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(54) Title: TWO CHAMBER PUMPS AND RELATED METHODS

(57) Abstract: 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 flow material delivery calculations after being calibrated or by knowing the initial volume of the flow material to be delivered.

# TWO CHAMBER PUMPS AND RELATED METHODS

### RELATED APPLICATIONS

[0001] This application is related to and claims priority from U.S. Patent Application Serial No. 12/538,018, filed August 7, 2009, entitled "Two Chamber Pumps and Related Methods," the content of which is incorporated by reference into this disclosure.

## **BACKGROUND**

[0002] The present disclosure relates to the field of pumps, especially those used to accurately dispense medication.

# **SUMMARY**

[0003] Two chamber pumps and related methods provide a platform for measuring flow rate in about real time without contacting the material being pumped. Sensors, such as pressure sensors, disposed in a sealed chamber allow for flow material delivery calculations after being calibrated or by knowing the initial volume of the flow material to be delivered. According to a feature of the present disclosure, a device is disclosed comprising a sealed first chamber, which is pressurizable according to embodiments; a second chamber for holding a flow material; at least one flow lumen in flow material communication with the second chamber; at least one sensor disposed in the first chamber; and a flow controller disposed along the flow lumen; and a microprocessor for computing flow rate from data provided by the sensor. A pressurized substance in the first chamber effects a change of volume of the second chamber. The microprocessor controls the flow controller, according to embodiments.

[0004] According to a feature of the present disclosure, a device is disclosed comprising a pressurizable first chamber, a second chamber for holding a flow material, at least one flow lumen in flow material 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

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microprocessor to compute at least flow rate of flow material transferred through the at least one flow lumen from the second chamber. A pressurized substance in the first chamber effects a change of volume of the second chamber whereby the fluid flow material flows from the second chamber through the flow lumen. The microprocessor controls the flow controller. 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 flow material; (c) at least one sensor disposed in the first chamber; (d) a flow lumen in flow material communication with the second chamber; and (e) a flow controller. A pressurized substance in the first chamber is able to cause the flow material to flow from the second chamber and through the flow restrictor thereby changing the volume of the second chamber.

#### **DRAWINGS**

[0005] 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:

[0006] Figure 1 is a cross sectional view of an embodiment of the pumps of the present disclosure having rigid outer casings;

[0007] Figure 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

[0008] Figure 3 is a cross sectional view of an embodiment of the pumps of the present disclosure.

# **DETAILED DESCRIPTION**

[0009] In the following detailed description of embodiments of the invention, reference is made to the accompanying drawings in which like references indicate similar elements, 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."

[0010] As used herein, the term "real time" shall be understood to mean the instantaneous moment of an event or condition, or the instantaneous moment of an event or condition plus short period of elapsed time used to make relevant measurements, optional computations, etc., and communicate the measurement, computation, or etc., wherein the state of an event or condition being measured is substantially the same as that of the instantaneous moment irrespective of the elapsed time interval. Used in this context "substantially the same" shall be understood to mean that the data for the event or condition remains useful for the purpose for which it is being gathered after the elapsed time period.

[0011] 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 sensor disposed therein to measure the volume in a pressured chamber that drives flow of a flow material from a flow material chamber. A flow material can be a fluid or a gas. 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 flow material flow from the pumps, while allowing for precise measurements for flow volumes in about real time without compromising sterility.

[0012] 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 flowing state, flow of flow material contained in second chamber 120 is effected.

[0013] Flow of flow material 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 flow materials from a source to a destination without appreciable loss of flow material.

[0014] 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. According to other embodiments, flow controller may comprise an active pump.

[0015] Fill device 150 is disposed along flow lumen 130 and facilitates the filling of second chamber 120 with flow material. Fill device 150 may comprise a one-way valve, according to embodiments, whereby flow material 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.

[0016] 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.

[0017] Sensor 115 is disposed in first chamber 110 to determine the volume of second chamber at predetermined intervals or in real time, as well as initial readings. The data collected from sensor will be used to measure flow material dispensed, as well as used to determine flow rate.

