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(71) Applicant(s)
New Health Sciences, Inc.

(72) Inventor(s)
Vernucci, Paul;Yoshida, Tatsuro

(74) Agent / Attorney
IP Gateway Patent and Trade Mark Attorneys Pty Ltd, PO Box 1321, SPRINGWOOD, QLD, 4127, AU

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(71) Applicant *(for all designated States except US)*: **NEW HEALTH SCIENCES, INC.** [US/US]; 6903 Rockledge Drive, Suite 230, Bethesda, MD 20817-1818 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VERNUCCI, Paul** [US/US]; 7 Dyer Street, Billerica, MA 01862 (US). **YOSHIDA, Tatsuro** [JP/US]; 1763 Commonwealth Avenue, West Newton, MA 02465 (US).

(74) Agent: **ALTMANN, Curtis, R.**; Arnold & Porter LLP, 555 12th Street, N.W., Washington, D.C. 20004 (US).

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(54) Title: METHOD AND SYSTEM FOR REMOVING OXYGEN AND CARBON DIOXIDE DURING RED CELL BLOOD PROCESSING USING AN INERT CARRIER GAS AND MANIFOLD ASSEMBLY

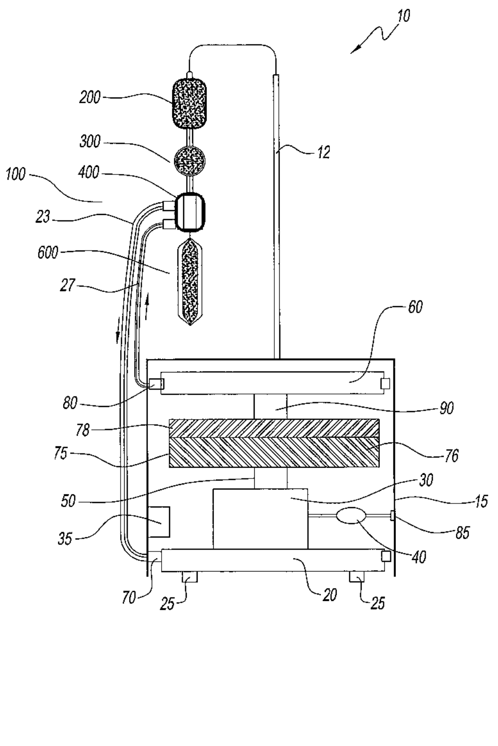

FIG. 1a

(57) Abstract: A portable assembly for processing red blood cells RBCs including a disposable blood collection set including a blood bag, an anaerobic storage bag and an oxygen and/or oxygen and carbon dioxide depletion device disposed between the blood collection bag and anaerobic storage bag. The portable assembly further provides for a gas circulation device in fluid communication with the oxygen or oxygen and carbon dioxide depletion device, The gas circulation device includes a pressure source that is able circulate flushing gas through the depletion device as RBCs pass from the blood collection bag, through the depletion device and into the anaerobic storage bag.

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METHOD AND SYSTEM FOR REMOVING OXYGEN AND CARBON DIOXIDE DURING RED CELL BLOOD PROCESSING USING AN INERT CARRIER GAS AND MANIFOLD ASSEMBLY

FIELD

The present disclosure relates to a portable blood treatment manifold assembly. More, particularly, the present disclosure relates to a portable blood treatment manifold assembly for leukoreduction and oxygen and/or carbon dioxide depletion of blood in preparation for blood storage and/or transfusion to a recipient.

DEFINITION

In the specification the term “comprising” shall be understood to have a broad meaning similar to the term “including” and will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps. This definition also applies to variations on the term “comprising” such as “comprise” and “comprises”.

BACKGROUND

The supplies of liquid blood in are currently limited by storage systems used in conventional blood storage practice. Using current systems, stored blood expires after about 42 days of refrigerated storage at a temperature above freezing (i.e.1-6°C) as packed blood cell preparations. Red blood cells (RBCs) may be concentrated from whole blood with separation of the liquid blood component (plasma). Expired blood cannot be used and is discarded.

There are periodic shortages of blood that occur due to donation fluctuation, emergencies and other factors. The logistics of blood supply and distribution impact the military, especially during times of combat and remote hospitals or medical facilities making blood processing or transfusions very difficult. Accordingly, there is a need to be able to rapidly prepare RBCs for storage or for transfusions in remote locations.

Storage of frozen blood is known in the art but such frozen blood has limitations. For a number of years, frozen blood has been used by blood banks and the military for certain high-demand and rare types of blood. However, frozen blood is difficult to handle. It must be thawed which makes it impractical for emergency situations. Once blood is thawed, it must be used within 24 hours. United States Patent No. 6,413,713 to Serebrennikov is directed to a method of storing blood at temperatures below 0° C.

U.S. Patent No. 4,769,318 to Hamasaki *et al.* and U.S. Patent No. 4,880,786 to Sasakawa *et al.* are directed to additive solutions for blood preservation and activation. U.S. Patent No. 5,624,794 to Bitensky *et al.,* U.S. Patent No. 6,162,396 to Bitensky *et al.,* and U.S. Patent No. 5,476,764 are directed to the storage of red blood cells under oxygen-depleted conditions. U.S. Patent No. 5,789,151 to Bitensky *et al* is directed to blood storage additive solutions.

Additive solutions for blood preservation and activation are known in the art. For example, Rejuvesol (available from enCyte Corp., Braintree, MA) is add to blood after cold storage (i.e., 4 ℃) just prior to transfusion or prior to freezing (i.e., at -80℃ with glycerol) for extended storage. U.S. Patent No. 6,447,987 to Hess *et al.* is directed to additive solutions for the refrigerated storage of human red blood cells.

In light of current technology, there is a need for a portable and cost effective apparatus and methodology for the preparation of RBCs that removes leukocytes and oxygen and/or carbon dioxide in advance of transfusion or in preparation for anaerobic storage.

The reference to prior art in the background above is not and should not be taken as an acknowledgment or any form of suggestion that the referenced prior art forms part of the common general knowledge in Australia or in any other country.

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SUMMARY OF THE DISCLOSURE

Accordingly, the present disclosure provides a system that is capable of removing oxygen and/or carbon dioxide and/or leukocytes from RBCs in advance of transfusion or for further storage in an anaerobic environment.

According one aspect of the disclosure there is provided a portable system for processing red blood cells (RBCs) comprising:

a gas circulation device providing a flushing gas capable of being placed in fluid communication with one or more oxygen or oxygen and carbon dioxide depletion devices, said gas circulation device comprising, in fluid communication with each other:

a flushing gas source;

a gas outlet manifold;

a first gas sterilization filter;

a second gas sterilization filter;

one or more gas sensor assemblies;

a gas inlet manifold; and

a controller,

wherein at least one of said one or more gas sensor assemblies is selected from the group consisting of an oxygen sensor, a carbon dioxide sensor, and a combination thereof, and said gas sensor assemblies comprise a partial pressure sensor.

The present disclosure also provides for a system and methodology for the preparation of RBCs in advance of transfusion or for further storage in an anaerobic environment.

