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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 October 2001 (18.10.2001)

PCT

(10) International Publication Number
WO 01/76656 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US01/11584

(22) International Filing Date: 6 April 2001 (06.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/543,984 6 April 2000 (06.04.2000) US

(71) Applicant: COBE CARDIOVASCULAR, INC. [US/US]; 14401 West 65th Way, Arvada, CO 80004 (US).

(72) Inventors: WEIMER, Kirk; 1275 South Boyero Court, Superior, CO 80027 (US). ELLINGBOE, Bruce; 10 Meadow Brook Road, Littleton, CO 80120 (US). LITTLE, James; 6255 Habitat Drive, Apt. 2008, Boulder, CO 80301 (US).

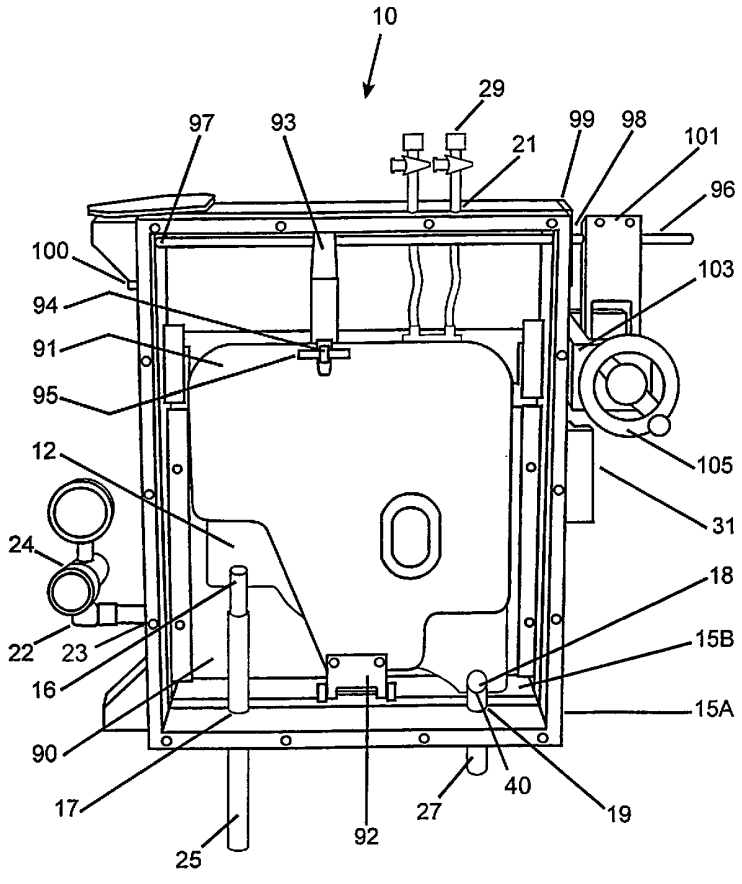
(74) Agents: POPOVICH, Thomas et al.; Popovich & Wiles, 80 South 8th Street, Suite 1902, Minneapolis, MN 55402 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: ASSEMBLY FOR EXTRACORPOREAL BLOOD HANDLING AND METHOD OF USE



(57) Abstract: An apparatus and method of extracorporeal blood handling is disclosed using a flexible reservoir enclosed within a rigid housing to draw and temporarily store venous blood during surgical procedures. A vacuum in the space between the flexible reservoir and the rigid housing as a gravity assistance to draw venous blood into the flexible reservoir. A vent may be provided to evacuate air, other gases and some foamy blood from the flexible reservoir and a pump may draw the blood out of the flexible reservoir. The primary motive forces on moving the venous blood from the patient are gravity and the vacuum force within the rigid housing, not any other pumps in the system.

WO 01/76656 A2

IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

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

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

ASSEMBLY FOR EXTRACORPOREAL BLOOD HANDLING AND METHOD OF USE

FIELD OF THE INVENTION

This invention generally relates to extracorporeal assemblies used to handle body fluids during surgical procedures and, more particularly, to extracorporeal assemblies involving closed, flexible reservoirs used in the drawing and temporary storage of blood from a patient during cardiopulmonary surgical procedures.

BACKGROUND

The terminology used in this specification may refer to venous blood, blood flowing through veins, or simply blood. These descriptions are not intended to limit the scope of this invention to venous (low oxygen saturation) blood. Such descriptions are used due to convention in the area of perfusion, and those skilled in the art will understand that the disclosed invention may be applied to both venous and arterial (highly oxygen saturated) blood. This specification also uses the terms negative pressure and vacuum interchangeably, and for the purposes of this specification considers them to be the same.

In many surgical procedures, blood is removed from a patient and passed through an extracorporeal blood handling circuit. For example, during cardiopulmonary bypass surgery, blood may be drawn directly from a patient's blood vessels and directed to an extracorporeal circuit for oxygenation, filtration and ultimately return to the patient. In a procedure such as a left ventricular assist, the extracorporeal oxygenation step may be omitted. In either event, before such extracorporeal processing, the drawn blood typically is stored temporarily in a reservoir, often referred to as a venous reservoir. The extracorporeal circuit acts as part of the patient's circulatory system, thereby

handling up to 2-6 liters of blood or more per minute. Since there is typically about 5-6 liters of blood in a patient's body, such an extracorporeal blood handling circuit is used to manage the patient's entire circulating blood flow during such surgical procedures, unlike some smaller volume extracorporeal blood handling systems used for collection and possible autotransfusion.

Also during surgical procedures, a patient's blood may be suctioned off the area surrounding the surgical site. This suctioned blood typically contains significantly more air and other contaminants than blood drawn directly from the blood vessels, and therefore requires greater or additional processing. Nonetheless, it is generally desirable to direct the suctioned blood to an extracorporeal circuit for temporary storage, processing and possible return to the patient.

Generally, blood is drawn from a patient for extracorporeal processing by gravity alone or by gravity plus mechanical assistance. The most common mechanical assistance procedures are referred to as kinetic assistance and vacuum assistance. Blood drawn from the veins of a patient, also known as venous blood, is under a lower pressure than arterial blood and thus gravity and/or mechanical assistance is desirable for venous drainage.

In a gravity system, the venous blood may be drawn into either an open or a closed reservoir. An open reservoir typically is a rigid or hard shell into which blood flows. The open reservoir may include a calibrated scale to allow an operator, or perfusionist, to readily determine the volume of blood in the reservoir. Open reservoirs have an interface between the ambient air and the top surface of the blood in the reservoir. As such, gas bubbles within the blood can migrate upward in the reservoir and escape. However, the exposure of the blood near the surface to the air may damage components of the blood.

A closed reservoir typically is a flexible shell or bag that may be deformed under pressure and may be suspended from a stand near the patient.

Blood typically flows into the closed, flexible reservoir from the bottom up. Because the closed, flexible reservoir usually deforms irregularly under pressure, it is not easily calibrated to show the volume of blood contained therein. On the other hand, since there is no ambient air to blood interface, closed, flexible reservoirs largely avoid blood damage caused by exposure to air. As a result, closed, flexible reservoirs are generally preferred to open reservoirs for use with blood in applications where the clinician is attempting to minimize blood damage.

Reliance on gravity alone to draw venous blood from a patient has numerous problems. Initiation and subsequent regulation of blood flow often requires the perfusionist to physically adjust the height of the reservoir relative to the patient. Small adjustments are difficult and subjective, while larger adjustments are limited by the height of the stand and the distance from the patient to the floor. The reservoir is typically placed well below the patient, often almost to the floor. Also, the force of gravity may be insufficient to generate the desired blood flows in some applications.

Further, there can be significant issues of maintaining proper blood volume in a closed, flexible reservoir. For example, as the closed, flexible reservoir fills with blood, the filling resistance of the bag increases. As a result, in procedures involving a closed, flexible reservoir, it is common for the perfusionist to use both a closed flexible reservoir and an open, rigid reservoir. Such an assembly not only exposes the blood to ambient air, it also adds complexity for the perfusionist to deal with two different reservoirs in the drawing of blood. The closed, flexible reservoir typically is placed at or near the floor and the open, rigid reservoir is moved up or down on a mounting pole to maintain a balance of blood in the two reservoirs.

A system known as kinetic assistance was developed to address the problems of relying on gravity alone to draw venous blood from the patient.

Typically, a kinetic assistance system uses a mechanical pump connected directly to the patient's venous drainage tube, and consequently, directly to the patient's circulatory system. The pump outflow is connected to a rigid, open venous reservoir and a second pump circulates the blood back to the patient, often after passing through an oxygenator. Kinetic assistance can place significant negative pressure directly on the patient's circulatory system and requires the operation and monitoring of two dynamic, hydraulic circuits. As surgical procedures have developed towards smaller cannulas, higher negative pressures are required to move adequate volumes of blood. This is a significant problem, as inadvertent application of highly negative pressures associated with some conventional systems may cause the patient's blood vessels to be damaged or even to collapse.

With the increased use of smaller cannulas, a more preferable system to augment gravity drainage is referred to as vacuum assistance. Such a system in conventional use draws blood into a closed, rigid reservoir by applying a vacuum force directly on the blood in the rigid reservoir. A pump then pumps the blood out of the reservoir, through an oxygenator, if appropriate, and back to the patient. Since the vacuum is applied within the rigid reservoir itself, a flexible, bag-type closed reservoir is impractical. That is, when a vacuum is created within a closed, flexible reservoir, it collapses. There are no known vacuum assistance assemblies that have used closed, flexible reservoirs for drawing venous blood in these applications.

Moreover, in existing vacuum assistance systems, the vacuum draws not only venous blood directly from the patient's circulatory system, but also blood suctioned from the surgical site. The suctioned blood is typically foamy, as it is drawn into the reservoir with large amounts of air and is often contaminated with other matter. The reservoir includes a defoamer that breaks down the air bubbles in the blood and filters out other contaminants before sending the blood

on to an oxygenator. Since the blood in the reservoir is under a vacuum in this system, the air in the bubbles expands even further, making the task of defoaming more difficult.

In both the kinetic and vacuum assistance systems, the perfusionist must manage two independent, dynamic blood circuits, one from the patient to the venous reservoir and another from the venous reservoir, through the oxygenator, and back to the patient. This dual circuit approach inevitably presents greater cost and operating complexity to what is typically an expensive and critically complex life sustaining procedure.

