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(54) Title: MULTI-USE DIALYSIS MACHINE PRIMING AND SOLUTION DELIVERY DEVICE

(57) Abstract: An accessory device for use with a hemodialysis system is provided. The accessory device is configured so that it can perform more than one function related to the operation of a hemodialysis machine, including acting as a priming cartridge.

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MULTI-USE DIALYSIS MACHINE PRIMING AND SOLUTION DELIVERY DEVICE

TECHNICAL FIELD

The present invention relates generally to blood cleansing systems and processes, and more particularly, to a multi-use dialysis machine accessory adapted to be used in priming and solution delivery schemes.

BACKGROUND

Hemodialysis is a common blood cleansing operation, wherein blood to be cleaned flows on one side of a semipermeable membrane and a physiologic solution (e.g., a dialysate) flows on the other side of the membrane, whereby toxins in the blood are transferred from one side to the other. The primary driving force in this treatment is diffusion.

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One of the more antiquated procedures in hemodialysis is that of priming the extracorporeal circuit. Typically the ends of the bloodlines are placed in a bucket while the circuit (including the dialyzer) is primed with saline. Periodically as the bucket fills, it needs to be emptied. This is usually performed by hand carrying the bucket to a sink by the patient care technician. This can be a labor-intensive process particularly when multiple machines are being set up at the same time. While, the difficulty of the priming has been addressed and solutions have been proposed, many of these solutions have proved less than effective and less than practical. For example, U.S. Patent Nos. 5,650,071 and 5,776,091 (which are hereby incorporated by reference in their entirety) disclose waste handling port within a dialysis machine. However, the fact that one must use this particular machine to obtain this desired feature reduces its flexibility. Thus, it would be more advantageous to have a more universal device that can perform this function but is adapted to be used with any type of dialysis machine. One of the functions of a hemodialysis system is to prepare a physiologic equivalent dialysate fluid and deliver it to the dialysis machine where it enters and flows through a compartment (e.g., a dialysate compartment of a hemodialysis cartridge). The physiologic equivalent dialysate is made of a suitable quality water to which a number of concentrates are added. For example, an acid concentrate and a sodium bicarbonate concentrate are typically added to water to form the physiologic equivalent dialysate fluid. Sodium bicarbonate concentrate is often in a powdered form that is stored in a container into which the water flows to form a sodium bicarbonate solution that is then introduced back into a water feed stream. The containers that hold the powered material are often in the form of single use cartridges and

thus once the operation is performed and the sodium bicarbonate powder is completely gone, the cartridge needs to be discarded and a new one is put in its place. Thus, the cartridge body itself is wasted as it cannot be reused. The inability to reuse the cartridge leads to increased operating costs. In addition and due to the single use nature of the cartridge, the cartridge is only capable of delivering one type of concentrate solution.

Thus, what is needed and has heretofore not been available is a multi-use accessory device for use with a hemodialysis system, wherein the accessory device is designed to be compatible with a number of available hemodialysis machines and is configured to perform a number of functions in such dialysis system.

SUMMARY

An accessory device for use with a hemodialysis system is provided. The accessory device is configured so that it can perform more than one function related to the operation of a hemodialysis machine.

According to one exemplary embodiment, the accessory device is constructed as a funnel-like member having a generally conical shaped body having a first open end and an opposing second open end. The open first end has an outer circumferential edge and an inner circumferential edge with a circumferential track being formed between the outer and inner circumferential edges. The circumferential track is configured to receive a sealing element (i.e., an O-ring) to provide a seal between two accessory devices that are mated with one another in a manner described below. The open first end further includes a plurality of

interlocking tabs that permit one accessory device to be releasably interlocked with another accessory device. The first end also includes other features for holding tubing conduits and the like.

Solution is introduced into the accessory device at the open first end and flows toward the open second end. Proximate to the open second end, the accessory device includes a particulate filter for filtering the solution. The solution then flows through a nozzle like part of the accessory device to the open second end. The accessory device can be formed of any number of different types of materials, including plastic materials.

In one embodiment, the accessory device is used in an extracorporeal priming operation. In this embodiment, the inlet (i.e., the open first end) of the accessory device is attached to a bloodline outlet, while the outlet (i.e., the open second end) of the accessory device is attached to a machine drain pump. The accessory device essentially functions as a bottomless container during the priming cycle, thereby eliminating the need for the technician to continuously empty a limited volume bucket that receives the priming solution.

In another embodiment, two accessory devices are mated with one another in a releasably interlocked manner to form a cartridge. The cartridge is arranged so that the two open first ends face another. In other words, one accessory device is inverted relative to the other accessory device. In this configuration, the open second end of the inverted accessory device acts as an inlet of the cartridge and the open second end of the other accessory device acts as an outlet of the cartridge. The cartridge can hold a concentrate, such as sodium bicarbonate, that is used to form the physiologic dialysate fluid or it can hold a

disinfectant/cleaning solution. When the cartridge contains a concentrate, it is arranged within a fluid flow path for generating the dialysate fluid (i.e., a concentrated solution delivery flow path) and when the cartridge contains the disinfectant/cleaning solution, it is arranged within a disinfectant/cleaning cycle flow path. The sealing element disposed between the two accessory devices within the circumferential track ensures that a fluid seal is formed between the two accessory devices.

Further aspects and features of the multi-use accessory disclosed herein can be appreciated from the appended Figures and accompanying written description.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a multi-use accessory device according to one embodiment for use in a dialysis system;

Fig. 2 is a top plan view of the multi-use accessory device of Fig. 1;

Fig. 3 is cross-sectional view of the multi-use accessory device of Fig. 1 taken along the line 3-3 of Fig. 2;

Fig. 4 is a schematic illustration of a dialysis system including the multi-use accessory device of Fig. 1 being used as a cartridge for holding a concentrate that is added to an aqueous stream to generate a dialysate fluid that is fed to a dialysis machine;

Fig. 5 is a schematic illustration of a dialysis system which is configured in a dialysis machine disinfection/cleaning cycle, wherein the accessory device of Fig. 1 is provided in the form of a cartridge for holding a cleaning agent that passes through the dialysis system for disinfection/cleaning of the dialysis system;

Fig. 6 is a schematic illustration of a dialysis system illustrating a manual priming operation for a dialysis machine, wherein the multi-use accessory device is used as a waste collection vessel; and

Fig. 7 is a schematic illustration of a dialysis system illustrating an automated priming operation for a dialysis machine, wherein the multi-use accessory device is used as a waste collection vessel.

