

A DIALYSIS APPARATUS

Field of Invention

- 5 The present invention generally relates to dialysis systems and apparatus, and more particularly relates to dialysis systems and apparatus configurations for reducing disposable waste.

Background

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Millions of people worldwide suffer from kidney-related problems, such as chronic kidney disease (CKD) and end-stage renal disease (ESRD), and they may require either dialysis, such as peritoneal dialysis or hemodialysis, or transplantation to maintain life. Hemodialysis is a procedure in which a dialysis machine takes over the function of the kidneys. In
15 peritoneal dialysis, the peritoneum in the patient's abdomen acts as a natural filtration membrane.

Current standard of care (SOC) for patients needing chronic peritoneal dialysis includes continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD).

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With a CAPD system a patient may use patient transfer sets to attach to an APD cyclor device through a patient line. Fresh dialysate can be pumped into the patient's peritoneal cavity through the patient transfer set and an implanted catheter in the peritoneal cavity. The dialysate in the peritoneal cavity absorbs waste products from the patient's body and waste dialysate is discharged out from the peritoneal cavity.

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Peritoneal dialysis offers greater flexibility for patients and allows them to perform dialysis at home.

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CAPD and APD are both life-sustaining therapeutic options that allow control of fluid and electrolytes in patients with End-Stage-Kidney-Disease (ESKD). However, both modalities need large volumes of dialysis fluid which requires large-scale infrastructure to manufacture and distribute to every patient's home. In some cases, around 15 litres of dialysis fluid may be required daily, creating a logistical challenge in provision of fluid to a patient. Additionally, the provision of this quantity of fluid, for example a supply for a month being 450 litres, may
35 take up large volume of storage space at a patients' homes.

Some APD systems, such as system 100 shown in Fig. 1, aim to reduce this logistical burden through PD dialysate generation technology. The APD system 100 in Fig. 1 utilizes water supply (for example tap water) in patients' care environment to generate dialysis grade sterile purified water via reverse osmosis or other methods, which is mixed with concentrates to produce dialysis solutions (dialysate) on-demand before the therapy delivery. This system may significantly reduce distribution infrastructure and storage space required by dialysate bags that are used by SOC PD modalities. This in turn reduces waste and hence is more environmentally friendly. Research has also shown that initiating patients on PD improves patient's outcomes and quality of life. However, uptake of PD may be challenging in the lower socio-economical groups due to lack of storage space. With PD systems such as system 100, the space requirement for dialysis treatment is reduced, possibly improving equity and access to care.

Current PD or APD systems may comprise multiple sterile parts, which are disposable after each therapy use (for example daily) to maintain sterility of the system and avoid patient infection. In order to provide a more environmentally friendly therapy for the user, it would be beneficial to reduce the amount of plastic used in each therapy. For example, by removing the need for disposable parts or components.

The reduction in disposable components may also provide cost reduction benefits when operating a PD system.

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 sterilization device for a dialysis apparatus.

Summary of Invention

Example embodiments as disclosed herein provide for a PD apparatus allowing a 'cassette-free' therapy, which may reduce an amount of plastic required for disposal for each therapy. In an example embodiment, patient connections may be made via the use of flexible tubes only.

In accordance with a first aspect of the present disclosure, a dialysis apparatus is provided. The dialysis apparatus comprises a controller configured to control a filling and a draining of a patient during a dialysis process. The dialysis apparatus further comprises a water

purification device configured to provide purified water to a fill bag to generate a dialysis fluid for infusion to a patient, and an inline pump positionable between the fill bag and the patient. The inline pump is configured to transfer dialysis fluid to the patient, for example during an inflow or patient filling phase of a dialysis procedure. The dialysis apparatus further comprises a fixed pump integrated within the water purification device. The fixed pump is configured to drain the patient of fluid, for example by draining dialysis fluid from a patient during an outflow or patient draining phase of a dialysis procedure. The dialysis apparatus further comprises a pressure sensor integrated with the water purification device. The pressure sensor is configured to monitor a pressure of dialysis fluid during both a patient filling (e.g. inflow) and patient draining (e.g. outflow) phase of a dialysis process or procedure.

In an alternative aspect, a dialysis apparatus is provided, comprising a controller configured to control a filling and a draining of a patient during a dialysis process; a water purification device configured to provide purified water to a fill bag to generate a dialysis fluid for infusion to a patient; a delivery tube configured to connect or connectable between the fill bag and the patient, wherein the apparatus is configured such that the delivery tube provides or enables fluid delivery to the patient passively or by gravitational forces, a fixed pump integrated within the water purification device, wherein the fixed pump is configured to drain the patient of fluid during a patient draining phase of a dialysis process, and a pressure sensor integrated with the water purification device, wherein the pressure sensor is configured to monitor a pressure of dialysis fluid during both a patient filling and a patient draining phase of a dialysis process.

In an embodiment, the dialysis apparatus further comprises a drain valve positioned on a drain line and upstream of the fixed pump, the drain valve configured to isolate the pressure sensor from the fixed pump during a patient filling phase of a dialysis process.

In an embodiment, the inline pump is configured to accept a portion of a delivery tube positioned between the fill bag and the patient.

In an embodiment, the dialysis apparatus further comprises one or more pinch valves configured to restrict a flow of fluid between one or more components of the apparatus.

In an embodiment, the one or more pinch valves are configured to accept a portion of a tube positioned between the respective one or more components of the apparatus.

In an embodiment, the one or more pinch valves comprise a plunger configured to pinch the tube and thereby restrict a flow of fluid within the tube.

5 In an embodiment, the dialysis apparatus further comprises at least one sensor positioned between one or more components of the apparatus, the sensor configured to detect one or more of bubble, turbidity, fluid flow rate and/or fluid pressure in a flow of fluid between the one or more components.

10 In an embodiment, the dialysis apparatus further comprises an integrated turbidity sensor to detect turbidity of a drained dialysate. The turbidity sensor may be provided within or at a drain and/or at the water purification device.

15 In an embodiment, the dialysis apparatus further comprises an integrated flow meter to detect a fluid volume drained from the patient. The flow meter may be provided within or at a drain and/or at the water purification device.

In an embodiment, the sensor is configured to accept a portion of a tube positioned between the respective one or more components of the apparatus.

20 In an embodiment, the controller is configured to control one or more of the water device, inline pump, fixed pump, and/or pressure sensor to provide for a filling and draining of a patient during a dialysis process.

25 In an embodiment, the controller is configured to control an introduction of purified water to the fill bag to convert the purified water into the dialysis fluid for infusion to a patient.

30 In an embodiment, the dialysis apparatus further comprises a weighing device configured to determine a volume of purified water delivered to the fill bag, and/or a delivered quantity of dialysis fluid to the patient.

In an embodiment, the dialysis apparatus further comprises a heating element configured to heat the dialysis fluid to a therapeutic temperature prior to delivery to the patient.

35 In an embodiment, the dialysis apparatus further comprises a mixer to mix the fill bag and thereby combine a dialysis concentrate and the purified water to generate the dialysis fluid before being delivered to the patient.

In an embodiment, the dialysis apparatus further comprises a last fill solution, wherein the dialysis apparatus is further configured to deliver the last fill solution after a patient has been substantially drained of dialysis fluid.

