injury or infection in the abdominal cavity allows infectious organisms into the peritoneum. Both types of peritonitis are life-threatening.

[0015] Current methods for determining peritonitis are subjective and place the burden on the patient. For example, patients may be told to observe the color and/or texture of their effluent fluid to look for peritonitis. Or, patients may be told to be aware of a full stomach feeling and/or fever. When the patient thinks peritonitis is oncoming or present, the patient has to bring an effluent sample to the clinic for testing. The above methods are subjective and place the burden on the patient. The below systems and methods are automatic and objective.

[0015a] In one aspect, the present disclosure includes a peritoneal dialysis ("PD") system comprising: a cycler having a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette; a catheter for placement within a patient's peritoneal cavity and for fluid communication with the patient line; and an impedance sensor operably coupled to one of the catheter, the patient line, or the drain line to sense an impedance of PD fluid residing within the patient, or removed from the patient, the impedance sensor configured for the detection of white blood cells to form a patient peritonitis determination, the control unit configured to make the peritonitis determination based on the sensed impedance and communicate the peritonitis determination.

Temperature Sensing For Peritonitis

[0016] In one primary ~~embodiment~~example, the temperature of used dialysis fluid exiting the patient is measured to detect peritonitis. In healthy patients, the temperature of used dialysis fluid is normal body temperature or about 37°C. In patients experiencing the onset of peritonitis, the used dialysis fluid exiting the patient may reside at an elevated temperature. The system and method of the first primary ~~embodiment~~example measure the effluent dialysis fluid and use the measurement to make a determination as to whether the patient may be experiencing the onset of peritonitis.

[0017] The temperature measurement may be made in a number of different ways. In one way, a temperature sensor, such as a thermocouple or thermistor is placed in a connector, such as a clamshell type connector, which clips removeably and selectively over the patient line. The

clamshell connector may be placed in any desired location around the patient line, for example, near the patient so that the temperature of the patient's effluent dialysis fluid may be taken immediately upon leaving the patient. In one ~~embodiment~~example, the temperature of the effluent fluid is compared to the temperature of the fresh dialysis fluid, which may be heated to body temperature or 37°C. In this manner, any temperature offset caused by the generally non-thermally conductive tubing is negated. For example, if the temperature of the 37°C fresh dialysis fluid is read through the tubing at an offset temperature of 32°C, the same offset will be assumed for the effluent fluid leaving the patient. The control unit reading the temperature signal will therefore look for a 32°C patient healthy signal and will trigger a potential peritonitis alert when the control unit sees a signal indicating a temperature above 32°C.

[0018] In an alternative ~~embodiment~~example, a more thermally conductive and medically safe material, such as stainless steel is spliced or fitted into the patient line. One or more thermally

conductive electrode is attached to the temperature sensor and allows for a more accurate temperature reading. Here, the control unit reading the temperature signal looks in one embodiment for a 37°C patient healthy signal and triggers a potential peritonitis alert when the control unit sees a signal indicating a temperature above 37°C. In this example, the control unit may or may not take the incoming temperature of fresh dialysis fluid into account.

[0019] In an ~~y embodiment~~example in which the temperature sensor is located remote from the cycler, the temperature sensor may send the measured signals in a wired or wireless manner to the cycler for interrogation. The temperature sensor is in one ~~embodiment~~example a passive device (e.g., two wires creating voltage based upon fluid temperature). If the temperature sensor does require power, power may be provided via a battery or from the cycler or a water purifier operating with the cycler via power wires.

[0020] In a further alternative ~~embodiment~~example, the temperature sensor, e.g., thermocouple or thermistor, is located within the dialysis machine or cycler and operates with the disposable cassette or the patient line extending from the disposable cassette. The temperature sensor contacts the flexible sheeting of the disposable cassette in one or more places in one ~~embodiment~~example. One or more thermally conductive contact may be formed in or added to the disposable cassette to help temperature sensing accuracy. As above, when sensing at or near the cassette, the control unit may or may not take the incoming temperature of fresh dialysis fluid into account.

[0021] Temperature sensing is performed alternatively in a drain line extending from the disposable cassette. The drain line is advantageous because sterility is less of an issue, such that the drain line is in one ~~embodiment~~example plugged into a reusable thermally conductive contact provided with the cycler or with a water purification device operating with the cycler.

