MEDICAL TREATMENT SYSTEM AND METHODS USING A PLURALITY OF FLUID LINES

BACKGROUND

Peritoneal Dialysis (PD) involves the periodic infusion of sterile aqueous solution (called peritoneal dialysis solution, or dialysate) into the peritoneal cavity of a patient. Diffusion and osmosis exchanges take place between the solution and the bloodstream across the natural body membranes. These exchanges transfer waste products to the dialysate that the kidneys normally excrete. The waste products typically consist of solutes like sodium and chloride ions, and other compounds normally excreted through the kidneys like urea, creatinine, and water. The diffusion of water across the peritoneal membrane during dialysis is called ultrafiltration.

Conventional peritoneal dialysis solutions include dextrose in concentrations sufficient to generate the necessary osmotic pressure to remove water from the patient through ultrafiltration.

Continuous Ambulatory Peritoneal Dialysis (CAPD) is a popular form of PD. A patient performs CAPD manually about four times a day. During a drain/fill procedure for CAPD, the patient initially drains spent peritoneal dialysis solution from his/her peritoneal cavity, and then infuses fresh peritoneal dialysis solution into his/her peritoneal cavity. This drain and fill procedure usually takes about 1 hour.

Automated Peritoneal Dialysis (APD) is another popular form of PD. APD uses a machine, called a cycler, to automatically infuse, dwell, and drain peritoneal dialysis solution to and from the patient's peritoneal cavity. APD is particularly attractive to a PD patient, because it can be performed at night while the patient is asleep. This frees the patient from the day-to-day demands of CAPD during his/her waking and working hours.

The APD sequence typically lasts for several hours. It often begins with an initial drain phase to empty the peritoneal cavity of spent dialysate. The APD sequence then proceeds through a succession of fill, dwell, and drain phases that follow one after the other. Each fill/dwell/drain sequence is called a cycle.

During the fill phase, the cycler transfers a predetermined volume of fresh, warmed dialysate into the peritoneal cavity of the patient. The dialysate remains (or "dwells") within the peritoneal cavity for a period of time. This is called the dwell phase. During the drain phase, the cycler removes the spent dialysate from the peritoneal cavity.

The number of fill/dwell/drain cycles that are required during a given APD session depends upon the total volume of dialysate prescribed for the patient's APD regimen, and is either entered as part of the treatment prescription or calculated by the cycler.

APD can be and is practiced in different ways.

Continuous Cycling Peritoneal Dialysis (CCPD) is one commonly used APD modality. During each fill/dwell/drain phase of CCPD, the cycler infuses a prescribed volume of dialysate. After a prescribed dwell period, the cycler completely drains this liquid volume from the patient, leaving the peritoneal cavity empty, or "dry." Typically, CCPD employs 4-8 fill/dwell/drain cycles to achieve a prescribed therapy volume.

After the last prescribed fill/dwell/drain cycle in CCPD, the cycler infuses a final fill volume. The final fill volume dwells in the patient for an extended period of time. It is drained either at the onset of the next CCPD session in the evening, or during a mid-day exchange. The final fill volume can contain a different concentration of dextrose than the fill volume of the successive CCPD fill/dwell/drain fill cycles the cycler provides.

Intermittent Peritoneal Dialysis (IPD) is another APD modality. IPD is typically used in acute situations, when a patient suddenly enters dialysis therapy. IPD can also be used when a patient requires PD, but cannot undertake the responsibilities of CAPD or otherwise do it at home.

Like CCPD, IPD involves a series of fill/dwell/drain cycles. Unlike CCPD, IPD does not include a final fill phase. In IPD, the patient's peritoneal cavity is left free of dialysate (or "dry") in between APD therapy sessions.

Tidal Peritoneal Dialysis (TPD) is another APD modality. Like CCPD, TPD includes a series of fill/dwell/drain cycles. Unlike CCPD, TPD does not completely drain dialysate from the peritoneal cavity during each drain phase. Instead, TPD establishes a base volume during the first fill phase and drains only a portion of this volume during the first drain phase. Subsequent fill/dwell/drain cycles infuse and then drain a replacement volume on top of the base volume. The last drain phase removes all dialysate from the peritoneal cavity.

There is a variation of TPD that includes cycles during which the patient is completely drained and infused with a new full base volume of dialysis.

TPD can include a final fill cycle, like CCPD. Alternatively, TPD can avoid the final fill cycle, like IPD.

APD offers flexibility and quality of life enhancements to a person requiring dialysis. APD can free the patient from the fatigue and inconvenience that the day to day

practice of CAPD represents to some individuals. APD can give back to the patient his or her waking and working hours free of the need to conduct dialysis exchanges.

Still, the complexity and size of past machines and associated disposables for various APD modalities have dampened widespread patient acceptance of APD as an alternative to manual peritoneal dialysis methods.

SUMMARY OF INVENTION

In one aspect, a system is disclosed for measuring an amount of liquid in a pumping chamber of a pneumatically actuated diaphragm pump. The sytem comprises a fluid inlet and fluid outlet valve connected to the pumping chamber; a diaphragm separating a pneumatically actuated control chamber from the pumping chamber, the control chamber fluidly connected to a reference chamber of known volume via a conduit that includes a reference chamber valve; the control chamber fluidly connected via one or more actuation valves to a source of positive or negative pneumatic pressure; and a controller configured to control the fluid inlet and outlet valves, the reference chamber valve, and the one or more actuation valves, and to receive pressure data from a first pressure sensor connected to the actuation chamber and a second pressure sensor connected to the reference chamber. The controller is configured to isolate the pumping chamber by closing the fluid inlet and outlet valves, charge the control chamber with a first pneumatic pressure; vent the reference chamber or fix a pneumatic pressure in the reference chamber that is different from the control chamber pneumatic pressure; measure a first control chamber pressure and a first reference chamber pressure, connect the control chamber to the reference chamber by opening the reference chamber valve, measure a third equalized pneumatic pressure in the control and reference chambers, and compute a control chamber volume based on an ideal gas model that assumes an adiabatic pressure equalization process in the reference chamber and a polytropic pressure equalization process in the control chamber.

A system of one or more computers can be configured to perform particular operations or actions by virtue of having software, firmware, hardware, or a combination of them installed on the system that in operation causes or cause the system to perform the actions. One or more computer programs can be configured to perform particular operations or actions by virtue of including instructions that, when executed by data processing apparatus, cause the apparatus to perform the actions. One general aspect

includes a system for flushing a port valve in a medical a liquid pumping cassette may include: at least one pump chamber; a port valve fluidly connected to a patient port on a port side of the valve and fluidly connected to the at least one pump chamber on the cassette side of the port valve; and a patient line fluidly connected to the patient port; and a reusable medical device may include: an occluder configured to occlude at least the patient line; a portion to receive the liquid pumping cassette; an actuation chamber to apply pressure to actuate each of the at least one pumping chamber; an actuator to close and open the port valve; and a controller to control the pressure system and the actuator; where the controller is configured to occlude the patient line before flushing the valve, the flushing of the valve may include actuating the at least one pump chamber to push liquid toward the port valve in an open position, then actuating the at least one pump chamber to pull liquid from the port valve. Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

Embodimentss may include one or more of the following features. The system where the controller actuates the port valve to a closed position before actuating the at least one pump chamber to pull liquid from the port valve. The controller actuates the at least one pump chamber to push liquid toward the port valve in an open position for a first predetermined period of time The system where the first predetermined period of time is equal to the second predetermined period of time. The system where the first predetermined period of time is 0.2 seconds. The system where the first predetermined period of time is less than 1 seconds. The controller actuates the at least one pump chamber to pull liquid from the port valve for a second predetermined period of time The controller tests the port valve for leakage after actuating the at least one pump chamber to pull liquid from the port valve. The controller tests the port valve for leakage after flushing the valve. The controller retracts the occluder before testing the port valve for leakage after flushing the valve. The controller flushes the valve valve two or more times. The controller flushes the valve valve 5 times. At least one pump chamber may include a first pump chamber and a second pump chamber and where the first pump chamber pushes liquid toward the port valve in an open position and the second pump chamber pulls liquid from the port valve. Embodimentss of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

One general aspect includes a system for flushing a port valve in a medical a liquid pumping cassette may include: at least one pump chamber, a port valve fluidly connected to a patient port on a port side of the valve and fluidly connected to the at least one pump chamber on the cassette side of the port valve, and a patient line fluidly connected to the patient port, and a reusable medical device may include: an occluder configured to occlude at least the patient line, a portion to receive the liquid pumping cassette, an actuation chamber to apply pressure to actuate each of the at least one pumping chamber, an actuator to close and open the port valve, a user interface configured to display visual information, and a controller to control the pressure system and the actuator, where the controller is configured to flush the port valve after the controller determines that the port valve leaks and issue an alert to the user interface if the controleler determins that the port valve leaks after the flushing the port valve. Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

Embodimentss may include one or more of the following features. A system where the valve flush includes occluding the patient line before actuating the at least one pump chamber to push liquid toward the port valve in an open position, then actuating the at least one pump chamber to pull liquid from the port valve. The valve flush includes occluding the patient line before repeating the steps of actuating the at least one pump chamber to push liquid toward the port valve in an open position and then actuating the at least one pump chamber to pull liquid from the port valve. The steps of actuating the at least one pump chamber to push liquid toward the port valve in an open position and then actuating the at least one pump chamber to pull liquid from the port valve are repeated two or more times. Embodimentss of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

One general aspect includes a method to flush a valve in a pumping cassette with at least one pumping chamber. The method also includes occluding the fluid line; and flushing the port valve with the following steps: pumping liquid with pump chamber toward the port valve where the port valve is open, and pulling liquid with the pump chamber from the port valve, Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

Embodimentss may include one or more of the following features. The method where the step of flushing the port valve is repeated two or more times. The port valve is closed during the step of pulling liquid with the pump chamber from the port valve. The port valve is open during the step of pulling liquid with the pump chamber from the port valve. The step of pumping liquid with pump chamber toward the port valve where the port valve is open occurs for a first predetermined period. The first predetermined period is equal to the second predetermined period. The first predetermined period is 0.2 seconds. The first predetermined period is less than one second. The method the method may include: un-occluding the fluid line after flushing the valve, testing the port valve for a leak after un-occluding the fluid line, and issuing an alert to the user when a leak is detected. The step of pulling liquid with the pump chamber from the port valve occurs for a second predetermined period. The at least one pumping chamber may include a first pump chamber and a second pump chamber and the method further may include the steps of: at least partially filling the first pump chamber with liquid, at least partially emptying the second pump chamber of liquid, and where pumping liquid with pump chamber toward the port valve may include actuating the first pump chamber to deliver liquid toward the port valve, where pulling liquid with the pump chamber from the port valve may include actuating the second pump chamber to pull liquid from the port valve. The at least one pumping chamber may include a first pump chamber and second pump chamber that are each a pneumatic diaphragm pump actuated by applying pressure a membrane attached to a body of the fluid pumping cassette and where the step of pumping liquid toward the port valve may include applying a positive pressure on the membrane over the first pump chamber and the step of pulling liquid with the pump chamber from the port valve may include applying a negative pressure on the membrane of second pump chamber. Embodimentss of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

One general aspect includes a method to flush a valve in a pumping cassette with at least one pumping chamber. The method also includes partially filling the at least one pumping chamber with liquid; occluding the fluid line, and flushing the port valve with the following steps: applying positive pressure with the pump chamber to the port valve where the port valve is open, and applying negative pressure with the pump chamber to the port valve, Other embodiments of this aspect include corresponding computer systems,

apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

Embodimentss may include one or more of the following features. The method where the step of flushing the port valve is repeated two or more times. The port valve is closed during the step of applying negative pressure with the pump chamber to the port valve. The port valve is open during the step of applying negative pressure with the pump chamber to the port valve. The step of applying positive pressure with the pump chamber to the port valve where the port valve is open and the step of applying negative pressure with the pump chamber to the port valve each occur for a first predetermined period. The first predetermined period is 0.2 seconds. The first predetermined period is less than one second. The method the method may include: un-occluding the fluid line after flushing the valve, testing the port valve for a leak after un-occluding the fluid line, and issuing an alert to the user when a leak is detected. Embodimentss of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

One general aspect includes a method to flush a valve in a pumping cassette with at least one pumping chamber. The method also includes occluding the fluid line; and flushing the port valve with the following steps: pulling liquid with the pump chamber from the port valve, where the port valve is open; and pumping liquid with the pump chamber toward the port valve where the port valve is closed; Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

Embodimentss may include one or more of the following features. The method where the step of flushing the port valve is repeated two or more times. The port valve is closed during the step of pulling liquid with the pump chamber from the port valve. Embodimentss of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

BRIEF DESCRIPTION OF THE DRAWINGS

Aspects of the invention are described below with reference to illustrative embodiments that are shown, at least in part, in the following figures, in which like numerals reference like elements, and wherein:

FIG. 1 shows a schematic view of an automated peritoneal dialysis (APD) system that incorporates one or more aspects of the invention;

FIG. 1A shows an alternative arrangement for a dialysate delivery set shown in FIG. 1;

FIG. 2 is a schematic view of an illustrative set for use with the APD system of FIG. 1;

FIG. 3 is an exploded perspective view of a cassette in a first embodiment;

FIG. 4 is a cross sectional view of the cassette along the line 4-4 in FIG. 3;

FIG. 5 is a perspective view of a vacuum mold that may be used to form a membrane having pre-formed pump chamber portions in an illustrative embodiment;

FIG. 6 shows a front view of the cassette body of FIG. 3;

FIG. 7 is a front view of a cassette body including two different spacer arrangements in an illustrative embodiment;

FIG. 8 is a rear perspective view of the cassette body of FIG. 3;

FIG. 9 is a rear view of the cassette body of FIG. 3;

FIG. 10 is a perspective view of the APD system of FIG. 1 with the door of the cycler in an open position;

FIG. 11 is a front view of a control surface of the cycler for interaction with a cassette in the FIG. 10 embodiment;

FIG. 12 is a front view and selected cross-sectional views of an embodiment of a control surface of the cycler;

FIG. 13 is an exploded view of an assembly for the interface surface of FIG. 11, with the mating pressure delivery block and pressure distribution module;

FIG. 14 is an exploded view of the integrated manifold;

FIG. 15 shows two isometric views of the integrated manifold;

FIG. 16 shows a schematic of the pneumatic system that controls fluid flow through the cycler;

FIG. 17 is an exploded perspective view of an occluder in an illustrative embodiment;

FIG. 18 is a partially exploded perspective view of the occluder of FIG. 17;

FIG. 19 is a top view of the occluder of FIG. 17 with the bladder in a deflated state;

FIG. 20 is a top view of the occluder of FIG. 17 with the bladder in an inflated state;

FIG. 21 is a schematic view of a pump chamber of a cassette and associated control components and inflow/outflow paths in an illustrative embodiment;

FIG. 22 is a schematic view of a control chamber of a cassette and associated control components including pressure sensors and inflow/outflow paths in an illustrative embodiment;

FIG. 23 is a pressure versus time plot for the reference chamber and the control chamber during a pumping and FMS process;

FIG. 24 is a flow chart of pneumatic steps of an FMS process;

FIG. 25A is a plot of the pumping chamber and reference chamber pressures during the +FMS process;

FIG. 25B is a plot of the pumping chamber and reference chamber pressures during the -FMS process;

FIG. 26A is an illustration of a polytropic conceptual model of the +FMS process involving three separate closed mass systems;

FIG. 26B is a plot of the polytropic expansion constant for +FMS verses control chamber volume.

FIG. 27A is an illustration of the polytropic conceptual model of the -FMS process involving three separate closed mass systems;

FIG. 27B is a plot of the polytropic expansion constant for -FMS verses control chamber volume.

FIG. 28 is a flow chart of basic AIA FMS calculation steps;

FIG. 29 is a more detailed flow chart of AIA FMS calculation steps;

FIG. 30 is a schematic block diagram illustrating an exemplary embodiments of control system for an APD system;

FIG. 31 is a schematic block diagram illustrating an exemplary arrangement of the multiple processors controlling the cycler and the safe line;

FIG. 32 is a schematic block diagram illustrating exemplary connections between the hardware interface processor and the sensors, the actuators and the automation computer;

FIG. 33 shows a schematic cross section of the cycler illustrating the components of the heater system for the heater bag;

FIG. 34 shows a flow of information between various subsystems and processes of the APD system;

FIG. 35 illustrates an operation of the therapy subsystem of FIG. 30;

FIG. 36 is a sequence diagram depicting interactions of therapy module processes during initial replenish and dialyze portions of the therapy;

FIGS. 37-42 show screen views relating to alerts and alarms that may be displayed on a touch screen user interface for the APD system;

FIG. 43 illustrates component states and operations for error condition detection and recovery;

FIG. 44 shows exemplary modules of a UI view subsystem for the APD system;

FIGS. 45-51 shows illustrative user interface screens for providing user information and receiving user input in illustrative embodiments regarding system setup, therapy status, display settings, remote assistance, and parameter settings;

FIG. 52 shows a flow chart depicting an embodiment of synchronization of operations between two pumping chambers of a pump cassette;

FIG. 53 shows a flow chart depicting another embodiment of synchronization of operations between two pumping chambers of a pump cassette;

FIG. 54 shows a schematic flow diagragm of the cassette;

FIGS. 55A-55C shows a cross-sectional view of a port valve in the cassette;

FIG. 56 shows a flow chart of the Valve Check procedure;

FIG. 57 shows a flow chart of the Valve Flush procedure;

FIG. 57A show flow charts of alternative Valve Flush procedure;

DETAILED DESCRIPTION

Although aspects of the invention are described in relation to a peritoneal dialysis system, certain aspects of the invention can be used in other medical applications, including infusion systems such as intravenous infusion systems or extracorporeal blood flow systems, and irrigation and/or fluid exchange systems for the stomach, intestinal tract, urinary bladder, pleural space or other body or organ cavity. Thus, aspects of the invention are not limited to use in peritoneal dialysis in particular, or dialysis in general.

APD System

FIG. 1 shows an automated peritoneal dialysis (APD) system 10 that may incorporate one or more aspects of the invention. As shown in FIG. 1, for example, the

system 10 in this illustrative embodiment includes a dialysate delivery set 12 (which, in certain embodiments, can be a disposable set), a cycler 14 that interacts with the delivery set 12 to pump liquid provided by a solution container 20 (e.g., a bag), and a control system 16 (e.g., including a programmed computer or other data processor, computer memory, an interface to provide information to and receive input from a user or other device, one or more sensors, actuators, relays, pneumatic pumps, tanks, a power supply, and/or other suitable components – only a few buttons for receiving user control input are shown in FIG. 1, but further details regarding the control system components are provided below) that governs the process to perform an APD procedure. In this illustrative embodiment, the cycler 14 and the control system 16 are associated with a common housing 82, but may be associated with two or more housings and/or may be separate from each other. The cycler 14 may have a compact footprint, suited for operation upon a table top or other relatively small surface normally found in the home. The cycler 14 may be lightweight and portable, e.g., carried by hand via handles at opposite sides of the housing 82.

The set 12 in this embodiment is intended to be a single use, disposable item, but instead may have one or more reusable components, or may be reusable in its entirety. The user associates the set 12 with the cycler 14 before beginning each APD therapy session, e.g., by mounting a cassette 24 within a front door 141 of the cycler 14, which interacts with the cassette 24 to pump and control fluid flow in the various lines of the set 12. For example, dialysate may be pumped both to and from the patient to effect APD. Post therapy, the user may remove all or part of the components of the set 12 from the cycler 14.

As is known in the art, prior to use, the user may connect a patient line 34 of the set 12 to his/her indwelling peritoneal catheter (not shown) at a connection 36. In one embodiment, the cycler 14 may be configured to operate with one or more different types of cassettes 24, such as those having differently sized patient lines 34. For example, the cycler 14 may be arranged to operate with a first type of cassette with a patient line 34 sized for use with an adult patient, and a second type of cassette with a patient line 34 sized for an infant or pediatric use. The pediatric patient line 34 may be shorter and have a smaller inner diameter than the adult line so as to minimize the volume of the line, allowing for more controlled delivery of dialysate and helping to avoid returning a relatively large volume of used dialysate to the pediatric patient when the set 12 is used for consecutive drain and fill cycles. A heater bag 22, which is connected to the cassette 24 by a line 26, may be placed on a heater container receiving portion (in this case, a tray) 142 of the cycler 14. The cycler 14 may pump fresh dialysate (via the cassette 24) into the heater bag 22 so that the dialysate

may be heated by the heater tray 142, e.g., by electric resistance heating elements associated with the tray 142 to a temperature of about 37 degrees C. Heated dialysate may be provided from the heater bag 22 to the patient via the cassette 24 and the patient line 34. In an alternative embodiment, the dialysate can be heated on its way to the patient as it enters, or after it exits, the cassette 24 by passing the dialysate through tubing in contact with the heater tray 142, or through an in-line fluid heater (which may be provided in the cassette 24). Used dialysate may be pumped from the patient via the patient line 34 to the cassette 24 and into a drain line 28, which may include one or more clamps to control flow through one or more branches of the drain line 28. In this illustrative embodiment, the drain line 28 may include a connector 39 for connecting the drain line 28 to a dedicated drain receptacle, and an effluent sample port 282 for taking a sample of used dialysate for testing or other analysis. The user may also mount the lines 30 of one or more containers 20 within the door 141. The lines 30 may also be connected to a continuous or real-time dialysate preparation system. (The lines 26, 28, 30, 34 may include a flexible tubing and/or suitable connectors and other components (such as pinch valves, etc.) as desired.) The containers 20 may contain sterile peritoneal dialysis solution for infusion, or other materials (e.g., materials used by the cycler 14 to formulate dialysate by mixing with water, or admixing different types of dialysate solutions). The lines 30 may be connected to spikes 160 of the cassette 24, which are shown in FIG. 1 covered by removable caps. In one aspect of the invention described in more detail below, the cycler 14 may automatically remove caps from one or more spikes 160 of the cassette 24 and connect lines 30 of solution containers 20 to respective spikes 160. This feature may help reduce the possibility of infection or contamination by reducing the chance of contact of non-sterile items with the spikes 160.

In another aspect, a dialysate delivery set 12a may not have cassette spikes 160. Instead, one or more solution lines 30 may be permanently affixed to the inlet ports of cassette 24, as shown in FIG. 1A. In this case, each solution line 30 may have a (capped) spike connector 35 for manual connection to a solution container or dialysate bag 20.

With various connections made, the control system 16 may pace the cycler 14 through a series of fill, dwell, and/or drain cycles typical of an APD procedure. For example, during a fill phase, the cycler 14 may pump dialysate (by way of the cassette 24) from one or more containers 20 (or other source of dialysate supply) into the heater bag 22 for heating. Thereafter, the cycler 14 may infuse heated dialysate from the heater bag 22 through the cassette 24 and into the patient's peritoneal cavity via the patient line 34. Following a dwell phase, the cycler 14 may institute a drain phase, during which the cycler

14 pumps used dialysate from the patient via the line 34 (again by way of the cassette 24), and discharges spent dialysis solution into a nearby drain (not shown) via the drain line 28.

The cycler 14 does not necessarily require the solution containers 20 and/or the heater bag 22 to be positioned at a prescribed head height above the cycler 14, e.g., because the cycler 14 is not necessarily a gravity flow system. Instead, the cycler 14 may emulate gravity flow, or otherwise suitably control flow of dialysate solution, even with the source solution containers 20 above, below or at a same height as the cycler 14, with the patient above or below the cycler, etc. For example, the cycler 14 can emulate a fixed head height during a given procedure, or the cycler 14 can change the effective head height to either increase or decrease pressure applied to the dialysate during a procedure. The cycler 14 may also adjust the rate of flow of dialysate. In one aspect of the invention, the cycler 14 may adjust the pressure and/or flow rate of dialysate when provided to the patient or drawn from the patient so as to reduce the patient's sensation of the fill or drain operation. Such adjustment may occur during a single fill and/or drain cycle, or may be adjusted across different fill and/or drain cycles. In one embodiment, the cycler 14 may taper the pressure used to draw used dialysate from the patient near the end of a drain operation. Because the cycler 14 may establish an artificial head height, it may have the flexibility to interact with and adapt to the particular physiology or changes in the relative elevation of the patient.

Cassette

In one aspect of the invention, a cassette 24 may include patient and drain lines that are separately occludable with respect to solution supply lines. That is, safety critical flow to and from patient line may be controlled, e.g., by pinching the lines to stop flow, without the need to occlude flow through one or more solution supply lines. This feature may allow for a simplified occluder device since occlusion may be performed with respect to only two lines as opposed to occluding other lines that have little or no effect on patient safety. For example, in a circumstance where a patient or drain connection becomes disconnected, the patient and drain lines may be occluded. However, the solution supply and/or heater bag lines may remain open for flow, allowing the cycler 14 to prepare for a next dialysis cycle; e.g., separate occlusion of patient and drain lines may help ensure patient safety while permitting the cycler 14 to continue to pump dialysate from one or more containers 20 to the heater bag 22 or to other solution containers 20.

In another aspect of the invention, the cassette may have patient, drain and heater bag lines at one side or portion of the cassette and one or more solution supply lines at another side or portion of the cassette, e.g., an opposite side of the cassette. Such an

arrangement may allow for separate occlusion of patient, drain or heater bag lines with respect to solution lines as discussed above. Physically separating the lines attached to the cassette by type or function allows for more efficient control of interaction with lines of a certain type or function. For example, such an arrangement may allow for a simplified occluder design because less force is required to occlude one, two or three of these lines than all lines leading to or away from the cassette. Alternately, this arrangement may allow for more effective automated connection of solution supply lines to the cassette, as discussed in more detail below. That is, with solution supply lines and their respective connections located apart from patient, drain and/or heater bag lines, an automated de-capping and connection device may remove caps from spikes on the cassette as well as caps on solution supply lines, and connect the lines to respective spikes without interference by the patient, drain or heater bag lines.

FIG. 2 shows an illustrative embodiment of a cassette 24 that incorporates aspects of the invention described above. In this embodiment, the cassette 24 has a generally planar body and the heater bag line 26, the drain line 28 and the patient line 34 are connected at respective ports on the left end of the cassette body, while the right end of the cassette body may include five spikes 160 to which solution supply lines 30 may be connected. In the arrangement shown in FIG. 2, each of the spikes 160 is covered by a spike cap 63, which may be removed, exposing the respective spike and allowing connection to a respective line 30. As described above, the lines 30 may be attached to one or more solution containers or other sources of material, e.g., for use in dialysis and/or the formulation of dialysate, or connected to one or more collection bags for sampling purposes or for peritoneal equilibration testing (PET test).

FIGS. 3 and 4 show exploded views (perspective and top views, respectively) of the cassette 24 in this illustrative embodiment. The cassette 24 is formed as a relatively thin and flat member having a generally planar shape, e.g., may include components that are molded, extruded or otherwise formed from a suitable plastic. In this embodiment, the cassette 24 includes a base member 18 that functions as a frame or structural member for the cassette 24 as well as forming, at least in part, various flow channels, ports, valve portions, etc. The base member 18 may be molded or otherwise formed from a suitable plastic or other material, such as a polymethyl methacrylate (PMMA) acrylic, or a cyclic olefin copolymer/ultra low density polyethylene (COC/ULDPE), and may be relatively rigid. In an embodiment, the ratio of COC to ULDPE can be approximately 85%/15%. FIG. 3 also shows the ports for the heater bag (port 150), drain (port 152) and the patient

(port 154) that are formed in the base member 18. Each of these ports may be arranged in any suitable way, such as, for example, a central tube 156 extending from an outer ring or skirt 158, or a central tube alone. Flexible tubing for each of the heater bag, drain and patient lines 26, 28, 34 may be connected to the central tube 156 and engaged by the outer ring 158, if present.

Both sides of the base member 18 may be covered, at least in part, by a membrane 15 and 16, e.g., a flexible polymer film made from, for example, polyvinyl chloride (PVC), that is cast, extruded or otherwise formed. Alternatively, the sheet may be formed as a laminate of two or more layers of poly-cyclohexylene dimethylene cyclohexanedicarboxylate (PCCE) and/or ULDPE, held together, for example, by a coextrudable adhesive (CXA). In some embodiments, the membrane thickness may be in the range of approximately 0.002 to 0.020 inches thick. In a preferred embodiment, the thickness of a PVC–based membrane may be in the range of approximately 0.012 to 0.016 inches thick, and more preferably approximately 0.014 inches thick. In another preferred embodiment, such as, for example, for laminate sheets, the thickness of the laminate may be in the range of approximately 0.006 to 0.010 inches thick, and more preferably approximately 0.008 inches thick.

Both membranes 15 and 16 may function not only to close or otherwise form a part of flowpaths of the cassette 24, but also may be moved or otherwise manipulated to open/close valve ports and/or to function as part of a pump diaphragm, septum or wall that moves fluid in the cassette 24. For example, the membranes 15 and 16 may be positioned on the base member 18 and sealed (e.g., by heat, adhesive, ultrasonic welding or other means) to a rim around the periphery of the base member 18 to prevent fluid from leaking from the cassette 24. The membrane 15 may also be bonded to other, inner walls of the base member 18, e.g., those that form various channels, or may be pressed into sealing contact with the walls and other features of the base member 18 when the cassette 24 suitably mounted in the cycler 14. Thus, both of the membranes 15 and 16 may be sealed to a peripheral rim of the base member 18, e.g., to help prevent leaking of fluid from the cassette 24 upon its removal from the cycler 14 after use, yet be arranged to lie, unattached, over other portions of the base member 18. Once placed in the cycler 14, the cassette 24 may be squeezed between opposed gaskets or other members so that the membranes 15 and 16 are pressed into sealing contact with the base member 18 at regions inside of the periphery, thereby suitably sealing channels, valve ports, etc., from each other.

Other arrangements for the membranes 15 and 16 are possible. For example, the membrane 16 may be formed by a rigid sheet of material that is bonded or otherwise made integral with the body 18. Thus, the membrane 16 need not necessarily be, or include, a flexible member. Similarly, the membrane 15 need not be flexible over its entire surface, but instead may include one or more flexible portions to permit pump and/or valve operation, and one or more rigid portions, e.g., to close flowpaths of the cassette 24. It is also possible that the cassette 24 may not include the membrane 16 or the membrane 15, e.g., where the cycler 14 includes a suitable member to seal pathways of the cassette, control valve and pump function, etc.

In accordance with another aspect of the invention, the membrane 15 may include a pump chamber portion 151 ("pump membrane") that is formed to have a shape that closely conforms to the shape of a corresponding pump chamber 181 depression in the base 18. For example, the membrane 15 may be generally formed as a flat member with thermoformed (or otherwise formed) dome-like shapes 151 that conform to the pump chamber depressions of the base member 18. The dome-like shape of the pre-formed pump chamber portions 151 may be constructed, for example, by heating and forming the membrane over a vacuum form mold of the type shown in FIG. 5. As shown in FIG. 5, the vacuum may be applied through a collection of holes along the wall of the mold. Alternatively, the wall of the mold can be constructed of a porous gas-permeable material, which may result in a more uniformly smooth surface of the molded membrane. In one example, the molded membrane sheet 15 is trimmed while attached to the vacuum form mold. The vacuum form mold then presses the trimmed membrane sheet 15 against the cassette body 18 and bonds them together. In one embodiment the membrane sheets 15,16 are heat-welded to the cassette body 18. In this way, the membrane 15 may move relative to the pump chambers 181 to effect pumping action without requiring stretching of the membrane 15 (or at least minimal stretching of the membrane 15), both when the membrane 15 is moved maximally into the pump chambers 181 and (potentially) into contact with spacer elements 50 (e.g., as shown in solid line in FIG. 4 while pumping fluid out of the pump chamber 181), and when the membrane 15 is maximally withdrawn from the pump chamber 181 (e.g., as shown in dashed line in FIG. 4 when drawing fluid into the pump chamber 181). Avoiding stretching of the membrane 15 may help prevent pressure surges or other changes in fluid delivery pressure due to sheet stretch and/or help simplify control of the pump when seeking to minimize pressure variation during pump operation. Other benefits may be found, including reduced likelihood of membrane 15 failure (e.g., due to tears in the membrane 15

resulting from stresses place on the membrane 15 during stretching), and/or improved accuracy in pump delivery volume measurement, as described in more detail below. In one embodiment, the pump chamber portions 151 may be formed to have a size (e.g., a define a volume) that is about 85-110% of the pump chamber 181, e.g., if the pump chamber portions 151 define a volume that is about 100% of the pump chamber volume, the pump chamber portion 151 may lie in the pump chamber 181 and in contact with the spacers 50 while at rest and without being stressed.

