Abstract: Devices and methods for more draining the bladder, preventing airlocks from forming in the drainage tube and clearing them when they do, and increasing the accuracy with which urine output is measured in an automated way. The device includes one or more lumens, a reservoir for receiving the bodily fluid, and a pumping mechanism that never fully obstructs outflow of bodily fluid. The device also includes additional measurements of the urine, such as specific gravity, oxygen tension, conductivity, gas pressures, and sediment, to improve the monitoring of fluid status, renal function, and other important patient parameters. Methods for detecting and clearing a drainage lines and taking measurements of multiple urine parameters for detecting acute kidney injury, urinary tract infection, intra-abdominal hypertension, abdominal compartment syndrome, or sepsis.

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SYSTEMS, DEVICES AND METHODS FOR URINE MONITORING

CROSS-REFERENCE TO RELATED APPLICATION


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

FIELD OF THE INVENTION

[0003] The present invention relates to the field of medical devices, in particular devices that aid emptying of the bladder, measure urine output and various urine parameters such as oxygen tension, urine conductance and urine specific gravity, monitor renal function, analyze urine content, and track fluid administration. The present invention further relates to medical devices capable of sensing physiologic data based on sensors incorporated into a catheter or implant adapted to reside in any of a urinary tract, gastrointestinal tract, rectal location, pre-peritoneal or other implanted site.

BACKGROUND OF THE INVENTION

[0004] It is estimated that 10% of all hospitalized and long-term care patients receive an in-dwelling urethral catheter. Almost all critically ill patients receive one, and in the ICU it is routine procedure to monitor urine output every hour. The amount of urine produced is an indicator of fluid status and renal function. However, numerous sources of error can cause erroneous measurements of this important indicator.
The most common device used to drain the bladder is the Foley catheter. Since its introduction, the design of a flexible tube with an anchoring balloon and eyelets that allow urine to drain through a central lumen has remained largely unchanged. However, it has been found that the current design of Foley catheters can result in a large residual volume remaining in the bladder, for example greater than 50mL in supine patients. See Fallis, Wendy M. Indwelling Foley Catheters Is the Current Design a Source of Erroneous Measurement of Urine Output? CRITICAL CARE NURSE 25.2 (2005): 44-51. In one study, mean residual volume was 96 mL in the ICU and 136 mL in the general ward. See, Garcia et al., Traditional Foley Drainage Systems—Do They Drain the Bladder?. J UROL. 2007 Jan; 177(1):203-7; discussion 207. A large residual volume of urine is also often found in the drain tube that connects the Foley catheter to the drainage bag.

The residual urine in the bladder and drain tube is a result of large air bubbles (air locks) that are formed in the tube and prevent the flow of urine from the bladder to the drainage bag. As a result, it has become routine procedure for nurses to manipulate the drainage tube prior to measuring urinary output, which helps empty the tubing. In the ICU, where measurements are made as often as every hour, this is a very repetitive and imprecise process.

In addition, the development of air locks has been found by the inventors to significantly skew intra-abdominal pressure readings (Burnett, DR, Luxon, ES, Hamilton, MH, Preventing Inaccurate Intra-Abdominal Pressure Readings Due to Air-Locks and Siphon Effects in Urinary Drainage Lines, INT J ABD RES. 1(1), 2013, p 91). This has not been recognized by the clinical community as an issue and another of our innovations is the detection and removal of air locks in the setting of intra-abdominal pressure measurements.

The present invention seeks to more effectively drain the bladder, prevent airlocks from forming in the drainage tube and clearing them when they do, and increase the accuracy with which urine output is measured in an automated way. The invention also seeks to incorporate additional measurements of the urine, including oxygen tension, conductance, and specific gravity, to improve the monitoring of fluid status, renal function, and other important patient parameters.
SUMMARY OF THE INVENTION

[0009] According to one aspect, the present invention relates to a device for draining bodily fluids, comprising one or more lumens configured to receive a bodily fluid from a patient body, a reservoir in fluid communication with the one or more lumens for receiving the bodily fluid, and a pumping mechanism to urge fluid through the one or more lumens. The pumping mechanism never fully obstructs outflow of said bodily fluid. In one alternative embodiment, the lumens have an interior diameter that maintains a siphon. The lumens may be less than ¼ inch in interior diameter. In some embodiments, the pumping mechanism cannot fully obstruct outflow even in the case of a system failure. In some embodiments, the pumping mechanism is peristaltic.

[0010] According to another aspect, embodiments of the present invention include a device for draining and measuring bodily fluids comprising multiple lumens, a pumping mechanism, and a volume or flow output measurement mechanism. In one alternative embodiment, the lumens have an interior diameter that maintains a siphon. The lumens may be less than ¼” inch in interior diameter. In some embodiments, the pumping mechanism urges fluid through the lumen without fully obstructing the lumen. In another alternative embodiment, the pumping mechanism is peristaltic. In some embodiments, the output measurement mechanism is pressure-based, resistance-based, capacitance-based, or optically-based.

[0011] According to a third aspect, embodiments of the present invention include a device for draining and measuring bodily fluids comprising one or more lumens, a pumping mechanism in fluid communication with the one or more multiple lumens, a volume or flow output measurement mechanism in fluid communication with the one or more multiple lumens, and at least one additional analysis mechanism. The additional analysis mechanism is configured to detect one or more physiological parameters from the bodily fluids contained within the volume or flow output measurement mechanism and received through the one or more multiple lumens. In some embodiments the lumens have an interior diameter that maintains a siphon. The lumens can be less than ¼” inch in interior diameter. In some embodiments, the pumping mechanism urges fluid through the lumen without fully obstructing the lumen. In some embodiments the pumping mechanism is peristaltic. In some embodiments, the output measurement mechanism is pressure-based, resistance-based, capacitance-based, or optically-based.
based, capacitance-based, or optically-based. In some embodiments, the additional analysis mechanisms analyze at least one of specific gravity, oxygen tension, conductivity, gas pressures, and sediment.

[0012] According to a fourth aspect, embodiments of the present invention provide a method of automatically clearing one or more lumens used for draining bodily fluids, comprising passing bodily fluids from a patient through at least one drainage line, receiving the bodily fluids into a reservoir via the drainage line, and applying one of a pulsatile mechanical, vibratory acoustic, thermal, vibratory, pinching, rolling or electromagnetic stimulus to cause at least one of a movement of the drainage line and the bodily fluids within. In some embodiments, the rolling stimulus comprises compressing the lumens sequentially such that the lumens are never all compressed at the same time.

[0013] According to a fifth aspect, embodiments of the present invention provide a method of detecting and clearing a drainage line having one or more lumens used for draining bodily fluids, comprising draining bodily fluids from a bodily organ via a drainage line, detecting a pressure spike in the drainage line while a pressure within the bodily organ remains constant; and using massaging rollers to create negative pressure through the drainage line until the pressure in the drainage line equals the pressure in the bodily organ.

[0014] According to a sixth aspect, embodiments of the present invention provide a method taking measurements of multiple urine parameters for detecting acute kidney injury, urinary tract infection, intra-abdominal hypertension, abdominal compartment syndrome, or sepsis. The urine parameters may include conductance, specific gravity, urine output, and oxygen tension.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0015] The novel features of the invention are set forth. 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:

[0016] Fig. 1 shows an exemplary sensing Foley catheter urine output collection system (hereinafter, the sensing Foley catheter system) configured to measure urine output from a human subject.
Fig. 2 shows an embodiment of the sensing Foley catheter urine system comprising a console in communication with the receptacle docking station that accommodates an urine collection receptacle.

Fig. 3 shows an embodiment of the sensing Foley catheter system configured as an automated infusion therapy system for a human subject.

Fig. 4 shows an urine receptacle configured to sense urine volume, accommodated within a receptacle docking station, per an embodiment of the sensing Foley catheter system.

Fig. 5 shows a urine receptacle that includes an RFID chip or circuitry, configured to collect and transmit data directly from within the receptacle to a RFID reader.

Fig. 6 shows a sensing Foley catheter that includes a pressure-sensing balloon, per an embodiment of the presently disclosed system.

Fig. 7 shows a sensing Foley catheter with a lumen (the third lumen, for example) used as a pressure sensing lumen.

Fig. 8 shows an example of peritoneal pressure sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system.

Fig. 9A shows an example of respiratory rate sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system. Fig. 9B shows a detailed portion of the respiratory profile of Fig. 9A, a portion of the period of normal respiration.

Fig. 10 shows an example of cardiac rate and relative cardiac output sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system, and an EKG trace as measured simultaneously and independently.

Fig. 11 shows an example of peritoneal sensing data from a pig, as provided by an embodiment of the sensing Foley catheter system.

Fig. 12 shows an example of respiratory rate sensing data from a pig, as provided an embodiment of the sensing Foley catheter system.

Figs. 13A-B show the placement of an exemplary embodiment of preperitoneal sensing implant.
Fig. 14 shows the sensitivity to peristaltic pulsations in air channels with a lumen diameter of 3 mm, 1 mm, and 0.5 mm.

Fig. 15 shows an embodiment for clearing the drainage line that uses a vacuum applied to the end of the drainage line.

Figs. 16A-16B show an embodiment of the clearing mechanism comprising a device for positive airflow near the start of the drainage line.

Fig. 17 shows a clearing mechanism comprising an apparatus for automated massaging, or squeezing, of the drainage line.

Fig. 18 shows another embodiment of the pinching or rolling stimulus, in which the lumens are compressed sequentially by rollers.

Fig. 19 shows another embodiment comprising multiple lumens organized circumferentially around a stiff member that the pinching or rolling mechanism rotates around.

Fig. 20 shows an alternative embodiment in which the lumens are organized such that they can only be completely compressed when pinched in a certain direction.

Fig. 21 shows a graph of the pressure profile, pressure (mmHg) over time (seconds) in the drain tube while the peristaltic roller pump is activated.

Fig. 22 is a table comparing IAP measurements using a standard drainage line and IAP sensor with the present invention in combination with a pressure-sensing Foley catheter under air lock and siphon effects.

Figs. 23A-D illustrate resistive or conductive methods for detecting urine; urine is detected by a change in resistance or conductance between two or more electrical leads.

Fig. 24 illustrates a method for detecting urine that is strain-based, in which an increase in urine volume stretches a balloon or bladder and is detected by one or more suitable strain transducer, including but not limited to electrical foil gages or fiber Bragg grating optical sensors.
Figs. 25A-C show methods for detecting urine that are weight- or pressure-based, in which an increase in urine volume increases the weight of the collection device and the pressure of the urine column.

Fig. 26 illustrates a method for detecting urine makes use of a magnetic float valve, which is initially held closed with a magnet.

Fig. 27 shows a small sample collection vessel self-emptying by means of a siphon that is triggered when the urine volume reaches a pre-determined level.

Figs. 28A-D illustrate the emptying sequence for the apparatus shown in Fig. 27.

Fig. 29 illustrates the use of the sample collection vessel and pressure tube to provide information about the volume and density (specific gravity) of the urine being collected.

Fig. 30 shows a table that lists combinations of parameters that allow for a fingerprint (unique combination of parameters) for the different causes of AKI (pre-renal, intrinsic and obstructive).

Fig. 31 illustrates the Urine Collection and Detection System (UCDS) algorithm.

Fig. 32 shows a comparison between Accuryn with a Standard System over a variety of parameters during constant urine production on a bench top model.

Figs. 33A-C show alternative retention balloon designs for urine catheters within the bladder, comprising one or more balloons to facilitate better urine drainage and decrease the likelihood of becoming obstructed.

Fig. 34 shows a urine drain tube that allows for partial compression and a motive force based on a vibrating element.

Fig 35 is an example of a collection reservoir that will not become obstructed with debris, clots or crystals in the urine.

Figs. 36A-B show embodiments of the sample collection vessels comprising siphon and overflow features.

Fig. 37 shows the pressure and volume relationships for a non-compliant pressure-sensing balloon.
[0053] Fig. 38A shows an example of a type 1 balloon. Fig. 38B shows an example of a type 2 balloon.

[0054] Fig. 39A shows an example of a drainage tube with a slit vent. Fig. 39B shows an example of a drainage tube with a spiral vent.

[0055] Fig. 40 shows another embodiment where airlock detection occurs using two conductive leads within the drainage tube: one near the patient end and one near the collection chamber.

[0056] Fig. 41 shows a drainage tube where the wires and pressure lumen run the length of the drainage tube and can connect directly to the reusable box that houses the pump and displays urine output in one step.

[0057] Fig. 42 shows a small float that can be used in the tube to completely drain when the siphon drains.

[0058] Fig. 43, which illustrates the drainage lumens and additional lumens.

[0059] Fig. 44 shows a gas permeable but liquid impermeable membrane to separate the urine from the gas in the sample chamber and allowing them to equilibrate.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0060] The preferred embodiments of the present invention are described in detail herein. However, alternative embodiments of various features of the device are also possible. Examples of these embodiments are provided below, but the scope of the invention is not limited to these specific configurations.

The Urine Output Collection System

[0061] Fig. 1 shows an exemplary sensing Foley catheter urine output collection system 1 (hereinafter, the sensing Foley catheter system) configured to measure urine output from a human subject. The sensing Foley catheter system comprises a urinary catheter 3 that empties into a urinary receptacle 5 equipped with urine sensors 7. The urine sensors report the level of urine via any suitable modality, such as conductivity, resistance, and/or impedance. The urine sensors may also detect or measure levels of bacteria, hemoglobin, or other substances of clinical interest in urine. A receptacle docking station 9 may connect the urinary receptacle 5 and transmit data to a control
unit either via wires or wirelessly. The receptacle docking station may also measure urine volume via weight or other methods. The receptacle docking station 9 is configured for data transmission to a data receiving and processing apparatus such as a bedside console or a central computer. In some embodiments, the docking station delivers data regarding the volume of urine in the urine receptacle, as well as data that are informative regarding electrical parameters of the urine, such as conductivity, resistance, or impedance. A console 11 in communication with the receptacle docking station 9 can trigger an alert if the urine output is too low or too high over a set period of time.

