

SYSTEM FOR PROVIDING DIALYSATE

Technical Field

5 The present disclosure generally relates to a system for providing dialysate to a patient.

Background

10 Millions of people worldwide suffer from kidney-related problems, such as chronic kidney disease (CKD), and they may require either dialysis, such as peritoneal dialysis, to maintain life. One mode of peritoneal dialysis is automated peritoneal dialysis (APD) which uses a cyclor. Current dialysis cyclers typically perform only exchanges of dialysate and do not provide the patient useful information about the dialysate.

15 Therefore, in order to address or alleviate at least one of the aforementioned problems and/or disadvantages, there is a need to provide an improved system for providing dialysate to a patient.

Summary

20 According to a first aspect of the present disclosure, there is a system for providing dialysate to a patient. The system comprises:

a dialysis cycler fluidly connectable to a source of a dialysate and to a patient line;

25 a water source device fluidly connected to the dialysis cycler; and

a drain line fluidly connected to the dialysis cycler, the drain line comprising:

one or more sensors for detecting properties of fluid flowing through the one or more sensors; and

30 a sensor bypass line,

wherein:

the dialysis cycler comprises at least one fluid inlet and at least one fluid outlet that are connectable to a source of dialysate, such that when in use, fluid

is circulated from the fluid outlet of the dialysis cyclor to the dialysate source and back to the fluid inlet of the dialysis cyclor;

the system comprises a plurality of fluid connections and valves, and the dialysis cyclor is configured together with the plurality of fluid connections and valves to selectively control flow along:

a first fluid flow path from the water source device, through the one or more sterilisers, to the dialysis cyclor;

a second fluid flow path from the dialysis cyclor through the drain line and the one or more sensors; and

a third fluid flow path from the dialysis cyclor through the drain line and the sensor bypass line, thereby bypassing the one or more sensors.

According to a second aspect of the present disclosure, there is a device for providing sterile purified water. The device comprises:

a water inlet for providing water to the device;

one or more pumps for providing flow of water through the device;

one or more conductivity sensors configured to detect a conductivity of water flowing through the device;

a reverse osmosis module configured to provide a purified water stream to downstream components of the device, the reverse osmosis module configured to provide a waste stream to a drain outlet;

one or more sterilisation systems selected from a filter, a UV steriliser and an ultrafiltration device for sterilising the purified water stream;

a water outlet configured to provide a sterilised purified water stream;

a heater configured to heat water flowing through the heater;

a chlorine sensor configured to detect a concentration of chlorine in water flowing through the chlorine sensor;

one or more peroxide sensors configured to detect a concentration of peroxide in water flowing through the peroxide sensor; and

a chemical disinfectant source and chemical pump for supplying chemical disinfectant to the device.

A system for providing dialysate to a patient according to the present disclosure is thus disclosed herein. Various features, aspects, and advantages of the present disclosure will become more apparent from the following detailed description of the embodiments of the present disclosure, by way of non-limiting examples only, along with the accompanying drawings.

Brief Description of the Drawings

Figures 1A and 1B are illustrations of a system for providing dialysate to a patient.

Figure 2 is a flowchart illustration of a process of using the system.

Figures 3A to 3H are illustrations of various fluid flow paths in the system.

Figures 4A to 4D are illustrations of the system comprising a disinfectant and heater.

Figures 5A to 5C are illustrations of filling a dialysate bag using the system comprising an air source.

Figures 6A to 6C are illustrations of a device for providing sterile purified water.

Figures 7A to 7N are illustrations of various fluid flow paths in the device.

Detailed Description

For purposes of brevity and clarity, descriptions of embodiments of the present disclosure are directed to a system for providing dialysate to a patient, in accordance with the drawings. While aspects of the present disclosure will be described in conjunction with the embodiments provided herein, it will be understood that they are not intended to limit the present disclosure to these embodiments. On the contrary, the present disclosure is intended to cover alternatives, modifications and equivalents to the embodiments described herein, which are included within the scope of the present disclosure as defined by the appended claims. Furthermore, in the following

detailed description, specific details are set forth in order to provide a thorough understanding of the present disclosure. However, it will be recognised by an individual having ordinary skill in the art, i.e. a skilled person, that the present disclosure may be practiced without specific details, and/or with multiple details arising from combinations of aspects of particular embodiments. In a number of instances, well-known systems, methods, procedures, and components have not been described in detail so as to not unnecessarily obscure aspects of the embodiments of the present disclosure.

In embodiments of the present disclosure, depiction of a given element or consideration or use of a particular element number in a particular figure or a reference thereto in corresponding descriptive material can encompass the same, an equivalent, or an analogous element or element number identified in another figure or descriptive material associated therewith.

