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T. S. HARGEST ET AL

3,496,878

SYSTEM AND APPARATUS FOR TRANSFER OF HUMAN FLUIDS

Filed April 7, 1967

2 Sheets-Sheet 1

Fig. 1.

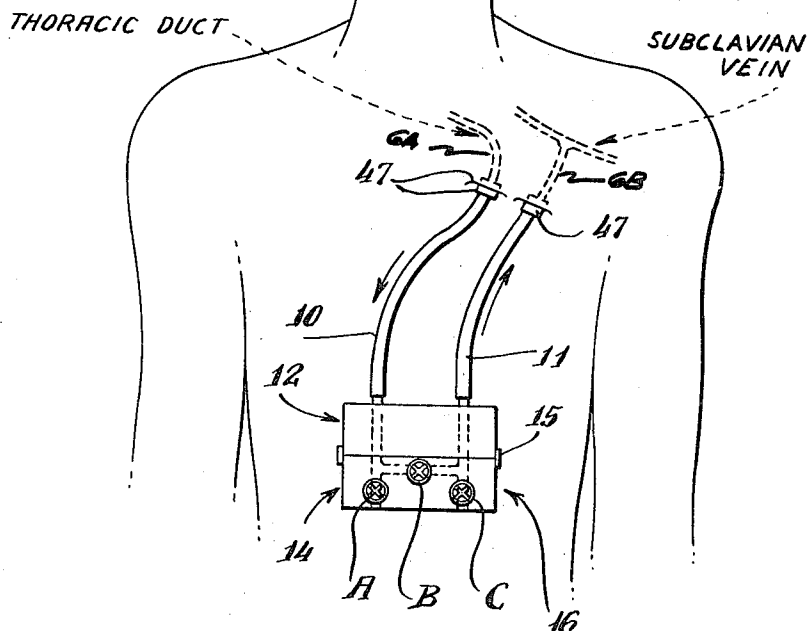
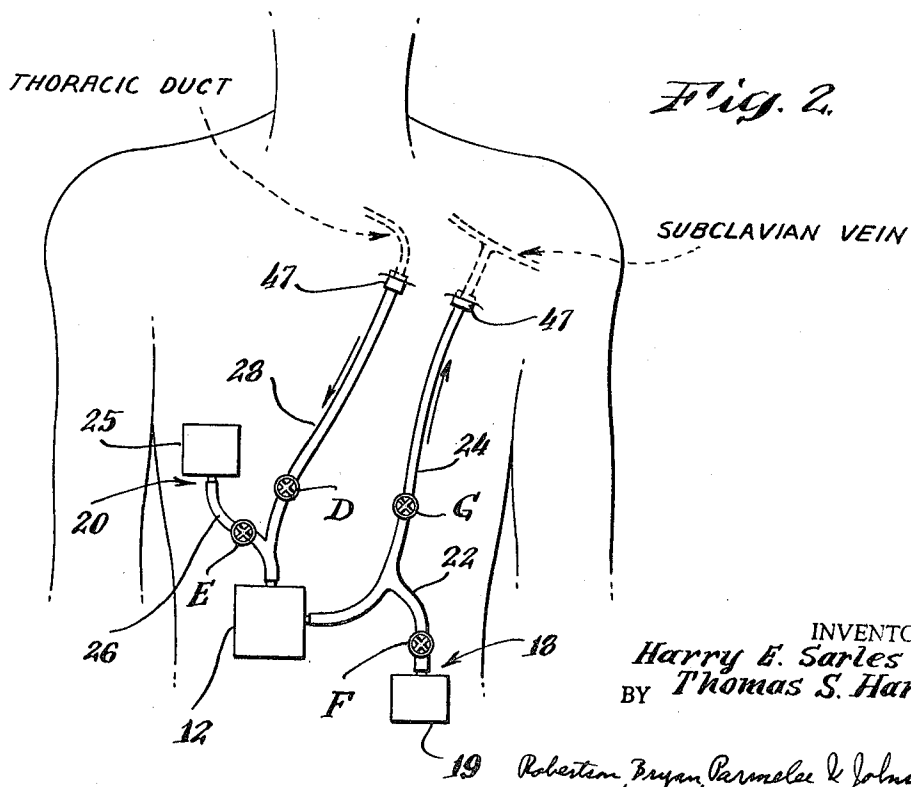


Fig. 2.



