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Peritoneal dialysis system having carbon dioxide injection to inhibit/remove calcium carbonate

Abstract

A peritoneal dialysis ("PD") system includes a PD fluid pump; a disinfection loop including the PD fluid pump, the disinfection loop including PD fluid used for disinfecting the disinfection loop; and a carbon dioxide (CO.sub.2), source positioned and arranged to supply CO.sub.2 to the disinfection loop to inhibit and/or remove the production of calcium carbonate (CaCO.sub.3) during a disinfection sequence. The PD system includes a control unit configured to open a valve to allow CO.sub.2 to be supplied, wherein the control unit may use a lookup table or algorithm to determine the desired pressure or pressure increase.

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Background/Summary

PRIORITY CLAIM (1) This application claims priority to and the benefit of U.S. Provisional Patent Application 63/293,383, filed Dec. 23, 2021, entitled “PERITONEAL DIALYSIS SYSTEM HAVING CARBON DIOXIDE INJECTION TO INHIBIT/REMOVE CALCIUM CARBONATE”, the entire contents of which are incorporated herein by reference and relied upon.

BACKGROUND
(1) The present disclosure relates generally to medical fluid treatments and in particular to dialysis fluid treatments.
(2) Due to various causes, a person's renal system can fail. Renal failure produces several physiological derangements. It is no longer possible to balance water and minerals or to excrete

daily metabolic load. Toxic end products of metabolism, such as, urea, creatinine, uric acid and others, may accumulate in a patient's blood and tissue.

(3) Reduced kidney function and, above all, kidney failure is treated with dialysis. Dialysis removes waste, toxins and excess water from the body that normal functioning kidneys would otherwise remove. Dialysis treatment for replacement of kidney functions is critical to many people because the treatment is lifesaving.

(4) One type of kidney failure therapy is Hemodialysis ("HD"), which in general uses diffusion to remove waste products from a patient's blood. A diffusive gradient occurs across the semi-permeable dialyzer between the blood and an electrolyte solution called dialysate or dialysis fluid to cause diffusion.

(5) Hemofiltration ("HF") is an alternative renal replacement therapy that relies on a convective transport of toxins from the patient's blood. HF is accomplished by adding substitution or replacement fluid to the extracorporeal circuit during treatment. The 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.

(6) Hemodiafiltration ("HDF") is a treatment modality that combines convective and diffusive clearances. HDF uses dialysis fluid flowing through a dialyzer, similar to standard hemodialysis, to provide diffusive clearance. In addition, substitution solution is provided directly to the extracorporeal circuit, providing convective clearance.

(7) Most HD, HF, and HDF treatments occur in centers. A trend towards home hemodialysis ("HHD") exists today in part because HHD can be performed daily, offering therapeutic benefits over in-center hemodialysis treatments, which occur typically bi- or tri-weekly. Studies have shown that more frequent treatments remove more toxins and waste products and render less interdialytic fluid overload than a patient receiving less frequent but perhaps longer treatments. A patient receiving more frequent treatments does not experience as much of a down cycle (swings in fluids and toxins) as does an in-center patient, who has built-up two or three days' worth of toxins prior to a treatment. In certain areas, the closest dialysis center can be many miles from the patient's home, causing door-to-door treatment time to consume a large portion of the day. Treatments in centers close to the patient's home may also consume a large portion of the patient's day. HHD can take place overnight or during the day while the patient relaxes, works or is otherwise productive.

(8) Another type of kidney failure therapy is peritoneal dialysis ("PD"), which infuses a dialysis solution, also called dialysis fluid, into a patient's peritoneal chamber via a catheter. The dialysis fluid is in contact with the peritoneal membrane in the patient's peritoneal chamber. Waste, toxins and excess water pass from the patient's bloodstream, through the capillaries in the peritoneal membrane, and into the dialysis fluid due to diffusion and osmosis, i.e., an osmotic gradient occurs across the membrane. An osmotic agent in the PD dialysis fluid provides the osmotic gradient. Used or spent dialysis fluid is drained from the patient, removing waste, toxins and excess water from the patient. This cycle is repeated, e.g., multiple times.

(9) There are various types of peritoneal dialysis therapies, including continuous ambulatory peritoneal dialysis ("CAPD"), automated peritoneal dialysis ("APD"), tidal flow dialysis and continuous flow peritoneal dialysis ("CFPD"). CAPD is a manual dialysis treatment. Here, the patient manually connects an implanted catheter to a drain to allow used or spent dialysis fluid to drain from the peritoneal chamber. The patient then switches fluid communication so that the patient catheter communicates with a bag of fresh dialysis fluid to infuse the fresh dialysis fluid through the catheter and into the patient. The patient disconnects the catheter from the fresh dialysis fluid bag and allows the dialysis fluid to dwell within the peritoneal chamber, 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. Manual peritoneal dialysis requires a significant amount of time and effort from the patient, leaving ample room for improvement.

(10) 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 dialysis fluid and to a fluid drain. APD machines pump fresh dialysis fluid from a dialysis fluid source, through the catheter and into the patient's peritoneal chamber. APD machines also allow for the dialysis fluid to dwell within the chamber and for the transfer of waste, toxins and excess water to take place. The source may include multiple liters of dialysis fluid including several solution bags.

(11) APD machines pump used or spent dialysate from the patient's peritoneal cavity, though the catheter, to drain. As with the manual process, several drain, fill and dwell cycles occur during dialysis. A “last fill” may occur at the end of the APD treatment. The last fill fluid may remain in the peritoneal chamber of the patient until the start of the next treatment, or may be manually emptied at some point during the day.

(12) In any of the above modalities using an automated machine, the automated machine operates typically with a disposable set, which is discarded after a single use. Depending on the complexity of the disposable set, the cost of using one set per day may become significant. Also, daily disposables require space for storage, which can become a nuisance for home owners and businesses. Moreover, daily disposable replacement requires daily setup time and effort by the patient or caregiver at home or at a clinic.

(13) For each of the above reasons, it is desirable to provide an APD machine that reduces disposable waste. In doing so, to the extent that deposits of calcium carbonate are created via disinfection, such deposits present a problem that may increase over time. A need exists accordingly for a PD system having a way to inhibit the production of calcium carbonate and/or to remove same if produced.

SUMMARY

(14) Known automated peritoneal dialysis (“PD”) systems typically include a machine or cycler that accepts and actuates a pumping cassette having a hard part and a soft part that is deformable for performing pumping and valving operations. The hard part is attached to tubes that extend to various bags. The disposable cassette and associated tubes and bags can be cumbersome for a patient at home to load for treatment. The overall amount of disposable items may also lead to multiple setup procedures requiring input from the patient, which can expose room for error.

(15) The APD system and associated methodology of the present disclosure, on the other hand, convert much of the fluid carrying portions of its PD system into reusable components, which are disinfected after treatment. Fluid lines within the machine or cycler are reused. Disposable items remaining may include a drain line leading to a drain bag or house drain and one or more PD fluid container or bag, such as different dextrose or glucose level PD fluid containers and a last bag container, e.g., containing icodextrine. In an embodiment, a disposable filter is placed at the distal end of the patient line to provide a final stage of PD fluid filtration prior to delivery to the patient.

