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(54) VOLUME MEASUREMENT USING GAS LAWS

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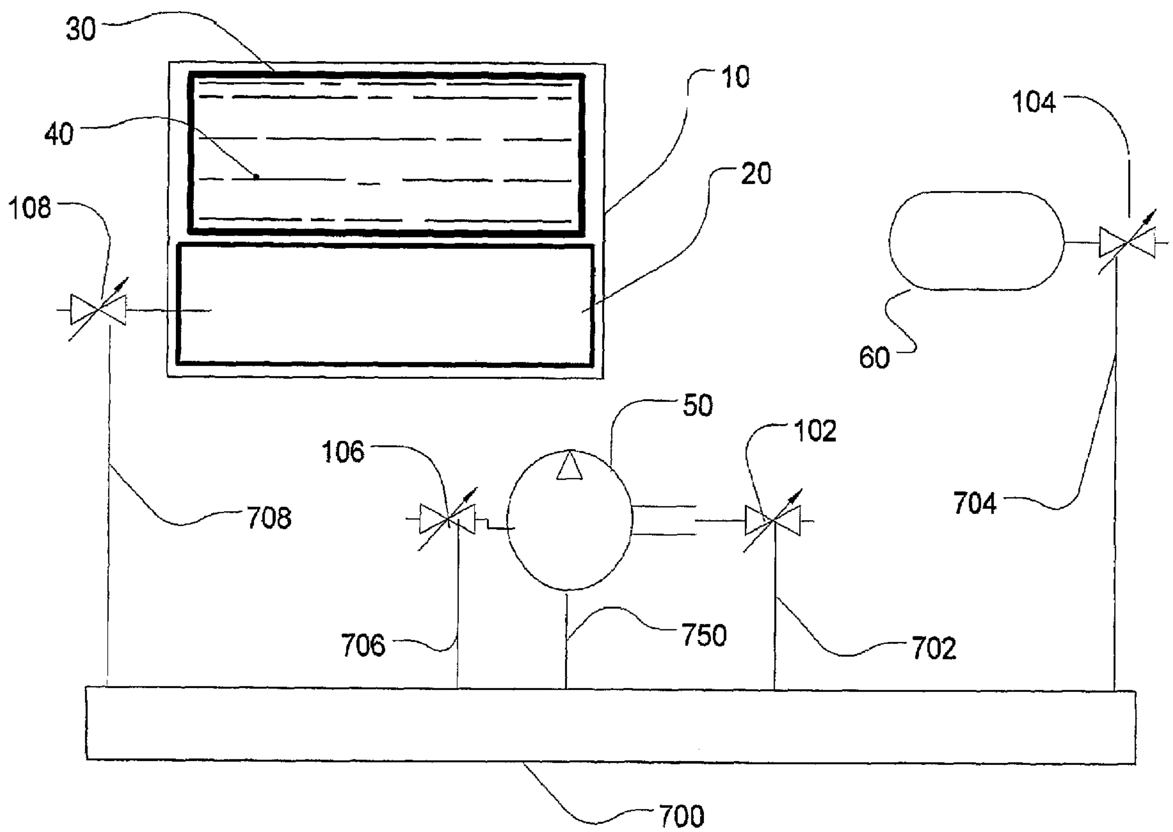
(57) **ABSTRACT**

A system and method for measuring fluid volume and changes in fluid volume over time, using a simple, low cost architecture is described.



