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(54) APPARATUS FOR EXTRACORPOREAL BLOOD TREATMENT

VORRICHTUNG ZUR EXTRAKORPORALEN BLUTBEHANDLUNG

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Description

Technical Field

[0001] The present invention relates to an apparatus for extracorporeal blood treatment according to claim 1.

[0002] In particular, the invention relates to a continuous renal replacement therapy (CRRT) system. CRRT systems are configured for delivering very specific treatments designed for patients versing in acute states of illness and who have temporarily lost their kidney function in its entirety. In this respect, CRRT systems may be structurally and/or operationally different from extracorporeal blood treatment systems designed for chronic patient care.

[0003] In contrast to chronic patients, acute patients temporarily experience complete loss of their kidney function typically due to a contemporaneous state of severe injury or during recovery from surgery. Consequently, acute patients are often extremely weak and typically not in a condition to be submitted to regular dialysis treatment, which could further deteriorate their state and lead to serious and possibly life-threatening complications.

[0004] Under circumstances as described, CRRT systems are designed to individually treat a patient exhibiting very poor health, without inducing further stress to the patient body, in particular without allowing vital parameters pertaining to the patient's blood to deviate from ideal or near-ideal values.

[0005] Within the scope of this document CRRT systems are, thus, inherently characterized by one or more of the following features.

[0006] CRRT involves renal replacement therapy, meaning an adjuvant therapy aimed firstly at facilitating continuous fluid removal in diuretic-resistant or acute renal failure patients. Therefore, CRRT systems inherently require a continuous net fluid removal from the patient. In other words, a CRRT system requires a fluid balance control system, such as a weight loss control system, configured to generate a continuous net weight loss rate (as opposed to merely controlling parameters to enable achieving a desired target weight loss as typically found in chronic patient care).

[0007] Furthermore, acute patients experience extravascular fluid overload, which cannot be safely removed within a short period of time (e.g. within a few hours of chronic treatment) without causing potentially severe consequences (e.g. hypovolemic shock, arrhythmia, hypoxemia, hypoventilation, etc.). Therefore, a CRRT system must inherently include a much more accurate control over system parameters, in particular flow rates, in order to ensure that the required low flow rates of both blood circulating extra-corporeally and of treatment fluid (infused in the extracorporeal circuit or diffused through the dialyzer) are used.

[0008] Moreover, CRRT treatment is performed continuously (e.g. for days or even weeks, without interruption). Therefore, treatment settings in CRRT are based on flow rate settings, rather than settings pertaining to some specified treatment time (which would be unknown as acute patients may require treatment for an unknown time). Consequently, operation of CRRT systems cannot be based on some pre-defined absolute weight loss to be achieved, but rather on a meticulously controlled fluid balance in the patient, requiring continuous adjustments to a number of operating parameters, which have to be controlled and maintained during the entire (and a priori unknown) treatment time, based on a set weight-loss rate.

[0009] Additionally, CRRT renal replacement therapy involves therapy substituting kidney functions for a relatively long time period and, thus, a CRRT system further requires at least either fresh dialysis liquid exchange in the dialyzer (in order to remove unwanted substances from blood and to add desired substances to the blood by diffusion) and/or fresh infusion fluid in combination with ultrafiltration (in order to remove unwanted substances from blood and to add desired substances to the blood by convection).

[0010] At least for the reasons set forth above, CRRT systems need to exhibit specific technical features enabling the system to:

- Allow setting of a weight loss rate,
- Continuously remove excess water in accordance with a set weight loss rate,
- Operate continuously at comparably low flow rates compatible with CRRT, and
- Balance ion equilibrium by means of proper dialysis being performed and/or by means of substitution fluid continuously being delivered at controlled flow rates.

Background of the Invention

[0011] An important issue in CRRT practice is the return of blood contained in the extracorporeal blood circuit, when treatment has to be stopped or interrupted under certain conditions, even though the extracorporeal blood circuit is generally used as long as possible. Conditions under which treatment has to be stopped or interrupted typically include, for example, vascular access problems, clotting occurring in the circuit (e.g. in any component thereof), Delta P and/or transmembrane pressure out of range, (automatically) unmanageable combination of alarms, and similar situations or combinations of the above, but also regular (planned) end of use of a blood circuit. Blood losses are mainly due to the

lack of blood return procedures at end of blood circuit use. Non-delivery of blood return procedure may occur due to technical issues and/or caregiver decisions driven by one of more of the following: equivocal clotting diagnostic and users messages which do not well discriminate clotting or membrane plugging events/alarms; lack of user strategy for changing extracorporeal blood circuit before clotting, etc., occurs; organizational issues, for example regarding the time required for starting an unplanned blood return procedure in an emergency situation (e.g. the time may be too long and may often lead to a clotting condition before the effective start of the return procedure, in particular during night shifts involving limited availability of staff). Even though preventive measures, such as citrate anticoagulation, may help to minimize occurrences of the aforementioned conditions, blood losses during CRRT remain significant, if the treatment process has to be stopped immediately, without return of blood from the extracorporeal blood circuit to the patient. WO 2004/069311 describes an extracorporeal blood treatment machine in which a blood circuit is equipped with an inlet line leading to a filtration unit and with an outlet line from the filtration unit. A fluid circuit comprises an inlet line leading to the filtration unit and an outlet line from the filtration unit so as to allow a fluid taken from a primary container to circulate within the filtration unit. There is further an infusion line acting on the outlet line of the blood circuit, which is supplied by an auxiliary fluid container. The inlet line of the fluid circuit is equipped with an infusion branch acting on the outlet line of the blood circuit so as to enable the intensive therapy machine to manage therapies with large exchange of fluids. The described fluid circuit may be used in CRRT.

[0012] DE 10011208 describes a filling and/or rinsing method in which a sterile liquid is fed through the extracorporeal blood circulation circuit of the blood dialysis and/or filtration device, with the sterile liquid filtered by passing through the blood dialysis membrane or a sterile filter. A branch line of the extracorporeal blood circulation circuit allows the sterile liquid to be fed to an empty reinfusion container. Also described are a blood dialysis and/or filtration device and a blood hose set for an extracorporeal blood circulation circuit of a blood dialysis and/or filtration device. The described method pertains to hemodialysis only. The reinfusion bag is used only for priming and rinsing and is left full of dialysis fluid so that blood restitution may be performed by opening a clamp and using the liquid contained in the reinfusion bag. After the hemodialysis treatment, the distal end of the blood supply conduit section is disconnected from the cannula, which is connected in the meantime, and is connected to the second outlet of the reinfusion bag. If the branch line branches off from the first section of the blood supply line very close to this distal end, it can also be sufficient to interrupt the cannula connection and simply open the clamp for connection with the reinfusion bag.

[0013] EP 2752210 describes a blood purification device similar to that described in document DE 10011208 mentioned above. The blood purification apparatus can suppress air bubbles from flowing to a distal end of an arterial blood circuit during an arterial blood return process and can reduce the burden on health care workers. The blood purification apparatus includes a control device that can perform a venous blood return process in which return of blood is performed by substituting a physiological saline solution for blood from a connection portion connected to a physiological saline solution supplying line to a distal end of a venous blood circuit in a blood circuit during return of blood; an arterial blood return process in which the return of blood is performed by substituting the physiological saline solution for the blood from the connection portion connected to the physiological saline solution supplying line to a distal end of an arterial blood circuit in the blood circuit; and a negative pressure applying process for releasing a negative pressure after applying the negative pressure to a flow route of an upstream side from an arrangement position of a blood pump in the arterial blood circuit, by allowing the blood pump to be in a normal rotation and causing an electromagnetic valve to switch over the physiological saline solution supplying line from a closing state to a circulating state.

[0014] None of the above-mentioned documents sufficiently addresses the issues pertaining to CRRT blood restitution described above. Therefore, there is a need for an apparatus and method facilitating an increase in the frequency of successful blood return procedures (e.g. more successfully blood return procedures) during and/or after CRRT. In accordance with embodiments of the present invention, blood contained in the extracorporeal blood circuit is returned to the patient using fluid from sources already connected to the blood treatment apparatus, which fluids are typically used during treatment of a patient (and eventually during priming). In some embodiments, therefore, a portion of fluid contained in any one container connected to the blood treatment apparatus, may be used during regular operation of the apparatus (e.g. during treatment) and a remaining portion of fluid contained in any one of the containers may be used during blood return. In some embodiments, there are several alternative possibilities for blood return, depending upon a remaining amount of fluid present in the container or containers when blood return is to be performed. For the purposes of this description, the term "connected" denotes components that are fluidly connected, or in fluid communication with one another, unless otherwise specified. Thus, for example, a fluid container connected to a fluid line denotes a configuration in which the fluid container is in fluid communication with the fluid line and/or configured to supply fluid to the fluid line. This also pertains to configuration in which the fluid supply and/or the fluid communication is selectively enabled or disabled (e.g. using a valve) and/or otherwise controlled (e.g. using a pump). Fluid flow may be monitored and/or controlled based on signals emitted e.g., by sensors configured to detect a weight of a container and/or a change in weight of a container, or by sensors configured to detect pump speed or pumped volumes. Sensors may include weight sensors (e.g. scales) configured to emit a signal indicative of a weight of a container and/or indicative of a change in weight of a container. Sensors may include sensors for detecting pump revolutions/speed such as Hall sensors and/or

sensors for detecting flow rates along infusion tubing. Based on such a signal, for example, a control unit can determine inter alia an amount of fluid present in a container and/or a fluid flow rate from the container. In some embodiments, such fluids include replacement fluid, dialysate fluid, pre-blood-pump (PBP) solution (e.g. for regional anticoagulation), and/or saline solution. Saline solution typically denotes a solution of sodium chloride (NaCl) in water with a concentration of 0.90% w/v of NaCl, 308 mOsm/L or 9.0 g per liter of water. Saline does not generally contain magnesium, calcium and/or potassium ions. The concrete composition of the dialysate may vary depending on the respective treatment. In some examples, dialysate is generally water-based and typically contains controlled amounts of sodium chloride, sodium bicarbonate or sodium acetate, calcium chloride, potassium chloride, and/or magnesium chloride; in some cases optionally glucose or phosphates. In some embodiments, blood return may be activated manually by a user or, for example based on operating parameters of the apparatus, automatically by the control unit of the apparatus.

[0015] Document WO2014110004 is directed to a method for cleaning a blood filter including pumping a physiologically safe fluid back and fourth through the insides and/or the outsides of a plurality of hollow fiber membranes of the blood filter to remove or loosen blood residuals, such as blood clots, proteins and/or biological fluid and injecting air into the physiologically safe fluid to form an air/fluid mixture. The method may also comprise a rinse-back procedure to push the blood in the circuit back to the patient through the arterial and the venous lines by using dialysate or a replacement fluid, such as saline.

Summary

[0016] A general aim of the present invention is providing an extracorporeal blood treatment apparatus, which generally improves blood return procedures in CRRT, both regular blood return after CRRT has taken place and acute blood return when CRRT is interrupted. In detail it is an aim of the present invention to provide an extracorporeal blood treatment apparatus, which facilitates an increase in the effectiveness of successful blood return procedures in CRRT, and/or which facilitates an increase in the number of successful blood return procedures in CRRT. A further aim of the invention is to make available an extracorporeal blood treatment apparatus provided with an extracorporeal blood circuit, which facilitates an increase in the effectiveness of successful blood return procedures (e.g. more effective blood return procedures) during and/or after CRRT. At least one of the above-indicated aims is attained by an apparatus in accordance with one or more of the appended claims.

[0017] Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of at least an embodiment of the invention, illustrated by way of non-limiting example in the accompanying figures of the drawings.

Brief Description of the Drawings

[0018] The description will now follow, with reference to the appended figures, provided by way of non-limiting example, in which:

- Figure 1 schematically shows the extracorporeal blood circuit of an extracorporeal blood treatment apparatus in accordance with embodiments of the present invention;
- Figure 2 schematically illustrates a configuration of an extracorporeal blood circuit during a known process for rinsing back blood from the extracorporeal blood circuit to a patient;
- Figure 3A shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a first embodiment of the present invention;
- Figure 3B schematically illustrates a first phase of the process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the first embodiment of the present invention;
- Figure 3C schematically illustrates a second phase of the process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the first embodiment of the present invention;
- Figure 3D shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a second embodiment of the present invention;
- Figure 4 shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a third embodiment of the present invention;
- Figure 5A shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a fourth embodiment of the present invention;
- Figure 5B schematically illustrates a first phase of the process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fourth embodiment of the present invention;
- Figure 5C schematically illustrates a second phase of the process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fourth embodiment of the present invention;
- Figure 5D schematically illustrates a third phase of the process for rinsing back blood from an extracorporeal blood

circuit to a patient in accordance with the fourth embodiment of the present invention;

- Figure 5E schematically represents a portion of the extracorporeal blood treatment apparatus in accordance with embodiments of the present invention;
- Figure 6 shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a fifth embodiment of the present invention; and
- Figure 7 schematically represents a portion of the extracorporeal blood treatment apparatus in accordance with embodiments of the present invention.

Detailed Description

[0019] Figure 1 schematically shows the extracorporeal blood circuit of an extracorporeal blood treatment apparatus in accordance with embodiments of the present invention.

[0020] An example of an extracorporeal blood circuit is schematically illustrated, but it is noted that the specific structure of the hydraulic circuit is not relevant for the purposes of the present invention and therefore other and different circuits to those specifically shown in figure 1 might be used in consequence of the functional and design needs of each single medical apparatus. Generally, the hydraulic circuit includes at least a blood circuit 10, 20, 30 (and, optionally, 33, 35) and a dialysate circuit 10, 40, 50. It is noted that the first chamber of treatment unit 10 is understood to be part of the blood circuit 10, 20, 30, and that the second chamber of treatment unit 10 is understood to be part of the dialysate circuit 10, 40, 50. Thus, treatment unit 10 may be considered a component of both the blood circuit and the dialysate circuit. In some embodiments, the hydraulic circuit includes additional fluid lines 40b, 60, 70, 70b. The hydraulic circuit exhibits a blood circuit including a blood removal line 20, a treatment unit 10, and a blood return line 30. The blood removal line 20 has a first end 20-1 designed to connect to the vascular system of a patient. In some embodiments, the first end 20-1 of the blood removal line 20 includes a connector (e.g. a Luer connector) configured to connect to a vascular access system of a patient. The particular manner of fluidly connecting the first end 20-1 of the blood removal line 20 to the vascular system of a patient may be realized in accordance with known components and methods. The blood removal line 20 further includes a second end 20-2 configured to connect to the treatment unit 10, in particular to an inlet port 12 of a first chamber of the treatment unit 10. The blood return line 30 has a first end 30-1 configured to connect to the treatment unit 10, in particular to an outlet port 14 of the first chamber of the treatment unit 10. The blood return line 30 further has a second end 30-2 designed to connect to the vascular system of the patient. In some embodiments, the second end 30-2 of the blood return line 30 includes a connector (e.g. a Luer connector) configured to connect to a vascular access system of a patient. The particular manner of fluidly connecting the second end 30-2 of the blood return line 30 to the vascular system of a patient may be realized in accordance with known components and methods. The treatment unit 10, for example a dialyzer, a plasma filter, a hemofilter, a hemodiafilter or an adsorption device, generally includes a first chamber and a second chamber, which are separated by a semipermeable membrane, for example of the hollow-fiber type or of the plate type. The treatment unit 10 includes the inlet port 12 and the outlet port 14, respectively configured to put the first chamber in fluid communication with the second end 20-2 of the blood removal line 20 and with the first end 30-1 of the blood return line 30. The hydraulic circuit further includes a dialysis line 40 configured for supplying dialysate to the treatment unit 10 and an effluent line 50 configured for discharging used fluid from the treatment unit 10 towards a drain or into a corresponding effluent fluid container. The dialysate line 40 has a first end 40-1 configured to connect to a dialysate container 48, such as a dialysate bag or other source of dialysate fluid, and a second end 40-2 configured to connect to an inlet port 16 of the second chamber of the treatment unit 10. The effluent line 50 has a first end 50-1 configured to connect to an outlet port 18 of the second chamber of the treatment unit 10 and a second end 50-2 configured to connect to an effluent fluid container 58 configured to receive used fluid from the second chamber of the treatment unit 10. In some embodiments, the second end 50-2 of the effluent line may be directly connected to a drain and configured to discharge used fluid directly to the drain. The treatment unit 10 further includes the inlet port 16 and the outlet port 18, respectively configured to put the second chamber in fluid communication with the second end 40-2 of the dialysate line 40 and with the first end 50-1 of the effluent line. The hydraulic circuit may also comprise one or more air separators 35 and/or blood warmers 33 and or gas exchangers. In the example of figure 1, the blood return line 30 includes an air separator 35. Further, the blood return line 30 includes a blood warmer 33 arranged upstream from the air separator 35 and configured to control a temperature of fluid flowing through the blood return line 30. Other air separators may be present in the blood circuit, for example positioned on the blood removal line 20. In case a gas exchanger for CO_2 removal is present in the circuit, the gas exchanger can be placed either upstream or downstream the treatment unit 10. Within the scope of this description, the terms "upstream" and "downstream" are based on a general direction of fluid flow along a fluid line and/or through components of the apparatus under treatment condition (e.g. generally from a first end of a line towards a second end of a line; and/or from an arterial access of a patient towards a venous access of a patient). In general (e.g. during treatment), fluid flows through the blood removal line 20, treatment unit 10, and blood return line 30 from the first end 20-1 of the blood removal line 20 towards the second end 30-2 of the blood return line 30. Further, fluid generally flows from containers 48, 68, and 78 towards the blood circuit, while used

fluid flows from the treatment unit 10 towards and into container 58 (or, alternatively, towards and into a drain; not shown). Unless otherwise specified, the terms upstream and downstream refer to the above general directions of fluid flow through lines and components during regular operation of the apparatus (e.g. during treatment). The hydraulic circuit further includes a replacement fluid container 78 and a pre-infusion line 70 having a first end 70-1 configured to connect to the replacement fluid container 78 and a second end 70-2 configured to connect to the blood removal line 20. The hydraulic circuit further includes a blood pump 22 and a replacement fluid pump 72. The extracorporeal blood treatment apparatus 1 further comprises a control unit 80, i.e. a programmed/programmable control unit, configured to control components of the hydraulic circuit (e.g. pumps, valves, clamps) and to receive signals from components (e.g. sensors). Figure 1 merely schematically shows control unit 80 as a separate component, because for reasons of clarity the individual connections between control unit 80 and other components of the extracorporeal blood treatment apparatus 1 are not shown. It is understood, however, that control unit 80 is connected to, for example, pumps (e.g. blood pump 22 and replacement fluid pump 78, as well as any other pumps, if present), sensors (e.g. sensors 21a, 21b, 31, 49, 59, 69, 79). This list of components controlled by or configured to send signals to the control unit 80 is not exhaustive. Other components may be connected to control unit 80 as generally known in the field.

