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(54) **AUTOMATED THERAPY SYSTEM AND METHOD**

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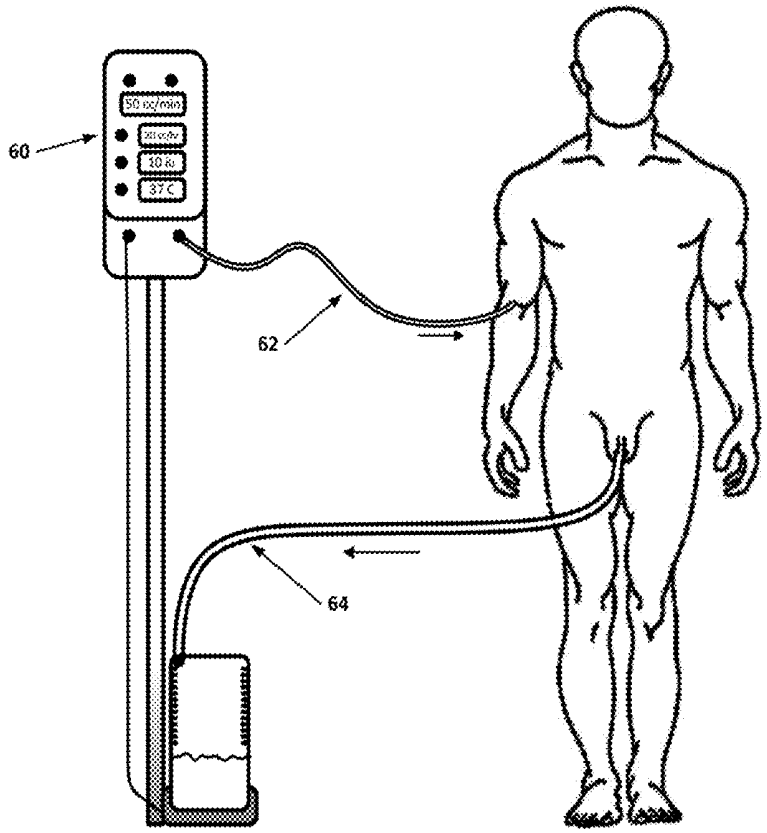
(57) **ABSTRACT**

An automated therapy system having an infusion catheter; a sensor adapted to sense a patient parameter; and a controller communicating with the sensor and programmed to control flow output from the infusion catheter into a patient based on the patient parameter without removing fluid from the patient. The invention also includes a method of controlling infusion of a fluid to a patient. The method includes the following steps: monitoring a patient parameter with a sensor to generate a sensor signal; providing the sensor signal to a controller; and adjusting fluid flow to the patient based on the sensor signal without removing fluid from the patient.