- 5 In an embodiment, one or more fluid paths within the apparatus, or fluidically linking the one or more components of the apparatus, are formed of disposable flexible tubing.

In an embodiment, the water purification device, controller, inline pump, fixed pump, and/or pressure sensor are configured as reusable components or non-disposable components.

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In an embodiment, the dialysis apparatus further comprises a check valve positioned between a patient and the fixed pump, the check valve configured to restrict a flow of fluid in a direction towards the patient.

- 15 In an embodiment, the inline pump is a peristaltic pump.

In accordance with a second aspect of the present disclosure, a dialysis apparatus is provided. The dialysis apparatus comprises a controller configured to control a filling and a draining of a patient during a dialysis process. The dialysis apparatus further comprises a
20 water purification device configured to provide purified water to a fill bag to generate a dialysis fluid for infusion to a patient, and a plurality of tubes configured to connect or connectable between the water purification device to the fill bag, the fill bag to a patient, and the patient to a drain, wherein the apparatus is configured such that the tubes provide or enable fluid delivery to and drainage from the patient passively or by gravitational forces,
25 and one or more pinch valves configured to restrict a flow of fluid within the plurality of tubes.

In an embodiment, the apparatus is configured such that the fill bag is positionable at a height above that of a patient.

- 30 In an embodiment, the dialysis apparatus further comprises a pump positioned between the water purification device and the fill bag, the pump configured to provide purified water to the fill bag.

- In an embodiment, the water purification device comprises a drain for draining used dialysis
35 fluid, the apparatus configured such that the drain is positionable at a height below that of a patient.

In an embodiment, the one or more pinch valves are configured to accept a portion of a tube of the plurality of tubes.

5 In an embodiment, the one or more pinch valves comprise a plunger configured to pinch the tube and thereby restrict a flow of fluid within the tube

10 In an embodiment, the dialysis apparatus further comprises at least one sensor configured to accept a portion of a tube of the plurality of tubes, the sensor configured to detect one or more of bubble, turbidity, fluid flow rate and/or fluid pressure in a flow of fluid between the one or more components of the apparatus.

In an embodiment, the dialysis apparatus further comprises an integrated turbidity sensor to detect turbidity of a drained dialysate. The turbidity sensor may be provided within or at a drain and/or at the water purification device.

15 In an embodiment, the dialysis apparatus further comprises an integrated flow meter to detect a fluid volume drained from the patient. The flow meter may be provided within or at a drain and/or at the water purification device.

20 In an embodiment, the controller is configured to control the water device and/or the one or more pinch valves to provide for a filling and draining of a patient during a dialysis process.

In an embodiment, the controller is configured to control an introduction of purified water to the fill bag to convert the purified water into the dialysis fluid for infusion to a patient.

25 In an embodiment, the dialysis apparatus further comprises a weighing device configured to determine a volume of purified water delivered to the fill bag, and/or a delivered quantity of dialysis fluid to the patient.

30 In an embodiment, the dialysis apparatus further comprises a heating element configured to heat the dialysis fluid to a therapeutic temperature prior to delivery to the patient.

In an embodiment, the dialysis apparatus further comprises a mixer to mix the fill bag and thereby combine a dialysis concentrate and the purified water to generate the dialysis fluid before being delivered to the patient.

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In an embodiment, the dialysis apparatus further comprises a last fill solution, wherein the dialysis apparatus is further configured to deliver the last fill solution after a patient has been substantially drained of dialysis fluid.

- 5 In an embodiment, one or more fluid paths within the apparatus, or fluidically linking the one or more components of the apparatus, are formed of disposable flexible tubing.

In an embodiment, the plurality of tubes are formed of disposable flexible tubing.

- 10 In an embodiment, the water purification device, controller, and one or more pinch valves are configured as reusable components.

- 15 In an embodiment, the dialysis apparatus further comprises a check valve positioned between a patient and the drain, the check valve configured to restrict a flow of fluid in a direction towards the patient.

- In an embodiment, the dialysis apparatus further comprises a fixed pump and/or pressure sensor integrated within the water purification device, wherein the fixed pump and/or pressure sensor is/are configured to drain the patient of fluid.

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In an embodiment, the inline pump is a peristaltic pump.

- In accordance with a third aspect of the present disclosure, a dialysis apparatus is provided. The dialysis apparatus comprises a controller configured to control a filling and a draining of
 25 a patient during a dialysis process . The dialysis apparatus further comprises a water purification device configured to provide purified water to a fill bag to generate a dialysis fluid for infusion to a patient, and a plurality of tubes configured to connect or connectable between the water purification device to the fill bag, the fill bag to a patient, and the patient to a drain, wherein the apparatus is configured such that the tubes provide or enable fluid
 30 delivery to, and drainage from, the patient. The dialysis apparatus further comprises an in-line pump positionable towards the patient, the in-line pump configured to control a flow of dialysis fluid to and from the patient.

- 35 In an embodiment, the dialysis apparatus further comprises a pressure sensor positioned at or towards the in-line pump. In an embodiment, the pressure sensor may be a disposable pressure sensor.

In an embodiment, the inline pump is configured to accept a portion of a delivery tube positioned between the fill bag and the patient, and/or a portion of a drain tube positioned between the patient and a drain.

- 5 In an embodiment, a portion of a plurality of the tubes positioned towards a patient comprises a shared delivery and drain tube, and the inline pump is configured to accept a portion of the shared tube.

- 10 In an embodiment, the dialysis apparatus further comprises one or more pinch valves configured to restrict a flow of fluid within the plurality of tubes, wherein the one or more pinch valves are configured to accept a portion of a tube of the plurality of tubes.

In an embodiment, the one or more pinch valves comprise a plunger configured to pinch the tube and thereby restrict a flow of fluid within the tube.

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In an embodiment, the dialysis apparatus further comprises at least one sensor configured to accept a portion of a tube of the plurality of tubes, the sensor configured to detect one or more of bubble, turbidity, fluid flow rate and/or fluid pressure in a flow of fluid between the one or more components of the apparatus.

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In an embodiment, the dialysis apparatus further comprises an integrated turbidity sensor to detect turbidity of a drained dialysate. The turbidity sensor may be provided within or at a drain and/or at the water purification device.

- 25 In an embodiment, the dialysis apparatus further comprises an integrated flow meter to detect a fluid volume drained from the patient. The flow meter may be provided within or at a drain and/or at the water purification device.

- 30 In an embodiment, the controller is configured to control the water device and/or the in-line pump to provide for a filling and draining of a patient during a dialysis process.

In an embodiment, the controller is configured to control an introduction of purified water to the fill bag to convert the purified water into the dialysis fluid for infusion to a patient.

- 35 In an embodiment, the dialysis apparatus further comprises a weighing device configured to determine a volume of purified water delivered to the fill bag, and/or a delivered quantity of dialysis fluid to the patient.

In an embodiment, the dialysis apparatus further comprises a heating element configured to heat the dialysis fluid to a therapeutic temperature prior to delivery to the patient.

5 In an embodiment, the dialysis apparatus further comprises a mixer to mix the fill bag and thereby combine a dialysis concentrate and the purified water to generate the dialysis fluid before being delivered to the patient.