[0021] The control unit 80 may, for example, comprise one or more digital microprocessor units or one or more analog units or other combinations of analog units and digital units. Relating, by way of example, to a microprocessor unit, once the unit has executed a specific program (for example a remotely supplied program or a locally stored program directly integrated into the microprocessor card or an associated memory unit), the unit is programmed, defining a plurality of functional blocks which constitute means each designed to perform respective operations as described in detail below. In some embodiments, the extracorporeal blood treatment apparatus 1 may further comprise a user interface (e.g. a graphic user interface or GUI). For reasons of clarity, the user interface is not shown in figure 1. The user interface is also connected to control unit 80 and configured to both present information to a user or operator by means of an output unit (e.g. screen, touchscreen, monitor, led elements, etc.) and to receive input from the user/operator by means of an input unit (e.g. keyboard, hardware button(s), mouse, touchscreen, voice recognition, optical recognition). The extracorporeal blood treatment apparatus 1 may further comprise one or more sensors configured to detect presence or absence of disposable or replaceable components and a corresponding type thereof. Such one or more sensors may include optical sensors, for example barcode or OR-code readers configured to read barcodes/QR-codes associated with components such as blood sets/circuits or cartridges. Such one or more sensors may further include radiofrequency or other sensors, for example RFID readers configured to read data from active/passive RFID-Tags associated with components such as fluid containers, blood sets/circuits, or cartridges. It is understood that the control unit 80 may collect configuration data, operational data, and/or status data from one or more components before, during, and after operation of the apparatus and/or treatment. The specific structure of the blood circuit is not fundamental to the present invention. Thus, with reference to figure 1, a brief description of a possible embodiment of a blood circuit is made, which is however provided purely by way of non-limiting example. The hydraulic circuit may further comprise one or more elements configured to prevent fluid flow through one or more lines. As shown in figure 1, the apparatus 1 may include a (venous) clamp 37 configured to receive a portion of the blood return line 30 and configured to clamp (e.g. close) fluid flow through the blood return line 30, in particular proximal to the second end 30-2 of the blood return line 30. Similarly, though not shown in figure 1 (see figures 3B, 3C instead), the apparatus 1 may further include an (arterial) clamp 27 configured to receive a portion of the blood removal line 20 and configured to clamp (e.g. close) fluid flow through the blood removal line 20, in particular proximal to the first end 20-1 of the blood removal line 20. In some embodiments, apparatus 1 may include one or more tube retaining elements configured to receive, retain, and/or otherwise keep in place portions, sections, or tracts of one or more fluid lines (e.g. lines 20, 30, 40, 40b 50, 60, 70, 70b). Such tube retaining elements may include corresponding clamping mechanisms or valves or other actuators configured to control (e.g. prevent, enable, restrict, regulate) fluid flow through the respective portions, sections, or tracts of fluid lines. The one or more elements (e.g. 27, 37) configured to control fluid flow and/or tube retaining elements may be controlled, by the control unit 80, to clamp (e.g. close) the blood return line 30 if, for example, the blood return to the vascular access has to be halted during a rinse-back procedure which requires to block flow in certain lines/tracts or directions, and/or in emergency situations or for safety reasons. Each one of the pumps included in the extracorporeal blood treatment apparatus 1, for example pumps 22 and 72, may comprise a positive displacement pump, such as a peristaltic pump. In the example of figure 1, blood pump 22 and replacement pump 72 each include a peristaltic pump. Peristaltic pumps generally operate on a respective pump tube tract (e.g. 22t, 42t, 52t, 62t, 72t) configured to operably connect with the respective pump (e.g. 22, 42, 52, 62, 72) such that pump motion (e.g. rotation) is transferred onto the pump tube tract, thereby moving a respective fluid along the respective pump tube tract and, thus, through the respective line or lines (e.g. 20, 40, 40b, 50, 60, 70, 70b) as well as other components (e.g. treatment unit 10, blood warmer 33, and/or air separator 35). The hydraulic circuit may further comprise a post-infusion line 70b, which branches off from the pre-infusion line 70 at a branch 73. The branch typically includes a flow controller (e.g. one or more valves or a clamp mechanism) configured to selectively enable fluid flow either through the pre-infusion line 70 or through the post infusion line 70b. In detail, replacement pump 72, active on the pre-infusion line 70 and arranged upstream branch 73 (with

respect to fluid flow from the replacement fluid container 78 towards branch 73), is configured to supply replacement fluid from the replacement fluid container 78 to the blood circuit 20, 30. Branch 73 (including, e.g., a flow controller, valve(s), and/or clamp(s); see above) is configured to selectively allow supply of replacement fluid from the replacement fluid container 78 through the pre-infusion line 70 or through the post-infusion line 70b. In case of pre-infusion, the replacement fluid is introduced into the blood removal line 20 at a first pre-infusion site 20-3b upstream the treatment unit 10 (with respect to fluid flow from the first end 20-1 of the blood removal line 20 to the second end 20-2 of the blood removal line 20). In case of post-infusion, the replacement fluid is introduced into the blood return line 30 downstream from the treatment unit 10 (with respect to fluid flow from the first end 30-1 of the blood return line 30 to the second end 30-2 of the blood return line 30). In some embodiments, the second end 70b-2 of the post-infusion line 70b is connected to the blood return line 30 via an air separator 35, such that replacement fluid can be introduced into the fluid flowing through the blood return line 30 within the air separator 35, which may improve mixing of the fluids and/or the effectiveness of the air separator 35 in separating gas/air from the fluid flowing there-through. As illustrated in figure 1, different sections of the hydraulic circuit exhibit corresponding (internal) volumes for processed fluids, which have to be taken into account when focusing on blood return. Volume V1 denotes a first volume in a first section of the blood removal line 20, between the first end 20-1 of the blood removal line 20 (e.g. patient access, catheter access) and a second pre-infusion site 20-3a upstream the blood pump 22 (see PBP pre-infusion described further below). Volume V2 denotes a second volume in a second section of the blood removal line 20 between the second pre-infusion site 20-3a and the first pre-infusion site 20-3b downstream from the blood pump 22 (and upstream from the treatment unit 10). Volume V2 includes the volume of the blood pump tract 22t. Volume V3 denotes a third volume in a third section of the blood removal line 20 between the first pre-infusion site 20-3b and the second end 20-2 of the blood removal line 20. Volume V4 denotes a fourth volume of the first chamber of the treatment unit 10. Volume V5 denotes a fifth volume in a first section of the blood return line 30 between the first end 30-1 of the blood return line 30 and an inlet connector 30-3a of the blood warmer 33. The blood warmer, if present, also includes an internal volume denoted as V_{33}. Notably other devices might be selectively included in the blood circuit, such as a gas exchanger for CO_2 removal (i.e. to perform $ECCO_2R$ therapies) and/or an adsorption device; these devices, if present, also includes respective volumes. In the following description volume V_{33} is referred to the blood warmer, however this should not be considered as limiting. Volume V6 denotes a sixth volume in the blood return line 30 between an outlet connector 30-3b of the blood warmer 33 and the second end 30-2 of the blood return line 30. Unless otherwise specified, volume V6 includes a volume V_{35} of fluid present in air separator 35. Table 1 shows some example values for typical volumes V1 to V6, depending upon the type of hydraulic circuit used. Typical volumes of blood circuit section / example of circuit for application in adults are in the following table

Circuit section	V1	V2	V3	V4	V5	V6	V33
Volume (ml)	3	40	5	80	5	35	25

[0022] The hydraulic circuit may further comprise a second dialysate line 40b, which branches off from the dialysate line 40 at a branch 43. The branch typically includes a flow controller (e.g. one or more valves or a clamp mechanism) configured to selectively enable fluid flow either (solely) through the dialysate line 40 (i.e. from the first end 40-1 thereof to the second end 40-2 thereof) or, alternatively, through the first part of the dialysate line 40 up to branch 43 and further through second dialysate line 40b and post infusion line 70b (i.e. from the first end of dialysate line 40 to branch 43, through second dialysate line 40b and post infusion line 70b, to the second end 70b-2 of post infusion line 70b). In detail, dialysate pump 42, active on the dialysate line 40 and arranged upstream the branch 43 (with respect to fluid flow from the dialysate container 48 towards branch 43), is configured to supply dialysate from the dialysate container 48 to treatment unit 10. Branch 43 (including, e.g., a flow controller, valve(s), and/or clamp(s); see above) is configured to selectively allow supply of dialysate from dialysate container 48 through the dialysate line 40 or through the second dialysate line 40b, and, subsequently further through post infusion line 70b.

[0023] Figure 2 schematically illustrates a configuration of an extracorporeal blood circuit during a known process for rinsing back blood from the extracorporeal blood circuit to a patient. The known process is described based on the hydraulic circuit shown in figure 1, but is typically applicable to a number of similar hydraulic circuits, which can, however, be structurally different from the hydraulic circuit shown in figure 1. The known process includes several aseptic and non-aseptic steps. The blood return procedure is performed using the blood pump 22 only and by connecting the first end 20-1 of the blood removal line 20 to a bag 88 containing infusion fluid. In preparation for the known return procedure, an infusion fluid bag 88 containing infusion fluid has to be provided/prepared. In first and second steps (non-aseptic), the patient access and the blood removal line 20 near the first end 20-1 thereof have to be closed, for example by clamping the line 20 proximate the first end 20-1 and by clamping the access catheter of the patient. In third and fourth steps (aseptic), the blood removal line 20 has to be disconnected from the catheter and the first end 20-1 of the blood removal line 20 has to be connected to the infusion fluid bag 88. Steps three and four are aseptic steps, which means

that the operator performing these steps is required to follow a strict protocol ensuring that these steps are performed in line with regulations of patient care. In a fifth step (non-aseptic), fluid communication from bag 88 to line 20 is enabled (e.g. by breaking a sealing pin on bag 88). In a sixth step (non-aseptic), the blood removal line 20 is unclamped (proximate the first end 20-1 thereof; see above). In a seventh step (non-aseptic), the blood return procedure is started by controlling the blood pump 22 to convey fluid contained in the blood removal line 20 towards the second end 30-2 of the blood return line. During this step, the infusion fluid from bag 88 gradually replaces the fluid in the blood circuit. In some examples, the volume of infusion fluid replacing the fluid in the blood circuit has to be determined by the operator performing the return procedure, who is also required to initiate, oversee, and stop the return process depending on the progress thereof. In other examples, the blood treatment apparatus may determine an amount of infusion fluid based on the hydraulic circuit used, in which cases the operator may still have to perform the return process as described above, for example by pressing a corresponding control key on the graphical user interface of the apparatus. In an eighth step (non-aseptic), the blood return procedure is stopped by controlling the blood pump 22 to stop. In a ninth step (non-aseptic), the return catheter is closed (e.g. clamped). In a tenth step (non-aseptic), fluid flow through the blood return line 30 is prevented, for example by closing (e.g. clamping) the blood return line 30 proximate its second end 30-2. In an eleventh step (aseptic), the return catheter is disconnected from the blood return line 30, which again is an aseptic step (see steps three and four above). It has been found that, using the known process, neither the flow rate during the blood return procedure nor the use of back-filtration can lead to a significant improvement in blood recovery. Instead, the volume of fluid returned was found to be the most relevant parameter in blood recovery, facilitating recovery of up to 85% when the returned volume was equal to the nominal volume of the blood circuit. Further, the necessity of aseptic and non-aseptic steps complicates the blood return process. This issue of aseptic and non-aseptic steps is even more relevant in CRRT systems, as described above. The blood return procedure in accordance with embodiments of the present invention focuses on several issues associated with known procedures. The return procedure is designed to use, as return fluid, the fluid from bags already connected to the CRRT system and previously used for treating the patient (e.g. being substitution fluid and/or PBP replacement fluid such as citrate compositions, such as the fluids included in pre-infusion fluid container 68, dialysis fluid container 48 and/or replacement fluid container 78). This allows the blood return procedure to start, if necessary, basically immediately, without prior preparation and connection of an additional bag of infusion fluid, albeit depending on a residual amount of fluid in such bags already connected to the CRRT system. Further, the blood return procedure can be performed with both the blood removal line and the blood return line remaining connected to the patient vascular system, such that an operator or nurse does not have to perform any non-aseptic actions. This allows for the blood return procedure to start or be started very quickly, thus substantially reducing the risks of (further) complications occurring before or during the blood return procedure (e.g. clotting, alarm(s), etc.). The volume of return fluid required to achieve a comparable blood recovery of about 80% is less than the volume of the blood circuit of a CRRT system (e.g. less than 200ml for a circuit for adult patient/circuit without blood warmer) and corresponds to less than 5% of the capacity of a typical 5-literfluid bag. In the vast majority of cases, therefore, there should be sufficient residual fluid amount in the connected bag or bags in order to fully perform the blood return procedure (e.g. to return at least 80% of blood). Even in cases where the residual fluid amount is less than the volume ideally required, it is much better to perform a partial blood return rather than no blood return at all. In an example in which only 100ml of residual fluid is available, which should only occur in very few cases, see above, this would still enable a blood recovery of about 50% of the volume contained in the blood circuit. It has been found that in CRRT, statistically, successful blood recovery (e.g., ratio of volume of fluid used for blood return to the circuit blood volume of at least 0.5) is achieved merely in about 43% of cases. However, in a higher number of cases (about 50% of cases), no blood has been recovered at all. Additionally, the rinse back procedures here-below described provides to the operator the possibility to stop and resume the blood return process at any time, as well as aborting it before full completion, depending on the circumstances.

Figure 3A shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a first embodiment of the present invention. Blood return process 100 generally includes rinsing back blood to a patient through the blood return line 30 using fluid from the PBP fluid container 68 and the replacement fluid container 78. Blood return process 100 is described with reference to figures 3B and 3C. Figure 3B schematically illustrates a first phase of the process 100 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the first embodiment of the present invention (see, in particular, steps 110 and 112 in figure 3A). Figure 3C schematically illustrates a second phase of the process 100 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the first embodiment of the present invention (see, in particular, steps 114 and 116 in figure 3A). In both figures 3B and 3C, dotted lines and components indicate components not involved in the respective step or phase of the rinse-back procedure. Blood return process 100 starts at step 101, in which the blood pump 22 is stopped, e.g. at the end of the treatment phase. In step 102, the requirements for performing process 100 are evaluated in a status check. This may include making sure that the fluid volume present in replacement fluid container 78 is greater than α * (V3+V4+V5+V6+V_{33}), with α being e.g. 1.0 (α is an operator settable parameter to determine the percentage of extracorporeal blood in volume V3+V4+V5+V6+V_{33} which is desired to restitute - α=1 means restituting 100% of extracorporeal blood in volume V3+V4+V5+V6+V_{33}), and that the fluid volume present in the PBP pre-infusion

container 68 is greater than or equal to V2. For the applicability of process 100 it is not relevant the fluid content, e.g. whether the PBP pre-infusion container 68 contains PBP solution having a low or a high concentration of citrate. The maximum usable fluid volume of PBP fluid is V2. The target return volume (using replacement solution) is $1.0*(V3+V5+V6+V_{33})$. The entire restitution volume (i.e. $V2 + 1.0*(V3+V5+V6+V_{33})$), thus is almost identical (e.g. about 99%) of the blood circuit volume. If the requirements are not met, process 100 may still be performed in order to rinse back at least some of the blood present in the blood circuit (see above). In some cases, minimum requirements may be defined, which determine whether the rinse-back procedure 100 is fully, partially, or not at all performed. For example, if the replacement fluid container 78 is empty, the rinse back procedure may be aborted. If the requirements are met, the blood return line 30 is closed proximate its second end 30-2. In step 104, the user is prompted to clamp the blood removal line 20 proximate the first end 20-1 thereof and in step 106 the successful clamping of the blood removal line 30 is checked and verified. If the clamping is not achieved or cannot be verified, the process 100 is started over, returning back to step 101. If the successful clamping of the blood removal line is verified, then the process continues at step 108, in which fluid flow through the blood return line 30 is enabled, in the present embodiment by opening venous clamp 37. In step 110, both the PBP fluid pump 62 and the blood pump 22 are controlled to return fluid (e.g. blood or PBP solution) from section V2 of the blood removal line 20 as shown in figure 3B. In this step, the flow rate of both pumps 22 and 62 is synchronized and controlled based e.g. on monitoring the access pressure. Further, venous pressure is monitored in order to detect an occlusion or clotting in the blood circuit. The volume of PBP fluid pumped into the blood circuit is monitored and controlled to not exceed V2 and may be determined based on the rotation of the PBP fluid pump 62 and/or based the weight of the pre-infusion fluid container 68 (e.g. a change in weight thereof) measured with a pre-infusion fluid scale 69. In step 112, the blood pump 22 and the PBP fluid pump 62 are stopped when the volume returned to the blood circuit reaches V2. In step 114, the replacement fluid pump 72 is controlled to return blood downstream from the pre-infusion site 20-3b as shown in figure 3C. The volume returned to the blood circuit may be determined either based on the rotation of the replacement fluid pump 72 and/or based on the weight of the replacement fluid container 78 (e.g. a change in weight thereof). Again, venous pressure is monitored in order to detect an occlusion or clotting in the blood circuit. In step 116, the replacement fluid pump 72 is stopped when the volume returned to the blood circuit reaches $V3+V4+V5+V6+V_{33}$. Subsequently, in step 118, the venous clamp 37 is closed and the process 100 ends at step 120. During all steps of the rinse-back procedure, the clamp 27 on the blood removal line 20 is closed to avoid any blood flow directed towards the arterial access to the patient (i.e. towards the first end of blood removal line 20-1). Blood return process 100 in accordance with the first embodiment of the invention allows for the return of substantially the entire volume of the blood circuit ($V2+V3+V4+V5+V6+V_{33}$; corresponding to about 99% of an adult set). The effectiveness of process 100 is determined by the theoretical effectiveness associated to the value α multiplied with the partial volume (see above). If, in an example, $\alpha = 1.0$, the restitution volume is almost equal (99%) to the blood circuit blood volume and the effectiveness of the return process is about 83/84/84% for an LF set/an HF set/an HF set with blood warmer. Not taking into consideration any delays due to switching times potentially necessary between different process steps, the duration of process 100 is largely proportional to the return flow-rate. The duration of process 100 in an example based on an adult set including a blood warmer is about 2:40 minutes at a flow rate of 100ml/min and a blood return effectiveness of 84%. Additionally, should no fluid be present in the pre-infusion fluid container 68, the rinse-back procedure of embodiment 1 may be equally used. Of course the steps 110 and 112 are not performed (i.e. blood in volume V2 is not restituted to the patient) and the procedure makes use of the medical fluid in the replacement container 78 only. Figure 3D shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a second embodiment of the present invention. Blood return process 200 generally includes rinsing back blood to a patient through the blood return line 30 using fluid from the PBP fluid container 68 and the replacement fluid container 78. In contrast to blood return process 100, blood return process 200 allows for returning to rinse-back using PBP fluid in case the residual volume of replacement fluid is not sufficient for reaching a target return volume. Though not exclusively, the user or the control unit 80 (e.g. automatically) selects a rinse-back procedure according to the first embodiment whenever the fluid volume in the replacement container 78 is sufficient, i.e. above the mentioned pre-defined volume equal to $\alpha*(V3+V4+V5+V6+V_{33})$. When the fluid volume is less than the pre-defined volume, a substantially complete rinse-back procedure may be achieved using a procedure in accordance with the second embodiment, which is described in the following. Blood return process 200 of the second embodiment is also described with reference to figures 3B and 3C. Figure 3B schematically illustrates a first phase of the process 200 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the second embodiment of the present invention. Figure 3C schematically illustrates a second phase of the process 200 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the second embodiment of the present invention. The first and second phases of process 200 largely correspond to steps 108 to 116 as described above and a shown in figure 3A (see corresponding step 208 in figure 3D). Process 200 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the second embodiment of the present invention further includes a third phase (see steps 214 and 216 in figure 3D), which is also illustrated in FIG. 3B. Blood return process 200 starts at step 201 in which blood pump is stopped. In step 202, the requirements for performing process 200 are evaluated in a status check. This may

