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Dialysis system having enhanced valve features

Abstract

A medical fluid system includes a medical fluid pump configured to pump a medical fluid; a tube through which medical fluid pumped by the medical fluid pump flows; a pinch valve positioned and arranged to occlude the tube to prevent medical fluid from flowing through the tube, the pinch valve including a motor; a current sensor positioned and arranged to sense a current drawn by the motor of the pinch valve; and a control unit operable with the current sensor to monitor the current drawn by the motor while the motor is causing the pinch valve to occlude the tube, the control unit configured to stop the motor when the monitored current indicates an occlusion of the tube.

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Background/Summary

PRIORITY CLAIM
(1) The present application is a national phase entry of PCT Patent Application No. PCT/US2023/020825, filed on May 3, 2023, which claims priority to and the benefit of Indian Provisional Application No. 202241028982, filed on May 19, 2022, the entire contents of which

are hereby incorporated by reference.

BACKGROUND

(2) The present disclosure relates generally to medical fluid treatments and in particular to dialysis fluid treatments that require fluid heating.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

(12) 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.

(13) Each of the above-identified dialysis modalities, except for CAPD (which typically does not involve machinery), uses automated valves to control whether dialysis fluid, blood or other fluid is able to flow or not flow. The valves also control the direction of fluid flow, such as where the fluid comes from or the destination to which the fluid flows. Different types of valves are used in dialysis system. One type of valve is used typically with a disposable cassette having a hard plastic part defining fluid flow paths and valve seats and one or more flexible membrane covering one or more side of the hard plastic part. The disposable cassette is typically loaded into a dialysis machine or cycler, which is able to close designated parts of the one or more plastic sheet against the valve seats to block fluid flow and to force or allow the plastic to move away from the valve seats to allow fluid flow.

(14) Another type of automated valve is a pinch valve that instead pinches closed a tube carrying the dialysis fluid, blood or other fluid to block fluid flow. There are generally two types of pinch valves, solenoid pinch valves and motorized pinch valves. Motorized pinch valves need to be configured for a particular tubing diameter and a particular tubing wall thickness. Tubing diameters and wall thicknesses are not always consistent for different sets of tubing, and the tubing wall thickness may further vary over time due to wear and tear via repeated pinching.

(15) An improved way to operate motorized pinch valves is needed accordingly.

SUMMARY

(16) The present disclosure sets forth a motorized valve for a medical fluid system, such as an automated peritoneal dialysis ("PD") system, which improves the usability of the valve. While the present system is described primarily in connection with PD, the improved motorized valve operation of the present disclosure applies to machines used for any dialysis modality described herein, such as online HD, HF, HDF, and acute HD, HF, HDF. The improved motorized valve operation of the present disclosure also applies to any medical fluid system in which a treatment fluid flow, or a patient fluid flow, is controlled via one or more valve.

(17) In a PD example, the system includes a PD machine or cycler. The PD machine is described herein primarily as having a pneumatically driven PD fluid pump and the electromechanically actuated motorized pinch valves of the present disclosure. Alternatively, however, the PD fluid pump may also be electromechanically driven, e.g., be a piston, gear, peristaltic or centrifugal pump. The PD machine or cycler is in one embodiment capable of delivering fresh, heated PD fluid

to the patient at, for example, 14 kPa (2.0 psig) or higher. The PD machine is capable of removing used PD fluid or effluent from the patient at, for example, −9 kPa (−1.3 psig) or an even greater negative pressure. Fresh PD fluid delivered to the patient may be first heated to a body fluid temperature, e.g., 37° C.

(18) The PD machine or cycler of the present system operates with motorized pinch valves under control of a control unit. The control unit may include one or more current sensor that operates with a processor and/or memory of the control unit. A dedicated current sensor may be provided for each motorized pinch valve, allowing completely independent actuation of each of the valves. Or, one or more current sensor may be provided for multiple motorized pinch valves, e.g., where it is assured that the timing of the initiation of the actuation of the multiple pinch valves will not overlap. The current sensors may be provided on a control board of the control unit or be located alternatively within the pinch valves, which may include a rotary nut motor under control of control unit. The rotary nut motor may be a stepper motor. The rotary nut located within rotary nut motor is translationally fixed, such that its rotation causes a threaded shaft to be threaded through the rotary nut so to translate in an accurate manner in both valve closing and valve opening directions. The end of threaded shaft that contacts the tube includes a rounded head or wedge that allows the tubes or lines to be occluded without damaging the tubing. The pinch valves also include a stop against which the rounded head or wedge compresses the tubes.