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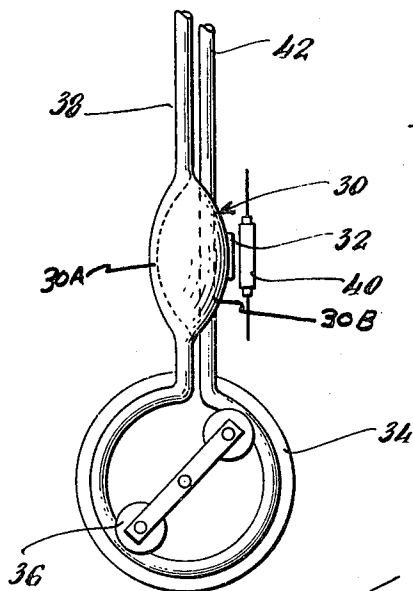


Fig. 3.

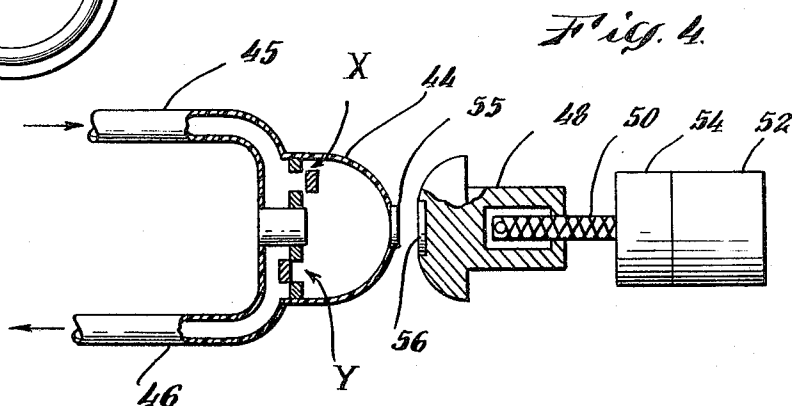


Fig. 4.

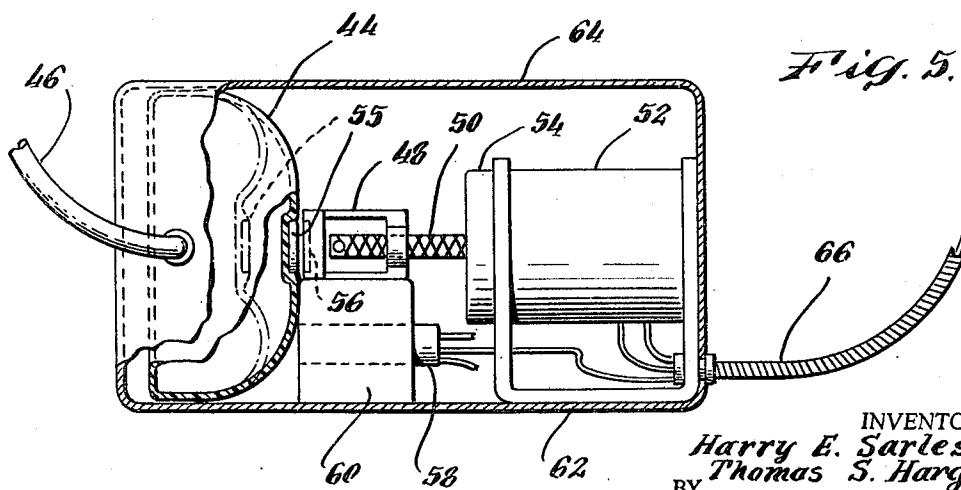


Fig. 5.