DETAILED DESCRIPTION OF EMBODIMENTS

Referring to Figs. 1 through 3, an accessory device 10 is provided for use in a dialysis system to perform a variety of functions as will be described in detail hereinafter. The accessory device 10 is a funnel-like member having an open first end 12 and an open second end 14. Due to its funnel shape, the accessory device 10 has a generally conically-shaped body that tapers inwardly from the open first end 12 towards the open second end 14. The accessory device 10 can be formed of any number of suitable materials, including a variety of plastic materials.

At the open first end 12, a plurality of interlocking tabs 20 are formed. The interlocking tabs 20 are arranged around the circumference of the open first end 12 and extend upwardly from the open first end 12. In one exemplary embodiment, some of the interlocking tabs 20 have a post 22 that extends upwardly from a peripheral edge of the open first end 12 and an interlocking body part 24 that is formed at a distal end of the post 22 opposite the peripheral edge. The interlocking body part 24 is preferably orientated substantially perpendicular to the post 22 and as best shown in Fig. 2, the post 22 and interlocking body

part 24 form an "L-shaped" locking member. Others of the interlocking tabs 20 are formed so that the interlocking body part 24 is not "L-shaped" but rather is a generally rectangular tab that is disposed substantially perpendicular to the post 22 at the distal end thereof. By providing two types of interlocking tabs 20, one accessory device 10 can mate with another accessory device, as will be described and illustrated hereinafter, to form an interlocked member. When interlocking two accessory devices 10 together, the open first ends 12 are arranged relative to one another and the one type of interlocking tabs 20 of one accessory device 10 are interlocked with the other type of interlocking tabs 20 formed on the other accessory device 10. By aligning and engaging the two types of interlocking tabs 20 and then rotating the two accessory devices 10 relative to one another, the two different types of interlocking tabs 20 mate with and interlock to form a joined, interlocked structure.

The open first end 12 has an outer circumferential edge 30 and an inner circumferential edge 32 spaced therefrom with a circumferential track 40 being formed therebetween. Preferably the edges 30, 32 extend above the circumferential track 40 so as to define walls of the track 40. The circumferential track 40 is configured to receive a sealing element (not shown), such as an O-ring, for producing a seal between two accessory devices 10 that are arranged to form the interlocked structure described above. For example, an O-ring fitted within the track 40 provides a fluid seal between two interlocked accessory devices 10. Preferably, one O-ring is provided in one track 40 and then when the other accessory device 10 is mated thereto, the O-ring will likewise be received in the other track 40 because the two tracks 40 are radially aligned with one overlying the other. The plurality of tabs 20

extend from the outer circumferential edge 30.

The open first end 12 also includes at least one external conduit clip 50 and at least one internal conduit clip 60. In the exemplary embodiment illustrated in Figs. 1 through 3, the accessory device 10 has a pair of external conduit clips 50. The pair of external conduit clips 50 are arranged in spaced relationship with respect to one another and in the illustrated embodiment, the external conduit clips 50 are arranged opposite one another along the circumference of the first end 12 (i.e., arranged 180° apart). Each external conduit clip 50 is connected to the outer circumferential edge 30 (between a pair of interlocking tabs 20) and extends outwardly therefrom. The external conduit clip 50 is a yoke-like member that has a pair of spaced fingers 52 that define an opening 54 therebetween. The external conduit clip 50 is configured so that a flexible conduit, i.e., tubing member, is frictionally received in the opening 54 and securely held in place by frictional engagement with the spaced fingers 52.

In the illustrated embodiment, there are a pair of internal conduit clips 60 arranged in spaced relationship with respect to one another (e.g., arranged 180° apart). Each internal conduit clip 60 is connected to the inner circumferential edge 32 and extends inwardly therefrom toward the center of the accessory device 10. The internal conduit clip 60 is preferably orientated substantially perpendicular to the inner circumferential edge 32. Preferably, the internal conduit clips 60 are offset from the external conduit clips 50. Each internal conduit clip 60 is a tab-like member having an opening 62 formed therein. The opening 62 defines a pair of opposing fingers 64 that frictionally hold a conduit (e.g., a tubing member) therebetween in the opening 62.

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As will be described hereinafter, one use of the accessory device 10 is in a priming operation for a dialysis machine and in this operation, the external conduit clips 50 hook onto main bloodline tubing (not shown) to thereby stabilize (i.e., keep upright) the accessory device 10. The internal conduit clips 60 are configured to hold a tubing member, such as a saline line or a main bloodline, in place so that the priming outflow remains directed downwardly into the accessory device 10 toward the open second end 14 that serves as an outlet. The volume capacity of the accessory device 10 is sufficient to accommodate typical priming volume flow rates.

The accessory device 10 includes an internal seat 70 formed proximate to the open second end 14. In the exemplary embodiment, the seat 70 has a generally annular shape and receives a particulate filter 80. It will be appreciated that the particulate filter 80 has a complementary shape relative to the seat 70 and the shape of the seat 70 is not limited to an annular shape. The particulate filter 80 is fitted within the seat 70 to filter fluid that is introduced into the accessory device 10 through the open first end 12. The seat 70 forms a neck portion of the accessory device 10 such that the fluid filtered therethrough is collected into and flows through a tube-like outlet member to the second end 14.

Fig. 4 is a schematic illustration of a conventional UF controlled dialysis system, generally indicated at 100. The system 100 includes a conduit 102 that carries water of a quality that permits the water to be used to form a physiologic equivalent dialysate fluid. For example, the water is of AAMI (Association for Advancement of Medical Instrumentation) quality. The conduit 102 is connected at one end to a heat exchanger 104 with an inlet valve

106 being disposed within the conduit 102 upstream of the heat exchanger 104. The inlet valve 106 can be any number of types of valves that are configured to permit or prevent water flow through the conduit 102 to the heat exchanger 104. The heat exchanger 104 is of a conventional design and is configured so that heat is exchanged between the water flowing through the conduit 102 and used dialysate that is flowing in an opposite direction.

After flowing through the heat exchanger 104, the water flows through a deaeration module 108 and then is mixed with certain concentrates to generate a physiologic equivalent dialysate fluid. In one exemplary embodiment, acid and bicarbonate concentrates are added to the water flowing in the conduit 102 to form the dialysate fluid that then flows into a flow balancing system 110. The flow balancing system 110 can include suitable devices in the art, for example, volumetric balance chambers as used in a Fresenius 2008 dialysis machine, available from Fresenius, Lexington, MA, U.S.A., or dual flow meters as used in a Baxter 1550 dialysis machine, available from Baxter, Deerfield, IL, U.S.A.

In the illustrated embodiment, the two concentrates are added upstream of the flow balancing system 110; however, it will be understood that the two concentrates can be added downstream of the flow balancing system as long as a UF pump 112 removes a specified volume of the dialysate fluid. More specifically, the UF pump 112 removes the equivalent volume that is infused.

