waste valve 18 and/or return to the dialysate feed via dialysate pump 15. A dialysate valve 17 controls the flow of dialysate from the dialysate supply 16. The dialyzer is a type of filter having a semi-permeable membrane, and is constructed such that the blood from the blood flow circuit flows through tiny tubes and the dialysate solution circulates around the outside of the tubes. Therapy is achieved by the passing of waste molecules (e.g., urea, creatinine, etc.) and water from the blood through the walls of the tubes and into the dialysate solution. At the end of treatment, the dialysate solution is discarded.

SUMMARY

The present disclosure generally relates to hemodialysis and similar extracorporeal blood treatment systems. The subject matter of the present disclosure involves, in some cases, interrelated products, alternative solutions to a particular problem, and/or a plurality of different uses of one or more systems and/or articles. Although the various systems and methods described herein are described in relation to hemodialysis, it should be understood that the various systems and method described herein are applicable to other dialysis systems and/or in any extracorporeal system able to treat blood or other bodily fluids, such as hemofiltration, hemodiafiltration, etc.

In one aspect, the present invention refers to a dialysis unit including:

a dialysate flow circuit including a dialyzer and an ultra-filtration pump; and a field programmable gate array that monitors an amount of ultrafiltration fluid withdrawn from a patient during a dialysis treatment by the dialysis unit by setting a given register to a first value and increasing the value of the register by a first incremental value for every pump stroke of the ultra-filtration pump and decreasing the value of the register by a second incremental value for each pre-determined increment of time, wherein the field programmable gate array enters a fail-safe state if the value of the register exceeds a pre-determined maximum value.

In another aspect, the present invention refers to a dialysis unit including:

a dialysate flow circuit including a dialyzer; and

an automatic computer processing unit that verifies before a start of a treatment that a safety system mediated by a field programmable gate array (FPGA) is operating properly

by exposing sensors in fluid paths in the dialysis unit to temperatures or conductivities that are outside pre-determined permissible ranges of values, and confirming that the FPGA safety system enters a fail-safe state in response to the temperatures or conductivities outside the predetermined permissible ranges of values, wherein the computer processing unit resets the FPGA after verifying that the safety system is operating properly by writing to one or more registers in the FPGA within a pre-determined interval of time.

Also described herein is: an example of a system including four fluid paths: blood; inner dialysate; outer dialysate and dialysate mixing. In some examples, these four paths are combined in a single cassette. In other examples, these four paths are each in a respective cassette. In still other examples, two or more fluid paths are included on one cassette.

In one example, there is provided a hemodialysis system having at least two fluid paths integrated into: 1) a blood flow pump cassette, 2) an inner dialysate cassette; 3) an outer dialysate cassette; and 4) a mixing cassette. The cassettes may be fluidly connected one to another. In some examples, one or more examples of these cassettes can be combined into a single cassette.

Also provided, in another example, is a hemodialysis system including a blood flow path through which untreated blood is drawn from a patient and is passed through a dialyzer and through which treated blood is returned to the patient. The blood flow path may include at least one blood flow pump located in a removable cassette.

The hemodialysis system also can include a first receiving structure for receiving the blood flow path's cassette, a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, a second receiving structure for receiving the dialysate flow path's cassette, and a control fluid path for providing a control fluid from an actuator mechanism to the cassettes for actuating each of the blood flow pump and the dialysate pump. In some instances, the dialysate flow path can include at least one dialysate pump located in a removable cassette.

In yet another example, a hemodialysis system is disclosed. The hemodialysis system, in this example, includes a blood flow path through which untreated blood is drawn from a patient and is passed through a dialyzer and through which treated blood is returned to the patient. The blood flow path may include at least one blood valve. The hemodialysis system may also include a control fluid path for providing a control fluid from an actuator mechanism to the blood valve for actuating the blood valve, a dialysate mixing system fluidly connected to the dialyzer (which may include at least one dialyzer valve), and a heating means or a heater for heating the dialysate.

A hemodialysis system is disclosed in yet another example that includes a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer and through which treated blood is returned to the patient. The blood flow path can include at least one blood flow pump. The hemodialysis system also can include a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer. The dialysate flow path may include at least one pneumatic pump.

In one example, the disclosure is directed to a hemodialysis system. In one set of examples, the hemodialysis system includes a blood flow path, a first cassette defining an inner dialysate fluid path, a dialyzer in fluid communication with the blood flow path and the inner dialysate fluid path, a second cassette defining an outer dialysate fluid path, and a filter fluidly connecting the first cassette to the second cassette.

In another set of examples, the hemodialysis system, includes a blood flow path, an inner dialysate fluid path, a dialyzer in fluid communication with the blood flow path and the inner dialysate fluid path, an outer dialysate fluid path, a filter fluidly connecting the inner dialysate fluid path and the outer dialysate fluid path, a first dialysate pump for pumping dialysate through the inner dialysate fluid path, and a

second dialysate pump for pumping dialysate through the outer dialysate fluid path, where the second dialysate pump and the first dialysate pump are operably connected such that flow through the inner dialysate fluid path is substantially equal to flow through the outer dialysate fluid path.

The hemodialysis system, in yet another set of examples, includes a blood flow path through which blood is drawn from a patient and passed through a dialyzer, and a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer. In some cases, the dialysate flow path comprises a balancing cassette which controls the amount of dialysate passing through the dialyzer, a mixing cassette which forms dialysate from water, and a directing cassette which passes water from a water supply to the mixing cassette and passes dialysate from the mixing cassette to the balancing cassette.