include checking whether the fluid volume present in replacement fluid container 78 is greater than α * (V3+V4+V5+V6+V_{33}) or not, with α being an operator prescription, whose typical value lies in the range between 0.75 and 1. In case the fluid volume is lower than the necessary fluid for the previously describe rinse-back procedure (1st embodiment), the status check may additionally include controlling that the fluid volume present in the PBP pre-infusion container 68 is much greater than V2 (e.g. PBP Volume >> V2). For the applicability of process 200 it is not relevant whether the PBP pre-infusion container 68 contains PBP solution having a low or a high concentration of citrate. However, the maximum usable fluid volume of PBP fluid depends on the citrate content. If the PBP solution is known to contain high citrate content or is unknown, the target return volume (using PBP solution) is V2+α*(V3+V5+V6+V_{33}), wherein the maximum allowable value for α is set at 0.75; this volume excludes the filter volume according to possible clotting of the filter. The reason for reducing the maximum returnable blood, is patient safety. Indeed, in case citrate is present, additional constraints should be considered. In more detail, the design should be such that it secures that the total amount of citrate (i.e. citrate fluid volume from PBP container 68 x citrate concentration) that might reach the patient is not excessive. This can be defined respectively to patient body weight and/or mean PBP flow rate used during blood treatment. Of course, definition of volume reaching patient shall consider worst case scenario where a significant fraction of the membrane filter is also clotted (meaning that actual volume V4 to rinse is much smaller than 'nominal' V4 volume). In such a case, an additional constrain based on mean PBP flow rate during previous patient blood treatment could be imposed, such as that no more than the equivalent of 10 min of mean PBP flow rate should be infused into the patient during the entire rinse-back procedure. In this respect, the control unit 80 stores PBP flow rate applied during treatment (e.g., the flow rate of citrate solution over time is measured by the control unit 80 and stored in a memory during treatment or the mean PBP flow rate applied during treatment is received as an input before rinse-back procedure); during the rinse-back procedure, the control unit 80 is configured to infuse into the patient less than the equivalent of 10 min of mean PBP flow rate. In other terms a maximum PBP volume form container 68 is calculated based on the mentioned relationship and no more than the calculated volume from PBP container 68 can be used for the rinse-back procedure, this allowing to infuse no more than the equivalent of 10 min of mean PBP flow rate. If the PBP solution is known to contain low citrate content, the target return volume (using PBP solution) is V2+a*(V3+V4+V5+V6+V_{33}); again α is settable to a maximum value of 0.75, however volume V4 is taken into consideration. In both cases an alternative target return volume is determined as V2 + a predetermined volume based on a previous therapy PBP setting. The second embodiment requires that the blood pump 22 is stopped and the blood return line 30 is closed proximate its second end 30-2. In step 204, the user is prompted to clamp the blood removal line 20 proximate the first end 20-1 thereof and in step 206 the successful clamping of the blood removal line 30 is checked and verified. If the clamping is not verified, the process 200 is started over, returning back to step 201. If the successful clamping of the blood removal line is verified, then the process continues at step 208, in which the same steps are performed as in steps 108, 110, 112, 114, and 116, as described with reference to process 100 above. The process 200 continues at step 214 in which both the PBP fluid pump 62 and the blood pump 22 are controlled to return fluid (e.g. PBP solution) from PBP fluid container 68 to the blood removal line 20 and further, as shown in figure 3B. This second rinse-back step using the PBP fluid pump 62 and the blood pump 22 is continued until the sum of the fluid volume returned in sub-step 114 of step 208 and in step 214 reaches the target return volume. Again, the volume returned to the blood circuit may be determined either based on the rotation of the respective fluid pumps 22, 62, and 72 and/or based on the weight of the respective fluid containers 68 and 78 (e.g. a change in weight thereof). As described above, during rinse back the venous pressure is monitored in order to detect an occlusion or clotting in the blood circuit. In step 216, the PBP fluid pump 62 and blood pump 22 are stopped when the volume returned to the blood circuit has reached the target return volume. Subsequently, in step 218, the venous clamp 37 is closed and the process 200 ends at step 220. Figure 4 shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a third embodiment of the present invention. Blood return process 300 generally includes rinsing back blood to a patient through the blood return line 30 only using fluid from the PBP fluid container 68. Blood return process 300 is described with reference to figure 3B. Figure 3B schematically illustrates the process 300 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the third embodiment of the present invention. Blood return process 300 starts at step 301 when blood pump is stopped. In step 302, the requirements for performing process 300 are evaluated in a status check. This may include making sure that the fluid volume present in PBP fluid container 68 is greater than α * (V2+V3+V4+V5+V6+V_{33}), with α being set at a desired limit (e.g. 0.75). For the applicability of process 300 it is not relevant whether the PBP pre-infusion container 68 contains PBP solution having a low or a high concentration of citrate. However, the maximum usable fluid volume of PBP fluid depends on the citrate content. The return procedure making use of citrate solution from PBP bag (i.e. pre-infusion container 68) has the same constrains above described in respect to the second embodiment and again the apparatus determines the maximum usable fluid from pre-infusion container 68 that is usable without infusing an excessive citrate amount into the patient (e.g. the equivalent of 10 min of mean PBP flow rate). If the PBP solution is known to contain high citrate content or is unknown, the target return volume is V2+0.75*(V3+V5+V6+V_{33}), this volume excluding the filter volume V4 according to possible clotting of the filter. If the PBP solution is known to contain low citrate content, the target return volume is V2+0.75*(V3+V4+V5+V6+V_{33}). In both

cases an alternative target return volume is determined as V2 + a predetermined volume of a previous therapy PBP setting. If the requirements are not met, in particular if the volume present in the PBP fluid container is not greater than α * (V2+V3+V4+V5+V6+V_{33}), process 300 may still be performed in order to rinse back at least some of the blood present in the blood circuit (see above). Again, in some cases, minimum requirements may be defined, which determine whether the rinse-back procedure 300 is fully, partially, or not at all performed. If the requirements are met the blood pump 22 is stopped and the blood return line 30 is closed proximate its second end 30-2. In step 304, the user is prompted to clamp the blood removal line 20 proximate the first end 20-1 thereof and in step 306 the successful clamping of the blood removal line 30 is checked and verified. If the clamping is not verified, the process 300 is started over, returning back to step 301. If the successful clamping of the blood removal line is verified, then the process continues at step 308, in which the PBP fluid pump 62 and the blood pump 22 are controlled to return fluid downstream from the second pre-infusion site 20-3a as shown in figure 3B. The volume returned to the blood circuit may be determined either based on the rotation of the PBP fluid pump 62 (and/ or the blood pump 22) and/or based on the weight of the PBP fluid container 68 (e.g. a change in weight thereof). Again, venous pressure is monitored in order to detect an occlusion or clotting in the blood circuit. In step 312, the PBP fluid pump 62 and the blood pump 22 are stopped when the volume returned to the blood circuit reaches α * (V2+V3+V4+V5+V6+V_{33}). In case this volume exceeds the maximum volume infusible from pre-infusion container 68 due to the citrate mentioned constraints, the rinse-back procedure is stopped as soon as the maximum infusible fluid volume is reached. Subsequently, in step 314, the venous clamp 37 is closed and the process 300 ends at step 316. The duration of process 300 is directly proportional to the blood flow-rate during the return phase and to the volume of the returned fluid. Figure 5A shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a fourth embodiment of the present invention. Blood return process 400 generally includes rinsing back blood to a patient through both the blood return line 30 and the blood removal line 20 only using fluid from the replacement fluid container 78. Blood return process 400 is described with reference to figures 5B, 5C, and 5D. Figure 5B schematically illustrates a first phase (see, in particular, step 404 in figure 5A) of the process 400 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fourth embodiment of the present invention. Figure 5C schematically illustrates a second phase (see, in particular, step 408 in figure 5A) of the process 400 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fourth embodiment of the present invention. Figure 5D schematically illustrates a third phase (see, in particular, step 410 in figure 5A) of the process 400 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fourth embodiment of the present invention. Blood return process 400 starts at step 401 and blood pump is stopped. In step 402, the requirements for performing process 400 are evaluated in a status check. This may include making sure that the fluid volume present in the replacement fluid container 78 is greater than α * (V1+V2+V3+V4+V5+V6+V_{33}), with α being set at a desired limit (e.g. up to 1.0). The blood return in process 400 is performed through both the blood removal line 20 and the blood return line 30. The fluid volume returned through the blood removal line 20 (i.e. on the access side) is α * (V1+V2) and the fluid volume returned through the blood return line (i.e. on the venous side) is α * (V3+V4+V5+V6+V_{33}). If the requirements are not met, in particular if the volume present in the replacement fluid container 78 is not greater than α * (V1+V2+V3+V4+V5+V6+V_{33}), process 400 may still be performed in order to rinse back at least some of the blood present in the blood circuit (see above). Again, in some cases, minimum requirements may be defined, which determine whether the rinse-back procedure 400 is fully, partially, or not at all performed. If the requirements are met the blood pump 22 is controlled, in step 404, to move a pre-determined volume of blood towards and through the treatment unit 10 as shown in FIG. 5B (in this specific case, the arterial clamp 27 is open, meaning that some blood is still withdrawn from the patient vascular access. The pre-determined volume of blood being returned serves to convey blood downstream from the first pre-infusion site 20-3b, which may contain gas or air (e.g. coming from the PBP solution) and typically is about 1.5 to 2.0 * (V1+V2). For process 400 to commence, it is not necessary to close any of the blood lines, for example the blood return line 30. At step 406, after the pre-determined volume of blood has been conveyed, the blood pump 22 is stopped and the arterial clamp 27 is closed. At step 408, the replacement fluid pump 72 is controlled to return fluid downstream from the second pre-infusion site 20-3a as shown in figure 5C, with the blood pump 22 stopped. At step 410, after a pre-determined delay after step 408 has been initiated and in parallel to the operation of the replacement fluid pump 78, the clamp 27 is opened and the blood pump 22 is controlled to operate in reverse, thereby returning blood towards the first end 20-1 of the blood removal line 20 at a pre-determined flow rate. This pre-determined flow rate is selected to be about 50% of the flow rate at which the replacement fluid pump 72 is controlled to operate. The pre-determined delay may be selected depending on the respective volumes to be returned. According to the fourth embodiment, the pre-determined delay may range from about 3 to 10 seconds, preferably about 5 seconds. The operation of both pumps 22 and 72 in accordance with steps 408 and 410 is illustrated in figure 5D. The blood pump 22 is controlled at (reverse) $Q_{return}/2$ (alternatively the blood pump may be controlled at reverse less than $Q_{return}/2$, e.g. $Q_{return}/4$) and to stop (see step 412) after a first target volume has been returned through the blood removal line 20. According to the fourth embodiment, the first target volume is α * (V1+V2). The volume returned may be determined either based on the rotation of the blood pump 22. The replacement fluid pump 72 is controlled at (forward) Q_{return} and to stop (see step 414) after a second target volume has been returned through the

blood return line 30. According to the fourth embodiment, the second target volume is α * (V3+V4+V5+V6+V_{33}). The volume returned may be determined either based on the rotation of the replacement fluid pump 72 and/or based on the weight of the replacement fluid container 78 (e.g. a change in weight thereof). Again, pressures in the blood removal line (i.e. access pressure) and in the blood return line (i.e. venous pressure) are monitored in order to detect an occlusion or clotting in the blood circuit. Subsequently, at step 416, the venous clamp 37 is closed and the process 400 ends at step 418. Process 400 allows for an effectiveness of about 85% for all circuits, based on α = 1.0, indicating the return volume being about equal to the blood circuit volume. Not taking into consideration any delays due to switching times potentially necessary between different process steps, the duration is largely proportional to the blood flow-rate during the initial phase of access line flushing and the flow-rate during the return phase. The duration of process 400 in an example based on a blood circuit volume of 200 ml and alpha = 1 is about 3:20 minutes at a flow rate of 100ml/min and a blood return effectiveness of 85%. Duration can be optimized by using a higher blood flow rate during initial step 404, where there is no change in patient blood volume. For example, the same blood flow rate as during treatment might be set. The blood return flow rate prescription of 100ml/min does apply and only to steps 408 and 410. Controlling the blood pump 22 in reverse at step 410 at the pre-determined flow rate of $Q_{return}/2$ may entail a significant advantage in that air / gas potentially introduced from the replacement bag 78 along pre-infusion line 70 are, thus, more likely to be conveyed towards the treatment unit 10 and through blood return line 30, which includes an air separator 35 configured to remove any air/gas from the fluid conveyed. It is noted that the volume returned through the blood return line 30 (e.g. V3+V4+V5+V6+V_{33}) is normally at least 3 times higher than the volume returned through the blood removal line 20 (e.g. V2 orV1+V2). In these conditions/circumstances, it is possible to significantly decrease the flow-rate in the blood removal line 20 as low as $Q_{return}/4$ while maintaining the same duration for the entire blood return process 400. Figure 5E schematically represents a portion of the extracorporeal blood treatment apparatus in accordance with embodiments of the present invention. With respect to process 400 above, the arrangement of blood pump 22 and sensor 21a (e.g. a pressure sensor including a pressure pod structure) may provide an additional advantage. As shown in figure 5E, the specific arrangement of the blood pump 22 and sensor 21a during the reverse operation of blood pump 22 may trap any (or most of) residual air/gas included in the fluid returned through blood removal line 20. Air/gas may be trapped in the region of pressure pod 21a and further at the outlet port of pump tract 22t. This further increases safety of process 400. Figure 6 shows a flow chart of a process for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with a fifth embodiment of the present invention. Blood return process 500 generally corresponds to a reduced version of above-described processes 100/200 or 400 and includes rinsing back blood to a patient through both the blood return line 30 only using fluid from the replacement fluid container 78. Process 500 may preferably be used in case no PBP fluid is available (e.g. PBP fluid container 68 is empty or not present), or if the residual volume of replacement fluid available in replacement fluid container 78 is too low (e.g. determined by weighing replacement fluid container 78 or by an air sensor in pre-infusion line 60 detecting bubbles caused by an empty container 68). Blood return process 500 is described with reference to figure 5C. Figure 5C schematically illustrates step 506 of process 500 for rinsing back blood from an extracorporeal blood circuit to a patient in accordance with the fifth embodiment of the present invention. Blood return process 500 starts at step 501. In step 502, the requirements for performing process 500 are evaluated in a status check. This may include making sure that the fluid volume present in the replacement fluid container 78 is greater than α * (V3+V4+V5+V6+V_{33}), with α being set at a desired limit (e.g. up to 1.0). The blood return in process 500 is performed through the blood return line 30. The fluid volume returned through the blood return line (i.e. on the venous side) is α * (V3+V4+V5+V6+V_{33}). If the requirements are not met, in particular if the volume present in the replacement fluid container 78 is not greater than α * (V3+V4+V5+V6+V_{33}), process 500 may still be performed in order to rinse back at least some of the blood present in the blood circuit (see above). Again, in some cases, minimum requirements may be defined, which determine whether the rinse-back procedure 500 is fully, partially, or not at all performed. If the requirements are met the monitor venous clamp 37 is open at step 504. At step 506, the replacement fluid pump 72 is controlled to return fluid downstream from the second pre-infusion site 20-3a as shown in figure 5C. The replacement fluid pump 72 is controlled to stop (see step 508) after the target volume has been returned through the blood return line 30. According to the fifth embodiment, the target volume is α * (V3+V4+V5+V6+V_{33}). The volume returned may be determined either based on the rotation of the replacement fluid pump 72 and/or based on the weight of the replacement fluid container 78 (e.g. a change in weight thereof). Again, pressure in the blood return line (i.e. venous pressure) is monitored in order to detect an occlusion or clotting in the blood circuit. Subsequently, at step 510, the venous clamp 37 is closed and process 500 ends at step 512. Process 500 allows for an effectiveness of about 77/82/87% for LF set/HF set/HF set with blood warmer sets (see above). For α = 1.0 the theoretical effectiveness is about 85% and the actual effectiveness of return process 500 is about 65/69/74 % for LF set/HF set/HF set with blood warmer. The duration of process 500 is proportional to the return flow rate. The duration of process 500 in an example based on an adult set including a blood warmer is about 2:20 minutes at a flow rate of 100ml/min and a blood return effectiveness of 74%. Figure 7 schematically represents a portion of the extracorporeal blood treatment apparatus in accordance with embodiments of the present invention, in particular a portion of the blood removal line 20 and PBP pre-infusion line 60. The extracorporeal blood circuit may further comprise an air bubble detector 23b, such as an ultrasonic

air bubble detector (UABD), and/or a (e.g. ultrasonic) flow meter 23a, as well as a flow controller 27 (e.g. a clamp or a valve). The integration of an UABD 23b into the blood removal line 20 allows for the detection of air bubbles in the blood or fluid returned to the patient. This is particularly useful in combination with rinse-back procedure 400 where in step 410 blood pump 22 is operated in reverse in order to rinse back blood towards the first end 20-1 of the blood removal line 20. As can be seen in figure 7, sensor 23b is configured to detect air/gas in the fluid returned to the patient towards the first end 20-1 of the blood removal line 20 so that in case the fluid should contain detectable amounts of air/gas the flow controller 27 can be activated and the air/gas can be prevented from passing through the patient access and from entering the cardiovascular system of the patient. A further advantage includes that fluid entering the extracorporeal circuit (e.g. during regular treatment) may be monitored for air/gas so that an abnormal introduction of air/gas into the extracorporeal circuit (e.g. due to a disconnection from the patient and/or from the PBP fluid container) can be prevented. In such cases, the blood removal line may be clamped (see flow controller 27) or an alarm condition may be activated. This, in turn, may allow staff to attend to the situation (e.g. reconnect patient access) or a corresponding blood return procedure to be initiated. In accordance with a further rinse-back procedure, also a medical fluid (e.g. fresh dialysis fluid) from dialysis fluid container 48 may be used. In particular, the control unit (80) checks whether there is sufficient fluid in the dialysis fluid container 48 to at least push the extracorporeal blood volume contained in the extracorporeal blood circuit downstream the post-infusion line injection point. If fluid is available, the blood pump is stopped (and arterial clamp 27 is closed). The dialysate pump 42 is activated and blood pushed back into the patient. In addition, particularly in case an air bubble detector is present in the blood removal line 20 (see figure 7) and enough dialysis fluid is in the dialysate container 48, the blood pump 22 may be activated in reverse pumping to pump blood towards the patient access (first end 20-1 of blood removal line 20). Arterial clamp 27 should be open and venous clamp 37 closed. Additionally dialysate pump 42 is to be activated and synchronized with blood pump 22. When target of restituted blood is achieved (or dialysis fluid in the dialysate container substantially terminated), the process is stopped. Clearly, the air bubble detector 23b verifies that no air is returned to the patient and the control unit 80 blocks the rinse-back in case air is detected. It is worth to note that the medical fluid contained in the dialysate container may be used to have further fluid available during any of the previously described embodiment in case the fluid contained in either (or both) the pre-infusion container 68 or the replacement container 78 is not sufficient for completely restitute the extracorporeal blood. In such a case, instead of terminating the described procedures, a further rinse-back step may be added making use of the dialysate fluid when infused in post dilution.

[0024] For example, in the second embodiment, once all maximum fluid from the pre-infusion container 68 has been used and in case blood is still in the extracorporeal blood circuit, the post-infusion line may be used to push back the blood still in the final portion of the blood return line downstream the post-infusion injection point. The same additional step may be performed in the third embodiment, once all maximum fluid from the pre-infusion container 68 has been used and in case blood is still in the extracorporeal blood circuit. As to blood return prescription, the description focused on the possibility to select α parameter value, e.g. from 0.75 to 1). However, the prescription values in each of the described embodiments might be entered as fluid volumes expressed as, e.g.

- a ratio to circuit blood volume (β); or
- a volume to be returned (V_{return}).

[0025] Referring for example to the first embodiment, the prescription would have been modified to: PBP fluid volume staying at value V2 and replacement fluid volume= β*V_{total}-V2, wherein V_{total} is the total blood circuit volume, namely V1+V2+V3+V4+V5+V6+V_{33}. As a further alternative, the operator may set flow rates as blood return prescription, and the apparatus checks fluid availability an proper (optimized) rinse-back procedure based on pre-set values.

[0026] In the previous description, sensors for determining the fluid content in the various containers have been described and used to determine the properfluid availability. However, the present invention is not limited to the presence and use of such sensors (e.g. scales). Indeed, in the case of volumetric systems (e.g. with no scales) and in a configuration where the system cannot automatically evaluate available fluid volumes (typically the case of volumetric systems with no information on container sizes), the operator might be prompted to confirm/assess available volumes (as status check) in either or both pre-infusion container, replacement container and dialysate container. Blood return process is kept unchanged with the addition of possible interruptions/re-routing in case an empty bag signal occur (e.g. from an air detector in the fluid circuit). While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover various modifications included within the scope of the appended claims.