[0062] Fig. 2 shows an embodiment of the sensing Foley catheter urine system comprising a console 11 in communication with the receptacle docking station 9 that accommodates a urine collection receptacle 5. The communication path between the docking station and the console may include a wired connection 13, as shown, or it may be a wireless connection. The console may record and display output/input data. The data from sensors associated with the sensing Foley catheter may be held in a memory, displayed, printed, or directly transmitted to a centralized data collection server.

[0063] In some embodiments, the bedside console or controller is portable and able to travel with the patient. Embodiments of console may be attachable to a patient's bed or an IV pole, or a wall mount; it typically has its own display, and is able to provide critical alerts. Some embodiment of console may be adapted to be able to operate on a battery backup for 4 or more hours, as for example when wall power is unavailable or has been lost. This portability feature of console is advantageous in situations where patients are usually not monitored, such as when a patient is in transit from his or her bed to another location. Embodiments of console may also be configured to communicate to a base station with alerts and centralized reporting and data collection. The controller or base station may also generate mobile alerts that may be sent to nurses or healthcare providers. Signal analysis and/or predictive algorithms may also be used to provide useful clinical data from sensors.

[0064] Fig. 3 shows an embodiment of the sensing Foley catheter system configured as an automated infusion therapy system for a human subject. In this embodiment the console 11 may integrate patient data, such as fluids received or urine
output recorded, and then automate therapeutic infusion via an infusion catheter 15 in response to these data. For example, delivery of fluids or drug solutions such as a physiological saline solution may be initiated or regulated if the patient is dehydrated, or a diuretic may be infused if the patient is fluid overloaded. In some embodiments, the console may trigger a local alert (e.g., audible beeping), or trigger a centralized alert (e.g., a system alarm) if urine output drops too low. This embodiment may be particularly beneficial to burns patients. The console may also integrate a hydrating or medicinal fluid infusion capability, such as an IV infusion pump (not shown), and may adjust infusion rates based on these data or based on data acquired from other sensors automatically. The console 11 may communicate wirelessly, as well, to these and other sensors within the body.

The Urine Receptacle And Receptacle Docking Station

[0065] Fig. 4 shows an urine receptacle 5 configured to sense urine volume, accommodated within a receptacle docking station, per an embodiment of the sensing Foley catheter system. The receptacle may detect urine output based upon level at which sensors 7 are triggered. For example, the sensors 7 may comprise electrical contacts 17 arranged as hash-marks, and when an electrical path is made between two contacts and all contacts below, the level can be reported at that level. The urine receptacle 5 may include electrical, optical, chemical or mechanical sensors.

Embodiments of the urine receptacle 5 may include also contain diffuse or discrete sensing areas that detect analytes of interest, e.g., hemoglobin, protein, glucose, bacteria, blood, leukocyte esterase. Sensing or data reporting of sensed data may be of either an intermittent or a continuous nature.

[0066] The urine receptacle 5 may include a capability to report sensing data to the bedside console, locally (e.g., by beeping) or centrally via piping data to a central information collection area. For example, an alert may be triggered if urine output drops below 30 cc/hr. in post-operative setting or below any otherwise predetermined threshold. The urine receptacle 5 may connect to a receptacle docking station 9 through electrical contacts; data communication among embodiments of the receptacle, docking station, and a console or central computer may also be wireless. If a receptacle docking station 9 is used, it may detect urine output based on weight or pressure of the urine receptacle 5 that is applied to base.
The urine receptacle 5 may include disposable or durable optical, electrical or chemical sensors capable of sensing and measuring urine content of analytes such as glucose, electrolytes, bacteria, hemoglobin, or blood. The urine receptacle 5 may include an interface with a specifically designed area of the urine receptacle to allow for this measurement, such as an optically clear window for optical measurement of blood. The receptacle docking station 9 may also grasp the urine receptacle in any manner so long as it secures the receptacle. The docking station or the receptacle may include an inductive antenna or RFID capabilities to allow for wireless querying and reporting of the level of urine or other fluid collection.

Fig. 5 shows a urine receptacle 5 that includes an RFID chip or circuitry 19, configured to collect and transmit data directly from within the receptacle to a RFID reader. When queried by an RFID reader 21, the urine receptacle 5 may detect impedance, resistance, capacitance or any other electrical or non-electrical property to measure the urine level and report this back to the reader. The RFID reader 21 may then trigger alert if urine output is out of a normal or desirable range. The RFID chip or circuitry 19 may be capable of detecting changes in optical, chemical, electrical, acoustic or mechanical properties, as well. RFID chips or circuitry 19 may be active or passive, and may contain an antenna to transmit a receptacle-identifying signal to the reader, and allow multiple receptacles to be queried simultaneously. The RFID chip or circuitry 19 may incorporate a small battery (to extend its range) in an active RFID embodiment, or it may be a passive chip powered by the transmission from the RFID reader. The RFID reader 21 may query a device from a distance to wirelessly check the urine output level or it may be centralized to query all receptacles within a unit, floor or hospital and issue an alert if urine output is out of a normal or desirable range. The RFID reader 21 may record urine output, as well, and functionally replace the individual unit console 11 shown in Figs. 1 - 3. The RFID reader 21 may also report data from other sensors within the system, including bladder temperature or presence of analytes (as detailed elsewhere) in the urine.

The Sensing Foley Catheter

Fig. 6 shows a sensing Foley catheter 3 that includes a pressure-sensing balloon 23, per an embodiment of the presently disclosed system. This embodiment of the sensing Foley catheter may include pH, nitrate, oxygen, hemoglobin and or
temperature sensor(s) 25 in the part proximal to the bladder. A retention balloon 27 may keep the sensing Foley catheter in its desired location. Drainage or infusion holes 29 may be used to deliver drugs or to heat or cool the body. The urethral portion 31 of the sensing Foley catheter 3 may include a perfusion or blood pressure sensor 33 in the form of an inflatable balloon to compress tissues while taking a reading, as well as additional sensors 35, such as a pulse oximeter, temperature sensor, electrode for EKG, EGG, or a window for visualization or for optical measurement of analytes within the urethral mucosa. The sensing Foley catheter 3 may be a multi-lumen catheter comprising electrical connections 39 and/or an optical fiber 37. Physiologic parameters that this catheter embodiment can sense may include, by way of example, blood pressure, oxygen saturation, pulse oximetry, heart rate, EKG, capillary fill pressure.

Fig. 7 shows a sensing Foley catheter with a lumen (the third lumen, for example) used as a pressure sensing lumen 41; this embodiment does not include a dedicated pressure-sensing balloon as does the embodiment of Fig. 6. In this device embodiment, the sensing Foley catheter is able to detect and report peritoneal, abdominal, and bladder pressure without a pressure-sensing balloon, as included in the embodiment described above. In this present embodiment, a slow infusion of fluid into the bladder may be accomplished through the third lumen of a standard 3-way Foley catheter, and pressure may be sensed using a pressure sensor in line with this third lumen. In this embodiment, all methods related to sensing respiratory rate, cardiac rate, relative cardiac output, relative stroke volume, and other physiologic parameters from the bladder pressure signal may still be used.

Pulse oximetry technology allows for a determination of blood oxygen concentration or saturation, and may be disposed anywhere along the urethral length of the catheter. In some embodiments, the sensor or sensors are disposed within the tubing of the device to ensure approximation to the urethral mucosa. With this technology, a healthcare provider can decompress the bladder with a urinary catheter and obtain pulse oximetry data in a repeatable and accurate manner. The power source for pulse oximetry may be incorporated within the urinary collecting receptacle or within the catheter itself. In some embodiments, the pulse oximeter is reusable and the catheter interface is disposable; in this arrangement the pulse oximeter is reversibly attached to the disposable catheter and removed when oxygen measurements are no
longer desired. Embodiments of the sensing Foley catheter may include an optically transparent, or sufficiently transparent, channel for the oximetry signal, such as a fiber-optic cable, transparent window, and an interface for the reusable oximeter. 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.

[0072] Embodiments of the sensing Foley catheter may be able to sense any one or more of a plurality of clinically relevant parameters, including but not limited to the following examples: urine pH, urine oxygen content, urine nitrate content, respiratory rate, heart rate, perfusion pressure of the bladder wall or the urethral wall, temperature inside the bladder or the urethra, electrocardiography via sensors on the bladder wall or the urethra, respiratory volume, respiratory pressure, peritoneal pressure, urine glucose, blood glucose via urethral mucosa and/or bladder mucosa, urine proteins, urine hemoglobin, blood pressure. In some embodiments, the catheter can sense multiple parameters, but some embodiments may be limited to as few as a single parameter for focused applications (for example, respiratory rate in a patient in respiratory distress). The respiratory rate, relative tidal volume, peritoneal pressure, heart rate and/or relative cardiac output and/or relative stroke volume may be measured simultaneously, as well, by connecting a balloon with a flaccid wall or semi-tense wall to an external pressure sensor via a lumen that may be filled with liquid and/or gas.

[0073] These parameters may be measured, alone or in concert with other parameters, through the use of pressure measurement modalities other than the external pressure sensor. These may include: a deflecting membrane inside of the catheter, MEMs technology, a catheter-based sensor and/or other embodiments.

**Sensors for Blood Pressure, Perfusion Pressure, and Relative Cardiac Output or Relative Stroke Volume**

[0074] In some embodiments, the sensing Foley catheter may include a blood pressure sensing element that may take any of several forms. One blood pressure sensing element includes an inflatable member (either a separate balloon or by way of a balloon in fluid communication with the retention and/or pressure sensing balloon) that can be optically analyzed as it is inflated to determine at which pressure the vessels within the urethra are blanched and blood flow is stopped. This approach
provides a reading of the perfusion pressure of the urethra, which reflects both the systemic blood pressure and vascular resistance. This embodiment of a perfusion pressure device may be used to provide early detection and/or monitoring of a variety of acute medical conditions such as sepsis, shock, hemorrhage, and can be particularly advantageous in detecting these conditions at an early stage.

[0075] Embodiments of this methodology may also be used to detect perfusion pressure in other areas of the body with an intermittently inflatable member and optical detection of blood flow or the presence of blood. Other modalities may be used to detect that the tissue has been blanched or ischemic, as well, with the common methodological aspect being that of the intermittent inflation within the lumen, body cavity or bodily tissues to provide the compression of the vasculature.

[0076] Relative cardiac output, relative stroke volume, and relative tidal volume may be calculated, based on the deflection of the pressure sensor and/or other force gauge. If sampled frequently enough (e.g., 2 Hz or faster), a respiratory excursion can be identified and quantified in a relative manner to the amplitude of the excursions at the time of catheter placement. Larger excursions mean either heavier breathing or, in the setting of an upward drift in the baseline, a higher peritoneal pressure. The small peaks on the oscillating respiratory wave, caused by the pumping heart, may be tracked as well, and the amplitude of this wave may be used, in the setting of a relatively constant peritoneal pressure, to determine the relative cardiac output and/or relative stroke volume.

[0077] Tissue perfusion information may also be provided by way of sensors disposed on the shaft of the catheter such that they contact the urethral wall when the catheter is in place. These sensing technologies may include pulse oximetry, microdialysis, pyruvate, lactate, pO2, pCO2, pH, perfusion index, near-infrared spectroscopy, laser Doppler flowmetry, urethral capnography, and orthogonal polarization spectroscopy. Any of these tests may also be performed on the urine or the bladder wall itself to generate measurements of tissue perfusion.

[0078] Relative cardiac output, relative stroke volume, and relative tidal volume may also be calculated, based on the deflection of the pressure sensor and/or other force gauge. If sampled with sufficient frequency (e.g., 2 Hz or greater), respiratory excursions can be quantified in a relative manner to the amplitude of the excursions at
the time of catheter placement. Larger excursions generally relate to heavier breathing, or in the setting of an upward drift in the baseline, a higher peritoneal pressure. The small peaks on the oscillating respiratory wave, caused by the pumping heart, may be tracked as well by using faster sampling rates (5 Hz or greater), and the amplitude of this wave may be used, in the setting of a relatively constant peritoneal pressure, to determine the relative cardiac output and/or relative stroke volume, in the setting of a known, stable peritoneal pressure, absolute stroke volume and/or cardiac output.