References to “an embodiment / example”, “another embodiment / example”, “some embodiments / examples”, “some other embodiments / examples”, and so on, indicate that the embodiment(s) / example(s) so described may include a particular feature, structure, characteristic, property, element, or limitation, but that not every embodiment / example necessarily includes that particular feature, structure, characteristic, property, element or limitation. Furthermore, repeated use of the phrase “in an embodiment / example” or “in another embodiment / example” does not necessarily refer to the same embodiment / example.

The terms “comprising”, “including”, “having”, and the like do not exclude the presence of other features / elements / steps than those listed in an embodiment. Recitation of certain features / elements / steps in mutually different embodiments does not indicate that a combination of these features / elements / steps cannot be used in an embodiment.

As used herein, the terms “a” and “an” are defined as one or more than one. The use of “/” in a figure or associated text is understood to mean “and/or” unless otherwise indicated. The term “set” is defined as a non-empty finite organisation of elements that

mathematically exhibits a cardinality of at least one (e.g. a set as defined herein can correspond to a unit, singlet, or single-element set, or a multiple-element set), in accordance with known mathematical definitions. The terms “first”, “second”, etc. are used merely as labels or identifiers and are not intended to impose numerical requirements on their associated terms.

Representative or exemplary embodiments of the present disclosure describe a system 100 for providing dialysate to a patient 102, with reference to Figure 1A. The system 100 includes a dialysis cyler 110, such as an APD cyler, fluidly connectable to a source of a dialysate 120 and to a patient line 130. The dialysis cyler 110 includes a cassette 112 which contains a fluidic system to move the fluid along path required by the current dialysis therapy stage.

When used herein, the “source of a dialysate” (dialysate source 120) may be a dialysate concentrate (which needs to be diluted to the desired strength for administration to the patient 102) or a dialysate solution of any suitable volume (e.g. a 5 L volume) that is pre-diluted to an appropriate concentration for administration to the patient 102. For example, the source of the dialysate may be a dialysate concentrate. For example, the dialysate source 120 may include one or more bags each having one or more dialysate concentrates.

In some embodiments as shown in Figure 1A, the dialysate source 120 is in the form of a single bag. The single bag may contain dual chambers as shown in Figure 1A, or may contain a single chamber, or may contain a plurality of chambers. In some embodiments as shown in Figure 1B, the dialysate source 120 is in the form of a series of bags, each of which may have a smaller volume than the single bag, such as multiple 2 L bags versus a 5 L large bag. The bags may be fluidly connected to a manifold configured to dispense fluid selectively, successively, or simultaneously from the bags. Each bag may have a V-shaped bottom part to facilitate dispensing of fluid from the bag. Additionally, a last fill bag 122 is connectable to the dialysis cyler 110 via a last fill bag line 124. For example, the last fill bag 122 may contain icodextrin solution.

The system 100 further includes a water source device 140 fluidly connected to the dialysis cyclor 110. The system 100 may include one or more sterilisers 150 configured to sterilise fluid between the water source device 140 and the dialysis cyclor 110. For example, the sterilisers 150 are integrated with the water source device 140 and/or
5 disposed outside of the water source device 140. The system 100 further includes a drain line 160 fluidly connected to the dialysis cyclor 110. The drain line 160 includes one or more sensors 170 for detecting properties of fluid flowing through the one or more sensors 170. The drain line 160 includes a sensor bypass line 180.

10 The dialysis cyclor 110 includes at least one fluid inlet and at least one fluid outlet that are connectable to the dialysate source 120, such that when in use, fluid is circulated from the fluid outlet of the dialysis cyclor 110 to the dialysate source 120 and back to the fluid inlet of the dialysis cyclor 110. The system 100 includes a plurality of fluid connections and valves, and the dialysis cyclor 110 is configured together with the
15 plurality of fluid connections and valves to selectively control flow along a plurality of fluid flow paths.

The fluid flow paths include a first fluid flow path from the water source device 140, through the one or more sterilisers 150, to the dialysis cyclor 110. The fluid flow paths
20 include a second fluid flow path from the dialysis cyclor 110 through the drain line 160 and one or more sensors 170. The fluid flow paths include a third fluid flow path from the dialysis cyclor 110 through the drain line 160 and sensor bypass line 180, thereby bypassing the one or more sensors 170. The fluid flow paths may optionally include a fourth fluid flow path from the water source device 140 to the drain line 160, and not
25 through the dialysis cyclor 110.

