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Rosenberg

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[54] **AUTOTRANSFUSION APPARATUS**

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[73] Assignee: **Pall Corporation**, Glen Cove, N.Y.

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[52] **U.S. Cl.** ..... **128/214 R**; 128/276

[51] **Int. Cl.** **A61m 05/00**; A61m 01/03

[58] **Field of Search** ..... 128/214 R, 214 C, 214.2, 128/276, 278

[56] **References Cited**

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Primary Examiner—Dalton L. Truluck

[57] **ABSTRACT**

A continuous-flow two-reservoir fluid medicament- or blood-feed system is provided, for administration of such fluids to patients, composed of two reservoirs, each filled by way of check valves from a common supply, and with common connections to a vacuum line. Application of vacuum draws the fluid from the supply into one of the reservoirs, while fluid is led from the other reservoir to the patient. When the first reservoir is full and the other empty, fluid is led from the filled reservoir, and the other empty reservoir is now refilled, while fluid flow to the patient can be continuous.

15 Claims, 4 Drawing Figures

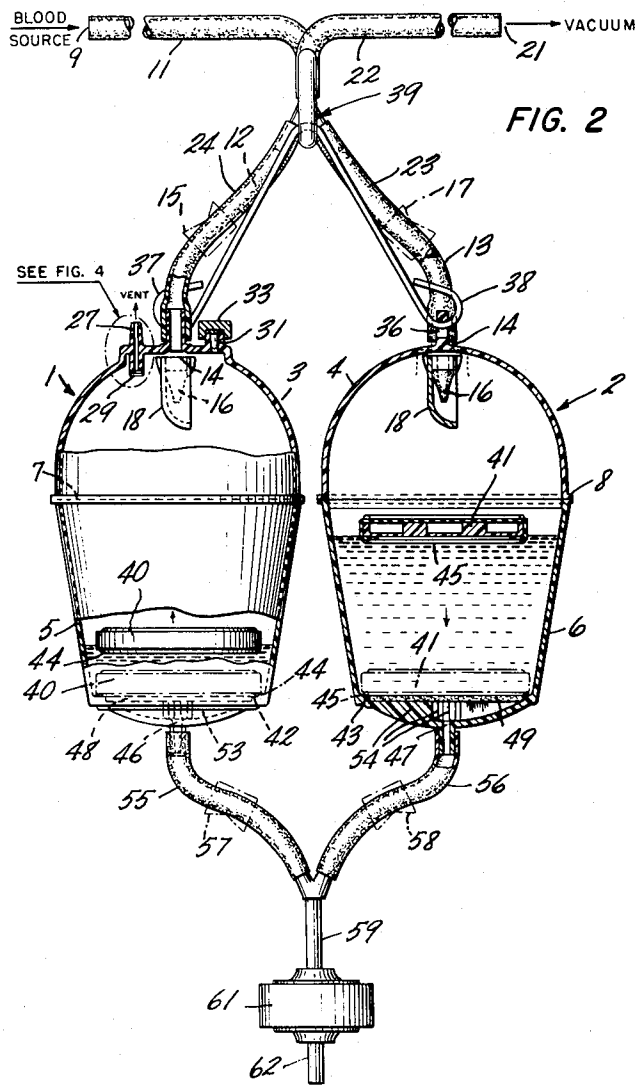
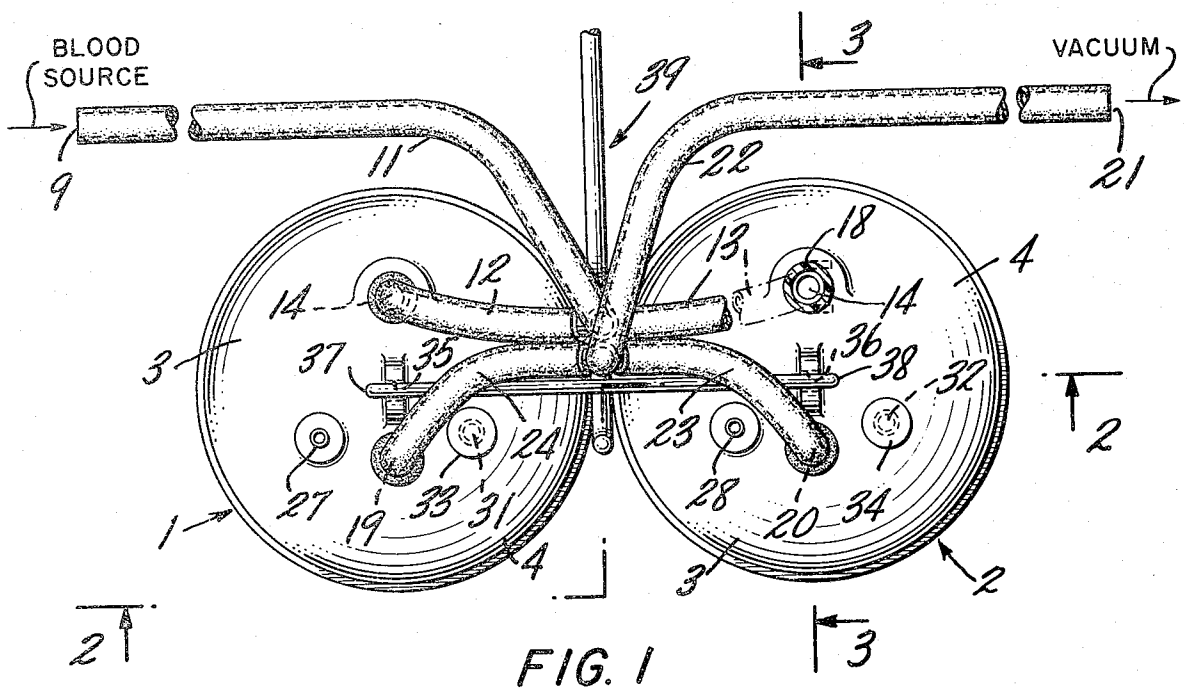