[0018] According to embodiments, and as well known and understood by artisans, methods for determination of the volume are expressly contemplated in the instant application. Pressure sensors may be used, as disclosed herein. According to embodiments, acoustic sensors, including

a loud speaker and one or more microphones may be used to accurately determine the volume of first chamber 110 or second chamber 120, thereby allowing for calculation of the volume of flow material in the chambers. Acoustic volume determination technology is disclosed in U.S. Pat. Nos. 5,575,310 and 5,755,683, which are incorporated by reference; and U.S. Provisional Application Serial No. 60/789,243, which is incorporated by reference. U.S. Pat Application Publication No. 2007/0219496, which is incorporated by reference, discloses still further methods for the determination of the volume of first chamber 110 or second chamber 120, including via optical, capacitive, deflection measure methods (detecting deflection of a membrane as pressure changes), thermal time of flight methods, or other methods for measuring the volume of a chamber. Each of these may be used instead of or in addition to pressure sensors.

[0019] Optionally, multiple sensors may be disposed in first chamber 110. For example, where Boyle's law is used to measure volume, a temperature sensor may be disposed in first chamber 100 along with a pressure sensor to improve accuracy of flow measurement. A plurality of the same sensors may be disposed into first chamber 110 in to more accurately determine the volume of second chamber 120.

[0020] Second chamber 120, according to embodiments, comprises a collapsible chamber that holds a flow material without appreciable leakage. When flow controller is in a state whereby flow is effected, flow from second chamber 120 is effected by the pressure differential across flow controller 140. Second chamber 120 may be made from PVC, polyisoprene, silicon, polyurethane, or other flexible materials.

[0021] According to embodiments, first chamber 110 comprises a rigid-walled chamber, as illustrated in Fig. 1. According to other embodiments, first chamber 110 comprises collapsible/movable wall(s), as illustrated in Fig. 2. According to embodiments, the collapsible/movable wall(s) illustrated in Fig. 2 comprises an elastomeric material, wherein the volume of first chamber 110 is predictably variable. To be predictably variable, for example, the modulus of elasticity is known, which provides a known total volume of first chamber as a function of pressure. According to other embodiments, the collapsible or movable wall comprises a non-stretchable material, whereby the volume of first chamber 110 is unaffected by changes in the pressure of first chamber 110.

[0022] According to embodiments and as shown in FIG. 3, second chamber 120 may be defined by a collapsible or movable diaphragm 125. Rather than collapsing second chamber 120, the movable or collapsible diaphragm 125 is moved whereby flow is effected.

[0023] For the purposes of the present application, second chamber 120 has three discrete states: empty, filled, and flowing. The empty state defines second chamber 120 when the volume is zero or a known empty volume. The filled state defines the second chamber 120 when it is filled with flow material. The flowing state defines a plurality of volumes where

$$V_{2 \text{ filled}} > V_{2 \text{ flowing}} > V_{2 \text{ empty}}.$$
 (1)

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

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

$$PV = nRT. (2)$$

[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:

$$V_1 + V_2 = c$$
. (3)

Thus, as flow material moves 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 flow material 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.

$$flowrate = \frac{\Delta V_2}{\Delta t}$$
 (4)

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 data collected from the sensors.

[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,

$$nR = k \tag{5}$$

where k is a constant. Thus,

$$PV = kT \tag{6}$$

$$\frac{PV}{T} = k \ . \tag{7}$$

[0028] Because first chamber 110 is sealed, k remains constant. Additionally, pressure sensor and optional temperature sensor disposed in first chamber 110 allows for measurement of  $P_{Ifilled}$ ,  $P_{Iflowing}$ ,  $T_{Ifilled}$ , and  $T_{Iflowing}$ , which provides data sufficient for calculation of  $V_{2filled}$ . Using  $V_{Ifilowing}$  can be calculated:

$$\frac{P_{1filled}V_{1filled}}{T_{1filled}} = \frac{P_{1flowing}V_{1flowing}}{T_{1flowing}} . \quad (8)$$