Typically, the acid concentrate is provided in liquid form and is disposed in some type of container 114 or other storage medium. The storage container 114 is in fluid communication with an inlet connector 116 that is itself in fluid communication with a conduit

118 that is connected at its other end to the conduit 102 which carries the water. The acid concentrate is dispensed through the inlet connector 116 in the correct, desired proportion using a volumetrically controlled pump 120 that is disposed along the conduit 118.

The sodium bicarbonate can come in a variety of forms including a liquid form and a solid form. When the sodium bicarbonate comes in liquid form, it is delivered the same way as the liquid acid concentrate is delivered. When the sodium bicarbonate comes in solid form, the sodium bicarbonate is stored in some type of container and is released at a predetermined rate to permit proper mixing with the water. According to one embodiment, the sodium bicarbonate is disposed in a disposable cartridge 130 that is filled with a predetermined amount of sodium bicarbonate powder. In the embodiment of Fig. 1, the cartridge 130 is constructed of two interlocking accessory devices 10. Each of the accessory devices 10 is a funnel type member with the cartridge 130 being formed by arranging and interlocking the two inlet ends of the funnel type members against one another. The cartridge 130 thus assumes an elongated diamond like shape as shown in Fig. 1 and a seal is formed between the two devices 10 as will be described. The cartridge 130 is filled with sodium bicarbonate powder.

When the two accessory devices 10 are interconnected to form the cartridge 130, the cartridge 130 is in fluid communication with an inlet connector 132 at one end of one of the accessory devices 10 and is also in fluid communication with an outlet connector 134 at an outlet end of the other of the accessory devices 10. The inlet connector 132 is connected to the conduit 102 by a conduit 136 which carries water from the main water conduit 102 (prior to introduction of the acid concentrate into the water) to the inlet connector 132. Thus, water

is teed off the main conduit 102 and carried through the conduit 136 to the cartridge 130, where the water enters through inlet connector 132. The cartridge 130 also includes a conduit 138 that is connected to the outlet connector 134 at one end and to the conduit 102 at the other end. A pump 140 is disposed along the conduit 138 for drawing the water through the conduit 136 into the cartridge 130, where the water mixes with sodium bicarbonate powder to form a bicarbonate solution that is withdrawn from the cartridge 130 and delivered through the conduit 138 to the main water conduit 102. The pump 140 infuses the correct proportion of sodium bicarbonate to make the physiologic equivalent dialysate fluid. While in Fig. 1, the conduit 138 is connected to the conduit 102 downstream of the conduit 118, it will be understood that the conduit 138 may be positioned upstream of the conduit 118 so long as both are orientated upstream of the flow balancing system 110 (according to this embodiment).

One advantage of the cartridge 130 is that following treatment completion, the cartridge 130 can be disassembled by removing the two funnel type members (the accessory devices) 10 and then additional sodium bicarbonate powder can be added to one or more of the funnel type members 10 before reassembling the members 10 to form the cartridge 130 that is now ready for reuse.

After flowing through the flow balancing system 110, the physiologic equivalent dialysate fluid flows through a dialysate conduit 150 to a dialysate inlet port 152 of a dialyzer 160. The dialyzer 160 is in the form of a dialyzer cartridge containing a semi-permeable membrane 162 that divides the dialyzer into a blood compartment 164 and a dialysate compartment 166. As blood passes through the blood compartment 164, toxins from the blood

transfer across the semi-permeable membrane 162 and into the dialysate compartment 166. The dialysate fluid that enters the inlet port 152 flows through the dialysate compartment 166 before being discharged through a dialysate outlet port 168.

The dialyzer cartridge 160 may of any type suitable for hemodialysis, hemodiafiltration, hemofiltration, or hemoconcentration, for example, the Fresenius F60, available from Fresenius Medical Care, Lexington, Massachusetts; the Baxter CT 110, available from Baxter Health Care, Baxter Health Care, Deerfield, Illinois, the Minntech Hemocor HPH 1000, available from Minntech Corporation, Minneapolis, Minnesota, or the Hospal Filtral 16, available from Hospal A.G., Switzerland. The semi-permeable membrane 162 is preferably a medium to high flux membrane, for example, the polysulfone, cellulose triacetate or acrylonitrile membranes available from Fresenius Medical Care, Lexington, Massachusetts; Minntech Corporation, Minneapolis, Minnesota; Baxter Health Care, Deerfield, Illinois; or Hospal A.G., Switzerland.

A conduit 170 is connected to the dialysate outlet port 168 for carrying spent dialysate fluid from the dialysate compartment 166 of the dialyzer 160. The conduit 170 is connected at another end to the flow balancing system 110 and a dialysate pump 181 is provided along the conduit 170 prior to the flow balancing system 110 for drawing the fresh dialysate fluid through the dialysate conduit 150 into the dialyzer 160 and then through the conduit 170 as spent dialysate fluid after transfer of the toxins into the dialysate fluid. After the flow balancing system 110, the spent dialysate fluid flows through the conduit 170 to the heat exchanger 104 before eventually being delivered to a drain or the like, generally indicated

at 180. A drain outlet valve 179 is disposed in the conduit 170 upstream of the drain 180. This valve 179 can be any number of types of valves and is configured to either permit fluid flow through the conduit 170 to the drain 180 or permit fluid flow through the conduit 170 to the drain 180.

The UF pump 112 is disposed within a conduit 113 that is connected between the

dialysate conduit 150 downstream of the flow balancing system 100 but upstream of the dialyzer 160 and the conduit 170 downstream of the flow balancing system 110.

Fig. 5 illustrates the accessory device 10 being used in a dialysis system that is configured to perform a machine disinfection/cleaning cycle operation. As in the dialysis mode illustrated in Fig. 1, two accessory devices 10 are arranged to form a cartridge 190. The two accessory devices 10 are interlocked by manipulation of the interlocking tabs 20 (Fig. 2) and are sealed by an O-ring 192. In this embodiment, instead of filling the cartridge 190 with a concentrate that is used to form the dialysate fluid, the cartridge 190 is filled with a disinfectant/cleaning agent. Typically, this agent comes in a powder form and in one exemplary embodiment, the agent is citric acid. Alternatively, the agent can be supplied in liquid form so long as the lowermost accessory device 10 forming the cartridge 190 has an auto-shut off feature at an outlet portion thereof when it is not connected to a prime connector 200.