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SYSTEM AND APPARATUS FOR TRANSFER OF HUMAN FLUIDS

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U.S. Cl. 103—152

6 Claims

ABSTRACT OF THE DISCLOSURE

This invention provides a system for removing, collecting and infusing a human body fluid. The human fluid being characterized by a natural availability determined by body functions and flowing at a low and at times intermittent flow rates and having low fluid pressure limits to safely maintain flow thereof. The system is arranged to remove the fluid from the body at one position and infuse it at a second position. There is included a station exterior of the human body for holding a volume of the fluid for collection, treatment, and infusion; and transferring means having a removal part connected to the station to deliver the fluid thereto from the first position and an infusion part to carry the fluid away from the station to infuse the fluid into the human body at the second body position.

BACKGROUND OF THE INVENTION

This invention has particular application to the removal, collection and infusion of a human body fluid. In the human body it sometimes becomes necessary to treat a fluid thereof to remove any toxic materials. The present invention provides an effectively safe means for removing a human body fluid, collecting it for treatment and infusing the body fluid after it has been treated.

The present invention has been effectively used in conjunction with the treatment of chronic renal failures which in the past required some technique for artificially cleansing the blood, a function normally performed by the kidneys. In recent developments, however, it has been found that the same beneficial results can be provided by dialyzing the lymph fluid of a patient instead of the blood, since the lymph fluid contains the poisons which are later discharged into the blood stream. An advantage of this approach to the problem is that the lymph fluid has a much lower flow rate than that of the blood in the individual. As a result of such advantage, the system provided by the present invention enables the patient to pursue normal living habits instead of being in bed either at the hospital or at home. Safety and simplicity is provided as well as portability, without being cumbersome to the patient.

Another advantage of the treatment of lymph fluid is that it is much safer than hemodialysis. Due to the critical nature of the blood circulatory system, if something goes wrong during hemodialysis, repair must be made within three minutes while with the lymph system (a non-critical system) the patient may have failure of the system for 36 hours before getting into difficulty. There is also less tendency of the lymph to clot.

The main problem which the lymph treatment has posed is to provide a means of transferring body fluids at very low, sometimes intermittent flow rates, with a very low, practically negligible removal pressure, on a demand basis, and to perform this function reliably and efficiently. This problem has been solved by the present invention which provides a means to remove a body fluid on demand and to transfer the fluid at very low, sometimes intermittently, flow rates. In addition, the present invention also provides means to perform the function with components

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which may be worn on the body. Thus, the lymph fluid of an individual may be treated safely and effectively without his having to remain in bed or to be confined for any unreasonable length of time.

SUMMARY OF THE INVENTION

According to our invention, a system is provided for removing, collecting and infusing human body fluid. Such human fluid being characterized by a natural availability determined by natural body functions and flowing at a low rate and at times intermittent flow rates and such fluid having low pressure limits to safely maintain flow thereof. The fluid being removed from the body at one position and infused at a second position. The system comprises a station exterior of the human body for holding a volume of the fluid for collection, treatment and infusion. Transferring means are provided which have a removal part connected to the station to deliver the fluid thereto, and an infusion part to carry the fluid away from the exterior station. The removal part is adapted for removing the fluid from the human body at the first position at a pressure compatible with the natural body pressure of the fluid at such first position. The infusion part is adapted to infuse the fluid into the human body at the second position at a pressure compatible with the natural body pressure of such a second position. A sensing device is provided in the transferring means for sensing demand for fluid flow and causing the fluid to flow on such demand at an average rate and pressure equal to that required by the natural body functions. The transferring means include connective tubing which is adapted to form fluid-tight connections with the body at said first and second positions.

According to another aspect of this invention, the transferring means may include a pumping apparatus having means for creating an intake pressure compatible with the natural body pressure of the fluid at the first body position, and other means for providing an output pressure compatible with the natural body pressure of the second position. The pumping apparatus may be a roller pump having several turns of tubing with a pair of oppositely disposed rollers circularly movably mounted within the middle of the turns of tubing to progressively compress the tubing at opposite points to entrap therebetween a predetermined quantity of fluid and to progressively move the body fluid through the tubing. The pumping apparatus is arranged to be actuated by the sensing device in the transferring means only when a predetermined volume of the human fluid has been removed from the human body at the first position.

