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(54) **APPARATUS AND METHOD FOR BEDSIDE
COLLECTION OF BODY FLUIDS AND
AUTOMATIC VOLUME LEVEL
MONITORING**

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(57) **ABSTRACT**

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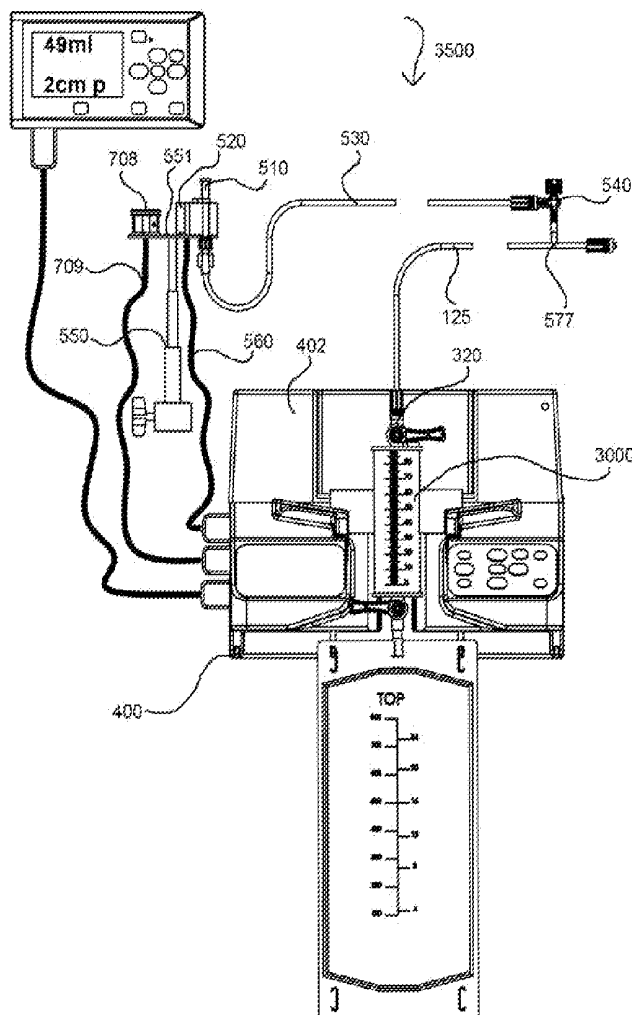
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§ 371 (c)(1),
(2), (4) Date: **Dec. 1, 2011**

A bedside apparatus and method designed to collect and monitor liquids output from a catheterized patient including an electronic unit and one of a plurality of defined disposable collecting and measuring rigid vessels that may differ in shape and size. Each defined vessel has at least one inlet to connect to a catheter outputting liquid from a patient in order to collect the liquid in the defined vessel. The defined vessel has at least one outlet valve to control draining of liquid from the vessel. An electronic unit has a configuration to receive the defined vessel and to securely mount and hold the defined vessel in a fixed relationship. The electronic unit further has a liquid level sensing device located in juxtaposition to the defined vessel to sense the level of liquid contained in the vessel.



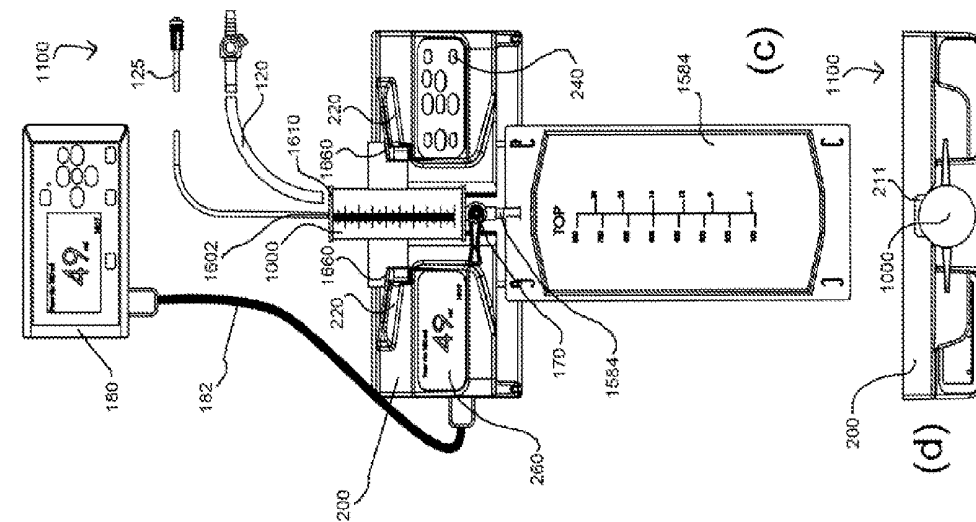


FIG.1

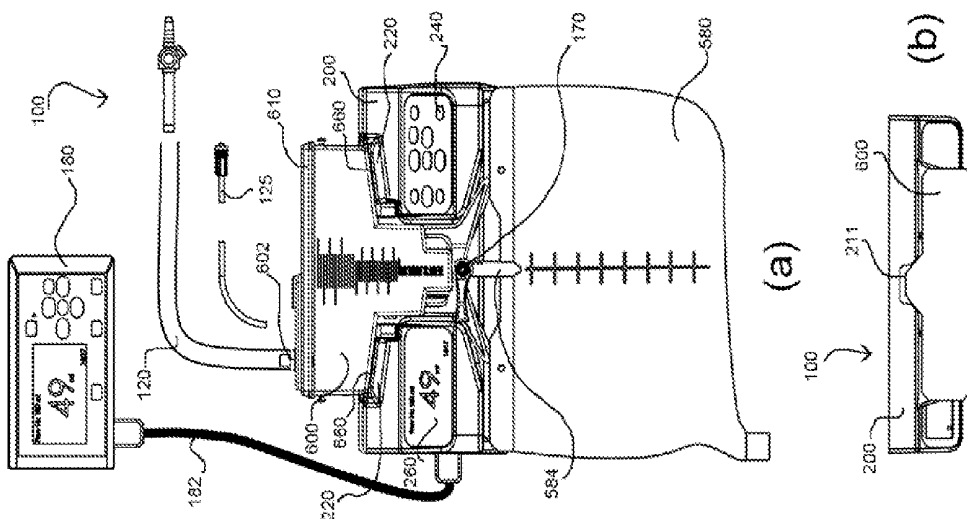
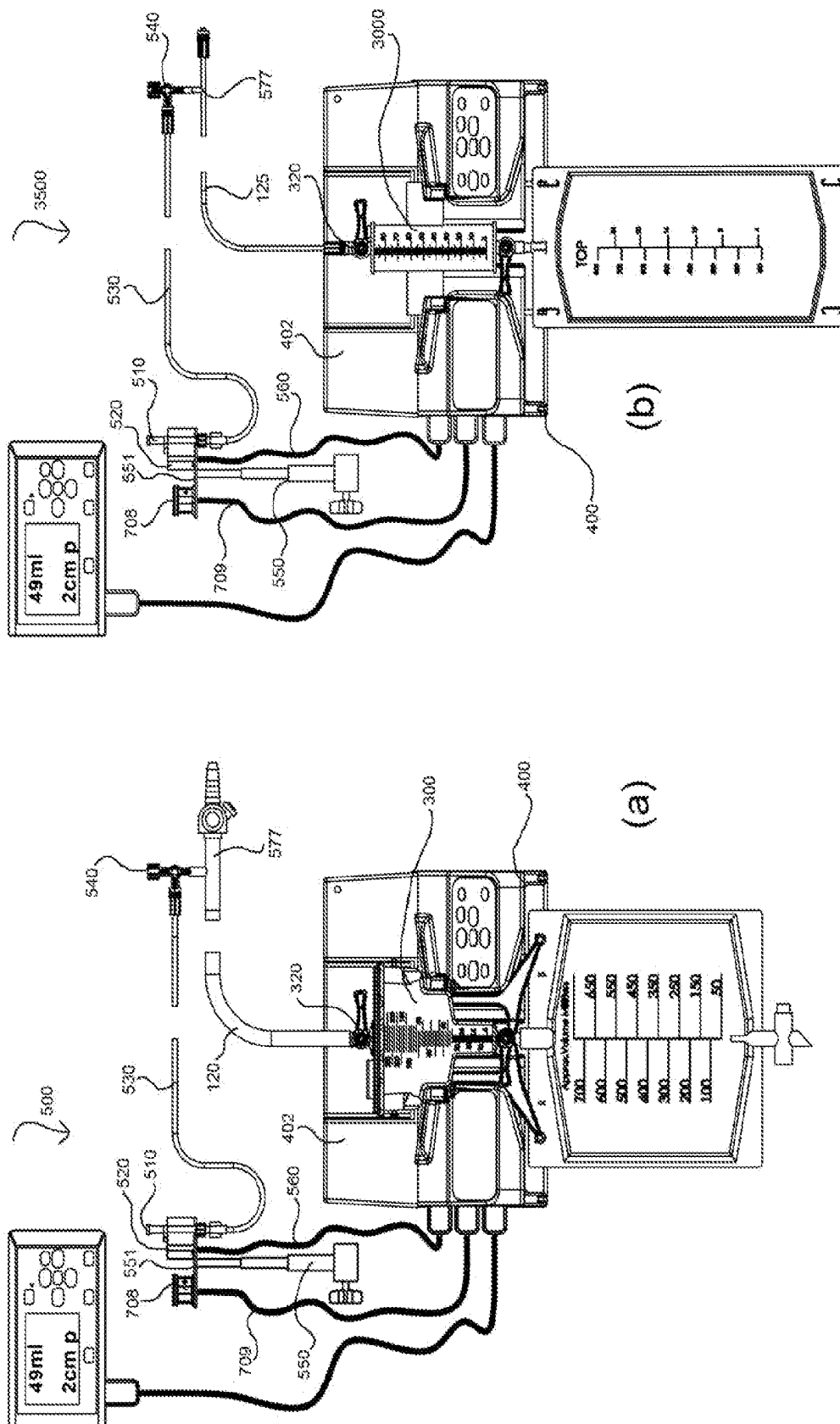


FIG. 2



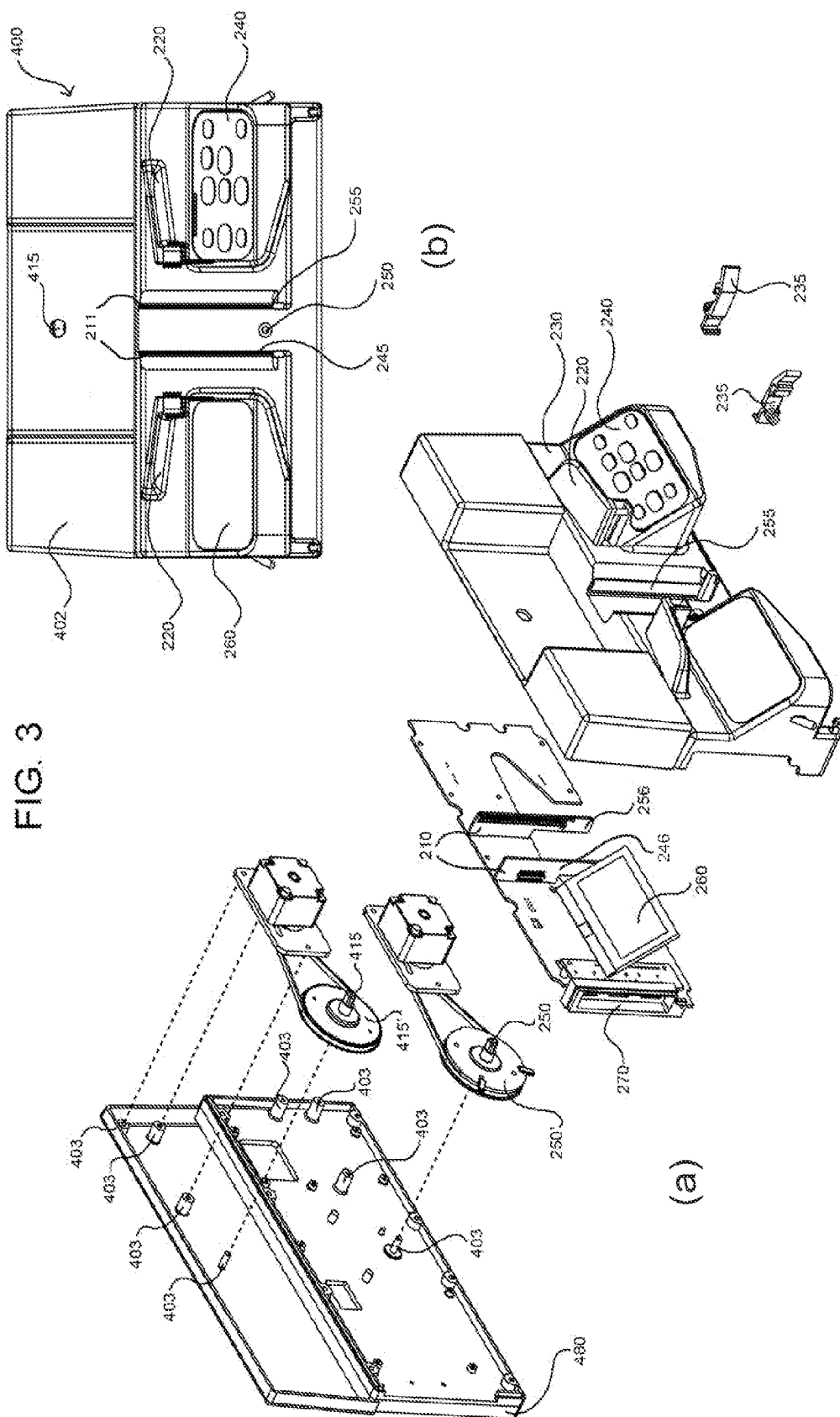
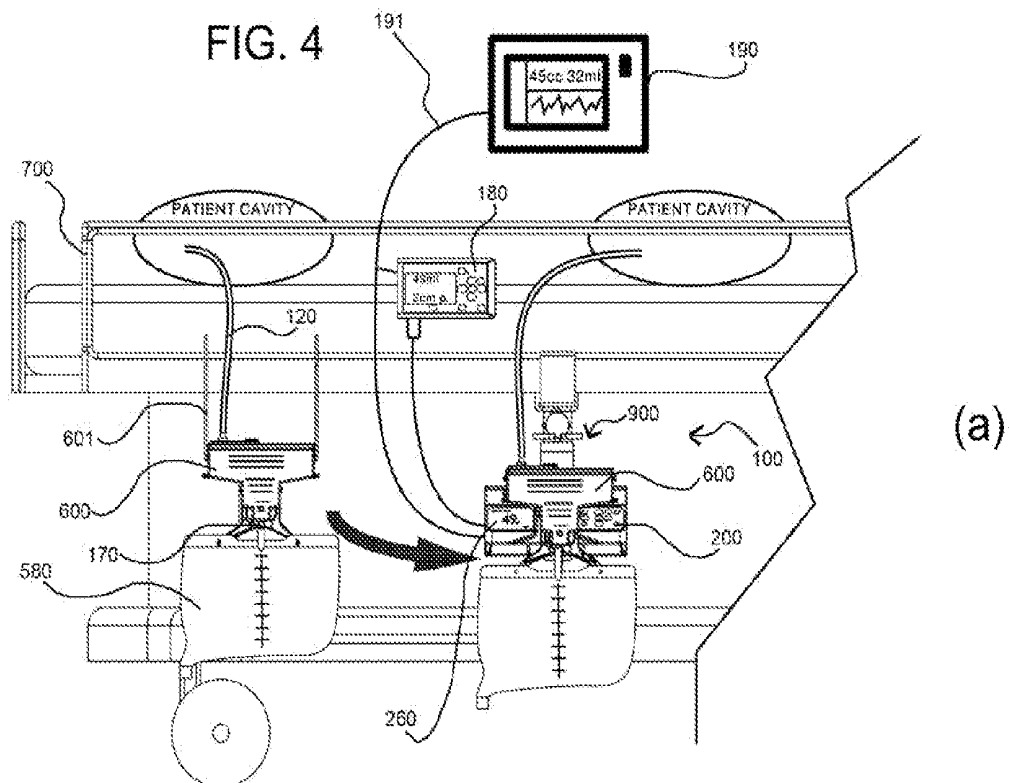
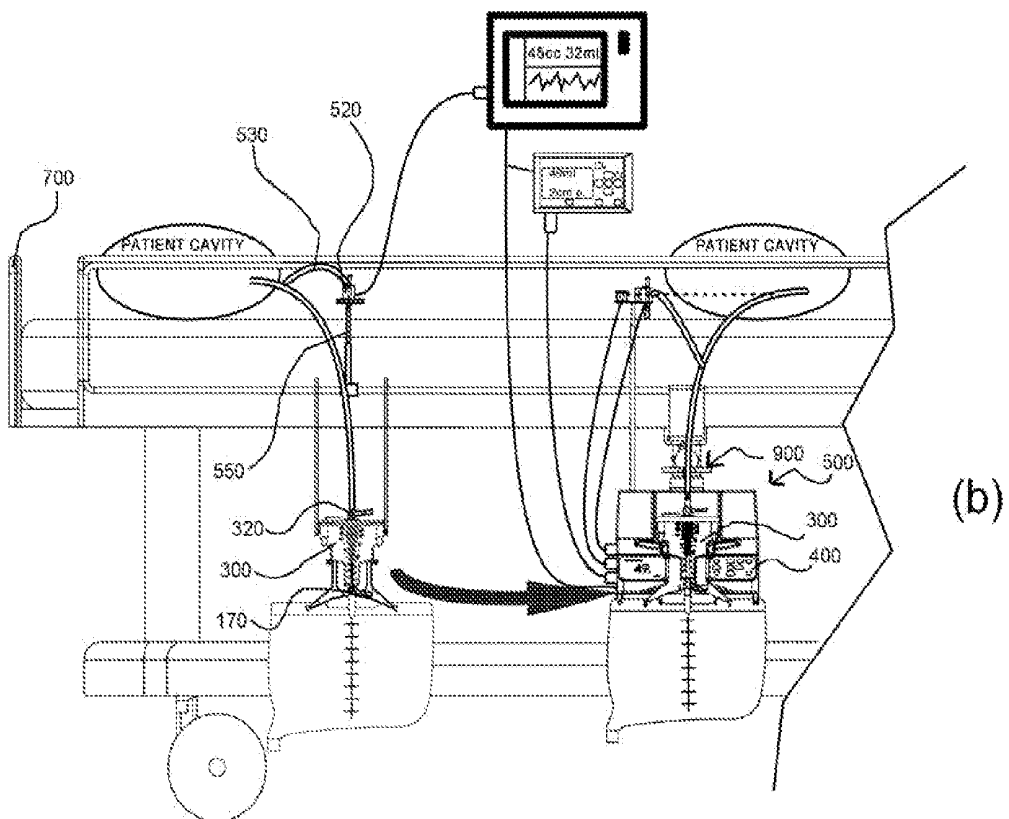