Sensors for Detecting Patient Movement

Bladder pressure, as sensed by an embodiment of the disclosed technology, may also be used to detect the level of patient movement (ranging, for example, between no substantial movement to a high level of movement) and to report the movement level to a healthcare provider. A short burst of peaks and valleys in bladder pressure activity can serve as a proxy for body movement in that such a bladder pressure profile is a strong indicator that the patient is using their abdominal muscles, likely for the purposes of sitting up and leaving the bed. This embodiment may be of particular benefit for patients that are at risk of falling. In a patient that is a fall-risk, a healthcare provider may be notified that the patient is sitting up and respond accordingly. Alternatively, the device may be used to report inactivity of a patient and/or lack of patient movement. The device may also report patient movement in the detection or diagnosis of seizure disorder. In this embodiment, the pressure variations may trigger an EEG or recording equipment to allow for intense period of monitoring during an episode suspected to be a seizure. In addition, or alternatively, a pressure sensor, acoustic sensor or other sensors may be used to detect bowel activity, patient movement, seizure activity, patient shivering, frequency of coughing, severity of coughing, sleep quality, speech detection, patient compliance (movement or lack thereof), and may alert the healthcare provider that the patient has not moved and must be turned or rolled. This movement-related information may also be relayed to a hypothermia device, a drug delivery device or other device to control mitigate seizure activity, shivering and/or coughing.
Sensitivity of the Pressure Sensor, Resolution of the Pressure Signal

[0080] The disclosed technology captures a high-resolution timed profile of peritoneal pressure that can be transduced and processed into distinct pressure profiles assignable to particular physiologic sources, including peritoneal pressure, respiratory rate, and cardiac rate. By tracking the pressure profile at a sufficiently rapid sampling rate, as provided by the technology, the pressure profile can be further resolved into relative pulmonary tidal volume, cardiac output, relative cardiac output, relative stroke volume, and absolute cardiac stroke volume.

[0081] Accordingly, aspects of the disclosed technology relate to fidelity and resolution of a pressure signal generated in response to changes in pressure within the bladder, such changes being reflective of a pressure profile within the peritoneal cavity, such pressure profile including input from the aforementioned physiologic sources. Aspects of the technology further relate to fidelity and resolution of the transduction of the pressure signal into a highly resolvable electrical signal. Aspects of the technology relate still further to processing the totality of the electrical signal profile, a surrogate for the pressure profile within the peritoneal cavity, into component profiles that can be assigned to the physiologic sources.

[0082] The sensitivity of an inflated balloon as a pressure sensor is a function, in part, of the pressure differential across the balloon membrane as a baseline condition. The balloon has the greatest sensitivity to pressure when the baseline pressure differential is near zero. As the baseline pressure differential increases, the sensitivity of the pressure-sensing balloon degrades. Accordingly, the disclosed technology provides an automatic priming method that maintains the balloon in an inflated state, but with a minimal pressure differential.

[0083] Embodiments of the technology include a pressure interface as may be represented by a balloon having either a compliant membrane or a non-compliant membrane. The conditions for optimal sensitivity of a compliant balloon and a non-compliant balloon are slightly different, although, in general, the sensitivity of each is best served by \( P_i \) and \( P_2 \) being approximately equal. A non-compliant balloon's maximum sensitivity is achieved when \( P_i \) is only slightly above \( P_2 \). For a compliant balloon, the maximum sensitivity is achieved when \( P_i \) is slightly above \( P_2 \) at the low
end of the (linear) elastic region of the spring constant of the compliant balloon material.

[0084] Pressure sensitivity considerations, per embodiments of the disclosed technology, are determined by Boyle's ideal gas law, by Hooke's relationship between stress and strain, and by Young's modulus that applies the Hooke relationship to materials.

- Boyle's Ideal Gas Law: \( PV = nRT \)
- Hooke's stress/strain law for balloon material: \( E = \frac{S}{e} \) (Young's modulus = stress/strain)

[0085] Fig. 37 shows the pressure and volume relationships for a non-compliant pressure-sensing balloon.

\[
\begin{align*}
\text{P}_i & \text{ is pressure in the detection balloon} \\
\text{V}_i & \text{ is volume in the detection balloon} \\
\text{P}_2 & \text{ is the pressure in the urinary bladder} \\
\text{V}_2 & \text{ is the volume in the catheter} \\
\text{P}_i < P < \text{P}_i(\text{V}_i+\text{V}_2)/\text{V}_2
\end{align*}
\]

[0086] To effectively capture physiologic pressure profiles, the profiles need to be sampled at a rate that is sufficient to resolve the inherent frequency of changes in the profile. This consideration is informed by the Nyquist-Shannon sampling theorem, which states that a sampling frequency of at least 2\(B\) samples/second is required to resolve an event that runs at a frequency of \(B\) cycles/second. As applied to a physiologic pressure cycle, for example, a cardiac rate of 70 beats/minute requires a sampling rate of at least 140 samples/minute to effectively capture the cycle. This relationship underlies aspects of the disclosed technology that specify the sampling rate particularly required to capture physiologic pressure cycles such as relative pulmonary tidal volume, cardiac output, relative cardiac output, relative stroke volume, and absolute cardiac stroke volume.

[0087] Another novel aspect of the present invention that is not intuitive and not described in the prior art is the ability to utilize a very small lumen for air transmission. Through experimentation by the inventors, it was determined that pressure signals with frequencies and magnitudes similar to those of IAP, respiratory, and cardiac signals are not degraded even as the inner diameter of the lumen
approaches 0.5 mm. Use of a very small lumen is advantageous because urinary catheters already have multiple lumens that compete for space and can limit how small the outer diameter of the catheter can be. Fig. 14 shows the sensitivity to peristaltic pulsations in air channels with a lumen diameter of 3 mm 103, 1 mm 105, and 0.5 mm 107. The data shows that little degradation of the signal took place when the air lumen size was decreased from a diameter of 3mm to diameters of 1mm and 0.5mm.

[0088] This data indicates the appropriateness of using the embodiment of the pressure transduction system in a small diameter pediatric catheter down to a size as small as 4F. Due to the lack of requirement for structural integrity that is found with the retention balloons (due to their higher pressure), the pressure lumen can easily be accommodated even in a 4F or 6F catheter that is typically provided without a retention balloon due to size constraints. In this embodiment, as well, the tip of the catheter can be lower profile than the rest of the Foley to allow for a consistently small diameter even with addition of the pressure sensing balloon. Thus, the catheter of the present invention is uniquely suited to the pediatric indication where there is a dire need for more appropriate, less invasive monitoring methods. In another embodiment, the retention balloon itself can be used as the pressure balloon, in order to minimize the number of required lumens. In one embodiment, the retention balloon is used in its fully inflated state, and is only used to track macro trends in IAP. In another embodiment, the retention balloon is only slightly inflated in order to increase balloon sensitivity to small changes in pressure. This embodiment allows for finer measurements of micro parameters, such as heart rate, relative stroke volume, relative cardiac output, respiratory rate, and relative tidal volume.

**Pressure Sensing Balloon Embodiments**

[0089] Expandable pressure sensing balloons, per embodiments of the technology, may assume one of at least two basic forms, type 1 or type 2. Fig. 38A shows an example of a type 1 balloon 301, and Fig. 38B shows an example of a type 2 balloon 303. In balloon embodiments of type 1, which may be generally likened to a conventional party balloon, the pressure-sensing balloon is formed from or includes a compliant or elastic membrane. Accordingly, the surface area of the membrane expands or contracts as a function of the expansion of the balloon. The elasticity of
the membrane determines various features of the balloon, as a whole, at different levels of expansion. Upon expansion, the balloon, if unconstrained, maintains a substantially constant or preferred form or shape, as determined by the mandrel upon which the balloon is formed. Upon expansion of the balloon from a minimal volume to its maximal volume, the membrane of the balloon maintains a level of tautness. Within the limits of elasticity of the compliant membrane, an increase in pressure during inflation results in a consequent expansion of volume. The balloon, on the whole may be considered partially compliant in that its shape responds to spatial constraints that it may encounter upon expansion or inflation, however the balloon does have a preferred or native shape, and such shape preference prevents a level of shape compliance or conformability such as that shown by a balloon of type 2.

In balloon embodiments of type 2, the expandable pressure-sensing balloon is formed from or includes a non-compliant, or non-elastic membrane, or a membrane that is substantially non-compliant or non-elastic. Accordingly, the surface area of the membrane does not expand or contract in accordance with the level of balloon expansion. Type 2 pressure-sensing balloons may be generally likened to a conventional Mylar® balloon. The inelasticity of the membrane determines various features of the balloon, as a whole, at different levels of expansion. Upon expansion of the balloon from a minimal volume to a level near its maximal volume, the membrane of the balloon is supple, and has a level of slackness. Expansion of a type 2 balloon occurs by way of outwardly directed smoothing of wrinkles and folds in the membrane. Deflation or compression of a type 2 balloon occurs by way of generally inwardly directed wrinkling and infolding. When a type 2 balloon is fully inflated (or substantially inflated) without being in a confining space, it assumes a preferred or native shape as determined by the geometry of the membrane or fabric of the balloon. However, in a state of partial inflation, the balloon, as a whole, is highly supple and conformable, broadly taking the shape as may be dictated by a confining space.

Expandable pressure sensing balloons, per embodiments of the technology, may also include features of both of the two basic forms, type 1 or type 2. In these embodiments, the membrane may include regions that are elastic (like type 1) and regions that are inelastic (like type 2). A balloon of this hybrid type would, as a whole, behave in a manner drawing from behavioral aspects of both type 1 and type 2 balloons, as described above. Further, type 1 balloons may be formed with a
membrane that is not of a homogeneous composition or thickness. In such embodiments, regions of different thickness or composition could have varying degrees of elasticity, thus affecting the behavior of these regions during expansion of the balloon. In still other embodiments, elasticity of the membrane may have a bias or polarity that tends to permit elasticity in one or more directions, and tends to disallow elasticity in one or more other directions.

**Priming, Repriming, and Automation of the Pressure Sensing Balloon**

[0092] An aspect of the disclosed technology that is particularly advantageous in achieving a high resolution signal from which pressure profiles from particular physiologic sources (such as peritoneal pressure, respiratory rate, and cardiac rate, relative pulmonary tidal volume, cardiac output, relative cardiac output, relative stroke volume, and absolute cardiac stroke volume) may be monitored relates to adjusting and maintaining a balance of pressure on either side of the pressure interface represented by the membrane of the pressure sensing balloon. This balance of pressure may be referred to as a pressure differential of zero, or as a zero pressure gauge. Pressure impinging on the external face of balloon (facing the internal aspect of the bladder) is subject to change according to the physiology of the patient. Pressure on the internal face of the balloon (which is in fluid communication with the fluid column) is subject to degradation because of fluid leakage and imperfect seals.

[0093] Upon first insertion of the Foley type catheter, external pressure is typically applied to the fluid column and against the pressure interface to a first approximation of pressure being exerted on the pressure interface from within the bladder. Pressure signals, as measured across a pressure interface, have a maximal amplitude when the pressure differential is zero. Accordingly, the amplitude of a pressure signal can be used to tune the pressure being applied from the fluid column against the pressure interface. This process of applying an appropriate amount of pressure against the interface may be referred to as priming the fluid column or priming the balloon. Inasmuch as pressures on either side of the pressure interface may change, as described above, the fluid column may need to be reprimed, from time to time. The necessity of repriming can be monitored by testing small changes in pressure so as to achieve maximal amplitude of a pressure signal profile.
Embodiments of the disclosed system and method include automatic priming by a controller. Accordingly, the priming system can detect the optimum target pressure and volume to inflate the balloon by monitoring sensed pressure signals and adding or removing air volume as needed. For example, upon insertion of the catheter, an autopriming circuit that regulates the balloon volume and pressure will inflate the balloon until it detects a physiologic-sourced pressure rate. Upon sensing that rate, the autopriming controller will add or subtract minute amounts of air in a routinized sequence until the amplitude of the sensed wave is greatest. The control feedback loop between the optimum priming (manifesting as balloon pressure and volume) and the sensed physiologic pressure profile iterates continuously and/or as needed to ensure high fidelity measurement of the physiologic data. In some embodiments, autopriming may be performed in the apparent background while the physiologic data is being transmitted and displayed; in other embodiments the system may suspend transmission of physiologic data during an autopriming sequence.

Examples of Data Delivered by Embodiments of the System

Figs. 8-12 show data collected using sensing Foley catheter systems. Embodiments of a sensing Foley catheter have been used to collect data from a human subject (Figs. 8 - 10) and from a pig (Figs. 11 - 12).

Fig. 8 shows an example of peritoneal pressure sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system. During this test period, the subject performs a respiratory sequence as follows: (1) breath being held at the end of an inspiration, (2) Valsalva maneuver (forced exhalation attempt against a closed airway), (3) normal respiration, (4) Valsalva maneuver, and (5) breath being held at the end of an expiration. The two breath holds can be clearly seen as plateaus in peritoneal pressure. Furthermore, the higher baseline value for end inspiratory pressure than for end expiratory pressure is consistent with expectations; as the lungs fill with air, peritoneal pressure increases.

Fig. 9A shows an example of respiratory rate sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system. During this test period, the subject performs a respiratory sequence as follows: (1) breath being held at the end of an inspiration, (2) Valsalva maneuver, (3) normal respiration, (4) Valsalva maneuvervalsalva, and (5) breath being held at the end of an expiration.
The Valsalva maneuvers are easily identified in this plot by the large momentary spikes in peritoneal pressure. This is consistent with expectations; during a Valsalva maneuver, peritoneal pressure spikes.

[0098] Fig. 9B shows a detailed portion of the respiratory profile of Fig. 9A, a portion of the period of normal respiration. Respirations are easily identified in this plot as periodic rising and falling of the peritoneal pressure. This behavior is due to the filling and emptying of the lungs with air, which increases and decreases peritoneal pressure, respectively.

[0099] Fig. 10 shows an example of cardiac rate and relative cardiac output sensing data from a human subject, as provided by an embodiment of the sensing Foley catheter system, and an EKG trace as measured simultaneously and independently. This plot first illustrates the ability of the sensing Foley catheter to measure cardiac rate, as is evident from the alignment of timing between the pressure and EKG signals. The plot also demonstrates the potential to measure relative cardiac output using the sensing Foley, as indicated by the area under the curve for each cardiac pulse. As the relative cardiac increases, the strength of the cardiac pulses increases, which results in a larger cardiac pulse measured in the bladder by the sensing Foley catheter and a larger area under the curve.