In still another set of examples, the hemodialysis system includes a cassette system, comprising a directing cassette, a mixing cassette and a balancing cassette. In some cases, the directing cassette is able to direct water from a water supply to the mixing cassette and direct dialysate from the mixing cassette to a balancing cassette, the mixing cassette is able to mix water from the directing cassette with dialysate from a dialysate supply precursor to produce a precursor, and the balancing cassette is able to control the amount of dialysate passing through a dialyzer.

In one set of examples, the hemodialysis system includes a blood flow path through which blood is drawn from a patient and passed through a dialyzer, the blood flow path including a blood flow pump, a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, where the dialysate flow path includes a dialysate pump, and a control fluid path through which a control fluid actuates the blood flow pump and the dialysate pump.

The hemodialysis system, in another set of examples, comprises a blood flow path through which blood is drawn from a patient and passed through a dialyzer; and a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer. In some cases, the dialysate flow path includes at least one pneumatic pump.

The hemodialysis system, in still another set of examples, includes a first pump comprising a pumping chamber and an actuation chamber, a second pump comprising a pumping chamber and an actuation chamber, a control fluid in fluidic

communication with each of the actuation chambers of the first and second pumps, and a controller able to pressurize the control fluid to control operation of the first and second pumps.

In yet another set of examples, the hemodialysis system includes a first valve comprising a valving chamber and an actuation chamber, a second valve comprising a valving chamber and an actuation chamber, a control fluid in fluidic communication with each of the actuation chambers of the first and second valves, and a controller able to pressurize the control fluid to control operation of the first and second valves.

In one set of examples, the hemodialysis system includes a blood flow path through which blood is drawn from a patient and passed through a dialyzer, a cassette containing at least a portion of the blood flow path, and a spike integrally formed with the cassette, the spike able to receive a vial of fluid, the integrally formed spike in fluidic communication with the blood flow path within the cassette.

The hemodialysis system, in another set of examples, includes a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer, a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, the dialyzer permitting dialysate to pass from the dialysate flow path to the blood flow path, and a gas supply in fluidic communication with the dialysate flow path so that, when activated, gas from the gas supply causes the dialysate to pass through the dialyzer and urge blood in the blood flow path back to the patient.

In yet another set of examples, the hemodialysis system includes a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer, a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, the dialyzer permitting dialysate to pass from the dialysate flow path to the blood flow path, a fluid supply, a chamber in fluid communication with the fluid supply and the dialysate fluid path, the chamber having a diaphragm separating fluid of the fluid supply from dialysate of the dialysate flow path, and a pressurizing device for pressurizing the fluid supply to urge the diaphragm against the dialysate in the chamber, so as to cause the dialysate to pass through the dialyzer and urge blood in the blood flow path back to the patient.

The hemodialysis system, in still another set of examples, includes a blood flow path through which untreated blood is drawn from a patient and passed through a

dialyzer, a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, the dialysate flow path and the blood flow path being in fluidic communication, and a pressure device able to urge dialysate in the dialysate flow path to flow into the blood flow path.

In one set of examples, the hemodialysis system includes a first housing containing a positive-displacement pump actuated by a control fluid, a fluid conduit fluidly connecting the positive-displacement pump with a control fluid pump, and a second housing containing the control fluid pump, where the second housing is detachable from the first housing.

In another set of examples, the hemodialysis system includes a housing comprising a first compartment and a second compartment separated by an insulating wall, the first compartment being sterilizable at a temperature of at least about 80 °C, the second compartment containing electronic components that, when the first compartment is heated to a temperature of at least about 80 °C, are not heated to a temperature of more than 60 °C.

The hemodialysis system, in yet another set of examples, includes a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer, the blood flow path including at least one blood valve; a control fluid path for providing a control fluid from an actuator mechanism to the blood valve for actuating the blood valve; a dialysate mixing system fluidly connected to the dialyzer, including at least one dialyzer valve; and a heater for heating the dialysate.

Another example of the present disclosure is directed to a valving system. In one set of examples, the valving system includes a valve housing containing a plurality of valves, at least two of which valves each comprises a valving chamber and an actuation chamber, each of the at least two valves being actuatable by a control fluid in the actuation chamber; a control housing having a plurality of fluid-interface ports for providing fluid communication with a control fluid from a base unit; and a plurality of tubes extending between the valve housing and the control housing, each tube providing fluid communication between one of the fluid-interface ports and at least one of the actuation chambers, such that the base unit can actuate a valve by pressurizing control fluid in the fluid interface port.

In one set of examples, the disclosure is directed to a valve including a first plate; a second plate, the second plate having an indentation on a side facing the first plate, the indentation having a groove defined therein, the groove being open in a direction facing the first plate; a third plate, wherein the second plate is located between the first and third plate; and a diaphragm located in the indentation between the first plate and the second plate, the diaphragm having a rim, the rim being held in the groove. The second plate may include a valve seat arranged so that the diaphragm may be urged by pneumatic pressure to seal the valve seat closed, the groove surrounding the valve seat. In some cases, a valve inlet and a valve outlet are defined between the second and third plates. In one example, a passage for providing pneumatic pressure is defined between the first and second plates.

Yet another example of the present disclosure is directed to a pumping system. The pumping system, in one set of examples, includes a pump housing containing a plurality of pumps, at least two of which pumps each includes a pumping chamber and an actuation chamber, each of the at least two pumps being actuatable by a control fluid in the actuation chamber; a control housing having a plurality of fluid-interface ports for providing fluid communication with a control fluid from a base unit; and a plurality of tubes extending between the pump housing and the control housing, each tube providing fluid communication between one of the fluid-interface ports and at least one of the actuation chambers, such that the base unit can actuate a pump by pressurizing control fluid in the fluid interface port.