FIG. 3

FIG. 4

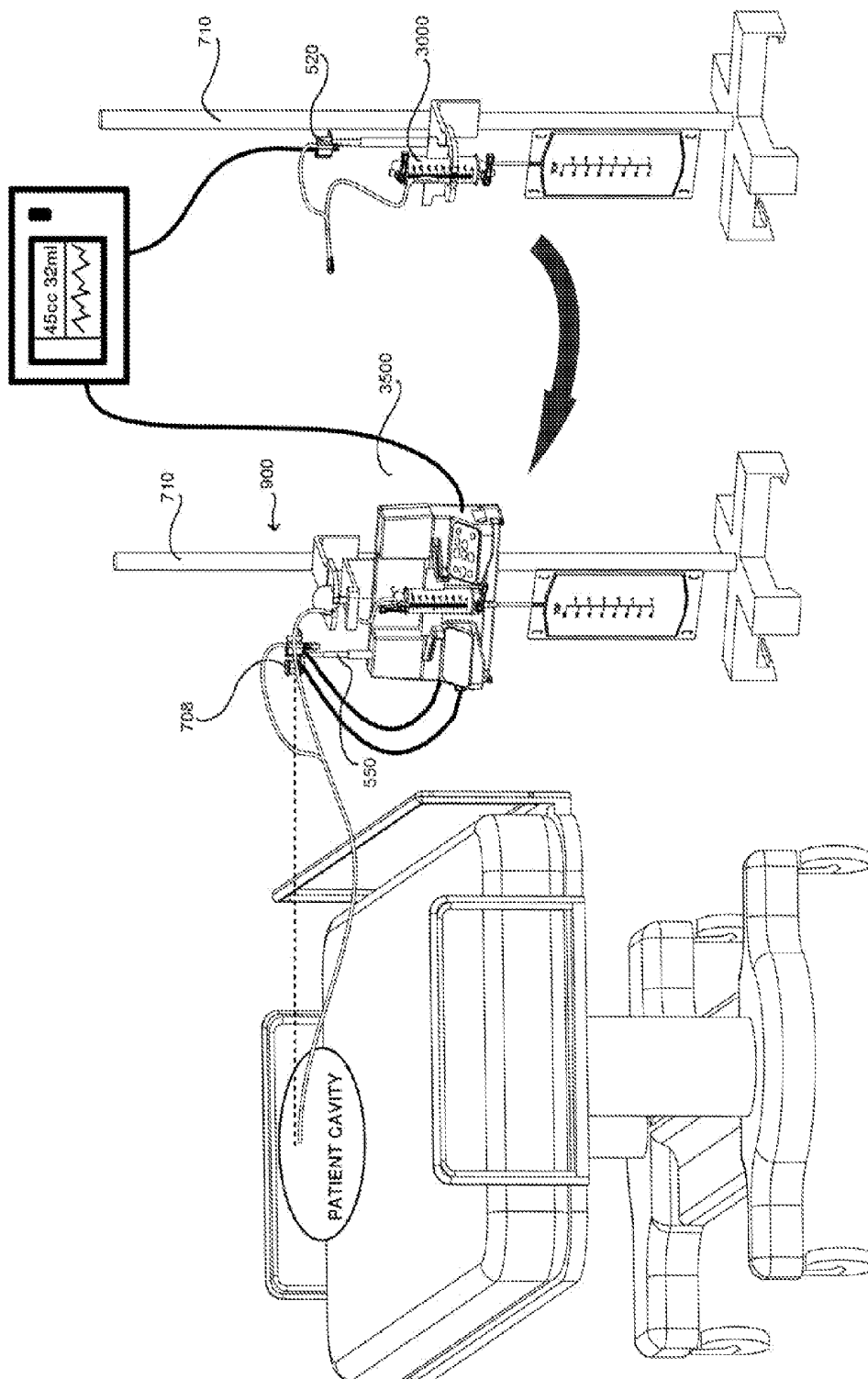


(a)



(b)

FIG. 5



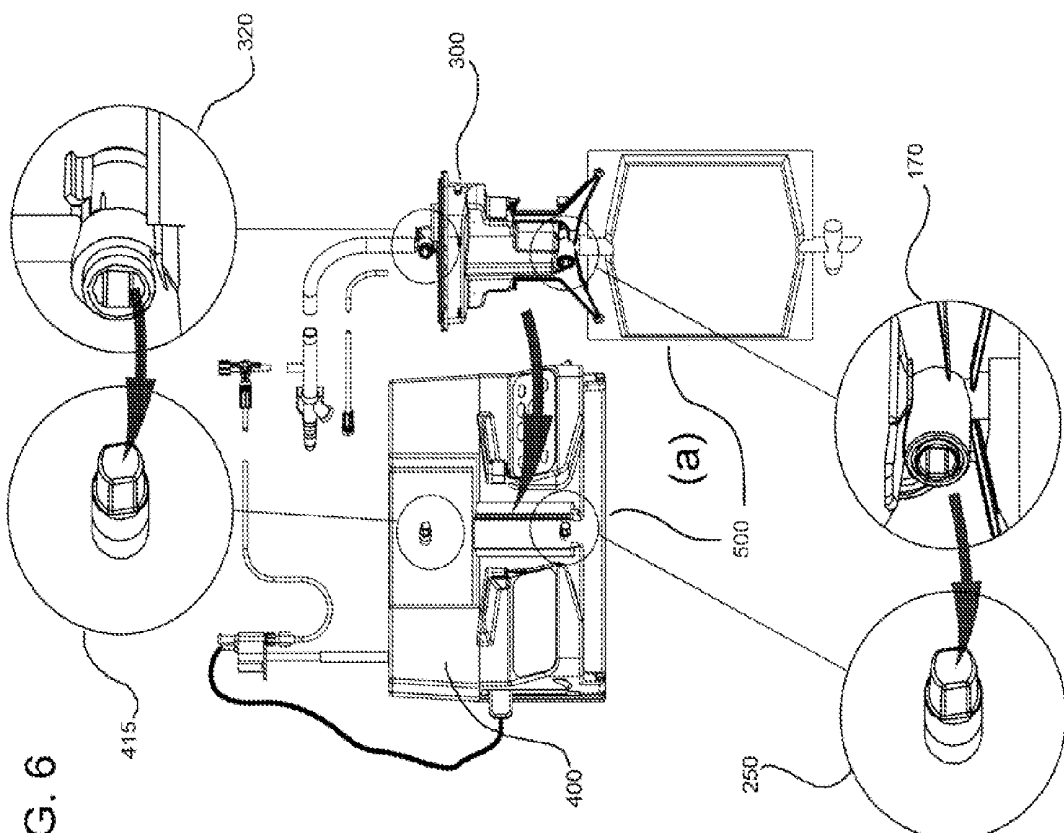
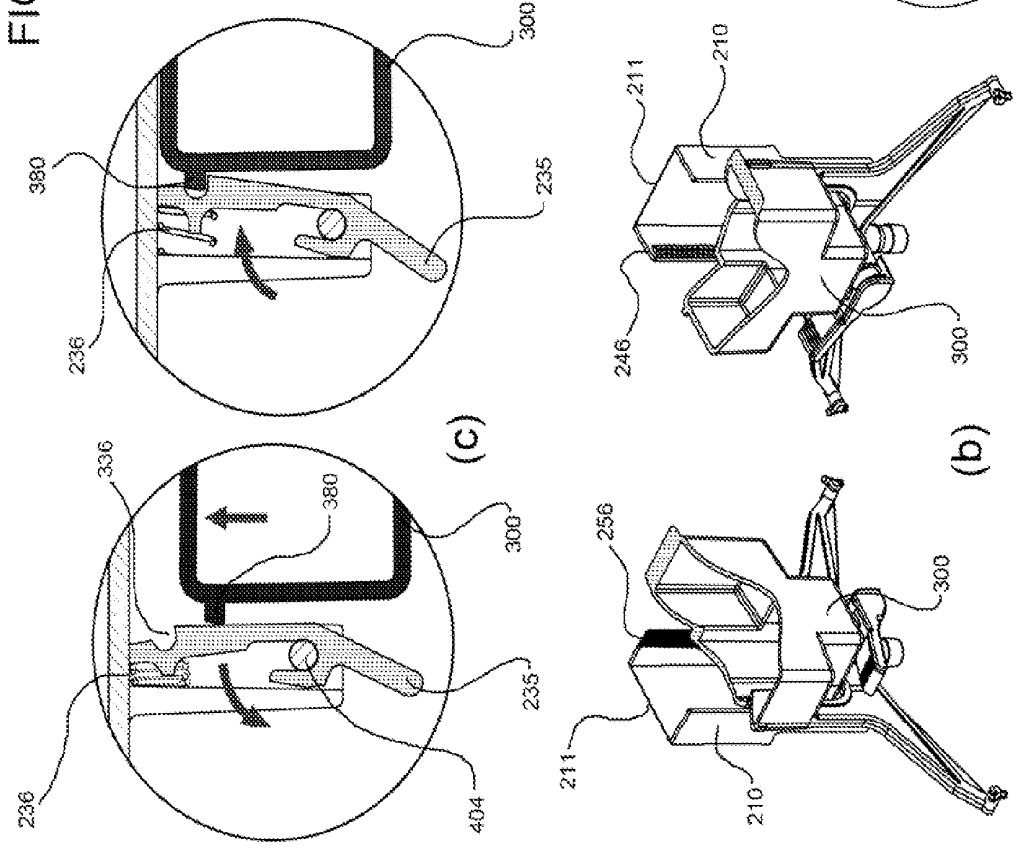


FIG. 6



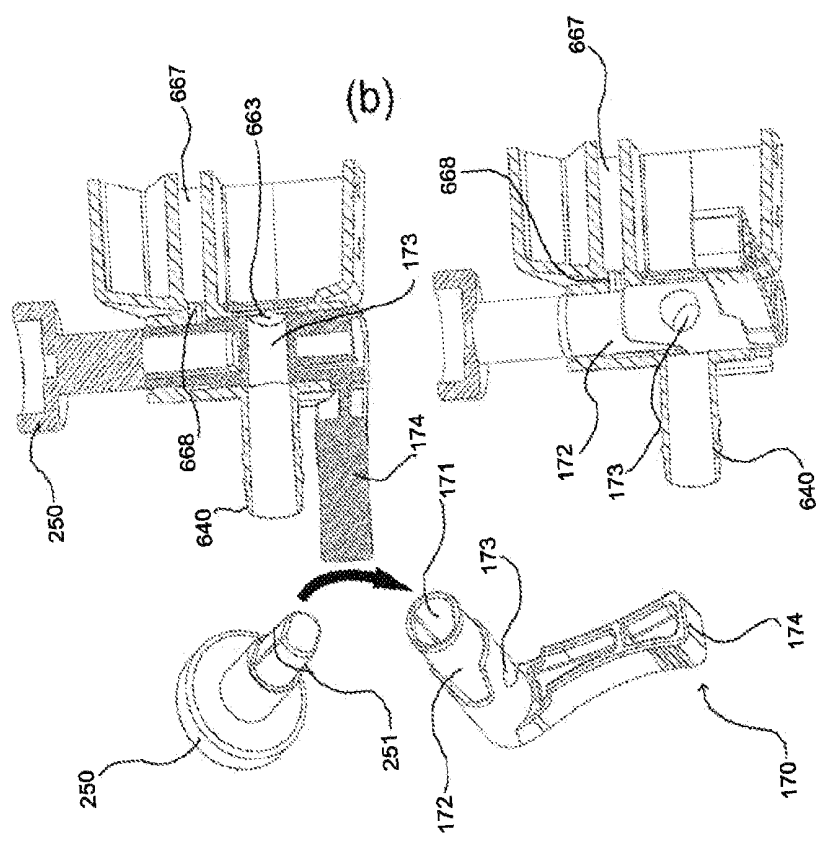
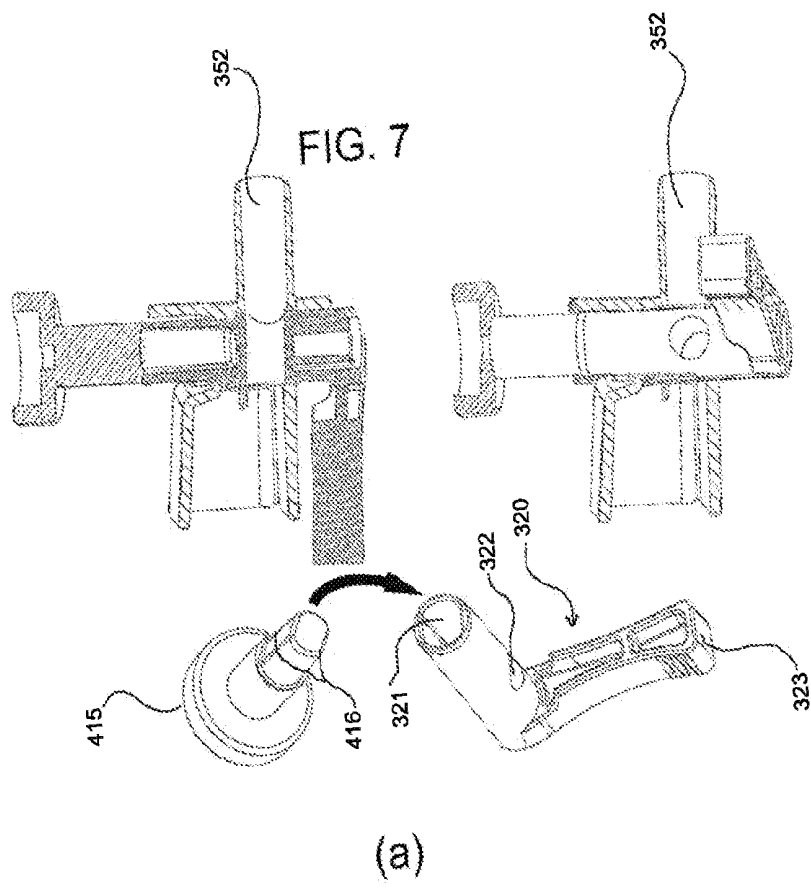
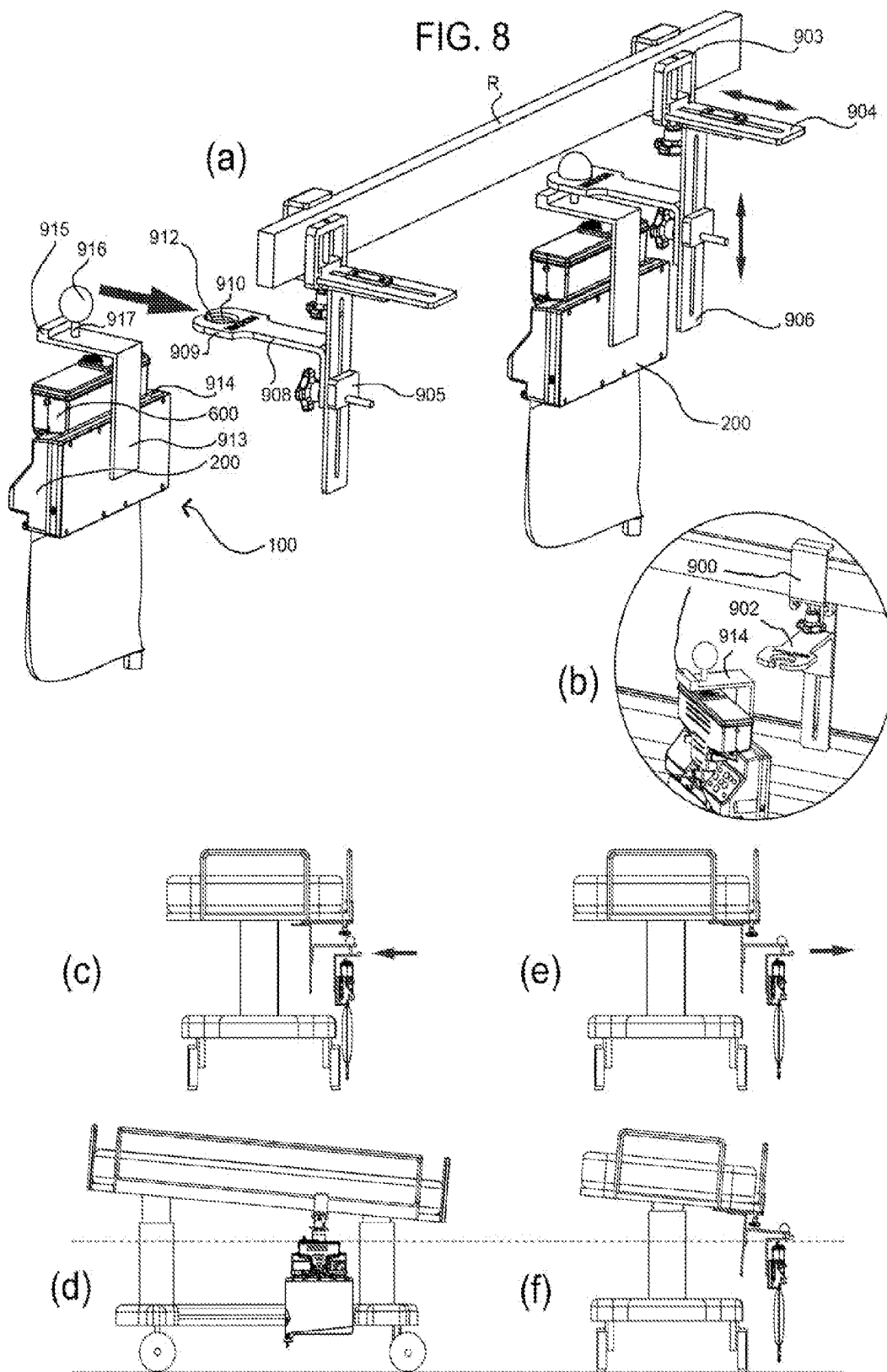
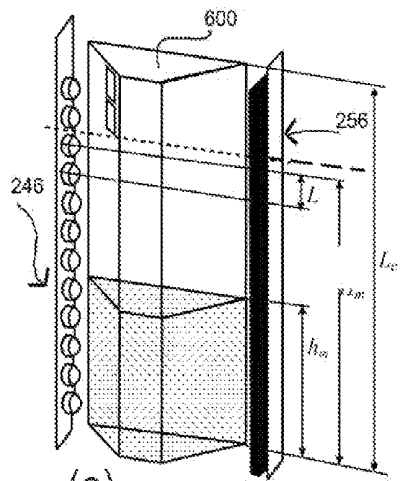


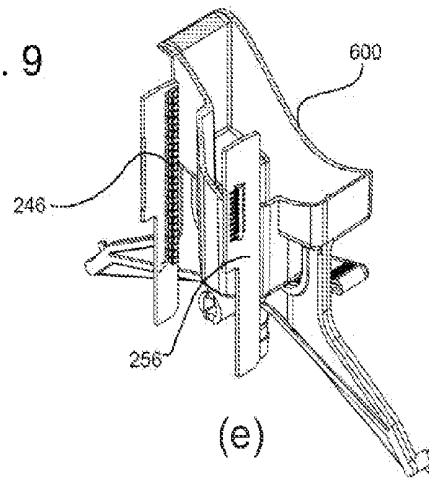
FIG. 8



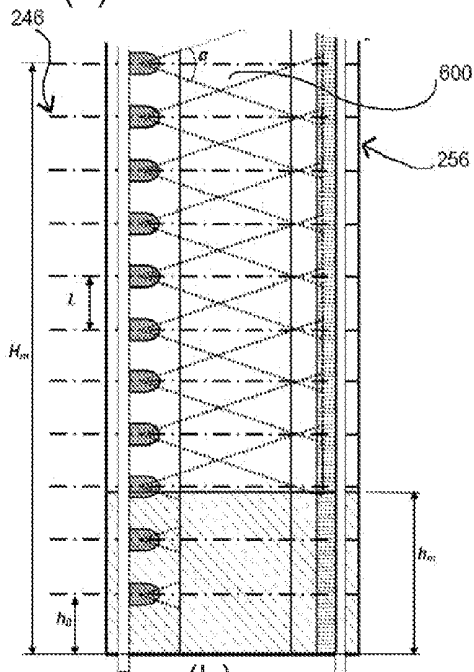


(a)

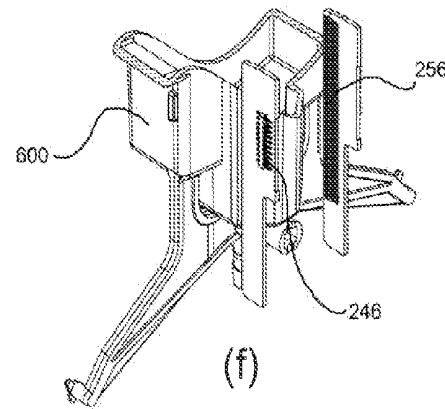
FIG. 9



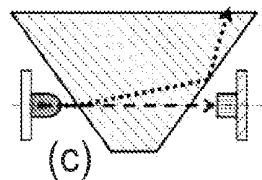
(e)



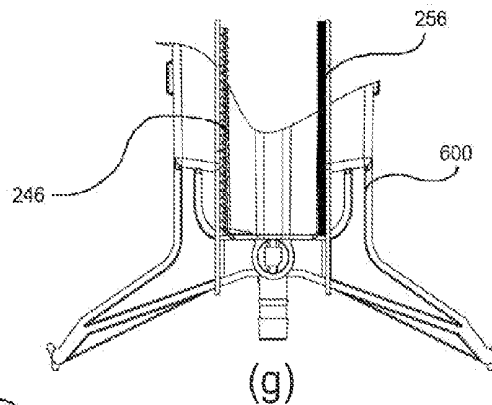
(b)



