



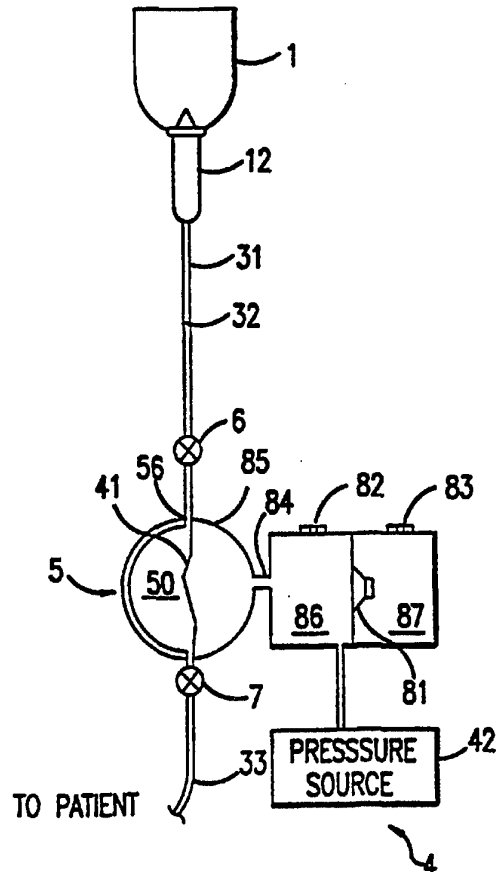
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| <p>(21) International Application Number: PCT/US96/06621 (22) International Filing Date: 9 May 1996 (09.05.96) (30) Priority Data: 08/481,606 7 June 1995 (07.06.95) US (71) Applicant: DEKA PRODUCTS LIMITED PARTNERSHIP [US/US]; 340 Commercial Street, Manchester, NH 03101 (US). (72) Inventors: MANNING, Robert; 403 Buck Street, Pembroke, NH 03275 (US). LARKINS, William, T.; 245 Carnegie Street, Manchester, NH 03104 (US). HOULE, Philip; 83 Bay Street, Manchester, NH 03104 (US). KAMEN, Dean, L.; 44 Gage Road, Bedford, NH 03102 (US). FAUST, Valentine; 75 South Bow Road, Bow, NH 03304 (US). (74) Agents: SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein, 11th floor, 125 Summer Street, Boston, MA 02110-0168 (US).</p> | | <p>(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p> |

(54) Title: INTRAVENOUS-LINE AIR-ELIMINATION SYSTEM

(57) Abstract

An-air elimination system is provided for an intravenous fluid delivery system for intravenous injection of fluid into a patient. An air-detection apparatus (5) is disposed in an intravenous fluid line (3). At the top end of the line (3) is attached a chamber (1, 2, 12) where air may be separated from the fluid. The separation chamber may be a drip chamber (12), a metering chamber (2) or the intravenous supply (1). When air is detected, a valve (11) or valves (7, 9) are switched, so that the intravenous fluid is prevented from flowing to the patient, and so that, when a pump (4) is turned on, the fluid is pumped to the separation chamber (1, 2, 12). In a preferred embodiment, the volume of the pump's fluid capacity is greater than the volume of the fluid capacity of the intravenous line (31) between the pump (4) and the separation chamber (1, 2, 12), so that the pump can force air back up the intravenous line all the way to the separation chamber.



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INTRAVENOUS-LINE AIR-ELIMINATION SYSTEM

5

DESCRIPTION

Technical Field

10 The present invention relates to apparatus and methods for eliminating air bubbles from intravenous lines.

Background Art

 It has been the object of many prior-art devices to detect the presence of air
15 bubbles in an intravenous line. Such devices would normally set off an alarm to alert the appropriate medical personnel, who would then lightly rap the line to urge the bubbles up the line away from the patient. It is a tedious procedure to urge all the bubbles all the way up the IV line to the IV fluid reservoir. It is even more difficult to remove bubbles located downstream of a pump. Since, in an IV line that is not being pumped at high pressure,
20 small bubbles usually do not pose much danger to the patient, busy medical personnel rarely go through the trouble of urging the bubbles all the way up the line. Consequently, the bubbles quickly move back down the line and are detected again, thereby setting off the alarm again. Thus, without an easy way of removing air from the IV line, the prior-art air-detection systems are more of a nuisance than an aid.

25 At least one medical apparatus in the prior art includes a line for recycling air removed from fluid back to a reservoir without opening the fluid flow loop to the environment. U.S. Patent No. 4,874,359 to White et al. discloses a modular, power augmented medical infusion apparatus to provide rapid transfusion of relatively large quantities of blood, blood components, colloid and fluids to patients who require large
30 quantities of these blood components to be rapidly transferred. The major components comprise a pair of filtered cardiotomy reservoirs, an air embolus sensor, a modular double roller pump, a heat exchanger, a bubble trap-filter and disposable fluid conduits. The bubble trap-filter is located in the distal most location of the recirculating loop just

upstream of the Y-connector to the patient and the air sensor just downstream of the cardiomy reservoir in the proximal location of the recirculating loop. Blood is circulated rapidly from the cardiomy reservoir through the heat exchanger wherein it is heated or cooled as needed and through an air bubble trap filter having a nominal filtering capability of 33 microns. A secondary path from the filter is provided to permit the air trapped in the filter to be recycled to the reservoir without opening the infuser loop to the environment. The air bubble detection system uses an infra-red analyzer as a sensor. The detection system is configured to stop the pump and sound an audible alarm. It does not control the recycling of trapped air from the filter.