Claims

1. An apparatus (1) for continuous renal replacement therapy, comprising:

a blood circuit (10, 20, 30, 60) comprising a blood removal line (20), a treatment unit (10), and a blood return line (30), the blood treatment unit comprising a semipermeable membrane, a first chamber, and a second chamber, the semipermeable membrane being configured for separating the first chamber from the second chamber, the blood removal line having a first end (20-1) destined to be connected to a vascular system of a subject and a second end (20-2) connected to an inlet port (12) of the first chamber, the blood return line (30) having a first end (30-1) connected to an outlet port (14) of the first chamber and a second end (30-2) destined to be connected to the vascular system;
a replacement fluid container (78) configured for containing a medical fluid;
an infusion line (70) having a first end (70-1) connected to the replacement fluid container (78) and a second end (70-2) connected to the blood circuit (10, 20, 30, 60);
a blood pump (22) active on the blood circuit;
a replacement fluid pump (72) active on the infusion line (70);
a control unit (80) connected to the replacement fluid pump (72) and to the blood pump (22) and configured for performing a rinse-back procedure for restituting blood to a patient, particularly at the end of the treatment, the rinse-back procedure comprising:

- conveying blood contained in the blood circuit (10, 20, 30, 60) towards the second end (30-2) of the blood return line (30) using the medical fluid, **characterized in that** the rinse back procedure further comprises:
- monitoring an amount of fluid present in the replacement fluid container (78) at the time of activation of the rinse-back procedure;
- determining a selected rinse-back mode from a group comprising more than one of a first rinse-back mode, a second rinse-back mode, a third rinse-back mode, a fourth rinse-back mode, and a fifth rinse-back mode, wherein the selected rinse-back mode is determined at least based on the amount of the medical fluid present in the fluid container.

2. The apparatus of the preceding claim, comprising a replacement fluid sensor (79) connected to the control unit (80) and configured to generate a replacement fluid signal indicative of an amount of replacement fluid present in the replacement fluid container (78), the control unit (80) being further configured to determine, based on the replacement fluid signal, a replacement fluid amount signal indicative of an amount of replacement fluid present in the replacement fluid container (78),
in particular the control unit (80) being further configured to determine, based on changes of the replacement fluid signal over time, a replacement fluid flow rate signal indicative of a flow rate of replacement fluid flowing from the replacement fluid container (78).

3. The apparatus of any one of the preceding claims, wherein the infusion line (70) is a pre-infusion line (70), the second end (70-2) of the pre-infusion line (70) being connected to the blood removal line (20) at a pre-infusion site (20-3b) located downstream from the blood pump (22) and upstream from the second end (20-2) of the blood removal line.

4. The apparatus of any of the preceding claims further comprising:

a dialysate container (48) configured for containing dialysate;
a dialysate line (40) having a first end (40-1) connected to the dialysate container and a second end (40-2) connected to an inlet port (16) of the second chamber; and
a dialysate pump (42) connected to the control unit (80) and active on the dialysate line, the apparatus further comprising a dialysate sensor (49) connected to the control unit (80) and configured to generate a dialysate signal indicative of an amount of dialysate present in the dialysate container (48).

5. The apparatus of any of the preceding claims further comprising:

- a second pre-infusion line (60);
- a pre-blood-pump (PBP) fluid pump (62) connected to the control unit (80) and active on the second pre-infusion line (60); and

- a PBP fluid container (68) configured for containing a second medical fluid, in particular the second medical fluid including citrate and/or citric acid, or a mix of both; wherein
the second pre-infusion line (60) has a first end (60-1) connected to the PBP fluid container (68) and a second end (60-2) connected to the blood removal line (20),
the control unit (80) being further configured to determine the selected rinse-back mode based on an amount of the medical fluid present in the replacement fluid container (78) and an amount of the second medical fluid present in the PBP fluid container;
in particular wherein the control unit (80) is further configured for monitoring an amount of fluid present in the PBP fluid container (68) at the time of activation of the rinse-back procedure.

6. The apparatus of the preceding claim further comprising a PBP fluid sensor (69) connected to the control unit (80) and configured to generate a PBP fluid signal indicative of an amount of PBP fluid present in the PBP fluid container (68), in particular wherein the control unit (80) is further configured to determine, based on changes of the PBP fluid signal over time, a PBP flow rate signal indicative of a flow rate of PBP fluid flowing from the PBP fluid container (68).

7. The apparatus of the preceding claims 5 or 6, wherein the control unit (80) is configured for performing the rinse-back procedure according to the first mode (100) and wherein the rinse-back procedure further comprises:

- blocking a fluid flow towards a first end (20-1) of the blood removal line (20);
- enabling (108) fluid flow through the blood return line (30);
- controlling (110) the blood pump (22) and the PBP pump (62) to convey fluid from the PBP fluid container (68) towards the treatment unit (10);
- controlling (112) the blood pump (22) and the PBP pump (62) to stop conveying fluid when a second predetermined amount of fluid has been conveyed;
- controlling (114) the replacement fluid pump (72) to convey fluid from the replacement fluid container (78) towards the treatment unit (10);
- controlling (116) the replacement fluid pump (72) to stop conveying fluid when an eighth predetermined amount of fluid has been conveyed; and, optionally
- disabling (118) fluid flow through the blood return line (30).

8. The apparatus of the preceding claim 7, wherein the control unit (80) is configured for enabling the rinse-back procedure according to the first mode, if an amount of fluid present in the replacement fluid container (78) is equal to or greater than the eighth predetermined amount and an amount of fluid present in the PBP fluid container (68) is equal to the second predetermined amount,

the second predetermined amount being for example $\alpha \cdot V2$, wherein
α is a constant value, and
V2 is a volume of the blood circuit included between a first and a second pre infusion sites (20-3b, 20-3a).

9. The apparatus of any of the preceding claims from 5 to 8, wherein the control unit (80) is configured for performing the rinse-back procedure according to the second mode (200) and wherein the rinse-back procedure further comprises:

- blocking a fluid flow towards a first end (20-1) of the blood removal line (20);
- enabling (208-108) fluid flow through the blood return line (30);
- controlling (208-110) the blood pump (22) and the PBP pump (62) to convey fluid from the PBP fluid container (68) towards the treatment unit (10);
- controlling (208-112) the blood pump (22) and the PBP pump (62) to stop conveying fluid when a second predetermined amount of fluid has been conveyed;
- controlling (208-114) the replacement fluid pump (72) to convey fluid from the replacement fluid container (78) towards the treatment unit (10); and
- if the amount of fluid conveyed by the replacement fluid pump (72) is less than an eighth predetermined amount of fluid, controlling (214) the blood pump (22) and the PBP pump (62) to convey fluid from the PBP fluid container (68) towards the treatment unit (10) until a total amount of fluid conveyed reaches the eighth predetermined amount of fluid; and, optionally
- disabling (218) fluid flow through the blood return line (30).

10. Apparatus of the preceding claim 9, wherein the control unit (80) is configured for enabling the rinse-back procedure

according to the second mode (200) if an amount of fluid present in the replacement fluid container (78) is equal to or greater than the eighth pre-determined amount and an amount of fluid present in the PBP fluid container (68) is equal to the second predetermined amount; and
the control unit is configured for disabling the rinse-back procedure according to the second mode if the amount of medical fluid present in the fluid container is less than a pre-determined minimum amount.

11. Apparatus of any of the preceding claims from 5 to 10, wherein the control unit (80) is configured for performing the rinse-back procedure according to the third mode (300) and wherein the rinse-back procedure further comprises:

- enabling (308) fluid flow through the blood return line (30);
- controlling (310) the blood pump (22) and the PBP pump (62) to convey fluid from the PBP fluid container (68) towards the treatment unit (10);
- controlling (312) the blood pump (22) and the PBP pump (62) to stop conveying fluid when a ninth predetermined amount of fluid has been conveyed; and, optionally
- disabling (314) fluid flow through the blood return line (30);

wherein the control unit (80) is configured for enabling said rinse-back procedure according to the third mode (300) if an amount of fluid present in the replacement fluid container (78) is equal to or greater than an eighth pre-determined amount and an amount of fluid present in the PBP fluid container (68) is equal to a second predetermined amount; and the control unit is configured for disabling the rinse-back procedure according to the third mode if the amount of medical fluid present in the fluid container is less than a pre-determined minimum amount.

12. The apparatus of any of the preceding claims from 5 to 11, wherein the control unit (80) is configured for performing the rinse-back procedure according to the fourth mode (400) and wherein the rinse-back procedure further comprises:

- controlling (404) the blood pump (22) to convey blood towards the treatment unit (10);
- controlling (406) the blood pump (22) to stop conveying blood when a tenth predetermined amount of blood has been conveyed;
- controlling (408) the replacement fluid pump (72) to convey fluid at a first flow rate from the replacement fluid container (78) towards the treatment unit (10) and, after a predetermined pumped fluid volume, controlling (410) the blood pump (22) to convey fluid in reverse at a second flow rate towards the first end (20-1) of the blood removal line (20), the first flow rate being higher than the second flow rate, optionally the first flow rate being about two times the second flow rate;
- controlling (412) the replacement fluid pump (72) to stop conveying fluid when a first target amount of fluid has been conveyed and controlling (414) the blood pump (22) to stop conveying fluid when a second target amount of fluid has been conveyed; and, optionally
- disabling (416) fluid flow through the blood return line (30).

13. The apparatus of any of the preceding claims from 5 to 12, wherein the control unit (80) is configured for performing the rinse-back procedure according to the fifth mode (500) and wherein the rinse-back procedure further comprises:

- enabling (504) fluid flow through the blood return line (30);
- controlling (506) the replacement fluid pump (72) to convey fluid from the replacement fluid container (78) towards the treatment unit (10);
- controlling (508) the replacement fluid pump (72) to stop conveying fluid when an eighth predetermined amount of fluid has been conveyed; and, optionally
- disabling (510) fluid flow through the blood return line (30);
wherein the control unit (80) is configured for enabling the rinse-back procedure according to the fifth mode (500) if an amount of fluid present in the replacement fluid container (78) is equal to or greater than the eighth pre-determined amount and an amount of fluid present in the PBP fluid container (68) is equal to a second predetermined amount; and
the control unit is configured for disabling the rinse-back procedure according to the fifth mode if the amount of medical fluid present in the fluid container is less than a pre-determined minimum amount.

14. The apparatus of any one of the preceding claims, wherein the rinse-back procedures comprise:

- conveying blood contained in the blood circuit (10, 20, 30, 60) towards the second end (30-2) of the blood return line using the medical fluid of the replacement fluid container (78) and/or a second medical fluid of a PBP

fluid container (68), while fluid flow through the blood removal line (20) is being prevented.

15. The apparatus of any one of claims from 7, 9, 11 and 13, wherein the rinse-back procedures according to the first, second, third and fifth modes, further comprise, prior to the step of enabling fluid flow through the blood return line (30):

- prompting a user to disable fluid flow through the blood removal line (30); and
- checking whether fluid flow through the blood removal line (30) has been disabled.

Patentansprüche

1. Vorrichtung (1) zur kontinuierlichen Nierenersatztherapie, umfassend:

einen Blutkreislauf (10, 20, 30, 60), umfassend eine Blutentfernungsleitung (20), eine Behandlungseinheit (10) und eine Blutrückführleitung (30), wobei die Blutbehandlungseinheit eine semipermeable Membran, eine erste Kammer und eine zweite Kammer umfasst, wobei die semipermeable Membran ausgestaltet ist, um die erste Kammer von der zweiten Kammer zu trennen, die Blutentfernungsleitung ein erstes Ende (20-1), das mit einem Gefäßsystem eines Subjekts zu verbinden ist, und ein zweites Ende (20-2) aufweist, das mit einem Einlassanschluss (12) der ersten Kammer verbunden ist, wobei die Blutrückführleitung (30) ein erstes Ende (30-1), das mit einem Auslassanschluss (14) der ersten Kammer verbunden ist, und ein zweites Ende (30-2) aufweist, das mit dem Gefäßsystem zu verbinden ist;
einen Ersatzfluidbehälter (78), der ausgestaltet ist, um ein medizinisches Fluid zu enthalten;
eine Infusionsleitung (70) mit einem ersten Ende (70-1), das mit dem Ersatzfluidbehälter (78) verbunden ist, und einem zweiten Ende (70-2), das mit dem Blutkreislauf (10, 20, 30, 60) verbunden ist;
eine Blutpumpe (22), die auf den Blutkreislauf einwirkt;
eine Ersatzfluidpumpe (72), die auf die Infusionsleitung (70) einwirkt;
eine Steuereinheit (80), die mit der Ersatzfluidpumpe (72) und der Blutpumpe (22) verbunden ist und ausgestaltet ist, um eine Rückspülprozedur zur Rückerstattung von Blut an einen Patienten durchzuführen, insbesondere am Ende der Behandlung, wobei die Rückspülprozedur umfasst:

- Transportieren von Blut, das in dem Blutkreislauf (10, 20, 30, 60) enthalten ist, in Richtung des zweiten Endes (30-2) der Blutrückführleitung (30) unter Verwendung des medizinischen Fluids, **dadurch gekennzeichnet, dass** die Rückspülprozedur des Weiteren umfasst:
- Überwachen einer Menge an Fluid, die in dem Ersatzfluidbehälter (78) zum Zeitpunkt der Aktivierung der Rückspülprozedur vorhanden ist;
- Bestimmen eines ausgewählten Rückspülmodus aus einer Gruppe, die mehr als einen von einem ersten Rückspülmodus, einem zweiten Rückspülmodus, einem dritten Rückspülmodus, einem vierten Rückspülmodus und einem fünften Rückspülmodus umfasst, wobei der ausgewählte Rückspülmodus mindestens basierend auf der Menge des medizinischen Fluids bestimmt wird, die in dem Fluidbehälter vorhanden ist.

2. Vorrichtung nach dem vorhergehenden Anspruch, umfassend einen Ersatzfluidsensor (79), der mit der Steuereinheit (80) verbunden ist und ausgestaltet ist, um ein Ersatzfluidsignal zu generieren, das eine Menge an Ersatzfluid angibt, die in dem Ersatzfluidbehälter (78) vorhanden ist, wobei die Steuereinheit (80) des Weiteren ausgestaltet ist, um basierend auf dem Ersatzfluidsignal ein Ersatzfluidmengensignal zu bestimmen, das eine Menge an Ersatzfluid angibt, die in dem Ersatzfluidbehälter (78) vorhanden ist,
wobei insbesondere die Steuereinheit (80) des Weiteren ausgestaltet ist, um basierend auf Änderungen des Ersatzfluidsignals im Zeitverlauf ein Ersatzfluidflussratensignal zu bestimmen, das eine Flussrate des Ersatzfluids angibt, die aus dem Ersatzfluidbehälter (78) fließt.

3. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Infusionsleitung (70) eine Präinfusionsleitung (70) ist, das zweite Ende (70-2) der Präinfusionsleitung (70) mit der Blutentfernungsleitung (20) an einem Präinfusionssitus (20-3b) verbunden ist, der sich nachgeordnet zu der Blutpumpe (22) und vorgeordnet zu dem zweiten Ende (20-2) der Blutentfernungsleitung befindet.

4. Vorrichtung nach einem der vorhergehenden Ansprüche, des Weiteren umfassend:

einen Dialysatbehälter (48), die ausgestaltet ist, um Dialysat zu enthalten;
eine Dialysatleitung (40) mit einem ersten Ende (40-1), das mit dem Dialysatbehälter verbunden ist, und einem

zweiten Ende (40-2), das mit einem Einlassanschluss (16) der zweiten Kammer verbunden ist; und
eine Dialysatpumpe (42), die mit der Steuereinheit (80) verbunden ist und auf die Dialysatleitung einwirkt, wobei die Vorrichtung des Weiteren einen Dialysatsensor (49) umfasst, der mit der Steuereinheit (80) verbunden ist und ausgestaltet ist, um ein Dialysatsignal zu generieren, welches eine Menge an Dialysat angibt, die in dem Dialysatbehälter (48) vorhanden ist.

5. Vorrichtung nach einem der vorhergehenden Ansprüche, des Weiteren umfassend:

- eine zweite Präinfusionsleitung (60);
- eine Präblutpump- (PBP)-Fluidpumpe (62), die mit der Steuereinheit (80) verbunden ist und auf die zweite Präinfusionsleitung (60) einwirkt; und
- einen PBP-Fluidbehälter (68), der ausgestaltet ist, um ein zweites medizinisches Fluid zu enthalten, wobei das zweite medizinische Fluid insbesondere Citrat und/oder Citronensäure und/oder ein Gemisch aus beiden einschließt; wobei

die zweite Präinfusionsleitung (60) ein erstes Ende (60-1), das mit dem PBP-Fluidbehälter (68) verbunden ist, und ein zweites Ende (60-2) aufweist, das mit der Blutentfernungsleitung (20) verbunden ist,
wobei die Steuereinheit (80) des Weiteren ausgestaltet ist, um den ausgewählten Rückspülmodus basierend auf einer Menge des medizinischen Fluids, die in dem Ersatzfluidbehälter (78) vorhanden ist, und einer Menge des zweiten medizinischen Fluids zu bestimmen, die in dem PBP-Fluidbehälter vorhanden ist;
wobei insbesondere die Steuereinheit (80) des Weiteren ausgestaltet ist, um eine Menge an Fluid zu überwachen, die in dem PBP-Fluidbehälter (68) zur Zeit der Aktivierung der Rückspülprozedur vorhanden ist.

6. Vorrichtung nach dem vorhergehenden Anspruch, des Weiteren umfassend einen PBP-Fluidsensor (69), der mit der Steuereinheit (80) verbunden ist und ausgestaltet ist, um ein PBP-Fluidsignal zu generieren, das eine Menge an PBP-Fluid angibt, die in dem PBP-Fluidbehälter (68) vorhanden ist, wobei die Steuereinheit (80) insbesondere des Weiteren ausgestaltet ist, um basierend auf Änderungen in dem PBP-Fluidsignal im Zeitverlauf ein PBP-Flussratensignal zu bestimmen, das eine Flussrate des PBP-Fluids angibt, die aus dem PBP-Fluidbehälter (68) fließt.

7. Vorrichtung nach den vorhergehenden Ansprüchen 5 oder 6, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem ersten Modus (100) durchzuführen, und wobei die Rückspülprozedur des Weiteren umfasst:

- Blockieren eines Fluidflusses in Richtung eines ersten Endes (20-1) der Blutentfernungsleitung (20) ;
- Aktivieren (108) von Fluidfluss durch die Blutrückführleitung (30);
- Steuern (110) der Blutpumpe (22) und der PBP-Pumpe (62), um Fluid aus dem PBP-Fluidbehälter (68) in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (112) der Blutpumpe (22) und der PBP-Pumpe (62), um das Transportieren von Fluid zu stoppen, wenn eine zweite vorbestimmte Menge an Fluid transportiert worden ist;
- Steuern (114) der Ersatzfluidpumpe (72), um Fluid aus dem Ersatzfluidbehälter (78) in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (116) der Ersatzfluidpumpe (72), um das Transportieren von Fluid zu stoppen, wenn eine achte vorbestimmte Menge an Fluid transportiert worden ist; und gegebenenfalls
- Deaktivieren (118) des Fluidflusses durch die Blutrückführleitung (30).

8. Vorrichtung nach dem vorhergehenden Anspruch 7, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem ersten Modus zu aktivieren, falls eine Menge an Fluid, die in dem Ersatzfluidbehälter (78) vorhanden ist, gleich oder größer als die achte vorbestimmte Menge ist, und eine Menge an Fluid, die in dem PBP-Fluidbehälter (68) vorhanden ist, gleich der zweiten vorbestimmten Menge ist,

wobei die zweite vorbestimmte Menge beispielsweise $\alpha \cdot V2$ ist, wobei
α ein konstanter Wert ist, und
V2 ein Volumen des Blutkreislaufs ist, das zwischen einem ersten und einem zweiten Präinfusionssitus (20-3b, 20-3a) eingeschlossen ist.