In some embodiments, when the dialysis cyclor 110 is connected to the dialysate source 120 comprising a dialysate concentrate, the dialysis cyclor 110 is configured together with the plurality of fluid connections and valves to selectively control flow
30 along a fluid flow path from the dialysate source 120 through the dialysis cyclor 110, the drain line 160, and the one or more sensors 170. In some embodiments, when the dialysis cyclor 110 is connected to the dialysate source 120 comprising a dialysate concentrate and to the patient line 130, the dialysis cyclor 110 is configured together

with the plurality of fluid connections and valves to selectively control flow along a fluid flow path from the dialysate source 120 through the dialysis cyclor 110 and the patient line 130. In some embodiments, when the dialysis cyclor 110 is connected to the patient line 130, the dialysis cyclor 110 is configured together with the plurality of fluid connections and valves to selectively control flow along a fluid flow path from the patient line 130 through the dialysis cyclor 110 and the drain line 160, optionally additionally through the sensor bypass line 180.

In embodiments where a dialysate solution is provided as the dialysate source 110, there is no need to further dilute it. As such, in these embodiments the water source device 140 is not used and the first fluid flow path remains in a closed state (i.e. the valves are closed to make the first flow path inaccessible). In contrast, when the dialysate source 110 is a dialysate concentrate, then the water source device 140 (and hence the first fluid flow path) allows water to be utilised to properly dilute the dialysate concentrate to the desired concentration for administration to the patient 102.

In embodiments that make use of water to dilute the dialysate concentrate, the water may come from any suitable source. This may be tap water (e.g. potable tap water), it may be water from reverse osmosis, or it may be water that may be in some way contaminated with matter that may be detrimental to the patient 102. The water source device 140 may include a reverse osmosis module for purifying water. For example, the reverse osmosis module includes a membrane with pores smaller than 0.1 nm to remove most of the dissolved solids, such as about 95% to 97%. The reverse osmosis module may supply water in case of disruptions in the tap water supply. The water source device 140 may include a pretreatment module having one or more of a filter (having a pore size of from 1 to 8 μm (e.g. about 5 μm) for particles removal, an activated carbon column for removal of chlorine and dissolved organics, and a water softener for hard water treatment.

The system 100 may include one or more sterilisers 150 to sterilise the water passing from or through the water source device 140. The sterilisers 150 may be disposed outside of the water source device 140 to ensure sterility of the water discharged from the water source device 140 after the disposable set is connected. Any steriliser 150

suitable to sterilise a fluid (e.g. water) may be used. For example, the sterilisers 150 may include one or more of an ultraviolet (UV) steriliser, a filter, and an ultrafiltration device, including any combination thereof. For example, the ultrafiltration device is configured to remove bacteria and endotoxins.

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The filter may be used to remove bacterial detritus, such as dead (or living) bacterial cells, endotoxins (e.g. pyrogens) and the like. In some embodiments, the filter may be made of a material that is positively charged or of a material that has been treated to be positively charged, particularly if the filter is intended to remove endotoxins. The filter may have any suitable filter size. For example, the filter may have a filter size of from about 0.1 to about 1 μm , such as about 0.2 μm . The filter may be a disposable filter.

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The UV steriliser may be any suitable UV device that is suitable for use in removing bacteria from a fluid. For example, the UV steriliser 453 reduces total organic carbon in the water and maintains sterility of the water.

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Figure 2 shows a flowchart of the process 200 of the patient 102 using the system 100 for dialysis.

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The process 200 includes a chlorine test 210 for testing the water. Figure 3A shows a fluid flow path (in dashed lines) for the chlorine test 210. In particular, the one or more sensors 170 include a chlorine sensor configured to detect a concentration of an active chlorine compound in fluid flowing through the chlorine sensor. The term “active chlorine compound” is intended to refer to any chlorine-containing compound that may be used to treat and disinfect drinking water. Examples of active chlorine compounds include, but are not limited to hypochlorite ion ClO^- (accompanied by any suitable counterion) chlorine dioxide (ClO_2) or chloramine NH_2Cl .

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The process 200 includes filling 220 the dialysate concentrate bag and mixing 230 the water with the dialysate concentrate to form the dialysate source 120. Figures 3B and 3C show fluid flow paths (in dashed lines) for the water filling 220 and mixing 230,

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respectively. For example, the system 100 may be configured to enable rapid bag filling for the dialysate concentrate bag, such as within 20-30 minutes.

The process 200 includes a conductivity test 240 for testing the dialysate. Figure 3D shows a fluid flow path (in dashed lines) for the conductivity test 240. In particular, the one or more sensors 170 include a conductivity sensor configured to detect a conductivity of fluid flowing through the conductivity sensor. It is noted that this may be used as a way to check peritoneal health. By using conductivity data captured from patient's drain section, we can establish the health of the patient's peritoneal membrane, such as described in <https://pubmed.ncbi.nlm.nih.gov/26185051/>.