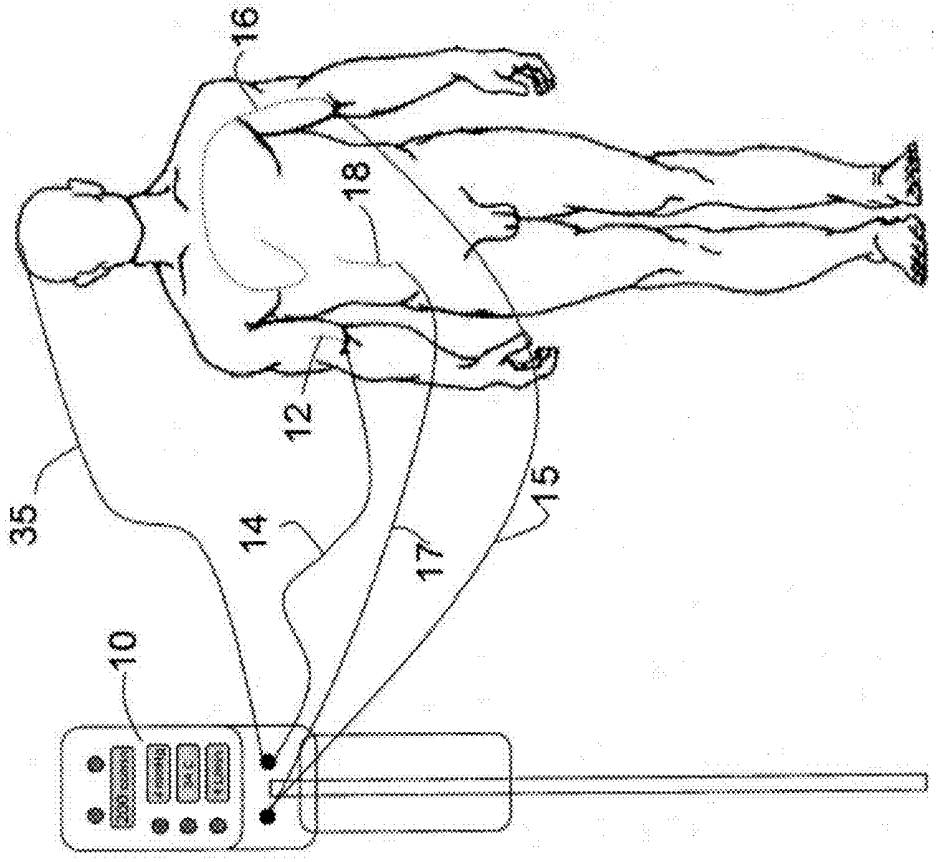


Figure 1

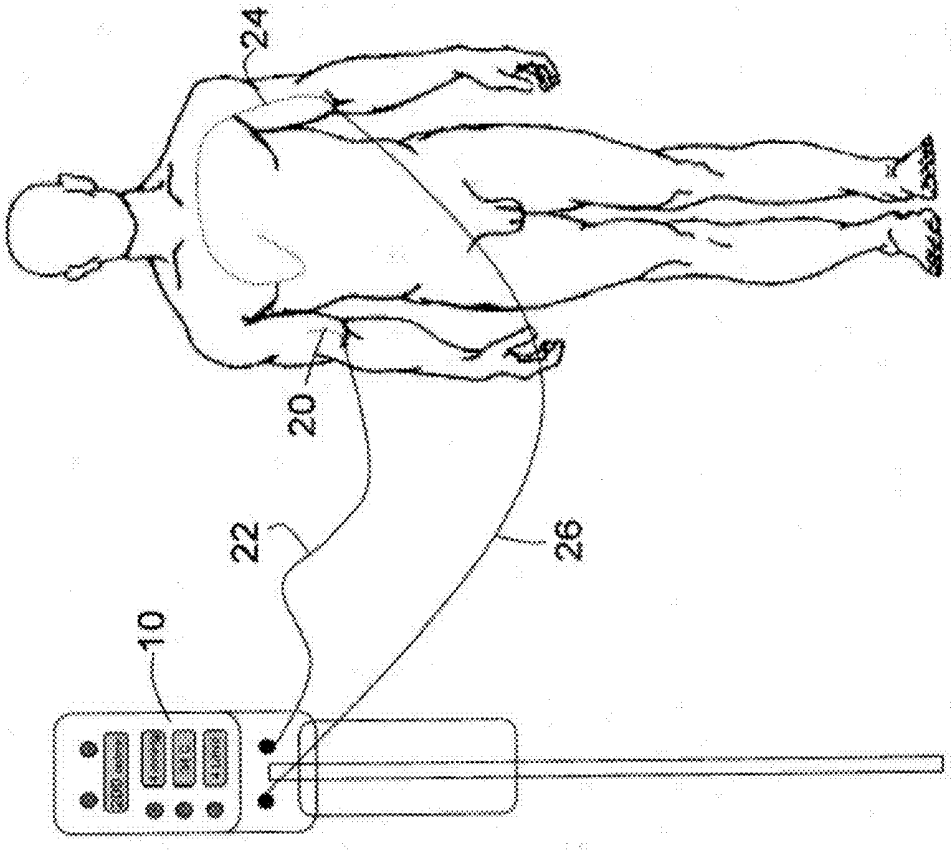


Figure 2

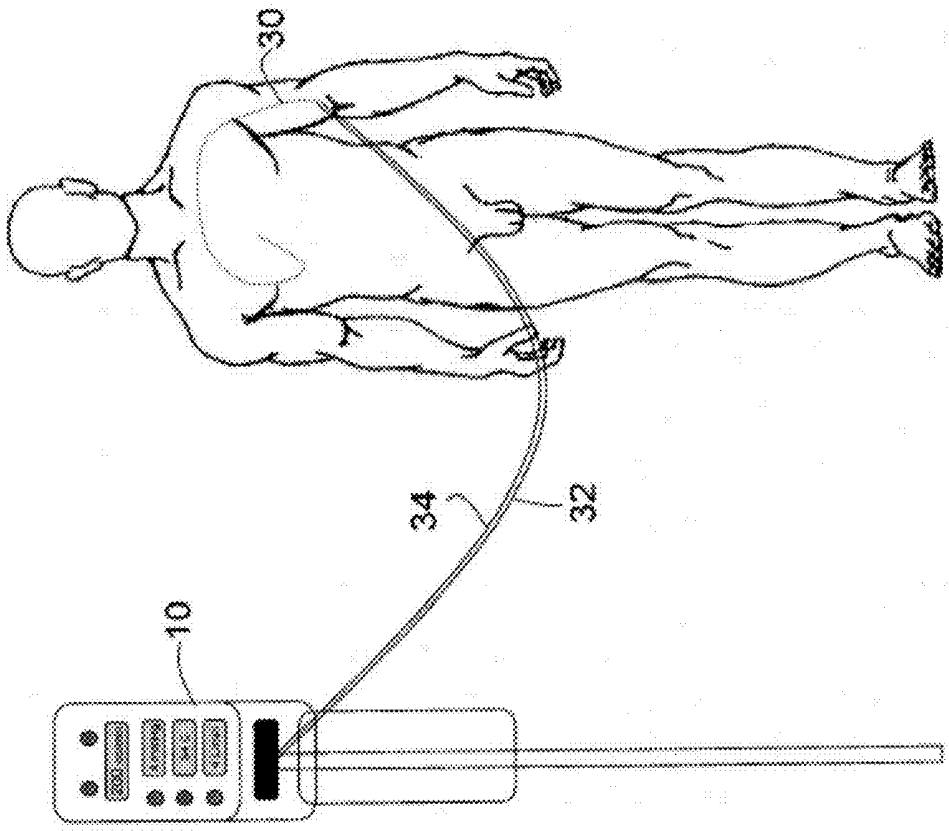


Figure 3

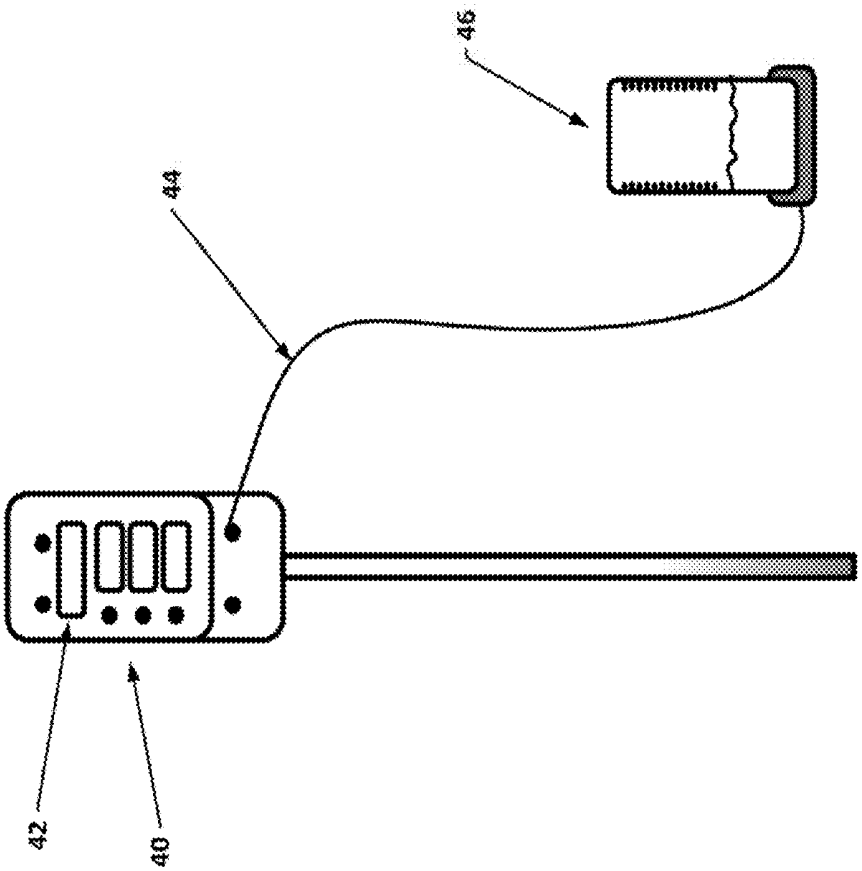


Figure 4

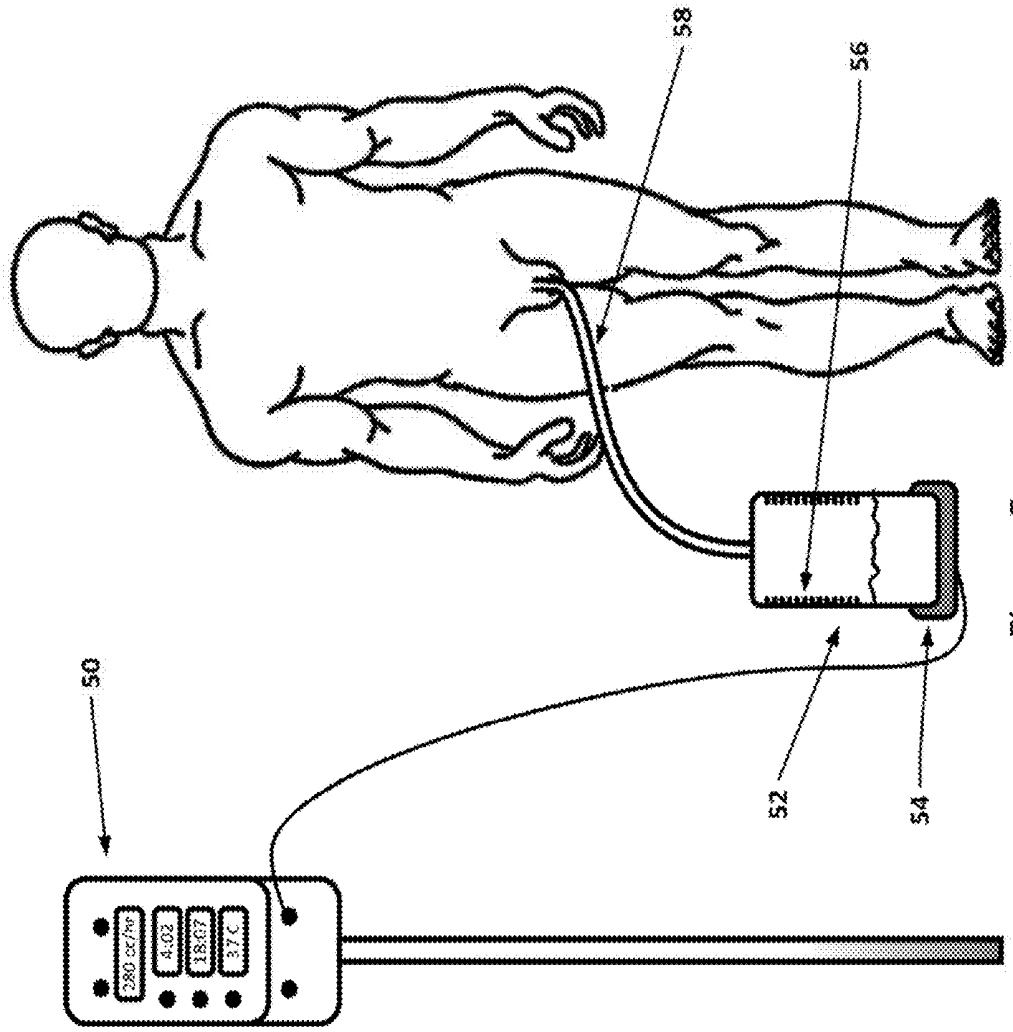


Figure 5

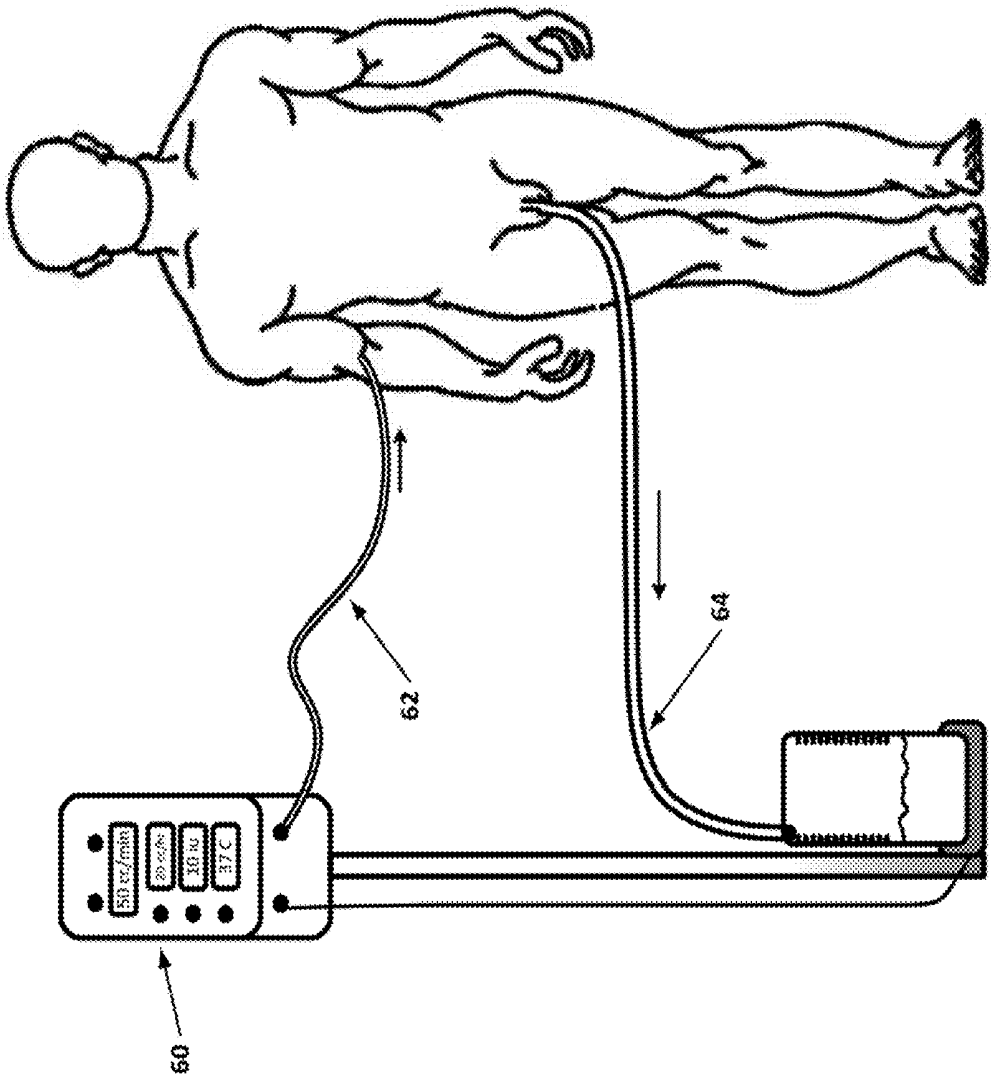


Figure 6

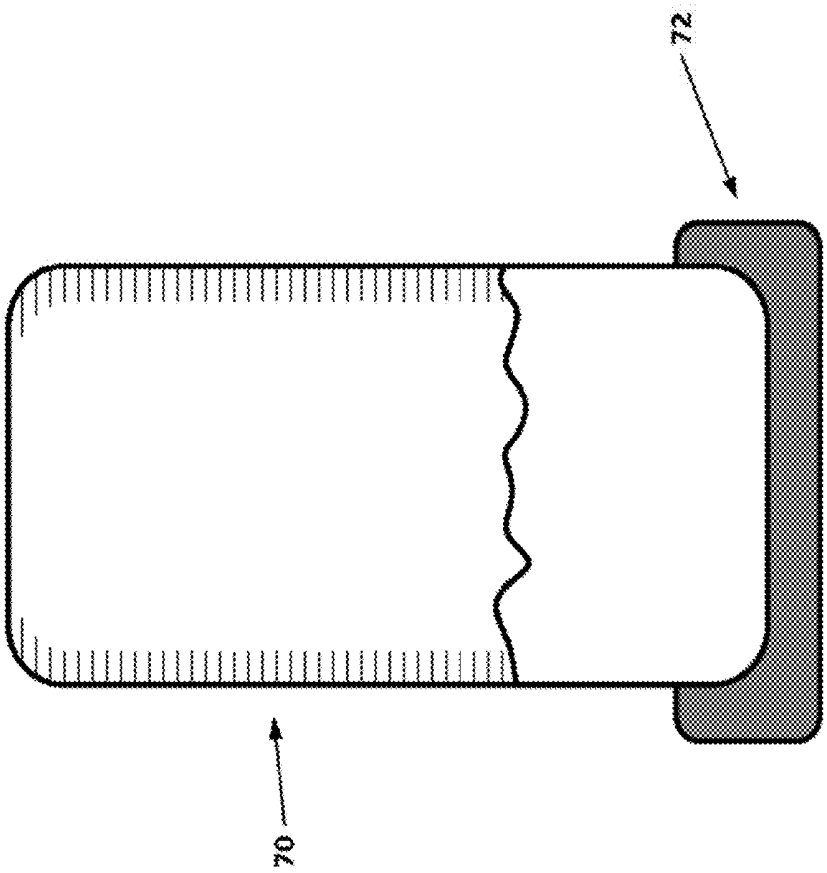


Figure 7

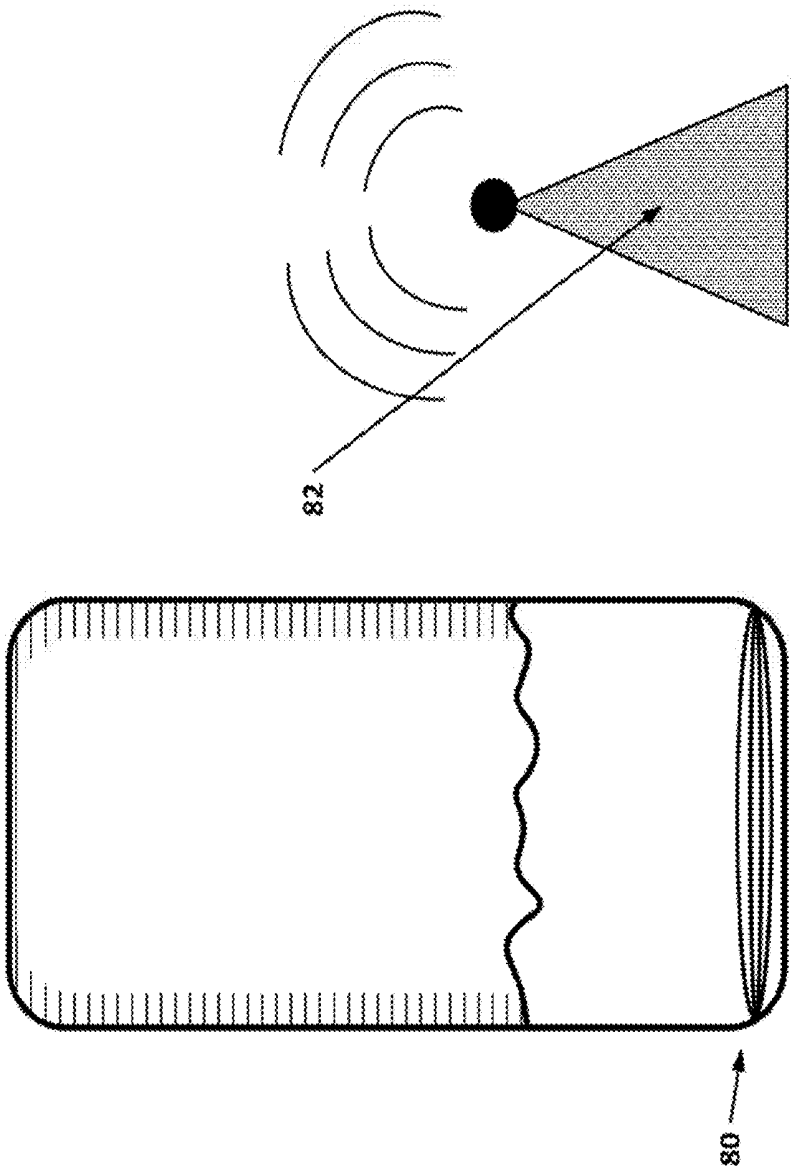


Figure 8

AUTOMATED THERAPY SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 13/937,102, filed Jul. 8 2013; which application is a continuation of U.S. application Ser. No. 13/354,210, filed Jan. 19, 2012, now U.S. Pat No. 8,480,648; which application is a continuation of U.S. application Ser. No. 12/098,365, filed Apr. 4, 2008, now U.S. Pat. No. 8,100,880; which application claims the benefit of U.S. Provisional Patent Application No. 60/921,974, filed Apr. 5, 2007 to Burnett, entitled "Safety Access Device, Fluid Output Monitor & Peritoneal Organ Preservation", all disclosures of which are incorporated by reference herein in their entirety.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND OF THE INVENTION