(19) The rotary nut motor rotates the rotary nut in a first direction, e.g., clockwise, to cause threaded shaft and rounded head to translate in a first direction towards the stop to occlude a tube. The rotary nut motor rotates the rotary nut in a second direction, e.g., counterclockwise, to cause the threaded shaft and the rounded head to translate in a second direction away from the stop, allowing medical fluid to flow through the tube.

(20) Prior art control of the motorized pinch valves can be deficient when the shaft is moved a set distance expected to fully occlude the tube fails to do so because the tube wall thickness at the point of contact has thinned due to repeated occlusion, for example. A corresponding fluid leak occurs. Also, if the diameter of the tube and/or tube wall thickness is/are different than what is expected for the set translation distance, a leak may occur even if the tube wall thickness has not been worn or thinned.

(21) The present method solves the above problems by monitoring the output of the motorized valves' corresponding current sensor during tube occlusion. The control unit of the machine or cycler determines if the output from the current sensor shows a spike or characteristic change indicating that the tube has been fully occluded and that threaded shaft and rounded head are pushing against the stop, which forces the rotary nut motor into a stalled condition. That is, the rotary nut motor will draw more current in an end-of-travel, fully occluded state, in an attempt to keep the rotary nut rotating. The additional current draw is detected by the current sensor. If the output from current sensor does not show a spike or characteristic change indicating that the tube has been fully occluded, then control unit continues to monitor the current sensor and to cause the rotary nut motor to rotate, further translating the threaded shaft and the rounded head. If the output from the current sensor does show a spike or characteristic change indicating that the tube has been fully occluded, then control unit depowers the rotary nut motor.

(22) 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 medical fluid system includes a medical fluid pump configured to pump a medical fluid; a tube through which medical fluid pumped by the medical fluid pump flows; a pinch valve positioned and arranged to occlude the tube to prevent medical fluid from flowing through the tube, the pinch valve including a motor; a current sensor positioned and arranged to sense a current drawn by the motor of the pinch valve; and a control unit operable with the current sensor to monitor the current drawn by the motor while the motor is causing the pinch valve to occlude the tube, the control unit configured to stop the motor when the monitored current indicates an

occlusion of the tube.
(23) In a second aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the monitored current increases to indicate the occlusion of the tube.
(24) In a third aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the current sensor is provided with the control unit or the pinch valve.
(25) In a fourth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the current sensor is configured to sense the current drawn by multiple motors of multiple pinch valves.
(26) In a fifth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the pinch valve includes a shaft driven by the motor.
(27) In a sixth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the motor is a rotary nut motor and the shaft is a threaded shaft.
(28) In a seventh aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the shaft includes a head that contacts the tube, the valve further including a stop against which the head occludes the tube.
(29) In an eighth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the tube is a first tube and the pinch valve is a first pinch valve, and wherein the control unit is operable with the current sensor or a second current sensor to monitor the current drawn by a second motor of a second pinch valve while the second motor is causing the second pinch valve to occlude the second tube, the control unit further configured to stop the second motor when the monitored current indicates an occlusion of the second tube.
(30) In a ninth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is further configured to operate the motor in an opposite direction, without monitoring the current drawn by the motor, to allow medical fluid to flow through the tube.
(31) In a tenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the tube is disposable or reusable.
(32) 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 wait momentarily after the monitored current initially indicates the occlusion of the tube before stopping the motor.
(33) In a twelfth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, a medical fluid system includes a medical fluid pump configured to pump a medical fluid; a tube through which medical fluid pumped by the medical fluid pump flows; a pinch valve positioned and arranged to occlude the tube to prevent medical fluid from flowing through the tube, the pinch valve including a motor; a sensor positioned and arranged to sense a characteristic change associated with the motor of the pinch valve when the tube is occluded; and a control unit operable with the sensor, the control unit configured to stop the motor when the characteristic change is sensed.
(34) In a thirteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the sensor is a current sensor, a resistance sensor, a hall effect sensor, or a current transformer.
(35) In a fourteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the characteristic change is a characteristic increase in current drawn by the motor.
(36) In a fifteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the control unit is configured to wait momentarily after the characteristic change is sensed before stopping the motor.
(37) In a sixteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, a method for controlling a motorized pinch valve for medical fluid flow includes (i) powering a motor of the motorized pinch valve such that a shaft of the motorized pinch valve move in a tube occlusion direction; (ii) monitoring a sensor output indicative of a current drawn by