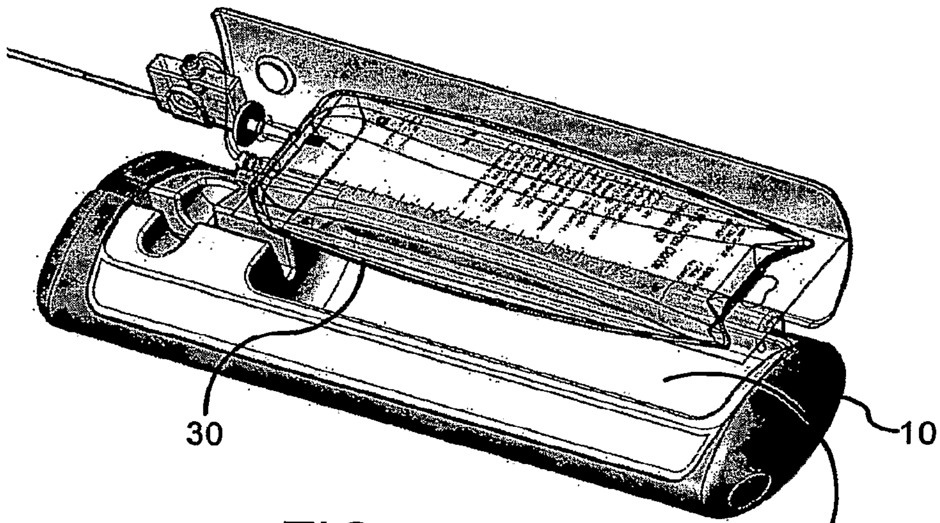


FIG. 1

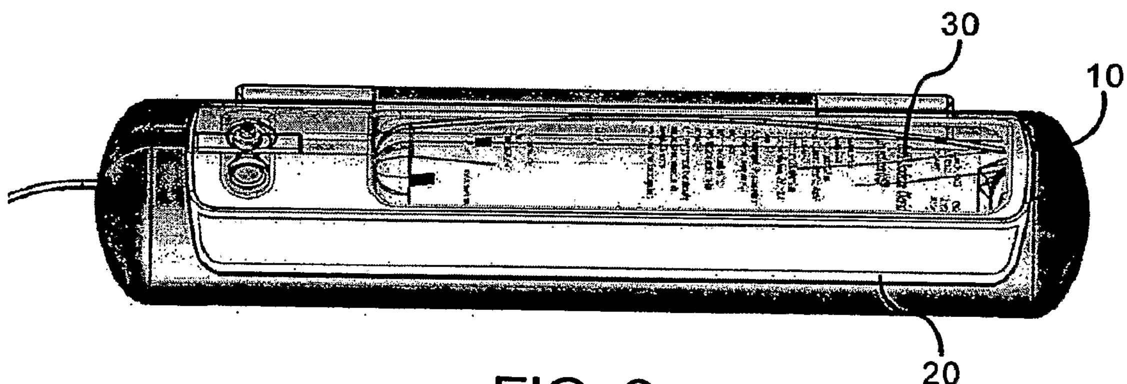


FIG. 2

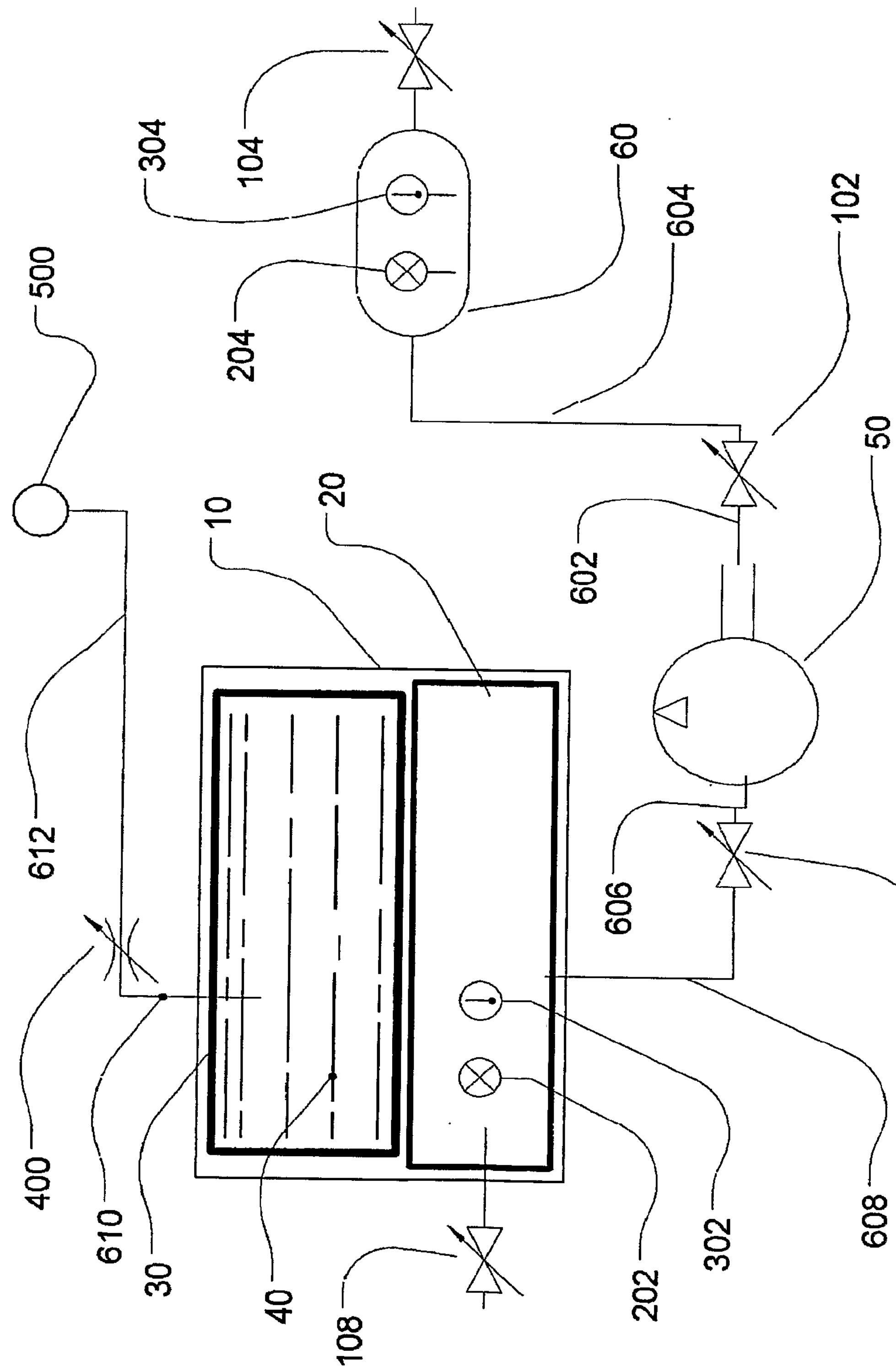

500
612
400
610
30
40
10
20
108
202
302
608
106
606
50
602
102
604
60
204
304
104

