



US 20090191067A1

(19) **United States**  
(12) **Patent Application Publication**  
**DiPerna**

(10) **Pub. No.: US 2009/0191067 A1**  
(43) **Pub. Date: Jul. 30, 2009**

(54) **TWO CHAMBER PUMPS AND RELATED METHODS**

**Publication Classification**

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(51) **Int. Cl.**  
**F04F 1/00** (2006.01)

(52) **U.S. Cl.** ..... **417/54; 417/65**

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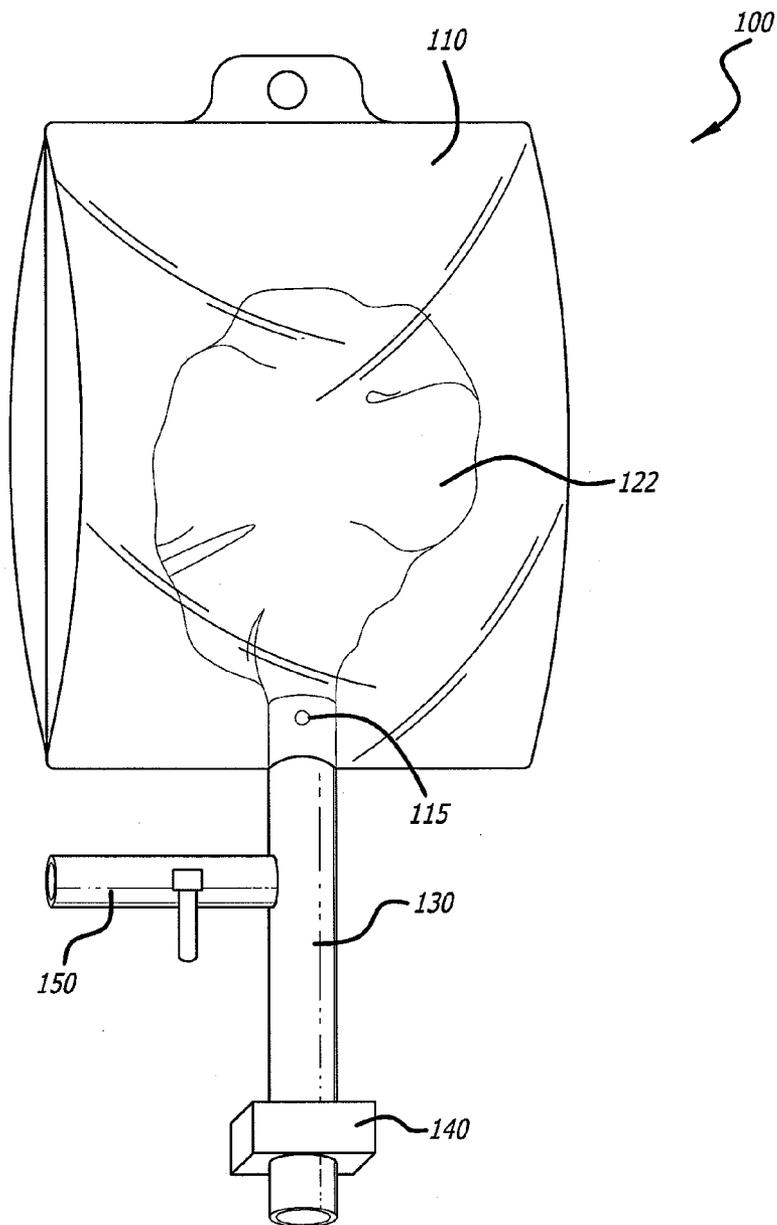
(57) **ABSTRACT**

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Two chamber pumps and related methods provide a platform for measuring flow rate in about real time without contacting the material being pumped. Pressure and optional temperature sensors disposed in a pressurized chamber allow for fluid delivery calculations after being calibrated or by knowing the initial volume of the fluid to be delivered.