The operation of the cartridge 190 and its placement in the dialysis system will now be described. Because the arrangement of the dialysis system in this operation is similar

to the arrangement in the dialysis mode of Fig. 4, only differences therebetween will be discussed. In the disinfection/cleaning mode of Fig. 5, the inlet connector 116 of the conduit 118 is connected to a rinse block port 196 that is in communication with the conduit 102. This results in the conduit 118 being a closed loop that only carries water that is flowing through the conduit 102. In addition, the connectors 132, 134 are connected so as to form a closed water loop. The cartridge 130 of Fig. 1 is removed and the inlet and outlet connectors 132, 134, respectively, are mated with one another so as to define a closed loop that carries water from the conduit 102 and then returns it thereto. The dialyzer 160 (Fig. 1) is also taken off line and removed from the fluid flow path by fluidly connecting the dialysate conduit 150 with the conduit 170 so to bypass the dialyzer 160. The dialysate conduit 150 can be connected to the conduit 170 using any number of techniques, including using connector 197, 198. As with the other modifications, the fluid coupling of the conduits 150, 170 defines a closed loop where the water continuously flows through the system.

A recirculation conduit 196 is fluidly connected between the conduit 102 and the conduit 170 as shown. One end is fluidly connected to the conduit 102 upstream of the heat exchanger 104, while the other end is fluidly connected to the conduit 170 downstream of the heat exchanger 104 but upstream of the drain outlet valve 179. A shut valve 199 is disposed within the recirculation conduit 197 such that in an open position, fluid can communicate between the conduit 102 and the conduit 170 and in a closed position, fluid is prevented from communicating between these two conduits 102, 170.

In this embodiment, the cartridge 190 is disposed within a closed loop that is

connected to the conduit 170 at both ends of the loop. More specifically and according to the exemplary embodiment shown in Fig. 5, an inlet end of the cartridge 190 is fluidly connected to a rinse connector 201 that is in fluid communication with the conduit 170 downstream of the heat exchanger 104 but upstream of the drain outlet valve 179. An outlet end of the cartridge 190 is fluidly connected to the prime connector 200 which is itself connected to a conduit 210 that is connected at its other end to the conduit 170 downstream of where the rinse connector 201 connects to the conduit 170. Furthermore, the conduit 210 must connect to the conduit 170 upstream of the recirculation conduit 197. A pump 220 is disposed in the conduit 210 for withdrawing a disinfectant/cleaning solution from the cartridge 190.

The operation of the disinfecting/cleaning mode is now described. As in the dialysis mode, water enters the system through conduit 102 and because the system is configured in a closed loop, the circuit is filled only with water as the concentrates and dialyzer are taken off line. Once the complete circuit is fully primed with water, both the inlet valve 106 and the drain outlet valve 179 are both closed. The shunt valve 199 is opened permitting the water to recirculate through the circuit. The pump 220 is then actuated. This results in water being drawn from the conduit 170 through the rinse connector 201 and into the cartridge 190. As the water flows through the cartridge 190, it contacts the cleaning agent disposed therein and a saturated aqueous cleaning solution is formed. The pump 220 draws the saturated cleaning solution out of the cartridge 190, through the prime connector 200, and through the conduit 210 and ultimately back to the conduit 170.

Because the shut valve 199 is opened, the aqueous cleaning solution that is

further mixed with water flowing through the conduit 170 flows through the recirculation conduit 197 to the conduit 102 and then completely through the entire closed loop circuit. In this manner, the cleaning solution runs through and is in contact with the various components of the system. The cleaning solution is recirculated through the entire system for a sufficient period of time for all of the components to be disinfected and/or cleaned. After this operation is completed, the system can be disassembled and then reconfigured to perform a different mode, e.g., dialysis mode of Fig. 4.

The amount of cleaning agent in the cartridge 190 can be measured out so that for a given fluid path volume of the machine, a desired amount of cleaner/disinfectant can be dispensed. Once again, the cartridge 190 is reusable and refillable.

Figs. 6 and 7 illustrate the accessory device 10 being used as a waste collection vessel with Fig. 6 illustrating an arrangement for performing a manual primping operation, while Fig. 7 illustrates an arrangement for performing an automated priming operation. The system of Fig. 6 is very similar to the dialysis system of Fig. 1 and therefore only differences will be described in any detail. The system of Fig. 6 illustrates the sodium bicarbonate being introduced in liquid form from a container or other storage medium 220. The physiologic equivalent dialysate fluid flows through the dialysate conduit 150 to the dialysate inlet port 152 of the dialyzer 160. In this embodiment, the fresh dialysate flowing through conduit 150 is pumped into either a dry or reprocessed dialyzer 160. In either case, the dialyzer 160 needs to be primed to remove the air or disinfectant. The dialysate fluid is pumped through the dialysate compartment 166 by operation of the pump 181 and is delivered through the conduit

170 eventually to the drain 180.

To prime the blood compartment 164, a saline bag or the like 230 is connected to a first section 232 of an arterial bloodline 234 using a saline conduit 237. A blood pump 241 is run at low speed to prime the first section 232 and a venous bloodline 236 and the blood compartment 164. The first section 232 is primed by gravity since the saline solution is free to flow by gravity through the saline conduit 237 to the first section 232. A second section 235 of the arterial bloodline 234 (i.e., post pump section) is primed by operation of the pump 241.

The first section 232 of the arterial bloodline 234 has an arterial line patient connector 238 and one end of the venous bloodline 236 has a venous line patient connector 240. In this embodiment, the arterial connector 238 and the venous connector 240 are in fluid communication with the open first end 12 of the accessory device 10 so that the priming solution drains into the accessory device 10. At the open second end 14, a connector 242 is provided and is in fluid communication with a drain conduit 250 that fluidly connects to the conduit 170. A waste pump 251 is disposed within the drain conduit 250 for withdrawing the priming solution from the accessory device 10 and then transporting the priming solution from the accessory device 10 to the conduit 170 where it is then delivered to the drain 180. The waste pump 251 is operated at a higher speed than the rate of the saline infusion into the arterial bloodline 234 to keep the accessory device 10 from overflowing. As in the dialysis mode, the shunt valve 199 remains closed while the drain outlet valve 179 remains open allowing excess priming solution to go to the drain 180.

Fig. 7 illustrates a system that is similar to the system of Fig. 6 except for the

blood side priming. In the embodiment of Fig. 7, to prime the blood compartment 164 of the dialyzer 160, the arterial and venous bloodlines 234, 236 are connected to one another using a recirculation connector 260. The blood pump 240 is operated in reverse at low speed. This causes dialysate fluid to be back-filtered across the semi-permeable membrane 162 into the blood compartment 164. In this manner, both the blood compartment 164 and the dialysate compartment 166 are filled with dialysate fluid. Since it takes several liters of fresh dialysate fluid to remove all of the residual air or disinfectant from the dialyzer 160, the saline conduit 237 extending from the first section 232 is unclamped from the saline bag (not shown) and is placed in fluid communication with the open first end 12 of the accessory device 10. If there is a vented cap on the end of the saline conduit 237, it can remain in place since it will allow passage of fluid but helps to keep the blood circuit sterile. The accessory device 10 and the waste pump 251 drain the priming fluid as shown and described with reference to Fig. 6.