[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:

$$\frac{P_{1flowing}^{\Delta t=0} V_{1flowing}^{\Delta t=0}}{T_{1flowing}^{\Delta t=0}} = \frac{P_{1flowing}^{\Delta t=x} V_{1flowing}^{\Delta t=x}}{T_{1flowing}^{\Delta t=x}}$$
(9)

[0030] where  $\Delta t$  is the elapsed time. According to embodiments, when  $\Delta t = 0$ , the *flowing* state is equal to the *filled* state. According to other embodiments, when  $\Delta t = 0$ , flow material has already been dispensed from second chamber 120 and  $\Delta t$  is set to zero (or the current value of  $\Delta t$  is treated as if it is zero) to determine a flow rate from that point forward. When  $\Delta t \geq 1$ , flow material has been dispensed from second chamber 120. Artisans will readily appreciate that each

time interval represented by  $\Delta t$  may represent the aggregate time since the flow of flow material for second chamber 120 began, according to embodiments. According to other embodiments,  $\Delta t$  may represent a snapshot from a known state of second chamber 120 to an unknown state after flow material has been dispensed.

[0031] To more clearly illustrate the principle of determining  $\Delta V_I$ , temperature will be assumed to be constant for the purposes of the next set of equations. Thus,

$$P_{1 \text{ filled}} V_{1 \text{ filled}} = P_{1 \text{ flowing}} V_{1 \text{ flowing}}$$
 (10)

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

$$V_{1flowing} = \frac{P_{1filled}V_{1filled}}{P_{1flowing}}. (11)$$

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

$$V_{1 \, filled} = c - V_{2 \, filled} \, (12)$$

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:

$$flowrate = \frac{V_{2 flowing} - V_{2 filled}}{\Delta t}$$
 (13)

Thus, to determine  $V_{Iflowing}$ , we can use the relationship expressed in equation (11). As  $V_{Ifilled}$  is unknown, substituting known values of c and  $V_{2filled}$ , the following equation results:

$$V_{1flowing} = \frac{P_{1filled} \left(c - V_{2filled}\right)}{P_{1flowing}}. (14)$$

Flowrate may be calculated as:

$$flowrate = \frac{\frac{P_{1filled}(c - V_{2filled})}{P_{1flowing}} - V_{1filled}}{\Delta t}.$$
 (15)

[0032] Adding temperature back to the equation allows for a more precise measurement of flow rate and is easily accomplished:

$$flowrate = \frac{\frac{P_{1filled}\left(c - V_{2filled}\right)}{P_{1flowing}} - V_{1filled}}{\Delta t} \left(\frac{T_{1flowing}}{T_{1filled}}\right). \quad (16)$$

[0033] According to embodiments, measurements of flow rate are taken at discrete time intervals. These time intervals may range from many measurements per fraction of seconds 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 via flow controllers, such as flow restrictors, flow metering devices, valves, or with mechanical devices used conjunction with second chamber 120. By coupling the measurement of flowrate to flow controllers, flow may be closely regulated by modulating the flow controllers in response to the measured flowrate. For example, if flow controller 140 comprises a clamp, then feedback system may open the clamp when additional flow of flow material 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 flow material.

[0034] According to embodiments, to dispense flow material from pump 100, a calibration step is necessary. The calibration step determines the volume of second chamber 120 prior to filling with a flow material ( $V_{2empty}$ ), which is necessary to determine flow rate, as described below using the ideal gas law or Boyle's law.

[0035] According to embodiments, the simplest method for the determination of  $V_{2empty}$  is to know the volume of flow material put into second chamber 120. This is accomplished by injecting a known amount of flow material into second chamber 120 via fill device 150 or using a disposable second chamber 120 (i.e., an IV bag) holding a known volume.