The kinetic and vacuum assistance systems must maintain a balance between applying sufficient negative pressure to keep the blood flowing and not applying too great a vacuum on the patient's circulatory system. To help maintain this balance, these systems continue to employ gravity as a force to draw blood from the patient. As a result, the perfusionist must carefully and continuously monitor the patient and the volume of blood circulating through the extracorporeal blood handling circuit. The perfusionist typically has a short period of time, usually a matter of seconds, to correct a stoppage of blood flow during such a surgical procedure.

Therefore, a need exists for an improved extracorporeal blood handling assembly and method of use, and particularly for an assembly using a closed, flexible reservoir.

SUMMARY

The present invention is directed to an extracorporeal blood handling assembly to assist a patient's circulatory system during surgical procedures. An extracorporeal blood handling assembly of the present invention comprises a flexible reservoir having an inlet, an outlet and a vent. The flexible reservoir is encompassed within a rigid housing, which is connected to a pump to adjust the

pressure within the rigid housing. A pump is connected to the flexible reservoir to withdraw blood from the flexible reservoir.

A further embodiment of the invention is directed to an extracorporeal blood handling assembly comprising a flexible reservoir encompassed by a rigid housing having at least two pieces releasably connected together, means to mount a flexible reservoir on the interior of the rigid housing and openings for an inflow conduit, an outflow conduit and a vent conduit. A pump is connected to the rigid housing to adjust the pressure within the rigid housing. Another pump is connected to the flexible reservoir to withdraw blood from the flexible reservoir. The inflow conduit, outflow conduit and vent conduit of the flexible reservoir pass through the corresponding openings in the rigid housing in a releasable, sealed relationship.

Yet another embodiment of the invention is directed to an extracorporeal blood handling assembly comprising a flexible reservoir within a fluid filled, rigid housing. The rigid housing is fluidly connected to a reservoir which is partially filled with fluid. Negative pressure applied to the air above the fluid in the reservoir draws fluid from the rigid housing, allowing the flexible reservoir to expand and drawing blood from the patient. A pump is connected to the flexible reservoir to withdraw blood from the flexible reservoir.

The invention is also directed to an extracorporeal blood handling assembly comprising a flexible reservoir within a fluid filled, rigid housing. The rigid housing is fluidly connected to a reservoir, which is at least partially filled with fluid and physically located below the rigid housing. Adjusting the volume of fluid in the fluid reservoir creates, maintains and adjusts the negative pressure on the flexible reservoir, drawing the desired blood flow from the patient. The volume of fluid in the fluid reservoir is controlled by, for example, drawing a vacuum on the air above the fluid in the reservoir or, for example, by the force of gravity upon adjusting the height of the fluid reservoir relative to

the flexible reservoir. A pump is connected to the flexible reservoir to withdraw blood from the flexible reservoir.

A still further embodiment of the invention is to provide a method for extracorporeal blood handling comprising removing blood from a patient through a conduit to a flexible reservoir in a rigid housing by reducing the pressure within the rigid housing. Blood is removed from the flexible reservoir through an outlet conduit by applying negative pressure to the outlet conduit and then returned to the patient.

In one aspect of the invention, volume control of the flexible reservoir can be achieved through the use of mechanical plates to limit the distension of the flexible reservoir. In another aspect of the invention, a flexible bladder can be used, which is connected with a tube to an exterior pump and a reservoir capable of adding or removing fluid to the bladder and blocking the flow of fluid into or out of the bladder. Use of either the plates or the bladder limit distention of the flexible reservoir and thus provide control from the outside, while under vacuum.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an isometric view of one embodiment of the disclosed invention showing a flexible reservoir and a rigid housing.

FIG. 2 is a front elevational view of the embodiment of the invention shown in FIG. 1.

FIG. 3 is a side interior sectional view of the embodiment of the invention shown in FIG. 1.

FIG. 4 is a schematic view of present invention showing a flexible reservoir and a rigid housing as part of an extracorporeal blood handling system and showing blood flow during normal bypass.

FIG. 5 is a schematic view of the embodiment shown in FIG. 4, showing

an alternative blood flow through the extracorporeal blood handling system, as during return of blood to the patient.

FIG. 6 is a schematic view of the embodiment shown in FIG. 4, showing another alternative blood flow through the extracorporeal blood handling system, as during removal of blood from the patient.

FIG. 7 is a schematic view of one embodiment of the invention showing a flexible reservoir within a fluid filled, rigid housing and a vacuum/fluid reservoir.

FIG. 8 is a schematic view of another embodiment of the invention showing a flexible reservoir within a fluid filled, rigid housing located above a vacuum/fluid reservoir.

FIG. 9 is a cross-sectional side view of an embodiment of the invention having a flexible bladder.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

One embodiment of the present invention is shown in FIGS. 1-3. FIGS. 1 and 2 generally show an assembly 10 for extracorporeal blood handling comprising a closed, flexible reservoir 12, having blood inlet port 16, a blood outlet port 18 and a vent outlet port 20. The blood inlet port 16 provides a connection for blood from the patient to the flexible reservoir 12. The blood outlet port 18 provides a connection for blood from the flexible reservoir 12 back to the patient. The vent outlet port 20 provides a connection for air and at least some foamy blood, if present, to be evacuated from the flexible reservoir 12. A preferred reservoir 12 for use with the present invention is shown and described in U.S. Patent Nos. 5,352,218; 5,693,039 and 5,720,741.

A rigid housing 14 encompasses the flexible reservoir 12 in a substantially sealed relationship to allow a vacuum to be drawn on the interior of the rigid housing 14 in the space between the rigid housing 14 and the

exterior surface of the flexible reservoir 12. The rigid housing 14 comprises sealed openings 17, 19, 21 for each of the ports 16, 18, 20 of the flexible reservoir 12. That is, the rigid housing 14 comprises an opening 17 to allow a conduit 25 to connect the patient or other source of blood to the blood inlet port 16, an opening 19 to allow a conduit 27 to connect the blood outlet port 18 back to the patient and an opening 21 to allow a conduit 29 to connect the vent outlet port 20 to a second reservoir for further processing, as will be further described below. The rigid housing 14 also comprises a vacuum conduit opening 23 to connect a vacuum conduit 22 to the interior of the rigid housing 14, so that a vacuum may be drawn on the interior of the rigid housing 14. A valve/gauge 24 may be connected to the vacuum conduit 23 or the vacuum conduit port 22 to measure and/or regulate the vacuum conditions within the rigid housing 14.

The openings 17, 19, 21, 23 form a seal around the respective port or conduit passing through the respective walls of the rigid housing 14, thereby allowing a vacuum to be drawn on the space between the rigid housing 14 and the exterior surface of the flexible reservoir 12. The assembly 10 may be manufactured as a disposable unit, with the flexible reservoir 12 assembled within the rigid housing 14, which may not be intended to be opened. Preferably, as shown in FIGS. 1-3, the rigid housing 14 comprises at least two pieces 15A and 15B that are releasably connected together, e.g., by one or more hinges and/or locking mechanisms such as mechanism 31, by a snap fit, sealed configuration or by other suitable mechanism. Each piece 15A and 15B forms a sealed relationship with its corresponding connecting piece, preferably with at least one elastomer strip. Most preferably, the rigid housing is shaped to contain and facilitate the repeated insertion and removal of a disposable flexible reservoir 12 for each use and the rigid housing 14 may be fabricated of plastic, such as clear polycarbonate.

Preferably, the flexible reservoir 12 is mounted on the interior of the

rigid housing 14. A variety of mechanisms may be employed to mount the flexible reservoir 12 on the interior of the rigid housing 14, including hooks corresponding to openings defined in the outside edges of the flexible reservoir 12, a swing arm to hold the flexible reservoir 12 against one side of the rigid housing 14, or hook and loop fasteners on the flexible reservoir 12 and the interior of the rigid housing 14.

The rigid housing may also comprise mechanisms to limit the distension of the flexible bag 12, and thereby adjust and limit its volume. Such a mechanism could take any of several different forms, including a swinging plate or arm, threaded plunger or a lever. In all cases the mechanism will be capable of changing the maximum volume of the flexible reservoir, and would also be capable of changing the volume of the reservoir during use as desired by the clinician. These volume changes would preferably be made without removing vacuum from the rigid shell.

The volume adjustment method employed in the embodiment depicted in FIGS. 1, 2 and 3 consists of two flat plates, the rear plate 90 rectangular and the front plate 91 approximately the same size and shape of the flexible reservoir 12 mounted within the rigid housing. The rear plate 90 is fixed to the rear housing 15B and slanted such that the flexible reservoir inlet 16 and outlet 18 align with the inlet port 17 and outlet port 19 of the rigid enclosure 15. The front plate 91 is attached to the rear plate by a hinge 92 at its bottom, below the flexible reservoir 12 and is shaped similarly to the flexible reservoir 12 with cutaway areas for the inlet 16 and outlet 40 ports of the flexible reservoir 12. The front plate 90 may be swung forward and backward to vary the maximum volume of the flexible reservoir 12 by an arm 93 equipped with a linkage 94 which engages a bar 95 attached to the top edge of the front plate 91. The arm 93 is fixed on a shaft 96 which extends through either side of the rear of the rigid housing 15B via o-ring sealed holes 97, 98. The shaft 96 passes through

bearing plates 99, 100 mounted to the exterior of the rear housing 15B at either end. Bearing plated 99 and 100 are preferably made from a material commercially available under the trade designation DELRIN. It is rotated by a second arm 101 mounted on the outer end of the shaft 96 and having two forks which accommodate a trunion block 102 running on a threaded rod 104 mounted in a bushing block 103. The bushing block is preferably made from a material commercially available under the trade designation DELRIN. The threaded rod 104 is actuated by a small handwheel 105. As the threaded rod 101 rotates, the threaded trunion block 102 travels forward and backward, causing the forked arm 101 to rotate the shaft 96 causing the arm 93 and linkage 94 to swing the front plate 91 forward and backward within the closed rigid housing 15. This change in the position of the front plate 91 allows the operator to vary the maximum volume of the flexible reservoir 12.

Provisions will also preferably be made in the present invention to allow for the monitoring of the volume of blood in the reservoir. This monitoring method could include the use of optical sensors, magnetic sensors, weight sensors, mechanical indicators, ultrasonic sensors, or displacement of fluid surrounding the flexible reservoir 12.