The advantage of the configuration illustrated in Fig. 7 is the automation aspect. A virtually unlimited supply of priming fluid can be pumped through the accessory device 10 without requiring any user monitoring.

It will be appreciated by persons skilled in the art that the present invention is not limited to the embodiments described thus far with reference to the accompanying drawing. Rather the present invention is limited only by the following claims.

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WHAT IS CLAIMED:

1. An accessory device for use with a hemodialysis machine comprising an a hollow body configured to be operatively coupled to the machine and being configured to perform more than one function related to the operation of the hemodialysis machine, the body including a first interlocking feature that permits it to be releasably interlocked with another inverted accessory device so as to form a sealed chamber for holding a material and a second feature that permits one or more conduits to be held along the body.

2. The accessory of claim 1, wherein the accessory device includes a first open end and an opposing second end with a particulate filter being disposed proximate the second end for filtering a solution that passes therethrough.

3. The accessory of claim 2, wherein at the open first end, a plurality of interlocking tabs are formed and are radially arranged therearound and extend upwardly therefrom, the plurality of interlocking tabs being part of the first interlocking feature.

4. The accessory of claim 3, wherein the interlocking tabs comprise two types of interlocking tabs so as to permit one accessory device to interlockingly mate with the other accessory device by interlocking the one type of tabs with the other type of tab.

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5. The accessory of claim 4, wherein the two accessory devices releasable interlock by aligning and engaging the two types of interlocking tabs and rotating one accessory device relative to the other to cause an interlocking between the two types of interlocking tabs.'

6. The accessory of claim 2, wherein the open first end has an outer circumferential edge and an inner circumferential edge with a circumferential track being formed therebetween for receiving a sealing element.

7. The accessory of claim 6, wherein the sealing element comprises an O-ring.

8. The accessory of claim 1, wherein the second feature comprises is formed at the open first end includes at least one external conduit clip and at least one internal conduit clip.

9. The accessory device of claim 8, wherein the internal conduit clip is formed along an inner surface of the funnel shaped member and includes an opening defined by a pair of spaced fingers so as to receive and frictionally hold a first conduit member.

10. The accessory device of claim 8, wherein the external conduit clip

comprises a yoke clip that has an opening defined by a pair of spaced fingers so as to receive and frictionally hold a second conduit member.

11. The accessory device of claim 8, wherein the external conduit clip comprises a pair of external clips that are circumferentially offset from a pair of inner conduit clips.

12. The accessory device of claim 1, wherein at the open first end, a plurality of first and second interlocking tabs are formed and are radially arranged therearound, with the first interlocking tabs extending upwardly therefrom, the plurality of interlocking tabs being part of the first interlocking feature that permit one accessory device to interlockingly mate with the other accessory device by interlocking the one type of tab of one accessory device with the other type of tab of the other accessory device, each second interlocking tab defining a slot that received a vertical wall segment of the first interlocking tab of the other accessory device.

13. The accessory of claim 1 used in a priming operation for the dialysis machine.

14. A disposable cartridge for holding a material and for use in a dialysis system, comprising:

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a pair of interlocking accessory devices as defined in claim 1, the pair of interlocking accessory devices being arranged such that open first ends of the accessory devices are interfaced against one another.

15. The cartridge of claim 14, wherein the open first ends are the end having the greatest diameter.

16. The cartridge of claim 14, wherein the material held in the sealed chamber is sodium bicarbonate.

17. The cartridge of claim 14, wherein each accessory device includes an annular track formed radially inward from the plurality of interlocking features that receives a sealing element to provide a seal between the two joined accessory devices by providing a seal between the two annular tracks.

18. A disposable cartridge for holding a material and for use in a dialysis system as a priming cartridge, comprising:

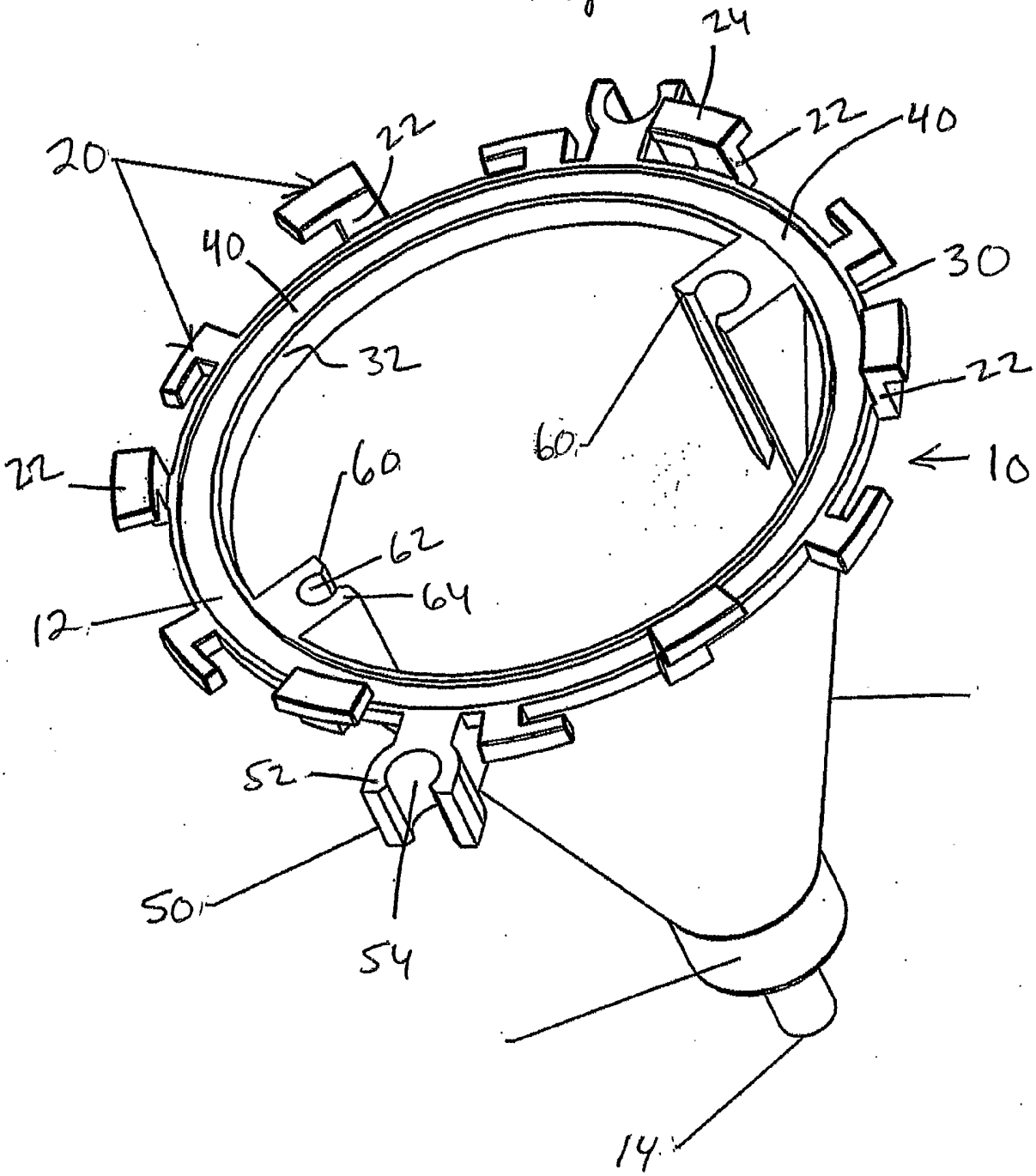
a pair of releasably interlocked accessory devices, each accessory device including a hollow body configured to be operatively coupled to a dialysis machine, the body including a first interlocking feature that permits it to be releasably interlocked with another inverted accessory device so as to form a sealed chamber for holding the material and a second