[0022] The control unit is programmed in one ~~embodiment~~example to alert the patient at the user interface of the cycler if an elevated temperature indicating peritonitis is detected. Alternatively or additionally, the control unit operates via a network and one or more server computer to enable a doctor or clinician to view effluent temperature data, e.g., on an ongoing basis, so that the clinician may determine if the patient is at risk of peritonitis. The data is displayed in one ~~embodiment~~example on a dashboard of a website for the patient, wherein the temperature data may be presented with a flag for the clinician when it is elevated, indicating peritonitis.

Bio-MEMS Sensing For Peritonitis

[0023] In a second primary ~~embodiment~~example, which may be used alternatively or in addition to the first ~~embodiment~~example, a bio-Micro-Electro-Mechanical-System ("bio-MEMS") sensor is used to detect peritonitis. The bio-MEMS sensor is used to look for the presence of white blood cells from the patient in the effluent, which is an indicator of peritonitis. In one implementation, effluent fluid from the cycler is pumped to drain. The drain line is connected to a lab-on-chip diagnostic detection device. The lab-on-chip or bio-MEMS device includes a container into which a sampling line extends, wherein the sampling line may extend or tee off of the drain line. The effluent sample entering the container of the bio-MEMS device first encounters a microfluidic pathway that splits the patient's white blood cells from the effluent fluid. The white blood cells are then weighed using a piezoelectric biosensor in one ~~embodiment~~example. The piezoelectric biosensor resonates with a frequency proportional to a change in the deposition rate of white blood cells.

[0024] The bio-MEMS device is placed alternatively in the patient line via a sample line and used to analyze effluent returning from the patient. In this manner, the bio-MEMS device may be used to sense fresh dialysis fluid delivered to the patient additionally if desired.

[0025] In one ~~embodiment~~example, the bio-MEMS device includes the electronics and processing to process raw signals from the piezoelectric biosensor and make a determination as to the presence or not of white blood cells. The bio-MEMS device may also include a user interface to indicate to the patient or caregiver present during treatment weather or not there is an indication of peritonitis. In an alternative ~~embodiment~~example, either one or both of (i) electronics and processing to process raw signals from the piezoelectric biosensor or (ii) the user interface for patient or caregiver communication may be provided instead by the cycler or perhaps a water purification device operable with the cycler.

[0026] As with the first primary ~~embodiment~~example, the control unit and processing for the second primary ~~embodiment~~example may alternatively or additionally operate via a network and one or more server computer to enable a doctor or clinician to view bio-MEMS data, e.g., on an ongoing basis, so that the clinician may determine if the patient is at risk of peritonitis. The data of the second primary ~~embodiment~~example may be displayed in combination with the data of the first primary ~~embodiment~~example to provide a combination of peritonitis indicators.

Impedance Monitoring For Peritonitis

[0027] In a third primary ~~embodiment~~example, which may be used alternatively or in addition to the first ~~embodiment~~example and/or the second ~~embodiment~~example, an impedance monitor is used to detect peritonitis. The impedance monitor is used to look for the presence of white blood cells from the patient in the effluent fluid, which again is an indicator of peritonitis. In various implementations, the impedance monitor may be placed anywhere that the patient's effluent fluid may be sensed, for example, in the patient's indwelling catheter, along the patient line or anywhere along the drain line. In any of these locations, the catheter or line is fitted with electrodes, e.g., in any of the ways discussed above for temperature sensing, but with the goal now of placing electrically conductive contacts in communication with the effluent dialysis fluid.

[0028] An electrically conductive and medically safe material, such as stainless steel, is spliced or fitted into the catheter, patient line or drain line in one ~~embodiment~~example, e.g., via a clamshell connector or a connector that is spliced into the drain line. The control unit controlling the impedance monitor in one ~~embodiment~~example causes an electrical frequency sweep to be generated in the effluent fluid. Such impedance spectroscopy (or obtaining complex impedance) may provide additional details about the content(s) of the effluent fluid. For example, the electrical properties of fibrin (normal, not indicating peritonitis) may vary from the electical properties of white blood cells (indicating peritonitis). Once the electrical properties of different substances within the effluent fluid are learned, the properties may be programmed into the control unit and used thereafter to determine what if anything is entrained in the effluent dialysate stream.

[0029] In any ~~embodiment~~example in which the impedance monitor is located remote from the cycler, the impedance monitor may send the measured signals in a wired or wireless manner to the cycler for interrogation. The impedance monitor as mentioned above has the ability to emit a frequency sweep into the effluent fluid and thus may receive power either via a battery or from the cycler or a water purifier operating with the cycler via power wires.

