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Hammond et al.

[11] **3,907,504**

[45] **Sept. 23, 1975**

[54] **BLOOD OXYGENATION SYSTEM INCLUDING AUTOMATIC MEANS FOR STABILIZING THE FLOW RATE OF BLOOD THERETHROUGH**

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[21] Appl. No.: **348,711**

[52] **U.S. Cl.** **23/258.5;** 128/DIG. 3; 137/565; 417/36; 417/37; 417/43

[51] **Int. Cl.**^{2} **A61M 1/03**

[58] **Field of Search** 23/258.5; 128/DIG. 3; 417/43, 36, 37; 137/565

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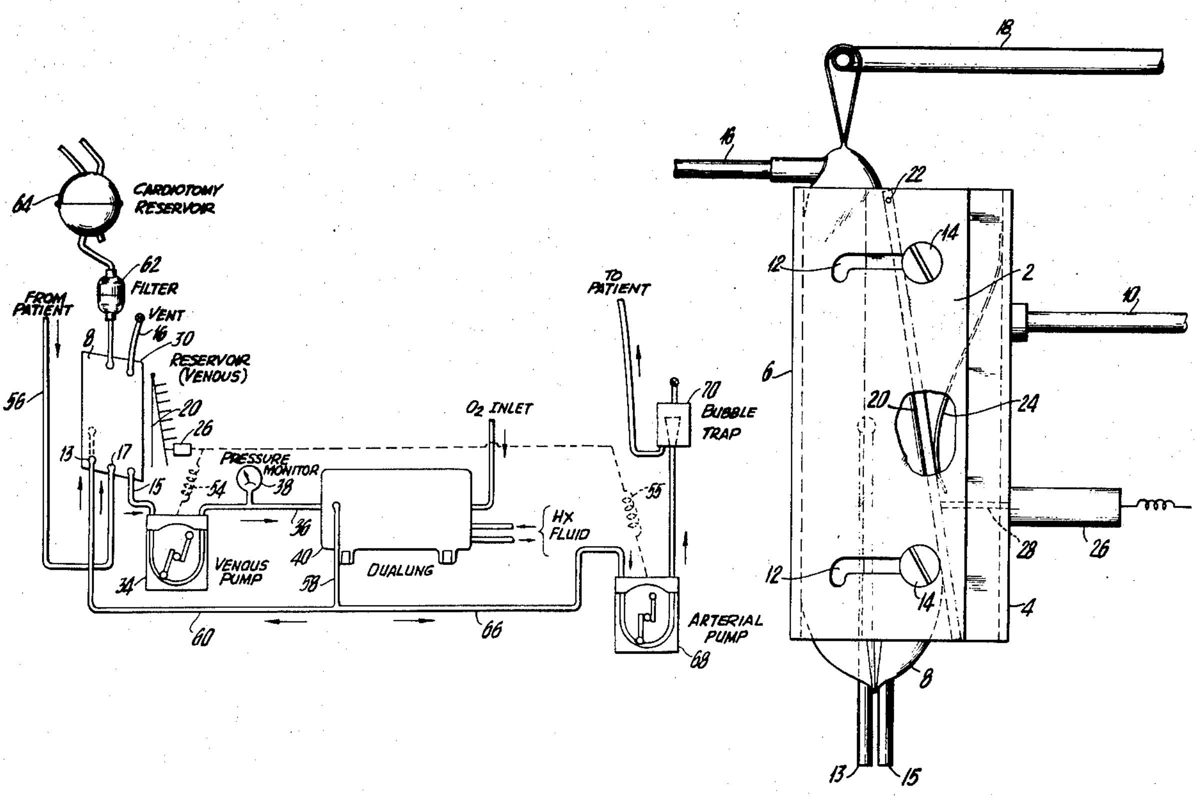
[57] **ABSTRACT**

An apparatus for sensing and signaling changes in the pressure and volume of a fluid passing therethrough, the apparatus comprising: (a) a hollow chamber; (b) a compliant reservoir for holding the fluid, the reservoir being located in the hollow chamber and being fitted with inlets and outlets for the fluid; and (c) a motion actuated means in the chamber for signaling changes in the size of the compliant reservoir. In one embodiment, the apparatus is used in an extracorporeal circuit to sense changes in the pressure and volume of blood and to signal the speed controller on a blood transfer pump in the blood circuit.

