlet supply line;

a blood outlet supply line;

a container having an approximately spherical internal wall, an inlet at a top end of the container connected to the blood inlet supply line, and an outlet at a bottom end of the container connected to the blood outlet supply line, the inlet being offset from a vertical axis of the approximately spherical internal wall such that blood entering the container through the inlet is directed to flow in around the approximately spherical wall in a spiral-like path; and

a self-sealing port located at a top of the container, the self-sealing port having an inner surface that is approximately flush with the internal wall of the container at the top of the container,

wherein when blood is supplied to the container via the blood inlet supply line and blood in the container is removed from the container via the blood outlet supply line, air in the blood entering the container remains in the container, and wherein any air in the container is substantially completely removed by introducing liquid into the container via the blood outlet supply line and removing liquid from the container via the blood inlet supply line.

17. The air trap of claim **16**, wherein the inlet, outlet and internal wall of the container and the self-sealing port are arranged to substantially eliminate stagnation regions.

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