(16) The APD system of the present disclosure incudes an APD cycler having a housing. At least one and perhaps three or more reusable PD fluid lines extend from the housing. When not connected to PD fluid containers or bags, the reusable PD fluid lines can be connected to disinfection connectors supported and provided by the housing. The reusable PD fluid lines may for example extend from a front of the housing and connect to disinfection connectors also provided at the front of the housing for ready access to the PD fluid lines. The reusable PD fluid lines may be color coded and/or keyed to match a colored or keyed connector of the PD fluid container or bag. The containers or bags may hold different dextrose or glucose level PD fluids, such as 1.36% glucose PD fluid, 2.27% glucose PD fluid, 3.86% glucose PD fluid and/or a last bag of a different formulation of PD fluid, such as icodextrin. The PD fluids may contain a bicarbonate component.

(17) Inside the housing, reusable tubing runs from each of the reusable PD fluid lines, through a PD fluid supply valve for each PD fluid line, to a PD fluid inline heater. In an embodiment, each of the valves of the APD cycler is an electrically actuated valve having a reusable valve body that occludes (e.g., when unpowered) or allows (e.g., when powered) PD fluid to flow through the body. The PD fluid inline heater is also electrically actuated in one embodiment and is, for example, a resistive heater having a reusable heater body that accepts PD fluid for heating. The inline heater in an embodiment is able to heat PD fluid from room temperature to body temperature, e.g., 37° C., at a flowrate of at least 200 milliliters ("ml")/minute. A temperature sensor is located adjacent to the heater, e.g., downstream from the heater to provide feedback for temperature control.

(18) Reusable tubing runs from the outlet of the PD fluid inline heater to an airtrap in one embodiment. Any of the tubing inside the housing of the cycler may be metal, e.g., stainless steel, or plastic, e.g., polyvinylchloride ("PVC") or a non-PVC material, such as polyethylene ("PE"), polyurethane ("PU") or polycarbonate ("PC"). In an embodiment, one or more level sensor is located adjacent to the airtrap so that a desired level or range of levels of PD fluid is/are maintained in the airtrap. A fluid line valve is located along a reusable fluid line downstream from the airtrap in an embodiment. At least one gas line valve located along at least one gas line may also be provided. The airtrap may be closed upstream by PD fluid supply valves to drain the airtrap when dictated by the output of the level sensors.

(19) A reusable PD fluid pump is located within the cycler housing and includes a reusable pump body that accepts PD fluid for pumping. That is, the pump does not require the PD fluid to flow within a disposable item, such as a tube or cassette. The PD fluid pump may be an electrically operated piston pump, which is inherently accurate so that a separate PD fluid volume measurement apparatus, such as a flowmeter, balance chamber or an apparatus using the ideal gas law, is not needed. The PD fluid pump may alternatively be an electrically operated, gear or centrifugal pump, which may operate with a separate PD fluid volume measurement apparatus.

(20) The PD fluid pump is controllable to pump to and from the patient at or below a pressure limit by controlling a level of current to the PD fluid pump. A positive patient pressure limit may for example be one to five psig (e.g., two psig (14 kPa)). A negative patient pressure limit may for example be −1.0 psig to −3.0 psig (e.g., −1.3 psig (−9 kPa)). The PD fluid pump is bidirectional and continuous in one embodiment, such that a single pump may be provided.

(21) The APD cycler of the APD system of the present disclosure includes a control unit having one or more processor and one or more memory that receives signals or outputs from pressure sensors, temperature sensors and possibly a conductivity sensor and that processes the signals or outputs as feedback. The control unit uses pressure feedback to control the PD fluid pump to run at safe patient pressure limits during treatment and safe system limits during disinfection. The control unit uses temperature feedback to control the PD fluid heater to heat the fresh PD fluid to, e.g., body temperature.

(22) The control unit also opens and closes the PD fluid valves in combination with the PD fluid pump and heater to run a priming sequence, a patient fill sequence, a patient drain sequence, and a disinfection sequence after a PD treatment, wherein each of the at least one reusable PD fluid supply line is connected to one of the at least one disinfection connectors, and wherein the reusable patient line is connected to the reusable patient line connector. The disinfection sequence readies the APD cycler for the next treatment. In an embodiment, unused PD fluid is heated after the final drain and is used for disinfection.

(23) The use of unused PD fluid containing bicarbonate as a disinfection fluid can lead to the formation of calcium carbonate in the disinfected flowpaths and flow components of the PD machine or cycler (forming a disinfection loop). The present system accordingly includes a source carbon dioxide (CO.sub.2), which is injected during disinfection to prevent and/or to remove the formation of calcium carbonate. The CO.sub.2 source is placed in fluid communication via a CO.sub.2 line controlled by a CO.sub.2 valve in one embodiment.

(24) The control unit is programmed to run a sequence that in one embodiment relies on a table stored in one or more memory of the control unit. The table in one implementation sets a pressure increase due to the CO.sub.2 injection or an overall pressure to be achieved by the CO.sub.2 injection as a function of at least one of solution bicarbonate composition and/or disinfection temperature setting. Generally, the more bicarbonate present in the PD fluid, the higher the pressure needed due to the injected CO.sub.2 gas. And generally, the higher the disinfection PD fluid temperature, the higher the pressure needed due to the injected CO.sub.2 gas. Experiments and/or calculations are performed varying bicarbonate levels against varied disinfection temperatures to determine how much CO.sub.2 gas pressure is needed to effectively block the formation of calcium carbonate precipitation, while efficiently using CO.sub.2 gas, so as not to waste CO.sub.2, and so that the CO.sub.2 source may be of a reasonable size, while still providing many disinfection sequences' worth of CO.sub.2.
(25) The table in another implementation may represent the mole fraction of CO.sub.2, which depends on the type of disinfection fluid, e.g., PD fluid, the temperature of the PD fluid and the pressure of the PD fluid, wherein the mole fraction values populate the spaces corresponding to a given temperature and pressure. A desired amount of CO.sub.2 is determined from a chemical equation in which the addition of CO.sub.2 to water contained in the disinfecting PD fluid creates carbonic acid, which when combined with calcium carbonate causes a chemical reaction that breaks the calcium carbonate into calcium and bicarbonate ions, which are suspended in the PD fluid and carried to drain. The control unit here uses the table to determine how much the disinfection fluid pressure needs to be increased via the injection of CO.sub.2 to achieve a desired amount of CO.sub.2 (e.g., in mmol). In an embodiment, a separate mole fraction table is stored and is accessible by the control unit for each possible disinfection fluid or PD fluid, e.g., one for 1.36% glucose PD fluid, another for 2.27% glucose PD fluid and a third for 3.86% glucose PD fluid, etc.
(26) A first step for introducing CO.sub.2 into the disinfection loop occurs when treatment has been completed and it is time for the control unit to perform disinfection. Prior to beginning the disinfection sequence, the control unit in one embodiment with the CO.sub.2 valve closed, the PD fluid pump not actuated and the heater unenergized, accesses a lookup table (or corresponding algorithm) that sets a pressure to achieve (or pressure increase) as a function of the bicarbonate level in the PD fluid used for disinfection and/or a disinfection fluid temperature. The control unit in another embodiment takes initial pressure and temperature measurements to obtain an initial CO.sub.2 mole fraction value from a stored table for the particular disinfecting fluid used. An optional pH sensor or CO.sub.2 sensor may be provided and used alternatively or additionally to determine the CO.sub.2 mole fraction, however, the lookup table for the particular disinfection fluid will suffice and eliminate the need for the extra sensors. In either embodiment, a pressure to achieve, or a pressure increase, due to CO.sub.2 gas injection is obtained and used.
(27) A second step for introducing CO.sub.2 occurs with the PD fluid pump not actuated and the heater unenergized. The control unit causes the CO.sub.2 valve to open, allowing CO.sub.2 to be injected into the PD fluid within the disinfection loop. The control unit may cause the CO.sub.2 to be pulsed or injected continuously. In either case, the control unit monitors the output of pressure sensor and stops injecting CO.sub.2 when the pressure achieves the needed pressure increase or overall pressure as determined from either of the lookup tables discussed herein.
(28) A third step for introducing CO.sub.2 occurs with the control unit causing the PD fluid heater to be energized and the PD fluid pump to be actuated to circulate heated, disinfection fluid (PD fluid) about the disinfection loop in any of the alternative manners described herein and at the elevated CO.sub.2 pressure. The heated disinfection fluid circulation takes place for a designated amount of time. During this time, the presence of the designated amount of CO.sub.2 at the elevated pressure prevents or removes calcium carbonate (CaCO.sub.3) according to the chemical reaction described herein.
(29) A fourth, perhaps optional, step for introducing CO.sub.2 occurs with the control unit causing