In some embodiments, the one or more sensors 170 include a peroxide sensor configured to detect a concentration of peroxide in fluid flowing through the peroxide sensor. In some embodiments, the one or more sensors 170 include a urea sensor configured to detect a concentration of urea flowing through the urea sensor. In some embodiments, the one or more sensors 170 include a creatinine sensor configured to detect a concentration of creatinine flowing through the urea sensor. In some embodiments, the one or more sensors 170 include a glucose sensor configured to detect a concentration of glucose flowing through, around or over the glucose sensor. In some embodiments, the one or more sensors 170 include a refractive index sensor configured to detect a refractive index of fluid flowing through the refractive index sensor. In some embodiments, the one or more sensors 170 include a contactless flow sensor. In some embodiments, the one or more sensors 170 include an optical sensor. It will be appreciated that the sensors 170 may include any combination of the exemplary sensors described herein.

The process 200 includes connecting 250 the patient line 130 to the patient 102. Figures 3E and 3F show fluid flow paths (in dashed lines) for priming the last fill bag line 124 and the patient line 130, respectively.

The process 200 includes draining 260 dialysate from the patient 102 at various stages of the dialysis therapy. Figure 3G shows a fluid flow path (in dashed lines) for draining the dialysate.

The process 200 includes filling 270 the last fill bag 122 at the end of dialysis. Figure 3H shows a fluid flow path (in dashed lines) for filling 270 the last fill bag 122.

- 5 The process 200 includes a disinfection step 280 to disinfect the system 100. In some embodiments as shown in Figure 4A, the system 100 includes disinfectant or heater 190. In one embodiment as shown in Figure 4B, the system 100 includes a source of disinfectant 192 fluidly connectable to the water source device 140, such that when in use, fluid flows through the disinfectant source 192 and the water source device 140, thereby providing disinfectant to the system 100. The disinfectant may include a compound comprising a peroxy group. For example, the compound comprising a peroxy group may be a peroxide or a peroxy acid. For example, the disinfectant may include one or both of hydrogen peroxide and peracetic acid.
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- 15 In some embodiments as shown in Figure 4C and 4D, the system 100 includes a heater 194 configured to disinfect fluid flowing through the water source device 140 and/or the one or more sensors 170. The heater 458 may be used between dialysis therapies to recirculate hot water (such as above 65 °C) through the system 100 to sterilise and disinfect the system 100 and prevent formation of biofilms. For example as shown in Figure 4C, the heater 194 may be located in the water source device 140. For example as shown in Figure 4D, the heater 194 may be located in the one or more sensors 170.
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In some embodiments as shown in Figure 5A, the system 100 includes an air source 105 fluidly connected to the dialysis cyclor 110 for providing air to the dialysate source 120 via the dialysis cyclor 110. More specifically, when the dialysis cyclor 110 is connected to the dialysate source 120 which contains a dialysate concentrate, the dialysis cyclor 110 is configured to provide air into the dialysate concentrate. The air source 105 may include a pump and a hydrophobic filter.

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As mentioned above, the one or more sensors 170 may include a conductivity sensor to detect fluid conductivity. Figure 5B shows the conductivity values of dialysate from a filling a 2 L bag of dialysate concentrate with water, as well as with and without air

mixing from the air source 105. For the air mixing, air was provided to the dialysate concentrate at 500 mL/min for about 30 seconds. The results show that, with air mixing, the conductivity values averaged about 11.4 and the deviation from the average was only about 0.3%, compared to 3.3% without air mixing. Figure 5C show other results of filling 2 L bags of dialysate concentrate with water without air mixing. The conductivity values averaged 11.4 (deviation 3.3%), 11.1 (deviation 4.1%), 11.2 (deviation 4.5%), and 11.6 (deviation 3.7%).

The dialysate drained from the patient 102 can potentially contain fibrins. These fibrins are generally protein “gel” like particles that can potentially clog systems. In one embodiment, the system 100 can achieve a clog free drain system due to the usage of valves that have an inner diameter that is sufficiently large that it cannot be clogged by fibrin (e.g. the valves used have a diameter that is greater than or equal to 25% of the size of the tubing used, such as greater than or equal to 50%, such as greater than or equal to 76%, such as greater than or equal to 90%). As will be appreciated, the tubing used herein may be in the range conventionally used in peritoneal dialysis devices. In current state-of-the-art systems, solenoid valves are used, which have smaller diameters.

Examples of valves that are sufficiently large to prevent clogging by fibrin include, but are not limited to ball valves that have a suitable inner diameter. In some embodiments, the valves that are sufficiently large to prevent clogging by fibrin do not include solenoid valves.

In addition, the system and device may also make use of a contactless flow sensor (to capture the patient’s drain volume, one of the health tracker indicators for PD patients) and an optical sensor to detect fibrin. As presence of fibrin can be an indicator of the onset of peritonitis. In alternative embodiments, prior to the drain content passing through a valve, a filter material configured to trap fibrin placed in the fluid pathway. In further embodiments, these configurations may be combined, which may help to minimise fibrin blockage in the event that the fibrin filter is structurally compromised.