7 Claims, 8 Drawing Figures



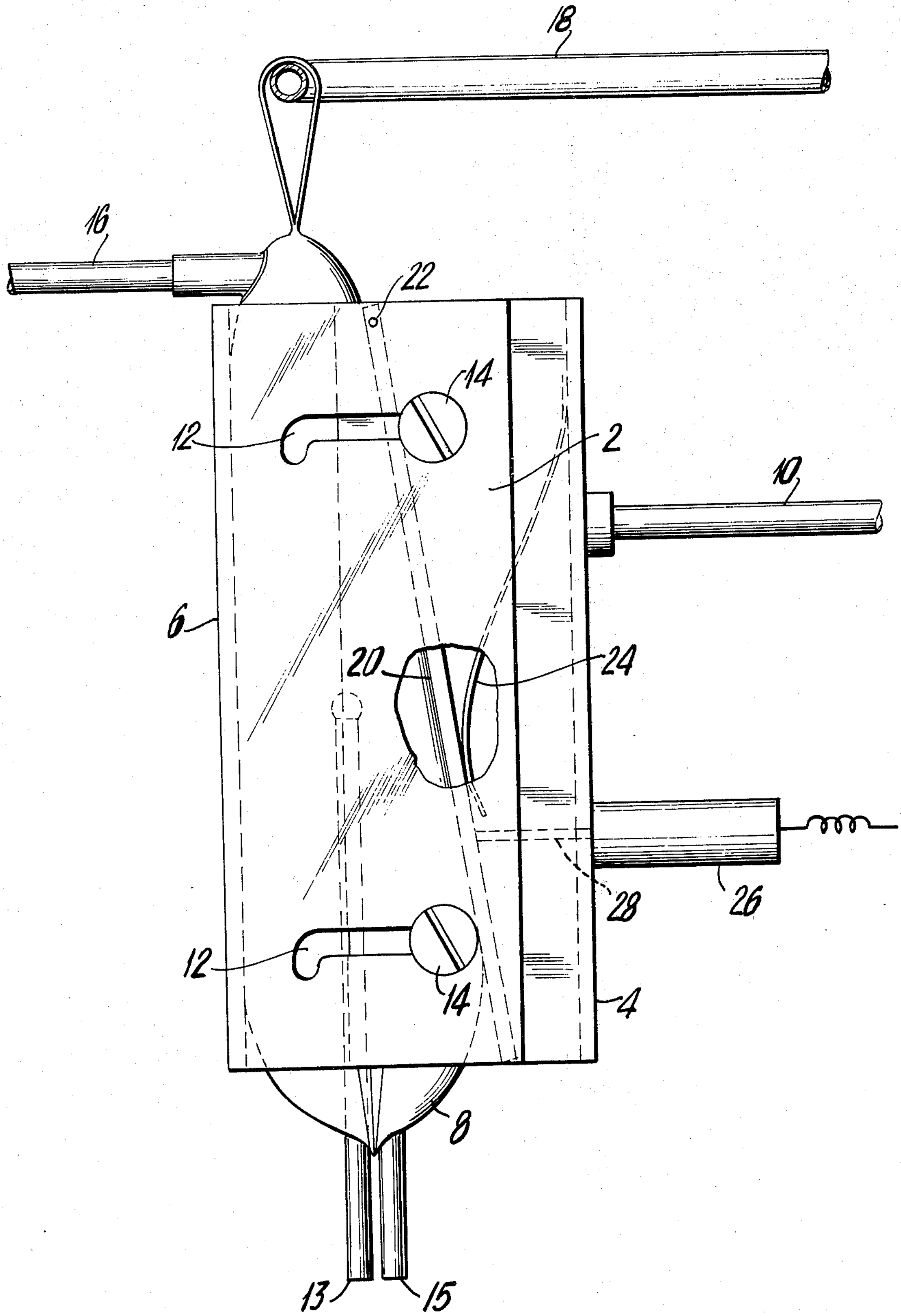
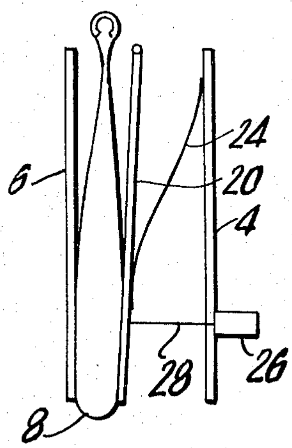
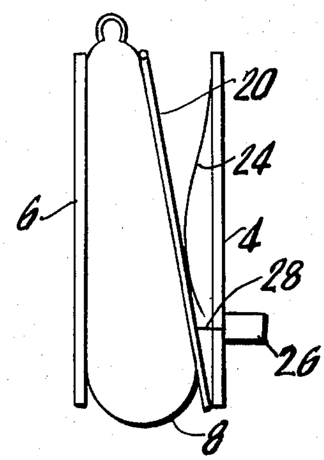