the PD fluid heater to be de-energized but continuing to allow the fluid pump to circulate cooled-down PD fluid. During a cool down period, the control unit monitors the output of the pressure sensor to see if the output returns to the pressure level prior to heating. If perhaps some leak of CO.sub.2 has occurred and the pressure falls below the CO.sub.2 injected pressure, then control unit may cause the CO.sub.2 valve to open to allow additional CO.sub.2 to be injected, e.g., so as to re-reach a desired pressure increase above the initial, starting pressure. The ammonia and/or CO.sub.2 sensor if provided may be used additionally or alternatively here to help meter additional CO.sub.2 into the disinfection loop.

(30) In light of the disclosure set forth herein, and without limiting the disclosure in any way, in a first aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, a peritoneal dialysis ("PD") system includes a PD fluid pump; a disinfection loop including the PD fluid pump, the disinfection loop including PD fluid used for disinfecting the disinfection loop; and a carbon dioxide (CO.sub.2), source positioned and arranged to supply CO.sub.2 to the disinfection loop to inhibit and/or remove the production of calcium carbonate (CaCO.sub.3) during a disinfection sequence.

(31) In a second aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes a CO.sub.2 valve located between the disinfection loop and the CO.sub.2 source, the CO.sub.2 valve opened to allow the CO.sub.2 to be supplied to the disinfection loop.

(32) In a third aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes a control unit configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to a desired pressure or pressure increase to inhibit and/or remove the production of calcium carbonate during the disinfection sequence.

(33) In a fourth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes at least one pressure sensor outputting to the control unit, the control unit configured to monitor the at least one pressure sensor output to detect the desired pressure or pressure increase.

(34) In a fifth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to use a lookup table to determine the desired pressure or pressure increase.

(35) In a sixth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit stores a disinfection temperature to which the PD fluid is heated for the disinfection sequence, and wherein the desired pressure or pressure increase in the lookup table corresponds to the disinfection temperature.

(36) In a seventh aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes at least one temperature sensor outputting to the control unit, the control unit configured to monitor the at least one temperature sensor output to detect the disinfection temperature.

(37) In an eighth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the lookup table is specific to the type of PD fluid used for disinfection.

(38) In a ninth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit knows a bicarbonate level for the PD fluid used for disinfection, and wherein the desired pressure or pressure increase in the lookup table corresponds to the bicarbonate level.

(39) In a tenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to take initial pressure and temperature readings prior to supplying CO.sub.2 to the disinfection loop, the control unit further configured to determine the initial amount of CO.sub.2 contained in the disinfection loop using the lookup table and the initial pressure and temperature readings.

(40) In an eleventh aspect of the present disclosure, which may be combined with any other aspect,

or portion thereof, the control unit is configured to use an algorithm to determine the desired pressure or pressure increase.
(41) In a twelfth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase prior to causing the PD fluid pump to run during the disinfection sequence.
(42) In a thirteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase while causing the PD fluid pump to run during the disinfection sequence.
(43) In a fourteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes a PD fluid heater, and wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase prior to causing the PD fluid heater to heat the PD fluid during the disinfection sequence.
(44) In a fifteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the PD system includes a PD fluid heater, and wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure while causing the PD fluid heater to heat the PD fluid during the disinfection sequence.
(45) In a sixteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid during a cool down period if a loss of pressure is detected by the control unit.
(46) In a seventeenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, any of the features, functionality and alternatives described in connection with any one or more of FIGS. **1** to **7** may be combined with any of the features, functionality and alternatives described in connection with any other of FIGS. **1** to **7**.
(47) It is accordingly an advantage of the present disclosure to provide a system for an automated peritoneal dialysis (“APD”) cycler that helps to ensure that calcium carbonate production is inhibited or that calcium carbonate is cleaned and removed during disinfection.
(48) It is another advantage of the present disclosure to provide a system for an APD cycler that efficiently uses carbon dioxide (CO.sub.2) during disinfection to prevent or remove the development of calcium carbonate.
(49) It is a further advantage of the present disclosure to provide a system for an APD cycler that helps to prevent the build-up of precipitates during disinfection.
(50) Additional features and advantages are described in, and will be apparent from, the following Detailed Description and the Figures. The features and advantages described herein are not all-inclusive and, in particular, many additional features and advantages will be apparent to one of ordinary skill in the art in view of the figures and description. Also, any particular embodiment does not have to have all of the advantages listed herein and it is expressly contemplated to claim individual advantageous embodiments separately. Moreover, it should be noted that the language used in the specification has been selected principally for readability and instructional purposes, and not to limit the scope of the inventive subject matter.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** is a schematic view of one embodiment of an automated peritoneal dialysis (“APD”)

machine or cycler and associated system of the present disclosure.
(2) FIG. **2** is a simplified schematic view of one embodiment of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure after treatment and prior to disinfection.
(3) FIG. **3** is a simplified schematic view of one embodiment of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure delivering CO.sub.2 to a disinfection loop.
(4) FIG. **4** is a simplified schematic view of one embodiment of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure pumping heated PD disinfection fluid containing delivered CO.sub.2 during disinfection.
(5) FIG. **5** is a simplified schematic view of one embodiment of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure optionally delivering CO.sub.2 to the disinfection loop during a cool down period.
(6) FIG. **6** is an example lookup table stored in a control unit of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure, the lookup table providing a pressure to achieve, or a pressure increase, due to CO.sub.2 injection, wherein the pressure is based on at least one of an amount of bicarbonate in the PD disinfection fluid and/or a disinfection fluid temperature.
(7) FIG. **7** is an example alternative lookup table stored in a control unit of an automated peritoneal dialysis ("APD") machine or cycler of the present disclosure, the lookup table providing a pressure to achieve, or a pressure increase, due to CO.sub.2 injection, wherein the pressure is based on a mole fraction of CO.sub.2.