In some embodiments, the second and/or third fluid flow paths include one or more valves, a contactless flow sensor, and an optical sensor, the optical sensor configured to detect fibrin, wherein the one or more valves have an inner diameter that is sufficiently large to prevent clogging by fibrin. The second and/or third fluid flow paths may include a fibrin filter or are fitted downstream from a fibrin filter.

In many embodiments, the water source device 140 may be integrated with the sterilisers 150 and sensors 170 together as a unitary device. Representative or exemplary embodiments of the present disclosure describe a system 300 for providing dialysate to the patient 102, with reference to Figure 6A. The system 300 includes a dialysis cycler 310, such as an APD cycler, fluidly connectable to a source of a dialysate 320 (e.g. a fluid generation bag containing dialysate concentrate) and to a patient line. Further as shown in Figure 6B, the dialysis cycler 310 includes a cassette 312, a heater 314, a pump 316, and a set of valves 318 fluidly connectable to other parts of the system 300. The cassette 312 contains a fluidic system to move the fluid along path required by the current dialysis therapy stage. Additionally, a last fill bag 322 is connectable to the dialysis cycler 310, wherein the last fill bag may contain icodextrin solution. It will be appreciated that various aspects of the system 100 apply equally to the system 300 and vice versa.

The system 300 includes a device 400 for providing sterile purified water. The device 400 includes a water purification unit 410 (such as including the sterilisers 150) and a water quality detection module 420 (such as including the sensors 170). The device 400 includes a water inlet 402, a water outlet 404, a drain inlet 406, and a drain outlet 408. The device 400 may be used with the dialysis cycler 310 to perform the process 200 for dialysis treatment of the patient 102. For example, a water source (e.g. tap water) is connected to the inlet 402 to provide water for diluting the dialysate concentrate in the fluid generation bag 320. For example, the device 400 may be configured to enable rapid bag filling for the dialysate concentrate bag, such as within 20-30 minutes. The mixed dialysate may then be tested for conductivity before filling the patient line.

Figure 6C shows a layout 450 of internal components of the device 400 for providing sterile purified water. The device 400 includes the water inlet 402 for providing water (from the water source such as tap water) to the device 400, and includes the water outlet 404 configured to provide a sterilised purified water stream. The device 400 includes one or more pumps 451 for providing flow of water through the device 400. The device 400 may include a pretreatment module having one or more of a filter (having a pore size of from 1 to 8 μm (e.g. about 5 μm) for particles removal, an activated carbon column for removal of chlorine and dissolved organics, and a water softener for hard water treatment.

The water source may be tap water (e.g. potable tap water), water from reverse osmosis, or water that may be in some way contaminated with matter that may be detrimental to the patient 102. The device 400 includes a reverse osmosis module 452 configured to provide a purified water stream to downstream components of the device 400, the reverse osmosis module 452 configured to provide a waste stream to the drain outlet 408. For example, the reverse osmosis module 452 includes a membrane with pores smaller than 0.1 nm to remove most of the dissolved solids, such as about 95% to 97%. The reverse osmosis module 452 may supply water in case of disruptions in the tap water supply. The pretreatment module and reverse osmosis module 452 are preferably designed so that the patient 102 can easily insert and replace consumable cartridges. For example, the consumable cartridges may have a single action twist lock mechanism.

The device 400 includes one or more sterilisers or sterilisation systems 150 for sterilising the purified water stream. Any sterilisation system 150 suitable to sterilise water may be used in the device 400. For example, the sterilisation systems 150 may include one or more of a UV steriliser 453, a filter, and an ultrafiltration device 454, including any combination thereof. The sterilisation systems 150 are preferably designed so that the patient 102 can easily insert and replace consumable cartridges. For example, the consumable cartridges may have a single action twist lock mechanism.

The filter may be used to remove bacterial detritus, such as dead (or living) bacterial cells, endotoxins (e.g. pyrogens) and the like. In some embodiments, the filter may be made of a material that is positively charged or of a material that has been treated to be positively charged, particularly if the filter is intended to remove endotoxins. The filter may have any suitable filter size. For example, the filter may have a filter size of from about 0.1 to about 1 μm , such as about 0.2 μm . The filter may be a disposable filter.

The UV steriliser 453 may be any suitable UV device that is suitable for use in removing bacteria from a fluid. For example, the UV steriliser 453 reduces total organic carbon in the water and maintains sterility of the water. For example, the ultrafiltration device 454 is configured to remove bacteria and endotoxins.

Optionally, the system 300 includes one or more sterilising filters 430 disposed outside of the device 400 to ensure sterility of the water discharged from the device 400 after the disposable set is connected. The sterilising filter 430 may be used to remove bacterial detritus, such as dead (or living) bacterial cells, endotoxins (e.g. pyrogens) and the like. The sterilising filter 430 may have any suitable filter size, such as about 0.2 μm .