[0030] In an alternative ~~embodiment~~example, the impedance monitor is located within the dialysis machine or cycler and operates with the disposable cassette or the patient or drain line extending from the disposable cassette. The impedance monitor extends through a rigid wall holding the disposable cassette sheeting in one or more places in one ~~embodiment~~example. In a further alternative ~~embodiment~~example, the impedance monitor is operable with the drain line located within a water purifier supplying purified water to the dialysis machine or cycler.

[0031] The control unit is programmed in one ~~embodiment~~example to alert the patient or caregiver at the user interface of the cycler if white blood cells indicating peritonitis are detected. Alternatively or additionally, the control unit operates via a network and one or more server computer to enable a doctor or clinician to view effluent impedance data, e.g., on an ongoing basis, so that the clinician may determine if the patient is at risk of peritonitis. The data is displayed in one ~~embodiment~~example on a dashboard of a website for the patient, wherein the effluent impedance data may be presented with a flag for the clinician when white blood cells are present, indicating peritonitis. The data of the third primary ~~embodiment~~example may be displayed in combination with the data of the first and/or second primary ~~embodiment~~examples to provide a combination of peritonitis indicators.

[0032] When the impedance monitor is placed in the indwelling catheter or in the patient line via a sample line and used to analyze effluent within the patient or returning from the patient, the impedance monitor may be used to sense fresh dialysis fluid delivered to the patient additionally if desired. When the impedance monitor is placed in the drain line, it may be used additionally to detect if dialysis fluid made at the point of use has been mixed properly.

Glucose Control for Diabetic Patients

[0033] Glucose (or dextrose) is the primary osmotic agent used with most PD solutions. The absorption of most of the peritoneal glucose load over a dwell period may have a detrimental effect on patients suffering from diabetes. Diabetes is a common cause of kidney failure leading to the need for dialysis treatment. In addition, daily exposure to glucose may induce hyperglycemia in PD patients, which can have serious consequences. Certain diabetic PD patients accordingly receive insulin with their PD treatment to help maintain a glucose balance. Patients receiving insulin with PD treatment, however, run the risk of trying to match the amount of insulin to the amount of PD treatment received.

[0034] In a fourth primary ~~embodiment~~example, which may be used alternatively or in additon to the first, second and/or third primary ~~embodiment~~examples, a bio-MEMS-insulin system and method are provided to match the amount of insulin to the amount of PD fluid used. The bio-MEMS-insulin system and method measures the glucose level of the effluent dialysis fluid leaving the patient. That measurement is then used to properly dose the patient with insulin for the next patient PD fill. In one ~~embodiment~~example, the patient is full of fluid from the previous treatment when beginning the current treatment. That effluent fluid is removed and at least a portion of which is delivered

to a MEMS affinity glucose sensor, which sends a signal to a control unit, which determines how much insulin to deliver to a PD supply volume to form a desired concentration of insulin for the initial fill. The corresponding amount of insulin is then delivered to a PD fluid supply bag to yield the desired concentration.

[0035] The MEMS affinity glucose sensor is used in one ~~embodiment~~example to measure glucose in the drained effluent. In one implementation, effluent fluid from the cycler is pumped to drain. The drain line is connected fluidically to the MEMS affinity glucose sensor. The MEMS affinity glucose sensor includes a container into which a sampling line extends, wherein the sampling line may extend or tee off of the drain line. The effluent sample entering the container of the MEMS affinity glucose sensor first encounters a microfluidic pathway that splits the glucose molecules from the effluent fluid. The glucose molecules are then weighed using a piezoelectric biosensor in one ~~embodiment~~example. The piezoelectric biosensor resonates with a frequency proportional to a change in the deposition rate of glucose molecules. Glucose absorbed at the end of an nth cycle is calculated using the equation for A_n discussed below. To compensate for the absorbed glucose for th enth cycle, the administration of the insulin dosage during the subsequent cycle would be calculated using an equation for I_{n+1} discussed below.