DETAILED DESCRIPTION

System Generally

(8) Referring now to the drawings and in particular to FIG. **1**, automated peritoneal dialysis ("APD") system **10** and associated methodology of the present disclosure includes an APD machine or cycler **20**. System **10** and cycler **20** attempt to eliminate disposable items as much as possible and instead provide the majority of its fluid carrying portions as reusable components, which are disinfected after treatment. Fluid lines within the machine or cycler are reused. In particular, FIG. **1** illustrates that cycler **20** includes a housing **22** from which reusable PD fluid supply lines **24***a* to **24***d* extend. FIG. **1** further illustrates that a reusable patient line **26** also extends from housing **22** of machine or cycler **20**. Reusable patient line **26**, which is typically longer than reusable PD fluid supply lines **24***a* to **24***d*, may be coiled or rolled up within the housing via a spool or hose reel **28** when reusable patient line **26** is not connected to a patient for treatment.
(9) When not connected to PD fluid containers or bags, the reusable PD fluid supply lines **24***a* to **24***d* and patient line **26** can be connected to dedicated connectors supported and provided by housing **22**. The reusable PD fluid supply and patient lines may for example extend from a front of housing **22** and connect to connectors also provided at the front of the housing for ready access to the PD fluid and patient lines. In the illustrated embodiment, distal ends **24***e* of reusable PD fluid supply lines **24***a* to **24***d* releasably attach in a fluid-tight manner to disinfection connectors **30***a* to **30***d*, respectively, provided at housing **22**. Distal end **26***d* of reusable patient line **26** releasably attaches in a fluid-tight manner to patient line connector **32** provided at housing **22**. Disinfection connectors **30***a* to **30***d* and patient line connector **32** are configured in one embodiment to close or shut automatically when reusable PD fluid supply lines **24***a* to **24***d* and reusable patient line **26**, respectively, are removed or not connected to the connectors.
(10) FIG. **1** also illustrates that housing **22** provides a drain line connector **34**, which may be releasably covered by a moveable, e.g., rotatable or slideable cover **34***c*. Drain line connector **34** receives a disposable drain line **36** for treatment, which may run to a drain container or bag or to a house drain. Disposable drain line **36** is disconnected from drain line connector **34** during disinfection.
(11) Disposable PD fluid or solution containers or bags (not illustrated because system **10** is in a disinfection configuration with the containers or bags removed) are connected respectively to

reusable PD fluid supply lines **24***a* to **24***d*. Distal ends **24***e* of reusable PD fluid supply lines **24***a* to **24***d* may be color coded and/or keyed to match a colored or keyed connector of a dedicated PD fluid container or bag. The containers or bags may hold the same or different dextrose or glucose level PD fluids, such as 1.36% glucose PD fluid, 2.27% glucose PD fluid, 3.86% glucose PD fluid and/or a last bag of a different formulation of PD fluid, such as icodextrin.

(12) It should be appreciated that any number of reusable PD fluid supply lines **24***a* to **24***d* and PD fluid containers or bags may be provided, including a single reusable PD fluid line and PD fluid container or more than one reusable PD fluid lines and PD fluid containers. In a further alternative embodiment, the PD fluid containers or bags are replaced by an online PD fluid generation source, which connects to and communicates fluidly with a single reusable PD fluid supply line.

(13) Besides disposable drain line **36** (and associated container if used) and the disposable PD fluid containers or bags, it is contemplated that in one embodiment, the only other disposable component of system **10** is a disposable filter set (not illustrated) removably connected by the patient at the distal end **26***d* of reusable patient line **26** to provide a final stage of PD fluid filtration prior to delivery to the patient. In an embodiment, the disposable filter set is spliced between the distal end **26***d* of reusable patient line **26** and the patient's transfer set, which leads to an indwelling PD catheter inserted into the patient.

(14) It is contemplated that any one, or more, or all of reusable PD fluid supply lines **24***a* to **24***d*, reusable patient line **26**, disinfection connectors **30***a* to **30***d*, patient line connector **32**, drain line connector **34**, drain line **36**, the PD fluid containers or bags and the patient line filter set be made of any one or more plastic, e.g., polyvinylchloride ("PVC") or a non-PVC material, such as polyethylene ("PE"), polyurethane ("PU"), polypropylene ("PP") or polycarbonate ("PC").

(15) FIG. **1** further illustrates that reusable supply tube **52***a* runs from each reusable PD fluid supply line **24***a* to **24***d*, via a PD fluid supply valve **54***a* to **54***d*, respectively, to a PD fluid inline heater **56**. In an embodiment, each of the valves of APD cycler **20**, including PD fluid supply valves **54***a* to **54***d*, is an electrically actuated valve having a reusable valve body that occludes (e.g., when unpowered for fail safe operation) or allows (e.g., when powered) PD fluid to flow through the body. In the illustrated embodiment, valve **54***d* is a three-way valve having a normally open port for receiving PD fluid from reusable PD fluid supply line **24***b* or **24***c* and a normally closed port for receiving PD fluid from reusable PD fluid supply line **24***d*. PD fluid inline heater **56** is also electrically actuated in one embodiment and is, for example, a resistive heater having a reusable heater body that accepts PD fluid for treatment and for disinfection heating. Inline heater **56** in an embodiment is able to heat PD fluid from room temperature or colder (e.g., if the PD fluid is stored in a cold environment) to body temperature, e.g., 37° C., at a flowrate of up to at least 200 milliliters ("ml")/minute.

(16) A first temperature sensor **58***a* is located adjacent to inline heater **56**, e.g., downstream from the heater to provide feedback for temperature control. If desired, a second temperature sensor (not illustrated) may be provided upstream from PD fluid heater **56** to enable the incoming temperature of fresh PD fluid to be taken into account for the heating algorithm. A second temperature sensor **58***b* is illustrated just downstream from PD fluid pump **70**, which is provided for example as a second check that fresh PD fluid exiting PD fluid pump **70** is at a desired temperature for treatment, e.g., body temperature or 37° C.

(17) In the illustrated embodiment, a flow switch **68** is located just upstream from PD fluid inline heater **56**. An output from flow switch **68** is used to make sure there is PD fluid flow through inline heater **56**. If the output (or lack thereof) from flow switch **68** indicates no or little PD fluid flow, which could be harmful to inline heater **56** if powered, causes system **10** to halt power to inline heater **56** and to stop treatment or disinfection if needed while (i) attempting to find a remedy to the no or low flow situation or (ii) causing an audio, visual or audiovisual alarm or alert at user interface **108**. Alternative ways for ensuring flow to the inline heater **56** in order to power the heater may be used alternatively.