[0003] Fluids and other substances are infused into patients for a variety of reasons. For example, fluids may be given to a patient intravenously to hydrate the patient or to control overall blood volume.

[0004] It is often important to control infusion of fluid into patients in order to optimize the therapy being provided. Monitoring of patient parameters can consume precious health care time and resources, however. Fluid infusion into patients is therefore not always optimized.

[0005] Mantle US 2006/0161107 describes a system that extracts fluid from a body cavity, processes the fluid and then recirculates fluid back into the cavity. Mantle does not describe infusion of a fluid into a patient without extraction of the fluid from the patient, however. In addition, the parameters on which the Mantle system is controlled are limited.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention provides an automated therapy system having an infusion catheter; a sensor adapted to sense a patient parameter; and a controller communicating, with the sensor and programmed to control flow output from the infusion catheter into a patient based on the patient parameter without removing fluid from the patient. In some embodiments, the sensor may be incorporated into the catheter, and in other embodiments, the sensor may be separate from the catheter. The sensor may be, e.g., an ECG sensor; an EEG sensor; a pulse oximetry sensor; a blood pressure sensor; a cardiac output sensor; a thermodilution cardiac output sensor; a cardiac stroke volume sensor; a heart rate sensor; a blood flow sensor; a pH sensor; a blood pO_2 sensor; an intracranial pressure sensor; and/or a solute sensor.

[0007] In embodiments of the invention, the catheter may be a peripheral venous catheter; a central venous catheter; an arterial catheter; or a peritoneal catheter (possibly incorporating an intraperitoneal pressure sensor).

