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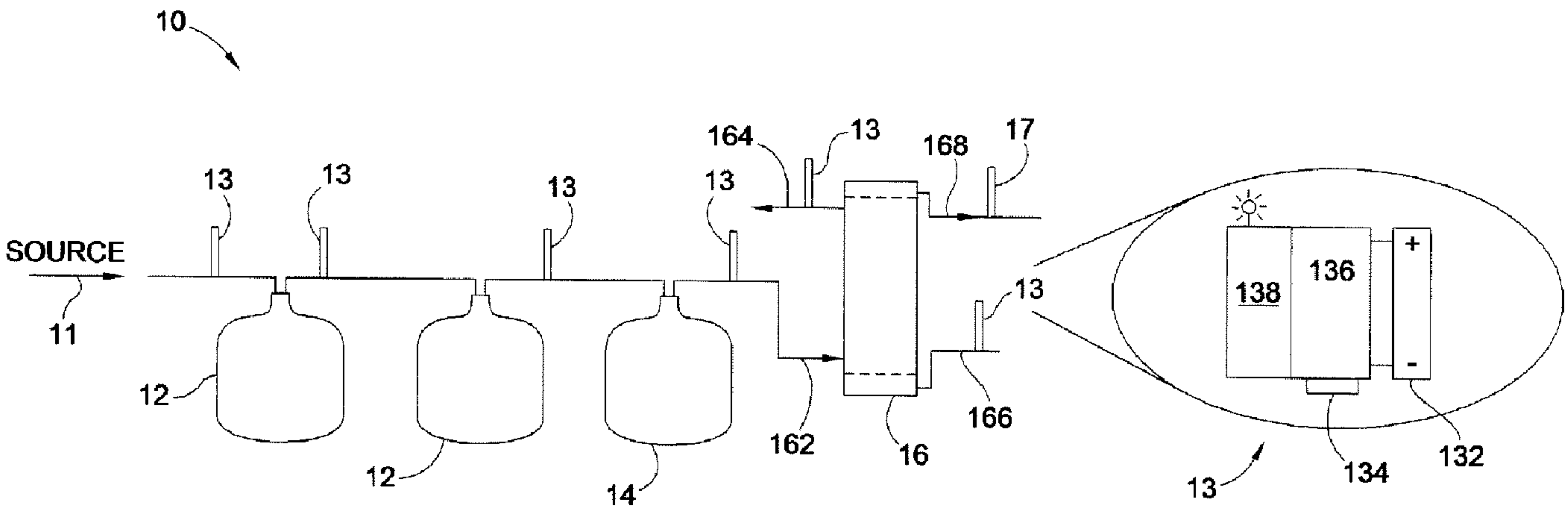

FIG. 1

(57) Abrégé/Abstract:
A system for monitoring water quality for dialysis, dialysis fluids, and body fluids treated by dialysis fluids, is disclosed. The system uses microelectromechanical systems (MEMS) sensors for detecting impurities in input water or dialysis fluid, and in the prepared dialysate. These sensors may also be used to monitor and check the blood of the patient being treated. These sensors include ion-selective sensors, for ions such as ammonium or calcium, and also include amperometric array sensors, suitable for ions from chlorine or chloramines, e.g., chloride. These sensors assist in the monitoring of water supplies from a city water main or well. The sensors may be used in conjunction with systems for preparing dialysate solutions from water for use at home or elsewhere.

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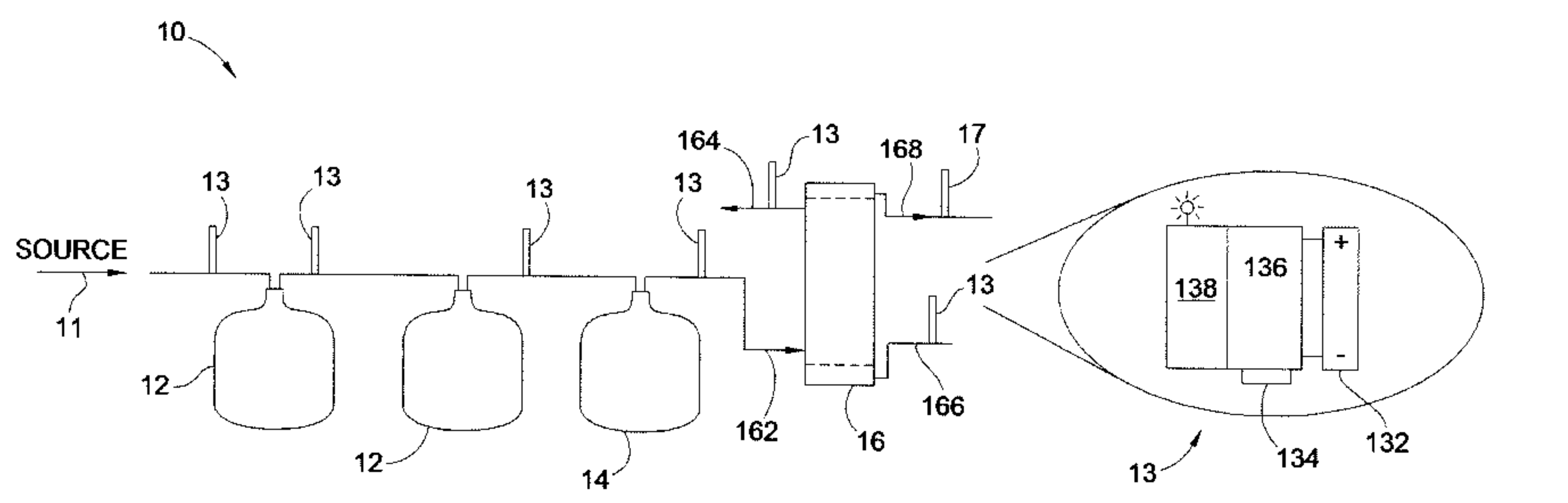

FIG. 1

(57) Abstract: A system for monitoring water quality for dialysis, dialysis fluids, and body fluids treated by dialysis fluids, is disclosed. The system uses microelectromechanical systems (MEMS) sensors for detecting impurities in input water or dialysis fluid, and in the prepared dialysate. These sensors may also be used to monitor and check the blood of the patient being treated. These sensors include ion-selective sensors, for ions such as ammonium or calcium, and also include amperometric array sensors, suitable for ions from chlorine or chloramines, e.g., chloride. These sensors assist in the monitoring of water supplies from a city water main or well. The sensors may be used in conjunction with systems for preparing dialysate solutions from water for use at home or elsewhere.

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IN-LINE SENSORS FOR DIALYSIS APPLICATIONS

BACKGROUND

[0001] This patent relates generally to medical fluid delivery systems and methods. More particularly, this patent discloses systems, methods and apparatuses for microelectromechanical systems (MEMS) sensors for sensing and measuring species in fluids involved in dialysis, such as peritoneal dialysis fluid, hemodialysis fluid, and blood.

[0002] Due to various causes, a person's renal system can fail. Renal failure produces several physiological impairments and difficulties. The balance of water, minerals and the excretion of daily metabolic load is no longer possible and toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissue.

[0003] Kidney failure and reduced kidney function have been treated with dialysis. Dialysis removes waste, toxins and excess water from the body that would otherwise have been removed by normal functioning kidneys. Dialysis treatment for replacement of kidney functions is critical to many people because the treatment is life saving.

[0004] Hemodialysis and peritoneal dialysis are two types of dialysis therapies used commonly to treat loss of kidney function. A hemodialysis ("HD") treatment utilizes the patient's blood to remove waste, toxins and excess water from the patient. The patient is connected to a hemodialysis machine and the patient's blood is pumped through the machine. Catheters or needles are inserted into the patient's veins and arteries, or an artificial graft so blood can flow to and from the hemodialysis machine. The blood passes through a dialyzer of the machine, which removes waste, toxins and excess water from the blood. The cleaned blood is returned to the patient. A large amount of dialysate, for example about 120 liters, is consumed to dialyze the blood during a single hemodialysis therapy. Hemodialysis treatment lasts several hours and is generally performed in a treatment center about three or four times per week.

[0005] Another form of kidney failure treatment involving blood is hemofiltration ("HF"), which is an alternative renal replacement therapy that relies on a convective transport of toxins from the patient's blood. This therapy is accomplished by adding substitution or replacement fluid to the extracorporeal circuit during treatment (typically ten to ninety liters of such fluid). That substitution fluid and the fluid accumulated by the patient in between treatments is ultrafiltered over the course of the HF treatment, providing a convective transport mechanism that is particularly beneficial in removing middle and large molecules.

[0006] Hemodiafiltration ("HDF") is another blood treatment modality that combines convective and diffusive clearances. HDF uses dialysate to flow through a dialyzer, similar to standard hemodialysis, providing diffusive clearance. In addition, substitution solution is provided directly to the extracorporeal circuit, providing convective clearance.

[0007] Peritoneal dialysis uses a dialysis solution, referred to as dialysate, which is infused into a patient's peritoneal cavity via a catheter. The dialysate contacts the peritoneal membrane of the peritoneal cavity. Waste, toxins and excess water pass from the patient's bloodstream, through the peritoneal membrane and into the dialysate due to diffusion and osmosis, i.e., an osmotic gradient occurs across the membrane. The spent dialysate is drained from the patient, removing waste, toxins and excess water from the patient. This cycle is repeated.