the motor while powering the motor; (iii) if a change in the sensor output characteristic of an occlusion of the tube is not detected, returning to (i); and (iv) if a change in the sensor output characteristic of the occlusion of the tube is detected, depowering the motor.

(38) In a seventeenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the sensor is a current sensor.

(39) In an eighteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the output characteristic of the occlusion of the tube includes an increase in current drawn by the motor.

(40) In a nineteenth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, wherein in (iv) the change in the sensor output characteristic of the occlusion of the tube is detected for a period of time sufficient to ensure that the change is due to the occlusion of the tube and not some other anomaly.

(41) In a twentieth aspect of the present disclosure, which may be combined with any other aspect, or portion thereof, the change in the sensor output characteristic of the occlusion of the tube is detected regardless of tube wear, tube softness or tube manufacturing tolerances.

(42) In a twenty-first 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 **6**D may be combined with any of the features, functionality and alternatives described in connection with any other of FIGS. **1** to **6**D.

(43) In light of the above aspects and present disclosure set forth herein, it is an advantage of the present disclosure to provide a medical fluid system having improved motorized pinch valve operation.

(44) It is another advantage of the present disclosure to provide a medical fluid system having improved motorized pinch valve flexibility, wherein the valves may operate with multiple different diameters/wall thicknesses of tubing and be able to compensate for tubing wall thickness variations.

(45) It is a further advantage of the present disclosure to provide a medical fluid system having simplified motorized pinch valves.

(46) Moreover, it is an advantage of the present disclosure to provide a medical fluid system having compact motorized pinch valves.

(47) It is yet another advantage of the present disclosure to provide a medical fluid system having effective leak proof tube pinching irrespective of tube thickness variation and wear due to repeated pinches.

(48) 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 FIGURES

(1) FIG. **1** is a sectioned schematic view of one embodiment for an APD system having the motorized pinch valve operation of the present disclosure.

(2) FIGS. **2**A and **2**B are top and side views, respectively, of one embodiment of a motorized pinch valve of the present disclosure.

(3) FIG. **3** is a process flow diagram of a prior art method of occluding a flexible tube using a motorized pinch valve.
(4) FIGS. **4**A and **4**B are schematic views illustrating a problem with the prior art operation of motorized pinch valves.
(5) FIG. **5** is a process flow diagram of the structure and method of the present disclosure for occluding a flexible tube using a motorized pinch valve.
(6) FIGS. **6**A to **6**D are schematic elevation views illustrating the structure and methodology of the present disclosure for occluding a flexible tube using a motorized pinch valve.