It would be beneficial to provide a stand-alone portable system that has an oxygen or an oxygen/carbon dioxide depletion (OCDD) device that removes oxygen or oxygen and or carbon dioxide from RBCs passing through the device. The OCDD device operates with a gas exchange system that pumps

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gas into the device through which RBCs that first passes through an oxygen or oxygen/carbon dioxide (OCDD) device to remove oxygen or oxygen/carbon dioxide from such RBCs. The RBCs are thereby depleted of oxygen or oxygen/carbon dioxide and deposited in a blood storage bag for extended storage or storage in advance of transfusion.

Further, it would be beneficial to provide a stand-alone portable system that pumps gas into the device through which RBCs pass through a leukoreduction filter and an oxygen and/or carbon dioxide (OCDD) device to remove leukocytes and oxygen or oxygen/carbon dioxide from such RBCs, respectively. The RBCs are thereby free of leukocytes and depleted of oxygen or oxygen/carbon dioxide and deposited in a blood storage bag for extended storage or storage in advance of transfusion.

Further, it would be beneficial to provide a standalone portable system that circulates oxygen depleted and or/carbon dioxide adjusted air or inert gas mixtures through an OCDD device to remove such gases from RBCs flowing through the filter in preparation for anaerobic storage or transfusion. Such system contains oxygen, carbon dioxide and/or partial pressure sensors between an inlet manifold that receives oxygen and/or carbon dioxide rich air or inert gas from an OCDD device and an outlet manifold. The sensors monitor and regulate oxygen and or carbon dioxide levels in air or inert gas mixtures received in the outlet manifold and monitor oxygen and carbon dioxide partial pressure of filtered gas that is pumped back to OCDD device.

Yet further, it would be beneficial to provide a standalone portable system that reduces leukocytes and circulates oxygen and/or carbon dioxide adjusted air or inert gas mixtures through an OCDD device to remove such gases from RBCs in preparation for anaerobic storage or transfusion. Such system contains oxygen, carbon dioxide and/or partial pressure sensors between an inlet manifold that receives oxygen and/or carbon dioxide rich air or inert gas mixtures from an OCDD device and an outlet manifold that feeds oxygen and carbon dioxide depleted air or inert gas mixtures back to the OCDD device. The sensors monitor and regulate oxygen and or carbon dioxide levels in gas received in the outlet manifold and monitor oxygen and carbon dioxide partial pressure of gas that is pumped back to OCDD device.

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A portable assembly for processing red blood cells RBCs including a disposable blood collection set including a blood bag, an anaerobic storage bag and an oxygen and/or oxygen and carbon dioxide depletion device disposed between the blood collection bag and anaerobic storage bag. The portable assembly further provides for a gas circulation device in fluid communication with the oxygen or oxygen and carbon dioxide depletion device, The gas circulation device includes a pressure source that is able circulate flushing gas through the depletion device as RBCs pass from the blood collection bag, through the depletion device and into the anaerobic storage bag.

A portable assembly for processing red blood cells (RBCs) including an oxygen or oxygen and carbon dioxide depletion (OCDD) device. The OCDD device includes a cartridge having an inlet and an outlet and a plurality of hollow fibers disposed between the inlet and the outlet for transporting RBCs through the OCDD device. The plurality of hollow fibers are surrounded by a continuous space. The portable assembly includes a gas exchange device in fluid communication with the OCDD device. The gas exchange device includes a pressure source that is able to circulate a flushing gas through the continuous space and remove oxygen and/or carbon dioxide from RBCs passing through the OCDD device.

These and other benefits and advantages of the present invention and equivalents thereof, may be achieved by the methods and compositions of the present disclosure described herein and manifest in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a illustrates a portable blood processing system according to the present disclosure;

Fig 1b illustrates an alternative embodiment of the present disclosure in which red blood cells are processed using a load cell;

Figure 1c illustrates the OCDD device of the embodiment of Fig. 1b directly connected to the processing system;

Fig. 1d illustrates a collection system that incorporates a flow regulator according to the embodiment of Fig. 1b;

Fig. 1e illustrates a collection system that incorporates a leukoreduction filter with an OCDD device;

Figs. 2a through 2c illustrate a leukoreduction filter incorporated into an OCDD device according to the embodiment of Fig. 1e;

Fig. 2d illustrates an OCDD device of the embodiment of Fig. 1a;

Fig. 3 illustrates an OCDD device according to a further embodiment of the present disclosure having OCCD device, leukoreduction filter and plasma separation device in a unitary structure.

<u>DETAILED DRESCRIPTION OF THE DISCLOSURE</u>

Referring to Fig. 1, a stand-alone blood processing system is shown and referenced using reference numeral 10. System 10 includes a housing 15 and supports a blood collection and depletion system 100 (hereinafter "collection system 100"). Collection system 100 includes a blood bag 200, a leukoreduction filter 300, an oxygen and/or carbon dioxide depletion (OCDD) device 400 and an anaerobic storage bag 600. Device 400 is able to deplete oxygen or alternatively, oxygen and carbon dioxide from gas from RBCs. Collection system 100 is suspended within system 10 to enable convenient movement and transport of blood preparation processes in locations that may be remote from a standard hospital or clinical setting. The orientation of system 100, permits RBCs in blood bag 200 to flow under the force of gravity to anaerobic storage bag 600. Although a single collection system 100 is shown, stand 12 of housing

15 could carry as many as ten or more such systems for processing. Housing 15 includes a gas circulation device including a pressure source such as a pump 30 or a vacuum or a pressurized container, a valve/pressure regulator 40 and further components that will be discussed further that enable gas to circulate and pass through OCDD device 400. Inlet 410 and outlet 415 (Fig. 2d) that area connected to tubing 427 and 426, respectively.

Collection system 100 includes a blood bag 200 that contains RBCs that have been collected from whole blood. Generally, whole blood is collected from a donor using traditional methods and processed using centrifugation to separate plasma and RBCs. Blood bag 200 is a standard blood collection bag. RBCs are collected in a blood bag 200 that may contain an additive. An additive solution, such as, for example, OFAS3, includes adenine, dextrose, mannitol, NaH_2PO_4, and optionally NaCl and/or NH_4Cl. Additive solution OFAS3 preferably comprises ingredients having the following ranges: about 0.5-4.0 mmole/liter of adenine, about 50-150 mmole/liter of dextrose, about 20-70 mmole/liter of mannitol, about 0-100 mmole/liter of NaCl, about 2-20 mmole/liter of NaH_2PO_4, and about 0-30 mmole/liter NH_4Cl. Preferably, OFAS3, has an adjusted pH from about 5.5-7.5 and includes about 2 mmole/liter adenine, about 110 mmole/liter dextrose, about 55 mmole/liter NaCl, and about 12 mmole/liter NaH_2PO_4 and an adjusted pH of about 6.5. Additives such as SAGM, PAGG-SM, AS-1, AS-3, AS-5, SOLX, MAPS, PAGG-GM or any additive approved for blood storage may also be used in this system.

RBCs contained in blood bag 200 flow under the force of gravity to leukoreduction filter 300 and through OCDD device 400. Leukoreduction is the process of removing white blood cells from the whole blood or RBCs. Leukocytes in blood products can cause immunosuppressive effects and can pre-dispose patients to an increased risk of viruses, fevers, and have deleterious effects on RBCs. Leukoreduction reduces RBC storage lesions, reduces primary alloimunization and reduces total number of transfusion reactions.