(21) Appl. No.: **12/020,498**

(22) Filed: **Jan. 25, 2008**



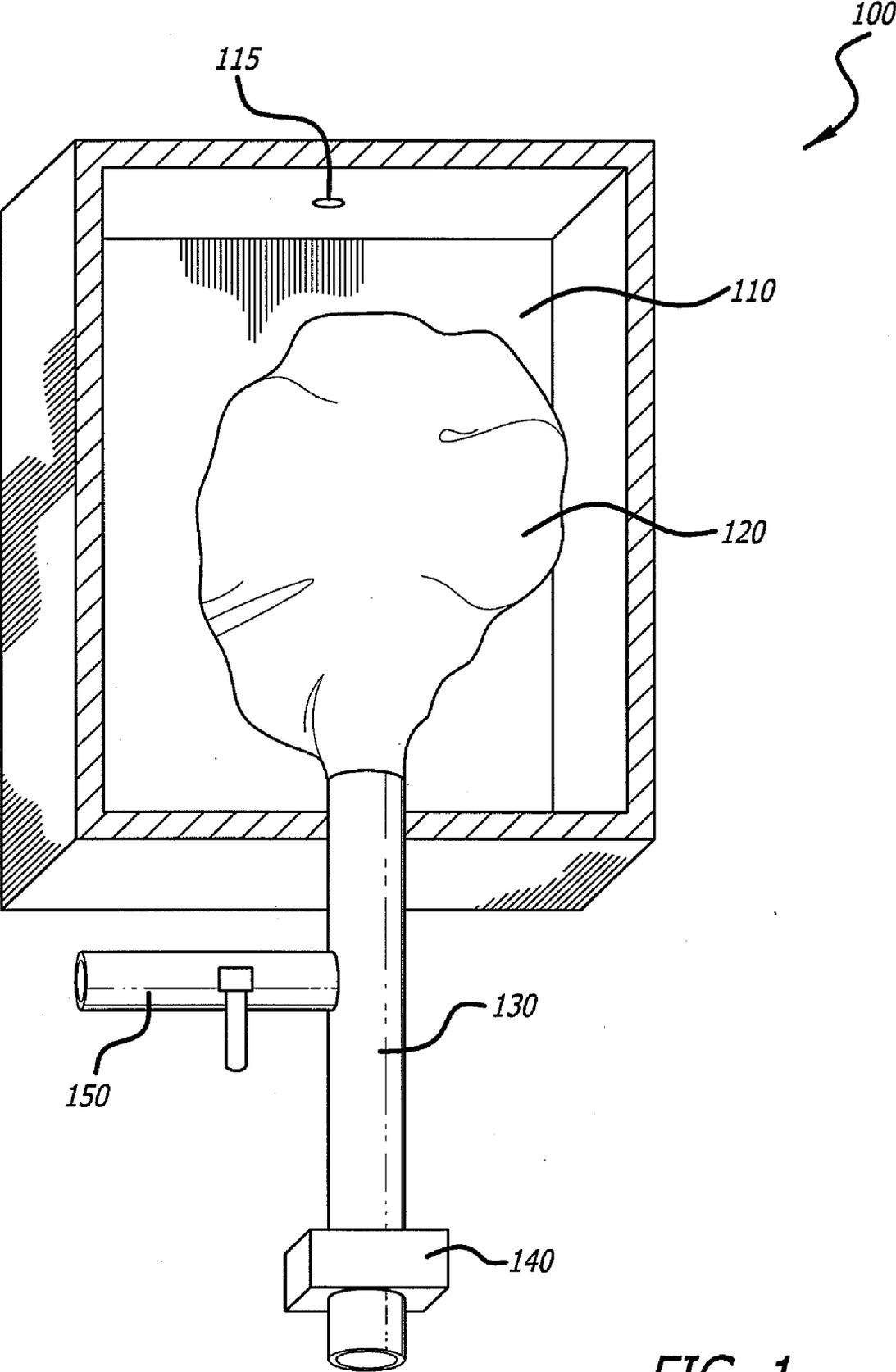


FIG. 1

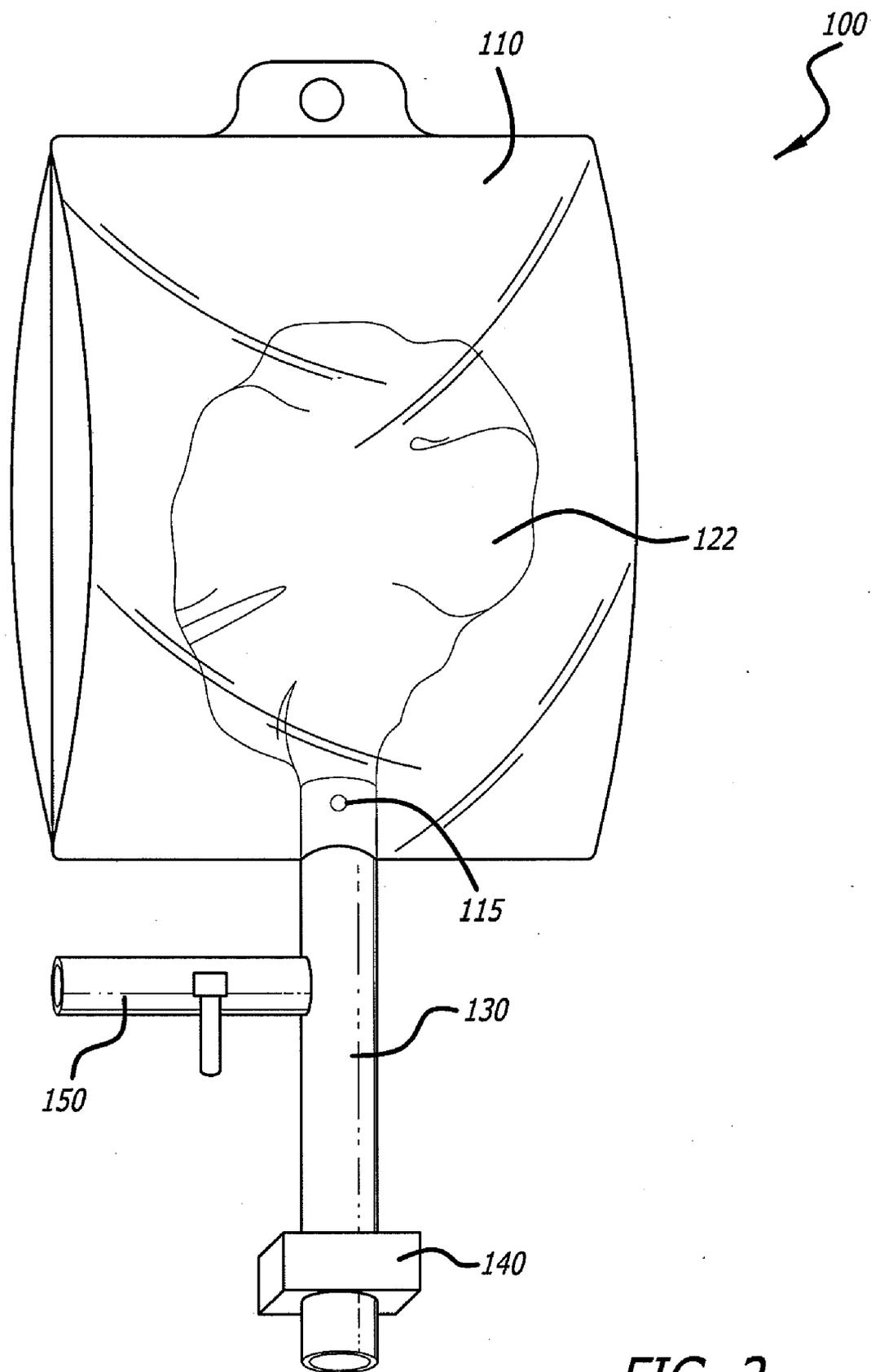


FIG. 2

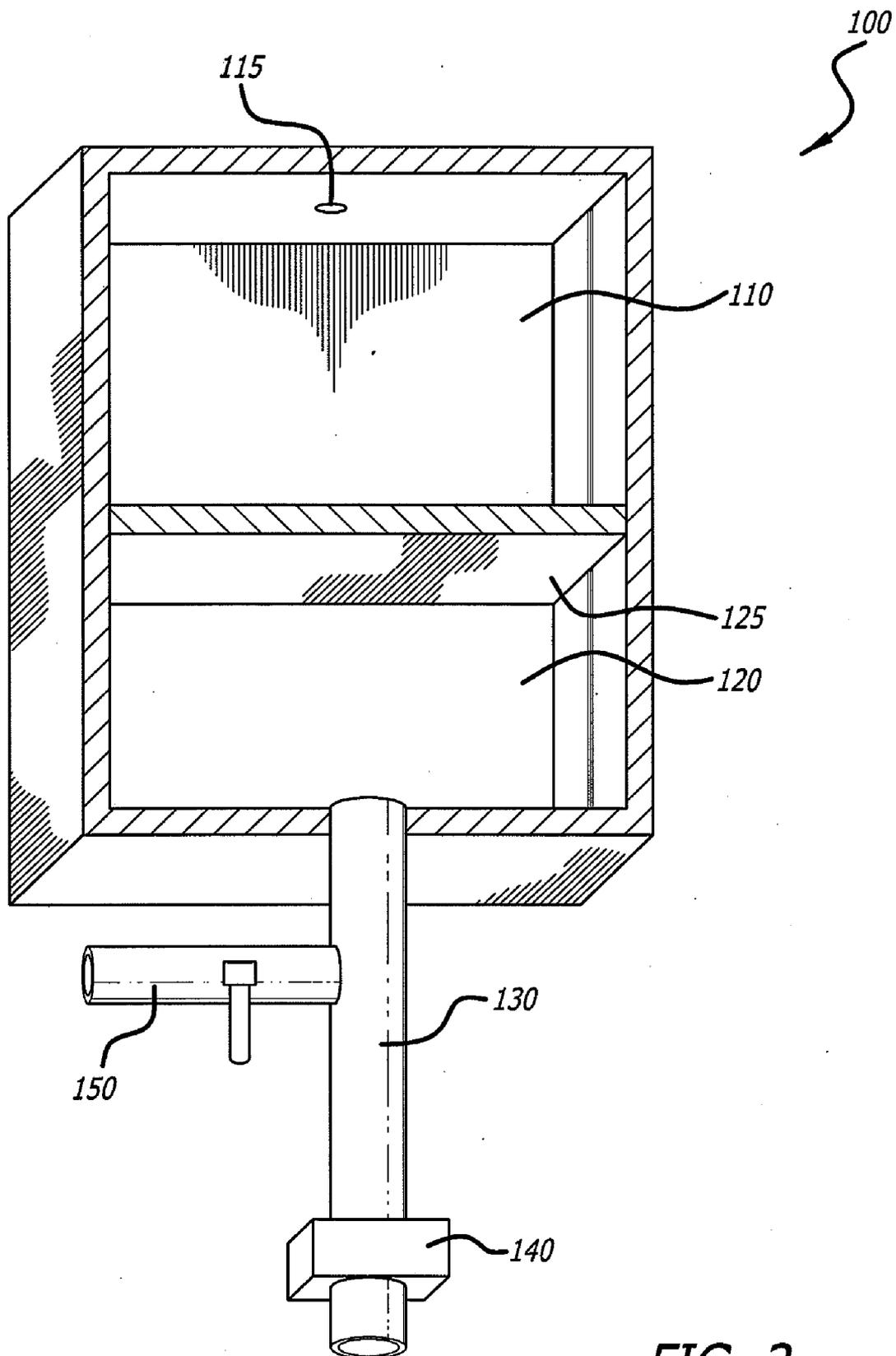


FIG. 3

**TWO CHAMBER PUMPS AND RELATED METHODS**

**BACKGROUND**

[0001] The present disclosure relates to the field of pumps, especially those used to accurately dispense medication.

**SUMMARY**

[0002] Two chamber pumps and related methods provide a platform for measuring flow rate in about real time without contacting the material being pumped. Pressure and optional temperature sensors disposed in a pressurized chamber allow for fluid delivery calculations after being calibrated or by knowing the initial volume of the fluid to be delivered.

[0003] According to a feature of the present disclosure, a device is disclosed comprising a pressurizable first chamber, a second chamber for holding a fluid, a flow lumen disposed exterior to the first chamber and in fluid communication with the second chamber, at least one pressure sensor disposed in the first chamber, and a flow controller disposed along the flow lumen. A pressurized substance in the first chamber is able to cause a: change of volume of the second chamber.