[0100] Fig. 11 shows an example of peritoneal sensing data from a pig, as provided by an embodiment of the sensing Foley catheter system. Fig. 12 shows an example of respiratory rate sensing data from a pig, as provided an embodiment of the sensing Foley catheter system.

Detection of Body Sounds

[0101] In some embodiments of the disclosed technology, acoustic detection of body sounds and sound transmission may also be achieved through the use of a microphone and/or an acoustic signal generator disposed within the sensing catheter or implant. Acoustic sound detection may also allow for the detection of speech, sleep apnea, sleep stage characterization, respiratory wheezes/rhonchi, pneumonia, asthma, acute respiratory distress, or other abnormal respiratory sounds, intestinal sounds, or cardiac sounds. In one embodiment, the device can be used to detect the return of bowel sounds following a period of intestinal paralysis or inactivity as typically occurs with abdominal surgery or injury.
Detection and Treatment of Infection

[0102] In some embodiments of the disclosed technology, indicators or markers of infection, such as, by way of example, urine nitrates, urine pH, oxygen, carbon dioxide or other gases, glucose, leukocyte esterase may also be continuously monitored. In these embodiments, a change in such infection markers in the urine may be detected and reported to prompt further investigation of a potential urinary tract infection and/or removal or replacement of the catheter. A catheter with this sensing capability may be able to be left in place for a longer duration for some patients, such as those considered at risk but who have not yet shown signs of infection. A shorter implantation period may be appropriate for patients who have already been diagnosed with an infection, in which case the catheter may be useful for monitoring resolution of an infection while the patient is being treated.

[0103] This application of the technology allows for infections to be prevented and/or treated early and has the potential to allow optimal residence time for each individual catheter versus the relatively arbitrary recommendation to remove and replace all Foley catheters after 7 days of dwell time. Urinary tract infections may also be rapidly detected and treated, thus resulting in a shorter overall hospital stay for these patients. Sensors within the catheter or within the collection reservoir may also detect urine flow rate (catheter or reservoir based), bacteria presence, procalcitonin, lactoferrin, leukocyte esterase, specific gravity, pH, protein, glucose, ketones, blood, leukocyte esterase, nitrite, bilirubin, urobilinogen, ascorbic acid. The pressure sensor may also allow for triggering of urine flow with increased bladder pressure, which mimics the natural flow of urine and sweeps bacteria downstream (and may reduce infection). In this scenario, a valve may be incorporated into the urine outflow line that may be intermittently opened and closed based on bladder pressure.

[0104] In another aspect, devices and methods of the disclosed technology may be directed to a rinsing lavage of the bladder, so as to treat infection or other insult or injury to the bladder. A lavage may serve, for example, to cleanse the bladder interior of bacteria or blood clots. Further, anti-infective agents may be delivered through embodiments of the disclosed catheter.
Embodiments of the Device in Other Peritoneal Sites

[0105] A balloon or an infusion catheter that slowly infuses fluid may also be used to sense peritoneal or intraabdominal pressure through placement in peritoneal sites other than the bladder, such as the rectum or stomach. Regardless of where the sensing occurs (bladder, rectum, stomach) or whether the pressure transmission medium is liquid or air, the method of determining parameters such as respiratory rate, cardiac rate, relative cardiac output, relative stroke volume, patient activity level, or peristaltic activity, data processing by way of algorithms may be applied to yield clinically applicable information. By applying the algorithms of this present technology (for example, by selectively filtering the noise, extracting frequencies, or reporting certain frequencies as physiologic signals), each of these parameters can be obtained from this peritoneal pressure signal. Other body sounds, such as bowel sounds, heart sounds, and respiratory sounds may also be transmitted and detected through the fluid filled or air-filled lumen in order to detect pathology related to changes in these sounds (for example, bowel obstruction, pneumonia, or decreased cardiac output).

[0106] In yet further embodiments, a fully implantable device or a device fully enclosed in a luminal site (temporary or long-term) may be used to sense these parameters, among the others disclosed above, and report these parameters externally to provide diagnostic information to the healthcare provider. These device embodiments that are implantable at sites in luminal organs or body cavities other than the urinary bladder are enabled with pressure sensing capability as well as one or more analyte sensing capabilities, and further are enabled with data processing capabilities to yield values for various physiologic parameters, as has been described above, in the context of the sensing Foley catheter.

[0107] Figs. 13A-B show the placement of an exemplary embodiment of preperitoneal sensing implant. One implantable version of this device employs a balloon 101 positioned in the pre-peritoneal space. The balloon is in fluid communication with a pressure sensor within the device and the pressure is intermittently reported externally. The fully implantable device may also be rechargeable and may report any of the above-mentioned parameters. In particular, the device may further be capable of extracting information from the pressure signal.
to give an indicator of respiratory rate, cardiac rate and/or relative cardiac output or
relative stroke volume. The implantable device may be placed fully within the
preperitoneal space or may be partially placed within the subcutaneous space. The
device may be recharged transdermally (either in its preperitoneal site or via a
tethered antenna implanted closer to the skin). The device may, alternatively, have its
battery changed once every few years or may be inductively powered or recharged by
a custom belt that may be worn over the device for all or part of the day.

[0108] The device may, alternatively, have therapeutic abilities and be able to
perform an action based on sensed parameters. In addition to calling help, the device
may be able to deliver a shock in response to changes in cardiac output, stroke
volume, and/or heart rate sensed by the device or deliver a drug in response to any
changes in the sensed parameters. The device may also, optionally, communicate
with the patient through a receiver or smart phone which may allow for automatic
uploading of data to a healthcare provider. In its ideal embodiment this device can be
implanted anywhere in the body but will provide optimal acoustic and pressure data if
placed in the pre-peritoneal space superior to the umbilicus just below the xiphoid.

[0109] This embodiment may measure respiratory rate, cardiac rate, relative cardiac
output, relative stroke volume, patient activity level, or peristaltic activity and data
processing by way of algorithms that may be applied to yield clinically applicable
information. By applying the algorithms of this present technology (for example, by
selectively filtering the noise, extracting frequencies, or reporting certain frequencies
as physiologic signals), each of these parameters can be obtained from this peritoneal
pressure signal. Other body sounds, such as bowel sounds, heart sounds, and
respiratory sounds may also be transmitted and detected through the fluid filled or air-
filled lumen in order to detect pathology related to changes in these sounds (for
example, bowel obstruction, pneumonia, or decreased cardiac output).

[0110] In its ideal configuration the design will have good hoop strength to support
the acoustic/pressure sensing membrane to ensure that capsular contracture does not
occur. In this embodiment the hoop may be constructed of nitinol to allow for its
compression into a tight delivery package, the preperitoneal space dissected using a
blunt dissection tool at an angle to the peritoneal lining and the device deployed into
this space in its larger configuration. In some embodiments, this design will also have
a small catheter accessing the peritoneal cavity to sense analytes within the peritoneal fluid and/or deliver compounds to this space.

[0111] This design will have optimal utility as a long-term implant monitoring chronic conditions *(i.e.,* monitoring for fluid on the lungs, cardiac output, etc. for congestive heart failure, monitoring heart rate and respiratory rate for any condition that can cause acute decompensation, etc.) in an ambulatory setting. In another embodiment of the device, temperature is also measured and tracked over time. In yet another embodiment, acceleration data is recorded and used to measure patient activity levels. The acceleration data may also be combined with other data, such as pressure and acoustic data, in order to more accurately identify events such as coughs or sneezes and filter out external artifacts. In yet another embodiment, the device may have offset electrodes to measure electrical cardiac activity. In yet another embodiment, the device may also have a glucose sensor that can continuously track the patient's blood glucose levels.

**Delivery of Therapeutic Hypothermia**

[0112] Some embodiments of the disclosed system may be functionally directed to the delivery of therapeutic hypothermia. In this clinical application, the catheter may be equipped to measure bladder pressure, as above, measure urethral temperature, and be able to drain urine and add fluid to the bladder. In this embodiment, the catheter may be used to warm or cool the patient (mild to moderate hyperthermia or mild to moderate hypothermia) via the infusion of a warm or cold fluid as appropriate. In the generation of mild to moderate hypothermia, the bladder may be evacuated then refilled to a set pressure with an ice-cold medium (a cold fluid, or a chilled slurry or slush) while the core body temperature is monitored. In this embodiment, an initial fill of the bladder with cold medium may be sufficient to generate the desired degree of hypothermia, or the temperature of the fluid may be tracked (in some embodiments, by way of a second temperature sensor in the bladder) and evacuated once it rises above a set temperature *(e.g.,* 15°C). If the desired patient temperature has not yet been reached, the bladder may then be refilled with the liquid/slurry and evacuated until the patient has achieved their target temperature.

[0113] In some embodiments, the delivery of therapeutic hypothermia process is automated by the system, requiring only that a clinician insert a sensing Foley catheter
embodiment, and then connecting the catheter to the temperature control system and/or any patient monitor that the clinician desires. In some embodiments, the infused fluid is a slush to take advantage of the much greater watt extraction capabilities of slush in comparison to a cold fluid. In some embodiments, the sensing Foley catheter is able to sense one or more of the other parameters mentioned above (such as respiratory rate, or oximetry) during and following this therapy. The cold medium (slush and/or fluid) may be used to induce hypothermia, and the bladder may be evacuated once the target temperature is reached. As the body temperature rises, the slush and/or fluid may be introduced into the bladder then evacuated, again, as the target temperature is reached. In this embodiment, the resting state of the bladder is the evacuated state and it only contains chilled fluid or ice when the body is not within target temperature range. In some embodiments, the slush may be formed on-demand in a manner that allows it to be carried into the field or ambulance, and then created on-site, in order to treat trauma or injury as it occurs. This on-demand aspect of the method embodiment may involve have a pre-frozen block of ice that is shaved or ground, or a compressed gas source that vents into the liquid, thereby causing a rapid drop in temperature. This compressed gas embodiment may be used either to generate a slush, or to cool the medium while allowing it to remain a liquid.

Related Embodiments

Variations of the embodiments described above for use in the bladder, may be reconfigured and/or resized for application in other luminal body sites such as the stomach, esophagus, small intestine, large intestine or rectum. In some embodiments, these data may be obtained through invasive access of the peritoneal cavity, cerebrospinal space or pleural space, ideally in instances where accessing these spaces is already performed for another purpose.

Embodiments of the technology include an implantable sensor for vital sign monitoring, as particularly suitable for a patient in battlefield or transport setting, prior to being secured into a hospital setting.

Further embodiments of the technology include a free-floating transmitting bladder embodiment, a free-floating transmitting stomach embodiment, an ingestible, self-destructing capsule, and a rectum sensor.

Embodiments of the Device for Other Applications
Some embodiments of the device may comprise methods of pressure measurement in other anatomic locations and/or combined with existing medical devices. In one embodiment, the pressure-sensing system of the present invention may be used with ascites shunts in order to ensure that the shunt is draining and has not become obstructed. In another embodiment, the pressure-sensing system may be used with dialysis catheters. In another embodiment, the system may be used with insulin delivery catheters. Generally, the system may be used with any shunting, infusing, or other similar applications where fluid blockage may be of a concern and a pressure measurement would help identify whether a blockage has occurred.

**Airlocks and Embodiments Of The Device With Line Clearing**

In some embodiments, the device is capable of handling a water droplet or other obstruction in an air-filled lumen and reporting its presence. Water droplets in an air-filled lumen (or air droplets in a water-filled lumen) can disturb or complicate pressure signals due to the surface tension of the water. In a hypothermic setting, moisture in an air lumen can condense and form obstructive water droplets. Accordingly, a pressure-transmission lumen in some embodiments of the disclosed technology may include a hydrophilic feature (such as a coating on the wall of the lumen itself, or a hydrophilic fiber running the length of the lumen) to wick moisture away from the lumen in order to maintain a continuous, uninterrupted air channel. A hygroscopic composition (silica gel, for example) may be used in line with the air infusion line or within the air infusion lumen itself to capture water or humidity. In some embodiments, a hygroscopic composition may be included within the catheter so that the air infusion circuit need not be serviced to replace this material.

In some embodiments of the disclosed technology, air may also be intermittently (and automatically) infused and extracted into the pressure-sensing balloon so that the balloon is in a constant state of being optimally primed. In the case of the wicking fiber or hydrophilic coating in the lumen, the air extraction may also contribute to removing and trapping any water from the air line. In the instance of a water (or other liquid)-filled lumen, a hydrophilic fiber or a hydrophilic coating on the inside of the pressure lumen will provide similar benefit in allowing this lumen to handle an air bubble. In this instance, an air bubble may distort the signal, but the air water interface surface tension is defused by a hydrophilic coating in the lumen of the catheter. Additionally, a custom extrusion and lumen shape may also be used to
prevent obstruction in the case of liquid and/or air-filled lumens. In some embodiments of the technology, for example, a catheter may have a lumen that is stellate in cross sectional profile. Such a lumen is generally immune from obstruction by a water droplet, as the droplet tends to cohere to itself and push away from the hydrophobic walls. This behavior tends to disallow filling of a cross-sectional space, and allows for an air channel to remain patent around the water droplet and communicate to the sensor. The same logic applies to an air bubble in water in a hydrophilic, stellate water lumen. In this instance the hydrophilic liquid will cling to the walls and allow for a continuous water column that excludes the air bubble to the center of the lumen. The same applies for a hydrophobic liquid in a hydrophobic lumen.