10 U.S. Patent No. 4,764,166 to Spani discloses an ultrasonic device for detecting the presence of air in the fluid line of an IV infusion device comprises a transmitter and a receiver which are positioned to pinchingly engage a portion of the fluid line therebetween. Both the transmitter and receiver have convex-shaped lenses which contact and cause a slight indentation of the tube for enhanced coupling therebetween.

15 U.S. Patent No. 4,734,269 to Clarke et al. discloses a venous reservoir bag with an integral high-efficiency bubble removal system. The system includes a container having an inlet for a fluid which includes liquid and gas bubbles, an outlet and upstream and downstream vents. A filter element is provided in the container between the inlet and the outlet. The filter element permits the passage of the liquid and inhibits the passage of the gas bubbles. The filter element is between the upstream and downstream vents so that gas bubbles can be vented through the upstream vent, and any gas bubbles downstream of the filter element can be vented through the downstream vent.

25 U.S. Patent No. 4,661,097 to Fischell et al. discloses a method for removing gas bubbles from the fluid handling system of a medication infusion system implanted in a patient. Specifically, Fischell discloses a method for removing fluid and/or gas bubbles from a fluid reservoir and pumping chamber by applying a vacuum or negative pressure to the inlet filter, thereby drawing gas bubbles from the pumping chamber. The invention utilizes a fluid pump of a single valve positive displacement design with the pump chamber in fluid communication with the fluid reservoir.

None of the above references disclose a system that, on detection of air in the intravenous fluid, shuts off flow of the fluid to the patient and forces the fluid towards the intravenous-fluid supply.

5

Summary of the Invention

The present invention provides an air elimination system an intravenous-fluid delivery system that intravenously injects fluid into a patient. The invention may include an intravenous (IV) line with a chamber disposed therein where air may separate from the fluid. Also disposed in the IV line is an air detector for detecting air in the fluid and
10 emitting a fault-condition signal, when an air bubble of a certain size is detected, or alternatively when any air bubble is detected. The IV line has a first portion between the separation chamber and the air detector, and a second portion between the air-detection means and the patient. A valve is disposed in the IV line's second portion, for permitting or preventing flow to the patient. A pump is used to urge fluid towards the separation
15 chamber upon activation. A controller, in communication with the air detector, controls the valve and the pump. In the event of a fault-condition signal, the controller sets the valve to prevent flow to the patient and activates the pump so as to move air and fluid from the air detector to the separation chamber. Otherwise, the pump and the valve may be used to permit flow to the patient or to pump fluid to the patient.

20 In one embodiment, a return line connects the chamber to a point in the IV line downstream of the air detector. A pair of valves, one being disposed in the IV line and the other in the return line--or alternatively a single shunt valve--are employed to permit flow either (i) through the return line or (ii) to the patient. When there is a fault condition, the pump urges fluid containing the air towards the separation chamber, preferably
25 through the return line. Alternatively, fluid may flow from the fluid source through the return line to a point below the detected air, so as to force the air up through the first portion of IV line.

In a preferred embodiment, a return line is not necessary. The air is forced up the first portion of the IV line by a reservoir of fluid located at or below where the air is
30 detected. By configuring the volume of this reservoir to be greater than the volume of the lumen of the IV line's first portion, the air can be forced up to the separation chamber. If

there is a great deal of air in the line, several iterations of this air-purging process may be necessary to eliminate all of the air.

Brief Description of the Drawings

5 FIG. 1 is a general view of an embodiment of an air elimination system according to the present invention.

 FIGS. 2 and 3 show alternative embodiments of the air elimination systems according to the present invention.

 FIG. 4 shows a preferred embodiment of an air-elimination system according to
10 the present invention.

 FIG. 5 is a flow chart depicting a preferred method of carrying out the invention.

 FIG. 6 shows a perspective view of a preferred shape for an inlet port to a pressure-conduction chamber, which may be used with the present invention.

 FIG. 7 shows a side view of the inlet-port shape shown in FIG. 6.

15 FIG. 8 shows a cross-section of the inlet port the shape of which is depicted in FIGS. 6 and 7.

Detailed Description of Specific Embodiments

 The invention provides an apparatus and method for eliminating air from
20 intravenous fluid delivery systems. In a preferred embodiment, an acoustic sensor is utilized to control the operation of a valve located downstream of the IV pump so that when air bubbles are detected, an isolation valve is closed to shut off the flow of IV fluid to the patient and the fluid containing the air is returned the metering chamber, the drip chamber or the intravenous-fluid source.

25 A system according to the present invention may include an apparatus that accurately dispenses IV fluid to the patient, using sound waves both to measure fluid flow and to detect the presence of air in the IV fluid. The apparatus includes a return line that carries fluid back to the metering chamber if and when the apparatus detects air in the fluid. Although almost any air-detection system may be used, it is intended that a
30 preferred embodiment of the present invention be used with an apparatus that uses sound

waves to measure flow and uses sound waves to detect air, such as that disclosed in the above-referenced U.S. Patent No. 5,349,852.

FIG. 1 shows an intravenous-fluid bag (or bottle) **1** and metering chamber **2**, from which an IV line **3** provides fluid to the patient. Disposed in the line is a pump **4**, an apparatus for detecting air and preferably for measuring flow rate **5**, and a valve **7**. The air-detection/fluid-measurement apparatus **5** is downstream of the pump **4**, and the valve **7** is located downstream of the apparatus **5**. One end of the return line **8** is connected to the IV line **3** between the air-detection apparatus **5** and valve **7**; its other end is connected to the metering chamber **2**. Another valve, a purge valve **9**, is located in the return line.