Providing greater control of the pressure used to generate a fill and delivery stroke of liquid into and out of a pump chamber may have several advantages. For example, it may be desirable to apply the minimum negative pressure possible when the pump chamber draws fluid from the patient's peritoneal cavity during a drain cycle. A patient may experience discomfort during the drain cycle of a treatment in part because of the negative pressure being applied by the pumps during a fill stroke. The added control that a pre-formed membrane can provide to the negative pressure being applied during a fill stroke may help to reduce the patient's discomfort.

A number of other benefits may be realized by using pump membranes pre-formed to the contour of the cassette pump chamber. For example, the flow rate of liquid through the pump chamber can be made more uniform, because a constant pressure or vacuum can be applied throughout the pump stroke, which in turn may simplify the process of regulating the heating of the liquid. Moreover, temperature changes in the cassette pump may have a smaller effect on the dynamics of displacing the membrane, as well as the accuracy of measuring pressures within the pump chambers. In addition, pressure spikes within the fluid lines can be minimized. Also, correlating the pressures measured by pressure transducers on the control (e.g. pneumatic) side of the membrane with the actual pressure of the liquid on the pump chamber side of the membrane may be simpler. This in turn may permit more accurate head height measurements of the patient and fluid source bags prior to therapy, improve the sensitivity of detecting air in the pump chamber, and improve the accuracy of volumetric measurements. Furthermore, eliminating the need to stretch the membrane may allow for the construction and use of pump chambers having greater volumes.

In this embodiment, the cassette 24 includes a pair of pump chambers 181 that are formed in the base member 18, although one pump chamber or more than two pump chambers are possible. In accordance with an aspect of the invention, the inner wall of pump chambers 181 includes spacer elements 50 that are spaced from each other and extend

from the inner wall of pump chamber 18 to help prevent portions of the membrane 15 from contacting the inner wall of pump chamber 181. (As shown on the right-side pump chamber 181 in FIG. 4, the inner wall is defined by side portions 181a and a bottom portion 181b. The spacers 50 extend upwardly from the bottom portion 181b in this embodiment, but could extend from the side portions 181a or be formed in other ways.) By preventing contact of the membrane 15 with the pump chamber inner wall, the spacer elements 50 may provide a dead space (or trap volume) which may help trap air or other gas in the pump chamber 181 and inhibit the gas from being pumped out of the pump chamber 181 in some circumstances. In other cases, the spacers 50 may help the gas move to an outlet of the pump chamber 181 so that the gas may be removed from the pump chamber 181, e.g., during priming. Also, the spacers 50 may help prevent the membrane 15 from sticking to the pump chamber inner wall and/or allow flow to continue through the pump chamber 181, even if the membrane 15 is pressed into contact with the spacer elements 50. In addition, the spacers 50 help to prevent premature closure of the outlet port of the pump chamber (openings 187 and/or 191) if the sheet happens to contact the pump chamber inner wall in a non-uniform manner. Further details regarding the arrangement and/or function of spacers 50 are provided in U.S. Patent 6,302,653 and 6,382,923, both of which are incorporated herein by reference.

In this embodiment, the spacer elements 50 are arranged in a kind of “stadium seating” arrangement such that the spacer elements 50 are arranged in a concentric elliptical pattern with ends of the spacer elements 50 increasing in height from the bottom portion 181b of the inner wall with distance away from the center of the pump chamber 181 to form a semi-elliptical domed shaped region (shown by dotted line in FIG. 4). Positioning spacer elements 50 such that the ends of the spacer elements 50 form a semi-elliptical region that defines the domed region intended to be swept by the pump chamber portion 151 of the membrane 15 may allow for a desired volume of dead space that minimizes any reduction to the intended stroke capacity of pump chambers 181. As can be seen in FIG. 3 (and FIG. 6), the “stadium seating” arrangement in which spacer elements 50 are arranged may include “aisles” or breaks 50a in the elliptical pattern. Breaks (or aisles) 50a help to maintain an equal gas level throughout the rows (voids or dead space) 50b between spacer elements 50 as fluid is delivered from the pump chamber 181. For example, if the spacer elements 50 were arranged in the stadium seating arrangement shown in FIG. 6 without breaks (or aisles) 50a or other means of allowing liquid and air to flow between spacer elements 50, the membrane 15 might bottom out on the spacer element 50 located at the outermost

periphery of the pump chamber 181, trapping whatever gas or liquid is present in the void between this outermost spacer element 50 and the side portions 181a of the pump chamber wall. Similarly, if the membrane 15 bottomed out on any two adjacent spacer elements 50, any gas and liquid in the void between the elements 50 may become trapped. In such an arrangement, at the end of the pump stroke, air or other gas at the center of pump chamber 181 could be delivered while liquid remains in the outer rows. Supplying breaks (or aisles) 50a or other means of fluidic communication between the voids between spacer elements 50 helps to maintain an equal gas level throughout the voids during the pump stroke, such that air or other gas may be inhibited from leaving the pump chamber 181 unless the liquid volume has been substantially delivered.

In certain embodiments, spacer elements 50 and/or the membrane 15 may be arranged so that the membrane 15 generally does not wrap or otherwise deform around individual spacers 50 when pressed into contact with them, or otherwise extend significantly into the voids between spacers 50. Such an arrangement may lessen any stretching or damage to membrane 15 caused by wrapping or otherwise deforming around one or more individual spacer elements 50. For example, it has also been found to be advantageous in this embodiment to make the size of the voids between spacers 50 approximately equal in width to the width of the spacers 50. This feature has shown to help prevent deformation of the membrane 15, e.g., sagging of the membrane into the voids between spacers 50, when the membrane 15 is forced into contact with the spacers 50 during a pumping operation.

In accordance with another aspect of the invention, the inner wall of pump chambers 181 may define a depression that is larger than the space, for example a semi-elliptical or domed space, intended to be swept by the pump chamber portion 151 of the membrane 15. In such instances, one or more spacer elements 50 may be positioned below the domed region intended to be swept by the membrane portion 151 rather than extending into that domed region. In certain instances, the ends of spacer elements 50 may define the periphery of the domed region intended to be swept by the membrane 15. Positioning spacer elements 50 outside of, or adjacent to, the periphery of the domed region intended to be swept by the membrane portion 151 may have a number of advantages. For example, positioning one or more spacer elements 50 such that the spacer elements are outside of, or adjacent to, the domed region intended to be swept by the flexible membrane provides a dead space between the spacers and the membrane, such as described above, while minimizing any reduction to the intended stroke capacity of pump chambers 181.

It should be understood that the spacer elements 50, if present, in a pump chamber may be arranged in any other suitable way, such as for example, shown in FIG. 7. The left side pump chamber 181 in FIG. 7 includes spacers 50 arranged similarly to that in FIG. 6, but there is only one break or aisle 50a that runs vertically through the approximate center of the pump chamber 181. The spacers 50 may be arranged to define a concave shape similar to that in FIG. 6 (i.e., the tops of the spacers 50 may form the semi-elliptical shape shown in FIGS. 3 and 4), or may be arranged in other suitable ways, such as to form a spherical shape, a box-like shape, and so on. The right-side pump chamber 181 in FIG. 7 shows an embodiment in which the spacers 50 are arranged vertically with voids 50b between spacers 50 also arranged vertically. As with the left-side pump chamber, the spacers 50 in the right-side pump chamber 181 may define a semi-elliptical, spherical, box-like or any other suitably shaped depression. It should be understood, however, that the spacer elements 50 may have a fixed height, a different spatial pattern that those shown, and so on.

Also, the membrane 15 may itself have spacer elements or other features, such as ribs, bumps, tabs, grooves, channels, etc., in addition to, or in place of the spacer elements 50. Such features on the membrane 15 may help prevent sticking of the membrane 15, etc., and/or provide other features, such as helping to control how the sheet folds or otherwise deforms when moving during pumping action. For example, bumps or other features on the membrane 15 may help the sheet to deform consistently and avoid folding at the same area(s) during repeated cycles. Folding of a same area of the membrane 15 at repeated cycles may cause the membrane 15 to prematurely fail at the fold area, and thus features on the membrane 15 may help control the way in which folds occur and where.

In this illustrative embodiment, the base member 18 of the cassette 24 defines a plurality of controllable valve features, fluid pathways and other structures to guide the movement of fluid in the cassette 24. FIG. 6 shows a plan view of the pump chamber side of the base member 18, which is also seen in perspective view in FIG. 3. FIG. 8 shows a perspective view of a back side of the base member 18, and FIG. 9 shows a plan view of the back side of the base member 18. The tube 156 for each of the ports 150, 152 and 154 fluidly communicates with a respective valve well 183 that is formed in the base member 18. The valve wells 183 are fluidly isolated from each other by walls surrounding each valve well 183 and by sealing engagement of the membrane 15 with the walls around the wells 183. As mentioned above, the membrane 15 may sealingly engage the walls around each valve well 183 (and other walls of the base member 18) by being pressed into contact

with the walls, e.g., when loaded into the cycler 14. Fluid in the valve wells 183 may flow into a respective valve port 184, if the membrane 15 is not pressed into sealing engagement with the valve port 184. Thus, each valve port 184 defines a valve (e.g., a "volcano valve") that can be opened and closed by selectively moving a portion of the membrane 15 associated with the valve port 184. As will be described in more detail below, the cycler 14 may selectively control the position of portions of the membrane 15 so that valve ports (such as ports 184) may be opened or closed so as to control flow through the various fluid channels and other pathways in the cassette 24. Flow through the valve ports 184 leads to the back side of the base member 18. For the valve ports 184 associated with the heater bag and the drain (ports 150 and 152), the valve ports 184 lead to a common channel 200 formed at the back side of the base member 18. As with the valve wells 183, the channel 200 is isolated from other channels and pathways of the cassette 24 by the sheet 16 making sealing contact with the walls of the base member 18 that form the channel 200. For the valve port 184 associated with the patient line port 154, flow through the port 184 leads to a common channel 202 on the back side of the base member 18. Common channel 200 may also be referred to herein as an upper fluidic bus and common channel 202 may also be referred to herein as a lower fluidic bus.

Returning to FIG. 6, each of the spikes 160 (shown uncapped in FIG. 6) fluidly communicates with a respective valve well 185, which are isolated from each other by walls and sealing engagement of the membrane 15 with the walls that form the wells 185. Fluid in the valve wells 185 may flow into a respective valve port 186, if the membrane 15 is not in sealing engagement with the port 186. (Again, the position of portions of the membrane 15 over each valve port 186 can be controlled by the cycler 14 to open and close the valve ports 186.) Flow through the valve ports 186 leads to the back side of the base member 18 and into the common channel 202. Thus, in accordance with one aspect of the invention, a cassette may have a plurality of solution supply lines (or other lines that provide materials for providing dialysate) that are connected to a common manifold or channel of the cassette, and each line may have a corresponding valve to control flow from/to the line with respect to the common manifold or channel. Fluid in the channel 202 may flow into lower openings 187 of the pump chambers 181 by way of openings 188 that lead to lower pump valve wells 189 (see FIG. 6). Flow from the lower pump valve wells 189 may pass through a respective lower pump valve port 190 if a respective portion of the membrane 15 is not pressed in sealing engagement with the port 190. As can be seen in FIG. 9, the lower pump valve ports 190 lead to a channel that communicates with the lower openings 187 of the pump

chambers 181. Flow out of the pump chambers 181 may pass through the upper openings 191 and into a channel that communicates with an upper valve port 192. Flow from the upper valve port 192 (if the membrane 15 is not in sealing engagement with the port 192) may pass into a respective upper valve well 194 and into an opening 193 that communicates with the common channel 200 on the back side of the base member 18.

As will be appreciated, the cassette 24 may be controlled so that the pump chambers 181 can pump fluid from and/or into any of the ports 150, 152 and 154 and/or any of the spikes 160. For example, fresh dialysate provided by one of the containers 20 that is connected by a line 30 to one of the spikes 160 may be drawn into the common channel 202 by opening the appropriate valve port 186 for the proper spike 160 (and possibly closing other valve ports 186 for other spikes). Also, the lower pump valve ports 190 may be opened and the upper pump valve ports 192 may be closed. Thereafter, the portion of the membrane 15 associated with the pump chambers 181 (i.e., pump membranes 151) may be moved (e.g., away from the base member 18 and the pump chamber inner wall) so as to lower the pressure in the pump chambers 181, thereby drawing fluid in through the selected spike 160 through the corresponding valve port 186, into the common channel 202, through the openings 188 and into the lower pump valve wells 189, through the (open) lower pump valve ports 190 and into the pump chambers 181 through the lower openings 187. The valve ports 186 are independently operable, allowing for the option to draw fluid through any one or a combination of spikes 160 and associated source containers 20, in any desired sequence, or simultaneously. (Of course, only one pump chamber 181 need be operable to draw fluid into itself. The other pump chamber may be left inoperable and closed off to flow by closing the appropriate lower pump valve port 190.)

With fluid in the pump chambers 181, the lower pump valve ports 190 may be closed, and the upper pump valve ports 192 opened. When the membrane 15 is moved toward the base member 18, the pressure in the pump chambers 181 may rise, causing fluid in the pump chambers 181 to pass through the upper openings 191, through the (open) upper pump valve ports 192 and into the upper pump valve wells 194, through the openings 193 and into the common channel 200. Fluid in the channel 200 may be routed to the heater bag port 150 and/or the drain port 152 (and into the corresponding heater bag line or drain line) by opening the appropriate valve port 184. In this way, for example, fluid in one or more of the containers 20 may be drawn into the cassette 24, and pumped out to the heater bag 22 and/or the drain.

Fluid in the heater bag 22 (e.g., after having been suitably heated on the heater tray for introduction into the patient) may be drawn into the cassette 24 by opening the valve port 184 for the heater bag port 150, closing the lower pump valve ports 190, and opening the upper pump valve ports 192. By moving the portions of the membrane 15 associated with the pump chambers 181 away from the base member 18, the pressure in the pump chambers 181 may be lowered, causing fluid flow from the heater bag 22 and into the pump chambers 181. With the pump chambers 181 filled with heated fluid from the heater bag 22, the upper pump valve ports 192 may be closed and the lower pump valve ports 190 opened. To route the heated dialysate to the patient, the valve port 184 for the patient port 154 may be opened and valve ports 186 for the spikes 160 closed. Movement of the membrane 15 in the pump chambers 181 toward the base member 18 may raise the pressure in the pump chambers 181 causing fluid to flow through the lower pump valve ports 190, through the openings 188 and into the common channel 202 to, and through, the (open) valve port 184 for the patient port 154. This operation may be repeated a suitable number of times to transfer a desired volume of heated dialysate to the patient.

When draining the patient, the valve port 184 for the patient port 154 may be opened, the upper pump valve ports 192 closed, and the lower pump valve ports 190 opened (with the spike valve ports 186 closed). The membrane 15 may be moved to draw fluid from the patient port 154 and into the pump chambers 181. Thereafter, the lower pump valve ports 190 may be closed, the upper valve ports 192 opened, and the valve port 184 for the drain port 152 opened. Fluid from the pump chambers 181 may then be pumped into the drain line for disposal or for sampling into a drain or collection container. (Alternatively, fluid may also be routed to one or more spikes 160/lines 30 for sampling or drain purposes). This operation may be repeated until sufficient dialysate is removed from the patient and pumped to the drain.

The heater bag 22 may also serve as a mixing container. Depending on the specific treatment requirements for an individual patient, dialysate or other solutions having different compositions can be connected to the cassette 24 via suitable solution lines 30 and spikes 160. Measured quantities of each solution can be added to heater bag 22 using cassette 24, and admixed according to one or more pre-determined formulae stored in microprocessor memory and accessible by control system 16. Alternatively, specific treatment parameters can be entered by the user via user interface 144. The control system 16 can be programmed to compute the proper admixture requirements based on the type of

dialysate or solution containers connected to spikes 160, and can then control the admixture and delivery of the prescribed mixture to the patient.

In accordance with an aspect of the invention, the pressure applied by the pumps to dialysate that is infused into the patient or removed from the patient may be controlled so that patient sensations of "tugging" or "pulling" resulting from pressure variations during drain and fill operations may be minimized. For example, when draining dialysate, the suction pressure (or vacuum/negative pressure) may be reduced near the end of the drain process, thereby minimizing patient sensation of dialysate removal. A similar approach may be used when nearing the end of a fill operation, i.e., the delivery pressure (or positive pressure) may be reduced near the end of fill. Different pressure profiles may be used for different fill and/or drain cycles in case the patient is found to be more or less sensitive to fluid movement during different cycles of the therapy. For example, a relatively higher (or lower) pressure may be used during fill and/or drain cycles when a patient is asleep, as compared to when the patient is awake. The cycler 14 may detect the patient's sleep/awake state, e.g., using an infrared motion detector and inferring sleep if patient motion is reduced, or using a detected change in blood pressure, brain waves, or other parameter that is indicative of sleep, and so on. Alternately, the cycler 14 may simply "ask" the patient – "are you asleep?" and control system operation based on the patient's response (or lack of response).

Set Loading and Operation

FIG. 10 shows a perspective view of the APD system 10 of FIG. 1 with the door 141 of the cycler 14 lowered into an open position, exposing a mounting location 145 for the cassette 24 and a carriage 146 for the solution lines 30. (In this embodiment, the door 141 is mounted by a hinge at a lower part of the door 141 to the cycler housing 82.) When loading the set 12, the cassette 24 is placed in the mounting location 145 with the membrane 15 and the pump chamber side of the cassette 24 facing upwardly, allowing the portions of the membrane 15 associated with the pump chambers and the valve ports to interact with a control surface 148 of the cycler 14 when the door 141 is closed. The mounting location 145 may be shaped so as to match the shape of the base member 18, thereby ensuring proper orientation of the cassette 24 in the mounting location 145. In this illustrative embodiment, the cassette 24 and mounting location 145 have a generally rectangular shape with a single larger radius corner which requires the user to place the cassette 24 in a proper orientation into the mounting location 145 or the door 141 will not close. It should be

understood, however, that other shapes or orientation features for the cassette 24 and/or the mounting location 145 are possible.

In accordance with an aspect of the invention, when the cassette 24 is placed in the mounting location 145, the patient, drain and heater bag lines 34, 28 and 26 are routed through a channel 40 in the door 141 to the left as shown in FIG. 10. The channel 40, which may include guides 41 or other features, may hold the patient, drain and heater bag lines 34, 28 and 26 so that an occluder 147 may selectively close/open the lines for flow. Upon closing of door 141, occluder 147 can compress one or more of patient, drain and heater bag lines 34, 28 and 26 against occluder stop 29. Generally, the occluder 147 may allow flow through the lines 34, 28 and 26 when the cycler 14 is operating (and operating properly), yet occlude the lines when the cycler 14 is powered down (and/or not operating properly). Occlusion of the lines may be performed by pressing on the lines, or otherwise pinching the lines to close off the flow path in the lines. Preferably, the occluder 147 may selectively occlude at least the patient and drain lines 34 and 28.

When the cassette 24 is mounted and the door 141 is closed, the pump chamber side of the cassette 24 and the membrane 15 may be pressed into contact with the control surface 148, e.g., by an air bladder, spring or other suitable arrangement in the door 141 behind the mounting location 145 that squeezes the cassette 24 between the mounting location 145 and the control surface 148. This containment of the cassette 24 may press the membranes 15 and 16 into contact with walls and other features of the base member 18, thereby isolating channels and other flow paths of the cassette 24 as desired. The control surface 148 may include a flexible gasket or membrane, e.g., a sheet of silicone rubber or other material that is associated with the membrane 15 and can selectively move portions of the membrane 15 to cause pumping action in the pump chambers 181 and opening/closing of valve ports of the cassette 24. The control surface 148 may be associated with the various portions of the membrane 15, e.g., placed into intimate contact with each other, so that portions of the membrane 15 move in response to movement of corresponding portions of the control surface 148. For example, the membrane 15 and control surface 148 may be positioned close together, and a suitable vacuum (or pressure that is lower relative to ambient) may be introduced through vacuum ports suitably located in the control surface 148, and maintained, between the membrane 15 and the control surface 148 so that the membrane 15 and the control surface 148 are essentially stuck together, at least in regions of the membrane 15 that require movement to open/close valve ports and/or to cause pumping

action. In another embodiment, the membrane 15 and control surface 148 may be adhered together, or otherwise suitably associated.

In some embodiments, the surface of the control surface 148 or gasket facing the corresponding cassette membrane overlying the pump chambers and/or valves is textured or roughened. The texturing creates a plurality of small passages horizontally or tangentially along the surface of the gasket when the gasket is pulled against the surface of the corresponding cassette membrane. This may improve evacuation of air between the gasket surface and the cassette membrane surface in the textured locations. It may also improve the accuracy of pump chamber volume determinations using pressure-volume relationships (such as, for example, in the FMS procedures described elsewhere), by minimizing trapped pockets of air between the gasket and the membrane. It may also improve the detection of any liquid that may leak into the potential space between the gasket and the cassette membrane. In an embodiment, the texturing may be accomplished by masking the portions of the gasket mold that do not form the portions of the gasket corresponding to the pump membrane and valve membrane locations. A chemical engraving process such as the Mold-Tech® texturing and chemical engraving process may then be applied to the unmasked portions of the gasket mold. Texturing may also be accomplished by any of a number of other processes, such as, for example, sand blasting, laser etching, or utilizing a mold manufacturing process using electrical discharge machining.

Before closing the door 141 with the cassette 24 loaded, one or more solution lines 30 may be loaded into the carriage 146. The end of each solution line 30 may include a cap 31 and a region 33 for labeling or attaching an indicator or identifier. The indicator, for example, can be an identification tag that snaps onto the tubing at indicator region 33. In accordance with an aspect of the invention and as will be discussed in more detail below, the carriage 146 and other components of the cycler 14 may be operated to remove the cap(s) 31 from lines 30, recognize the indicator for each line 30 (which may provide an indication as to the type of solution associated with the line, an amount of solution, etc.) and fluidly engage the lines 30 with a respective spike 160 of the cassette 24. This process may be done in an automated way, e.g., after the door 141 is closed and the caps 31 and spikes 160 are enclosed in a space protected from human touch, potentially reducing the risk of contamination of the lines 30 and/or the spikes 160 when connecting the two together. For example, upon closing of the door 141, the indicator regions 33 may be assessed (e.g., visually by a suitable imaging device and software-based image recognition, by RFID techniques, etc.) to identify what solutions are associated with which lines 30. The aspect

of the invention regarding the ability to detect features of a line 30 by way of an indicator at indicator region 33 may provide benefits such as allowing a user to position lines 30 in any location of the carriage 146 without having an affect on system operation. That is, since the cycler 14 can automatically detect solution line features, there is no need to ensure that specific lines are positioned in particular locations on the carriage 146 for the system to function properly. Instead, the cycler 14 may identify which lines 30 are where, and control the cassette 24 and other system features appropriately. For example, one line 30 and connected container may be intended to receive used dialysate, e.g., for later testing. Since the cycler 14 can identify the presence of the sample supply line 30, the cycler 14 can route used dialysate to the appropriate spike 160 and line 30. As discussed above, since the spikes 160 of the cassette 24 all feed into a common channel, the input from any particular spike 160 can be routed in the cassette 24 in any desired way by controlling valves and other cassette features.

With lines 30 mounted, the carriage 146 may be moved to the left as shown in FIG. 10 (again, while the door 141 is closed), positioning the caps 31 over a respective spike cap 63 on a spike 160 of the cassette 24 and adjacent a cap stripper 149. The cap stripper 149 may extend outwardly (toward the door 141 from within a recess in the cycler 14 housing) to engage the caps 31. For example, the cap stripper 149 may include five fork-shaped elements that engage with a corresponding groove in the caps 31, allowing the cap stripper 149 to resist left/right movement of the cap 31 relative to the cap stripper 149. By engaging the caps 31 with the cap stripper 149, the caps 31 may also grip the corresponding spike cap 63. Thereafter, with the caps 31 engaged with corresponding spike caps 63, the carriage 146 and cap stripper 149 may move to the right, removing the spike caps 63 from the spikes 160 that are engaged with a corresponding cap 31. One possible advantage of this arrangement is that spike caps 63 are not removed in locations where no solution line 30 is loaded because engagement of the cap 31 from a solution line 30 is required to remove a spike cap 63. Thus, if a solution line 30 will not be connected to a spike 160, the cap on the spike 160 is left in place. The cap stripper 149 may then stop rightward movement (e.g., by contacting a stop), while the carriage 146 continues movement to the right. As a result, the carriage 146 may pull the terminal ends of the lines 30 from the caps 31, which remain attached to the cap stripper 149. With the caps 31 removed from the lines 30 (and the spike caps 63 still attached to the caps 31), the cap stripper 149 may again retract with the caps 31 into the recess in the cycler 14 housing, clearing a path for movement of the carriage 146 and the uncapped ends of the lines 30 toward the spikes 160. The carriage 146 then moves

left again, attaching the terminal ends of the lines 30 with a respective spike 160 of the cassette 24. This connection may be made by the spikes 160 piercing an otherwise closed end of the lines 30 (e.g., the spikes 160 may pierce a closed septum or wall in the terminal end), permitting fluid flow from the respective containers 20 to the cassette 24. In an embodiment, the wall or septum may be constructed of a flexible and/or self-sealing material such as, for example, PVC, polypropylene, or silicone rubber.

In accordance with an aspect of the invention, the heater bag 22 may be placed in the heater bag receiving section (e.g., a tray) 142, which is exposed by lifting a lid 143. In this embodiment, the cycler 14 includes a user or operator interface 144 that is pivotally mounted to the housing 82, as discussed below. To allow the heater bag 22 to be placed into the tray 142, the interface 144 may be pivoted upwardly out of the tray 142. As is known in the art, the heater tray 142 may heat the dialysate in the heater bag 22 to a suitable temperature, e.g., a temperature appropriate for introduction into the patient. In accordance with an aspect of the invention, the lid 143 may be closed after placement of the heater bag 22 in the tray 142, e.g., to help trap heat to speed the heating process, and/or help prevent touching or other contact with a relatively warm portion of the heater tray 142, such as its heating surfaces. In one embodiment, the lid 143 may be locked in a closed position to prevent touching of heated portions of the tray 142, e.g., in the circumstance that portions of the tray 142 are heated to temperatures that may cause burning of the skin. Opening of the lid 143 may be prevented, e.g., by a lock, until temperatures under the lid 143 are suitably low.

In accordance with another aspect of the invention, the cycler 14 includes a user or operator interface 144 that is pivotally mounted to the cycler 14 housing and may be folded down into the heater tray 142. With the interface 144 folded down, the lid 143 may be closed to conceal the interface 144 and/or prevent contact with the interface 144. The interface 144 may be arranged to display information, e.g., in graphical form, to a user, and receive input from the user, e.g., by using a touch screen and graphical user interface. The interface 144 may include other input devices, such as buttons, dials, knobs, pointing devices, etc. With the set 12 connected, and containers 20 appropriately placed, the user may interact with the interface 144 and cause the cycler 14 to start a treatment and/or perform other functions.

FIG. 11 shows a plan view of the control surface 148 of the cycler 14 that interacts with the pump chamber side of the cassette 24 (e.g., shown in FIG. 6) to cause fluid pumping and flow path control in the cassette 24. When at rest, the control surface 148,

which may be described as a type of gasket, and comprise a sheet of silicone rubber, may be generally flat. Valve control regions 1481 may (or may not) be defined in the control surface 148, e.g., by a scoring, groove, rib or other feature in or on the sheet surface, and be arranged to be movable in a direction generally transverse to the plane of the sheet. By moving inwardly/outwardly, the valve control regions 1481 can move associated portions of the membrane 15 on the cassette 24 so as to open and close respective valve ports 184, 186, 190 and 192 of the cassette 24, and thus control flow in the cassette 24. Two larger regions, pump control regions 1482, may likewise be movable so as to move associated shaped portions 151 of the membrane 15 that cooperate with the pump chambers 181. Like the shaped portions 151 of the membrane 15, the pump control regions 1482 may be shaped in a way to correspond to the shape of the pump chambers 181 when the control regions 1482 are extended into the pump chambers 181. In this way, the portion of the control sheet 148 at the pump control regions 1482 need not necessarily be stretched or otherwise resiliently deformed during pumping operation.

Each of the regions 1481 and 1482 may have an associated vacuum or evacuation port 1483 that may be used to remove all or substantially all of any air or other fluid that may be present between the membrane 15 of cassette 24, and the control surface 148 of cycler 14, e.g., after the cassette 24 is loaded into the cycler 14 and the door 141 closed. This may help ensure close contact of the membrane 15 with the control regions 1481 and 1482, and help control the delivery of desired volumes with pump operation and/or the open/closed state of the various valve ports. Note that the vacuum ports 1482 are formed in locations where the control surface 148 will not be pressed into contact with a wall or other relatively rigid feature of the cassette 24. For example, in accordance with one aspect of the invention, one or both of the pump chambers of the cassette may include a vacuum vent clearance region formed adjacent the pump chamber. In this illustrative embodiment as shown in FIGS. 3 and 6, the base member 18 may include vacuum vent port clearance or extension features 182 (e.g., recessed areas that are fluidly connected to the pump chambers) adjacent and outside the oval-shaped depressions forming the pump chambers 181 to allow the vacuum vent port 1483 for the pump control region 1482 to remove any air or fluid from between membrane 15 and control surface 148 (e.g., due to rupture of the membrane 15) without obstruction. The extension feature may also be located within the perimeter of pump chamber 181. However, locating vent port feature 182 outside the perimeter of pump chamber 181 may preserve more of the pumping chamber volume for pumping liquids, e.g., allows for the full footprint of pump chamber 181 to be used for

pumping dialysate. Preferably, extension feature 182 is located in a vertically lower position in relation to pump chamber 181, so that any liquid that leaks between membrane 15 and control surface 148 is drawn out through vacuum port 1483 at the earliest opportunity. Similarly, vacuum ports 1483 associated with valves 1481 are preferably located in a vertically inferior position with respect to valves 1481.

FIG. 12 shows that control surface 148 may be constructed or molded to have a rounded transition between the base element 1480 of control surface 148 and its valve and pump control regions 1481, 1482. The junctions 1491 and 1492 may be molded with a small radius to transition from base element 1480 to valve control region 1481 and pump control region 1482, respectively. A rounded or smooth transition helps to prevent premature fatigue and fracture of the material comprising control surface 148, and may improve its longevity. In this embodiment, channels 1484 leading from vacuum ports 1483 to the pump control regions 1482 and valve control regions 1481 may need to be lengthened somewhat to accommodate the transition feature.

The control regions 1481 and 1482 may be moved by controlling a pneumatic pressure and/or volume on a side of the control surface 148 opposite the cassette 24, e.g., on a back side of the rubber sheet that forms the control surface 148. For example, as shown in FIG. 13, the control surface 148 may be backed by a mating or pressure delivery block 170 that includes control chambers or depressions 171A located in association with each control region 1481, and control chambers or depressions 171B, located in association with each control region 1482, and that are isolated from each other (or at least can be controlled independently of each other if desired). The surface of mating or pressure delivery block 170 forms a mating interface with cassette 24 when cassette 24 is pressed into operative association with control surface 148 backed by mating block 170. The control chambers or depressions of mating block 170 are thus coupled to complementary valve or pumping chambers of cassette 24, sandwiching control regions 1481 and 1482 of control surface 148 adjacent to mating block 170, and the associated regions of membrane 15 (such as shaped portion 151) adjacent to cassette 24. Air or other control fluid may be moved into or out of the control chambers or depressions 171A, 171B of mating block 170 for the regions 1481, 1482, thereby moving the control regions 1481, 1482 as desired to open/close valve ports of the cassette 24 and/or effect pumping action at the pump chambers 181. In one illustrative embodiment shown in FIG. 13, the control chambers 171A may be arranged as cylindrically-shaped regions backing each of the valve control regions 1481. The control chambers or depressions 171B may comprise ellipsoid, ovoid or hemi-spheroid voids or

depressions backing the pump control regions 1482. Fluid control ports 173A may be provided for each control chamber 171A so that the cycler 14 can control the volume of fluid and/or the pressure of fluid in each of the valve control chambers 1481. Fluid control ports173C may be provided for each control chamber 171B so that the cycler 14 can control the volume of fluid and/or the pressure of fluid in each of the volume control chambers 1482. For example, the mating block 170 may be mated with a manifold 172 that includes various ports, channels, openings, voids and/or other features that communicate with the control chambers 171B and allow suitable pneumatic pressure/vacuum to be applied to the control chambers 171B. Although not shown, control of the pneumatic pressure/vacuum may be performed in any suitable way, such as through the use of controllable valves, pumps, pressure sensors, accumulators, and so on. Of course, it should be understood that the control regions 1481, 1482 may be moved in other ways, such as by gravity-based systems, hydraulic systems, and/or mechanical systems (such as by linear motors, etc.), or by a combination of systems including pneumatic, hydraulic, gravity-based and mechanical systems.