FIG. 3

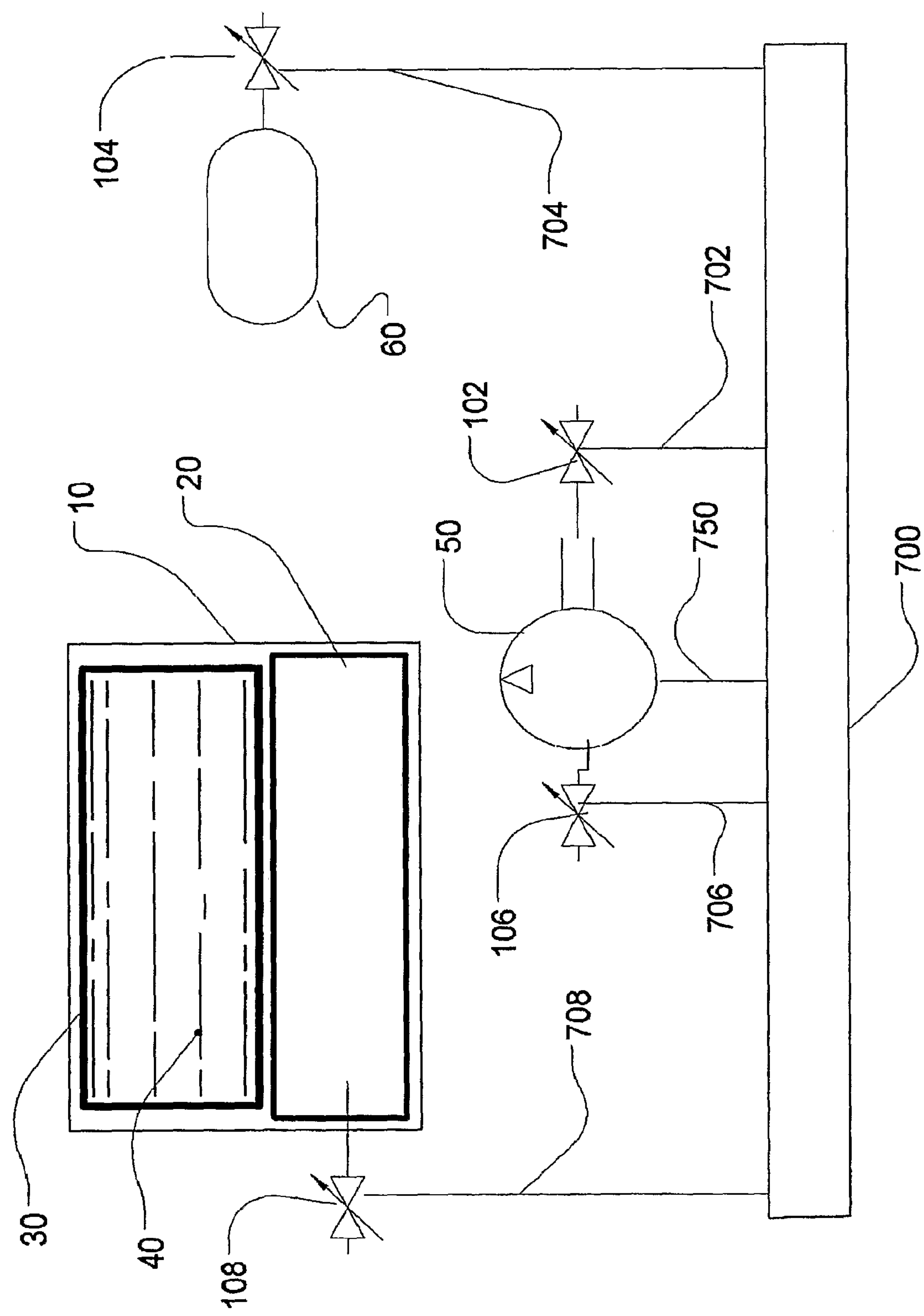


FIG. 4

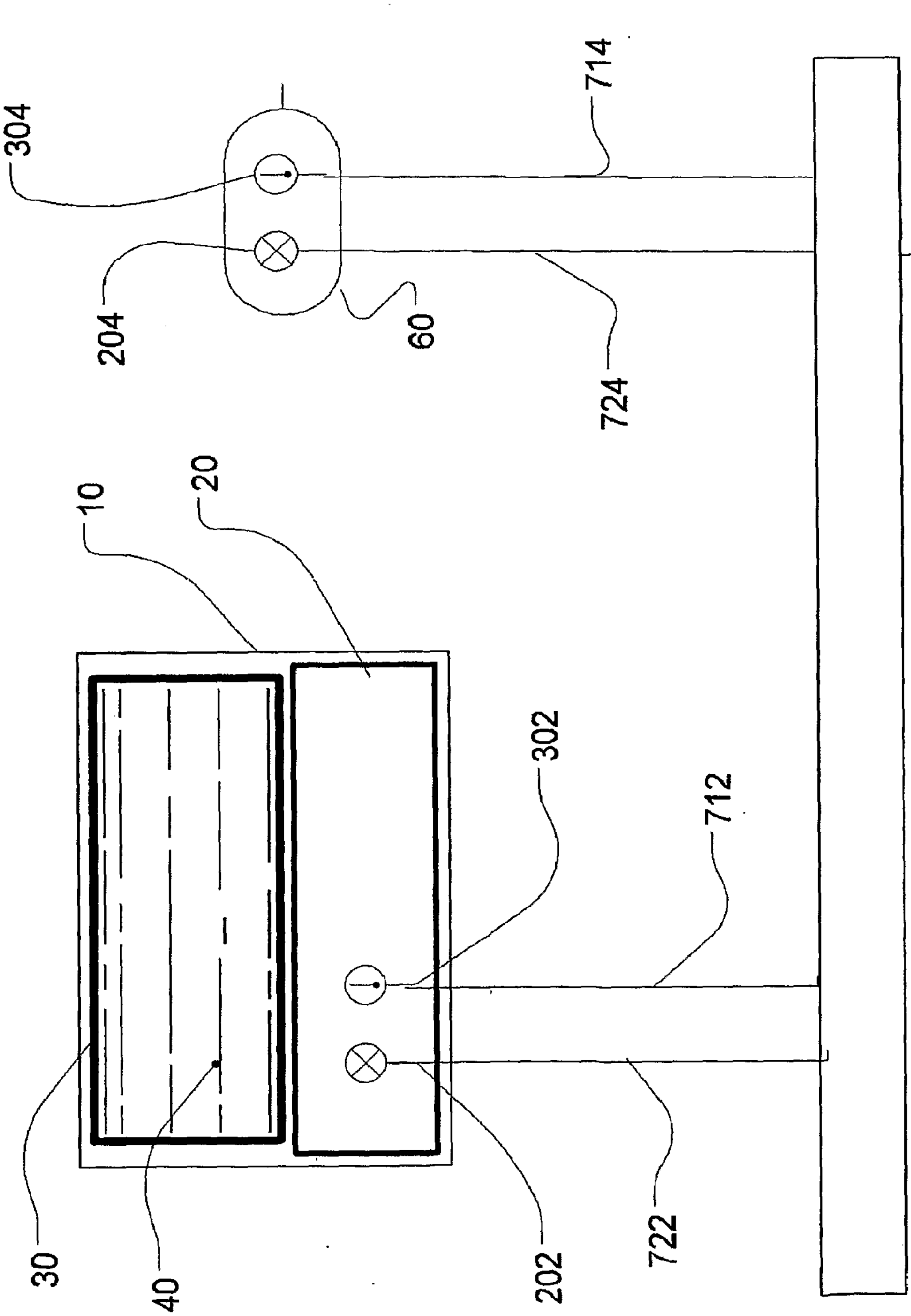


FIG. 5

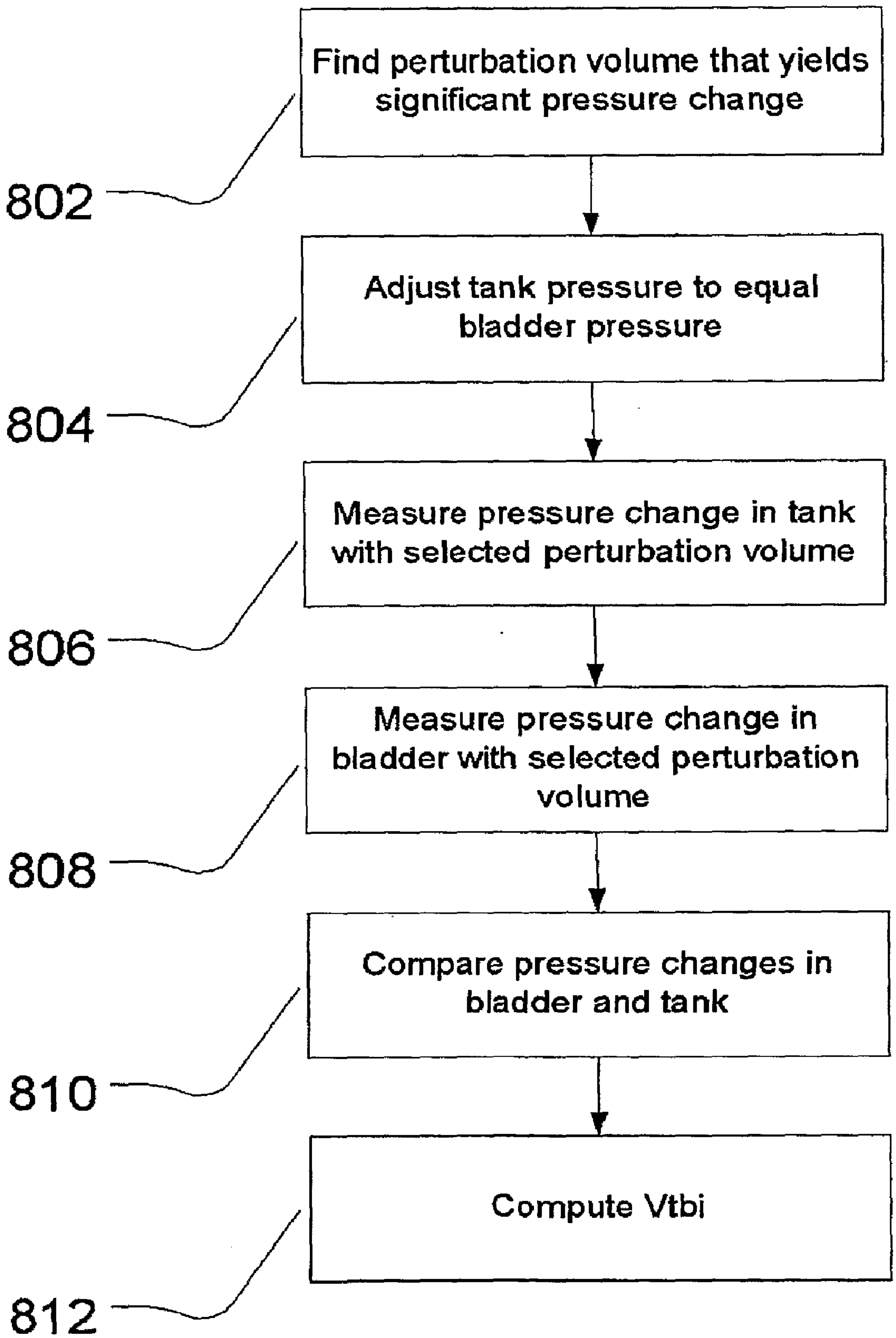

Find perturbation volume that yields significant pressure change
802
Adjust tank pressure to equal bladder pressure
804
Measure pressure change in tank with selected perturbation volume
806
Measure pressure change in bladder with selected perturbation volume
808
Compare pressure changes in bladder and tank
810
Compute Vtbi
812