The process of leukoreducing RBCs preferably occurs after the RBCs have been separated from the plasma and can occur before or after removal of oxygen and carbon dioxide have been removed from the RBCs. In either case, leukoreduction should occur before storage of RBCs and anaerobic storage bag 600.

Referring to FIGS. 2a, 2b, and 2c leukoreduction filter 300 is incorporated into OCDD device 500. OCDD device 500 includes a cartridge 505, an inlet 510, a leukoreduction filter 520, a plurality of hollow fibers 530, and a fiber support 540 to hold the plurality of hollow fibers 530. OCDD device 500 also includes an outlet 515 for passage of RBCs. Leukoreduction filter 520 is preferably a fibrous or a felt-like filtering material that captures leukocytes, prior to such leukocytes travelling through plurality of hollow fibers 530. Fiber support 540 supports the plurality of hollow fibers 530 in a vertical configuration and may be made from a material such as polyurethane or a similar material. Either whole blood or RBC flow through filter 520 during leukoreduction process. OCDD device 500 is in communication with gas from pump 30 via an inlet 524 and an outlet 528.

OCDD cartridge 500 contains approximately 5000 fibers for the passage of RBCs. More or fewer fibers may be used to generate a sufficient surface area for gas exchange to reduce the oxygen and/or carbon dioxide concentrations to the desired levels. Plurality of hollow fibers 530 are for the purpose of removing oxygen or oxygen and carbon dioxide from RBC and will be discussed further below. Gas spaces 550, outside of hollow fibers and inside of cartridge 505, that surround plurality of hollow fibers 530 and are filled with a carrier gas. Gas permeable material or porous materials of plurality of hollow fibers 530 enable oxygen and carbon dioxide to pass from RBCs to carrier gas when such gas is circulated through OCDD device 500. OCDD device 500 depletes, 0_2 and 002, or 02, or CO_2 alone, or 02 with specific levels of CO_2 by supplying an appropriate composition of flushing gas. Gases appropriate for depletion for use in OCDD devices are any inert gasses that will not cause harm to the RBCs or blood recipient, for example, Ar, He, N_2, Ar/CO_2, He/CO_2 or N_2/CO_2.

RBCs flow into OCDD device 500 to be depleted of oxygen or oxygen and carbon dioxide. OCDD device 500 reduces the degree of RBC hemoglobin oxygen saturation levels to less than 3 % and the carbon dioxide partial pressure to less than 50 Torr at 37 °C. OCDD device 500 is a combination oxygen and carbon dioxide filter that removes oxygen and carbon dioxide from RBCs to enhance the storage life of such RBCs and promotes optimal transfusion. OCDD device 500 is used with housing 115 and stand 12 of Fig. 1e and contains same components as embodiment of Fig. 1a.

Alternatively, as shown in Fig. 2d, an OCDD device 400 does not contain the leukoreduction capability and is only capable of depleting oxygen or oxygen and carbon dioxide from RBCs passing there through. Fig. 2d illustrates an OCDD device 400 that has an inlet 410 for the entry of RBCs, an outlet 415 for the passage of RBCs, and a plurality of fibers 430 through which such RBCs pass to be deleted of oxygen and/Oor carbon dioxide gas. OCDD device 400 also contains an entry port 424 for flushing gas and an exit port 428 for the egress of flushing gas and a plurality of spaces 450 that surround plurality of fibers 430 that are inside of cartridge 405 and where gas exchange from RBCs to flushing gas occurs. The circulation of gas through OCDD device 400 via entry port 424, exit port 428 and plurality of spaces 450 ensures that the partial pressure of oxygen and carbon dioxide in RBCs stored in bags 600 is at acceptable levels for optimal storage of RBCs.

Referring to Fig. la, again, housing 15 includes an inlet manifold 20, a pump 30, an outlet manifold 60 and an inlet valve/pressure regulator 40. OCDD cartridge 400 is connected to inlet manifold 20 and outlet manifold 60 by tubing 27 and 13 or direct connections 128 and 124 (Fig. 1c) respectively. A first oxygen/carbon dioxide sensor 50 and a second oxygen/carbon dioxide sensor 90 are disposed between inlet manifold 20 and outlet manifold 60. System 10 is connectable to an AC outlet or other supply of power for operation of pump 30. Alternatively, system 10 can connect to a battery for remote operation of system 10.

Housing 15 contains a disposable or re-usable sorbent cartridge 75 that is disposed between inlet manifold 20 and outlet manifold 60 to purify and air or inert gas mixture that has passed through OCDD device 400. Sorbent cartridge 75 is a large cartridge that is preferably iron based or other inorganic and/or organic compound that can physically or chemically absorb oxygen or oxygen/carbon dioxide. Sorbent cartridge 75 contains an oxygen and/or a carbon dioxide sorbent 76. As an alternative to a large sorbent pack or organic and inorganic compounds, oxygen and carbon dioxide can also be depleted from oxygen and carbon dioxide rich air or inert gas mixture by using membrane filters designed for gas separation, such as those found in nitrogen generator systems. In addition to oxygen or oxygen/carbon dioxide sorbent 76, sorbent cartridge 75 also includes activated charcoal filter 78 to absorb volatiles produced by oxygen or oxygen/carbon dioxide sorbent. Charcoal filter 78 also includes a HEPA filter to remove any particulates.

System 10 also includes various sterilization filter sensor assemblies 70, 80 and 85. Sterilization filter sensor assembly 70 are dispose between tubing 23 and inlet manifold 20. Sterilization filter sensor assembly 80 is disposed between outlet manifold 60 and tubing 27. Filters 70 and 80 capture any pathogens and/or particulates that could enter gas flow between respective tubing and manifold and compromise filtration and or purification of RBCs. Filters in 70 and 80 filter sensor assemblies monitor levels partial pressures of oxygen and carbon dioxide for an individual OCDD 400 (or 500). Sterilization filter 85 is disposed between external portion of housing 15 and inlet valve pressure regulator 40. Sterilization filter sensor assembly 85 monitors gas entering pump 30. Filter in filter sensor assembly 85 capture pathogens and particulates between system 10 and ambient air or inert gas mixture and are also able to sense levels of oxygen, carbon dioxide, temperature and pressure and humidity. Filter sensor assemblies 70, 80 and 85 also function as sensors and are in communication with controller 35. Controller 35 is programmed with predetermined set points to monitor and control concentration and flow rate of oxygen and carbon dioxide, temperature, humidity and total pressure of the gas mixtures. Should levels not be appropriate, a warning signal, such as a light or alarm, informs an operator that sorbent cartridge, sterilization filter or HEPA filter should be replaced.

Housing 15 includes casters 25 to permit movement and positioning of system 10. System 10 also includes a large sorbent cartridge 75 or hollow fiber gas separation module.