[0036] The MEMS affinity glucose sensor in one ~~embodiment~~example includes the electronics and processing to process raw signals from the piezoelectric biosensor and make a determination as to the proper concentration of insulin to prepare with the PD solution. The MEMS affinity glucose sensor may also include a user interface to indicate to the patient or caregiver present during treatment that the proper insulin level is being determined. In alternative ~~embodiment~~examples, either one or both of (i) electronics and processing to process raw signals from the piezoelectric biosensor or (ii) the user interface for patient or caregiver communication are provided instead by the cycler or perhaps a water purification device operable with the cycler. The PD cycler may operate with pre-prepared PD dialysis fluid or with PD dialysis fluid prepared at the point of use. With pre-prepared PD dialysis fluid, insulin is added to a heater bag or to an insulin port on the bag of the solution. With PD dialysis fluid prepared at the point of use, insulin may be added to the mixed dialysis fluid or to any component thereof (purified water, osmotic agent or electrolyte).

[0037] ~~t~~The control unit of the cycler operates via a network and one or more server computer in one ~~embodiment~~example to enable a doctor or clinician to view insulin usage data, e.g., on a

per-treatment basis, so that the clinician may confirm that insulin is being delivered properly. The data is displayed in one ~~embodiment~~example on a dashboard of a website for the patient, wherein the insulin volume and concentration with PD fluid may be viewed. The data of the fourth primary ~~embodiment~~example may be displayed in combination with the data of the first, second and/or third primary ~~embodiment~~examples to provide a desired combination of data.

[0038] In light of the disclosure herein and without limiting the disclosure in any way, in a first ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis ("PD") system includes: a cycler including a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette; and a temperature sensor operably coupled to one of the patient line, drain line or disposable cassette to sense a temperature of effluent PD fluid removed from a patient, the sensed temperature used to form a patient peritonitis determination, the control unit configured to communicate the peritonitis determination.

[0039] In a second ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the sensed temperature is sent to the control unit, and wherein the control unit is configured to analyze the sensed temperature.

[0040] In a third ~~aspect~~example of the present disclosure, which may be combined with the second ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the sensed temperature is sent to the control unit wired or wirelessly.

[0041] In a fourth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a network and at least one doctor or clinician computer in communication with the control unit via the network, the control unit configured to communicate the peritonitis determination to at least one of a patient or caregiver via a user interface of the cycler or the at least one doctor or clinician computer via the network.

[0042] In a fifth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a water purifier configured to supply purified water to the disposable set, the water purifier including a water

purifier control unit, wherein the sensed temperature is sent to the water purifier control unit, wherein the water purifier control unit is configured to analyze the sensed temperature, and wherein the cycler control unit and the water purifier control unit are in communication to allow the cycler control unit to communicate the peritonitis determination.

[0043] In a sixth ~~aspect~~example of the present disclosure, which may be combined with the fifth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, either the cycler control unit or the water purifier control unit is configured to analyze the sensed temperature.

[0044] In a seventh ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the temperature sensor is placed in a connector configured to couple to the patient line or the drain line.

[0045] In an eighth ~~aspect~~example of the present disclosure, which may be combined with the seventh ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the connector is (i) a clamshell connector that fits around the patient line or the drain line or (ii) configured to be spliced between two sections of the patient line or the drain line.

[0046] In a ninth ~~aspect~~example of the present disclosure, which may be combined with the seventh ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the connector includes electrodes positioned and arranged to contact (a) effluent fluid flowing through the patient line or the drain line or (b) the patient line or the drain line directly.

[0047] In a tenth ~~aspect~~example of the present disclosure, which may be combined with the ninth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, in (b) a thermally conductive segment is spliced between sections of the patient line or the drain line, the connector connected directly to the thermally conductive segment.

[0048] In an eleventh ~~aspect~~example of the present disclosure, which may be combined with the ninth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the connector includes leads extending from the electrodes to (i) the control unit, (ii) a control unit of a water purifier configured to supply purified water to the disposable set, or (iii) a wireless module provided with the connector.

[0049] In a twelfth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the PD system is configured to analyze the sensed temperature of the effluent PD fluid removed from the patient by comparing the sensed

temperature to a temperature of fresh PD fluid delivered to the patient and sensed by the temperature sensor.

[0050] In a thirteenth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the PD system is configured to analyze the sensed temperature of the effluent PD fluid removed from the patient by looking for an increase in temperature due to peritonitis or the onset thereof.

[0051] In a fourteenth ~~aspect~~example of the present disclosure, which may be combined with the thirteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the increase in temperature due to peritonitis or the onset thereof is detectable regardless of whether the sensed temperature is offset due to sensing through the patient line, the drain line or the disposable cassette.

[0052] In a fifteenth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is a first peritonitis indicator, and which includes at least one different peritonitis indicator useable in combination with the first peritonitis indicator to form an overall peritonitis determination.