FIG. 6

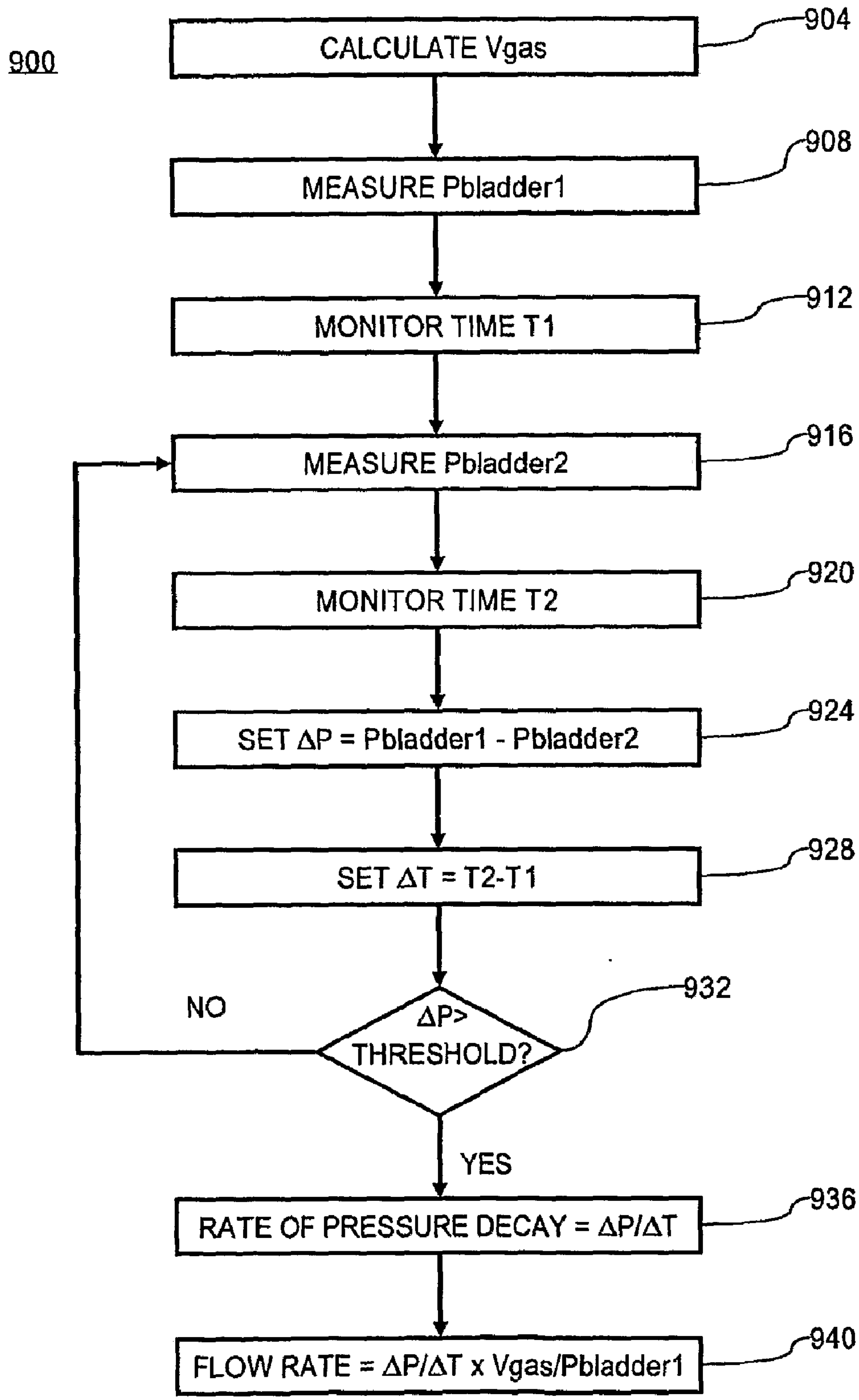

900
CALCULATE Vgas
904
MEASURE Pbladder1
908
MONITOR TIME T1
912
MEASURE Pbladder2
916
MONITOR TIME T2
920
SET ΔP = Pbladder1 - Pbladder2
924
SET ΔT = T2-T1
928
NO
ΔP> THRESHOLD?
932
YES
RATE OF PRESSURE DECAY = ΔP/ΔT
936
FLOW RATE = ΔP/ΔT x Vgas/Pbladder1
940

FIG. 7

VOLUME MEASUREMENT USING GAS LAWS

BACKGROUND

[0001] The present disclosure relates to fluid flow control devices and more particularly to feedback control infusion pumps.

[0002] The primary role of an intravenous (IV) infusion device has been traditionally viewed as a way of delivering IV fluids at a certain flow rate. In clinical practice, however, it is common to have fluid delivery goals other than flow rate. For example, it may be important to deliver a certain dose over an extended period of time, even if the starting volume and the actual delivery rate are not specified. This scenario of "dose delivery" is analogous to driving an automobile a certain distance in a fixed period of time by using an odometer and a clock, without regard to a speedometer reading. The ability to perform accurate "dose delivery" would be augmented by an ability to measure the volume of liquid remaining in the infusion.

[0003] Flow control devices of all sorts have an inherent error in their accuracy. Over time, the inaccuracy of the flow rate is compounded, so that the actual fluid volume delivered is further and further from the targeted volume. If the volume of the liquid to be infused can be measured, then this volume error can be used to adjust the delivery rate, bringing the flow control progressively back to zero error. The ability to measure fluid volume then provides an integrated error signal for a closed feedback control infusion system.

[0004] In clinical practice, the starting volume of an infusion is not known precisely. The original contained volume is not a precise amount and then various concentrations and mixtures of medications are added. The result is that the actual volume of an infusion may range, for example, from about 5% below to about 20% above the nominal infusion volume. The nurse or other user of an infusion control device is left to play a game of estimating the fluid volume, so that the device stops prior to completely emptying the container, otherwise generating an alarm for air in the infusion line or the detection of an occluded line. This process of estimating often involves multiple steps to program the "volume to be infused." This process of programming is time consuming and presents an unwanted opportunity for programming error. Therefore, it would be desirable if the fluid flow control system could measure fluid volume accurately and automatically.

[0005] If fluid volume can be measured then this information could be viewed as it changes over time, providing information related to fluid flow rates. After all, a flow rate is simply the measurement of volume change over time.

[0006] The formulation of the ideal gas law, PV=nRT, has been commonly used to measure gas volumes. One popular method of using the gas law theory is to measure the pressures in two chambers, one of known volume and the other of unknown volume, and then to combine the two volumes and measure the resultant pressure. This method has two drawbacks. First, the chamber of known volume is a fixed size, so that the change in pressure resultant from the combination of the two chambers may be too small or too large for the measurement system in place. In other words, the resolution of this method is limited. Second, the energy efficiency of this common measurement system is low, because the potential energy of pressurized gas in the chambers is lost to atmosphere during the testing. The present invention contemplates an improved volume measurement system and method and apparatus that overcome the aforementioned limitations and others.

SUMMARY

[0007] In one aspect, a method for determining the volume of fluid remaining in an infusion is provided.

[0008] In another aspect, a method for determining fluid flow rate over an extended period of time is provided.

[0009] In another aspect, a method for determining fluid flow rate over a relatively short period of time is provided.

[0010] One advantage of the present disclosure is that long term doses can be delivered on time, because the remaining fluid volume can measured, so that flow rate errors do not accumulate over time.

[0011] Another advantage of the present disclosure is that nurses or other users of the infusion system will not have to estimate, enter, and re-enter the volume to be infused. This will reduce the workload for the user and will eliminate opportunities for programming error.

[0012] Another advantage is found in that volume measurements made over time can be used to accurately compute fluid flow rate.