[0004] According to a feature of the present disclosure, a device is disclosed comprising a pressurizable first chamber, a second chamber for holding a fluid, a flow lumen disposed at least partially exterior to the first chamber and in fluid communication with the second chamber, at least one pressure sensor disposed in the first chamber, a flow controller disposed along the flow lumen, and a microprocessor to compute at least flow rate of fluid transferred through the flow lumen from the second chamber. A pressurized substance in the first chamber is able to cause a change of volume of the second chamber by causing fluid to flow from the second chamber through the flow lumen and the microprocessor controls the flow controller.

[0005] According to a feature of the present disclosure, a method is disclosed comprising providing a pump having: (a) a pressurizable first chamber, (b) a second chamber for holding a fluid, (c) at least one pressure sensor disposed in the first chamber, (d) a flow lumen in fluid communication with the second chamber, and (e) a flow controller. A pressurized substance in the first chamber is able to cause a change of volume of the second chamber.

**DRAWINGS**

[0006] The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

[0007] FIG. 1 is a cross sectional view of an embodiment of the pumps of the present disclosure having rigid outer casings;

[0008] FIG. 2 is a cross sectional view of an embodiment of the pumps of the present disclosure, where the outer casing of the pump is a collapsible bag; and

[0009] FIG. 3 is a cross sectional view of an embodiment of the pumps of the present disclosure.

**DETAILED DESCRIPTION**

[0010] In the following detailed description of embodiments of the invention, reference is made to the accompanying drawings in which like references indicate similar ele-

ments, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that, other embodiments may be utilized and that logical, mechanical, biological, electrical, functional, and other changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims. As used in the present disclosure, the term "or" shall be understood to be defined as a logical disjunction and shall not indicate an exclusive disjunction unless expressly indicated as such or notated as "xor."

[0011] According to the present disclosure, the term "real time" shall be defined as the instantaneous state or lagging the instantaneous state by the time taken to compute a measurement describing the instantaneous state, provided the measurement computed reasonably approximates the instantaneous state at the beginning of the measurement process and the instantaneous state at the end of the measurement process.