[0008] There are various types of peritoneal dialysis therapies, including continuous ambulatory peritoneal dialysis ("CAPD"), automated peritoneal dialysis ("APD"), tidal flow APD and continuous flow peritoneal dialysis ("CFPD"). CAPD is a manual dialysis treatment. The patient manually connects an implanted catheter to a drain, allowing spent dialysate fluid to drain from the peritoneal cavity. The patient then connects the catheter to a bag of fresh dialysate, infusing fresh dialysate through the catheter and into the patient. The patient disconnects the catheter from the fresh dialysate bag and allows the dialysate to dwell within the peritoneal cavity, wherein the transfer of waste, toxins and excess water takes place. After a dwell period, the patient repeats the manual dialysis procedure, for example, four times per day, each treatment lasting about an hour. Manual peritoneal dialysis requires a significant amount of time and effort from the patient, leaving ample room for improvement.

[0009] Automated peritoneal dialysis ("APD") is similar to CAPD in that the dialysis treatment includes drain, fill, and dwell cycles. APD machines, however, perform the cycles automatically, typically while the patient sleeps. APD machines free patients from having to manually perform the treatment cycles and from having to transport supplies during the day. APD machines connect fluidly to an implanted catheter, to a source or bag of fresh dialysate and to a fluid drain. APD machines pump fresh dialysate from a dialysate source, through the catheter, into the patient's peritoneal cavity, and allow the dialysate to dwell within the cavity, and allow the transfer of waste, toxins and excess water to take place. The source can be multiple sterile dialysate solution bags.

[0010] APD machines pump spent dialysate from the peritoneal cavity, though the catheter, to the drain. As with the manual process, several drain, fill and dwell cycles occur during APD. A "last fill" may occur at the end of CAPD and APD, which remains in the peritoneal cavity of the patient until the next treatment.

[0011] Both CAPD and APD are batch type systems that send spent dialysis fluid to a drain. Tidal flow systems are modified batch systems. With tidal flow, instead of removing all of the fluid from the patient over a longer period of time, a portion of the fluid is removed and replaced after smaller increments of time.

[0012] Continuous flow, or CFPD, systems may clean or regenerate spent dialysate instead of discarding it. The systems pump fluid into and out of the patient, through a loop. Dialysate flows into the peritoneal cavity through one catheter lumen and out another catheter lumen. The fluid exiting the patient passes through a reconstitution device that removes waste from the dialysate, e.g., via a urea removal column that employs urease to enzymatically convert urea into ammonia. The ammonia is then removed from the dialysate by adsorption prior to reintroduction of the dialysate into the peritoneal cavity. Additional sensors are employed to monitor the removal of ammonia. CFPD systems are typically more complicated than batch systems.

[0013] In each of the kidney failure treatment systems discussed above, it is important to monitor and control the composition of the dialysis fluid, including the water used to make the dialysis fluid. The purity of the incoming water is obviously important. In home situations, there is typically no control or monitoring of the water from a city main or from a person's well. Once the dialysis fluid is made, it may be useful to at least check its complete composition, at least to insure that the proper fluid is being used. At present this cannot be done without taking a sample to a lab for testing and analysis. If more than one type of fluid is being used for peritoneal or other dialysis treatment, it may be useful to check the composition of each container, to insure that the proper containers have been procured and are connected correctly to the peritoneal dialysis machine.

[0014] Dialysis fluid may be used in more than one pass, i.e., hemodialysis fluid may be routed more than once through the dialyzer before it is filtered or purified and peritoneal dialysis fluid may also be used in multi-pass therapies. There is at present no easy way to monitor the composition of the fluid before the first pass, or after the first or second pass, short of taking a sample and sending it to a laboratory for analysis. Using a plurality of standard sensors at one or more points in the fluid circuits would be very expensive and would also occupy space that is not available at the bedside of the patient, whether in a home-care or even in an institutional-care setting.

SUMMARY

[0015] There are many embodiments of the present invention, in which MEMS sensors are used to sense and quantify analytes of interest in dialysis fluid and in water for use in dialysis fluid. The MEMS sensors are useful in dialysis fluid intended for both peritoneal dialysis and hemodialysis.

[0016] In a first embodiment of the present invention, a system for preparing dialysis fluid is provided. The system includes a first purification vessel which includes a purification medium for water, and a device for pumping or measuring the water. The system also includes a heater for heating the water and a mixing chamber configured for receiving water from the device and for mixing the water with a concentrate to form a fresh dialysis solution. A filter for filtering the fresh dialysis solution is provided, as well as a microelectromechanical systems (MEMS) sensor that is placed in fluid communication with an output from a vessel selected from the first purification vessel, the heater, the mixing chamber and the filter.

[0017] In a second embodiment of the present invention, a system for preparing dialysis fluid is provided. The system includes a first purification cartridge that includes a purification medium for water, and also includes a heater for heating water received from the first purification cartridge. The system also includes first and second pumps for pumping and metering first and second concentrates, and a mixing chamber configured for receiving the first and second concentrates from the first and second pumps and for mixing the first and second concentrates. The mixing chamber

is used to mix the water with the first and second concentrates to form a fresh dialysis solution. The system further includes a filter for filtering the fresh dialysis solution, and a microelectromechanical systems (MEMS) sensor placed in fluid communication with an output of a vessel selected from the first purification vessel, the heater, the mixing chamber and the filter, wherein the MEMS sensor is suitable for sensing at least two substances in a stream selected from the group consisting of water from the first purification cartridge, the fresh dialysis solution and the filtered dialysis solution.

[0018] In a third embodiment of the invention, a method for preparing dialysis solution is provided. The method includes the steps of furnishing a supply of water and purifying the water in at least one pass through a purification medium. The method also includes the steps of heating the water and adding the water to at least one dialysis concentrate to form a dialysis solution. In addition, the method includes the steps of filtering the dialysis solution and sensing at least two characteristics of the water with a microelectromechanical systems (MEMS) sensor.

[0019] In a fourth embodiment of the invention, a method of preparing dialysis solution is disclosed. This method includes the steps of furnishing a supply of water and spent dialysate and purifying the water and the spent dialysate in at least one pass through a purification medium. The purification medium may be in one vessel or more than vessel, as described below. The method also includes the steps of heating the water and adding the water and at least one dialysis concentrate to form a dialysis solution. In addition, the method includes filtering the formed dialysis solution and sensing at least two characteristics of a stream selected from the group consisting of the water, the formed dialysis solution and the spent dialysis solution, using a microelectromechanical systems (MEMS) sensor.

[0020] In a fifth embodiment, a method of purifying dialysis solution is disclosed. The method includes the steps of furnishing a supply of spent dialysate and purifying the spent dialysate in at least one pass through a purification medium in a vessel to form a purified dialysate. The method also includes the steps of filtering the spent dialysate to form a filtered dialysate, and sensing at least two characteristics of a stream selected from the group consisting of the spent dialysate, the purified dialysate and the filtered dialysate. The characteristics are sensed with a microelectromechanical systems (MEMS) sensor.

[0021] Another embodiment is a method for performing dialysis. The method includes the steps of providing a dialysis machine and a supply of dialysis fluid and also includes the steps of sensing and determining a composition of the dialysis fluid with a MEMS sensor. The MEMS sensor is suitable for sensing and detecting at least two ions in the dialysis fluid. The method also includes the steps of performing dialysis on a patient using the dialysis fluid, and sensing and determining a composition of the dialysis fluid after the step of performing dialysis, using a MEMS sensor. Additionally, the method includes the steps of purifying the dialysis fluid after the step of performing dialysis, and sensing and determining a composition of the dialysis fluid after the step of purifying with a MEMS sensor. The method includes a step of reusing the dialysis fluid if the composition of the dialysis fluid after the step of purifying is suitable for dialysis.

[0022] Additional features and advantages are described herein, and will be apparent from the following Detailed Description and the figures.

BRIEF DESCRIPTION OF THE FIGURES

[0023] Fig. 1 is a schematic view of a first system for purifying water or spent dialysis solution before hemodialysis;

[0024] Fig. 2 is a schematic view of a second system for purifying water or spent dialysis solution before hemodialysis;

[0025] Fig. 3 is a schematic view of a third system for purifying water and preparing dialysis solution, directed more to peritoneal dialysis;

[0026] Fig. 4 is a schematic view of a system for purifying water and preparing dialysis solution, especially for peritoneal dialysis;

[0027] Fig, 5 is a perspective view of a hemodialysis machine with a system for treating, purifying, and reusing spent dialysate; and

[0028] Fig. 6 is a schematic view of a system for preparing dialysis solution using MEMS sensors.

DETAILED DESCRIPTION

[0029] MEMS sensors are used in embodiments of the present invention to detect and quantify analytes of interest in dialysis fluids. MEMS sensors are capable of detecting numerous properties and species in a variety of aqueous fluids. These fluids include water, dialysis fluid, spent dialysis fluid and even blood. The properties include pH, conductivity, temperature, oxidation-reduction potential and total hardness. Species include ammonia or ammonium, total dissolved solids (TDS), carbonate, bicarbonate, calcium, magnesium, sodium, potassium, chloride and others.