In operation, and as shown in Fig. 1, RBCs flow from collection bag 200 into OCDD cartridge directly or via leukoreduction filter. Flushing gas is simultaneously circulated through OCDD cartridge 400. The flow of oxygen or oxygen/carbon dioxide adjusted gas and oxygen/carbon dioxide rich gas to and from OCDD cartridge 400 is carried by tube 27 and tube 23, respectively. Tube 23 is connected to inlet manifold 20 and tube 27 is connected to outlet manifold 60. Tube 23 is connected to inlet manifold by a sterilization filter sensor assembly 70. Similarly, outlet manifold 60 is connected to tube 27 by sterilization filter 80.

After oxygen rich air or inert gas mixture egressing from OCDD device 400 via tubing 23, such air or inert gas mixture is received at inlet manifold 20, and pumped via 30 pump 30 through sensor 50. Pump 30 operates to maintain gas flow through system 10. Pump 30 is preferably an electrically driven pump that regulates pressures and flows. Pump 30 is connected to a valve 40, preferably a one way valve and pressure regulator that accepts ambient air or inert gas mixture at ambient pressure or insert gasses at elevated pressures. Sensor 50 and sensor 90 measure partial pressure of oxygen and carbon dioxide, in addition to gas partial pressure, temperature, flowrate total pressure and humidity of the entire portable assembly. Air or inert gas is purified in cartridge 75 and returned to OCDD 400 to continue to depletion RBCs before such RBCs flow into anaerobic storage bag 600.

Figs. 1b through 1d show an alternative embodiment of a housing 115. Housing 115 contains similar gas exchange components as housing 15. Namely, housing 115 also contains an inlet manifold 20, a pump 30, an outlet manifold 60 and an inlet valve/pressure regulator 40 contained within housing 115. Housing 115 also contains a load cell 6 that is connected to bag 200 and a flow regulator valve 470. Load cell 6 measures the unit weight in bag 200 and communicates change in mass in bag to a controller 35 that communicates with flow regulator valve 470 to monitor flow of RBCs through OCDD device 400. By monitoring change of mass of RBCs in bag 200, valve 470 can be adjusted to ensure that RBCs remain in OCDD device 400 for adequate oxygen or oxygen and carbon dioxide removal. Controller 35 is in electrical communication with load cell 6, flow regulator valve 470 and oxygen saturation sensor 475. Oxygen saturation sensor 475 measures oxygen saturation levels in RBCs. Controller 35 receives signals indicative of oxygen saturation levels and in turn sends signal to adjust flow regulator valve 470 to assure adequate oxygen depletion levels in RBCs. The several bags 200 (Fig. 1b) can be connected to housing 115 and be similarly equipped with a flow regulator valve 470 although only one flow regulator 470 is shown. Housing 115 has an outside surface to which OCCD devices 400 can be directly connected via couplings. By configuring OCDD devices 400, as shown in Figs. 1b through 1d, so that they are directly connected to housing 115 via couplings 124 and 128, the need for tubing of the embodiment of Fig. 1a is eliminated. The configuration of housing 115 can also be used with devices 500 that include leukoreduction capability.

Referring to Fig. 3, a multifunction OCDD device 700 is a combination leukoreduction filter 710, OCDD device 720, in combination with a plasma separator 730. Multifunction OCDD device 700 eliminates the need for separation of the whole blood, received from donor, which is currently a separated by using a centrifuge. By combining these three devices into a single device, the need for a separate centrifuge, a highly costly and cumbersome device, is eliminated. This embodiment contains a leukreduction portion 710, a OCDD device 720 and a plasma separator 730. Plasma flows through port 740 to a further collection bag for further processing. Accordingly, in this embodiment, whole blood can be collected from a donor, leukocytes can be removed, oxygen, or oxygen and carbon dioxide can be removed and plasma and platelets can be removed to pass RBCs through device. The RBCs are then deposited into collection bag 600 for storage or transfusion to a recipient. Multifunction OCDD 700 as part of collection system 100 and system 10 permit rapid transformation of whole blood to stored RBCs for immediate storage or transfusion to a recipient.

Although the present disclosure describes in detail certain embodiments, it is understood that variations and modifications exist known to those skilled in the art that are within the disclosure. Accordingly, the present disclosure is intended to encompass all such alternatives, modifications and variations that are within the scope of the disclosure as set forth in the disclosure.

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CLAIMS:

1. A portable system for processing red blood cells (RBCs) comprising:

   a gas circulation device providing a flushing gas capable of being placed in fluid communication with one or more oxygen or oxygen and carbon dioxide depletion devices, said gas circulation device comprising, in fluid communication with each other:
   a flushing gas source;
   a gas outlet manifold;
   a first gas sterilization filter;
   a second gas sterilization filter;
   one or more gas sensor assemblies;
   a gas inlet manifold; and
   a controller,

   wherein at least one of said one or more gas sensor assemblies is selected from the group consisting of an oxygen sensor, a carbon dioxide sensor, and a combination thereof, and said gas sensor assemblies comprise a partial pressure sensor.

2. The portable system according to claim 1, further comprising a housing containing said gas circulation device, wherein said housing further comprises a sorbent disposed between said flushing gas source and said gas outlet manifold for removing oxygen or oxygen and carbon dioxide from said flushing gas.

3. The portable system according to claim 1 or claim 2, wherein said one or more gas sensor assemblies comprise a first gas sensor assembly comprising a first partial pressure sensor disposed between said flushing gas source and said sorbent and a second gas sensor assembly comprising a second partial pressure sensor disposed between said sorbent and said gas outlet manifold, wherein said gas sensor assemblies detect a level of oxygen or carbon dioxide in said flushing gas.

4. The portable system according to any one of claims 1 to 3, further comprising one or more load cell and one or more flow regulator valves in communication with said controller, wherein said one or more flow regulator valves are configured to control the flow of RBCs through said one or more oxygen or oxygen and carbon dioxide

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depletion devices and said one or more load cells are configures to measure the load of RBCs collected in an anaerobic storage bag.

5. The portable system according to claim 4, wherein said controller communicates a signal to restrict or facilitate a flow of RBCs through said one or more flow regulator valves in response to a signal from said one or more load cells.

6. The portable system according to claim 4 or claim 5, further comprising an oxygen saturation sensor capable of measuring the level of oxygen saturation in RBCs flowing through said one or more oxygen and carbon dioxide depletion devices and in communication with said controller, wherein said controller communicates a signal to said one or more flow regulator valves to restrict or facilitate the flow of RBCs through said one or more flow regulator valves.

7. The portable system according to any one of claims 1 to 6, wherein said flushing gas comprises Ar, He, N_2, Ar/CO_2, He/CO_2 or N_2/CO_2,or any combination of inert gasses and/or CO_2.

8. The portable system according to any one of claims 1 to 7, wherein said flushing gas source is selected from the group consisting of a pump, a vacuum or a pressurized container.

9. The portable system according to any one of claims 1 to 8, wherein said one or more gas sensor assemblies further comprise a temperature, a gas flow rate, a total pressure or a humidity detector.