[0012] The present disclosure discloses a pump that is able to measure flow rates or adjust flow rates in about real time. The pumps of the present disclosure comprise two chambers with at least a pressure sensor disposed therein to measure pressures in a pressured chamber that drives flow of a fluid from a liquid chamber. Flow controllers are disposed as part of the pump to either prevent flow or regulate and ensure consistent flow rate. The operation of the pumps of the present disclosure maintain sterile conditions for the fluid flow from the pumps, while allowing for precise measurements for flow volumes without compromising sterility.

[0013] According to embodiments and as illustrated in FIG. 1, pump 100 comprises first chamber 110 and second chamber 120. First chamber is a chamber that is pressurized such that the pressure in first chamber exceeds the pressure of second chamber. Consequently, when pump 100 is in an open state, flow of fluid contained in second chamber 120 is effected.

[0014] Flow of fluid from second chamber is through flow lumen 130. Flow lumen may be surgical or medical tubing, pipes, and other similar devices designed for the flow of fluids from a source to a destination without appreciable loss of fluid.

[0015] According to embodiments, flow controller 140 may be disposed along flow lumen 130 to control flow. Control of flow, according to embodiments, may be an on/off type device, such as a clamp, whereby when flow controller is open flow is effected and when flow controller 140 is closed, flow is prevented. Flow controller 140 may also comprise, according to embodiments, a flow restrictor to ensure constant or predictable flow. According to embodiments, flow controller 140 may comprise a plurality of flow restrictors, clamps, etc.

[0016] Fill device 150 is disposed along flow lumen 130 and facilitates the filling of second chamber 120 with fluid. Fill device 150 may comprise a one-way valve, according to embodiments, whereby fluid is flowed through valve and into second chamber 120. Fill device 150 is a luer actuated port, according to embodiments. According to optional embodiments, fill valve comprises a device for putting a prefilled second chamber 120, such as a typical intravenous bag, into first chamber 110 after which first chamber 110 is pressurized.

[0017] According to embodiments, and as shown in FIG. 1, first chamber 110 is a chamber that is able to be pressurized. According to embodiments, first chamber 110 may be made from any suitable rigid material, for example polycarbonate, ABS, or polyethylene. According to different embodiments, first chamber 110 may be made from flexible materials, for example PVC, polyethylene, silicon, polyurethane, or various rubbers. According to embodiments, first chamber 110 is sealed to prevent leakage of gas contained therein. According to embodiments, first chamber 110 may have a valve for repressurization or adjustment of pressure, as desired. According to embodiment and as illustrated in FIG. 2, first chamber 110 comprises a bag-like or collapsible device.

[0018] Pressure sensor 115 is disposed in first chamber 100 to measure pressure at predetermined intervals, as well as initial pressure readings to be used to determine flow rate. Optionally, a temperature sensor may also be disposed in first chamber 100 to improve accuracy of flow measurement. Multiple pressure and temperature sensors may be used to more accurately determine pressure and temperature in first chamber 110.

[0019] Second chamber 120, according to embodiments, comprises a collapsible chamber that holds a fluid without appreciable leakage. When flow controller is in a state whereby flow is effected, flow from second chamber is effected by the pressure differential between first chamber 110 and second chamber 120. Second chamber may be made from PVC, polyisoprene, silicon, polyurethane, or other flexible materials.

[0020] According to embodiments and as shown in FIG. 3, second chamber 120 may be defined by a collapsible or movable diaphragm 225. Rather than collapsing second chamber 120, the movable or collapsible diaphragm 125 is moved whereby flow is effected.

[0021] To dispense fluid from pump 100, a calibration step is necessary. The calibration step determines the initial volume of second chamber 120 ( $V_{2i}$ ), which is necessary to determine flow rate, as described below using the ideal gas law. According to embodiments, the most simple method for the determination of  $V_{2i}$  is to know the volume of fluid put into second chamber 120. This is accomplished by injecting a known amount of fluid into second chamber 120 via fill device 150 or using a disposable second chamber 120 (i.e., an IV bag) holding a known volume.