[0053] In a sixteenth ~~aspect~~example of the present disclosure, which may be combined with the fifteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the at least one different peritonitis indicator useable in combination with the first peritonitis indicator is obtained from at least one of a white blood cell biosensor or a white blood cell impedance sensor.

[0054] In a seventeenth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is provided in combination with insulin injection made using feedback from a patient effluent glucose biosensor.

[0055] In an eighteenth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis ("PD") system includes: a cycler including a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator; and a bio-MEMS device in fluid communication with the disposable cassette, the bio-MEMS device configured to collect white

blood cells from effluent PD fluid removed from a patient, the collected white blood cells used to form a patient peritonitis determination, the control unit configured to communicate the peritonitis determination.

[0056] In a nineteenth ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, an indication of the collected white blood cells is sent to the control unit, and wherein the control unit is configured to analyze the indication of the collected white blood cells.

[0057] In a twentieth ~~aspect~~example of the present disclosure, which may be combined with the nineteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the indication of the collected white blood cells is sent to the control unit wired or wirelessly.

[0058] In a twenty-first ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a network and at least one doctor or clinician computer in communication with the control unit via the network, the control unit configured to communicate the peritonitis determination to at least one of a patient or caregiver via a user interface of the cycler or the at least one doctor or clinician computer via the network.

[0059] In a twenty-second ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the bio-MEMS device is placed in fluid communication with a sample port of the disposable cassette.

[0060] In a twenty-third ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the bio-MEMS device includes a control unit having at least one of electronics, processing and memory, wherein either the cycler control unit or the bio-MEMS device control unit is configured to analyze the sensed temperature.

[0061] In a twenty-fourth ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the bio-MEMS device includes (i) a microfluidic chip forming a microfluidic pathway sized and configurd to split the white blood cells from a remainder of effluent fluid and (ii) a piezoelectric biosensor that resonates with a frequency proportional to a property of the collected white blood cells.

[0062] In a twenty-fifth ~~aspect~~example of the present disclosure, which may be combined with the twenty-fourth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the property of the collected white blood cells includes a change in the deposition rate of the white blood cells.

[0063] In a twenty-sixth ~~aspect~~example of the present disclosure, which may be combined with the twenty-fourth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the frequency proportional to a property of the collected white blood cells is used to form the peritonitis determination.

[0064] In a twenty-seventh ~~aspect~~example of the present disclosure, which may be combined with the twenty-fourth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the piezoelectric biosensor operates with a collection area for collecting the white blood cells.

[0065] In a twenty-eighth ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the bio-MEMS device is in wired communication with the control unit or includes a wireless module for wireless communication with the control unit.

[0066] In a twenty-ninth ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system is configured to analyze an amount of white blood cells removed from the effluent PD fluid to make the peritonitis determination.

[0067] In a thirtieth ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is a first peritonitis indicator, and which includes at least one different peritonitis indicator useable in combination with the first peritonitis indicator to form an overall peritonitis determination.

[0068] In a thirty-first ~~aspect~~example of the present disclosure, which may be combined with the thirtieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the at least one different peritonitis indicator useable in combination with the first peritonitis indicator is obtained from at least one of a patient effluent PD fluid temperature sensor or a white blood cell impedance sensor.

[0069] In a thirty-second ~~aspect~~example of the present disclosure, which may be combined with the eighteenth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is provided in combination with insulin injection made using feedback from a patient effluent glucose biosensor.

[0070] In a thirty-third ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis ("PD") system includes: a cycler having a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette; a catheter for placement within a patient's peritoneal cavity and for fluid communication with the patient line; and an impedance sensor operably coupled to one of the catheter, patient line, or drain line to sense an impedance of PD fluid residing within the patient, or removed from the patient, the sensed impedance used to detect white blood cells to form a patient peritonitis determination, the control unit configured to communicate the peritonitis determination.

[0071] In a thirty-fourth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the sensed impedance is sent to the control unit, and wherein the control unit is configured to analyze the sensed impedance.

[0072] In a thirty-fifth ~~aspect~~example of the present disclosure, which may be combined with the thirty-fourth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the sensed impedance is sent to the control unit wired or wirelessly.

[0073] In a thirty-sixth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a network and at least one doctor or clinician computer in communication with the control unit via the network, the control unit configured to communicate the peritonitis determination to at least one of a patient or caregiver via a user interface of the cycler or the at least one doctor or clinician computer via the network.