9. Vorrichtung nach einem der vorhergehenden Ansprüche von 5 bis 8, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem zweiten Modus (200) durchzuführen, und wobei die Rückspülprozedur des Weiteren umfasst:

- Blockieren eines Fluidflusses in Richtung eines ersten Endes (20-1) der Blutentfernungsleitung (20) ;
- Aktivieren (208-108) von Fluidfluss durch die Blutrückführleitung (30);
- Steuern (208-110) der Blutpumpe (22) und der PBP-Pumpe (62), um Fluid aus dem PBP-Fluidbehälter (68) in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (208-112) der Blutpumpe (22) und der PBP-Pumpe (62), um das Transportieren von Fluid zu stoppen, wenn eine zweite vorbestimmte Menge an Fluid transportiert worden ist;
- Steuern (208-114) der Ersatzfluidpumpe (72), um Fluid aus dem Ersatzfluidbehälter (78) in Richtung der Behandlungseinheit (10) zu transportieren; und
- falls die Menge an Fluid, die durch die Ersatzfluidpumpe (72) transportiert worden ist, kleiner als eine achte vorbestimmte Menge an Fluid ist, Steuern (214) der Blutpumpe (22) und der PBP-Pumpe (62), um Fluid aus dem PBP-Fluidbehälter (68) in Richtung der Behandlungseinheit (10) zu transportieren, bis eine Gesamtmenge an transportiertem Fluid die achte vorbestimmte Menge an Fluid erreicht; und gegebenenfalls
- Deaktivieren (218) des Fluidflusses durch die Blutrückführleitung (30).

10. Vorrichtung nach dem vorhergehenden Anspruch 9, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem zweiten Modus (200) zu aktivieren, falls eine Menge an Fluid, die in dem Ersatzfluidbehälter (78) vorhanden ist, gleich oder größer als die achte vorbestimmte Menge ist, und eine Menge an Fluid, die in dem PBP-Fluidbehälter (68) vorhanden ist, gleich der zweiten vorbestimmten Menge ist; und
die Steuereinheit ausgestaltet ist, um die Rückspülprozedur gemäß dem zweiten Modus zu deaktivieren, falls die Menge an medizinischem Fluid, die in dem Fluidbehälter vorhanden ist, kleiner als eine vorbestimmte Mindestmenge ist.

11. Vorrichtung nach einem der vorhergehenden Ansprüche von 5 bis 10, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem dritten Modus (300) durchzuführen, und wobei die Rückspülprozedur des Weiteren umfasst:

- Aktivieren (308) von Fluidfluss durch die Blutrückführleitung (30);
- Steuern (310) der Blutpumpe (22) und der PBP-Pumpe (62), um Fluid aus dem PBP-Fluidbehälter (68) in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (312) der Blutpumpe (22) und der PBP-Pumpe (62), um das Transportieren von Fluid zu stoppen, wenn eine neunte vorbestimmte Menge an Fluid transportiert worden ist; und gegebenenfalls
- Deaktivieren (314) des Fluidflusses durch die Blutrückführleitung (30);

wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem dritten Modus (300) zu aktivieren, falls eine Menge an Fluid, die in dem Ersatzfluidbehälter (78) vorhanden ist, gleich oder größer als eine achte vorbestimmte Menge ist und eine Menge an Fluid, die in dem PBP-Fluidbehälter (68) vorhanden ist, gleich einer zweiten vorbestimmten Menge ist; und die Steuereinheit ausgestaltet ist, um die Rückspülprozedur gemäß dem dritten Modus zu deaktivieren, falls die Menge an medizinischem Fluid, die in dem Fluidbehälter vorhanden ist, kleiner als eine vorbestimmte Mindestmenge ist.

12. Vorrichtung nach einem der vorhergehenden Ansprüche von 5 bis 11, wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem vierten Modus (400) durchzuführen, und wobei die Rückspülprozedur des Weiteren umfasst:

- Steuern (404) der Blutpumpe (22), um Blut in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (406) der Blutpumpe (22), um das Transportieren von Blut zu stoppen, wenn eine zehnte vorbestimmte Menge an Blut transportiert worden ist;
- Steuern (408) der Ersatzfluidpumpe (72), um Fluid mit einer ersten Flussrate aus dem Ersatzfluidbehälter (78) in Richtung der Behandlungseinheit (10) zu transportieren, und nach einem vorbestimmten gepumpten Fluidvolumen Steuern (410) der Blutpumpe (22), um Fluid in Gegenrichtung mit einer zweiten Flussrate in Richtung des ersten Endes (20-1) der Blutentfernungsleitung (20) zu transportieren, wobei die erste Flussrate höher als die zweite Flussrate ist, wobei die erste Flussrate gegebenenfalls etwa das Doppelte der zweiten Flussrate ist;
- Steuern (412) der Ersatzfluidpumpe (72), um das Transportieren von Fluid zu stoppen, wenn eine erste Zielmenge an Fluid transportiert worden ist, und Steuern (414) der Blutpumpe (22), um das Transportieren von Fluid zu stoppen, wenn eine zweite Zielmenge an Fluid transportiert worden ist; und gegebenenfalls
- Deaktivieren (416) des Fluidflusses durch die Blutrückführleitung (30).

13. Vorrichtung nach einem der vorhergehenden Ansprüche von 5 bis 12, wobei die Steuereinheit (80) ausgestaltet ist,

um die Rückspülprozedur gemäß dem fünften Modus (500) durchzuführen, und wobei die Rückspülprozedur des Weiteren umfasst:

- Aktivieren (504) von Fluidfluss durch die Blutrückführleitung (30);
- Steuern (506) der Ersatzfluidpumpe (72), um Fluid aus dem Ersatzfluidbehälter (78) in Richtung der Behandlungseinheit (10) zu transportieren;
- Steuern (508) der Ersatzfluidpumpe (72), um das Transportieren von Fluid zu stoppen, wenn eine achte vorbestimmte Menge an Fluid transportiert worden ist; und gegebenenfalls
- Deaktivieren (510) des Fluidflusses durch die Blutrückführleitung (30);

wobei die Steuereinheit (80) ausgestaltet ist, um die Rückspülprozedur gemäß dem fünften Modus (500) zu aktivieren, falls eine Menge an Fluid, die in dem Ersatzfluidbehälter (78) vorhanden ist, gleich oder größer als die achte vorbestimmte Menge ist und eine Menge an Fluid, die in dem PBP-Fluidbehälter (68) vorhanden ist, gleich einer zweiten vorbestimmten Menge ist; und
die Steuereinheit ausgestaltet ist, um die Rückspülprozedur gemäß dem fünften Modus zu deaktivieren, falls die Menge an medizinischem Fluid, die in dem Fluidbehälter vorhanden ist, kleiner als eine vorbestimmte Mindestmenge ist.

14. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Rückspülprozeduren umfassen:

- Transportieren von Blut, das in dem Blutkreislauf (10, 20, 30, 60) enthalten ist, in Richtung des zweiten Endes (30-2) der Blutrückführleitung unter Verwendung des medizinischen Fluids des Ersatzfluidbehälters (78) und/oder eines zweiten medizinischen Fluids aus einem PBP-Fluidbehälter (68), während Fluidfluss durch die Blutentfernungsleitung (20) hindurch verhindert wird.

15. Vorrichtung nach einem der Ansprüche 7, 9, 11 und 13, wobei die Rückspülprozeduren gemäß dem ersten, zweiten, dritten und fünften Modus des Weiteren vor dem Schritt des Aktivierens von Fluidfluss durch die Blutrückführleitung (30) umfassen:

- Auffordern eines Benutzers, den Fluidfluss durch die Blutentfernungsleitung (30) hindurch zu deaktivieren; und
- Prüfen, ob der Fluidfluss durch die Blutentfernungsleitung (30) hindurch deaktiviert worden ist.

Revendications

1. Appareil (1) pour une thérapie de remplacement rénal continue, comprenant :

un circuit sanguin (10, 20, 30, 60) comprenant une ligne de prélèvement de sang (20), une unité de traitement (10) et une ligne de retour de sang (30), l'unité de traitement de sang comprenant une membrane semi-perméable, une première chambre et une seconde chambre, la membrane semi-perméable étant configurée pour séparer la première chambre de la seconde chambre, la ligne de prélèvement de sang ayant une première extrémité (20-1) destinée à être reliée au système vasculaire d'un sujet et une seconde extrémité (20-2) reliée à un orifice d'entrée (12) de la première chambre, la ligne de retour de sang (30) ayant une première extrémité (30-1) reliée à un orifice de sortie (14) de la première chambre et une seconde extrémité (30-2) destinée à être reliée au système vasculaire ;
un récipient de fluide de remplacement (78) configuré pour contenir un fluide médical ;
une ligne de perfusion (70) ayant une première extrémité (70-1) reliée au récipient de fluide de remplacement (78) et une seconde extrémité (70-2) reliée au circuit sanguin (10, 20, 30, 60) ;
une pompe à sang (22) active sur le circuit sanguin ;
une pompe à fluide de remplacement (72) active sur la ligne de perfusion (70) ;
une unité de commande (80) reliée à la pompe à fluide de remplacement (72) et à la pompe à sang (22) et configurée pour réaliser une procédure de rinçage pour restituer du sang à un patient, notamment en fin de traitement, la procédure de rinçage comprenant :

- l'acheminement du sang contenu dans le circuit sanguin (10, 20, 30, 60) vers la seconde extrémité (30-2) de la ligne de retour de sang (30) à l'aide du fluide médical, **caractérisé en ce que** la procédure de rinçage comprend en outre :
- la surveillance d'une quantité de fluide présente dans le récipient de fluide de remplacement (78) au

moment de l'activation de la procédure de rinçage ;
- la détermination d'un mode de rinçage sélectionné à partir d'un groupe comprenant plus d'un mode de rinçage parmi un premier mode de rinçage, un deuxième mode de rinçage, un troisième mode de rinçage, un quatrième mode de rinçage et un cinquième mode de rinçage, le mode de rinçage sélectionné étant déterminé au moins sur la base de la quantité de fluide médical présente dans le récipient de fluide.

2. Appareil selon la revendication précédente, comprenant un capteur de fluide de remplacement (79) relié à l'unité de commande (80) et configuré pour générer un signal de fluide de remplacement indiquant une quantité de fluide de remplacement présent dans le récipient de fluide de remplacement (78), l'unité de commande (80) étant en outre configurée pour déterminer, sur la base du signal de fluide de remplacement, un signal de quantité de fluide de remplacement indiquant une quantité de fluide de remplacement présent dans le récipient de fluide de remplacement (78),
en particulier, l'unité de commande (80) étant en outre configurée pour déterminer, sur la base des variations du signal de fluide de remplacement dans le temps, un signal de débit de fluide de remplacement indiquant un débit de fluide de remplacement s'écoulant à partir du récipient de fluide de remplacement (78).

3. Appareil selon l'une quelconque des revendications précédentes, la ligne de perfusion (70) étant une ligne de pré-perfusion (70), la seconde extrémité (70-2) de la ligne de pré-perfusion (70) étant reliée à la ligne de prélèvement de sang (20) au niveau d'un site de pré-perfusion (20-3b) situé en aval de la pompe à sang (22) et en amont de la seconde extrémité (20-2) de la ligne de prélèvement de sang.

4. Appareil selon l'une quelconque des revendications précédentes comprenant en outre :

un récipient de dialysat (48) configuré pour contenir du dialysat ;
une ligne de dialysat (40) ayant une première extrémité (40-1) reliée au récipient de dialysat et une seconde extrémité (40-2) reliée à un orifice d'entrée (16) de la seconde chambre ; et
une pompe à dialysat (42) reliée à l'unité de commande (80) et active sur la ligne de dialysat, l'appareil comprenant en outre un capteur de dialysat (49) relié à l'unité de commande (80) et configuré pour générer un signal de dialysat indiquant une quantité de dialysat présente dans le récipient de dialysat (48).

5. Appareil selon l'une quelconque des revendications précédentes comprenant en outre :

- une seconde ligne de pré-perfusion (60) ;
- une pompe à fluide pré-sanguin (PBP) (62) reliée à l'unité de commande (80) et active sur la seconde ligne de pré-perfusion (60) ; et
- un récipient de fluide PBP (68) configuré pour contenir un second fluide médical, en particulier le second fluide médical comprenant du citrate et/ou de l'acide citrique, ou un mélange des deux ; la seconde ligne de pré-perfusion (60) ayant une première extrémité (60-1) reliée au récipient de fluide PBP (68) et une seconde extrémité (60-2) reliée à la ligne de prélèvement de sang (20),
l'unité de commande (80) étant en outre configurée pour déterminer le mode de rinçage sélectionné sur la base d'une quantité de fluide médical présente dans le récipient de fluide de remplacement (78) et d'une quantité du second fluide médical présente dans le récipient de fluide PBP ;
en particulier, l'unité de commande (80) étant en outre configurée pour surveiller une quantité de fluide présente dans le récipient de fluide PBP (68) au moment de l'activation de la procédure de rinçage.

6. Appareil selon la revendication précédente, comprenant en outre un capteur de fluide PBP (69) relié à l'unité de commande (80) et configuré pour générer un signal de fluide PBP indiquant une quantité de fluide PBP présente dans le récipient de fluide PBP (68), en particulier l'unité de commande (80) étant en outre configurée pour déterminer, sur la base des variations du signal de fluide PBP dans le temps, un signal de débit PBP indiquant un débit de fluide PBP s'écoulant à partir du récipient de fluide PBP (68).

7. Appareil selon les revendications précédentes 5 ou 6, l'unité de commande (80) étant configurée pour réaliser la procédure de rinçage selon le premier mode (100) et la procédure de rinçage comprenant en outre :

- le blocage d'un écoulement de fluide vers une première extrémité (20-1) de la ligne de prélèvement de sang (20) ;
- l'activation (108) de l'écoulement du fluide dans la ligne de retour de sang (30) ;
- la commande (110) de la pompe à sang (22) et de la pompe PBP (62) pour acheminer le fluide du récipient

de fluide PBP (68) vers l'unité de traitement (10) ;
- la commande (112) de la pompe à sang (22) et de la pompe PBP (62) pour arrêter l'acheminement du fluide lorsqu'une seconde quantité prédéterminée de fluide a été acheminée ;
- la commande (114) de la pompe à fluide de remplacement (72) pour acheminer le fluide du récipient de fluide de remplacement (78) vers l'unité de traitement (10) ;
- la commande (116) de la pompe à fluide de remplacement (72) pour arrêter l'acheminement du fluide lorsqu'une huitième quantité prédéterminée de fluide a été acheminée ; et, éventuellement
- la désactivation (118) de l'écoulement du fluide dans la ligne de retour de sang (30).

8. Appareil selon la revendication 7 précédente, l'unité de commande (80) étant configurée pour activer la procédure de rinçage selon le premier mode, si une quantité de fluide présente dans le récipient de fluide de remplacement (78) est égale ou supérieure à la huitième quantité prédéterminée et qu'une quantité de fluide présente dans le récipient de fluide PBP (68) est égale à la seconde quantité prédéterminée,

la seconde quantité prédéterminée étant par exemple $\alpha \cdot V2$,
α étant une valeur constante, et
V2 étant un volume du circuit sanguin compris entre un premier et un second site de pré-perfusion (20-3b, 20-3a) .

9. Appareil selon l'une quelconque des revendications précédentes de 5 à 8, l'unité de commande (80) étant configurée pour réaliser la procédure de rinçage selon le deuxième mode (200) et la procédure de rinçage comprenant en outre :

- le blocage d'un écoulement de fluide vers une première extrémité (20-1) de la ligne de prélèvement de sang (20) ;
- l'activation (208-108) de l'écoulement du fluide dans la ligne de retour de sang (30) ;
- la commande (208-110) de la pompe à sang (22) et de la pompe PBP (62) pour acheminer le fluide du récipient de fluide PBP (68) vers l'unité de traitement (10) ;
- la commande (208-112) de la pompe à sang (22) et de la pompe PBP (62) pour arrêter l'acheminement du fluide lorsqu'une seconde quantité prédéterminée de fluide a été acheminée ;
- la commande (208-114) de la pompe à fluide de remplacement (72) pour acheminer le fluide du récipient de fluide de remplacement (78) vers l'unité de traitement (10) ; et
- si la quantité de fluide acheminée par la pompe à fluide de remplacement (72) est inférieure à une huitième quantité de fluide prédéterminée, la commande (214) de la pompe à sang (22) et de la pompe PBP (62) pour acheminer le fluide du récipient de fluide PBP (68) vers l'unité de traitement (10) jusqu'à ce que la quantité totale de fluide acheminée atteigne la huitième quantité de fluide prédéterminée ; et, éventuellement
- la désactivation (218) de l'écoulement du fluide dans la ligne de retour de sang (30).

10. Appareil selon la revendication précédente 9, l'unité de commande (80) étant configurée pour activer la procédure de rinçage selon le deuxième mode (200) si une quantité de fluide présente dans le récipient de fluide de remplacement (78) est égale ou supérieure à la huitième quantité prédéterminée et qu'une quantité de fluide présente dans le récipient de fluide PBP (68) est égale à la seconde quantité prédéterminée ; et
l'unité de commande étant configurée pour désactiver la procédure de rinçage selon le deuxième mode si la quantité de fluide médical présente dans le récipient de fluide est inférieure à une quantité minimale prédéterminée.

11. Appareil selon l'une quelconque des revendications précédentes de 5 à 10, l'unité de commande (80) étant configurée pour réaliser la procédure de rinçage selon le troisième mode (300) et la procédure de rinçage comprenant en outre :

- l'activation (308) de l'écoulement du fluide dans la ligne de retour de sang (30) ;
- la commande (310) de la pompe à sang (22) et de la pompe PBP (62) pour acheminer le fluide du récipient de fluide PBP (68) vers l'unité de traitement (10) ;
- la commande (312) de la pompe à sang (22) et de la pompe PBP (62) pour arrêter l'acheminement du fluide lorsqu'une neuvième quantité prédéterminée de fluide a été acheminée ; et, éventuellement
- la désactivation (314) de l'écoulement de fluide dans la ligne de retour de sang (30) ;
- l'unité de commande (80) étant configurée pour activer ladite procédure de rinçage selon le troisième mode (300) si une quantité de fluide présente dans le récipient de fluide de remplacement (78) est égale ou supérieure à une huitième quantité prédéterminée et qu'une quantité de fluide présente dans le récipient de fluide PBP (68) est égale à une seconde quantité prédéterminée ; et l'unité de commande étant configurée pour désactiver la procédure de rinçage selon le troisième mode si la quantité de fluide médical présente dans le récipient de fluide est inférieure à une quantité minimale prédéterminée.

12. Appareil selon l'une quelconque des revendications précédentes de 5 à 11, l'unité de commande (80) étant configurée pour réaliser la procédure de rinçage selon le quatrième mode (400) et la procédure de rinçage comprenant en outre :

- la commande (404) de la pompe à sang (22) pour acheminer le sang vers l'unité de traitement (10) ;
- la commande (406) de la pompe à sang (22) pour arrêter l'acheminement du sang lorsqu'une dixième quantité prédéterminée de sang a été acheminée ;
- la commande (408) de la pompe à fluide de remplacement (72) pour acheminer le fluide à un premier débit depuis le récipient de fluide de remplacement (78) vers l'unité de traitement (10) et, après un volume de fluide pompé prédéterminé, la commande (410) de la pompe à sang (22) pour acheminer le fluide en sens inverse à un second débit vers la première extrémité (20-1) de la ligne de prélèvement de sang (20), le premier débit étant plus élevé que le second débit, éventuellement le premier débit étant environ deux fois le second débit ;
- la commande (412) de la pompe à fluide de remplacement (72) pour arrêter l'acheminement du fluide lorsqu'une première quantité cible de fluide a été acheminée et la commande (414) de la pompe à sang (22) pour arrêter l'acheminement du fluide lorsqu'une seconde quantité cible de fluide a été acheminée ; et, éventuellement
- la désactivation (416) de l'écoulement du fluide dans la ligne de retour de sang (30).