Referring now to FIGS. 4-6, the assembly 10 is shown as part of a larger extracorporeal blood handling system 30. The patient 32, or other source of blood, is connected by conduit 25 to the inlet port 16 of the flexible reservoir 12. The blood is returned to the patient 32, or the other source of blood, through the outlet port 18, the conduit 27, the pump 36, and the oxygenator 38. A safety outlet closure valve 40 (see FIG. 2) may be placed between the flexible reservoir 12 and the pump 36. Among other things, the safety venous outlet valve 40, which is an integral component of the COBE VRB closed reservoir (see U.S. Patent Nos. 5,352,218; 5,693,039 and 5,720,741) as part of outlet port 18 may be used to prevent the pump 36 from applying excessive

negative pressure on the flexible reservoir 12 when there is insufficient or no blood in the flexible reservoir 12.

Air, other gases and relatively small amounts of blood may be vented from the flexible reservoir 12 through the vent outlet port 20 and the vent conduit 29 to waste or to a second reservoir 46, typically referred to as a cardiotomy reservoir. A pump 44, or other means of negative pressure, may be connected to the vent conduit 29 to draw this material through the vent outlet port 20. A vent outlet check valve 42 may be connected to restrict air from flowing back into the flexible reservoir 12. A hydrophobic filter also may be provided to the vent outlet port 20 to facilitate the separation of air from blood in the venting process.

Another source of blood from the patient is blood suctioned from the surgical site or otherwise. The volume of suctioned blood and blood vented from the flexible reservoir 12 is significantly less than the volume of blood circulating through the extracorporeal system, typically in the range of about 0.1 to 0.5 liters per minute. Nonetheless, it is often desirable to temporarily store, process, and possibly return to the patient this suctioned blood and vented blood. A vacuum source 52 draws suctioned blood from the surgical site of the patient 32 through a conduit 48 to the second reservoir 46. The suctioned blood is typically more contaminated, more foamy and generally more difficult to process for return to the patient 32. As a result, the second reservoir 46 preferably is a rigid, open reservoir to allow easier monitoring of blood volume and easier treatment of unwanted air, other gas and other contaminants. The blood from the second reservoir 46 may require additional processing steps, such as defoaming, filtration and oxygenation before being returned to the patient 32.

The vacuum conduit 22 is connected to a suitable source of vacuum 34, which is typically available in the operating room environment. The vacuum

source 34 is regulated to the desired negative pressure through the use of an appropriate vacuum regulator 24. Preferably, the level of negative pressure is adjusted to maintain the flexible reservoir 12 at a predetermined, fixed volume. That is, the flexible reservoir is preferably fully expanded to the mechanical or hydraulic limits imposed in fixing its desired volume. As set forth below, this negative pressure level represents the maximum level of negative pressure that would be applied to the patient's circulatory system in the event of a venous occlusion. The mechanical limit is the volume limit imposed by the adjustable plates in the embodiment depicted in FIGS. 1, 2 and 3 or a swinging arm, threaded plunger or lever, depending on the mechanism employed. The hydraulic limit is the fixed volume limit maintained by the hydraulic systems as described in FIGS. 7-9. In the case of the systems in FIG. 7, the hydraulic limit is maintained by a level sensor 76 in the vacuum/fluid reservoir 64 feeding back to the electronic vacuum regulator 72.

In operation, the blood inlet conduit 25 makes a fluid connection from the circulatory system of the patient 32 to the flexible reservoir 12 and the blood outlet conduit 27 makes another fluid connection from the flexible reservoir 12 through pump 36 and back to the patient 32. This completes an entirely hydraulic circuit from the patient and back. The vent outlet port 20 is connected to a pump 44, or other suitable means capable of removing air or other gas trapped in the bag, either continuously or as desired, to the second reservoir 46. If not previously installed, the flexible reservoir 12, with little or no distention, is mounted within the inside of the rigid housing 14. The rigid housing 14 is substantially sealed around the flexible reservoir 12 and the conduits 25, 27, 29 connected thereto.

After each of the conduits 25, 27, 29 are connected to their respective ports 16, 18, 20 of the flexible reservoir 12, and the rigid housing 14 has been sealed closed, the vacuum source 34 begins to draw a vacuum in the space

between the exterior surface of the flexible reservoir 12 and the interior surface of the rigid housing 14. This vacuum will apply a vacuum force on the walls of reservoir 12 , and consequently, also to the inside of the flexible reservoir 12. This vacuum force inside the flexible reservoir 12 draws blood directly from the vasculature of the patient 32 through the blood inlet conduit 25 through the inlet port 16 and into the flexible reservoir 12. After the flexible reservoir 12 begins to fill, and preferably is substantially full of blood, the pump 36 may be started, drawing blood from the flexible reservoir 12 through the outlet conduit 27 for eventual return to the patient 32. Preferably, the pump 36 is a roller or centrifugal pump having a capacity of about 0 to about 8 liters per minute, and operates at about 2 to about 6 liters per minute.

Throughout this process, the flexible reservoir 12 is being pulled open by the vacuum force. Preferably the negative pressure within the rigid housing 14 is from about 0 mmHg to about negative 120 mmHg, and more preferably is from about negative 20 mmHg to about negative 60 mmHg.

Alternatively, the vacuum force inside the flexible reservoir 12 may be generated, maintained and regulated by other mechanisms, such as a vacuum/fluid reservoir system. Referring now to FIG. 7, a vacuum/fluid reservoir 64 is fluidly connected by conduit 61 to the rigid housing 14. The vacuum/fluid reservoir 64 is connected by conduit 69 to a vacuum regulator 72 and to a vacuum source 74. A sensor 76 measures the level of liquid 66 in the vacuum/fluid reservoir 64.

In operation, the flexible reservoir 12 is essentially emptied of fluid, including gas, and installed within the rigid housing 14, which is then closed and filled with liquid 66. The vacuum/fluid reservoir 64 is partially filled with liquid 66, thereby leaving a volume of air 68 in the vacuum/fluid reservoir 64. Preferably, sensor 76 is then calibrated to display the volume of the flexible reservoir 12 as zero. Vacuum source 74, through the vacuum regulator 72,

applies a desired negative pressure on the air 68 in the vacuum/fluid reservoir 64. As air 68 is evacuated, liquid 66 is drawn from the rigid housing 14 into the vacuum/fluid reservoir 64, which causes the flexible reservoir 12 to expand and draw blood from the patient. Preferably, the flexible reservoir 12 is maintained at a constant volume by using a feedback loop between the electronic vacuum regulator 72 and the continuous level sensor 76. Alternatively, the vacuum regulator 72 may be used to maintain a constant negative pressure, while the volume of the flexible reservoir 12 is monitored to make sure the fluid volume in reservoir 12 is maintained within safe operating limits.

Because of the head pressure of the liquid 66, the negative pressure on the surface of the flexible reservoir 12 will vary with the height of the vacuum/fluid reservoir 64 with respect to the flexible reservoir 12. As such, the vacuum pressure is preferably measured in the rigid housing 14, instead of at the vacuum regulator 72, or alternatively the level of fluid 66 in the rigid housing 14 is compensated for in the regulator setting. A preferred arrangement would place the vacuum/fluid reservoir 64 no higher than necessary to allow adequate flow from it into the rigid enclosure 15 when filling the rigid enclosure and high enough so that the level of the fluid in the vacuum/fluid reservoir 64 would always be above the top of the interior of the rigid enclosure 15. This will ensure that adequate vacuum is available to lift the column of fluid in the vacuum/fluid reservoir and exert a net negative pressure at the surface of the flexible reservoir 12. Also, the vacuum/fluid reservoir's aspect ratio (height to width) is preferably minimized to minimize the variation in pressure at the surface of the flexible reservoir 12 as the volume of the flexible reservoir is varied. Volume of the vacuum/fluid reservoir 64 should be greater than the volume of the rigid enclosure 15 to ensure that the rigid enclosure 15 would remain full of fluid during operation.

An alternative vacuum/fluid reservoir system of the present invention is shown in FIG. 8. In this embodiment, the rigid housing 14 is physically located above a vacuum/fluid reservoir 64, which is fluidly connected by conduit 61 to the rigid housing 14. A sensor 76 measures the level of liquid 66 in the vacuum/fluid reservoir 64.

In operation, the flexible reservoir 12 is emptied of fluid, including gas, and installed within the rigid housing 14, which is then closed and filled with liquid 66. The conduit 61 is filled with liquid 66, while the vacuum/fluid reservoir 64 is at least partially filled with liquid 66, leaving a volume of air 68 in the vacuum/fluid reservoir 64. Preferably, sensor 76 is then calibrated to display the volume of the flexible reservoir 12 as zero. A vacuum on the flexible reservoir 12 is generated by the presence and weight of the liquid 66 and is adjusted by adjusting the height of the vacuum/fluid reservoir with respect to the flexible reservoir 12.

Alternatively, the vacuum on the flexible reservoir 12 may be generated and adjusted by changing the volume of liquid 66 in the vacuum/fluid reservoir 64. This may be accomplished by a number of ways. For example, liquid 66 may simply be added or withdrawn from the vacuum/fluid reservoir 64. The vacuum/fluid reservoir 64 may be constructed to have an adjustable volume, such as by connecting two rigid plates with a bellows or convoluted gasket. The vacuum/fluid reservoir 64 may then be held rigidly at a desired volume, with a separate vacuum regulator attached. Alternatively, the vacuum/fluid reservoir 64 may be spring loaded to maintain a constant vacuum by varying its volume. In any event, such a system does not require a pump or other vacuum source operating on the flexible reservoir 12, the rigid housing 14 or the vacuum/fluid reservoir 64 to draw blood from the patient.

Another alternative method for limiting the volume of the flexible reservoir 12 as illustrated in FIG. 9 is to include within the rigid housing a

second flexible reservoir or bladder 110 in close proximity to the flexible reservoir 12 and attached to one or both of the interior walls of the rigid housing. This second flexible reservoir or bladder 110 is connected via a port 111 in the rigid housing to a fluid or gas source with a reservoir of adequate volume 112 and a pump 113 capable of moving fluid or gas into or out of this second flexible reservoir or bladder 110 to limit the maximum volume of the flexible reservoir 12. Care should be taken in designing the second flexible reservoir or bladder 110 so as not to allow the occlusion of the outlet 40 or inlet 16 (see FIG. 1) of the flexible reservoir 12. The above described mechanism serves to allow the adjustment of the volume of the flexible reservoir 12 within the closed rigid housing in a way similar to the swinging arm or plate or threaded plunger referred to elsewhere but with fewer and less costly components.