[0074] In a thirty-seventh ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified

otherwise, the PD system includes a water purifier configured to supply purified water to the disposable set, the water purifier including a water purifier control unit, wherein the sensed impedance is sent to the water purifier control unit, wherein the water purifier control unit is configured to analyze the sensed impedance, and wherein the cycler control unit and the water purifier control unit are in communication to allow the cycler control unit to communicate the peritonitis determination.

[0075] In a thirty-eighth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the impedance sensor is located within a connector configured to couple to the catheter, the patient line or the drain line.

[0076] In a thirty-ninth ~~aspect~~example of the present disclosure, which may be combined with the thirty-eighth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the connector is (i) a clamshell connector that fits around the catheter, the patient line or the drain line or (ii) configured to be spliced between two sections of the catheter, the patient line or the drain line.

[0077] In a fortieth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the impedance sensor includes electrodes positioned and arranged within the catheter, the patient line or the drain line, the connector positioned over the electrodes.

[0078] In a forty-first ~~aspect~~example of the present disclosure, which may be combined with the fortieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the connector includes leads extending from the electrodes to (i) the control unit, (ii) a control unit of a water purifier configured to supply purified water to the disposable set, or (iii) a wireless module provided with the connector.

[0079] In a forty-second ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system is configured to analyze the sensed impedance of the PD fluid residing within the patient, or removed from the patient, via a frequency sweep that moves from a start frequency to a stop frequency.

[0080] In a forty-third ~~aspect~~example of the present disclosure, which may be combined with the forty-second ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified

otherwise, the frequency sweep is generated by a frequency generator provided by or operable with the control unit.

[0081] In a forty-fourth aspect of the present disclosure, which may be combined with the forty-second aspect in combination with any other aspect listed herein unless specified otherwise, the PD system is configured to take an impedance measurement at two or more frequencies of the frequency sweep.

[0082] In a forty-fifth ~~aspect~~example of the present disclosure, which may be combined with the forty-second ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the frequency sweep enables fluid having white blood cells and residing within the patient, or removed from the patient, to be determined by measuring, over at least a portion of the frequency sweep, higher impedances for the fluid having white blood cells than impedances for fluid not having white blood cells. And, the measured impedances for fluid not having white blood cells (i) are determined based on standard impedances or (ii) are determined based on impedances established for the patient.

[0083] In a forty-sixth ~~aspect~~example of the present disclosure, which may be combined with the forty-second ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the frequency sweep enables fluid having white blood cells and residing within the patient, or removed from the patient, to be distinguished from fluid having fibrin, wherein the fluid having fibrin yields higher impedances over at least a portion of the sweep than the fluid having white blood cells.

[0084] In a forty-seventh ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is a first peritonitis indicator, and which includes at least one different peritonitis indicator useable in combination with the first peritonitis indicator to form an overall peritonitis determination.

[0085] In a forty-eighth ~~aspect~~example of the present disclosure, which may be combined with the forty-seventh ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the at least one different peritonitis indicator useable in combination with the first peritonitis indicator is obtained from at least one of a patient effluent PD fluid temperature sensor or a white blood cell biosensor.

[0086] In a forty-ninth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the peritonitis determination is provided in combination with insulin injection made using feedback from a patient effluent glucose biosensor.

[0087] In a fiftieth ~~aspect~~example of the present disclosure, which may be combined with the thirty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis ("PD") system includes: a cycler including a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator; an insulin source in fluid communication with the disposable set; and a micro-electro-mechanical-system ("MEMS") affinity glucose sensor positioned and arranged to receive effluent PD fluid removed from a patient, the MEMS affinity glucose sensor configured to provide a glucose assessment concerning glucose absorbed by a patient, the glucose assessment used to determine an insulin dose, and wherein the control unit is configured to deliver the insulin dose from the insulin source to the patient via the pump actuator operating with the pump chamber of the disposable cassette.

[0088] In a fifty-first ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a dialysis fluid source in fluid communication with the disposable set, and wherein the control unit is configured to deliver the insulin dose from the insulin source to the patient mixed with fresh dialysis fluid from the dialysis fluid source.

[0089] In a fifty-second ~~aspect~~example of the present disclosure, which may be combined with the fifty-first ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the dialysis fluid source is a point of use dialysis fluid source, wherein the fresh dialysis fluid is mixed within a mixing bag along with insulin from the insulin bag.