FIG. 2


BLOOD SOURCE
VACUUM
9
11
39
3
22
21
18
13
4
12
14
14
3
37
35
36
38
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2
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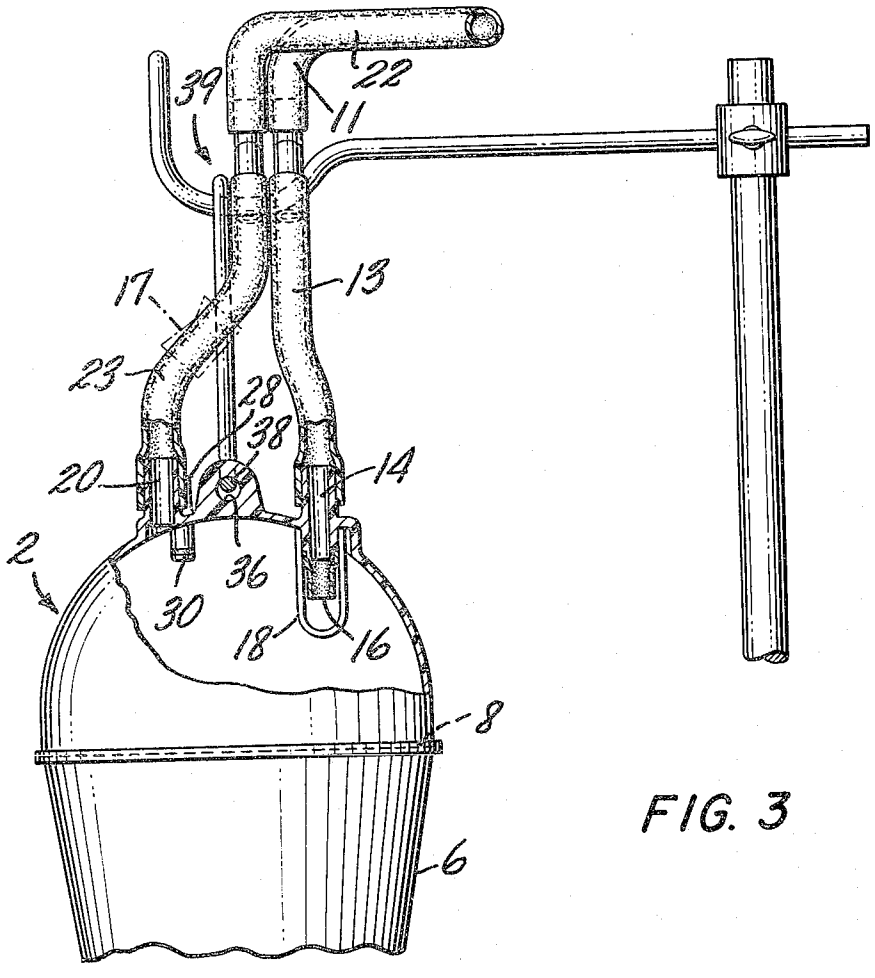
FIG. 1