[0030] A MEMS sensor includes a substrate with a plurality of electrode sensor elements adapted to measure relevant species of an aqueous analyte. The sensor elements include, for example, electrodes and selective membranes. These elements, together with any support circuitry required to drive the sensor element, make up the complete sensor. For example, the substrate can include a plurality of electrodes covered by ion-selective membranes and an amperometric sensor including a working electrode and a counter electrode. In one application, the substrate, including the sensor elements, is connected to an analyzer capable of calculating one or more desired properties, such as the disinfection index of a water sample. Optionally, the substrate includes additional sensor elements configured to measure additional species. These element may include an ammonia sensor, an oxygen sensor, or a sensor for a mutagenic species, such as an immunosensor or a DNA probe. Sensors may also be used to detect and quantify additional physical properties, such as temperature, conductivity and oxidation-reduction potential.

[0031] Exemplary sensors can be fabricated on silicon substrates. They may alternatively be fabricated on other types of substrates such as, for example, ceramic, glass, SiO_2, or plastic, using conventional processing techniques. Exemplary sensors can also be fabricated using combinations of such substrates situated proximate to one another. For example, a silicon substrate having some sensor components (e.g., sensing elements) can be mounted on a ceramic, SiO_2, glass, plastic or other type of substrate having other sensor components. These other sensor components may include sensing elements, one or more reference electrodes, or both. Conventional electronics processing techniques can be used to fabricate and interconnect such composite devices. These techniques are also described in U.S. Pat. No. 4,743,954 and U.S. Pat. No. 5,102,526, which are hereby incorporated herein by reference.

[0032] The sensors can utilize micro-array sensor chip technology on a silicon platform. For example, ion-selective electrode-based sensor elements can be implemented in a silicon-based embodiment, such as that as described by Brown, "Solid-state Liquid Chemical Sensors" (Miniaturized Analytical Devices

Microsymposium, Chemistry Forum, 1998, pp. 120-126), the disclosure of which is hereby incorporated herein by reference. Alternative silicon-based sensor devices, and the manners in which such devices can be fabricated, are described in U.S. Pat. No. 4,743,954 ("Integrated Circuit for a Chemical-Selective Sensor with Voltage Output"), U.S. Pat. No. 5,102,526 ("Solid State Ion Sensor with Silicone Membrane"), and U.S. patent application Ser. No. 09/768,950 ("Micromachined Device for Receiving and Retaining at Least One Liquid Droplet, Method of Making the Device and Method of Using the Device"), the disclosures of which are hereby incorporated herein by reference. The chip platform can be based on other electrochemical solid state sensor technology that is well known in the art, as shown by Brown et al. in Sensors and Actuators B, vol. 64, June 2000, pp. 8-14, the disclosure of which is hereby incorporated herein by reference. The silicon chip incorporates a combination of chemically-selective sensors and physical measurements that work in concert to deliver chemical profiling information on a test sample as small as one drop, and which are also suitable for continuous, on-line sensing and monitoring of fluids.

[0033] As described in U.S. Pat. Appl. Publ. 20080109175, which is hereby incorporated herein by reference, sensors for use in systems disclosed herein can be fabricated using known lithographic, dispensing and screen printing techniques. These include conventional microelectronics processing techniques. These techniques can provide sensors having sensing elements with micro-sized features integrated at the chip level, and can be integrated with low-cost electronics, such as ASICs (application specific integrated circuits). Such sensors and electronics can be manufactured at low cost, thereby enabling wide distribution of such sensors for general use. The sensor may be a MEMS sensor as sold by Sensicore, Inc., Ann Arbor, Michigan, U.S.A. These sensors use microelectromechanical systems (MEMS) technology, that is, very small devices with very small components. These sensors are described in numerous patents and patent publications from Sensicore, including U.S. Pat. Nos.: 7,100,427; 7,104,115; 7,189,314; and 7,249,000, each of which is hereby incorporated by reference in its entirety and relied upon. These MEMS sensors are also described in numerous patents pending, including U.S. Pat. Appl. Publications: 20050251366; 20060020427; 20060277977; 20070050157; 20070219728; and 20080109175, each of which is hereby incorporated by reference in its entirety and relied on.

[0034] The microelectromechanical system (MEMS) sensors may be used in many aspects of dialysis fluid preparation and processing to ensure patient safety, comfort, economy and convenience, as well as treatment efficacy. The economy and convenience arise from the use at home of the embodiments described below, as well as many other embodiments that are not described here, but will be obvious to those having skill in dialysis arts.

[0035] Fig. 1 illustrates a first embodiment of a system 10 for preparing fresh dialysis solution from spent dialysate using MEMS sensors to sense, measure, and report various characteristics of the dialysate. In this system, dialysis fluid enters from a source 11 of dialysis fluid, such as the effluent from a spent dialysate pump that forms part of a hemodialysis machine. Fig. 1 depicts a plurality of sensors 13, located at several points around the system 10. The intent is not to suggest that a sensor is needed at every point depicted, but rather to demonstrate the plurality of locations where a sensor may advantageously be placed.

[0036] Each sensor 13, as shown in the inset, includes a power source 132, such as a battery, a sensing element 134 with a working portion 136, and optionally, a module 138 for remote communication, such as to a controller of the system. The power source may be furnished by electrical wiring from a controller of the hemodialysis machine, or from another power source, such as a convenience outlet or a modular power supply for a series of MEMS sensors.

[0037] Sensor element 134 is a MEMS sensor and working portion 136 includes the circuitry necessary to process signals from the sensor and convert them to useful information. These signals may be sent to a controller of the hemodialysis machine via wired connections, or the MEMS sensor may include a remote communications capability. In this embodiment, the signal processing circuitry and wireless transmitter or radio 138 are small and compact, and are easily placed into the sensor housing at the sensing site. One suitable remote communications module is a wireless module in accord with the ZigBee/IEEE 805.15.4 standard. This is a standard for a very low power radio system with a very limited range, about 10-20 feet. Modules made in accordance with this standard may be purchased from Maxstream, Inc., Lindon, UT, U.S.A., Helicomm, Inc., Carlsbad, CA, U.S.A., and ANT, Cochrane, Alberta, Canada. The modules are very small and are suitable for such remote applications. As noted, the sensor 13 optionally includes a power supply and may also include an ADC converter to convert analog data from the sensing element into digital data. The digital data is thus formatted, at least by the sensor, before transmission to the controller of the hemodialysis machine or other extracorporeal processing machine controller.

[0038] MEMS sensors include sensors which may be placed in-line between one vessel and a succeeding vessel, and also include sensors which may be placed within a vessel, such as a processing vessel or cartridge, or a storage vessel. Many MEMS sensors are capable of detecting many species of ions or contaminants, and some are also capable of sensing and relaying a temperature, pH (as in hydrogen or hydronium ion concentration), conductivity, total dissolved solids (TDS), and so forth.

[0039] Hemodialysis Applications

[0040] Returning to Fig. 1, system 10 includes a source 11 of water or spent dialysis fluid, with a MEMS sensor 13 placed at the source for monitoring characteristics of the incoming water or fluid. A first processing vessel 12, such as a bed of activated carbon or charcoal, is placed downstream of the source 11. The bed of activated carbon or charcoal is excellent for removing a number of contaminants, including small particles and also including heavy metals, chlorine, chloramines, and organics, among others. The bed of activated carbon or charcoal is relatively non-selective in the types of contaminants removed. If desired, a second processing vessel 12 or bed of activated carbon or charcoal may be used, with a second sensor 13 placed downstream of the second vessel. This will allow the user time to change beds, for instance, if a dialysis treatment is needed after the sensor for the first bed has indicated that the effluent is above an acceptable limit for a particular contaminant, such as chloramine, β_2-microglobulin, or creatinine.

[0041] After one or two beds of activated carbon or charcoal, another vessel 14 for purification of the water or spent dialysate may be used, with a fourth sensor downstream of vessel 14. This vessel may include any desired purification substance, and may include a single adsorbent or more than one layer of different adsorbents. Vessel 14 may include a layer of urease and zirconium phosphate for converting urea into ammonium ions and then removing the ammonium by forming ammonium phosphate. Alternatively, or in addition, there may be a layer of zirconium oxide for removing phosphates or sulfates. Vessel 14 may also include an ion exchange resin suitable for exchanging ions of waste substance for ions that are desirable in dialysis solutions, such as calcium or magnesium ions, and also bicarbonate or acetate ions. The ion exchange resin may include filtering beds of carbon or charcoal before or after, or before and after, the resin itself. These supplemental beds also help to purify the final product, whether water for making dialysate or refreshed dialysate for service to the patient.

[0042] In the embodiment of Fig. 1, once the rejuvenated dialysis fluid leaves vessel 14, it is routed to the dialysate side of a dialyzer 16, used for hemodialysis. A dialyzer may be compared to a shell-and-tube heat exchanger, with the dialysate on the shell side and the blood of the patient running through the tube side counter-current to the dialysis fluid. In this embodiment, the dialysis fluid enters through inlet port 162 and leaves through dialysis fluid outlet port 164, where an additional MEMS sensor may sense and measure a variety of species within the exiting dialysis fluid. Once the dialysis fluid leaves through outlet port 164, it may be disposed of or may be sent again to be filtered and purified for another pass.