In another aspect of our invention, an apparatus is provided for removing the human fluid from the body at a first position and for infusing the human fluid at a second position. Such human fluid being characterized by a natural availability determined by body functions and flowing at a low rate and at times intermittent flow rates and having low fluid pressure limits to safely maintain the flow thereof. The apparatus comprises an elastic collapsible chamber for removing and holding a volume of the human fluid. The chamber having an inherent elasticity which is only sufficient to cause removal of the fluid from the human body at the first position at a pressure compatible with the natural body pressure of the fluid at such first position and to release the fluid when compressed. The chamber having extended therefrom an inlet and outlet which are adapted to form fluid-tight connections with the body at the first and second positions. Compressing means are provided near the expansible chamber to compress the chamber to release the human fluid therefrom. The compression means being adapted to compress the chamber at a rate so that the fluid is released at a pressure compatible with the natural body

pressure of the second position. Control means are provided for actuating the compressing means when the chamber is holding the volume of human fluid. The control means cause the fluid to flow at an average rate as required by the natural body functions.

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic view of a system embodying the present invention;

FIGURE 2 is a schematic view of an alternate system according to the present invention;

FIGURE 3 is a partial view of a particular embodiment of a roller pump according to this invention;

FIGURE 4 is a partial plan view of a particular embodiment of a positive displacement pump with some parts sectioned according to this invention; and

FIGURE 5 is a side elevational view of the positive displacement pump illustrated in FIG. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1 and 2, alternate embodiments of the general system according to the present invention are schematically shown. In FIG. 1, there is a one-station system illustrated whereby a human fluid removed from a first position in a human body is collected at the same station at which the human fluid may be injected into the system for infusion by the system into the body at a second position.

For purposes of illustration, the description hereinbelow, will be directed toward the specific use of the present system for the removal of the lymph fluid from the thoracic duct, the collection of the lymph fluid and the infusion of the lymph fluid into the stub of the thoracic duct or into the subclavian vein.

As seen in FIG. 1, the system of the invention is arranged to remove, collect and infuse a human fluid, such as lymph fluid. The system has a transferring means with a removal part shown as an inflow tubing 10 which is connected at one end at one body position, i.e., severed thoracic duct 6A, and on its other end to the intake of a pump 12. The body fluid is removed at a pressure compatible with the pressure of the fluid in the thoracic duct so as to provide safe flow thereof. A disconnectible container 14 is directly connected to the pump 12 in a fluid-tight relationship to form a collection-infusion station 16. At this station, the lymph fluid may be collected and removed from the system for treatment or the fluid in the container 14 may be transported in the system for infusion at a second body position, such as the stub of the thoracic duct 6B at the subclavian vein; FIGS. 1 and 2. The fluid is collected by closing valves B and C and opening valve A and operating the pump 12 as described hereinafter. When the container 14 is filled, and the pump stopped, it is disconnected and the collected fluid may be treated using any of several medical techniques including a water dialysis which will be described hereinbelow.

After the lymph fluid has been treated or any toxic materials or impurities removed therefrom, the fluid is placed in the container 14 or a similar container which is connected to the pump 12 by hook fasteners 15. The fluid is then pumped through the infusion part of the system here shown as the output tubing 11 and is infused into the subclavian vein. This infusion operation is accomplished by closing valves A and B and opening valve C, thus allowing the pump 12 to transfer the treated fluid from the connected container 14 to be infused into the subclavian vein.

As shown in FIG. 1, the one-station system can be used to merely circulate the human fluid from one position of the body to a second position. This circulation operation is accomplished by closing valves A and C and opening valve B. Thus, the human fluid can be circulated continually as required by the body characteristics from the severed thoracic duct 6A to the subclavian vein.