FIG.1



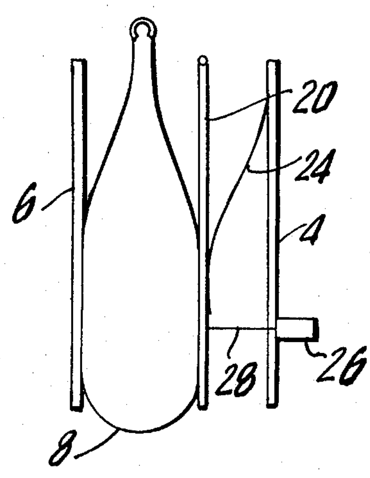
P= ~2 MM HG
V= 200 ML
S= 0 RPM

FIG. 2a



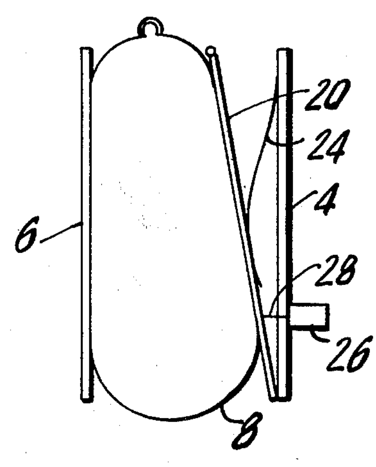
P= 20 MM HG
V= 400 ML
S= MAX

FIG. 2c



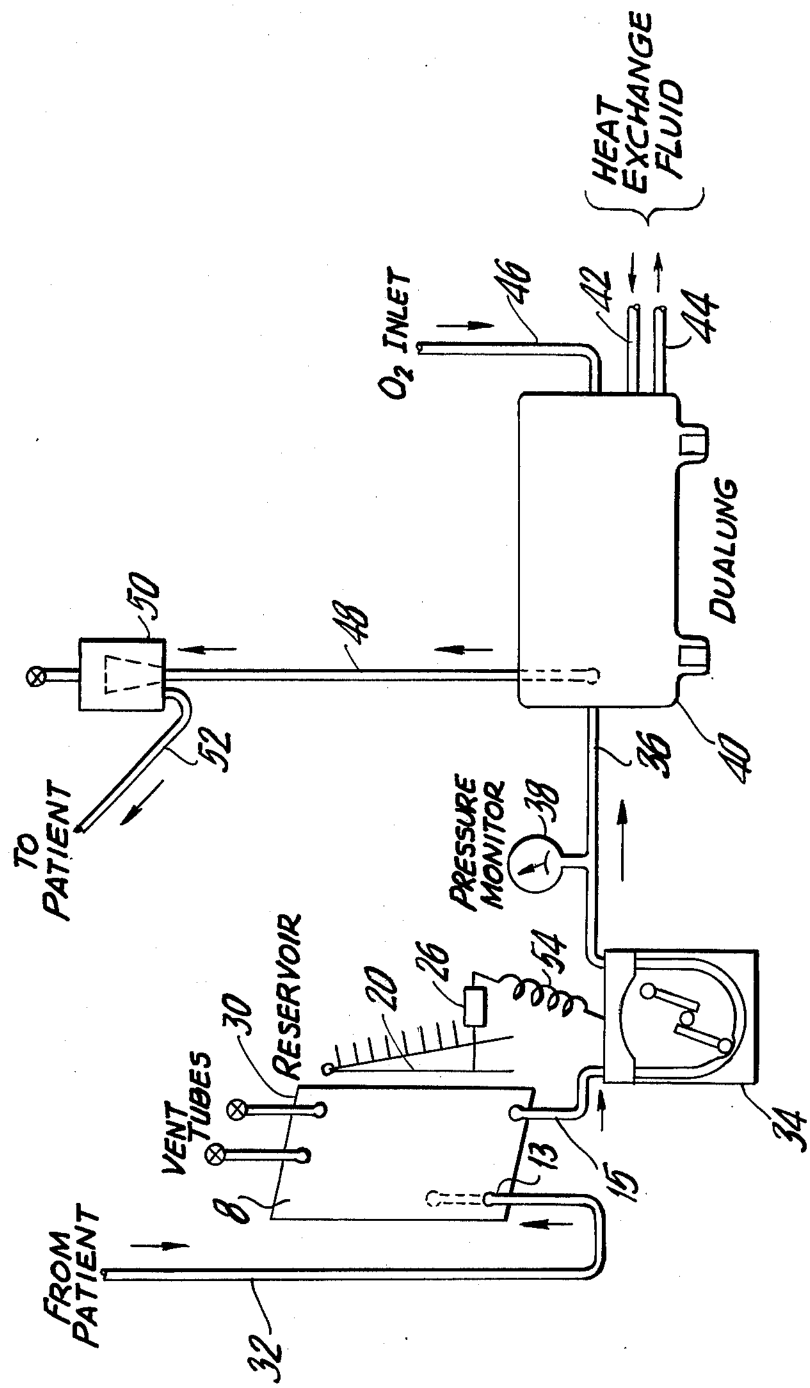
P= ~2 MM HG
V= 500 ML
S= 0 RPM

FIG. 2b



P= 20 MM HG
V= 700 ML
S= MAX

FIG. 2d


HEAT EXCHANGE FLUID
O_2 INLET
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42
44
DUALUNG
50
48
52
TO PATIENT
40
36
38
PRESSURE MONITOR
54
26
20
RESERVOIR
30
VENT TUBES
8
13
15
34
FROM PATIENT
32