The disclosure is generally directed to a pumping cassette in another example. In one set of examples, the pumping cassette includes at least one fluid inlet, at least one fluid outlet, a flow path connecting the at least one fluid inlet and the at least one fluid outlet, and a spike for attaching a vial to said cassette. The spike may be in fluidic communication with the flow path in some cases.

In one example, the disclosure is generally directed to a pumping cassette for balancing flow to and from a target. In one set of examples, the pumping cassette includes a cassette inlet, a supply line to the target, a return line from the target, a cassette outlet, a pumping mechanism for causing fluid to flow from the cassette inlet to the supply line and from the return line to the cassette outlet, and a balancing chamber. In some cases, the pumping mechanism includes a pod pump comprising a rigid curved

wall defining a pumping volume and having an inlet and an outlet, a pump diaphragm mounted within the pumping volume; and an actuation port for connecting the pod pump to a pneumatic actuation system so that the diaphragm can be actuated to urge fluid into and out of the pumping volume, wherein the pump diaphragm separates the fluid from a gas in fluid communication with the pneumatic actuation system. In certain instances, the balancing chamber includes a rigid curved wall defining a balance volume; and a balance diaphragm mounted within the balance volume, where the balance diaphragm separates the balance volume into a supply side and a return side, each of the supply side and the return side having an inlet and an outlet. In some cases, fluid from the cassette inlet flows to the supply side inlet, fluid from the supply side outlet flows to the supply line, fluid from the return line flows to the return side inlet, and fluid from the return side outlet flows to the cassette outlet.

In another set of examples, the pumping system includes a system inlet, a supply line to the target, a return line from the target, a system outlet, a pumping mechanism for causing fluid to flow from the system inlet to the supply line and from the return line to the system outlet, and a balancing chamber.

In one example, the pumping mechanism includes a pod pump comprising a rigid spheroid wall defining a pumping volume and having an inlet and an outlet, a pump diaphragm mounted within and to the spheroid wall, and a port for connecting the pod pump to a pneumatic actuation system so that the diaphragm can be actuated to urge fluid into and out of the pumping volume. In some cases, the pump diaphragm separates the fluid from a gas in fluid communication with the pneumatic actuation system;

In certain instances, the balancing chamber includes a rigid spheroid wall defining a balance volume, and a balance diaphragm mounted within and to the spheroid wall. In one example, the balance diaphragm separates the balance volume into a supply side and a return side, each of the supply side and the return side having an inlet and an outlet. In some cases, fluid from the system inlet flows to the supply side inlet, fluid from the supply side outlet flows to the supply line, fluid from the return line flows to the return side inlet, and fluid from the return side outlet flows to the system outlet. The pumping mechanism may also include valving mechanisms located at each of the inlets and outlets of the supply side and the return side. The valving mechanisms may be pneumatically actuated.

Yet another example of the disclosure is directed to a cassette. In one set of examples, the cassette includes a first flow path connecting a first inlet to a first outlet, a second flow path connecting a second inlet to a second outlet, a pump able to pump fluid through at least a portion of the second flow path, and at least two balancing chambers, each balancing chamber comprising a rigid vessel containing a diaphragm dividing the rigid vessel into a first compartment and a second compartment, the first compartment of each balancing chamber being in fluidic communication with the first flow path and the second compartment being in fluidic communication with the second flow path.

In another set of examples, the cassette includes a first flow path connecting a first inlet to a first outlet; a second flow path connecting a second inlet to a second outlet; a control fluid path; at least two pumps, each pump comprising a rigid vessel containing a diaphragm dividing the rigid vessel into a first compartment and a second compartment, the first compartment of each pump being in fluidic communication with the control fluid path and the second compartment being in fluidic communication with the second flow path; and a balancing chamber able to balance flow between the first flow path and the second flow path.

The cassette, in still another set of examples, includes a first flow path connecting a first inlet to a first outlet, a second flow path connecting a second inlet to a second outlet, and a rigid vessel containing a diaphragm dividing the rigid vessel into a first compartment and a second compartment. In some cases, the first compartment are in fluidic communication with the first fluid path and the second compartment being in fluidic communication with the second flow path.

Still another example of the disclosure is generally directed at a pump. The pump includes, in one set of examples, a first rigid component; a second rigid component, the second rigid component having on a side facing the first plate a groove defined therein, the groove being open in a direction facing the first rigid component; and a diaphragm having a rim, the rim being held in the groove by a friction fit in the groove but without contact by the first rigid component against the rim. In some cases, the first and second rigid components define, at least partially, a pod-pump chamber divided by the diaphragm into separate chambers, and further define, at least partially, flow paths into the pod-pump chamber, wherein the groove surrounds the pod-pump chamber.

In another set of examples, the pump includes a substantially spherical vessel containing a flexible diaphragm dividing the rigid vessel into a first compartment and a second compartment, the first compartment and the second compartment not in fluidic communication with each other, whereby movement of the diaphragm due to fluid entering the first compartment causes pumping of fluid within the second compartment to occur.