[0013] Another advantage is found in that volume measurements may be made using an inexpensive and simple pumping mechanism.

[0014] Another advantage is found in that volume measurements may be made without significant loss of energy.

[0015] Another advantage is found in that volume measurements may be made over a wide range of volumes.

[0016] Another advantage of the present disclosure is that its simplicity, along with feedback control, makes for a reliable architecture.

[0017] Other benefits and advantages of the present disclosure will become apparent to those skilled in the art upon a reading and understanding of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating preferred embodiments and are not to be construed as limiting the invention.

[0019] FIGS. **1** and **2** are perspective and side views of an infusion pump in accordance with an exemplary embodiment.

[0020] FIG. **3** is a functional block diagram showing the fluidic connections of a volume measurement system according to an exemplary embodiment.

[0021] FIG. **4** is a functional block diagram showing the control elements of a volume measurement system according to an exemplary embodiment.

[0022] FIG. **5** is a functional block diagram showing the sensing elements of the system.

[0023] FIG. **6** is a flow chart diagram outlining an exemplary method of volume measurement.

[0024] FIG. **7** is a flow chart outlining an exemplary method of calculating flow rate based on pressure decay.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0025] Referring to the drawings, wherein like numerals reference numerals are used to indicate like or analogous components throughout the several views, FIG. **1** depicts an exemplary volume and flow measurement system in accordance with an exemplary embodiment of the present invention. The system includes a pressure frame **10** that is of known total volume and contains within it an air bladder **20**, and a flexible bag **30** that contains within it a liquid to be infused **40**.

[0026] Referring now to FIG. **2**, the air bladder **20** is connected to an air pump **50** via a bladder connection line **608**, a bladder valve **106**, and a bladder valve line **606**. The air bladder **20** may be vented to atmosphere via a bladder vent valve **108**.

[0027] A calibration tank **60** of known volume is connected to the air pump **50** via a tank connection line **604**, a tank valve **102**, and a tank valve line **602**. The tank **60** may be vented to atmosphere via a tank vent valve **104**.

[0028] The liquid **40** is fluidically coupled to an output **500** via a liquid drain line **610**, going through a fluid flow resistor **400** and through an output line **612**. The liquid **40** may be, for example, a medication fluid, intravenous solution, or the like, and the output **500** may be, for example, a patient or subject in need thereof.

[0029] The tank **60** is connected to a tank pressure sensor **204** and an optional tank temperature sensor **304**. The bladder **20** is connected to a bladder pressure sensor **202** and an optional bladder temperature sensor **302**.

[0030] Referring now to FIG. **4**, an electronic module includes a processing unit **700** such as a microprocessor, microcontroller, controller, embedded controller, or the like, and is preferably a low cost, high performance processor designed for consumer applications such as MP3 players, cell phones, and so forth. More preferably, the processor **700** is a modern digital signal processor (DSP) chip that offers low cost and high performance. Such processors are advantageous in that they support the use of a 4th generation programming environment that may substantially reduce software development cost. It also provides an ideal environment for verification and validation of design. It will be recognized that the control logic of the present development may be implemented in hardware, software, firmware, or any combination thereof, and that any dedicated or programmable processing unit may be employed. Alternately the processing unit **700** may be a finite state machine, e.g., which may be realized by a programmable logic device (PLD), field programmable gate array (FPGA), field programmable object arrays (FPOAs), or the like. Well-known internal components for processor **700**, such as power supplies, analog-to-digital converters, clock circuitry, etc, are not shown in FIG. **3** for simplicity, and would be understood by persons skilled in the art. Advantageously, the processing module may employ a commercially available embedded controller, such as the BLACKFIN® family of microprocessors available from Analog Devices, Inc., of Norwood, Mass.

[0031] With continued reference to FIG. **4**, the processing unit **700** controls the air pump **50** via a pump control line **750**. The processor **700** controls the tank vent valve **104** via a tank vent valve control line **704**. The processor **700** controls the tank valve **102** via a tank valve control line **702**. The processor **700** controls the bladder vent valve **108** via a bladder vent valve control line **708**. The processor **700** controls the bladder valve **106** via a bladder valve control line **706**.

[0032] With reference now to FIG. **5**, the processor **700** can measure pressure and temperature from the bladder **20** and tank **60**. The processor **700** reads the pressure in the tank **60** via a tank pressure sensor **204**, which is coupled to the via tank pressure line **724**. The processor **700** reads the pressure in the bladder **20** via a bladder pressure sensor **202**, which is coupled to the processor **700** via a tank pressure line **722**. The processor **700** reads temperature of the gas in the tank **60** via a tank temperature sensor **304**, which is coupled to the processor **700** via a tank temperature line **714**. The processor **700** reads the temperature of the gas in the bladder **20** via a bladder temperature sensor **302**, which is coupled to the processor **700** via a bladder temperature line **712**.

Volume Measurement

[0033] Ultimately, the objective of volume measurement is to know the quantity of liquid **40** remaining in an infusion and how that quantity changes over time.

[0034] The pressure frame **10** defines a rigid container of known volume, V_{frame}. This volume is known by design and is easily verified by displacement methods. Within the pressure frame **10**, there is the air bladder **20**, which has a nominal capacity greater than the volume V_{frame}. When expanded, the bladder must conform to the geometry of the rigid container and its contents. The volume of liquid **40** to be infused, V_{tbi}, is equal to V_{frame}, less the fixed and known volume of the bladder **20** itself, V_{blad}, less any incompressible materials of the bag **30**, V_{bag}, and less the volume of gas in bladder **20**, V_{gas}. Once the value V_{gas} is computed, then it is trivial to compute V_{tbi}.

$$V_{tbi}=V_{frame}-V_{blad}-V_{bag}-V_{gas}$$

[0035] With the following method, at any given point in time, the volume of air contained in the bladder, V_{gas}, can be measured and V_{tbi} can be subsequently computed.