FIG.3

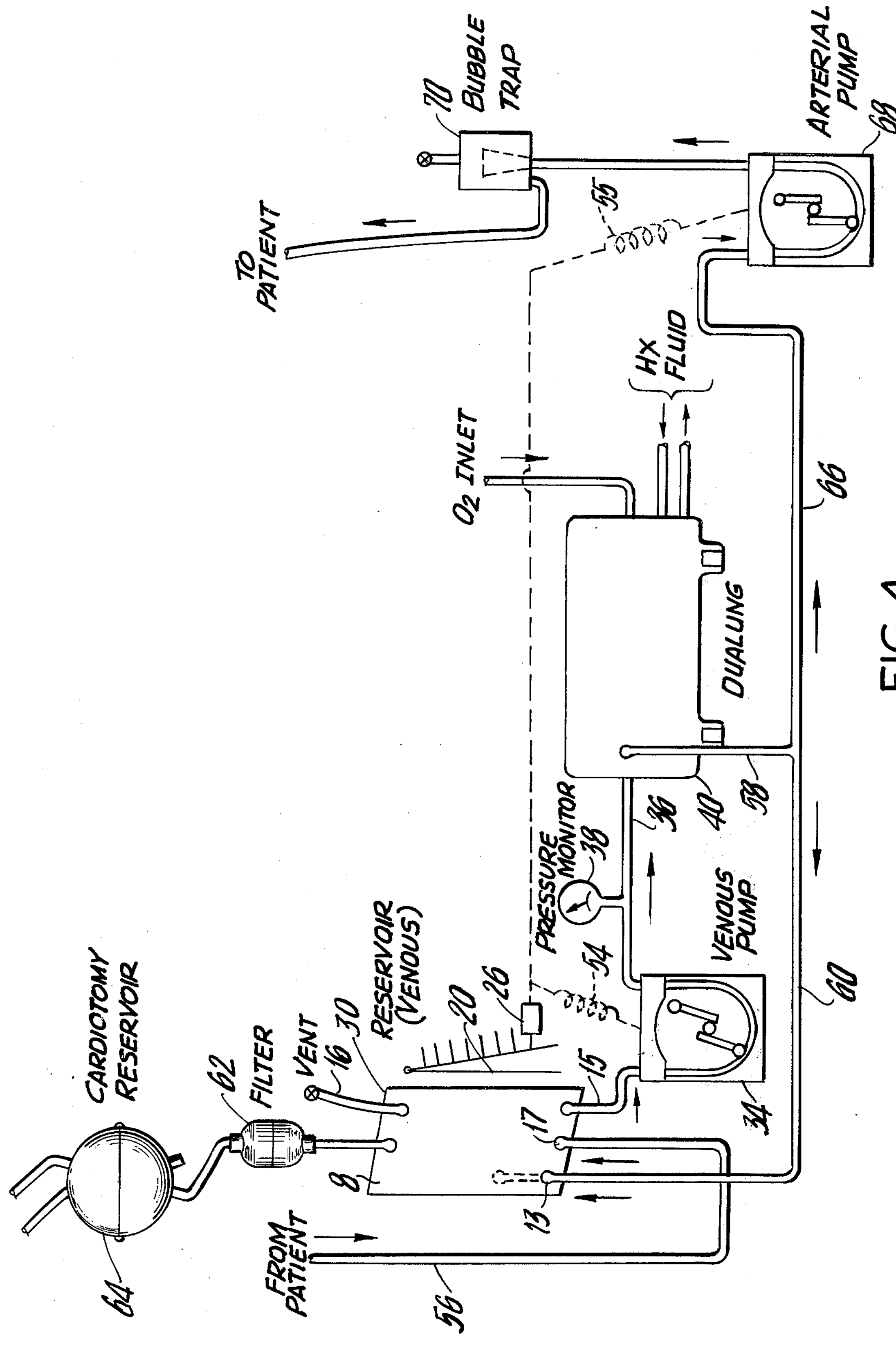