FIG. 14 shows an exploded view of an integrated pressure distribution module or assembly 2700 for use in a fluid flow control apparatus for operating a pumping cassette, and suitable for use as pressure distribution manifold 172 and mating block 170 of cycler 14. FIG. 15 shows a view of an integrated module 2700 comprising a pneumatic manifold or block, ports for supply pressures, pneumatic control valves, pressure sensors, a pressure delivery or mating block and a control surface or actuator that includes regions comprising flexible membranes for actuating pumps and valves on a pumping cassette. The integrated module 2700 may also include reference chambers within the pneumatic manifold for an FMS volume measurement process for determining the volume of fluid present in a pumping chamber of a pumping cassette. The integrated module may also comprise a vacuum port, and a set of pathways or channels from interfaces between the actuator and flexible pump and valve membranes of a pumping cassette to a fluid trap and liquid detection system. In some embodiments, the pneumatic manifold may be formed as a single block. In other embodiments, the pneumatic manifold may be formed from two or more manifold blocks mated together with gaskets positioned between the manifold blocks. The integrated module 2700 occupies a relatively small space in a fluid flow control apparatus, and eliminates the use of tubes or flexible conduits connecting the manifold ports with corresponding ports of a pressure delivery module or block mated to a pumping cassette. Among other possible advantages, the integrated module 2700 reduces the size and

assembly cost of the pneumatic actuation assembly of a peritoneal dialysis cycler, which may result in a smaller and less expensive cycler. Additionally, the short distances between pressure or vacuum distribution ports on the pressure distribution manifold block and corresponding pressure or vacuum delivery ports on a mating pressure delivery block, together with the rigidity of the conduits connecting the ports, may improve the responsiveness of an attached pumping cassette and the accuracy of cassette pump volume measurement processes. When used in a peritoneal dialysis cycler 14, in an embodiment, an integrated module comprising a metallic pressure distribution manifold mated directly to a metallic pressure delivery block may also reduce any temperature differences between the control volume 171B and the reference chamber 174 of the cycler 14, which may improve the accuracy of the pump volume measurement process.

An exploded view of the integrated module 2700 is presented in FIG. 14. The actuator surface, mounted on a mating block or pressure delivery block, is analogous or equivalent to the gasket or control surface 148, that includes flexible regions arranged to move back and forth to pump fluid and/or open and close valves by pushing or pulling on a membrane 15 of a pump cassette 24. With respect to cycler 14, the control surface 148 is actuated by the positive and negative pneumatic pressure supplied to the control volumes 171A, 171B behind the control regions 1481, 1482. The control surface 148 attaches to the pressure delivery block or mating block 170 by fitting tightly on a raised surface 2744 on the front surface of the mating block 170 with a lip 2742. The mating block 170 may include one or more surface depressions 2746 to align with and support the oval curved shape of one or more corresponding pump control surfaces 1482, forming a pump control chamber. A similar arrangement, with or without a surface depression, may be included in forming a valve control region 171A to align with a corresponding control surface 1481 for controlling one or more valves of a pumping cassette. The mating block 170 may further include grooves 2748 on the surface of depression 2746 of mating block 170 behind the pump control surface 1482 to facilitate the flow of control fluid or gas from the port 173C to the entire back surface the pump control surface 1482. Alternatively, rather than having grooves 2748, the depression 2746 may be formed with a roughened surface or a tangentially porous surface.

The mating block 170 connects the pressure distribution manifold 172 to the control surface 148, and delivers pressure or vacuum to various control regions on control surface 148. The mating block 170 may also be referred to as a pressure delivery block in that it provides pneumatic conduits to supply pressure and vacuum to the valve control regions

1481 and the pump control regions 1482, vacuum to the vacuum ports 1483 and connections from the pump control volumes 171B to the pressure sensors. The ports 173A connect the valve control volumes 171A to the pressure distribution manifold 172. The ports 173C connect the pump control volume 171B to the pressure distribution manifold 172. The vacuum ports 1483 are connected to the pressure distribution manifold 172 via ports 173B. In one embodiment, the ports 173B extend above the surface of the pressure delivery block 170 to pass through the control surface 148 to provide vacuum at port 1483 without pulling the control surface 148 onto the port 173B and blocking flow.

The pressure delivery block 170 is attached to the front face of the pressure distribution manifold 172. The ports 173A, 173B, 173C line up with pneumatic circuits on the pressure distribution manifold 172 that connect to valve ports 2714. In one example, the pressure delivery block 170 is mated to the pressure distribution manifold 172 with a front flat gasket 2703 clamped between them. The block 170 and manifold 172 are held together mechanically, which in an embodiment is through the use of bolts 2736 or other types of fasteners. In another example, rather than a flat gasket 2703, compliant elements are placed in or molded in either the pressure delivery block 170 or the pressure distribution manifold 172. Alternatively, the pressure delivery block 170 may be bonded to the pressure distribution manifold 172 by an adhesive, double sided tape, friction welding, laser welding, or other bonding method. The block 170 and manifold 172 may be formed of metal or plastic and the bonding methods will vary depending on the material.

The pressure distribution manifold 172 contains ports for the pneumatic valves 2710, reference chambers 174, a fluid trap 1722 and pneumatic circuitry or of the integrated module 2700 connections provides pneumatic connections between the pressure reservoirs, valves, and contains ports 2714 that receive multiple cartridge valves 2710. The cartridge valves 2710 include but are not limited to the binary valves 2660 controlling flow to valve control volumes 171A, the binary valves X1A, X1B, X2, X3 controlling flow to pump control volumes 171B, and the binary valves 2661-2667 controlling flow to the bladders 2630, 2640, 2650 and pressure reservoirs 2610, 2620. The cartridge valves 2710 are pressed into the valve ports 2714 and electrically connected to the hardware interface 310 via circuit board 2712.

The pneumatic circuitry in the pressure distribution manifold 172 may be formed with a combination of grooves or slots 1721 on the front and back faces and approximately perpendicular holes that connect the grooves1721 on one face to valve ports 2714, the fluid trap 1722 and to grooves and ports on the opposite face. Some grooves 1721 may connect

directly to the reference chambers 174. A single perpendicular hole may connect a groove 1721 to multiple valve ports 174 that are closely spaced and staggered. Sealed pneumatic conduits are formed when the grooves 1721 are isolated from one another by, in one example, the front flat gasket 2703 as shown in FIG. 14.

The presence of liquid in the fluid trap 1722 may be detected by a pair of conductivity probes 2732. The conductivity probes 2732 slide through a back gasket 2704, a back plate 2730 and holes 2750 before entering the fluid trap 1722 in the pressure distribution manifold 172.

The back plate 2730 seals the reference volumes 174, the grooves 1721 on the back face of the pressure distribution manifold 172 and provides ports for the pressure sensors 2740 and ports for pressure and vacuum lines 2734 and vents to the atmosphere 2732. In one example, the pressure sensors may be IC chips soldered to a single board 2740 and pressed as a group against the back gasket 2704 on the back plate 2730. In one example, bolts 2736 clamp the back plate 2730, pressure distribution manifold 172 and pressure delivery block 170 together with gaskets 2703, 2702 between them. In another example, the back plate 2730 may be bonded to the pressure delivery manifold 172 as described above. The assembled integrated module 2700 is presented in FIG. 16.

FIG. 16 presents a schematic of the pneumatic circuit in the integrated manifold 2700 and pneumatic elements outside the manifold. The pump 2600 produces vacuum and pressure. The pump 2600 is connected via 3 way valves 2664 and 2665 to a vent 2680 and the negative or vacuum reservoir 2610 and the positive reservoir 2620. The pressure in the positive and negative reservoirs 2620, 2610 are measured respectively by pressure sensors 2678, 2676. The hardware interface 310 controls the speed of the pump 2600 and the position of 3-way valves 2664, 2665, 2666 to control the pressure in each reservoir. The auto-connect stripper element bladder 2630 is connected via 3-way valve 2661 to either the positive pressure line 2622 or the negative or vacuum line 2612. The automation computer 300 commands the position of valve 2661 to control the location of the stripper element 2630. The occluder bladder 2640 and piston bladder 2650 are connected via 3-way valves 2662 and 2663 to either the pressure line 2622 or vent 2680. The automation computer 300 commands valve 2663 to connect the piston bladder 2650 to the pressure line 2622 after the door 141 is closed to securely engage the cassette 24 against the control surface 148. The occluder bladder 2640 is connected to the pressure line 2622 via valve 2662 and restriction 2682. The occluder bladder 2640 is connected to the vent 2680 via valve 2662. The orifice

2682 advantageously slows the filling of the occluder bladder 2640 that retracts the occluder 147 in order to maintain the pressure in the pressure line 2622. The high pressure in the pressure line 2622 keeps the various valve control surfaces 171A and the piston bladder 2650 actuated against the cassette 24, which prevents flow to or from the patient as the occluder 147 opens. Conversely the connection from the occluder bladder 2640 to the vent 2680 is unrestricted, so that occluder 147 can quickly close.

The valve control surfaces 1481 are controlled by the pressure in the valve control volume 171A, which in turn is controlled by the position of the 3-way valves 2660. The valves 2660 can be controlled individually via commands from the automation computer 300 passed to the hardware interface 310. The valves controlling the pumping pressures in the pump control volumes 171B are controlled with 2-way valves X1A, X1B. The valves X1A, X1B in one example may be controlled by the hardware interface 310 to achieve a pressure commanded by the automation computer 300. The pressure in each pump control chamber 171B is measured by sensors 2672. The pressure in the reference chambers is measured by sensors 2670. The 2-way valves X2, X3 respectively connect the reference chamber 174 to the pump control chamber 171B and the vent 2680.

The fluid trap 1722is to the vacuum line 2612 during operation as explained elsewhere in this application. The fluid trap 1722 is connected by several lines to the ports 173B in the pressure delivery block 170. The pressure in the fluid trap 1722 is monitored by pressure sensor 2674 that is mounted on the back plate 2730.

The vacuum ports 1483 may be employed to separate the membrane 15 from the control surface 148 at the end of therapy before or during the opening the door. The vacuum provided by the negative pressure source to the vacuum ports 1483 sealingly engages the membrane 15 to the control surface 148 during therapy. In some instances a substantial amount of force may be needed to separate the control surface from the cassette membrane 15, preventing the door 141 from freely rotating into the open position, even when the application of vacuum is discontinued. Thus, in an embodiment, the pressure distribution module 2700 is configured to provide a valved channel between the positive pressure source and the vacuum ports 1483. Supplying positive pressure at the vacuum ports 1483 may aid in separating the membrane 15 from the control surface 148, thereby allowing the cassette 24 to separate more easily from the control surface 148 and allow the door 141 to open freely. The pneumatic valves in the cycler may be controlled by the automation computer 300 to provide a positive pressure to the vacuum ports 1483. The manifold 172 may include a separately valved channel dedicated for this purpose, or

alternatively it may employ the existing channel configurations and valves, operated in a particular sequence.

In one example the vacuum ports 1483 may be supplied with positive pressure by temporarily connecting the vacuum ports 1483 to the positive pressure reservoir 2620. The vacuum ports 1483 are normally connected to the vacuum reservoir 2610 via a common fluid collection chamber or fluid trap 1722 in the manifold 172 during therapy. In one example, the controller or automation computer may open valve X1B between the positive pressure reservoir and the volume control chamber 171B and the valve X1A between the negative pressure reservoir and the same volume control chamber 171B simultaneously, which will pressurize the air in the fluid trap 1722 and the vacuum ports 1483. The pressurized air will flow through the vacuum ports 1483 and between the membrane 15 and the control surface 148, breaking any vacuum bond between the membrane and control surface. However, in the illustrated manifold, the stripper element 1491 of the cap stripper 149 may extend while the positive pressure is supplied to common fluid collection chamber 1722 fluid, because the stripper bladder 2630 is connected to a the vacuum supply line 2612. In this example, in a subsequent step, the fluid trap 1722 may be valved off from the now-pressurized vacuum line and the two valves X1A, X1B connecting the positive and vacuum reservoirs to the volume control chamber 171B may be closed. The vacuum pump 2600 is then operated to reduce the pressure in the vacuum reservoir 2610 and the vacuum supply line 2612, which in turn allows the stripper element 1491 to be withdrawn. The door 141may then be opened after detaching the cassette 24 from the control surface 148 and retracting the stripper element 1491.

In accordance with an aspect of the disclosure, the vacuum ports 1483 may be used to detect leaks in the membrane 15, e.g., a liquid sensor in a conduit or chamber connected to a vacuum port 1483 may detect liquid if the membrane 15 is perforated or liquid otherwise is introduced between the membrane 15 and the control surface 148. For example, vacuum ports 1483 may align with and be sealingly associated with complementary vacuum ports 173B in mating block 170, which in turn may be sealingly associated with fluid passages 1721 leading to a common fluid collection chamber 1722 in manifold 172. The fluid collection chamber 1722 may contain an inlet through which vacuum can be applied and distributed to all vacuum ports 1483 of control surface 148. By applying vacuum to the fluid collection chamber 1722, fluid may be drawn from each of the vacuum ports 173B and 1483, thus removing fluid from any space between the membrane 15 and the control surface 148 at the various control regions. However, if there is liquid

present at one or more of the regions, the associated vacuum port 1483 may draw the liquid into the vacuum ports 173B and into the lines 1721 leading to the fluid collection chamber 1722. Any such liquid may collect in the fluid collection chamber 1722, and be detected by one or more suitable sensors, e.g., a pair of conductivity sensors that detect a change in conductivity in the chamber 1722 indicating the presence of liquid. In this embodiment, the sensors may be located at a bottom side of the fluid collection chamber 1722, while a vacuum source connects to the chamber 1722 at an upper end of the chamber 1722. Therefore, if liquid is drawn into the fluid collection chamber 1722, the liquid may be detected before the liquid level reaches the vacuum source. Optionally, a hydrophobic filter, valve or other component may be placed at the vacuum source connection point into the chamber 1722 to help further resist the entry of liquid into the vacuum source. In this way, a liquid leak may be detected and acted upon by controller 16 (e.g., generating an alert, closing liquid inlet valves and ceasing pumping operations) before the vacuum source valve is placed at risk of being contaminated by the liquid.

In the example schematic shown in FIG. 16, a calibration port 2684 is depicted. The calibration port 2684 may be used to calibrate the various pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 in the pneumatic system. For example, a pressure reference may be connected to the pneumatic circuit of the cycler via the calibration port 2684. With the pressure reference connected, the valves of the pneumatic system may be actuated so as to connect all of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 to the same fluid volume. A known pressure may then be established in the pneumatic system using the pressure reference. The pressure readings from each of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may be compared to the known pressure of the pressure reference and the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may then be calibrated accordingly. In some embodiments, selected pressure sensors of the pressure sensors 2672, 2674, 2676, 2677, 2678 may be connected and brought to the pressure of the reference for calibration in groups or individually.

Any fluid handling device (i.e. base unit) that is configured to actuate diaphragm-based pumps and valves on a removable cassette can take advantage of its pneumatic (or hydraulic) cassette interface to receive a calibrating reference pressure via a specialized calibrating cassette (or ‘cassette fixture’). A calibrating cassette can have the same overall dimensions as a standard fluid pumping cassette, so that it can provide a sealing interface with the cassette interface or control surface of the base unit. One or more of the pump or valve regions can be allowed to communicate with a corresponding region of the interface

to which it mates, so that a reference pneumatic or hydraulic pressure can be introduced through the calibrating cassette and into the pneumatic or hydraulic flow paths of the base unit (e.g. via a pneumatic or hydraulic manifold).

For example, in a pneumatically operated peritoneal dialysis cycler, the pneumatic circuitry of the cycler may be accessed directly through the cassette interface of the cycler. This may for example, be accomplished using a modified cassette or cassette fixture which allows the control surface 148 to create a seal against the cassette fixture. Additionally, the cassette fixture may be constructed to include at least one access port in fluid communication with a vacuum port 173B of the cassette interface. In the absence of a vacuum port (e.g. in embodiments having slits or perforations in the control surface) the access port may instead be placed in communication with the vacuum vent feature of the cassette interface or control surface.

The cassette fixture (or calibrating cassette) may be constructed to have a direct flow path from an external cassette port to the access port facing the device interface, the external cassette port then being available for connection to a pressure reference. As described above, all or some of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may be placed into fluid communication with a common volume, through the appropriate actuation of pneumatic control valves in the pressure distribution manifold. A known pressure may be established in that volume using the pressure reference. The pressure readings from each of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may be compared to the known pressure of the pressure reference and the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may then be calibrated accordingly.

In some embodiments of a pressure distribution manifold, it may not be possible for all of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 to be connected to a common volume at one time. In that case, the flow paths to the individual pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may need to be opened in a sequential manner to ensure calibration of all sensors. Additionally, it should be noted that once calibrated, one or more of the pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 may be used to calibrate other pressure sensors 2670, 2672, 2674, 2676, 2677, 2678 in a pressure distribution manifold of a base unit or cycler. The previously calibrated pressure sensor or sensors may be placed into a common volume with the uncalibrated pressure sensor (e.g. via suitable valve actuations). The pressure of the common volume may be known via the calibrated pressure sensor(s). The uncalibrated pressure sensor's reading may be compared to the known pressure of the common volume and then calibrated accordingly.

Occluder

In one aspect of the disclosure, an occluder for opening/closing one or more flexible lines may include a pair of opposed occluding members, which may be configured as resilient elements, such as flat plates made of a spring steel (e.g., leaf springs), having a force actuator configured to apply a force to one or both of the occluding members to operate the occluder. In certain embodiments, the force actuator may comprise an expandable or enlargable member positioned between the resilient elements. With the expandable member in a reduced size condition, the resilient elements may be in a flat or nearly flat condition and urge a pinch head to engage with one or more lines so as to pinch the lines closed. However, when the expandable member urges the resilient elements apart, the resilient elements may bend and withdraw the pinch head, releasing the lines and allowing flow through the lines. In other embodiments, the occluding members could be essentially rigid with respect to the levels of force applied by the force actuator. In certain embodiments, the force actuator may apply a force to one or both opposed occluding members to increase the distance between the occluding members in at least a portion of the region where they are opposed to effect opening or closing of the flexible tubing.

FIG. 17 shows an exploded view and FIG. 18 shows a partially assembled view of an illustrative embodiment of an occluder 147 that may be used to close, or occlude, the patient and drain lines 34 and 28, and/or other lines in the cycler 14 or the set 12 (such as, for example, the heater bag line 26). The occluder 147 includes an optional pinch head 161, e.g., a generally flat blade-like element that contacts the tubes to press the tubes against the door 141 and pinch the tubes closed. In other embodiments, the function of the pinch head could be replaced by an extending edge of one or both of occluding members 165. The pinch head 161 includes a gasket 162, such as an O-ring or other member, that cooperates with the pinch head 161to help resist entry of fluid (air or liquid for example) into the cycler 14 housing, e.g., in case of leakage in one of the occluded lines. The bellows gasket 162 is mounted to, and pinch head 161 passes through, a pinch head guide 163 that is mounted to the front panel of the cycler housing, i.e., the panel exposed by opening the door 141. The pinch head guide 163 allows the pinch head 161 to move in and out of the pinch head guide 163 without binding and/or substantial resistance to sliding motion of the pinch head 161. A pivot shaft 164 attaches a pair of opposed occluder members, comprising in the illustrated embodiment spring plates 165, that each include a hook-shaped pivot shaft bearing, e.g., like that found on standard door hinges, to the pinch head 161. That is, the openings of shaft guides on the pinch head 161, and the openings formed by the hook-shaped bearings

on the spring plates 165 are aligned with each other and the pivot shaft 164 is inserted through the openings so the pinch head 161 and the spring plates 165 are pivotally connected together. The spring plates 165 may be made of any suitable material, such as steel, and may be arranged to be generally flat when unstressed. The opposite end of the spring plates 165 includes similar hook-shaped bearings, which are pivotally connected to a linear adjustor 167 by a second pivot shaft 164. In this embodiment, the force actuator comprises a bladder 166 is positioned between the spring plates 165 and arranged so that when fluid (e.g., air under pressure) is introduced into the bladder, the bladder may expand and push the spring plates 165 away from each other in a region between the pivot shafts 164. The bladder 166 may be attached to one or both spring plates 165 by pressure sensitive adhesive (PSA) tape. A linear adjustor 167 is fixed to the cycler housing 82 while the pinch head 161 is allowed to float, although its movement is guided by the pinch head guide 163. The linear adjustor 167 includes slot holes at its lower end, allowing the entire assembly to be adjusted in position and thus permitting the pinch head to be appropriately positioned when the occluder 147 is installed in the cycler 14. A turnbuckle 168 or other arrangement may be used to help adjust the position of the linear adjustor 167 relative to the housing 82. That is, the pinch head 161 generally needs to be properly positioned so that with the spring plates 165 located near each other and the bladder 166 substantially emptied or at ambient pressure, the pinch head 161 suitably presses on the patient and drain lines so as to pinch the tubes closed to flow without cutting, kinking or otherwise damaging the tubes. The slot openings in the linear adjustor 167 allows for this fine positioning and fixing of the occluder 147 in place. An override release device, such as provided by release blade 169 is optionally positioned between the spring plates 165, and as is discussed in more detail below, may be rotated so as to push the spring plates 165 apart, thereby withdrawing the pinch head 161 into the pinch head guide 163. The release blade 169 may be manually operated, e.g., to disable the occluder 147 in case of power loss, bladder 166 failure or other circumstance.

Additional configurations and descriptions of certain components that may be instructive in constructing certain embodiments of the occluder are provided in U.S. Patent 6,302,653. The spring plates 165 may be constructed from any material that is elastically resistant to bending forces and which has sufficient longitudinal stiffness (resistance to bending) to provide sufficient restoring force, in response to a bending displacement, to occlude a desired number of collapsible tubes. In the illustrated embodiment, each spring plate is essentially flat when unstressed and in the shape of a sheet or plate. In alternative

embodiments utilizing one or more resilient occluding members (spring members), any occluding member(s) that is elastically resistant to bending forces and which has sufficient longitudinal stiffness (resistance to bending) to provide sufficient restoring force, in response to a bending displacement to occlude a desired number of collapsible tubes may be utilized. Potentially suitable spring members can have a wide variety of shapes as apparent to those of ordinary skill in the art, including, but not limited to cylindrical, prism-shaped, trapezoidal, square, or rectangular bars or beams, I-beams, elliptical beams, bowl-shaped surfaces, and others. Those of ordinary skill in the art can readily select proper materials and dimensions for spring plates 165 based on the present teachings and the requirements of a particular application.

FIG. 19 shows a top view of the occluder 147 with the bladder 166 deflated and the spring plates 165 located near each other and in a flat or nearly flat condition. In this position, the pinch head 161 is fully extended from the pinch head guide and the front panel of the cycler 14 (i.e., the panel inside of the door 141) and enabled to occlude the patient and drain lines. FIG. 20, on the other hand, shows the bladder 166 in an inflated state in which the spring plates 165 are pushed apart, thereby retracting the pinch head 161 into the pinch head guide 163. Note that the linear adjustor 167 is fixed in place relative to the cycler housing 82 and thus fixed relative to the front panel of the housing 82. As the spring plates 165 are moved apart, the pinch head 161 moves rearward relative to the front panel since the pinch head 161 is arranged to move freely in and out of the pinch head guide 163. This condition prevents the pinch head 161 from occluding the patient and drain lines and is the condition in which the occluder 147 remains during normal operation of the cycler 14. That is, as discussed above, various components of the cycler 14 may operate using air pressure/vacuum, e.g., the control surface 148 may operate under the drive of suitable air pressure/vacuum to cause fluid pumping and valve operation for the cassette 24. Thus, when the cycler 14 is operating normally, the cycler 14 may produce sufficient air pressure to not only control system operation, but also to inflate the bladder 166 to retract the pinch head 161 and prevent occlusion of the patient and drain lines. However, in the case of system shut down, failure, fault or other condition, air pressure to the bladder 166 may be terminated, causing the bladder 166 to deflate and the spring plates 165 to straighten and extend the pinch head 161 to occlude the lines. One possible advantage of the arrangement shown is that the return force of the spring plates 165 is balanced such that the pinch head 161 generally will not bind in the pinch head guide 163 when moving relative to the pinch head guide 163. In addition, the opposing forces of the spring plates 165 will tend to reduce

the amount of asymmetrical frictional wear of the pivot shafts and bushings of the assembly. Also, once the spring plates 165 are in an approximately straight position, the spring plates 165 can exert a force in a direction generally along the length of the pinch head 161 that is several times larger than the force exerted by the bladder 166 on the spring plates 165 to separate the spring plates 165 from each other and retract the pinch head 161. Further, with the spring plates 165 in a flat or nearly flat condition, the force needed to be exerted by fluid in the collapsed tubing to overcome the pinching force exerted by the pinch head 161 approaches a relatively high force required, when applied to the spring plates at their ends and essentially parallel to the plane of the flattened spring plates, to buckle the spring plates by breaking the column stability of the flattened spring plates. As a result, the occluder 147 can be very effective in occluding the lines with a reduced chance of failure while also requiring a relatively small force be applied by the bladder 166 to retract the pinch head 161. The dual spring plate arrangement of the illustrative embodiment may have the additional advantage of significantly increasing the pinching force provided by the pinch head, for any given force needed to bend the spring plate, and/or for any given size and thickness of spring plate.

In some circumstances, the force of the occluder 147 on the lines may be relatively large and may cause the door 141 to be difficult to open. That is, the door 141 must oppose the force of the occluder 147 when the pinch head 161 is in contact with and occluding lines, and in some cases this may cause the latch that maintains the door 141 in a closed state to be difficult or impossible to operate by hand. Of course, if the cycler 14 is started and produces air pressure to operate, the occluder bladder 166 can be inflated and the occluder pinch head 161 retracted. However, in some cases, such as with a pump failure in the cycler 14, inflation of the bladder 166 may be impossible or difficult. To allow opening of the door, the occluder 147 may include a manual release. In this illustrative embodiment, the occluder 147 may include a release blade 169 as shown in FIGS. 17 and 18 which includes a pair of wings pivotally mounted for rotary movement between the spring plates 165. When at rest, the release blade wings may be aligned with the springs as shown in FIG. 18, allowing the occluder to operate normally. However, if the spring plates 165 are in a flat condition and the pinch head 161 needs to be retracted manually, the release blade 169 may be rotated, e.g., by engaging a hex key or other tool with the release blade 169 and turning the release blade 169, so that the wings push the spring plates 165 apart. The hex key or other tool may be inserted through an opening in the housing 82 of the cycler 14,

e.g., an opening near the left side handle depression in the cycler housing 82, and operated to disengage the occluder 147 and allow the door 141 to be opened.

Pump Volume Delivery Measurement

In another aspect of the invention, the cycler 14 may determine a volume of fluid delivered in various lines of the system 10 without the use of a flowmeter, weight scale or other direct measurement of fluid volume or weight. For example, in one embodiment, a volume of fluid moved by a pump, such as a pump in the cassette 24, may be determined based on pressure measurements of a gas used to drive the pump. In one embodiment, a volume determination can be made by isolating two chambers from each other, measuring the respective pressures in the isolated chambers, allowing the pressures in the chambers to partially or substantially equalize (by fluidly connecting the two chambers) and measuring the pressures. Using the measured pressures, the known volume of one of the chambers, and an assumption that the equalization occurs in an adiabatic way, the volume of the other chamber (e.g., a pump chamber) can be calculated. In one embodiment, the pressures measured after the chambers are fluidly connected may be substantially unequal to each other, i.e., the pressures in the chambers may not have yet completely equalized. However, these substantially unequal pressures may be used to determine a volume of the pump control chamber, as explained below.

For example, FIG. 21 shows a schematic view of a pump chamber 181 of the cassette 24 and associated control components and inflow/outflow paths. In this illustrative example, a liquid supply, which may include the heater bag 22, heater bag line 26 and a flow path through the cassette 24, is shown providing a liquid input at the upper opening 191 of the pump chamber. The liquid outlet is shown in this example as receiving liquid from the lower opening 187 of the pump chamber 181, and may include a flow path of the cassette 24 and the patient line 34, for example. The liquid supply may include a valve, e.g., including the valve port 192, that can be opened and closed to permit/impede flow to or from the pump chamber 181. Similarly, the liquid outlet may include a valve, e.g., including the valve port 190, that can be opened and closed to permit/impede flow to or from the pump chamber 181. Of course, the liquid supply could include any suitable arrangement, such as one or more solution containers, the patient line, one or more flow paths in the cassette 24 or other liquid source, and the liquid outlet could likewise include any suitable arrangement, such as the drain line, the heater bag and heater bag line, one or more flow paths in the cassette 24 or other liquid outlet. Generally speaking, the pump

chamber 181 (i.e., on the left side of the membrane 14 in FIG. 21) will be filled with an incompressible liquid, such as water or dialysate, during operation. However, air or other gas may be present in the pump chamber 181 in some circumstances, such as during initial operation, priming, or other situations as discussed below. Also, it should be understood that although aspects of the invention relating to volume and/or pressure detection for a pump are described with reference to the pump arrangement of the cassette 24, aspects of the invention may be used with any suitable pump or fluid movement system.

FIG. 21 also shows schematically to the right of the membrane 15 and the control surface 1482 (which are adjacent each other) a control chamber 171B, which may be formed as a void or other space in the mating block 170A associated with the pump control region 1482 of the control surface 1482 for the pump chamber 181, as discussed above. It is in the control chamber 171B that suitable air pressure is introduced to cause the membrane 15/control region 1482 to move and effect pumping of liquid in the pump chamber 181. The control chamber 171B may communicate with a line L0 that branches to another line L1 and a first valve X1 that communicates with a pressure source 84 (e.g., a source of air pressure or vacuum). The pressure source 84 may include a piston pump in which the piston is moved in a chamber to control a pressure delivered to the control chamber 171B, or may include a different type of pressure pump and/or tank(s) to deliver suitable gas pressure to move the membrane 15/control region 1482 and perform pumping action. The line L0 also leads to a second valve X2 that communicates with another line L2 and a reference chamber 174 (e.g., a space suitably configured for performing the measurements described below). The reference chamber 174 also communicates with a line L3 having a valve X3 that leads to a vent or other reference pressure (e.g., a source of atmospheric pressure or other reference pressure). Each of the valves X1, X2 and X3 may be independently controlled. Pressure sensors may be arranged, e.g., one sensor at the control chamber 171B and another sensor at the reference chamber 174, to measure pressure associated with the control chamber and the reference chamber. These pressure sensors may be positioned and may operate to detect pressure in any suitable way. The pressure sensors may communicate with the control system 16 for the cycler 14 or other suitable processor for determining a volume delivered by the pump or other features.

As mentioned above, the valves and other components of the pump system shown in FIG. 21 can be controlled so as to measure pressures in the pump chamber 181, the liquid supply and/or liquid outlet, and/or to measure a volume of fluid delivered from the pump chamber 181 to the liquid supply or liquid outlet. Regarding volume measurement, one

technique used to determine a volume of fluid delivered from the pump chamber 181 is to compare the relative pressures at the control chamber 171B to that of the reference chamber 174 in two different pump states. By comparing the relative pressures, a change in volume at the control chamber 171B can be determined, which corresponds to a change in volume in the pump chamber 181 and reflects a volume delivered from/received into the pump chamber 181. For example, after the pressure is reduced in the control chamber 171B during a pump chamber fill cycle (e.g., by applying negative pressure from the pressure source through open valve X1) so as to draw the membrane 15 and pump control region 1482 into contact with at least a portion of the control chamber wall (or to another suitable position for the membrane 15/region 1482), valve X1 may be closed to isolate the control chamber from the pressure source, and valve X2 may be closed, thereby isolating the reference chamber 174 from the control chamber 171B. Valve X3 may be opened to vent the reference chamber to ambient pressure, then closed to isolate the reference chamber. With valve X1 closed and the pressures in the control chamber and reference chamber measured, valve X2 is then opened to allow the pressure in the control chamber and the reference chamber to start to equalize. The initial pressures of the reference chamber and the control chamber, together with the known volume of the reference chamber and pressures measured after equalization has been initiated (but not yet necessarily completed) can be used to determine a volume for the control chamber. This process may be repeated at the end of the pump delivery cycle when the sheet15/control region 1482 are pushed into contact with the spacer elements 50 of the pump chamber 181. By comparing the control chamber volume at the end of the fill cycle to the volume at the end of the delivery cycle, a volume of liquid delivered from the pump can be determined.

Polytropic FMS for Pump Volume Delivery Measurement

Introduction to FMS

In another aspect of the disclosure, the cycler 14 in FIG. 1 may determine a volume of fluid delivered in various lines of the system 10 without the use of a flowmeter, weight scale or other direct measurement of fluid volume or weight. For example, in one embodiment, a volume of fluid moved by a diaphragm pump, such as a pneumatically driven diaphragm pump including a cassette 24, may be determined based on pressure measurements of a gas used to drive the pump.