[0043] The other side of the dialyzer is connected to the patient's blood. Blood enters through the inlet header 166, flows through many hundred or thousand tiny porous tubes, and then leaves through the outlet header 168. The tiny porous tubes allow water and toxic substances in the blood, such as creatinine and urea, to flow from the blood side to the dialysis solution side. In addition, electrolytes and bicarbonate buffer may flow from the dialysis solution side to the blood side. The cleansed blood is then sent to an air detector or air trap before returning to the patient. An additional sensor 13 may be used to check the composition of the incoming blood for contaminants or other species near inlet header 166. An additional sensor 17 may be used to check for contaminants or other species near outlet header 168. Sensor 17 may be tuned for different species than sensor 13, for example, measuring pH, phosphates or urea, may be very important to determine the condition of the cleansed blood as it is returned to the patient.

[0044] It is understood that other cleansing and purifying devices may be used to purify incoming water or to cleanse spent dialysate fluid for reuse. These alternatives include filters, such as small particle filters and even ultrafilters, such as submicron filters, for removing bacterial or endotoxin contaminants. A second embodiment of a system 20 that advantageously uses MEMS sensors is depicted in Fig. 2. System 20 includes first and second purifying vessels 22, which may be small cartridges rather than gallon-size vessels. A MEMS sensor 23, as described above, senses and measures levels of the desired contaminants or species, as described above.

[0045] In system 20, there is also an 5 micron filter 24 followed by a reverse-osmosis filter 25, with a waste outlet 252 to drain. The reverse-osmosis filter 27 may be equipped with a MEMS sensor 23 that includes a temperature sensor, for proper operation of the reverse-osmosis filter. The MEMS sensor may also include one or more sensors that monitor specific ions or substances, such as ammonia or ammonium, total dissolved solids (TDS), Ca^{++}, Mg^{++}, Na^{+}, K^{+}, Cl^{-}, and so forth. After reverse-osmosis, the system may include a UV-light generator 26, wherein the light generated is cidal to bacteria and other harmful microorganisms. Additionally, the light may be used to dissociate chloride ion from nitrogen atoms in chloramine molecules, thus removing chloramines from the water or dialysis fluid. Ultraviolet light for these applications is typically UV-C, with a wavelength from about 180-290 nm. Lamps with a wavelength of about 185 nm or about 254 nm are preferred. Without being bound to any particular theory, it is believed that UV light penetrates the outer cell walls of microorganisms, where it passes through the cell body, reaches the DNA and alters the genetic material, and is thus cidal to the microorganism. Other desired wavelengths may be used.

[0046] An ultrafilter 27 is placed downstream of the UV light generator, followed by the dialyzer. Dialyzer 28 has a dialysis fluid inlet 282 and a dialysis fluid outlet 284, each of which may also be equipped with a MEMS sensor 23. Dialyzer 28 has a blood inlet header 286 and a blood outlet header 288 opposite the inlet header. The composition of the blood at the outlet may be sensed and monitored by a MEMS sensor 29 that is tuned, as above, for a particular component or property of the blood that is important, such as pH, phosphate, or urea.

[0047] The patient or a caregiver may take special note of the sensor readings from sensor 29 and from the last sensor 23 at the dialysis fluid outlet 284. Readings of the composition or the state of the blood is important to gauge whether the dialysis treatment is working and whether dialysis should be continued as is or whether some modification to the patient's prescription may be needed, whether dialysis fluid, duration or frequency of the treatment, and so forth. Of course, a comparable result may also be achieved by analyzing the composition of the spent dialysis fluid, since the waste that leaves the patient's body must either remain in the dialyzer or enter the dialysis fluid. The condition of the spent dialysis fluid is thus important. If the fluid has toxic components within certain high ranges, it may be expedient not to re-use any part of the fluid and to instead replace it with fresh dialysis fluid. If the range is more reasonable, a user or caregiver may decide to recycle and refresh at least part of the spent fluid, rather than sending it to drain. The composition of the spent dialysate also provides information on the efficacy of the dialysis therapy, albeit not as precisely as monitoring the patient's blood. While not depicted in Fig. 2, it is understood that there may be one or more metering pumps or flow meters to control the flow of dialysis fluid to and from dialyzer 28 or any of the process vessels or cartridges upstream of dialyser 28. It should be understood that many of the techniques and much of the equipment described above may be applicable to both hemodialysis and peritoneal dialysis applications.

[0048] Peritoneal Dialysis Applications

[0049] A system 30 designed for peritoneal dialysis is depicted in Fig. 3. System 30 accepts water or spent dialysate fluid from a source 31, such as a water tap or an outlet from a patient yielding spent dialysate. The system includes at least one vessel 32 for purifying the water or spent dialysate. In a manner similar to that described above for the other systems, first vessel 32 may include activated carbon or charcoal, or may include more than one layer for selectively or non-selectively adsorbing impurities or wastes from either water or from spent dialysis fluid. The system includes a MEMS sensor 33, as discussed above. In this system, the spent dialysis fluid or water is sent to a dialysis fluid preparation system 34, of which one embodiment is described below in Fig. 6.

[0050] In one example, the dialysis fluid preparation system may simply be a container with a known quantity of concentrate of known composition. For example, system 34 may be a flexible container with a known volume (liquid) or a known mass (solid) of a known concentrate for a single component dialysis solution, e.g., a dialysis lactate solution. A dialysis lactate solution typically contains electrolytes, lactate, and glucose. The water source 31 and necessary controls, such as a control valve in series with the water source of the vessel 32, are used to admit the proper amount of water to system 34, where the components are mixed and dissolved to form the desired solution. The amount of water or spent dialysate admitted may be measured, for example, by monitoring a positive-displacement pump for the fluid or water, or an accurate positive-displacement meter in series with the in-flow Alternatively, the amount of water or fluid can be controlled by weighing the mass admitted, e.g., by placing container 34 on a weigh scale, mass cell, or other device.

[0051] It is understood that dialysis solution preparation may include heating or pressurization, or both heating and pressurization, and hence at least one temperature sensor or temperature element and at least one pressure sensor or pressure element may be used in the dialysis fluid preparation. The resulting dialysis solution is checked at least once after its preparation by MEMS sensor 35.

[0052] In this embodiment, the fresh dialysis fluid is stored in at least one container 36 and its temperature is sensed and monitored by at least one temperature element or temperature sensor. When the dialysis fluid is needed, it is pumped via pump 37 through a filter 38, which routes the impurities to a drain and sends the purified filtrate to a peritoneal dialysis machine 39. The contents of the fluid may be checked by an additional MEMS sensor 35 at the input to the peritoneal dialysis machine. As is well known to those in peritoneal dialysis arts, the peritoneal dialysis machine may operate in one or more modes to route dialysis fluid to the peritoneum of the patient for a dwell period, or for a continuous flow-through mode, or other mode. The dialysis fluid may be routed to the patient P through the inlet lumen 391 of a two-lumen catheter, as shown. When the dwell time is reached, or if the flow-through is continuous, the dialysis fluid is routed from the patient through the outlet lumen 392 of a two lumen catheter. The make-up of the spent dialysis fluid returned from the patient may be checked by an additional MEMS sensor 33 for the parameters discussed above.

[0053] There are other embodiments that may advantageously use MEMS sensors for the preparation of dialysis solutions, including solutions for hemodialysis and for peritoneal dialysis. Another system directed more towards peritoneal dialysis is depicted in Fig. 4. System 40 includes a water source 41, which may be a municipal water source, or other water source, or may be a source of spent dialysate. A first filter or treatment vessel 42 is intended to remove impurities such as described above, the filter followed by a first MEMS sensor 43. In this embodiment, the purified water or dialysis fluid is then routed to a system 44 for producing dialysis fluid, one embodiment of which is depicted below in Fig. 6. As noted above, temperature and pressure elements may advantageously be used in preparation of dialysis fluid from concentrates. The composition of the resulting dialysis fluid is sensed and checked at a second MEMS sensor 43, as the dialysis fluid is routed to one or more storage containers 45, where the temperature may be monitored by one or more temperature elements to ensure safe storage.

[0054] When the dialysis fluid is needed, it is pumped by pump 46 to a peritoneal dialysis machine 47, and then to and from the patient by a catheter with two lumens, input lumen 471 and output lumen 472. In this embodiment, the spent dialysate is routed to a reverse osmosis filter 48, with the waste routed to a drain. In this embodiment, there are also first and second vessels or filters 49a, 49b, which may be used to remove contaminants, as described above, or may be used with ion exchange resins to remove contaminants and add desirable components. An electro-deionization process unit may also be used to remove ionic contaminants. An ultrafilter 49c is used to filter the solution and to route waste to the drain. Other embodiments may also be used. MEMS sensors 13, 29 may be used as indicated, such as after the dialysate is returned from the patient, and after the treatment vessels or filters, and the ultrafilter. MEMS sensors 13, 29 and 43 may be the same or may be tuned or capable of sensing different species, different ions, or different substances, as desired and as explained above.

[0055] Fig. 5 depicts a home hemodialysis system 50 with a water or dialysate recycling system 52 as described above. System 50 includes an incoming city water tap 51 to a water or dialysate recycling system 52, which also includes a drain 59 for waste water. Fresh dialysis fluid is sent through tubing 53 to a storage container S adjacent hemodialysis machine H with dialyzer 54. As is well known to those with skill in dialysis arts, the patient P has a vascular access site 55 for an arterial needle A_N and a venous needle V_N. The patient P is connected to the hemodialysis machine H via tubing 56. Spent dialysis fluid is returned to the recycling system 52 via tubing 57.