When air, or a certain amount of air, is detected, valve **7** is closed and purge valve **9** is opened. The pump **4** is turned on, forcing the fluid and the air bubbles in the air-detection apparatus **5** to return to the metering chamber **2**. The metering chamber **2** allows the air bubbles to separate from the IV fluid. Other devices, such as a drip chamber, or even the IV bag (or bottle) **1**, may be used to allow the air to separate from the fluid. When the air has been eliminated from the apparatus, purge valve **9** may be closed and the IV system may return to its normal pumping mode. A digital controller **10** receives information from the detector **5** regarding the presence of air, controls the opening and closing of valves **7** and **9**, and controls the pump **4**. The air detector **5**, as well as the controller **10**, may be made a part of an IV fluid control system, such as that disclosed in U.S. Patent Nos. 5,349,852 or 4,976,162. The system disclosed in patent no. 4,976,162 uses two valves, A and B, for isolating a portion of the IV fluid during a volume measurement cycle, and these are shown as valves **6** and **7** in FIG. 1; the valve B of patent no. 4,976,162 is used as valve **7** of the present invention. Valve **6** of the present invention corresponds to valve A.

In another embodiment of the present invention, the pump **4** may be located in the IV line **3** downstream of the air detector **5** but upstream of the point where the return line **8** is connected to the IV line **3**, as shown in FIG. 2. The system shown in FIG. 2 has the return line returning to a simple drip chamber **12** instead of a metering chamber. FIG. 3 shows another embodiment, wherein the pump **4** is disposed in the return line **8** and the return line **8** returns fluid to the reservoir **1**, and wherein a single shunt valve **11** is used

instead of two separate valves 7 and 9. A disadvantage of the FIG. 3 embodiment is that the pump 4 cannot, of course, be used to pump IV fluid to the patient.

In all the foregoing embodiments it is preferred that, when air is detected, the fluid and the air bubbles from the detector 5 is pumped back to the reservoir, metering chamber
5 or drip chamber through the return line 8. In another embodiment the pump 4 may be reversed so that the IV fluid and air bubbles in the air detector 5 are forced up the IV line 3 back to the reservoir, with fluid in the return line 8 replenishing that which has been pumped out of the detector 5. The disadvantage of such an embodiment is that the return
10 line 8 must be attached to the reservoir, metering chamber or drip chamber below the water-line; otherwise the pump will draw air into the return line instead of fluid, and, if the pumping continues long enough, this air will move into the IV line 3 and the air detector 5.

A disposable cassette may be used in the present invention. The cassette may include the disposable portions of the valves 6 and 7, the pump 4 and the air detector 5.
15 The pump 4 and the air detector 5 may use the same chamber--specifically, a pressure-conduction chamber--to perform the air detection and the pumping. The valves and pressure-conduction chamber disclosed in U.S. Patent No. 5,088,515, which is incorporated herein by reference, may be used as valves 6, 7 and/or 9, and for the air detector 5 and/or the pump 4. The body of the cassette is made of relatively rigid
20 material, such as a thermoplastic, and one or several flexible membranes are disposed on the rigid body to form the membranes of the valves and the pressure-conduction chamber. The flexible tube portions of the IV line 3 and the return line 8 may be connected to the rigid portion of the cassette, so as to communicate with the fluid passageways within the cassette. The disposable cassette is placed into a housing that can actuate the valves 7 and
25 8, and that can detect the presence of air and/or the amount of fluid in the pressure-conduction chamber.

FIG. 4 shows a preferred embodiment of the invention. In the FIG. 4 embodiment, a return line is not used, and the fluid containing the air is forced up the portion 31 of the IV line between the separation chamber--which is, in the depicted arrangement, the drip
30 chamber 12--and the air detector 5. As noted above, the embodiments shown in FIGS. 1, 2 and 3 can force the fluid containing the air up through the IV line, by introducing

additional fluid from below the air detector by the return line. In the FIG. 4 embodiment, the pressure-conduction chamber **50**, where the air is detected, is able to hold a maximum volume of fluid that is greater than the volume of fluid contained in the lumen **32** of the IV line's upper portion **31**. This arrangement permits all of the air that may be present in the IV fluid in the pressure-conduction chamber **50** to be forced up through the IV line's upper portion **31** to the drip chamber **12**, or other separation chamber. This arrangement limits the length of the IV line's upper portion **31**. If it is desired to have a longer upper portion **31** to the IV line, then the diameter of the upper portion's lumen **32** must be made smaller and/or the maximum volume of the pressure-conduction chamber must be increased. It is, however, undesirable to make the pressure-conduction chamber too large, because if it is too large the accuracy of the flow-rate measurements may be reduced.

As with the embodiments of FIGS. 1-3, the pressure-conduction chamber **50**, along with the portions of the valves **6**, **7** that come into contact with the IV fluid, are preferably located in a cassette, which is disposable along with the upper portion **31** and the lower portion **33** of the IV line. The rest of the hardware for detecting air is located in a housing that receives and holds the cassette, and which does not come into direct contact with the IV fluid. Hardware that may be used to detect air bubbles in pressure-conduction chamber **50** is described in U.S. Patent No. 5,349,852. A preferred embodiment of such an air-detection system uses a loudspeaker **81** mounted between two chambers **86**, **87**. The forward chamber **86** is connected to the cavity **84** that receives the pressure-conduction chamber **50** by a port **84** that is tuned for creating a resonance. The forward chamber **86** has a microphone **82** for detecting the resonance, and the rear chamber **87** has a microphone **83** for use in calibrating the air-detection system. This air-detection system can also function as a volume-measurement system, measuring the volume of the IV fluid in the pressure-conduction chamber **50** (as described for instance in U.S. Patent No. 5,349,852), so that the flow rate to the patient can be monitored and controlled.