In another set of examples, the pump is a reciprocating positive-displacement pump. In one example, the pump includes a rigid chamber wall; a flexible diaphragm attached to the rigid chamber wall, so that the flexible diaphragm and rigid chamber wall define a pumping chamber; an inlet for directing flow through the rigid chamber wall into the pumping chamber; an outlet for directing flow through the rigid chamber wall out of the pumping chamber; a rigid limit wall for limiting movement of the diaphragm and limiting the maximum volume of the pumping chamber, the flexible diaphragm and the rigid limit wall forming an actuation chamber; a pneumatic actuation system that intermittently provides a control pressure to the actuation chamber. In some cases, the pneumatic actuation system includes an actuation-chamber pressure transducer for measuring the pressure of the actuation chamber, a gas reservoir having a first pressure, a variable valve mechanism for variably restricting gas flowing between the actuation chamber and the gas reservoir, and a controller that receives pressure information from the actuation-chamber pressure transducer and controls the variable valve so as to create the control pressure in the actuation chamber, the control pressure being less than the first pressure.

Still another example of the disclosure is directed to a method. The method, in one set of examples, includes acts of providing a first pump comprising a pumping chamber and an actuation chamber, and a second pump comprising a pumping chamber and an actuation chamber, urging a common fluid into the actuation chambers of each of the first and second pumps, and pressurizing the common fluid to pump fluids through each of the first and second pumps.

In another set of examples, the method includes acts of providing a first valve comprising a valving chamber and an actuation chamber, and a second valve comprising a valving chamber and an actuation chamber, urging a common fluid into the actuation

chambers of each of the first and second valves, and pressurizing the common fluid to at least partially inhibit fluid flow through each of the first and second valves.

In yet another set of examples, the method is a method for measuring the clearance of a dialyzer, the dialyzer being located in a blood flow path, through which untreated blood can be drawn from a patient and passed through the dialyzer, and in a dialysate flow path, through which dialysate can flow from a dialysate supply through the dialyzer, the blood flow path being separated from the dialysate flow path by membranes in the dialyzer. In one example, the method includes acts of urging a liquid through the dialysate flow path to the dialyzer, so as to keep the membranes wet and prevent the flow of a gas through the membranes, urging a gas through the blood flow path to the dialyzer so as to fill the blood flow path in the dialyzer with the gas, measuring the volume of gas in the dialyzer, and calculating the clearance of the dialyzer based on the volume of gas measured in the dialyzer.

The method, in still another set of examples, is a method for measuring the clearance of a dialyzer. In one example, the method includes acts of applying a pressure differential across the dialyzer, measuring the flow rate of the dialyzer, and determining the clearance of the dialyzer based on the pressure differential and the flow rate.

In yet another set of examples, the method is a method for measuring the clearance of a dialyzer. In one example, the method includes acts of passing water through the dialyzer, measuring the amount of ions collected by the water after passing through the dialyzer, and determining the clearance of the dialyzer based on the amount of ions collected by the water after passing through the dialyzer. In another set of examples, the method includes acts of passing water through the dialyzer, measuring the conductivity of the water, and determining the clearance of the dialyzer based on changes in the conductivity of the water.

In one set of examples, the method is a method for introducing a fluid into blood. The method includes, in one example, acts of providing a cassette including an integrally formed spike for receiving a vial of fluid, and a valving mechanism for controlling flow of the fluid from the vial into the cassette, attaching a vial containing the fluid to the spike, pumping blood through the cassette, and introducing the fluid from the vial into the blood.

In one set of examples, the method includes acts of providing a hemodialysis system comprising a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer, and a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, putting the blood flow path and the dialysate flow path into fluidic communication, and urging dialysate through the dialysate flow path to cause blood in the blood flow path to pass into the patient.

The method, in another set of examples, includes acts of providing a hemodialysis system comprising a blood flow path through which untreated blood is drawn from a patient and passed through a dialyzer, and a dialysate flow path through which dialysate flows from a dialysate supply through the dialyzer, putting the blood flow path and the dialysate flow path into fluidic communication, and urging a gas into the dialysate flow path to cause flow of blood in the blood flow path.

The method is a method of performing hemodialysis, in still another set of examples. In one example, the method includes acts of providing a blood flow path, through which untreated blood can be drawn from a patient and passed through a dialyzer; providing a dialysate flow path, through which dialysate can flow from a dialysate supply through the dialyzer; providing ingredients for preparing a total volume of dialysate; providing water for mixing with the dialysate ingredients; mixing a volume of water with a portion of the ingredients so as to prepare a first partial volume of dialysate, the first partial volume being less than the total volume; pumping the partial volume of dialysate through the dialysate flow path and through the dialyzer; pumping blood through the blood flow path and through the dialyzer, while the first partial volume of dialysate is being pumped to the dialyzer; and mixing a volume of water with a portion of the ingredients so as to prepare a second partial volume of dialysate and storing the second partial volume of dialysate within a vessel while the blood and the first partial volume of dialysate are pumped through the dialyzer.

In another example, the method includes acts of passing blood from a patient and dialysate through a dialyzer contained within a hemodialysis system at a first rate, and forming dialysate within the hemodialysis system at a second rate that is substantially different from the first rate, wherein excess dialysate is stored within a vessel contained within the hemodialysis system.

Another example of the disclosure is directed to a hemodialysis system comprising a dialysis unit and a user interface unit. The dialysis unit comprises an automation computer and dialysis equipment. The user interface unit comprises a user interface computer and a user interface, the user interface being adapted to display information and receive inputs. The automation computer is configured to receive requests for safety-critical information from the user interface computer and to access the safety-critical information on behalf of the user interface computer. The user interface computer is configured to display information related to a dialysis process via the user interface using the safety-critical information.

A further example of the disclosure is directed to a method of managing a user interface in a hemodialysis system. The method comprises receiving an input related to a dialysis process at a user interface associated with a user interface computer and, in response to the input, transmitting a request for safety-critical information from the user interface computer to an automation computer associated with dialysis equipment. The method further comprises accessing the safety-critical information on behalf of the user interface computer and, using the safety-critical information, displaying information related to the dialysis process via the user interface.