10 In an embodiment, the dialysis apparatus further comprises a last fill solution, wherein the dialysis apparatus is further configured to deliver the last fill solution after a patient has been substantially drained of dialysis fluid.

In an embodiment, one or more fluid paths within the apparatus, or fluidically linking the one or more components of the apparatus, are formed of disposable flexible tubing.

15 In an embodiment, the plurality of tubes are formed of disposable flexible tubing.

In an embodiment, the water purification device, controller, and inline pump are configured as reusable components.

20 In an embodiment, the dialysis apparatus further comprises a check valve positioned between a patient and the drain, the check valve configured to restrict a flow of fluid in a direction towards the patient.

25 In an embodiment, the inline pump is a peristaltic pump.

In an embodiment, the controller is configured to control any one or more of the components forming the apparatus as described in the first, second or third aspect herein. For example, the controller may be configured to control the water device, inline pump(s), fixed pump(s), pressure sensors(s), valves(s), heater(s), mixer(s), and/or weighing scale(s) to provide for a
30 filling and draining of a patient during a dialysis process.

In an embodiment, the dialysis apparatus may further comprise a sterilizing grade filter positioned between the water purification device and the fill bag. The filter may be provided to ensure water generated by the water purification device is sterile when introduced to the
35 fill bag.

In accordance with a fourth aspect of the present disclosure, a method is provided. The method, comprises a method of operating the apparatus of any one of the first, second or third aspects.

- 5 In accordance with a fifth aspect of the present disclosure, a method is provided. The method, comprises transferring purified water from a water purification device to a fill bag to generate a dialysis fluid for infusion to a patient. The method further comprises, a patient filling phase. During the patient filling phase, the method comprises the steps of transferring the dialysis fluid to a patient passively or by gravitational forces. The method further
- 10 comprises, a patient draining phase. During the patient draining phase, the method comprises the steps of draining fluid from the patient passively or by gravitational forces. The method further comprises a step of actuating one or more pinch valves to restrict a flow of fluid within fluid paths to switch between a patient filling and a patient draining phase.
- 15 In an embodiment, the method comprises the step of positioning the fill bag at a height above that of a patient.

In an embodiment, the method comprises the step of positioning a drain at a height below that of a patient.

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- In accordance with a sixth aspect of the present disclosure, a method is provided. The method, comprises transferring purified water from a water purification device to a fill bag to generate a dialysis fluid for infusion to a patient. The method further comprises, a patient filling phase. During the patient filling phase, the method comprises the steps of transferring
- 25 the dialysis fluid to a patient via an in-line pump positionable towards the patient. The method further comprises, a patient draining phase. During the patient draining phase, the method comprises the steps of draining fluid from the patient via in-line pump positionable towards the patient.

- 30 In an embodiment, the method further comprises the step of monitoring a pressure of dialysis fluid during both a patient filling and a patient draining phase via a pressure sensor positioned towards the patient.

In an embodiment, the pressure sensor may be a disposable pressure sensor.

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In accordance with a seventh aspect of the present disclosure, a method is provided. The method, comprises transferring purified water from a water purification device to a fill bag to

generate a dialysis fluid for infusion to a patient. The method further comprises, a patient filling phase. During the patient filling phase, the method comprises the steps of transferring the dialysis fluid to a patient via an inline pump positionable between the fill bag and the patient. The method further comprises, a patient draining phase. During the patient draining phase, the method comprises the steps of draining fluid from the patient via a fixed pump integrated within the water purification device. The method further comprises the step of monitoring a pressure of dialysis fluid during both a patient filling and a patient draining phase via a pressure sensor integrated with the water purification device.

10 In an embodiment, the method further comprises the step of controlling, via a controller, a flow and/or volume of dialysis fluid delivered to the patient. The controller may monitor a weighing scale configured to determine a volume of dialysis fluid delivered to the patient. The controller may additionally or alternatively be configured to control the in-line and/or fixed pump based on a pressure in the dialysis line and/or drain line determined from the pressure sensor, for example, to reduce a fluid flow in the dialysis line and/or drain line to ensure patient safety should an over-pressure be determined.

In an embodiment, the patient filing phase comprises a first step of closing a drain valve positioned on a drain line, and upstream of the fixed pump, such that the pressure sensor is isolated from the fixed pump during the patient filing phase of a dialysis process.

20 It will be understood that any one or more of the embodiments described in relation to the first, to seventh aspects may be combined to form one or more additional aspects or embodiments. For example, dialysis apparatus or methods as described herein may comprise a combination of features from the first to seventh, including combinations of pumps, sensors, valves, and gravity fed configurations as described herein, along with corresponding methods of operating said apparatus or components.

Brief Description of the Drawings

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FIG. 1 illustrates an example dialysis apparatus or system.

FIG. 2 illustrates a cassette for a dialysis apparatus.

35 **FIG. 3A** illustrates an example embodiment of a dialysis apparatus.

FIG. 3B to 3F illustrate various components of a dialysis apparatus according to example embodiments.

FIG. 4A illustrates an example embodiment of a dialysis apparatus.

FIG. 4B and 4C illustrate various components of a dialysis apparatus according to example embodiments.

FIG. 5A illustrates an example embodiment of a dialysis apparatus.

FIG. 5B and 5C illustrate various components of a dialysis apparatus according to example embodiments.

Description

For purposes of brevity and clarity, descriptions of embodiments of the present disclosure are directed to a dialysis apparatus or system, 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 recognized 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.

In an example embodiment, an APD apparatus or system, such as system 100 shown in Fig. 1, may comprise 3 main modules:

A cycler 120, which may be configured to fill and drain a patient with dialysate during a PD procedure. Additionally, in example embodiments the cycler may be configured to detect turbidity of dialysate from patient as described herein.

A water device (WD) 140, which may be configured to purify water, for example tap or mains or municipal water into dialysis grade water (or equivalent).

A cart 160 configured to house either or both of the cycler 120 and water device 140 for easy transportation of the APD system 100. In an example embodiment the cart 160, and/or cycler 120 may be configured to mix a concentrate with the purified water, for example using an integrated mixer to ensure homogeneity of dialysate fluid.

In an example embodiment, the cyclor 120 may comprise a disposable cassette 200 as shown in Fig. 2. The cassette 200 may comprise one or more tubes 220 to create a sterile fluid path from a dialysate container to the patient, and from the patient to a drain container or drain line. The cassette 200 may further comprise one or more pumps, sensors, and/or valves to control dialysis fluid flow to and/or from a patient.

The cassette 200 may be pre-sterilized and provided sterile to a user of system 100. In an example embodiment, all cyclor 120 – cassette 200 interactions are designed or configured to control a flow of dialysate in and out of a patient while maintaining sterility. In an example embodiment, a PD therapy may require the use of one cassette 200 for each therapy to maintain sterility, with the cassette 200 disposed after therapy is completed.

However, in order to provide a ‘greener’ or lower waste therapy for a user, it may be beneficial to reduce the amount of plastic used or disposed of in each therapy. Accordingly, the embodiments described in this disclosure may provide for ‘Cassette-free’ therapy, which may reduce the amount of plastic required to be disposed of for each therapy. In example embodiments disclosed herein, connections may be made via the use of flexible tubes only, and as such, systems and methods as disclosed herein may be configured such that only the flexible tubes are contaminated during a therapy, and therefore disposed of.