[0056] The MEMS sensors 13 described above may be used at several points in system 50. One or more sensors 13 may be deployed within the dialysate recycling system 52, for instance, to check on the incoming water from source 51 or the returned dialysate from tubing 57. Depending on the water or dialysis quality, a decision is made whether to send the returned dialysate to the drain 59 or to reuse the dialysate by cleaning, filtering, and replenishing the dialysate. A second MEMS sensor may be used to monitor the quality and composition of the dialysate sent to, or stored in, dialysis fluid storage container S. As a third example, another MEMS sensor 13 may be deployed within hemodialysis machine H to monitor the composition of the returned dialysate or species within the patient's blood. As discussed above, this sensor can help the patient or the caregiver determine whether the dialysis process is changing the appropriate parameters of the blood or the dialysis fluid, thus giving an indication of whether the therapy is working as effectively as desired.

[0057] A system for preparing dialysis fluid from concentrate using make-up water or cleansed dialysis fluid is depicted in Fig. 6. One system 60 for producing dialysate is depicted in Fig. 6. System 60 receives water from water source 61 and passes the water through one or more purification vessels 61a, 61b, as described above. MEMS sensors 13 are used to sense and report the sensed quantities of impurities or other components of the water as it flows from the first and second vessels. The water passes through control valve 61c and is heated, if desired, using in-line heater 61d. The heated water flows through lines 61e, 61f to A and B concentrate pumps 62, 63, for pumping concentrate respectively from reservoirs 62a, 63a. The pumps are positive displacement pumps, such as gear pumps, vane pumps, or piston pumps, to pump precise amounts of A or B concentrate. One embodiment uses small ceramic piston pumps, available from Fluid Metering, Inc., Long Island, New York, U.S.A. Other pumps may be used. Other embodiments use proportioning or ratiometric pumps, whose flow of A or B concentrate may be set, and which thereafter pump A and B concentrate in a ratio proportional to the water metered out by the pumps.

[0058] Other than volumetric ratio, the pumps may be controlled by a feedback loop that includes a MEMS conductivity monitor. The concentrate pump is sped up if the conductivity at the conductivity sensor 64e is too low or is slowed if the conductivity at the probe is too high. Since the characteristic volumes of the concentrate pumps are known, there are limits on the amount of cycling needed to produce a stable dialysis solution. A controller for the system keeps track of the amounts of concentrate pumped, and also keeps track of the amount of incoming water and A concentrate that is pumped, thus keeping precisely proportioned flows.

[0059] In this embodiment, A concentrate pump 62 pumps A concentrate to mixing vessel 64 through line 62a, the vessel not filled but retaining an air gap at its top, while the correct ratio of water also flows to the vessel through line 61f. After the water and the A concentrate are mixed, the mixture is deaerated by spraying using precision metering pump 64a, nozzle 64c, and air trap 64b. Other embodiments such as a simple restriction creating a starved intake to pump 64a, could be substituted for the sprayer to remove the air from the solution. The mixture is monitored by temperature sensor 64d and MEMS conductivity sensor 64e. Vessel 64 includes a level sensor L. The deaerated acid mixture is then sent to the B mix chamber 65, where B concentrate from the B concentrate pump through line 63b is added, in this case in-line.

[0060] The B mix chamber 65 is equipped with a second MEMS sensor 66 to monitor the composition of the finished dialysis solution. This sensor can check the conductivity of the finished solution, and may also check other parameters or qualities of the solution. For example, a WaterPoint™ 870 Sensor, from Sensicore, Inc., may be used to check several parameters, including conductivity, pH, temperature, total dissolved solids (TDS, based on sodium ions), calcium, magnesium, total hardness, carbonate alkalinity, and other parameters. Many of these are very useful to a patient or to a caregiver preparing dialysis solution, since these measurements are directly related to the quality and make-up of the dialysis solution. As a check, this MEMS sensor can also sense and report general water quality, such as the concentrations of total and free ammonia (related to urea in the dialysate), chlorine, and chloramines. Other embodiments may use more than two concentrates, and the system may be changed to use a separate pump to pull the proper amount from each container of concentrate. Any of these systems may thus prepare a customized solution or prescription for each patient. The MEMS sensors may be used to monitor and control the process, as well as the final product, in any of these embodiments.

[0061] The dialysis solution is then pumped by supply pump 67 through filter 67a, to remove particles larger than 150 micrometers. Control valve 68 controls the flow of dialysis solution from system 60. If the correct level of continuity has not been achieved, the freshly-prepared dialysis solution may be recycled as desired through the filter and the mixing chamber, as shown, until the proper mixing and purity has been achieved. The dialysis solution can then be pumped through a final filter, endotoxin filter 69, and checked by final MEMS sensor 13 after the filter, on its way to a storage container or for use. The endotoxin filter is intended to remove bacteria, such as *E. coli* and *P. aeruginosa*, as well as endotoxins. This filter could be an ultrafilter such as those made by Medica SRL, Mirandola, Italy, or from Nipro Corp., Osaka, Japan.

[0062] The process described above is only one method for preparing a dialysis solution. Other dialysis solutions may be used, including those requiring an osmotic agent, such as a small amount of dextrose, glucose, sodium or potassium polyacrylate, or mixtures of these, or other components. These solutions are prepared in generally similar ways, some embodiments using powders, some using concentrates, some using solutions. Any such embodiments, including MEMS sensors, are intended to fall within the scope of the present invention. Embodiments using powders may require a conventional stirred-tank vessel, or vessel suitable for mixing powders using a stirrer or using flow, often turbulent flow, to insure a good mixing. For home use, this may be any suitable mixer capable of maintaining and preserving sterility, when used with the MEMS sensors described above.

[0063] In addition to the MEMS sensors described above, other MEMS sensors are presently in development and testing. These include MEMS sensors that are capable of sensing and quantifying organic materials. These sensors work in the same manner as the other MEMS sensors, but operate by detecting analytes that are associated with an organic substance rather than an inorganic ion, such as ammonium or chlorine. These MEMS sensors are, or will be, capable of sensing total organic carbon (TOC), and also specific substances, such as urea, creatinine, β_2-microglobulin, heparin, and glucose or other sugar or osmotic agent in the dialysis fluid. MEMS sensors could also be used to detect levels of bacteria, endotoxins, and viruses in the water or spent dialysis fluid. In addition, MEMS sensors may be used to detect analytes of interest in the blood, such as proteins in general, including albumin, free hemoglobin and hematocrit.

[0064] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present subject matter and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A system (20, 40, 60) for preparing dialysis fluid, comprising:

a first purification vessel (49a, 61a) comprising a purification medium for water, the medium selected from the group consisting of a charcoal, an activated carbon, and a combination thereof;

a device for pumping or measuring the water;

a heater (61d) for heating the water;

a mixing chamber (64, 65) configured for receiving the water from the device and for mixing the water with a concentrate to form a fresh dialysis solution;

a filter (24, 67a, 69) for filtering the fresh dialysis solution; and

a microelectromechanical systems (MEMS) sensor (13) placed in fluid communication with an output from a vessel selected from the group consisting of the first purification vessel (49a, 61a), the device, the heater (61d), the mixing chamber (64, 65) and the filter (24, 67a, 69).

2. The system (60) according to Claim 1, wherein the MEMS sensor (13) comprises an ion-selective sensor suitable for sensing two or more of an ion selected from the group consisting of ammonium, sodium, calcium, magnesium, potassium, carbonate, bicarbonate, hydrogen or hydronium, hydroxyl, chloramine and chloride.

3. The system (60) according to Claims 1 or 2, wherein the MEMS sensor (13) comprises an ion-selective sensor suitable for sensing at least two parameters selected from the group consisting of pH, calcium, total hardness, carbon dioxide and ammonia.

4. The system (60) according to any of the preceding claims, wherein the MEMS sensor (13) is an amperometric sensor suitable for sensing chlorine and chloramines.

5. The system (60) according to any of the preceding claims, wherein the MEMS sensor (13) further comprises a power source (132) and a radio (138) for remote communications.

6. The system (60) according to any of the preceding claims, wherein the water comprises fresh water or a spent dialysis solution.

7. The system (40, 60) according to any of the preceding claims, further comprising a second purification vessel (49b, 61b) placed downstream of the first purification vessel (49a, 61a), the second purification vessel (49b, 61b) further comprising a purification medium selected from the group consisting of a non-selective purification medium, a selective purification medium, an electro-deionization cartridge and an ion-exchange resin.

8. The system (60) according to any of the preceding claims, further comprising a water pump in operable communication with the first purification vessel or the heater.

9. The system (60) according to any of the preceding claims, wherein the MEMS sensor (13) is suitable for measuring a plurality of substances in an aqueous solution or mixture.

10. The system (20, 40, 60) according to Claim 1, further comprising:

first and second pumps (62, 63) for pumping and metering first and second concentrates;

wherein the first purification vessel (61a) is a first purification cartridge (61a); the heater (61d) is configured for heating the water received from the first purification cartridge (61a); the mixing chamber (65) is configured for receiving the first and second concentrates from the first and second pumps (62, 63) and for mixing the first and second concentrates with the water to form a fresh dialysis solution; and the MEMS sensor (13) is suitable for sensing at least two substances in a stream selected from the group consisting of water from the first purification cartridge (61a), the fresh dialysis solution and the filtered fresh dialysis solution.