Air in the blood is capable of migrating to the top of the flexible reservoir 12. By providing a vent outlet port 20, vent conduit 29 and pump 44, the air or other gas in the flexible reservoir 12 may be removed from the blood. The venting of the flexible reservoir 12 is desirable in a dynamic extracorporeal blood handling assembly, particularly with continuous, or nearly continuous blood flow through reservoir 12. For example, in a cardio-pulmonary surgical procedure, the extracorporeal blood handling assembly acts as part of the patient's circulatory system, often handling about 2 to about 6 liters or more of blood per minute. Absent an effective vent of the flexible reservoir 12, small amounts of air or other gases could accumulate in the flexible reservoir 12 and eventually reduce the volume of the reservoir available for blood and could potentially be returned to the patient's circulatory system and cause patient injury.

Because the flexible reservoir 12 is held open to a predetermined, mechanical limit by the vacuum force, the volume of the flexible reservoir

remains constant, regardless of blood flow volume or pressure, within normal operating parameters. This fixed volume may be changed or adjusted to allow expansion of the flexible reservoir 12 to any one of various preselected volumes. However, once the volume of the flexible reservoir 12 is fixed, it remains constant, under normal operating parameters. This further reduces the workload of the perfusionist, who is generally responsible for managing the circulating blood volume of the patient 32.

Referring again specifically to FIGS. 4-6, the controlled negative pressure at the blood inlet port 16 may also be used as the driving force to manage patient blood volume located between the patient 32, the closed, flexible reservoir 12, and an open, second reservoir 46. Typically, the inlet conduit 25 comprises a single conduit from the patient 32 to the flexible reservoir 12. Additionally, a first control conduit 25A may branch from the inlet conduit 25 to the second reservoir 46 and a second control conduit 25B may connect the second reservoir 46 back to the inlet conduit 25. Alternatively, the first control conduit 25A may directly connect the patient 32 to the second reservoir 46 and/or the second control conduit 25B may directly connect the second reservoir 46 to the flexible reservoir 12. A flow control mechanism, such as a clamp, a valve, or other suitable means, may be used to allow full, partial or no flow in each of the first control conduit 25A, the second control conduit 25B and the inlet conduit 25. In the embodiment shown in FIGS. 4-6, such a flow control mechanism on the inlet conduit 25 may be placed between the connection with the first control conduit 25A and the connection with the second control conduit 25B.

For example, referring to FIGS. 4-6, by using the clamps 51A, 51B, and 51C, it is possible to remove circulating volume from the patient 32 by increasing second reservoir 46 volumes, as shown in FIG. 6 (clamp 51A is open and clamps 51B and 51C are closed); to add circulating volume to the patient

32 by reducing second reservoir 46 volume, as shown in FIG. 5 (clamp 51A is closed and clamps 51B and 51C are open); or to maintain current circulating volume, as shown in Fig. 4 (where clamps 51A and 51B are closed and clamp 51C is open). In conventional systems, it is necessary to move the closed and open reservoirs up and down relative to the patient elevation to change reservoir volume levels and reintroduce such blood back into the patient's circulatory volume. This is not necessary using the present invention.

The motive force moving the blood through the blood outlet conduit 27 is the pump 36, not the vacuum force or gravity, as in prior systems. That is, blood movement out of the blood outlet conduit 27 generally stops when the pump 36 stops. If a preferable peristalic pump is used for pump 36, this occludes the outlet tubing repeatedly during operation and then provides a constant occlusion when pump 36 is stopped thereby even stopping gravity outflow from reservoir 12. The vacuum force is required to hold the outflow conduit 27 open to its desired volume and to provide negative pressure regulation to the blood inlet port 16, and subsequently, the circulatory system of the patient 32. The vacuum force is thus the maximum negative force to which the patient's circulatory system is exposed. But the vacuum force does not move blood out of the flexible reservoir 12.

An outlet valve 40 may be provided to automatically close off the blood outlet conduit if the volume of blood in the flexible reservoir 12 drops to an insufficient level, or to zero. If valve 40 closes, pump 36 will no longer draw blood, or anything else, from the flexible reservoir 12. Pump 36 presents a negative pressure to the interior of the flexible reservoir 12, which may collapse the flexible reservoir if there is no blood therein, and thus will not draw blood into the flexible reservoir 12. This will consequently not apply a negative pressure through inlet 16 or conduit 25 on the circulatory system of the patient 32. The flexible reservoir 12 thereby acts as a pressure buffer between the

pump 36 and the circulatory system of the patient 32. This limits the maximum amount of negative pressure applied to the patient 32, which is important as excessive negative pressure can seriously damage the patient's circulatory system.

The disclosed invention also allows the use of roller pumps in venous blood drainage assistance, in a single pump, single circuit system. Until now, kinetic assistance was performed using centrifugal pumps because of the low negative stall pressure generated by the centrifugal pump. Low stall pressure is critical when a mechanical pump is acting directly on the patient's circulatory system, as high negative stall pressure may cause vascular damage and injury to the patient. Roller pumps are typically simpler and less costly to operate, in part due to the expensive disposable components required in centrifugal pumps.

The flexible reservoir 12 may hold up to about 2 liters of blood, or even more. If a cannula is occluded, the flexible reservoir 12 can supply the pump 36 with the entire volume of blood in the flexible reservoir 12. When it is full with about 2 liters of blood, the perfusionist has up to about 30 seconds to recognize and attempt to resolve the problem before there is no additional blood to process and/or return to the patient 32.

Blood removed from the flexible reservoir 12 through the blood outlet conduit 27 may then be processed for return to the patient. In operations such as a bypass operation, this blood is passed through an oxygenator 38, and perhaps a filter, before being returned directly to the blood vessels of the patient 32. The oxygenator should be of sufficient capacity so as process the desired blood flow from both the venous reservoir 12 and the second reservoir 46, including maximum blood flows of up to about 2 to about 6 liters or more of blood per minute, as well as possible periods of time with little or no blood flow. In operations such as a left ventricular assist, the oxygenator mechanism and/or step may be omitted.

Unlike conventional sealed, rigid vacuum assist systems, the present invention is not a two circuit system, requiring the perfusionist to manage and monitor two independent and dynamic hydraulic circuits. In the disclosed invention, the circulating volume of the blood may be managed with a single blood pump and a single blood pump control, simplifying and reducing the workload of the perfusionist and reducing the cost and complexity of the equipment.

The disclosed invention may also be used in a number of other applications, such as where it is desirable to safely connect a single inexpensive pump circuit directly to a patient's circulatory system. These applications could include kidney dialysis pump systems and "at the table" cardio-pulmonary bypass systems, among others.

The foregoing description of the present invention has been presented for purposes of illustration and description. The description is not intended to limit the invention to the forms disclosed herein. Consequently, variations and modifications commensurate with the above teachings, and the skill or knowledge of the relevant art, are within the scope of the present invention. The embodiments described herein are further intended to explain the best mode known for practicing the invention and to enable others skilled in the art to utilize the invention in such, or other, embodiments and with various modifications required by the particular applications or uses of the present invention. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

What is claimed is:

1. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

a fluid contained within the fluid-containing portion of the rigid housing; and

a fluid reservoir fluidly connected to the fluid-containing portion of the interior space of the rigid housing.

2. The vacuum assisted blood storage system of claim 1 in which the fluid reservoir is configured so that its height is adjustable.

3. The vacuum assisted blood storage system of claim 1 further comprising:

a vacuum source connected to the fluid reservoir.

4. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed

interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and blood outlet configured for connection to the extracorporeal blood circuit, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

a fluid contained within the fluid-containing portion of the rigid housing; and

means for adding and removing the fluid from the fluid-containing portion of the interior space of the rigid housing.

5. The vacuum assisted blood storage system of claim 4 in which the means for adding and removing fluid from the rigid housing is configured so that its height is adjustable.

6. The vacuum assisted blood storage system of claim 4 further comprising:

a vacuum source connected to the means for adding and removing fluid from the rigid housing.

7. A method for regulating a vacuum assisted blood storage system of an extracorporeal blood circuit comprising:

providing a rigid housing having an interior surface defining an enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood

outlet configured for connection to the extracorporeal blood circuit, and a fluid reservoir fluidly connected to the fluid-containing portion of the interior space of the rigid housing, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

connecting the blood inlet and blood outlet to the extracorporeal blood circuit;

emptying the flexible blood reservoir of substantially all fluid;

filling the fluid-containing portion of the interior space of the rigid housing with liquid;

partially filling the fluid reservoir with liquid, thereby creating a liquid-filled portion of the fluid reservoir and an air-filled portion of the fluid reservoir;

withdrawing the liquid from the fluid-containing portion of the interior space of the rigid housing and into the fluid reservoir, thereby applying negative pressure to the interior space of the rigid housing, thereby causing the flexible blood reservoir to expand, thereby causing the blood reservoir to fill with a volume of blood; and

controlling the volume of blood in the flexible blood reservoir by regulating withdrawal of liquid from the fluid-containing portion of the interior space of the rigid housing.

8. The method of claim 7 in which the step of controlling the volume of blood in the flexible blood reservoir comprises:

providing the fluid reservoir in a configuration so that its height is adjustable; and

adjusting the height of the fluid reservoir to regulate withdrawal of liquid from the fluid-containing portion of the interior space of the

rigid housing.

9. The method of claim 7 in which the step of controlling the volume of blood in the flexible blood reservoir comprises:

providing a vacuum source in fluid communication with the air-filled portion of the fluid reservoir;

operating the vacuum source so that it applies a negative pressure to the air-filled portion of the fluid reservoir, thereby causing liquid to be withdrawn from the fluid-containing portion of the interior space of the rigid housing and into the liquid-filled portion of the fluid reservoir; and

regulating the negative pressure applied to the air-filled portion of the fluid reservoir by the vacuum source.

10. The method of claim 9 wherein the step of regulating the negative pressure applied to the air-filled portion of the fluid reservoir comprises:

providing a vacuum regulator positioned between the vacuum source and the fluid reservoir; and

adjusting the vacuum regulator so that the vacuum source applies negative pressure to the air-filled portion the fluid reservoir, thereby transmitting negative pressure to the interior space of the rigid housing.

11. The method of claim 10 wherein the negative pressure transmitted to the interior space of the rigid housing is between 0 mmHg and -120 mmHg.

12. The method of claim 10 wherein the negative pressure transmitted to the interior space of the rigid housing is between -20 mmHg and -60 mmHg.

13. The method of claim 7 wherein the negative pressure applied to the interior space of the rigid housing is adjusted to maintain the flexible blood reservoir at a predetermined fixed volume.

14. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the flexible blood reservoir having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit; and

a mechanism attached to the interior surface of the rigid housing, the mechanism being adjustably positioned to limit expansion of the flexible blood reservoir within the interior space of the rigid housing.

15. The vacuum assisted blood storage system of claim 14, wherein the mechanism is selected from the group consisting of swinging arms, swinging plates, threaded plungers, and levers.

16. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the

flexible blood reservoir being expandable; and

means for limiting expansion of the blood reservoir within the interior space of the rigid housing.

17. A method of regulating a vacuum assisted blood storage system of an extracorporeal circuit comprising:

providing a rigid housing having an interior surface defining an enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the flexible blood reservoir being expandable, a source of negative pressure in communication with the interior space of the rigid housing, and a mechanism attached to the interior surface of the rigid housing, the mechanism being adjustably positioned to limit expansion of the blood reservoir within the interior space of the rigid housing;

connecting the blood inlet and blood outlet to the extracorporeal blood circuit;

applying negative pressure to the interior space of the rigid housing, causing the flexible blood reservoir to expand; and

adjusting the position of the mechanism to limit expansion of the blood reservoir.

18. The method of regulating a vacuum assisted blood storage system for use in an extracorporeal blood circuit of claim 17, wherein the mechanism is selected from the group consisting of swinging arms, swinging plates, threaded plungers, and levers.

19. A vacuum assisted blood storage system for use in an

extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the flexible blood reservoir having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the flexible blood reservoir being expandable; and

a sensor for monitoring blood volume in the reservoir selected from the group comprising optical sensors, magnetic sensors, weight sensors, and more mechanical indicators; and a sensor measuring displacement of fluid from the interior space of the rigid housing.

20. A method of regulating a vacuum assisted blood storage system for use in an extracorporeal circuit comprising:

providing a rigid housing having an interior surface defining an enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the flexible blood reservoir being expandable, and a source of negative pressure in communication with the interior space of the rigid housing;

connecting the blood inlet and blood outlet to the extracorporeal blood circuit;

applying negative pressure to the interior space of the rigid housing, causing the flexible blood reservoir to expand; and

adjusting the negative pressure to maintain the flexible blood reservoir at a predetermined fixed volume.

21. The method of regulating a vacuum assisted blood storage system of claim 20, wherein the predetermined fixed volume is determined by a hydraulic limit of expansion of the flexible blood reservoir.

22. The method of regulating a vacuum assisted blood storage system of claim 20, wherein the predetermined fixed volume is determined by a mechanical limit of expansion of the flexible blood reservoir.

23. The method of regulating a vacuum assisted blood storage system of an extracorporeal circuit of claim 22, wherein the mechanical limit of expansion of the flexible blood reservoir is provided by a mechanism attached to the interior surface of the rigid housing, the mechanism being adjustably positioned to limit expansion of the flexible blood reservoir.

24. The method of regulating a vacuum assisted blood storage system of claim 23, wherein the mechanism is selected from the group comprising swing arms, swing plates, threaded plungers, and levers.

25. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior

space of the rigid housing;

a fluid contained within the fluid-containing portion of the rigid housing; and

a spring-loaded fluid reservoir fluidly connected to the fluid-containing portion of the interior space of the rigid housing.

26. A method for regulating a vacuum assisted blood storage system of an extracorporeal circuit comprising:

providing a rigid housing having an interior surface defining an enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, and a spring-loaded fluid reservoir fluidly connected to the fluid-containing portion of the interior portion of the rigid housing, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

connecting the blood inlet and blood outlet to the extracorporeal blood circuit;

emptying the flexible blood reservoir of substantially all fluid;

filling the fluid-containing portion of the interior space of the rigid housing with liquid;

partially filling the fluid reservoir with liquid, thereby creating a liquid-filled portion of the fluid reservoir and an air-filled portion of the fluid reservoir, the liquid-filled portion of the fluid reservoir defining a liquid volume;

withdrawing liquid from the fluid-containing portion of the

internal space of the rigid housing and into the fluid reservoir, thereby applying negative pressure to the fluid-containing portion of the interior space of the rigid housing, thereby causing the flexible blood reservoir to expand; and

regulating the negative pressure applied to the fluid-containing portion of the internal space of the rigid housing by varying the liquid volume in the liquid-filled portion of the spring-loaded fluid reservoir.

27. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

a fluid contained within the fluid-containing portion of the rigid housing;

a fluid reservoir fluidly connected to the fluid-containing portion of the interior space of the rigid housing;

a continuous level sensor attached to the fluid reservoir for monitoring a liquid level in the fluid reservoir;

a vacuum source in communication with the fluid reservoir;

an electronic vacuum regulator positioned between the vacuum source and the fluid reservoir; and

a feedback loop connected to the electronic vacuum regulator and the continuous level sensor.

28. A method for regulating a vacuum assisted blood storage system of an extracorporeal circuit comprising:

providing a rigid housing having an interior surface defining an enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, a fluid reservoir fluidly connected to the fluid-containing portion of the interior portion of the rigid housing, a continuous level sensor attached to the fluid reservoir for monitoring a liquid level in the fluid reservoir, a vacuum source in communication with the fluid reservoir, an electronic vacuum regulator positioned between the vacuum source and the fluid reservoir, and a feedback loop connected to the electronic vacuum regulator and the continuous level sensor, the exterior surface of the blood reservoir and the interior surface of the rigid housing together defining a fluid-containing portion of the interior space of the rigid housing;

connecting the blood inlet and the blood outlet to the extracorporeal circuit;

emptying the flexible blood reservoir of substantially all fluid;

filling the fluid-containing portion of the interior space of the rigid housing with liquid;

partially filling the fluid reservoir with liquid to a desired liquid level, thereby creating a fluid-filled portion of the fluid reservoir and an air-filled portion of the fluid reservoir, the liquid level being monitored

by the continuous level sensor;

applying negative pressure to the air-filled portion of the fluid reservoir, causing liquid to be drawn from the fluid-containing portion of the internal space of the rigid housing and into the fluid-filled portion of the fluid reservoir, thereby causing the flexible blood reservoir to expand, creating a blood reservoir volume; and

regulating the blood reservoir volume by having the feedback loop adjust the vacuum regulator in response to signals from the continuous level sensor in order to maintain a constant liquid level in the fluid reservoir, thereby maintaining a constant blood reservoir volume.

29. A vacuum assisted blood storage system for use in an extracorporeal blood circuit comprising:

a rigid housing having an interior surface defining an enclosed interior space;

a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit;

a flexible bladder contained within the interior space of the rigid housing, and having fluid therein;

a fluid reservoir fluidly connected to the flexible bladder; and

a pump connected to the fluid reservoir capable of moving fluid into or out of the flexible bladder.

30. A method for regulating a vacuum assisted blood storage system of an extracorporeal circuit comprising:

providing a rigid housing having an interior surface defining an

enclosed interior space, a flexible blood reservoir contained within the interior space of the rigid housing, the blood reservoir having an exterior surface, the blood reservoir further having a blood inlet and a blood outlet configured for connection to the extracorporeal blood circuit, and a flexible bladder having fluid therein, the bladder being fluidly connected to a fluid reservoir and a pump;

connecting the blood inlet and blood outlet to the extracorporeal blood circuit;

emptying the flexible blood reservoir of substantially all fluid;

filling the flexible bladder with a fluid;

partially filling the fluid reservoir with fluid;

withdrawing fluid from the flexible bladder and into the fluid reservoir, thereby applying negative pressure to the fluid-containing portion of the interior space of the rigid housing, thereby causing the flexibel blood reservoir to expand; and

regulating the negative pressure applied to the flexible bladder of the internal space of the rigid housing by varying the fluid volume in the flexible bladder.

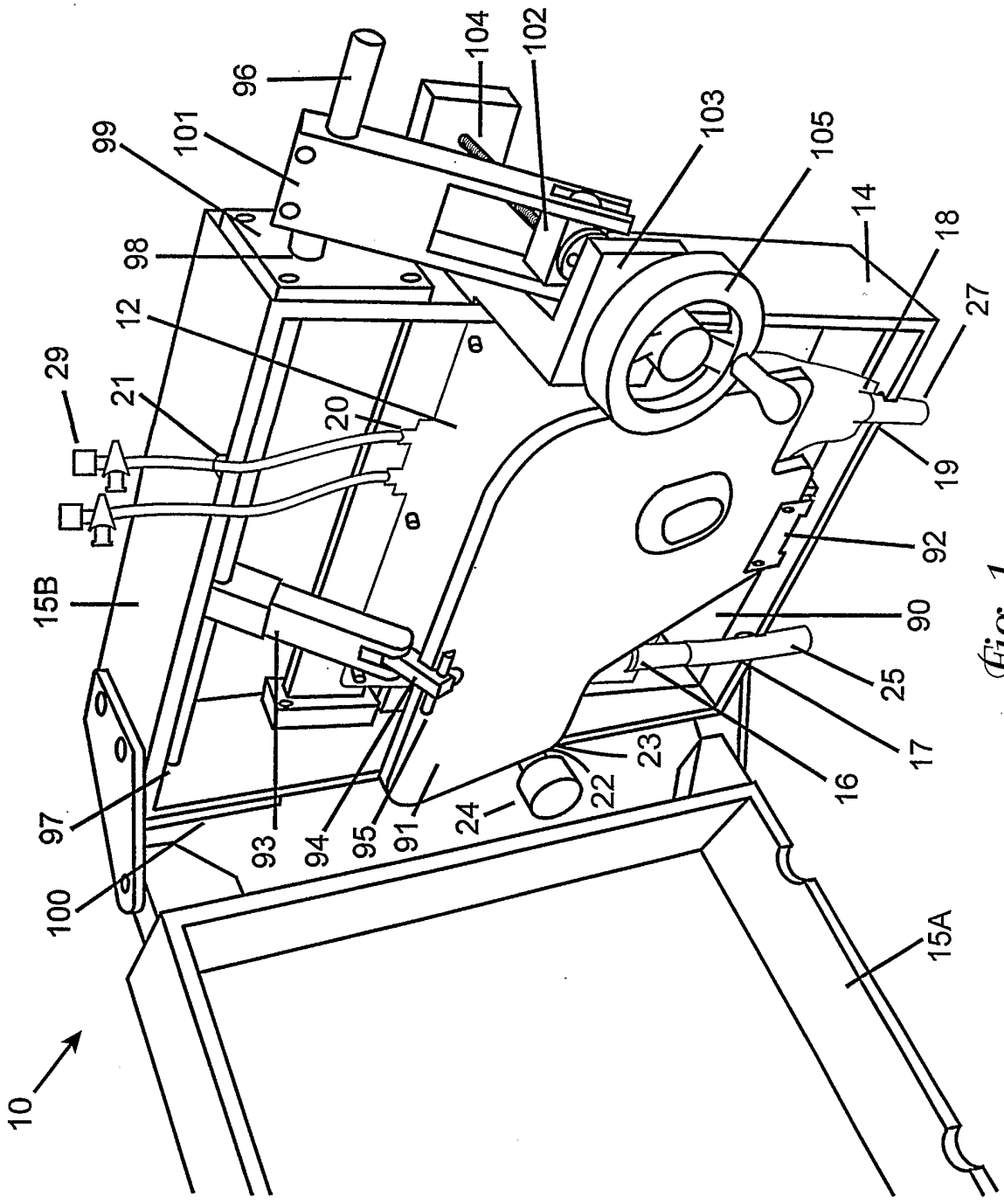

10
15A
15B
16
17
18
19
20
21
22
23
24
25
27
29
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
12
14