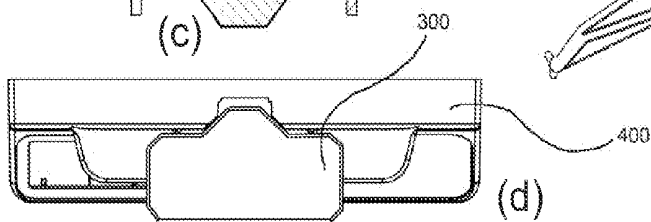
(f)



(c)



(g)



(d)

FIG. 10

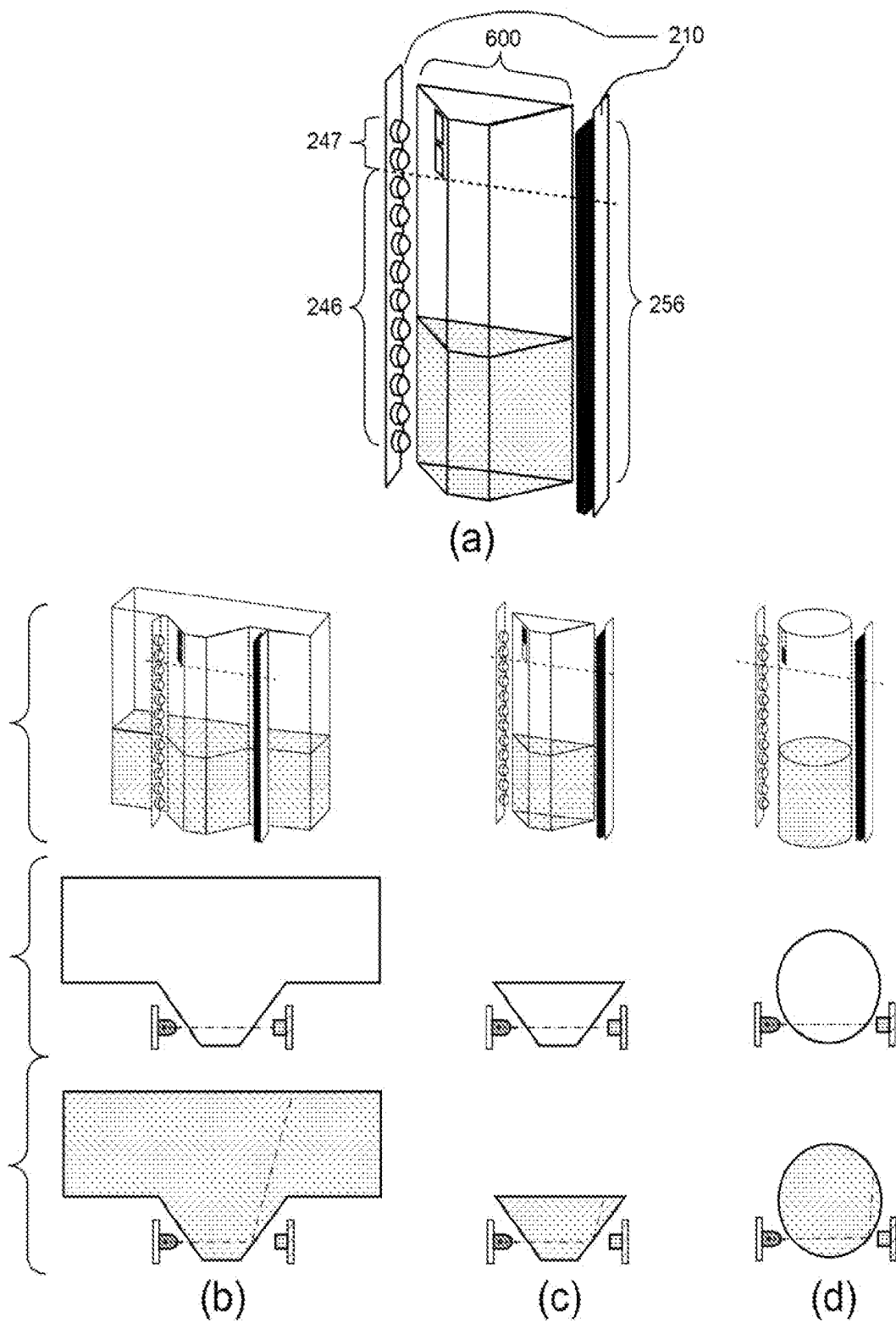


FIG. 11

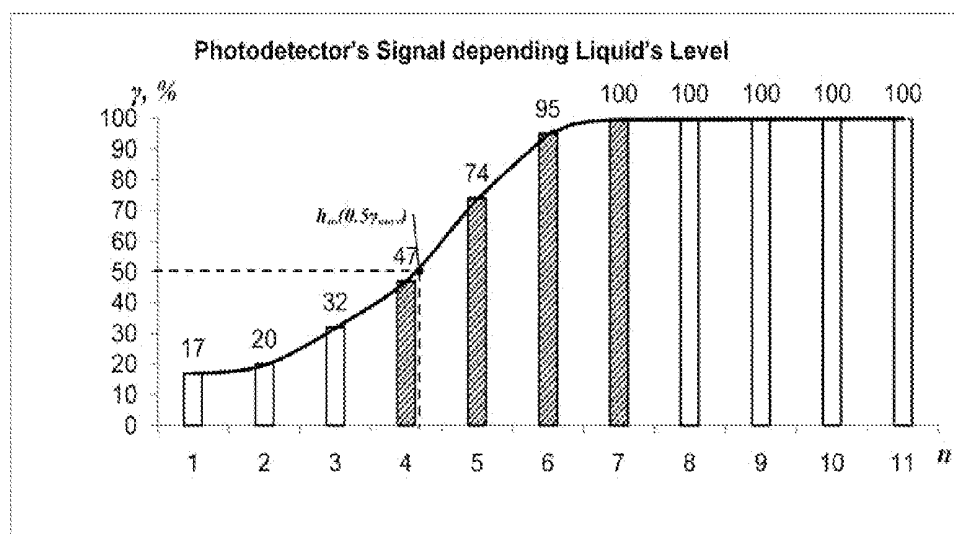
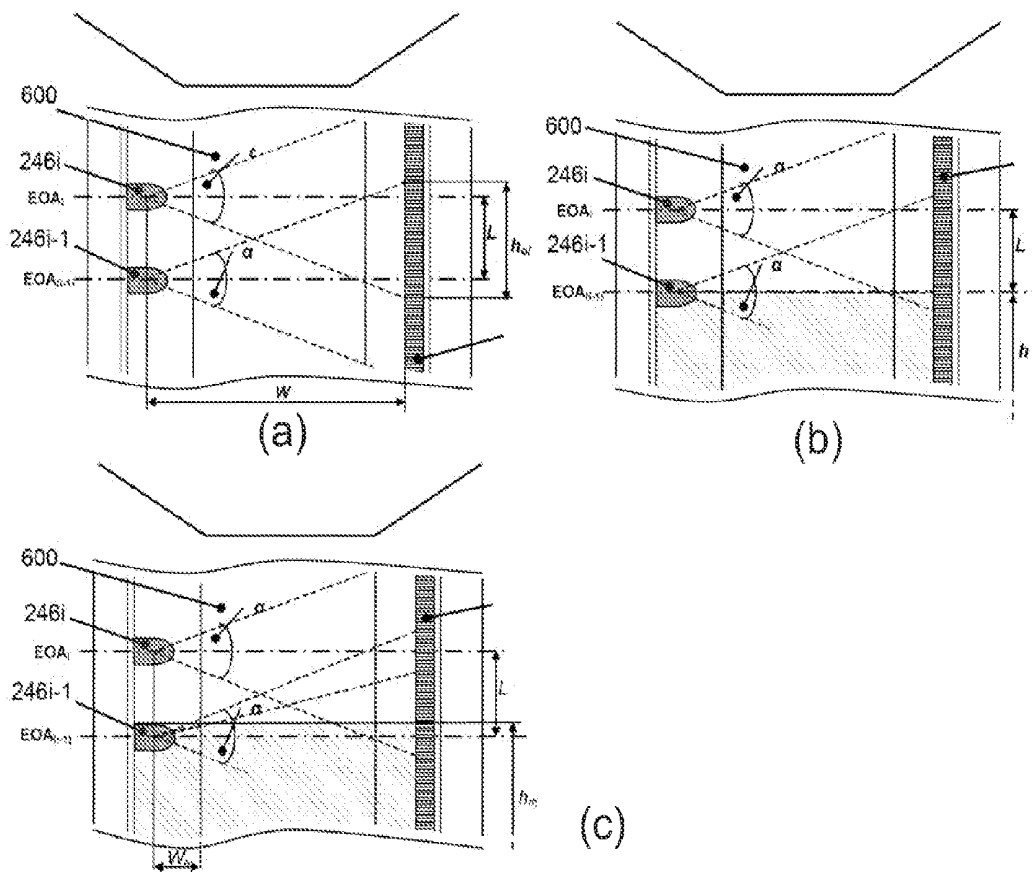
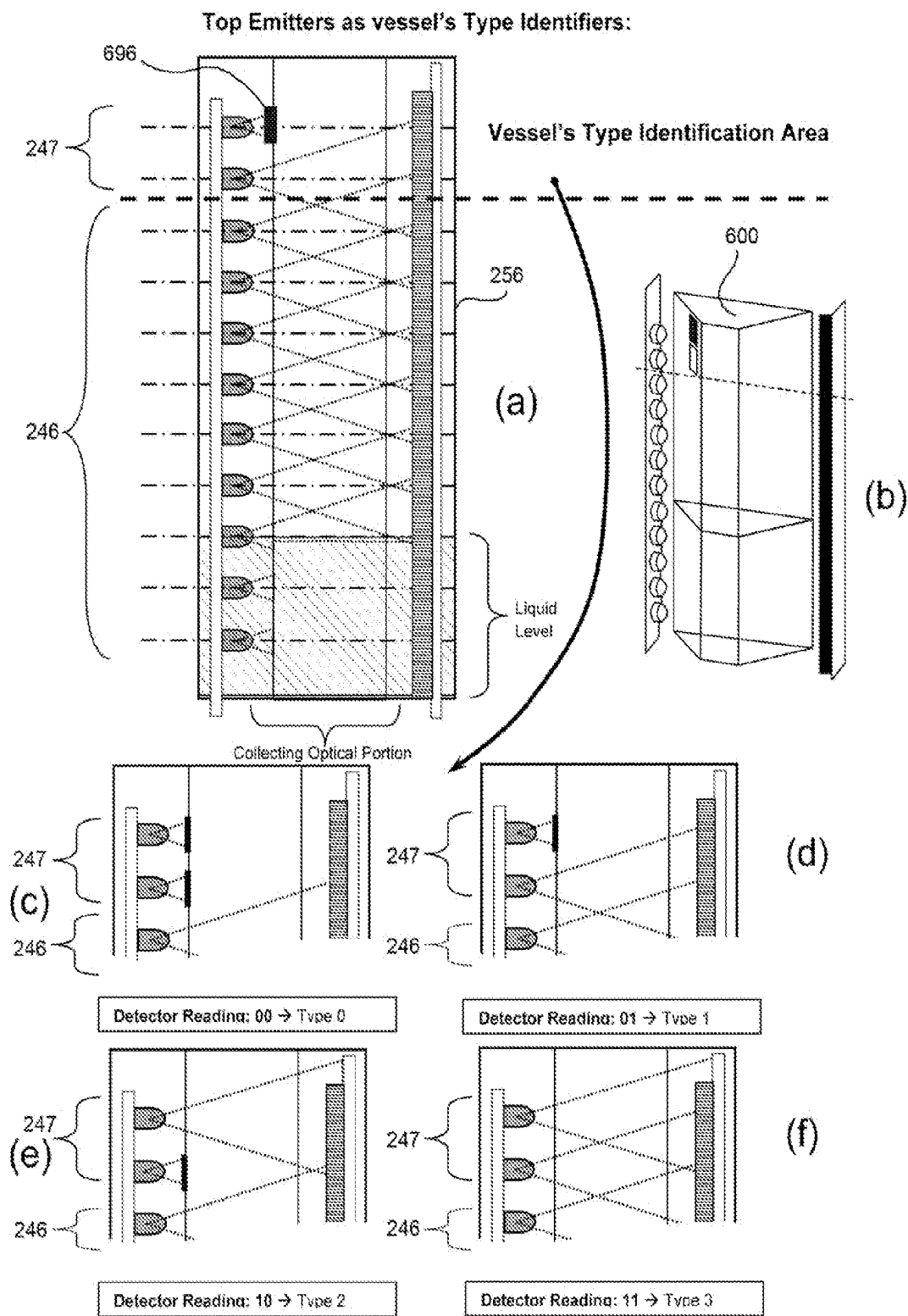
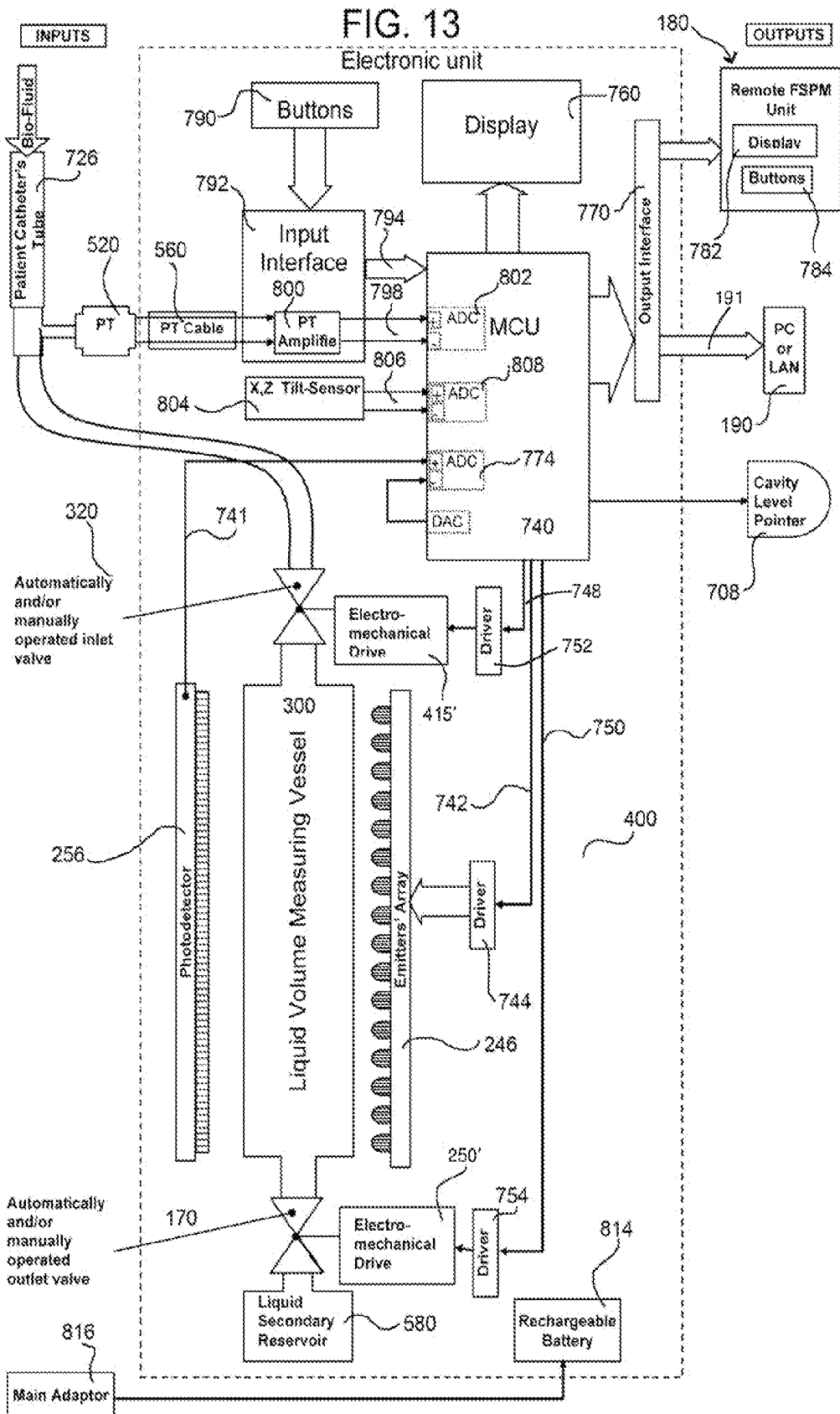