[0036] 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 flow material, the pressure and temperature of first chamber are measured. The initial volume of second chamber 120 is then calculated after flow material is put into second chamber 120 using an equation to measure flow rate, which is derived in detail below:

$$V_{1filled} = \frac{P_{1empty}T_{1empty}T_{1filled}}{T_{1empty}P_{1filled}} (17)$$

$$V_{2 \text{ filled}} = c - V_{1 \text{ filled}}$$
 (18)

[0037] where  $V_{Ifilled}$  is the volume of second chamber 120 after it is filled with a flow material;  $V_{Ifilled}$  is the volume of the first chamber 110 when second chamber is filled; c is the fixed volume of pump 100;  $P_{Iempty}$ ,  $T_{Iempty}$ , and  $V_{Iempty}$  are the pressure, temperature, and volume respectively of first chamber 110 prior to filling second chamber 120; and  $P_{Ifilled}$ ,  $T_{Ifilled}$ , and  $V_{Ifilled}$  are the pressure, temperature, and volume of first chamber 110 after filling second chamber 120 with a flow material. According to embodiments, flow is effected because the pressure of first chamber 110 and the pressure in second chamber 120 exceed the pressure at the point of delivery of the flow material. 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, according to equation (17), substituting empty values with filled values.

[0038] 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, for example as shown in Fig. 2, which expands or contracts 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  $V_I$ , the change in the volume of first chamber 110 is reasonably predictable, for example when using embodiments similar to that illustrated in Fig. 2.

[0039] Accuracy of the determination of the change in  $V_I$  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. Accordingly, first chamber 110 would be designed 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  $V_1$ .

[0040] Referring again to the calibration step, as the volume of second chamber 120 increases during filling with the flow material, the volume of first chamber 110 is decreased and the pressure within first chamber 110 increases. At the same time, if 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.

[0041] According to alternative-type embodiments, a method for accounting for the change in  $V_I$  due to expansion or contraction of the material from which first chamber 110 is made is accomplished by use of values from a lookup table that approximates change in volume of first chamber 110 as a function of pressure within first chamber 110. 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  $V_I$  at a plurality of given measured pressures.

[0042] 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 (3).

[0043] 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.

$$V_1 + V_2 = c + V_1^E \tag{19}$$

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

$$V_1 = c + V_1^E - V_2.$$
(20)

[0044] Thus, in systems where first chamber 110 is made from expandable materials, equation (16) is modified to account for the expanded first chamber 110:

$$flowrate = \frac{\frac{P_{1filled}\left(c + V_{1}^{E} - V_{2filled}\right)}{P_{1flowing}} - V_{1filled}}{\Delta t} \left(\frac{T_{1filowing}}{T_{1filled}}\right). \quad (21)$$

[0045] 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.

[0046] 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.

#### **CLAIMS**

- 1. A device comprising:
  - a pressurizable first chamber;
  - a second chamber for holding a flow material;
  - at least one flow lumen in flow material communication with the second chamber;
  - at least one sensor disposed in the first chamber;
  - a flow controller disposed along the flow lumen; and
  - a microprocessor for computing flow rate from data provided by the 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 flow material.
  - 3. The device of claim 1, wherein the sensor is a pressure sensor.
- 4. The device of claim 3, further comprising at least one temperature sensor disposed in the first chamber.
  - 5. The device of claim 1, wherein the flow controller is a flow restrictor.
  - 6. The device of claim 1, wherein the flow controller is a flow metering device.
- 7. The device of claim 1, wherein the first chamber is pressurized prior to filling the second chamber with the flow material.
- 8. The device of claim 1, wherein the first chamber is made from an expandable material.
- 9. The device of claim 8, wherein the expansion of the expandable material is a function of the pressure of the first chamber.

- 10. A device comprising:
  - a pressurizable first chamber;
  - a second chamber for holding a flow material;
  - at least one flow lumen in flow material communication with the second chamber;
  - at least one sensor disposed in the first chamber;
  - a flow controller disposed along the flow lumen; and
- a microprocessor to compute at least flow rate of flow material 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 flow material flows from the second chamber through the flow lumen; and

wherein the microprocessor controls the flow controller.