The pressure-conduction chamber **50** containing the IV fluid is separated from the air (or other gas) in the housing's cavity **85** by a fluid-impermeable membrane **41**. By applying a pressure against this membrane **41**, such as by a pressure source **42** through the forward chamber **86** and the port **84** of the air-detection system, the fluid can be forced out of the pressure-conduction chamber **50**. If valve **6** is closed and valve **7** open, then the

IV fluid is pumped towards the patient. If air (or at least a previously set amount of air) is detected in the pressure-conduction chamber **50**, the control system causes outlet valve **7** to remain closed, opens inlet valve **6**, and activates the pressure source **42** so as to force the fluid up through the upper portion **31** of the IV line.

5 Preferably, the pressure-conduction chamber **50** is held so that the port **56** leading from the inlet valve **6** is located at the upper end of the chamber **50** so that any air bubbles are likely to be located near the port **56** when the pumping arrangement is activated to force the bubble up to the drip chamber **12**. Thus, when the pressure source **42** applies the pressure against the membrane **41**, the bubble will immediately be forced all the way to
10 the drip chamber **12**. A membrane **41** having a structure that collapses asymmetrically may be used to obtain an uneven collapse of the membrane **41** when gas pressure is applied from the pressure source **42**, wherein the collapse begins in the lower half of the membrane **41** so as to force the fluid and any bubbles in the bottom half of the chamber **50** to the top of the chamber, before the top portion of the membrane **50** collapses. When
15 the top portion of the membrane collapses, the fluid remaining in the chamber **50** is forced up through the upper portion **31** of the IV line **3**.

 If the bubble is large enough, not all of the bubble may have been forced all the way to the drip chamber **12** after the pressure source **42** has forced all of the IV fluid out of the pressure conduction chamber **50**. In such a situation, several iterations of the
20 purging process may be required. Specifically, after the membrane **41** is forced to the left as far as it can go so that no more fluid (including both the IV fluid and the air) can be forced out of the pressure-conduction chamber **50**, more IV fluid can be allowed to flow from the drip chamber **12** through the upper portion **31** of the IV line into the pressure-conduction chamber **50**, in order to fill the pressure-conduction chamber to its maximum
25 volume. A portion of the original air bubble or bubbles should have separated from this additional IV fluid in the drip chamber. This additional IV fluid can be allowed to flow to the pressure-conduction chamber **50** by force of gravity alone, or preferably the pressure source **42** (which can include a reciprocating piston, a pump, or positive- and negative-pressure sources) can provide a negative pressure to the membrane **41**, so as to draw IV
30 fluid into the pressure-conduction chamber **50** more quickly. The size of the air bubble should now be much smaller. If it is large enough to have a fault-condition signal

generated by the air detection system, valve 6 will be opened, and a positive pressure reapplied to the membrane 41 by the pressure source 42. What is left of the bubble is then forced up the IV line's upper portion 31, and some or all of the bubble should enter the drip chamber and separate from the IV fluid. If a portion of the bubble still remains in the
5 pressure-conduction chamber 50 after it is again refilled, the purging process is repeated.

The foregoing process is represented in the flowchart of FIG. 5. This process shows how air may be routinely purged from the IV fluid before reaching the patient and without requiring the intervention of any medical personnel. Although it is preferred to use the pumping mechanism (e.g., a peristaltic pump, or a pressure source 42 acting on
10 the membrane 41 as shown in FIG. 4), to draw fluid into the chamber 50 from the fluid source 1 or to force fluid to the patient, gravity may be used instead. Additional steps may be added to the process--after no air is detected and before the outlet valve 7 is opened, and then after the outlet valve 7 is closed and before the inlet valve 6 is opened--in order to measure the amount of fluid dispensed to the patient.

15 The present invention is useful for re-priming an IV line after an IV source 1 has emptied and been replaced. Frequently, in such situations the whole upper portion 31 of the IV line may be filled with air. (With the present invention, the air-detection system should have kept the IV line's lower portion 33 filled with IV fluid.) Once the new IV source 1 is provided, air in the pressure-conduction chamber 50 is forced up through IV
20 line's upper portion 31. IV fluid from the source 1 should be present in the drip chamber 12, so that when the system draws fluid down to the pressure-conduction chamber, at least some of that fluid should be IV fluid. The air and the IV fluid are then forced out of the pressure-conduction chamber 50 again--with the air being forced out first since the liquid should have fallen to the bottom of the pressure-conduction chamber 50. Once again,
25 fluid is drawn into the pressure-conduction chamber 50, and since the air should have separated from the liquid in the drip chamber 12, more IV fluid should be drawn into the pressure-conduction chamber 50 than before. These steps are repeated until the air detector senses that the pressure-conduction chamber 50 is filled with IV fluid without any air bubbles (or until the amount of air is sufficiently low).

30 In the situation where the air bubble is not located near the inlet port 56 but instead is sticking to the membrane 41 or the wall of the pressure-conduction chamber 50, several

repetitions of forcing fluid up and down the IV line's upper portion **31** will usually dislodge the bubble, thereby allowing the bubble to float up towards the inlet port **56** which should be at the top of the pressure-conduction chamber. Once the bubble moves near the inlet port **56**, it should be forced out of the pressure-conduction chamber **50** with the next purge of fluid up the IV line's upper portion **31**.