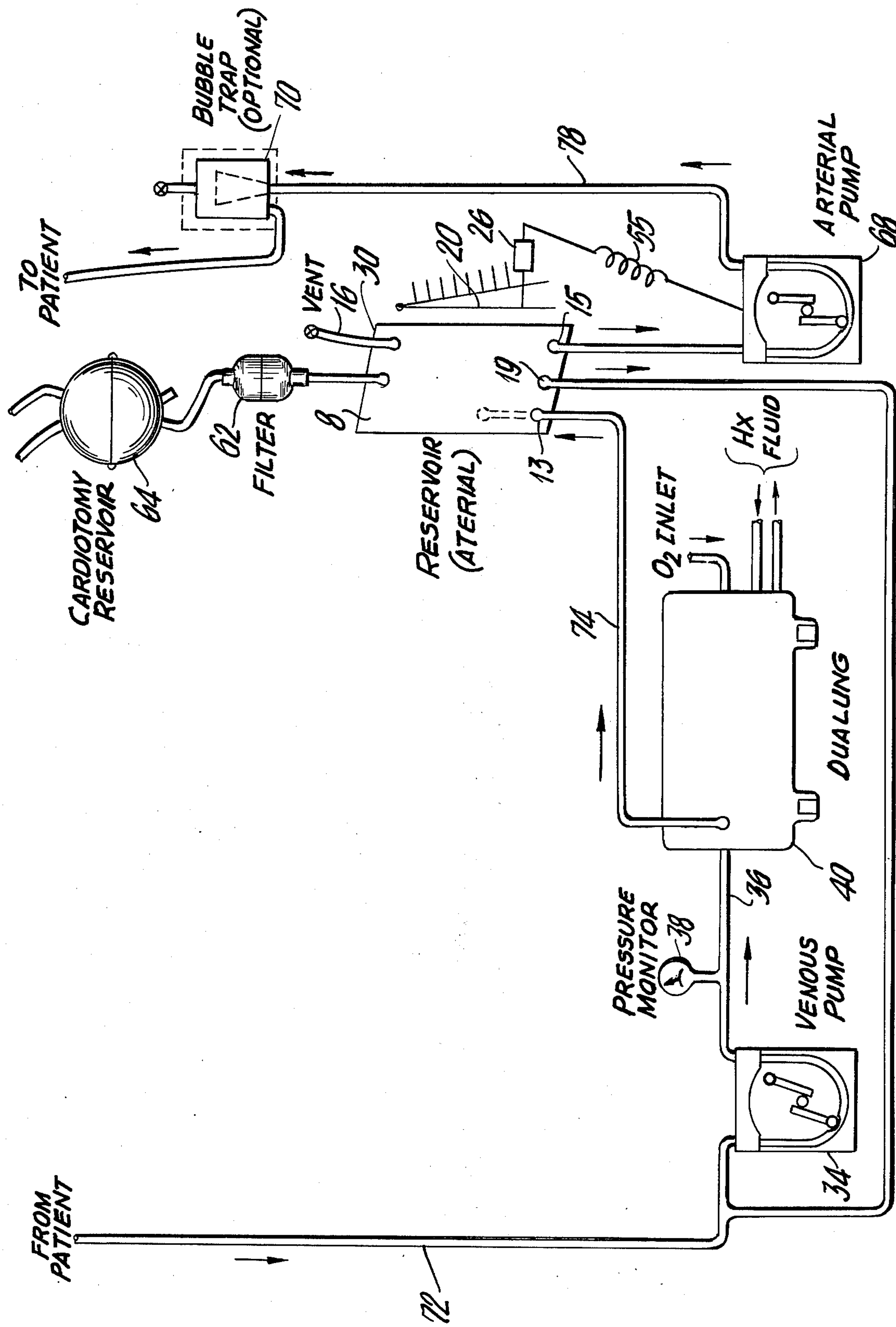