FIG. 12





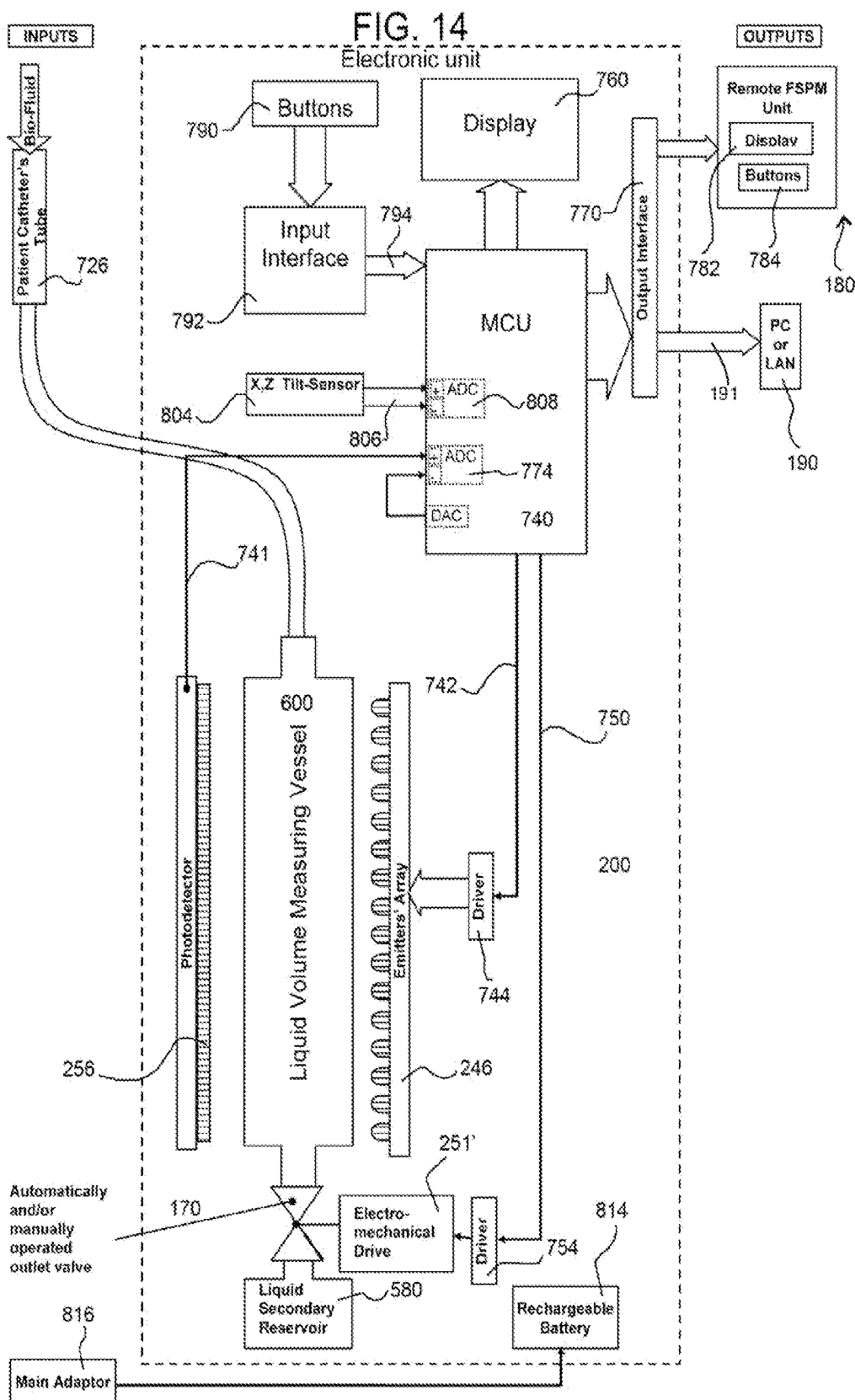


FIG. 15

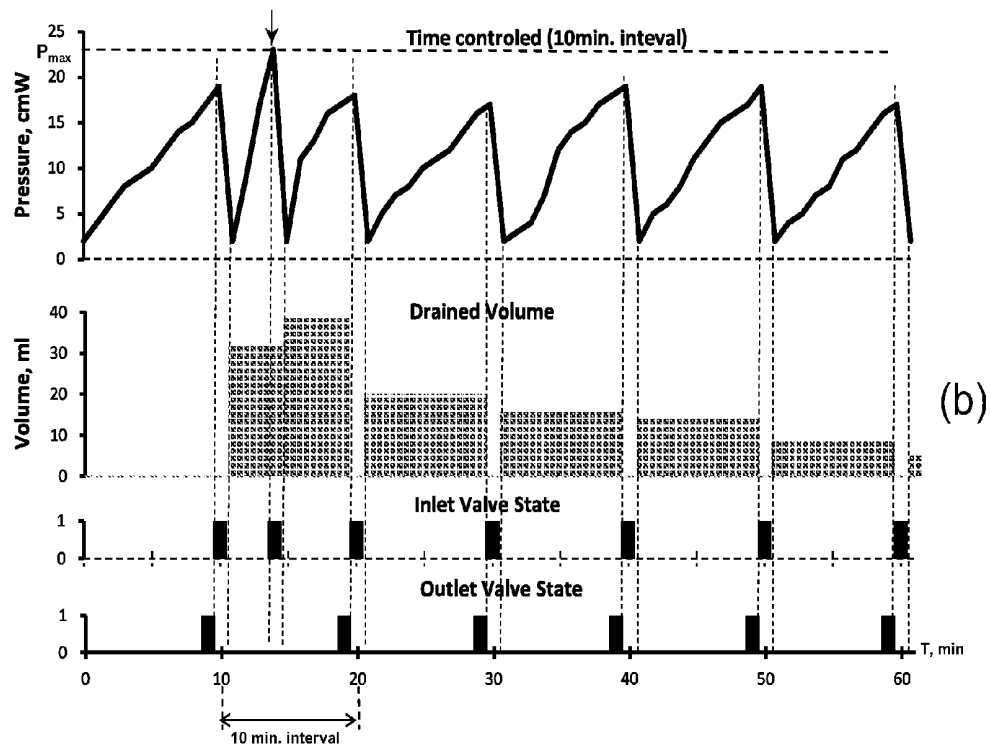
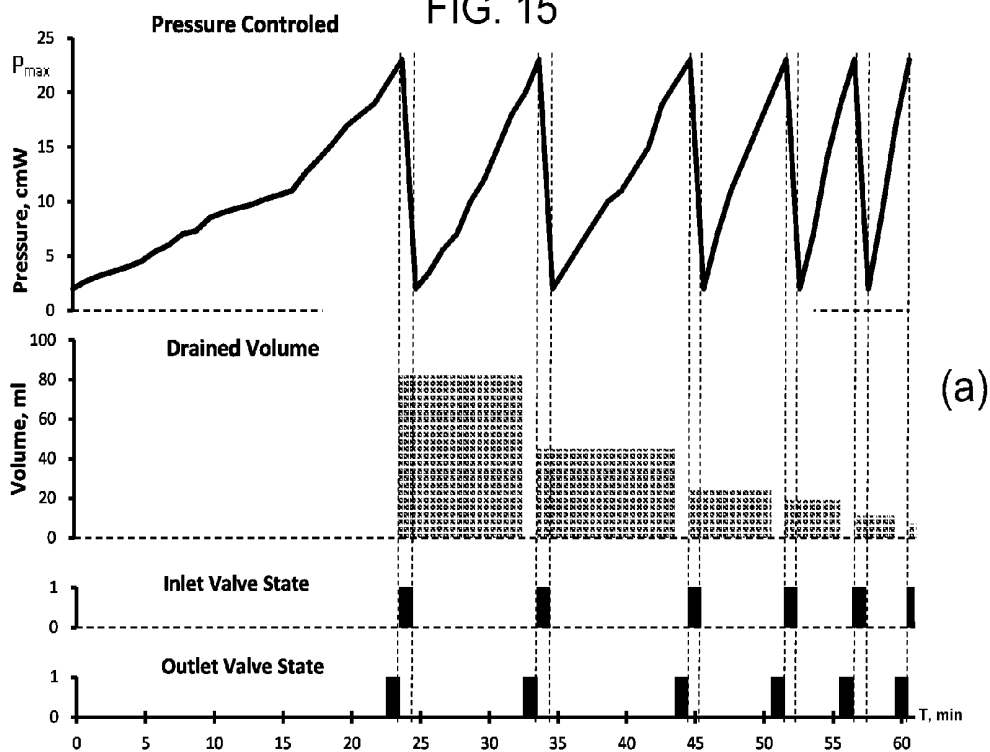
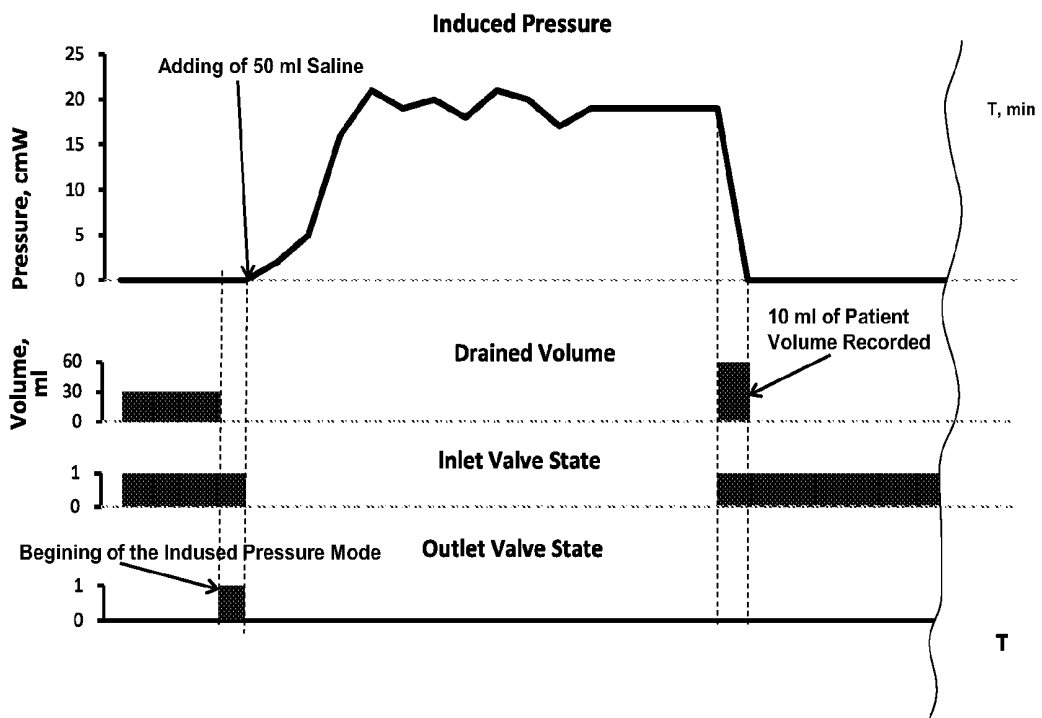


FIG. 16

Induced Pressure Mode



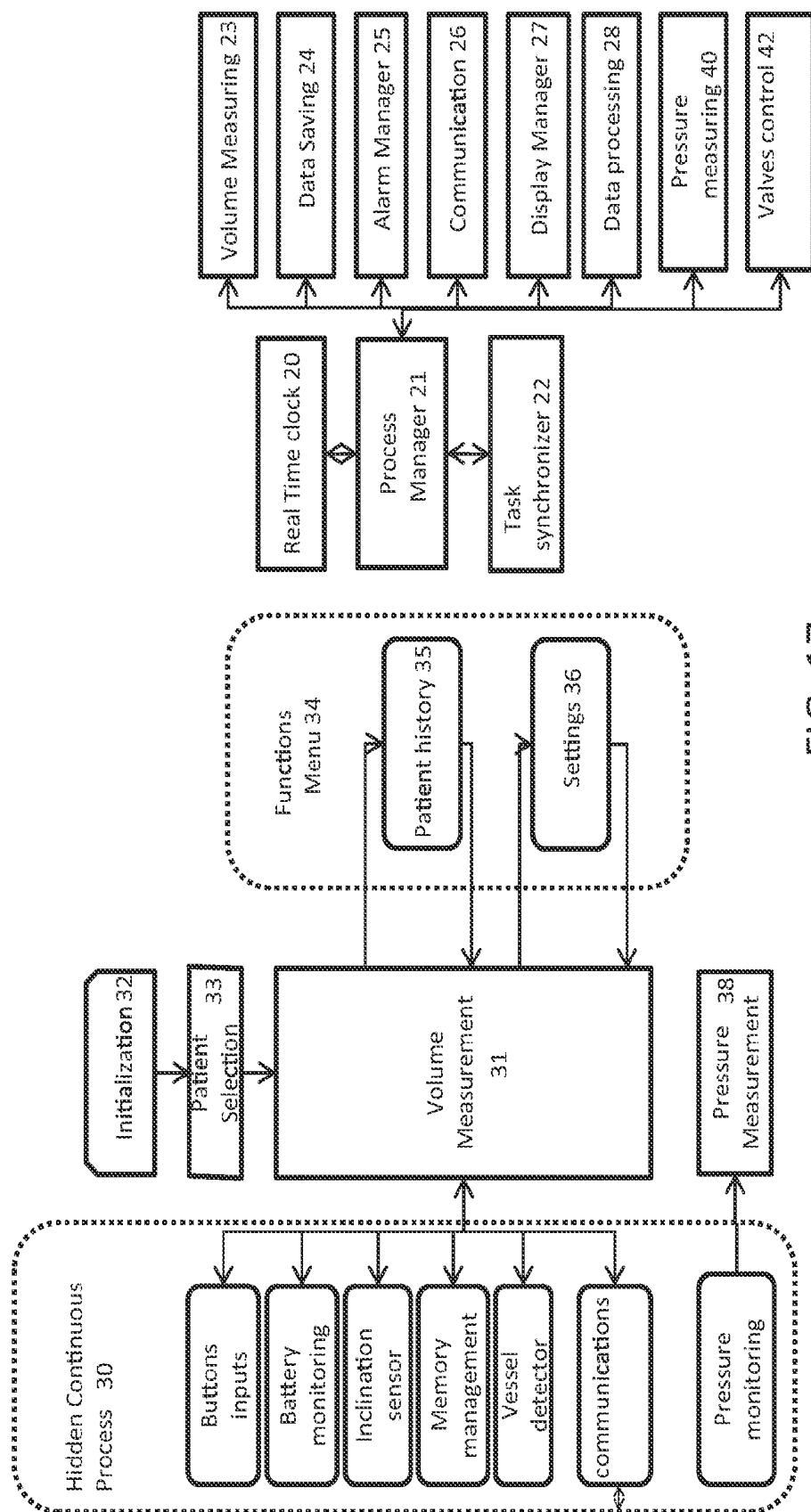


FIG. 17

Device mode	Event	Possible reason	Display indication	
General	Vessel is not in the cradle Sensors do not show vessel when they should	unit has been turned on and if the URX is not in the cradle	Insert URX	
		vessel is misplaced		
		vessel was removed from the cradle		
	Calibration Fail	Dirty vessel	Check URX Check Valve	
		valve is not rotating as commanded		
		The valve has been rotated manually.		
	To much environmental light	Direct sun light	Too much light	
		inclination greater than corrigible	Straight device	
	Pressure Measurement 38*	Pressures level out of limits*	Measured cavity over- pressurized	Pressure Alarm* red light buzzer
			DPT reading out of scale	
Inlet valve is open, No pressure drop				
Pressure Measurement 31	Battery voltage of the reaches limits	20%> Bat.>10%	Low batt icon "Low Battery " Automatic shut down	
		10%> Bat.>5%		
		5%> Bat. >1%		
Pressure Measurement 38*	Memory is reaching the limit Communication Problem		Low memory Communication problem	

FIG. 18

FIG. 19

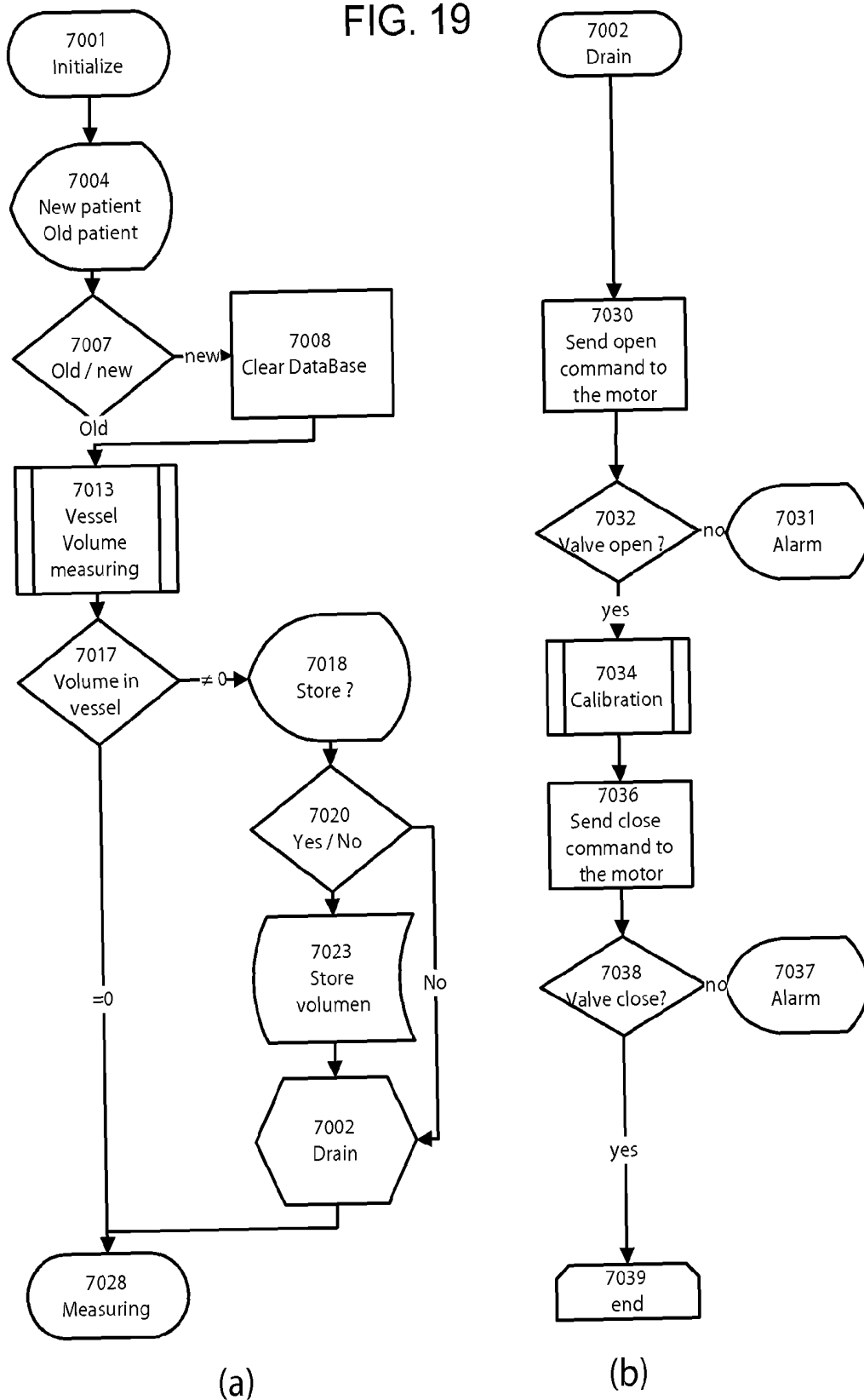


FIG. 20

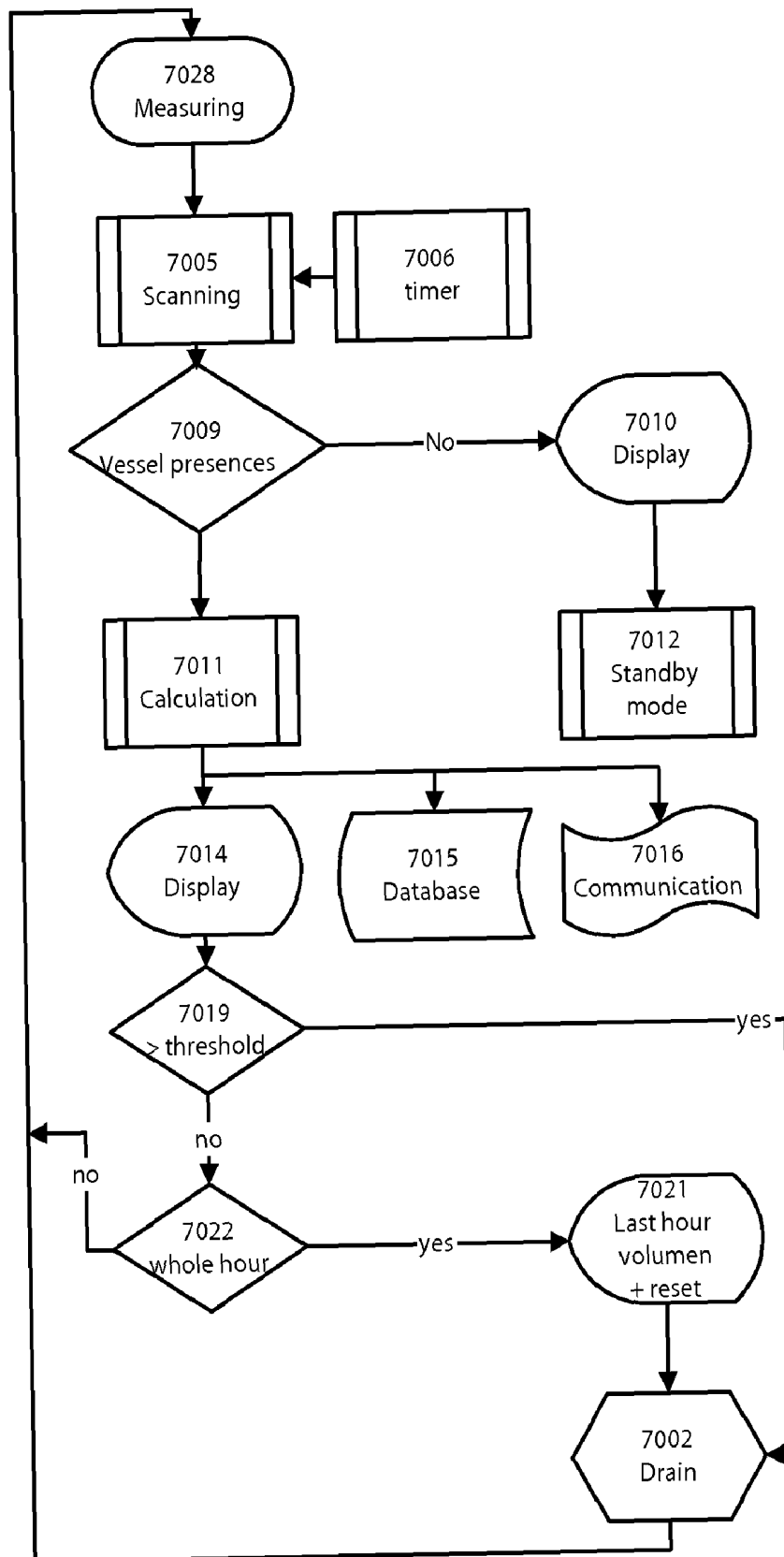
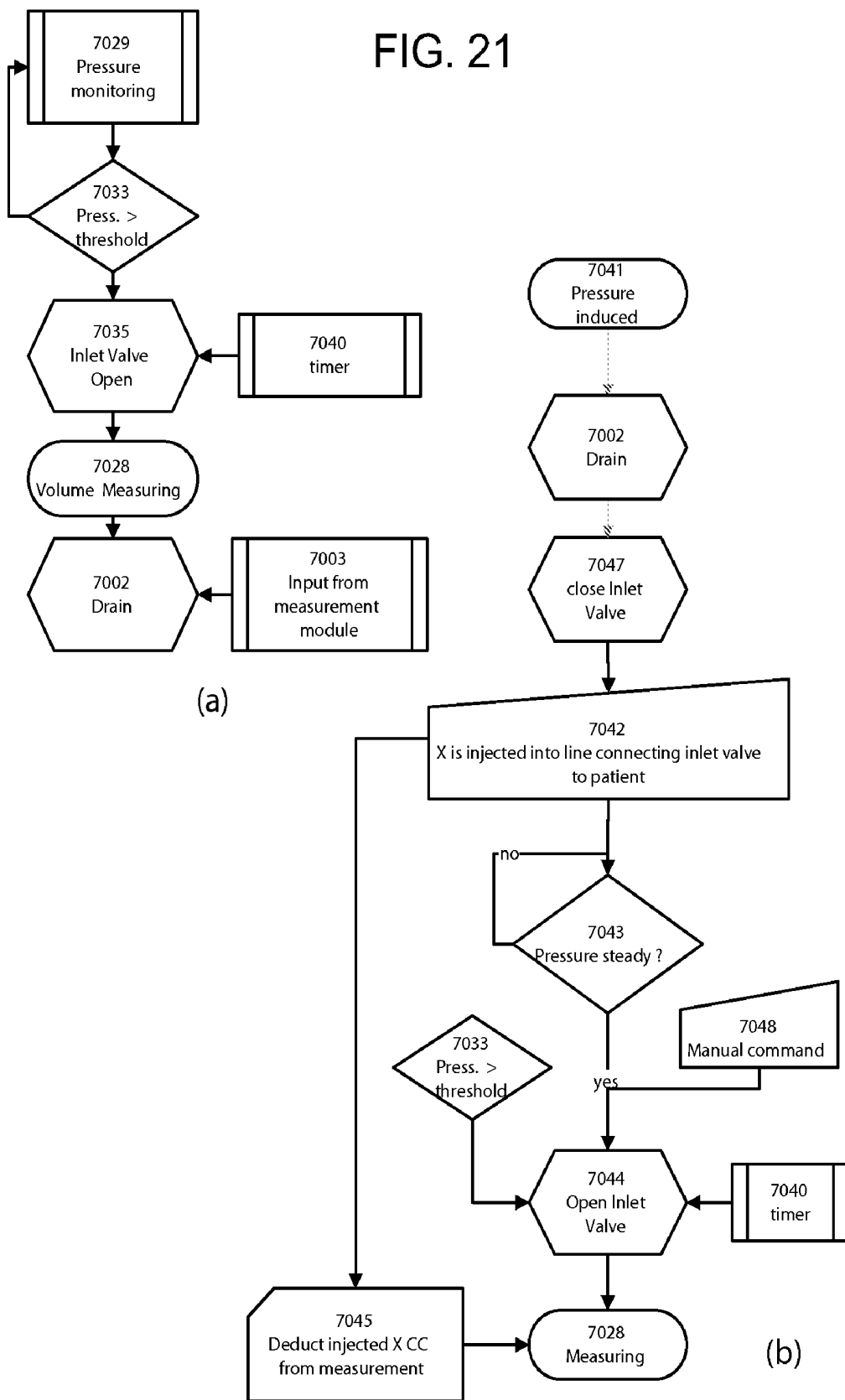