[0036] For purposes of economy and flexibility, the pump **50** may be an imprecise air pump, such as that of a rolling diaphragm variety, although other types of pumps are also contemplated. The output of such a pump may vary significantly with changes in back pressure, temperature, age of the device, power supply variation, etc. One advantage of the device and method disclosed herein is that they allow an imprecise pump to be used in a precision application, by calibrating the pump in situ.

[0037] FIG. **6** shows the steps leading to computation of V_{tbi}. Shown as step **802**, the first step is to find an optimum amount of air mass, N_{pump}, to add to the bladder to effect a significant pressure change, for example, on the order of about 10%. If the amount of air mass added to the bladder is too small, then the pressure change will not be measurable with accuracy. If the amount of the air mass is too great, then pressure in the bladder will increase more than necessary and energy will be wasted.

[0038] The initial pressure in the bladder **20**, $P_{bladder1}$, is measured using the bladder pressure sensor **202**. The tank valve **102** is set to a closed state via the tank control valve line **702** from the processor **700**. The bladder valve **106** is set to an open state via the tank control valve line **706** from the processor **700**. The pump **50** is activated by the processor **700** via the pump control line **750** for a period of time, S_{test}, nominally, for example, about 250 milliseconds. A new measurement of the pressure in the bladder **20** is made, $P_{bladder2}$. Based on the percent of pressure change from this pumping action, a new pump activation time, S_{pump}, will be computed. This calculation needs no precision; it is only intended to find an amount of pumping that provides a significant change in pressure, $P_{deltatarget}$, in bladder **20**, for example, on the order of about 10%.

$$S_{pump} = S_{test} * \frac{P_{deltatarget}}{(P_{bladder2} - P_{bladder1}) / P_{bladder1}}$$

[0039] In step **804**, the pump **50** or the tank vent valve **104** are activated to increase or decrease, respectively, the pressure, P, in the tank **60**, so that it approximately equals the pressure, $P_{bladder}$, in bladder **20**. The combination of valve and pump settings required for such adjustments are shown in the table below:

	Pump 10	Bladder Valve 106	Bladder Vent Valve 108	Tank Valve 102	Tank Vent Valve 104
Increase $P_{bladder}$	ON	OPEN	CLOSED	CLOSED	CLOSED
Decrease $P_{bladder}$	OFF	CLOSED	OPEN	CLOSED	CLOSED
Increase P_{tank}	ON	CLOSED	CLOSED	OPEN	CLOSED
Decrease P_{tank}	OFF	CLOSED	CLOSED	CLOSED	OPEN

[0040] Adjustments made in step **804** can be made iteratively until P_{tank} is roughly equal to $P_{bladder}$, for example, within about 5% of the relative pressure measured in $P_{bladder}$. This does not need to be a precise process. Following the adjustment, the pressure in tank **60**, P_{tank2}, is recorded.

[0041] In step **806**, the system is configured to increase the pressure in tank **60**, as shown in the above table. The pump **50** is activated for a time period equal to S_{pump} After a delay of approximately five seconds, the pressure in the tank **60** is measured, P_{tank3}. This delay is to reduce the effect of an adiabatic response from the increase in pressure in the tank **60**.

[0042] In step **808**, the system is configured to increase the pressure in bladder **20**, as shown in the above table. The pump **50** is activated for a period equal to S_{pump}. After a delay of approximately five seconds, the pressure in the bladder **20** is measured, $P_{bladder3}$. This delay is to reduce the effect of an adiabatic response from the increase in pressure in the bladder **20**.

[0043] Because the initial pressures in the bladder **20** and the tank **60** were approximately equal, the quantity of air mass injected into tank **60** in step **806** and into bladder **20** in step **808** will be roughly equal, even though the pump **50** need not be a precise metering device.

[0044] We take advantage of several simplifications. First, the ambient temperature for sequential steps **806** and **808** is unchanged. Second, the atmospheric pressure during sequential steps **806** and **808** is unchanged. These conditions simplify the ideal gas law formula and allow the use of gauge pressure measurements, rather than absolute pressure.

[0045] In step **810**, the volume of gas in the bladder **20**, V_{gas}, can be calculated with a reduced form of PV=nRT:

$$V_{gas} = \frac{V_{tank} * (P_{tank3} - P_{tank2})}{(P_{bladder3} - P_{bladder2})}$$

[0046] As examples of this calculation, if the pressure change were the same in the bladder **20** and the tank **60**, then V_{gas} would be equal to V_{tank}. If the pressure change in the bladder **20** were 20% as large as that in the tank **60**, then V_{gas} would be 5 times greater than V_{tank}.

[0047] Step **812** derives the value for V_{tbi} from V_{gas}, using known values for V_{frame} Vblad, and V_{bag} and using the calculated value of V_{gas}, from step **810**.

$$V_{tbi} = V_{frame} - V_{blad} - V_{bag} - V_{gas}$$

[0048] The valves **102**, **106**, **104**, and **108** can be configured in many ways, including multiple function valves and or manifolds that toggle between distinct states. The depiction herein is made for functional simplicity and ease of exposition, not necessarily economy or energy efficiency.

Flow Rate Calculation

[0049] Once the fluid volume has been computed, multiple measurements made over time will yield knowledge of fluid flow rate, which is, by definition, fluid volume changing over time. Repeated measurements of volume over time provided more and more resolution of average flow rate. The average flow rate and the volume of liquid **40** remaining to be infused can be used to estimate the time at which the fluid volume will be delivered. If the infusion is to be completed within some specified period of time, any error between the specified time and the estimated time can be calculated and the flow rate can be adjusted accordingly.

[0050] There are situations where the short-term flow rate is of interest. Rather than make repeated volume measurements over a short period of time, there is an alternative approach. Once the gas volume in bladder **20** is known, then the observation of pressure decay in the bladder can be converted directly to a flow rate. It is important to know that the measurement of pressure decay, by itself, is not adequate to compute flow rate. For example, if the pressure were decaying at a rate of 10% per hour, this information cannot be converted into flow rate, unless the starting gas volume is known. As an example, if V_{gas} has been measured to be 500 ml and the absolute pressure is decaying at a rate of 5% per hour, then the flow rate is 5% of 500 ml per hour or 25 ml per hour. The knowledge of the initial volume is critical to compute fluid flow rate.