39
22
11
17
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23
28
38
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14
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6

FIG. 3

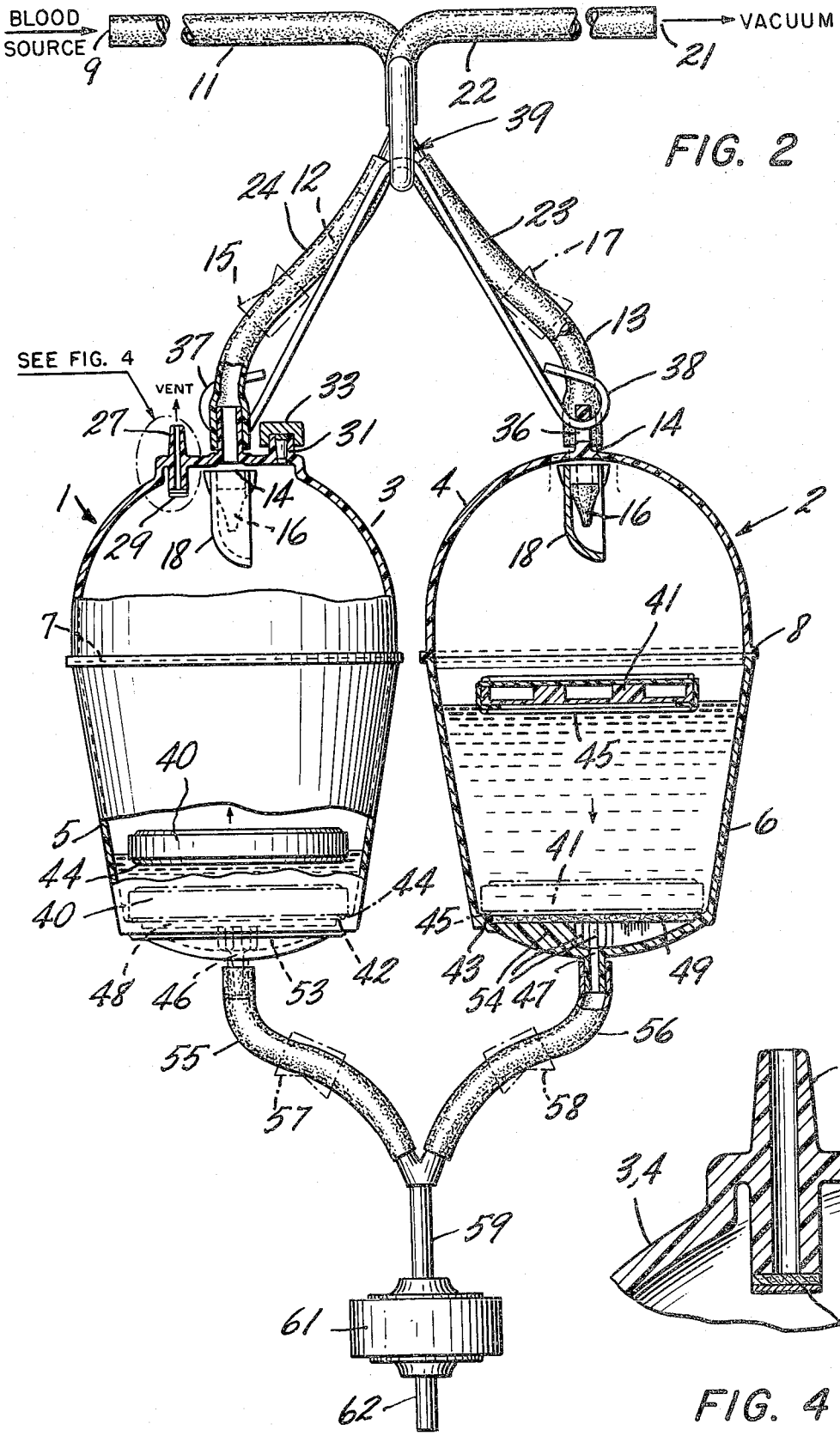

FIG. 2

FIG. 4

AUTOTRANSFUSION APPARATUS

During surgery, the surgeon has the choice of discarding the blood removed from the patient in the course of the operation and replacing it by donor blood, or of salvaging and reinfusing the patient's own blood. The former technique is generally referred to as blood transfusion, although in fact the term is generic to both cases, while the salvaging and reuse of the patient's own blood is referred to as autotransfusion.

In many cases, of course, autotransfusion is not applicable, and donated blood must be used. If available, however, autotransfusion has a number of advantages. The blood used needs no time-consuming typing or cross-matching. It is inexpensive, warm and fresh, and contains prime factors and bactericidal properties which are absent in banked donor blood. Moreover, blood lost in hemorrhages during surgery can also be collected and reinfused, which practically eliminates hemorrhaging as a dangerous problem in the course of surgery. In addition, there are virtually no fatal reactions, and nonfatal reactions are noted in only a small percentage of cases.

According to Dyer, (*Amer. J. of Surgery*, Vol. **112**, Dec. **1966, 874–878**), the intraoperative autotransfusion technique originated in **1874,** when Highmore surmised, after seeing a patient become exsanguinated after a postpartum hemorrhage, that he might have been able to save the patient if he could have collected, defibrinated, and reinfused the blood.

In **1885,** Duncan employed intraoperative autotransfusion on a patient with a traumatic leg amputation, and was successful. Later, techniques were developed using mopping, lading, bulb suction and line suction to collect the blood, with citrate or hemodilution as an anticoagulant, and cheesecloth and fine gauze as a filter. The blood was processed in rooms adjacent surgery, and returned for reinfusion. These techniques were remarkably successful, and interest in autotransfusion increased as a result during the period from **1914** to the early **1940**s.