In one embodiment, the volume determination is accomplished with a process herein referred to as the two-chamber Fluid Measurement System (2-chamber FMS) process. The

volume of fluid pumped by the diaphragm pump may be calculated from the change in the volume of the pneumatic chamber on one side of the diaphragm. The volume of the pneumatic chamber may be measured at the end of each fill and deliver stroke, so that the difference in volume between sequential measurements is the volume of fluid moved by the pump.

The volume of the pneumatic chamber or first chamber is measured with the 2-chamber FMS process that comprises closing the liquid valves into and out of the diaphragm pump, isolating the first chamber from a second chamber of a known volume (reference chamber), pre-charging the first chamber to a first pressure, while pre-charging the second chamber to a second pressure, then fluidically connecting the two chambers, and recording at least the initial and final pressures in each chamber as the pressures equalize. The volume of first chamber may be calculated from at least the initial and final pressures and the known volume of the second chamber.

If the first chamber is precharged to a pressure above the pressure in the second chamber then the 2-chamber FMS process is referred to as positive FMS or +FMS. If the first chamber is precharged to a pressure less than the pressure in the second chamber, then the 2-chamber FMS process is referred to as negative or –FMS. Referring now to FIG. 22, the first chamber is the control chamber 6171 and the second chamber is the reference chamber 6212.

The form of the algorithm to calculate the first chamber volume may depend on the heat transfer characteristics of the first and second chamber and the fluid lines that connect the two chambers. The amount of heat transfer between the structure and the gases during equalization affects the pressures in both the first and second chamber during and after equalization. During equalization, the gas in the chamber with the higher pressure expands toward the other chamber. This expanding gas will cool to a lower temperature and consequently a lower pressure. The cooling of the expanding gas and the loss in pressure may be moderated or reduced by heat transfer from the warmer structure. At the same time, the gas in the chamber initially at a lower pressure is compressed during equalization. The temperature of this compressing gas will rise along with the pressure. The heating of the compressing gas and the rise in pressure may be moderated or reduced by heat transfer from the cooler structure.

The relative importance of heat transfer between the structure(chamber walls, solid material within the chambers) and the gas is a function of the average hydraulic diameter of the chamber, the thermal diffusivity of the gas and the duration of the equalization process.

In one example, the two volumes are filled with heat absorbing material such as foam or other matrix that provide enough surface area and thermal mass that the gas temperatures are constant in each chamber during pressure equalization, so that the expansion and compression processes can be modeled as isothermal. In another example, the two chambers are sized and shaped to provide negligible heat transfer, so the expansion and compression processes can be modeled as adiabatic. In another example, the shape and size of the control chamber 6171 changes from measurement to measurement, In measurements after a fill stroke when the control chamber 6171 is small and all the gas is relatively near the chamber wall 6170 or the diaphragm 6148, theheat transfer between the gas and the structure is significant. In measurements after a deliver stroke, the control chamber 6171 is large and open, so that much of the gas is relatively isolated from the chamber walls 6170 or diagphragm 6148 and heat transfer to the gas is neglible. In measurements after a partial stroke the heat transfer between the structure and the gas is significant, but not sufficient to assure constant temperature. In all these measurements, the expansion and compression processes can be modeled as polytropic and the relative importance of heat transfer can be varied from one measurement to the next. A polytropic model can accurately model the equalization process for all geometries and capture the effects of different levels of heat transfer in the first and the second chambers. A more detailed model of the equalization process will more accurately determine the volume of the first chamber from the knowledge of the pressures and the volume of the second chamber.

This section describes an algorithm to calculate the volume of the first chamber 6171 for a polytropic 2-chamber FMS process. The first sub-section describes the two volume FMS or 2-chamber FMS process for an exemplary arrangement of volumes, pressure sources, valves and pressure sensors. The next sub-section conceptually describes the polytropic FMS algorithm for data from a +FMS process and then presents the exact equations to calculate the first volume from the pressure data. The next sub-section presents the concept and equations of the polytropic FMS algorithm for data from a –FMS process. The last sub-section presents the process to calculate the volume of the first chamber 6171 using either set of equations.

The model being described can be applied to any system or apparatus that uses a pneumatically actuated diaphragm pump. The components of the system include a diaphragm pump having at least one pump chamber inlet or outlet with a valved connection to either a fluid source or fluid destination; a pneumatic control chamber separated from the pump chamber by a diaphragm that provides positive or negative pressure to the pump

chamber for fluid delivery or filling; the pneumatic control chamber has a valved connection to a reference chamber of known volume and to a positive or negative pressure source; a controller controls the valves of the system and monitors pneumatic pressure in the control chamber and reference chamber. An example of the system is illustrated schematically in FIG. 22, although the specific arrangement of inlets, outlets and fluid and pneumatic conduits and valves can vary to some degree from this illustration. The following description will use a peritoneal dialysis cycler and pump cassette as an example, but the invention is by no means limited to this particular application.

Hardware for 2-chamber FMS Process

Referring now to FIG. 22, which schematically presents elements of the cycler and the cassette 624 that are involved in the 2-chamber FMS process. The cassette 624 includes two liquid valves 6190, 6192 that are fluidically connected to a liquid supply 6193 and liquid outlet 6191. The cassette 624 includes a diaphragm pump with a variableliquid volume pump chamber 6181 separated by a flexible membrane 6148 from the control chamber 6171. The control chamber 6171 volume is defined by the membrane 6148 and the chamber wall 6170. The control chamber 6171 is the first chamber of unknown volume described above.

A control line 6205 also leads to a connection valve 6214 that communicates with a reference line 6207 and a reference chamber 6212 (e.g., a space suitably configured for performing the measurements described below). The reference chamber 6212 is the second chamber with a known volume described above. The reference chamber 6212 also communicates with an exit line 6208 having a second valve 6216 that leads to a vent 6226 to atmospheric pressure. In another example the vent 6226 may be a reservoir controlled to a desired pressure by one or more pneumatic pumps, a pressure sensor and controller. Each of the valves 6220, 6214 and 6216 may be independently controlled by the controller 61100.

The pressure source 6210 is selectively connected to the control chamber 6171 via lines 6209 and 6205. The pressure source 6210 may include one or more separate reservoirs which are held at specified and different pressures by one or more pneumatic pumps. Each pneumatic pump may be controlled by the controller 61100 to maintain the specified pressure in each reservoir as measured by pressure sensors. A first valve 6220 may control the fluid connection between the pressure source 6210 and the control chamber 6171. The controller 61100 may selectively connect one of the reservoirs in the pressure source 6210 to line 6209 to control the pressure in the control chamber as measured by pressure sensor

6222. In some examples, the controller 61100 may be part of a larger control system in the APD cycler.

The control chamber 6171 is connected to the control pressure sensor 6222 via line 6204. A reference pressure sensor 6224 may be connected to the reference chamber 6212 via line 6203. The pressure sensors 6222, 6224 may be an electromechanical pressure sensor that measures the absolute pressure such as the MPXH6250A by Freescale Semiconductors of Japan. The control pressure sensor 6222 and the reference pressure sensor 6224 are connected to the controller 61100, which records the control and reference pressures for subsequent volume calculations. Alternatively, the pressure sensors 6222, 6224 may be relative pressure sensors that measure the pressure in the control and reference chambers relative to the ambient pressure and the controller 61100 may include an absolute pressure sensor to measure the ambient pressure. The controller 61100 may combine the relative pressure signals from sensors 6222, 6224 and the absolute ambient pressure sensor to calculate the absolute pressures in the control chamber 6171 and reference chamber 6212 respectively.

The valves and other components of the FMS hardware shown in FIG. 22 can be controlled by the controller 61100 to execute the 2-chamber FMS process and measure the resulting pressures in control chamber 6171 and in the reference chamber 6212, then calculate the volume of the control chamber 6171. The controller 61100 may be a single micro-processor or multiple processors. In one example, the pressure signals are received by an A-D board and buffered before being passed to the 61100 controller. In another example, a field-programable-gate-array (FPGA) may handle all the I/O between the controller 61100 and the valves and sensors. In another example, the FPGA may filter, store and / or process the pressure data to calculate volume of the control chamber.

2-chamber FMS Process in APD Cycler

Referring now to pressure vs time plot of FIG. 23 and the elements in **FIG. 22**. An exemplary pumping and measurement process is described in the plot of the control chamber pressure 6300 and the reference chamber pressure 6302 verses time. As described above, after closing the inlet valve 6192 and opening the outlet valve 6190, the chamber pressure is controlled to a positive value 6305 that pushed fluid out of the pump chamber 6181 during the deliver stroke 6330. At the end of the deliver stroke 6330, the outlet fluid valve is closed and a +FMS process may occur to measure the volume of the control chamber 6171. The FMS process as described elsewhere may consist of bringing the control chamber

pressure 6330 to a precharging pressure 6307 and allowing a period of pressure stabilization 6338, followed by a equalization process 6340. In other examples, the control chamber pressure 6330 may be returned to near atmospheric pressure before being increased to the precharge pressure 6307. At the end of equalization process 6340, the reference chamber pressure 6302 and possibly the control chamber pressure 6300 can be returned to near atmospheric values.

The fill stroke 6320 occurs after opening the inlet valve 6192 and brings the control chamber pressure 6300 to a negative pressure 6310, while the reference chamber remains near atmospheric, or at a measured and constant pressure. The negative pressure pulls fluid into the pump chamber 6181. At the end of the fill stroke 6320, the inlet valve 6192 is closed and a +FMS process may occur to determine the volume of the control chamber 6171. In some embodiments, a - FMS process may occur after the +FMS process. The –FMS process may comprise precharging the control chamber to negative pressure 6317, allowing pressure statilization 6342 and finally an equalization process 6345. The control chamber volume determined from –FMS process may be compared to the control chamber volume determined from the +FMS process to determine whether there is a volume of air or gas in the pump chamber 6181. (For example, if the pump chamber includes an air trap comprising ribs or standoffs on the pump chamber rigid wall, air can accumulate among the standoffs, the diaphragm at its full excursion can be prevented from compressing it by the standoffs, and the air may not be detected by a +FMS process alone). In one example, a –FMS process occurs after the deliver stroke 6330.

The +FMS and –FMS processes are described in more detail by referring to the flow chart in FIG. 24, elements in FIG. 22, and the pressure vs. time plots of FIGS. 25A, 25B. The 2-chamber FMS process begins with step 6410 where the position of the membrane 6148 is fixed. The position of the membrane 6148 may be fixed by closing both hydraulic valves 6190, 6192. In some examples, the position of membrane 6148 will vary as the control chamber pressure changes, if gas bubbles are present in the liquid. However the volume of incompressible liquid between the hydraulic valves 6190, 6192 is fixed. The 2-chamber FMS process will generally measure the volume of air or gas on both sides of the membrane 6148, so any bubbles in the pump chamber 6181 on the liquid side of the membrane 6148 are included in the measured volume of the control chamber 6171.

In step 6412, the control chamber 6171 is fluidically isolated from the reference chamber 6212 by closing connection valve 6214. Then the reference chamber 6212 and control chamber 6171 are fluidically isolated from each other in step 6412. In an

embodiment, the reference chamber 6212 is connected to the vent 6226 in step 6424 by opening the second valve 6216. The controller 61100 holds the second valve 6216 open, until reference pressure sensor 6224 indicates that the reference pressure has reached ambient pressure. Alternatively, the controller 61100 may control the second valve 6216 to achieve a desired initial reference pressure in the reference chamber 6212 as measured by the reference pressure sensor 6224. Alternatively, the connection valve 6214 may be closed and the second valve 6216 is open before the FMS process begins. In step 6428, once the desired pressure in the reference chamber 6212 is achieved, the second valve 6216 is closed, which fluidically isolates the reference chamber 6212. The reference chamber steps 6424 and 6428 may be programmed to occur concurrently with the control chamber steps 6414 and 6418.

In step 6414, the control chamber 6171 is pressurized to a desired pressure by connecting the control chamber 6171 to the pressure source 6210 by opening the first valve 6220. The controller 61100 monitors the pressure in the control chamber 6171 with pressure sensor 6222 and controls the first valve 6220 to achieve a desired precharge pressure. The desired precharge pressure may be significantly above the initial reference pressure of the reference chamber 6212 or significantly below the initial reference pressure. In one example, the control chamber 6171 is precharged to approximately 40 kPa above the reference pressure for a +FMS process. In another example, the control chamber 6171 is precharged to approximately 40 kPa below the reference pressure for a –FMS process. In other embodiments, the precharge pressures may be any pressure within the range of 10% to 180% of the initial reference pressure.

The controller 61100 closes the first valve 6220 in step 6418 and monitors the pressure in the control chamber 6171 with pressure sensor 6222. The pressure in the control chamber 6171 may move toward ambient pressure during step 6418 due to gas thermally equalizing with the control chamber wall 6170 and membrane 6148. A large change in pressure during step 6418 may indicate a pneumatic or liquid gross leak that would invalidate a measurement. The 2-chamber FMS process may be aborted or the calculated volume of the control chamber 6171 may be discarded if the rate of pressure change exceeds a pre-determined allowable rate. The rate of pressure change may be examined after a delay from the pressurization step 6414 to allow the gas in the control chamber 6171 to approach thermal equilibrium with the boundaries 6172, 6148 of the control chamber 6171. . In one example, the maximum allowed rate of pressure change during step 6418 is 12 kPA/sec. The 2-chamber FMS process may be aborted and restarted if the rate of pressure change exceeds this predetermined value. In another embodiment, the maximum allowable rate of pressure

change is a function of – and will vary based on – the calculated control chamber volume. In one example, the maximum allowed pressure change is 3 kPA/sec for a 25 ml volume and 25 kPA/sec for 2 ml volume. In one example, the FMS process may be carried to completion regardless of the leak rate resulting in a calculated volume of the control chamber 6171. The calculated volume may be discarded and the FMS process restarted if the measured rate of pressure change exceeds the allowable limit for the calculated control chamber volume.

The control chamber 6171 and the reference chamber 6212 are fluidically connected in step 6432, when the controller 61100 opens the connection valve 6214 between the two chambers. The controller 61100 monitors the pressures in each chamber with the pressure sensors 6222, 6224 as the pressure in the control chamber 6171 and reference chamber 6212 equalize. The controller 61100 may record the initial pressure pair and at least one pressure pair at the end of equalization in step 6432. A pressure pair refers to a signal from the control pressure sensor 6222 and a signal from the reference pressure sensor 6224 recorded at approximately the same time. Step 6432 extends from a period of time just before the connection valve 6214 is open to a point in time, when the pressure in the control chamber 6171 and reference chamber 6212 are nearly equal.

The 2-chamber FMS process is completed in step 6436, where the recorded pairs of pressures are used to calculate the volume of the control chamber 6171. The calculation of the control chamber 6171 volume is described in detail below.

The +FMS process is sketched as pressure vs. time plot in FIG. 25A. Reference numbers corresponding to those of the steps in FIG. 24 are included to indicate where those steps are depicted in FIG. 25A. The pressure of the control chamber 6171 is plotted as line 6302. The pressure of the reference chamber is plotted as line 6304. The pressure vs. time plot begins after steps 6410, 6412, 6424, 6428 of FIG. 24 have been completed. At this point the pressure in the reference chamber 6212 is at the desired reference pressure 6312. The pressure in the control chamber 6171 begins at an arbitrary pressure 6306 and during step 6414 increases to the precharge pressure 6316. The arbitrary pressure 6306 may be the pressure of the control chamber 6171 at the conclusion of a previous pumping operation. In another embodiment, the arbitrary pressure 6306 may atmospheric pressure. The control chamber pressure 6302 may drop during step 6418. In step 6432, the control chamber pressure 6302 and reference chamber pressure 6304 equalize toward an equilibrium pressure 6324.

The -FMS process is sketched as pressure vs. time plot in FIG. 25B. The pressure of the control chamber 6171 (FIG. 22) is plotted as line 6302. The pressure of the reference

chamber 6312 (FIG. 22) is plotted as line 6304. The horizontal time axis is divided in periods that correspond to the process steps identified with the same reference numbers in FIG. 24. The pressure vs. time plot begins when the pressure in the reference chamber 6212 (line 6302) is at the desired reference pressure 6312 and the pressure in the control chamber 6171 (line 6304) is at an arbitrary pressure. During step 6414, the control chamber pressure 6302 decreases to the negative precharge pressure 6317. The control chamber pressure 6302 may rise during step 6418 as the gas cooled by the sudden expansion of step 6414 is heated by the control chamber walls 6172, 6148. In step 6432, the control chamber pressure 6302 and reference chamber pressure 6304 equalize toward an equilibrium pressure 6324.

Polytropic +FMS Algorithm

Referring now to FIG. 22, for illustrative purposes, the equalization process involves the fluid volumes of three distinct structures: control chamber 6171, reference chamber 6212 and the manifold passages 6204, 6205, 6207, 6209 connecting the two chambers 6171, 6212. In one example, each structure has significantly different hydraulic diameters and thus different levels of heat transfer between the structure and the gas. In this example, the reference chamber 6212 has an approximately cubic shape with a hydraulic diameter of approximately 3.3 cm. Heat transfer during the approximately 30 microsecond equalization process is negligibly small and the gas in the reference chamber 6212 volume is likely to be compressed adiabatically, and can be modeled as such. In contrast, in an exemplary construction, the manifold passages 6204, 6205, 6207, 6209, have an approximately 0.2 cm hydraulic diameter, which is about 15 times smaller than the hydraulic diameter of the reference chamber 6212 volume. Heat transfer in the manifold passages 6204, 6205, 6207, 6209 is high and the gas passing through these passages 6204, 6205, 6207, 6209 is more likely to compress or expand isothermally at approximately the temperature of the manifold walls. The hydraulic diameter of the control chamber 6171 in this example has a minimum of value of approximately 0.1 cm when the pumping chamber 6181 is full of liquid at the end of a fill stroke and the control chamber 6171 is at a minimum volume. The hydraulic diameter of the control chamber 6171 in this example has a maximum value of approximately 2.8 cm when the pumping chamber 6181 has delivered the liquid and the control chamber 6171 is at a maximum volume. The expansion of gas in the control chamber 6171 can be more appropriately modeled with a polytropic coefficient that varies with the size of the control chamber 6171. When the control chamber 6171 volume is at a minimum and the expansion process will be nearly isothermal, the polytropic coefficient can

be set to approximately 1. When the control chamber 6171 is at a maximum and the expansion process is near adiabatic, the polytropic coefficient may be set to approximately the ratio of specific heats (cp/cv), which equals 1.4 for air. For 2-chamber FMS measurements at partial strokes, the expansion process will occur with significant heat transfer, but not enough to be isothermal. The polytropic coefficient may be set to a value between 1 and 1.4 for measurements at partial strokes. Since the volume of the control chamber 6171 is the unknown quantity of this analysis, the polytropic coefficient for the control chamber 6171 may be based on an estimate of control chamber 6171 volume.

Referring now to FIG. 26A, the gas in the structures of the control chamber 6510, the reference chamber 6520 and the manifold lines 6530, 6531 can be modeled as three gas masses, 6512, 6532, 6522 that do not mix, but expand, contract, and move through the structures 6510, 6520, 6530, 6531. Conceptually, for modeling purposes, these masses 6512, 6532, 6522 are each a closed-system that may move, change size and exchange energy with the structures, but mass may not enter nor exit the closed-system. The closed-system model is a well understood concept in thermodynamics and fluid dynamics. These masses may also be referred to as a control chamber system 6512, reference chamber system 6522 and a manifold or interconnecting line system 6532.

The volume of the control chamber 6510 can be calculated from the measured control chamber 6510 and reference chamber 6520 pressures based on thermodynamic models of the three masses 6512, 6532, 6522. The control chamber mass or gas 6512 is the gas that occupies the control chamber 6510 at the end of the equalization process. The reference chamber gas 6522 is the gas that occupies the reference chamber 6520 at the beginning of the equalization process. The manifold gas 6532 fills the balance of the structure between the control chamber gas 6512 and the reference chamber gas 6522, including a connecting conduit between the control and reference chambers.

The volume and temperature of the three closed-systems, 6512, 6532, 6522 may then calculated from initial conditions, pressure pairs, heat transfer assumptions and the constraint of a fixed total volume for the three closed-systems. The pressure equalization can be modeled with a different polytropic coefficient for each volume 6510, 6520, 6530, 6531 to capture the relative importance of heat transfer in each. The constant mass, ideal gas and polytropic process equations for the three systems, 6512, 6532, 6522 can be combined and arranged to calculate the volume of the control chamber 6510. The following paragraphs describe the derivation of one or more sets of equations that allow calculation of the control

chamber 6510 volume based on pressures measured during the pressure equalization step of the FMS process (see, 6432 of FIGS. 24 and 25A).

Description of Closed Systems for +FMS

The upper image in FIG. 26A presents the position of the three closed-systems 6512, 6532, 6522 at the start of pressure equalization in the +FMS process. The lower image presents the positions of the three closed systems 6512, 6532, 6522 at the end of the pressure equalization. During the equalization process, the locations of the closed systems 6512, 6532, 6522 are between the two extremes presented in FIG. 26A. By way of an example, neither the control chamber system 6512 nor the reference chamber system 6522 fill their respective structures. The following paragraphs present the closed systems 6512, 6532, 6522 in more detail.

The control chamber gas system 6512 is the gas that fills the control chamber 6510 after pressure equalization. Before pressure equalization, the control chamber gas system 6512 is compressed to the precharge pressure that is higher than the final equalization pressure and therefore does not occupy the entire control chamber 6510. The control chamber gas system 6512 may be modeled as expanding in a polytropic process during pressure equalization of the +FMS process, where the pressure and the volume are related by:

$$p_f V_{CC}^{nCC} = \text{constant}$$

where p_f is the equalized pressure, V_{CC} is the volume of the control chamber 6510, and nCC is the polytropic coefficient for the control chamber 6510.

The reference gas system 6522 is the gas that occupies the entire reference volume 6520 before equalization. The reference gas system 6522 is compressed during equalization as the higher pressure gas in the control chamber 6510 expands and pushed the manifold gas system 6532 into into the reference chamber 6520 In one example shown in FIG. 14, the reference chambers (depicted as 174 in FIG. 14) are sufficiently open or devoid of interior features/elements that compression or expansion processes during pressure equalization may be modeled as adiabatic. In this case, the polytropic coefficient (n) may be set equal to approximately the specific heat ratio of the gas present in the chamber. The pressure and the volume of the reference chamber gas 6522 are related by:

$$p_{RO} V_{Ref}^{nR} = \text{constant}$$

where p_{R0} is the initial reference pressure, V_{Ref} is the volume of the reference chamber, and nR is the specific heat ratio for the gas in the reference chamber (nR = 1.4 air).

In another example, where the chamber 6520 is at least partially filled with a heat absorbing material such as open cell foam, wire mesh, particles, etc. that provides for a near-isothermal expansion, the polytropic coefficient for the reference chamber (nR) may have a value of approximately 1.0.

In the +FMS process, the conduit or manifold gas system 6532 occupies all of the volume of the interconnecting volume 6530, 6531 and a fraction 6534 of the control chamber 6510 before equalization. After equalization, the conduit gas system 6532 occupies the interconnecting volume 6530, 6531 and part of the reference volume 6520. The portion of the conduit gas system 6532 that exists in interconnecting volume 6530 on the control chamber side of the valve 6540 is herein labeled as 6533. The portion of the conduit gas system 6532 that exits in the interconnecting volume 6531 on the reference chamber side of the valve 6540 is referred to as 6535. The portion of the conduit gas system 6532 that exist in the control chamber 6510 pre-equalization is herein labeled as 6534. The portion of the conduit gas system 6532 that exists in the reference chamber 6520 after equalization is referred to as 6536.

In one example the interconnecting volumes 6530 and 6531 may be narrow passages that provide high heat transfer and assure the conduit gas system 6532 in volumes 6530 and 6531 is near the temperature of the solid boundaries or walls of the passages. The temperature of the structure surrounding the interconnecting volumes 6530, 6531 or manifold passages is herein referred to as the wall temperature (T_w). In another example, the temperature of the conduit gas system 6532 in volumes 6530, 6531 is in part a function of the wall temperature. The portion of the conduit or manifold gas system in the control chamber 6534 may be modeled with the same temperature as control chamber gas system 6512. The control chamber portion of the conduit gas system 6534 experiences the same expansion as the control chamber gas system 6512 and may be conceived of as having the same temperature as the control chamber gas system 6512. The portion of the lines or manifold gas system in the reference chamber 6536 may be modeled with a temperature that is in part a function of the wall temperature. In another example, the reference chamber portion of the conduit gas system 6536 may be modeled as not interacting thermally with the boundaries of the reference chamber 6520, so that the temperature of the conduit gas system portion 6536 is a function of the wall temperature and the reference chamber 6520 pressures.

The equations in this section use the following nomenclature:

variables

γ: specific heat ratio

n: polytropic coefficient

p: pressure

V: volume

T: temperature

superscripts:

n: polytropic coefficient

nCC: polytropic coefficient for the control chamber

nR: polytropic coefficient for the reference chamber

subscripts:

c: control chamber system

CC: physical control chamber

f: value at end of equalization

i: i^{th} value

IC: physical interconnecting volume or manifold passages

IC_R: physical interconnecting volume on the reference chamber side of valve

IC_CC: physical interconnecting volume on the control chamber side of valve

l: lines or interconnecting/manifold system

0: value at start of equalization

pmp: pump

r: reference system

Ref: physical reference chamber

w: wall of interconnecting volume

The equations for the control chamber 6510 may derived from the conceptual model of the three separate mass systems in FIG. 26A and the understanding that the total volume of the control chamber mass 6510, reference chamber mass 6520 and interconnecting volumes mass 6530, 6531 is fixed. This relationship can be expressed as the sum of the volume changes of each closed system 6512, 6522, 6532 being zero for each i^{th} set of values from the start to the end of pressure equalization:

$$0 = \begin{matrix}\text{change in volume of} \\ \text{control chamber mass}\end{matrix} + \begin{matrix}\text{change in volume of} \\ \text{interconnecting mass}\end{matrix} + \begin{matrix}\text{change in volume of} \\ \text{reference chamber mass}\end{matrix}$$

$$0 = \Delta V_{ci} + \Delta V_{ri} + \Delta V_{li} \quad (13)$$

where the i^{th} value of ΔV_{ci}, ΔV_{ri}, ΔV_{li} represents these values at the same point in time. Equations can be developed for the volume change of the control chamber gas system (ΔV_{ci}), the reference gas system (ΔV_{ri}), and the conduit gas system (ΔV_{li}) based on the pressure / volume relationship of a polytropic process and the ideal gas law. The equation for the i^{th} volume change of the control chamber gas system 6512 is equal to the i^{th} volume of the control chamber mass 6512 less the volume of the control chamber mass 6512 at the start of equalization. The volume of the control chamber mass 6512 at time i is calculated from the volume of the control chamber 6510 times the ratio of the final control chamber 6510 pressure over the control chamber 6510 pressure at time i, raised to one over the polytropic coefficient for the control chamber 6510:

$$\begin{matrix}\text{currrent change in volume} \\ \text{of control chamber mass}\end{matrix} = \begin{matrix}\text{current volume of} \\ \text{control chamber mass}\end{matrix} - \begin{matrix}\text{initial volume of} \\ \text{control chamber mass}\end{matrix}$$

$$\Delta V_{ci} = V_{CC}\left(\frac{P_{ee\,f}}{P_{ee\,i}}\right)^{1/nCC} - V_{CC}\left(\frac{P_{ee\,f}}{P_{ee\,o}}\right)^{1/nCC} \quad (14)$$

The equation for the reference gas system volume change (ΔV_r) is derived from the pressure / volume relationship for a polytropic process. The equation for the i^{th} volume change of the reference chamber gas system 6522 is equal to the i^{th} volume of the reference chamber mass 6522 less the volume of the reference chamber mass 6522 at the start of equalization. The volume of the reference chamber mass 6522 at time i is calculated from the structural volume of the reference chamber 6520 times the ratio of the initial reference chamber 6520 pressure over the reference chamber 6520 pressure at time i, raised to one over the polytropic coefficient for the reference chamber 6520:

$$\begin{matrix}\text{currrent change in volume} \\ \text{of reference chamber mass}\end{matrix} = \begin{matrix}\text{current volume of} \\ \text{reference chamber mass}\end{matrix} - \begin{matrix}\text{initial volume of} \\ \text{reference chamber mass}\end{matrix}$$

$$\Delta V_{ri} = V_{Ref}\left(\frac{P_{Ref\,o}}{P_{Ref\,i}}\right)^{1/nR} - V_{Ref} \quad (15)$$

The equation for the volume change of the interconnecting gas system 6532 (ΔV_l) is derived from the constant mass gas of the system ($V * \rho = \text{constant}$). The equation for the i^{th} volume change of the conduit gas system 6532 is equal the current volume of the system less the original volume of the interconnecting gas system 6532. The current volume of the interconnecting or line gas system 6532 is the initial volume times the ratio of initial over current density of the system. The initial volume of the interconnecting gas system 6532 is the sum of the volumes 6534, 6533 and 6535 pictured in the upper image FIG. 26A:

$$\begin{matrix}\text{currrent change in volume} \\ \text{of interconnecting mass}\end{matrix} = \begin{matrix}\text{current volume of} \\ \text{interconnecting mass}\end{matrix} + \begin{matrix}\text{initial volume of} \\ \text{interconnecting mass}\end{matrix}$$

$$\Delta V_{li} = (\Delta V_{cf} + V_{IC})\frac{\rho_{l\,o}}{\rho_{l\,i}} - (\Delta V_{cf} + V_{IC}). \tag{16}$$

The density terms ρ_{l0}, ρ_{li} are the average density of the gases in the conduit gas system at the start of equalization and at some point, i, during equalization. The conduit gas system 6532 includes gases as different temperatures and pressures. The conduit gas system 6532 includes gas in the volume in the control chamber 6510 in a volume labeled 6534, gas in manifold passages on the control chamber side of the valve 6540 labeled 6533, gas in manifold passages on the reference chamber side of the valve 6540 labeled 6535, and gas in the reference chamber labeled 6536.

These four equations may be combined develop an expression for the volume (V_{CC}) of the control chamber 6510 as a function of the measured pressure pairs at the start of pressure equalization ($P_{CC\,0}$, $P_{Ref\,0}$), at any point during the equalization ($P_{CC\,i,}$ $P_{Ref\,i}$), the control chamber 6510 pressure at approximately the end of equalization ($P_{CC\,f}$) and the fixed volumes of the reference chamber (V_{Ref}) and interconnecting volume (V_{IC}):

$$V_{CC} = \frac{V_{Ref}\left[\left(\frac{P_{Ref\,o}}{P_{Ref\,i}}\right)^{1/nR} - 1\right] + V_{Ie}\left(\frac{\rho_{l\,o}}{\rho_{l\,i}} - 1\right)}{\left[1 - \left(\frac{P_{ee\,f}}{P_{ee\,i}}\right)^{1/nee}\right] + \left[\left(\frac{P_{ee\,f}}{P_{ee\,o}}\right)^{1/nee} - 1\right]\left(\frac{\rho_{l\,o}}{\rho_{l\,i}}\right)} \tag{17}$$

where the densities of the manifold or line system 6532 ($\rho_{l\,o}$, $\rho_{l\,i}$) are evaluated with the initial pressure pairs ($P_{CC\,0}$, $P_{Ref\,0}$) and any pressure pair ($P_{CC\,i,}$ $P_{Ref\,i}$) during equalization along with the associated temperatures as described below.