DETAILED DESCRIPTION

(7) Referring now to the drawings and in particular to FIG. **1**, an example system **10** including the motorized pinch valve operation of the present disclosure is illustrated. System **10** includes a dialysis machine **20**, such as an automated peritoneal dialysis ("PD") machine, operating a medical fluid handling device **70**, such as a dialysis fluid cassette. While present system **10** is described primarily in connection with PD, the improved motorized valve operation of the present disclosure applies to machines used for any dialysis modality described herein, such as online HD, HF, HDF, and acute HD, HF, HDF. The improved motorized valve operation of the present disclosure also applies to any medical fluid system in which a treatment fluid flow, or a patient fluid flow, is controlled via one or more valve.
(8) PD machine **20** in the illustrated embodiment includes a housing **22** defining a pump interface **24** having a pump actuator or pump actuation area **26** for actuating medical fluid handling device **70**. Pump actuation area **26** in the illustrated embodiment is actuated pneumatically via a positive pneumatic line **28** extending from a positive pneumatic source **30** to perform a pump-out or discharge stroke, e.g., to push (i) fresh, heated dialysis fluid to a peritoneal cavity **14** of patient **12** via a patient line **16** and patient transfer set **18**, for example, at 14 kPa (2.0 psig) or higher, (ii) fresh dialysis fluid at a higher system pressure to a heating container (not illustrated) to be heated to body temperature, e.g., 37° C., by a dialysis fluid heater (not illustrated), or (iii) used dialysis fluid at a higher system pressure to a drain. Pump actuation area **26** in the illustrated embodiment is actuated pneumatically via a negative pneumatic line **32** extending from a negative pneumatic source **34** to perform a pump-in or draw stroke, e.g., to pull (i) fresh dialysis fluid from a dialysis fluid source **40** through a supply line **42** at a higher system pressure, (ii) fresh, heated dialysis fluid from the heating container (not illustrated) at a higher system pressure, or (iii) used dialysis fluid from the peritoneal cavity **14** of patient **12** via patient line **16** and transfer set **18**, for example, at −9 kPa (−1.3 psig) or perhaps at a greater negative pressure.
(9) Patient line **16** may be from three to seven meters long, e.g., approximately 4.5 or 6.7 meters, have an inner diameter of, for example, two to four millimeters ("mm"), and a wall thickness of about one mm. Supply line **42** may also have an inner diameter of, for example, two to four mm, and a wall thickness of about one mm. PD machine **20** also provides a pressure sensor **44** for measuring positive pneumatic pressure in positive pneumatic line **28** and a pressure sensor **46** for measuring negative pneumatic pressure in negative pneumatic line **32**. PD machine **20** further includes plural electrically operated pneumatic valves, e.g., valves **48**, **50**, **52** and **56**. Pneumatic valve **48** is positioned in positive pneumatic line **28** to selectively allow positive pressure from source **30** to reach pump actuation area **26**. Pneumatic valve **50** is positioned in negative pneumatic line **32** to selectively allow negative pressure from source **34** to reach pump actuation area **26**. A vent valve **52** is provided in a vent line **54** in communication with positive pneumatic line **28** to selectively vent positive pressure in line **28** and pump actuation area **26** to atmosphere. A second vent valve **56** is provided in a vent line **58** in communication with negative pneumatic line **32** to selectively vent negative pressure in line **32** and pump actuation area **26** to atmosphere. In an alternative embodiment, a single vent valve and line may be provided to vent both positive and negative pressure from pump actuation area **26** to atmosphere.
(10) FIG. **1** further illustrates that PD machine **20** includes a positive pneumatic pressure regulator

66, e.g., a variable orifice valve, located along positive pneumatic line **28**, and a negative pressure regulator **68**, e.g., a variable orifice valve, located along negative pneumatic line **32**. Positive pneumatic pressure regulator **66** sets the positive pneumatic pressure delivered to pump actuation area **26** to a desired and controlled level, which is also the pressure of fresh or used PD fluid pumped out of dialysis fluid cassette **70**. Negative pneumatic pressure regulator **68** sets the negative pneumatic pressure drawn at pump actuation area **26** to a desired and controlled level, which is also the pressure of fresh or used PD fluid pumped into dialysis fluid cassette **70**. In an alternative embodiment, PD machine **20** may be configured pneumatically such that a single pressure regulator, e.g., variable orifice valve, operates at different times as a positive pneumatic pressure regulator and a negative pneumatic pressure regulator.

(11) Pressure sensors **44** and **46**, pneumatic valves **48**, **50**, **52** and **56**, and variable orifice valves or regulators **66** and **68** either output to or are under the control of a control unit **60** of PD machine **20**. Control unit **60** in the illustrated embodiment includes one or more processor **62***a* and one or more memory **62***b*. Control unit **60** may have any one or more of a master controller, safety controller, video controller, and/or sub- or delegate controller.