[0008] Another aspect of the invention provides a method of controlling infusion of a fluid to a patient. The method includes the following steps: monitoring a patient parameter with a sensor to generate a sensor signal; providing the sensor signal to a controller; and adjusting fluid flow to the patient based on the sensor signal without removing fluid from the patient. In some embodiments, the method includes the step of monitoring cardiac output with the sensor and, possibly, adjusting fluid flow to the patient based on cardiac output monitored by the sensor. In embodiments of the invention, the patient parameter includes an electrocardiogram; an electroencephalogram; blood oxygen saturation; blood pressure; cardiac. output; cardiac stroke volume; heart rate; blood flow; total circulating blood volume; whole body oxygen consumption; pH; blood pO_2; osmolarity; peritoneal cavity compliance; intrathoracic pressure; bladder pressure; and/or rectal pressure.

[0009] In some embodiments, the adjusting step includes the step of adjusting fluid flow to achieve or maintain patient euvolumia; adjusting flow of a therapeutic agent (such as a chilled medium) to the patient; adjusting fluid flow to the patient through a peripheral venous catheter; adjusting fluid flow to the patient through a central venous catheter; adjusting fluid flow to the patient through an arterial catheter; and/or adjusting fluid flow to the patient's peritoneal cavity.

[0010] Yet another aspect of the invention provides a method of treating hypotension in a patient. The method includes the following steps: monitoring a patient parameter (such as blood pressure or cardiac output) with a sensor to generate a sensor signal; providing the sensor signal to a controller; and adjusting fluid flow to the patient based on the sensor signal without removing fluid from the patient.

[0011] Still another aspect of the invention provides a method of treating sepsis in a patient. The method includes the following steps: monitoring a patient parameter (such as blood pressure, central venous pressure, or cardiac output) with a sensor to generate a sensor signal; providing the sensor signal to a controller; and adjusting fluid flow to the patient based on the sensor signal without removing fluid from the patient. Prevention of hypotension and/or hypovolemia is critical in the care of patients that have suffered severe hemorrhage or are septic. These patients are very difficult to monitor and treat, taking significant nursing time and still resulting in suboptimal therapy due to the intermittent nature of the blood pressure, central venous pressure and/or cardiac output cheeks. The present invention, then, will optimize fluid flow to the patient while also freeing up the already over-taxed nursing staff for other duties.

[0012] Yet another aspect of the invention provides a method of inducing and reversing therapeutic hypothermia in a patient. The method includes the steps of: monitoring intracranial pressure to generate a sensor signal; providing the sensor signal to a controller; and adjusting rate of hypothermia induction or rewarming based on intracranial pressure (such as by adjusting fluid flow to the patient), or depth of hypothermia, based on the sensor signal.

[0013] In some embodiments of the invention, irrigation and/or lavage of bodily tissues, cavities or spaces (or other patient interventions) may be optimized using a sensor or sensors to report electrical, chemical, acoustic, mechanical properties, pressure, temperature, pH or other parameters surrounding the access device in order to automate and optimize the irrigation/lavage.

[0014] Embodiments of the invention include a peritoneal catheter containing one or more sensors which may detect changes in electrocardiograph monitoring, electroencephalograph monitoring, pulse oximetry (either internally or peripherally), peritoneal cavity compliance, intrathoracic pressure, intraperitoneal pressure, intraperitoneal pressure waveforms, bladder pressure, rectal pressure, cardiac output, cardiac stroke volume, cardiac rate, blood flow (e.g., in superior mesenteric, celiac, renal or other arteries), pressure in veins (particularly the inferior vena cava or those that empty into the inferior vena cava, e.g., femoral vein), pressure in arteries (particularly those distal to the aorta, e.g., the femoral artery), total circulating blood volume, blood oxygenation (e.g., in rectal mucosa, peripheral fingers and toes, etc.), whole body oxygen consumption, pH and/or arterial pO_2 (or any other parameter that shows a measurable change with increased peritoneal pressure) to ensure safety of automated or manual peritoneal lavage. The invention also includes methods of performing peritoneal lavage using such devices.

[0015] Embodiments of the invention include an intravascular catheter containing one or more sensors which may detect changes in electrocardiograph monitoring, electroencephalograph monitoring, pulse oximetry (either internally or peripherally), partial pressure of oxygen or CO_2, pH, temperature, blood pressure, central venous pressure, cardiac output, cardiac stroke volume, cardiac rate, blood flow (e.g., in superior mesenteric, celiac, renal or other arteries), total circulating blood volume, pressure in veins (particularly those that empty into the inferior vena cava, e.g., femoral vein), pressure in arteries (particularly those distal to the aorta, e.g., the femoral artery), blood oxygenation (e.g., in rectal mucosa, peripheral fingers and toes, etc.), whole body oxygen consumption, pH and/or arterial pO_2 (or any other parameter that shows a measurable change with intravascular volume overload) to ensure safety of manual or automated intravascular infusion. The invention also includes methods of using such devices.

[0016] Other embodiments of the invention include control of the rate of infusion to minimize negative effects observed by the sensors. The invention may be used to induce and/or maintain hypothermia or hyperthermia; maximize hydration and/or intravascular volume in a patient receiving intravenous fluids (such as, e.g., post-operative patients, post-hemorrhage patients, septic patients or other intensive care patients),

[0017] Disclosed is a method and device for detection of intake and/or output in an individual. Fluid detection may be fully automated and the user may be alerted if volumes become too low or too high. The data may also be automatically routed to a centralized data collection server so that it may be collected and accessed without the requirement for nursing or other healthcare personnel to record the information manually. The output receptacle, in particular, may contain wireless technology, ie RFID, as well to optimize data collection and reduce nursing burden.

[0018] In reviewing the obstacles of urine output monitoring and data collection, then, it becomes clear that what is needed for widespread adoption is an easily implemented system capable of accurately measuring urine output wherein the use of the device reduces the nursing burden while reporting any issues with urine output in a timely manner. The present invention may also measure and report bladder temperature in real-time and this information may be used to alert the healthcare providers of changes in therapy and/or may be used to control and direct depth of therapeutic hypothermia. The reservoir/receptacle may also contain sensors capable of detecting other materials of interest within the fluid including, but not limited to: hemoglobin, blood, bacteria, leukocyte esterase, glucose, protein, particulate matter, etc. This information may also trigger an alert to provide real-time data monitoring of these parameters. Additionally, the present invention anticipates the use of wired or, ideally, wireless transmission of data to allow for centralized collection of data and centralized reporting. This is, once again, useful in reducing healthcare provider burden by allowing fewer personnel to monitor the data from all of the patients utilizing said system.