The device 400 further includes sensors 170 for measuring various properties of the water flowing through the device 400. The sensors 170 include a chlorine sensor 455 configured to detect a concentration of chlorine, such as an active chlorine compound, in water flowing through the chlorine sensor 455. The sensors 170 include one or more conductivity sensors 456 configured to detect a conductivity of water flowing through the device 400. The sensors 170 include one or more peroxide sensors 457 configured to detect a concentration of peroxide in water flowing through the peroxide sensor 457. The sensors 170 may include one or more flow sensors or flowmeters 458 to measure water flow through the device 400. This ensures accurate volume of the sterilised purified water stream discharged from the device 400, particularly the volume of water filling the dialysate source 420.

The device 400 further includes a heater 459 configured to heat water flowing through the heater 459. The heater 459 may be used between dialysis therapies to recirculate hot water (such as above 65 °C) through the device 400 to sterilise and disinfect the device 400 and prevent formation of biofilms. The device 400 further includes a chemical disinfectant source 460 and chemical pump 461 for supplying chemical disinfectant to the device 400. When in use, the chemical disinfectant flows through the device 400 to disinfect the device 400. The chemical disinfectant may include a compound comprising a peroxy group. For example, the compound comprising a peroxy group may be a peroxide or a peroxy acid, such as hydrogen peroxide and peracetic acid.

In some embodiments, the device 400 further includes a controller and a plurality of fluid connections and valves, wherein the controller and plurality of fluid connections and valves are configured to selectively provide fluid flow through a plurality of fluid flow paths.

The fluid flow paths include a first fluid flow path comprising one or more of the conductivity sensors 456, one or more of the peroxide sensors 457, the reverse osmosis module 452, the water outlet 404, and one or more of the filter, the UV steriliser 453, and the ultrafiltration device 454.

The fluid flow paths include a second fluid flow path comprising one or more of the conductivity sensors 456, one or more of the peroxide sensors 457, the reverse osmosis module 452, the filter, the UV steriliser 453, and the heater 459.

The fluid flow paths include a third fluid flow path comprising one or more of the conductivity sensors 456, one or more of the peroxide sensors 457, the reverse osmosis module 452, the filter, the UV steriliser 453, the heater 459, and the chlorine sensor 455.

The fluid flow paths include a fourth fluid flow path comprising one or more of the conductivity sensors 456, one or more of the peroxide sensors 457, the reverse osmosis module 452, the filter, the UV steriliser 453, and the chlorine sensor 455.

The fluid flow paths include a fifth fluid flow path comprising the chemical pump 461, one or more of the conductivity sensors 456, the chlorine sensor 455, and the drain outlet 408.

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Each of the first to fifth fluid flow paths may optionally comprise components for fluidly connecting the device 400 to the system 300 for performing dialysis. This allows for the fluid flow paths to include the cassette 312, and other connections (e.g. connected to the dialysate source 320 bag containing continuous ambulatory peritoneal dialysis fluid). Each of the second to fourth fluid flow paths may optionally be configured as recirculating fluid flow paths or may terminate at the drain outlet 408. Each of the first to fifth fluid flow paths may optionally comprise one or more of a urea sensor, a creatinine sensor, and a glucose sensor. It will be appreciated that the device 400 may include any combination of the exemplary sensors described herein.

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Figure 7A shows the fluid flow path (in dashed lines) in the device 400 for a chlorine test using the chlorine sensor 455, including the open/closed or on/off states of the fluid connections and valves of the device 400.

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Figure 7B shows the fluid flow path (in dashed lines) in the device 400 for filling the dialysate concentrate bag to form the dialysate source 420, including the open/closed or on/off states of the fluid connections and valves of the device 400.

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Figure 7C shows the fluid flow path (in dashed lines) in the device 400 for a conductivity test using the conductivity sensors 456, including the open/closed or on/off states of the fluid connections and valves of the device 400.

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Figure 7D shows the fluid flow path (in dashed lines) in the device 400 for draining dialysate from the patient 102, including the open/closed or on/off states of the fluid connections and valves of the device 400.

Figure 7E shows the fluid flow path (in dashed lines) in the device 400 for flushing the drain line, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 5 Figure 7F shows the fluid flow path (in dashed lines) in the device 400 for a first step in sanitizing the device 400 using hot water or in water recirculation, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 10 Figure 7G shows the fluid flow path (in dashed lines) in the device 400 for a second step in sanitizing the device 400 using hot water or in water recirculation, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 15 Figure 7H shows the fluid flow path (in dashed lines) in the device 400 for sanitizing the device 400 using chemical disinfectant from the chemical disinfectant source 460, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 20 Figure 7I shows the fluid flow path (in dashed lines) in the device 400 for a first step in recirculating the chemical disinfectant in the device 400 to sanitize the device 400, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 25 Figure 7J shows the fluid flow path (in dashed lines) in the device 400 for a second step in recirculating the chemical disinfectant in the device 400 to sanitize the device 400, including the open/closed or on/off states of the fluid connections and valves of the device 400.

