SUMMARY OF INVENTION

~~Aspects~~Embodiments of the invention relate to various components, systems and methods for use in medical applications, including medical infusion operations such as peritoneal dialysis. In some cases, ~~aspects~~embodiments of the invention are limited to applications in peritoneal dialysis, while others to more general dialysis applications (e.g., hemodialysis) or infusion applications, while others to more general methods or processes. Thus, ~~aspects~~embodiments of the invention are not necessarily limited to APD systems and methods, although many of the illustrative embodiments described relate to APD.

According to an aspect of the present invention, there is provided a dialysis system comprising: a pumping cassette having a generally planar body and a first flexible membrane on a side of the cassette overlying a pumping chamber on the cassette; a cycler having a control surface including a second flexible membrane arranged to contact and mate with the first flexible membrane of the pumping cassette, the cycler being arranged to move one or more portions of the second flexible membrane to move at least a portion of the first flexible membrane overlying a pumping chamber on the cassette to cause fluid flow in the pumping chamber, the cycler further including at least one port at the control surface arranged to remove fluid in a space between the first and second flexible membranes to draw the first and second flexible membranes toward each other and to introduce fluid into the space to move the first and second flexible membranes away from each other, a source of positive pressure and a source of negative pressure; a valved manifold to control flow of positive or negative pressure to the at least one port via a fluid trap in the valved manifold, the fluid trap comprising a sensor to detect liquid drawn from the at least one port when negative pressure is applied to the at least one port; and a controller configured to control the valved manifold to selectively provide negative pressure or positive pressure to the at least one port.

In one ~~aspect~~embodiment of the invention, a tubing state detector may be included with a dialysis system for detecting the presence or absence of a tubing segment, such as a portion of a patient line to be connected to a patient access for delivering dialysate to the peritoneal cavity. The tubing state detector may include a first light emitter having a first optical axis directed toward a space in which a tubing segment is to be positioned, and a second light emitter, adjacent to the first light emitter and having a second optical axis directed toward the space. An optical sensor may be positioned on a side of the space opposite the first and second light emitters and arranged to receive light emitted by the first and second light emitters to determine a presence or absence of a tubing segment in the space.

In one embodiment, the first optical axis may be approximately collinear with a sensor optical axis of the optical sensor, and may pass approximately through a center of a tubing segment when the tubing segment is positioned in the space. In contrast, the second optical axis may be approximately parallel to the first optical axis, and thus, the second optical axis may be offset from the center of the tubing segment and sensor optical axis.

The optical sensor may be arranged to detect a range of light levels when a tubing segment is in the space, e.g., a light level that is higher and/or lower that a light level detected when the tubing segment is absent from the space. However, the optical sensor may detect a lower light level from the second light emitter when a tubing segment is in the space that is detected when the tubing segment it absent from the space. For example, with a tubing segment in the space, a detected light level for both the first and second light emitters may be within about 15-20% of a calibration light level for the first and second light emitters, where the calibration light level is a level detected when a tubing segment is known to be absent from the space. However, with a tubing segment not in the space, a detected light level for the second light emitter may be less than about 15-20% of the calibration light level for the second light emitter. This lower light level detection may be used to determine that a tubing segment is in the space.

In another embodiment, the tubing state detector may be arranged to detect whether there is liquid present in the tubing segment, e.g., whether the patient line is properly primed for use. For example, the detector may include a third light emitter having a third optical axis that is arranged at an oblique angle relative to the sensor optical axis. The oblique angle may be between 90 and 180 degrees, e.g., about 110-120 degrees. The optical sensor and third light emitter may be arranged such that with a tubing segment in the space and the tubing segment containing no liquid, a light level detected by the optical sensor may be over about 150% of a calibration light level detected with no tubing segment in the space. In addition, with a tubing segment in the space and containing liquid, the optical sensor may detect a light level from the third light emitter that is less than about 125% of the calibration light level. Thus, the optical sensor and third light emitter may be arranged such that with a tubing segment in the space and the tubing segment containing no liquid, a light level detected by the optical sensor may be over a threshold level, and with a tubing segment in the space and the tubing segment containing liquid, a light level detected by the optical sensor is less than the threshold level. This arrangement may allow the detector to determine whether liquid is contained in the patient line, e.g., whether the patient line is properly primed. In one embodiment, the third light emitter and the optical sensor may be arranged such that the optical sensor receives light from the third light emitter both when a tubing segment in the space is filled with liquid and when a tubing segment in the space is empty of liquid. Thus, the presence or absence of liquid in the tubing segment may be determined based on a detected light intensity rather than the presence or absence of light. This may help the system avoid false condition detection that might result if the detector were to use the absence of detected light to indicate a condition, such as the presence of liquid in the tubing segment. That is, since the optical sensor detects light from the third light emitter regardless of the presence of liquid, the optical sensor may be able to determine whether the third light emitter is operating properly (or at all). The space in which the tubing segment is held may be arranged to receive and hold the tubing segment, which may have a cylindrical outer surface, without substantially deforming the tubing segment. Thus, the detector may operate without deforming the tubing segment, thereby avoiding potential problems such as pinching, reduced flow in the tubing segment, etc.

In another ~~aspect~~embodiment of the invention, a tubing state detector for detecting whether liquid is contained in a tubing segment may include a fill state light emitter having an optical axis that is arranged to pass through a space in which a tubing segment is to be positioned. The space may be arranged to receive a tubing segment having a cylindrical outer surface and to

hold the tubing segment without substantially deforming the tubing segment. Thus, the detector may be useable with common tubing frequently used in dialysis systems and without requiring special purpose fittings or other components. An optical sensor may be positioned on a side of the space opposite the fill state light emitter and arranged to receive light emitted by the fill state light emitter to determine a presence or absence of liquid in the tubing segment. In one embodiment, the optical sensor may have a sensor optical axis that is arranged at an oblique angle to the optical axis of the fill state light emitter, and may be arranged to detect whether liquid is present in the tubing segment or not. The oblique angle may be between 90 and 180 degrees, e.g., about 110-120 degrees, and the optical sensor may be arranged to receive light from the fill state light emitter whether there is liquid present in the tubing segment or not.

The optical sensor and fill state light emitter may be arranged such that with a tubing segment in the space and the tubing segment containing no liquid, a light level detected by the optical sensor is over a threshold level, and such that with a tubing segment in the space and the tubing segment containing liquid, a light level detected by the optical sensor is less than the threshold level. Thus, if the optical sensor detects a light level below a threshold, e.g., below about 125-150% of a light level detected with no tubing segment in the space, a determination may be made that the tubing segment is filled with liquid. The fill state light emitter (as with other light emitters) may be a light emitting diode or other electromagnetic radiation emitting component, such as a device that emits infrared, UV, visible light, or other light in the visible and/or invisible spectrum.

In one embodiment, the tubing state detector may include a first light emitter having a first optical axis directed toward the space, and a second light emitter having a second optical axis directed toward the space. The second light emitter may be adjacent the first light emitter, and the second optical axis may be parallel to the first optical axis. The optical sensor may be positioned on a side of the space opposite the first and second light emitters and arranged to receive light emitted by the first and second light emitters to determine a presence or absence of a tubing segment in the space. For example, the first and second light emitters may be arranged with respect to each other and the optical sensor as described above, e.g., the first optical axis may pass through a center of a tubing segment in the space, the second optical axis may be offset from the tubing segment center, etc.

In another ~~aspect~~embodiment of the invention, a peritoneal dialysis system may include at least one pump arranged to pump dialysate for delivery to a peritoneal cavity of a patient, and a patient line fluidly coupled to the at least one pump such that dialysate delivered from the

pump is directed to the patient line. The patient line may have a distal end arranged for connection to a patient, e.g., for connection to a patient access to deliver dialysate to a peritoneal cavity of the patient. A patient line state detector may be arranged to be associated with the patient line and to detect both a presence of the patient line and a priming condition of the patient line. For example, the patient line state detector may be arranged to receive the distal end of the patient line to detect the presence of the distal end and whether the distal end of the patient line is filled with fluid. This arrangement may be useful to allow the system and a patient to confirm that the patient line is sufficiently full of dialysate before connecting the patient line to the patient access connection.