Fig. 1

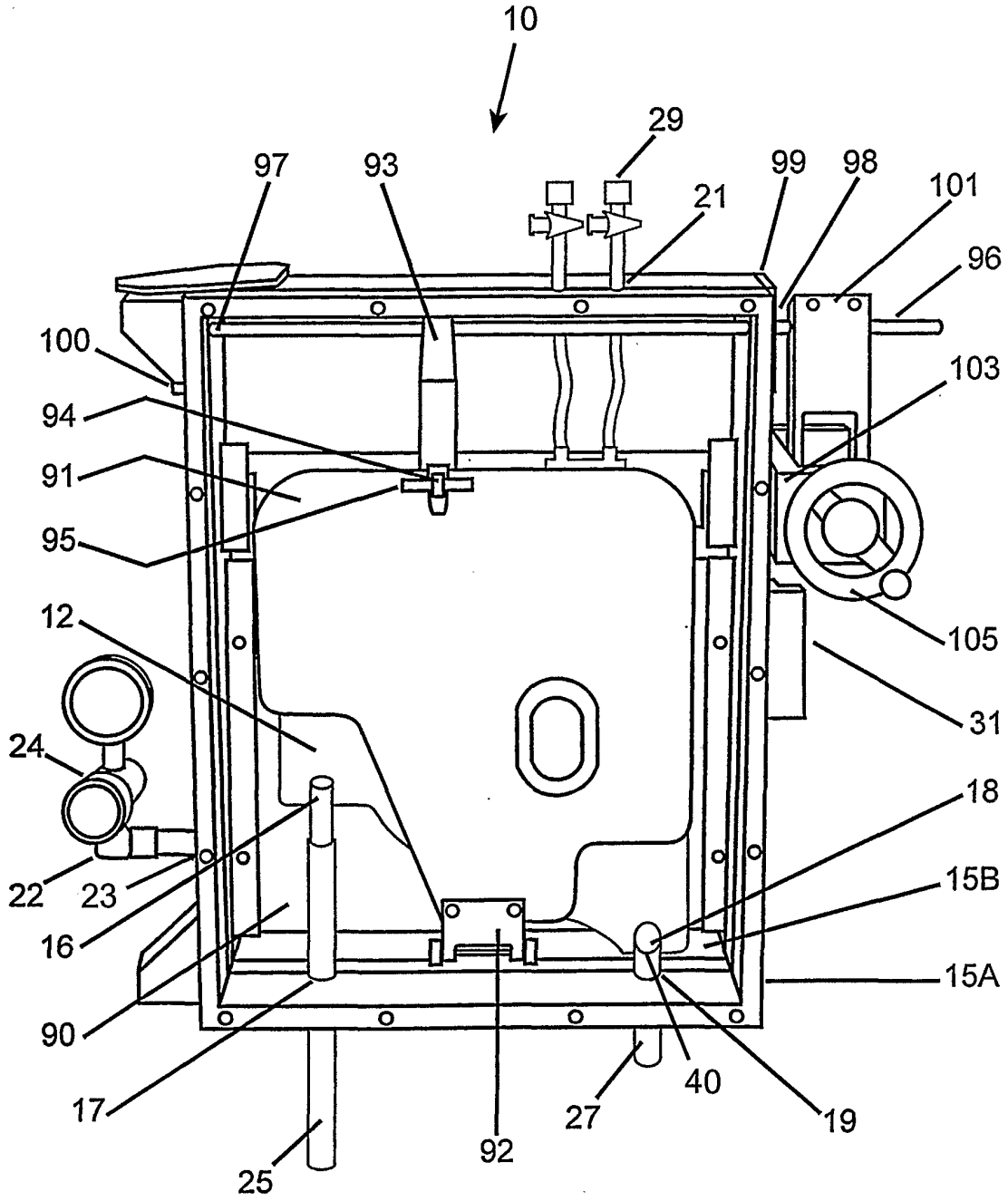

10
29
97
93
99
98
101
21
96
100
103
94
91
95
12
105
31
24
18
22
23
15B
16
15A
90
17
40
19
27
92
25

Fig. 2

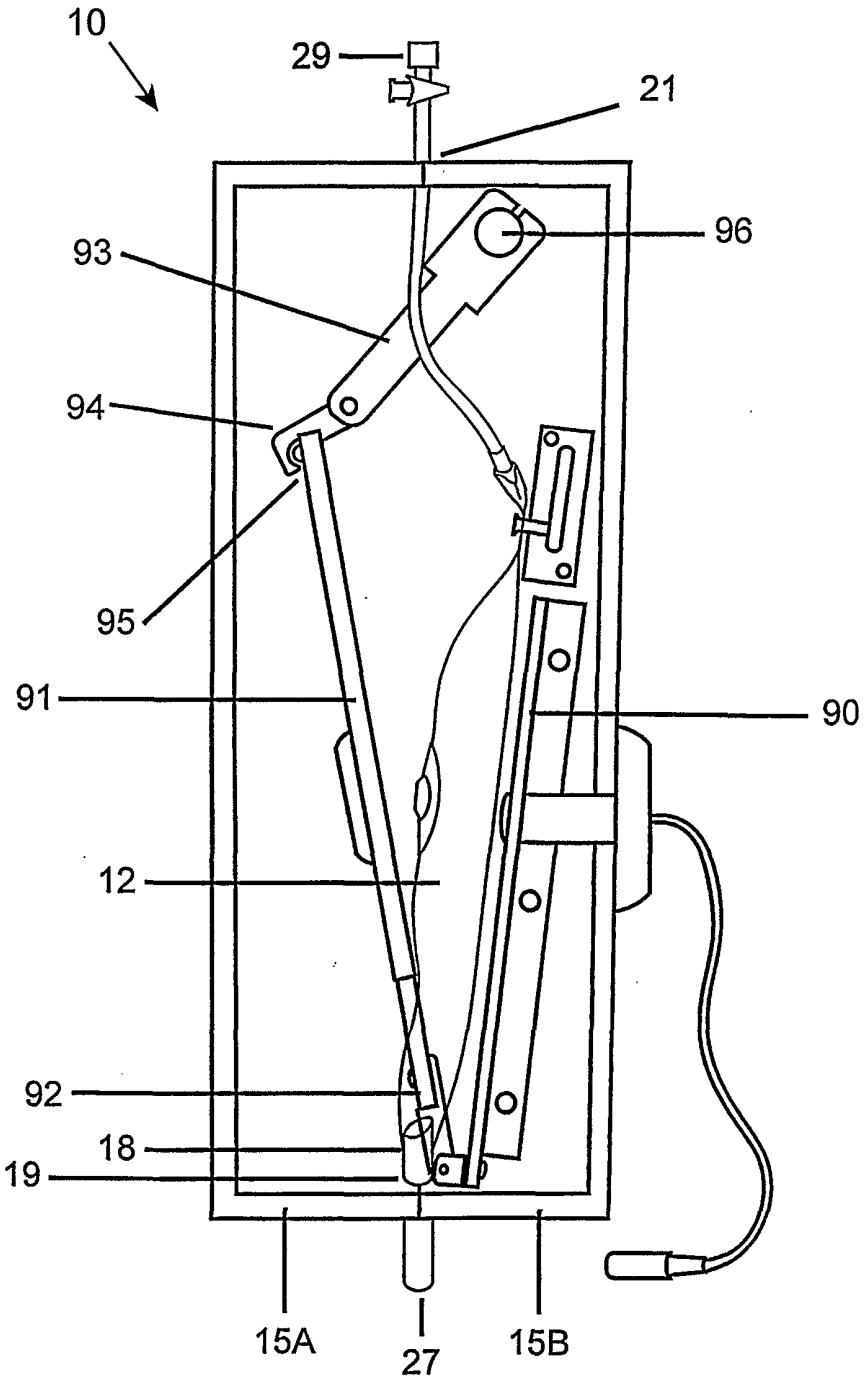


Fig. 3

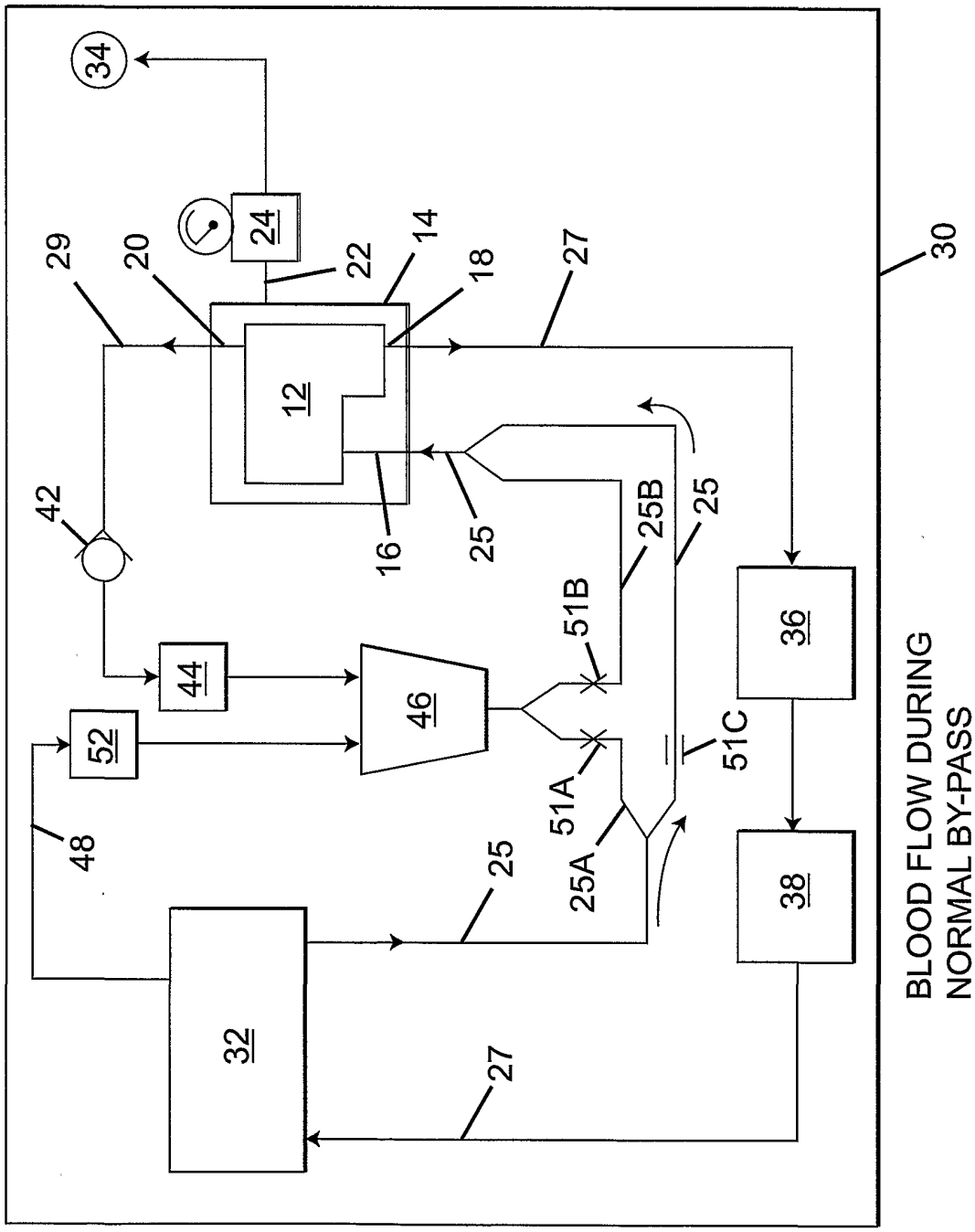

34
24
29
20
22
14
18
27
30
12
42
16
25
25B
25
51B
36
44
46
52
51A
51C
48
25A
25
38
32
27
BLOOD FLOW DURING
NORMAL BY-PASS

Fig. 4