13. Appareil selon l'une quelconque des revendications précédentes de 5 à 12, l'unité de commande (80) étant configurée pour réaliser la procédure de rinçage selon le cinquième mode (500) et la procédure de rinçage comprenant en outre :

- l'activation (504) de l'écoulement de fluide dans la ligne de retour de sang (30) ;
- la commande (506) de la pompe à fluide de remplacement (72) pour acheminer le fluide du récipient de fluide de remplacement (78) vers l'unité de traitement (10),
- la commande (508) de la pompe à fluide de remplacement (72) pour arrêter l'acheminement du fluide lorsqu'une huitième quantité prédéterminée de fluide a été acheminée ; et, éventuellement
- la désactivation (510) de l'écoulement du fluide dans la ligne de retour de sang (30) ;

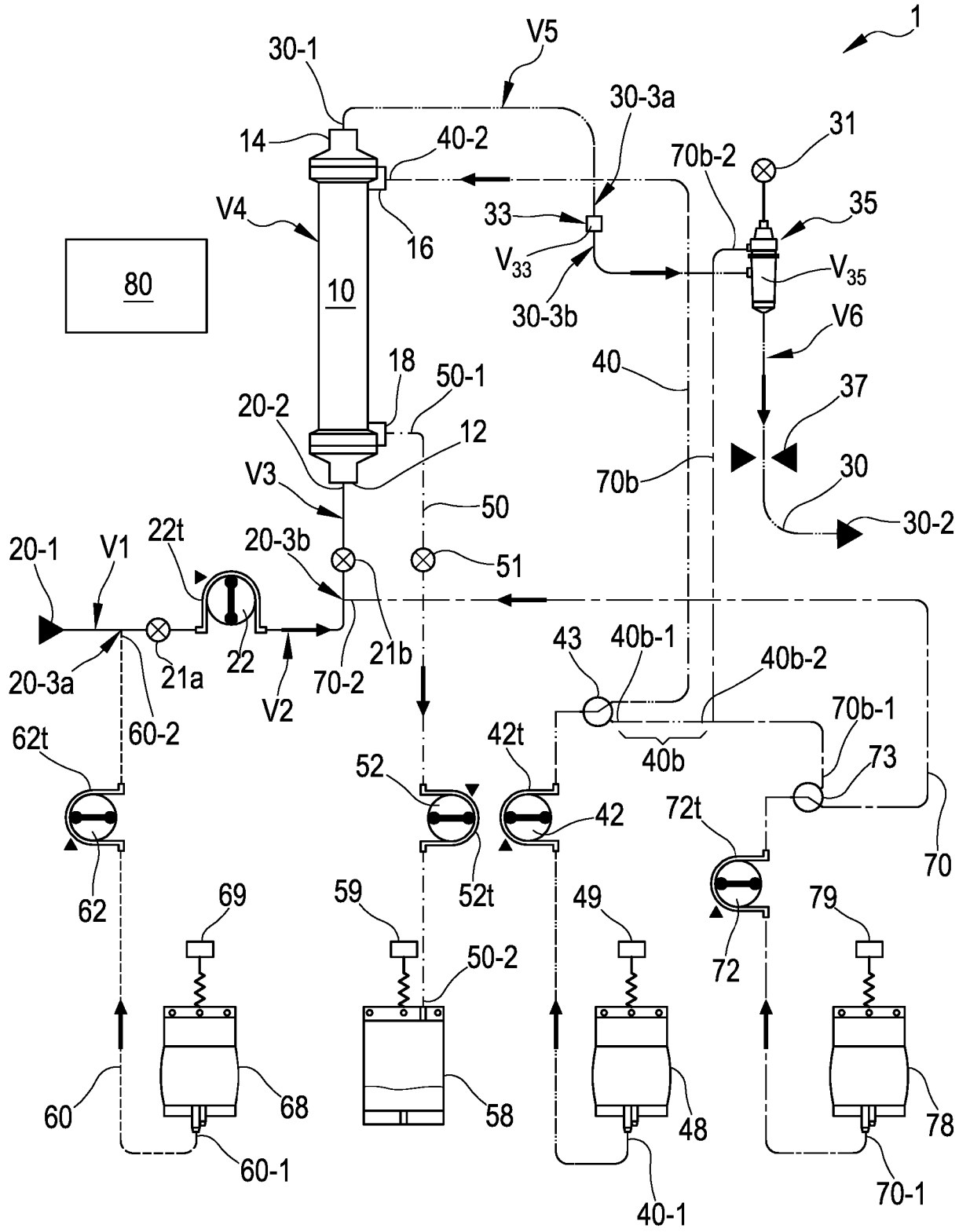
l'unité de commande (80) étant configurée pour activer la procédure de rinçage selon le cinquième mode (500) si une quantité de fluide présente dans le récipient de fluide de remplacement (78) est égale ou supérieure à la huitième quantité prédéterminée et si une quantité de fluide présente dans le récipient de fluide PBP (68) est égale à une seconde quantité prédéterminée ;
et l'unité de commande étant configurée pour désactiver la procédure de rinçage selon le cinquième mode si la quantité de fluide médical présente dans le récipient de fluide est inférieure à une quantité minimale prédéterminée.

14. Appareil selon l'une quelconque des revendications précédentes, les procédures de rinçage comprenant :

- l'acheminement du sang contenu dans le circuit sanguin (10, 20, 30, 60) vers la seconde extrémité (30-2) de la ligne de retour de sang à l'aide du fluide médical du récipient de fluide de remplacement (78) et/ou d'un second fluide médical d'un récipient de fluide PBP (68), tout en empêchant l'écoulement du fluide à travers la ligne de prélèvement de sang (20).

15. Appareil selon l'une quelconque des revendications de 7, 9, 11 et 13, les procédures de rinçage selon le premier, le deuxième, le troisième et le cinquième mode, comprenant en outre, avant l'étape d'activation de l'écoulement de fluide dans la ligne de retour de sang (30) :

- l'invitation de l'utilisateur à désactiver l'écoulement du fluide dans la ligne de prélèvement de sang (30) ; et
- la vérification que l'écoulement de fluide dans la ligne de prélèvement de sang (30) a été désactivé.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V5
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14
40-2
31
70b-2
V4
33
35
16
80
10
V_{33}
V_{35}
30-3b
V6
18
50-1
40
20-2
37
12
70b
V3
30
50
30-2
20-1
V1
22t
20-3b
51
43
40b-1
40b-2
22
21b
20-3a
21a
70-2
V2
70b-1
62t
60-2
42t
40b
73
52
42
72t
70
62
69
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52t
49
79
50-2
72
60
68
58
48
78
60-1
40-1
70-1

FIG.1

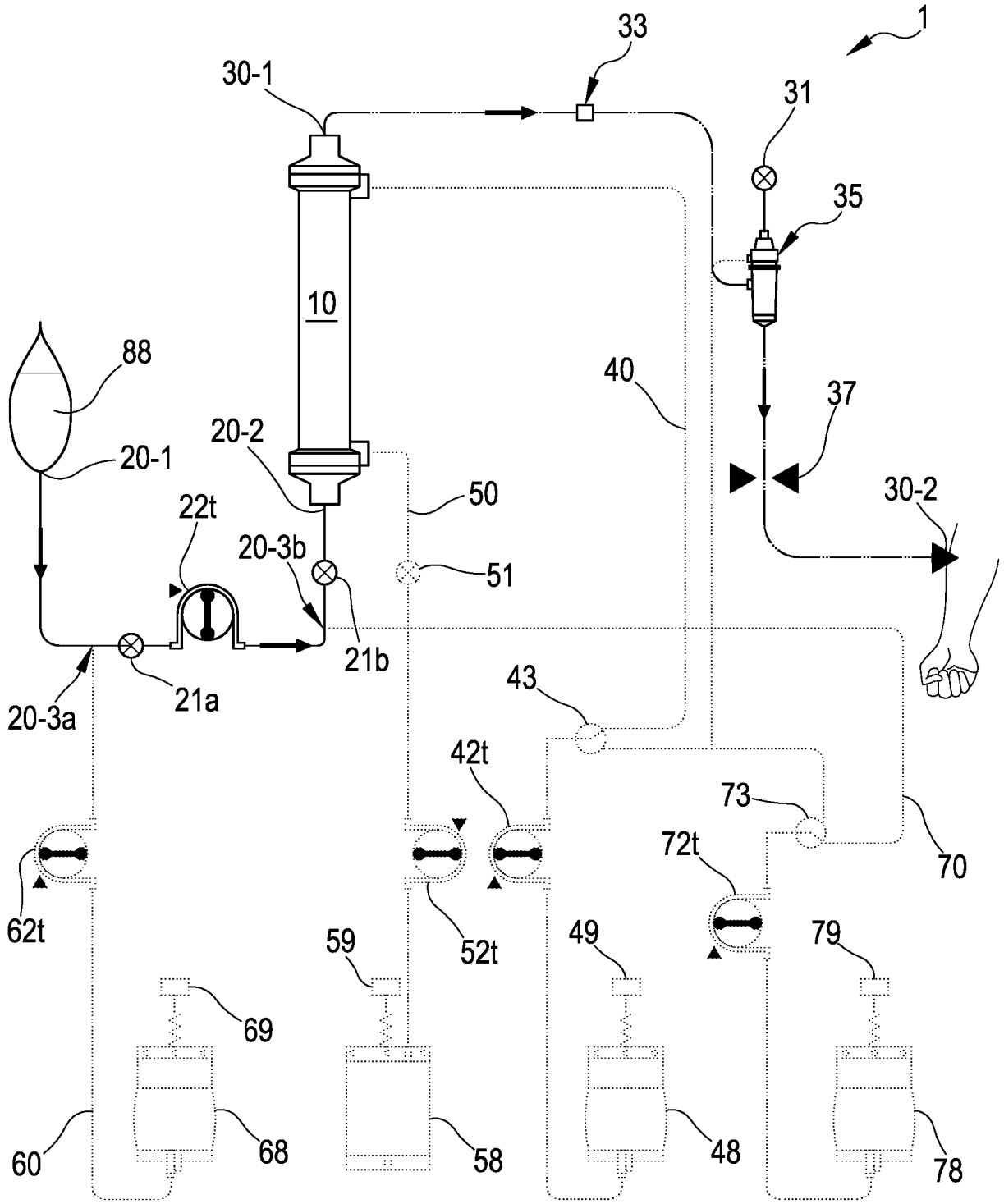
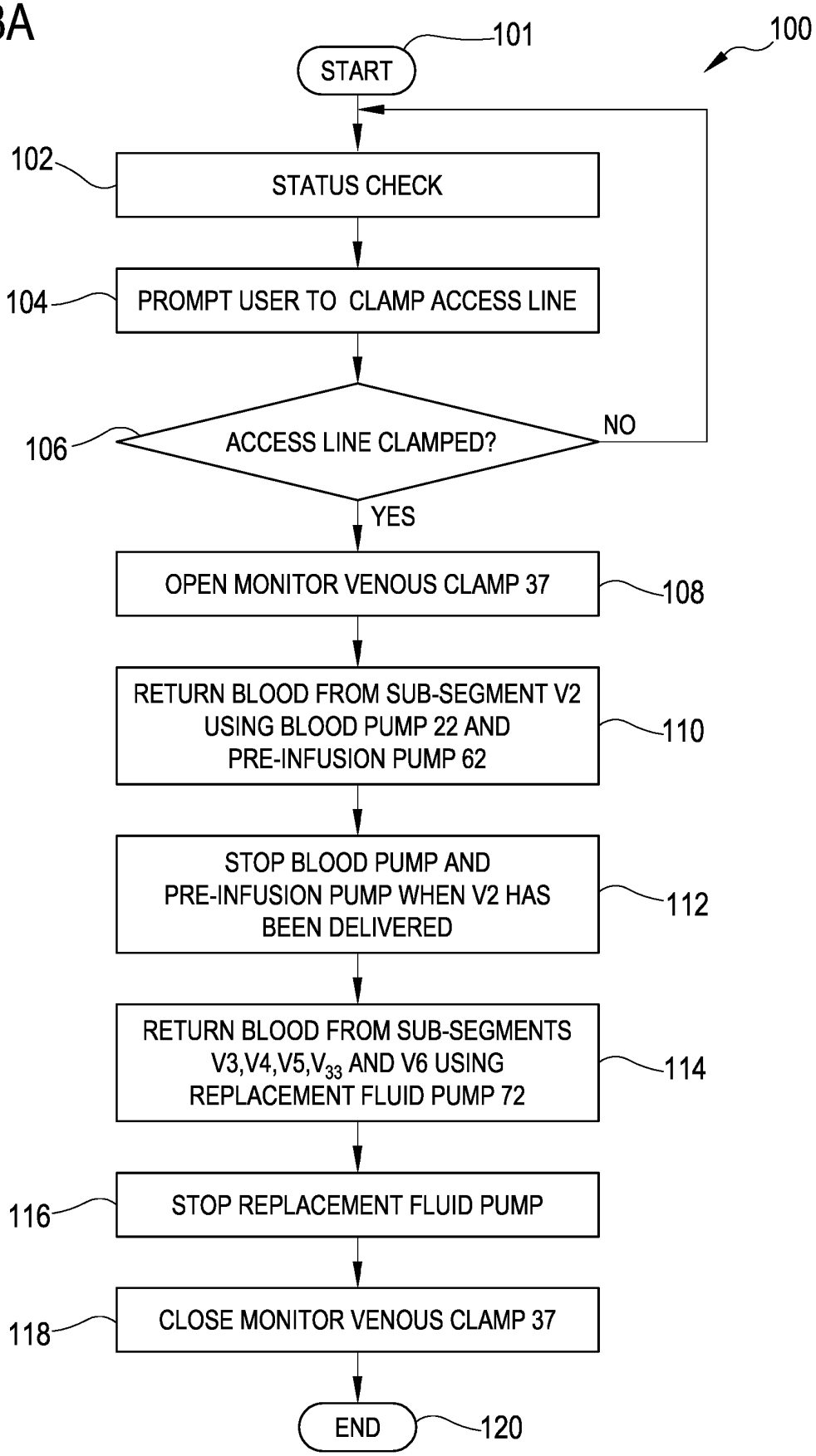


FIG.2 (PRIOR ART)

FIG.3A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START
102
STATUS CHECK
104
PROMPT USER TO CLAMP ACCESS LINE
106
ACCESS LINE CLAMPED?
NO
YES
OPEN MONITOR VENOUS CLAMP 37
108
RETURN BLOOD FROM SUB-SEGMENT V2 USING BLOOD PUMP 22 AND PRE-INFUSION PUMP 62
110
STOP BLOOD PUMP AND PRE-INFUSION PUMP WHEN V2 HAS BEEN DELIVERED
112
RETURN BLOOD FROM SUB-SEGMENTS V3,V4,V5,V33 AND V6 USING REPLACEMENT FLUID PUMP 72
114
116
STOP REPLACEMENT FLUID PUMP
118
CLOSE MONITOR VENOUS CLAMP 37
END
120

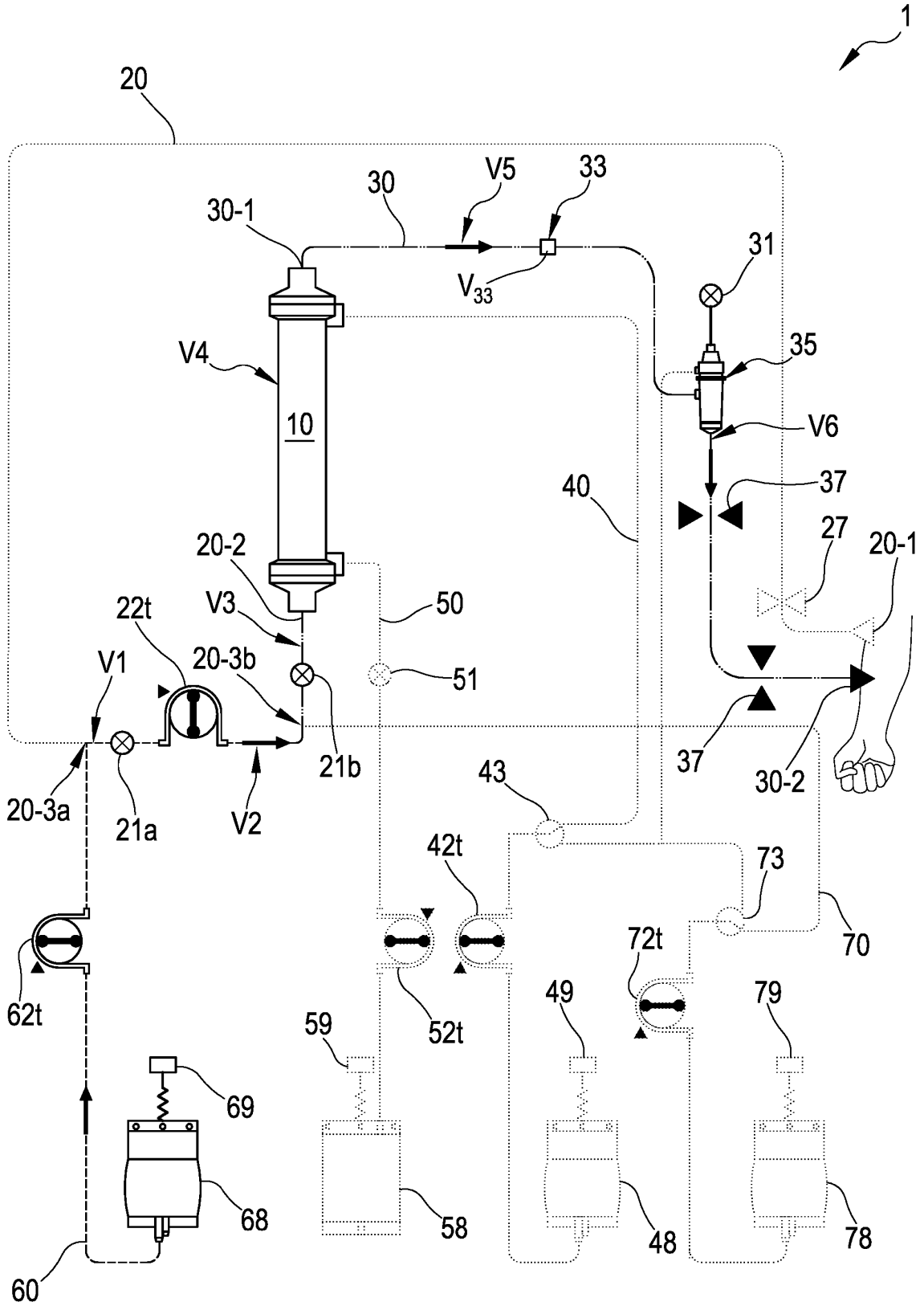

1
20
30
V5
33
30-1
V_{33}
31
V4
10
35
V6
40
37
27
20-1
20-2
V3
50
22t
V1
20-3b
51
37
30-2
20-3a
21a
V2
21b
43
42t
73
70
72t
62t
49
79
59
52t
69
68
58
48
78
60