The patient line state detector may include a cavity to receive the distal end of the patient line, one or more light emitters associated with the cavity arranged to direct light into the cavity, and one or more light detectors arranged to detect light emitted by the one or more light emitters. In one embodiment, a single light detector may be used to determine both the presence or absence of the patient line, as well as whether liquid is present in the patient line. The patient line state detector may be arranged in any of the ways that the tubing state detectors described above may be arranged. For example, first and second light emitters may be arranged adjacent each other and on a side of a cavity to receive the patient line that is opposite an optical sensor. A third light emitter may be arranged to have its optical axis arranged at an oblique angle to a sensor axis of the optical sensor, and thereby enable detection of liquid in the patient line. Other features of the tubing state detectors described above may be incorporated into the patient line state detector, including the detection and use of relative light levels to indicate a presence of the patient line and/or liquid in the patient line, and so on.

In another ~~aspect~~embodiment of the invention, a method for detecting a presence of a tubing segment includes emitting first light along a first optical axis toward a space in which a tubing segment is to be optionally positioned, and emitting second light along a second optical axis toward the space, wherein the first and second light are emitted from a first side of the space. At least portions of the first and second light may be sensed on a second side of the space opposite the first side, and a presence or absence of a tubing segment in the space may be determined based on the sensed portions of the first and second light. The second optical axis may be approximately parallel to the first optical axis, and the first optical axis may pass through a center of the tubing segment. In one embodiment, a first calibration level of the first light may be detected with no tubing segment in the space, and a first light level may be detected of the first light when a tubing segment is in the space. The first light level

may be higher, or lower, than the first calibration level. However, a second calibration level of the second light may be detected with no tubing segment in the space, and a second light level may be detected of the second light when a tubing segment is in the space, where the second light level is lower than the second calibration level. Thus, the detection of a second light level that is lower than the second calibration level may indicate the presence of a tubing segment in the space. In one embodiment, a detected second light level for the second light may be less than about 15-20% of the second calibration level with a tubing segment in the space.

In another ~~aspect~~embodiment of the invention, a method for detecting a presence of liquid in a tubing segment may include emitting light along an optical axis toward a space in which a tubing segment is positioned, where the tubing segment has a cylindrical outer surface, and sensing light along a sensor optical axis that extends into the space, where the sensor optical axis is arranged at an oblique angle (e.g., about 110-120 degrees) relative to the optical axis. A presence or absence of liquid in the tubing segment in the space may be determined based on a sensed light level sensed along the sensor optical axis. For example, a determination may be made that fluid is not present in the tubing segment if a light level detected along the sensor optical axis is over a threshold level, and a determination may be made that fluid is present in the tubing segment if a light level detected along the sensor optical axis is below a threshold level. The threshold level may be approximately equal to about 125-150% of a light level detected along the sensor optical axis with no tubing segment in the space.

In one ~~aspect~~embodiment of the invention, a disposable fluid handling cassette, such as that useable with an APD cycler device or other infusion apparatus, includes a generally planar body having at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid that includes a channel. A patient line port may be arranged for connection to a patient line and be in fluid communication with the at least one pump chamber via at least one flowpath, and a membrane may be attached to the first side of the body over the at least one pump chamber. In one embodiment, the membrane may have a pump chamber portion with an unstressed shape that generally conforms to the pump chamber depression in the body and is arranged to be movable for movement of fluid in the useable space of the pump chamber. If the cassette body include two or more pump chamber depressions, the membrane may likewise include two or more pre-shaped pump portions. In other embodiments, the membrane need not be included with the cassette, e.g., where a control surface of the cycler interacts with the cassette to control pumping and/or valve functions.

In some embodiments, the membrane may close at least some of the flowpaths of the body. That is, the body may be formed with open flow channels that are closed on at least one side by the membrane. In one embodiment, the body may include flowpaths formed on opposite planar sides, and at least some of the flowpaths on a first side may communicate with flowpaths on the second side.

In one embodiment, one or more spikes on the cassette (e.g., for receiving dialysate solution) may be covered by a spike cap that seals the spike closed and is removable.

In another ~~aspect~~embodiment of the invention, a disposable fluid handling cassette, for use with a reusable automated peritoneal dialysis cycler device, includes a generally planar body having at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid that includes a channel, a patient line port arranged for connection to a patient line, the patient line port being in fluid communication with the at least one pump chamber via at least one flowpath, and a flexible membrane attached to the first side of the body over the at least one pump chamber. A pump chamber portion of the membrane over the at least one pump chamber may have an unstressed shape that generally conforms to usable area of the pump chamber depression in the body and be arranged to be movable for movement of fluid in the pump chamber. In one embodiment, the cassette is configured for operative engagement with a reusable automated peritoneal dialysis cycler device.

The cassette may include a drain line port arranged for connection to a drain line, the drain line port being in fluid communication with the at least one pump chamber via at least one flowpath, and/or a plurality of solution line spikes that are in fluid communication with the at least one pump chamber via at least one flowpath. The pump chamber portion of the membrane may be generally dome shaped, and may include two pump chamber portions that have a shape that generally conforms to usable area of a corresponding pump chamber depression. In one embodiment, a volume of the pump chamber portion may be between 85-110% of the useable volume of the pump chamber depression. In another embodiment, the pump chamber portion may be arranged to be 85-110% of the depth of the useable area of the pump chamber depression. In another embodiment, the pump chamber portion may be arranged to have a size that is between 85-100% of the circumference of the useable area of the pump chamber depression. The useable area of the pump chamber may be defined at least in part by one or more spacer elements that extend from an inner wall of the depression. In one embodiment, a plurality of spacer elements may be of graduated lengths or varying height that define a generally dome-shaped region or other shape. The spacer elements may be arranged in a concentric elliptical pattern or other shape when viewed in plan. One or

more breaks in the pattern may be provided, e.g., to allow communication between voids. In one embodiment, the spacer elements may be arranged to minimize deformation of the membrane at edges of the spacer elements when the membrane is forced against the spacer elements. In another embodiment, one or more spacers may be configured to inhibit the membrane from covering the fluid inlet and/or outlet of the pump chamber.

In another ~~aspect~~embodiment of the invention, a fluid handling cassette for use with a fluid handling system of a medical infusion device includes a generally planar body having at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid that includes a channel, the at least one pump chamber including one or more spacer elements that extend from an inner wall of the depression, a patient line port arranged for connection to a patient line, the patient line port being in fluid communication with the at least one pump chamber via at least one flowpath, a drain line port arranged for connection to a drain line, the drain line port being in fluid communication with the at least one pump chamber via at least one flowpath, and a plurality of solution line spikes being in fluid communication with the at least one pump chamber via at least one flowpath.

In one ~~aspect~~embodiment of the invention, a disposable component system for use with a fluid line connection system of a peritoneal dialysis system includes a fluid handling cassette having a generally planar body with at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid, a solution line spike located at a first end of the body, the solution line spike being in fluid communication with the at least one pump chamber via at least one flowpath, and a spike cap configured to removably cover the solution line spike, wherein the cap includes at least one raised feature (e.g., an asymmetrical or symmetrical flange) to aid in removal of the cap for connection to a solution line prior to the commencement of a peritoneal dialysis therapy.

In one embodiment, the cassette includes a skirt arranged around the spike to receive the end of the spike cap, and there may be a recess between the skirt and the spike that are arranged to aid in forming a seal between the spike cap and skirt.

In another embodiment, a solution line cap may be removably connected to a solution line, and the solution line cap may include a recessed feature (such as a symmetrical or asymmetrical groove). At least a portion of the solution line cap may include a flexible material, such as silicone rubber. The recessed feature may aid in the removal of a spike cap from the cassette.

In another embodiment, the spike cap includes a second raised feature that may function as a stop for the solution line cap.

In another embodiment, a main axis of one or more spikes is in substantially a same plane as the generally planar body of the fluid handling cassette.

In another ~~aspect~~embodiment of the invention, a fluid handling cassette for use with a peritoneal dialysis system includes a generally planar body with at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid, and a spike located at a first end of the body for engagement with a dialysate solution line. The spike may be in fluid communication with the at least one pump chamber via at least one flowpath and include a distal tip and a lumen arranged so that the distal tip of the spike is positioned substantially near the longitudinal axis of the spike. In one embodiment, the lumen may be positioned substantially off the longitudinal axis.

In another ~~aspect~~embodiment of the invention, a disposable component system for use with a fluid line connection system of a peritoneal dialysis system includes a spike cap configured to removably cover a spike of a fluid handling cassette. The cap may include at least one feature to aid in removal of the cap for connection to a solution line prior to the commencement of a peritoneal dialysis therapy. The feature may be a raised feature, or a recessed feature, and may be configured for engagement with a solution line cap.