feature that permits one or more conduits to be held along the body, wherein the second feature is formed at an open first end of the device and includes at least one external conduit clip for holding a first conduit member and at least one internal conduit clip for holding a second conduit member, the two interlocked accessory devices having an inlet port at one end for receiving a fluid that mixes with the material and an outlet port at an opposite end where a mixture of the material and fluid is discharged.

19. The cartridge of claim 18, wherein the material is sodium bicarbonate and the first conduit member is a blood carrying conduit member, while the second conduit member is a

20. The cartridge of claim 18, wherein each accessory device includes an internal seat formed in the chamber that receives a particulate filter such that fluid entering through the inlet port passes through one particulate filter before entering the chamber and the mixture passes through the other particulate filter before being discharged through the outlet port.

Fig. 1



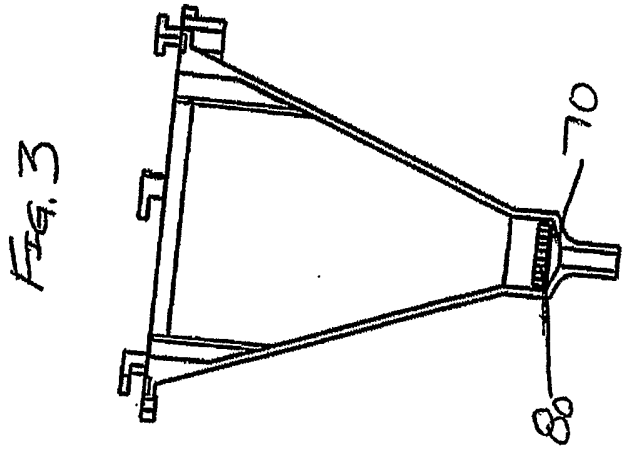


FIG. 3

SECTION 3-3

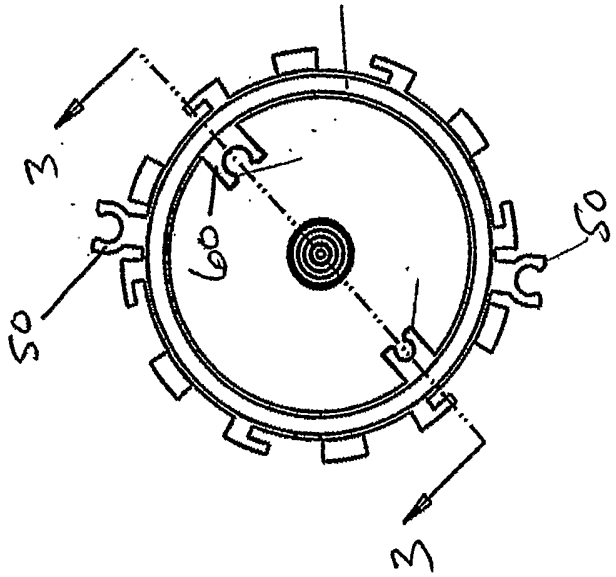


FIG. 2

Fig 4

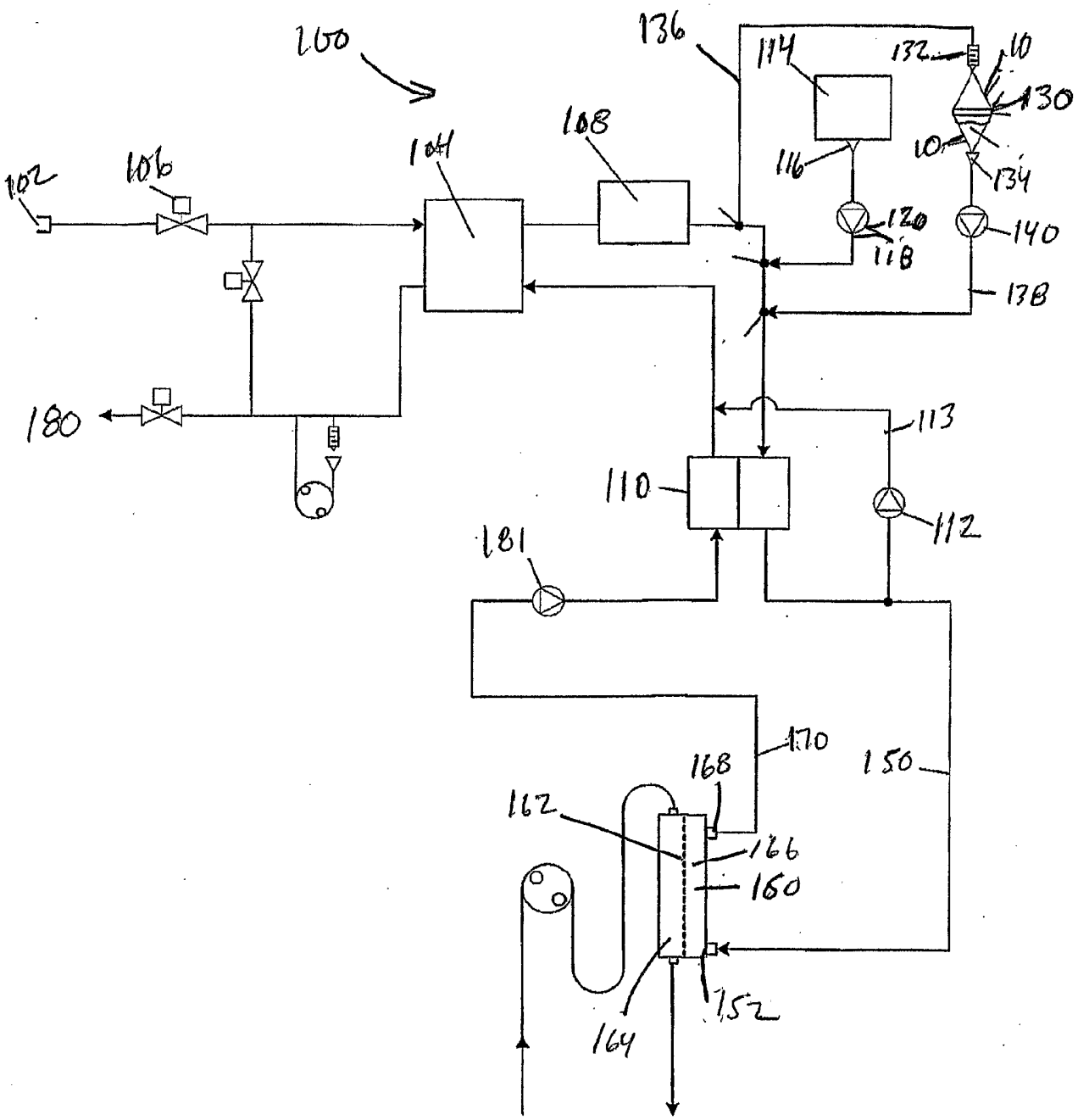

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Fig. 5

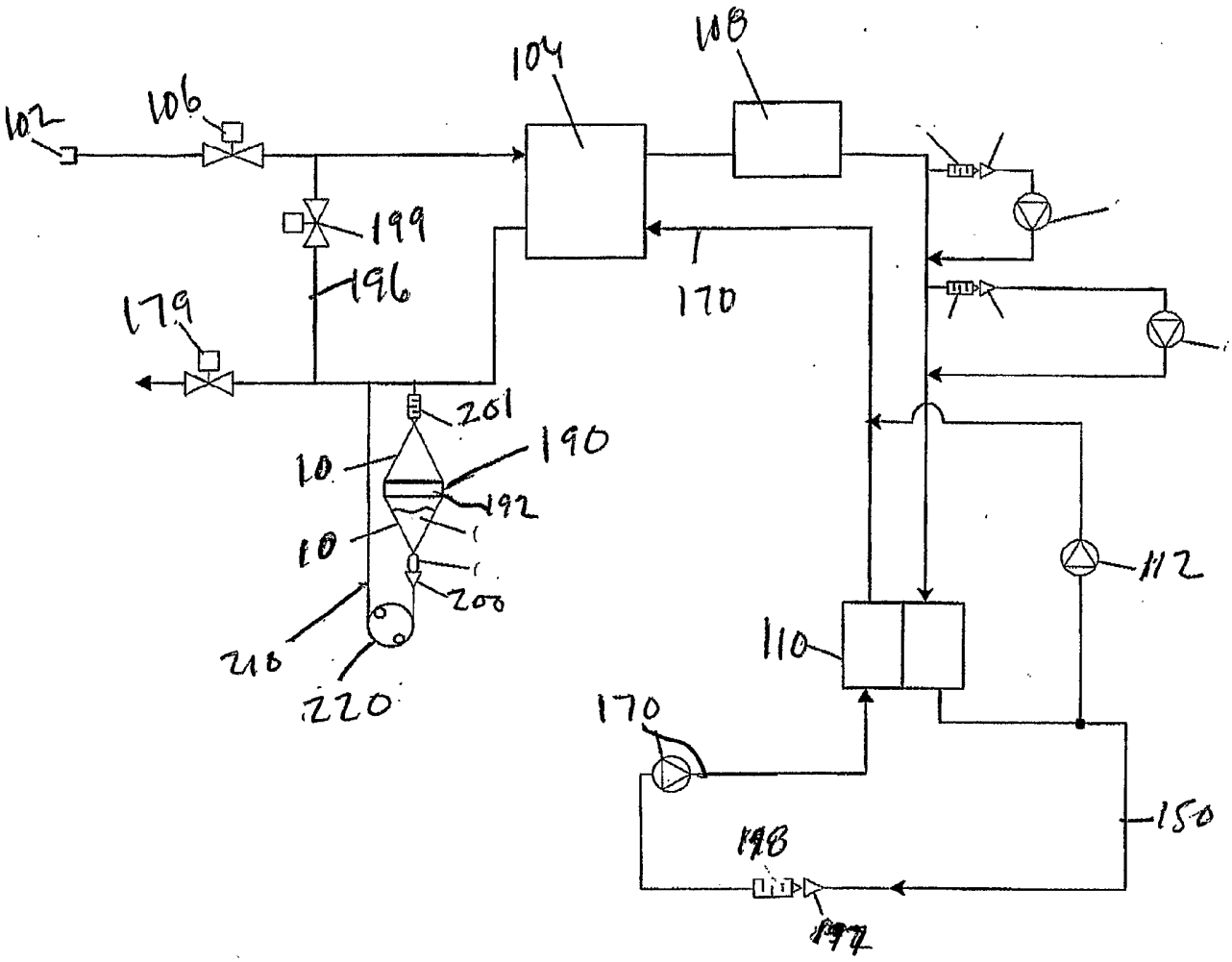
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Fig 6