11. The system (60) according to Claim 10, wherein the MEMS sensor (13) further comprises a radio transmitter (138) for communicating with a controller of a dialysis machine.

12. The system (20, 60) according to Claims 10 or 11, further comprising an ultrafilter (27) for removing bacteria and microorganisms from the water or from the dialysis solution.

13. The system (20, 60) according to any one of Claims 10 to 12, further comprising a reverse osmosis filter (25) for cleaning the water or the dialysis solution.

14. The system (20, 60) according to Claim 12, further comprising an ultraviolet light source (26) for irradiating the water or dialysis solution, the ultraviolet light source placed upstream of the filter ultrafilter (27).

15 The system (60) according to any one of Claims 10 to 14, further comprising an air trap (64b) for removing air from the fresh dialysis solution.

16. The system (60) according to any one of Claims 10 to 15, wherein the water comprises fresh water or a spent dialysis solution.

17. A dialysis solution preparation system (60) comprising a controller configured to:

furnish a supply of water;

purify the water in at least one pass through a purification medium;

heat the water;

add the water to at least one dialysis concentrate to form a dialysis solution;

filter the dialysis solution; and

sense at least two characteristics of the water with a first microelectromechanical systems (MEMS) sensor (13).

18. The dialysis solution preparation system (60) according to Claim 17, wherein the first MEMS sensor (13) senses using an ion-selective membrane or an amperometric cell.

19. The dialysis solution preparation system (60) according to Claims 17 or 18, which is further configured to sense a characteristic of the dialysis solution with a second MEMS sensor (13).

20. The dialysis solution preparation system (60) according to any one of Claims 17 to 19, wherein the purification medium is selected from the group consisting of activated carbon and charcoal.

21. The dialysis solution preparation system (60) according to any one of Claims 17 to 20, wherein the dialysis solution formed comprises make-up for a spent dialysis solution, and wherein the dialysis solution preparation system further configured to sense at least two characteristics of the spent dialysis solution with a third MEMS sensor (66).

22. The dialysis solution preparation system (60) according to any one of Claims 17 to 21, wherein the water comprises fresh water or a purified spent dialysis solution.

23. A dialysis solution preparation system (10, 60) comprising a controller configured to:

furnish a supply of water and spent dialysate;

purify the water and the spent dialysate in at least one pass through a purification medium, wherein the purification medium may be in one vessel (12, 61a) or more than vessel (12, 14, 61a, 61b);

heat the water;

add the water and at least one dialysis concentrate to form a dialysis solution;

filter the formed dialysis solution; and

sense at least two characteristics of a stream selected from the group consisting of the water, the formed dialysis solution and the spent dialysis solution with a microelectromechanical systems (MEMS) sensor (13).

24. The dialysis solution preparation system (10, 60) according to Claim 23, which is further configured to send a signal from the MEMS sensor (13) to a remote controller.

25. The dialysis solution preparation system (10, 60) according to Claims 23 or 24, which is further configured to perform peritoneal dialysis or hemodialysis.

26. The dialysis solution preparation system (10, 60) according to any one of Claims 23 to 25, which is further configured to remove air from the formed dialysis solution.

27. A dialysis solution purification system (10) comprising a controller configured to:

furnish a supply of spent dialysate;

purify the spent dialysate in at least one pass through a purification medium in a vessel (12) to form a purified dialysate;

filter the spent dialysate to form a filtered dialysate; and

sense at least two characteristics of a stream selected from the group consisting of the spent dialysate, the purified dialysate and the filtered dialysate with a microelectromechanical systems (MEMS) sensor (13).

28. The dialysis solution purification system (10) according to Claim 27, wherein the dialysis solution purification system (10) is a portable dialysis system in which the vessel (12) is a cartridge, the portable dialysis system configured to conduct dialysis while being worn.

29. The dialysis solution purification system (10) according to Claims 27 or 28, wherein the vessel is configured to adsorb impurities from the spent dialysate and release desirable ions into the spent dialysate as the spent dialysate passes through the vessel (12).

30. The dialysis solution purification system (10) according to any one of Claims 27 to 29, which is further configured to make fresh dialysate from water and concentrate and add the fresh dialysate to the filtered dialysate.

31. A system (10, 40) for performing dialysis, the system comprising a controller configured to:

provide a dialysis machine (47) and a supply (45) of dialysis fluid;

sense and determine a composition of the dialysis fluid with a first MEMS sensor (43) configured to sense and detect at least two ions in the dialysis fluid;

perform dialysis on a patient using the dialysis fluid;

sense and determine a composition of the dialysis fluid after dialysis is performed with a second MEMS sensor (13);

purify the dialysis fluid after dialysis is performed;

sense and determine a composition of the dialysis fluid after the dialysis fluid is purified with a third MEMS sensor (29); and

reuse the dialysis fluid if the composition of the purified dialysis fluid is suitable for dialysis.

32. The system (10, 40) according to Claim 31, which is configured to sense and determine using a MEMS sensor (13, 43, 29), the sensor comprising an ion-selective sensor suitable for sensing two ions selected from the group consisting of ammonium, sodium, calcium, magnesium, potassium, carbonate, bicarbonate, hydrogen or hydronium, hydroxyl, chloramine and chloride.

33. The system (10, 40) according to Claims 31 or 32, wherein the MEMS sensor (13, 43, 29) comprises an ion-selective sensor suitable for sensing at least two parameters selected from the group consisting of pH, calcium, total hardness, carbon dioxide and ammonia.

34. The system (10, 40) according to any one of Claims 31 to 33, wherein the MEMS sensor (13, 43, 29) is an amperometric sensor suitable for sensing chlorine or chloramines.

35. The system (10, 40) according to any one of Claims 31 to 34, the system configured to send the compositions to a controller of the dialysis machine.

36. The system (10, 40) according to any one of Claims 31 to 35, wherein the dialysis is peritoneal dialysis or hemodialysis.

37. The system (10) according to any one of Claims 31 to 36, wherein the dialysis is hemodialysis and the system is further configured to sense and determine a composition of blood of a patient with a fourth MEMS sensor (13).