In another ~~aspect~~embodiment of the invention, a disposable component system for use with a fluid line connection system of a peritoneal dialysis system includes a solution line cap for removable attachment to a solution line, wherein the solution line cap includes at least one feature to aid in removal of a spike cap to enable connection between a solution line and a spike prior to the commencement of a peritoneal dialysis therapy. The feature may be a raised feature, or a recessed feature, and may be configured for engagement with a spike cap. Indicia may e associated with a solution line, e.g., so that a solution associated with the line may be identified and affect at least one function of the peritoneal dialysis system.

In another ~~aspect~~embodiment of the invention, a medical infusion fluid handling system, such as an APD system, may be arranged to de-cap and connect one or more lines (such as solution lines) with one or more spikes or other connection ports on a fluid handling cassette. This feature may provide advantages, such as a reduced likelihood of contamination since no human interaction is required to de-cap and connect the lines and spikes. For example, an APD system may include a carriage arranged to receive a plurality of solution lines each having a connector end and a cap. The carriage may be arranged to move along a first direction so as to move the connector ends of the solution lines along the first direction, and a cap stripper may be arranged to engage with caps on the solution lines on the carriage. The cap stripper may be arranged to move in a second direction transverse to the first direction, as

well as to move with the carriage along the first direction. For example, the carriage may move toward a cassette in an APD cycler in a first direction so as to engage caps on the solution lines with caps on spikes of the cassette. The cap stripper may engage the caps (e.g., by moving in a direction transverse to the motion of the carriage) and then move with the carriage as the carriage pulls away from the cassette to remove the caps from the spikes. The carriage may then pull the connector ends of the solution lines from the caps on the cap stripper, which may retract to allow the carriage to engage the now exposed solution line connector ends with the exposed spikes on the cassette.

In one embodiment, the carriage may include a plurality of grooves that each receive a corresponding solution line. By positioning solution lines in corresponding grooves, each of the lines may be more easily individually identified, e.g., by reading a barcode or other identifier on the line, and controlling the system accordingly. The carriage may be mounted to a door of a cycler housing, and a carriage drive may move the carriage along the first direction. In one embodiment, the carriage drive may engage the carriage when the door is moved to a closed position, and disengage from the carriage when the door is moved to an open position.

In one embodiment, the cap stripper may include a plurality of fork-shaped elements arranged to engage with a corresponding cap on a solution line carried by the carriage. The fork-shaped elements may hold the caps when they are removed from the solution lines, and each of the solution line caps may itself hold a spike cap. In another embodiment, the cap stripper may include a plurality of rocker arms each associated with a fork-shaped element. Each of the rocker arms may be arranged to move to engage a spike cap, e.g., to assist in removing the spike cap from the corresponding spike. Each of the rocker arms may be arranged to engage with a corresponding spike cap only when the associated fork-shaped element engages with a cap on a solution line. Thus, the cap stripper may not engage or remove spike caps from the cassette in locations where there is no corresponding solution line to connect with the spike.

In another ~~aspect~~ embodiment of the invention, a method for connecting fluid lines in a medical infusion fluid handling system, such as an APD cycler, may involve locating solution lines and spikes of a cassette in an enclosed space away from human touch. The solution lines and/or spikes may have caps removed and the lines connected to spikes while in the enclosed space, thus providing the connection while minimizing potential contamination at the connection, e.g., by fingers carrying pathogens or other potentially harmful substances. For example, one method in accordance with this ~~aspect~~embodiment of the invention includes providing a

plurality of solution lines each having a connector end and a cap, providing a fluid handling cassette having a plurality of spikes each covered by a spike cap, enclosing the connector ends of the plurality of solution lines with caps covering the connector ends and the plurality of spikes with spike caps covering the spikes in a space that prevents human touch of the caps or spike caps, removing the caps from the connector ends of the plurality of solution lines without removing the caps or connector ends from the space, removing the spike caps from the spikes without removing the spike caps or spikes from the space, engaging the caps with respective ones of the spike caps, and fluidly connecting the plurality of connector ends to corresponding spikes while maintaining the connector ends and spikes in the space and protected from human touch.

In one embodiment, the solution line caps and spike caps may be engaged with each other before their removal from the lines or spikes, and then may be removed from both the lines and the spikes while engaged with each other. This technique may simplify the de-capping/capping process, as well as allow for easier storage of the caps.

In another embodiment, the solution lines may be disconnected from the spikes, and the connector ends of the lines and the spikes may be re-capped, e.g., after a treatment is completed.

In another ~~aspect~~embodiment of the invention, a dialysis machine may include a fluid handling cassette having a plurality of spikes and a plurality of spike caps covering a respective spike, a plurality of solution lines each having a cap covering a connector end of the respective line, and a cap stripper arranged to remove one or more caps from a connector end of a solution line, and remove one or more spike caps from a spike on the cassette while the one or more caps are secured to a corresponding one of the spike caps. As discussed above, the machine may be arranged to automatically fluidly connect a connector end of a solution line with a corresponding spike after the caps are removed.

In another ~~aspect~~embodiment of the invention, a dialysis machine, such as an APD system, may include a cassette having a plurality of fluid spikes and a plurality of spike caps covering a respective spike, a carriage arranged to receive a plurality of solution lines each having a cap covering a connector end of the respective line, and a cap stripper arranged to engage one or more caps covering a connector end of a line. The carriage and cap stripper may be configured to engage one or more caps on a connector end of a line while the one or more caps are engaged with a corresponding spike cap covering a spike on the cassette, and to remove the spike cap from the spike and the cap from the connector end of the solution line,

and to fluidly connect the spike and the connector end of the solution line after the caps are removed.

In another ~~aspect~~embodiment of the invention, a dialysis machine may include a cap stripper that is arranged to remove one or more caps on a connector end of a solution line, remove one or more spike caps from spikes on a fluid handling cassette, and to retain and reattach the caps to the solution lines and the spike caps to the spikes on the cassette.

In another ~~aspect~~embodiment of the invention, a fluid line connection system for a peritoneal dialysis system includes a fluid handling cassette having a generally planar body with at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid, a plurality of dialysate solution line spikes located at a first end of the body, the solution line spikes being in fluid communication with the at least one pump chamber via at least one flowpath and arranged so that the spikes are generally co-planar with the generally planar body of the fluid handing cassette, and a carriage arranged to receive a plurality of solution lines, where each solution line has a connector end. The carriage may be arranged to automatically fluidly connect a connector end of a solution line with a corresponding spike.

In one embodiment, the carriage is arranged to move the solution lines and respective caps along a first direction substantially parallel to the generally planar body of the fluid handling cassette. A carriage drive that moves the carriage only the first direction may include a drive element and a pneumatic bladder or screw drive to move the drive element along the first direction. A cap stripper may be provided that is arranged to remove one or more caps from a connector end of a solution line, and remove one or more spike caps from a spike on the cassette while the one or more caps are secured to a corresponding one of the spike caps. In one embodiment, the cap stripper may be arranged to r retain and reattach the caps to the solution lines and the spike caps to the spikes on the cassette.

In another ~~aspect~~embodiment of the invention, a peritoneal dialysis system may include a cycler device with components suitable for controlling delivery of dialysate to the peritoneal cavity of a patient. The cycler device may have a housing that encloses at least some of the components and have a heater bag receiving section. (The term "heater bag" is used herein to refer to any suitable container to heat dialysate, such as a flexible or rigid container, whether made of polymer, metal or other suitable material.) A lid may be mounted to the housing and be movable between an open position in which a heater bag is placeable in the heater bag receiving section and a closed position in which the lid covers the heater bag receiving section. Such an arrangement may allow for faster or more efficient heating of dialysate in

the heater bag, e.g., because heat may be retained by the lid. Also, the lid may help prevent human touch of potentially hot surfaces.

In one embodiment, the dialysis system may include a fluid handling cassette with a heater bag port attached to a heater bag line, a patient port attached to a patient line, and at least one pump chamber to move fluid in the patient line and the heater bag line. A heater bag may be attached to the heater bag line and be arranged for placement in the heater bag receiving section.

In another embodiment, the system may include an interface (such as a visual display with a touch screen component) that is movably mounted to the housing and is movable between a first position in which the interface is received in the heater bag receiving section, and a second position in which the interface is located out of the heater bag receiving section (e.g., a position in which a user may interact with the interface). Thus, the interface may be hidden from view when the system is idle, allowing the interface to be protected. Also, storing the interface in the heater bag receiving section may make the system more compact, at least in an "as stored" condition.