[0019] In addition, the system of the present invention anticipates the use of RFID technology within or attached to the reservoir itself which may be remotely queried and interrogated by one or more RFID readers. The data collected may be encrypted and specific to each receptacle such that the up.ne output reported may be securely associated with an individual patient. In its optimal embodiment, the reservoir may contain conducting channels connected to the RFID circuitry which determine the urine level by detection of the level of a simple short-circuit through the conducting fluid itself which may then be reported by the RFID chip to the reader. This cheap, easy-to-use system overcomes the obstacles of previous attempts to automate urine output monitoring.

[0020] In addition, information collected using the present invention may be used to automatically adjust therapeutic hypothermia, delivery of medicine or other interventions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0022] FIG. **1** shows an automated infusion system in which infusion is controlled based on patient parameters sensed by multiple sensors.

[0023] FIG. **2** shows an automated infusion system in which a sensor controlling infusion is separate from the infusion catheter.

[0024] FIG. **3** shows an automated infusion system in which sensing and infusion are performed with the same catheter.

[0025] FIG. **4**—Console with optional sensor lead (may be wireless).

[0026] FIG. **5**—Sensor-based Urine Output Measurement.

[0027] FIG. **6**—Console with automated infusion therapy system.

[0028] FIG. **7**—Volume-sensing Urine Receptacle with Dock.

[0029] FIG. **8**—Volume-sensing Urine Receptacle—RFID Embodiment

DETAILED DESCRIPTION OF THE INVENTION

[0030] FIGS. **1-3** show embodiments of the invention wherein intravenous fluid delivery may be automated, or

manually adjusted, based on feedback from one or more sensors. In these embodiments, the infusion catheter may have a sensor to aid in insertion, but this is not necessary for this invention.

[0031] In one embodiment, the infusion catheter also is used to detect the parameters used to optimize therapy. FIG. **1** shows an infusion system with an infusion controller **10** operably connected to an intravenous infusion catheter **12** via an infusion line **14**. Infusion catheter **12** also has a sensor (not shown) attached to or associated with it to monitor a patient parameter. The sensor also communicates with controller **10** either through line **14** or via some other communication channel. Suitable patient parameters include electrocardiograph monitoring, electroencephalograph monitoring, pulse oximetry (either internally or peripherally), blood pressure, central venous pressure, cardiac output, cardiac stroke volume, cardiac rate, blood flow (e.g., in superior mesenteric, celiac, renal or other arteries), total circulating blood volume, pressure in veins (particularly those that empty into the inferior vena cava, e.g., femoral vein), pressure in arteries (particularly those distal to the aorta, e.g., the femoral artery), blood oxygenation (e.g., in rectal mucosa, peripheral fingers and toes, etc.), whole body oxygen consumption, pH, arterial pO_2, or any other parameter that shows a measurable change with intravascular volume overload.

[0032] As shown in FIG. **1**, additional catheters, here envisioned as a peripherally inserted central catheter (PICC) **16** and/or a peritoneal catheter **18**, or additional sensors on infusion catheter **12** may be used to monitor these or other parameters, and to optimize the infusion rate and achieve euvolemia without fluid overload or dehydration. Flow of fluid and/or a fluid/solid mixture an ice slurry) to catheters **16** and/or **18** is controlled by controller **10** through lines **14**, **15** and/or **17**, respectively. The information from the sensors may then be transmitted to central controller **10**, which integrates all of this information to determine the flow of intravenous fluid through catheter **12** and/or catheter **16** and flow of peritoneal fluid through catheter **18**. This information may be used to achieve or maintain euvolemia (e.g., in sepsis, hemorrhagic shock, etc.) or to maximize infusion for delivery of a therapeutic, agent, e.g., chilled fluid and/or solids to achieve hypothermia. Alternatively, catheters **16** and **18** may be used with sensors to Obtain patent information, and fluid may be infused into the patient solely through catheter **16** or catheter **18**. In yet further embodiments, the depth of hypothermia and/or rate of hypothermia induction or rewarming may be tailored based on intracranial pressure sensor(s) (not shown) communicating with controller **10** via communication line **35**. This system and method may be used with any method of inducing hypothermia (e.g., cooling blankets, intravascular catheters, intravenous fluid infusion, peritoneal lavage, etc.) so long as the change in temperature, particularly rewarming, is controlled at least in pan by an intracranial pressure sensor,

[0033] The sensor or sensors, whether cables/catheters or percutaneous monitoring technologies, and whether wired or wireless, may also be separate from the infusion line so long as the information from this sensor or sensors is transferred to the control unit in order to optimize fluid flow. Thus, as shown in FIG. **2**, the patient parameter sensor may be associated with PICC **24** and communicate with controller via line **26**, and infusion to the patient may be via line **22** and infusion catheter **20**, as controlled by controller **10**. In some embodiments, of course, sensing and infusion may be performed through a single catheter, such as PICC **30**, and controlled by controller **10** through lines **32** and **34**, as shown in FIG. **3**. In some embodiments, the infusion and monitoring device of the current invention may incorporate an access sensor, such as that described in a commonly owned patent application, U.S. patent application Ser. No. 12/098,355, filed Apr. 4, 2008, titled "Device And Method For Safe Access To A Body Cavity".

[0034] One example of such a device is a peripheral venous, central venous or arterial catheter that is capable of maintaining hydration without causing fluid overload. The catheter may incorporate a sensor that may detect central venous pressure, total circulating blood volume, peripheral venous pressure, cardiac output or osmolarity, and/or solute concentrations (e.g., chloride, sodium, etc.) in order to prevent fluid overload. The sensor may also be external to the catheter, so long as the output of said sensor is capable of controlling fluid flow through the catheter. In this embodiment, fluid flow is controlled by the output of the sensor, which is integrated by a fluid flow control unit which alters the rate of fluid flow based on this output. This embodiment may allow the user to bolus large volumes of fluids or solids into the vascular space in order to rehydrate, induce hypothermia or reverse hypothermia, or deliver a therapeutic agent or maintain blood pressure in sepsis.

[0035] In addition, this technology may provide a fully automated mechanism to optimize fluid flow into the vessel without fluid overloading the patient. Without this automated fluid delivery coupled to hemodynamic parameter monitoring, the patient is in danger of dehydration or fluid overload from infusion of fluid into any body cavity. This technology may also be applied to liquid or solid infusion into any body cavity or space in so long as the fluid flow is automated based on feedback from sensors within the body (possibly incorporated into the catheter itself) in order to optimize the volume of infusion.

[0036] This device and method of automating fluid flow based on hemodynamic sensor-based feedback may also be used to generate intravenous hypothermia. In its current state, IV hypothermia induction is limited due to concerns of fluid overload. If the hemodynamic parameters of the patient can be measured and fluid flow directly or indirectly controlled based on the output of these measurements, the volume of fluid can be maximized while ensuring hemodynamic instability. In this embodiment, the sensor may be incorporated within the catheter, and fluid flow into the vasculature may be tailored based on central venous pressure, total circulating, blood volume, peripheral venous pressure, cardiac output or osmolarity, and/or solute concentrations (e.g., chloride, sodium, etc.) in order to prevent fluid overload.