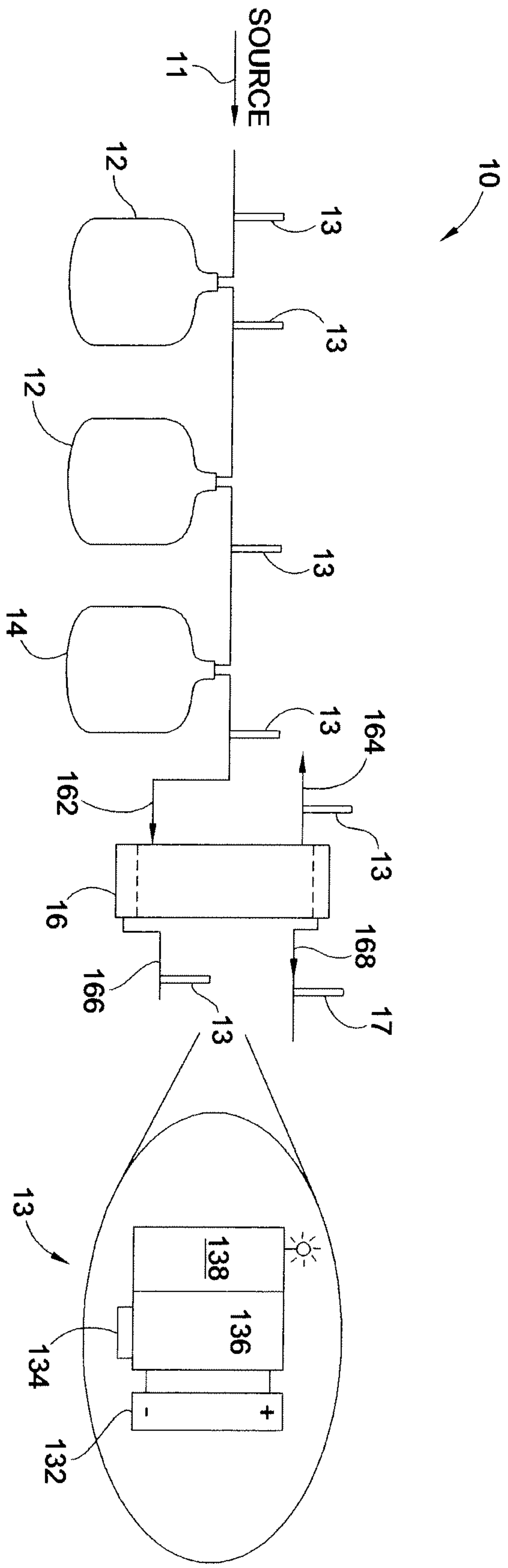
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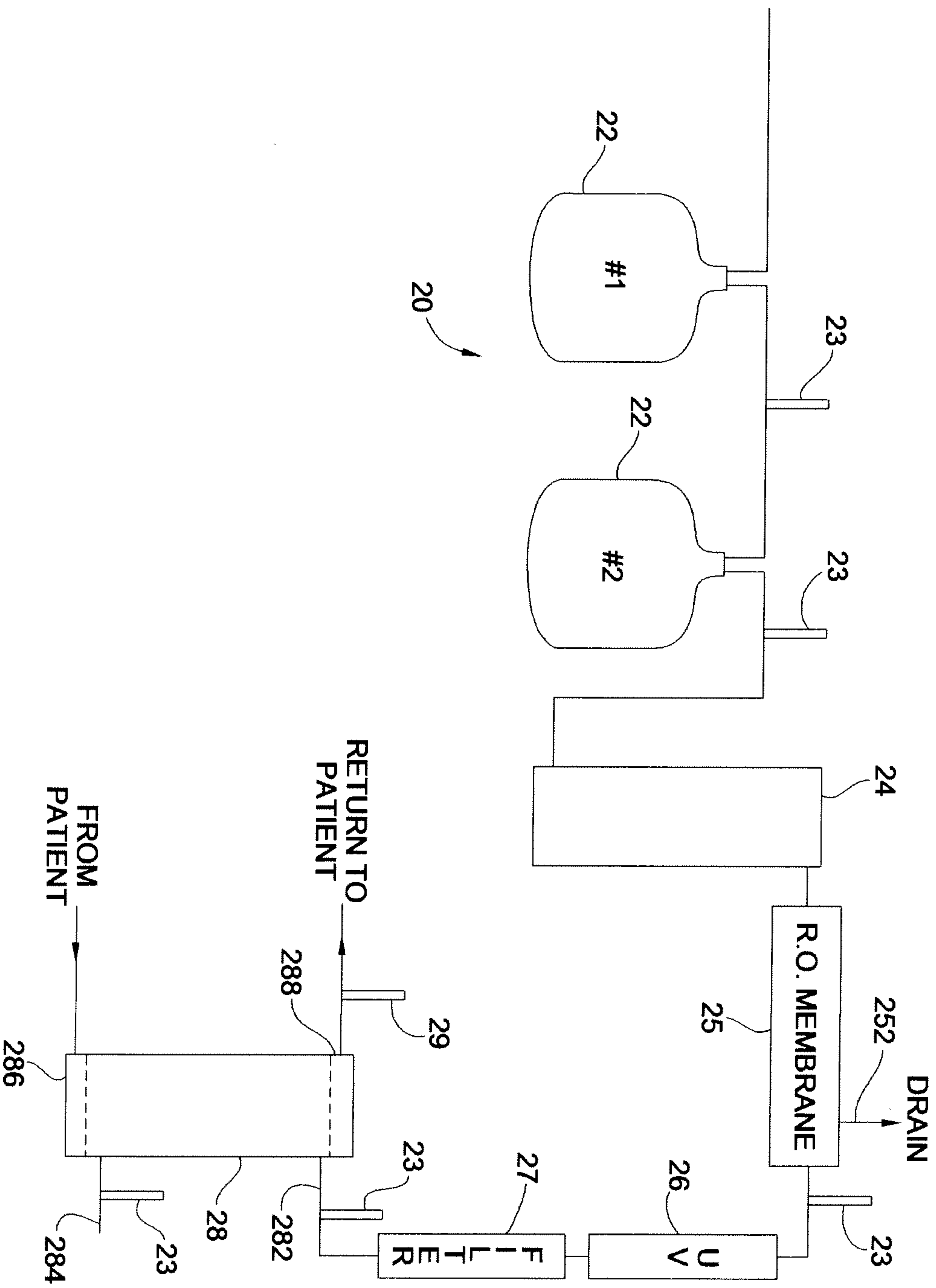
FIG. 1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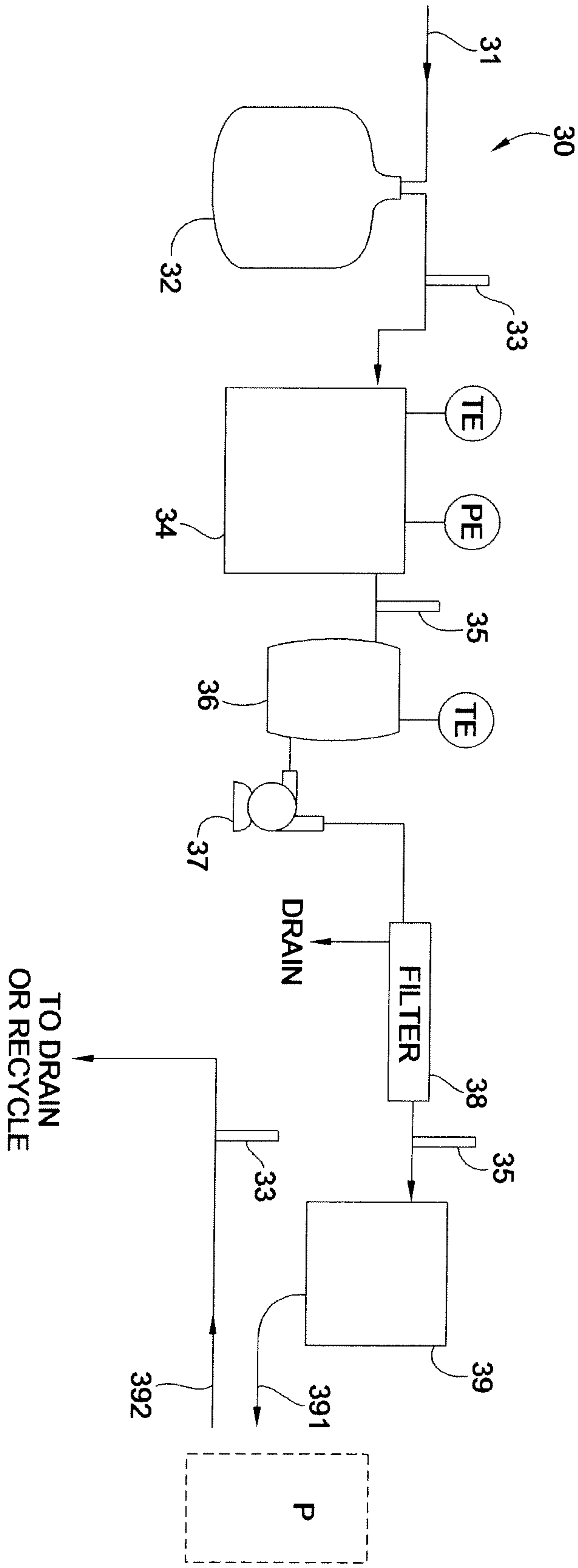
R.O. MEMBRANE
25
252
DRAIN
23
U V
26
F I L T E R
27
23
282
28
23
284
286
288
29
RETURN TO PATIENT
FROM PATIENT

FIG. 2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30
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TO DRAIN
OR RECYCLE
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392
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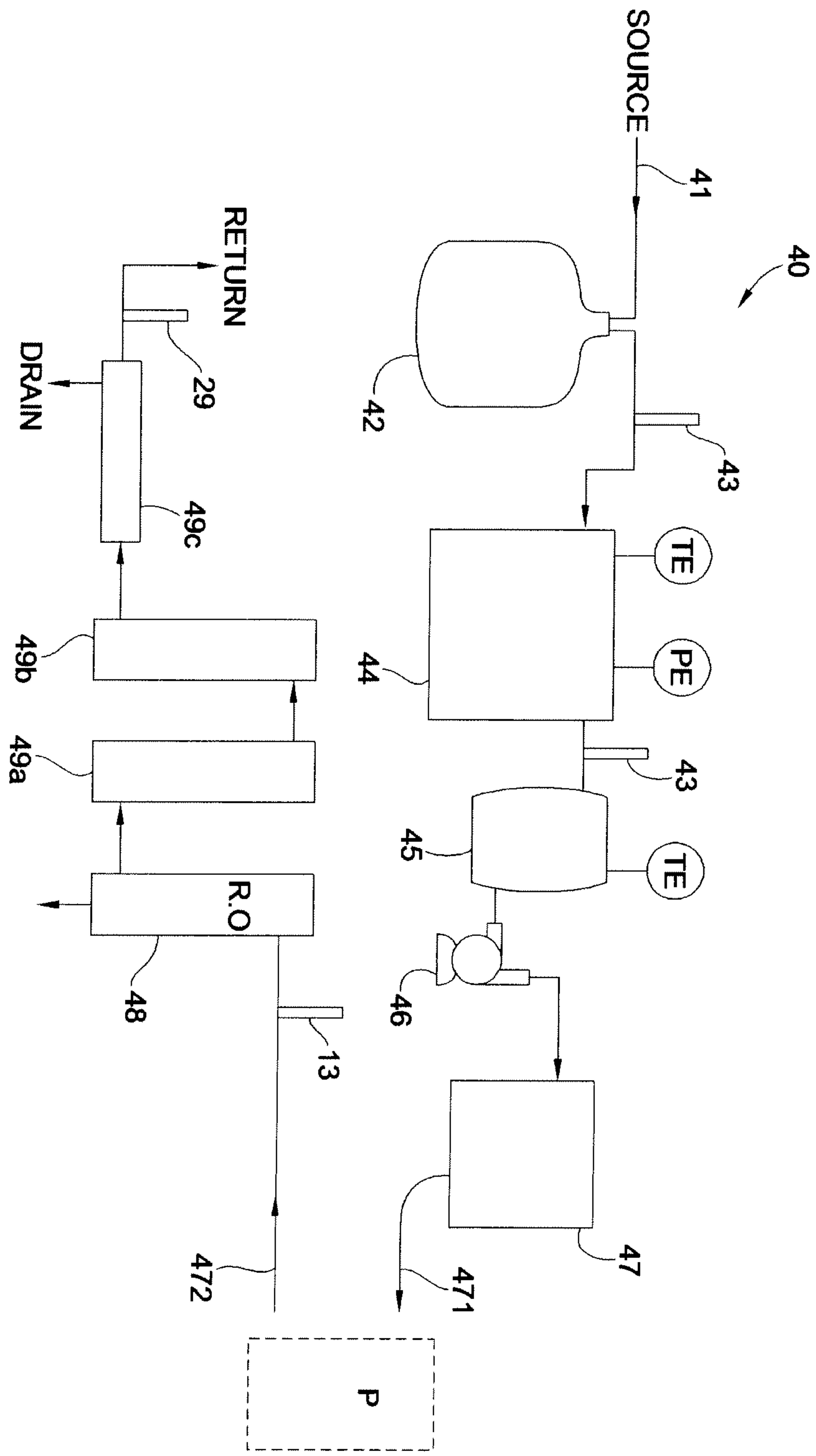
FIG. 3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44
PE
43
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R.O
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49b
49c
DRAIN
29
RETURN