Fig. 3A illustrates an example embodiment of a dialysis apparatus 300 comprising a passive or gravity fed delivery and/or drain of dialysate. In an example embodiment, the apparatus 300 comprises a water device 310, which may be configured to provide purified water as described herein. Water path 312 may be provided to delivery purified water from water device 310 to a fill bag 320. The fill bag may receive and convert the purified water to a dialysis fluid for infusion to a patient 330, where dialysis fluid path 322 illustrates an example embodiment of a dialysis path as described herein.

Dialysis apparatus 300 may further comprise a drain fluid path 332, to drain dialysis fluid from patient 330. As described herein, the one or more fluid paths, including water path 312, dialysis fluid path 322, and/or drain path 332, may comprise passive fluid paths, and may be configured to flow or enable fluid delivery to patient 330, or from patient 330, via gravitational forces. Put another way, the one or more fluid paths in apparatus 300 may be gravity fed or configurable to be gravity fed.

In an example embodiment, apparatus 300 may be configured such that the fill bag 320 is positionable at a height above that of a patient 330, which may enable a flow of dialysis fluid

to the patient 330 via gravity. Similarly, the water purification device 310 may comprise a drain for draining used dialysis fluid from patient 330, the apparatus 300 may be configured such that the drain is positionable at a height below that of a patient 300, which may enable a flow of dialysis fluid from the patient 330 via gravity.

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In an example embodiment, the water device 310 may further comprise a drain to which drain fluid path 332 connects to drain a patient 330 of dialysis fluid. However, it will be understood that in alternative embodiments the drain path 332 may be connected to a separate drain (not shown).

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Dialysis apparatus 300 may further comprise one or more sensors 340, explained in more detail below in reference to Fig. 3B. Alternatively, or in addition, dialysis apparatus 300 may further comprise one or more pinch valves 350a-d, explained in more detail below in reference to Fig. 3C.

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Dialysis apparatus 300 may further comprise a mixing and/or heating and/or weighing apparatus 360, which may be attached or form part of fill bag 320, and is explained in more detail below in reference to Fig. 3D.

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Dialysis apparatus 300 may further comprise a controller, configured to control a filling and a draining of a patient during a dialysis process. The controller may control the water device 310, the sensors 340, and/or the one or more pinch valves 350a-d to provide for a filling and draining of a patient during a dialysis process. The controller may also control an introduction of purified water to the fill bag 320 to convert the purified water into the dialysis fluid for infusion to a patient.

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Fig. 3B illustrates a sensor 340 according to an example embodiment. The sensor 340 may comprise a bubble sensor, flow sensor, and/or turbidity sensor. The sensor 340 may comprise an individual sensor, or a set of sensors, and/or a combination sensor which may perform one or more of the following:

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A bubble sensor to detect presence of bubbles within a fluid line 322, 332, and/or detect potential leaks in the fluid path.

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A flow sensor to allow detection of flow volume of fluid in and/or out of the patient 330.

A turbidity sensor to allow detection of turbid fluid and therefore a potential peritoneal infection, for example, a high turbidity dialysate drained from the patient 330 may indicate a possibility of peritonitis.

As described herein the sensor 340 may be configured to accommodate a section of a pre-sterilized tube (such as fluid tube 302 as described in Fig. 3E below), that may form the fluid paths 312, 322, 332 as described herein. In this way, no portion of the sensor 340 may be in direct contact with the sterile dialysate, and/or drain fluid, such that sterility may be maintained.

In an example embodiment, the sensor 340 may comprise an ultrasonic transmitter 342, and an ultrasonic sensor or detector 344, which may be configured to transmit ultrasonic frequencies through tube 302 to provide detection of one or more of bubbles, flow, and/or turbidity as described herein. It will be understood that other sensor regimes may be utilised, for example, features 342 and 344 could comprise an optical emitter and receiver, respectively, to provide for the sensing described herein.

Fig. 3C illustrates a pinch valve 350a to 350d according to various example embodiments. In example embodiments, the pinch valves 350a-d may be configured to pinch a tube, and thereby occlude or control a flow of fluid through the tube. The pinch valves 350a-d may also be configured to control direction of a fluid flow into and/or out of the patient 330, by changing an occlusion of one or more tubes making up a dialysis apparatus as described herein. The valves 350a-d may function by pinching a flexible tube, such as tubes 302 as described herein, to close a fluid flow path. Releasing the pinch on the tube 302 may then allow an open flow of fluid. In an example embodiment, no portion of the pinch valve 350a-d may be in direct contact with a sterile dialysate fluid and/or drain fluid, such that sterility may be maintained.

In an example embodiment, the pinch valves 350a-d may comprise a plunger 352 configured to actuate and pinch a fluid flow 354 through the valve 350a-d. For example, the fluid flow 354 may be in a tube 302 positionable within the pinch valve 350a-d. The pinch valve 350a-d may further comprise a sleeve 356, for example an elastomer sleeve, to receive a tube 302. The elastomer sleeve may provide protection and/or resilience from the plunger 352 to the tube 302.

Fig. 3D illustrates a fluid apparatus 360 according to an example embodiment. The fluid apparatus 360 may comprise one or more of a heater, a mixer, and/or a weighing scale as

described herein. In an example embodiment, the heater may be used to heat a dialysate fluid to a therapeutic temperature via the fill bag 320 prior to patient fill. Alternatively, or in addition, the mixer may be used mix the dialysate concentrate with the purified water to create a homogenous mixture of dialysate as described herein. Alternatively, or in addition,

5 the weighing scale may be configured to confirm that an amount of water added to a dialysate bag is correct, and may also be configured to confirm an amount of dialysate filled to the patient is accurate.

It will be understood that the heater, mixer, and/or weighing scale as described herein may

10 be provided in a combined apparatus 360, and/or separate apparatus (not shown).

Fig 3E illustrates a fluid tube 302 according to an example embodiment, which may be formed of a disposable flexible tube (e.g. silicone, PVC, etc.). The various fluid paths including the water path 312, dialysis fluid path 322 and drain path 332 may be provided or

15 formed of the fluid tube 302 as described herein. Put another way, the fluid paths as described herein may consist of disposable flexible tubes (e.g. silicone, PVC, etc.). In an example embodiment, the fluid tube 302 can be pinched by a pinch valve, such as pinch valve 350a-d as described in relation to Fig. 3C. In an example embodiment the tube set or fluid tube 302 can be sterilized and provided to the user as a sterile set, and may be

20 disposable or disposed of after a dialysis procedure.

Fig. 3F illustrates a last fill bag 370 according to an example embodiment. This optional last fill bag 370 may be used in the event a last fill is required by the patient 330. In an example embodiment, the last fill is provided as a sterile pre-mixed solution, and may not require any

25 mixing. The last fill may be provided to a patient 330 and configured to be left within a patient to end a dialysis therapy.