(18) Reusable tube **52***b* runs from the outlet of PD fluid inline heater **56** to an airtrap **60** in the illustrated embodiment of FIG. **1**. Any of the reusable tubing inside the housing of cycler **20**, including reusable tubes **52***a* and **52***b*, may be made of metal, e.g., stainless steel or plastic, e.g., polyvinylchloride ("PVC") or a non-PVC material, such as polyethylene ("PE"), polyurethane ("PU"), polypropylene ("PP"), polyether ether ketone ("PEEK"), or polycarbonate ("PC"). In an embodiment, one or more level sensor **62***a* and **62***b* is located adjacent airtrap **60**, so that a desired level or range of levels of PD fluid is/are maintained in the airtrap. A fluid line valve **54***e* is located downstream from airtrap **60** in the illustrated embodiment and receives fresh, heated PD fluid from the airtrap. A gas line valve **54***g* is located along a gas line **52***g* extending from a top of airtrap **60**. Airtrap **60** may be closed upstream by PD fluid supply valves **54***a* to **54***d* to drain the airtrap when dictated by the output of level sensor **62***a* or **62***b*.

(19) A reusable fluid line **52***c* and gas line **52***g* run between fluid line valve **54***e* and gas line valve **54***g*, respectively, and a PD fluid pump **70** located within housing **22** of cycler **20**. PD fluid pump **70** includes a reusable pump body that accepts PD fluid for pumping. That is, pump **70** does not require the PD fluid to flow within a disposable item, such as a tube or cassette. The reusable pump body of pump **70** itself accepts the PD fluid. PD fluid pump **70** may be of a type, e.g., piston pump, which is inherently accurate so that a separate PD fluid volume measurement apparatus, such as a balance chamber or flowmeter, is not needed. PD fluid pump **70** may alternatively be a less accurate gear or centrifugal pump that does operate with a PD fluid volume measurement apparatus. PD fluid pump **70** is controllable to pump to and from the patient at or below a pressure limit by controlling a level of current to the PD fluid pump. A positive patient pressure limit may for example be one to five psig (e.g., two psig (14 kPa)). A negative patient pressure limit may for example be −1.0 psig to −3.0 psig (e.g., −1.3 psig (−9 kPa)). PD fluid pump **70** is also capable of supplying lower pressures if needed, e.g., for small children or babies. PD fluid pump **70** is bidirectional and continuous in one embodiment, such that a single pump may be provided.

(20) FIG. **1** further illustrates that a fresh PD fluid patient line valve **54***f* is located in an embodiment along reusable fresh PD fluid patient tube or line **52***f* between downstream temperature sensor **58***b* and spool or hose reel **28**. Fresh PD fluid patient tube or line **52***f* communicates fluidly with a fresh PD fluid lumen of dual lumen reusable patient line **26** in one embodiment. A used PD fluid patient line valve **54***u* is located in an embodiment along reusable used PD fluid patient tube or line **52***u* between PD fluid pump **70** (via cross **64***a*) and spool or hose reel **28**. Used PD fluid patient tube or line **52***u* communicates fluidly with a used PD fluid lumen of dual lumen reusable patient line **26** in one embodiment. A drain line valve **54***h* is located along reusable drain tube or line **52***h* that extends from a tee **66** to drain line connector **34**.

(21) A first patient pressure sensor **72***a* is located along fresh PD fluid patient tube or line **52***f* between PD fluid pump **70** and spool or hose reel **28** to measure positive patient PD fluid pressure. A second patient pressure sensor **72***b* is located along gas line **52***g* to measure negative patient PD fluid pressure during a patient drain (gas is at same negative pressure as used PD fluid via fluid communication at cross **64***a*). Third and fourth pressures sensor **72***c* and **72***d* are located along reusable disinfection tube or line **52***d*.

(22) As discussed above, patient line connector **32** is located at APD cycler housing **22** and accepts dual lumen reusable patient line **26** during disinfection and generally while the patient is not undergoing treatment. Patient line connector **32** in one embodiment includes a sealed fluidic U-turn or 180 degree turn that allows disinfection fluid, e.g., heated PD fluid, to flow from one lumen of the dual lumen patient line to another lumen of the dual lumen patient line. Dual lumen reusable patient line **26** is therefore included in the disinfection loop.

(23) As further discussed above, drain line **36** is flexible and disposable in one embodiment and connects to drain line connector **34** extending from housing **22** of APD cycler **20** during treatment. After treatment, drain line **36** may be removed during the disinfection sequence. Drain line connector **34** receives an internal, reusable drain tube or line **52***h* for delivering used PD fluid to

drain line **36** during a patient drain. Drain line connector **34** also receives vent tube or line **52***v* for delivering gas, such as air or carbon dioxide (CO.sub.2), to drain line **36** during treatment. A vent valve **54***v* is located along vent tube or line **52***v*.

(24) A reusable disinfection tube or line **52***d* as illustrated in FIG. **1** extends to a second cross **64***b* along with vent tube or line **52***v* and used PD fluid patient tube or line **52***u*. Reusable disinfection tube or line **52***d* includes a disinfection valve **54***s*. Disinfection tube or line **52***d* handles disinfection fluid, e.g., fresh, heated PD fluid, vent tube or line **52***v* handles vented gas, e.g., air, while used PD fluid patient tube or line **52***u* handles used PD fluid during treatment.

(25) A bypass line **52***y* as illustrated in FIG. **1** is located between disinfection connectors **30***c* and **30***d* for use during disinfection. A similar bypass line **52***z* is provided between disinfection connectors **30***a* and **30***b*. During disinfection, heated disinfection fluid, such as PD fluid, is directed through bypass lines **52***y* and **52***z* to fully disinfect disinfection connectors **30***a* to **30***d*.

(26) FIG. **1** also illustrates that system **10** includes a carbon dioxide (CO.sub.2) source **80**, which may be connected fluidly to the disinfection loop for example between PD fluid pump **70** and pressure sensor **72***a*, e.g., via CO.sub.2 line **52***o*. A CO.sub.2 valve **54***o* is located along CO.sub.2 line **52***o*. As discussed in detail below, system **10** causes a desired and efficient amount of CO.sub.2 gas to be metered from CO.sub.2 source **80** into the disinfection fluid, e.g., PD fluid, just prior to disinfection to prevent and/or remove any build-up of calcium carbonate (CaCO.sub.3) as the PD fluid is heated. CO.sub.2 source **80** may for example be initially pressurized to 70 kPa (10 psig) to provide ample pressure over multiple disinfection sequences according to the pressurization scheme discussed herein.