FIG. 21



**APPARATUS AND METHOD FOR BEDSIDE
COLLECTION OF BODY FLUIDS AND
AUTOMATIC VOLUME LEVEL
MONITORING**

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] This invention relates to a bedside apparatus and method for the collecting, measuring and monitoring of the output volume of liquids, especially urine and CSF, drained from a catheterized patient, at specific medical conditions, by means of an optical refraction method with an option to monitor also pressure from the drained organ and to correlate it to the drained volume, and to a computer readable media containing programmed instructions for carrying out the steps of the method.

[0003] 2. Prior Art

[0004] The importance of monitoring discharged body fluid's volume level has long been known to the medical profession. For example, low urine output in critically ill patients can be an early sign of deteriorating patient condition as a result of renal failure, high intraabdominal pressure, or congestive heart failure even before changes in other vital signs, such as, blood pressure, temperature, pulse and respiration are observed. In addition, for a critically ill patient, changes in hemodynamic measurement of cardiac output such as arterial blood pressure, central venous pressure and left arterial pressure are meaningless, if these changes are not correlated with changes in the perfusion of major organs, such as, the kidney.

[0005] In addition to urine drainage measurement, the bladder pressure measurement can give good indication of the intra-abdominal pressure. High intra-abdominal pressure (IAP) occurs frequently in patients with acute abdominal syndromes, such as, ileus, intestinal perforation, peritonitis, acute pancreatitis or trauma. An elevated IAP may lead to intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS). Both IAH and ACS are etiologically related to an increased morbidity and mortality of critically ill patients.

[0006] The increase of the volume within the elastic structure of the abdominal wall causes an increase of overall pressure in the cavity and organs, and it may decrease tissue blood perfusion. An increase in abdominal pressure may lead to distant effects in other parts of the body, such as increased intracranial pressure, pericardial tamponade and tension pneumothorax or extremity compartment syndrome.

[0007] Monitoring Inner Cranial Pressure (ICP) and CSF are also of vital importance due to the dangerous nature of an increase in the ICP of a patient. The cranium is a rigid container, and an increase in any of its contents—brain, blood, or CSF—will increase the ICP. In addition, any increase in one of the components must be at the expense of the other two; this relationship is known as the *Monro-Kellie doctrine*. Injury to the brain occurs both at the time of the initial trauma and subsequently due to ongoing cerebral ischemia. In an intensive care unit, raised intracranial pressure (intracranial hypertension) is seen frequently after a severe diffuse brain injury (one that occurs over a widespread area) and leads to cerebral ischemia by compromising cerebral perfusion.

[0008] Cerebral perfusion pressure (CPP), the pressure causing blood flow to the brain, is normally fairly constant due to auto regulation, cerebral perfusion pressure is calculated by subtracting the intracranial pressure from the mean arterial pressure: $CPP = MAP - ICP$. One of the main dangers

of increased ICP is that it can cause ischemia by decreasing CPP. Once the ICP approaches the level of the mean systemic pressure, it becomes more and more difficult to squeeze blood into the intracranial space. As an intracranial mass lesion or oedematous brain expands, some compensation is possible as cerebrospinal fluid (CSF) and blood move into the spinal canal and extra cranial vasculature, respectively. Beyond this point, further compensation is impossible, ICP rises dramatically and only external removal of CSF can lower the ICP level.

[0009] Monitoring of CSF & Urine Output

[0010] Urine output is being measured manually by means of various measuring collecting systems. Such systems normally contains a collecting and measuring rigid transparent vessel hanged by the bedside to allow gravitational drainage, having a graduated scale and an inlet tube connected to a catheter. The measuring rigid transparent vessel has an emptying valve being connected to a secondary elastic reservoir. The liquid output volume is measured and then emptied to the secondary reservoir at predetermined hourly intervals. The above volume metering procedure also enables to visualize during the measurement intervals the optical visualized properties of the drained urine, such as, color, turbidity and possible sedimentation which gives more clinical information.

[0011] Manually Measurement of intra-abdominal pressure on a catheterized patient using the bladder is done by injecting a known quantity of saline through the Foley catheter into the bladder, then closing the drainage and measuring the pressure inside the bladder by means of pressure transducer.

[0012] Intracranial pressure is manually measured with the use of pressure transducers. A catheter is surgically inserted into one of the brain's lateral ventricles and is used to drain CSF (cerebrospinal fluid) in order to decrease ICP's. This type of drain is known as an EVD (extra ventricular drain). The CSF is drained into a rigid transparent vessel in the same manner as described above, but instead of using a gravitational drainage approach, a liquid column gauge procedure is used where the CSF drainage will be depended on the water column height, which is defined by the height of the rigid container. This drainage, as in the urine volume metering system, enables to visualize during the measurement intervals the CSF color, turbidity and possible sedimentation which provides more clinical information.

[0013] Different designs of collecting vessel, which differ in their collecting volume capacity and accuracy, are used for a variety of procedures in different hospital wards. For instance, for pediatric urine measurement a small rigid container is needed as opposed for adults where a larger container is required. Also, for intensive care units and operating rooms the accuracy of the urine drainage measurement has to be substantially higher than in other wards, therefore, the urine collecting vessel used is require to have a higher degree of accuracy. In the case of CSF drainage a small and precise collecting vessel is required.

[0014] Clinicians have been searching for a methodology for the automatic collection and data analysis of fluids outputs like Urine and Cerebrospinal-fluids (CSF) in real time. Manual procedures require measurement of contained volume by the end of a preselected time interval, thus consuming costly nursing time, and in addition risking the accuracy of the measurement due to inaccurate scale reading and non-precise following of the preselected time interval. Another factor relates to the increased risk of cross contamination due

to the frequent manual operation of the system. In addition, all liquid output results are recorded manually and cannot be transferred automatically to a ward computer network unless the observed data is typed-in.

[0015] All of the above are some of the main reasons for the desirability of more accurate online electronic liquids output measuring and monitoring systems.

[0016] Electronic meters for monitoring urine output of a patient are well known and feature different measuring techniques. An ultrasonic measuring technique is shown in U.S. Pat. No. 4,448,205, U.S. Pat. No. 4,658,834, U.S. Pat. No. 5,891,051 and U.S. Pat. No. 6,582,379. In the ultrasonic systems described, the patient fluid is discharged into a container with an ultrasound transducer mounted to a housing adjacent the container and acoustically coupled to a wall of the container. When a sound wave hits the interface between the air and the liquid in the container, the signal is reflected. The measurement of the volume is being done by determining the time duration required for the transmitted energy to travel from the transducer to the upper surface of the collecting urine pool and back again.

[0017] Drawbacks of these types of measurements techniques are due to the sensitivity of the measurement. Tilting of the measuring vessel, particles such as blood in the liquid, foam and temperature changes of the liquid can all cause inaccurate readings? In addition there is a great need for transducer calibration and there might be risk of ultrasonic interference with other ultrasonic measuring devices. There is also accumulation of the drained urine without the possibility of being able to measure new fresh specimens of urine according to predetermined time intervals or desired volume quantity. As a result of this drained fluid accumulation, it is not possible to view the optical properties of the freshly drain urine which can provide additional important information.

[0018] Use of a method of weighing the body of drained fluid mass with a force transducer/weight cell is described in patents DE 3544676, EP 0242128B1, U.S. Pat. No. 5,769,087 and U.S. Pat. No. 5,776,077, where the accumulated body fluid is suspended from the force transducer/weight cell. This measurement is very much effected by the movement of the measured bag and the inclination of the bag from its horizontal state, which can easily lead to hardly detectable false measurements. Moreover, as mentioned above, the measured liquids are being accumulated with no ability to view the optical properties of fresh urine output specimens.

[0019] Using a drops counting method is described in EP 0901778A2 and U.S. Pat. No. 6,640,649B1, and requires having a drip chamber with a sensor that includes a light source located on one side of the chamber and a light detector located on the opposite side of the chamber. The system preferably includes a filter upstream of the drip outlet and some type of restriction, "drop generating orifice", to enable to "create a standard drop". The main problem with this type of method is the fact that the drained fluid can be viscose and may include foreign objects and sedimentation, which can lead to occluded filters and a blocked drop generation orifice. Furthermore, with this method, as well as with the ones mentioned above, it is not possible to view the optical properties of freshly drained urine, which can provide additional important information.

[0020] In addition to the above methods there are also optical methods, such as the one described in the U.S. Pat. No. 4,343,516. As described, there is a chamber of specific configuration having two electronic controlled valves located

above and below the chamber and an optical sensor situated at the top of the chamber below the upper valve. The lower valve is closed when urine enters the chamber until the point where the urine level reaches the optical sensor at which time, by virtue of electronic control, the upper valve will close and the lower valve will open, allowing the urine to pass into a collection receptacle drainage bag. These methods have the drawback that the measurement is related to the chamber volume, so until the chamber is filled there is no possibility to know the amount of drained urine. The volume range of the chamber is usually between 5-10 cubic centimeters. In case of movement of the chamber the urine can accidentally reach the optical sensor and the lower valve will be opened and the measurement will not be accurate. For the visualizing of the optical properties 10 cubic cm could be a too small volume and the "turnover" of the urine might be too fast.

[0021] Another optical method is described in U.S. Pat. No. 4,745,929. In this method, the drainage system comprises a container having a rigid conduit to receive the liquid and a receptacle to receive the urine after its accumulation in the conduit. The filling and emptying of the conduit is done as in the previously described optical method, but in this method the height of the liquid in the conduit is measured. This measurement is done by using a pair of emitters (LEDs) and detectors, where the level of the liquid is detected by means of refraction. The main drawback of this method is the fact that there is no possibility to measure the liquid level when it lays in-between the pair of LEDs.

[0022] Automatic measurement of ICP & CSF can be seen in the German patent EP 174954981. In this system the CSF is pumped out in accordance to the ICP measurement. The problems with this method are, risk of accidental over pumping and that the fact that the CSF cannot be visualized, since it is drained into one container after the peristaltic pump. In addition, the measurement of the amount of CSF is calculated from the number of turns of the peristaltic pump, according to the tubing size used, which leads to inaccurate readings due to changes in the tube.

SUMMARY OF THE INVENTION

[0023] This invention relates to a bedside apparatus and method for the collecting, measuring and monitoring of the output volume of liquids, especially urine and CSF, drained from a catheterized patient, at specific medical conditions, by means of an optical refraction method with an option to monitor also pressure from the drained organ and to correlate it to the drained volume. The liquid drained from a patient can be drained from an orifice, such as the drainage of urine by using a Foley catheter, or from a patient cavity, such as drainage of excess CSF by using a ventricular drain.

[0024] More specifically, the invention relates to a medical apparatus and method that electronically measures and displays the discharge of body fluids. The apparatus is comprised of a reusable electronic housing and a disposable plastic container adapted to be received and removed from a cavity defined by the electronic housing. The liquid output is measured outside or externally of the disposable container, by using a novel optical level metering system. The disposable container has a measuring scale and inlet and outlet stopcock like valves that engage or couple with shaft like connector endings of electrical motor drives, which in turn, enables to open and close the flow of drained fluids into an out of the

container automatically. The opening of the outlet valve enables the emptying of the container to an elastic accumulation drainage bag.

[0025] This novel disposable container is designed in a way that it can also be manually operated or viewed in order to monitor the process of body fluids drainage. This way, the disposable part of the apparatus can be operated or viewed manually, and when a more exact monitoring is needed, it can be plugged into the reusable electronic system, or the reusable electronic system can be activated, for automatic monitoring without the need to disconnect the patient. Vice versa, when there is no more need for automatic measurement, the disposable system can be disconnected or deactivated from the reusable electronic system and manual monitoring can be resumed. This feature is not available in any of the prior art.

[0026] Also within the scope of this invention, the drained liquid is measured in the collecting container until it reaches a predetermined height or reaches the end of a preset time interval. The height and time intervals can be adjusted to any time interval and/or accumulated volume protocol according to the clinical procedure needs. This adjustment cannot be done in any of the prior art.

[0027] Furthermore, while plugged in or activated to automatically measure and monitor the liquids output volume, the apparatus and method mimics currently used clinical procedures of urine and CSF volume metering, enabling the clinical staff to view other collected fluid characteristics like color, which can indicate blood in the liquid, turbidity, sedimentation and ease of aspirating sampling of liquid at any given time interval. These features are lacking in the majority of the prior art, where the drained body liquid is being continuously accumulated and visualizing the liquid in relation to time intervals is not possible.

[0028] The apparatus and method measures and monitors the liquid output volume in the collecting container by means of a novel optical refraction method using a specific algorithm. The apparatus is capable to identify the height of any collected liquids, from the bottom of the disposable container to the highest limit of the optical segment (height of the facing and vertically parallel LEDs and photo detector arrays). The particular measuring technique of the present invention for determining the liquid's surface height is accomplished by scanning the space of the transparent measuring vessel or collecting container that is placed between a vertically oriented array of light emitters and an elongated photodetector. The scanning is based on the refraction of the emitters' rays on the boundary of two medias due to the special measuring vessel's (collecting container's) construction.

[0029] The scanning is accomplished by the reusable electronic component that contains a specially designed optical cavity for receiving and holding the collecting container in a proper orientation. The optical scanning, as noted above, comprises an optical segment composed of a vertically oriented LED emitter array and an elongated vertically oriented photodetector, both of which are positioned vertically facing each other and horizontally spaced in such a way that whenever the collecting container or vessel is mounted and held in the cavity defined by the reusable electronic unit or component, the optical part of the collecting container or vessel is vertically situated between the array of LED emitters and the photodetector. The height of the optical segment of the reusable electronic component extends the entire height of the optical portion of the collecting container or vessel and the light emitted by the LED emitters of the array are transmitted

through the optical portion of the measuring collecting container or vessel. The reusable electronic unit or component thus functions to detect continuously the height of the collected liquid column in the collecting container or vessel by means of the photodetector, which produces an output indicative of the intensity of the detected light.

[0030] Due to the inventive apparatus and method of measuring liquid level height, the measurement can be done regardless of the characteristics of the liquids. The apparatus will function in the very same manner at different liquid temperatures, in case of clear transparent up to highly dense dark liquids, with different fluid viscosities or weights, and also in cases where the fluids contains high contents of colloid particles, such as blood clots, that can emerge in the CSF, or some sedimentation that can appear in the urine, regardless of the shape and size of the particles.

[0031] Since different requirements are demanded in different hospital wards (adult and pediatric intensive care, general and neurosurgical intensive cares), different designs of the collecting vessel with different capacities are required in order to provide higher, lower or variable resolution of the fluid column, different sampling ports, and other features as will be evident from the following detailed description. The present invention functions with different designs of collecting vessels and the apparatus and method have the capability to "recognize" the particular type of collecting vessel being used by means of a novel optical technique.

[0032] In the apparatus and method of the present invention the electronic system, the same disposable container and elastic or flexible bag is used and an emptying valve is opened automatically on a preselected time basis, for example, an hourly basis, or responsive to the liquid having accumulated to a predetermined level.

[0033] The container includes hangers for holding the elastic or flexible bag. Thus, the elastic or flexible bag can be exchanged without the need to disengage the container from the electronic reusable part. This is an advantage over most automatic drained liquid measuring apparatuses, where, when the disposable container is full there is a need to stop measurement and exchange the disposable container. In this inventive apparatus and method there is not such a need because the measurement is done outside or externally of the container, which allows the elastic or flexible bag to be exchanged without affecting the level measurement that is being carried out relative to the container. In addition, since the container has a novel overflow feature, similar but different to manually designed containers currently in use, when the drained liquids are being accumulated and there is a malfunction in the automatic valve opening, the novel overflow design enables excess liquids to drain into the elastic or flexible bag, as opposed to other automatically monitoring apparatuses that do not possess such a characteristic of the disposable container part.

[0034] It is further in the scope of this invention that the accumulation of fluid can be done continuously as described above or in relation to pressure measurement from the drained area. In order for this aspect of the invention to perform, the inlet of the drained liquids to the container is blocked using an upper stopcock like valve in addition to the lower valve. This upper valve can prevent the drainage of the liquids and enable the pressure accumulation in the drained organ, such as the bladder, which gives an indication of intra-abdominal pressure, or the cranial cavity, giving an indication of the inner cranial pressure (ICP). The upper valve is opened automati-

cally according to a predetermined pressure or a predetermined time. In either case the pressure is continuously measured. In addition, after opening the upper valve, the amount of drained liquid is recorded. The pressure measurement in correlation with time and liquid accumulation can give indications of different medical conditions, both in intra-abdominal pressure measurement and in CSF/ICP measurements.