In an example embodiment, the apparatus 300 as described herein may be operated to provide therapy as described herein in the following sequence or method:

At a first step, the water device 310 may provide purified water via water path 312 to the fill bag 320. In an example embodiment, the water device may provide purified water to a concentrate bag, which may in an example comprise dialysis concentrate, to produce a dialysis fluid. The purified water may be delivered from the water device 310 to fill bag 320

35 via a pump, and may be controlled by pinch valve 350a.

In an example embodiment, the heater apparatus 360, which may comprise either or both of a mixer and/or a weighing scale, may be used to heat and mix the purified water and the dialysis concentrate together, where the weighing scale may provide for measurement of a quantity of each fluid to provide a correct mixture, and/or confirm that a final volume is correct for delivery to a patient. When a correct volume is reached, valve 350a may be closed to stop a flow of purified water to the fill bag 320.

During a second step, an inflow valve 350b may be opened to allow dialysis fluid or dialysate to flow from the fill bag 320 to the patient 330 via gravity. In an example embodiment, the weighing scale 360 may be used to monitor a volume of fluid entering the patient 330, and the valve 350b may be closed once an appropriate volume of fluid has been reached or delivered into the patient 330.

In an example embodiment, for example during or prior to the second step, one or more of the water path 312, dialysis fluid path 322 and/or drain path 332 as described herein may be primed, for example by filling tubes 302 forming the paths with fluid to purge air from the apparatus fluid paths.

During a third step, an outflow valve 350c may be opened to allow dialysate flow to a drain via drain path 332 via gravity to a drain, where the drain may be positioned in water device 310, or provided as a separate drain (not shown).

In an example embodiment, the sensor 340 may comprise a bubble and flow sensor, and may be configured to monitor a volume of fluid drained from the patient 330 via drain line 332. The drain valve 350c may be closed when sufficient fluid has drained such that the patient 330 is deemed to be empty.

In an example embodiment, the above steps may be repeated multiple times until an entire dialysis therapy is completed. It will be understood that the order of the steps outlined above may be varied, and steps may be removed or added as required to provide for a low waste gravity fed dialysis apparatus that may minimise a number or quantity of disposable parts.

In an example embodiment, dialysis fluid line 322 and drain line 332 may be combined, for example via a T-piece, before entering a patient 330. Alternatively, dialysis fluid line 322 and drain line 332 may be provided as separate lines to and from the patient 330. In either case, the sensor 340, and/or pinch valve 350b, may be provided to act on both dialysis fluid line 322 and drain line 332. It will be understood that, in an example embodiment, by retaining

pinch valve 350c in a closed position, the drain line 332 may be closed, allowing dialysis fluid to flow into the patient 330 via dialysis fluid line 322. Similarly, by opening pinch valve 350c (and optionally closing pinch valves 350a and/or 350d), dialysis fluid may drain from the patient 330. In this way, the dialysis fluid line 322 and drain line 332 may share a section of tubing close to a patient 330.

In an example embodiment, the apparatus 300 may comprise a last fill valve 350d to control fluid flow from a last fill bag 370, an example of which is illustrated in Fig. 3F. The last fill valve 350d may be opened to allow the last fill dialysate 370 to flow into the fill bag 320 via gravity. In an example embodiment, this may allow the last fill dialysate to be heated and/or mixed prior to the last fill stage as described herein, for example, via apparatus 360. The last fill stage may also be infused to a patient via gravity, and delivery quantity may be monitored via weighing scale forming part of apparatus 360, as described above in relation to dialysis fluid, and via dialysis fluid line 322.

In an example embodiment, an integrated turbidity sensor may be provided within the water device 310 forming a drain, where the turbidity sensor may be used to detect turbidity of the drained dialysate.

In an example embodiment, an integrated flow meter may be provided within the water device 310 forming a drain, where the integrated flow meter may be used to detect a fluid volume drained from the patient during an outflow.

Fig. 4A illustrates an example embodiment of a dialysis apparatus 400 comprising a pump 410 configured to control a flow of dialysis fluid to and from the patient 330.

The example embodiment of Fig. 4A may comprise any one or more of the features as described in Fig. 3B to 3F as described herein, for example, one or more of a water device 310, which may be configured to provide purified water as described herein. Water path 312 may be provided to delivery purified water from water device 310 to a fill bag 320. The fill bag may receive and convert the purified water to a dialysis fluid for infusion to a patient 330, where dialysis fluid path 322 illustrates an example embodiment of a dialysis path as described herein.

Dialysis apparatus 400 may further comprise a drain fluid path 332, to drain dialysis fluid from patient 330.

In an example embodiment, the water device 310 may further comprise a drain to which drain fluid path 332 connects to drain a patient 330 of dialysis fluid. However, it will be understood that in alternative embodiments the drain path 332 may be connected to a separate drain (not shown).

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Dialysis apparatus 400 may further comprise one or more sensors 340, explained in more detail above in reference to Fig. 3B. Alternatively, or in addition, dialysis apparatus 400 may further comprise one or more pinch valves 350a-d, explained in more detail above in reference to Fig. 3C.

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Dialysis apparatus 400 may further comprise a mixing and/or heating and/or weighing apparatus 360, which may be attached or form part of fill bag 320, and is explained in more detail above in reference to Fig. 3D.

15 In an example embodiment, dialysis apparatus 400 may comprise one or more in-line pumps 410 positioned towards a patient. For example, along a dialysis fluid path 322, and/or a drain path 332. In an example embodiment, the one or more in-line pumps 410 may be configured to control a flow of dialysis fluid to and from a patient. The one or more in line pumps 410 may comprise peristaltic pumps.

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Dialysis apparatus 400 may further comprise a controller, configured to control a filling and a draining of a patient during a dialysis process. The controller may control the water device 310, the sensors 340, the in-line pump 410, and/or the one or more pinch valves 350a-d to provide for a filling and draining of a patient during a dialysis process. The controller may
25 also control an introduction of purified water to the fill bag 320 to convert the purified water into the dialysis fluid for infusion to a patient.

Fig. 4B illustrates an example embodiment of a peristaltic pump 410. The pump 410 may comprise a rotary and/or linear peristaltic pump, and may be configured to pump a prepared
30 dialysate into the patient 330 during an inflow procedure. In an example embodiment, the usage of a peristaltic pump may ensure sterility of dialysis fluid is maintained, for example by providing a configuration such that no portion of the pump is in direct contact with the sterile dialysate. In an example embodiment, pump 410 may comprise a rotor 412 configured to compress tube 302 and thereby push fluid through tube 302.

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In an example embodiment, dialysis apparatus 400 may comprise one or more pressure sensors 420, which may be positioned towards a patient. For example, along a dialysis fluid

path 322, and/or a drain path 332. In an example embodiment, the one or more pressure sensors 420 may be configured to detect pressure of fluid flowing into and/or out of patient. In this way, patient safety may be improved, and increased accuracy of control of a flow of dialysis fluid 332 and/or drain fluid 332 to and from a patient 330 may be achieved. The one or more in pressure sensors 420 may comprise in-line pressure sensors.