FIG. 4

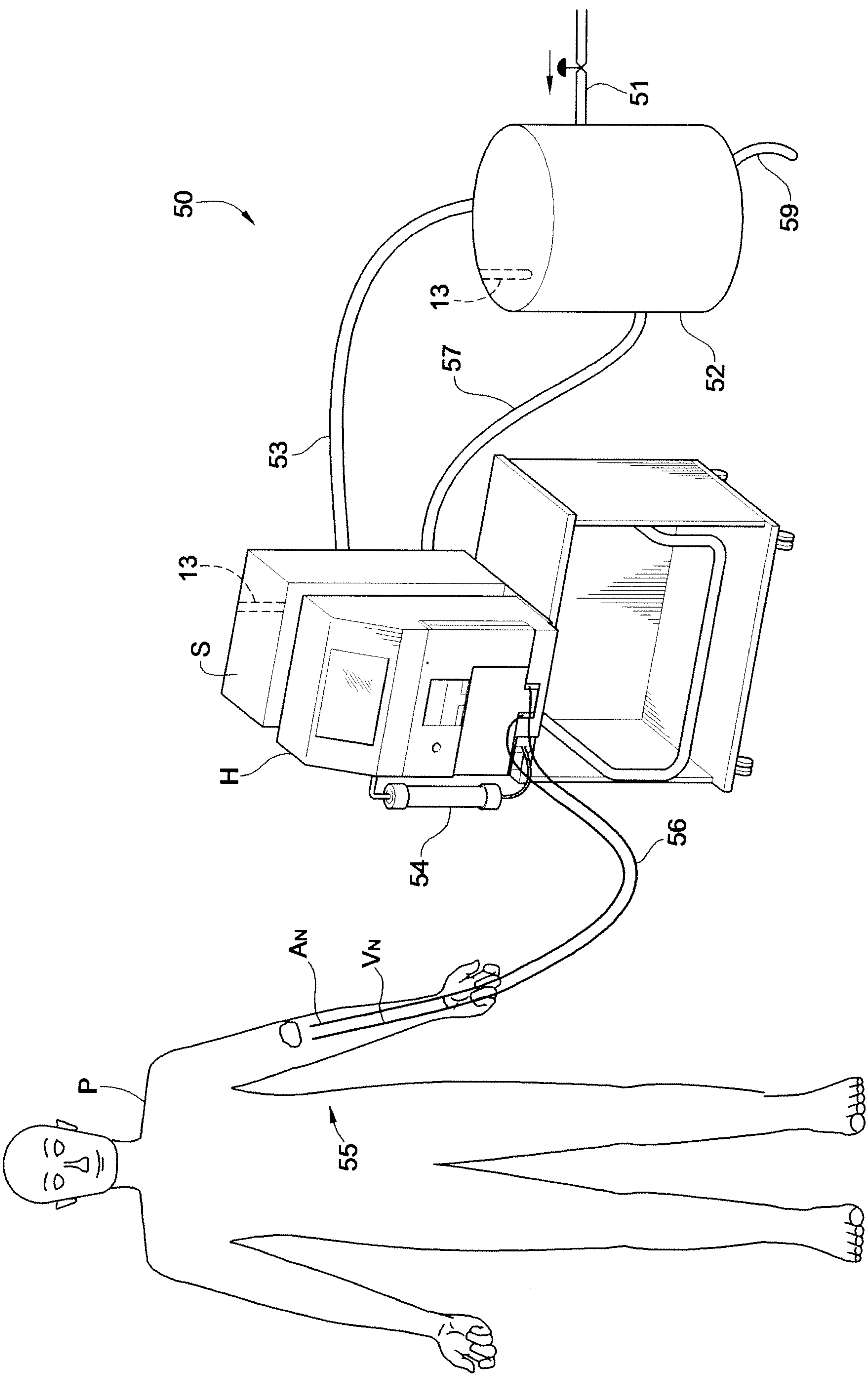

FIG. 5

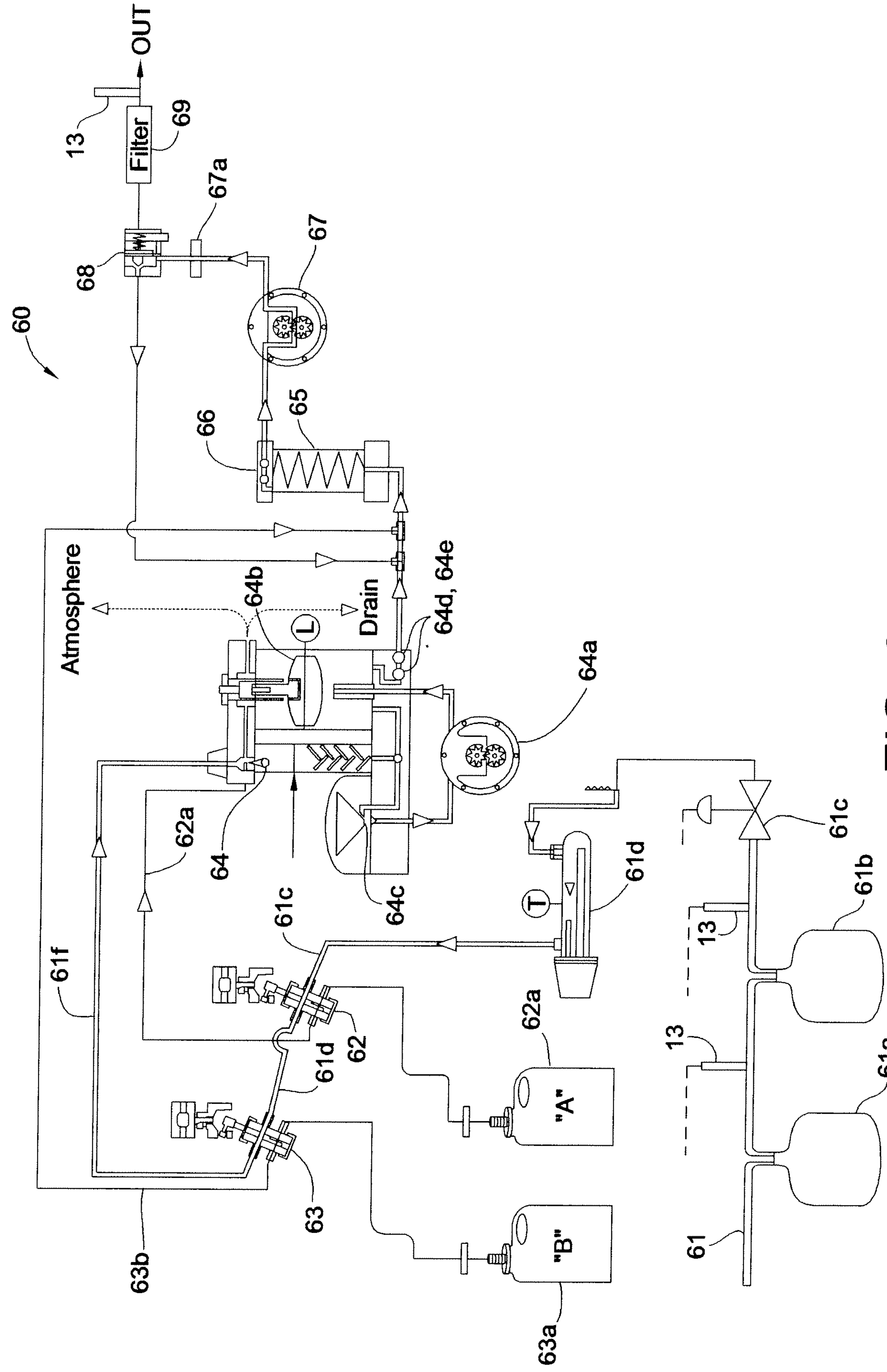
OUT
13
Filter
69
67a
68
67
60
66
65
Atmosphere
64b
Drain
64d, 64e
64a
64
62a
64c
61c
61d
T
61f
62
61d
62a
"A"
63
63b
"B"
63a
61c
61b
13
13
61a
61

FIG. 6


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SOURCE
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164
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168
17
12
12
14
162
16
166
13
138
136
+
-
13
134
132

FIG. 1