10. The method of processing red blood cells (RBCs) comprising:

filtering a flushing gas source through a gas circulation device to generate sterile flushing gas, said gas circulation device comprising, in fluid communication with each other:

a flushing gas source providing said flushing gas;
a gas outlet manifold;
a first gas sterilization filter;
a second gas sterilization filter;
one or more gas sensor assemblies;
a gas inlet manifold; and
a controller,

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wherein said one or more gas sensor assemblies are selected from the group consisting of an oxygen sensor, an oxygen partial pressure sensor, a carbon dioxide sensor, a carbon dioxide partial pressure sensor, and combinations thereof;

providing said sterile flushing gas to an oxygen or oxygen and carbon dioxide depletion (OCDD) device; and

flowing said RBCs through said OCDD device to remove oxygen or oxygen and carbon dioxide from said RBCs, producing oxygen or oxygen and carbon dioxide reduced RBCs.

11. The method according to claim 10, wherein said gas circulation device is contained in a housing comprising:

a sorbent disposed between said flushing gas source and said gas outlet manifold, and

said method further comprises removing oxygen or oxygen and carbon dioxide from said flushing gas, and

determining levels of oxygen or oxygen and carbon dioxide in said flushing gas,

wherein said one or more gas sensor assemblies comprises a first gas sensor assembly comprising a first partial pressure sensor disposed between said flushing gas source and said sorbent, and a second gas sensor assembly comprising a second partial pressure sensor disposed between said sorbent and said gas outlet manifold.

12. The method according to claim 10 or claim 11, wherein said gas circulation device further comprises one or more load cells in communication with said controller to regulate one or more flow regulator valves, and said method further comprises measuring the load of unprocessed RBCs, and controlling said flowing.

13. The method according to claim 12, wherein said controller detects a signal from said one or more load cells and then communicates a signal to restrict or facilitate a flow of RBCs through said one or more flow regulator valves.

14. The method according to any one of claims 10 to 12, wherein said flushing gas comprises Ar, He, N2, Ar/CO2, He/CO2, N2/CO2, a combination of inert gasses, a combination of inert gasses with or without CO2.

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15. The method according to any one of claims 10 to 14, further comprising adding an additive solution to said RBCs prior to said flowing.

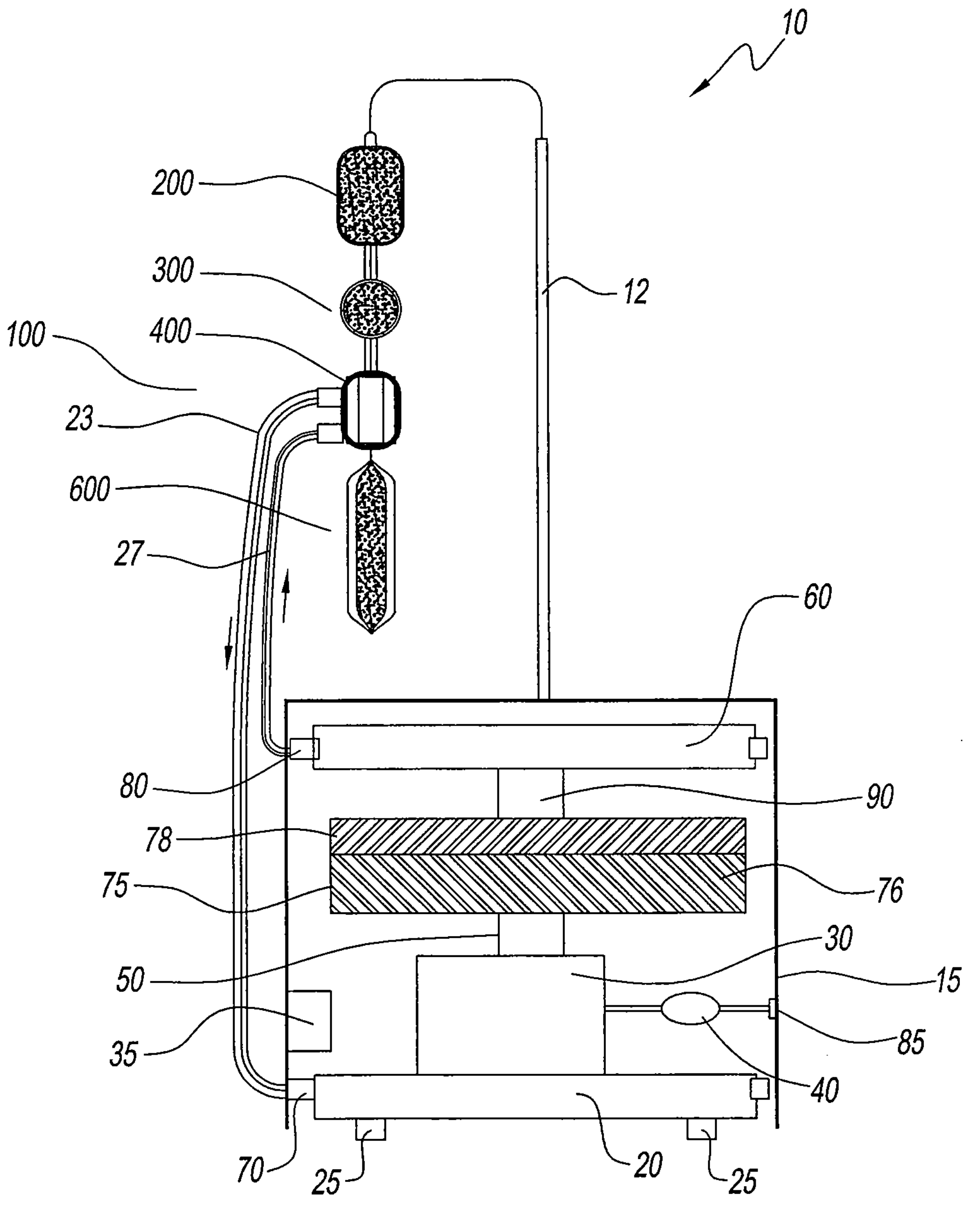
16. The method according to claim 15, wherein said additive solution is selected from the group consisting of OFAS3, SAGM, PAGG-SM, AS-1, AS-3, SOLX, MAPS, and PAGG-GM, wherein said OFAS3 has a pH ranging from about 5.5 to about 7.5.

17. The method according to any one of claims 10 to 16, wherein said RBCs flow into said OCDD device directly or via a leukoreduction filter, and said method further comprises leukoreducing said RBCs.

18. The method according to any one of claims 10 to 17, wherein said leukoreduction filter, and said method further comprises leukoreducing said oxygen or oxygen and carbon dioxide reduced RBCs.

19. The method according to any one of claims 10 to 18, wherein said OCDD device further comprises a plasma separator, and said method further comprises separating plasma from said RBCs prior to said flowing.

20. The method according to any one of claims 10 to 19, wherein said one or more gas sensor assemblies further comprise a temperature, a gas flow rate, a total pressure, or a humidity detector.