Fig. 4C illustrates an example embodiment of a pressure sensor 420. In an example embodiment, the pressure sensor 420 may also comprise an occlusion sensor. In an example embodiment, the pressure sensor 420 may be configured such that no portion of the sensor contacts the sterile dialysis fluid. In this way, sterility of dialysis fluid may be maintained. In an example embodiment, pressure sensor 420 may comprise a transducer 422, configured to monitor a pressure in fluid tube 302 positioned within or passing through sensor 420. Arrow 424 in Fig. 4C illustrates a flow direction of fluid through tube 302, however it will be understood the pressure sensor 420 may similarly operate if a fluid flow is reversed.

In an example embodiment, the apparatus 400 as described herein may be operated to provide therapy as described herein in the following sequence or method:

At a first step, the water device 310 may provide purified water via water path 312 to the fill bag 320. In an example embodiment, the water device may provide purified water to a concentrate bag, which may in an example comprise dialysis concentrate, to produce a dialysis fluid. The purified water may be delivered via a pump, and may be controlled by pinch valve 350a.

In an example embodiment, the heater apparatus 360, which may comprise either or both of a mixer and/or a weighing scale, may be used to heat and mix the purified water and the dialysis concentrate together, where the weighing scale may provide for measurement of a quantity of each fluid to provide a correct mixture, and/or confirm that a final volume is correct for delivery to a patient. When a correct volume is reached, valve 350a may be closed to stop a flow of purified water to the fill bag 320.

During a second step, the pump 410 may draw the prepared dialysate from the fill bag 320 to fill the patient 330 during a fill procedure. In example embodiments, one or more valves may be actuated to change the fluid flow path to a delivery phase. For example, valve 350a may be opened, and valves 350c and 350d may be closed, to allow the pump 410 to transfer dialysis fluid from fill bag 320 to a patient 330 via dialysis fluid line 322.

In an example embodiment, for example during or prior to the second step, one or more of the water path 312, dialysis fluid path 322 and/or drain path 332 as described herein may be primed, for example by filling tubes 302 forming the paths with fluid to purge air from the apparatus fluid paths.

In an example embodiment, the weighing scale 360 may be used to monitor a volume of fluid entering the patient 330, and the pump 410 may be stopped once a required volume is achieved. The pressure and/or occlusion sensor 420 may be configured to monitor a pressure within the patient line 322 during this process to improve patient safety, where the apparatus 400 may be configured to shut off or slow down pump 410 if a pressure is detected above a pre-set value.

During a third step of outflow or drain of patient 330, the pump 410 may be reversed such that the pump 410 is configured to draw a dwelled dialysate from the patient 330 as part of a drain procedure. In example embodiments, one or more valves may be actuated to change the fluid flow path from a delivery to a drain phase. For example, valves 350a and 350d, may be closed, and valve 350c may be opened, to allow the pump 410 to draw a dwelled dialysate from a patient 330 and transfer this via drain line 332 to a drain as described herein.

In example embodiments, the pressure and/or occlusion sensor 420 may be configured to monitor a pressure within the patient line 322 and/or drain line 332 during the third step or draining process to improve patient safety, where the apparatus 400 may be configured to shut off or slow down pump 410 if a pressure is detected above a pre-set value.

In an example embodiment, sensor 340 may be used to monitor a volume of fluid drained from the patient 330, and a valve, for example valve 350c, may be closed once the patient 330 is deemed to be empty.

In an example embodiment, the above steps may be repeated multiple times until an entire dialysis therapy is completed. It will be understood that the order of the steps outlined above may be varied, and steps may be removed or added as required to provide for a low waste dialysis apparatus that may minimise the number or quantity of disposable parts, and/or provide for control of flow of a dialysis fluid to and from a patient via a pump positioned towards a patient as described herein.

In an example embodiment, the apparatus 400 may comprise a last fill valve 350d to control fluid flow from a last fill bag 370, an example of which is illustrated in Fig. 3F. The last fill valve 350d may be opened to allow the last fill dialysate 370 to flow into the fill bag 320 via gravity, or be drawn via a pump, for example pump 410. In an example embodiment, this may allow the last fill dialysate to be heated and/or mixed prior to the last fill stage as described herein, for example via apparatus 360. The last fill stage may also be infused to a patient via the pump 410 as described herein, and delivery quantity may be monitored via weighing scale forming part of apparatus 360, as described above in relation to dialysis fluid, and via dialysis fluid line 322.

In an example embodiment, an integrated turbidity sensor may be provided within the water device 310 forming a drain, where the turbidity sensor may be used to detect turbidity of the drained dialysate.

In an example embodiment, an integrated flow meter may be provided within the water device 310 forming a drain, where the integrated flow meter may be used to detect a fluid volume drained from the patient during an outflow.

Fig. 5A illustrates an example embodiment of a dialysis apparatus 500 comprising a drain pump 510 and a pressure sensor 520 integrated with a water device 310. In an example embodiment, the fixed pump 510 integrated within the water purification device 310 may be configured to drain the patient of fluid. Additionally, the pressure sensor 520 integrated with the water purification device may be configured to monitor a pressure of dialysis fluid infusion during both a patient filling and patient draining phase of a dialysis process.

In an example embodiment, the apparatus 500 may provide an inflow process and dialysis fluid to a patient 330 via a pump 512, which may be configured to provide dialysis fluid to a patient 330 via dialysis fluid line 322 as described herein, for example in regard to Fig. 4A and Fig. 4B. In an example embodiment, pump 512 may comprise a peristaltic pump. In an alternative embodiment, apparatus 500 may provide an inflow process and thereby provide dialysis fluid to a patient 330 via gravity fill, in line with that described in regard to Fig. 3A. In this way, peristaltic pump 512 may not be required in some embodiments. In this alternative example, the fixed pump 510 may be used to actively drain the patient 330 via drain line 332.

The example embodiment of Fig. 5A may comprise any one or more of the features as described in Fig. 3A to 3F, and/or 4A to 4C as described herein, for example, one or more of a water device 310, which may be configured to provide purified water as described herein.

Water path 312 may be provided to delivery purified water from water device 310 to a fill bag 320. The fill bag 320 may receive and convert the purified water to a dialysis fluid for infusion to a patient 330, where dialysis fluid path 322 illustrates an example embodiment of a dialysis path as described herein.

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Dialysis apparatus 500 may further comprise a drain fluid path 332, to drain dialysis fluid from patient 330.

10 In an example embodiment, the water device 310 may further comprise a drain to which drain fluid path 332 connects to drain a patient 330 of dialysis fluid. However, it will be understood that in alternative embodiments the drain path 332 may be connected to a separate drain (not shown).

15 Dialysis apparatus 500 may further comprise one or more sensors 340, explained in more detail above in reference to Fig. 3B. Alternatively, or in addition, dialysis apparatus 500 may further comprise one or more pinch valves 350a-d, explained in more detail above in reference to Fig. 3C.

20 Dialysis apparatus 500 may further comprise a mixing and/or heating and/or weighing apparatus 360, which may be attached or form part of fill bag 320, and is explained in more detail above in reference to Fig. 3D.

25 Dialysis apparatus 500 may further comprise a controller, configured to control a filling and a draining of a patient during a dialysis process. The controller may control the water device 310, the sensors 340 and/or 520, the pumps 510 and/or 512, and/or the one or more pinch valves 350a-d and/or 530 to provide for a filling and draining of a patient during a dialysis process. The controller may also control an introduction of purified water to the fill bag 320 to convert the purified water into the dialysis fluid for infusion to a patient.