(27) FIG. **1** further illustrates that a gas or CO.sub.2 pressure regulator **74** and a CO.sub.2 pressure sensor **76** may optionally be located along CO.sub.2 line **52***o* upstream from CO.sub.2 valve **54***o*. CO.sub.2 pressure regulator **74** enables CO.sub.2 source **80** to be pressurized to a higher level so that is lasts longer. Regulator **74** then regulates the high incoming pressure from CO.sub.2 source **80** down to a smoothly outputted desired output pressure. The desired operating pressure for example may be slightly above the pressures (or pressure increases) to be achieved, which are obtained from table **110** or table **120** as discussed below in connection with FIGS. **6** and **7**, respectively. CO.sub.2 pressure sensor **76** reads and outputs a pressure corresponding to the CO.sub.2 pressure remaining within CO.sub.2 source **80**. A one-way or check valve **78** may also be provided and oriented so as to prevent fresh or used PD fluid from entering CO.sub.2 line **52***o*.

(28) FIG. **1** still further illustrates that APD cycler **20** of system **10** of the present disclosure includes a control unit **100** having one or more processor **102** and one or more memory **104** that receive, store and process signals or outputs from the pressure sensors **72***a* to **72***d*, CO.sub.2 pressure sensor **76** if provided, temperature sensors **58***a* and **58***b*, flow switch **68** and possibly a conductivity sensor (not illustrated). Control unit **100** uses pressure feedback from pressure sensors **72***a* and **72***b* to control PD fluid pump **70** to pump fresh and used PD at safe patient and system pressure limits. Control unit **100** uses temperature feedback from temperature sensor **58***a* to control inline PD fluid heater **56** to heat the fresh PD fluid to, e.g., body temperature or 37° C. for treatment, and to 85° C. for disinfection. Control unit **100** uses flow switch feedback from flow switch **68** to determine whether to power PD fluid inline heater **56**. Control unit **100** as discussed herein further uses feedback from pressure sensor **72***a* (and perhaps pressure sensor **72***b*) to determine how much CO.sub.2 has been delivered to a disinfection loop via CO.sub.2 line **52***o*.

(29) Control unit **100** as illustrated in FIG. **1** also includes a video controller **106** that interfaces with a user interface **108**, which may include a display screen operating with a touchscreen and/or one or more electromechanical button, such as a membrane switch. User interface **108** may also include one or more speaker for outputting alarms, alerts and/or voice guidance commands. User interface **108** may be provided with cycler **20** as illustrated in FIG. **1** and/or be a remote user interface operating with control unit **100**. Control unit **100** may also include a transceiver (not illustrated) and a wired or wireless connection to a network, e.g., the internet, for sending treatment

data to and receiving prescription instructions from a doctor's or clinician's server interfacing with a doctor's or clinician's computer.

(30) Control unit **100** opens and closes PD fluid valves **54***a* to **54***h*, **54***o*, **54***s*, **54***u* and **54***v* in combination with the operation of PD fluid pump **70** and inline heater **56** to run a priming sequence, multiple patient fill sequences, multiple patient drain sequences, and a disinfection sequence after a PD treatment. The disinfection sequence readies APD cycler **20** for the next treatment. In an embodiment, remaining fresh PD fluid is heated after the final patient drain and is used as the disinfection fluid for disinfection.

(31) To form a disinfection loop **90** for the disinfection sequence, each reusable PD fluid supply line **24***a* to **24***d* is connected to a respective disinfection connector **30***a* to **30***d*, reusable patient line **26** is connected to reusable patient line connector **32**, and drain line **36** is removed in one embodiment, so that drain line connector **34** may close shut. As illustrated in FIG. **1**, disinfection loop **90** includes patient line connector **32** (including its U-turn or 180 degree turn), both lumens of reusable dual lumen patient line **26**, used PD fluid patient tube or line **52***u*, reusable disinfection tube or line **52***d*, reusable drain tube or line **52***h*, vent tube or line **52***v*, drain line connector **34**, reusable PD fluid supply lines **24***a* to **24***d*, bypass lines **52***y*, **52***z*, and reusable tubes or lines **52***a* to **52***c* and **52***f*. Disinfection loop **90** also includes the insides of all flow components and fluid-contacting sensors located along the above-listed lines.

(32) Control unit **100** may sequence certain of the valves along disinfection loop **90** during disinfection. For example, PD fluid supply valve **54***a* may be sequenced open and closed during disinfection to allow disinfection fluid to flow through supply valve **54***a* or be forced completely through reusable PD fluid supply line **24***a*. Control unit **100** may also cause PD fluid pump **70** to run sequentially in forward and reverse states during disinfection, so that the disinfection fluid may flow clockwise and counterclockwise through disinfection loop **90**. Control unit **100** also causes inline heater **56** to heat the disinfection fluid, e.g., fresh PD fluid, to a desired disinfection temperature, such as 70° C. to 95° C.

(33) The use of PD fluid containing bicarbonate as a disinfection fluid likely leads to the formation of calcium carbonate (CaCO.sub.3) in the disinfected flowpaths and flow components of disinfection loop **90** of PD machine or cycler **20**. Carbon dioxide (CO.sub.2) from source **80** is provided accordingly just prior to disinfection to prevent and/or to remove the formation of calcium carbonate. FIGS. **2** to **5** illustrate a simplified version of disinfection loop **90**, showing important components to the CO.sub.2 injection from source **80**, including PD fluid inline heater **56**, first temperature sensor **58***a*, PD fluid pump **70**, fresh PD fluid patient pressure sensor **72***a*, CO.sub.2 source **80**, CO.sub.2 line **52***o*, CO.sub.2 valve **54***o* and control unit **100**. It should be appreciated however that the sequences described in connection with FIGS. **2** to **5** are equally applicable to the full disinfection loop **90** of PD machine or cycler **20** of system **10** in FIG. **1**.

Lookup Table Based on Bicarbonate Level and/or Disinfection Temperature

(34) Referring now to FIG. **6**, the sequences of FIGS. **2** to **5** in an embodiment rely on a table **110** (or corresponding algorithm) stored in one or more memory **104** of control unit **100**, which sets a pressure to achieve, or a pressure increase, due to the injection of CO.sub.2 based on at least one of a bicarbonate level in the PD disinfection fluid or a disinfection fluid temperature. As illustrated in FIG. **6**, table **100** sets a pressure increase due to the CO.sub.2 injection or an overall pressure to be achieved (P.sub.11 to P.sub.46) by the CO.sub.2 injection as a function of at least one of solution bicarbonate composition (b.sub.1 to b.sub.4) and disinfection fluid temperature setting (T.sub.1 to T.sub.6). FIG. **6** accordingly illustrates the pressure (or pressure increase) to achieve as a function of both bicarbonate level and disinfection fluid temperature setting in a two dimensional array. FIG. **6** could alternatively however base the pressure (or pressure increase) to achieve as a function of only one of bicarbonate level or disinfection fluid temperature

(35) Generally, the more bicarbonate present in the fresh PD fluid, the higher the pressure in table **110** needed due to the injected CO.sub.2 gas. And generally, the higher the disinfection PD fluid

temperature, the higher the pressure in table **110** needed due to the injected CO.sub.2 gas. To populate table **110**, experiments and/or calculations are performed varying bicarbonate levels against varied disinfection fluid temperatures to determine how much CO.sub.2 gas pressure is needed to effectively block the formation of calcium carbonate precipitation, while efficiently using CO.sub.2 gas, so as not to waste CO.sub.2, and so that the CO.sub.2 source **80** may be of a reasonable size, while still providing many disinfection sequence's worth of CO.sub.2.