[0022] According to embodiments, calibration may also be accomplished by calculating, using the ideal gas law, the volume of second chamber 120 from a known starting volume in an empty state. If second chamber 120 occupies a known empty volume, for example using the pump of FIG. 3, wherein the diaphragm rests at a set position when second chamber 120 is empty, for example 0 ml or 10 ml, then prior to filling of second chamber 120 with a fluid, the pressure and temperature of first chamber are measured. The initial volume of second chamber 120 is then calculated after fluid is put into second chamber 120 using an equation to measure flow rate, which is derived in detail below:

$$V_{2empty} = \frac{P_{1i}T_{1f}(c - V_{2filled})}{P_{1f}T_{1i}} \quad (1)$$

For the purposes of the present application, second chamber 120 has three discrete states: empty, filled, and flowing. The empty state defines second chamber when the volume is 0 or

a known empty volume. The filled state defines the second chamber when it is filled with fluid. The flowing state defines a plurality of volumes where

$$V_{2filled} > V_{2flowing} > V_{2empty} \quad (2)$$

Typically,  $V_{2flowing}$  is representative of the state wherein fluid is being delivered from pump 100 to a patient, for example. However,  $V_{2flowing}$  may also be used for calculations during the filling of second chamber 120 with fluid.

[0023] According to embodiments, flow is effected because the pressure of first chamber 110 exceeds the fluid pressure in second chamber 120. Accordingly, flow rate may be calculated with high precision and in about real time. Prior to determination of flow rate, the filled state of pump 100 must be measured.

[0024] Calculation of flow rate is based on the ideal gas law, that is:

$$PV = nRT \quad (3)$$

[0025] Because the total volume of pump 100 is known, that is the volume of first chamber 110 ( $V_1$ ) plus the volume of second chamber 120 ( $V_2$ ) is a constant, as shown:

$$V_1 + V_2 = c \quad (4)$$

Thus, as fluid flows from  $V_2$  to a delivery target, such as a patient, the volume of  $V_1$  increases proportionally. Consequently, if  $V_1$  is determined in a filled state and  $V_1$  is determined in a flowing state at a time interval after fluid begins to flow from second chamber 120, the change in volume of  $V_1$  over the time interval  $t$  is the flow rate over that time interval.

$$flowrate = \frac{\Delta V_2}{\Delta t} = \left| \frac{\Delta V_1}{\Delta t} \right| \quad (5)$$

where  $\Delta t$  is the time interval over which  $\Delta V_1$  and  $\Delta V_2$  are measured.

[0026] However, the volume of second chamber ( $V_2$ ) is not measured directly. Rather, changes in  $V_2$  are measured indirectly from the changing volume of  $V_1$ . Measurements of the volume of  $V_1$  are accomplished with pressure sensor and optional temperature sensor.

[0027] Turning again to the ideal gas law, because first chamber 110 is sealed, the number of molecules ( $n$ ) of gas in first chamber 110 remains constant. Additionally,  $R$  is constant. Therefore,

$$nR = k \quad (6)$$

where  $k$  is a constant. Thus,

$$PV = kT \quad (7)$$

$$\frac{PV}{T} = k \quad (8)$$

[0028] Because first chamber 110 is sealed,  $k$  remains constant throughout the flow of fluid from second chamber 120. Additionally, pressure sensor and optional temperature sensor disposed in first chamber 110 allows for measurement of  $P_{1filled}$ ,  $P_{1flowing}$ ,  $T_{1filled}$ , and  $T_{1flowing}$ . Finally, the filled volume ( $V_{2filled}$ ) of second chamber 120 is known, which allows calculation of  $V_{1filled}$  and therefore calculation of  $V_{1flowing}$ . The following equation for first chamber 110 results:

$$\frac{P_{1, \text{filled}} V_{1, \text{filled}}}{T_{1, \text{filled}}} = \frac{P_{1, \text{flowing}} V_{1, \text{flowing}}}{T_{1, \text{flowing}}} \tag{9a}$$

**[0029]** Artisans will understand the filled state comprises the end state at each discrete time interval in which flow rate is measured. Indeed, according to embodiments, the filled state of the prior time interval may comprise the filled of the succeeding time interval, and so forth as shown as the alternative to equation (9a).

$$\frac{P_{1, \text{flowing}_{\tau=x}} V_{1, \text{flowing}_{\tau=x}}}{T_{1, \text{flowing}_{\tau=x}}} = \frac{P_{1, \text{flowing}_{\tau=x+y}} V_{1, \text{flowing}_{\tau=x+y}}}{T_{1, \text{flowing}_{\tau=x+y}}} \tag{9b}$$

where  $\tau$  is a time interval, when  $x=0$ , the flowing state is equal to the filled state, and  $y \geq 1$  time interval. Artisans will readily appreciate that  $\tau$  or  $\Delta t$  may represent the aggregate time from the start of flow of fluid from second chamber 120 to the time being measured or may be indicative of any arbitrary time interval after the start of flow of fluid from second chamber 120 to the time being measured.