30 Fig. 5B illustrates an example embodiment of a pump 510. As described herein, the pump 510 may comprise a fixed or permanent pump within the water device 310, and may be configured to drain the patient 330 during an outflow process. The pump 510 may comprise a fixed or integrated pump as described herein, and may be integrated in water device 310. The pump may comprise any type of pump, for example a diaphragm or centrifugal pump,
35 configured to drain a patient 330 of dialysis fluid.

In an example embodiment, pump 510 may alternatively comprise a peristaltic pump as described herein, for example, that described in relation to Fig. 4B.

In an example embodiment, the pressure sensor 520 may comprise a sensor in line with that disclosed in Fig. 4C. As described herein, the pressure sensor may be fixed or a permanent pressure sensor 520 within the water device 310, and may be configured to detect hydraulic pressure within the drain line 332, and/or one or more fluid lines within the apparatus 500, for example, dialysis fluid line 322.

Fig. 5C illustrates an example embodiment of a valve 530, which may comprise a permanent valve 530 within the water device 310 as described herein. In an example embodiment the valve may comprise a plunger 532 configured to actuate and thereby occlude a fluid path 534, which may comprise a tube 302 as described herein. The valve 530 may be configured to isolate the permanent pressure sensor 520 from the fixed pump 510 and/or the drain line 332. Advantageously, this may allow the apparatus 500 to be configured to detect pressure building within the apparatus 500, for example, in the dialysis fluid line 322 during an inflow phase of the dialysis process. In an example embodiment, the pressure sensor 520 may be positioned upstream of the valve 530, which may allow the pressure sensor 520 to monitor pressure in the apparatus 500, for example in fluid lines 322 and 332.

In an example embodiment, dialysis fluid line 322 and drain line 332 may be combined, for example via a T-piece, before entering a patient 330. In this way, the dialysis fluid line 322 and drain line 332 may share a section of tubing close to a patient 330. Alternatively, dialysis fluid line 322 and drain line 332 may be provided as separate lines to and from the patient 330. In either case, the sensor 520, may be provided to act on both dialysis fluid line 322 and drain line 332. It will be understood that, in an example embodiment, by retaining valve 530 in a closed position, the drain line 332 may be closed, yet fluidically connected to the patient 330. This may allow a pressure of a dialysis fluid flowing into the patient 330 via dialysis fluid line 322 to be determined. It will be understood that initial flushing may be carried out to fill a drain line 332 as a first step, and/or to avoid contamination of the dialysis fluid line 322. In an example embodiment, valve 350c may be opened to enable the sensor 520 to monitor a pressure within the dialysis fluid line 322. However, it will be understood that valve 350c may be omitted, and water device valve 530 may be used to allow pressure monitoring and patient draining as described above.

In an example embodiment, by closing pinch valves 350a and/or 350d, a pressure of a dialysis fluid draining from the patient 330 (or being drained from patient 330 by pump 510) may be determined by sensor 520 as described herein.

- 5 In an example embodiment, the apparatus 500 as described herein may be operated to provide therapy as described herein in the following sequence or method:

At a first step, the water device 310 may provide purified water via water path 312 to the fill bag 320. In an example embodiment, the water device may provide purified water to a
 10 concentrate bag, which may in an example comprise dialysis concentrate, to produce a dialysis fluid. The purified water may be delivered via a pump, and may be controlled by pinch valve 350a.

In an example embodiment, the heater apparatus 360, which may comprise either or both of
 15 a mixer and/or a weighing scale, may be used to heat and mix the purified water and the dialysis concentrate together, where the weighing scale may provide for measurement of a quantity of each fluid to provide a correct mixture, and/or confirm that a final volume is correct for delivery to a patient. When a correct volume is reached, valve 350a may be closed to stop a flow of purified water to the fill bag 320.

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During a second step, the peristaltic pump 512 may draw the prepared dialysate from the fill bag 320 to fill the patient 330 during a fill procedure. In an example embodiment, the weighing scale 360 may be used to monitor a volume of fluid entering the patient 330, and the pump 512 may be stopped once the required volume is achieved. In an alternative
 25 example embodiment as described herein, the patient may be filled via a gravity feed.

In an example embodiment, for example during or prior to the second step, one or more of the water path 312, dialysis fluid path 322 and/or drain path 332 as described herein may be primed, for example by filling tubes 302 forming the paths with fluid to purge air from the
 30 apparatus fluid paths.

In an example embodiment, the water device valve 530 within the water device may be closed during a fill procedure. As described above, this may allow the permanent pressure sensor 520 to act at a 'patient' pressure sensor, allowing the pressure sensor 520 to monitor
 35 a pressure of a dialysis fluid line 322 to the patient. In the event of a flow occlusion, the pressure built up in the dialysis fluid line 322 may be transferred via drain fluid line 332 and sensed by this pressure sensor 520. It will be understood that a priming step may be carried

out to prime drain fluid line 332 to allow sensor 520 to be fluidically connected to dialysis fluid line 322 and patient 330 to enable sensing of pressure during a patient fill process.

In an example embodiment, during an outflow or patient draining stage, the permanent pump 510 within the water device 310 may be used to draw a dwelled dialysate from the patient 330. As part of this, water device valve 530 may be opened, and valves 350a and 350d may be closed. The permanent pressure sensor 520 may be used to monitor the pressure within the drain line 330 to improve patient safety. The sensor 340 may be used to monitor the volume of fluid drained from the patient 330, and the water device valve 530 may be closed once the patient 330 is deemed to be empty.

In an example embodiment, the above steps may be repeated multiple times until an entire dialysis therapy is completed. It will be understood that the order of the steps outlined above may be varied, and steps may be removed or added as required to provide for a low waste dialysis apparatus that may minimise the number or quantity of disposable parts, and/or provide for patient safety by allowing monitoring of a pressure in an inflow and outflow phase of a dialysis process.

In an example embodiment, the apparatus 500 may comprise a last fill valve 350d to control fluid flow from a last fill bag 370. The last fill valve 350d may be opened to allow the last fill dialysate 370 to flow into the fill bag 320 via gravity. In an example embodiment, this may allow the last fill dialysate to be heated and/or mixed prior to the last fill stage as described herein, for example via apparatus 360. The last fill stage may also be infused to a patient via the pump 512 as described herein, and delivery quantity may be monitored via weighing scale forming part of apparatus 360. Pressure may be monitored via water device sensor 520 as described above in regard to a patient fill phase.

In an example embodiment, an integrated turbidity sensor within the water device 310 can be used to detect turbidity of the drained dialysate. In an example embodiment, an integrated flow meter within the water device 310 may be used to detect fluid volume drained from the patient during an outflow. In an example embodiment, a 1-way valve (check valve) may be provided within the drain line 332, which may be used to mitigate backflow from the non-sterile permanent components of the drain to the sterile disposable components. This check valve may have minimal crack pressure (e.g. a duckbill valve, etc.).

In example embodiments as described herein, fluid may be pumped or moved via the use of a rotary peristaltic pump, such as pumps 410 and 512 as described herein. Figure 4B

illustrates an example embodiment of a peristaltic pump, which may operate by using rollers to compress a flexible tube, pushing fluid through the tube.