[0035] As mentioned above, the correlation between time, pressure and volume of the drained liquid can give good indication of the patient clinical situation. For example, in intra-abdominal pressure measurement, if there is a rapid elevation of the measured pressure (above 15 mm Hg) in a short time, compounded with a very low urine volume output, one can suspect an abdominal compartment syndrome. Vice versa, for the same time intervals and the same pressure elevation, if the urine output is high, then one will not suspect any difficult clinical condition. As the abdominal compartment syndrome is treated, the same bladder pressure will be reached after longer time intervals and the urine volume output will increase.

[0036] In another example, for ICP/CSF correlation the situation is somewhat different. Elevated ICP (above 20 mm Hg) is correlated with high volume of drained liquid, such as CSF or blood. The lower the ICP measurement in the same time intervals with decreased liquid drainage volume can indicate a recovery of the patient, due to less bleeding or resume possibility for CSF absorption.

[0037] Other and further objects and advantages of the apparatus and method of the present invention will become apparent from the following detailed description of preferred embodiments of the invention when taken in conjunction with the appended drawings

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] FIGS. 1(a) to (d) show schematically in a front view two preferred embodiments of a single motor valve Fluid Secretion Pressure Monitor (FSPM) apparatus according to the present invention.

[0039] FIGS. 2(a) to (b) show schematically in a front view two preferred embodiments of a double motor valve Fluid Secretion Pressure Monitor (FSPM) apparatus according to the present invention.

[0040] FIGS. 3(a) to (b) show a double valve Electronic unit used in the Fluid Secretion Pressure Monitor (FSPM) of FIGS. 2 in an exploded view and in an assembly view.

[0041] FIGS. 4(a) to (b) show schematically in front view how the Fluid Secretion Pressure Monitor (FSPM) apparatus of the present invention can be adapted for converting urine output and intra-abdominal pressure measurement procedures to automatic procedures.

[0042] FIG. 5 shows schematically in front view how a manual measurement of an ICP (intra-cranial pressure) measurement and CSF (Cerebrospinal Fluid drainage) manual measurement is converted to automatic measurement by the apparatus of the present invention.

[0043] FIGS. 6(a) to (c) show schematically how a disposable container is engaged with an electronic unit of a FSPM apparatus according to the present invention.

[0044] FIGS. 7(a) to (b) show schematically and partially in section views of the inlet & outlet valves of a FSPM apparatus according to the present invention in their open & closed positions and how the shafts engage

[0045] FIGS. 8(a) to (f) show schematically how a Fluid Secretion Pressure Monitor (FSPM) apparatus is hung on a bed, and also on a hospital pole as seen in FIG. 5.

[0046] FIGS. 9(a) to (g) are schematic views illustrating emission across the optical gap of the Electronic unit and how the determination of liquid level is made and also show schematically details of the optical unit of the present invention.

[0047] FIGS. 10(a) to (d) show schematically the optical unit of the present invention and illustrates how liquid level and identify the type of vessel mounted on the electronic unit is determined.

[0048] FIGS. 11(a) to (d) are further schematic views and a graph illustrating in more detail the operation of the optical unit of the present invention.

[0049] FIGS. 12(a) to (f) are schematic views illustrating determination of the type of vessel mounted on the Electronic unit

[0050] FIG. 13 is a block diagram of the inventive apparatus, 2-VALVE FSPM, showing details of the electronic components and their interaction.

[0051] FIG. 14 is a block diagram of the inventive apparatus, 1-VALVE FSPM, showing details of the electronic components and their interaction

[0052] FIGS. 15(a) and (b) show graphs illustrating pressure release schemes for the inventive apparatus.

[0053] FIG. 16 is a graph illustrating the induced pressure mode of operation.

[0054] FIG. 17 is a block diagram showing the software main modules of the inventive apparatus.

[0055] FIG. 18 is a block diagram showing details of the software warnings and alarms.

[0056] FIG. 19 is a flow chart illustrating initiation and drain routines.

[0057] FIG. 20 is a flow chart illustrating the measuring routine.

[0058] FIG. 21 is a flow chart illustrating routines relevant to a double valve system including monitoring pressure threshold and pressure routines.

DETAIL DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

[0059] Referring now to the drawings preferred embodiments of the present invention will now be described in detail. Referring initially to FIG. 1, two preferred embodiments of a single motor valve Fluid Secretion Pressure Monitor (FSPM) apparatus according to the present invention are shown, namely, preferred embodiment of the Fluid Secretion Pressure Monitor (FSPM) apparatus, FIGS. 1(a & b) 100 and preferred embodiment of the Fluid Secretion Pressure Monitor (FSPM) apparatus, FIGS. 1(c & d) 1100. The two embodiments measure, in an automatic way, accumulated liquids in disposable vessels having a single motor for operating in an electromechanically way the outlet valve of the disposable vessels, which will be explained in detail hereafter. The opening of the outlet valve is fluid level depended and time as will hereafter be explained in detail.

[0060] The two preferred embodiment of FIG. 1 have the same electronic unit 200 with two different disposable collecting plastic vessel containers. In FIG. 1(i a) a rectangular shaped container 600 can be seen and in FIG. 1(c) a burette type container 1000 can be seen.

[0061] The collecting vessel 600 has a cover 610 provided with an inlet 602, the corresponding burette type 1000 has a cover 1610 provided with an inlet 1602. Coupled to the upper

inlet **602** & **1602** is a high flow drainage tube **120** or alternatively, a low flow drainage tube **125**. The use of a high or low flow drainage tube depends on the liquid draining. For example, for urine a high flow tube is used whereas for CSF a low flow tube is used. Both containers are provided with a shoulder like area, **660** in vessel **600** and **1660** in burette **1000**. The shoulder areas serve to mount the vessels on mounting ledges **220** of electronic unit **200**. Both disposable vessels have the same outlet valve **170**. A secondary flexible reservoir **580** of vessel **600** and secondary reservoir **1580** of vessel **1000** are connected via an inlet port **584** and **1584**, respectively, that engages with lower outlet connector, (not shown) of the collecting vessel **600** and **1000**, respectfully. In FIG. **1** display panel **260** and control panel **240** of electronic box **200** can be seen. An optional remote control and display unit **180** can be also seen connected to the electronic unit **200** by an appropriate cable **182**. In FIGS. **1b** and **1d**, top views, shows the disposable vessels inter-engaged with optical segment cavity **211** of electronic unit **200**, which will be explained in further details with respect to the FIGS. **3** & **6** and FIG. **10**.

[0062] Referring now to FIGS. **2(a)** and **(b)**, two preferred embodiments of a double motor valve Fluid Secretion Pressure Monitor (FSPM) apparatus are shown, namely, in FIG. **2(a)** **500** and in FIG. **2(b)** **3500**. This apparatus measures in an automatic way the accumulated liquids of disposable vessels having a double motor for operating in an electromechanically way the outlet & the inlet valves of the disposable vessels, which will be explained thereafter. In FIGS. **2** the two preferred embodiments of the Fluid Secretion Pressure Monitor (FSPM) apparatus the opening of the inlet valve is pressure & time dependent and the opening of the outlet valve is fluid level & time dependent.

[0063] The two preferred embodiments of FIG. **2** use the same FSPM unit **400** with two different disposable collecting plastic vessel containers. In FIG. **2(a)** small rectangular shaped container **300** can be seen and in FIG. **2(b)** a burette shaped container type **3000** can be seen. The collecting vessels **300** & **3000** have the same inlet valve **320**. In addition to the inlet valve there is a telescopic pole or rod **550** that can be attached to the bed frame or can be mounted on or be a part of the electronic unit box housing **402**. On the rod there is a stand **551** for mounting a pressure transducer **520** and a height beam indicator **708**. The telescopic rod **550** can be adjusted so that pressure transducer (DPT) **520** and height beam indicator **708** can be at the level of the patient's drained cavity. The drainage tube, either high-flow **120** or low-flow **125**, is branched at **577** via a stopcock **540**. The stopcock **540** is connected to the DPT **520** via a conduit or tube **530**. The DPT **520** is provided with a priming port **510**. The DPT **520** functions for converting pressure sensed to a corresponding electrical signal indicative of pressure sensed and outputs a signal via DPT cable **560** to the electronic unit **400** for processing. The height beam indicator **708** gets its power supplied from the electronic unit **400** via cable **709**. All other features are the same as for the single valve FSPM units.

[0064] The overall operation of the Double motor FSPM apparatus is as follows. The double motor FSPM is first placed besides the patient at a convenient height where the DPT **520** can be raised or lowered to the level of the organ to be drained by means of the telescopic rod **550**. After the mounting the FSPM and the DPT is at the appropriate levels, the DPT line **530** is primed with saline through the priming port **510** while the stopcock **540** is at the open position towards the outlet of the drainage tube. Zeroing of the pres-

sure transducer is done and the drainage tube is connected to the patient via a catheter (not shown). The unit can be powered on and the patient's bio-fluids drainage and cavity pressure measurements can be initialized as will be explained in detail with reference to flow charts illustrated in FIGS. **15** & **19** and in FIGS. **20** & **21(a)**.

[0065] In addition to automatic measurement of pressure where the drained fluid is accumulated in the drained cavity, there is additional way of measuring pressure, especially intra-abdominal pressure, by adding a predetermined fluid, testing the intra-abdominal pressure & then opening inlet valve for drainage either in an automatic way or by pressing a button that opens the inlet valve, see flow chart illustrated in FIGS. **16** & **21b**.

[0066] FIG. **3** shows a double valve Electronic unit according to the present invention. FIG. **3** depicts the electronic unit **400**. Unit **400** consists of a housing **402** preferably of metal or molded from a suitable plastic or a combination thereof wherein housing **402** has a back cover **480** and a front cover **230**. The front cover **230** in its middle portion defines an optical segments cavity **211** of U-shaped configuration for optical segment **210**. The legs of the configuration define opposite vertical slits **245** and **255**. Behind slit **245** is positioned a series or array of LEDs **246** mounted in housing **402** and arranged in a vertical row to shine their light out slit **245**. Behind slit **255** is positioned a photo-detector strip **256** aligned with the LEDs to receive the light emanating out of slit **245**. The top two LEDs serve to identify the type of collection vessel mounted onto the electronic unit, as will be explained in greater detail hereinafter in FIGS. **10** and **12(a)** to **(f)**. Housing **402** has upper mounting ledges **220** inclined downwardly toward each other such that all types of collection vessels as can be nested. When collection vessels are nested in housing **402**, their hind part is situated into the optical segments cavity **211** as to allow light from the LEDs behind slit **245** to pass horizontally through the collection vessel on path to the photo-detector behind slit **255**. This mechanism will be explained in more detail in FIG. **9-12**.

[0067] Clamping brackets **235** are mounted on the front of housing **402** and located just below the proximal ends of the inclined upper mounting ledges **220** such to maintain alignment and juxtaposition to side notches or projections of any of the disposable containers. When the tabs of the clamping brackets **235** are manipulated, the brackets **235** lock into the side notches or projections to securely hold the collection vessels in proper position. The conjunction of the electronic unit & the disposable vessel will be described in greater details with reference to FIG. **6**.

[0068] A cable plug or terminal box in segment **270** is present on the left side wall of housing **402** and serves the purpose of providing a connection terminal for cables interconnecting the electronics of the electronic unit **400** with external functions, such as, the DPT **520** cable **560** & the height beam indicator **708** power supplied cable **709**, an optional remote control and display unit **180** and an optional PC/monitor or any other patient monitoring system(s) and in addition to supply power to the system and recharge the battery **2000**. A display LCD panel **260** is mounted in the housing **402** in an inclined manner on the left side of the front of the housing **402**, for the purpose of displaying information under the control of the electronics contained in the housing **402**. A control panel **240** with control buttons is mounted in the housing **402** in an inclined manner on the right side of the

front of the housing **402**, for the purpose of providing a means to control the electronics contained in the housing **402**.

[0069] The connections and operation of the inlet and outlet valves includes a shaft's engagement segment **250** and its electromechanical driver **250'** positioned as indicated by dashed line and anchored by snap array **403**. Wherein the lower snap array **403** correspond with the lower shaft engagement segment **250** and electromechanical—the name driver **250'** and the upper snap array **403** correspond with the upper shaft engagement segment **415** and electromechanical driver **415'**.

[0070] For a one-valve system, electronic unit **400** does not include any parts or features from above the upper mounting ledges **220** namely the upper shaft engagement segment **415** and electromechanical driver **415**.

[0071] The coupling of shaft's engagement segments **250** and **415** to vessel valves is explained in greater detail with reference to FIG. 6.

[0072] FIGS. 4(a) and 4(b) show how the currently used urine output & intra-abdominal pressure measurement procedures are converted to automatic procedures. FIG. 4(a) depicts urine drainage procedure, and FIG. 4(b) depicts the urine drainage procedure with the possibility to measure intra abdominal pressure which is a reflection of the pressure measured in the bladder.

[0073] In FIG. 4(a) a typical hospital bed **700** is shown. On the left side, a manual operated disposable Drainage device **600** is and is currently used for measurement of the urine output via a drainage tube **120**. The device is hung on the hospital bed using hanging straps **601** or in any convenient other means from the frame of the bed below the drained patient cavity, the bladder. In the manual procedure urine is drained and accumulated in the disposable rigid container **600**, every hour on the hour a nurse comes, measures the accumulated urine, writes it in the patient chart, open the outlet valve **170** and urine will be drained from the rigid container to the secondary flexible reservoir **580**.

[0074] On the right hand side of the bed the FSPM a single motor apparatus **100** is hung via a hanging mechanism **900**, which will be explained in greater details with reference to FIG. 8. FSPM apparatus **100** is comprises of the manual drainage device **600**, plugged in the electronic **200** unit, thus converting the same manual procedure to an automatic one, by measuring the accumulated urine in the disposable container via a level detection mechanism that will be explained in further details in FIGS. 9-12 & 14 & 19-20 displaying the measurement on the electronic unit display panel **260** and/or remote control and display unit **180**. The electronic unit **200** and the remote unit **180** can be connected via communication cable **191** to a PC, monitor or to any other patient monitoring system **190**.

[0075] FIG. 4(b) shows the possibility of urine drainage with intra- abdominal pressure measurement. On the left side, a manual operated disposable drainage device **300** is hung on the hospital bed **700** using hanging straps **601** or any other means for hanging, to hang the disposable drainage device below the drained patient cavity, the bladder. In addition to the outlet valve **170** there is an inlet valve **320**. In addition to the inlet valve, a pressure transducer **520** is mounted on telescopic pole **550** that can be adjusted to the level of the patient's drained cavity. A DPT is connected via tube **530** to the drainage tube **120**, thus when closing the inlet valve **320** in container **300** enabling the measurement of the bladder pressure, which gives an indication of the intra abdominal pres-

sure, the pressure of the abdomen can be measured due to accumulation of fluid in the bladder by the patient's own urine or can be induced due to predetermined fluid insertion. On the right hand side of the bed **700**, the FSPM double motor apparatus **500** is hung via the same hanging mechanism **900** as above. FSPM unit **500** is comprised of the manual drainage device **300**, plugged into the electronic **400** unit, thus converting the same manual function to an automatic procedure, in addition to measuring the accumulated urine, the intra abdominal pressure can be measured in an automatic way when closing the inlet valve **300** in the disposable as described with reference to FIGS. 2, 13, 19, 20 and 21.

[0076] Shown in FIG. 5 is the manner of converting the currently used ICP—(intra-cranial pressure) measurement and CSF—(Cerebrospinal Fluid drainage) manual measurements to automatic procedures. On the right hand side can be seen a double valve manual burette disposable container **3000**. The unit is vertically adjustable and fixable by conventional known means on a hospital stand pole **710**. The burette **3000** is connected to a DPT **520** via a tube connected to the drainage tube in the same way as previously explained regarding the manual procedure. On the left hand side, closer to the bed, is the FSPM double motor apparatus **3500** mounted on a hospital stand pole **710** via hanging mechanism **900** comprises of the same manual burette **3000** plugged in with the double motor electronic unit **400**. Pole **550** is fixable and mounted on the electronic unit **400**, having a height level indicator **708** and pressure transducer **520**. The components are connected in the same manner as described with respect to FIG. 4b. This shows the manual procedure to measure ICP and to drain the CSF according to the pressure measured, thus opening the inlet valve of the disposable container **3000**, manually or automatically when measured pressure is above the threshold measurement, this will be explained in greater details hereafter in FIG. 15.

[0077] FIG. 6 shows all engagement elements of the disposable container **300** regarding the electronic unit **400** composing a part of the FSPM **500**. FIG. 6 shows the assembly of the double motor FSPM unit **500**, which is composed of the disposable vessel **300** engaged in to the electronic double valve unit **400**. In FIG. 6(a) the disposable unit **300** can be seen from its back side, before engaging into the electronic unit **400**. In the two details of this figure, the upper & the lower shafts **415** & **250**, respectfully, of electronic unit **400** and inlet & outlet valve **320** & **170**, respectfully, of disposable container **300** valves **320** & **170** can be seen before engaging. A detailed explanation will follow regarding FIG. 7. In addition to the valves and shafts engagement, there can also be seen in FIG. 6(b) an enlarged view illustrating the main elements of the optical segment **210** and their specific relative positioning with respect to the of the disposable container **300**. Container **300** is fully engaged into optical cavity **211** of the electronic unit **400**, as shown from two different sides the container **300** and photo detector strip **256** and led array **246** of optical segment **210**.

[0078] FIG. 6(c) shows the engagement of the disposable container **300** with its side notches or projections **380** with the electronic unit **400** by means of clamps **235**. This is shown in two steps, initiation stage and engagement step. Initially clamp **235** pivots counter clockwise on axis **404** as vessel **300** is pressed into place. In the engagement step, clamp **235** pivoting clockwise on axis **404** due to spring pressure **236**. In this position notch or projection **380** stays in cavity or slot **336** until release of vessel **300** by manually turning clamp

counter-clockwise. This clamping feature or functionality is relevant to all containers within the scope of the application.

[0079] FIG. 7 shows views partly in section of the inlet and outlet valves in their open and closed positions and shows the shafts engagement. FIG. 7(a) and FIG. 7(b) show the inlet and outlet valves, respectively, and includes partial sectional views of the collection vessel 600 and 300, respectively. The outlet valve 170 in FIG. 7(b) has an overflow feature to allow passage of liquid during vessel overflow, regardless of being open or closed. This overflow feature pertains to the outlet valve exclusively. The valves are both of stopcock-like valves where one end of the valve shaft is fitted with a handle and the other end of the valve shaft is designed to engage the output drive of the motor that can automatically rotate the valve between its open and closed positions responsive to the motor drive signals.

[0080] When the outlet valve 170 is in open position, it creates an alignment between orifice 663 and the drainage hole 173 to allow fluid passage from vessel to outlet connector 640. In addition the open position seals the overflow passageway 172 from the outlet connector 640. When the outlet valve 170 is in closed position, it seals the orifice 663 from the drainage hole 173 and creates an overlap between the overflow passageway 172 and outlet connector 640 to allow overflow liquid to pass from overflow channel 667 via orifice 668 to the overflow passageway 172 and out from outlet connector 640. As noted above, flow out of the collecting vessel is controlled by the outlet valve 170, which is driven by a suitable electro-mechanical driver 250' (shown in FIG. 3) via a drive shaft engagement segment 250 with a protrusion 251. The protrusion 251 has a non-circular periphery and fits into the geometrically corresponding cavity 171 inside the outlet valve 170. Outlet valve 170 can also be opened or closed manually by lever 174. Outlet valve 170 is depicted with vessel 600, as an example; all said features for the outlet valve 170 pertain to all other vessels 600, 1000, 300, 3000 as well.

[0081] The inlet valve 320 of FIG. 7(a) controls the flow into the collection vessel 300. Unlike the outlet valve 170, the inlet valve 320 has no overflow compensation and only maintains two positions, opened to allow flow into vessel from inlet connector 352 via drainage hole 322 and into vessel and closed to inhibit said flow. The open and closed position of inlet valve 320 can be controlled by the electro-mechanical driver 415' (shown in FIG. 3) or by a manual lever 323. Motion transmission from the electro-mechanical driver 415' is achieved via the drive shaft engagement segment 415 with a protrusion 416. The protrusion 416 fits into a geometrically corresponding cavity 321 inside inlet valve 320. Inlet valve 320 is depicted with vessel 300 as an example; all said features for the inlet valve 320 pertain to vessel 3000 as well.