**[0030]** To more clearly illustrate the principle of determining  $\Delta V_1$ , temperature will be assumed to be constant for the purposes of the next set of equations. Thus,

$$P_{1, \text{filled}} V_{1, \text{filled}} = P_{1, \text{flowing}} V_{1, \text{flowing}} \tag{10}$$

Therefore, solving for  $V_{1, \text{flowing}}$  of first chamber 110 yields

$$V_{1, \text{flowing}} = \frac{P_{1, \text{filled}} V_{1, \text{filled}}}{P_{1, \text{flowing}}} \tag{11}$$

However,  $V_{1, \text{filled}}$  is unknown and must be calculated from the total volume of pump  $c$  and from knowing the filled volume ( $V_{2, \text{filled}}$ ) of fluid put into second chamber 120:

$$V_{1, \text{filled}} = c - V_{2, \text{filled}} \tag{12}$$

Thus, the total amount of volume flowed may be calculated using the equation, based on the proportionality of flow between first chamber 110 and second chamber 120:

$$\text{flowrate} = \frac{V_{2, \text{flowing}} - V_{2, \text{filled}}}{\Delta t} = \left| \frac{V_{1, \text{flowing}} - V_{1, \text{filled}}}{\Delta t} \right| \tag{13}$$

Thus, to determine  $V_{1, \text{flowing}}$ , we can use the relationship expressed in equation (ii). As  $V_{1, \text{filled}}$  is unknown, substituting known values of  $c$  and  $V_{2, \text{filled}}$ , the following equation results:

$$V_{1, \text{flowing}} = \frac{P_{1, \text{filled}}(c - V_{2, \text{filled}})}{P_{1, \text{flowing}}} \tag{14}$$

Using equation (13) and based on the fact that  $V_{2, \text{flowing}} = -(V_{1, \text{flowing}})$ , flow rate may be calculated as

$$\text{flowrate} = \left| \frac{\frac{P_{1, \text{filled}}(c - V_{2, \text{filled}})}{P_{1, \text{flowing}}} - V_{1, \text{filled}}}{\Delta t} \right| \tag{15}$$

**[0031]** Adding temperature back to the equation allows for a more precise measurement of flow rate and is easily accomplished:

$$\text{flowrate} = \left| \frac{\frac{P_{1, \text{filled}}(c - V_{2, \text{filled}})}{P_{1, \text{flowing}}} - V_{1, \text{filled}}}{\Delta t} \left( \frac{T_{1, \text{flowing}}}{T_{1, \text{filled}}} \right) \right| \tag{16}$$

**[0032]** According to embodiments, measurements of flow rate are taken at discrete time intervals. These time intervals may range from many measurements per second to measurements taken over the course of minutes, hours, or days, depending on the specific application. Accordingly, measuring flow rate provides about real-time feedback, which may be used to adjust flow rate. By coupling the measurement of flow rate to flow controllers, flow may be closely regulated. For example, if flow controller 140 comprises a clamp, then feedback system may open the clamp when additional flow of fluid is needed and close the clamp when too much flow has occurred. Thus, the combination of a flow controller and the about real-time flow measurement provides a platform to deliver measurably accurate volumes of a fluid.

**[0033]** According to embodiments, first chamber 110 may be made from expandable materials. In such embodiments, first chamber 110 may be a disposable bag or similar flexible-type container such as an IV-type bag, that tend to expand or contract depending on the pressure within the first chamber. Thus, the above equations must account for the effects expansion or contraction due to change of pressure within first chamber 110. In other words, as pressure increases, the volume within first chamber 110 will change in a predictable way and visa versa. For example, by including in the calculations a factor incorporating the modulus of elasticity of the material from which first chamber 110 is made into the  $V_1$ , the change in the volume of first chamber 110 is reasonably predictable.

**[0034]** Accuracy of the determination of the change in  $V_1$  attributable to the elasticity of the material from which first chamber is made is improved by calibrating the system at a known initial pressure of first chamber 110 and volume of second chamber 120. Thus, first chamber 110 is designed and made to have a known volume in this initial state. As pressure increases, the calculated additional volume due to expansion of first chamber 110 may be added to the initial volume to derive an accurate value of  $V_1$ .

**[0035]** Referring again to the calibration step, as the pressure of second chamber 120 increases as it is charged with the fluid, the volume of first chamber 110 is decreased and the pressure within first chamber 110 increases. At the same time, because first chamber 110 is made from non-rigid materials there will be predictable expansion of the dimensions of first chamber 110, with increased resulting volume. Thus, to determine the actual volume of first chamber 110 after the initial state, the pressure of first chamber is measured and volume is calculated as described previously, taking into account the

incremental volume increase or decrease of first chamber 110 observed due to elasticity of material from which first chamber 110 is made.