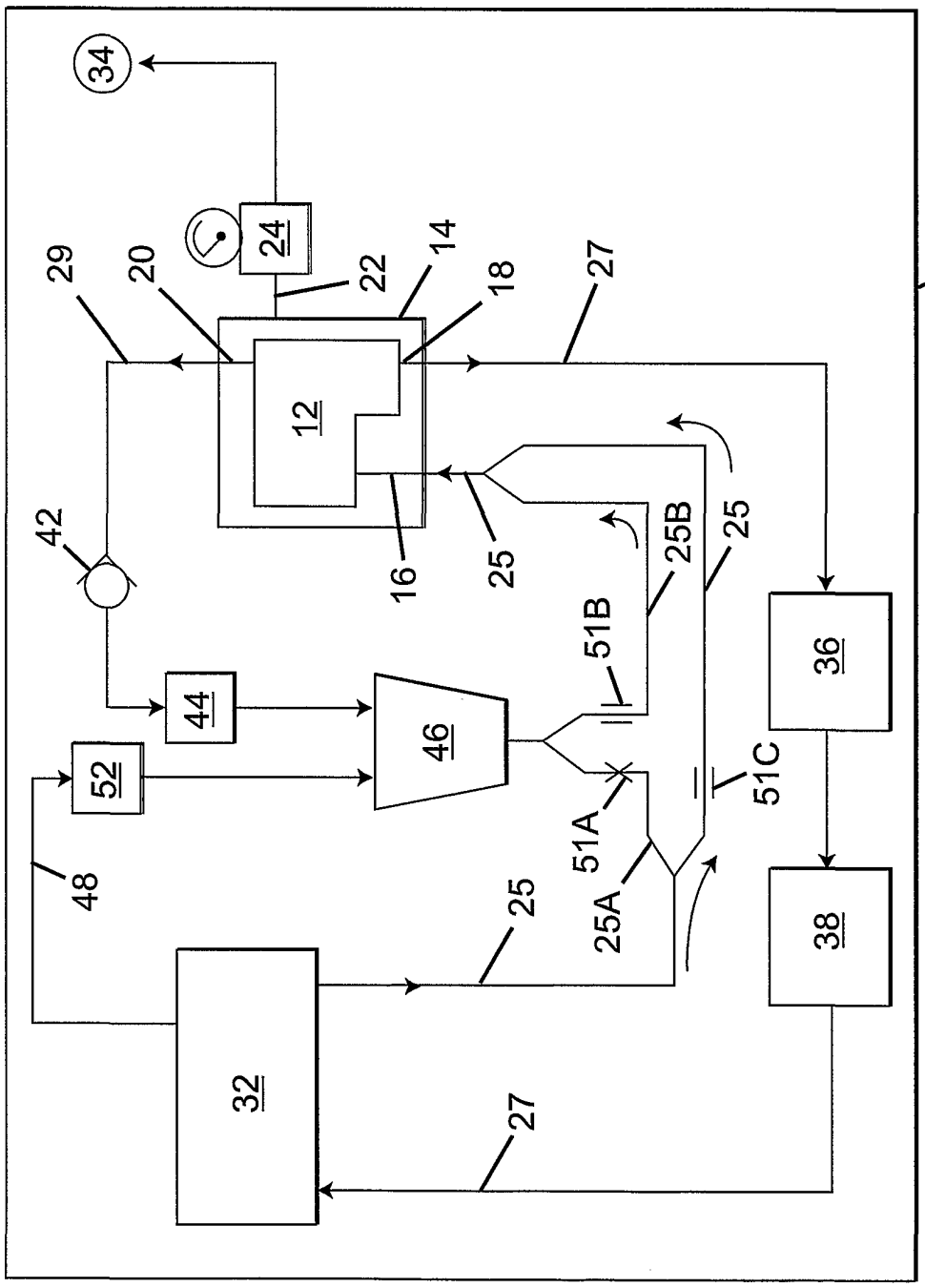

34
24
29
20
22
14
18
27
30
12
42
16
25
25B
25
51B
44
46
36
52
51C
51A
48
25A
25
38
32
27
BLOOD FLOW DURING
DE-SEQUESTRATION
(RETURNING BLOOD TO PATIENT)

Fig. 5

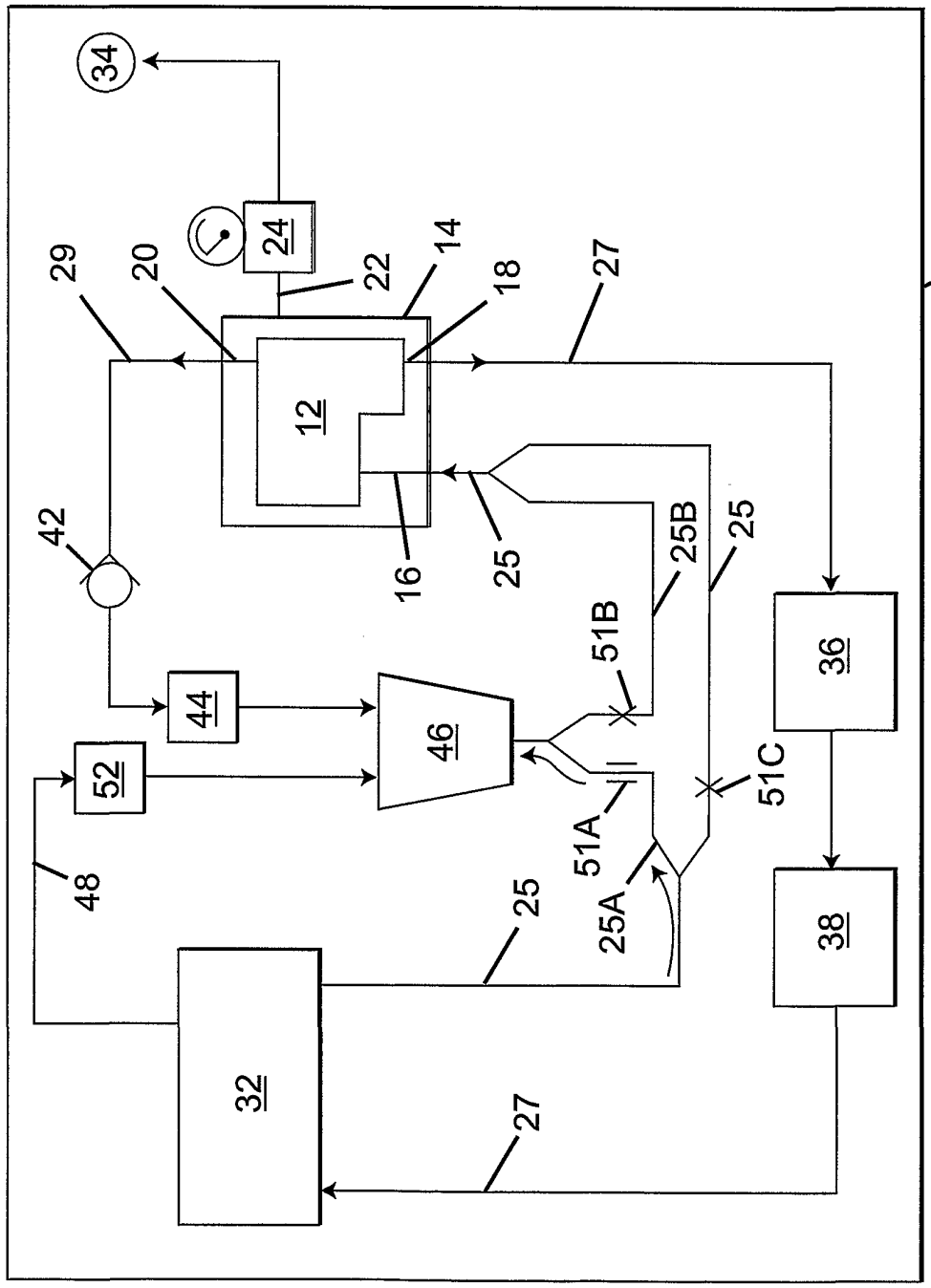

34
24
22
14
18
27
29
20
30
12
42
16
25
25B
25
51B
36
44
46
52
51C
51A
48
25A
25
38
32
27
BLOOD FLOW DURING
BLOOD SEQUESTRATION
(REMOVING BLOOD FROM PATIENT)