However, during the period since World War II, interest in autotransfusion decreased as the use of donor blood transfusions increased, possibly assisted by ready availability of donated blood.

In **1951,** Stager ["Blood Conservation by Autotransfusion," *Arch, Surg.* **63, 78 (1951)**] and later, Weekes, Stone and McCann ["A Plea for Autotransfusion," *U. Obst. & Gynaec. Brit. Emp.* **16, 7 (1960)**] advocated a closed system of autotransfusion, using an improvised setup incorporating a conventional donor transfusion bottle into a tonsil suction system. Blood foaming, introduced by suction, was minimized by floating glass balls which served to catch fibrin. Although there was some hemolysis caused by vacuum, this was well tolerated in the tests carried out by Stager.

Ferrara ["Autotransfusion, Its Use in Acute Hemothorax," *South. M. J.*, **50, 516 (1957)**] reported successful closed autotransfusion in acute hemothorax and hemoperitoneum via trocar thoracostomy and peritoneal tap. According to Lamm ["Emergency Autotransfusion Before Laparotomy," *J.A.M.A.* **185, 1043 (1965)**] autotransfusion is also being used in coronary sinus suction in cardiac bypass.

One of the difficulties in the application of autotransfusion techniques has been the lack of suitable apparatus. Dyer, in his article in the *American Journal of Surgery* referred to above, set forth the standards and criteria for autotransfusion apparatus:

"Unquestionably, an available means of emergency, intraoperative autotransfusion for general use would be a timely asset to the patient, surgeon, and hospital. Such an apparatus must meet certain standards and criteria before it would be used.

An autotransfusion apparatus must simultaneously collect, measure, and process blood from a body cavity without disturbing the surgical field; it must work simply, rapidly, and safely to anticoagulate, defoam, defat, filter, and redeliver the blood. It must be capable of handling large as well as small volumes for the entire procedure.

The apparatus must be simple, safe, and inexpensive and should be compact, easily stored, and unbreakable. It must be able to be set up for use immediately, well in advance of procurement of available donor blood. It should cause no more hemolysis than is found when administering donor blood form a bank.