In another ~~aspect~~embodiment of the invention, a dialysis system includes a supply of pneumatic pressure and/or vacuum suitable for controlling pneumatically-operated components of the system, a pneumatically-operated component that is fluidly connected to the supply of pneumatic pressure and/or vacuum, and a control system that provides pneumatic pressure or vacuum to the pneumatically-operated component and subsequently isolates the pneumatically-operated component from the supply of pneumatic pressure or vacuum for a substantial period of time before again providing pneumatic pressure or vacuum to the pneumatically-operated component. Such an arrangement may be useful for components that are actuated relatively infrequently, such as the occluder arrangement described herein. Small motions of some components may cause the component to emit noise that may be found bothersome by a patient. By isolating the component from the pneumatic pressure/vacuum, the component may avoid slight movement caused by variations in the supply pressure/vacuum, e.g., resulting from draws on the pressure/vacuum by other system components. In one embodiment, the substantial period of time may be 5 minutes or more, 1 hour or more, 50% or more of a time period required to deliver or remove a volume of dialysate suitable for a dialysis treatment with respect to a patient's peritoneal cavity, or other suitable periods.

In another ~~aspect~~embodiment of the invention, a dialysis system includes a supply of pneumatic pressure and/or vacuum suitable for controlling pneumatically-operated components of the

system, a pneumatically-operated component that is fluidly connected to the supply of pneumatic pressure and/or vacuum, and a control system that provides pneumatic pressure or vacuum to the pneumatically-operated component and controls the pneumatic pressure or vacuum so as to reduce noise generated by the pneumatically-operated component. For example, the pneumatically-operated component may include at least one moving part (such as a pump diaphragm), and the control system may reduce the pneumatic pressure or vacuum provided to the pneumatically-operated component so as to slow movement of the moving part as the moving part stops and/or changes direction (e.g., the pressure/vacuum may be controlled to slow movement of the diaphragm before the diaphragm changes direction). In another embodiment, a pulse width modulation control of a pressure/vacuum supply valve may be used, e.g., to reduce noise emitted by moving parts of the valve.

In another ~~aspect~~embodiment of the invention, a dialysis system includes a supply of pneumatic pressure and vacuum suitable for controlling pneumatically-operated components of the system. A first pneumatically-operated component may be fluidly connected to the supply of pneumatic pressure and/or vacuum, and have a first output line to release pneumatic pressure. A second pneumatically-operated component may be fluidly connected to the supply of pneumatic pressure and/or vacuum, and have a second output line to release pneumatic vacuum. A space, such as that defined by an accumulator, manifold or sound-insulated chamber, may be fluidly connected to both the first and second output lines. A control system may provide pneumatic pressure or vacuum to the pneumatically-operated components so that when the first and second components release pressure/vacuum during operation, the released pressure/vacuum may be received into the common space (e.g., a manifold). In some circumstances, gas under positive pressure released by components may be balanced by negative pressure released by other components, thus reducing noise generated.

In another ~~aspect~~embodiment of the invention, a peritoneal dialysis system may include a fluid handling cassette having a patient line fluidly connected to and leading from the peritoneal cavity of a patient, and which includes at least one pump chamber to move dialysate solution in the patient line. A cycler device may be arranged to receive and interact with the fluid handling cassette and cause the at least one pump chamber to move dialysate solution in the patient line. The cycler may include a control system arranged to control the at least one pump chamber to operate in a priming operation to force dialysate solution into the patient line so as to remove any air in the patient line, and may be adapted to interact with two types of fluid handling cassettes that differ with respect to a volume of the patient line connected to

the cassette body. A first type of cassette may have a relatively low volume patient line (e.g., for pediatric applications), and a second type of cassette may have a relatively high volume patient line (e.g., for adult applications), and the control system may detect whether a cassette received by the cycler is a first type or a second type and to adjust cycler operation accordingly.

In one embodiment, the control system may detect whether a cassette received by the cycler is a first type or a second type by determining the volume of the patient line during priming, and to adjust the amount of fluid moved through the cassette during operation of the system. In another embodiment, indicia, such as a barcode, on the cassette may be detected by the cycler and cause the cycler to adjust a pumping operation based on the type of cassette.

In another ~~aspect~~embodiment of the invention, a dialysis machine includes a fluid handling cassette having a plurality of spikes and at least one pump chamber to move fluid in the spikes, a plurality of solution lines each engaged with a respective spike on the cassette, and a control system that reads indicia on each of the solution lines to determine a type for each of the solution lines. The control system may adjust a pumping operation or other cycler operation based in the identity of one or more of the solution lines. For example, a solution line may be identified as being an effluent sampling line and the pumping operation may be adjusted to direct used dialysate from a patient to the effluent sampling line during a drain cycle.

In another ~~aspect~~embodiment of the invention, a method of automatically recovering from a tilt condition in a dialysis system may include (A) detecting an angle of tilt of at least a portion of a dialysis system, the portion of the dialysis system including machinery for performing a dialysis therapy, (B) determining that a tilt condition exists in which the angle of tilt exceeds a predetermined threshold, (C) in response to (B), pausing the dialysis therapy, (D) monitoring the angle of tilt while the dialysis therapy is paused, (E) determining that the tilt condition no longer exists, and (F) in response to (E), automatically resuming the dialysis therapy.

In another ~~aspect~~ embodiment of the invention, a patient data interface for a dialysis system includes a device port comprising a recess in a chassis of at least a portion of the dialysis system and a first connector disposed within the recess. A patient data storage device may include a housing and a second connector coupled to the housing, where the second connector is adapted to be selectively coupled to the first connector. The recess may have a first shape and the housing may have a second shape corresponding to the first shape such that when the first and second connectors are coupled, the housing of the patient data storage

device is received at least partially within the recess. The first and second shapes may be irregular and the patient data storage device may have a verification code that is readable by the dialysis system to verify that the patient data storage device is of an expected type and/or origin.

In another ~~aspect~~embodiment of the invention, a method for providing peritoneal dialysis includes delivering or withdrawing dialysate with respect to the patient's peritoneal cavity at a first pressure, and adjusting a pressure at which dialysate is delivered or withdrawn to minimize patient sensation of dialysate movement. In one embodiment, the pressure may be adjusted during a same fill or empty cycle of a peritoneal dialysis therapy, and/or within different fill or empty cycles of a peritoneal dialysis therapy. For example, when withdrawing dialysate from a patient, the pressure at which dialysate is withdrawn may be reduced when an amount of dialysate remaining in the peritoneal cavity drops below a threshold volume. Reducing the pressure (negative pressure or vacuum) near the end of a drain cycle may reduce the sensation the patient may have of the dialysate withdrawal.

In another ~~aspect~~embodiment of the invention, a method for providing peritoneal dialysis includes providing a first solution to a patient's peritoneal cavity using a reusable cycler device during a first treatment of peritoneal dialysis, and providing a second solution to the patient's peritoneal cavity using the reusable cycler device during a second treatment of peritoneal dialysis immediately subsequent to the first treatment, where the second solution has a different chemical makeup relative to the first solution. The different solutions may be created by mixing liquid material from two or more solution containers that are connected to the cycler (e.g., via a cassette mounted to the cycler). The solution containers may be automatically identified by the cycler, e.g., by reading a barcode, RFID tag, or other indicia.

In another ~~aspect~~embodiment of the invention, a medical infusion system includes a housing that encloses at least some of the components of the system, and a control surface attached to the housing and constructed and arranged to control the operation of a fluid handling cassette that may be removably mounted to the housing. The control surface may have a plurality of movable portions arranged to control fluid pumping and valve operations of the cassette, and at least one of the movable portions may have an associated vacuum port arranged to draw fluid from a region near the movable portion.

In one embodiment, the control surface includes a sheet of resilient polymer material, and each of the movable portions may have an associated vacuum port. In another embodiment, the cassette includes a membrane that is positionable adjacent the control surface, and the vacuum port is arranged to remove fluid from a space between the membrane

and the control surface. A liquid sensor may be arranged to detect liquid drawn into the vacuum port, e.g., in case the membrane ruptures, allowing liquid to leak from the cassette.