TO PATIENT
70
BUBBLE TRAP
ARTERIAL PUMP
68
55
HX FLUID
O_2 INLET
DUALUNG
66
40
PRESSURE MONITOR
VENOUS PUMP
60
34
54
26
20
RESERVOIR (VENOUS)
30
16
VENT
62
FILTER
CARDIOTOMY RESERVOIR
64
8
17
15
13
FROM PATIENT
56

FIG.4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78
TO PATIENT
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VENT
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30
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26
55
15
19
CARDIOTOMY RESERVOIR
64
62
FILTER
8
13
RESERVOIR (ATERIAL)
HX FLUID
O2 INLET
74
DUALUNG
76
40
36
PRESSURE MONITOR
38
VENOUS PUMP
34
FROM PATIENT
72

FIG.5

BLOOD OXYGENATION SYSTEM INCLUDING AUTOMATIC MEANS FOR STABILIZING THE FLOW RATE OF BLOOD THERETHROUGH

This invention relates to an apparatus for sensing and signaling changes in the pressure and volume of fluids passing therethrough. More particularly, it is concerned with an apparatus which can sense the amount of liquid in a reservoir, e.g., one used in an extracorporeal fluid circuit and, using this signal, to modulate the speed of a pump in the circuit.

BACKGROUND OF THE INVENTION

Various sensors are known which can detect the amount of liquid in a reservoir used in an extracorporeal circuit and, using this signal, modulate the speed of a pump in the circuit. If the circuit is used, for example, to oxygenate blood, such sensor-controllers operate almost automatically, considerably simplifying the perfusionist's task. In this way, for example, a two-pump circuit, generally needed with membrane lungs, is reduced to the operational simplicity of a one-pump circuit by having an automatically controlled arterial pump. Also, such an automatic pump speed controller can be used to sense a venous reservoir being filled by gravity drainage from the patient and thus control the venous pump.

Among the prior art sensors are those which are weighing devices. These suffer serious disadvantages because they have two to four large tubes and two small tubes connected to a compliant or rigid reservoir, and the preload due to these tubes adversely affects the functioning of the weighing mechanism. Another device is based on the principle of an optical detection of the liquid level in the reservoir. However, the optical technique is complicated, lacks reliability, is applicable mainly only to rigid reservoirs, and generally is adapted to give only on-off rather than modulated pump control signals.

In a novel way, the device of the present invention can sense the amount of liquid in a reservoir, e.g., one used in an extracorporeal circuit and, using this signal, modulate the speed of a pump in the circuit. The present device provides the stated advantages simply, reliably, and in a method consistent with maintaining sterility in the blood.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 illustrates a vertical plan view, partially in section, of a compliant reservoir pressure and volume sensing and signaling device, which is one embodiment of this invention;

FIGS. 2 *a–d* illustrate semi-diagramatically, the device of FIG. 1 in which the compliant reservoir is shown to assume typical configurations under the influence of various fluid pressures and volumes;

FIG. 3 is a schematic, partial plan view, showing how the device of FIG. 1 can be used to keep the pump in a gravity drainage, single pump, extracorporeal circuit at the proper speed;

FIG. 4 is a schematic, partial plan view, showing how the device of FIG. 1 can be used to keep either the venous pump or the arterial pump of a two-pump gravity drainage system automatically at proper speed; and

FIG. 5 is a schematic, partial plan view, showing how the device of FIG. 1 can automatically control the speed of an arterial pump in a two-pump venous pump suction circuit.

Although FIGS. 3–5 relate specifically to a membrane lung of the type described in the copending application of D. R. Ingenito, W. P. Mathewson, D. R. Ryon and Gunnar E. Walmet, Ser. No. 247,987, filed on Apr. 21, 1972, now U.S. Pat. No. 3,839,204 issued Oct. 1, 1974, and assigned to the assignee of the present invention, it will be understood that the device of this invention can be used equally effectively with other membrane lungs and even different types of fluid gas-exchanger and/or heat-exhanger.

DESCRIPTION OF THE INVENTION

In its broadest aspects, the invention contemplates a device for continually sensing changes in reservoir distention/pressure and for signaling the changes to operate an external controller. In a preferred feature, the device will include means for varying the maximum volume of the reservoir. This allows one compliant reservoir to be used in an extracorporeal circuit for a variety of patient sizes.

According to the present invention, there is provided an apparatus for sensing and signaling changes in the pressure and volume of a fluid passing therethrough, said apparatus comprising:

a. a hollow chamber;

b. a compliant reservoir for holding said fluid, said reservoir being disposed within said hollow chamber and including an inlet and an outlet port for said fluid; and

c. motion actuated means in said hollow chamber for signaling changes in the size of said compliant reservoir.

Referring to FIG. 1, there is shown a preferred embodiment of the invention, in the form of a compliant reservoir pump speed controller. The sensor-controller is constructed of hollow chamber **2** comprised of "U" shaped base **4** of metal, plastic or the like and U shaped cover piece **6** also of metal, plastic or other suitable material of construction. Preferably, cover piece **6** and/or base **4** will be of transparent material, such as clear plastic to allow the fluid in compliant reservoir **8** to be visually observed for any bubbles, clots, suspended foreign matter, and the like. To facilitate mounting, base **4** can be fitted with holder support **10.** Adjustment slots **12** and lock screws **14** are provided in cover **6** and base **4** to permit changing the maximum volume of hollow chamber **2.**

Compliant reservoir **8** is constructed of any suitable flexible material, such as metal, plastic and the like, preferably poly(vinyl chloride), silicone rubber, etc., and is fitted with inlet **13** and outlet **15**, for fluid. It is desirable to provide that inlet **13** be tubular and that it terminate somewhat high up into the reservoir so that any bubbles in the fluid will be trapped by rising to the top of the reservoir instead of being drawn out of outlet **15.** In the embodiment shown in FIG. **1**, one or more vents, **16**, are provided at the top of reservoir **8**, and these can also serve conveniently as a sample port. For convenience, reservoir support **18** can be provided to hold the reservoir within the hollow chamber, e.g. by grasping a ring or other suitable fixture attached thereto.