The apparatus should be a closed system, available in any operating room for use by regular operating room personnel."

In an endeavor to meet these requirements, Dyer proposed in the article and in U.S. Pat. No. **3,492,991,** patented Feb. **3, 1970,** an autotransfusion apparatus based on one or two chambers of a capacity from **600** to **1,000** ml. The chambers are cylindrical, with both ends closed off by rubber or plastic seals. The upper plug is provided with a minimum of three ports, a first to apply vacuum to the container, a second to provide an inlet for blood from the operative field or source of blood, and a third open to the atmosphere to permit emptying of the chamber of blood. To prevent foaming of the blood, the inner surface of the chamber is coated with an antifoaming agent, or the chamber can also be filled or partially filled with a coarse metal or plastic wool, surface-treated with silicone. A fine wire screen is placed over the exit port of each chamber to act as a filter to remove fibrin or other debris from the blood. Another filter is provided in blood-recipient apparatus connected to the outflow.

In the two-chamber system shown in FIG. **3** of the article and in FIG. **3** of the patent, a dual tubing system connects the two chambers to the vacuum line, the blood suction line, and the medication line, and surgical clamps or other conventional clamping means are used for closing the lines in a manner to permit the chambers to be used alternately, so that blood is delivered from one chamber while the other is being filled.

The two-chamber apparatus has certain advantages over the single chamber. In the single chamber, it is difficult to add measured amounts per unit volume of anticoagulant or other medicament to the blood. It is also difficult to measure the amount of blood delivered, except by shutting off the unit when it has been emptied, and then refilling it, which of course interrupts the flow of blood during the refilling.

In the two-chamber system, these problems are avoided since one chamber can be on-stream while the other is being filled, and the amount of anticoagulant is easily measured according to the volume of blood in the container before the chamber is put on-stream. However, the two-chamber system also presents problems. It is necessary to close off all lines not on-stream, to prevent cross-flow between the chambers during application of vacuum to one chamber. All of the valves

are manually operated, and their operation has to be carefully synchronized, so as to maintain flow, and prevent flow of air to the patient when the chamber on-stream becomes empty. The system thus requires continuous attention. During an operation, it is not always certain that attention can be given to the apparatus at the time when it is required, which is precisely when the chamber on-stream is empty, not sooner, and not later.

In accordance with the invention, an improved autotransfusion apparatus is provided, having two chambers, with simplified control of the cycling of the flow of fluid between the chambers, and safeguards to prevent cross-flow between the chambers, and passage of air to a patient from an empty chamber. As soon as one chamber is empty, influent fluid flow can be switched to the empty chamber, while the previously filled chamber is put on-stream, without danger of drawing air from the chamber that is filled into the chamber being filled. When this chamber on-stream is empty, the filled chamber is put on-stream, and so the chambers are cycled alternately, to maintain a continuous flow of blood from the apparatus. The apparatus also includes a device for controlling and inhibiting foaming during entry of fluid into each chamber.

The apparatus in accordance with the invention comprises, in combination, first and second fluid chambers each having a fluid inlet, a fluid outlet, a line connection to a source of vacuum, and a vent connection to atmospheric pressure; a check valve at the fluid inlet restricting flow through the inlet line to flow towards the chamber at fluid pressures within the chamber below the pressure in the inlet line; optionally, a check valve at the fluid outlet, restricting fluid flow through the outlet except at a higher downstream fluid pressure, a vent in each chamber that is open to the atmosphere at all times; and means for alternately opening and closing the vacuum line to each chamber, in synchronization, so that when the vacuum line is open to the first chamber it is closed to the second; and when the vacuum line is closed to the first chamber, it is open to the second.

The vent in each chamber is preferably provided with a flow-resistant filter having a pore size such that bacteria cannot pass through it, restricting flow into the chamber from the atmosphere so that a vacuum can be drawn on the chamber without closing the vent. Thus, the vent is open so the atmosphere at all times, and allows the chamber to reach equilibrium with atmospheric pressure when vacuum is not applied.

A suitable flow-resistant filter is glass cloth coated with polytetrafluoroethylene and adhered to a paper base, having a pore size of less than 3 microns and an open area less than 5%, but any porous material of comparable pore size and open area can be used.