- 30 Figure 7K shows the fluid flow path (in dashed lines) in the device 400 for a first step in flushing the chemical disinfectant from the device 400 after chemical sanitization, including the open/closed or on/off states of the fluid connections and valves of the device 400.

Figure 7L shows the fluid flow path (in dashed lines) in the device 400 for a second step in flushing the chemical disinfectant from the device 400 after chemical sanitization, including the open/closed or on/off states of the fluid connections and valves of the device 400.

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Figure 7M shows the fluid flow path (in dashed lines) in the device 400 for a peroxide test using the peroxide sensors 457, including the open/closed or on/off states of the fluid connections and valves of the device 400.

10 Figure 7N shows the fluid flow path (in dashed lines) in the device 400 during operation with a reverse osmosis water bag 440 providing water to the water inlet 402, including the open/closed or on/off states of the fluid connections and valves of the device 400.

In the foregoing detailed description, embodiments of the present disclosure in relation
15 to systems 100,300 for providing dialysate are described with reference to the provided figures. The description of the various embodiments herein is not intended to call out or be limited only to specific or particular representations of the present disclosure, but merely to illustrate non-limiting examples of the present disclosure. The present disclosure serves to address at least one of the mentioned problems and
20 issues associated with the prior art. Although only some embodiments of the present disclosure are disclosed herein, it will be apparent to a person having ordinary skill in the art in view of this disclosure that a variety of changes and/or modifications can be made to the disclosed embodiments without departing from the scope of the present disclosure. Therefore, the scope of the disclosure as well as the scope of the following
25 claims is not limited to embodiments described herein.

Claims

1. A system for providing dialysate to a patient, the system comprising:
 - a dialysis cyclor fluidly connectable to a source of a dialysate and to a patient line;
 - a water source device fluidly connected to the dialysis cyclor; and
 - a drain line fluidly connected to the dialysis cyclor, the drain line comprising:
 - one or more sensors for detecting properties of fluid flowing through the one or more sensors; and
 - a sensor bypass line,wherein:
 - the dialysis cyclor comprises at least one fluid inlet and at least one fluid outlet that are connectable to a source of dialysate, such that when in use, fluid is circulated from the fluid outlet of the dialysis cyclor to the dialysate source and back to the fluid inlet of the dialysis cyclor;
 - the system comprises a plurality of fluid connections and valves, and the dialysis cyclor is configured together with the plurality of fluid connections and valves to selectively control flow along:
 - a first fluid flow path from the water source device, through the one or more sterilisers, to the dialysis cyclor;
 - a second fluid flow path from the dialysis cyclor through the drain line and the one or more sensors; and
 - a third fluid flow path from the dialysis cyclor through the drain line and the sensor bypass line, thereby bypassing the one or more sensors.
2. The system according to claim 1, further comprising one or more sterilisers configured to sterilise fluid flowing between the water source device and the dialysis cyclor, optionally wherein the one or more sterilisers comprises one or more of a UV steriliser, a filter, and an ultrafiltration system.
3. The system according to claim 1 or 2, wherein when the dialysis cyclor is connected to the dialysate source comprising a dialysate concentrate, the dialysis

cycler is configured together with the plurality of fluid connections and valves to selectively control flow along a fluid flow path from the dialysate source through the dialysis cycler, the drain line, and the one or more sensors.

- 5 4. The system according to any one of claims 1 to 3, wherein when the dialysis cycler is connected to the dialysate source comprising a dialysate concentrate and to a patient line, the dialysis cycler is configured together with the plurality of fluid connections and valves to selectively control flow along a fluid flow path from the dialysate source through the dialysis cycler and the patient line.

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5. The system according to any one of claims 1 to 4, wherein when the dialysis cycler is connected to a patient line, the dialysis cycler is configured together with the plurality of fluid connections and valves to selectively control flow along a fluid flow path from the patient line through the dialysis cycler and the drain line, optionally
15 additionally through the sensor bypass line.

6. The system according to any one of claims 1 to 5, wherein the dialysis cycler is configured together with the plurality of fluid connections and valves to selectively control flow along: a fourth fluid flow path from the water source device to the drain
20 line, and not through the dialysis cycler.

7. The system according to any one of claims 1 to 6, further comprising a heater configured to disinfect fluid flowing through the water source device and/or the one or more sensors.

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8. The system according to any one of claims 1 to 7, further comprising a source of disinfectant fluidly connectable to the water source device, such that when in use, fluid flows through the disinfectant source and the water source device, thereby providing disinfectant to the system, optionally wherein the disinfectant comprises a
30 compound comprising a peroxy group.