Still another example of the disclosure is directed to a computer storage media encoded with instructions that, when executed, perform a method. The method comprising acts of receiving, from a user interface associated with a user interface computer, an input related to a dialysis process and, in response to the input, transmitting a request for safety-critical information from the user interface computer to an automation computer associated with dialysis equipment. The method further comprises accessing the safety-critical information on behalf of the user interface computer, transmitting the safety-critical information to the user interface computer, accessing screen design information stored within the user interface computer and, using the safety-critical information and the screen design information, causing the user interface to display information related to the dialysis process.

In another example, the present disclosure is directed to a method of making one or more of the examples described herein, for example, a hemodialysis system. In another example, the present disclosure is directed to a method of using one or more of the examples described herein, for example, a hemodialysis system.

In yet another example, the disclosure relates to a control architecture for such a hemodialysis system comprising a user interface model layer, a therapy layer, below the user interface model layer, and a machine layer below the therapy layer. The user interface model layer is configured to manage the state of a graphical user interface and receive inputs from a graphical user interface. The therapy layer is configured to run state machines that generate therapy commands based at least in part on the inputs from the graphical user interface. The machine layer is configured to provide commands for the actuators based on the therapy commands.

A further example of the disclosure is directed to a method for disinfecting fluid pathways in a dialysis system. The method comprises storing, on at least one storage medium, disinfection parameters including a disinfection temperature and a disinfection time. The method further comprises circulating a fluid in the fluid pathways, monitoring a temperature of the fluid at each of a plurality of temperature sensors, and determining that disinfection of the fluid pathways is complete when the temperature of the fluid at each of the plurality of temperature sensors remains at or above the disinfection temperature for at least the disinfection time.

Another example of the disclosure is directed to at least one computer-readable medium encoded with instructions that, when executed on at least one processing unit, perform a method for disinfecting fluid pathways in a dialysis system. The method comprises electronically receiving disinfection parameters including a disinfection temperature and a disinfection time. The method further comprises controlling a plurality of actuators to circulate a fluid in the fluid pathways, monitoring a temperature of the fluid at each of a plurality of temperature sensors, and determining whether the temperature of the fluid at each of the plurality of temperature sensors remains at or above the disinfection temperature for at least the disinfection time.

A further example of the disclosure is directed to a method for controlling the administration of an anticoagulant in a dialysis system. The method comprises storing, on at least one storage medium, an anticoagulant protocol comprising a maximum amount of anticoagulant, automatically administering the anticoagulant according to the anticoagulant protocol, and prohibiting the administration of additional anticoagulant after determining that the maximum amount of anticoagulant has been administered.

Another example of the disclosure is directed to at least one computer-readable medium encoded with instructions that, when executed on at least one processing unit, perform a method for controlling the administration of an anticoagulant in a dialysis system. The method comprises electronically receiving an anticoagulant protocol comprising a maximum amount of anticoagulant, controlling a plurality of actuators to administer the anticoagulant according to the anticoagulant protocol, and prohibiting the administration of additional anticoagulant after determining that the maximum amount of anticoagulant has been administered.

A further example of the disclosure is directed to a method for determining a fluid level in a dialysate tank of a dialysis system. The method comprises tracking a first number of strokes delivering fluid to the dialysate tank, tracking a second number of strokes withdrawing fluid from the dialysate tank, and determining a fluid level in the dialysate tank based, at least in part, on the first number of strokes, the second number of strokes, and a per-stroke volume.

A further example of the disclosure is directed to a method for determining a fluid level in a dialysate tank of a dialysis system. The method comprises charging a reference chamber of a known volume to a predetermined pressure and venting the reference chamber to the dialysate tank. The method further comprises, after venting the reference chamber to the dialysate tank, determining a pressure in the dialysate tank. In addition, the method comprises determining a fluid level in the dialysate tank based, at least in part, on the determined pressure in the dialysate tank.

Another example of the disclosure is directed to a method for returning blood to a patient in the event of a power failure condition in a dialysis system that uses compressed air to actuate pumps and/or valves during a dialysis process, wherein the dialysis system comprises a dialyzer having a membrane that separates a blood flow path from a dialysate flow path. The method comprises identifying a power failure condition in a dialysis system. The method further comprises, in response to the identification of a power failure condition, releasing compressed air from a reservoir associated with the dialysis system. In addition, the method comprises using the released compressed air, increasing a pressure in the dialysate flow path to cause blood in the blood flow path to return to the patient.

A further example of the disclosure is directed to a method for returning extracorporeal blood to a patient, in an extracorporeal treatment system, using a source of compressed gas in the event of a power failure. The extracorporeal treatment system comprises a filter having a semi-permeable membrane that separates a blood flow path from an electrolyte solution flow path. The compressed gas is in valved communication with an electrolyte solution container, and the electrolyte solution container is in valved communication with the electrolyte solution flow path. The method comprises, in response to a termination of electrical power to one or more electrically actuated valves that control a distribution of compressed gas or a distribution of electrolyte solution flow in the extracorporeal treatment system, causing one or more first electrically actuated valves to open a first fluid pathway between the compressed gas and the electrolyte solution container, causing one or more second electrically actuated valves to open a second fluid pathway between said electrolyte solution container and said filter, causing one or more third electrically actuated valves to close an alternate fluid pathway in said electrolyte solution flow path if said alternate fluid pathway diverts electrolyte solution away from said filter; and using the compressed gas to increase pressure in the electrolyte solution flow path to cause blood in the blood flow path to return to the patient.