The filter can be made hydrophobic or nonwetted by the liquid in the system so as not to accept blood or other medicament in its pores and thus block the passage of air therethrough.

The fluid is provided with a deflector directing inlet flow to impinge upon a wall of the chamber, so as to flow in a thin film down the wall, and afford an extended surface area for defoaming, thereby avoiding the need for a defoaming agent. The deflector can take the form of a turned end of the inlet tube, or the inlet tube outlet can be directed towards a wall of the chamber, and can be specially shaped to provide a wide thin film of fluid flowing along the wall.

The apparatus also includes, in each chamber, a float valve, which moves on and with the fluid level in the chamber, and when the fluid level sinks to the level of the valve seat at the bottom of the chamber, the float valve sinks into sealing engagement with the valve seat, and closes off the fluid outlet from the chamber. This prevents air from entering the outlet line leading to the patient.

The float valve can take the form of a disc, which is free in the chamber, and is light enough to float on the surface of the fluid. The disc can be provided with a resilient peripheral ring which seals flat on its lower surface against an annular valve seat surrounding the outlet. A suitable material is a polypropylene or other low density plastic with a rubber sealing ring about its periphery.

At the outlet from each chamber, below the valve seat, a coarse filter is provided, to prevent obstruction of the outlet line. A nonwoven plastic fiber cloth can be used, such as a bonded glass, nylon or polyester fiber mat.

The means for alternately closing and opening the vacuum lines to the chamber in synchronization can be manually operated, such as clamps or valves, but for fully automatic operation, such means is operated by a photoelectric level detector or a float in each chamber, actuating the means when the chamber is empty, to switch the cycle so that the filled chamber is put on-stream and the empty chamber is put on the filling cycle.

A preferred embodiment of the invention is shown in the drawings, in which:

FIG. 1 is a top view of an autotransfusion apparatus.

FIG. 2 is a side view, partly in section, taken along the line 2—2 of FIG. 1.

FIG. 3 is another side view, partly in section, taken along the line 3—3 of the autotransfusion apparatus of FIG. 1.

FIG. 4 is a detailed view of the vent and filter combination encircled in dashed lines in FIG. 2.

The apparatus shown in the Figures comprises two thermoplastic blood reservoirs 1 and 2 of polycarbonate, each in upper 3, 4 and lower 5, 6 sections, fused together at the seam 7, 8. Each reservoir is connected to a source of blood 9 by way of fluid lines 11, 12, 13, entering the top of blood reservoirs 1, 2 at inlets 14, each of which is provided with and terminates in a deflector 18 directing blood flow against the wall of the upper sections 3, 4 of the reservoirs. The reservoirs are also connected at their tops at outlets 19, 20 to a source of vacuum 21 by way of lines 22, 23, 24, with two clamps 15, 17 controlling the application of vacuum to one reservoir at a time; or completely closing off both reservoirs from the vacuum, as desired. One three-way clamp can also be used instead of clamps 15, 17. The clamps are arranged to be operated manually, but operation can also be controlled by an automatic mechanism.

Each reservoir at the top is further provided with a vent 27, 28 which is in the form of a male Luer tip, and is open to the atmosphere. The vents are each provided with a filter 29, 30 (best seen in FIG. 4) which restricts flow into the reservoirs from the open atmosphere, to permit maintaining a partial vacuum in the reservoir. The vents also allow the reservoirs to reach atmo-

spheric pressure when vacuum is not applied, such as when the reservoir is discharging blood or other fluid to the patient.

Also provided at the top of each reservoir is a medicament inlet **31, 32,** with a female Luer socket for addition of anticoagulant or other composition to the contents of the reservoir. Each inlet is closed by cap **33, 34,** when not in use.

There is also an integral eye **35, 36** on each reservoir, which receives the hooks **37, 38** for suspending the reservoirs from an IV stand **39.**

Within each reservoir is a float valve **40, 41,** which floats freely on the surface of the fluid in the reservoir. At the bottom of each reservoir is a valve seat **42, 43** and about the external periphery of the float valve, which is a disc of polypropylene or other low density plastic, is a sealing ring **44, 45** of resilient material such as rubber. This seals at its lower surface against the valve seat **42, 43,** to close off the outlets **46, 47.** Across the outlet line below the valve seat is a filter **48, 49,** which is supported on a recess **51, 52** and on a plurality of ribs **53, 54** projecting upwardly from the bottom wall of lower section **5, 6** and radially about the outlets **46,** 47. The filters **48, 49** are nonwoven mats of polyester fiber.