Preferably, the inlet port **56** is shaped so that a small bubble will not tend to stick to an edge of the port while allowing liquid to flow past it. If the bubble is large, it is likely that at least a portion of it will be forced up through the IV line's upper portion **31**, regardless of the port's shape; a small bubble, however, may be more difficult to dislodge. (Small bubbles are less of a concern than large bubbles, so the air-detection system may be calibrated to ignore bubbles that are small enough.) To prevent such sticking of a small bubble, the port **56** preferably flares out so that the corner where the port **56** meets the inner wall of the pressure-conduction chamber **50** is greater than 90° , making the corner less likely a place where the bubble will stick. However, the mouth of the port **56** cannot be so large that liquid can easily flow by the bubble when fluid is exiting the pressure-conduction through the port **56**. In order to accomplish this, the port must be sized and shaped so that the surface tension of the IV fluid being forced upward from the pressure-conduction chamber **50** forces a bubble located at the port **56** up through the inlet valve **6**. It is also preferable that the port **56** be sized and shaped so that when liquid is pulled back into the pressure-conduction chamber **50**, the bubble can hover near the port as liquid passes around it. A preferred inlet port **56** shape is shown in FIGS. 6 and 7. The port's size increases from the end **57** that connects to the IV line's upper portion **31** to the end **58** leading into the pressure-conduction chamber. FIG. 8 shows a cross-section of the inlet valve **56**. Since the pressure-conduction chamber is preferably curved--and preferably generally hemispherical--in order to make it easier for the pressure-conduction chamber's membrane (item **41** in FIG. 4) to force as much fluid as possible out of the pressure-conduction chamber, the mouth at the chamber end **57** of the port **56** is curved. It has been found that providing an inlet port to the pressure-conduction chamber with this shape improves the air-elimination system's ability to purge bubbles from the chamber.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various

modifications can be made without departing from the spirit and the scope of the invention , as set forth in the claims hereinbelow.

What is claimed is:

1. An air-elimination system, for a fluid delivery system for injection of intravenous fluid into a patient, comprising:
 - separation means for permitting the separation of air from the intravenous fluid;
 - 5 an intravenous line in fluid communication with the separation means;
 - air-detection means, disposed in the intravenous line, for detecting air in the fluid and emitting a fault-condition signal, the intravenous line having a first portion between the separation means and the air-detection means, and a second portion between the air-detection means and the patient;
 - 10 valve means, disposed in the intravenous line's second portion, for permitting or preventing flow to the patient;
 - pump means for urging fluid towards the separation means upon activation; and control means, in communication with the air-detection means, for (i) setting the valve means to prevent flow to the patient and activating the pump means, so as to move the
 - 15 fluid containing air from the air-detection means to the separation means, in response to a fault-condition signal, and otherwise (ii) setting the valve means to permit flow to the patient;
 - wherein the pump means includes a chamber disposed in the intravenous line upstream from the valve means, wherein pressure may be applied to the fluid in the
 - 20 chamber; and
 - wherein the intravenous line's first portion has a first volume, the chamber has a second volume, the first volume is less than the second volume, and the pump means upon activation causes the intravenous fluid in the chamber to flow into the intravenous line's first portion.
 - 25
2. A system according to claim 1, wherein the air-detection means tests for the presence of air in the chamber of the pump means.
3. A system according to claim 2, wherein the air-detection means includes
- 30 flow-measurement means for measuring fluid flow rate.

4. A system according to claim 3, wherein control means includes means for, in the absence of a fault-condition signal, setting the valve means to permit flow to the patient and activating the pump means, so as to move fluid to the patient through the intravenous line's second portion.

5

5. A system according to claim 1, wherein control means includes means for, in the absence of a fault-condition signal, setting the valve means to permit flow to the patient and activating the pump means, so as to move fluid to the patient through the intravenous line's second portion.

10

6. A system according to claim 1, wherein the separation means includes a metering chamber.

7. A system according to claim 1, wherein the separation means includes a
15 drip chamber.

8. A system according to claim 1, wherein the separation means includes an intravenous fluid reservoir.

20 9. An air-elimination system, for a fluid delivery system for injection of intravenous fluid into a patient, comprising:

separation means for permitting the separation of air from the intravenous fluid;

an intravenous line in fluid communication with the separation means;

25 air-detection means, disposed in the intravenous line, for detecting air in the fluid and emitting a fault-condition signal, the intravenous line having a first portion between the separation means and the air-detection means, and a second portion between the air-detection means and the patient;

valve means, disposed in the intravenous line's second portion, for permitting or preventing flow to the patient;

30 pump means for urging fluid towards the separation means upon activation; and control means, in communication with the air-detection means, for (i) setting the valve

means to prevent flow to the patient and activating the pump means, so as to move the fluid containing air from the air-detection means to the separation means, in response to a fault-condition signal, and otherwise (ii) setting the valve means to permit flow to the patient;

- 5 wherein the pump means includes a supply of liquid for forcing the fluid containing air up the first portion of the intravenous line to the separation means; and
 wherein the pump means includes a chamber for holding fluid, and the pump means's supply of liquid is intravenous fluid held in the chamber.

10 10. A system according to claim 9, wherein the air-detection means test for the presence of air into the pump means's chamber, and the pump means, upon activation, forces fluid containing air out of the chamber upstream through the first portion of the intravenous line.

15 11. A method for eliminating air from an intravenous fluid delivery system, comprising the steps of:

- providing a separation chamber where air may separate from the fluid;
- providing an intravenous line downstream of the separation chamber;
- providing an air detector in the intravenous line;

20 providing a pump in the intravenous line;

- providing a valve in the intravenous line downstream of the pump and the air detector;
- using the air detector to detect air in the fluid;
- generating a signal when a specified amount of air is detected in the fluid;

25 closing the valve in response to the signal;

- using the pump to urge fluid upstream through the intravenous line to the separation chamber in response to the signal; and
- wherein the intravenous line has a volume capacity of fluid between the pump and the separation chamber, the pump has a volume capacity of fluid, and the pump's volume

30 capacity is greater than the volume capacity of the intravenous line between the pump and the separation chamber.