In another ~~aspect~~embodiment of the invention, a volume of fluid moved by a pump, such as a pump in an APD system, may be determined based on pressure measurement and certain known chamber and/or line volumes, but without direct measurement of the fluid, such as by flow meter, weight, etc. In one embodiment, a volume of a pump chamber having a movable element that varies the volume of the pump chamber may be determined by measuring pressure in the pump chamber, and a reference chamber both while isolated from each other, and after the two chambers are fluidly connected so that pressures in the chambers may equalize. In one embodiment, equalization of the pressures may be assumed to occur in an adiabatic way, e.g., a mathematical model of the system that is based on an adiabatic pressure equalization process may be used to determine the pump chamber volume. In another embodiment, pressures measured after the chambers are fluidly connected may be measured at a time before complete equalization has occurred, and thus the pressures for the pump and reference chambers measured after the chambers are fluidly connected may be unequal, yet still be used to determine the pump chamber volume. This approach may reduce a time between measurement of initial and final pressures, thus reducing a time during which heat transfer may take place and reducing error that may be introduced given the adiabatic model used to determine the pump chamber volume.

In one ~~aspect~~embodiment of the invention, a method for determining a volume of fluid moved by a pump includes measuring a first pressure for a pump control chamber when the pump control chamber is isolated from a reference chamber. The pump control chamber may have a volume that varies at least in part based on movement of a portion of the pump, such as a pump membrane or diaphragm. A second pressure may be measured for the reference chamber when the reference chamber is isolated from the pump control chamber. The reference chamber may have a known volume. A third pressure associated with the pump control chamber after fluidly connecting the reference chamber and the pump control chamber may be measured, but the measurement may occur before substantial equalization of pressures between the pump control and reference chambers has occurred. Similarly, a fourth pressure associated with the reference chamber after fluidly connecting the reference chamber and the pump control chamber may be measured, but before substantial equalization of pressures between the pump control and reference chambers has occurred. A volume for the pump control chamber may be determined based on the first, second, third and fourth measured pressures.

In one embodiment, the third and fourth pressures are measured at approximately a same time and the third and fourth pressures are substantially unequal to each other. For example, equalization of the pressures in the pump control and reference chambers may occur after an equalization time period once the pump control and reference chambers are fluidly connected, but the third and fourth pressures may be measured at a time after the pump control and reference chambers are fluidly connected that is approximately 10% to 50% of the equalization time period. Thus, the third and fourth pressures may be measured long before (in time sense) the pressures in the chambers have fully equalized. In another embodiment, the third and fourth pressures may be measured at a time when the pressures in the chambers has reached approximately 50-70% equalization, e.g., the pressures in the chambers have changed from an initial value that is within about 50-70% of an equalized pressure value. Thus, a time period between measurement of the first and second pressures and measurement of the third and fourth pressures may be minimized.

In another embodiment, a model for determining the volume of the pump control chamber may incorporate an assumption that an adiabatic system exists from a point in time when the first and second pressures are measured for the isolated pump control chamber and the reference chamber until a point in time when the third and fourth pressures are measured.

To determine a volume of fluid moved by the pump, the steps of measuring the first, second, third and fourth pressures and the step of determining may be performed for two different positions of a pump membrane to determine two different volumes for the pump control chamber. A difference between the two different volumes may represent a volume of fluid delivered by the pump.

As mentioned above, this ~~aspect~~embodiment of the invention may be used in any suitable system, such as a system in which the pump is part of a disposable cassette and the pump control chamber is part of a dialysis machine used in a dialysis procedure.

In one embodiment, the first and/or second pressure may be selected from a plurality of pressure measurements as coinciding with a point in time at which a pressure in the pump control chamber or reference chamber (as appropriate) first begins to change from a previously stable value. For example, the point in time may be identified based on a determination of when a best fit line for a plurality of consecutive sets of measured pressures first deviates from a constant slope. This approach may help identify initial pressures for the pump control and reference chambers that are as late in time as possible, while reducing error in the pump volume determination.

reference chamber in equal but opposite directions, and the volume of gas in the reference chamber at the time of the fourth pressure measurement is calculated from the known volume of the reference chamber, and the second and fourth pressures. The change in volume of gas in the reference chamber may be assumed to be the difference between the known volume of the reference chamber and the calculated value of the volume of gas in the reference chamber at the time of the fourth pressure measurement. Also, the change in volume of gas in the pump control chamber may be assumed to be the difference between the initial volume of the pump control chamber and the volume of gas in the pump control chamber at the time of the third pressure measurement, wherein the change in volume of gas in the pump control chamber is equal to but opposite the change in volume of gas in the reference chamber.

In another ~~aspect~~embodiment of the invention, a method for determining a volume of fluid moved by a pump includes providing a fluid pump apparatus having a pump chamber separated from a pump control chamber by a movable membrane, and a reference chamber that is fluidly connectable to the pump control chamber, adjusting a first pressure in the pump control chamber to cause the membrane to move and thereby move fluid in the pump chamber, isolating the reference chamber from the pump control chamber and establishing a second pressure in the reference chamber that is different from a pressure in the pump control chamber, fluidly connecting the reference chamber and the pump control chamber to initiate equalization of pressures in the pump control chamber and the reference chamber, and determining a volume for the pump control chamber based on the first and second pressures, and an assumption that the pressures in the pump control and reference chambers initiate equalization in an adiabatic way.

In one embodiment, third and fourth pressures for the pump control and reference chambers, respectively, may be measured after fluidly connecting the reference chamber and the pump control chamber, and the third and fourth pressures may be used to determine the volume for the pump control chamber. The third and fourth pressures may be substantially unequal to each other. Similar to that mentioned above, the adjusting, isolating, fluidly connecting and determining steps may be repeated, and a difference between the two determined volumes for the pump control chamber may be determined, where the difference represents a volume of fluid delivered by the pump.

In another embodiment, the pump is part of a disposable cassette and the pump control chamber is part of a dialysis machine used in a dialysis procedure.

In another ~~aspect~~embodiment of the invention, a medical infusion system includes a pump control chamber, a control surface associated with the pump control chamber so that at least a portion

of the control surface is movable in response to a pressure change in the pump control chamber, a fluid handling cassette having at least one pump chamber positioned adjacent the control surface and arranged so that fluid in the at least one pump chamber moves in response to movement of the portion of the control surface, a reference chamber that is fluidly connectable to the pump control chamber, and a control system arranged to adjust a pressure in the pump control chamber and thus control movement of fluid in the pump chamber of the fluid handling cassette. The control system may be arranged to measure a first pressure for the pump control chamber when the pump control chamber is isolated from the reference chamber, measure a second pressure for the reference chamber when the reference chamber is isolated from the pump control chamber, fluidly connect the pump control chamber and the reference chamber, measure third and fourth pressures associated with the pump control chamber and the reference chamber, respectively, after fluidly connecting the reference chamber and the pump control chamber, and determine a volume for the pump control chamber based on the first, second, third and fourth measured pressures and a mathematical model that defines equalization of pressure in the pump control and reference chambers as occurring adiabatically when the pump control and reference chambers are fluidly connected.

In one embodiment, the third and fourth pressures are substantially unequal to each other, e.g., the third and fourth pressures may be measured prior to substantial equalization of pressures in the pump control and reference chambers.

In another ~~aspect~~embodiment of the invention, a method for determining a volume of fluid moved by a pump includes measuring a first pressure for a pump control chamber when the pump control chamber is isolated from a reference chamber, the pump control chamber having a volume that varies at least in part based on movement of a portion of the pump, measuring a second pressure for the reference chamber when the reference chamber is isolated from the pump control chamber, measuring a third pressure associated with both the pump control chamber and the reference chamber after fluidly connecting the reference chamber and the pump control chamber, and determining a volume for the pump control chamber based on the first, second and third measured pressures.

In one embodiment, the third pressure may be measured after complete equalization of pressures in the pump control and reference chambers is complete. In one embodiment, a model used to determine the pump chamber volume may assume an adiabatic system in equalization of pressure between the pump chamber and the reference chamber.

In one ~~aspect~~embodiment of the invention, a method for determining a presence of air in a pump chamber includes measuring a pressure for a pump control chamber when the pump control

chamber is isolated from a reference chamber, the pump control chamber having a known volume and being separated from a pump chamber, that is at least partially filled with liquid, by a membrane, measuring a pressure for the reference chamber when the reference chamber is isolated from the pump control chamber, the reference chamber having a known volume, measuring a pressure after fluidly connecting the reference chamber and the pump control chamber and prior to a time when the pressure in the chambers has equalized, and determining a presence or absence of an air bubble in the pump chamber based on the measured pressures and known volumes.