Another important element in the device of this invention is the means for sensing the amount of liquid in reservoir **8.** This can comprise a plate adjacent the reservoir, the plate being movable with changes in reservoir shape induced by fluid pressure and volume changes and a transducer actuated by motion from the sensor plate for supplying a signal to an external recorder or controller. The sensor plate can be of the linear translating or, preferably, a pivoting type, and preferably is biased, e.g., with a spring, against the reservoir. Many different transducers can be used to convert the motion of the sensor plate to a different form of signal energy, but when used as a pump controller, it is preferred to use a linear motion actuated potentiometer or a linear motion actuated autotransformer.

Referring again to FIG. 1, sensor plate **20** is shown hinged to base **4** at hinge point **22** and is seen to contact compliant reservoir **8** along a fairly substantial area of contact. Leaf spring **24** biases sensor plate **20** against reservoir **8.** The transducer comprises linear potentiometer **26** having rod **28,** of metal, strategically located to transmit changes in the position of sensor plate **20** to the potentiometer.

In operation, as compliant reservoir **8** fills up with fluid, sensor plate **20** deflects against spring **24.** Conversely as reservoir **8** empties, sensor plate **20** follows it and moves out. As sensor plate **20** moves, metal rod **28** connected to linear motion actuated potentiometer **26** has its resistance varied. The resistance is the speed controlling signal in a suitable pump motor speed controller (not shown in FIG. **1**).

If it is desired to change the maximum volume of the reservoir, cover plate **6** can be moved with respect to base **4** and locked in the new position with screws **14.** This is shown, along with typical pressures and volumes in the reservoir (pressures measured near the top of the reservoir to avoid hydrostatic head contributions), at various positions in FIG. **2.**

For medical use, it is desirable that all parts of the device be made of plastic. This increases the electrical resistance between the blood and any electrical components used in the sensor to insure patient safety in the event of an electrical failure. Alternately, metal parts, if used, can be covered with an insulator. The materials in contact with blood should be easily sterilizable and be biocompatible.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **3-5** show how the device of this invention can be used as a reservoir sensing pump speed controller in extracorporeal circuits for oxygenating or otherwise treating body fluids, e.g., blood, and the like, before their return to the patient.

Referring to FIG. **3,** reservoir sensing pump controller **30** is used in a gravity drainage, single pump, extracorporeal circuit to keep the pump at the proper speed. Blood from the patient (not shown) passes by gravity through conduit **32** into inlet port **13** on sensor device **30.** The blood leaves through port **15** and is pumped, e.g., with roller type pump **34** (Sarns Corp., Ann Arbor, Mich, or the like) through conduit **36** past pressure monitoring gauge **38** to the inlet port of membrane type blood-gas exchanger **40** (GE-DUALUNG, General Electric Co., Schenectady, N.Y., or the like) which is fitted with inlet **42** and outlet **44** for heat exchange fluid and inlet conduit **46** for oxygen. The oxygenated blood exits the membrane lung through conduit **48** and, after being led to bubble trap **50,** is returned to the patient through conduit **52.** Shown schematically in combination with reservoir **8** are hinged sensor plate **20** and linear potentiometer **26** which supplies a pump speed varying signal through conductor **54** to pump **34.** As changes in volume or pressure in the system expand or contract reservoir **8,** the pump speed is varied automatically to compensate.

Referring to FIG. **4,** reservoir sensing pump controller **30** is used to keep either the venous pump or, preferably, the arterial pump of a two-pump gravity drainage system automatically at proper speed. Blood from the patient (not shown) passes by gravity through conduit **56** into inlet port **17** on sensor device **30.** The blood leaves through port **15** and is pumped by roller type venous pump **34** through conduit **36** past pressure monitoring gauge **38** to an inlet port of membrane type blood-gas exchanger **40.** Oxygenated blood exits the exchanger through conduit **58** and is split into two streams, one being recycled to controller **30** through conduit **60** and entrance port **13.** Complaint reservoir **8** is fitted with one vent tube **16** and a second vent tube includes filter **62** and cardiotomy reservoir **64.** The other oxygenated blood stream is transferred through conduit **66** and pumped by roller type arterial pump **68** to bubble trap **70** before being returned to the patient. Shown schematically in combination with reservoir **8** are hinged sensor plate **20** and linear potentiometer **26** which supplies a pump speed varying signal. If venous pump **34** is controlled, signal conductor **54** is used. Alternatively, and preferably, if arterial pump **68** is controlled, signal conductor **55** is used. In either case the pump speed is varied automatically to compensate for changes in blood pressure and volume within reservoir **8.**