9. The system according to any one claims 1 to 8, wherein the one or more sensors comprises one or more of:

a chlorine sensor configured to detect a concentration of an active chlorine compound in fluid flowing through the chlorine sensor;

a peroxide sensor configured to detect a concentration of peroxide in fluid flowing through the peroxide sensor;

5 an urea sensor configured to detect a concentration of urea flowing through the urea sensor;

a creatinine sensor configured to detect a concentration of creatinine flowing through the urea sensor; and

10 a glucose sensor configured to detect a concentration of glucose flowing through, around or over the glucose sensor.

10. The system according to any one claims 1 to 9, wherein the one or more sensors comprises a conductivity sensor configured to detect a conductivity of fluid flowing through the conductivity sensor.

15

11. The system according to any one of claims 1 to 10, wherein the one or more sensors comprises a refractive index sensor configured to detect a refractive index of fluid flowing through the refractive index sensor.

20 12. The system according to any one of claims 1 to 11, wherein the dialysate source comprises one or more bags each comprising one or more dialysate concentrates.

13. The system according to any one of claims 1 to 12, further comprising an air source fluidly connected to the dialysis cyclor, and when the dialysis cyclor is connected to the dialysate source comprising a dialysate concentrate, the dialysis cyclor is configured to provide air into the dialysate concentrate, optionally wherein the air source comprises a pump and a hydrophobic filter.

25 14. The system according to any one of claims 1 to 13, wherein the water source device comprises a reverse osmosis membrane for purifying water.

15. The system according to any one of claims 1 to 14, wherein the water source device comprises a pretreatment module comprising one or more of:

a filter having a pore size of from 1 to 8 μm ;
an activated carbon column; and
a water softener.

5 16. The system according to any one of claims 1 to 15, wherein the second and/or third fluid flow paths comprise one or more valves, a contactless flow sensor and an optical sensor, the optical sensor configured to detect fibrin, wherein the one or more valves have an inner diameter that is sufficiently large to prevent clogging by fibrin, optionally wherein the second and/or third fluid flow paths comprise a fibrin filter or are
10 fitted downstream from a fibrin filter.

17. A device for providing sterile purified water, the device comprising:
a water inlet for providing water to the device;
one or more pumps for providing flow of water through the device;
15 one or more conductivity sensors configured to detect a conductivity of water flowing through the device;
a reverse osmosis module configured to provide a purified water stream to downstream components of the device, the reverse osmosis module configured to provide a waste stream to a drain outlet;
20 one or more sterilisation systems selected from a filter, a UV steriliser and an ultrafiltration device for sterilising the purified water stream;
a water outlet configured to provide a sterilised purified water stream;
a heater configured to heat water flowing through the heater;
a chlorine sensor configured to detect a concentration of chlorine in
25 water flowing through the chlorine sensor;
one or more peroxide sensors configured to detect a concentration of peroxide in water flowing through the peroxide sensor; and
a chemical disinfectant source and chemical pump for supplying chemical disinfectant to the device.

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18. The device according to claim 17, comprising a controller and a plurality of fluid connections and valves, which controller and plurality of fluid connections and valves are configured to selectively provide fluid flow through:

a first fluid flow path comprising one or more of the conductivity sensors, one or more of the peroxide sensors, the reverse osmosis module, the water outlet and, and one or more of the filter, the UV steriliser, and the ultrafiltration device;

5 a second fluid flow path comprising one or more of the conductivity sensors, one or more of the peroxide sensors, the reverse osmosis module, the filter, the UV steriliser, and the heater;

a third fluid flow path comprising one or more of the conductivity sensors, one or more of the peroxide sensors, the reverse osmosis module, the filter, the
10 UV steriliser, the heater, and the chlorine sensor,

a fourth fluid flow path comprising one or more of the conductivity sensors, one or more of the peroxide sensors, the reverse osmosis module, the filter, the UV steriliser, and the chlorine sensor;

a fifth fluid flow path comprising the chemical pump, one or more of the
15 conductivity sensors, the chlorine sensor, and the drain outlet;
wherein:

each of the first to fifth fluid flow paths optionally comprises components for fluidly connecting the device to a system for performing dialysis; and

each of the second to fourth fluid flow paths is optionally configured as
20 recirculating fluid flow paths or optionally terminates at the drain outlet.

19. The device according to claim 18, wherein each of the first to fifth fluid flow paths optionally comprises components for fluidly connecting the device to a system for performing dialysis; and wherein each of the second to fourth fluid flow paths is
25 optionally configured as recirculating fluid flow paths or optionally terminates at the drain outlet.

20. The device according to claim 18 or 19, wherein each of the first to fifth fluid flow paths further comprise one or more of a urea sensor, a creatinine sensor, and a
30 glucose sensor.