In one embodiment, a model used to determine the presence or absence of an air bubble assumes an adiabatic system from a point in time when the pressures are measured for the isolated pump control chamber and the reference chamber until a point in time after the chambers are fluidly connected. In another embodiment, the pressure for the pump control chamber is measured with the membrane drawn toward a wall of the pump control chamber.

In another ~~aspect~~embodiment of the invention, an automated peritoneal dialysis system includes a reusable cycler that is constructed and arranged for coupling to a disposable fluid handling cassette containing at least one pumping chamber. The disposable fluid handling cassette may be configured to be connected in fluid communication with the peritoneum of a patient via a first collapsible tube and with a second source and/or destination (such as a solution container line) via a second collapsible tube. An occluder may be configured and positioned within the cycler to selectively occlude the first collapsible tube while not occluding the second collapsible tube. In one embodiment, the occluder can occlude a plurality of collapsible tubes, such as a patient line, a drain line and/or a heater bag line. The cassette may have a generally planar body with at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid, a patient line port located at a first end of the body arranged for connection to the first collapsible tube, and a solution line port located at a second end of the body opposite the first end, and arranged for connection to the second collapsible tube. The occluder may be configured and positioned within the cycler to selectively occlude the first tube and a third collapsible tube (e.g., for a drain) while not occluding the second collapsible tube.

In another embodiment, the occluder includes first and second opposed occluding members pivotally connected to each other, a tube contacting member connected to, or comprising at least a portion of, at least one of the first and second occluding members, and a force actuator constructed and positioned to apply a force to at least one of the first and second occluding members. Application of the force by the force actuator may cause the tube

contacting members to move between a tube occluding and an open position. The occluder may include a release member configured and positioned to enable an operator to manually move the tube contacting member from the tube occluding position to the open position even with no force applied to the occluding member by the force actuator. The force actuator may apply a force sufficient to bend both the first and second occluding members, so that upon application of the force by the force actuator to bend the first and second occluding members, the tube contacting member may move between a tube occluding and an open position. The occluding members may be spring plates pivotally connected together at opposite first and second ends, and the tube contacting member may be a pinch head connected to the spring plates at the first ends, while the second ends of the spring plates may be affixed directly or indirectly to a housing to which the occluder is connected. In one embodiment, the force actuator comprises an inflatable bladder positioned between the first and second occluding members. The force actuator may increase a distance between the first and second occluding members in a region where the first and second occluding members are in opposition so as to move the tube contacting member between a tube occluding and an open position. In one embodiment, the force actuator may bend one or both of the occluding members to move the tube contacting member from a tube occluding position to an open position.

Various ~~aspects~~features of the invention are described above and below with reference to illustrative embodiments. It should be understood that the various ~~aspects~~embodiments of the invention may be used alone and/or in any suitable combination with other ~~aspects~~embodiments of the invention. For example, the pump volume determination features described herein may be used with a liquid handling cassette having the specific features described, or with any other suitable pump configuration.

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;

CLAIMS

1. A dialysis system comprising:

a pumping cassette having a generally planar body and a first flexible membrane on a side of the cassette overlying a pumping chamber on the cassette; and

a cycler having a control surface including a second flexible membrane arranged to contact and mate with the first flexible membrane of the pumping cassette, the cycler being arranged to move one or more portions of the second flexible membrane to move at least a portion of the first flexible membrane overlying a pumping chamber on the cassette to cause fluid flow in the pumping chamber, the cycler further including at least one port at the control surface arranged to remove fluid in a space between the first and second flexible membranes to draw the first and second flexible membranes toward each other and to introduce fluid into the space to move the first and second flexible membranes away from each other.

2. The system of claim 1, wherein the at least one port includes a vacuum port arranged to selectively remove fluid in the space between the first and second flexible membranes, or introduce fluid into the space between the first and second flexible membranes.

3. The system of claim 2, wherein the fluid removed between the between the first and second flexible membranes includes air or liquid, and the fluid introduced between the first and second flexible membranes includes air.

4. The system of claim 1, wherein the control surface is a sheet of resilient polymer material.

5. The system of claim 1, wherein the control surface include a plurality of movable portions, at least one movable portion being arranged to interact with the portion of the first flexible membrane overlying the pumping chamber, and at least one other movable portion being arranged to interact with another portion of the first flexible membrane to control flow in a channel of the pumping cassette.

6. The system of claim 1, wherein the control surface includes a plurality of ports to remove fluid in a space between the first and second flexible membranes.

7. The system of claim 6, wherein the plurality of ports are also arranged to introduce fluid into the space between the first and second flexible membranes.

8. The system of claim 1, wherein the cycler includes a valved manifold to control flow of negative and positive pressure to the at least one port.

9. The system of claim 1, wherein the valved manifold is controllable to selectively provide negative pressure to the at least one port and positive pressure to the at least one port.

10. The system of claim 1, wherein the at least one port includes a hole in the second flexible membrane.

11. The system of claim 1, wherein introduction of fluid into the space between the first and second flexible membranes assists in separating the pumping cassette from the control surface of the cycler.

12. The system of claim 1, wherein the cycler includes a pressure delivery block that backs the control surface and includes control chambers or depressions in association with corresponding control regions of the control surface, each control chamber or depression being arranged to move the corresponding control region based on a fluid pressure in the control region or depression.

13. A system for mating a fluid pumping cassette with a base unit that provides positive and negative pressure to the pumping cassette comprising:

a pumping cassette having a generally planar body and a first flexible membrane on a side of the cassette overlying a pumping chamber on the cassette;

a base unit comprising a source of positive pressure, a source of negative pressure, a pressure distribution manifold, a pressure delivery block, and a control surface;

the pressure distribution manifold comprising valved channels between the positive and negative pressure sources and the pressure delivery block;

the pressure delivery block comprising a depression in valved fluid communication with the positive and negative pressure sources, the depression arranged to mate with a pumping chamber of the cassette;

the control surface comprising a second flexible membrane and positioned on the pressure delivery block so as to be interposed between the first flexible membrane of the cassette and the depression of the pressure delivery block; wherein

the pressure distribution manifold is configured to provide a valved channel between the negative pressure source and the region between the opposing first and second flexible membranes to generate a vacuum seal between the first and second flexible membranes for operation of the pumping cassette, and

the pressure distribution manifold is configured to provide a valved channel between the positive pressure source and a region between the opposing first and second flexible membranes to facilitate disengagement of the pumping cassette from the base unit.

14. A method for performing peritoneal dialysis using a pre-determined total volume of dialysate and comprising a plurality of therapy cycles, each cycle comprising infusing dialysate into a peritoneal cavity, allowing dialysate to dwell in the peritoneal cavity for a period of time, and draining dialysate from the peritoneal cavity, the method comprising:

selecting a value for a maximum volume of dialysate that may reside in the peritoneal cavity;

selecting a value for a first infusion volume of dialysate to be infused into the peritoneal cavity;

estimating a volume of ultrafiltration fluid produced in the peritoneal cavity during a therapy cycle;

measuring the volume of dialysate infused in the peritoneal cavity during a cycle;

measuring the volume of dialysate drained from the peritoneal cavity during the cycle;

estimating a volume of residual dialysate remaining in the peritoneal cavity; and

initiating a new therapy cycle before the total of the infused volume plus the estimated ultrafiltered volume of fluid have been drained as long as an estimated residual volume of dialysate in the peritoneal cavity plus the amount of the infused volume plus the estimated ultrafiltered volume in the new therapy cycle does not exceed the maximum volume of dialysate that may reside in the peritoneal cavity.

15. The method of claim 14, further comprising selecting a maximum time to drain dialysate from the peritoneal cavity, and adding one or more additional therapy cycles to the plurality of therapy cycles and reducing the volume of dialysate infused during a new therapy cycle to a second infusion volume if the estimated residual volume remaining in the

peritoneal cavity plus the first infusion volume plus the estimated ultrafiltered volume exceeds the maximum volume of dialysate that may reside in the peritoneal cavity.

16. The method of claim 14, wherein the infusion and draining of dialysate is performed by a pump of a peritoneal dialysis apparatus, and wherein a controller of the peritoneal dialysis apparatus controls the measurement of the volumes infused and drained, and determines whether the estimated remaining volume plus the amount of the first infused volume plus the estimated ultrafiltered volume exceeds the maximum volume of dialysate that may reside in the peritoneal cavity.