10
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300
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100
23
600
27
12
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78
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35
85
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70
25
20
25

FIG. 1a

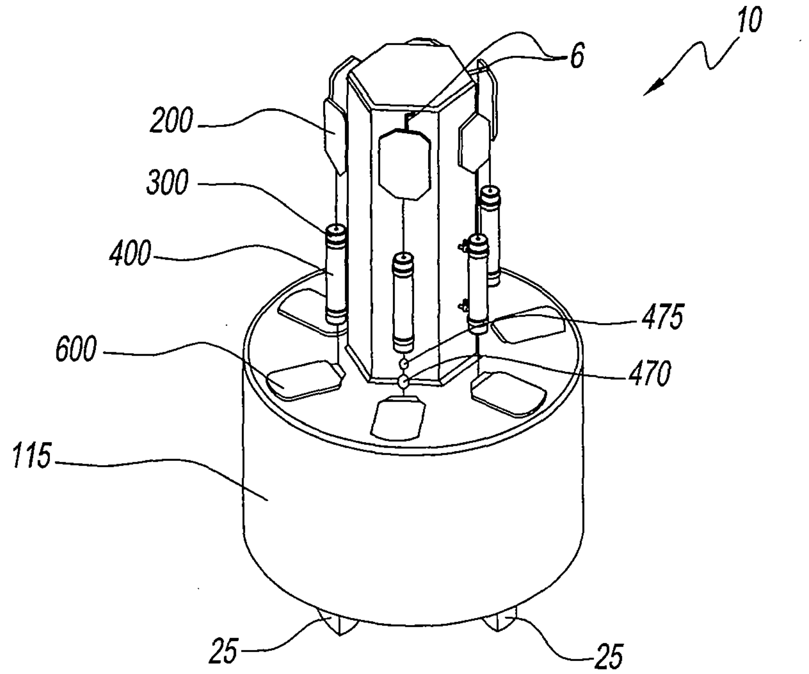

FIG. 1b

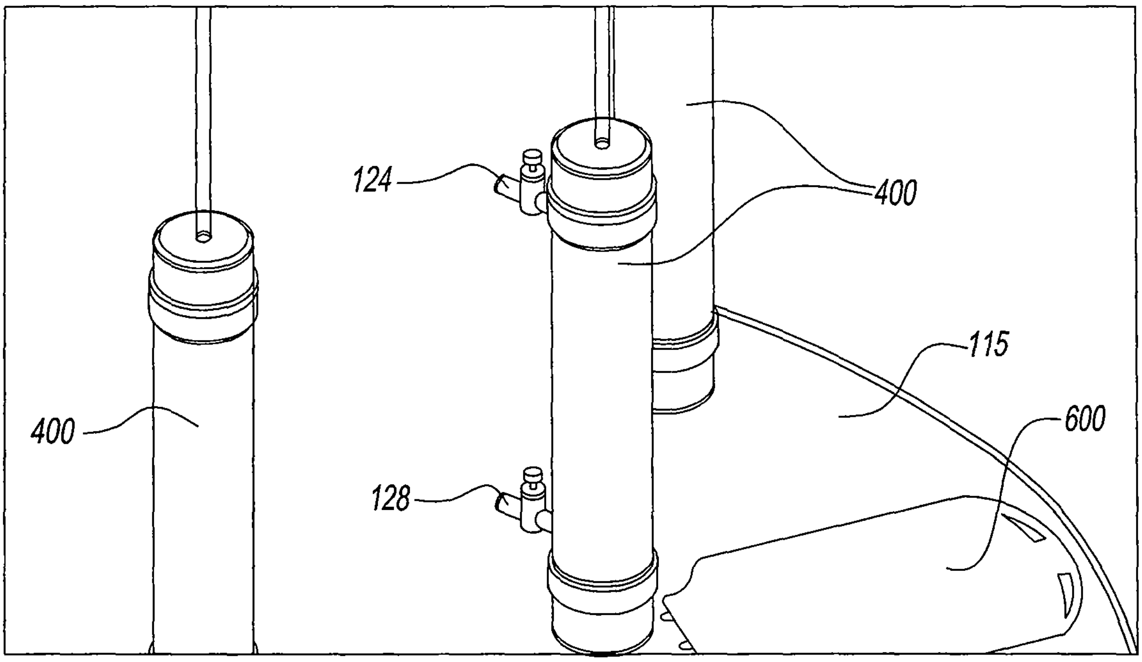

FIG. 1c

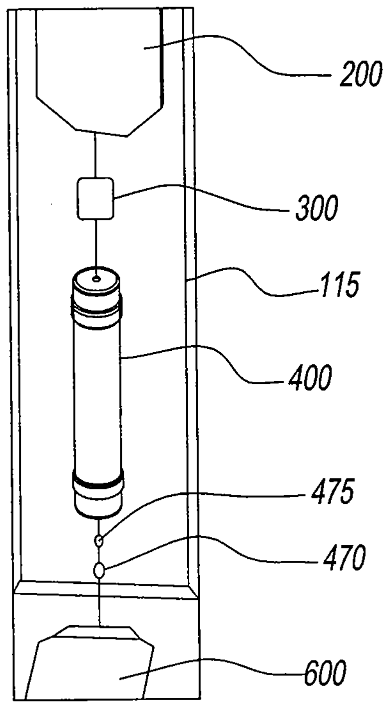

FIG. 1d

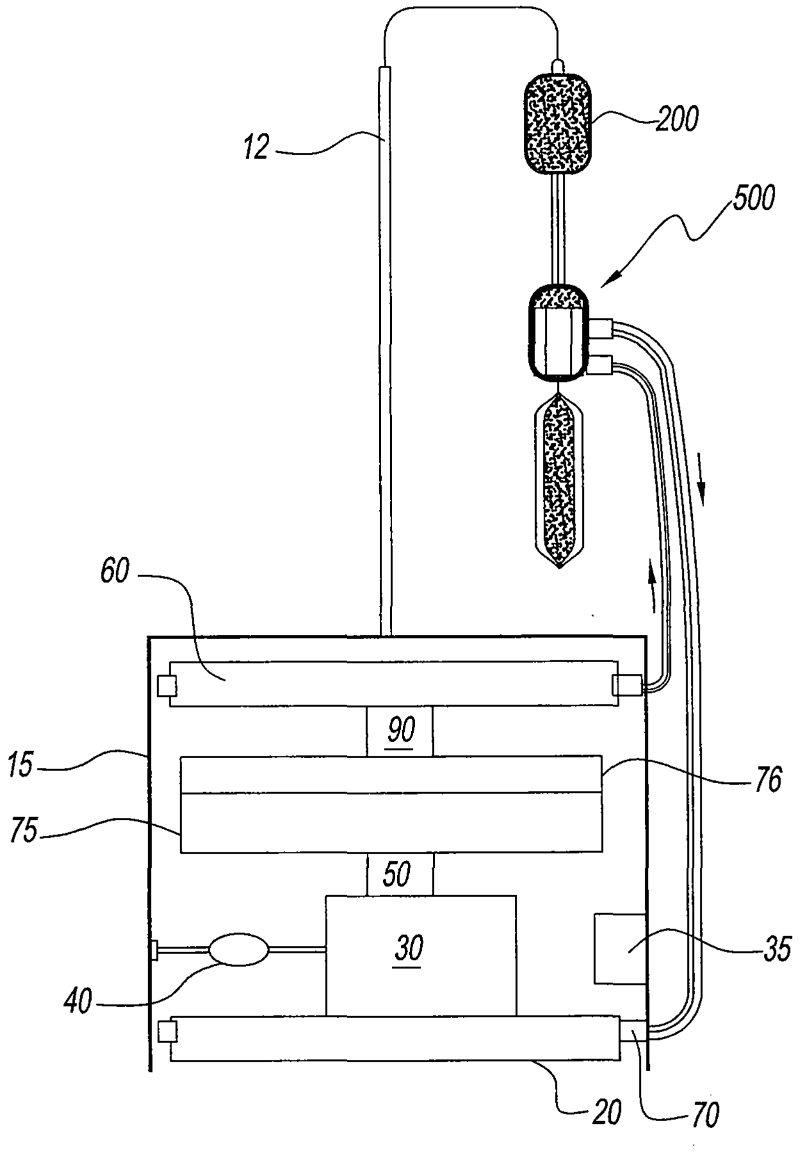

FIG. 1e

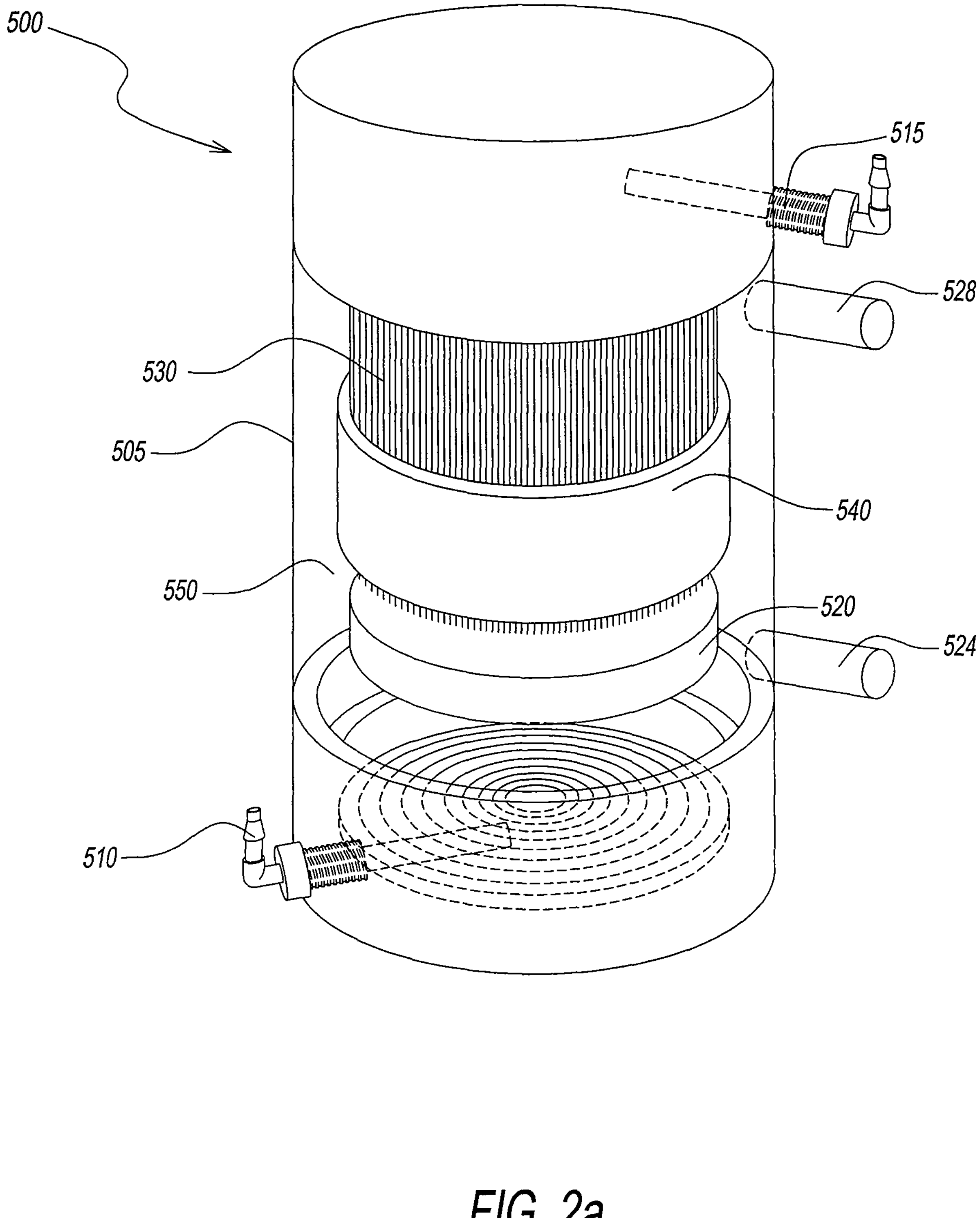

FIG. 2a