(12) In the illustrated embodiment of FIG. **1**, medical fluid handling device or disposable cassette **70** is provided with a pump actuation chamber **72** that mates with pump actuation area **26** to form an overall pumping chamber. Medical fluid handling device **70** in the illustrated embodiment includes a flexible membrane, diaphragm or sheet **74**, which may be sized to fit pump actuation chamber **72** or be sized to cover a whole side of medical fluid handling device **70** (as illustrated), wherein a portion of the membrane **74** covers pump actuation chamber **72**, and wherein such portion may be at least substantially flat or be pre-domed or pre-shaped to fit into one or both pump actuation area **26** and pump actuation chamber **72**. Control unit **60** causes negative pressure from source **34** to be applied to flexible membrane **74** to pull the sheet against the wall of pump actuation area **26** to correspondingly pull fresh or used PD fluid into pump actuation chamber **72**. To do so, control unit causes valves **48**, **52** and **56** to be closed and valve **50** to be open. During the filling of pump actuation chamber **72**, pressure sensor **46** measures negative pumping pressure, which is used as feedback in a pressure control routine to set the level of negative pneumatic pressure applied at pump actuation area **26** via negative pressure regulator **68**.

(13) Control unit **60** causes positive pressure from source **30** to be applied to flexible membrane **74** to push the sheet against the wall of pump actuation chamber **72** to correspondingly push fresh or used PD fluid from pump actuation chamber **72**. To do so, control unit causes valves **50**, **52** and **56** to be closed and valve **48** to be open. During the discharge of pump actuation chamber **72**, pressure sensor **44** measures positive pumping pressure, which is used as feedback in a pressure control routine to set the level of positive pneumatic pressure applied at pump actuation area **26** via positive pressure regulator **66**.

(14) Control unit **60** is able to determine the flowrate of fresh and used PD fluid pumped by PD machine **20** of system **10** in at least one of a plurality of different ways. In one way, the fixed volumes of pump actuation area **26** and pump actuation chamber **72** collectively form a known full stroke volume. Control unit **60** counts the number of full strokes delivered, multiplies the count by the known full stroke volume, and divides the result by the corresponding amount of time needed to perform the number of full strokes delivered to determine a local or current PD fluid flowrate.

(15) Alternatively or additionally, control unit **60** takes before and after fill or discharge stroke pressure measurements and uses an ideal gas law algorithm, as is known in the art, to determine a resulting volume of fresh or used PD fluid pulled into or discharged from pump actuation chamber **72**. To do so, PD machine **20** may provide positive and negative known and fixed volume reference chambers (not illustrated), which may be pneumatically connected to positive and negative vent lines **54** and **58**, respectively. Control unit **60** may then add consecutive fill or discharge stroke volumes determined by the ideal gas law algorithm and divide the sum by the corresponding amount of time needed to perform the consecutive fill or discharge strokes to determine a local or

current PD fluid flowrate. The ideal gas law algorithm method of determining local or current flowrate is advantageous because full stokes of diaphragm or sheet **74** through pump actuation area **26** and pump actuation chamber **72** are not required. Partial strokes may be performed and taken into account in determining local or current flowrate.

(16) It should be appreciated that it is likely that PD machine **20** provides two pump actuation areas **26** and pump actuation chambers **72**, which operate in an alternating manner (one filling while the other discharging), so that the flowrate of fresh or used PD fluid is for the most part continuous. Moreover, while FIG. **1** illustrates a pneumatically driven pump actuation area **26** and pump actuation chamber **72**, the PD fluid pumping of system **10** may alternatively be electromechanically driven, e.g., via a piston, gear, peristaltic or centrifugal pump.

(17) Regardless of the type of pumping employed by system **10**, PD machine **20** includes electromechanical motorized pinch valves **80***a*, **80***b* under control of control unit **60** in the illustrated embodiment. As illustrated in FIG. **1**, motorized pinch valve **80***a* is operable with supply line **42**, while motorized pinch valve **80***b* is operable with patient line **16**. While FIG. **1** illustrates two motorized pinch valves **80***a*, **80***b*, PD machine **20** of system **10** may include additional motorized pinch valves, such as an additional fluid valve for an additional pump actuation chamber **72** (operating in an alternating manner to provide more continuous flow) and additional fluid valves for multiple supply lines **42**, a fluid heater line, and/or a drain line, which are not illustrated to simplify FIG. **1**.