Fig. 6

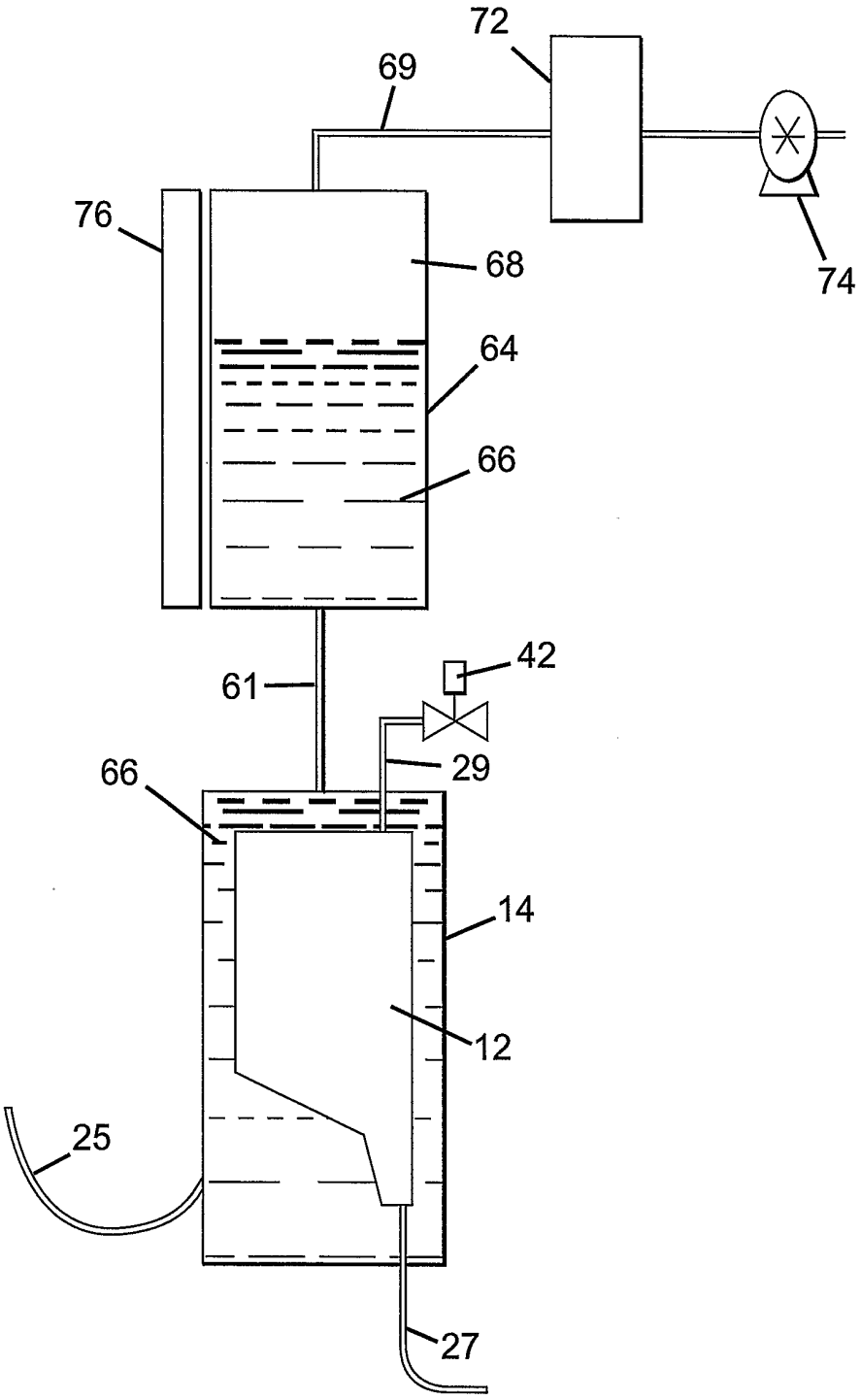


Fig. 7

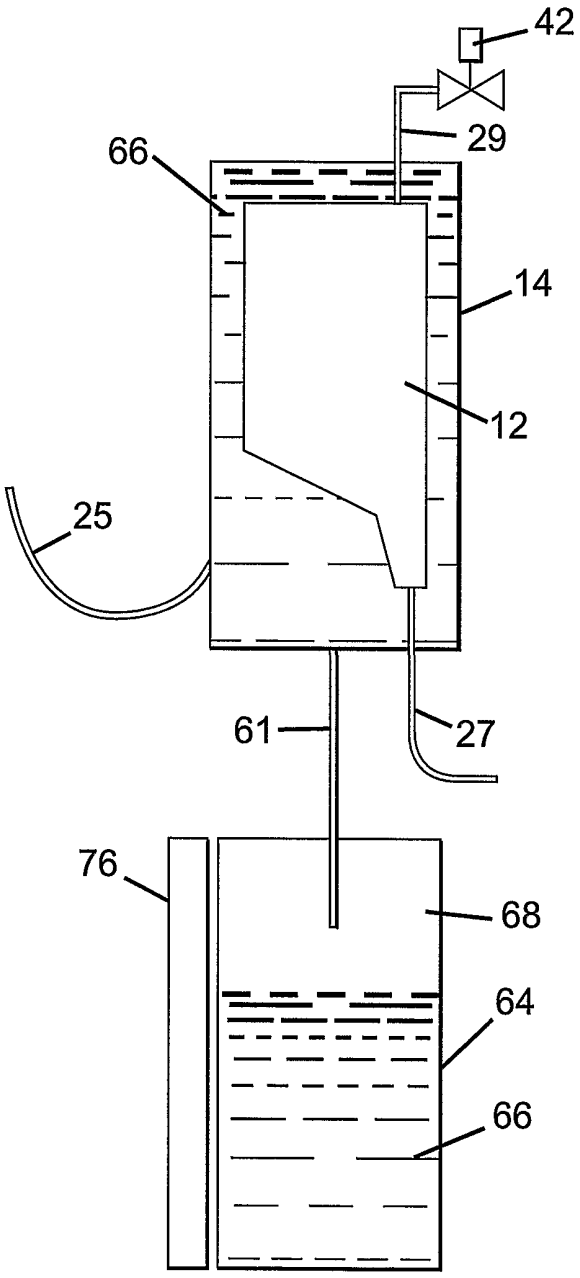


Fig. 8

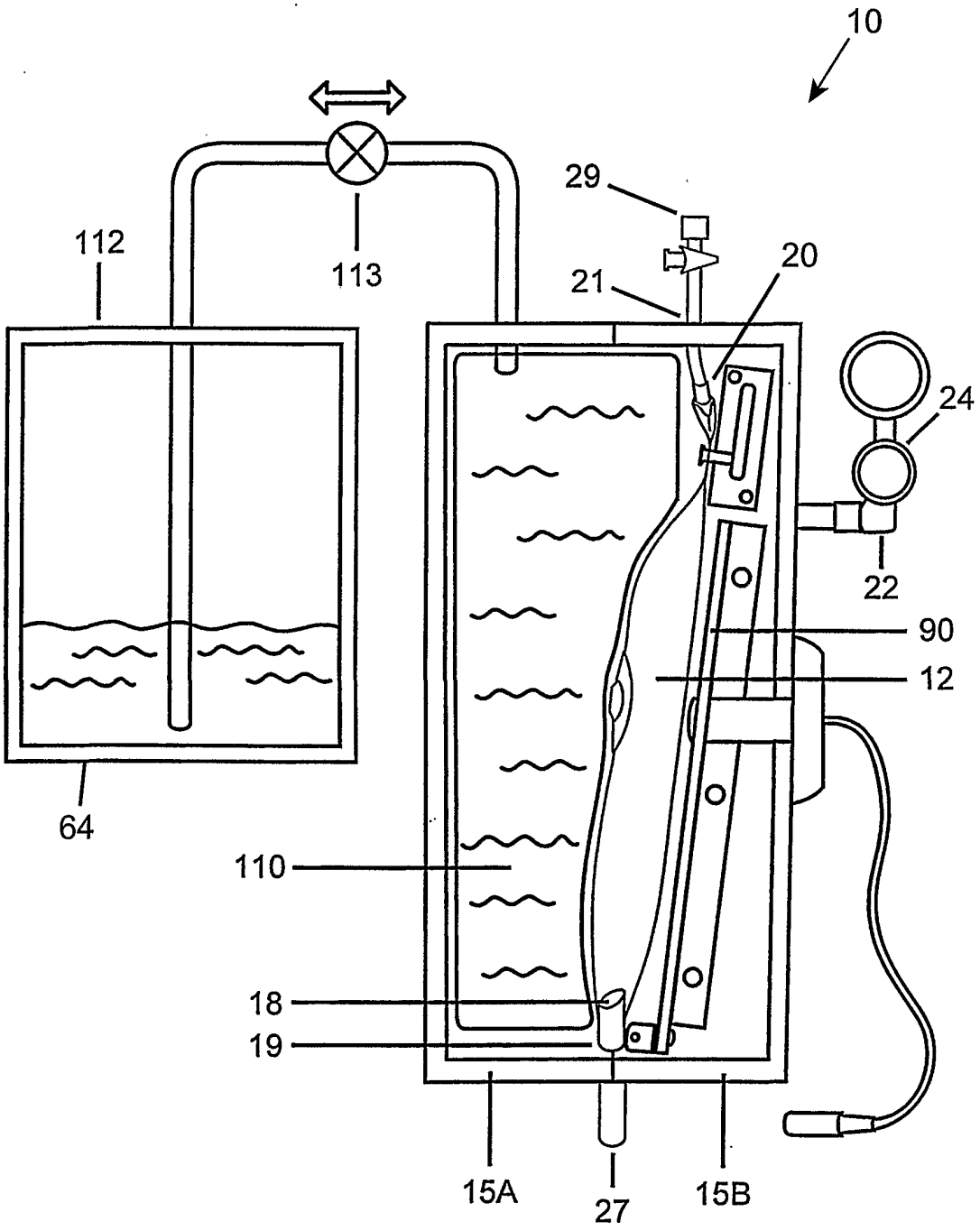


Fig. 9