[0037] In one embodiment, the fluid infusion catheter also may function as a thermodilution cardiac output sensor such that the same fluid that is used to generate hypothermia may also be used to detect cardiac output. This information may then be relayed, either directly or indirectly, back to the fluid infusion controller to increase, decrease or even halt fluid flow based on these parameters. For example, if cardiac output is low and venous pressure or total circulating volume is low, the patient has a low circulating volume and large volumes of fluid may be safely delivered. If the cardiac output is normal, fluid may also be safely delivered, but the cardiac output must be monitored to ensure that it does not

begin to decrease (an indication of fluid overload). Blood flow, as detected by, for instance, thermodilution may be determined in a peripheral vessel as well. These data, while relatively useless on their own in a clinical setting due to variability in peripheral blood flow, may provide a baseline flow profile which may be rechecked over time in order to compare flow within that individual vessel to the baseline flow. Relatively improved flow may be correlated to improved cardiac output, while a relative reduction in flow may be correlated to fluid overload.

[0038] This same system may be used to infuse normal fluids or hypothermic fluids to sepsis patients or patients requiring intensive maintenance of their hemodynamic status. Sepsis patients that are aggressively monitored do much better than those that are not. Aggressive monitoring is very nurse-intensive, however. A system that provides automated optimal fluid infusion based on sensed parameters to ensure that fluid overload does not occur and that fluid infusion is not insufficient would be an improvement over current methods of treating sepsis patients. The devices and methods for automated sensor-based input to control fluid flow to a patient may be applicable to a wide range of conditions and should not be limited to the narrow scope of the conditions requiring fluid infusion described here.

[0039] The logic controller of the present invention may provide improved safety by monitoring for any of the deleterious changes expected with excess fluid flow, e.g., into the peritoneal cavity or vascular space. Examples of monitored parameters that may signal a warning or automatically result in an adjustment to rate of fluid infusion/extraction and/or fluid temperature include: electrocardiograph monitoring, electroencephalograph monitoring, pulse oximetry (either internally or peripherally), peritoneal cavity compliance, intrathoracic pressure, intraperitoneal pressure, intraperitoneal pressure waveforms, bladder pressure, rectal pressure, cardiac output, cardiac stroke volume, cardiac rate, total circulating blood volume, blood flow (e.g., in superior mesenteric, celiac, renal or other arteries), pressure in veins (particularly those that empty into the IVC, e.g., femoral vein), pressure in arteries (particularly those distal to the aorta, e.g., the femoral artery), blood oxygenation (e.g., in rectal mucosa, peripheral fingers and toes, etc.), whole body oxygen consumption, pH and arterial pO_2 and any other parameter that shows a measurable change once the peritoneal or vascular spaces have been overloaded.

[0040] These parameters in particular have been found to change with increases in peritoneal pressure, with significantly negative impact on each parameter found at 40 mmHg. Thus, monitoring for these changes in conjunction with a peritoneal infusion catheter of the present invention will allow for even greater safety with peritoneal infusion. These parameters may be measured a variety of ways and the data transmitted either wirelessly or via wires to the logic controller in order to alert the healthcare provider or to automatically adjust the fluid flow/temperature in order to optimize both the flow of the peritoneal fluid and patient safety.

[0041] FIG. **4** illustrates a console **40** with optional sensor lead **44** which may or may not be wireless. The console itself may record output/input data **42**. This data may be held in memory, printed or directly transmitted to a centralized data collection server. Said console may connect to the urine receptacle **46** to determine urine output either via a wire or wirelessly.

[0042] FIG. **5** illustrates sensor-based Urine Output Measurement. In this instance, the console **50** or RFID reader can trigger alert if urine output is too low or too high over a set period of time. May also have intravenous infusion capabilities to provide input and output data and tailor delivery of fluids and/or medicines (ie diuretics) via an automated system based on the urine output feedback. The device may include an optional Docking Station **54**—ideally reusable, may connect to receptacle **52** and transmit data to control unit either via wires or, ideally, wirelessly. May also measure urine level via weight, etc. Optional Urine Level Sensors **56** may report level of urine via conductivity, resistance, impedance, etc. Sensors may also continuously or intermittently detect bacteria, hemoglobin or other substances of interest in urine. Urinary catheter **58** is also shown.

[0043] FIG. **6** illustrates a console **60** with automated infusion therapy system. Console may integrate patient data, ie fluids received, urine output recorded, etc. to automate therapy, ie delivery of fluids or LASIX if the pt is dehydrated or fluid overloaded respectively. May also trigger local alert (ie beeping) and centralized alert (ie system alarm) if urine output drops too low. The console may also integrate a fluid infusion or medicine infusion capabilities, ie an IV infusion pump, and may adjust infusion rates based on this data or data acquired from other sensors in an automated fashion. The console may communicate wirelessly as well, to these and any other sensors within the body. Infusion catheter **62** is also shown—may deliver drugs or fluid based on urine output and other parameters Urinary catheter **64** is also shown.

[0044] FIG. **7** illustrates a volume-sensing Urine Receptacle with reusable communicating and/or sensing element. The receptacle **70** itself may detect urine output based upon level at which sensors are triggered-ie have hash-marks represent electrical contacts and when an electrical path is made between two contacts, and all contacts below, the level can be reported at that level. May be electrical, optical, chemical or mechanical sensors. May also contain diffuse or discrete sensing areas that may detect the presence of absence of certain materials of interest, ie hemoglobin, protein, glucose, bacteria, blood, leukocyte esterase, etc. either intermittently or continuously. May report any and/or all of this information to the console, locally (via beeping, etc.) or centrally via piping data to a central information collection area. Alerts triggered if urine output drops below 30 cc/hr in post-operative setting or any otherwise defined threshold. May also be disposable and connect to the docking station **72** which may communicate the data from said, receptacle wirelessly. The docking station may be connected anywhere on said receptacle, or optionally, not included at all. If a docking station is used, it may detect urine output based simply upon weight or pressure applied to base. May contain disposable or, ideally, durable optical, electrical or chemical sensors capable of sensing glucose, electrolytes, bacteria, hemoglobin, blood, etc. May interface with specifically designed area of the urine receptacle to allow for this measurement-ie an optically clear window for optical measurement of blood, etc. May also fasten onto the urine receptacle in any position so long as it engages the receptacle. This or the receptacle itself may contain an inductive antenna and/or RFID capabilities to allow for wireless querying and reporting of the level of urine or other fluid collection.