Extending from the outlets **46, 47** are outlet lines **55,** 56 each of which is provided with a manually operated clamp **57, 58,** but check valves such as duckbill valves can be provided instead. A three-way clamp can also be used, and can be automatically operated, if desired. The lines **55, 56** join into line **59,** which leads to a further filter **61,** such as a filter for microemboli, in the case of blood. From the filter, the line **62** leads to the patient, by way of standard administration set.

Operation of the device is as follows. Let it be supposed that reservoir **1** is empty, and reservoir **2** filled. (In the Figures, reservoir **1** is being filled, and reservoir **2** is being emptied, so that the apparatus as shown is shortly beyond this point in time.) Anticoagulant first is added through the inlet **31** into reservoir **1,** and the cap **33** is replaced. Then, clamp **15** is opened and clamp **17** is closed, so that vacuum is applied to reservoir **1** but not to reservoir **2.** Clamp **57** is closed, while clamp **58** is opened, so that under a head of pressure of blood in reservoir **2,** the blood flows by gravity from the bottom of the reservoir through filter **49** and outlet **47** via lines **56, 59** to the filter **61,** and then through line **62,** to the patient or other reference point to which blood is to be supplied. The vent **28** is always open, permitting such flow freely; and since the vent is protected by the bacteria filter **30,** the interior of the reservoir **2** remains sterile.

Meanwhile, vacuum from the source **21** is applied to reservoir **1** so that blood is drawn from the supply **9** through lines **11** and **12,** and duckbill valve **16** and deflector **18** into the reservoir. The blood is projected against the wall of the upper section **3,** and courses down the wall in a thin film allowing the foam to break and the air to escape. The filling operation continues until the reservoir contains one unit of blood. As the blood level rises in the reservoir, the float valve **40,** which has already been dislodged by the application of vacuum, rises, and opens the outlet **46,** but the clamp **57** is closed, so flow from the reservoir cannot begin. Then, the clamp **15** is closed so as to close off the application of vacuum to the reservoir. If reservoir **2** is still not empty, the clamp **57** can remain closed until it is. When reservoir **2** is empty, the clamp **17** is opened so as to apply vacuum to reservoir **2** and the clamp **57** is opened so that the feed of blood begins from reservoir **1.** Clamp **58** is closed. Now blood is drawn from the supply **9** through lines **11** and **13** into reservoir **2.** This continues with the blood feed continuing from reservoir **1** through outlet **46,** lines **55** and **59** to filter **61** to the patient. When reservoir **2** is filled, the clamp **17** is closed and clamp **15** is opened so as to put reservoir **1** on-stream as before, and the cycle is then repeated. Throughtout the cycle, however, blood has been continuously supplied to filter **61** and lines **62.**

If desired, by automatic operation of the clamps **15,** 17, 57 and **58,** the device can be made entirely automatic with a continuous blood flow to the patient.

The device shown is most useful for the continuous supply of blood either in transfusion or in operations in which blood circulation systems are used. The device can also be employed for the administration of any kind of medicament to a patient from a source of supply, and ensures continuous administration of the medicament while the supply remains filled.

If desired, the filter **61** in line **59** can be replaced by two filters which are placed in lines **55, 56,** before the point of junction with line **59.** In this event, the clamps **57, 58** would follow the filters, rather than precede it, as in the device shown.

While the check valves shown in the drawing are of the duckbill type, any type of check valve can be used, including unbrella valves, flap valves, and poppet valves.