In some embodiments, the catheter may include an air channel, and a sensor incorporated within the catheter itself or a fluid lumen that is capable of transmitting the pressure back to a sensor.

Some embodiments of the device may incorporate mechanisms to keep the drainage line clear of blockages in order to maintain an empty, flaccid bladder and avoid false positive IAP measurements. These blockages may be caused by airlocks in the drainage tube or by crystals, blood clots, or other physical blockages. Any of the embodiments to keep the line clear as described in Burnett US Provisional Patent Application S/N 61/840,162 (which is incorporated herein by reference in its entirety) would be suitable. In one embodiment, this is accomplished with active line clearing, such as a bellows to provide negative pressure or a pump to clear obstructions. This embodiment allows for clearing of both airlocks and physical blockages. In another embodiment, the line clearing is passive, and may be accomplished with vents that allow air to escape the drainage line instead of forming airlocks. In yet another embodiment, the IAP measurements from the present device may be combined with urine output measurements obtained with the Burnett device, in any manner they have disclosed.

Automated Drainage Line-Clearing Device

One embodiment of the sensing Foley catheter system also includes an automated drainage line-clearing device. The drainage line is the tube that connects the Foley catheter to the drainage bag. Fig. 15 shows an embodiment for clearing the
drainage line that uses a vacuum applied to the end of the drainage line. The vacuum, transmitted through the drainage line 112 and then the Foley catheter to the bladder of the patient, facilitates better draining than if the vacuum were not in place. In one aspect, the vacuum is created by a bellows 111 attached to the urine collection device or receptacle 5. The bellows 111 is expanded in its natural state, but is compressed before the urine catheter is inserted into the patient. Once the catheter is in place, the bellows 111 is released, and the restoring force creates a negative pressure in the urine collection device. In another embodiment, the restoring force may also be created by a spring within the bellows 111. In another aspect, the vacuum is created by a pump.

The pump may be any suitable pump, including but not limited to diaphragm pumps, peristaltic pumps, or vane pumps. The pump may be powered by a wall outlet, battery, human power, or any other suitable source. In another aspect, the vacuum is in the range of 0 to -50 mmHg.

[0123] Figs. 16A-16B, show an embodiment of the clearing mechanism comprising a device for positive airflow 113 near the start of the drainage line 112. Said positive airflow facilitates drainage by forcing urine to flow through the drainage line. In one aspect, shown in Fig. 16A, the positive airflow device comprises a one-way valve 115 at the end of the urine catheter that allows urine to only flow toward the urine collection device, and prevents air from entering the catheter. In another aspect, the positive airflow device comprises a diaphragm 116 attached to the start of the drainage line. Said positive airflow device also comprises a one-way valve 117 that allows air to enter the drainage line but prevents air or urine from exiting and a one-way valve 118 that allows air to enter the diaphragm but prevents air from exiting. Therefore, as the diaphragm 116 is compressed, it forces air to flow through the drainage line 112. When compression is relieved, the diaphragm 116 expands into its natural state and new air is introduced through one-way valve 118. Said one-way valves 117 and 118 could be any suitable valves, including but not limited to umbrella valves and duckbill valves. In another aspect, shown in Fig. 16B, the diaphragm 121 is not located at the start of the drainage line 112, but is connected to the start of said drainage line through a lumen 123 or tube that runs from the start of the drainage line to the diaphragm 121. The diaphragm 121 also comprises a one-way valve 127 that allows air to enter the drainage line but prevents air or urine from exiting and a one-way valve 125 that allows air to enter the diaphragm but prevents air from exiting. In
yet another aspect (not shown), the positive airflow device comprises a pump. The pump may be any suitable pump, including but not limited to a diaphragm pump, peristaltic pump, or vane pump. The pump may be powered by a wall outlet, battery, human power, or any other suitable source. In yet another aspect, the positive airflow device comprises a syringe attached to the drainage tube. The syringe may attach to the drainage tube with a luer lock, septum valve, or any other suitable interface.

[0124] In another embodiment, the clearing mechanism comprises a coating on the inside of the drainage tube to reduce surface tension and facilitate drainage. In one aspect, said coating is a hydrophobic polymer, including but not limited to PTFE or FEP.

[0125] In yet another embodiment, the clearing mechanism comprises a tubular hydrophobic vent filter (not shown) that can be inserted into the drainage lumen of the device such that air will be evacuated throughout its length. A segmental hydrophobic vent can also be incorporated at set intervals to ensure that air is evacuated from the tube as it passes these regions. While others have attempted to prevent air locks with a hydrophobic vent filter at the interface of the Foley catheter and drainage tube, this approach still results in air locks regularly if the vent is not at the zenith of the drainage tube and pointed downward (such that the drainage tube end of the vent is below the Foley catheter side). In the preferred design, the hydrophobic vent will be interspaced at minimum of 1-2 foot intervals to prevent submersion of the vents in urine (a problem that found with the currently-used urinary catheter which is vented only at the Foley adapter). By providing redundancy, the present invention prevents the failure of the vent due to submersion since all of the intermittent vents would have to be submerged which is not possible, based on our benchtop tests with a redundant loop. In the ideal configuration the vent will be a PTFE or ePTFE material and will be affixed with a barb and or grommeted into the tube at intervals to allow for easy manufacturability. In an alternative embodiment, the vent takes the form of a slit or spiral that runs the length of the drainage tube, thereby allowing air to escape the tube at any point. This prevents the drainage tube from being positionally dependent when preventing and/or eliminating airlocks.

Fig. 39A shows an example of a drainage tube with a slit vent 272, and Fig. 39B shows an example of a drainage tube with a spiral vent 273.
In an alternative embodiment, air locks are prevented by means of an extendable drainage tube (not shown), which prevents pockets of air from forming in the high portions of the tube and urine from gathering in the low portions. An extendable tube prevents this from occurring by keeping the tube as straight as possible between the urinary catheter and the collection bag. In one aspect, the extendable drainage tube is composed of multiple telescopic sections that can be extended or collapsed to match the distance from the patient to the collection bag. In another aspect, the drainage tube is pleated to form an accordion, which can be extended or collapsed as necessary. In yet another aspect, the tube is coiled. In yet another aspect, the drainage tube is retractable by means of a spring coil that wraps the tubing around a wheel to achieve the appropriate length.

In another embodiment, the clearing mechanism comprises a tube with an inner diameter less than 0.25 inches as the drainage tube (not shown), such that no air pockets are able to move up the length of the tube. This is possible due to the surface tension within the smaller tubes, which prevent movement of fluid when one end of the tube is closed to atmosphere (as in the case of the bladder). Thus, the drainage tube always remains full of urine, and for each volume of urine produced the same volume of urine must exit the drainage tube, as urine is incompressible. In another embodiment, the inner diameter is less than 0.125 inches. In another aspect, said drainage tube acts as a siphon and provides a small, safe amount of vacuum to the bladder.

The use of small-diameter tubing also results in a smaller volume of residual urine in the drainage tube compared with the prior art. Having a smaller residual volume is preferential, as it allows urine to move more quickly from the patient's bladder to the collection vessel. The speed of this transport is important in order to take measurements of the urine that has been produced more recently. This is particularly important for patients with low rates of urine production, as it takes their urine even longer to be transported from the bladder to the collection vessel. For example, for a patient producing only 10 mL/hr of urine with a standard drainage tube (around 40 mL residual volume), measurements of their urine in the collection vessel will lag true urine production by 4 hours. By contrast, with smaller tubing (such as tubing having around 5 mL residual volume), measurements will only lag true production by 30 minutes.
[0129] In another embodiment, shown in Fig. 17, the clearing mechanism comprises an apparatus for automated massaging, or squeezing, of the drainage line 112. In one aspect, the squeezing apparatus comprises a peristaltic pump 129. Said peristaltic pump 129 also provides slight vacuum to the bladder, which helps to facilitate drainage as described herein. In another aspect, the squeezing mechanism comprises a slider-crank mechanism attached to a rotary motor. In another aspect, the squeezing mechanism comprises a solenoid. In another aspect, the clearing mechanism further comprises one-way valves on either side of the squeezing mechanism to force urine and air to only flow down the tube and further provide vacuum to the bladder.

[0130] In another embodiment, air locks are removed through use of a pulsatile mechanical, vibratory acoustic, thermal, or electromagnetic stimulus that results in movement of the drainage tubing and/or the fluid within. This vibration, in combination with the pressure gradient driving the urine preferentially from the patient to the urine drainage bag, allows the urine to move forward in small increments until the resistance of the air lock has been overcome. At this point, a siphon is created and normal drainage can resume. The pulsatile stimulus is effective due to the hysteresis involved in the flow of the urine in the presence of a pressure gradient. Small movements of the urine due to energy pulses will have a net effect of moving the urine away from the patient. In one aspect using pulsatile energy, a vibratory stimulus is employed. The vibratory stimulus described can be created using a coin vibration motor, eccentric motor, or other similar means.

[0131] As an alternative to the vibratory stimulus, the drainage tube may be pinched or rolled intermittently, which has a similar net effect of moving the urine away from the patient due to hysteresis. This pinching or rolling may be achieved using a peristaltic-like mechanism, slider-crank mechanism, or other similar means. An alternative approach would be to use a pneumatic or hydraulic pump to cycle compression and decompression, like a sphygomanometer, on different sections of the tube to mimic manual milking of the tube. This approach is distinct from the automated massaging or squeezing described above, in that only a slight pulse of stimulus is required. The pulsatile approach, then, can avoid generating vacuum in the bladder, which may adversely affect bladder tissue. The vibratory or pinching stimulus may be placed near the patient, near the drainage tube, or anywhere in between.
[0132] In another aspect using pulsatile energy, an acoustic stimulus is employed. The acoustic stimulus may be of a subsonic frequency designed to agitate the fluid but not the patient (due to the stimulus being below the range of hearing). The stimulus may also be in the sonic range or even in the supersonic range to achieve higher energy delivery. In the acoustic embodiment, the pressure waves will be transmitted down the fluid column generating the same hysteresis effect.

[0133] In another aspect using pulsatile energy, an electromagnetic stimulus is employed. The electromagnetic stimulus may be a cuff or other device external to the drainage tube that creates pulses of electromagnetic energy. This energy has an effect on the salts in the urine, effectively agitating it slightly toward the drainage bag. The principles underlying this method are that of an electromagnetic pump, which is used in other applications. The electromagnetic approach takes advantage of the same hysteresis effect as the other approaches, and has the same effect of removing air locks by agitating the urine toward the drainage back until a siphon effect is achieved.

[0134] In another aspect using pulsatile energy, a thermal stimulus is employed. The thermal stimulus may be used to rapidly heat and cool a small portion of the drainage tubing, thereby expanding and contracting the urine or air within. In the expansion phase, the leading edge of the urine or air preferentially expands toward the drainage bag, due to the pressure gradient. Similarly, in the contraction phase, the tailing edge of the urine or air moves toward the drainage bag. The thermal stimulus thus takes advantage of the same hysteresis effect as the other approaches. Rapid heating of the urine or air can be achieved with a heating coil, chemical reaction, or other similar means, while rapid cooling of the urine or air can be achieved with a Peltier cooler, chemical reaction, gas expansion, or other similar means.

[0135] In another embodiment the mechanical, acoustic, electromagnetic, thermal, vibratory or pinching stimulus may be continuous, scheduled, or sensor-based. In the continuous embodiment, the stimulus is always on. In the scheduled embodiment, the stimulus repeats itself after a given time period, such as, but not limited to, every 1 minute, 5 minutes, 10 minutes, 30 minutes, or 1 hour. In the sensor-based embodiment, the mechanical, acoustic, electromagnetic, thermal, vibratory or pinching stimulus is applied whenever an air lock is suspected or detected based on urine output and sensed pressures. This detection can be accomplished in a variety of
ways, including, but not limited to, a flow sensor, an optical sensor that distinguishes between urine and air, or an in-line oxygen sensor. Furthermore, each of these embodiments could be expected to interfere with pressure measurements in the sample collection vessel described below and will preferably be performed immediately after a siphon activation to allow for minimization of the risk of missing a vessel emptying or interfering with a specific gravity measurement.

[0136] Fig. 18 shows another embodiment of the pinching or rolling stimulus, the lumens are compressed sequentially by rollers 131 such that they are never all compressed at the same time. This feature serves to prevent all lumens from becoming obstructed, a scenario that could cause urine to back up in the patient's bladder and lead to detrimental conditions. Having multiple lumens that are only compressed one at a time also helps reduce the amount of negative pressure that is applied to the bladder wall. This prevents trauma to the soft tissues. In one aspect, the lumens lay side-by-side in a strip fashion, and the pinching or rolling mechanisms are offset such that they can only compress one lumen at a time.

[0137] Preferably, an entire drain tube will be cleared with one roll; at a minimum, one half of a drain tube height should be cleared, given a maximum air lock height. Advantageously, these rollers can handle high viscosity urine. The rollers comprise cam profiles that may be round or oval—which can provide varying pressure for clearing clots. Should a blood clot obstruction occur at a Foley catheter inlet hole, the rollers can be used to temporarily reverse the flow of urine to dislodge the clot, or (as previously described) intentional vibration of the fluid column can be used to dislodge the clot. The roller position can be selectively controlled so as to avoid "parking" on tubes. This ensures that flow is completely unobstructed from the bladder to the drainage bag. Controlling the parked location can be accomplished with any suitable means, including, but not limited to a stepper motor, current sensing of the motor (current will drop when the rollers are not compressing the tubes), a limit switch, an encoder, magnetic positioning, detection of a change in tube diameter as it is compressed, and/or pressure sensors on the lumen or roller. However, in certain instances, parking the rollers on the tubing may be beneficial for selectively limiting the flow if it is too high for the chamber to handle, particularly when first intubating the bladder. In these instances, selective control of the roller position will be used to ensure one of the tubes is compressed.
The rollers can be activated manually, using a timed means, or automatically triggered if, based on the number or urine drips in a chamber, no urine output is detected for a specified number of minutes. Suction trauma to the soft tissues is prevented by setting the roller speed is set so that is occurs slowly enough to remain quasi-static. In the event of an air lock with an empty bladder, for example, in one embodiment the roller would pull gentle suction on one tube, but the suction transmitted to the bladder would be limited by the ability of fluid to move from one tube to the other by virtue of their being joined at the proximal end of the tube where it connects to the Foley catheter.