Referring to FIG. **5,** reservoir sensing pump controller **30** is used to keep the arterial pump in a two-pump venous pump suction circuit automatically at the proper speed. Blood from the patient (not shown) flows through conduit **72** into roller type venous pump **34** and pumped through conduit **36** to an inlet port of membrane type blood-gas exchanger **40.** Oxygenated blood exits the exchanger through conduit **74** and enters compliant reservoir (arterial) **8** through entrance port **13.** Compliant reservoir **8** is fitted with vent tube **16** and with cardiotomy reservoir **64** coupled to reservoir **8** through filter **62.** Part of the oxygenated blood in reservoir **8** exits through port **19** and circulates back through the venous pump circuit via conduit **76.** Another part of the volume of oxygenated blood in reservoir **8** exits through port **15** to roller type arterial pump **68** where it is pumped through conduit **78,** and, optionally, bubble trap **70,** back to the patient. Shown schematically in combination with reservoir **8** are hinged sensor plate **20** and linear potentiometer **26** which supplies a pump speed varying signal through conductor **55** to pump **68,** automatically varying the pump speed to compensate for changes in blood pressure and volume within reservoir **8.**

Obviously, many other variations are possible in the light of the above specific embodiments. For example, FIGS. **4** and **5** illustrate how the sensor can be located in the venous and arterial two-pump circuits. Several other variations are possible. Illustratively, in FIG. **5.** decoupling conduit **76** between the reservoir and the inlet to venous pump **34** can be clamped off resulting in coupled pump speeds, i.e., arterial pump **68** will follow the settings of venous pump **34.** Moreover, the reservoir sensor's control in FIG. **4** can be moved to run the circuit exactly as shown in FIG. 5 to achieve automatic operation. In both venous and arterial reservoir circuits, the venous pump is desirably set somewhat faster than the anticipated rate of drainage from the patient. Excess flow will recirculate through a decoupling line (**60** in FIG. **4**; **76** in FIG. **5**). A sensor controlled arterial pump will return just the venous drainage back to the patient. This has two major advantages: (i) lessened manpower drain during partial supports; and (ii) smaller liquid inventories needed in the reservoir during all cases due to the ability of the machine to compensate more rapidly than a human operator. Other variations will include an arterial pump speed sensor with high and low speed set-point alarms, especially useful for automatic operation, because a sudden change of speed will usually indicate a problem with the perfusion. It will be obvious also that the locations of the cardiotomy reservoir can be changed from those shown in FIGS. **4** and **5**, without departing from the invention.

The above description demonstrates that the present invention discloses a reservoir sensing and signaling device which is simple and offers unique advantages over other pre-existing designs meant to serve the same function.

Many variations of the present invention are possible without departing from the spirit or scope of the appended claims.

We claim:

1. An apparatus for extracorporeally oxygenating the blood of a living patient comprising in combination

i. at least one pumping means for the blood,

ii. oxygenating means for the blood,

iii. means for sensing and signalling changes in the pressure and volume of blood passing through said apparatus, said sensing and signalling means comprising:

a. a hollow chamber of a selectively fixed and adjustable volume and comprising a base piece and a cover piece;

b. a compliant reservoir for holding said blood, said reservoir being disposed within said hollow chamber and including an inlet and an outlet port for said blood; said hollow chamber substantially limiting the maximum expansion volume of said complaint reservoir, and

c. motion activated means in said hollow chamber for generating an electrical signal proportionate to changes in the size of said compliant reservoir, and

d. adjusting means movably attaching said cover piece to said base piece to permit selective adjustment of the volume of said hollow chamber by movement of said cover piece relative to said base piece, and

iv. pump speed controlling means being operatively connected to receive said signal from said motion activated means and to automatically adjust the operation of said pumping means so as to move said blood through said apparatus at a flow rate responsive to said signal.

2. An apparatus as defined in claim **1** wherein two pumping means are utilized, one being a venous pumping means located upstream of said oxygenating means and the other being an arterial pumping means located downstream of said oxygenating means and wherein said pump speed controlling means is operatively connected to said arterial pumping means to automatically adjust the flow rate thereof responsive to said signal.

3. An apparatus as defined in claim **1** wherein said oxygenating means for the blood is a membrane type blood-gas exchanging means.

4. An apparatus as defined in claim **1** wherein a single pumping means is utilized in the apparatus.

5. An apparatus as defined in claim **4** wherein the single pumping means is a venous pumping means located upstream of said oxygenating means.

6. An apparatus as defined in claim **1** which also includes a blood heat exchanging means.

7. An apparatus as defined in claim **6** wherein said oxygenating means for the blood is a membrane type bood-gas exchanging means and the blood heat exchanging means is integral therewith.

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