(18) FIG. **1** illustrates that control unit **60** may further include one or more current sensor **64***a*, **64***b* that operates with one or more processor **62***a* and/or one or more memory **62***b*. A dedicated current sensor **64***a*, **64***b* may be provided for each motorized pinch valve **80***a*, **80***b*, respectively, allowing completely independent actuation of each of the valves. Or, one or more current sensor **64***a*, **64***b* may be provided for multiple motorized pinch valves **80***a*, **80***b*, e.g., where it is assured that the timing of the initiation of the actuation of the pinch valves **80***a*, **80***b* does not overlap. While current sensors **64***a*, **64***b* are illustrated as being provided with control unit **60**, e.g., on a control board of control unit **60**, current sensors **64***a*, **64***b* may alternatively be located within pinch valves **80***a*, **80***b*, respectively.

(19) FIGS. **2**A and **2**B illustrate motorized pinch valves **80***a*, **80***b* in more detail. In the illustrated embodiment, motorized pinch valves **80***a*, **80***b* each include a rotary nut motor **82** under control of control unit **60**. Rotary nut motor **82** may be a stepper motor. The rotary nut located within rotary nut motor **82** is translationally fixed, such that its rotation causes a threaded shaft **84** threaded through the rotary nut to translate in an accurate manner in both valve closing and valve opening directions. The end of threaded shaft **84** that contacts the tube, e.g., patient line **16** or supply line **42** in FIG. **1**, is provided with a rounded head or wedge **86** that allows tubes or lines **16**, **42** to be occluded without damaging the lines or tubes. Pinch valves **80***a*, **80***b* in FIGS. **2**A and **2**B also include a stop **88** against which rounded head or wedge **86** compresses tubes or lines **16**, **42**. Rotary nut motor **82** rotates the rotary nut in a first direction, e.g., clockwise, to cause threaded shaft **84** and rounded head **86** to translate in a first direction towards stop **88** to occlude tubes or lines **16**, **42**. Rotary nut motor **82** rotates the rotary nut in a second direction, e.g., counterclockwise, to cause threaded shaft **84** and rounded head **86** to translate in a second direction away from stop **88** to allow medical fluid flow through tubes or lines **16**, **42**.

(20) FIG. **3** illustrates a prior art method **100** of occluding a flexible tube using a motorized pinch valve. At oval **102**, method **100** begins. At block **104**, a rotary nut motor, such as a stepper motor, moves a commanded number of steps that, in combination with the geometry of the threaded shaft, are calculated to create an amount of translational movement of the threaded shaft and rounded head needed to occlude the tubing or lines. The motor is stopped when the commanded number of motor steps have been moved as illustrated at block **106**. At oval **108**, method **100** ends. FIGS. **4**A and **4**B illustrate a problem with method **100**. When the contacted portion of tubes or lines **16**, **42** have their expected thickness as in FIG. **4**A, translating the threaded shaft and rounded the

calculated fixed distance (to the dotted line) causes tubes or lines **16**, **42** to be properly occluded. But when the contacted portion of tubes or lines **16**, **42** have thinned, e.g., due to repeated pinching or occlusion or to a manufacturing tolerance in which the tube wall is manufactured so as to be thinner than as specified or intended, as in FIG. **4**B, translating the threaded shaft and rounded head the calculated fixed distance (to the dotted line) does not cause tubes or lines **16**, **42** to be properly occluded, such that a leak is created.

(21) FIG. **5** illustrates method **110** of the present disclosure for occluding a flexible tube **16**, **42** using a motorized pinch valve **80***a*, **80***b*. At oval **112**, method **110** begins. At block **114**, control unit **60** causes rotary nut motor **82** to rotate and begin to translate threaded shaft **84** and rounded head **86** towards stop **88**. At bock **114**, control unit **60** also begins to monitor the output of the current sensor **64***a*, **64***b* associated with pinch valve **80***a*, **80***b*. As discussed above, any current sensor **64***a*, **64***b* may be associated with one or more motorized pinch valve **80***a*, **80***b*.