Fig. 19 shows another embodiment comprising multiple lumens organized circumferentially around a stiff member that the pinching or rolling mechanism rotates around, thereby compressing one lumen at a time and avoiding complete obstruction of all lumens. Fig. 20 shows an alternative embodiment in which the lumens are organized such that they can only be completely compressed when pinched in a certain direction, or. A plurality of rolling or pinching mechanisms are used to compress the tube sequentially from multiple directions, and each mechanism can only compress those lumens that are designed to be compressed in that direction. Fig. 20 illustrates an example of lumen geometries that are only fully compressed in a preferential direction. In the non-preferential direction, the lumens cannot be completely compressed. In this example, lumens will be compressed with the illustrated pinching force, while lumens will not. Alternatively, a single rolling or pinching mechanism rotates around the tube to compress it sequentially from multiple directions. In another embodiment of the sequential pinching or rolling stimulus, the portion of the tube that is pinched or rolled is only a small portion of the entire drainage tube, such that the geometry of the rest of the drainage tube is not limited to the geometries required to facilitate sequential compression of the lumens. In another embodiment of the peristaltic pumps used for massaging, squeezing, or pulsing, the pump is a finger-style peristaltic pump that uses linear motion to stimulate the drainage tubing.

In another embodiment, a pressure sensing lumen may be incorporated into the tubing to allow for measurement of pressure within the drain tube, Foley catheter or bladder itself. This pressure measurement can be used to control the pump or line clearing mechanism to allow for effective air lock removal without the generation of
negative pressure and suction trauma in the bladder. This device may also be used in combination with a pressure sensing Foley catheter as described in US Pat. App. No. US2013066166, S/N/ 13/414,307 (which is incorporated herein by reference in its entirety). This combination will allow for the effective measurement of true bladder pressure and activation of the pump to ensure that the sensed bladder pressure is truly a result of intra-abdominal hypertension and not the result of a confounding air lock. The sensing balloon of the Foley can also be incorporated proximally into the Foley catheter or be attached to the drainage tube in order to minimize the intravesical profile of the device. The sensing lumen could also be another lumen in the tube that conducts the pressure through the lumen to the pressure sensor and roller pump. In the absence of an air lock, the pressure seen in fluid communication with the inside of the bladder is actually a vacuum. In order to provide an accurate measurement of bladder pressure in the setting of a siphon effect (i.e. with a vented Foley drain system or in the absence of any air lock) the pumping mechanism can actually be driven backwards until it has offset the siphon effect. There will still be no net movement of fluid in this scenario and the pump action will be increased until further increases do not generate an increase in sensed pressure. At this point the true bladder pressure can be read and the flow from the bladder can be allowed to resume.

[0141] Fig. 21 shows a graph of the pressure profile, pressure (mmHg) 149 over time (seconds) 151 in the drain tube while the peristaltic roller pump is activated. The graph shows an airlock being formed and pressure building 153, vacuum generated in drainage tube/Foley catheter by peristaltic action of pump and detected by pressure sensor 155, elimination of airlock with the pump parked on one tube 157, and airlock eliminated with the pump parked on none of the tubes 159. No matter how the vacuum is generated (peristaltic pump, integrated gear pump, etc.) the bladder is at risk of suction trauma. This suction trauma can cause mucosal irritation and bleeding and can increase the risk of bladder infection. Monitoring the pressure and activating/deactivating pump operation based on the sensed pressure mitigates this risk and allows for effective line clearance without exposing the bladder to excessive vacuum. In addition, in the event that a siphon effect is generated, purposefully occluding one of the outflow tubes can decrease the overall vacuum generated within the bladder. Temporarily reversing the action of the pump can offset the siphon and provide a true bladder pressure.
Fig. 22 is a table comparing IAP measurements using a standard drainage line and IAP sensor with the present invention in combination with a pressure-sensing Foley catheter under air lock 161 and siphon 163 effects. A sheep bladder was used to compare pressure measurements between standard drainage technologies and the present invention. In the presence of an air lock, traditional technologies to measure IAP report false positive values, whereas the Accuryn device shows greater accuracy. In the absence of an air lock, but in the presence of a siphon (due to a full drainage tube), the traditional technology reports accurate values if used intermittently, with a valve in place to temporarily block flow from the bladder to the drainage tube. The present device also reports accurate values in the presence of a siphon. However, when used continuously without a valve, the traditional technology severely underreports the true pressure. Without air lock prevention and elimination, IAP cannot be accurately and reliably measured. In addition, respiratory rate, tidal volume, heart rate, cardiac output and stroke volume readings from the bladder may be diminished and/or corrupted due to the floating baseline of pressure within the bladder.

In yet another embodiment (not shown), the present invention and the pressure-sensing Foley catheter can be used together to detect and clear obstructions from blood clots or other obstructions. During milking of the drainage tube, if the pressure in the drainage tube spikes while the pressure within the bladder remains unchanged, this is indicative of a blockage between the bladder and the termination of the pressure sensing lumen. To clear this blockage, additional negative pressure can be generated using the massaging rollers until the pressure suddenly drops and matches the pressure within the bladder. This is indicative that the blockage has been cleared. In yet another embodiment, blockages such as those from blood clots can be prevented by ensuring that the inner diameter of the drainage lumen/tube only gets larger or remains the same size from the bladder to the drainage bag. When the opposite occurs, this creates the potential for bottlenecks that can become a site for obstruction.

In addition, any and all of the aforementioned inventions may be utilized in other drainage tubes including tubes draining liquid (urinary, pleural, cardiac, bile, wound, peritoneal dialysate, drain tubes, etc.) or tubes pulling air (i.e. pneumothorax evacuation, etc.). Chest tubes, in particular, have been noted to be susceptible to air
locks and pressure accumulation within the chest wall which can subsequently lead to poor outcomes. These tubes would greatly benefit from an air lock prevention/removal feature, particularly if this feature were controlled by pressure measurement near the chest wall to control the degree of vacuum/suction generated by the pump.

[0145] In addition to eliminating air locks, the air lock clearance designs detailed above (with the exception of the passive venting design) have been found to effectively clear deposits and blood clots from urine drainage lines in the bench top model. These problems plague current urine drainage tubes, particularly those with smaller lumen drain tubes and monitoring technologies at the drainage bag, and this invention provides an advance in the state of the art by automating the clearing of these drainage blocking debris and clots. This feature is particularly useful when used in conjunction with pressure sensing either in a balloon at the tip of the Foley or in fluid communication with the bladder. This allows for the monitoring of pressure and vacuum in the bladder and allows for more aggressive pumping based on actual bladder pressure until the clot/obstruction is cleared. Without this pressure/vacuum sensing, the pumping of fluid in the drain tube may generate clinical sequelae in the bladder, such as suction trauma, due to the exposure of the bladder mucosa to excessive vacuum.

[0146] In another aspect of the present invention, an automated urine output measurement device is provided, comprising one or more methods for detection of passing urine and a number of its parameters.

[0147] Figs. 23A-E illustrate resistive or conductive methods for detecting urine; urine is detected by a change in resistance or conductance between two or more electrical leads. Fig. 23A, the urine is controlled to create drips 163, which pass between two or more leads 165 and change the resistance or conductance between the leads 165. When the change in resistance or conductance is detected, a drip 163 is counted and the calibrated volume of said drop 163 is added to the total urine output volume. In order to create uniform drips for drip counting, urine should be allowed to run along a tube for drip counting. In cases where the viscosity of the urine is changing dramatically, the size of each drip may be affected, which could interfere with the conversion of drips to volume. However, this issue can be overcome by using
real time drip calibration, where the volume of drips is calculated based on volume at conductivity leads. With each triggering of the conductivity leads, the known volume at that level is divided by the number of drips since the last emptying to calculate the volume of each drip. Alternatively, the change in the pressure signal may be used to account for changes in viscosity that lead to varying drip size; more viscous drips will be larger and therefore have a larger "splash" pressure wave. If accounting for viscosity by means of varying drip size, this information may also be displayed as another parameter in the urinalysis, including real-time and trending data. Because viscosity and specific gravity of urine are closely related, this parameter may also be used in place of true specific gravity measurements.

[0148] Fig. 23B shows the collection device with embedded electrical leads 167 on the inside which make contact with the urine only when it has risen to a certain level, at which point the collection device is emptied by opening a valve 169, tilting, or some other similar method, and the calibrated volume is added to the total urine output volume. In another aspect, shown in Fig. 23C, the collection device has embedded electrical leads 171 on the inside that run the height of said collection device, and are always in contact with the urine. The total urine output volume is determined by the resistance or conductance measured between said leads 171, which changes as the volume of urine increases. In yet another aspect for any of the resistive or conductive embodiments described herein, shown in Fig. 23D, the leads 173 do not make physical contact with the urine, but instead the urine fills a balloon or bladder 175 within the urine collection device, which expands and makes contact with the leads. The balloon or bladder 175 can be made of any suitable elastomeric material, including but not limited to silicone, polyurethane, or nylon. In another aspect, the resistance or conductance of the urine is used as an indicator of the density, or specific gravity, of the urine, which is another indicator of the fluid status and renal function of the patient.

[0149] Fig. 40 shows another embodiment where airlock detection occurs using two conductive leads 274 within the drainage tube: one near the patient end and one near the collection chamber. If the drainage tube is full of urine (not air locked), the resistance between the two leads will be relatively low. If an air lock forms, the resistance will increase significantly, which we will detect and then activate the pump
to remove the air lock. This feature will allow for the pump to only be activated when necessary and conserve battery power.

[0150] In other embodiments, shown in Figs. 23A-D, the method for detecting urine is capacitive, in which urine is detected by a change in the capacitance between two or more electrical plates or leads. The electrical plates or leads can take any of the same forms as described for the resistive detection methods herein, including as a drip counter, can be in direct contact with the urine or through a balloon or bladder, and can use capacitance as an indicator of specific gravity.

[0151] In other embodiments, shown in Figs. 23A-D, the method for detecting urine is thermal, in which urine is detected by a change in the temperature of one or more probes 2. The probes 2 can take any of the same forms as described for the resistive detection methods herein, including as a drip counter, and can be in direct contact with the urine or through a balloon or bladder 4. The probes can comprise any suitable temperature transducer, including but not limited to thermistors or thermocouples.

[0152] In other embodiments, shown in Figs. 23A-D, the method for detecting urine is optical, in which urine is detected by one or more optical sensors 2, including but not limited to infrared emitter-detector pairs or cameras. The optical sensors 2 can take any of the same forms as described for the resistive detection methods herein, including as a drip counter, and can use urine clarity as an indicator of specific gravity. The optical sensors may detect changes in opacity in the urine. They may also look at the color spectrum to detect red, which could signal blood, or white, which could signal pus. The optical sensors may also detect bacteria, cells and urinary casts, which are small particles made up of white blood cells, red blood cells, or kidney cells. The overall opacity of the urine may also be indicative of certain diseases, i.e. rhabdomyolysis, internal hemorrhage, etc.

[0153] In another embodiment, the method for detecting urine is microfluidic, in which the urine passes through a microfluidic flow detection chip and is integrated to determine total urine output volume. In another aspect, the microfluidic chip measures volume instead of flow, and adds a discrete volume of urine to total urine output volume each time said discreet volume passes through the chip.

[0154] Fig. 24 illustrates a method for detecting urine that is strain-based, in which an increase in urine volume stretches a balloon or bladder 177 and is detected by one
or more suitable strain transducer 179, including but not limited to electrical foil
gages or fiber Bragg grating optical sensors. In one aspect, said balloon or bladder
177 contains the entire urine output volume, which is measured continuously. In
another aspect, said balloon or bladder 177 fills to a certain volume, indicated by the
strain transducer 179, and is emptied into a larger storage container. With each
emptying, the calibrated volume is added to the total urine output volume. The
balloon or bladder 177 can be made of any suitable elastomeric material, including
but not limited to silicone, polyurethane, or nylon. In another aspect, the balloon or
bladder is made of an electroactive polymer that compresses when voltage is applied.

Figs. 25A-C show methods for detecting urine that are weight- or pressure-

[0155] based, in which an increase in urine volume increases the weight of the collection
device and the pressure of the urine column. In one aspect, shown in Fig. 25A, the
urine collection device is placed on top of a device to measure force 181, such as but
not limited to a scale. In another aspect, shown in Fig. 25B, the urine collection
device is hung from said measurement device 183. In another aspect, said collection
device fills to a certain volume, indicated by the measurement device 183, and is
emptied into a larger storage container. With each emptying, the calibrated volume is
added to the total urine output volume. In another embodiment, shown in Fig. 25C,
the method for detecting urine is pressure-based, in which an increase in urine volume
is detected by one or more pressure transducers 185, including but not limited to
piezoelectric or potentiometric sensors. Said transducers 185 provide an indication of
the height of the urine, which is converted to volume by multiplying by the known
cross-sectional area of the urine collection device.