[0082] FIG. 8 depicts the hanging mechanism of the FSPM and illustrates how the mounting apparatus 900 and the way the FSPM unit 100 is engaged or disengaged with the mounting assembly 902. Apparatus 900 consists of two sub units, the L-shape member 914 and the assembly 902 which consists of 4 units 903, 904, 906, 908. The member 904 is clamped to the bed rail R by lockdown of sliding flange 903. Member 906 is L-shaped and its short leg is held by the member 904 such to allow 906 to slide relative to 904 in the grooved direction. Member 908 is L-shaped and its short leg is held by the member 906 by a conventional pin and slot arrangement 905 as depicted in FIG. 8(a) to allow 908 vertical movements with respect to 906. The long leg of member 908 terminates in

an enlargement 909 that defines a circular through bore 910 that has a notched opening 912 along its long axis. Thus the bracket 902 can be adjusted in three dimensions relative to R, the horizontal plane and vertically.

[0083] Another L-shape member 914 has one leg 913 fixed to the back of electronic unit 200 of the FSPM unit 100 with the other leg 915 extending over the top of the collection vessel 600, a cubic shaped counter balance weight is located at the extended end of 915 to counter the weight of FSPM unit 100. The free end of leg 915 has a projection 916 in the shape of a sphere having a greater diameter than the bore 910 mounted on a short stub 917 that has a diameter less than the opening 912. Stub 917 holds the sphere or ball 916 spaced above leg 915. The FSPM unit 100 is mounted on the bracket 902 by sliding the rod or stub 917 through the opening 912 and seating the ball 916 in the through bore 910. This mounting assembly maintains the FSPM unit 100 in its horizontal leveled position. The spherical joint 916 is a gravity centering joint which maintains the FSPM unit 100 aligned with gravity regardless of the bed tilt. The engagement of the FSPM unit 100 on the bracket 902 is shown from another angle in FIG. 8(b) the anti-tilt effect is shown more graphically in FIGS. 8(c) to 8(f). The same anti-tilt hanging is used when hanging the system on a hospital pole in order to avoid tilting when pole is moving as seen in FIG. 5 and in FIGS. 8(c) to 8(f) where the automatic adjustment due to gravity is shown in front view and side view. FIGS. 8(c) and 8(e) show the bed 700 positioned horizontally and FIGS. 8(d) and 8(f) show the bed 700 positioned with a tilt. The FSPM unit 100 remains horizontal despite the bed tilt since the ball 916 acts as a spherical joint in bore 910, causing gravitational alignment.

[0084] FIGS. 8(c) and 8(f) give additional illustration of the adjustability of Member 906 relative to member 904 to allow retraction under the bed line.

[0085] Referring to FIGS. 9 to 11, the measuring of the liquid's surface height h_m is accomplished by scanning the space of the optical segment 210 of the transparent measuring vessel 600, 1000 or 300, 3000 that is placed between vertically oriented light emitter diodes (LED) array 246 and an elongated photodetector 256. This scanning is based on the refraction of the emitters' rays on the boundary of two media due to the special measuring vessel's construction. FIG. 10 illustrates various vessel configurations and shows how light is refracted in dependence on whether there is liquid present in the light path as it traverses the vessel. Three vessel shapes are shown and the effect of light refraction is depicted for each. LEDs 247 are used for vessel identification as will be explained hereinafter.

[0086] FIGS. 9 to 13 show the scanning in more detail and show how it is controlled and processed by the electronic unit 200 that contains optical cavity 211, in which the optical segment 210, composed of array 246 and elongated photo detector 256, is vertically positioned and mounted. The optical segment's height extends the entire vessel's optical part's height and the light emitted by the LEDs is transmitted through the measuring vessel optical part. The electronic unit 200 is designed, under the control of MCU 740, to continuously and serially and cyclically light the LEDs for a defined interval from bottom to top, to detect the intensity or luminance of detected light by the photodetector 256 for each LED in succession and to output signals correlated to the detected intensity or luminance, which are stored in memory. These

output signals are processed by MCU 740 to determine the height of the collected liquid column as will be explained in detail in the following.

[0087] As seen in FIGS. 9 to 12 the liquid column height H_m inside the optical part is smaller than the electronic unit's optical cavity height L_c . The array column 246 has n light emitters designed to emit a diverging light of specified viewing angle α . The measuring height H_m contains $(n-1)$ distances (L) between neighboring emitters' optical axis: $H_m = (n-1) L$. The geometrical parameters of the measuring vessel's optical part provide the desired degree of emitter rays' refraction. FIGS. 9 to 12 show, respectively, vertical and horizontal cross sections of the optical part. Thus, the output signal level of the photodetector 256, enables measuring the height of liquid column. To provide a continuous measurement scale independent of the emitters' positions, the LED array 246 is constructed such that every emitter's diverging ray partially overlaps the rays of the neighbor emitters, see FIGS. 9 to 12 showing a vertical cross section of optical segment, where:

[0088] 1_i and 1_{i-1} neighbor emitters of emitters' array 246;

[0089] EOA_i and $EOA_{(i-1)}$ —neighbor emitters' optical axis;

[0090] W —distance between the emitters' array and the photodetector;

[0091] h_{ov} —overlap.

[0092] The value of overlap is defined by the above-mentioned geometric parameters of the optical system.

$$h_{ov} = 2W \cdot \tan\left(\frac{\alpha}{2}\right) - L \quad (1)$$

[0093] Thus, varying W , L and/or α , can achieve the required value of overlap.

[0094] The algorithm, set forth below, for processing measurement results for the signals of the photodetector, illuminated sequentially by neighboring emitters, is based on the argument that in the case of 50% photo detector's luminance, the liquid's surface level either coincides with the optical axis of the corresponding emitter. In this case the liquid's surface level is calculated by using the following expression:

$$h_m = h_0 + nL \quad (2)$$

[0095] Where:

[0096] h_m —liquid's surface height;

[0097] h_0 —height of lowest emitter's optical axis;

[0098] n —emitter's number (in this case $n=i-1$).

[0099] If the liquid's surface level is between two neighbor emitters (FIG. 32c and FIG. 33) so the h_m is determinable from two values of the photodetector's output signal; see FIG. 11 showing a graph of the photodetector's illuminance vs. detector.

$$h_m \approx h_0 + nL + \frac{\gamma_i + \gamma_{max} - 2 \cdot \gamma_{(i-1)}}{(\gamma_i + \gamma_{max}) \cdot \frac{L}{W_{es}} - \gamma_{(i-1)}} \cdot L \quad (3)$$

[0100] Where:

[0101] h_m , height of the liquid surface relative to the bottom of the measuring vessel;

[0102] n —The emitter's number shaded by the liquid more then to 50%;

[0103] L —distance between neighbor emitters' optical axis;

[0104] h_0 —height of the 1st emitter's optical axis.

[0105] $\gamma_i, \gamma_{(i-1)}$ —photo detector's illuminance caused with emitters number: $n=i$ and $n=i-1$;

[0106] W_{es} —distance from the emitter to the measuring vessel in a longitudinal cross section.

[0107] A tilt sensor may be used to determine the vertical orientation of the collecting vessel 600. Alternatively, the assembly can be mounted on an anti-tilt device as explained herein. Also, averaging the photodetector's signals significantly reduces the influence of the irregular and periodic fluctuations of photo signals. This influence reduction is caused both, by optical and/or mechanical causes, and also by electromagnetic interference. The averaging of the signals is carried out in three steps:

[0108] 1. multiple scanning with simultaneous recording of the results in the temporary memory;

[0109] 2. analysis of the recorded results and the removing of the "artifacts", i.e. results differing significantly from the others;

[0110] 3. averaging and storing of the remaining results for data processing.

[0111] Thus in data processing, after above mentioned steps, only "cleaned" and averaged results are used.

[0112] To compensate the impact of external lighting, the measuring vessel's scanning order is organized as follows:

[0113] a. measuring the signal with the non-activated emitters (γ_{NAE}), while averaging the signal and recording the result in the temporary memory;

[0114] b. generating an output analog signal, using the internal DAC, which is equal to the temporary stored value: $\gamma_{REF} = \gamma_{NAE}$, and feeding it to the negative input of the measuring differential ADC;

[0115] c. measuring the difference of the signal γ_{AE} when the emitter is activated and feeding this result to the positive input of differential ADC, and the signal to the negative input:

$$\gamma_i = \gamma_{AE} - \gamma_{NAE};$$

[0116] d. storing the result γ_i in the memory as the tasked signal's value.

[0117] Thus, the value stored in memory (γ_i) does not contain an external light component (γ_{NAE}). Implementation via the multiprocessor of the system of the above-described sequence for each measurement of the photodetector's signal, given the high-speed of the measurements, allows for a high level of compensation on the influence of external illumination on the measurement results.

[0118] Increasing the number of mutually overlapping emitters (by reducing the distance between their optical axes and/or increasing the emitter's viewing angle) significantly improves the resolution and accuracy of measurement when using a more detailed calculating algorithm.

[0119] Scanning results that are stored in memory perform the tabulated function of illuminance from the emitter's number:

$$\gamma_i = F(i), \text{ where } 0 \leq i \leq n \quad (4)$$

[0120] This function is the source of DATA for calculation via the computer of the system of the liquid level height. In order to find h_m , any interpolation method, say Lagrange Polynomial Interpolation can be used. For the interpolation, it is reasonable to use only a few points that can provide con-

crete information about the value of h_m . According to the Lagrange Polynomial Interpolation, the function $\gamma=F(h_m)$ can be written for any virtual emitter placed so that its optical axis height is equal to liquid's level h_m . In this case, the photodetector's signal caused by this emitter is equal to half of the maximal possible signal:

$$\frac{1}{2} \gamma_{max} = \sum_{j=n_b}^{n_t} \gamma_i \cdot \frac{\prod_{j=n_b, j \neq i}^{n_t} (h_m - h_0 - j \cdot L)}{h_m^{(n_t - n_b - 1)} \cdot \prod_{j=n_b, j \neq i}^{n_t} (i - j)} \quad (5)$$

[0121] Where:

[0122] h_m —height of the liquid surface relative to the bottom of the measuring vessel;

[0123] n_t —the number of the top emitter used for interpolation;

[0124] n_b —the number of the bottom emitter used for interpolation;

[0125] L —distance between neighbor emitters' optical axis;

[0126] h_0 —height of the 0-emitter's optical axis;

[0127] γ_i —photo detector's illuminance caused with the i -emitter ($n_b \leq i \leq n_t$);

[0128] After the height is found, the tabulated function $v_i=F(h_i)$ is used to calculate the liquid volume v_m . To calculate v_m , the above mentioned interpolation method is used again:

$$v_m = \sum_{j=n_b}^{n_t} v_i \cdot \frac{\prod_{j=n_b, j \neq i}^{n_t} (h_m - h_0 - j \cdot L)}{h_m^{(n_t - n_b - 1)} \cdot \prod_{j=n_b, j \neq i}^{n_t} (i - j)} \quad (6)$$

[0129] Where:

[0130] v_m —desired value of liquid volume in the measuring vessel;

[0131] v_i —value of liquid volume corresponding height of the i -emitter's optical axis, defined with function $v_i=F(h_i)$, that is specific for every type of vessel.

[0132] For deviation from the horizontal corrections, if necessary, the invention uses a two horizontal coordinates' tilt-sensor, which provides the measuring of the horizontal deviation values for correction of the volume measurement.

$$v_{mnh} = F_d(v_m, \delta_x, \delta_z) \quad (7)$$

[0133] Where:

[0134] v_{mnh} —measured value of liquid's volume at any horizontality deviation;

[0135] v_m —measured value of liquid's volume without horizontal deviation;

[0136] δ_x, δ_z —horizontal deviation's angle in two optical system's coordinates' axis.

[0137] FIGS. 12(a) to (f) show a novel identification device and technique for automatically determining the type of vessel connected to the electronic unit 200 and/or the optional double motor electronic unit 400. As shown the identification approach for the type of vessel connected to the electronic unit 200 and/or the optional double motor electronic unit 400 reads the light intensity received from the two upper emitters or vessel type identifiers 247 and compares their individual

values against the known minimal light intensity value indicating unobstructed passage of light through the vessel walls. By placing opaque tabs 696 on the vessel wall at the precise location where the two said vessel type identifiers 247 are located, which effectively prevents the light emanating from them from reaching the elongated optical photodetector 256, four different types of collecting vessels can be recognized. This can be clearly visualized on FIG. 12, where by covering or not the beams emanating from the two vessel type identifiers 247, according to the four possible combinations shown, four different photodetector's 256 reading are obtained. These readings are then compared against known ones identifying each particular vessel type. As a result of this, during regular operation the liquid level is not permitted to reach the vessel type identifiers 247.

[0138] The operation of the FSPM unit 100 automatically is as follows. The valve 170 is closed and bio-fluid is allowed to drain into vessel 600 for predetermined or preselected time intervals. The volume is periodically measured by calculating as previously described, recorded and saved to memory. At the end of a time interval, valve 170 is opened and the bio-fluid is drained into the secondary reservoir 580, which is drained or replaced when full. At the same time the volume of the vessel is monitored and if the volume reaches a preset level before the time interval has elapsed, this volume is recorded and saved to memory and valve 170 is opened to drain vessel 600. Volume is calculated as previously described. Data regarding the volume and time can be displayed on display 260. Alternatively, a graph can be plotted showing volume vs. time and shown on display 260 and saved to memory. Also, the apparatus can be monitored and operated manually by a nurse and emptied manually by the nurse manipulating valve 170 to open to drain and close to collect bio-fluid and recording the volume and time.

[0139] The overall operation of the Double motor FSPM unit 400 automatically is as follows. The double motor FSPM unit 400 is first placed besides the patient at a convenient height where the DPT 520 can be raised or lowered to the level of the organ to be drained by means of the extendable tube 550. After the double motor FSPM unit 500 is in place, the DPT line 530 is primed with saline through the priming port 510 while the stopcock 540 is at the open position. After the DPT cable 560 has being connected to the double motor Electronic Unit 400, and the high flow high flow drainage tube 570 is connected to the patient, the unit can be powered on and the patient's bio-fluids drainage and measurement can be initialized.

[0140] The double motor FSPM unit 400 is programmed to record and evaluate the physical values of fluid pressure and volume vs. time in order to determine the particular intra-abdominal pressure of the patient at all times. This is achieved by use of a double valve approach, where each valve 320 and 170 is attached to one of the servo motors of the double motor Electronic Unit 400, and the valves are controlled by software commands in accordance to the specifications of the end users.

[0141] The different evaluative options of the double motor FSPM unit 400 are as follow: to record and evaluate volume and pressure at set intervals of time and/or to record and evaluate volume and time at peak intervals of intra-abdominal pressure. In order to evaluate volume and pressure at set intervals of time, the double motor FSPM unit 400 opens the upper inlet valve 320 and begins draining the bio-fluids from the patient, while keeping the outlet valve 170 closed. As the

bio-fluids are being drained, the double motor Electronic Unit 400 records and displays the pressure inputs from the DPT 520 and the volume level inside the collecting vessel 300 at predetermined or preselected time intervals. The volume level inside the collecting vessel 300 is measured by the vertically oriented array of LED's serially and cyclically emitting light through the LED slit that is detected by the vertically oriented photodetector via juxtaposed slit 255. The sensed and detected light is processed in the MCU, in the manner described previously in order to determine the level of the bio-fluids inside the said double valve collecting vessel 300. The system is programmed so that the measured level is plotted against time, recorded and displayed to show volume accumulation of the bio-fluids. After a predetermined or preselected time, the level in vessel 300 is measured and valve 170 is turned from closed to open and the fluid is drained from the collection vessel 300 to the secondary reservoir 580. By the same token, if the level that is constantly being monitored reaches a predetermined or preselected level before the time interval has elapsed, valve 170 is turned to open and fluid is drained from the collecting vessel 300. These functions are recorded and saved in memory and processed by the MCU and displayed appropriately on the display 260 of electronic unit 400. Also, the DPT 520 continually detects and monitors the pressure in the cavity or organ being monitored and this is plotted against time and liquid volume see FIG. 14. The electronic unit 400 is programmed to monitor the pressure in the cavity or organ of the patient being monitored by frequently cycling valve 320, and to close valve 320 periodically at set time intervals or whenever the monitored cavity pressure reaches a preset maximum value, whereupon the valve 170 is opened to drain the vessel 300 see the plot of FIG. 15. The operation of the unit can be manually controlled by a nurse checking the status of liquid volume and cavity pressure and manipulating valves 320 and 170 at appropriate times, while recording the pressure, volume and time.

[0142] FIGS. 9 and 11 are schematic views illustrating emission across the optical gap and the determination of liquid level. FIG. 10 shows various vessel configurations. FIGS. 12(a) to (f) are schematic views illustrating the process of determining the type of vessel mounted on the electronic unit. FIG. 13 is a block diagram of the inventive apparatus showing details of the electronic components for a double valve FSPM unit and their interaction. FIG. 14 is a block diagram showing the components for a single valve FSPM unit and their interaction.

[0143] FIG. 13 illustrates schematically a block diagram of the measuring components and the electronic components of the FSPM double valve unit. The simplified block diagram is shown in FIG. 14, which illustrates the 1-valve FSPM unit. The double valve FSPM unit is shown in FIG. 13 within the dotted lines and consists of an automatically and/or manually operated inlet valve 320 leading from a disposable pressure transducer 520. The inlet to the pressure transducer is the patient's catheter tube 726 originating from a cavity of the patient, such as the patient's bladder and carrying bio-fluids. Valved inlet 320 introduces the patient's bio-fluids into a double valved liquid measuring vessel. Liquid is drained from vessel via an automatically and/or manually operated outlet valve 170 and passed to a secondary liquid reservoir. Liquid level is measured in vessel 300 by a vertical array of LEDs 246 coacting with a vertically oriented photodetector strip 256 connected via line 741 to ADC 774. The LEDs-Array 246 are powered and controlled by MCU 740 via line 742 and

driver circuit 744. Valved inlet and outlet 320 and 170 are operated by conventional electromechanical drives 250' and 415', which in turn are powered and controlled by MCU 740 via lines 748, 750 and drivers 752, 754. MCU 740 outputs to a display 760 and to an output interface 770, which in turn can send its signals to a remote control FSPM unit 180 having a display 782 and control buttons 784 for a manual operator to input, output, and program or control. Output interface 770 can also be coupled to a PC or LAN 783 and is coupled to a cavity level pointer 785. Buttons 790 are connected to input, output, and program or control the MCU 740 via an input interface 792, which is coupled to the MCU 740 via serial bus 794.

[0144] The disposable pressure transducer 520 generates an output of pressure and transmits its output signal via DPT cable 560 to the input interface 792 where it is processed in amplifier 800 and transmitted via lines 798 to ADC 802 connected to the MCU 740 where the signals are processed. An X, Z tilt-sensor 804 generates tilt signals and transmits them via lines 806 to ADC 808 connected to the MCU 740 where the signals are processed. The output of the photodetector strip 736 outputs a luminance signal via line 810 to MCU 740 where it is processed. A rechargeable battery 814 is included as the power source for all components of the FSPM double valve unit and is connectable to mains or AC power source 816 for recharging. It will be appreciated that in the above description both inlet valve and outlet valve are included. Thus, the block diagram, with appropriate adjustment, can be used for both the double valve & single valve FSPM units. The connections, coactions and components for the single valve FSPM are shown in block diagram in FIG. 14.

[0145] Referring again to FIGS. 9 to 11, the measuring of the liquid's surface height h_m is accomplished by scanning the space of the optical segment 210 of the transparent measuring vessel 600, 1000 or 300, 3000 that is placed between vertically oriented light emitter diodes (LED) array 246 and an elongated photodetector 256. This scanning is based on the refraction of the emitters' rays on the boundary of two media due to the special measuring vessel's construction. FIG. 10 illustrates various vessel configurations and shows how light is refracted in dependence on whether there is liquid present in the light path as it traverses the vessel. Three vessel shapes are shown and the effect of light refraction is depicted for each. LEDs 247 are used for vessel identification as explained herein.