The densities of the conduit gas system ($\rho_{l\,o}$, $\rho_{l\,i}$) in equations (16) may be calculated from the volume-weighted average density for each physical volume (i.e. control chamber 6510, reference chamber 6520, and interconnecting volumes 6530, 6531):

$$\rho_{li} = \frac{\rho_{CCi}(\Delta V_{cf} - \Delta V_{ci}) + \rho_{IC_CC} V_{IC_CC} + \rho_{IC_R} V_{IC_R} - \rho_{ri}\Delta V_{ri}}{(\Delta V_{cf} - \Delta V_{ci} + V_{IC_CC} + V_{IC_R} + \Delta V_{ri})} \quad (18)$$

$$\rho_{CCi} = \frac{P_{CCi}}{R\,T_{CCi}} = \text{density of gas in control chamber}$$

$$\rho_{IC_CCi} = \frac{P_{CCi}}{R\,T_{IC_CC}} = \begin{matrix}\text{density of gas in manifold line} \\ \text{on control chamber side of valve}\end{matrix}$$

$$\rho_{IC_Ri} = \frac{P_{Refi}}{R\,T_{IC_CC}} = \begin{matrix}\text{density of gas in manifold line} \\ \text{on reference chamber side of valve}\end{matrix}$$

$$\rho_{ri} = \frac{P_{Refi}}{R\,T_{lr}} = \begin{matrix}\text{density of gas in} \\ \text{reference chamber}\end{matrix}$$

where R is the universal gas constant for air, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lr} , may be functions in part of the temperature of the interconnecting volume walls. In another example, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lr} , may be functions in part of the temperature of the interconnecting volume walls and the gas temperature of the control chamber (T_{CCi}). In another example, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lr}, may be the interconnecting wall temperature (T_W). In another example, the temperatures may be control chamber temperature (T_{CCi}). The value of ΔV_{ri} is calculated from equation (14). The value of ΔV_{cf} - ΔV_{ci} is the volume of 6534 and is calculated as

$$\Delta V_{cf} - \Delta V_{ci} = V_{CC\,Est}\left[1 - \left(\frac{P_{CC\,f}}{P_{CC\,i}}\right)^{1/nCC}\right] \quad (19)$$

The density of the conduit gas system 6532 before pressure equalization may be calculated from an equation similar to (18) that is the volume-weighted average density for each physical volume (i.e. control chamber 6510 and interconnecting volumes 6530, 6531):

$$\rho_{IO} = \frac{\frac{P_{CCi}(\Delta V_{cf})}{T_{CC\,O}} + \frac{P_{CC} V_{IC_CC}}{T_W} + \frac{P_{Ref} V_{IC_R}}{T_W}}{R(\Delta V_{cf} + V_{IC_CC} + V_{IC_R})} \quad (20)$$

The change in the control chamber gas system volume (ΔV_{cf}) used in equation (18) is calculated from the physical volume of the control chamber 6510 times the quantity one minus the ratio of the final control chamber pressure over the initial control chamber pressure raised to one over the polytropic coefficient for the control chamber:

$$\Delta V_{cf} = V_{CC\,Est} \left[1 - \left(\frac{P_{ee\,f}}{P_{ee\,i}}\right)^{1/nCC}\right]. \quad (21)$$

An estimate of the control chamber 6510 volume can be derived by assuming constant temperature for the conduit gas system 6532, so that the density ratio ($\rho_{l\,0}/\rho_{l\,f}$) is equal to the pressure ratio ($P_{l\,0}/P_{l\,f}$). To futher simplfy the estimate, the polytropic coefficient is replaced by the specific heat ratio (γ). In this simpler equation, the control chamber 6510 volume is a function of the measured pressure pairs at the start of pressure equalization ($P_{CC\,0}$, $P_{Ref\,0}$) and at the end of equalization ($P_{CC\,f}$, $P_{Ref\,f}$) and the fixed volumes of the reference chamber (V_{Ref}) and interconnecting volume (V_{IC}):

$$V_{CC\,Est} = \frac{V_{Ref}\left[\left(\frac{P_{Ref\,o}}{P_{Ref\,f}}\right)^{\frac{1}{\gamma}}-1\right]+V_{Ie}\left(\frac{P_{ee\,o}}{P_{ee\,f}}-1\right)}{\left[\left(\frac{P_{ee\,f}}{P_{ee\,o}}\right)^{\frac{1}{\gamma}}-1\right]\left(\frac{P_{ee\,o}}{P_{ee\,f}}\right)}. \quad (22)$$

The gas in the three closed systems 6512, 6522, 6532 may be modeled as an ideal gas, so the temperature can be determined from the initial conditions and the new pressure or volume:

$$T_i = T_O \left(\frac{p_o}{p_i}\right)^{(n-1)/n} \quad \text{or} \quad T_i = T_O \left(\frac{V_o}{V_i}\right)^{n-1} \quad (23)$$

The initial temperature of the gas in the control chamber ($T_{CC\,0}$) may be calculated from the temperature of the interconnecting volume walls, the precharge pressure 6316 (FIG. 25A) and the pressures in the control chamber 6510 just before precharge 6306. The the compression of gas in the control volume to the precharge pressure can be modeled as a polytropic process and using the ideal gas law in equation (23). The control chamber 6510 pressure before precharging 6306 is referred herein as the pumping pressure (Ppmp):

$$T_{CC\,O} = T_W \left(\frac{P_{pmp}}{P_{ee\,o}}\right)^{\frac{1}{nee}-1}. \quad (24)$$

The temperature of the gas in the control chamber 6510 at the i^{th} step ($T_{CC\,i}$) during expansion may be calculated from the initial control chamber 6510 temperature, the

precharge pressure 6316 (FIG. 25A) and the i^{th} control chamber 6510 pressure ($P_{CC\,i}$) using equation (23):

$$T_{CC\,i} = T_{CC\,O}\left(\frac{P_{CC\,O}}{P_{CC\,i}}\right)^{\frac{1}{nCC}-1} \qquad (25)$$

The value of the polytropic coefficient for the control chamber gas system (nCC) used in equations 14, 17, 19, 21,25 may vary with the volume of the control chamber 6510 and range from approximately 1 for small volumes to approximately the specific heat ratio for large volumes. The specific heat ratio for air and other systems of predominantly diatomic molecules is 1.4. In one example the value of nCC (for +FMS) can be expressed as a function of the estimated control chamber volume (eqn 22):

$$nCC = 1.4 - 3.419 \times 10^{-5}(23.56 - V_{CCEst})^{3.074} \qquad (26)$$

A method to determine a relationship between the volume of the control chamber (V_{CC}) and its polytropic coefficient (nCC) is described in a following section.

Polytropic -FMS Algorithm

A –FMS alogirthm similar to the +FMS algorithm, described above, can be developed to calculate the volume of the control chamber 6171 in FIG. 22 from the control chamber 6171 and reference chamber 6212 pressures for a –FMS process. In the –FMS process the first chamber (e.g. 6171) is precharged to a pressure below the known second chamber (e.g. 6212).

Referring now to FIG. 26B, the gas in the structures of the control chamber 6510, the reference chamber 6520 and the manifold lines 6530, 6531 can be modeled as three gas masses, 6512, 6532, 6522 that do not mix, but expand, contract, and move through the structures 6510, 6520, 6530, 6531. The volume of the control chamber 6510 can be calculated from the measured control chamber 6510 and reference chamber 6520 pressures based on thermodynamic models of the three masses 6512, 6522, 6532. In the –FMS algorithm, the control chamber mass 6512 is the gas that occupies the control chamber 6510 at the start of the equalization process. The reference chamber mass 6522 is the gas that occupies the reference chamber 6520 at the end of the equalization process. The manifold

gas 6532 fills the balance of the structure between the control chamber gas 6512 and the reference chamber gas 6522.

The volume and temperature of the three conceptual closed-systems, 6512, 6532, 6522 may then be calculated from initial conditions, pressure pairs, heat transfer assumptions and the constraint of a fixed total volume for the 3 closed-systems 6512, 6532, 6522. The pressure equalization can be modeled with a different polytropic coefficient for each volume 6510, 6520, 6530, 6531 to capture the relative importance of heat transfer in each. The constant mass, ideal gas and polytropic process equations for the three systems, 6512, 6522, 6532 can be combined and arranged to calculate the volume of the control chamber 6510. The following paragraphs describe the derivation of one or more sets of equations that allow calculation of the control chamber 6510 volume based on pressures measured during the pressure equalization step of the -FMS process.

Description of Closed Systems for -FMS

The upper image in FIG. 26B presents the positions of the three closed-systems 6512, 6522, 6532 at the start of pressure equalization in the -FMS process. The lower image presents the positions of the three closed systems 6512, 6522, 6532 at the end of the pressure equalization. During the equalization process, the locations of the closed systems 6512, 6522, 6532 are between the two extremes presented in FIG. 26B. By way of an example, neither the control chamber system 6512 nor the reference chamber system 6522 fill their respective structures 6510, 6520. The following paragraphs present the closed systems in more detail.

The control chamber gas system 6512 in the –FMS algorithm is the gas that fills the control chamber 6510 before equalization. The control chamber gas system 6512 is compressed during pressure equalization as the initially higher pressure reference chamber gas system 6522 expands and pushes the manifold gas system 6532 into the control chamber 6510. The control chamber gas system 6512 may modeled with a polytropic compression during pressure equalization of the -FMS process, where the pressure and the volume are related by:

$$p_O V_{CC}^{nCC} = \text{constant}$$

where p_0 is the intial pressure in the control chamber 6510, V_{CC} is the volume of the control chamber 6510, and nCC is the polytropic coefficient for the control chamber 6510.

The reference gas system 6522 in the –FMS algorithm is the gas that occupies the entire reference volume 6520 after equalization. The reference gas system 6522 expands during equalization as the higher pressure gas in the reference chamber 6520 pushes the manifold gas system 6532 out of the reference chanber 6520 and toward the control chamber 6510. In one example shown in FIG. 14, the reference chambers (labeled 174 in FIG. 14) are sufficiently open or devoid of interior features/elements that compression or expansion processes during pressure equalization may be modeled as adiabatic, so the polytropic coefficient (nR) may be set equal to approximately the specific heat ratio of the gas present in the chamber. The pressure and the volume of the reference chamber gas 6522 are related by:

$$p_{RO}V_{Ref}^{nR} = \text{constant}$$

where p_{R0} is the initial reference chamber 6520 pressure, V_{Ref} is the volume of the reference chamber 6520, and nR is the specific heat ratio for the reference chamber (nR = 1.4 air). In another example, where the reference chamber 6520 is filled with a heat absorbing material such as open cell foam, wire mesh, particles, etc that provides for a near-isothermal expansion, the polytropic coefficient for the reference chamber (nR) may have a value of approximately 1.0.

In the -FMS process, the conduit or manifold gas system 6532 occupies all of the volume of the interconnecting volume 6530, 6531 and a fraction 6536 of the reference chamber 6520 before equalization. After equalization, the conduit gas system 6532 occupies the interconnecting volume 6530, 6531 and a fraction 6534 of the control chamber 6510. The portion of the conduit gas system 6532 that exists in interconnecting volume 6530 on the control chamber side of the valve 6540 is herein labeled as 6533. The portion of the conduit gas system 6532 that exits in the interconnecting volume 6531 on the reference chamber side of the valve 6540 is referred to as 6535. The portion of the conduit gas system 6532 that exists in the control chamber 6510 is herein labeled as 6534. The portion of the conduit gas system 6532 that exists in the reference chamber 6520 is referred to as 6536.

In one example the interconnecting volumes 6530 and 6531 may be narrow passages that provide high heat transfer that assure the conduit gas system 6532 in volumes 6530 and 6531 is near the temperature of the solid boundaries or walls of the passages. The temperature of the structure surrounding the interconnecting volumes 6530, 6531 or manifold passages is herein referred to as the wall temperature (T_W). In another example, the temperature of the conduit gas system 6532 in volumes 6530, 6531 is in part a function of

the wall temperature. The portion of the conduit gas system in the control chamber 6534 may be modeled with the same temperature as control chamber gas system 6512. The control chamber portion of the conduit gas system 6534 experiences the same expansion as the control chamber gas system 6512 and may be conceived of as having the same temperature as the control chamber gas system 6512. The portion of the lines or manifold gas system in the reference chamber 6536 may be modeled with a temperature that is in part a function of the wall temperature. In another example, the reference chamber portion of the conduit gas system 6536 may be modeled as not interacting thermally with the boundaries of the reference chamber 6520, so that the temperature of the conduit gas system portion in the reference chamber 6536 is a function of the wall temperature and the reference chamber 6520 pressures.

The equations in this section use the following nomenclature:

variables

γ: specific heat ratio

n: polytropic coefficient

p: pressure

V: volume

T: temperature

superscripts:

n: polytropic coefficient

nCC: polytropic coefficient for the control chamber

nR: polytropic coefficient for the reference chamber

subscripts:

c: control chamber system

CC: physical control chamber

f: value at end of equalization

i: i^{th} value

IC: physical interconnecting volume or manifold passages

IC_R: physical interconnecting volume on the reference chamber side of valve

IC_CC: physical interconnecting volume on the control chamber side of valve

l: lines or manifold/interconnecting system

0: value at start of equalization

pmp: pump

r: reference system

Ref: physical reference chamber

w: wall temperature of interconnecting volume

The equations for the control chamber 6510 may derived from the conceptual model of the three separate mass systems in FIG. 26B and the understanding that the total volume of the control chamber mass 6512, reference chamber mass 6522 and interconnecting volumes mass 6532is fixed. This relationship can be expressed as the sum of the volume changes of each closed system 6512, 6522, 6532 being zero for each i^{th} set of values from the start to the end of pressure equalization:

$$0 = \begin{matrix}\text{change in volume of}\\ \text{control chamber mass}\end{matrix} + \begin{matrix}\text{change in volume of}\\ \text{interconnecting mass}\end{matrix} + \begin{matrix}\text{change in volume of}\\ \text{reference chamber mass}\end{matrix}$$

$$0 = \Delta V_{ci} + \Delta V_{ri} + \Delta V_{li} \tag{13}$$

where the i^{th} value of $\Delta V_{ci}, \Delta V_{ri}, \Delta V_{li}$ represents these values at the same point in time. Equations can be developed for the volume change of the control chamber gas system (ΔV_{ci}), the reference gas system (ΔV_{ri}), and the conduit gas system (ΔV_{li}) based on the pressure / volume relationship of a polytropic process and the ideal gas law. The equation for the i^{th} volume change of the control chamber gas system 6512 is equal to the i^{th} volume of the control chamber mass 6512 less the volume of the control chamber mass 6512 at the start of equalization. The volume of the control chamber mass 6512 at time i is calculated from the volume of the control chamber 6510 times the ratio of the final control chamber 6510 pressure over the control chamber 6510 pressure at time i, raised to one over the polytropic coefficient for the control chamber 6510:

$$\begin{matrix}\text{currrent change in volume}\\ \text{of control chamber mass}\end{matrix} = \begin{matrix}\text{current volume of}\\ \text{control chamber mass}\end{matrix} + \begin{matrix}\text{initial volume of}\\ \text{control chamber mass}\end{matrix}$$

$$\Delta V_{ci} = V_{CC}\left(\frac{P_{ee\,o}}{P_{ee\,i}}\right)^{1/nCC} - V_{CC} \tag{27}$$

The equation for the reference gas system volume change (ΔV_r) is derived from the pressure / volume relationship for a polytropic process. The equation for the i^{th} volume change of the reference chamber gas system 6522 is equal to the i^{th} volume of the reference chamber mass 6522 less the volume of the reference chamber mass 6522 at the start of

equalization. The volume of the reference chamber mass 6522 at time i is calculated from the structural volume of the reference chamber 6520 times the ratio of the initial reference chamber 6520 pressure over the reference chamber 6520 pressure at time i, raised to one over the polytropic coefficient for the reference chamber 6520:

$$\begin{array}{c}\text{currrent change in volume}\\ \text{of reference chamber mass}\end{array} = \begin{array}{c}\text{current volume of}\\ \text{reference chamber mass}\end{array} + \begin{array}{c}\text{initial volume of}\\ \text{reference chamber mass}\end{array}$$

$$\Delta V_{ri} = V_{Ref}\left(\frac{P_{Ref\,f}}{P_{Ref\,i}}\right)^{1/nR} - V_{Ref}\left(\frac{P_{Ref\,f}}{P_{Ref\,o}}\right)^{1/nR} \quad (28)$$

The equation for the volume change of the interconnecting gas system 6532 (ΔV_l) is derived from the constant mass gas of the system ($V * \rho = \text{constant}$). The equation for the i^{th} volume change of the conduit or manifold gas system 6532 is equal the current volume of the system 6532 less the original volume of the system 6532. The current volume of the interconnection or manifold gas system 6532 is the initial volume times the ratio of initial over current density of the system 6532. The initial volume of the interconnecting gas system 6532 is the sum of the volumes 6534, 6533 and 6535 pictured in FIG. 26B:

$$\begin{array}{c}\text{currrent change in volume}\\ \text{of interconnecting mass}\end{array} = \begin{array}{c}\text{current volume of}\\ \text{interconnecting mass}\end{array} + \begin{array}{c}\text{initial volume of}\\ \text{interconnecting mass}\end{array}$$

$$\Delta V_{li} = (\Delta V_{Rf} + V_{IC})\frac{\rho_{l\,o}}{\rho_{l\,i}} - (\Delta V_{Rf} + V_{IC}). \quad (29)$$

The density terms ρ_{l0}, ρ_{li} are the average density of the gases in the conduit gas system 6532 at the start of equalization and at some point, i, during equalization. The conduit gas system 6532 includes gases as different temperatures and pressures. The conduit gas system 6532 includes gas in the volume of the control chamber 6510 in a volume labeled 6534, gas in manifold passages on the control chamber side of the valve 6540 labeled 6533, gas in manifold passages on the reference chamber side of the valve 6540 labeled 6535, and gas in the reference chamber labeled 6536.

These four equations may be combined develop an expression for the volume (V_{CC}) of the control chamber 6510 as a function of the measured pressure pairs at the start of pressure equalization ($P_{CC\,0}$, $P_{Ref\,0}$), at any point during the equalization ($P_{CC\,i,}$ $P_{Ref\,i}$), the

reference chamber 6520 pressure at approximately the end of equalization ($P_{Ref\,f}$) and the fixed volumes of the reference chamber (V_{Ref}) and interconnecting volume (V_{IC}):

$$V_{CC} = \frac{V_{Ref}\left[\left(\frac{P_{Ref\,f}}{P_{Ref\,i}}\right)^{1/nR} - \left(\frac{P_{Ref\,f}}{P_{Ref\,o}}\right)^{1/nR}\right] + (\Delta V_{Rf} + V_{Ie})\left(\frac{\rho_{l\,o}}{\rho_{l\,i}} - 1\right)}{\left[1 - \left(\frac{P_{ee\,o}}{P_{ee\,i}}\right)^{1/nee}\right]} \tag{30}$$

where the densities of the line system 6532 ($\rho_{l\,o}$, $\rho_{l\,i}$) are evaluated with the initial pressure pairs ($P_{CC\,0}$, $P_{Ref\,0}$) and any pressure pair ($P_{CC\,i}$, $P_{Ref\,i}$) during equalization along with the associated temperatures as described below.

The densities of the conduit gas system ($\rho_{l\,o}$, $\rho_{l\,i}$) in equations (29) may be calculated from the volume-weighted average density for each physical volume (i.e. control chamber 6510, reference chamber 6520, and interconnecting volumes 6530, 6531):

$$\rho_{li} = \frac{-\rho_{CCi}(\Delta V_{cf}) + \rho_{IC_{ee}} V_{IC_{ee}} + \rho_{IC_R} V_{IC_R} + \rho_{ri}\Delta V_{ri}}{(\Delta V_{cf} + V_{IC_CC} + V_{IC_R} + \Delta V_{ri})} \tag{31}$$

$$\rho_{CCi} = \frac{P_{CCi}}{R\,T_{CCi}} = \text{density of gas in control chamber}$$

$$\rho_{IC_CCi} = \frac{P_{CCi}}{R\,T_{IC_CC}} = \text{density of gas in manifold line on control chamber side of valve}$$

$$\rho_{IC_Ri} = \frac{P_{Refi}}{R\,T_{IC_CC}} = \text{density of gas in manifold line on reference chamber side of valve}$$

$$\rho_{ri} = \frac{P_{Refi}}{R\,T_{lr}} = \text{density of gas in reference chamber}$$

where R is the universal gas constant for air, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lc} , may be functions in part of the temperature of the interconnecting volume walls. In another example, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lcr} , may be functions in part of the temperature of the interconnecting volume walls and the gas temperature of the reference chamber ($T_{Ref\,i}$). In another example, the temperatures, T_{IC_CC}, T_{IC_R}, T_{lc}, may be the interconnecting wall temperature (T_W). In another example, the temperatures may be reference chamber temperature ($T_{Ref\,i}$).

The value of ΔV_{cf} for equation (31) is calculated from equation (27), where the final control chamber pressure (P_{CCf}) is used for P_{CCi} and $V_{CC\ Est}$ is used for V_{CC}.

The value of ΔV_{ri} for equation (31) is calculated from equation (28).

The density of the conduit gas system 6532 before pressure equalization may be calculated from a equation similar to equation (31) that is the volume-weighted average density for each physical volume (i.e. control chamber 6510 and interconnecting volumes 6530, 6531):

$$\rho_{lO} = \frac{\frac{P_{ref\,O}(\Delta V_{rf})}{T_W} + \frac{P_{CC}V_{IC_CC}}{T_W} + \frac{P_{Ref}V_{IC_R}}{T_W}}{R(\Delta V_{rf} + V_{IC_CC} + V_{IC_R})} \tag{32}$$

An estimate of the control chamber 6510 volume can be derived by assuming constant temperature for the conduit or manifold gas system 6532, so that the density ratio ($\rho_{l\,O}/\rho_{l\,f}$) is equal to the pressure ratio ($P_{l\,O}/P_{l\,f}$). To futher simplfy the estimate, the polytropic coefficient is replaced by the specific heat ratio (γ). In this simpler equation, the volume of the control chamber (V_{CC}) in the –FMS process can be expressed as a function of three pressures [i.e. the measured pressure pair at the start of pressure equalization ($P_{CC\,O}$, $P_{Ref\,O}$), and a single equalization pressure (P_f)], as well as the fixed volumes of the reference chamber (V_{Ref}) and interconnecting volume (V_{IC}), and the polytropic coefficients for the reference chamber (nR) and control chamber (nCC):

$$V_{CC\,Est} = \frac{V_{Ref}\left[1-\left(\frac{P_f}{P_{Ref\,o}}\right)^{1/y}\right] + (\Delta V_{Rf} + V_{Ie})\left(\frac{P_{ee\,o}}{P_f} - 1\right)}{\left[1-\left(\frac{P_{ee\,o}}{P_f}\right)^{1/y}\right]}. \tag{33}$$

The gas in the three closed systems 6512, 6522, 6532 may be modeled as an ideal gas, so the temperature can be determined from the initial conditions and the new pressure or volume:

$$T_i = T_O\left(\frac{p_o}{p_i}\right)^{(n-1)/n} \quad \text{or} \quad T_i = T_O\left(\frac{V_o}{V_i}\right)^{n-1} \tag{23}$$

The initial temperature of the gas in the control chamber ($T_{CC\,0}$) may be calculated from the temperature of the interconnecting volume walls, the precharge pressure 6316 (FIG. 25B) and the pressures in the control chamber 6510 just before precharge 6306 (see FIG.

25B) modeling it as polytropic process and using the ideal gas law in equation (23). The control chamber pressure before precharging 6306 is referred herein as the pumping pressure (Ppmp):

$$T_{CC\,0} = T_W \left(\frac{P_{pmp}}{P_{ee\,o}}\right)^{\frac{1}{nee}-1} \quad (24)$$

The value of the polytropic coefficient for the control chamber gas system (nCC) may vary with the volume of the control chamber 6510 and range from approximately 1 for small volumes to approximately the specific heat ratio for large volumes. The specific heat ratio for air and other systems of predominantly diatomic molecules is 1.4. In one example the value of nCC for – FMS can be expressed as a function of the estimated control chamber volume (equation 21):

$$nCC = 1.507 - 1.5512 \times 10^{-5}(23.56 - V_{CC\,Est})^{3.4255} \quad (34)$$

A method to determine a relationship between the volume of the control chamber (V_{CC}) and its polytropic coefficient (nCC) is described in a following section.

Determing the Polytropic Coefficient n_{CC}

The value of polytropic coefficient n_{CC} may be determined experimentally or analytically. In possible understanding, the polytropic coefficient compares the potential temperature change of the gas due to heat transfer with the structure to temperature change caused by pressure changes. The value of the polytropic coefficient may vary with the pressure changes, the rate of pressure changes and the shape and size of the gas volume.

In one embodiment, the polytropic coefficient n_{CC} is determined experimentally by creating control chamber 6171 (FIG. 22) with a known volume and excuting the +FMS process or the -FMS processes and recording the control chamber and reference chamber pressures during equalization. The polytropic +FMS algorithm comprising eqns (17), (18), (20) is applied to the set of pressure measurements and the known control chamber volume (V_{CC}) in order to solve for the value of the polytropic coefficient for the control chamber (n_{CC}). This process to determine the polytropic coefficient was repeated for several different volumes ranging 1.28 ml, which is the typical of the control chamber 6171 after a fill stroke to 23.56 ml which is typical of the control chamber 6171 after a deliver stroke. The FMS process may be repeated several times for each volume to improve the accuracy of the determination of n_{CC}. One example of this experimental determination n_{CC} for +FMS

process is shown in FIG. 27A, where the value of n_{CC} is plotted versed the estimated volume of the control chamber ($V_{CC\ Est}$) as calculated by eqn (22) for six different volumes. A power equation was fit to the data to produce eqn (26) which expresses the polytropic coefficient in terms of the estimated volume control chamber. The plot in FIG. 27A plots the value, 1.4-n_{CC}, vs. 23.56-$V_{CC\ Est}$ in order to better fit the data with simple equation.

In a similar faishon, the poltytropic coefficient (n_{CC}) for –FMS may be determined by applying the –FMS process to a known control chamber volume and recording the control chamber and reference chamber pressures during equalization. The polytropic -FMS algorithm comprising eqns (30), (31), (32) is applied to the set of pressure measurements and the known control chamber volume (V_{CC}) in order to solve for the value of the polytropic coefficient for the control chamber (n_{CC}). This process to determine the polytropic coefficient was repeated for several different volumes. An example of the resulting values for n_{CC} for the -FMS process is shown in FIG. 27B, where the value of n_{CC} is plotted versed the estimated volume of the control chamber ($V_{CC\ Est}$) as calculated by eqn (33) for six different volumes. A power equation was fit to the data to produce eqn (34) which expresses the polytropic coefficient (n_{CC}) in terms of the estimated volume control chamber ($V_{CC\ Est}$). The plot in FIG. 27B plots the value, 1.507-n_{CC}, vs. 23.56-$V_{CC\ Est}$ in order to better fit the data with simple equation.

In one embodiment, the fixed known control chamber volume is created by attaching a machined volume to the front of the mounting plate 170 (FIG. 13), so that machined volume is sealed to the mounting plate and covers the ports 173C connecting the control chamber to pressure source and pressure sensor.

Polytropic FMS Calculation Procedure for V_{CC}

Referring now for FIGS. 28 and 29 that present flowcharts to calculate the volume of the control chamber from the pressure data recorded during an 2-chamber FMS process and the polytropic FMS algorithm. The flowchart in FIG. 28 presents a relatively simple process that requires a minimum of pressure data to calculate the volume of the control chamber (V_{CC}). The flowchart in FIG. 29 describes a more complex calculation to more accurately calculate the volume of the control chamber (V_{CC}) that requires multiple pressure pairs during the equalization process.

The simple polytropic FMS calculation procedure presented in FIG. 28 is executed by a processor or controller and starts with step 6400 that comprises completing either the +FMS or –FMS process described above and storing in memory multiple pressure

pairs that were recorded during the equalization process. In step 6614, the controller analyzes the multiple pressure pairs to identify the intial control chamber pressure ($P_{CC\ 0}$) and the initial reference pressure ($P_{Ref\ 0}$) as the control chamber and reference pressures when the equalization process starts. Methods or procedures to identify the start of equalization or the initial pressures are described in a previous section titled Pump Volume Delivery Measurement, where the initial control chamber and reference chamber pressures are referred to as Pd and Pr. In step 6618, the controller analyzes the multiple pressure pairs to identify the final control chamber pressure ($P_{CC\ f}$) and the final reference pressure ($P_{Ref\ f}$) when the control chamber and reference chamber pressures have nearly equalized or are changing at a sufficient low rate. One or more methods to identify when the control chamber and reference chamber pressures have nearly equalized are described in a previous section titled Pump Volume Delivery Measurement.

Alternatively, steps 6614 and 6618 to identify the intial and final pressures for the control chamber and referenc chamber may occur during the FMS process 6400. The controller or FPGA processor may identify the intial and final pressures and store only those values. In one example, the intial pressures could be the control chamber and reference pressures, when the connection valve opens and the final pressures could the the control chamber and reference pressures when the second valve opens to vent the reference and control chambers after equalization.

In step 6620, the volume of the control chamber is estimated from the initial and final pressures using either eqn (22) for a +FMS process or eqn (34) for a –FMS process. In step 6641, for a +FMS process, the resulting estimate of the control chamber volume ($V_{CC\ Est}$) is then used in eqns (26) to calculate the polytropic coefficient for the control chamber (n_{CC}). This polytropic value (n_{CC}) and the estimated volume ($V_{CC\ Est}$) along with intial and final pressure pairs are supplied to eqns (17), (18), (19) for a +FMS process to calucated the control chamber volume (V_{CC}). In step 6641 for a –FMS process, the polytropic coefficient (n_{CC}) is calculated with eqn 34 and the control chamber volume (V_{CC}) is calculated with eqns. (30), (31), (32).

A processor such as controller 61100 in FIG. 22, may perform steps 6614- 6618 (FIG. 28) on the stored pressure pairs. In an alternative embodiment, a processor 61100 may perform steps 6614 and 6618 during the pressure equalization without storing the pressure pair

A more complex calculation of the control chamber volume (V_{CC}) is described in FIG. 29. The initial steps of completing the FMS 6400, indentifying the intial control

chamber pressure ($P_{CC\,0}$) and intial reference chamber pressure ($P_{Ref\,0}$) 6614, indentifying the final control chamber pressure ($P_{CC\,f}$) and final reference chamber pressure ($P_{Ref\,f}$) 6618, and estimating the control chamber volume ($V_{CC\,Est}$) 6620 are the same as described above for FIG. 28.

The steps 6624, 6628, 6630 and 6640 are similar to the calculation steps described above in the section titled Pump Volume Delivery Measurement, except that the calculation of the control chamber volume (V_{CC}) is based on eqns. (17), (18), (19) for a +FMS process and eqns. (30), (31),(32) for a –FMS process. In step 6624, the pressure pairs of the control chamber pressure ($P_{CC\,i}$) and reference chamber pressure ($P_{r\,i}$) are corrected by interpolations with previous subsequent pressure pairs to calculate pressures pairs ($P_{CC\,i}^{*}$, $P_{r\,i}^{*}$) that occurred at exactly the same time. In other embodiments step 6624 is skipped and subsequent calculations use the uncorrected pressure pair ($P_{CC\,i}$, $P_{r\,i}$). In step 6628, a control chamber volume (V_{CC}) is calculated for each pressure pair. In steps 6630, 6640, the optimization algorithm described in the section titled Pump Volume Delivery Measurement is carried to out identify the optimal final pressure pair ($P_{CC\,f}$, $P_{Ref\,f}$) and the resulting control chamber volume (V_{CC}).

In an alternative embodiment, the calculations described FIGS. 28, 29 may be carried out in a processor that is separate from the controller 61100 in FIG. 22. The calculations may for example be carried out in the FPGA that also handles the input and output signals to and from the actuators, valves and pressure sensors.

Air Detection with the Polytropic FMS Algorithm

Referring now to FIG. 21, another aspect of the invention involves the determination of a presence of air in the pump chamber 181, and if present, a volume of air present. Such a determination can be important, e.g., to help ensure that a priming sequence is adequately performed to remove air from the cassette 24 and/or to help ensure that air is not delivered to the patient. In certain embodiments, for example, when delivering fluid to the patient through the lower opening 187 at the bottom of the pump chamber 181, air or other gas that is trapped in the pump chamber may tend to remain in the pump chamber 181 and will be inhibited from being pumped to the patient unless the volume of the gas is larger than the volume of the effective dead space of pump chamber 181. As discussed below, the volume of the air or other gas contained in pump chambers 181 can be determined in accordance with aspects of the present invention and the gas can be purged from pump chamber 181 before the volume of the gas is larger than the volume of the effective dead space of pump chamber 181.

A determination of an amount of air in the pump chamber 181 may be made at the end of a fill stroke, and thus, may be performed without interrupting a pumping process. For example, at the end of a fill stroke during which the membrane 15 and the pump control region 1482 are drawn away from the cassette 24 such that the membrane 15/region 1482 are brought into contact with the wall of the control chamber 172. A +FMS procedure as described in FIG. 24 may be carried out to measure the pressure equalization and calculate the apparent volume of the control chamber 171B as described above. However, the +FMS procedure after a fill stroke, provided that the membrane is off the spacers 50, will also measure the volume of any gas or air bubbles on the liquid side of the membrane 15.