[0156] Fig. 26 illustrates a method for detecting urine makes use of a magnetic float

valve 187, which is initially held closed with magnet 189. As urine fills the
measurement container, the float 187 becomes submerged under the urine and the
buoyant force increases until it eventually overcomes the magnetic force, breaking
free and opening the valve 191. The urine is then allowed to pass through the valve
191 as the float 187 descends, eventually reengaging with magnetic force and closing
the valve 191. Cycles of the valve opening and closing are counted by any suitable
means, including but not limited to optical sensors or resistive sensors 193, as
described herein. In another aspect, the float 187 has detectors on its surface,
including but not limited to electrical leads 195, which detect the degree to which the
float is submerged. The degree to which the float becomes submerged before breaking free from the magnetic force is dependent on the density, or specific gravity, of the urine, which is another indicator of the fluid status and renal function of the patient.

[0157] In another embodiment, the method for detecting urine makes use of an impeller, fan, water wheel, or any other suitable device that rotates in the presence of flowing fluid, in which passing urine causes rotations that are detected by means such as but not limited to magnetic or optical encoders. With each rotation, a calibrated volume of urine is added to the total urine output volume.

[0158] In another embodiment, the conductance of the urine is measured. This measurement can be accomplished with any of the methods previously described, including using conductive wires or strips to measure the conductance of the urine between them. The wires, strips, or other potential embodiments may also be used to measure urine output volume, as described above, or may be standalone devices used exclusively for the measurement of urine conductance.

[0159] In another embodiment, the specific gravity of the urine is measured. This measurement can be accomplished with any of the methods previously described, including using resistance/conductance, capacitance, urine clarity (with optical sensors), or a float/hydrometer. These parameters may also be used to measure urine output volume as described above, or may be standalone devices used exclusively for the measurement of specific gravity. In yet another embodiment, specific gravity is obtained by measuring the pressure just prior to the voiding of the disposable sample collection vessel at a known column height of urine. Density of the urine is thus calculated \( \rho = \frac{P}{g} \) and converted to specific gravity by dividing by the density of water.

This method allows for calculation of specific gravity using the pressure sensor already being used to measure urine output volume. Additional embodiments for measuring specific gravity include, but are not limited to, using refraction measurements, vibration measurements, or any other known methods for measuring specific gravity.

[0160] In another embodiment, the oxygen tension of the urine is measured. In one aspect of the embodiment, this measurement is made using an electrochemical sensor such as, but not limited to, Clark type electrodes that make use of a silver/silver
chloride anode and platinum cathode to reduce available oxygen or those that make use of phosphorescence quenching.

[0161] In another embodiment, prevention of contamination from ambient air on measurements of oxygen tension is accomplished by filling the sample collection vessel with nitrogen gas before use and connecting it to the distal end of the urinary catheter in such a manner that very little to no ambient air is introduced into the vessel. This can be accomplished with the use of a valve, septum or other similar feature. As an alternative to filling the sample collection vessel with nitrogen, it may be evacuated of air prior to use through use of vacuum packaging or other appropriate means. Yet another alternative embodiment may be to include an oxygen absorber in the vessel. Said oxygen absorber can be made from any appropriate material that reacts with available oxygen, including, but not limited to, iron oxide or ascorbic acid. This oxygen-absorbing material may be in the form of loose granules or pellets, in packages, or in rolls or strips. Furthermore, said collection vessel and drainage tubing may be made from a substantially oxygen impermeable material, such as but not limited to glass, metals such as stainless steel, or plastics such as vinyl, polyurethane, PMMA or other oxygen impermeable polymers. This prevents atmospheric oxygen from contaminating the urine samples prior to analysis.

[0162] In yet another embodiment, the effects of changing conductivity on measurements of oxygen tension are corrected for using the conductivity measurements already being made. This embodiment is preferred, as changing conductivity levels will affect the readings of oxygen tension using the electrochemical sensors described herein. Therefore, prior to use, the present invention will be calibrated such that the relationship between conductivity, measured oxygen tension, and actual oxygen tension is known and accounted for.

[0163] In an alternative embodiment, the oxygen and conductance measurements are made within the drainage tube or urinary catheter itself. Measurements are made in-line in order to prevent mixing with previous urine or atmospheric gases or particles. Said measurements are accomplished by placing the oxygen sensor and conductance leads within the drainage tube or urinary catheter.

[0164] In yet another embodiment, a thermistor, thermocouple or similar temperature sensor is included to take measurements of the urine along the length of
the drainage tube. Currently-used Foley catheters are first attached to the drainage bag, then additional connections are made for temperature, pressure, etc. However, as shown in Fig. 41, if the wires 275 and pressure lumen 276 run the length of the drainage tube, then they could connect directly to the reusable box that houses the pump and displays urine output in one step. The connections for the wires can be secured with snap fits, pogo pins, magnetic connectors, or any other similar means. The connection for the pressure lumen can be secured with a barb and gasket, Luer lock, or any other similar means. The temperature, pressure, and any other data could then be integrated into the display.

This measurement is included to account for potential temperature dependencies of the other measurements, such as conductance or oxygen tension. The temperature reading from the sensor is thus included in the algorithm to provide fully calibrated results. The temperature measurement may also be an additional parameter to incorporate into the others to further distinguish between causes of AKI, to detect UTI, to determine the development or status of AKI or to monitor the response the therapy/therapeutic intervention.

In another embodiment, measurements of the described parameters can be obtained with each filling of the 5-10 cc sample collection vessel, which takes a few minutes. Though not continuous, this frequency is effectively as clinically useful as continuous measurements for urine oxygen tension, urine conductance and urine specific gravity. For urine output volume, continuous measurements can be obtained between emptying of the sample collection vessel by means of counting drips, which appear as spikes in the pressure readings. The size of the drips is consistent and known based on the geometry of the drainage line exit. Therefore, continuous measurements of urine output volume can be obtained with drip-rate (sub-cc) precision.

Another embodiment comprises a pressure tube inside a measurement vessel. The pressure tube should have a large diameter/cross-sectional area to overcome surface tension effects and to increase the magnitude of the signal. The material of the tube should be hydrophobic to reduce surface tension. Fig. 42 shows a small float 277 that can be used in the tube 278 to completely drain when the siphon drains. As the urine empties, the weight of the float purges the tube.
Fig. 27 shows a small sample collection vessel 201 self-emptying by means of a siphon that is triggered when the urine volume reaches a pre-determined level. Urine enters the sample collection vessel 201 through drainage tubing 199. As urine enters the sample collection vessel, it may pass an oxygen sensor 207. Once in the sample collection vessel, the urine level is measured by means of a pressure tube 197 that converts pressure to height, based on the urine density, and height to volume, based on the cross-sectional area of the sample collection vessel. While the urine is filling the sample collection vessel, additional measurements of conductance, specific gravity, oxygen tension, or carbon dioxide, nitric oxides, nitrogen, and any other gas pressures may be made by means of sensors 205 and 209. As the urine level rises in the sample collection vessel, it also rises in the self-emptying siphon 203, which eventually drains the urine into the larger collection vessel 211.

Figs. 28A-D illustrate the emptying sequence for the apparatus shown in Fig. 27. In Fig. 28A, the urine is filling the sample collection vessel, which is partially full. In Fig. 28B, the urine has reached the level just before the siphon will be triggered. In Fig. 28C, the siphon has been activated and the urine is draining from the sample collection vessel into the larger collection vessel. Finally, in Fig. 28D the sample collection vessel has emptied completely and the filling process starts over.

Pressure changes in the collection vessel can signal key events, such as overflow and backflow, in urine monitoring. For example, when the pressure in the sample collection vessel rises and then remains high with drips, then urine is overflowing. If the pressure continues to rise with no drips, then the urine is backing up; since this is a failure mode, a clinician should be alerted. Backflow can be prevented by having the user empty the bladder and clamping the disposable tubing and drainage portion before removing them. Alternatively or in addition, the direction of flow of the urine should be marked on the drain tube so that the user can see if it is back-flowing. Alternatively, an air vent at the top of the drainage tube can open when the disposable tubing is removed. Opening this air vent eliminates the siphon effect within the drainage tube, which then to allows the urine to empty into the drainage bag.

The sample collection vessel or chamber needs to be protected from bacteria and encrustation. By raising the temperature of the chamber between the drain tube
and collection bag to temperatures higher than 30 degrees Celsius, encrustation can be prevented. Bacteria, such as *Escherichia coli*, *Candida spp*, *Enterococcus spp*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Enterobacter spp*, other gram-negative bacteria, *Staphylococcus spp*, *Proteus mirabilis*, *Enterococcus faecalis* and *Staphylococcus aureus* may also be killed by either high or low temperatures, for example temperatures above 50 degrees Celsius for over 30 minutes. As an alternative, the chamber may be irradiated with UV. A stand-alone clamp-o device may be used for the chamber, as well as the other drainage tubes and Foley catheters. Removal of oxygen from the chamber will kill aerobic bacteria present. The presence of silicone, or other oil—liquid, capsule or as coating—and silver in the chamber will prevent bacterial growth.

**[0172]** Figs. 36A-B show embodiments of the sample collection vessels comprising siphon and overflow features. Fig. 36A shows a sample collection vessel 265 comprising a siphon 267 which, during normal operation should always empty the vessel. An overflow tube will be used if the siphon fails or is clogged, etc.; the urine will pour into the overflow tube 269 in order to prevent backup of urine in the vessel. Fig. 36B shows a sample collection vessel 265 with a siphon 267 and an overflow ledge. Instead of using a small tube, the overflow is a large "ledge" 271. A large ledge is less likely to become clogged than an overflow tube.

**[0173]** Fig. 29 illustrates the use of the sample collection vessel and pressure tube to provide information about the volume and density (specific gravity) of the urine being collected. Each filling of the collection vessel is indicated by a rise in pressure, and each emptying is indicated by a sudden decrease in pressure. Because the vessel empties once it reaches a pre-determined volume, these emptyings can be counted to calculate the volume of urine that has passed. Additionally, the specific gravity can be calculated with each emptying of the vessel, as the density of the urine will determine the pressure at each emptying. In another embodiment, the known volume could be further detected by appropriate placement of the conduction sensing electrodes near the fill line for siphon activation. Once the fluid level reaches these electrodes, the pressure is detected and converted into a specific gravity.

**[0174]** Taking measurements of multiple urine parameters as described, such as conductance, specific gravity, urine output and oxygen tension, provides a synergistic
source of information that is more informative than each of these measurements taken alone. This is because a change in any individual parameter could be the result of any number of possible conditions. For a given combination of changing parameters, however, the list of possible conditions that may have caused the change is much smaller. For example, increasing specific gravity in the presence of stable conductance is indicative of urinary deposition of non-conductive solutes, while increasing specific gravity in the presence of decreasing conductance, decreasing oxygen tension, and decreasing urine output is indicative of ischemia (or prerenal) acute kidney injury (AKI).

Fig. 30 shows a table that lists combinations of parameters that allow for a fingerprint (unique combination of parameters) for the different causes of AKI (pre-renal, intrinsic and obstructive). In addition, there may be a unique fingerprint with respect to the timing of changes of the parameters, which may also determine the causes of AKI (e.g. it is plausible that some parameters change faster for intrinsic AKI caused by glomerulonephritis versus intrinsic AKI caused by acute tubular necrosis). This multi-parametric approach may also facilitate the choice of effective therapies to treat AKI since different causes of AKI have different effective therapies (e.g. recombinant alkaline phosphatase is effective at treating intrinsic (septic) AKI but ineffective at treating non-septic AKI).

In addition to detecting AKI, the present invention is capable of detecting urinary tract infections (UTIs), as indicated by decreasing oxygen tension, carbon dioxide levels, increasing specific gravity, and relatively stable urine output and conductance. The detection of UTI can be achieved in the absence of AKI, and possibly in the presence of AKI, by combining urinary markers for a unique fingerprint of UTI. The unique UTI fingerprint can alert clinicians to the presence of UTI.

In addition to detecting AKI and UTI using the described parameters, these parameters may be used in combination with intra-abdominal pressure (IAP), respiratory rate (RR), heart rate (HR), cardiac output (CO) and/or stroke volume (SV) readings, which are already used for detecting conditions such as intra-abdominal hypertension (IAH), abdominal compartment syndrome (ACS) and sepsis. This combination of parameters may be accomplished by using the present invention in
conjunction with a pressure-sensing Foley catheter, such as one described by Burnett WO2012/122267A1 and also described in an Application for Federal Assistance (SF 424 (R&R) titled^ novel device for improving sepsis outcomes through hemodynamic optimization^ (Tracking Number: GRANTI 1282036, Funding Opportunity Number: 12-088)). Adding IAP, RR, HR, CO and/or SV measurements to the algorithm described herein may increase the sensitivity and specificity of detecting AKI or UTI. On the other hand, adding the measurements obtained by the present invention to an IAP, RR, HR, CO and/or SV measurement algorithm may increase the sensitivity and specificity of detecting IAH, ACS or sepsis. Other clinical applications include the treatment of trauma and burns.

[0178] The present invention can be used in a variety of hospital settings (e.g. emergency room, operating room, intensive care unit, ward). At any time, the device may be used to monitor the progression of AKI, and whether it is improving or declining. Its algorithms work to alert clinicians to a newly developed case of AKI or to a change in the status of AKI. The device may be placed before insult to the kidney occurs (e.g. patients undergoing cardiac surgery to detect if insult to the kidneys begins intra-operatively) in order to detect initiation of AKI. It may be placed when insult to the kidney is already present in order to detect the degree of insult at that time. The device may also be used to monitor the response the therapy/therapeutic intervention (e.g. renal replacement therapy, fluid resuscitation).