An alternate system is shown in FIG. 2, which is a two station system wherein the human fluid may be removed from the system for collection at one station 18 while a human fluid may be injected into the system at a separate and second station 20 for infusion of the fluid into the body at a second position. In this system, the fluid is collected into a container 19 connected by branch tubing 22 extending from the outflow tubing 24 of the pump 12. The collection operation is accomplished by closing valves E and G and keeping valves D and F open. When the container 19 is filled with the human fluid, for example, lymph fluid from the thoracic duct 6A, valve F is closed and valve G is opened and the container 19 is removed from the tubing 22. The fluid may then be treated, for example, by a water dialysis. After the fluid has been treated, it is placed into a similar container 25 which is connected to tubing 26 extended to the inflow tubing 28 to the pump 12. Thus, the human fluid is injected into the system at the infusion-station 20 as illustrated in FIG. 2. The fluid is then infused into the subclavian vein via the thoracic duct stub 6B by closing valves D and F and opening valves E and G and with the pump 12 in operation. Thus, the fluid is pumped through the outflow tubing 24 and infused into the subclavian vein.

The two-station system, as the one-station system, can also be used to simply circulate the human fluid. This is done by closing valves E and F and opening valves D and G.

In the treatment of the lymph fluid, the main purpose is often to remove any toxic materials that may be in the fluid or to remove any impurities which may be harmful to the internal system of the human body. There are different techniques which may be used such as dialysis of the fluid with either water or a solution of water and suitable chemicals to sterilize the human fluid. This may be done by dialyzing the fluid against a tap water bath employing a twin coil artificial kidney manufactured by the Travenol Division of Baxter Laboratories, Inc. This method is commonly used for treating a removed human fluid. However, the lymph fluid may be subjected to irradiation or other types of treatment, i.e., filtration for purification of the fluid.

In extracorporeal circulation of lymph fluid for such purposes as dialysis, irradiation, or collection, and the like, it is of paramount importance to maintain the integrity of the patient's thoracic duct. It is therefore essential to avoid subjecting the duct to any excessive suction pressure which could cause the walls of the duct to collapse like a wet soda straw, thereby interrupting flow and, worse yet, perhaps rupturing the walls and making it impossible to reestablish effective internal circulation.

Therefore, the extracorporeal circulation of the lymph requires a means of pumping the fluid at very low, sometimes intermittent flow rates, with a very low, practically negligible suction head.

Such a means is provided by the pumping apparatus of the present invention. The present pumping apparatus is basically a demand pump, which operates only when it senses that the patient's natural lymphatic system is furnishing lymph through the duct 6A.

With respect to FIGS. 3, 4 and 5, respective embodiments of particular pumps are illustrated that may be used in the present system. In FIG. 3, a roller type of pump is shown, which includes an expansible chamber 30 with a rigid side 30A and a flexible side 30B on which is mounted a magnet 32. Extended from the chamber 30 are several turns of tubing 34 with a pair of oppositely deposited rollers 36 circularly movably mounted within the middle of the turns of tubing 34. With this arrangement, when the chamber 30 fills with a human fluid flowing therein through the inflow tubing 38, the magnet 32 mounted on the flexible side 30A of the chamber 30 comes in close proximity to a magnetic switch 40 which actuates a motor (not shown) to turn the rollers 36. Thus,

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the turns of tubing 34 are progressively compressed by the rollers to squeeze the human fluid therefrom and pull a suction on the chamber 30. As the chamber is emptied (emptied position shown by dotted line) the magnet 32 moves away from the switch 40 which disconnects the motor. From the roller pump and through the outflow tubing 42 the lymph is infused into the subclavian vein; FIGS. 1 and 2.

In FIGS. 4 and 5 a positive displacement plunger pump is shown. The pump includes an expansible chamber 44 which has an intake tubing 45 connected to lines 10, 28 and outlet 46 extended from the output of the chamber 44 into lines 11 or 24; FIGS. 1 and 2. The tubings 10, 28 and 11, 24 extend from the chamber and have tips 47 (as shown in FIGS. 1 and 2) adapted to form fluid-tight connections with the respective body conduits, such as the thoracic duct 6A and the thoracic stub 6B leading to the subclavian vein; FIGS. 1 and 2. The tips 47 may be made of Teflon.