The volume of the control chamber when the membrane 15 is against the control chamber wall 172 is generally a known value based on the design and manufacturing process. This minimum control chamber volume is $V_{CC\ Fix}$. The control chamber volume measured during a +FMS procedure at the end of a fill command is V_{CC+}. If the measured control chamber volume (V_{CC+}) is greater than $V_{CC\ Fix}$, then the control system 16 or controller 61100 may command a –FMS procedure that calculates a control chamber volume (V_{CC-}). If the –FMS procedure gives substantially the same control chamber volume as the +FMS, then the controller may recognize that the fill line is occluded. Alternatively if the –FMS procedure produces a smaller control chamber volume, then the controller recognizes the difference as the size of the sum of the air bubbles (V_{AB}):

$$V_{AB} = V_{CC+} - V_{CC-} \qquad (30)$$

A similar method may be used at the end of the deliver stroke, when the membrane 15 is against the spacers 50. A +FMS procedure will not measure the volume of air in the liquid, but only the volume of air in the control chamber 171B, when the membrane 15 is against the spacers 50. However, a –FMS procedure will pull the membrane away from the spacers 50 and will measure the volume of air on the dry side (i.e. control chamber 171B) and the liquid side (pump chamber 181) of the membrane 15. Therefore for the air volume in the liquid (V_{AB}) can also be determined at the end of the deliver stroke:

$$V_{AB} = V_{CC-} - V_{CC+} \quad . \qquad (31)$$

Head Height Detection

In some circumstances, it may be useful to determine the heightwise location of the patient relative to the cassette 24 or other portion of the system. For example, dialysis patients in some circumstances can sense a "tugging" or other motion due to fluid flowing into or out of the patient's peritoneal cavity during a fill or drain operation. To reduce this sensation, the cycler 14 may reduce the pressure applied to the patient line 34 during fill and/or drain operations. However, to suitably set the pressure for the patient line 34, the cycler 14 may determine the height of the patient relative to the cycler 14, the heater bag 22, drain or other portion of the system. For example, when performing a fill operation, if the patient's peritoneal cavity is located 5 feet above the heater bag 22 or the cassette 24, the cycler 14 may need to use a higher pressure in the patient line 34 to deliver dialysate than if the patient's peritoneal cavity is located 5 ft below the cycler 14. The pressure may be adjusted, for example, by alternately opening and closing a binary pneumatic source valve for variable time intervals to achieve the desired target pump chamber pressure. An average desired target pressure can be maintained, for example, by adjusting the time intervals to keep the valve open when the pump chamber pressure is below the target pressure by a specified amount, and to keep the valve closed when the pump chamber pressure is above the target pressure by a specified amount. Any adjustments to maintain the delivery of a complete stroke volume can be made by adjusting the fill and/or delivery times of the pump chamber. If a variable orifice source valve is used, the target pump chamber pressure can be reached by varying the orifice of the source valve in addition to timing the intervals during which the valve is opened and closed. To adjust for patient position, the cycler 14 may momentarily stop pumping of fluid, leaving the patient line 34 in open fluid communication with one or more pump chambers 181 in the cassette (e.g., by opening suitable valve ports in the cassette 24). However, other fluid lines may be closed, such as the upper valve ports 192 for the pump chambers 181. In this condition, the pressure in the control chamber for one of the pumps may be measured. As is well known in the art, this pressure correlates with the "head" height of the patient, and can be used by the cycler 14 to control the delivery pressure of fluid to the patient. A similar approach can be used to determine the "head" height of the heater bag 22 (which will generally be known), and/or the solution containers 20, as the head height of these components may have an effect on pressure needed for pumping fluid in a suitable way.

Control System

The control system 16 described in connection with FIG. 1 has a number of functions, such as controlling dialysis therapy and communicating information related to the dialysis therapy. While these functions may be handled by a single computer or processor, it may be desirable to use different computers for different functions so that the embodimentss of those functions are kept physically and conceptually separate. For example, it may be desirable to use one computer to control the dialysis machinery and another computer to control the user interface.

FIG. 30 shows a block diagram illustrating an exemplary embodiments of control system 16, wherein the control system comprises a computer that controls the dialysis machinery (an "automation computer" 300) and a separate computer that controls the user interface (a "user interface computer" 302). As will be described, safety-critical system functions may be run solely on the automation computer 300, such that the user interface computer 302 is isolated from executing safety-critical functions.

The automation computer 300 controls the hardware, such as the valves, heaters, and pumps that implement the dialysis therapy. In addition, the automation computer 300 sequences the therapy and maintains a "model" of the user interface, as further described herein. As shown, the automation computer 300 comprises a computer processing unit (CPU)/memory 304, a flash disk file system 306, a network interface 308, and a hardware interface 310. The hardware interface 310 is coupled to sensors/actuators 312. This coupling allows the automation computer 300 to read the sensors and control the hardware actuators of the APD system to monitor and perform therapy operations. The network interface 308 provides an interface to couple the automation computer 300 to the user interface computer 302.

The user interface computer 302 controls the components that enable data exchange with the outside world, including the user and external devices and entities. The user interface computer 302 comprises a computer processing unit (CPU)/memory 314, a flash disk file system 316, and a network interface 318, each of which may be the same as or similar to their counterparts on the automation computer 300. The Linux operating system may run on each of the automation computer 300 and the user interface computer 302. An exemplary processor that may be suitable for use as the CPU of the automation computer 300 and/or for use as the CPU of the user interface computer 302 is Freescale's Power PC 5200B®.

Via the network interface 318, the user interface computer 302 may be connected to the automation computer 300. Both the automation computer 300 and the user interface computer 302 may be included within the same chassis of the APD system. Alternatively, one or both computers or a portion of said computers (e.g., display 324) may be located outside of the chassis. The automation computer 300 and the user interface computer 302 may be coupled by a wide area network, a local area network, a bus structure, a wireless connection, and/or some other data transfer medium.

The network interface 318 may also be used to couple the user interface computer 302 to the Internet 320 and/or other networks. Such a network connection may be used, for example, to initiate connections to a clinic or clinician, upload therapy data to a remote database server, obtain new prescriptions from a clinician, upgrade application software, obtain service support, request supplies, and/or export data for maintenance use. According to one example, call center technicians may access alarm logs and machine configuration information remotely over the Internet 320 through the network interface 318. If desired, the user interface computer 302 may be configured such that connections may only be initiated by the user or otherwise locally by the system, and not by remote initiators.

The user interface computer 302 also comprises a graphics interface 322 that is coupled to a user interface, such as the user interface 144 described in connection with FIG. 10. According to one exemplary embodiments, the user interface comprises a display 324 that includes a liquid crystal display (LCD) and is associated with a touch screen. For example, a touch screen may be overlaid on the LCD so that the user can provide inputs to the user interface computer 302 by touching the display with a finger, stylus or the like. The display may also be associated with an audio system capable of playing, among other things, audio prompts and recorded speech. The user may adjust the brightness of the display 324 based on their environment and preference. Optionally, the APD system may include a light sensor, and the brightness of the display may be adjusted automatically in response to the amount of ambient light detected by the light sensor.

The brightness of the display may be set by the users for two different conditions: high ambient light and low ambient light. The light sensor will detect the ambient light level and the control system 16 will set the display brightness to the preselected levels for either high or low ambient light based on the measured ambient light. The user may select the brightness level for high and low ambient light by selection a value from 1 to 5 for each condition. The user interface may be a slider bar for each condition. In another example

the user may select a number. The control system may set the button light levels to match the display light levels.

The LCD display and/or the touch screen of the display 324 may develop faults, where they do not display and/or respond correctly. One theory, but not the only theory, of the cause is an electro-static discharge from a user to the screen that changes the values in the memories of the drivers for the LCD display and touch screen. The software processes UIC executive 354 or the AC executive 354 may include a low priority sub-process or thread that checks the constant memory registers of the drivers for the touch screen and LCD display. If thread finds that any of the constant values in the memory registers are different from those stored elsewhere in the User Interface computer 302 or automation computer 300, then the thread calls for another software process to reinitialize the drivers for LCD display and/or the touch screen. In one embodiment, the LCD display is driven by a Kieko Epson S1d13513 chip and the touch screen is driven by Wolfson Microelectronics WM97156 chip. Examples of the constant register values include but are not limited to the number of pixels display on the screen, the number colors displayed.

In addition, the user interface computer 302 comprises a USB interface 326. A data storage device 328, such as a USB flash drive, may be selectively coupled to the user interface computer 302 via the USB interface 326.

In addition, a USB Bluetooth adapter 330 may be coupled to the user interface computer 302 via the USB interface 326 to allow, for example, data to be exchanged with nearby Bluetooth-enabled devices. For example, a Bluetooth-enabled scale in the vicinity of the APD system may wirelessly transfer information concerning a patient's weight to the system via the USB interface 326 using the USB Bluetooth adapter 330. Similarly, a Bluetooth-enabled blood pressure cuff may wirelessly transfer information concerning a patient's blood pressure to the system using the USB Bluetooth adapter 330. The Bluetooth adapter may be built-in to the user interface computer 302 or may be external (e.g., a Bluetooth dongle).

The USB interface 326 may comprise several ports, and these ports may have different physical locations and be used for different USB device. For example, it may be desirable to make the USB port for the patient data key accessible from the front of the machine, while another USB port may be provided at and accessible from the back of the machine. A USB port for the Bluetooth connection may be included on the outside of the chassis, or instead be located internal to the machine or inside the battery door, for example.

As noted above, functions that could have safety-critical implications may be isolated on the automation computer. Safety-critical information relates to operations of the APD system. For example, safety-critical information may comprise a state of a APD procedure and/or the algorithms for implementing or monitoring therapies. Non safety-critical information may comprise information that relates to the visual presentation of the screen display that is not material to the operations of the APD system.

By isolating functions that could have safety-critical implications on the automation computer 300, the user interface computer 302 may be relieved of handling safety-critical operations. Thus, problems with or changes to the software that executes on the user interface computer 302 will not affect the delivery of therapy to the patient. Consider the example of graphical libraries (e.g., Trolltech's Qt® toolkit), which may be used by the user interface computer 302 to reduce the amount of time needed to develop the user interface view. Because these libraries are handled by a process and processor separate from those of the automation computer 300, the automation computer is protected from any potential flaws in the libraries that might affect the rest of the system (including safety-critical functions) were they handled by the same processor or process.

Of course, while the user interface computer 302 is responsible for the presentation of the interface to the user, data may also be input by the user using the user interface computer 302, e.g., via the display 324. To maintain the isolation between the functions of the automation computer 300 and the user interface computer 302, data received via the display 324 may be sent to the automation computer for interpretation and returned to the user interface computer for display.

Although FIG. 30 shows two separate computers, separation of the storage and/or execution of safety-critical functions from the storage and/or execution of non safety-critical functions may be provided by having a single computer including separate processors, such as CPU/memory components 304 and 314. Thus, it should be appreciated that providing separate processors or "computers" is not necessary. Further, a single processor may alternatively be used to perform the functions described above. In this case, it may be desirable to functionally isolate the execution and/or storage of the software components that control the dialysis machinery from those that control the user interface, although the invention is not limited in this respect.

Other aspects of the system architecture may also be designed to address safety concerns. For example, the automation computer 300 and user interface computer 302 may include a "safe line" that can be enabled or disabled by the CPU on each computer. The

safe line may be coupled to a voltage supply that generates a voltage (e.g., 12 V) sufficient to enable at least some of the sensors/actuators 312 of the APD system. When both the CPU of the automation computer 300 and the CPU of the user interface computer 302 send an enable signal to the safe line, the voltage generated by the voltage supply may be transmitted to the sensors/actuators to activate and disable certain components. The voltage may, for example, activate the pneumatic valves and pump, disable the occluder, and activate the heater. When either CPU stops sending the enable signal to the safe line, the voltage pathway may be interrupted (e.g., by a mechanical relay) to deactivate the pneumatic valves and pump, enable the occluder, and deactivate the heater. In this way, when either the automation computer 300 or the user interface computer 302 deems it necessary, the patient may be rapidly isolated from the fluid path, and other activities such as heating and pumping may be stopped. Each CPU can disable the safe line at any time, such as when a safety-critical error is detected or a software watchdog detects an error. The system may be configured such that, once disabled, the safe line may not be re-enabled until both the automation computer 300 and user interface computer 302 have completed self-tests.

FIG. 31 shows a block diagram of the software subsystems of the user interface computer 302 and the automation computer 300. In this example, a “subsystem” is a collection of software, and perhaps hardware, assigned to a specific set of related system functionality. A “process” may be an independent executable which runs in its own virtual address space, and which passes data to other processes using inter-process communication facilities.

The executive subsystem 332 includes the software and scripts used to inventory, verify, start and monitor the execution of the software running on the CPU of the automation computer 300 and the CPU of the user interface computer 302. A custom executive process is run on each of the foregoing CPUs. Each executive process loads and monitors the software on its own processor and monitors the executive on the other processor.

The user interface (UI) subsystem 334, handles system interactions with the user and the clinic. The UI subsystem 334 is implemented according to a “model-view-controller” design pattern, separating the display of the data (“view”) from the data itself (“model”). In particular, system state and data modification functions (“model”) and cycler control functions (“controller”) are handled by the UI model and cycler controller 336 on the automation computer 300, while the “view” portion of the subsystem is handled by the UI

screen view 338 on the UI computer 302. Data display and export functionality, such as log viewing or remote access, may be handled entirely by the UI screen view 338. The UI screen view 338 monitors and controls additional applications, such as those that provide log viewing and a clinician interface. These applications are spawned in a window controlled by the UI screen view 338 so that control can be returned to the UI screen view 338 in the case of an alert, an alarm or an error.

The therapy subsystem 340 directs and times the delivery of the dialysis treatment. It may also be responsible for verifying a prescription, calculating the number and duration of therapy cycles based upon the prescription, time and available fluids, controlling the therapy cycles, tracking fluid in the supply bags, tracking fluid in the heater bag, tracking the amount of fluid in the patient, tracking the amount of ultra-filtrate removed from patient, and detecting alert or alarm conditions.

The machine control subsystem 342 controls the machinery used to implement the dialysis therapy, orchestrating the high level pumping and control functionality when called upon by the therapy subsystem 340. In particular, the following control functions may be performed by the machine control subsystem 342: air compressor control; heater control; fluid delivery control (pumping); and fluid volume measurement. The machine control subsystem 342 also signals the reading of sensors by the I/O subsystem 344, described below.

The I/O subsystem 344 on the automation computer 300 controls access to the sensors and actuators used to control the therapy. In this embodiments, the I/O subsystem 344 is the only application process with direct access to the hardware. Thus, the I/O subsystem 344 publishes an interface to allow other processes to obtain the state of the hardware inputs and set the state of the hardware outputs.

FPGA

In some embodiments, the Hardware Interface 310 in Fig 33 may be a separate processor from the automation computer 300 and the User Interface 302 that may perform a defined set of machine control functions and provide an additional layer of safety to the cycler controller 16. A second processor, such as a field programmable gate array (FPGA) may increase the responsiveness and speed of the cycler 14 by moving some computing tasks from the automation computer 300 to the hardware interface 310 (e.g., an FPGA), so that the automation computer 300 can devote more resources to fluid management and therapy control, as these comprise resource-intensive calculations. The hardware interface 310 may control the pneumatic valves and record and temporarily store data from the

various sensors. The real time control of the valves, pressure levels and data recording by the hardware interface 310 allows the automation computer 300 to send commands and receive data, when the software processes or functions running on the automation computer 300 are ready for them.

A hardware interface processor 310 may advantageously be implemented on any medical fluid delivery apparatus, including (but not limited to) a peritoneal dialysis cycler 14, in which fluid is pumped by one or more pumps and an arrangement of one or more valves from one or more source containers of fluid (e.g., dialysate solution bags, or a heater bag containing fluid to be infused) to a patient or user. It may also be implemented on a fluid delivery apparatus that is configured to pump fluid from a patient or user (e.g., peritoneal dialysis cycler) to a receptacle (e.g., drain bag). A main processor may be dedicated to controlling the proper sequence and timing of pumps and valves to perform specific functions (e.g., pumping from a solution bag to a heater bag, pumping from a heater bag to a user, or pumping from a user to a drain receptacle), and to monitor the volumes of fluid pumped from one location to the next. A secondary (hardware interface) processor (e.g. an FPGA) may correspondingly be dedicated to collect and store data received from various sensors (e.g., pressure sensors associated with the pumps, or temperature sensors associated with a heating system) at an uninterrupted fixed rate (e.g., about 100 Hz or 200 Hz), and to store the data until it is requested by the main processor. It may also control the pumping pressures of the pumps at a rate or on a schedule that is independent from any processes occurring in the main processor. In addition to other functions (see below) it may also open or close individual valves on command from the main processor.

In one example the Hardware Interface 310 may be a processor that performs a number of functions including but not limited to:

- Acquiring pneumatic pressure sensor data on a predictable and fine resolution time base;
- Storing the pressure data with a timestamp until requested by automation computer 300;
- Validating the messages received from that automation computer 300;
- Providing automated control of one or more pneumatic valves 2660-2667;

- Controlling some valves with a variable pulse width modulation (PWM) duty cycle to provide Pick & Hold functionality and/or control some valves with current feedback;
- Provide automated and redundant safety checking of valve combinations, maximum pressures and temperatures and ability.
- Independent of the other computers 300, 302 putting the cycler 14 into a failsafe mode as needed.
- Monitoring status of buttons on the cycler 14 and controlling the level of button illumination;
- Detecting the presence of solution caps 31 and/or spike caps 63;
- Control of the pneumatic pump;
- Control of the prime sensor LED and detector;
- Detecting over-voltages and testing hardware to detect over-voltages;
- Controlling and monitoring one or more fluid detectors;
- Monitoring the latch and proximity sensor 1076 on the door 141;
- Monitoring critical voltages at the system level.

The Hardware Interface 310 may comprise a processor separate from the processors in the automation computer 300 and user interface 302, A to D converts and one or more IO boards. In another embodiment, the hardware interface is comprised of a FPGA (Field Programmable Gate Array). In one embodiment the FPGA is a SPARTAN® 3A in the 400K gate and 256 ball package made by Xilinx Inc. of California. The Hardware Interface 310 is an intelligent entity that is employed to operate as an independent safety monitor for many of the Control CPU functions. There are several safety critical operations where either the Hardware Interface or the Control CPU serves as a primary controller and the other serves as a monitor.

The hardware interface 310 serves to monitor the following automation computer 300 functions including but not limited to:

- Monitoring the integrity of system control data being received from the automation computer 300;
- Evaluating the commanded valve configurations for combination that could create a patient hazard during therapy;
- Monitoring the fluid and pan temperature for excessive high or low temperatures;
- Monitoring and testing the overvoltage monitor; and

- Provide a means for the automation computer 300 to validate critical data returned from the hardware interface.

FIG. 32 is a schematic representation of one arrangement of the automation computer 300, the UI computer 302 and the hardware interface processor 310. The hardware interface 310 is connected via a communication line to the automation computer 300 and connects to the sensors and actuators 312 in the cycler 14. A voltage supply 2500 provides power for the safety critical actuators that can be enabled or disabled by any of the computers 300, 302, 310. The safety critical actuators include but are not limited to the pneumatic valves, the pneumatic pump and a safety relay on the heater circuit. The pneumatic system is configured to safe condition when unpowered. The pneumatic safe condition may include occluding the lines 28,34 to the patient, isolating the control chambers 171B and/or closing all the valves 184, 186, 190, 192, on the cassette 24. Each computer 300, 302, 310 controls a separate electrical switch 2510 that can each interrupt power to the valves, pump and safety relay. If any of the three computers detects a fault condition, it can put the cycler 14 in a failsafe condition by opening one of the three switches 2510. The electrical switches 2510 are controlled by the safety executive process 352, 354 in the UI computer 302, and automation computer 300 respectively.

FIG. 33 is a schematic illustration of the connections between the Hardware Interface 310, the various sensors, the pneumatic valves, the bag heater and the automation computer 300. The Hardware Interface 300 controls each of the pneumatic valves 2660-2667 and the pneumatic pump or compressor 2600 via pulse-width-modulated DC voltages. FIG. 33 presents an alternative embodiment of the safe line 2632 supplying power to the pneumatic valves 2660-2667, pump 2600 and heater safety relay 2030, in which a single switch 2510 is driven by an AND gate 2532 connected to the three computers 300, 302, 310. The prime sensor is controlled and monitored by the Hardware Interface 310. The brightness of the button LEDs is controlled by the Hardware Interface 310 via a PWM'd voltage.

The data signals from the buttons, pressure sensors, temperature sensors and other elements listed in FIG. 33 are monitored by the Hardware Interface 310, and the data is stored in a buffer memory until called for by the automation computer 300. The digital inputs are connected directly to the Hardware Interface 310. The analog signals from pressure, temperature, current sensors and others are connected to Analog-to-Digital-Converter (ADC) boards that convert the analog signals to digital values and may a scale and/or offset the digital values. The outputs of the ADCs are communicated over SPI buses

to the Hardware Interface 310. The data is recorded and stored in the buffer at a fixed rate. Some of the data signals may be recorded at a relatively slow rate, including the pressure data on the pressure reservoirs and the fluid trap, temperatures, and current measurements. The low speed data may be recorded at 100 Hz. The adiabatic FMS volume measurement algorithm can be improved with high speed pressure data that is recorded at regular intervals. In a preferred embodiment, the pressure data from the sensors on the control volume 171B and the reference chamber 174 are recorded at 2000 Hz. The data may be stored in random-access-memory (RAM) along with a time stamp. The rate of data collection may preferably proceed independently of the automation computer 300 and of processes or subroutines on the hardware interface. The data is reported to the automation computer 300, when a process calls for that value.

The transfer of data between the hardware interface 310 to the automation computer 300 may occur in a two step process where a data packet transferred and stored in a buffer before being validated and then accepted for use by the receiving computer. In one example, the sending computer transmits a first data packet, followed by a second transmission of the cyclic redundancy check (CRC) value for the first data packet. The receiving computer stores the first data packet in a memory buffer and calculates a new CRC value first data packet. The receiving computer then compares the newly calculated CRC value to the CRC value received and accepts the first data packet if the two CRC values match. The cyclic redundancy check (CRC) is an error-detecting code commonly used in digital networks and storage devices to detect accidental changes to raw data. Blocks of data entering these systems get a short check value attached, based on the remainder of a polynomial division of their contents; on retrieval the calculation is repeated, and corrective action can be taken against presumed data corruption if the check values do not match. The data is not transferred between the automation computer and hardware interface if CRC values do not match. If multiple consecutive data packets fail the CRC test, the receiving computer may signal an alarm and put the machine in a fail-safe condition by de-energizing the safe line 2632. In one example, the alarm condition occurs on the third consecutive failed CRC check.

The automation computer 300 passes commands to open selected valves and set specified pressures in specified volumes to the hardware interface 300. The hardware interface 310 in turn controls the valve position by providing a PWM'd voltage to each valve. The hardware interface 310 opens valves as requested with a pick-and-hold algorithm, where the valve is initially actuated with a high voltage or current, and then held

in place with a lower voltage or current. Pick-and-hold operation of valves may advantageously reduce the power draw and the level of heat dissipation inside the cycler 14.

The hardware interface 310 controls the pressure in the specified volume by opening and closing the valves between the specified volume and the appropriate pressure reservoir based on the measured pressure in the specified volume. The hardware interface 310 may also control the pressure in the pressure reservoirs by opening and closing the valves between a pneumatic pump and one of the pressure reservoirs based on the measured pressure in the reservoir. The specified volumes may include each of the control chambers 171B, the reference volumes 174, the fluid trap and the positive and negative reservoirs. The hardware interface 310 may control the pressure in each of these specified volumes via a number of control schemes, including but not limited to on-off control, or proportional control of the valve with a PWM signal. In one example, as described above, the hardware interface 310 implements an on-off controller, sometimes referred to as a bang-bang controller, which sets a first and second limit and closes the valve when the pressure exceeds the upper second limit and opens the valve when the pressure is less than the first lower limit. In another example, the hardware interface 310 may operate valves between the specified volume and both pressure reservoirs to achieve a desired pressure. In other examples the automation computer 300 may specify one or more valves and command a specific valve to control the pressure as measured by a specified sensor.

The hardware interface 310 controls the position and operation of the Auto-Connect carriage. The movement and positioning of the Auto-Connect carriage 146 is controlled in real time by the hardware interface based on the measured position of the carriage 146. The automation computer 300 may command a particular function or position for the carriage. The hardware interface 310 carries out the commanded function without burdening memory or processing of the automation computer 300. The positioning of the carriage 146 is controlled with a feedback loop from a position sensor. Alternatively, the presence of the caps 31 and/or spike caps 63 can be detected by a range of sensing technologies, including but not limited to vision systems, optical sensors that can be blocked by a solution cap 31 and/or spike cap 63, or, for example, a micro-switch on the stripper element 1491.

The hardware interface 310 may implement safety functions independently of the automation computer 300 or the user interface computer 302. The independent action of the hardware interface 310 to disable the safety line 2632 and/or signal an alarm to the safety executives 352, 354 further reduces the possibility of an unsafe condition occurring. The hardware interface 310 may send an alarm and/or de-energize the safe line 2632 for defined

valve combinations at any time. Shutting the cycler down based on disallowed valve positions protects the patient and preserves the ability to complete the therapy (after a reset if needed). The hardware interface 310 may also alarm and de-energize the safe line at unsafe conditions including excessive temperature on the heater pan and/or bag button, excessive pressure in control chamber or reservoir. The hardware interface may alarm and de-energize the safe line when water or other liquid is detected in the fluid trap.

Database and User Interface systems

The database subsystem 346, also on the user interface computer 302, stores all data to and retrieves all data from the databases used for the onboard storage of machine, patient, prescription, user-entry and treatment history information. This provides a common access point when such information is needed by the system. The interface provided by the database subsystem 346 is used by several processes for their data storage needs. The database subsystem 346 also manages database file maintenance and back-up.

The UI screen view 338 may invoke a therapy log query application to browse the therapy history database. Using this application, which may alternatively be implemented as multiple applications, the user can graphically review their treatment history, their prescription and/or historical machine status information. The application transmits database queries to the database subsystem 346. The application can be run while the patient is dialyzing without impeding the safe operation of the machine.

The remote access application, which may be implemented as a single application or multiple applications, provides the functionality to export therapy and machine diagnostic data for analysis and/or display on remote systems. The therapy log query application may be used to retrieve information requested, and the data may be reformatted into a machine neutral format, such as XML, for transport. The formatted data may be transported off-board by a memory storage device, direct network connection or other external interface 348. Network connections may be initiated by the APD system, as requested by the user.

The service interface 356 may be selected by the user when a therapy is not in progress. The service interface 356 may comprise one or more specialized applications that log test results and optionally generate a test report which can be uploaded, for example, to a diagnostic center. The media player 358 may, for example, play audio and/or video to be presented to a user.

According to one exemplary embodiments, the databases described above are implemented using SQLite®, a software library that implements a self-contained, server-less, zero-configuration, transactional SQL database engine.

The executive subsystem 332 implements two executive modules, the user interface computer (UIC) executive 352 on the user interface computer 302 and the automation computer (AC) executive 354 on the automation computer 300. Each executive is started by the startup scripts that run after the operating system is booted and includes a list of processes it starts. As the executives go through their respective process lists, each process image is checked to ensure its integrity in the file system before the process is launched. The executives monitor each child process to ensure that each starts as expected and continue monitoring the child processes while they run, e.g., using Linux parent-child process notifications. When a child process terminates or fails, the executive either restarts it (as in the case of the UI view) or places the system in fail safe mode to ensure that the machine behaves in a safe manner. The executive processes are also responsible for cleanly shutting down the operating system when the machine is powering off.

The executive processes communicate with each other allowing them to coordinate the startup and shutdown of the various application components. Status information is shared periodically between the two executives to support a watchdog function between the processors. The executive subsystem 332 is responsible for enabling or disabling the safe line. When both the UIC executive 352 and the AC executive 354 have enabled the safe line, the pump, the heater, and the valves can operate. Before enabling the lines, the executives test each line independently to ensure proper operation. In addition, each executive monitors the state of the other's safe line.

The UIC executive 352 and the AC executive 354 work together to synchronize the time between the user interface computer 302 and the automation computer 300. The time basis is configured via a battery backed real-time clock on the user interface computer 302 that is accessed upon startup. The user interface computer 302 initializes the CPU of the automation computer 300 to the real-time clock. After that, the operating system on each computer maintains its own internal time. The executives work together to ensure sufficiently timekeeping by periodically performing power on self tests. An alert may be generated if a discrepancy between the automation computer time and the user interface computer time exceeds a given threshold.

FIG. 34 shows the flow of information between various subsystems and processes of the APD system. As discussed previously, the UI model 360 and cycler controller 362 run on

the automation computer. The user interface design separates the screen display, which is controlled by the UI view 338, from the screen-to-screen flow, which is controlled by the cycler controller 362, and the displayable data items, which are controlled by the UI model 360. This allows the visual representation of the screen display to be changed without affecting the underlying therapy software. All therapy values and context are stored in the UI model 360, isolating the UI view 338 from the safety-critical therapy functionality.

The UI model 360 aggregates the information describing the current state of the system and patient, and maintains the information that can be displayed via the user interface. The UI model 360 may update a state that is not currently visible or otherwise discernable to the operator. When the user navigates to a new screen, the UI model 360 provides the information relating to the new screen and its contents to the UI view 338. The UI model 360 exposes an interface allowing the UI view 338 or some other process to query for current user interface screen and contents to display. The UI model 360 thus provides a common point where interfaces such as the remote user interface and online assistance can obtain the current operational state of the system.

The cycler controller 362 handles changes to the state of the system based on operator input, time and therapy layer state. Acceptable changes are reflected in the UI model 360. The cycler controller 362 is implemented as a hierarchical state machine that coordinates therapy layer commands, therapy status, user requests and timed events, and provides view screen control via UI model 360 updates. The cycler controller 362 also validates user inputs. If the user inputs are allowed, new values relating to the user inputs are reflected back to the UI view 338 via the UI model 360. The therapy process 368 acts as a server to the cycler controller 362. Therapy commands from the cycler controller 362 are received by the therapy process 368.

The UI view 338, which runs on the UI computer 302, controls the user interface screen display and responds to user input from the touch screen. The UI view 338 keeps track of local screen state, but does not maintain machine state information. Machine state and displayed data values, unless they are in the midst of being changed by the user, are sourced from the UI model 360. If the UI view 338 terminates and is restarted, it displays the base screen for the current state with current data. The UI view 338 determines which class of screens to display from the UI model 360, which leaves the presentation of the screen to the UI view. All safety-critical aspects of the user interface are handled by the UI model 360 and cycler controller 362.

The UI view 338 may load and execute other applications 364 on the user interface computer 302. These applications may perform non-therapy controlling tasks. Exemplary applications include the log viewer, the service interface, and the remote access applications. The UI view 338 places these applications within a window controlled by the UI view, which allows the UI view to display status, error, and alert screens as appropriate. Certain applications may be run during active therapy. For example, the log viewer may be run during active therapy, while the service interface and the remote access application generally may not. When an application subservient to the UI view 338 is running and the user's attention is required by the ongoing therapy, the UI view 338 may suspend the application and regain control of the screen and input functions. The suspended application can be resumed or aborted by the UI view 338.

FIG. 35 illustrates the operation of the therapy subsystem 340 described in connection with FIG. 31. The therapy subsystem 340 functionality is divided across three processes: therapy control; therapy calculation; and solution management. This allows for functional decomposition, ease of testing, and ease of updates.

The therapy control module 370 uses the services of the therapy calculation module 372, solution management module 374 and machine control subsystem 342 (FIG. 31) to accomplish its tasks. Responsibilities of the therapy control module 370 include tracking fluid volume in the heater bag, tracking fluid volume in the patient, tracking patient drain volumes and ultra filtrate, tracking and logging cycle volumes, tracking and logging therapy volumes, orchestrating the execution of the dialysis therapy (drain-fill-dwell), and controlling therapy setup operations. The therapy control module 370 performs each phase of the therapy as directed by the therapy calculation module 370.

The therapy calculation module 370 tracks and recalculates the drain-fill-dwell cycles that comprise a peritoneal dialysis therapy. Using the patient's prescription, the therapy calculation module 372 calculates the number of cycles, the dwell time, and the amount of solution needed (total therapy volume). As the therapy proceeds, a subset of these values is recalculated, accounting for the actual elapsed time. The therapy calculation module 372 tracks the therapy sequence, passing the therapy phases and parameters to the therapy control module 370 when requested.

The solution management module 374 maps the placement of solution supply bags, tracks the volume in each supply bag, commands the mixing of solutions based upon recipes in the solution database, commands the transfer of the requested volume of mixed or

unmixed solution into the heater bag, and tracks the volume of mixed solutions available using the solution recipe and available bag volume.

FIG. 36 shows a sequence diagram depicting exemplary interactions of the therapy module processes described above during the initial 'replenish' and 'dialyze' portions of the therapy. During the exemplary initial replenish process 376, the therapy control module 370 fetches the solution ID and volume for the first fill from the therapy calculation module 372. The solution ID is passed to the solution management module 374 with a request to fill the heater bag with solution, in preparation for priming the patient line and the first patient fill. The solution management module 374 passes the request to the machine control subsystem 342 to begin pumping the solution to the heater bag.