- 11. The device of claim 10, further comprising a fill port for filling the second chamber with the flow material.
  - 12. The device of claim 10, wherein the sensor is a pressure sensor.
- 13. The device of claim 12, further comprising at least one temperature sensor disposed in the first chamber.
  - 14. The device of claim 10, wherein the flow controller is a flow restrictor.
- 15. The device of claim 10, wherein the first chamber is pressurized prior to filling the second chamber with the flow material.
- 16. The device of claim 10, 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 flow material transferred through the flow lumen from the second chamber.
  - 17. A method comprising:

providing a pump having:

(a) a pressurizable first chamber;

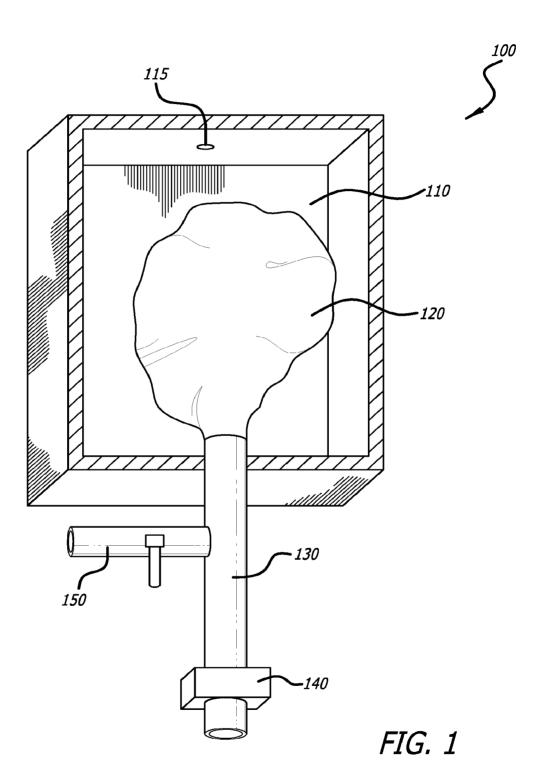
- (b) a second chamber for holding a flow material;
- (c) at least one sensor disposed in the first chamber;
- (d) a flow lumen in flow material communication with the second chamber; and
  - (e) a flow controller;

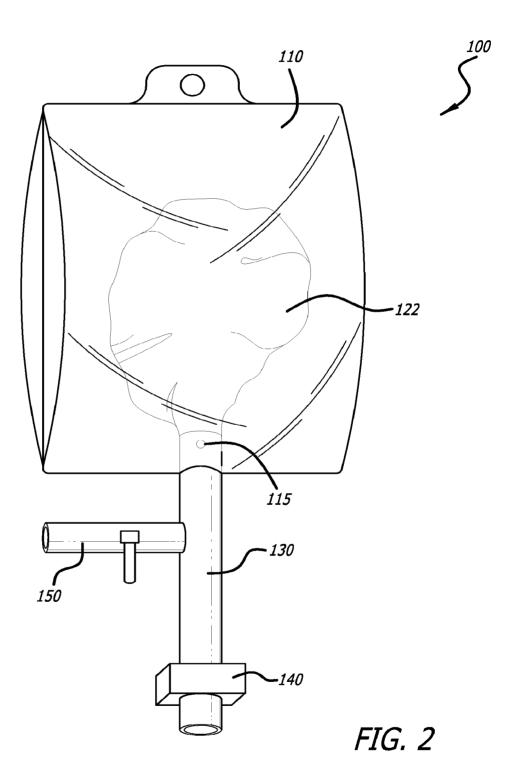
wherein a pressurized substance in the first chamber is able to cause the flow material to flow from the second chamber and through the flow restrictor thereby changing the volume of the second chamber.

- 18. The method of claim 17, wherein the sensor is a pressure sensor.
- 19. The method of claim 18, further comprising providing at least one temperature sensor disposed in the first chamber.
  - 20. The method of claim 18, wherein the flow controller is a flow restrictor.
  - 21. The method of claim 17, wherein the flow controller is a flow metering device.
- 22. The method of claim 18, 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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