17. The method of claim 15, wherein the infusion and draining of dialysate is performed by a pump of a peritoneal dialysis apparatus, and wherein a controller of the peritoneal dialysis apparatus controls the measurement of the volumes infused and drained, determines whether the estimated remaining volume plus the amount of the first infused volume plus the estimated ultrafiltered volume exceeds the maximum volume of dialysate that may reside in the peritoneal cavity, and determines an amount by which a second infused volume may be reduced from the first infused volume if one or more therapy cycles are added to the plurality of therapy cycles, wherein the method further comprises reducing the volume of dialysate infused during a new therapy cycle to the second infusion volume if the estimated residual volume remaining in the peritoneal cavity plus the first infusion volume plus the estimated ultrafiltered volume exceeds the maximum volume of dialysate that may reside in the peritoneal cavity.

18. A peritoneal dialysis system for performing peritoneal dialysis using a pre-determined total volume of dialysate and arranged to employ a plurality of therapy cycles comprising a fill phase in which dialysate is delivered from the dialysis system via a patient line, a dwell phase, and a drain phase in which fluid is drained via a drain line, the system comprising:

at least one pump chamber controllable to move fluid;

a patient line in fluid communication with the at least one pump chamber to receive dialysate from the at least one pump chamber for delivery;

a drain line in fluid communication with the at least one pump chamber to deliver fluid to the at least one pump chamber;

a plurality of valves to selectively control flow in flow channels of the dialysis system; and

a control system arranged to control the dialysis system to perform the following:

control the at least one pump chamber and the plurality of valves to deliver a first infusion volume of dialysate to the patient line as part of a therapy cycle;

measure a volume of dialysate delivered to the patient line during the therapy cycle;

control the at least one pump chamber and the plurality of valves to receive fluid from the drain line as part of the therapy cycle;

measure a volume of fluid received from the drain line during the therapy cycle;

estimate a volume of ultrafiltration fluid produced during the therapy cycle;

estimate a volume of residual fluid for the therapy cycle based on the measured volume of fluid received, the estimated ultrafiltration fluid produced and the measured volume of dialysate delivered;

determine a value for a maximum volume of fluid at the end of a dwell phase; and

initiate a next therapy cycle if the estimated residual volume of fluid for the cycle plus a volume of dialysate to be delivered for the next therapy cycle plus an estimated volume of ultrafiltration fluid produced for the next therapy cycle does not exceed the maximum volume of fluid at the end of a dwell phase.

19. A system for controlling a temperature of a solution line connector having a pierceable seal through which a hollow spike may be connected, comprising:

a carriage on which the connector is placed;

a sensor mounted on the carriage to detect the temperature of the connector;

a heating or cooling element positioned near the connector to affect the temperature of the connector; and

a controller to receive temperature data from the sensor and to control the heating or cooling element.

20. The system of claim 19, wherein the carriage is mounted in a door of a peritoneal dialysis apparatus, and is moveable to carry the solution line connector to a spike of a pumping cassette mounted in the peritoneal dialysis apparatus when the door is in a closed position.

21. A gasket for transferring positive or negative pressure from a peritoneal dialysis apparatus to a pumping cassette, the cassette having a generally planar body and a first flexible membrane covering one or more pump or valve chambers on the cassette, the gasket comprising:

one or more control regions, each comprising a second flexible membrane arranged to align with one or more pumping or valve chambers on the pumping cassette, the pumping or valve chambers each bounded by at least a portion of the first flexible membrane, each said portion of the first flexible membrane arranged to make direct contact with an opposing control region;

a perimeter region arranged to fit the gasket securely over a pressure delivery block of the peritoneal dialysis apparatus, the pressure delivery block configured to channel positive or negative pressure to the one or more control regions; wherein

a surface of each of the control regions facing the first flexible membrane is roughened or textured to form a porous layer of the surface of the control region when placed in contact with the first flexible membrane.

22. A disposable component system for use with a fluid line connection system of a peritoneal dialysis system, the disposable component system comprising:

a fluid handling cassette comprising:

a generally planar body with at least one pump chamber formed as a depression in a first side of the body and a plurality of flowpaths for fluid;

a solution line spike located at a first end of the body, the solution line spike being in fluid communication with the at least one pump chamber via at least one flowpath; and

a spike cap configured to removably cover the solution line spike, wherein the cap includes at least a flange on an outer surface of the spike cap to aid in removal of the cap from the spike for connection of the spike to a solution line, and a barb on the outer surface of the spike cap configured to engage the spike cap with a hole of a solution line cap.

23. The disposable component system of claim 22, wherein the fluid handling cassette further comprises at least two or more posts arranged around the base of each spike to center a base of the spike cap on the solution line spike, wherein an inner surface of the spike cap and an outer surface of the solution line spike are in fluid communication with an external surface of the fluid handling cassette.

24. The disposable component system of claim 23, wherein an inner surface of the base of the spike cap comprises a plurality of interrupted ribs forming an inner circumference of the spike cap, and wherein the outer surface of the solution line spike remains in fluid communication with the external surface of the fluid handling cassette.

25. The disposable component system of claim 22, wherein the spike cap comprises at least two or more longitudinal ribs on the inner surface near a distal end of the spike cap, the longitudinal ribs being arranged to center the spike cap on a distal portion of the solution line spike.

26. The disposable component system of claim 22, wherein the spike cap comprises a tapered blunt distal end arranged to guide an engagement of the spike cap with a hole of the solution line cap.

27. A pressure distribution module for a fluid flow control apparatus configured to operate a membrane-based pumping cassette, the module comprising:

a manifold comprising an inlet port for positive pressure and an inlet port for negative pressure, and a plurality of channels and valves arranged to selectively connect a source of positive or negative pressure to a plurality of outlet channels;

a pressure delivery block configured to mate with a side of the manifold, wherein a plurality of outlet channels of the manifold fluidly connect with opposing ports on a first side of the pressure delivery block, the opposing ports on the first side of the pressure delivery block fluidly connected to corresponding outlet ports on an opposing second side of the pressure delivery block; and

a control gasket mounted on the second side of the pressure delivery block and having a plurality of control regions, each control region having a first side positioned opposite an outlet port of the pressure delivery block, and each control region having an opposing second side configured to contact and actuate a pumping or valve membrane of a pumping cassette; wherein

each control region may be positively or negatively pressurized through a corresponding outlet port of the pressure delivery block.

28. The module of claim 27, wherein the manifold includes a chamber in fluid communication with the inlet port for negative pressure and in fluid communication with one

or more outlet ports of the pressure delivery block, the chamber arranged at a lower side of the manifold to collect any fluid received from the one or more outlet ports.

29. The module of claim 28, further comprising one or more liquid sensors arranged to detect a presence of liquid in the chamber.

30. The module of claim 28, wherein the inlet port for negative pressure and the one or more outlet ports are connected at an upper end of the chamber.

31. The module of claim 27, wherein the first side of the pressure delivery block is a rear face of the pressure delivery block, and the side of the manifold with which the rear face of the pressure delivery block is mated is a front face of the manifold.

32. The module of claim 31, wherein the second side of the pressure delivery block is a front face of the pressure delivery block.

33. The module of claim 32, wherein the manifold includes a plurality of valves to control flow between an inlet port for positive or negative pressure and one or more outlet channels, each of the valves being received in a corresponding valve port formed in a side face of the manifold.

34. The module of claim 33, wherein the plurality of valves each include a cartridge valve received in a corresponding valve port.

35. The module of claim 27, wherein the manifold includes a plurality of valves to control flow between an inlet port for positive or negative pressure and one or more outlet channels.

36. The module of claim 35, wherein the manifold includes a plurality of valve ports that each receive a cartridge valve.

37. The module of claim 27, wherein at least some of the outlet channels are formed by grooves in the side of the manifold to which the pressure delivery block is mated.

38. A heating system for a peritoneal dialysis apparatus comprising:

a pumping apparatus configured to pump dialysate into or out of a heater bag;

an electric heater configurable to operate at an AC line voltage in a range of about 100 to 120 volts or an AC line voltage in a range of about 200 to 240 volts;

a controller configured to control a temperature of the dialysate using the electrical heater; and

a universal power supply configured to convert line voltage to one or more DC voltages to power the pumping apparatus and controller, and to configure the electric heater to operate at a voltage in a range of about 100 to 120 volts or in a range of about 200 to 240 volts, based on a measured current flow through the electrical heater.

39. The heating system of claim 38, wherein the electric heater comprises two heating elements, an end of each heating element connected to a common point; wherein the universal power supply comprises one or more electrical switches connecting the heating elements to line voltage in a configuration that is switchable between a parallel or series configuration; and wherein the universal power supply comprises a circuit to measure electrical current through the electrical heater, and a power supply controller arranged to control the electrical switches to configure the heating elements based on the measured current.