Having regard to the foregoing disclosure, the following is claimed as the inventive and patentable embodiments thereof:

1. An autotransfusion apparatus shaving two chambers with simplified control of the cycling of the flow of fluid between the chambers and safeguards to prevent cross-flow between the chambers and passage of air to a patient from an empty chamber, comprising, in combination, first and second fluid chambers each having a fluid inlet, a fluid outlet, a line connection to a source of vacuum, and a vent connection to atmospheric pressure; the vent being provided with a flow-resistant filter having a pore size such that bacteria cannot pass through it, and restricting flow into the chamber from the atmosphere so that a vacuum can be drawn on the chamber without closing the vent, while allowing the chamber to reach equilibrium with atmospheric pressure when vacuum is not applied; the filter not being wetted by the liquid in the system so as not to accept blood or other medicament in its pores and thus block the passage of air therethrough; a check valve at the fluid inlet restricting flow through the inlet line to flow towards the chamber at fluid pressures within the chamber below the pressure in the inlet line; and means for alternately opening and closing the vacuum line to each chamber, so that when the vacuum line is open to the first chamber it is closed to the second; and when the vacuum line is closed to the first chamber, it is open to the second.

2. An autotransfusion apparatus according to claim **1,** having a check valve at the fluid outlet, restricting fluid flow through the outlet except at a higher upstream fluid pressure.

3. An autotransfusion apparatus according to claim **1,** having a vent in each chamber that is open to the atmosphere at all times.

4. An autotransfusion apparatus according to claim 1, in which the flow-resistant filter has a pore size of less than 3 microns and an open area less than 5%.

5. An autotransfusion apparatus according to claim 1, having two chambers with simplified control of the foaming of fluid entering the chambers in which the fluid inlet directs flow to impinge upon a wall of the chamber; so as to flow in a thin film down the wall, and afford an extended surface area for defoaming.

6. An autotransfusion apparatus according to claim 5, having a deflector at the inlet end of the fluid inlet.

7. An autotransfusion apparatus according to claim 6 in which the deflector is a turned end of the inlet tube.

8. An autotransfusion apparatus according to claim 5 in which the inlet tube outlet is directed towards a wall of the chamber.

9. An autotransfusion apparatus according to claim 1, having two chambers with simplified prevention of the passage of air to a patient from an empty chamber, comprising, a float valve in each chamber, moving on and with the fluid level in the chamber, and a valve seat at the bottom of the chamber, so that when the fluid level sinks to the level of the valve seat, the float valve sinks into sealing engagement with the valve seat, and closes off the fluid outlet from the chamber, preventing air from entering the outlet.

10. An autotransfusion apparatus according to claim 9 in which the float valve is a disc, which is free in the chamber, and is light enough to float on the surface of the fluid, and is provided with a resilient peripheral ring which seals against a valve seat on its lower surface, and an annular valve seat surrounding the outlet, against which the ring seals.

11. An autotransfusion apparatus according to claim 9 in which, at the outlet from each chamber, below the valve seat, a coarse filter is provided, to prevent obstruction of the outlet line.

12. An autotransfusion apparatus according to claim 11 in which the coarse filter is a nonwoven plastic fiber cloth.

13. An autotransfusion apparatus having two chambers with simplified control of the cycling of the flow of fluid between the chambers and safeguards to prevent cross-flow between the chambers and passage of air to a patient from an empty chamber, comprising, in combination, first and second fluid chambers each having a fluid inlet, a fluid outlet, a line connection to a source of vacuum, and a vent connection to atmospheric pressure provided with a flow-resistant filter having a pore size such that bacteria cannot pass through it; a check valve at the fluid inlet in each chamber, restricting flow through the inlet line to flow towards the chamber at fluid pressures within the chamber below the pressure in the inlet line; the fluid inlet directing inlet flow to impringe upon a wall of the chamber, so as to flow in a thin film down the wall, and afford an extended surface area for defoaming; a float valve in each chamber, moving on and with the fluid level in the chamber, and a valve seat at the bottom of the chamber, so that when the fluid level sinks to the level of the valve seat, the float valve sinks into sealing engagement with the valve seat, and closes off the fluid outlet from the chamber, preventing air from entering the outlet; and means for alternately opening and closing the vacuum line to each chamber, in synchronization, so that when the vacuum line is open to the first chamber it is closed to the second; and when the vacuum line is closed to the first chamber, it is open to the second.

14. An autotransfusion apparatus according to claim 13, in which each chamber has a check valve at the fluid outlet, restricting fluid flow through the outlet except at a higher upstream fluid pressure.

15. An autotransfusion apparatus according to claim 13, in which each chamber and float valve are shaped so as to guide the float valve into sealing engagement with the valve seat.

* * * * *