The chamber 44 is an elastic dome-shaped structure with two valves in the base, an input valve X and an outlet valve Y. Both valves are normally closed, and may themselves be elastic mounted. The chamber 44 may be made of silastic, a product of Dow Corning Company. Silastic is preferred because of its inertness and compatibility with the human body.

The normal position of the chamber 44 is fully extended, as shown by the solid line in FIG. 5. The chamber can be compressed by exerting a force on it, which compression decreases the volume inside the chamber. When the force is removed, the dome being elastic tries to resume its normal extended position and in so doing exerts a suction pressure on the inlet lines 10 and 28.

As shown in FIG. 5, the elastic chamber 44 is compressed by a plunger 48. The plunger is thread-mounted on a cross-threaded shaft 50 and moves in a plane transverse to the chamber 44. The plunger 48 also slides along the top of a guide 60 when compressing the chamber 44. The cross-threaded shaft 50 is driven by a motor 52. The drive of the shaft 50 may be reduced through a gear train 54 to an appropriately slow rate to maintain a low output pressure from the chamber 44. With this arrangement, the plunger 48 runs up and down shaft 50 to compress and then release the chamber 44 so that the fluid therein is released at a pressure compatible with the natural body pressure of the body position at which the fluid is infused.

Whenever the lymph fluid is discharged through the thoracic duct into the intake 45 and approaches the inlet valve X, it enters the chamber 44. The valve X has a very low threshold or opening pressure, so the slightest flow of lymph fluid is sufficient to open the valve X and permit lymph fluid to enter the chamber 44. The amount that may enter is governed by the position of the chamber. If the chamber 44 is restrained on the outside only by atmospheric pressure it will extend to its normal position as permitted by the body pressure within the thoracic duct 6A. As the lymph fluid fills the elastic chamber 44, the chamber expands to its full size, solid line in FIG. 5).

The inherent elasticity of the walls of the chamber 44 causes it to always want to take its normal shape as shown in FIGS. 4 and 5. This, in turn, causes a suction in inlet 45 and induces the flow of lymph fluid thereinto. Accordingly, care must be exercised to select a chamber 44 which has only enough elasticity to induce a suction pressure that is compatible with the human body fluid pressure. Too much elasticity in the chamber 44 could cause collapse of the thoracic duct 6A.

When the chamber is fully expanded, a magnet 55 on its head activates a switch 56 on the head of the plunger 48 so that the motor 52 drives the shaft 50 (reduced through the gear train 54) to an appropriate slow rate. The drive of the shaft 50 causes the plunger 48 to move to the left, FIG. 5, to compress the chamber 44, pumping the lymph fluid out at a pressure compatible

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with the body pressure of the subclavian vein into which the lymph is infused. At the slightest pressure on the chamber 44 the inlet valve X closes and the outlet valve Y opens. The plunger travels only a certain distance and then retracts because of the reverse threads of the shaft 50 on which it is mounted.

When the plunger 48 retracts, the switch 56 breaks contact with the magnet 55 on the chamber 44; thereby the switch 56 is opened. However, another switch 58 keeps the motor circuit closed until the plunger 48 has retracted to its starting position, the extreme right (FIG. 5). At that position, the plunger 48 trips open the second switch 58 and thus, the pumping operation is stopped. The plunger remains in this position until the elastic chamber 44 has been filled enough so as to cause the contact of the magnet 55 on its head with the switch 56 on the head of the plunger 48, to restart another cycle. Thus, the need for pumping fluid is sensed by the operation of switch 56 when the chamber is full. The fluid pressure in the outlet 46 is maintained within the safe limits by the low speed of the plunger 48.

The structure of the pump, as shown in FIG. 5, is such that various parts are enclosed. The chamber 44, with the guide 60 and motor 52 are mounted on the base 62 of the pump. The parts are enclosed by a cover 64 resting on the base. The pump may be powered by a battery pack (not shown) which is connected to the pump by means of a flexible cable 66.