(36) Control unit **100** at the beginning of each disinfection sequence knows the bicarbonate level from the prescribed PD fluid used for the just-ended treatment. Control unit **100** also knows and sets the disinfection fluid temperature, which may be the same or be different for different disinfection sequences. Control unit **100** accesses table **110** (or corresponding algorithm) and finds the operating pressure (or pressure increase) to achieve based on the known bicarbonate level and the known disinfection fluid temperature. It should be appreciated that table **110** could alternatively compare disinfection fluid temperature against the type of bicarbonate-based PD fluid used, which is basically the same as comparing disinfection fluid temperature against bicarbonate level. It should also be appreciated that PD fluids not containing bicarbonate do not have the precipitation issues discussed herein. So when using a PD fluid for disinfection that does not contain bicarbonate, control unit **100** does not access table **110** and does not inject CO.sub.2 gas from CO.sub.2 source **80**.

Lookup Table Based on Mole Fraction

(37) Referring now to FIG. **7**, the sequences of FIGS. **2** to **5** in an alternative embodiment rely on a table **120** (or corresponding algorithm) stored in one or more memory **104** of control unit **100**, which uses a mole fraction of CO.sub.2. Table **120** of FIG. **7** represents the mole fraction of CO.sub.2, which depends on the type of disinfection fluid, e.g., type of PD fluid, PD fluid temperature (left-hand column, ° C.) and PD fluid pressure (upper row, kPA), wherein the mole fraction values populate the spaces corresponding to a given temperature and pressure. In an embodiment, a separate table (like table **120**) is stored and is accessible by control unit **100** for each possible disinfection fluid or PD fluid, e.g., one for 1.36% glucose PD fluid, another for 2.27% glucose PD fluid and a third for 3.86% glucose PD fluid.

(38) In one example for using a table **120** in FIG. **7**, the following information is taken as being known and may be stored (or a portion thereof) in control unit **100**: disinfection loop **90** volume is 200 ml CO.sub.2 source **80** holds 18 g of CO.sub.2 CO.sub.2 molar mass is 44.01 g/mol CaCO.sub.3 molar mass is 100.0869 g/mol disinfection fluid molar mass (assume that of H.sub.2O) is 18.02 g/mol disinfection fluid H.sub.2O density (assume that of H.sub.2O) is 0.96859 g/ml calcium content (Ca)′ of disinfection fluid is 1.25 mmol/L)

(39) On a per disinfection sequence basis using the following chemical reaction for eliminating calcium carbonate, where H.sub.2CO.sub.3 is carbonic acid and HCO.sub.3 is bicarbonate, and wherein H.sub.2O is obtained from the PD fluid used for disinfection:

(40) ##STR00001## max CaCO.sub.3=1.25×0.2 mmol=0.25 mmol.fwdarw.0.25e.sup.−3×100.0869 g=0.025021725 g CaCO3 1 mmol Ca.sup.2+.fwdarw.2 mmol H.sup.+ needed CO.sub.2=2×mmol CaCO.sub.3=0.5 mmol CO.sub.2.fwdarw.0.5e.sup.−3×44.01 g=0.022005 g CO.sub.2 one tank of 18 g CO.sub.2 with an effective use of 45%.fwdarw.18/0.022005×0.45=368 cycles of CO.sub.2

(41) A goal of the CO.sub.2 injection is to increase the pressure measured by pressure sensor **72***a*, so that dissolved CO.sub.2 is maintained during the heated disinfection sequence at a predetermined amount calculated above to be 0.5 mmol. An assumption that the source of PD fluid used for disinfection, e.g., a bag of such fluid, is in equilibrium with the ambient surroundings regarding temperature and pressure is made, such that the initial partial pressure of CO.sub.2 may be assumed to be roughly 0.04 kPa (partial pressure of CO.sub.2 at ambient). Using table **120** of FIG. **7**, and extrapolating from the 0.031 molar fraction valve at 5 kPa and 25° C. yields about 0.00031 molar fraction of CO.sub.2 at normal ambient conditions ((0.04 kPa/5 kPa) is roughly 1/10 of 0.031, which equals 0.00031 molar fraction).

(42) In the example it is also assumed (and would be known in a commercial implementation) that the volume of disinfection or PD fluid circulated in disinfection loop **90** is 200 milliliters ("ml"). Knowing the density of the PD disinfection fluid (using density of water in the example), 200 ml of PD fluid equals 193.72 grams or 10.75 mols of the fluid in disinfection loop **90**. At normal ambient conditions (5 kPa and 25° C.) 10.75 mols×0.00031 molar fraction yields 0.0033 mmols of CO.sub.2, which drops to 0.0012 mmols CO.sub.2 at 85° C. (0.00011 molar fraction×10.75 mols) as extrapolated from table **120** of FIG. **7** for 0.04 kPa at 85° C., which is a typical disinfection temperature. The drop dictates that 0.5012 (0.0012+0.5) mmols of CO.sub.2 needs to be injected into the heated PD fluid. 0.5012 (0.0012+0.5) mmols of CO.sub.2 in turn yields a needed molar fraction of 0.5012/10.75=0.0466, which in turn yields a partial pressure increase of about 21 kPa (3 psig) at 85° C. according to table **120** of FIG. **7**.

(43) Using the table **120** of FIG. **7** and the above knowns based on solid assumptions, which are programmed into control unit **100**, control unit **100** can thereby calculate for a given PD fluid to be used as a disinfecting fluid, and a given disinfection temperature (each of which may be programmed into control unit **100** at the time of treatment, or be known from a patient's prescription), the pressure at which the disinfecting PD fluid needs to be increased via CO.sub.2 pressure from source **80**, wherein the pressure is set in one embodiment by downstream CO.sub.2 pressure regulator **74**.

CO.SUB.2 .Injection Steps

(44) FIG. **2** illustrates a first step in which a PD treatment has been completed and it is time for control unit **100** to perform disinfection. Prior to beginning the disinfection sequence, control unit **100** in one embodiment, with CO.sub.2 valve **54***o* closed (not shaded), PD fluid pump **70** not actuated and inline heater **56** unenergized, finds the pressure (or pressure increase) to be achieved from table **110** of FIG. **6** based on a known bicarbonate level and/or disinfection temperature. Control unit **100** in an alternative embodiment, with CO.sub.2 valve **54***o* closed, PD fluid pump **70** not actuated and inline heater **56** unenergized, takes initial pressure and temperature measurements via pressure sensor **72***a* and temperature sensor **58***a*, respectively, to obtain an initial CO.sub.2 mole fraction value from the table **120** of FIG. **7**. An optional pH sensor or CO.sub.2 sensor (not illustrated) may be provided and used alternatively or additionally to determine the initial CO.sub.2 mole fraction, however, the table **120** of FIG. **7** for the disinfection fluid will suffice and eliminates the need for extra sensors.