[0036] According to alternative-type embodiments, a method for accounting for the change in  $V_1$  due to expansion or contraction of first chamber 110 is to lookup the approximate change in volume of first chamber 110 as pressure within first chamber 110 increases or decreases in a lookup table. The lookup table, according to embodiments, is based upon averaged value for a plurality of the same first chamber 110 having the same dimensional parameters and will provide a reasonably approximate factor to add or subtract to  $V_1$  at a plurality of given measured pressures.

[0037] These principles are illustrated in the following equations. Let  $V_1^E$  be the supplemental volume of first chamber as first chamber 110 expands or contracts. In systems where first chamber 110 is made from rigid materials, the volume of first chamber 110 plus the volume of second chamber 120 is constant, as expressed in equation (4).

$$V_1 + V_2 = c \tag{4}$$

In system where first chamber 110 is made from expandable materials, however, a factor must be added to  $c$  denoting the added or lost volume occurring due to expansion or contraction of the first chamber 110.

$$V_1 + V_2 = c + V_1^E \tag{17}$$

Thus, the volume of  $V_1$  may be calculated as:

$$V_1 = c + V_1^E - V_2 \tag{18}$$

[0038] Thus, in systems where first chamber 110 is made from expandable materials, equation (16) is modified to account for the expanded first chamber 110:

$$flowrate = \left[ \frac{P_{1,filled}(c + V_1^E - V_{2,filled}) - V_{1,filled}}{P_{1,flowing} \Delta t} \left( \frac{T_{1,flowing}}{T_{1,filled}} \right) \right] \tag{19}$$

[0039] Artisans will readily recognize that  $V_1^E$  may be calculated if the modulus of elasticity is known or may be simply recorded as a set of values within a table for quick lookup, especially in situations where a microprocessor is not designed to perform series of complex calculations or where power consumption is an issue.

[0040] While the apparatus and method have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

1. A device comprising:
  - a pressurizable first chamber;
  - a second chamber for holding a fluid;
  - at least one flow lumen in fluid communication with the second chamber;
  - at least one pressure sensor disposed in the first chamber;
  - and
  - a flow controller disposed along the flow lumen;

a microprocessor for computing flow rate from data provided by the pressure sensor;

wherein a pressurized substance in the first chamber effects a change of volume of the second chamber; and wherein the microprocessor controls the flow controller.

2. The device of claim 1, further comprising a fill port for filling the second chamber with the fluid.

3. The device of claim 1, further comprising at least one temperature sensor disposed in the first chamber.

4. The device of claim 1, wherein the flow controller is a clamp.

5. The device of claim 1, wherein the flow controller is a flow restrictor.

6. The device of claim 1, wherein the first chamber is pressurized prior to filling the second chamber with the fluid.

7. The device of claim 1, wherein the first chamber is made from an expandable material.

8. The device of claim 7, wherein the expansion of the expandable material is a function of the pressure of the first chamber.

9. A device comprising:

- a pressurizable first chamber;
- a second chamber for holding a fluid;
- at least one flow lumen in fluid communication with the second chamber;
- at least one pressure sensor disposed in the first chamber;
- a flow controller disposed along the flow lumen; and
- a microprocessor to compute at least flow rate of fluid transferred through the at least one flow lumen from the second chamber;

wherein a pressurized substance in the first chamber effects a change of volume of the second chamber whereby the fluid flows from the second chamber through the flow lumen; and

wherein the microprocessor controls the flow controller.

10. The device of claim 9, further comprising a fill port for filling the second chamber with the fluid.

11. The device of claim 9, further comprising at least one temperature sensor disposed in the first chamber.

12. The device of claim 9, wherein the flow controller is a clamp.

13. The device of claim 9, wherein the flow controller is a flow restrictor.

14. The device of claim 9, wherein the first chamber is pressurized prior to filling the second chamber with the fluid.

15. The device of claim 9, further comprising at least one temperature sensor; wherein the microprocessor gathers data from the temperature sensor to compute the at least a flow rate of fluid transferred through the flow lumen from the second chamber.

16. A method comprising:

- providing a pump having:
  - (a) a pressurizable first chamber;
  - (b) a second chamber for holding a fluid;
  - (c) at least one pressure sensor disposed in the first chamber;
  - (d) a flow lumen in fluid communication with the second chamber; and
  - (e) a flow controller;

wherein a pressurized substance in the first chamber is able to cause the fluid to flow from the second chamber and through the flow restrictor thereby changing the volume of the second chamber.

**17.** The method of claim **17**, further comprising providing at least one temperature sensor disposed in the first chamber.

**18.** The method of claim **17**, wherein the flow controller is a clamp.

**19.** The method of claim **17**, wherein the flow controller is a flow restrictor.

**20.** The method of claim **17**, further comprising a microprocessor for computing flow rate from data provided by the pressure sensor;

wherein the microprocessor controls the flow controller.

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