[0090] In a fifty-third ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the disposable set includes a patient line and a drain line in fluid communication with the disposable cassette, the MEMS affinity glucose sensor in fluid communication with the drain line.

[0091] In a fifty-fourth ~~aspect~~example of the present disclosure, which may be combined with the fifty-third ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the MEMS affinity glucose sensor is located along the drain line upstream of a drain container.

[0092] In a fifty-fifth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a water purifier, wherein the dialysis fluid source is a point of use dialysis fluid source using purified water from the water purifier, and wherein the MEMS affinity glucose sensor is provided with the water purifier.

[0093] In a fifty-sixth ~~aspect~~example of the present disclosure, which may be combined with the fifty-fifth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the water purifier is in wired or wireless communication with the cycler, wherein the water purifier is configured to determine the insulin dose from the glucose assessment and deliver the insulin dose to the cycler for delivery.

[0094] In a fifty-seventh ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the MEMS affinity glucose sensor is in wired or wireless communication with the cycler, wherein the control unit of the cycler is configured to determine the insulin dose from the glucose assessment sent from the MEMS affinity glucose sensor to the control unit.

[0095] In a fifty-eighth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the MEMS affinity glucose sensor is configured to determine the insulin dose from the glucose assessment.

[0096] In a fifty-ninth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the glucose assessment is indicative of an amount or concentration of glucose absorbed by the patient.

[0097] In a sixtieth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the MEMS affinity glucose sensor includes (i) a microfluidic chip forming a microfluidic pathway sized and configurd to split glucose molecules from a remainder of effluent fluid and (ii) a

piezoelectric biosensor that resonates with a frequency proportional to a property of the collected glucose molecules.

[0098] In a sixty-first ~~aspect~~example of the present disclosure, which may be combined with the sixtieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the property of the collected glucose molecules includes a change in the deposition rate of the glucose molecules.

[0099] In a sixty-second ~~aspect~~example of the present disclosure, which may be combined with the sixtieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the frequency proportional to a property of the collected glucose molecules is used to form the insulin determination.

[00100] In a sixty-third ~~aspect~~example of the present disclosure, which may be combined with the sixtieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the piezoelectric biosensor operates with a collection area for collecting the glucose molecules.

[00101] In a sixty-fourth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the control unit is programmed assuming the lower the concentration of glucose in the effluent, the higher the amount of glucose absorbed by the patient.

[00102] In a sixty-fifth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes a network and at least one doctor or clinician computer in communication with the control unit via the network, the control unit configured to communicate the insulin dose to at least one of a patient or caregiver via a user interface of the cycler or the at least one doctor or clinician computer via the network.

[00103] In a sixty-sixth ~~aspect~~example of the present disclosure, which may be combined with the fiftieth ~~aspect~~example in combination with any other ~~aspect~~example listed herein unless specified otherwise, the PD system includes at least one peritonitis indicating device selected from a patient effluent PD fluid temperature sensor, a white blood cell biosensor or a white blood cell impedance monitor.

[00104] In a sixty-seventh ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis

("PD") system includes: a cycler including a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a pump portion sized and arranged to be held by the cycler such that the pump portion is in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette; a catheter for placement within a patient's peritoneal cavity and for fluid communication with the patient line; and an impedance sensor operably coupled to one of the catheter, patient line, or drain line to sense an impedance of PD fluid residing within the patient, or removed from the patient, the sensed impedance used to detect white blood cells to form a patient peritonitis determination.

[00105] In a sixty-eighth ~~aspect~~example of the present disclosure, which may be combined with any other ~~aspect~~example listed herein unless specified otherwise, a peritoneal dialysis ("PD") system includes: a pump actuator and a control unit in operable communication with the pump actuator; a disposable set including a pump portion sized and arranged to be placed in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette; a catheter for placement within a patient's peritoneal cavity and for fluid communication with the patient line; and an impedance sensor operably coupled to one of the catheter, patient line, or drain line to sense PD fluid residing within the patient, or removed from the patient, over a frequency sweep that moves from a start frequency to a stop frequency, the sensed impedance frequency sweep used to detect white blood cells to form a patient peritonitis determination.

[00106] In a sixty-ninth ~~aspect~~example of the present disclosure, any of the structure and functionality disclosed in connection with Figs. 1 to 20B may be included or combined with any of the other structure and functionality disclosed in connection with Figs. 1 to 20B.

[00107] In light of the present disclosure and the above ~~aspect~~examples, it is therefore an advantage of the present disclosure to provide an improved peritoneal dialysis ("PD") system and method.