12. A method according to claim 11, wherein after the pump is used to urge the fluid upstream to the separation chamber, the pump is used to draw additional fluid from the separation chamber to the pump while the valve is kept closed.

5 13. A method according to claim 12, wherein after the pump is used to draw additional fluid and while the valve is kept closed, the air detector is again used to detect air in the fluid and generates a signal when a specified amount of air is detected in the fluid, and upon this signal, the pump again forces the fluid to the separation chamber.

10 14. A method according to claim 13, wherein the signal is generated when any air is detected in the fluid.

15 15. An air-elimination system, for an intravenous fluid delivery system for intravenous injection of fluid into a patient, comprising:

a separation chamber where air may separate from the fluid;

an intravenous-fluid conduit in fluid communication with the separation chamber and the patient;

a pressure-conduction chamber disposed in the conduit, the intravenous conduit having a first portion between the separation chamber and the pressure-conduction chamber, and a second portion between the pressure-conduction chamber and the patient;

20 a detector of air in the intravenous-fluid conduit in the pressure-conduction chamber, wherein the detector emits a fault-condition signal upon the detection of air in the pressure-conduction chamber;

a valve disposed in the intravenous conduit's second portion;

25 pressure-generation means for urging fluid out of the pressure-conduction chamber upon activation; and

a controller, in communication with the air detector, for controlling the valve and activating the pressure-generation means.

30 16. A system according to claim 15, wherein the volume of the conduit's first portion is less than the pressure-conduction chamber's volume.

17. A system according to claim 16, wherein the pressure-generation means includes means for drawing fluid into the pressure-conduction chamber.

18. A system according to claim 16, wherein the pressure-conduction chamber
5 is defined at least in part by a membrane, the membrane having first and second faces, the first face being in contact with the intravenous fluid, and wherein the pressure-generation means provides a supply of gas in contact with the membrane's second face.

19. A system according to claim 18, wherein the membrane has a structure that
10 causes the membrane to collapse asymmetrically such that the membrane collapses first in the chamber's lower half.

20. A port for the removal of air bubbles in a liquid from a chamber, the port increasing in cross-sectional area nearer the chamber so as to reduce the likelihood that a
15 bubble will stick to an edge of the port, and the port being shaped and sized so that, when the liquid forced out from the chamber through the port, the liquid's surface tension forces a bubble located at the port through the port without allowing the liquid to flow by the bubble easily.