It is to be particularly noted that when the inlet 45 and outlet 46 are connected in the closed flow systems shown in FIGS. 1 and 2, the collapsing of the chamber 44 by the plunger 48 pumps the fluid out and the motor 52 returns the plunger to its starting position as shown in FIG. 5 where it is stopped until the chamber 44 is again filled. Thus, the system only pumps fluid as it naturally flows and on demand.

Illustrative of the actual conditions of operation of the invention are the following data. The pumping apparatus illustrated in FIGS. 3, 4 and 5 transfer lymph fluid at rates from approximately 10 cc. per hour to 1200 cc. per hour. The rotating rollers 36 and the shaft 50 have a maximum speed of 80 r.p.m. with the plunger 48 operating at 1 ft. per min. to give a maximum pumping capacity of 600 cc. per hour for the pump of FIG. 3 and 1200 cc. per hour for the pump of FIGS. 4 and 5.

Although the various features of the invention have been shown as applied to several embodiments of the invention, it will be evident that changes may be made in such details and certain features may be used without departing from the principles of the invention.

What is claimed is:

1. A system for removing, collecting and infusing a human body fluid, such human fluid being characterized by a natural availability determined by natural body functions and flowing at a low rate and at times intermittent flow rates and having low fluid pressure limits to safely maintain flow thereof, said fluid being removed from the body at one position and infused at a second position, said system comprising:

- (a) a station exterior of said human body for holding a volume of said fluid for collection, treatment and infusion;
- (b) transferring means having a removal part connected to said station to deliver said fluid thereto and an infusion part to carry said fluid away from said station;
- (c) said removal part having a reservoir to collect said fluid for subsequent infusion adapted for removing said fluid from said human body at said first position at a pressure compatible with the natural body pressure of said fluid at such first position;
- (d) said infusion part adapted to infuse said fluid into said human body at said second position at a pressure compatible with the natural body pressure of such second position; and

(e) a device in said transferring means for sensing a quantity of fluid and causing said fluid to flow on demand at an average rate and pressures equal to that required by said natural body functions.

2. A system according to claim 1, wherein said transferring means includes connective tubing which forms fluid-tight connections with the body at said first and second positions.

3. A system according to claim 1, wherein said transferring means includes a pumping apparatus having means for creating an intake pressure compatible with the natural body pressure of said fluid at said first body position and other means for providing an output pressure compatible with the natural body pressure of said second position.

4. A system according to claim 3, wherein said pumping apparatus is a roller pump having several turns of tubing with a pair of oppositely disposed rollers circularly movably mounted within the middle of said turns of tubing to progressively compress said tubing at opposite points to entrap therebetween a predetermined quantity of fluid and to progressively move the body fluid through said tubing.

5. A system according to claim 3, wherein said pumping apparatus is arranged to be actuated by said device in said transferring means only when a predetermined volume of human fluid has been removed from said human body.

6. An apparatus for removing a human fluid from the body at a first position and for infusing the human fluid at a second position, such human fluid being characterized by a natural availability determined by body functions and flowing at a low rate and at times intermittent flow rates and having low fluid pressure limits to safely maintain flow thereof, said apparatus comprising:

(a) an elastic collapsible chamber for removing and holding a volume of said human fluid, said cham-

ber having an inherent elasticity which is only sufficient to cause removal of said fluid from said human body at said first body position at a pressure compatible with the natural body pressure of said fluid at such position and to release said fluid when compressed, said chamber having extended therefrom an inlet and outlet which are adapted to form fluid-tight connections with the body at said first and second positions;

(b) compressing means positioned near the elastic chamber to compress said chamber to release the human fluid therefrom, said compression means adapted to compress the chamber at a rate so that said fluid is released at a pressure compatible with the natural body pressure of said second body position; and

(c) control means for actuating said compressing means only when said chamber is holding said volume of human fluid and causing said fluid to flow at an average rate as required by said natural body functions.

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U.S. Cl. X.R.

103—148; 128—214