[0045] FIG. **8** illustrates a volume-sensing Urine Receptacle **80** with RFID capabilities. This embodiment may contain RFID circuitry to collect and transmit data directly from within the receptacle to a RFID Reader. When queried by the RFID reader may simply detect impedance, resistance, capacitance or any other electrical or nonelectrical property to detect the urine level and report this back to the reader. Reader may then trigger alert if urine output is high or low. The RFID chip may be capable of detecting changes in optical, chemical, electrical, acoustic or mechanical properties, as well. May be active or passive RFID and may contain antenna in any position and, ideally, may transmit a unique signal to identify the receptacle to the reader and allow multiple receptacles to be queried at once. The RFID chip may incorporate a small battery (to extend its range) in an active RFID embodiment or may be passive in nature and be powered solely by the transmissions from said RFID reader. The RFID Reader **82** may query device from a distance to wirelessly check the urine output level or may be centralized to query all receptacles within a unit, floor or hospital and issue an alert if urine output drops too low (or is too high). May record urine output, as well, and replace the individual unit consoles illustrated in FIGS. **1-3**. The RFID reader may also report data from other sensors within said system, including bladder temperature or presence of certain materials within the urine, ie blood, hemoglobin, leukocyte esterase, other indicators of bacterial infection, protein, glucose, etc.

[0046] In another embodiment, a urinary catheter capable of sensing physiologic parameters is envisioned. Additional sensing capabilities may include: blood pressure, oxygen saturation, puke oximetry, heart rate, EKG, capillary fill pressure, etc. In particular, the incorporation of pulse oximetry technology to allow for blood oxygen concentration or saturation determination with a urinary catheter is envisioned. This device may function by incorporating pulse oximetry capabilities anywhere along the length of the catheter, but ideally the sensor or sensors will be contained within the tubing of the device to ensure approximation to the urethral mucosa. With this invention, the healthcare provider will be able to decompress the bladder with a urinary catheter and obtain pulse oximetry data in a repeatable and accurate manner. The power source for this device may be incorporated within the urinary drainage bag or within the catheter itself Ideally, the pulse oximeter will be reusable and the catheter interface will be disposable wherein the pulse oximeter is simply reversibly attached to the disposable catheter and removed once measurements of oxygen are no longer desired. The urinary catheter, then, may contain an optically transparent, or sufficiently transparent, channel for the oximetry signal, ie a fiber-optic cable, transparent window, etc., and an interface for the reusable oximeter and otherwise be a standard urinary catheter. This method and device for urethral pulse oximetry may be used in conjunction with any of the other embodiments detailed herein or may be a stand-alone device in and of itself.

Detailed Description of the Preferred Embodiments

[0047] I. Device: Automated Urine Output Measurement

[0048] II. Indications for Use (IFU): Any condition requiring urine output monitoring

[0049] III. Preferred Methods for Use:

[0050] a. Upon placement of a Foley catheter, ideally with a temperature sensor or intra-vesicular sensor/probe, the receptacle component of the Automated Urine Output Measurement system is attached to the output tubing

[0051] b. The receptacle is attached to a stationary object, or the patient themselves and the data ID for the receptacle is entered into the RFID reader, which may be centralized and capable of querying all Automated Urine Output Measurement receptacles within a predefined range or area

[0052] c. The RFID reader then queries, and optionally powers, the RFID chip within the receptacle which reports the fluid level based on the impedance, conductance or other electrical properties of sensors within the bag

[0053] d. This data is transmitted to centralized data collection point where it may be monitored by an individual

[0054] e. If certain thresholds are not met, ie 30 cc/hr urine output, local alarms (ie a beeping) or remote alarms (ie an alert at the centralized monitoring station) may be triggered

[0055] f. The information obtained from the receptacle may be used in a feedback loop to automate the delivery and/or extraction of fluids and/or medicines from the patient to optimize therapy

[0056] g. In conjunction with urine output measurement the healthcare professional may also attach an oximeter to a specifically designed site on the urinary catheter in order to obtain pulse oximetry measurements

[0057] h. Once the measurements have been completed, the oximeter may be reused (or disposed of) and the urinary catheter either removed or kept in place

1.-**8**. (canceled)

9. An apparatus for automated, real-time measurement of urine output, comprising:

a catheter configured for insertion into a bladder of a patient;

an output receptacle in fluid communication with the catheter for collecting urine from the bladder of the patient;

at least one sensor in communication with the output receptacle, wherein the at least one sensor is configured to detect one or more biological parameters of urine collected within the output receptacle; and

a controller in communication with the at least one sensor, wherein the controller is programmed to automatically transmit data relating to the one or more biological parameters of the urine collected within the output receptacle to a remote data collection server.

10. The apparatus of claim **9** wherein the at least one sensor comprises a temperature sensor for sensing a temperature of the patient.

11. The apparatus of claim **9** wherein the at least one sensor comprises an EKG sensor for sensing an EKG of the patient.

12. The apparatus of claim **9** wherein the at least one sensor comprises a heart sensor for sensing a heart rate of the patient.

13. The apparatus of claim **9** wherein the at least one sensor is configured to detect for a presence of blood, bacteria, protein, or hemoglobin in the urine collected within the output receptacle.

14. The apparatus of claim **13** wherein the at least one sensor comprises an optical sensor.

15. The apparatus of claim **9** wherein the at least one sensor comprises a mechanical sensor.

16. The apparatus of claim **9** wherein the output receptacle comprises an optically clear window.

17. The apparatus of claim **9** wherein the data is associated with a particular individual patient.

18. The apparatus of claim **9** wherein the data is encrypted.

19. A method of automating real-time measurement of urine output, comprising:

receiving urine via a catheter from a bladder of a patient into an output receptacle;

detecting for one or more biological parameters of the urine collected within the output receptacle via at least one sensor in communication with the output receptacle;

processing the one or more biological parameters via a controller in communication with the at least one sensor; and

transmitting data relating to one or more biological parameters of the urine to a remote data collection server.

20. The method of claim **19** wherein detecting further comprises detecting a temperature of the patient.

21. The method of claim **19** wherein detecting further comprises sensing an EKG of the patient.

22. The method of claim **19** wherein detecting further comprises sensing a heart rate of the patient.

23. The method of claim **19** wherein detecting further comprises detecting for a presence of blood, bacteria, protein, or hemoglobin in the urine collected within the output receptacle.

24. The method of claim **23** wherein detecting comprises detecting for the presence via an optical sensor.

25. The method of claim **19** wherein transmitting further comprises associating the data with a particular individual patient.

26. The method of claim **19** wherein transmitting further comprises encrypting the data prior to transmitting.

* * * * *

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[标]申请(专利权)人(译)	BURNETT丹尼尔 - [R HALL GREGORYW 赫曼森CHRISTOPHER RAJGURU AMIT		
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摘要(译)

一种具有输注导管的自动治疗系统;适于感测患者参数的传感器;以及控制器，其与所述传感器通信并被编程以基于所述患者参数控制从所述输注导管输出到患者体内的流量而不从所述患者移除流体。本发明还包括一种控制流体向患者的输注的方法。该方法包括以下步骤：用传感器监测患者参数以产生传感器信号;将所述传感器信号提供给控制器;以及基于所述传感器信号调节到所述患者的流体流量，而不从所述患者移除流体。