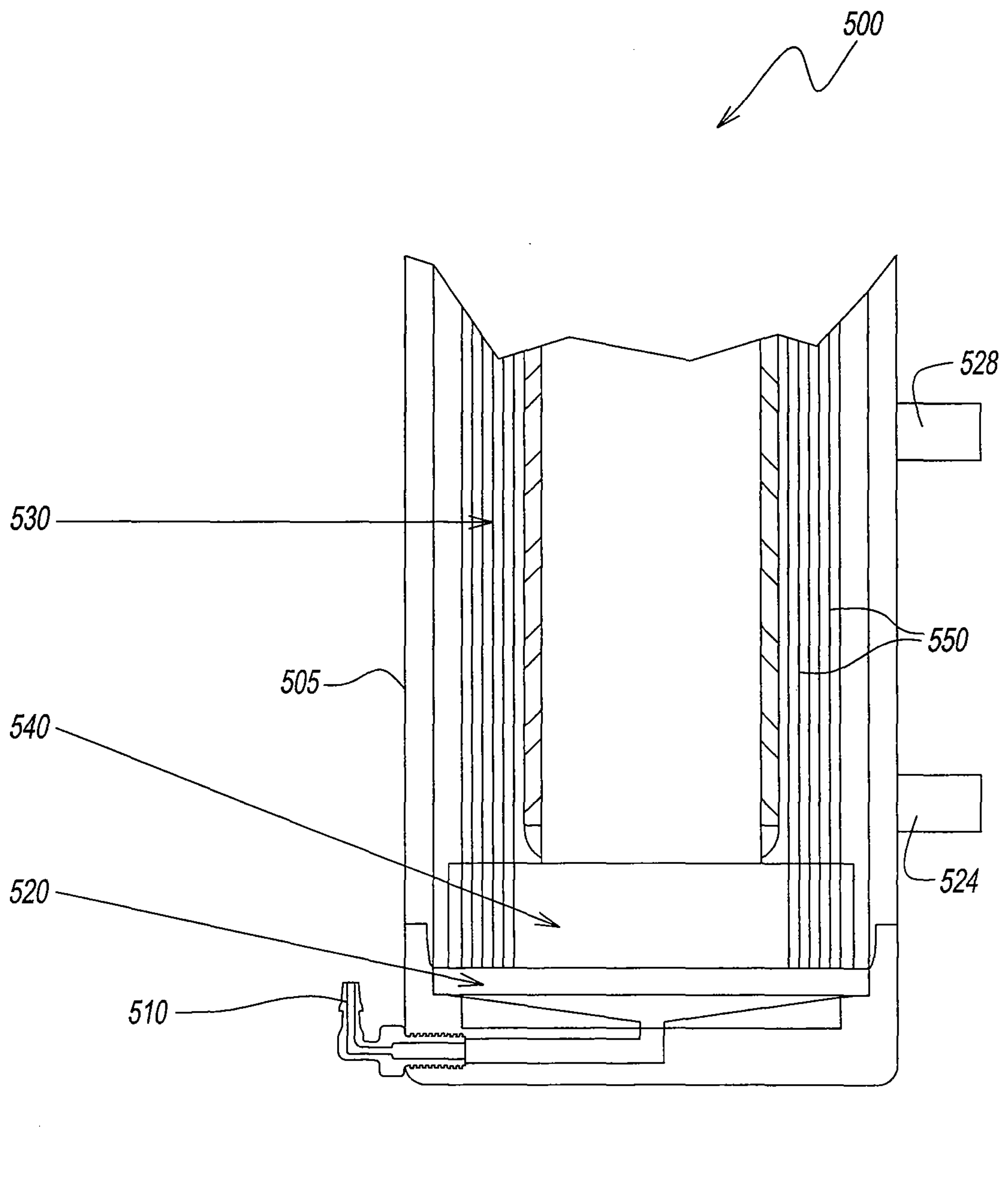

FIG. 2b

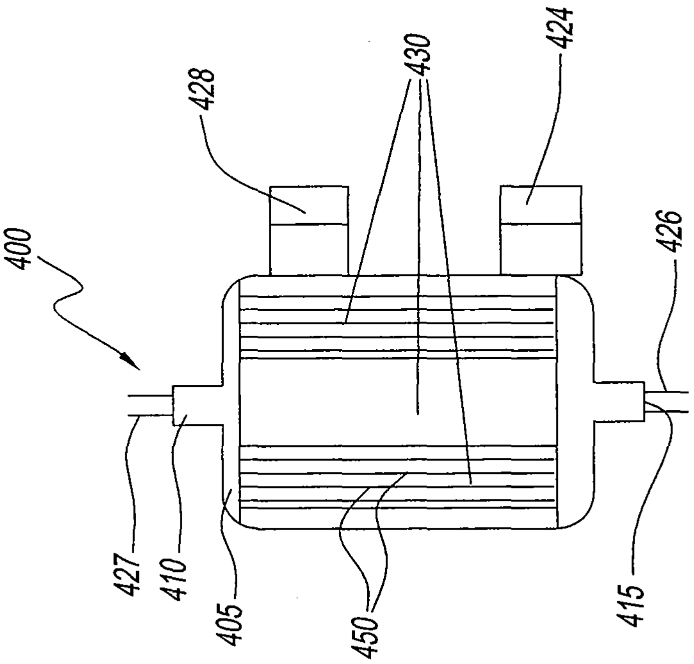
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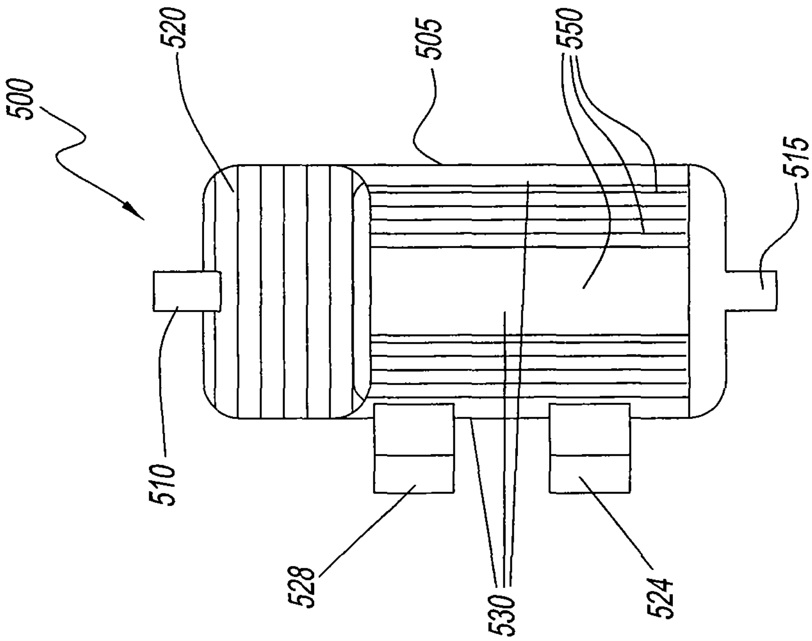
FIG. 2d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530
524

FIG. 2c

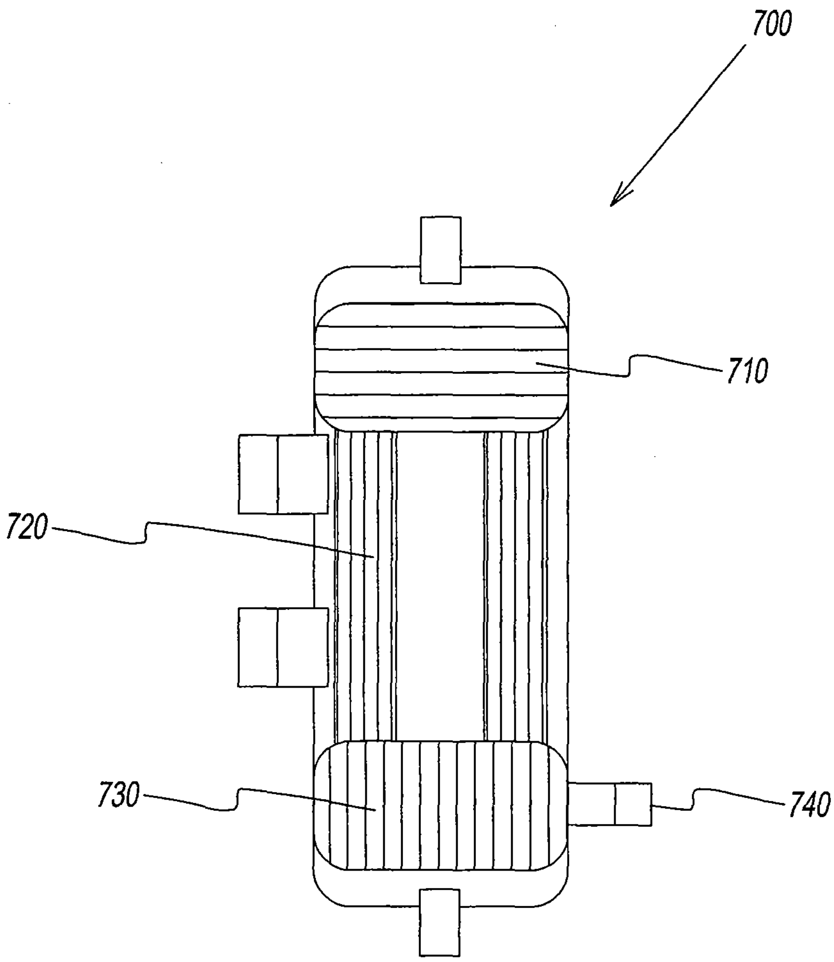

FIG. 3