Another example of the disclosure is directed to a method for returning extracorporeal blood to a patient, in an extracorporeal treatment system, using a source of compressed gas in the event of a power failure. The extracorporeal treatment system comprises a filter having a semi-permeable membrane that separates a blood flow path from an electrolyte solution flow path. The compressed gas is in valved communication with an electrolyte solution container, and the electrolyte solution container is in valved communication with the electrolyte solution flow path. The method comprises , in response to a termination of electrical power to one or more electrically actuated valves that control a distribution of compressed gas or a distribution of electrolyte solution flow in the extracorporeal treatment system: causing one or more electrically actuated valves to open a fluid pathway between the compressed gas and the electrolyte solution container, and, using the compressed gas, causing flow of an electrolyte solution from the electrolyte solution container through the filter to cause blood in the blood flow path to return to the patient.

Another example of the disclosure relates to a pressure distribution module. In certain examples, a pressure distribution module is described that comprises one or more manifold blocks; at least one gasket; one or more output ports; one or more supply lines; and

at least one valve wherein, a first manifold block includes a face therein in which is formed multiple channels, the channels being sealed to form fluid passages by compressing a first gasket against the channels with a rigid backing plate, wherein the supply lines are formed as passages through the manifold block that pass under one or more of the channels, each supply line being connected to a separate source of pneumatic pressure or vacuum, and wherein the valve is fluidically connected to at least one supply line and an output port via holes in the manifold block fluidically connecting the one or more channels to the valve, supply line and output port.

In certain examples the pressure distribution module comprises two or more manifold blocks; two or more gaskets; one or more output ports; one or more supply lines; and

at least one valve wherein, a first manifold block includes a face having a plurality of channels formed therein, a second manifold block includes a first face having a plurality of channels formed therein and an opposing second substantially smooth face, wherein the channels on the first manifold block are sealed to form fluid passages by compressing one of the gaskets against the channels with the second substantially smooth face of the second manifold block, wherein the supply lines are formed by passages through the manifold blocks that pass under at least some of the channels, each supply line being connected to a separate source of pneumatic pressure or vacuum when the module is configured in an operative configuration, and wherein at least one valve is fluidically connected to at least one of the supply lines and to at least one output port via at least one hole penetrating from one or more of the channels to the valve, the supply line and the output port.

Another example of the disclosure relates to hemodialysis systems. In certain examples, a hemodialysis system is disclosed that comprises a plurality of pneumatically operated diaphragm pumps and valves that control the flow of blood and dialysate in a hemodialysis apparatus, the pumps and valves being actuated by a pressure source having a first positive pressure, a pressure source having a second positive

pressure that is less than the first positive pressure, or a pressure source having a negative pressure, wherein the pumps and valves that contact blood in an extracorporeal circuit of the system, when the system is connected to a patient, are fluidly connected to the second positive pressure source or the negative pressure source.

In certain examples, the hemodialysis system comprises a plurality of diaphragm based reciprocating pumps; a plurality of diaphragm based valves; and a pressure distribution module comprising a plurality of valves requiring electrical power for actuation and configured for supplying a pressurized fluid to operate the diaphragm based reciprocating pumps and the diaphragm based valves to control the flow of blood and dialysate in the hemodialysis system, wherein the pressure distribution module is configured to facilitate control of the system to operate the pumps and valves to assume open or closed positions as necessary to allow blood in an extracorporeal circuit of the system as connected to a patient during operation to be pushed back to the patient upon the loss of electrical power or control in the hemodialysis system.

Another example of the disclosure relates to heater circuits for a dialysis unit. In certain examples, the heater circuit comprises a dialysate path flow for carrying a flow of dialysate for use in a dialysis unit; a heater arranged to heat dialysate in the dialysate flow path; a heater temperature sensor arranged to sense a heater temperature of a portion of the heater; a pump to controllably move fluid in the dialysate flow path;

a heater control circuit to control the heater using a first control loop to achieve a desired heater temperature by providing a heater control signal to control a heater power, wherein one or more gains are used by the heater control circuit to generate the heater control signal and the one or more gains are varied based on an operating mode of the dialysis unit.

Another example of the disclosure relates to dialysis units including a field programmable gate array (FPGA). In certain examples, the dialysis unit includes a dialysate flow circuit including a dialyzer; and a field programmable gate array (FPGA) that monitors at least conductivity and temperature of dialysate in the flow circuit upstream of a dialyzer and enters a fail-safe state if the measured conductivity exceeds a value, and/or is outside of a range of values, wherein the value or range of values is different for different modes of therapy, or the value or range of values is different for different patients.

In certain examples, the dialysis unit includes a dialysate flow circuit including a dialyzer and an ultra-filtration pump; and a field programmable gate array that monitors an amount of ultrafiltration fluid withdrawn from a patient during dialysis treatment by the dialysis unit by setting a given register to a first value and increasing the value of the register by a first incremental value for every pump stroke of the ultra-filtration pump and decreasing the value of the register by a second incremental value for each pre-determined increment of time, wherein the field programmable gate array enters a fail-safe state if the value of the register exceeds a pre-determined maximum value.

In certain examples, the dialysis unit includes a dialysate flow circuit including a dialyzer; and an automatic computer processing unit that verifies before a start of a treatment that a safety system mediated by a field programmable gate array (FPGA) is operating properly by exposing sensors in fluid paths in the dialysis unit to temperatures or conductivities that are outside pre-determined permissible ranges of values, and confirming that the FPGA safety system enters a fail-safe state in response to the temperatures or conductivites outside the predetermined permissible ranges of values, wherein the computer processing unit resets the FPGA after verifying that the safety system is operating properly by writing to one or more registers in the FPGA within a pre-determined interval of time.