[00108] It is another advantage of the present disclosure to provide a PD system and method that enable peritonitis to be determined on an objective basis.

[00109] It is a further advantage of the present disclosure to provide a PD system and method that enable peritonitis to be determined automatically without over-burdening the patient.

CLAIMS

The invention is claimed as follows:

1. A peritoneal dialysis ("PD") system comprising:

a cycler including a pump actuator and a control unit in operable communication with the pump actuator;

a disposable set including a disposable cassette having a pump chamber, the disposable cassette sized and arranged to be held by the cycler such that the pump chamber is in operable communication with the pump actuator, the disposable set including a patient line and a drain line extending from the disposable cassette;

a catheter for placement within a patient's peritoneal cavity and for fluid communication with the patient line; and

an impedance sensor operably coupled to one of the catheter, the patient line, or the drain line to sense an impedance of PD fluid residing within the patient, or removed from the patient, the ~~sensed impedance used to detect~~impedance sensor configured for the detection of white blood cells to form a patient peritonitis determination, the control unit configured to make the peritonitis determination based on the sensed impedance and communicate the peritonitis determination.

2. The PD system of Claim 1, wherein the sensed impedance is sent to the control unit, and wherein the control unit is configured to analyze the sensed impedance.

3. The PD system of Claim 2, wherein the sensed impedance is sent to the control unit wired or wirelessly.

4. The PD system of Claim 1, which includes a network and at least one doctor, or clinician, computer in communication with the control unit via the network, the control unit configured to communicate the peritonitis determination to at least one of a patient or caregiver via a user interface of the cycler or the at least one doctor, or clinician, computer via the network.

5. The PD system of Claim 1, which includes a water purifier configured to supply purified water to the disposable set, the water purifier including a water purifier control unit, wherein the sensed

impedance is sent to the water purifier control unit, wherein the water purifier control unit is configured to analyze the sensed impedance, and wherein the cycler control unit and the water purifier control unit are in communication to allow the cycler control unit to communicate the peritonitis determination.

6. The PD system of Claim 1, wherein the impedance sensor is located within a connector configured to couple to the catheter, the patient line, or the drain line.

7. The PD system of Claim 6, wherein the connector is (i) a clamshell connector that fits around the catheter, the patient line, or the drain line, or (ii) configured to be spliced between two sections of the catheter, the patient line, or the drain line.

8. The PD system of Claim 6, wherein the impedance sensor includes electrodes positioned and arranged within the catheter, the patient line, or the drain line, the connector positioned over the electrodes.

9. The PD system of Claim 8, wherein the connector includes leads extending from the electrodes to (i) the control unit, (ii) a control unit of a water purifier configured to supply purified water to the disposable set, or (iii) a wireless module provided with the connector.

10. The PD system of Claim 1, ~~which~~wherein the control unit is configured to analyze the sensed impedance of the PD fluid residing within the patient, or removed from the patient, via a frequency sweep that moves from a start frequency to a stop frequency.

11. The PD system of Claim 10, wherein the frequency sweep is generated by a frequency generator provided by or operable with the control unit.

12. The PD system of Claim 10, ~~which~~wherein the control unit is configured to take an impedance measurement at two or more frequencies of the frequency sweep.

13. The PD system of Claim 10, wherein the frequency sweep enables fluid having white blood cells and residing within the patient, or removed from the patient, to be determined by measuring, over at least a portion of the frequency sweep, higher impedances for the fluid having white blood cells than impedances for fluid not having white blood cells.

14. The PD system of Claim 10, wherein the frequency sweep enables fluid having white blood cells and residing within the patient, or removed from the patient, to be distinguished from fluid having fibrin, wherein the fluid having fibrin yields higher impedances over at least a portion of the frequency sweep than the fluid having white blood cells.

15. The PD system of Claim 1, wherein the peritonitis determination is a first peritonitis indicator, and ~~which includes~~the control unit is configured to obtain at least one different peritonitis indicator useable in combination with the first peritonitis indicator to form an overall peritonitis determination.

16. The PD system of Claim 15, wherein the at least one different peritonitis indicator useable in combination with the first peritonitis indicator is obtained from at least one of a patient effluent PD fluid temperature sensor or a white blood cell biosensor.

17. The PD system of Claim 1, wherein the peritonitis determination is provided in combination with an insulin injection made using feedback from a patient effluent glucose biosensor.