During the exemplary dialyze process 378, the therapy control module 370 executes one cycle (initial drain, fill, dwell-replenish, and drain) at a time, sequencing these cycles under the control of the therapy calculation module 372. During the therapy, the therapy calculation module 372 is updated with the actual cycle timing, so that it can recalculate the remainder of the therapy if needed.

In this example, the therapy calculation module 372 specifies the phase as "initial drain," and the therapy control module makes the request to the machine control subsystem 342. The next phase specified by the therapy calculation module 372 is "fill." The instruction is sent to the machine control subsystem 342. The therapy calculation module 372 is called again by the therapy control module 370, which requests that fluid be replenished to the heater bag during the "dwell" phase. The solution management module 374 is called by the therapy control module 370 to replenish fluid in the heater bag by calling the machine control subsystem 342. Processing continues with therapy control module 370 calling the therapy calculation module 372 to get the next phase. This is repeated until there are no more phases, and the therapy is complete.

Pump Monitor / Math Repeater

The Pump Monitor / Math Repeater process is a software process or function that runs on the automation computer 300 separate from the safety executive 354. The Pump Monitor / Math Repeater process is implemented in as two separate threads or sub-functions that run independently. The math repeater thread, herein referred to as the MR thread, confirms the FMS calculation result. The Pump Monitor thread, referred to as the PM thread, monitors the net fluid and air flow across relevant endpoints from information provided in the routine status messages from the Machine process 342. The relevant

endpoints may include but not be limited to 5 potential bag spikes, the heater bag, patient port and drain port. The PM thread will also monitor the heater pan temperature via information from the IO Server process. The PM thread will signal an alarm to the safety executive 354, if predefined limits for fluid flow, air flow or temperature are exceeded.

The MR thread accepts the high speed pressure data and repeats the FMS calculation described above to recalculate the fluid volume displaced. The MR thread compares its recalculated fluid volume to the volume calculated by the Machine process 342 and sends a message to the safety executive. In another example, the MR thread declares and error condition if the two fluid volume values do not match.

The PM thread monitors several aspects of the pumping process as a safety check on the functioning of the cycler 14. The PM thread will declare an invalid pump operation error condition if the Hardware Interface 310 reports valves open that do not correspond to the commanded pump action by the Machine subsystem 342. An example of an invalid valve condition would be if any port valve 186, 184 (FIG. 6) are open, while the pump was in an idle mode. The state of valves in the cassette is mapped to the state of the corresponding pneumatic valves 2710, which are energized by the hardware interface 310. Another example of an invalid valve condition would be a port valve 184, 186 that is open that does not correspond to the specified source or sink of fluid.

The PM thread will declare an error condition if excess fluid is pumped to the patient while the heater button temperature sensor 2426 (Fig. 33) reports less than a given temperature. In a preferred embodiment, the PM thread will declare an error condition more than 50 ml of fluid is pumped to the patient while the button temperature is less than 32^{o}C.

The PM thread will maintain a numerical accumulator on the amount of fluid pumped to the patient. If total volume of fluid pumped to the patient exceeds a specified amount, the PM thread will declare an error. The specified amount may be defined in the prescription information and may include an additional volume equal to one chamber volume or approximately 23ml.

The PM thread will maintain a numerical accumulator on the amount of air measured in the pumping chamber by the FMS method for air taken from each bag. If the total amount of air from any bag exceeds the maximum allowed volume of air for that bag, then the PM thread will declare an error. In a preferred embodiment, the maximum allowed air volume for the heater bag is 350 ml and the maximum allowed air volume for a supply bag is 200 ml. A large air volume from a bag indicates that it may contain a leak to the atmosphere.

The maximum allowed air volume for the heater bag may be larger to account for out-gassing when the fluid is heated.

Alert/Alarm Functions

Conditions or events in the APD system may trigger alerts and/or alarms that are logged, displayed to a user, or both. These alerts and alarms are a user interface construct that reside in the user interface subsystem, and may be triggered by conditions that occur in any part of the system. These conditions may be grouped into three categories: (1) system error conditions, (2) therapy conditions, and (3) system operation conditions.

"System error conditions" relate to errors detected in software, memory, or other aspects of the processors of the APD system. These errors call the reliability of the system into question, and may be considered "unrecoverable." System error conditions cause an alarm that is displayed or otherwise made known to the user. The alarm may also be logged. Since system integrity cannot be guaranteed in the instance of a system error condition, the system may enter a fail safe mode in which the safe line described herein is disabled.

Each subsystem described in connection with FIG. 31 is responsible for detecting its own set of system errors. System errors between subsystems are monitored by the user interface computer executive 352 and automation computer executives 354. When a system error originates from a process running on the user interface computer 302, the process reporting the system error terminates. If the UI screen view subsystem 338 is terminated, the user interface computer executive 352 attempts to restart it, e.g., up to a maximum of three times. If it fails to restart the UI screen view 338 and a therapy is in progress, the user interface computer executive 352 transitions the machine to a fail safe mode.

When a system error originates from a process running on the automation computer 300, the process terminates. The automation computer executive 354 detects that the process has terminated and transitions to a safe state if a therapy is in progress.

When a system error is reported, an attempt is made to inform the user, e.g., with visual and/or audio feedback, as well as to log the error to a database. System error handling is encapsulated in the executive subsystem 332 to assure uniform handling of unrecoverable events. The executive processes of the UIC executive 352 and AC executive 354 monitor each other such that if one executive process fails during therapy, the other executive transitions the machine to a safe state.

"Therapy conditions" are caused by a status or variable associated with the therapy going outside of allowable bounds. For example, a therapy condition may be caused by an

out-of-bounds sensor reading. These conditions may be associated with an alert or an alarm, and then logged. Alarms are critical events, generally requiring immediate action. Alarms may be prioritized, for example as low, medium or high, based on the severity of the condition. Alerts are less critical than alarms, and generally do not have any associated risk other than loss of therapy or discomfort. Alerts may fall into one of three categories: message alerts, escalating alerts, and user alerts.

The responsibility for detecting therapy conditions that may cause an alarm or alert condition is shared between the UI model and therapy subsystems. The UI model subsystem 360 (FIG. 34) is responsible for detecting alarm and alert conditions pre-therapy and post-therapy. The therapy subsystem 340 (FIG. 31) is responsible for detecting alarm and alert conditions during therapy.

The responsibility for handling alerts or alarms associated with therapy conditions is also shared between the UI model and therapy subsystems. Pre-therapy and post-therapy, the UI model subsystem 360 is responsible for handling the alarm or alert condition. During a therapy session, the therapy subsystem 340 is responsible for handling the alarm or alert condition and notifying the UI Model Subsystem an alarm or alert condition exists. The UI model subsystem 360 is responsible for escalating alerts, and for coordinating with the UI view subsystem 338 to provide the user with visual and/or audio feedback when an alarm or alert condition is detected.

"System operation conditions" do not have an alert or alarm associated with them. These conditions are simply logged to provide a record of system operations. Auditory or visual feedback need not be provided.

Actions that may be taken in response to the system error conditions, therapy conditions, or system operation conditions described above are implemented by the subsystem (or layer) that detected the condition, which sends the status up to the higher subsystems. The subsystem that detected the condition may log the condition and take care of any safety considerations associated with the condition. These safety considerations may comprise any one or combination of the following: pausing the therapy and engaging the occluder; clearing states and timers as needed; disabling the heater; ending the therapy entirely; deactivating the safe line to close the occluder, shut off the heater, and removing power from the valves; and preventing the cycler from running therapies even after a power cycle to require the system to be sent back to service. The UI subsystem 334 may be responsible for conditions that can be cleared automatically (i.e., non-latching conditions) and for user recoverable conditions that are latched and can only be cleared by user interaction.

Each condition may be defined such that it contains certain information to allow the software to act according to the severity of the condition. This information may comprise a numeric identifier, which may be used in combination with a lookup table to define priority; a descriptive name of the error (i.e., a condition name); the subsystem that detected the condition; a description of what status or error triggers the condition; and flags for whether the condition implements one or more actions defined above.

Conditions may be ranked in priority such that when multiple conditions occur, the higher priority condition may be handled first. This priority ranking may be based on whether the condition stops the administration of therapy. When a condition occurs that stops therapy, this condition takes precedence when relaying status to the next higher subsystem. As discussed above, the subsystem that detects a condition handles the condition and sends status information up to the subsystem above. Based on the received status information, the upper subsystem may trigger a different condition that may have different actions and a different alert/alarm associated with it. Each subsystem implements any additional actions associated with the new condition and passes status information up to the subsystem above. According to one exemplary embodiments, the UI subsystem only displays one alert/alarm at a given time. In this case, the UI model sorts all active events by their priority and displays the alert/alarm that is associated with the highest priority event.

A priority may be assigned to an alarm based on the severity the potential harm and the onset of that harm. Table 1, below, shows an example of how priorities may be assigned in this manner.

POTENTIAL RESULT OF FAILURE TO RESPOND TO THE CAUSE OF ALARM CONDITION	**ONSET OF POTENTIAL HARM**		
	IMMEDIATE	**PROMPT**	**DELAYED**
death or irreversible injury	high priority	high priority	medium priority
reversible injury	high priority	medium priority	low priority
minor discomfort or injury	medium priority	low priority	low priority or no alarm signal

Table 1

In the context of Table 1, the onset of potential harm refers to when an injury occurs and not to when it is manifested. A potential harm having an onset designated as "immediate" denotes a harm having the potential to develop within a period of time not usually sufficient for manual corrective action. A potential harm having an onset designated as "prompt" denotes a harm having the potential to develop within a period of time usually sufficient for manual corrective action. A potential harm having an onset designated as "delayed" denotes a harm having the potential to develop within an unspecified time greater than that given under "prompt."

FIGS. 37-42 show exemplary screen views relating to alerts and alarms that may be displayed on a touch screen user interface. FIG. 37 shows the first screen of an alarm, which includes a diagram 380 and text 382 instructing a user to close their transfer set. The screen includes a visual warning 384, and is also associated with an audio warning. The audio warning may be turned off my selecting the "audio off" option 386 on the touch screen. When the user has closed the transfer set, the user selects the "confirm" option 388 on the touch screen. FIG. 38 shows a similar alarm screen instructing a user to close their transfer set. In this case, an indication that draining is paused 390 and an instruction to select "end treatment" are provided 392.

As previously discussed, alerts generally do not have associated risk other than loss of therapy or discomfort. Thus, an alert may or may not cause the therapy to pause. Alerts can be either "auto recoverable," such that if the event clears the alert automatically clears, or "user recoverable," such that user interaction with the user interface is needed to clear the alert. An audible alert prompt, which may have a volume that may be varied within certain limits, may be used to bring an alert to the attention of a user. In addition, information or an instruction may be displayed to the user. So that such information or instruction may be viewed by the user, an auto-dim feature of the user interface may be disabled during alerts.

In order to reduce the amount of disturbance to the user, alerts may be categorized into different types based on how important an alert is and how quick a user response is required. Three exemplary types of alerts are a "message alert," an "escalating alert," and a "user alert." These alerts have different characteristics based on how information is visually presented to the user and how the audible prompt is used.

A "message alert" may appear at the top of a status screen and is used for informational purposes when a user interaction is not required. Because no action needs to be taken to clear the alert, an audible prompt is generally not used to avoid disturbing, and possibly waking, the patient. However, an audible alert may be optionally presented. FIG. 39 shows

an exemplary message alert. In particular, FIG. 39 shows an under-temperature message alert 394 that may be used to inform a user when the dialysate is below a desired temperature or range. In this case, a user does not need to take any action, but is informed that therapy will be delayed while the dialysate is heated. If the patient desires more information, the "view" option 396 may be selected on the touch screen. This causes additional information 398 concerning the alert to appear on the screen, as shown in FIG. 40. A message alert may also be used when there is a low flow event that the user is trying to correct. In this case, a message alert may be displayed until the low flow event is cleared to provide feedback to the user on whether the user fixed the problem.

An "escalating alert" is intended to prompt the user to take action in a non-jarring manner. During an escalating alert, a visual prompt may displayed on the touch screen and an audible prompt may be presented (e.g., once). After a given period of time, if the event that caused the alert is not cleared, a more emphatic audible prompt may be presented. If the event causing the alert is not cleared after an additional period of time, the alert is escalated to a "user alert." According to one exemplary embodiments of a user alert, a visual prompt is displayed until the alert is cleared and an audible prompt, which can be silenced, is presented. The UI subsystem does not handle the transition to from escalating alert to user alert. Rather, the subsystem that triggered the original event will trigger a new event associated with the user alert. FIG. 41 shows a screen view displaying information concerning an escalating alert. This exemplary alert includes an on-screen alert message 400 and a prompt 402 instructing the user to check the drain line for kinks and closed clamps, as well as and an audible prompt. The audible prompt may be continuous until it is silenced by the user. FIG. 42 shows a screen view including an "audio off" option 404 that may be selected to silence the audible prompt. This alert can be used directly, or as part of the escalating alert scheme.

Each alert/alarm is specified by: an alert/alarm code, which is a unique identifier for the alert/alarm; an alert/alarm name, which is a descriptive name of the alert/alarm; an alert/alarm type, which comprises the type of alert or level of alarm; an indication of whether an audible prompt is associated with the alert/alarm; an indication of whether the alert and associated event can be bypassed (or ignored) by the user; and the event code of the event or events that trigger the alert/alarm.

During alarms, escalating alerts and user alerts, the event code (which may be different from the alert or alarm code, as described above) may be displayed on the screen so that the user can read the code to service personnel if needed. Alternatively or additionally, a voice

guidance system may be used so that, once connected to a remote call center, the system can vocalize pertinent information about the system configuration, state, and error code. The system may be connected to the remote call center via a network, telephonic connection, or some other means.

An example of a condition detected by the therapy subsystem is described below in connection with FIG. 43. The condition results when the APD system is not positioned on a level surface, which is important for air management. More particularly, the condition results when a tilt sensor detects that APD system is tilted beyond a predetermined threshold, such as 35°, with respect to a horizontal plane. As described below, a recoverable user alert may be generated by the therapy subsystem if the tilt sensor senses an angle with an absolute value greater than the predetermined threshold. To avoid nuisance alarms, the user may be directed to level the APD system before therapy begins. The tilt threshold may be lower during this pre-therapy period (e.g., 35°). The user may also be given feedback concerning whether the problem is corrected.

When the tilt sensor detects an angle of tilt exceeding a threshold value during therapy, the machine subsystem 342 responds by stopping the pump in a manner similar to detecting air in the pump chamber. The therapy subsystem 340 asks for status and determines that the machine layer 342 has paused pumping due to tilt. It also receives status information concerning the angle of the machine. At this point, the therapy subsystem 340 generates a tilt condition, pauses therapy, and sends a command to the machine subsystem 342 to pause pumping. This command triggers clean-up, such as taking fluid measurement system (FMS) measurements and closing the patient valve. The therapy subsystem 340 also starts a timer and sends an auto recoverable tilt condition up to the UI model 360, which sends the condition to the UI view 338. The UI view 338 maps the condition to an escalating alert. The therapy subsystem 340 continues to monitor the tilt sensor reading and, if it drops below the threshold, clears the condition and restarts therapy. If the condition does not clear before the timer expires, the therapy subsystem 340 triggers a user recoverable “tilt timeout” condition that supersedes the auto-recoverable tilt condition. It sends this condition to the UI model 360, which sends the condition to the UI view 338. The UI view 338 maps the condition to a user alert. This condition cannot be cleared until a restart therapy command is received from the UI subsystem (e.g., the user pressing the resume button). If the tilt sensor reading is below the threshold, the therapy resumes. If it is not below the threshold, the therapy layer triggers an auto recoverable tilt condition and starts the timer.

Prioritized Audible Signals

The cycler may provide audible signals and voice guidance to the user to communicate a range of information including but not limited to number selection, sound effects (button selection, action selection), machine condition, operational directions, alerts, and alarms. The cycler controller 16 may cause a speaker to annunciate audible signals and vocalizations from stored sound files stored in memory on one or both of the computers 300, 302 in the control system 16. Alternatively, vocalizations may be stored and produced by a specialized voice chip.

In some instances, the cycler may have multiple audible signals to annunciate at the same time or sequentially in a very short time. The annunciation of several signals in a short period of time may overwhelm the user resulting in annoyance or the loss of critical safety information. The cycler controller 16 may assign priorities to each audible signal and suppress the lower priority signals to allow the clear communication of higher priority audible signals. In one instance, the audible signals are prioritized from the highest priority alarm signals to the lowest priority annunciation of a sequence of numbers:

1. Alarms
2. Alerts
3. Sound Effects
4. Voice Guidance
5. Annunciation for a sequence of numbers.

Alarms and alerts are described above. Sound effects may confirm sounds to indicate that a button, or choice has been selected. Sound effects may also announce or confirm a particular action is being taken by the cycler. Voice guidance may include voiced instructions to execute a particular procedure, access help, contact a call center and other directing instructions. Annunciation for a sequence of numbers may include reading back to the user or the call center the number that the user had just keyed in or it may read the user allowable values for requested input.

Screen Display

As discussed previously, the UI view subsystem 338 (FIG. 34) is responsible for the presentation of the interface to the user. The UI view subsystem is a client of and interfaces with the UI model subsystem 360 (FIG. 34) running on the automation computer. For example, the UI view subsystem communicates with the UI model subsystem to determine

which screen should be displayed to the user at a given time. The UI view may include templates for the screen views, and may handle locale-specific settings such as display language, skin, audio language, and culturally sensitive animations.

There are three basic types of events that occur in the UI view subsystem. These are local screen events that are handled by the individual screens, model events in which a screen event must propagate down to the UI model subsystem, and polling events that occur on a timer and query the UI model subsystem for status. A local screen event only affects the UI view level. These events can be local screen transitions (e.g., in the case of multiple screens for a single model state), updates to view settings (e.g., locality and language options), and requests to play media clips from a given screen (e.g., instructional animations or voice prompts). Model events occur when the UI view subsystem must consult with the UI model subsystem to determine how to handle the event. Examples that fall into this category are the confirmation of therapy parameters or the pressing of the "start therapy" button. These events are initiated by the UI view subsystem, but are handled in the UI model subsystem. The UI model subsystem processes the event and returns a result to the UI view subsystem. This result drives the internal state of the UI view subsystem. Polling events occur when a timer generates a timing signal and the UI model subsystem is polled. In the case of a polling event, the current state of the UI view subsystem is sent to the UI model subsystem for evaluation. The UI model subsystem evaluates the state information and replies with the desired state of the UI view subsystem. This may constitute: (1) a state change, e.g., if the major states of the UI model subsystem and the UI view subsystem are different, (2) a screen update, e.g., if values from the UI model subsystem change values displayed on-screen, or (3) no change in state, e.g., if the state of the UI model subsystem and the UI view subsystem are identical. FIG. 44 shows the exemplary modules of the UI view subsystem 338 that perform the functions described above.

As shown in FIG. 44, the UI model client module 406 is used to communicate events to the UI model. This module 406 is also used to poll the UI model for the current status. Within a responsive status message, the UI model subsystem may embed a time to be used to synchronize the clocks of the automation computer and the user interface computer.

The global slots module 408 provides a mechanism by which multiple callback routines (slots) can subscribe to be notified when given events (signals) occur. This is a "many-to-many" relationship, as a slot can be bound to many signals, and likewise a signal can be bound to many slots to be called upon its activation. The global slots module 408 handles

non-screen specific slots, such as application level timers for UI model polling or button presses that occur outside of the screen (e.g., the voice prompt button).

The screen list class 410 contains a listing of all screens in the form of templates and data tables. A screen is made up of a template and an associated data table that will be used to populate that screen. The template is a window with widgets laid out on it in a generic manner and with no content assigned to the widgets. The data table includes records that describe the content used to populate the widgets and the state of the widgets. A widget state can be checked or unchecked (in the case of a checkbox style widget), visible or hidden, or enabled or disabled. The data table can also describe the action that occurs as a result of a button press. For example, a button on window 'A' derived from template '1' could send an event down to the UI model, whereas that same button on window 'B' also derived from template '1' could simply cause a local screen transition without propagating the event down to the UI model. The data tables may also contain an index into the context-sensitive help system.

The screen list class 410 forwards data from the UI model to the intended screen, selects the proper screen-based data from the UI model, and displays the screen. The screen list class 410 selects which screen to display based on two factors: the state reported by the UI model and the internal state of the UI view. In some cases, the UI model may only inform the UI view that it is allowed to display any screen within a category. For example, the model may report that the machine is idle (e.g., no therapy has been started or the setup phase has not yet occurred). In this case, it is not necessary to confer with the UI model when the user progresses from a menu into its sub-menu. To track the change, the UI view will store the current screen locally. This local sequencing of screens is handled by the table entries described above. The table entry lists the actions that respective buttons will initiate when pressed.

The language manager class 412 is responsible for performing inventory on and managing translations. A checksum may be performed on the list of installed languages to alert the UI view if any of the translations are corrupted and or missing. Any class that wants a string translated asks the language manager class 412 to perform it. Translations may be handled by a library (e.g., Qt®). Preferably, translations are requested as close as possible to the time of rendering. To this end, most screen template member access methods request a translation right before handing it to the widget for rendering.

A skin comprises a style-sheet and images that determine the "look and feel" of the user interface. The style-sheet controls things such as fonts, colors, and which images a widget

will use to display its various states (normal, pressed, disabled, etc.). Any displayed widget can have its appearance altered by a skin change. The skin manager module 414 is responsible for informing the screen list and, by extension, the screen widgets, which style-sheet and skin graphics should be displayed. The skin manager module 414 also includes any animated files the application may want to display. On a skin change event, the skin manager will update the images and style-sheet in the working set directory with the proper set, which is retrieved from an archive.

The video manager module 416 is responsible for playing locale-appropriate video given a request to display a particular video. On a locale change event, the video manager will update the videos and animations in the working set directory with the proper set from an archive. The video manager will also play videos that have accompanying audio in the audio manager module 418. Upon playback of these videos, the video manager module 416 will make the appropriate request to the audio manager module 418 to play the recording that belongs to the originally requested video clip.

Similarly, the audio manager module 418 is responsible for playing locale-appropriate audio given a request to play a particular audio clip. On a locale change event, the audio manager will update the audio clips in the working set directory with the proper set from an archive. The audio manager module 418 handles all audio initiated by the UI view. This includes dubbing for animations and sound clips for voice prompts.

The database client module 420 is used to communicate with the database manager process, which handles the interface between the UI view subsystem and the database server 366 (FIG. 34). The UI view uses this interface to store and retrieve settings, and to supplement therapy logs with user-provided answers to questions about variables (e.g., weight and blood pressure).

The help manager module 422 is used to manage the context-sensitive help system. Each page in a screen list that presents a help button may include an index into the context-sensitive help system. This index is used so that the help manager can display the help screen associated with a page. The help screen may include text, pictures, audio, and video.

The auto ID manager 424 is called upon during pre-therapy setup. This module is responsible for capturing an image (e.g., a photographic image) of a solution bag code (e.g., a datamatrix code). The data extracted from the image is then sent to the machine control subsystem to be used by the therapy subsystem to identify the contents of a solution bag, along with any other information (e.g., origin) included in the code.

Using the modules described above, the UI view subsystem 338 renders the screen views that are displayed to the user via the user interface (e.g., display 324 of FIG. 30). FIGS. 45-51 show exemplary screen views that may be rendered by the UI view subsystem. These screen views illustrate, for example, exemplary input mechanisms, display formats, screen transitions, icons and layouts. Although the screens shown are generally displayed during or before therapy, aspects of the screen views may be used for different input and output functions than those shown.

The screen shown in FIG. 45 is an initial screen that provides the user the option of selecting between "start therapy" 426 to initiate the specified therapy 428 or "settings" 430 to change settings. Icons 432 and 434 are respectively provided to adjust brightness and audio levels, and an information icon 436 is provided to allow the user to solicit more information. These icons may appear on other screens in a similar manner.

FIG. 46 shows a status screen that provides information the status of the therapy. In particular, the screen indicates the type of therapy being performed 438, the estimated completion time 440, and the current fill cycle number and total number of fill cycles 442. The completion percentage of the current fill cycle 444 and the completion percentage of the total therapy 446 are both numerically and graphically displayed. The user may select a "pause" option 448 to pause therapy.

FIG. 47 shows a menu screen with various comfort settings. The menu includes brightness arrows 450, volume arrows 452 and temperature arrows 454. By selecting either the up or down arrow in each respective pair, a user can increase or decrease screen brightness, audio volume, and fluid temperature. The current brightness percentage, volume percentage and temperature are also displayed. When the settings are as desired, a user may select the "OK" button 456.

FIG. 48 shows a help menu, which may be reached, for example, by pressing a help or information button on a prior screen. The help menu may include text 458 and/or an illustration 460 to assist the user. The text and/or illustration may be "context sensitive," or based on the context of the prior screen. If the information provided to the user cannot conveniently be provided in one screen, for example in the case of a multi-step process, arrows 462 may be provided to allow the user to navigate backward and forward between a series of screens. When the user has obtained the desired information, he or she may select the "back" button 464. If additional assistance is required, a user may select the "call service center" option 466 to have the system contact the call service center.

FIG. 49 illustrates a screen that allows a user to set a set of parameters. For example, the screen displays the current therapy mode 468 and minimum drain volume 470, and allows a user to select these parameters to be changed. Parameters may be changed in a number of ways, such as by selecting a desired option from a round robin style menu on the current screen. Alternatively, when the user selects a parameter to be changed, a new screen may appear, such as that shown in FIG. 50. The screen of FIG. 50 allows a user to adjust the minimum drain volume by inputting a numeric value 472 using a keypad 474. Once entered, the user may confirm or cancel the value using buttons 476 and 478. Referring again to FIG. 49, a user may then use the "back" and "next" arrows 480, 482 to navigate through a series of parameters screens, each including a different set of parameters.

Once all desired parameters have been set or changed (e.g., when the user has navigated through the series of parameters screens), a screen such as that shown in FIG. 51 may be presented to allow a user to review and confirm the settings. Parameters that have changed may optionally be highlighted in some fashion to draw the attention of the user. When the settings are as desired, a user may select the "confirm" button 486.

Pump Operation Synchronization

In various embodiments, during pumping, pump chambers of a cassette may be synchronized. The following description of pump operations may apply to any device that operates a pump cassette having two or more pumps. In an embodiment, such a device may be, for example a peritoneal dialysis cycler. In other embodiments, it may be an intravenous infusion pump system or an extracorporeal circulation pumping system using a pump cassette (such as, e.g., a hemodialysis or cardiopulmonary bypass system), or another type of pumping system using a pump cassette. Exemplary systems in which the following pump synchronizing operations may be implemented include for example, the peritoneal dialysis systems disclosed in US Patent Nos. 5,350,357, 5,431,626, 5,438,510, 5,474,683 and 5,628,908. They may also include, for example, the hemodialysis system disclosed in US Patent Nos. 8,246,826, 8,357,298, 8,409,441 and 8,393,690. They may also include, for example, the cardiopulmonary bypass systems disclosed in US Patent No. 8,105,265. In the following description, the term cycler is intended to encompass other pumping devices (such as those noted above) that may incorporate the use of a pump cassette.

A number different synchronization schemes may be used. Such synchronization schemes may serve to temporally dictate when various steps of a pumping operation occur (i.e. the filling and delivery of a cassette pumping chamber and any associated volume measurements, venting, etc.). Additionally, such synchronization schemes may serve to temporally structure pumping operations occurring across multiple pumping chambers of a cassette.

In some embodiments, pumping operations may use different synchronization schemes when different tasks are being performed. For example, a first type of chamber synchronization scheme may be used when draining fluid from a patient, , while a second type of chamber synchronization scheme may be used when emptying a remaining dialysate volume from a heater bag (or other reservoir) after a therapy has concluded. The synchronization scheme selected may be optimized for handling relatively large throughputs of fluid volume. The synchronization scheme may also be optimized to minimize patient discomfort. Depending on the task being performed, one or more of a number of synchronization schemes may be assigned to each different pumping operation as appropriate.

FIG. 52 depicts a flowchart detailing a number of example steps which may be used to synchronize pumping operations in a two-chamber pump cassette. As shown in the example embodiment, the flowchart depicts a synchronization scheme for a two-chamber cassette, although the procedure may readily be generalized for a multi-chamber cassette. For example, a similar scheme may be used for a cassette with additional pump chambers (e.g. sets of chambers ganged together such that they operate in parallel). As shown, at step 4000, the controller may cause Chamber A to execute a fill step. A fill step entails subjecting the target chamber of the cassette to a negative pressure while that chamber is in fluidic communication with a desired source reservoir. In some embodiments, the negative pressure may be applied for a predetermined time period sufficient to substantially fill the target chamber. If only a partial fill volume is desired, then the cycler controller may estimate any desired pump fill volume by calculating a relationship between the fill volume and the time taken to reach that fill volume through a series of volume measurements at periodic intervals during a fill cycle.

In step 4002, the device or cycler (via a device controller) may then make a measurement of the volume which was filled in Chamber A. Any type of volume measurement means may be used to perform this step, including, for example, pressure measurements in relation to a reference chamber (FMS), acoustic volume sensing, pump

membrane position sensing, etc. As shown in FIG. 52, an FMS-type measurement may be used, including any of the FMS methods described herein. The measurement of the current volume in the chamber may be compared to a previous measurement (e.g. the volume measurement taken after a preceding delivery) to determine the volume with which the chamber was filled. Additionally, in some embodiments, this measurement may be an indirect measurement from which the current volume may be inferred, such as, for example: the time spent in the fill mode before measurement as a percentage of a reference time representing complete filling; optical, ultrasonic or electrical capacitive detection or estimation of the relative position of the pump membrane in the pumping chamber, as an indication of the percentage of a full liquid volume when the membrane is fully retracted; or a variation in the pressure waveform detected as the pump membrane travels through its excursion, modeled against an empirically determined reference variation during testing. At about this time, the cycler may also begin step 4004, the filling of Chamber B.

The cycler may deliver the volume contained in Chamber A to a desired destination in step 4006. A deliver step may entail subjecting the designated chamber of the cassette to a positive pressure while that chamber is in fluidic communication with a desired destination reservoir. In some embodiments, the positive pressure may be applied for a predetermined time period sufficient to substantially deliver most or all of the volume of the designated chamber. After delivering Chamber A, in step 4008, the cycler may then make a measurement of the volume which was delivered by Chamber A during step 4006. In some embodiments, measurement of the current volume in the chamber may be compared to a previous measurement (e.g. the volume measurement taken in step 4002) to determine the volume delivered from Chamber A. Chamber B may continue to fill as steps 4002, 4006, and 4008 are completed.

As shown, after step 4008 is completed, the cycler may wait for a predetermined time period to elapse before Chamber A is refilled. This period of time may be selected so that it is about equal to the amount of time which will be needed to complete step 4004, which can be determined empirically, for example, through a series of pumping steps at the beginning of a therapy.

After filling of Chamber B is complete, in step 4010, the cycler may then make a measurement of the volume which was filled in Chamber B during step 4004. In some embodiments, this may take place while Chamber A is waiting for the predetermined time period to elapse, or alternatively at the end of the time period. Thus, while the measurement is being taking in step 4010, Chamber A may return to step 4000 and begin refilling.

The cycler may then deliver the volume in Chamber B in step 4012. Step 4012 may occur while Chamber A is refilling. After delivering from Chamber B, in step 4014 the cycler may then make a measurement of the volume which was delivered from Chamber B during step 4012. Again, this may occur as Chamber A is refilling.

As shown, after step 4014 is completed, the device may wait for a predetermined time period to elapse before Chamber B is refilled. This period of time may be selected so that it is about equal to the amount of time which will be needed to complete step 4000. After Chamber A has finished refilling, the device may, as described above, take a measurement of the volume refilled in step 4002. At this point, the device may return to step 4004 and being refilling of Chamber B. The example steps in the flowchart may repeat as necessary until a desired task is complete (e.g. patient is drained to empty).

FIG. 53 depicts another embodiment for synchronizing pumping operations in a two-chamber cassette. As shown in the example embodiment, the flowchart depicts a synchronization scheme for a two-chamber pump cassette, although the procedure can readily be generalized for use on a cassette with additional chambers (e.g. sets of chambers ganged together such that they operate in parallel). As shown, at step 4020, the device may cause Chamber A to execute a fill step. In step 4022, the device may then make a measurement of the volume which was filled in Chamber A during step 4020. As before, any type of suitable sensor or suitable measurement means may be used to perform this step. As shown in FIG. 53, an FMS-type measurement, such as any of those described herein may be used. In other embodiments, and as previously noted, acoustic volume sensing or any of other suitable measurement means may be used.