40. The heating system of claim 39, wherein the power supply controller is arranged to measure electrical current through the electric heater in a series configuration, and to control the one or more electrical switches to change the configuration of the heating elements if the measured current is less than a pre-determined value.

41. A method of configuring heating elements of an electrical heater for a peritoneal dialysis apparatus, the electrical heater comprising two heating elements, an end of each heating element connected to a common point, the method comprising:

configuring the heating elements initially in a series configuration;

connecting the electrical heater to line voltage;

measuring electrical current flow through the electrical heater;

determining from the measured current flow whether the line voltage is in a range of about 100-120 volts, or in a range of about 200-240 volts;

providing a user of the peritoneal dialysis apparatus with information about the determined line voltage; and

receiving a verification signal from the user before finally configuring the heating elements in either a series configuration or a parallel configuration.

42. A heating system for a peritoneal dialysis apparatus comprising:

a heater bag containing dialysate solution and positioned on a heater pan;

a pumping apparatus configured to pump dialysate into and out of the heater bag;

an electrical heating element to heat the heater pan;

one or more heater pan temperature sensors to detect a temperature of the heater pan;

a dialysate temperature sensor mounted in the heater pan, thermally isolated from the heater pan, and configured to contact an outer surface of the heater bag; and

a controller programmed to perform an inner control loop process that modulates electrical power provided to the heating element to achieve a target heater pan temperature as measured by the one or more heater pan temperature sensors, and programmed to perform an outer control loop process that determines the target heater pan temperature based on a difference between a pre-determined target dialysate temperature and the dialysate temperature as measured by the dialysate temperature sensor.

43. A liquid heating system comprising:

a heater bag containing a liquid and positioned on a heater pan;

a pumping apparatus configured to pump liquid into and out of the heater bag;

an electrical heating element to heat the heater pan;

one or more heating pan temperature sensors to detect a temperature of the heater pan;

a liquid temperature sensor mounted in the heater pan, thermally isolated from the heater pan, and configured to contact an outer surface of the heater bag; and

a controller programmed to perform an inner control loop process that modulates electrical power provided to the heater element to achieve a target heater pan temperature as measured by the one or more heater pan temperature sensors, and programmed to perform an outer control loop process that determines the target heater pan temperature based on a difference between a pre-determined target liquid temperature and an equilibrium temperature, wherein

the equilibrium temperature is a weighted average of the liquid temperature and the heater pan temperature, the liquid temperature being weighted by a thermal capacitance,

mass, or volume of liquid present in the heater bag, and the heater pan temperature being weighted by a thermal capacitance, mass, or volume of the heater pan.

44. A liquid heating system comprising:

a heater bag containing a liquid and positioned on a heater pan;

a pumping apparatus configured to pump liquid into and out of the heater bag;

an electrical heating element to heat the heater pan;

one or more heating pan temperature sensors to detect the temperature of the heater pan;

a liquid temperature sensor mounted in the heater pan, thermally isolated from the heater pan, and configured to contact an outer surface of the heater bag; and

a controller programmed to perform an inner control loop process that modulates electrical power provided to the heater element to achieve a target heater pan temperature as measured by the one or more heater pan temperature sensors, and programmed to perform an outer control loop process that determines the target heater pan temperature based on a difference between a pre-determined target liquid temperature and an equilibrium temperature, wherein

the equilibrium temperature is a weighted average of the liquid temperature and the target heater pan temperature, the liquid temperature being weighted by a thermal capacitance, mass, or volume of liquid present in the heater bag, and the target heater pan temperature being weighted by the thermal capacitance, mass, or volume of the heater pan.

45. The liquid heating system of claim 44, wherein the inner control loop process includes an integrator element that generates a integral value with anti-windup logic to limit an integral value of a difference between the target heater pan temperature and the measured heater pan temperature.

46. The liquid heating system of claim 44, wherein the inner control loop process includes a maximum heater power command, the outer control loop process includes a maximum target heater pan temperature, and the outer control loop process includes an integrator element that is applied if:

a rate of change of the liquid temperature is less than a pre-determined value;

the liquid temperature is within a pre-determined range of the target liquid temperature;

the amount of liquid in the heater bag is greater than a pre-determined value; or

neither an output value of the inner control loop process, nor an output value of the outer control loop process are at pre-determined maximum values.

47. The liquid heating system of claim 44, wherein the controller is configured to set the electrical power to zero if the pan temperature exceeds a pre-determined value.

48 A control system for a medical fluid delivery apparatus comprising:

a pumping apparatus configured to pump fluid to a patient from one or more source containers of fluid, or from a patient to a receptacle, the apparatus comprising one or more pumps, one or more valves, and fluid connections among the pumps, valves and the source containers or receptacle of fluid;

one or more pressure sensors to detect pumping pressures of the one or more pumps;

a first processor configured to control a sequence and timing of valve and pump operations to implement a pumping of fluid from one or more source containers to the patient or from the patient to the receptacle, and configured to monitor one or more volumes of fluid being pumped; and

a second processor configured to implement commands of the first processor and to provide data to the first processor, wherein the second processor is configured to:

collect and store data received from the pressure sensors at pre-determined fixed rate;

provide the stored data to the first processor on command from the first processor;

control the pumping pressure of the one or more pumps on a pre-determined fixed schedule; and to

open or close the valves on command from the first processor.

49. A power management system for a medical device while operating on battery power comprising:

a medical device having a plurality of functions, each function associated with one of a pre-determined number of levels of power consumption;

an electronic circuit configured to measure an amount of charge remaining in a battery powering the medical device, and to associate the amount of charge with one of the pre-determined levels of power consumption; and

a controller configured to allow the medical device to perform one or more functions of the plurality of functions, as long as the one or more functions and the measured amount of charge are associated with the same level of power consumption.

CLAIMS:

1. A dialysis system comprising:

a pumping cassette having a generally planar body and a first flexible membrane on a side of the cassette overlying a pumping chamber on the cassette;

a cycler having a control surface including a second flexible membrane arranged to contact and mate with the first flexible membrane of the pumping cassette, the cycler being arranged to move one or more portions of the second flexible membrane to move at least a portion of the first flexible membrane overlying a pumping chamber on the cassette to cause fluid flow in the pumping chamber, the cycler further including

at least one port at the control surface arranged to remove fluid in a space between the first and second flexible membranes to draw the first and second flexible membranes toward each other and to introduce fluid into the space to move the first and second flexible membranes away from each other,

a source of positive pressure and a source of negative pressure;

a valved manifold to control flow of positive or negative pressure to the at least one port via a fluid trap in the valved manifold, the fluid trap comprising a sensor to detect liquid drawn from the at least one port when negative pressure is applied to the at least one port; and

a controller configured to control the valved manifold to selectively provide negative pressure or positive pressure to the at least one port.

2. The system of claim 1, wherein the at least one port includes a vacuum port arranged to selectively remove fluid in the space between the first and second flexible membranes, or introduce fluid into the space between the first and second flexible membranes.

3. The system of claim 2, wherein the fluid removed between the between the first and second flexible membranes includes air or liquid, and the fluid introduced between the first and second flexible membranes includes air.

4. The system of claim 1, wherein the control surface is a sheet of resilient polymer material.

5. The system of claim 1, wherein the control surface include a plurality of movable portions, at least one movable portion being arranged to interact with the portion of the first flexible membrane overlying the pumping chamber, and at least one other movable portion being arranged to interact with another portion of the first flexible membrane to control flow in a channel of the pumping cassette.

6. The system of claim 1, wherein the control surface includes a plurality of ports to remove fluid in a space between the first and second flexible membranes.

7. The system of claim 6, wherein the plurality of ports are also arranged to introduce fluid into the space between the first and second flexible membranes.

8. The system of claim 1, wherein the at least one port includes a hole in the second flexible membrane.

9. The system of claim 1, wherein introduction of fluid into the space between the first and second flexible membranes assists in separating the pumping cassette from the control surface of the cycler.

10. The system of claim 1, wherein the cycler includes a pressure delivery block that backs the control surface and includes control chambers or depressions in association with corresponding control regions of the control surface, each control chamber or depression being arranged to move the corresponding control region based on a fluid pressure in the control region or depression.

11. The system of claim 1, wherein the cycler further comprises a pressure sensor configured to monitor pressure in the fluid trap.