Another example of the disclosure relates to methods implemented by an operative set of processor executable instructions configured for execution by a computer processor. In certain examples, the method comprises determining if a tablet is connected to a base through a physical connection; establishing a first communications link between the tablet and the base through the physical connection; updating, if necessary, an interface program on the tablet and the base through the first communications link; establishing a second communications link between the tablet and the base using the first communications link; and communicating data from the base to the tablet using the second communications link.

In certain examples, the method comprises communicating data between a tablet and a base as long as a link quality value is above a predetermined threshold; entering into a headless state if the link quality value falls below the predetermined threshold; remaining in the headless state as long as the link quality value remains below the predetermined threshold; and determining if the link quality value returns above the

predetermined threshold; and exiting the headless state if the link quality value has returned to above the predetermined threshold.

In certain examples, the method comprises communicating data between a tablet and a base as long as a link quality value is above a first predetermined threshold; entering into a headless state if the link quality value falls below the first predetermined threshold; remaining in the headless state as long as the link quality value remains below a second predetermined threshold; determing if the link quality value increases above the second predetermined threshold; and exiting the headless state if the link quality value exceeds the second predetermined threshold.

Another example of the disclosure relates to pumping systems. In certain examples, the pumping system comprises a reciprocating positive-displacement pump comprising: a rigid chamber wall; a rigid limit structure; a flexible membrane attached to the rigid chamber wall and interposed between the rigid chamber wall and the rigid limit structure, such that the flexible membrane and rigid chamber wall together define a pumping chamber and the flexible membrane and the rigid limit structure together define an actuation chamber, and wherein the rigid limit structure is constructed and positioned to limit movement of the membrane and limit a maximum volume of the pumping chamber; an inlet for directing flow through the rigid chamber wall into the pumping chamber; and an outlet for directing flow through the rigid chamber wall out of the pumping chamber; an actuation system that alternately provides either a positive or a negative pressure to the actuation chamber; wherein the actuation system includes:

a reservoir containing a control fluid at either a positive or a negative pressure, and a valving mechanism for controlling a flow of control fluid between the actuation chamber and the reservoir; an actuation-chamber pressure transducer for measuring a pressure of the actuation chamber; and a controller that receives pressure information from the actuation-chamber pressure transducer and controls the valving mechanism via a valve control signal to provide a given pressure with a superimposed periodic variation to the actuation-chamber, and calculates a first cross-correlation between the said valve control signal and said actuation-chamber pressure and calculates a second cross-correlation between the said valve control signal shifted a quarter period and said actuation-chamber pressure and calculates a correlation number by the sum of the

squares of the said first and second cross-correlation values and uses said correlation number in evaluating the flow through the pump.

In certain examples, the pumping system comprises more than one reciprocating positive-displacement pump comprising: a rigid chamber wall;
a rigid limit structure; a flexible membrane attached to the rigid chamber wall and interposed between the rigid chamber wall and the rigid limit structure, such that the flexible membrane and rigid chamber wall together define a pumping chamber and the flexible membrane and the rigid limit structure together define an actuation chamber, and wherein the rigid limit structure is constructed and positioned to limit movement of the membrane and limit a maximum volume of the pumping chamber; an inlet for directing flow through the rigid chamber wall into the pumping chamber; and an outlet for directing flow through the rigid chamber wall out of the pumping chamber; an actuation system that alternately provides either a positive or a negative pressure to the actuation chamber; wherein the actuation system includes: a reservoir containing a control fluid at either a positive or a negative pressure, and a valving mechanism for controlling a flow of control fluid between the actuation chamber and the reservoir; an actuation-chamber pressure transducer for measuring a pressure of the actuation chamber; and a controller that receives pressure information from the actuation-chamber pressure transducer and controls the valving mechanism via a valve control signal to provide a given pressure with a superimposed periodic variation to the actuation-chamber, wherein a frequency of the said superimposed periodic variation is different for each reciprocating positive-displacement pump.

In certain by events, the pumping system comprises a reciprocating positive-displacement pump comprising: a rigid chamber wall; a rigid limit structure;
a flexible membrane attached to the rigid chamber wall and interposed between the rigid chamber wall and the rigid limit structure, such that the flexible membrane and rigid chamber wall together define a pumping chamber and the flexible membrane and the rigid limit structure together define an actuation chamber, and wherein the rigid limit structure is constructed and positioned to limit movement of the membrane and limit a maximum volume of the pumping chamber; an inlet for directing flow through the rigid chamber wall into the pumping chamber; and an outlet for directing flow through the rigid chamber wall out of the pumping chamber; an actuation system that alternately

provides either a positive or a negative pressure to the actuation chamber; wherein the actuation system includes: a reservoir containing a control fluid at either a positive or a negative pressure, and a valving mechanism for controlling a flow of control fluid between the actuation chamber and the reservoir; an actuation-chamber pressure transducer for measuring a pressure of the actuation chamber; and a controller that receives pressure information from the actuation-chamber pressure transducer and controls the valving mechanism via a valve control signal to provide a given pressure with a superimposed periodic variation to the actuation-chamber, and calculates a first cross-correlation between the said valve control signal and said actuation-chamber pressure and uses said first cross-correlation value in evaluating the flow through the pump.