FIG.3B

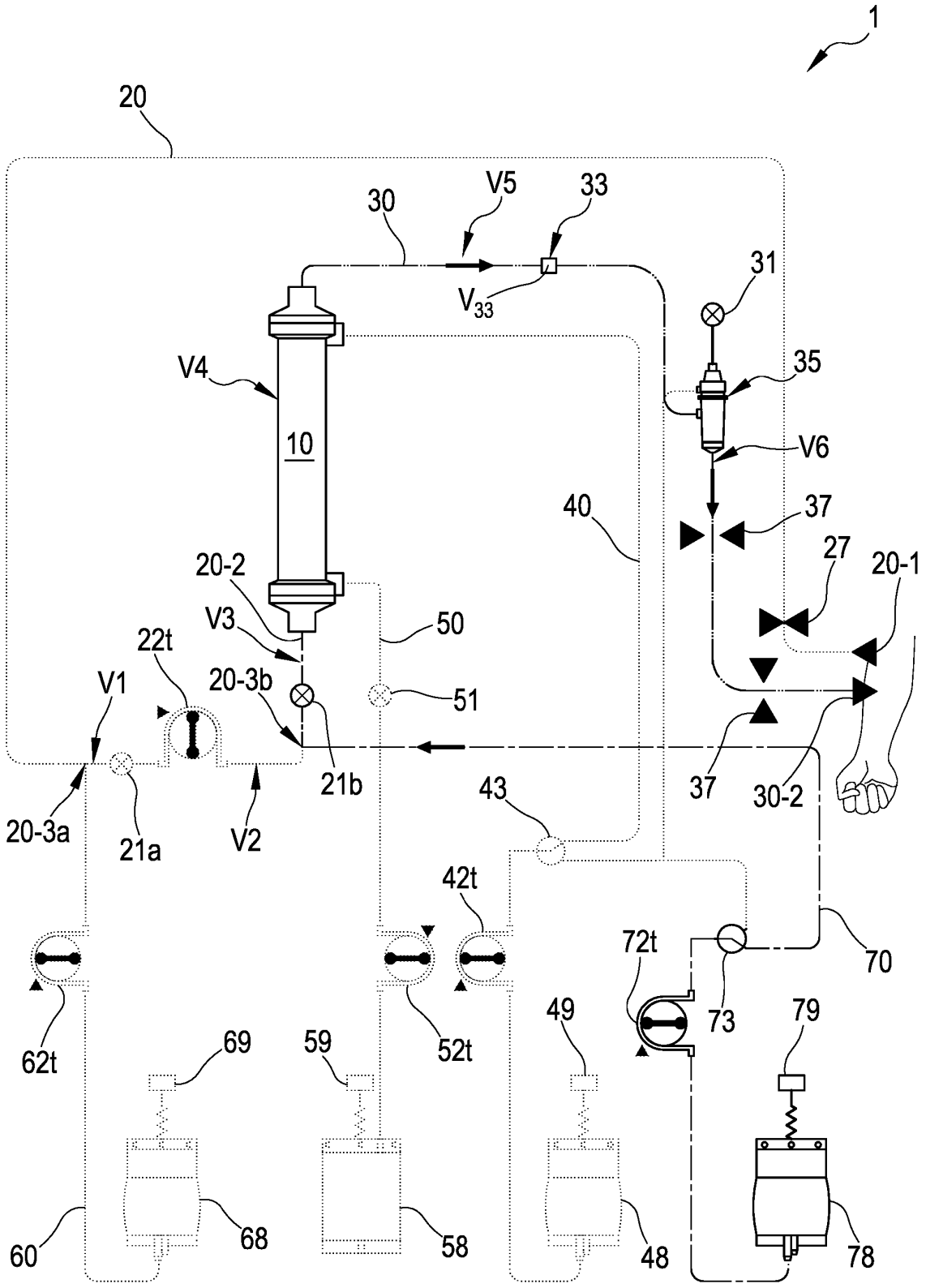

1
20
30
V5
33
V_{33}
31
35
V4
10
V6
40
37
27
20-1
20-2
V3
50
22t
V1
20-3b
51
20-3a
21a
V2
21b
37
30-2
43
42t
72t
70
62t
52t
73
79
49
69
59
60
68
58
48
78

FIG.3C

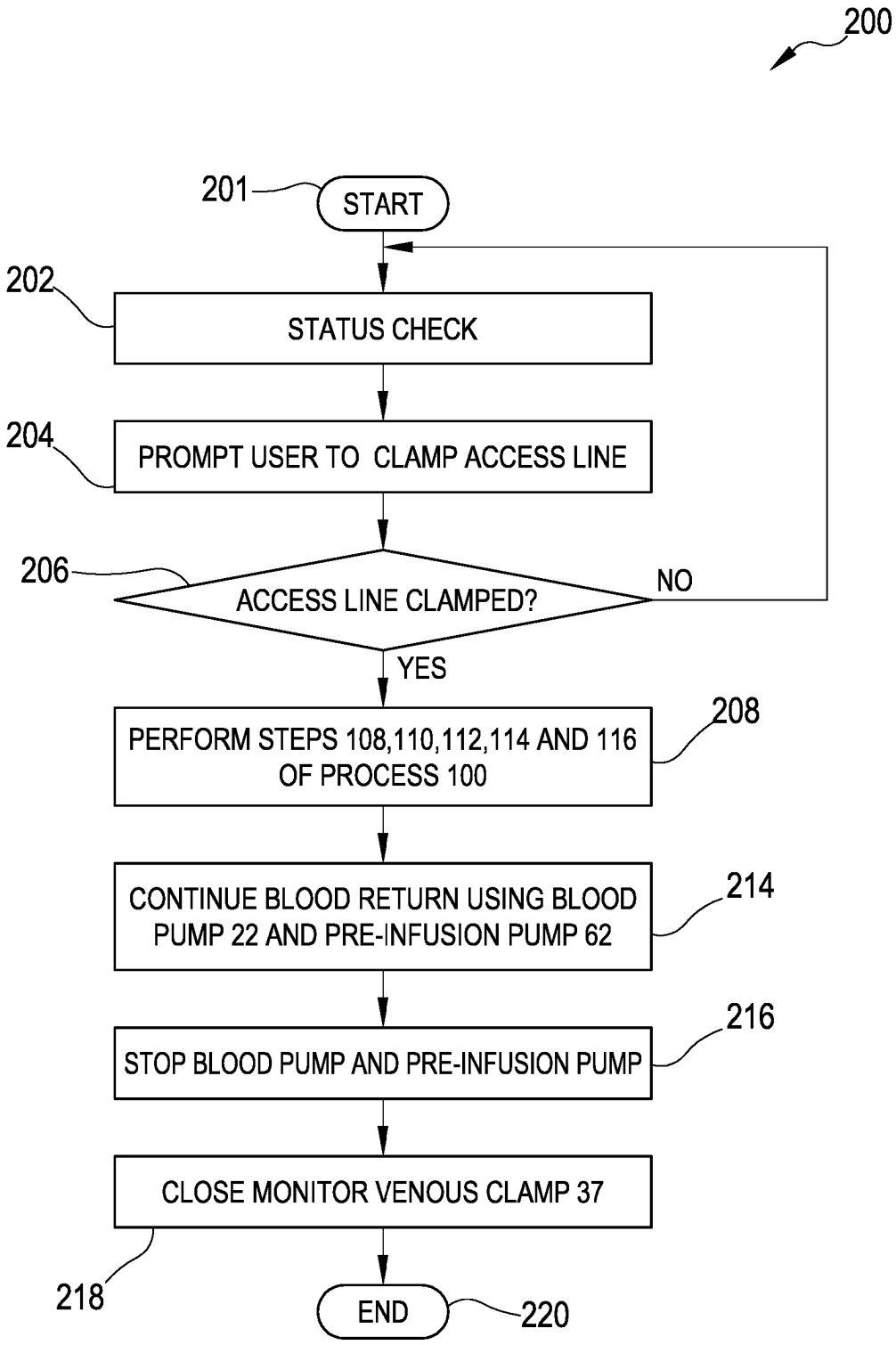

200
201
START
202
STATUS CHECK
204
PROMPT USER TO CLAMP ACCESS LINE
206
ACCESS LINE CLAMPED?
NO
YES
208
PERFORM STEPS 108,110,112,114 AND 116 OF PROCESS 100
214
CONTINUE BLOOD RETURN USING BLOOD PUMP 22 AND PRE-INFUSION PUMP 62
216
STOP BLOOD PUMP AND PRE-INFUSION PUMP
CLOSE MONITOR VENOUS CLAMP 37
218
END
220

FIG.3D

FIG.4

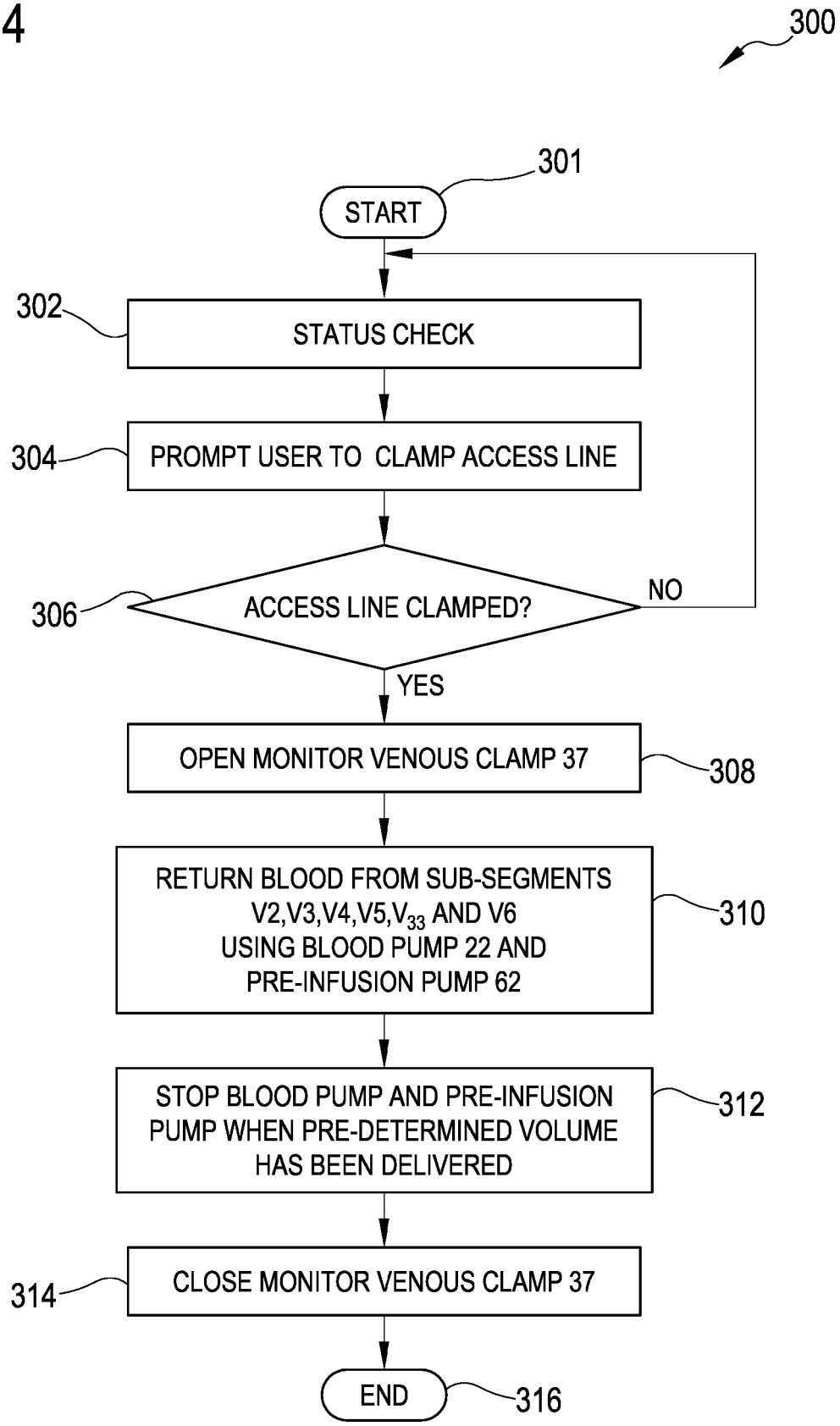
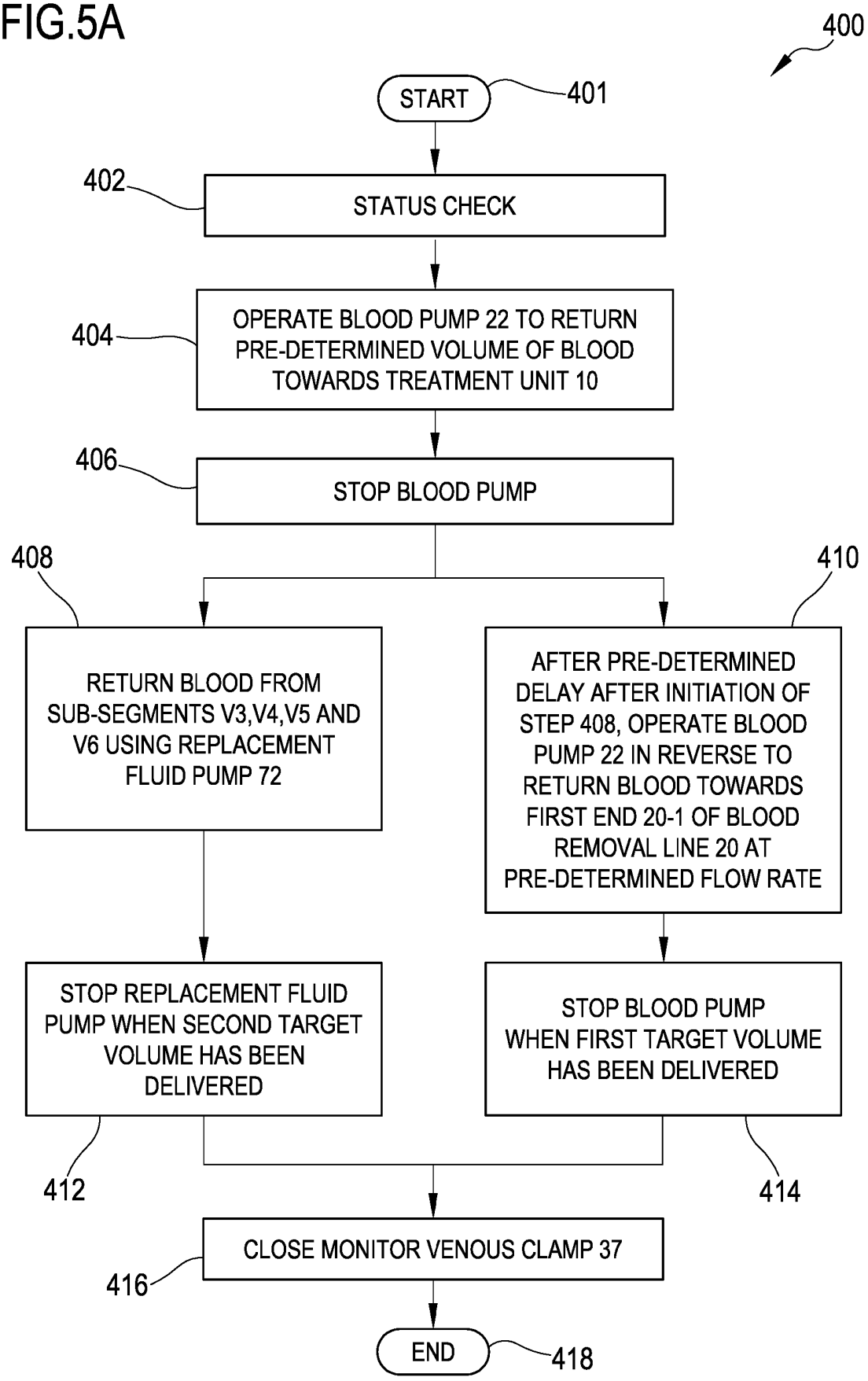

300
301
START
302
STATUS CHECK
304
PROMPT USER TO CLAMP ACCESS LINE
306
ACCESS LINE CLAMPED?
NO
YES
OPEN MONITOR VENOUS CLAMP 37
308
RETURN BLOOD FROM SUB-SEGMENTS V2,V3,V4,V5,V33 AND V6 USING BLOOD PUMP 22 AND PRE-INFUSION PUMP 62
310
STOP BLOOD PUMP AND PRE-INFUSION PUMP WHEN PRE-DETERMINED VOLUME HAS BEEN DELIVERED
312
314
CLOSE MONITOR VENOUS CLAMP 37
END
316

FIG.5A


400
START
401
402
STATUS CHECK
404
OPERATE BLOOD PUMP 22 TO RETURN PRE-DETERMINED VOLUME OF BLOOD TOWARDS TREATMENT UNIT 10
406
STOP BLOOD PUMP
408
410
RETURN BLOOD FROM SUB-SEGMENTS V3,V4,V5 AND V6 USING REPLACEMENT FLUID PUMP 72
AFTER PRE-DETERMINED DELAY AFTER INITIATION OF STEP 408, OPERATE BLOOD PUMP 22 IN REVERSE TO RETURN BLOOD TOWARDS FIRST END 20-1 OF BLOOD REMOVAL LINE 20 AT PRE-DETERMINED FLOW RATE
STOP REPLACEMENT FLUID PUMP WHEN SECOND TARGET VOLUME HAS BEEN DELIVERED
STOP BLOOD PUMP WHEN FIRST TARGET VOLUME HAS BEEN DELIVERED
412
414
CLOSE MONITOR VENOUS CLAMP 37
416
END
418

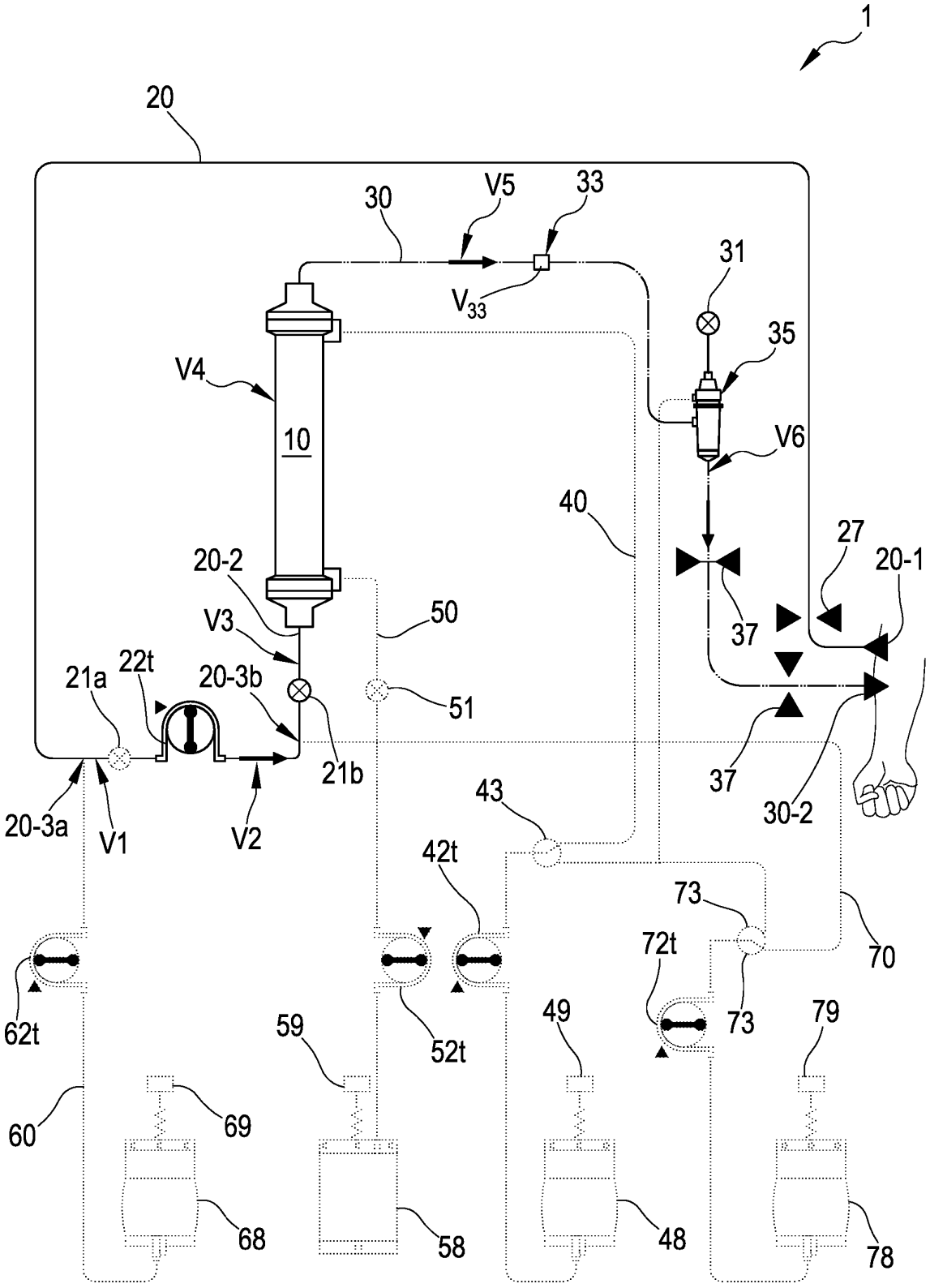

1
20
30
V5
33
V_{33}
31
35
V4
10
V6
40
27
20-1
20-2
50
V3
37
22t
21a
20-3b
51
21b
37
30-2
20-3a
V1
V2
43
42t
73
72t
70
62t
59
52t
49
73
79
60
69
68
58
48
78