(45) FIG. **3** illustrates a second step in which control unit **100**, with PD fluid pump **70** not actuated and inline heater **56** unenergized, causes CO.sub.2 valve **54***o* to open (valve shaded), allowing CO.sub.2 to be injected into the PD fluid within disinfection loop **90**. Control unit **100** may pulse CO.sub.2 or inject the CO.sub.2 continuously, but in either case control unit **100** monitors the output of pressure sensor **72***a* and stops injecting CO.sub.2 when the pressure achieves the needed pressure (or pressure increase (e.g., about 21 kPa (3 psig) at 85° C.)) from table **110** of FIG. **6** or table **120** of FIG. **7**.

(46) FIG. **4** illustrates a third step in which control unit **100** causes inline heater **56** to be energized and PD fluid pump **70** to circulate heated, disinfection fluid (PD fluid) about disinfection loop **90** in any of the alternative manners described above and at the elevated pressure obtained in FIG. **3**. Heated disinfection fluid circulation takes place for a designated amount of time. During this time, the presence of the designated amount of CO.sub.2 at the elevated pressure prevents or removes calcium carbonate (CaCO.sub.3) according to the chemical reaction shown above. It should be appreciated that while CO.sub.2 valve **54***o* is shown as being closed (not shaded) in FIG. **4**, in an alternative embodiment, control unit **10** may cause CO.sub.2 valve **54***o* to be opened so as to allow CO.sub.2 gas to be injected into disinfection loop **90** during a part or all of the heat disinfection.

(47) FIG. **5** illustrates a fourth and perhaps optional step in which control unit **100** causes inline heater **56** to de-energize but continues to allow fluid pump **70** to circulate cooled-down PD fluid. During a cool down period, control unit **100** monitors the output of pressure sensor **72***a* to see if the

output returns to the pressure level prior to heating in FIG. **4**. If perhaps some leakage of CO.sub.2 has occurred and the pressure falls below the CO.sub.2 injected pressure at the end of FIG. **3**, then control unit **100** may cause CO.sub.2 valve **54***o* to open (valve shaded) to allow additional CO.sub.2 to be injected, e.g., so as to re-reach the needed pressure increase (e.g., about 21 kPa (3 psig)) above the initial, starting pressure. The ammonia and/or CO.sub.2 sensor if provided may be used additionally or alternatively here. Note that the cooled-down PD fluid will have a higher mole fraction of CO.sub.2, such that the CO.sub.2 pressure will not need to be increased to the earlier level, e.g., to 21 kPa.

(48) Control unit **100** in one embodiment causes valves **54***e*, **54***f*, **54***g*, **54***h* and **54***u* to be closed and CO.sub.2 valve **54***o* to open, so that PD fluid patient tube or line **52***f* is pressurized with CO.sub.2 gas to whatever pressure remains within CO.sub.2 source **80**. Here, first patient pressure sensor **72***a* reads the pressure remaining within CO.sub.2 source **80** and sends a corresponding signal to control unit **100**. In an alternative embodiment illustrated in FIG. **1**, CO.sub.2 pressure sensor **76** is provided upstream from pressure regulator **74** so as to be able to read the pressure remaining within CO.sub.2 source **80** and send a corresponding signal to control unit **100**. In either situation, control unit **100** in an embodiment is configured to send a message to a central location when it determines that the pressure level within CO.sub.2 source **80** is running low, so that a new CO.sub.2 source **80** may be ordered and delivered to the patient. User interface **108** may also provide an audio, visual or audiovisual message to the patient that CO.sub.2 source **80** is running low but that a new supply is on the way. Upon the patient receiving the new CO.sub.2 source **80**, user interface **108** may also provide an audio, visual or audiovisual instructions to the patient as to how to replace the existing CO.sub.2 source **80** with a new CO.sub.2 source **80**.

(49) 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. It is therefore intended that such changes and modifications be covered by the appended claims. For example, while FIGS. **2** to **5** illustrate readings being taken from a single pressure sensor and temperature sensor, control unit **100** may alternatively analyze pressure and temperature outputs from multiple pressure and temperature sensors located at different locations along disinfection loop **90**. As noted herein, the pressures listed in tables **110** and **120** of FIGS. **6** and **7**, respectively, may be absolute pressure values or pressure increase or pressure delta values.

Claims

1. A peritoneal dialysis (“PD”) system comprising: a PD fluid pump; a disinfection loop including the PD fluid pump, the disinfection loop including PD fluid used for disinfecting the disinfection loop; and a carbon dioxide (CO.sub.2) source positioned and arranged to supply CO.sub.2 to the disinfection loop to inhibit the production of and/or remove calcium carbonate (CaCO.sub.3) during a disinfection sequence.

2. The PD system of claim 1, which includes a CO.sub.2 valve located between the disinfection loop and the CO.sub.2 source, the CO.sub.2 valve opened to allow the CO.sub.2 to be supplied to the disinfection loop.

3. The PD system of claim 2, which includes a control unit configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to a desired pressure or pressure increase to inhibit the production of and/or remove calcium carbonate during the disinfection sequence.

4. The PD system of claim 3, which includes at least one pressure sensor outputting to the control unit, the control unit configured to monitor the at least one pressure sensor output to detect the desired pressure or pressure increase.

5. The PD system of claim 3, wherein the control unit is configured to use a lookup table to determine the desired pressure or pressure increase.

6. The PD system of claim 5, wherein the control unit stores a disinfection temperature to which

the PD fluid is heated for the disinfection sequence, and wherein the desired pressure or pressure increase in the lookup table corresponds to the disinfection temperature.

7. The PD system of claim 6, which includes at least one temperature sensor outputting to the control unit, the control unit configured to monitor the at least one temperature sensor output to detect the disinfection temperature.

8. The PD system of claim 5, wherein the lookup table is specific to the type of PD fluid used for disinfection.

9. The PD system of claim 5, wherein the control unit knows a bicarbonate level for the PD fluid used for disinfection, and wherein the desired pressure or pressure increase in the lookup table corresponds to the bicarbonate level.

10. The PD system of claim 5, wherein the control unit is configured to take initial pressure and temperature readings prior to supplying CO.sub.2 to the disinfection loop, the control unit further configured to determine the initial amount of CO.sub.2 contained in the disinfection loop using the lookup table and the initial pressure and temperature readings.

11. The PD system of claim 3, wherein the control unit is configured to use an algorithm to determine the desired pressure or pressure increase.

12. The PD system of claim 3, wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase prior to causing the PD fluid pump to run during the disinfection sequence.

13. The PD system of claim 3, wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase while causing the PD fluid pump to run during the disinfection sequence.

14. The PD system of claim 3, which includes a PD fluid heater, and wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure increase prior to causing the PD fluid heater to heat the PD fluid during the disinfection sequence.

15. The PD system of claim 3, which includes a PD fluid heater, and wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid to the desired pressure or pressure while causing the PD fluid heater to heat the PD fluid during the disinfection sequence.

16. The PD system of claim 3, wherein the control unit is configured to cause the CO.sub.2 valve to open to allow the CO.sub.2 to pressurize the PD fluid during a cool down period if a loss of pressure is detected by the control unit.