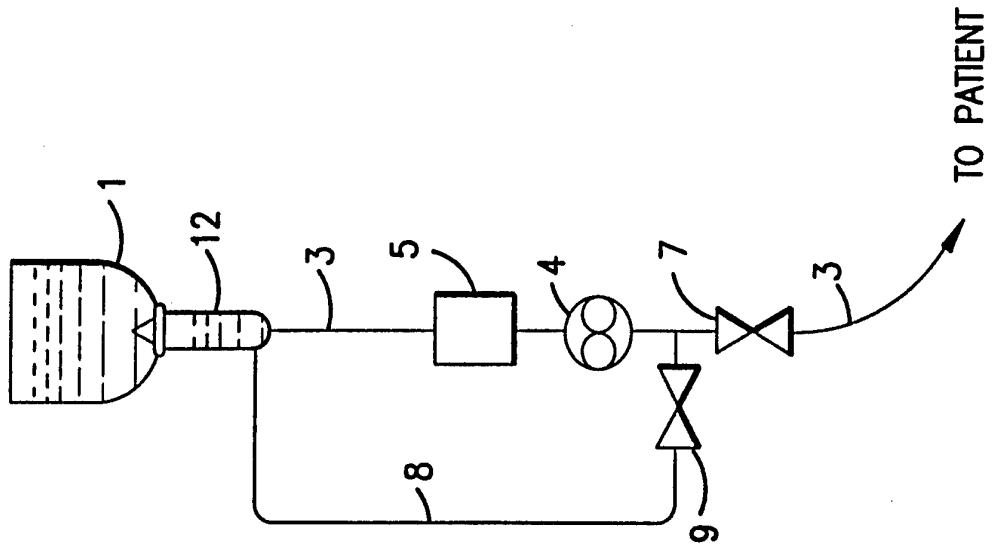


FIG. 2

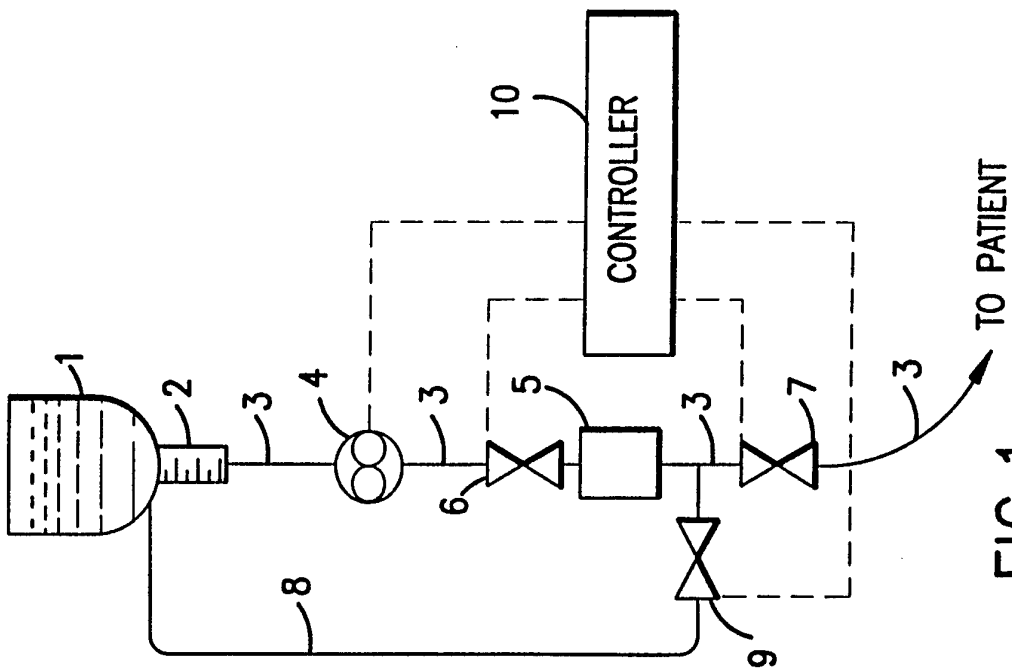
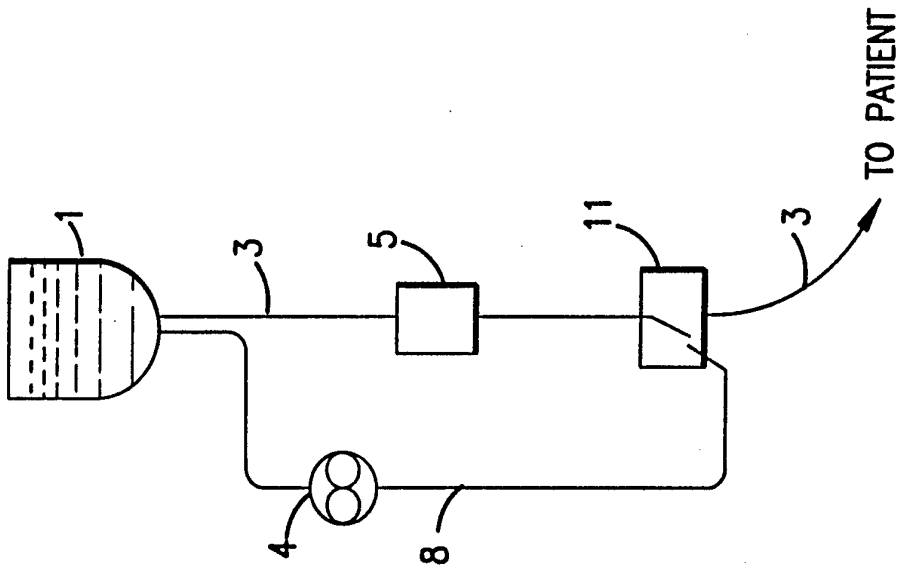
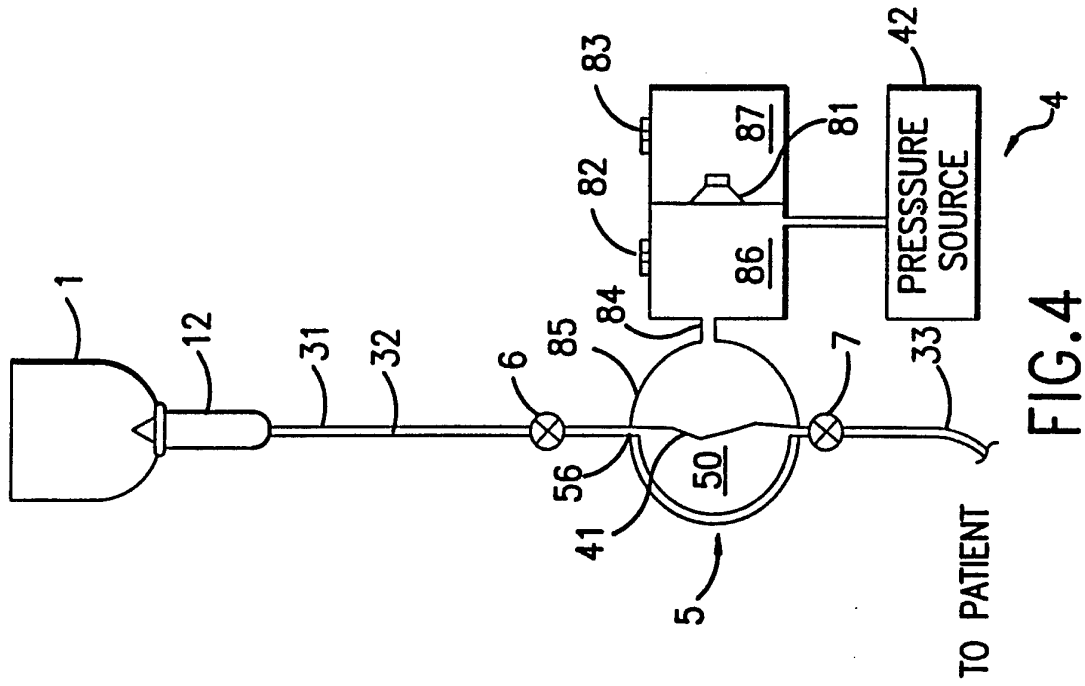