In certain examples, the pumping system comprises a reciprocating positive-displacement pump comprising: a rigid chamber wall; a rigid limit structure; a flexible membrane attached to the rigid chamber wall and interposed between the rigid chamber wall and the rigid limit structure, such that the flexible membrane and rigid chamber wall together define a pumping chamber and the flexible membrane and the rigid limit structure together define an actuation chamber, and wherein the rigid limit structure is constructed and positioned to limit movement of the membrane and limit the maximum volume of the pumping chamber; an inlet for directing flow through the rigid chamber wall into the pumping chamber; an outlet for directing flow through the rigid chamber wall out of the pumping chamber; and an actuation system that alternately provides either a positive or a negative pressure to the actuation chamber; wherein the actuation system includes: a reservoir containing a control fluid at either a positive or a negative pressure, and a valving mechanism for controlling a flow of control fluid between the actuation chamber and the reservoir; an actuation-chamber pressure transducer for measuring a pressure of the actuation chamber; and a controller that receives pressure information from the actuation-chamber pressure transducer and in a first time period controls the valving mechanism to complete a full stroke by moving the diaphragm from a position touching the rigid limit structure to a position touching the rigid chamber wall and to record the value of a stroke parameter at the end of said full stroke and in a subsequent time period controls the valving mechanism to complete partial strokes by

moving the diaphragm until the said stroke parameter is a fraction of the full stroke value.

Another example of the disclosure relates to methods for performing hemodialysis using and ultrafiltration pump to control the volume of fluid removed from the patient. In certain examples, the method comprises setting an ultrafiltration pumping rate over a planned duration of hemodialysis to achieve a pre-determined volume of fluid to be removed from the patient;

periodically backflushing a pre-determined volume of dialysate from a dialysate source through a dialyzer membrane to an extracorporeal blood circuit connected to the patient; and adjusting the ultrafiltration pumping rate to remove the volume of fluid backflushed during the course of hemodialysis.

Another example of the disclosure relates to systems for administering a dose of medication to a patient whose vascular system is fluidly connected to an extracorporeal blood circuit comprising an arterial flow path for delivering fluid from the patient to a dialyzer and a venous flow path for delivering fluid from the dialyzer to the patient. In certain examples, the system comprises a vial of medication fluidly connected to a medication pump, the medication pump in valved fluid communication with a primary fluid pump in the extracorporeal circuit; a first gas bubble detector for detecting gas bubbles in the arterial flowpath; medication pump valves and primary fluid pump inlet and outlet valves under control of a controller to direct fluid flow from the dialyzer to the patient either via the arterial flowpath or the venous flowpath, wherein in a first arrangement, the controller arranges the valves to cause medication to flow from the medication pump to the patient via the arterial flowpath, and in a second arrangement, the controller arranges the valves to cause medication to flow from the medication pump to the patient via the venous flowpath if the controller receives a signal from the gas bubble detector indicating the presence of one or more gas bubbles in the arterial flowpath.

Other advantages and novel features of the present disclosure will become apparent from the following detailed description of various non-limiting examples of the disclosure when considered in conjunction with the accompanying figures. In cases where the present specification and a document incorporated by reference include conflicting and/or inconsistent disclosure, the present specification shall control. If two

CLAIMS

1. A dialysis unit including:

a dialysate flow circuit including a dialyzer and an ultra-filtration pump; and

a field programmable gate array that monitors an amount of ultrafiltration fluid withdrawn from a patient during dialysis treatment by the dialysis unit by setting a given register to a first value and increasing the value of the register by a first incremental value for every pump stroke of the ultra-filtration pump and decreasing the value of the register by a second incremental value for each pre-determined increment of time, wherein the field programmable gate array enters a fail-safe state if the value of the register exceeds a pre-determined maximum value.

2. A dialysis unit including:

a dialysate flow circuit including a dialyzer; and

an automatic computer processing unit that verifies before a start of a treatment that a safety system mediated by a field programmable gate array (FPGA) is operating properly by exposing sensors in fluid paths in the dialysis unit to temperatures or conductivities that are outside pre-determined permissible ranges of values, and confirming that the FPGA safety system enters a fail-safe state in response to the temperatures or conductivites outside the predetermined permissible ranges of values, wherein the computer processing unit resets the FPGA after verifying that the safety system is operating properly by writing to one or more registers in the FPGA within a pre-determined interval of time.

3. The dialysis unit of claim 2, wherein the automatic computer processing unit is configured to perform said verification before a patient is connected to the dialysis unit, and wherein the automatic computer processing unit is configured to set a status indicating that the patient is connected to the dialysis unit while performing the step of exposing sensors in fluid paths in the dialysis unit to temperatures or conductivities that are outside pre-determined permissible ranges of values.

4. The dialysis unit of claim 2, wherein the automatic computer processing unit is configured to command the pumping of dialysate heated to a temperature of about

42 degrees Celsius while performing the step of exposing sensors in fluid paths in the dialysis unit to temperatures or conductivities that are outside pre-determined permissible ranges of values.

5. The dialysis unit of claim 1, wherein said field programmable gate array is configured to monitor a pre-treatment ultrafiltration volume, and wherein said dialysis unit further comprises an automatic computer processing unit that is configured to assign a nominal ultrafiltration pump rate to the field programmable gate array, operate the ultra-filtration pump at a pre-determined rate above the nominal ultrafiltration pump rate, and verify that the field programmable gate array enters the fail-safe state prior to the start of the dialysis treatment.

6. The dialysis unit of claim 1, wherein the pre-determined maximum value is fixed or programmable.

7. The dialysis unit of claim 1, wherein the field programmable gate array is configured to also enter the fail-safe state if the value of the register decreases to zero from the first value.