[0146] FIGS. 15(a) and 15(b) show pressure release schemes. The parameters for these schemes are P_{max} : Pre-determined threshold pressure for opening of Inlet Valve; Drained Volume: the recorded volume of the liquid collected in the vessel after the inlet valve opening; Inlet Valve State: can be either closed or open denoted 0 or 1, respectively; and Outlet Valve State: can be either closed or open denoted 0 or 1, respectively.

[0147] FIG. 15(a) depicts graphically the dependencies of pressure, volume, inlet valve and outlet valve for a pressure controlled release scheme. The pressure is measured in the fluid line from the inlet valve to the patient and is compared to a threshold value P_{max} . Upon crossing the threshold value, the outlet valve is open briefly to empty the vessel and then closed. After outlet valve has closed the inlet valve is opened briefly to allow the release of pressure from the patient by releasing fluid into the vessel. The new volume of said fluid in vessel is measured and denoted as "Drained Volume". In this figure it can be seen that there is a pressure rise in the drained

cavity, while there is decreasing in the fluid output, this can be indicative of an intra-abdominal pressure rise.

[0148] FIG. 15(b) depicts graphically the dependencies of pressure, volume, inlet valve and outlet valve for a time controlled release scheme. The difference from the pressure controlled release scheme is that in addition to the release by crossing pressure threshold value P_{max} (arrow) the pressure is released periodically wherein period is defined by user. In this figure the period is 10 min. as with the pressure controlled release scheme, prior to pressure release the outlet valve is opened briefly and then closed followed by opening of the inlet valve. Subsequently fluid passes from the patient to the vessel, the pressure drops, the inlet valve is closed and the Drained Volume is measured. In this figure if the drained cavity is the bladder although there is no raise in pressure there is lowering of the urine output that can be due to different clinical situations, not related to rise in intra-abdominal pressure.

[0149] FIG. 16 depicts graphically the dependencies of pressure, volume, inlet valve and outlet valve for an induced pressure scheme. Inlet and outlet Valve State: can be either closed or open denoted 0 or 1, respectively; occasionally there is a need to induce pressure within the patient. When this mode is selected both valves open briefly to zero the system and closed again a known amount of Saline (e.g. 50 ml) is injected into the patient from the line connecting inlet valve to patient, pressure builds up, is measured and released according to one or more predefined triggers (i.e. steady pressure, threshold reached, manual release and timer). The release of pressure is done by opening the inlet valve after which the amount of volume (e.g. 10 ml) is registered by deducting the amount injected into patient (e.g. 50 ml) from the volume in vessel (e.g. 60 ml). After pressure has been released by opening of the inlet valve the system reverts to its previous monitoring and pressure release scheme. The schematic of induced pressure is also described in FIG. 21b.

[0150] FIG. 17 depicts, in block form, the software main modules wherein a real time clock 20 connected to process manager block 21 which is also connected to task synchronizer block 22. The process manager 21 controls the volume measuring block 23, data saving block 24, alarm manager 25, communication block 26, display manager 27, data processing block 28, pressure measuring 40 and valves control 42. The main process and functions are also shown in FIG.17 and consist of hidden continuous processes 30 including button inputs, battery monitoring, inclination sensor, memory management, vessel detector, communications and pressure monitoring. The communications process relays data internal and external to process 30. Process 30 feeds volume measurement block 31 that is controlled by initialization 32 and patient selection 33. Block 31 interacts with functions menu 34 that includes patient history 35 and settings 36. Warnings and alarms are provided depending on device mode and events. Volume measurement 31 reacts responsive to events including vessel not in cradle, valve is jammed, sensors not showing vessel properly, battery problem, contents of memory reaching limit and communication problem detected. The responsive warning or alarm is set forth in detail in FIG. 18

[0151] FIG. 18 shows, in block form, the software Warnings and alarms. The various scenarios for an event mode, (possible reason) and the consequential display are as follows:

[0152] Device Mode:

[0153] Volume measurement 31:

[0154] Event: Vessel is not in the cradle or sensors do not show vessel when they should (vessel removed or misplaced). In this event the display will show "Insert URX".

[0155] Event: calibration fails: (dirty vessel). Display: "Insert URX"

[0156] Event: the valve is jammed or not in position (valve is not rotating as commanded).

[0157] Display: "check URX"

[0158] Event: the valve is jammed or not in position (the valve has been rotated manually).

[0159] Display: "check Valve"

[0160] Event: too much environmental light (direct sunlight). Display: "Too much light"

[0161] Event: device inclined (bed inclined greater than compostable). Display: "Straight device".

[0162] Pressure Measurement 38:

[0163] Event: pressure level out of limits (measured cavity over pressurized or DPT reading out of scale). Display: "Pressure alarm"+buzzer+red light.

[0164] Event: pressure level out of limits (inlet valve is open, NO pressure drop). Display: "Check DPT".

[0165] General:

[0166] Event: battery voltage reaches limit (20% to 10%). Display: Low battery icon.

[0167] Event: battery voltage reaches limit (10% to 5%). Display: "Low Battery".

[0168] Event: battery voltage reaches limit (5% to 1%). Action: automatic shutdown.

[0169] Event: memory is reaching the limit. Display: "Low memory"

[0170] Event: communications problem. Display: "Communication problem"

[0171] FIG. 19(a) depicts the system flow chart for the initialization routine 7001, which initializes the system on power on. Thereafter routine 7004 waits for user input as to the patient identity 7007 whether it be old or new, which in the first case (old) will continue from previous point and in the second case (new) the system will clear the data base 7008. Vessel volume measuring 7013 will check the absence or presence of liquid in the vessel, 7017 in which case if null the measuring subroutine 7028 is activated and if not then a display routine 7018 "The vessel is not empty, store current volume?" is activated and system waits for user input 7020, if 'No' then system skips to subroutine 7002 and drains the vessel. If 'Yes' the system stores the volume 7023 and continues to the Drain subroutine 7002 and drains the vessel. After Drain 7002 the system activates the measuring subroutine 7028.

[0172] FIG. 19(b) Upon activation of subroutine 7002 a command to open motor 7030 is sent, system checks if the valve has opened 7032, if 'no' then an alarm is activated 7031, if 'yes' then the calibration subroutine 7034 is activated. Upon completion of the calibration subroutine 7034 a command is sent to motor 7036 to close valve. System checks if valve was closed 7038 if 'no' then the alarm 7037 is activated, if 'yes' then the system ends current subroutine 7002 by activating end block 7039. After end 7039 the system resumes the parent routine.

[0173] FIG. 20 depicts the flow chart for the measuring subroutine 7028 that scans for a vessel 7005 every clock tick predefined by timer 7006. Vessel presence 7009 is checked, if 'no' activates the display 7010, "insert vessel" which initiates

standby mode **7012** until placement of vessel. If 'yes' calculates **7011** the volume of liquid and updates the display **7014**, database **7015** and sends data via communication **7016**. System compares the volume **7019**, if larger than threshold value (e.g. 100 CC) the system initiates Drain subroutine **7002**, if smaller than threshold value then the system checks if a whole hour has past **7022**, if 'no' then system continues to beginning of measuring subroutine **7028**, If 'yes' then the system updates the previous hour display and measured volume, and zeroes the current hour display **7021**. Subsequently the system will initiate the Drain subroutine **7002** and returns to head of subroutine **7028**.

[**0174**] FIG. **21** depicts pressure threshold and induced pressure routines relevant to double valve systems. FIG. **21(a)** depicts the pressure monitoring **7029** routine wherein the monitored pressure is compared to threshold **7033**. This process is looped as long as pressure is lower than threshold. If pressure exceeds threshold or timer trigger **7040** is induced then the inlet valve is open **7035**. Subsequently volume is measured **7028** and the system is drained **7002**. During pressure measuring routine **7029** the Drain subroutine **7002** can also be activated by measurement module **7003** according to settings defined in measurement module **7003**. FIG. **21(b)** concerns the pressure induced Routine **7041** and is activated when pressure is induced by manually injection of saline into the patient via the drain line connected to the inlet valve. Upon initiation the drain subroutine **7002** is activated and when finished the inlet valve is closed **7047**. A predefined amount 'X' of Saline is injected into line connecting inlet valve and patient **7042**. The inlet valve is opened **7044** upon any one of the following triggers: pressure reaches steady value **7043**; pressure crosses threshold **7033**, timer opening **7040** and manual command **7048**. Any combination of said triggers can be used and is predefined in software definitions. After the opening of inlet valve **7044** the measuring subroutine **7028** is activated with a deduction of the 'X' volume of Saline injected **7045**.

[**0175**] Summarizing the foregoing, the Fluid Secretion Pressure Monitor (FSPM) unit includes as its main components a disposable molded plastic collecting vessel and a reusable electronic unit. The collecting vessel has a cover provided with an inlet that includes a port or connector and may include a venting filter and a sampling port. The collecting vessel may be configured with an upper enlarged portion the top part of which is rectangular in cross section with knobs projecting on opposite sides for hanging the vessel on a bed; an intermediate portion and a lower portion constituting the rest of the vessel. The vessel may have a hexagonal part with a rear part trapezoidal in cross section with the smaller base of the trapezoid at the rear and serving as the optical portion. The front face of each of the portions of the collecting vessel can be marked with indicia to indicate a collected fluids measuring scale. Wall sections define inclined under shoulders for mounting on the electronic unit. The container may have a bifurcated hanger support for hanging secondary reservoirs.

[**0176**] The secondary reservoir has an inlet port that engages with lower outlet connector of the collecting vessel. An outlet valve operable manually or automatically by an electromechanism controls the outlet of the collecting vessel. For urine a high flow tube is used. For CSF a low flow tube is used. The vessel also contains an overflow arrangement as a security measure.

[**0177**] Also, a double motor, double valved FSPM unit can be provided and it can be connected to a disposable pressure

transducer (DPT) fixed at the level of the organ being drained via a tube and a stopcock provided with a control knob.

[**0178**] Further relative to the optical portion of the vessel there is juxtaposed an optical segment that consists of clamping brackets, the vessel type identifiers, the light emitting diodes (LEDs) and the photodetector strip to effect measurements responsive to the controls imposed by the electronic unit. Also, special provision is made for mounting of the apparatus bedside in a horizontal manner. A drainage tube leads from a catheter inserted into a body cavity, e.g., the patient's bladder, and is connected to the inlet of the apparatus that leads to the collection vessel. If a double motor FSPM unit is being used an upper inlet valve is present and a pole or rod is attached to the bed frame or a free stand is provided on which is slidingly mounted a pressure transducer and a height beam indicator that can be adjusted or controlled to the level of the patient's drained cavity. A second tube leads from the drained cavity or is taken off the drainage tube and is operatively connected to a pressure transducer. Both the transducer and height beam indicator output electrical signals indicative of the values sensed and transmit these signals to the electronic unit. Also a remote unit can be electrically coupled to the FSPM unit via an operative cable.

[**0179**] Liquid level is measured in the vessel by an optical segment that consists of a vertical array of LEDs coating with a vertically oriented photodetector strip. The LEDs are powered and controlled by a microprocessor computing unit according to software programs, as explained above.

[**0180**] A rechargeable battery can be included as the power source for all components of the FSPM unit. The rechargeable battery can be recharged through the USB port of the FSPM unit when connected to a computer, or through an AC power adapter connected to an external power source.

[**0181**] The measuring of the liquid's surface height h_m is accomplished by scanning the space of the optical segment of the optical portion of the transparent measuring vessel. This scanning is based on the refraction of the emitters' rays on the boundary of two media due to the special measuring vessel's construction. Various vessel configurations can be used. A novel identification device and technique is included for automatically determining the type of vessel connected to the electronic unit that uses the two upper emitters for vessel type identifiers using opaque tabs. Special programs have been described for the operation of the FSPM unit automatically in several modes.

[**0182**] In addition to the foregoing, the invention relates to a computer readable media that has recorded program instructions for carrying out the software programs shown in the flowcharts of FIGS. **19-21** and by means of the apparatus illustrated in FIGS. **13** and **14**.

[**0183**] The above description sets forth preferred embodiments of the present invention. Various modifications and changes to the preferred embodiments will be apparent to those of ordinary skill in the art without departing from the teachings, spirit and scope of the present invention. Such modifications and changes are deemed to come within the scope of the appended claims.

1. A bedside apparatus designed to collect and monitor liquids output from a catheterized patient comprising an electronic unit including a liquid level sensing device and one of a plurality of defined disposable collecting and measuring rigid vessels; each defined vessel having at least one inlet to connect to a catheter outputting liquid from a patient in order to collect said liquid in said defined vessel; said defined vessel

having at least one outlet valve to control draining of liquid from said vessel; and said electronic unit having a configuration to receive and hold the defined vessel securely in a fixed relationship with a portion of the vessel coacting with the level sensing device of the electronic unit so that liquid contained in said vessel can be sensed and a signal indicative thereof can be outputted.

2. Bedside apparatus according to claim 1 further including an inlet valve controlling said at least one inlet.

3. Bedside apparatus according to claim 1 wherein the liquid level sensing device functions according to refractive properties of collected liquids in said defined vessel.

4. Bedside apparatus according to claim 1 wherein the liquid level sensing device of said electronic unit is operative continuously based on an algorithm capable to sense the fluid height in a continuous manner to measure output height of collected liquids in the disposable defined vessel using optical refraction and to output an electrical signal indicative of liquid level.

5. Bedside apparatus according to claim 1 further including a computer programmed to receive the output signal and to calculate the volume of the collect liquids indicative thereof.

6. Bedside apparatus according to claim 1 wherein the electronic unit further includes an optical identifier capable of differentiating between different defined types of vessels.

7. Bedside apparatus according to claim 1 wherein an input control valve is provided on the vessel input.

8. Bedside apparatus according to claim 1 wherein the electronic unit further operatively controls includes at least one electrical motor having an output drive shaft that operatively engages with the at least one valve, and a microcontroller operatively coupled to the liquid level sensing device and to the at least one electric motor to control operation of said at least one electric motor to open or close the at least one valve in response to predetermined conditions of operation of the microcontroller.

9. Bedside apparatus according to claim 1 wherein the electronic unit further includes at least two fixation clamps to fixate, mount and hold said defined vessel in said fixed relationship.

10. Bedside apparatus according to claim 1 wherein the electronic unit further operatively controls the at least one valve to control draining of liquid from said defined vessel according to one of predetermined time intervals and predetermined fluid level thus enabling clinical staff to view collected liquid characteristics including color, blood in the fluid and sedimentation.

11. Bedside apparatus according to claim 1 wherein the liquid level sensing device of the electronic unit comprises an LED emitting array and an elongated photodetector that are vertically positioned facing each other to receive a portion of the defined vessel inserted between them.

12. Bedside apparatus according preceding claim 1 further comprising a monitoring device for monitoring pressure in a draining organ of a catheterized patient and for providing an output signal indicative of the monitored pressure, and the electronic unit further comprising a controller for controlling the upper inlet valve of the disposable defined collecting vessel responsive to the output signal responsive to the monitored pressure.

13. Bedside apparatus according to claim 12 wherein said controller opens the inlet valve in response to receiving a signal indicative of a predetermined pressure.

14. Bedside apparatus according to claim 12 wherein said controller opens the inlet valve in response to a predetermined time.

15. Bedside apparatus according to claim 1 wherein the apparatus further includes a hanging device to hold the apparatus horizontally.

16. Bedside apparatus according to claim 1 wherein the apparatus further includes a tilt sensor device to determine the horizontal position of the device.

17. Method for collecting and monitoring liquids output from a catheterized patient comprising the steps of providing an electronic unit including a liquid level sensing device and one of a plurality of defined disposable collecting and measuring rigid vessels having at least one inlet; connecting at least one of the defined vessels to a catheter outputting liquid from a patient; collecting said output liquid in said defined vessel; controlling the draining of liquid from said vessel by at least one outlet valve; configuring said electronic unit to receive and hold the defined vessel securely in a fixed relationship with a portion of the vessel coacting with the level sensing device of the electronic unit; sensing liquid contained in said vessel; and

outputting a signal indicative of liquid contained in said vessel.

18. Method according to claim 17 further including the step of controlling said at least one inlet.

19. Method according to claim 17 including the step of sensing liquid level according to refractive properties of collected liquids in said defined vessel.

20. Method according to claim 17 including the steps of continuously measuring output height of collected liquids in the disposable defined vessel using optical refraction and continuously outputting an electrical signal indicative of liquid level.

21. Method according to claim 17 further including the step continuously calculating the volume of the collect liquids in said vessel.

22. Method according to claim 17 including the further step optically identifying the defined type of vessel.

23. Method according to claim 17 including the further step of controlling the vessel input.

24. Method according to claim 17 including the further step of the operatively controlling at least one electrical motor having an output drive shaft that operatively engages with the at least one valve in the inlet, and microcontrolling operatively the liquid level sensing device and the at least one electric motor to open or close the at least one valve in response to predetermined conditions of operation of the microcontroller.

25. Method according to claim 17 including the further step of holding said defined vessel in said fixed relationship with the electronic unit.

26. Method according to claim 17 including the further steps of operatively controlling the at least one valve to control draining of liquid from said defined vessel according to one of predetermined time intervals and predetermined fluid level thus enabling clinical staff to view collected liquid characteristics including color, blood in the fluid and sedimentation.

27. Method according to claim 17 including the steps of sensing the liquid level in the vessel by emitting light through a portion of the vessel and detecting the emitted light to determine the level of liquid in the vessel.

28. Method according to claim **17** including the further step of emitting light in a vertical array through a portion of the vessel; detecting by an elongated vertically oriented photodetector light passing through the vessel, and determining from light received by the photodetector the level in the vessel.

29. Method according to claim **17** comprising the further step of monitoring pressure in a draining organ of a catheterized patient; providing an output signal indicative of the monitored pressure; and controlling the upper inlet of the disposable defined collecting vessel responsive to the output signal indicative of the monitored pressure.

30. Method according to claim **17** including the steps of inducing pressure by administrating fluid into the draining organ, and adjusting the volume of liquid output recorded volume by subtracting the additional fluid administrated to induce pressure.

31. Method according to claim **17** including the step of opening the upper inlet in response to receiving a signal indicative of a predetermined pressure.

32. Method according to claim **17** including the step of opening the upper inlet in response to receiving a signal indicative of a predetermined time.

33. Method according to claim **17** including the further step of hanging the defined vessel horizontally from a bed.

34. Method according to claim **17** including the further step of monitoring the vessel for a tilt, outputting a signal responsive to the tilt condition of the vessel, and determining responsive to the output signal the horizontal orientation of the vessel.

35. Method according to claim **17** including the further step of overflowing fluid in the vessel if it rises above a predetermined threshold, and draining the overflowing fluid through a bypass channel in the outlet valve.

36. Computer readable media having recorded thereon program instructions for collecting and monitoring liquids output from a catheterized patient including monitoring liquid level in a defined disposable collecting and measuring rigid vessel having at least one inlet to which is connected a catheter outputting liquid from a body cavity and having at least one outlet that is controllable; opening the at least one outlet valve in response to a signal generated by a sensed condition of the liquid in the vessel; calculating the volume of liquid in the vessel in response to the sensed condition; draining liquid contained in said vessel in response to the sensed condition; and outputting a signal indicative of the calculated value of liquid contained in said vessel at the time of the sensed condition.

37. Computer readable media according to claim **36** wherein the sensed condition is one of volume and time.

38. Computer readable media according to claim **36** including instructions for monitoring pressure in the body cavity, and outputting a signal indicative of the monitored pressure.

39. Computer readable media according to claim **36** including controlling the inlet to the vessel responsive to the pressure in the body cavity.

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专利名称(译)	用于床边收集体液和自动体积水平监测的装置和方法		
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摘要(译)

一种床边设备和方法，设计用于收集和监测从导管插入的患者输出的液体，所述导管插入的患者包括电子单元和可以在形状和尺寸上不同的多个限定的一次性收集和测量刚性容器中的一个。每个限定的容器具有至少一个入口，该入口连接到输出来自患者的液体的导管，以便在限定的容器中收集液体。限定的容器具有至少一个出口阀，以控制从容器中排出液体。电子单元具有接收限定的容器并以固定关系牢固地安装和保持限定的容器的构造。电子单元还具有液位传感装置，该液位传感装置与限定的容器并置，以检测容器中包含的液体的液位。