FIG. 1



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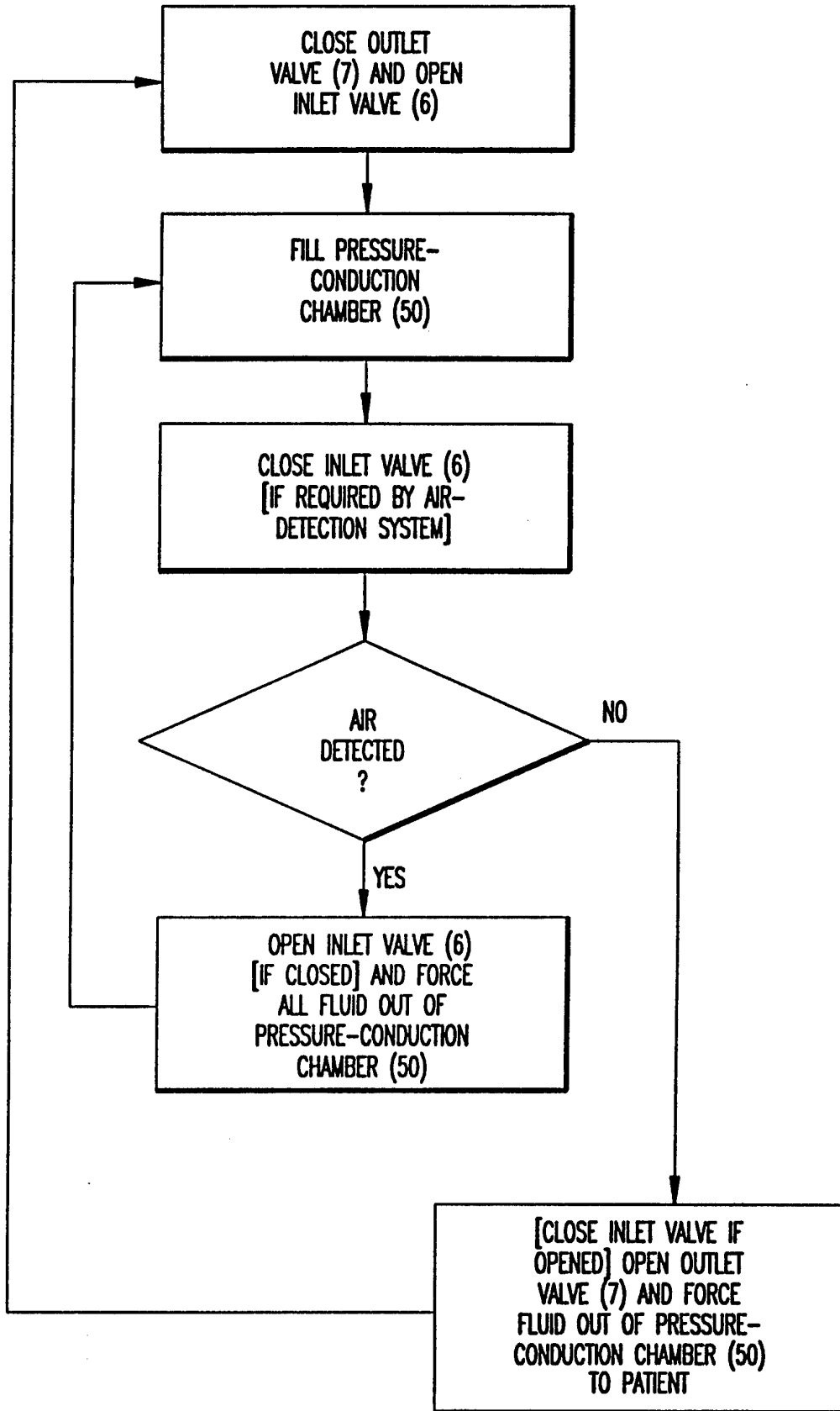


FIG.5

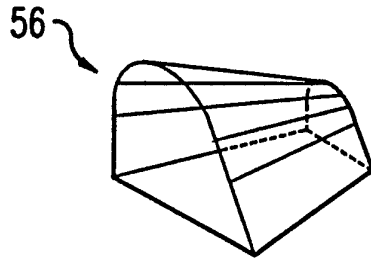


FIG. 6

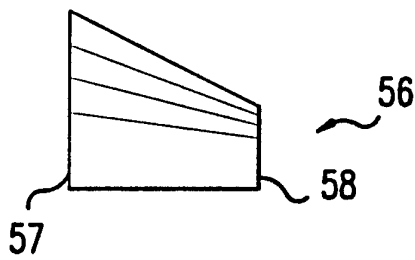


FIG. 7

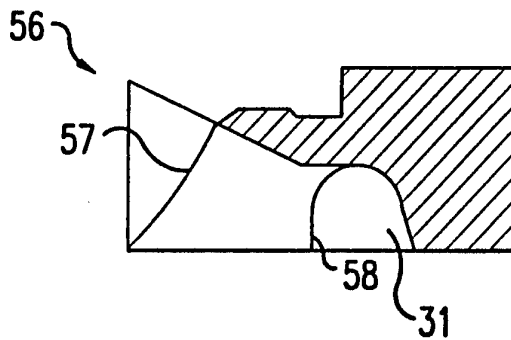


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/06621

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | see abstract; figures see column 2, line 49 - column 4, line 6 --- | 1,11 |
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| | -/-- | |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *&* document member of the same patent family

Date of the actual completion of the international search

11 September 1996

Date of mailing of the international search report

19. 09. 96

Name and mailing address of the ISA

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Fax (+ 31-70) 340-3016

Authorized officer

Zeinstra, H

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INTERNATIONAL SEARCH REPORT

national application No.

PCT/US 96/06621

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 1-19 Air elimination system with air detector, and method
2. Claims: 20 Port for the removal of air bubbles

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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