(22) At diamond **116**, control unit **60** determines if the output from current sensor **64***a*, **64***b* shows a spike or characteristic change indicating that tube or line **16**, **42** has been fully occluded and that threaded shaft **84** and rounded head **86** are pushing against stop **88**, which forces rotary nut motor **82** into a stalled condition. That is, rotary nut motor **82** will draw more current in an end-of-travel, fully occluded state, in an attempt to keep its rotary nut rotating. The additional current draw is detected by current sensor **64***a*, **64***b*. If the output from current sensor **64***a*, **64***b* at diamond **116** does not show a spike or characteristic change indicating that tube or line **16**, **42** has been fully occluded, then method **110** returns to block **114**, where control unit **60** continues monitor current sensor **64***a*, **64***b* and to cause rotary nut motor **82** to rotate, translating threaded shaft **84** and rounded head **86** towards stop **88**. If the output from current sensor **64***a*, **64***b* at diamond **116** does show a spike or characteristic change indicating that tube or line **16**, **42** has been fully occluded, then method **110** moves to block **118**, where control unit **60** causes rotary nut motor **82** to stop. At oval **120**, method **110** ends.

(23) FIGS. **6**A to **6**D illustrates method **110** in more detail via the sequential display of motorized pinch valve **80***a*, **80***b* during occlusion. In FIG. **6**A, control unit **60** causes rotary nut motor **82** to be powered and for threaded shaft **84** and rounded head **86** to begin translating. The corresponding output from current sensor **64***a*, **64***b* as shown on display **90** indicates that rotary nut motor **82** during the beginning of the occlusion initially draws a normal or expected amount of current. In FIG. **6**B, control unit **60** continues to cause rotary nut motor **82** to be powered and for threaded shaft **84** and rounded head **86** to continue translating so as to contact and begin to compress tube or line **16**, **42**. The corresponding output from current sensor **64***a*, **64***b* as shown on display **90** indicates that rotary nut motor **82** during the initial tube contacting portion of the occlusion continues to draw a normal or expected amount of current.

(24) In FIG. **6**C, control unit **60** continues to cause rotary nut motor **82** to be powered and for threaded shaft **84** and rounded head **86** to continue translating so as to continue the occlusion of tube or line **16**, **42**. The corresponding output from current sensor **64***a*, **64***b* as shown on display **90** indicates that rotary nut motor **82** during the further tube contacting portion of the occlusion continues to draw a normal or expected amount of current. In FIG. **6**D, control unit **60** attempts to continue to cause rotary nut motor **82** to rotate and for threaded shaft **84** and rounded head **86** to continue translating so as to continue the occlusion of tube or line **16**, **42**. But because tube or line **16**, **42** is fully compressed between rounded head **86** and stop **88**, the rotary nut can no longer rotate. Rotary nut motor **82** enters a stall condition and draws more current in an attempt to keep the rotary nut rotating. The corresponding output from current sensor **64***a*, **64***b* as shown on display **90** detects the additional current draw, indicating that threaded shaft **84** and rounded head **86** have fully occluded tube or line **16**, **42**, such that head **86** is now pressing against stop **88**. Control unit **60** quickly senses the current spike or characteristic increase and cuts power to rotary nut motor **82**. Tube or line **16**, **42** is fully occluded in FIG. **6**D. In an embodiment, control unit **60** is programmed to wait for a period of time, such as about a second, to ensure that the current spike or characteristic

increase is due to total tube or line **16**, **42** occlusion and not some other current spike anomaly. That is, control unit **60** may cause rotary nut motor **82** to continue to push against tube or line **16**, **42** for, e.g., about a second after first seeing the current spike or characteristic increase. Small current spikes not indicating a full occlusion occur typically due to noise. But after seeing the characteristic increase for, e.g., about a second, control unit **60** safely determines a full occlusion of tube or line **16**, **42**. It should be appreciated however that care is taken to ensure that motor **82** is not powered long enough for it to become heated.

(25) In an embodiment, control unit **60** does not monitor the output from current sensor **64***a*, **64***b* in causing the rotary nut motor **82** to rotate in an opposite, tube opening direction. Here, control unit **60** may be programmed to run rotary nut motor **82** in the opposite direction for a determined number of stepper motor steps, or until a limit switch is triggered (e.g., to allow for a less expensive non-stepper motor to be used), wherein it is known that the tip of rounded head **86** is clear from tube or line **16**, **42**, so that the tube may open fully to allow medical fluid, e.g., PD fluid, to flow therethrough.