FIG.5B

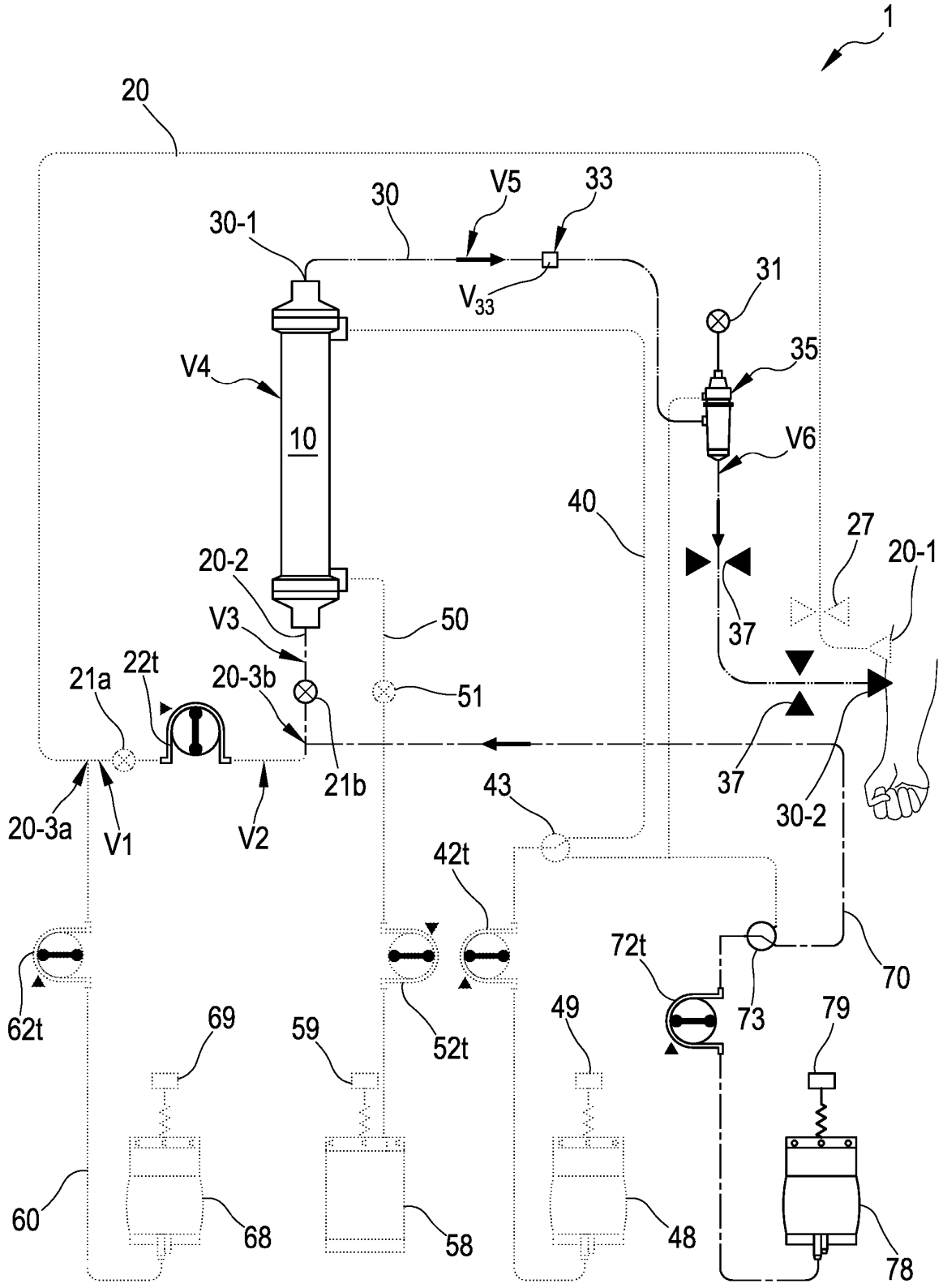

1
20
30
V5
33
30-1
V_{33}
31
35
V4
10
V6
40
27
20-1
20-2
V3
50
37
21a
22t
20-3b
51
21b
37
30-2
43
20-3a
V1
V2
42t
72t
70
62t
69
59
52t
49
73
79
60
68
58
48
78

FIG.5C

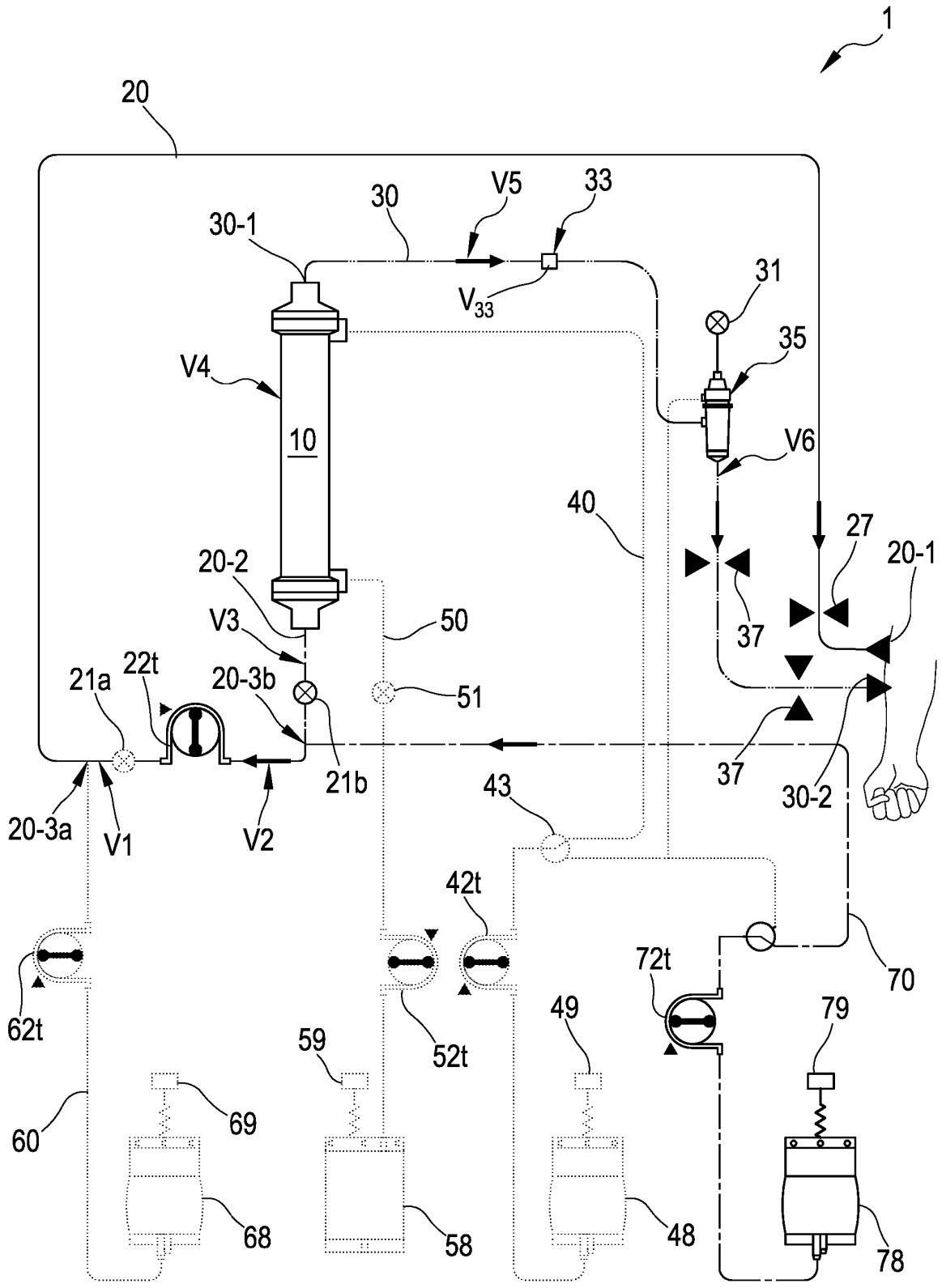

1
20
30
V5
33
30-1
V_{33}
31
35
V4
10
V6
40
27
20-1
20-2
50
37
V3
21a
22t
20-3b
51
37
30-2
21b
43
20-3a
V1
V2
42t
72t
70
62t
52t
49
79
59
60
69
68
58
48
78

FIG.5D

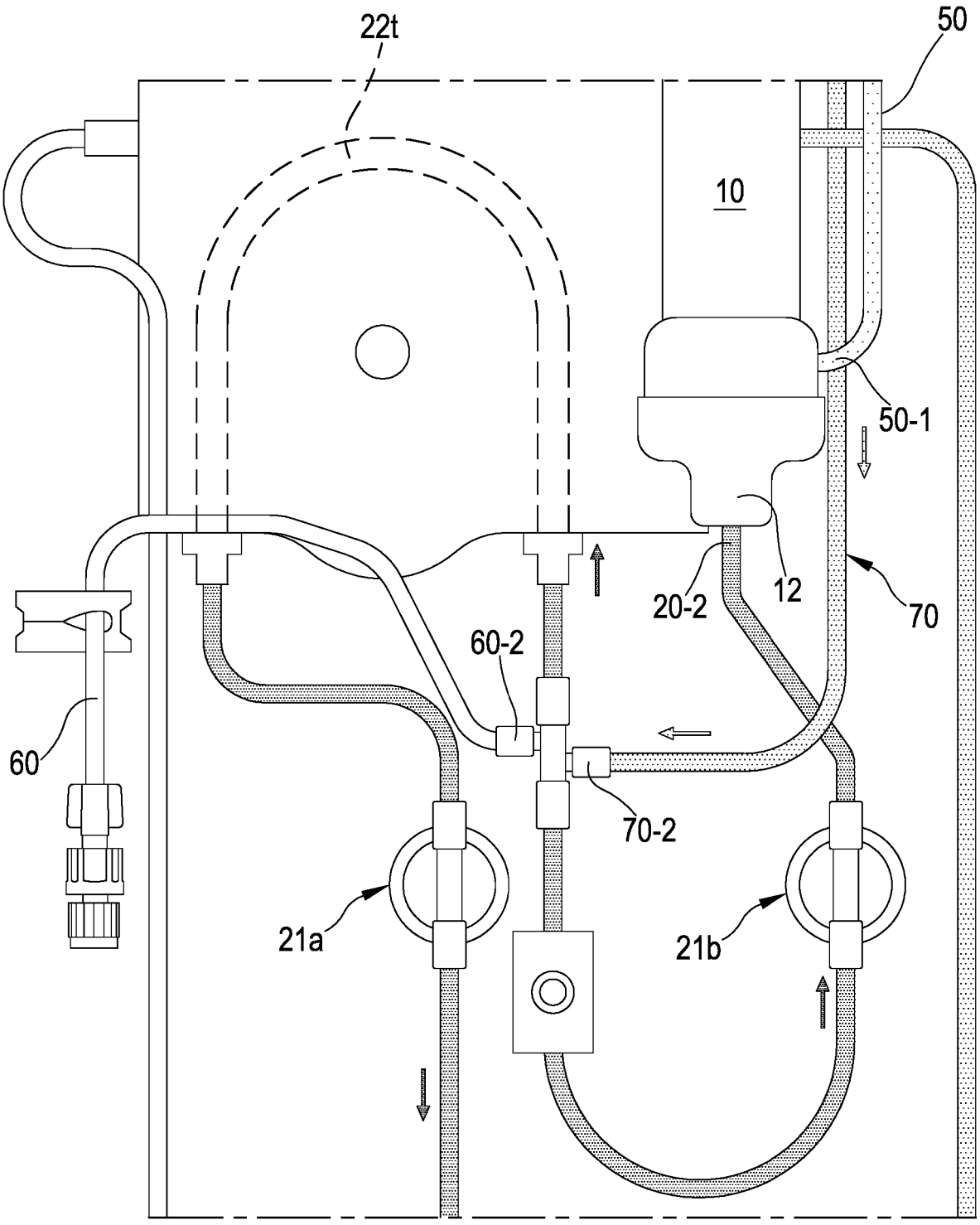


FIG.5E

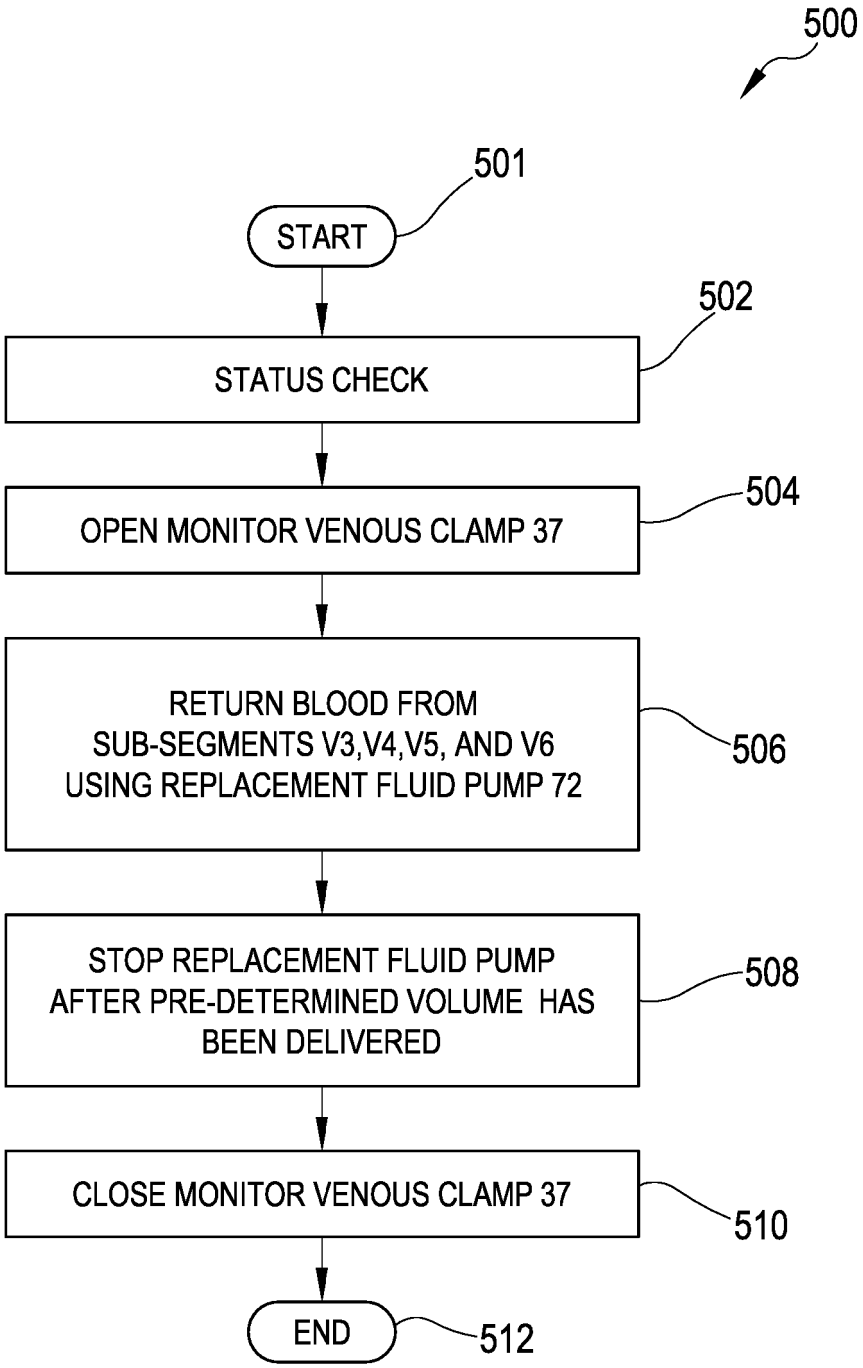

500
501
START
502
STATUS CHECK
504
OPEN MONITOR VENOUS CLAMP 37
RETURN BLOOD FROM SUB-SEGMENTS V3,V4,V5, AND V6 USING REPLACEMENT FLUID PUMP 72
506
STOP REPLACEMENT FLUID PUMP AFTER PRE-DETERMINED VOLUME HAS BEEN DELIVERED
508
CLOSE MONITOR VENOUS CLAMP 37
510
END
512

FIG.6

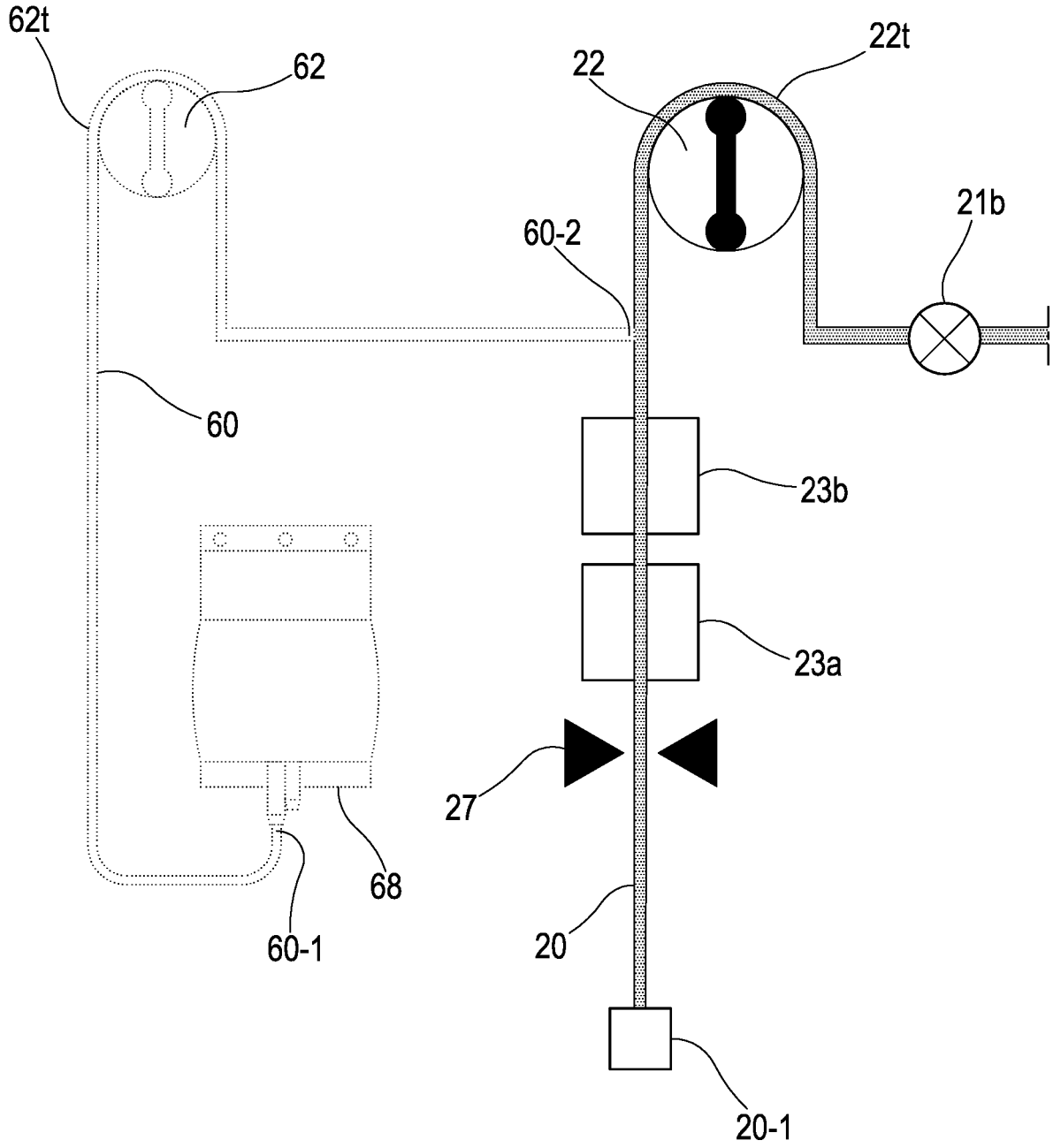


FIG.7

REFERENCES CITED IN THE DESCRIPTION

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- DE 10011208 **[0012] [0013]**
- EP 2752210 A **[0013]**
- WO 2014110004 A **[0015]**