The cycler may then deliver the volume contained in Chamber A to its destination in step 4024. At this time, the cycler may also begin step 4028, the filling of Chamber B. After delivering Chamber A, in step 4026, the cycler may make a measurement of the volume which was delivered from Chamber A during step 4024. Chamber B may continue to fill as steps 4024 and 4026 are completed.

As shown, after step 4026 is completed, the cycler may check to see that the volume in Chamber A was appropriately delivered. This may, for example involve comparing the measurements from steps 4022 and 4026. The cycler may use this comparison to determine whether a predetermined amount or proportion of the fill volume was delivered. When the predetermined amount or proportion of the fill volume is delivered, the cycler may consider the chamber fully delivered. In the event that the cycler determines that the Chamber A volume was not fully delivered, the cycler may perform steps 4024 and 4026 again. These

steps may be repeated until the cumulative volume from each attempt falls within the predetermined amount or proportion of the measurement from step 4022. In some embodiments, there may be a limit to the number of times these steps may be repeated before the cycler proceeds to the next step and attempts to deliver Chamber B. In some embodiments, once this limit is reached, and if a predetermined amount of fluid has not been delivered, an occlusion alarm or the like may be triggered by the cycler controller.

After it has been determined that Chamber A has been fully delivered, step 4030 may be performed. In step 4030, the cycler may make a measurement of the volume which was filled into Chamber B during step 4028. Additionally, after it is determined that the full volume of Chamber A has been fully delivered (or a retry limit has been reached) the cycler may check to see if a predetermined period of time has elapsed. In the event that the predetermined period of time has not elapsed, the cycler may wait for the remainder of the predetermined time period to elapse before Chamber A is refilled. This period of time may be selected such that it is about equal to the amount of time which will be needed to complete step 4028. Step 4032 may also be performed after the predetermined period of time has elapsed. It may be desirable that step 4032 begin after Chamber A has begun being refilled.

After delivering Chamber B, in step 4034, the cycler may then make a measurement of the volume which was delivered from Chamber B during step 4032. Chamber A may continue to fill as steps 4032 and 4034 are completed.

As shown, after step 4034 is completed, the cycler may check to see that the volume in Chamber B was fully delivered. This may, for example involve comparing the measurements from steps 4030 and 4034. The cycler may use this comparison to determine whether a predetermined amount or proportion of the fill volume was delivered. In the event that the cycler determines that the Chamber B volume was not fully delivered, the cycler may perform steps 4032 and 4034 again. These steps may be repeated until the cumulative volume from each attempt falls with the predetermined amount or proportion of the measurement from step 4030. In some embodiments, there may be a limit to the number of times these steps are repeated before the device proceeds to a next step and attempts to deliver Chamber A. If a limit exists, once it is reached, an occlusion alarm or the like may be triggered by the system controller. In other embodiments, once this limit is reached, the cycler may enter a troubleshooting mode to test for various conditions (e.g. an occlusion) and issue an alert or alarm if necessary.

After it has been determined that Chamber B has been fully delivered, step 4022 may be performed. In step 4022, the cycler may make a measurement of the volume which was filled into Chamber A during step 4020. Additionally, after it is determined that the full volume of Chamber B has been fully delivered (or a limit of attempts has been reached) the cycler may check to see if a predetermined period of time has elapsed. In the event that the predetermined period of time has not elapsed, the cycler may wait for the remainder of the predetermined time period to elapse before Chamber B is refilled. This period of time may be selected such that it is about equal to the amount of time that will be needed to complete step 4020. Step 4024 may also be performed after the predetermined period of time has elapsed. Step 4024 preferably may begin after the refilling of Chamber B has begun. The example steps in the flowchart may be repeated as necessary until a desired task is complete (e.g. patient is drained to empty).

Valve Flush Procedure

The cycler pumps dialysate and other liquids through a disposable cassette to deliver Automated Peritoneal Dialysis (APD) to a patient. The disposable cassette comprises two or more pump chambers and several valves that are actuated by the cycler. Referring now to Fig. 55A, the valves 184 consist of a volcano valve that is sealed closed by a membrane 15 that is pushed against the valve seat 184A by movement of the valve region 1481. This section describes a Valve Flush procedure to recover the operation of a valve in the cassette after a Valve Check executed by the cycler indicates that the valve may be leaking.

Referring now to FIG. 10, the cycler 14 receives the cassette 24 into a cavity 145 located on the door 141. Closing the door 141 places the cassette against the control surface 148 that includes valve regions 1481 (FIG. 12) aligned with valves in the cassette and pump regions 1482 (FIG. 12) that align the pumps of the cassette 24. The cycler 14 moves the pump regions and valve regions toward the cassette body by supplying positive pressure behind the pump regions and valve regions or away from the cassette body by supplying negative pressure behind the pump regions and valve regions to operate the pumps and control the valves in the cassette as described above and referring to Figs. 11-14. The fluid lines 34, 28, 26 connect the cassette 24 respectively to the patient, a drain, and a heater bag. The fluid lines 34, 28 pass by the occluder 147 that is configured to selectively deploy and pinch these fluid lines 34, 28 closed, when commanded by the control system.

The operations of the cassette 24 can be understood by referring to a schematic drawing of the cassette 24 in Fig. 54. In this embodiment, 4 bags of solution are fluidly connected to

the cassette 24 via 4 solution port valves BP1-BP4. Port valve BP5 may optionally be fluidly connected to a fifth solution bag or a fluid line. The port valves BP1-BP5 are fluidly connected to a bottom channel 202 that is fluidly connected to the patient valve PP and the bottom valves C1B, C2B of pump chamber-1 and pump chamber-2. The patient valve PP connects the cassette to the patient line 34. The heater bag 26 and drain line 28 are connected by a heater bag valve HP and a drain valve DP to a top channel 200. The top channel 200 is connected to pump chamber-1 and pump chamber 2 via top pump valves C1T and C2T respectively. The cycler 14 delivers an APD therapy by a number of operations that may include moving liquid through the cassette by action of the pump chambers and valves.

On occasion, particles occur in or enter the cassette 24. The particles may have precipitated out of solution in the solution bags, heater bag, fluid lines, or the cassette itself. Referring to Fig. 55A, particles or other solids may be drawn into the volcano valve 184. When the membrane 15 is not sealed to the valve seat 184A, the bottom channel 202 is connected to the port 154 via port valve well 183. The port 154 is fluidly connected to the patient line 34 that may be selectively occluded by the occluder 147. The valve region 1481 displaces the membrane against the valve seat 184A when the positive pressure applied to the valve region 1481 is greater than the pressure in the valve 184. Particles may adhere to the valve seat 184A or the part of the membrane 15 that seals against the valve seat 184A. A particle or other material in either location may prevent the membrane from sealing against the valve seat, which may result in liquid passing through the valve 184 even though the cycler has applied pressure at the valve region 1481 to close the valve 184. In an alternate embodiment, the channel is the top channel 200 that connects via the drain port valve DP to the drain line 28.

Referring now to Fig. 55C, in a further alternate embodiment, the port valve 184 is connected via port 154 to a fluid line 807 that is not occluded. The non-occluded fluid line 807 may be one of the solution bags or the heater bag. In one example, the non-occluded fluid line 807 may be connected to the drain line or the patient line when the occluder is not occluding the fluid line.

The cycler regularly runs a Valve Check that tests some or all of the valves for leakage before and during operation of the APD system. In one example, the Valve Check is run before the therapy starts. In one example, the cycler runs the Valve Check during therapy. In one example, the cycler runs the Valve Check before each pumping operation including but not limited to pulling liquid from the solution bags, pumping dialysate liquid to the

heater bag, pulling warm dialysate from the heater bag, delivering dialysate to the patient, withdrawing liquid or used dialysate from the patient, and pumping used dialysate or other liquids to the drain. The cycler will alert the user that a Valve Check has failed. A leaking valve may cause the cycler to end therapy. The patient may be given the choice to restart therapy with a new cassette or end therapy prematurely.

A Valve Flush procedure is described below that removes particles from the valve seat or the membrane near the valve seat. The Valve Flush procedure may be performed on a target valve after a Valve Check failure. The target valve being one of the port valves connected to the channel (top or bottom) that failed the Valve Check. The Valve Flush procedure often results in the target port valve passing the subsequent Valve Check procedure. In one exemplary embodiment the Valve Flush procedure isolates the patient from the cassette by closing the occluder. The Valve Flush then uses at least one pump chamber to alternatively push and pull liquid through a valve that may be leaking. After the particles are displaced away from the valve seat, the membrane is again able to form a seal with the valve seat, allowing for a successful result in the Valve Check.

In an alternate Valve Flush, a fluid line is not occluded during the Valve Flush as shown in Fig. 55C. The fluid line is not occluded when the Valve Flush is applied to port valves connected to fluid lines that cannot be occluded such as one of the solution port valves BP1-BP5 or the heater bag valve HP. In addition, this alternative Valve Flush can be applied to the patient line 34 or drain line 28 while holding the occluder in an open position. In this alternate Valve Flush, the valve is flushed as liquid is pumped back and forth through an open valve to displace the particles away from the valve seat. After the particles are displaced away from the valve seat, the membrane is again able to form a seal with the valve seat, allowing for a successful result in the Valve Check.

Valve Check Procedure

The control system 16 (Fig. 30) regularly performs a Valve Check to confirm that the port valves (HP, DP, PP, BP1-BP5) achieve liquid seals when closed. Referring now to Fig. 54 that shows a schematic of the cassette 24 and the flow chart in Fig. 56 that describes the Valve Check procedure 840. The control system 16 may initiate a Valve Check 840 before starting therapy and / or during therapy. In one example, the control system 16 executes a Valve Check 840 before each pumping operation. A controller in the automation computer 300 initiates the Valve Check in step 842, at which point all valves on the cassette are closed and the two pump chambers are empty of liquid. The valves include the solution

port valves BP1-BP5, the patient port valve PP, the heater bag port valve HP, the drain port valve DP, and the pump chamber valves (C1B, C1T, C2B, C2T). Next, the controller starts two parallel process that move forward by alternating between steps to test the valves connected to the top channel 200 and steps to test valves connected to the bottom channel 202. The top channel test starts in step 846, where pump chamber-1 is connected to the top channel 200 by opening the top pump chamber valve C1T. In step 856, the bottom channel 202 is connected to pump chamber-2 by opening bottom pump chamber valve C2B. In step 848, the cycler applies a predetermined pre-charge to pump chamber-1, before applying the same pre-charge pressure to pump chamber-2 in step 858. In one example, the pre-charge pressure is the pressure in the negative-reservoir. In another example the pre-charge pressure is the pressure in the positive-reservoir. In step 850, 860 the valves from the pump chambers to the channels 202, 200 are closed. A single FMS measurement is taken on pump chamber-1 in step 852, before taking a single FMS measurement on pump chamber 2 in step 862. The FMS measurement is described above, in section "2-chamber FMS Process in APD Cycler". In steps 854, if a gross leak is detected, the controller issues an alert that a leak exists in the top channel in step 878. In steps 864, if a gross leak is detected, the controller issues an alert that a leak exists in the bottom channel in step 888. A gross leak being a leak that is greater than a predetermined gross leak threshold. In one exemplary embodiment, the predetermined gross leak threshold is 12 ml. The volume of the leak in the first FMS measurement is relative to an assumed empty pump.

A leak in the top channel indicates that either the heater bag port valve HP or the drain port valve DP are leaking. This alert may be displayed to the user on the screen 144 (FIG. 10) and / or with an audible alert. In one exemplary embodiment, the control system may then end therapy after detecting a leak in from the top channel. The patient may be given a choice to restart therapy with a new cassette or end therapy prematurely. In another exemplary embodiment, the control system may execute a valve flush on the heater bag port valve HP and / or the drain port valve DP and then repeat the Valve Check.

A leak in the bottom channel indicates that either the patient port valve PP or one of the solution port valves BP1-BP5 are leaking. The controller will proceed to Valve Flush described in Fig. 57, if the leak occurs in the bottom channel.

If gross leaks do not occur in either channel, then controller repeats steps 846-864 to open a pump chamber valve 846,856, pressurize the pumps 848, 858, close the chamber valves 850, 860, and repeat a second FMS measurement on pump chamber-1 852 and then a

second FMS measurement on pump chamber-2 862. Steps 854, 864 do not check for gross leaks and transfers to step 870 after the 2nd FMS measurement.

The first and second FMS measurement volumes of pump chamber-1 are compared in step 872 and for pump chamber 2 in step 882. If the difference between the two FMS measurements for pump chamber-1 is larger than a predetermined value in step 874, then the controller issues an alert that a leak exists in the top channel in step 878. This alert may be displayed to the user on the screen 144 (FIG. 10) and / or as an audible alert. The control system may then end therapy. The patient may be given a choice to restart therapy with a new cassette or end therapy prematurely. In another exemplary embodiment, the control system may execute a valve flush on the heater bag port valve HP and / or the drain port valve DP and then repeat the Valve Check.

In step 882, if the difference of the two FMS measurements of pump chamber-2 are larger than the predetermined value, the controller moves to step 888. In step 888, the controller may issue a bottom channel leak alert and / or proceed to the Valve Flush as described in Figs. 57, 57A. In one example, if controller detects a leak alert in a channel immediately after completing a Valve Flush on a valve connected to that channel, the controller signals a leak alert and does not proceed to Valve Flush. The leak alert to the user will be displayed on the screen 144 (FIG. 10) and / or as an audible alert. The control system may then end therapy. The patient may be given a choice to restart therapy with a new cassette or end therapy prematurely.

If the difference of the two FMS measurements of pump chamber-1 in step 874 and the difference of the two FMS measurements of pump chamber-2 in step 884 are both less than a predetermined value the Valve Check is passed and the controller proceeds with the planned pumping operation.

Valve Flush Procedure

In one exemplary embodiment the controller will run the Valve Flush procedure 900, when the Valve Check 840 returns a “Bottom Channel Leak” result. Referring now to Figs. 54, 57, one exemplary embodiment of the Valve Flush procedure 900 is shown as a flow chart. The Valve Flush procedure uses the two pump chambers to move liquid past the valve seat of the target valve in a oscillating manner. The pumps push and then pull a volume of liquid past the valve seat to flush particulates away from the valve sealing surfaces of the volcano valve and the membrane.

Before starting the Valve Flush procedure 900, the cassette pumps are stopped and the pump chambers 800, 805 are isolated by closing pump chamber valves C1B, C1T, C2B, C2T . The controller empties the pump chambers in a Dump step 892 before starting the Valve Flush procedure 900. In the Dump step, pump chamber-1 800 and pump chamber-2 805 are emptied by pumping any fluid into the drain line 28 (Fig. 54). The controller repeats the Dump step 892A after completing the flush procedure.

Continuing to refer to Figs. 54, 57, the Valve flush procedure 900 starts by setting up pump chamber-1 800 and pump chamber-2 805 to respectively pump liquid toward and pull liquid away from the target valve. In one embodiment, the target valve is the patient port valve PP connected to the patient line. In step 904, the controller closes all the port valves connected to the bottom channel 202, then at least partially fills pump chamber-1 800 from the heater bag line 26 in step 906. In step 908, pump chamber-1 is pressurized with a positive pressure. In one example the pump chamber-1 is pressurized by the controller connecting the actuation chamber behind pump chamber-1 to a positive pressure source. In one example, pump chamber-1 is pressurized to the pressure of the positive pressure reservoir. In step 910, pump chamber-2 805 is delivered to the drain line 28 and the drain port valve DP and pump chamber valve C2T are closed. In step 912, pump chamber-2 is pressurized to a negative pressure. In one example the pump chamber-2 is pressurized to a negative pressure by the controller connecting the actuation chamber behind pump chamber-2 to a negative pressure source. In one example, pump chamber -2 is pressurized to the pressure of the negative pressure reservoir.

In one exemplary embodiment, before starting the pressure oscillation sequence 920, the controller isolates the patient and the drain from the oscillating pressure. In step 914, the occluder 147 (Fig. 55A) pinches closed the patient line 34. Step 914 isolates the patient from pressure oscillations during the Valve Flush and isolates a small volume downstream of the target valve. Step 914 may have the additional benefit of not affecting the volumes of fluid pumped to or pulled from the patient. Step 914 separates the Valve Flush from the therapeutic movement of dialysate, and the liquid used to flush the target valve is not delivered to the patient but delivered to drain before therapy is resumed.

Referring now to Figs. 55A, 57, before starting the pressure oscillation sequence 920, the target valve is closed by positive pressure 1481 on the membrane 15 that seals the membrane against the valve seat 184A. In one embodiment, the bottom pump chamber valve C1B of the pump chamber-1 is opened in step 922 before opening the target valve in step 924. Referring now to Fig. 55B, the membrane 15 moves away from the valve seat

184A due to the positive pressure applied to fluid channel 202 in step 922 and the negative pressure applied to the membrane 15 through the valve region 1481 when the target valve is opened in step 924. One theory among others has a small volume 185 (cross hatched area) move past the valve seat 184A in step 924 as the applied pressure on the valve region 1481 is reduced and the membrane lifts off the valve seat 184A. In this theory, the cassette and fluid line 34 downstream of the valve are effectively rigid at the pressure applied to the pump chamber so that the only changes in the volume of liquid in the cassette are due to movement of the membrane 15. In this theory, the volume of liquid 185 is the volume added to the liquid side of the cassette as the membrane 15 over the target valve lifts off the valve seat 184A. In step 926, bottom pump chamber valve C1B is closed a predetermined amount of time after opening the target valve in step 924, which isolates the bottom channel 202 and the fluid line 34 from the pumping pressure, but does not reduce the pressure in the channel or fluid line. Alternatively, the bottom pump chamber valve C1B is closed a predetermined amount of time after it opens. In one example, the predetermined time is 0.2 seconds. In other examples the predetermined open time for the bottom pump chamber valve C1B is 0.1 second, 0.5 second and more than 1 second.

In step 928, the target valve is commanded closed by applying a positive valve pressure 1481 to the membrane 15. In this example, the pump chamber-1 and the valves are actuated by the same positive pressure, so although 1481 is applying a positive pressure to close the target valve, the membrane 15 above the target valve does not move because the residual pressure in the channel 202 from the pump chamber-1 applies a nearly equal and opposite pressure to the membrane 15 above the valve. In step 928, the membrane 15 above the valve does not move, which causes the target valve to remain open. In step 930, the bottom pump chamber valve C2B opens and exposes the bottom channel 202, the target valve, and the fluid line 34 to the negative pressure applied to pump chamber-2 805. The positive pressure applied by 1481 to the membrane above the target valve in step 924 is now greater than the negative pressure in the target valve and the membrane moves toward the valve seat 184A and pushes the volume of liquid 185 back through valve 184 and toward the bottom channel 202. Finally in step 930 after a predetermined amount of time, the bottom pump chamber valve C2B closes, which leaves the bottom channel at the negative pressure and completing the pressure oscillations sequence 920. In one example, the predetermined time is 0.2 seconds. In other examples the predetermined open time for bottom pump chamber valve C2B is 0.1 second, 0.5 second and more than 1 second.

The controller may repeat steps 922, 924, 926 and 928 to execute the pressure oscillation sequence 920 more than one time. In one example, the pressure oscillation sequence 920 is repeated five times. In other examples, the pressure oscillation step is repeated more than 2 times, more than 3 times, or more than 5 times.

Once the pressure oscillation sequence 920 is repeated the predetermined number of times, the controller places the cycler and the cassette in condition to execute a pumping operation or perform a valve check. In step 932, the controller depressurizes the pump chambers by connecting the actuation chambers behind pump chamber-1 and pump chamber-2 to atmosphere. In step 934, the occluder is retracted from occluding the patient and drain lines. Next, the pump chamber-2 is filled with liquid from the heater bag line 26 and then both pump chambers 800, 805 are delivered to the drain line 28 in step 938. Finally all the port valves HP, DP, PP, BP1-5 and pump chamber valves C1T, C1B, C2T, C2B are closed in step 940 completing the Valve Flush procedure 900.

In an exemplary embodiment, the valve flush sequence 900 is applied to the drain port valve DP as the drain line 28 may also be closed by the occluder 147. In this embodiment, the target valve is the drain port valve DP and the channel is the top channel 200. Further in this embodiment, the bottom pump chamber valves C1B and C2B are replaced by the top pump chamber valves C1T and C2T respectively.

In an exemplary embodiment, the valve flush sequence 900 may be applied to any port valve that is connected to an occludable line. In this embodiment, the target valve is any port valve connected to an occludable line and the channel 200, 202 is the channel from the pump chambers to the target valve.

In another exemplary embodiment, the fluid line between the cassette 24 and the occluder 147 is pliable at the positive pressures applied by the pump chamber-1. In this exemplary embodiment one theory among others holds that the pressurized liquid from pump chamber-1 push a small amount of liquid in the bottom channel toward and in some cases through the target valve until fluid line 34 between the port 154 and the occluder 147 is pressurized. The amount of liquid that flows through the target valve may be larger than the volume 185.

Referring now to Fig. 55C, 57A, in an alternate embodiment where the port valve is connected to a fluid line that is not occludable, a Valve Flush 900A may be implemented that does not include the occluder and holds the target valve open during an alternate pressure oscillation sequence 920A. In this alternative embodiment the Valve Flush procedure 900A starts by setting up the pump chamber-1 800 and the pump chamber-2 805

to respectively pump liquid toward and pull liquid away from the target valve. Alternate Valve Flush 900A differs from the Valve Flush 900 in that the occluder is not closed and the target valve 184 is held open as pump chamber-1 and pump chamber-2 move liquid from the channel 200, 202 through valve 184 and then reverse the flow of liquid back into the channel 200, 202. In step 915, negative pressure is applied to the valve region 1481 that pulls the membrane 15 away from the valve seat 184A and opening valve 184. The pressure oscillation sequence 920A starts by opening the bottom pump chamber valve C1B in step 922 which pushes fluid from the bottom channel 202 through the target valve 184. In step 926 the pump chamber-1 pushes liquid toward the target valve 184 for a predetermined period of time before closing the bottom pump chamber valve C1B. In step 930, the bottom pump chamber valve C2B is opened which draws liquid back through the target valve 184 and into the bottom channel 202 for a predetermined period of time. The resulting liquid flow 203 in the target valve 184 flows back and forth across the valve seat 184A. This oscillating flow may move particles away from the valve seat 184A and the part of the membrane 15 that contacts the valve seat. Moving particles and other material away from the valve seat may allow the membrane to seal against the valve seat and the valve to pass the subsequent Valve Check.

In one example, the predetermined time is 0.2 seconds. In other examples the predetermined open time for either bottom pump chamber valve C1B or C2B is 0.1 second, 0.5 second and more than 1 second. Pressure oscillation sequence 920A will repeat steps 922, 926, 930 a predetermined number of times. In one example, the pressure oscillation sequence is repeated five times. In other examples, the pressure oscillation step is repeated more than 2 times, more than 3 times, or more than 5 times. After completing the pressure oscillation sequence 920A, the controller closes the target valve in step 931, then places the cycler and the cassette in condition to execute a pumping operation or perform a valve check in steps 932-892A. In step 932, the controller depressurizes the pump chambers by connecting the actuation chambers behind pump chamber-1 and pump chamber-2 to atmosphere. Next, the pump chamber-2 is filled with liquid from the heater bag line 26 and then both pump chambers 800, 805 are delivered to the drain line 28 in step 938. Finally all the port valves HP, DP, PP, BP1-5 and pump chamber valves C1T, C1B, C2T, C2B are closed in step 940 completing the Valve Flush procedure 900.

After executing the Valve Flush 900 or the alternate Valve Flush 900A, the controller executes a second Valve Check 840. If the Valve Check fails after executing a Valve Flush, the controller will issue an alert. This alert may be displayed to the user on the screen 144

(FIG. 10) and / or as an audible alert. The control system may then end therapy. The patient may be given a choice to restart therapy with a new cassette or end therapy prematurely.

While aspects of the invention have been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications, and variations will be apparent to those skilled in the art. Accordingly, embodiments of the invention as set forth herein are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention.

CLAIMS

1. A system for flushing a port valve in a medical device comprising:

a liquid pumping cassette comprising:

at least one pump chamber;

a port valve fluidly connected to a patient port on a port side of the valve and fluidly connected to the at least one pump chamber on the cassette side of the port valve; and

a patient line fluidly connected to the patient port; and

a reusable medical device comprising:

an occluder configured to occlude at least the patient line;

a portion to receive the liquid pumping cassette;

an actuation chamber to apply pneumatic pressure to the at least one pumping chamber, wherein the pneumatic pressure may be selectively varied;

a valve actuator to close and open the port valve; and

a controller to control the pneumatic pressure and the valve actuator;

wherein the controller is configured to occlude the patient line before flushing the valve, the controller is configured to flush the valve through an application of positive pneumatic pressure to the at least one pump chamber to push liquid toward the port valve in an open position for a first period of time, followed by an application of negative pneumatic pressure to the at least one pump chamber to pull liquid from the port valve for a second period of time.

2. The system of claim 1, wherein:

the controller is configured to direct the actuator to close the port valve before actuating the at least one pump chamber to pull liquid from the port valve; or

the first predetermined period of time is equal to the second predetermined period of time, optionally wherein the first predetermined period of time is less than 1 second further optionally wherein the first predetermined period of time is 0.2 seconds; or

the controller is configured to test the port valve for leakage after the application of negative pressure to the at least one pump chamber to pull liquid from the port valve; or

the controller is configured to test the port valve for leakage after flushing the valve; or

the controller is configured to retract the occluder before testing the port valve for leakage after flushing the valve.

3. The system of claim 1, wherein:

the controller is configured to flush the port valve two or more times, optionally wherein the controller is configured to flush the port valve 5 times; or

at least one pump chamber comprises a first pump chamber and a second pump chamber and wherein the controller is configured to supply the positive pressure to the first pump chamber that pushes liquid toward the port valve in an open position and configured to supply negative pressure to the second pump chamber that pulls liquid from the port valve; or

the valve actuator is a pneumatic actuator, optionally wherein the valve actuator is driven by the same pressure driving the pump actuator.

4. A system for flushing a port valve in a medical device comprising:

a liquid pumping cassette comprising:

at least one pump chamber;

a port valve fluidly connected to a patient port on a port side of the valve and fluidly connected to the at least one pump chamber on a cassette side of the port valve; and

a patient line fluidly connected to the patient port; and

a reusable medical device comprising:

an occluder configured to occlude at least the patient line;

a portion to receive the liquid pumping cassette;

an actuation chamber to apply pressure to actuate each of the at least one pumping chamber;

an actuator to close and open the port valve;

a user interface configured to display visual information; and

a controller to control the pressure system and the actuator;

wherein the controller is configured to execute a valve flush procedure on the port valve when the controller determines that the port valve leaks wherein the controller is configured to issue an alert to the user interface when the controller determines that the port valve leaks after the completion of the valve flush procedure.

5. The system of claim 4, wherein:

the valve flush procedure includes an occlusion of the patient line before the application of positive pressure to the at least one pump chamber to push liquid toward an open port valve, then the application of negative pressure to the at least one pump chamber to pull liquid from the port; or

the valve flush includes putting the patient line in an occluded state before repeating the steps of application of positive pressure to the at least one pump chamber to push liquid toward an open port valve, then the application of negative pressure to the at least one pump chamber to pull liquid from the port valve, optionally wherein the steps of application of positive pressure to the at least one pump chamber to push liquid toward an open port valve, then the application of negative pressure to the at least one pump chamber to pull liquid from the port are repeated two or more times.

6. A method to flush a valve in a pumping cassette with at least one pumping chamber, a port valve fluidly connecting the pump chamber to a port when the port valve is open and isolating the pump chamber when the port valve is closed, the port being fluidly connected to a fluid line external to the cassette comprising:

occluding the fluid line; and

flushing the port valve with the following steps:

opening the port valve;

pumping liquid with pump chamber toward the port valve; and

pulling liquid with the pump chamber from the port valve;

7. The method of claim 6, wherein:

the steps of flushing the port valve are repeated two or more times; or

the controller is configured to attempt to close the port valve before the step of pulling liquid with the pump chamber from the port valve; or

the port valve is open during the step of pulling liquid with the pump chamber from the port valve; or

the step of pumping liquid with the pump chamber toward the port valve occurs for a first predetermined period; or

the step of pulling liquid with the pump chamber from the port valve occurs for a second predetermined period, optionally wherein the second predetermined period is equal to the first predetermined period, further optionally wherein the first predetermined period is less than one second, still further optionally wherein the first predetermined period is 0.2 seconds; or

the method further comprises un-occluding the fluid line after flushing the valve, testing the port valve for a leak after un-occluding the fluid line, and issuing an alert to the user when a leak is detected.

8. The method of claim 6, wherein:

the at least one pumping chamber comprises a first pump chamber and a second pump chamber, and the method further comprises the steps of at least partially filling the first pump chamber with liquid; at least partially emptying the second pump chamber of liquid, wherein pumping liquid with the pump chamber toward the port valve comprises actuating the first pump chamber to deliver liquid toward the port valve, and wherein pulling liquid with the pump chamber from the port valve comprises actuating the second pump chamber to pull liquid from the port valve; or

the at least one pumping chamber comprises a first pump chamber and second pump chamber that are each a pneumatic diaphragm pump actuated by applying pressure to a membrane attached to a body of the fluid pumping cassette, wherein the step of pumping liquid toward the port valve comprises applying a positive pressure on the membrane over the first pump chamber and the step of pulling liquid with the pump chamber from the port valve comprises applying a negative pressure on the membrane of the second pump chamber.

9. A method to flush a valve in a pumping cassette with at least one pumping chamber, a port valve fluidly connecting the pump chamber to a port when the port valve is open and isolating the pump chamber when the port valve is closed, the port being fluidly connected to a fluid line external to the cassette comprising:

at least partially filling the at least one pumping chamber with liquid;

occluding the fluid line; and

flushing the port valve with the following steps:

opening the port valve;

applying a positive pressure with the pump chamber to the port valve; and
applying a negative pressure with the pump chamber to the port valve.

10. The method of claim 9, wherein:
the steps of flushing the port valve are repeated two or more times; or
the port valve is commanded closed before the step of applying negative pressure with the pump chamber to the port valve, optionally wherein the port valve is a diaphragm pump and the port valve is commanded closed by applying the positive pressure to the diaphragm; or
the port valve is open during the step of applying negative pressure with the pump chamber to the port valve; or
the step of applying positive pressure with the pump chamber to the port valve wherein the port valve is open and the step of applying negative pressure with the pump chamber to the port valve each occur for a first predetermined period, optionally wherein the first predetermined period is less than one second, further optionally wherein the first predetermined period is 0.2 seconds.

11. The method of claim 9, wherein the port valve is open during the step of applying negative pressure with the pump chamber to the port valve, and the method further comprises:
un-occluding the fluid line after flushing the valve;
testing the port valve for a leak after un-occluding the fluid line; and
issuing an alert to the user when a leak is detected.

12. A method to flush a port valve in a pumping cassette with two pumping chambers, a common path that fluidly connects the two pumping chamber to the port valve, the port valve fluidly connecting the common path to a port when the port valve is open and isolating the common path when the port valve is closed, the port being fluidly connected to a fluid line external to the cassette comprising:
at least partially filling the first pumping chamber with liquid;
at least partially delivering the second pumping chamber to a drain
occluding the fluid line; and
flushing the port valve with the following steps:
opening the port valve;
applying a positive pressure to the first pump chamber to push liquid through port valve; and
applying a negative pressure to the second pump chamber to pull liquid from the port valve;

13. The method to flush a port valve of claim 12, wherein:
the method further comprises repeating the steps of applying positive pressure to the first pump chamber and applying negative pressure to the second pump chamber; or
the positive pressure is applied for a first period of time and the negative pressure is applied for a subsequent and second period of time, optionally wherein the first period of time is equal to the second period of time; or

the port valve is a pneumatic diaphragm valve and is actuated by either the positive pressure or the negative pressure; or

the method further comprises applying positive pressure to the port valve diaphragm after the step of applying positive pressure to the first pump chamber and before applying negative pressure to the second pump chamber; or

the method further comprises venting the pressures applied to the first pump chamber and second pump chamber after applying negative pressure to the second pump chamber.

14. The method to flush a port valve of claim 12, wherein:

the method further comprises venting the pressures applied to the first pump chamber and second pump chamber after applying negative pressure to the second pump chamber and opening the occluder after venting the pressures; or

the method further comprises filling the second pump chamber from a liquid supply after applying negative pressure to the second pump chamber and optionally

the method further comprises delivering the first pump chamber and the second pump chamber to a drain.

15. The method to flush a port valve of claim 12, wherein:

the method further comprises testing the port valve for leaking after applying negative pressure to the second pump chamber, and optionally the method further comprises alerting the user after detecting a leak.