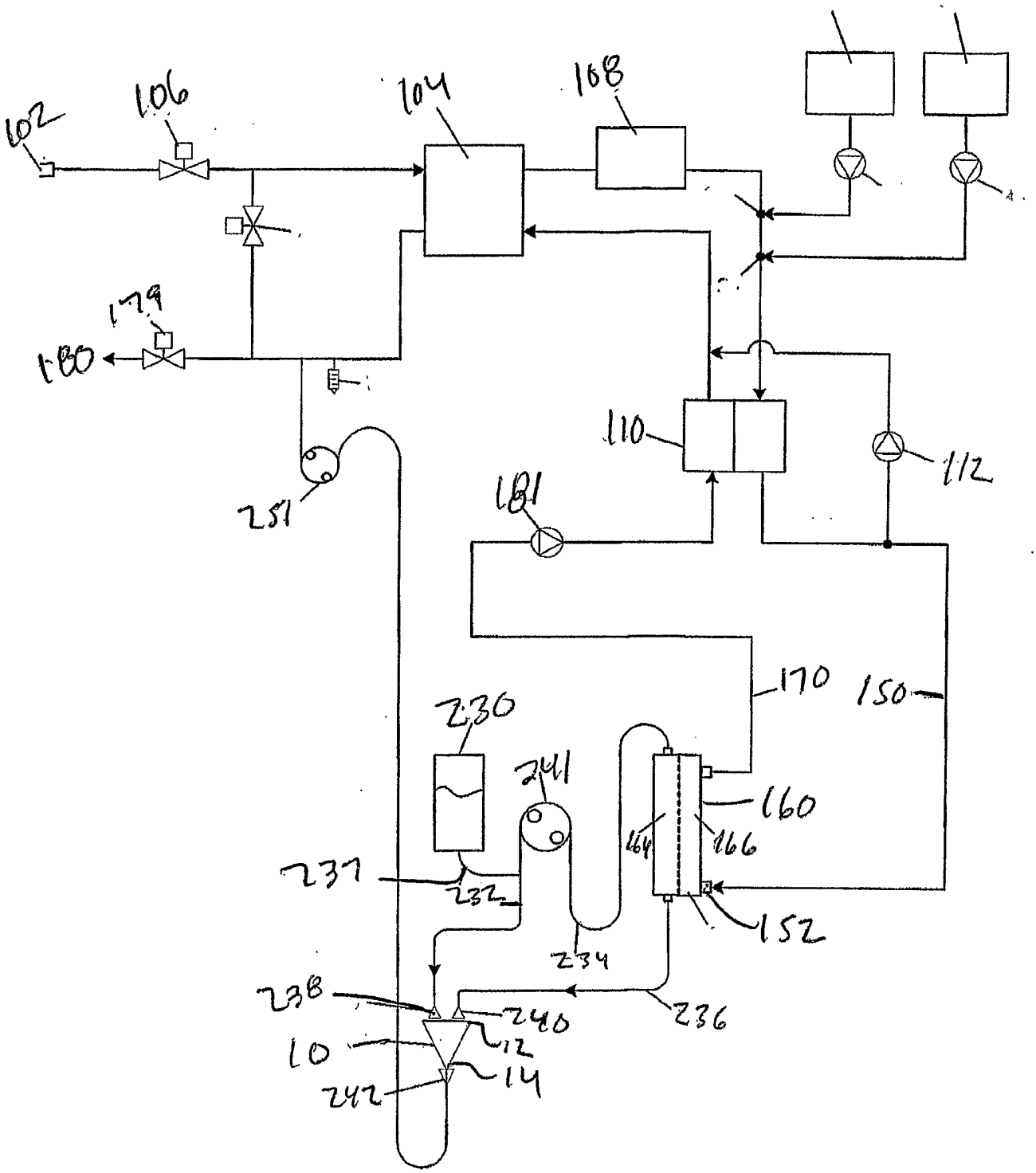
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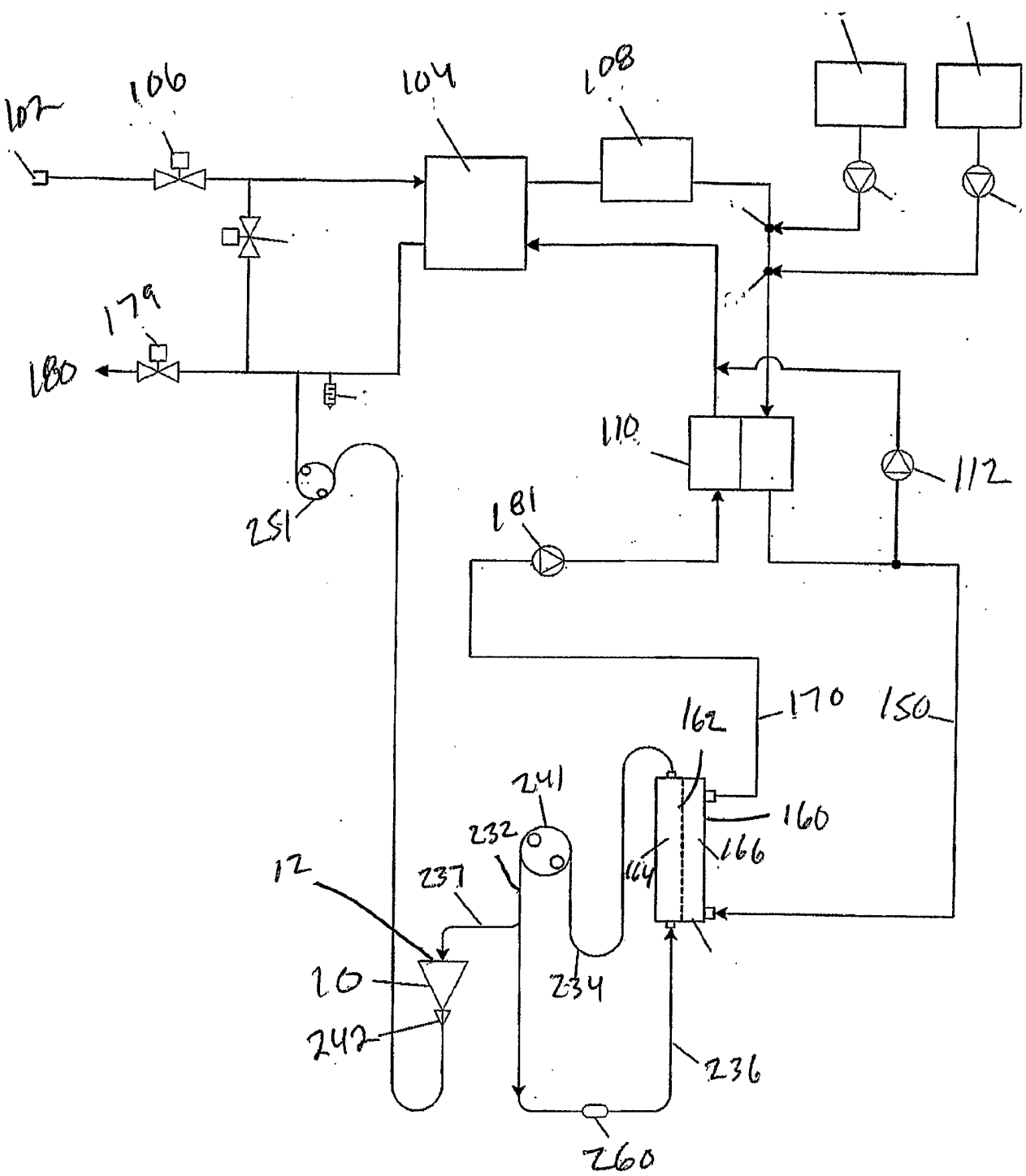
Fig. 7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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/18650

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : C02F 1/44; B01D 61/00
US CL : 422/100-104; 210/646,647, 195.1, 195.2
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 422/100-104; 210/646,647, 195.1, 195.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,676,185 A (STARR et al) 14 October 1997 (14.10.1997) entire document	1-6,9,12-17 --- 7,8,10,11,18-20
Y	US 6,103,200 A (BABASHAK) 15 August 2000 (15.08.2000) entire document	1-20
Y	US 2,694,515 A (GREEN) 16 November 1954 (16.11.1954) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search
05 September 2005 (05.09.2005)

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