[0051] The measurement of pressure decay is a simple procedure of observing the time the absolute pressure of $P_{bladder}$ to drop by a small, but significant, amount, preferably for example about 2%. Because the processor **700** is capable of measuring times from microseconds to years, this measurement carries a very wide dynamic range. By observing a 2% drop, the change in pressure is well above the noise floor of the pressure measurement system.

[0052] A flow chart outlining an exemplary process **900** for calculating flow rate by monitoring the rate of pressure decay in the bladder **20** is shown in FIG. **7**. At step **904**, the volume of gas in the bladder **20** is calculated as detailed above. At step **908**, the pressure in the bladder **20**, $P_{bladder1}$ is measured using the sensor **202** at time T**1**, which is recorded in step **912**. The pressure in the bladder **20** is measured again at step **916** and the time T**2** is recorded at step **920**. The change in pressure, ΔP, between the time T**1** and the time T**2** is calculated in step **924** as $P_{bladder1} - P_{bladder2}$ and the change in time, ΔT is calculated as T**2**-T**1** at step **928**. At step **932**, it is determined whether ΔP is greater than some predetermined or prespecified threshold value, e.g., about 2% with respect to $P_{bladder1}$ If ΔP has not reached the threshold value at step **932**, the process returns to step **916** and continues as described above. If ΔP has reached the threshold value at step **932**, the rate of pressure decay is calculated as $\Delta P/\Delta T$ at step **936**. The flow rate is then calculated as $\Delta P/\Delta T \times V_{gas} - P_{bladder1}$ at step **940**.

[0053] The invention has been described with reference to the preferred embodiments. Modifications and alterations will occur to others upon a reading and understanding of the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A method of measuring a volume of liquid in a flexible container, comprising:

placing the flexible container within a first rigid container of known volume, the first rigid container containing an inflatable bladder;

pressurizing the inflatable bladder with a gas;

pressurizing a second rigid container of known volume with a gas, the pressure of the gas in the bladder being approximately equal to the pressure of the gas in the second rigid container;

delivering a first molar quantity of gas to the bladder to cause a measurable increase in pressure in the bladder;

delivering a second molar quantity of gas to the second rigid container to cause a measurable increase in pressure in the second rigid container, the first molar quantity of gas being approximately equal to the second molar quantity of gas;

measuring the increase in pressure in the bladder;

measuring the increase in pressure in the second rigid container;

calculating the volume of gas in the bladder using the known volume of the second rigid container, the measured increase in pressure in the bladder, and the measured increase in pressure in the second rigid container; and

calculating the volume of liquid in the flexible container by subtracting the calculated volume of gas in the bladder from the known volume of the first rigid container.

2. The method of claim **1**, further comprising:

subtracting the known volume of incompressible materials within the first rigid container from the known volume of the first rigid container.

3. The method of either one of claims **1** and **2**, wherein said gas is air.

4. The method of any one of claims **1**-**3**, wherein said gas is delivered to said first and second rigid containers with a pump.

5. The method of claim **5**, wherein said pump is not a precise metering device.

6. The method of any one of claims **1**-**5**, further comprising:

prior to delivering said first and second molar quantities of gas, adjusting the pressure in one or both of said bladder and said second rigid container.

7. The method of any one of claims **1**-**6**, further comprising:

monitoring the pressure in said bladder; and

calculating a flow rate of liquid exiting the flexible container.

8. A method for calculating a flow rate of liquid exiting a flexible container contained within a rigid container of known volume, the rigid container containing an inflatable bladder, the inflatable bladder pressurized with a gas to urge the liquid out of the flexible container, said method comprising:

calculating the volume of gas in the inflatable bladder;

determining the initial pressure in the inflatable bladder;

monitoring the pressure decay in the inflatable bladder over time until the change in pressure reaches some preselected threshold value;

calculating the rate of pressure decay; and

calculating the flow rate using the rate of pressure decay, the calculated volume of gas in the inflatable bladder, and the initial pressure in the inflatable bladder.

9. A fluid delivery system, comprising:

a pressure frame (**10**) of known total volume;

an inflatable bladder (**20**) within said pressure frame;

said pressure frame adapted to receive a flexible bag (**30**) containing a liquid to be infused (**40**);

a calibration tank (**60**) of known volume;

a pump (**50**) fluidically coupled to said bladder and said calibration tank for selectively delivering a gas to said bladder and said calibration tank;

a first pressure sensor (**202**) coupled to said bladder for sensing the pressure of a gas in said bladder;

a second pressure sensor (**204**) coupled to said calibration tank for sensing the pressure of a gas in said calibration tank;

a processing unit (**700**) coupled to said first and second pressure sensors and said first and second temperature sensors for storing pressure and temperature information from said first and second pressure sensors and said first and second temperature sensors;

said processing unit coupled to said pump for controlling operation of said pump; and

said processing unit further including means for calculating one or both of:

a volume of liquid in the flexible container; and

a flow rate of fluid exiting the flexible container.

10. The fluid delivery system of claim **9**, further comprising:

a first vent valve (**108**) fluidically coupled to said bladder for selectively venting gas within said bladder; and

a second vent valve (**104**) fluidically coupled to said calibration tank for selectively venting within said calibration tank.

11. The fluid delivery system of either one of claims **9** and **10**, further comprising:

a first inlet valve (**106**) fluidically coupled to said bladder and said pump; and

a second inlet valve (**102**) fluidically coupled to said calibration tank and said pump.

12. The fluid delivery system of any one of claims **9**-**11**, further comprising:

a first temperature sensor (**302**) coupled to said bladder for sensing the temperature of the gas in said bladder; and

a second temperature sensor (**304**) coupled to said calibration tank for sensing the temperature of a gas in said calibration tank.

13. The fluid delivery system of any one of claims **9**-**12**, wherein the gas is air.

14. The fluid delivery system of any one of claims **9**-**13**, wherein said pump is not a precise metering device.

* * * * *