[0179] Fig. 31 illustrates the Urine Collection and Detection System (UCDS) algorithm. First, urine output, oxygen pressure, conductivity, and specific gravity are measured 401. If there are no changes in these parameters 403, nothing happens and the device continues to take measurements. If urine output, oxygen pressure, and conductivity is decreasing and specific gravity is increasing 405, an alert is thrown for pre-renal AKI 407. If oxygen pressure and specific gravity are decreasing, urine output is rapidly decreasing, and conductivity is increasing 409, an alert is thrown for intrinsic AKI 411. If urine output is decreasing rapidly, conductivity is increasing rapidly, and oxygen pressure and specific gravity are steady 413, an alert is thrown for post-renal AKI 415. If oxygen pressure is decreasing rapidly, specific gravity is increasing, and urine output and conductivity are steady 417, an alert is thrown for UTI 419.
The current invention utilizes a small volume urine sample collection vessel (preferably 5-10 cc in volume) that dumps into the larger collection vessel and performs urinalysis on a mixed fluid of urine production over a given time interval. The current invention has also demonstrated feasibility in that even at pathologically low flow rates, the urine being analyzed consists of a mixture of a fraction of an hour's worth of urine collection. Additionally, the device is able to accommodate any catheter flow rate (i.e., an uneven flow rate) and any flow rate in or out of the sample collection vessel. Regarding conductance, the present invention measures overall conductance as opposed to concentrations of specific analytes, which are relatively difficult and expensive to perform. Finally, the proposed device does not require the use of calibration fluids, which are expensive and cumbersome to use.

By combining air lock prevention/clearing with precision urine output measurements, highly accurate urine output measurements can be obtained using the present invention. Fig. 32 shows a comparison between Accuryn with a Standard System over a variety of parameters during constant urine production on a bench top model. Urine production is kept steady at 15 cc/min, as shown in the first graph for both systems. In the standard system, the first component to fill with urine is the tube, which fills to a certain amount, becomes air locked, and plateaus. During this plateau, urine begins to collect inside the bladder. Urine then continues to collect in the bladder and the drainage tube such that the pressure inside the bladder equals the pressure due to the air lock. Only when the bladder pressure is high enough to produce an airlock tall enough for the urine to reach the top of the drainage tube does drainage into the bag begin. At this point, urine output measurement using the standard system is accurate. However, once the line is milked (emptied), the cycle repeats itself. As a result, the urine output measurements using a standard drainage system are normally incorrect. With the Accuryn system, however, the drainage tube is always completely full (with a much smaller volume than that of the standard tube), which allows the bladder to remain completely empty and measured urine output to accurately match that of true urine production.

Figs. 33A-C show alternative retention balloon designs for urine catheters within the bladder 251, comprising one or more balloons to facilitate better urine drainage and decrease the likelihood of becoming obstructed. In one embodiment, shown in Fig. 33A, the balloon comprises two or more separated sections 253,
between which are drainage holes, such that tissue intrusion is prevented. In another embodiment, shown in Fig. 33B, the balloon comprises two or more arched members that act as a cage around the drainage holes. In yet another embodiment, shown in Fig. 33C, the balloon comprises an eccentric balloon that prevents tissue intrusion into the drainage holes.

[0183] Fig. 34 shows a urine drainage tube that allows for partial compression and a motive force based on a vibrating element. In this most preferred embodiment, the section of the tube that is subjected to the vibrational or mechanical motive force may be at most 90% compressed and, therefore, will not have the inherent risk of occlusion that would occur with the stall of a typical pump. Compression may be applied circumferentially or along one or more sides. Compression may be as little as 5% and as much as 90% and may be applied at a point or along a length of the tube. Compression of the tube is, preferably, intermittent and may be of sufficient force to clear blood clots from the urine drain tube.

[0184] Fig. 35 shows an embodiment of collection reservoir that will not become obstructed with debris, clots or crystals in the urine. In this embodiment (unlike the self-siphoning reservoir) the urine will collect and be continuously pooled and mixed in the collection vessel, before being collected in a urine drain bag. Changes in metabolites, conductance, urinary oxygen tension, specific gravity, etc. will be slower to be reflected in this embodiment, but it will not be subject to the clogging in cases with high protein, blood, debris or crystal content. In order to prevent delays in measurement the volume in the base of the reservoir will, preferably, be minimized with a volume of, at most, 20cc and preferably as little as 1cc. The reservoir is preferably disposable and may be instrumented with a pressure sensor connection, conductance electrodes, specific gravity monitor, etc.

[0185] In yet another embodiment of the present invention, the method of preventing airlocks is combined with the method of measuring urine output. This combined method is the only way to ensure that urine output measurements accurately reflect true urine production, as airlocks lead to retained urine in the bladder that is not accounted for in the measurement vessel. One preferred embodiment of this method is the combination of urine output measurement with passive air lock prevention using a vented tube. The vented tube preferably has multiple vents or a
continuous vent, as described above, or may comprise an internal vent tube. Another preferred embodiment of this method is the combination of urine output measurement with active air lock prevention using any of the methods described above. However, it should be understood by any person of ordinary skill in the art that the current invention applies to any technique of combining air lock prevention and elimination with any technique to measure urine output. The details disclosed are preferred embodiments, but do not limit the scope of the invention.

[0186] In yet another embodiment of the present invention, any potential misalignment of the measurement vessel, which could skew urine output readings, can be detected and accounted for. One such method of accounting for misalignment is to have multiple pressure-sensing tubes at the bottom of the measurement vessel, and to use these results to obtain the correct result. For example, in the simplest case, two pressure-sensing tubes are on either side of the measurement vessel. As the vessel tips to the side, one of the pressure-sensing tubes reads a higher than true pressure and the other reads a lower than true pressure. The difference of these readings can be used to calculate the angle at which the measurement vessel is tipped, and therefore used to account for the misalignment and provide the correct result. Another such method of accounting for misalignment is to have multiple conductive leads around the perimeter of the measurement vessel. Depending which leads have detected the presence of liquid, the angle of misalignment can be calculated and accounted for.

[0187] In yet another embodiment of the present invention, the drainage tube has additional lumens beyond those used for drainage, as shown in Fig. 43, which illustrates the drainage lumens 279 and additional lumens 280. These lumens can be used to measure pressure in the bladder or drainage tube, house a thermistor from the Foley to the console, house wires for detecting the conductivity along the drainage tube for air lock detection, or for carrying/transmitting any additional relevant data to the console.

[0188] In yet another embodiment of the present invention, measurements of gas partial pressures are made after the gas in the urine has had the change to equilibrate with gas in a small sample chamber. As shown in Fig. 44, this is accomplished by using a gas permeable but liquid impermeable membrane 281 to separate the urine 282 from the gas in the sample chamber 283 and allowing them to equilibrate.
Equilibration is performed in one aspect by passive transport between the urine and gas in the sample chamber. In another aspect, the gas is pulled through a looping channel made of the gas permeable membrane in order to maximize the amount of time it has to equilibrate with the urine. In another aspect, the gas is actively pumped into and out of the sample chamber whenever a measurement is taken to prevent contamination between samples. Once equilibration has been achieved, the measurement of the gas pressures is performed with known technologies, such as any means of performing a capnograph to measure carbon dioxide, any means of measuring oxygen (such as a lambda sensor), and any means of measuring the other gases described above.

[0089] In another embodiment of the present invention, creatinine clearance can be measured by infusing methylene blue (or any other similar marker) into the patient and measuring creatinine output in their urine. The time until initial detection and rate of clearance give an indication of how well the kidneys are functioning. By synchronizing intermittent infusions of markers with the measurement of these markers in urine, near-continuous information about the kidney function of the patient can be obtained.

[0090] Unless defined otherwise, all technical terms used herein have the same meanings as commonly understood by one of ordinary skill in the medical arts.

Specific methods, devices, and materials are described in this application, but any methods and materials similar or equivalent to those described herein can be used in the practice of the present invention. While embodiments of the invention have been described in some detail and by way of illustrations, such illustrations are for purposes of clarity of understanding only, and are not intended to be limiting. Various terms have been used in the description to convey an understanding of the invention; it will be understood that the meaning of these various terms extends to common linguistic or grammatical variations thereof. Further, while some theoretical considerations may have been advanced in furtherance of providing an understanding of the technology, the appended claims to the invention are not bound by such theory. Moreover, any one or more features of any embodiment of the invention can be combined with any one or more other features of any other embodiment of the invention, without departing from the scope of the invention. Still further, it should be understood that the invention is not limited to the embodiments that have been set forth for purposes
of exemplification, but is to be defined only by a fair reading of claims appended to the patent application, including the full range of equivalency to which each element thereof is entitled.
CLAIMS
1. A device for draining bodily fluids, comprising:
one or more lumens configured to receive a bodily fluid from a patient body;
a reservoir in fluid communication with the one or more lumens for receiving
the bodily fluid;
a pumping mechanism to urge fluid through the one or more lumens, wherein
said pumping mechanism never fully obstructs outflow of said bodily fluid.

2. The device of claim 1, wherein the lumens have an interior diameter
that maintains a siphon.

3. The device of claim 2, wherein the lumens are less than ¼ inch in
interior diameter.

4. The device of claim 1, wherein even with a system failure, the
pumping mechanism cannot fully obstruct outflow.

5. The device of claim 1, wherein the pumping mechanism is peristaltic.

6. A device for draining and measuring bodily fluids comprising multiple
lumens, a pumping mechanism, and a volume or flow output measurement
mechanism.

7. The device of claim 6, wherein the lumens have an interior diameter
that maintains a siphon.

8. The device of claim 7, wherein the lumens are less than 1/4" inch in
interior diameter.
9. The device of claim 6, wherein the pumping mechanism urges fluid through the lumen without fully obstructing the lumen.

10. The device of claim 6, wherein the pumping mechanism is peristaltic.

11. The device of claim 6 claimed wherein the output measurement mechanism is pressure-based, resistance-based, capacitance-based, or optically-based.

12. A device for draining and measuring bodily fluids, comprising:
   one or more lumens;
   a pumping mechanism in fluid communication with the one or more multiple lumens;
   a volume or flow output measurement mechanism in fluid communication with the one or more multiple lumens; and
   at least one additional analysis mechanisms configured to detect one or more physiological parameters from the bodily fluids contained within the volume or flow output measurement mechanism and received through the one or more multiple lumens.

13. The device of claim 12 wherein the lumens have an interior diameter that maintains a siphon.

14. The device of claim 13 wherein the lumens are less than 1/4” inch in interior diameter.

15. The device of claim 12, wherein the pumping mechanism urges fluid through the lumen without fully obstructing the lumen.
16. The device of claim 12 wherein the pumping mechanism is peristaltic.

17. The device of claim 12 wherein the output measurement mechanism is pressure-based, resistance-based, capacitance-based, or optically-based.

18. The device of claim 12, wherein the additional analysis mechanisms analyze at least one of specific gravity, oxygen tension, conductivity, gas pressures, and sediment.

19. A method of automatically clearing one or more lumens used for draining bodily fluids, comprising:

   passing bodily fluids from a patient through at least one drainage line;

   receiving the bodily fluids into a reservoir via the drainage line; and

   applying one of a pulsatile mechanical, vibratory acoustic, thermal, vibratory, pinching, rolling or electromagnetic stimulus to cause at least one of a movement of the drainage line and the bodily fluids within.

20. The method of claim 19, wherein the rolling stimulus comprises compressing the lumens sequentially such that the lumens are never all compressed at the same time.

21. A method of detecting and clearing a drainage line having one or more lumens used for draining bodily fluids, comprising:

   draining bodily fluids from a bodily organ via a drainage line;

   detecting a pressure spike in the drainage line while a pressure within the bodily organ remains constant; and

   using massaging rollers to create negative pressure through the drainage line until the pressure in the drainage line equals the pressure in the bodily organ.
22. A method taking measurements of multiple urine parameters for detecting acute kidney injury, urinary tract infection, intra-abdominal hypertension, abdominal compartment syndrome, or sepsis.

23. The method of claim 22, wherein the urine parameters include conductance, specific gravity, urine output, and oxygen tension.
### Drain Line Status

<table>
<thead>
<tr>
<th></th>
<th>Backpressure: Handrail w/ air lock</th>
<th>Siphon: Handrail w/o air lock</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bard® &amp; AbViser™ Intermittent</strong> (pressure transducer w/ valve)</td>
<td>+20.7</td>
<td>-0.9</td>
</tr>
<tr>
<td></td>
<td>False Positive</td>
<td>Accurate</td>
</tr>
<tr>
<td><strong>Bard® &amp; AbViser™ Continuous</strong> (pressure transducer w/o valve)</td>
<td>+12.9</td>
<td>-19.5</td>
</tr>
<tr>
<td></td>
<td>False Positive</td>
<td>False Negative</td>
</tr>
<tr>
<td><strong>Theranova Accuryn™</strong></td>
<td>-0.3</td>
<td>-0.3</td>
</tr>
<tr>
<td></td>
<td>Accurate</td>
<td>Accurate</td>
</tr>
</tbody>
</table>

**Fig. 22**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Condition</th>
<th>AKI</th>
<th>UTI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre</td>
<td>Intr</td>
</tr>
<tr>
<td>Urine Oxygen Tension</td>
<td>↓ then ↑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Output</td>
<td>↑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Conductance</td>
<td>↓ then ↑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>↑↑↑↑↑↑↑↑↑↑↑</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 29

Fig. 30