(26) FIGS. **5** and **6**A to **6**D show that the structure and corresponding methodology of motorized pinch valve **80***a*, **80***b* the present disclosure successfully occlude tubes or lines **16**, **42** regardless of the diameter of the tube (tube **16**, **42** has to fit initially in the space between rounded head **86** and stop **88** in FIG. **6**A), and regardless of whether the wall thickness of tube **16**, **42** varies over time due to repeated occlusion or whether tube **16**, **42** has become softer over repeated occlusions in which case tube **16**, **42** needs to be compressed more to form a good seal. Successful occlusion of tubes or lines **16**, **42** also occurs regardless of manufacturing tolerances.

(27) 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 system **10** is illustrated as operating with a disposable cassette **70**, system **10** may alternatively use durable or reusable components, which are for example disinfected, such as heat disinfected after use. Here, flexible lines or tubes **16**, **42** may instead be provided inside PD machine or cycler **20**, wherein the lines are disinfected after treatment. Also, while sensors **64***a*, **64***b* are described as being current sensors, other types of sensors may be used, such as resistance sensors, hall effect sensors, and current transformers.

Claims

1. A medical fluid system comprising: a medical fluid pump configured to pump a medical fluid; a tube through which the medical fluid pumped by the medical fluid pump flows; a pinch valve positioned and arranged to occlude the tube to prevent the medical fluid from flowing through the tube, the pinch valve including a motor; a current sensor positioned and arranged to sense a current drawn by the motor of the pinch valve; and a control unit operable with the current sensor to monitor the current drawn by the motor while the motor is causing the pinch valve to occlude the tube, the control unit configured to stop the motor when the monitored current indicates an occlusion of the tube.

2. The medical fluid system of claim 1, wherein the monitored current increases to indicate the occlusion of the tube.

3. The medical fluid system of claim 1, wherein the current sensor is provided with the control unit or the pinch valve.

4. The medical fluid system of claim 1, wherein the current sensor is configured to sense the current drawn by multiple motors of multiple pinch valves.

5. The medical fluid system of claim 1, wherein the pinch valve includes a shaft driven by the motor.

6. The medical fluid system of claim 5, wherein the motor is a rotary nut motor and the shaft is a

threaded shaft.
7. The medical fluid system of claim 5, wherein the shaft includes a head that contacts the tube, the pitch valve further including a stop against which the head occludes the tube.
8. The medical fluid system of claim 1, wherein the tube is a first tube and the pinch valve is a first pinch valve, and wherein the control unit is operable with the current sensor or a second current sensor to monitor a second current drawn by a second motor of a second pinch valve while the second motor is causing the second pinch valve to occlude the second tube, the control unit further configured to stop the second motor when the monitored second current indicates an occlusion of the second tube.
9. The medical fluid system of claim 1, wherein the control unit is further configured to operate the motor in an opposite direction, without monitoring the current drawn by the motor, to allow the medical fluid to flow through the tube.
10. The medical fluid system of claim 1, wherein the tube is disposable or reusable.
11. The medical fluid system of claim 1, wherein the control unit is configured to wait momentarily after the monitored current initially indicates the occlusion of the tube before stopping the motor.
12. A medical fluid system comprising: a medical fluid pump configured to pump a medical fluid; a tube through which the medical fluid pumped by the medical fluid pump flows; a pinch valve positioned and arranged to occlude the tube to prevent the medical fluid from flowing through the tube, the pinch valve including a motor; a sensor positioned and arranged to sense a characteristic change associated with the motor of the pinch valve when the tube is occluded; and a control unit operable with the sensor, the control unit configured to stop the motor when the characteristic change is sensed.
13. The medical fluid system of claim 12, wherein the sensor is a current sensor, a resistance sensor, a hall effect sensor, or a current transformer.
14. The medical fluid system of claim 12, wherein the characteristic change is a characteristic increase in current drawn by the motor.
15. The medical fluid system of claim 12, wherein the control unit is configured to wait momentarily after the characteristic change is sensed before stopping the motor.