The apparatus, systems, and methods as described herein may be configured to:

- 5 1) Move fluid in/out of the patient 330 via generation of a positive/negative pressure.
- 2) Sense/limit a pressure while fill/drain is performed, in order to prevent injury to the patient 330.
- 3) Control fluid flow through the apparatus 300, 400, 500 via a series of pinch valves, such as valves 350a-d described in Fig. 3C and valve 530 as described in Fig. 5C. The
10 pinch valves may be opened/closed via the use of a plunger 352/532 to pinch the various tubes 302 as described herein.
- 4) Detect bubbles passing to and from the patient, for example via sensor 340 as described in Fig. 3B. Bubbles can indicate a potential leak within the apparatus or at the connection between the components of the dialysis apparatus 300, 400, 500 and the patient
15 330.
- 5) Sensor 340 may also incorporate a turbidity sensor to detect a turbidity of drained dialysate via drain line 332 from the patient 330. High turbidity from drained dialysate may be an indication of peritonitis (bacterial infection of the peritoneal membrane).
- 20 As outlined herein, the various dialysis apparatus embodiments disclosed may comprise non-disposable components, configured to remain sterile during a dialysis process, and comprising pumps, valves, and/or sensors. The non-disposable components may be formed of materials that are resistant to corrosion, wear, and/or microbial growth to ensure long-term usability. In example embodiments, only the tubes 302 as described in relation to Figs. 3A,
25 4A and 5A may be disposable after a typical dialysis therapy delivery process.

It will be understood that any one or more of the embodiments described in relation to Figures 3A, 4A, and/or 5A may be combined to form one or more additional aspects or
30 embodiments. For example, dialysis apparatus as described herein may comprise a combination of features from Figures 3A to 5C, including combinations of pumps, sensors, valves, and gravity fed configurations to provide for a low waste dialysis apparatus that may minimise the number or quantity of disposable parts.

Although various embodiments herein describe a dialysis apparatus and system for use with
35 a peritoneal dialysis process, it will be appreciated that the systems and apparatus as described herein can be used for other dialysis apparatuses or systems such as a

hemodialysis apparatus. Various aspects of the dialysis apparatus for peritoneal dialysis as described will apply similarly or analogously for a hemodialysis apparatus or system.

5 In the foregoing detailed description, embodiments of the present disclosure in relation to a dialysis apparatus 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 issues associated with the prior art. Although only some
10 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 claims is not limited to embodiments described herein.

Claims

1. A dialysis apparatus, comprising:

a controller configured to control a filling and a draining of a patient during a dialysis process;

a water purification device configured to provide purified water to a fill bag to generate a dialysis fluid for infusion to a patient;

an inline pump positionable between the fill bag and the patient, wherein the inline pump is configured to transfer dialysis fluid to the patient during a patient filling phase of a dialysis process, or a delivery tube configured to connect or connectable between the fill bag and the patient, wherein the apparatus is configured such that the delivery tube provides or enables fluid delivery to the patient passively or by gravitational forces;

a fixed pump integrated within the water purification device, wherein the fixed pump is configured to drain the patient of fluid during a patient draining phase of a dialysis process; and

a pressure sensor integrated with the water purification device, wherein the pressure sensor is configured to monitor a pressure of dialysis fluid during both a patient filling and a patient draining phase of a dialysis process.

2. The dialysis apparatus of claim 1, further comprising a drain valve positioned on a drain line and upstream of the fixed pump, the drain valve configured to isolate the pressure sensor from the fixed pump during a patient filling phase of a dialysis process.

3. The dialysis apparatus of claim 1 or claim 2, wherein the inline pump is configured to accept a portion of a delivery tube positioned between the fill bag and the patient.

4. The dialysis apparatus of any preceding claim, further comprising one or more pinch valves configured to restrict a flow of fluid between one or more components of the apparatus.

5. The dialysis apparatus of claim 4, wherein the one or more pinch valves are configured to accept a portion of a tube positioned between the respective one or more components of the apparatus.

6. The dialysis apparatus of any preceding claim, further comprising at least one sensor positioned between one or more components of the apparatus, the sensor configured to

detect one or more of bubble, turbidity, fluid flow rate and/or fluid pressure in a flow of fluid between the one or more components.

7. The dialysis apparatus of claim 6, wherein the sensor is configured to accept a portion of a tube positioned between the respective one or more components of the apparatus.

8. The dialysis apparatus of any preceding claim, wherein the controller is configured to control one or more of the water device, inline pump, fixed pump, and/or pressure sensor to provide for a filling and draining of a patient during a dialysis process.

9. The dialysis apparatus of any preceding claim, wherein the controller is configured to control an introduction of purified water to the fill bag to convert the purified water into the dialysis fluid for infusion to a patient.

10. The dialysis apparatus of any preceding claim, further comprising a weighing device configured to determine a volume of purified water delivered to the fill bag, and/or a delivered quantity of dialysis fluid to the patient.

11. The dialysis apparatus of any preceding claim, further comprising a heating element configured to heat the dialysis fluid to a therapeutic temperature prior to delivery to the patient.

12. The dialysis apparatus of any preceding claim, further comprising a mixer to mix the fill bag and thereby combine a dialysis concentrate and the purified water to generate the dialysis fluid.

13. The dialysis apparatus of any preceding claim, further comprising a last fill solution, wherein the dialysis apparatus is further configured to deliver the last fill solution after a patient has been substantially drained of dialysis fluid.

14. The dialysis apparatus of any preceding claim, wherein one or more fluid paths within the apparatus, or fluidically linking the one or more components of the apparatus, are formed of disposable flexible tubing.

15. The dialysis apparatus of any preceding claim, wherein one or more of the water purification device, controller, inline pump, fixed pump, and/or pressure sensor are configured as reusable components.

16. The dialysis apparatus of any preceding claim, wherein the inline pump is a peristaltic pump.

17. The dialysis apparatus of any preceding claim, further comprising a sterilizing grade filter positioned between the water purification device and the fill bag, and/or a check valve positioned between a patient and the fixed pump, the check valve configured to restrict a flow of fluid in a direction towards the patient.

18. A method, comprising:

- transferring purified water from a water purification device to a fill bag to generate a dialysis fluid for infusion to a patient; and

- during a patient filling phase, transferring the dialysis fluid to a patient via an inline pump positionable between the fill bag and the patient,

- during a patient drain phase, draining fluid from the patient via a fixed pump integrated within the water purification device; and

- monitoring a pressure of dialysis fluid during both a patient filling and a patient draining phase via a pressure sensor integrated with the water purification device.

19. The dialysis method of claim 18, wherein the patient filling phase comprises a first step of closing a drain valve positioned on a drain line, and upstream of the fixed pump, such that the pressure sensor is isolated from the fixed pump during the patient filling phase of a dialysis process.

20. The dialysis method of claim 18 or 19, further comprising the step of controlling, via a controller, a flow and/or volume of dialysis fluid delivered to the patient, optionally wherein the controller monitors a weighing scale configured to determine a volume of dialysis fluid delivered to the patient, and optionally wherein the controller is configured to control the inline and/or fixed pump based on a pressure in the dialysis line and/or drain line determined from the pressure sensor.