May 12, 1970 C. P. E. VON WRANGELL 3,511,238

SYSTEM FOR TRANSFERRING HUMAN FLUIDS WITHOUT CLOTTING THEREOF

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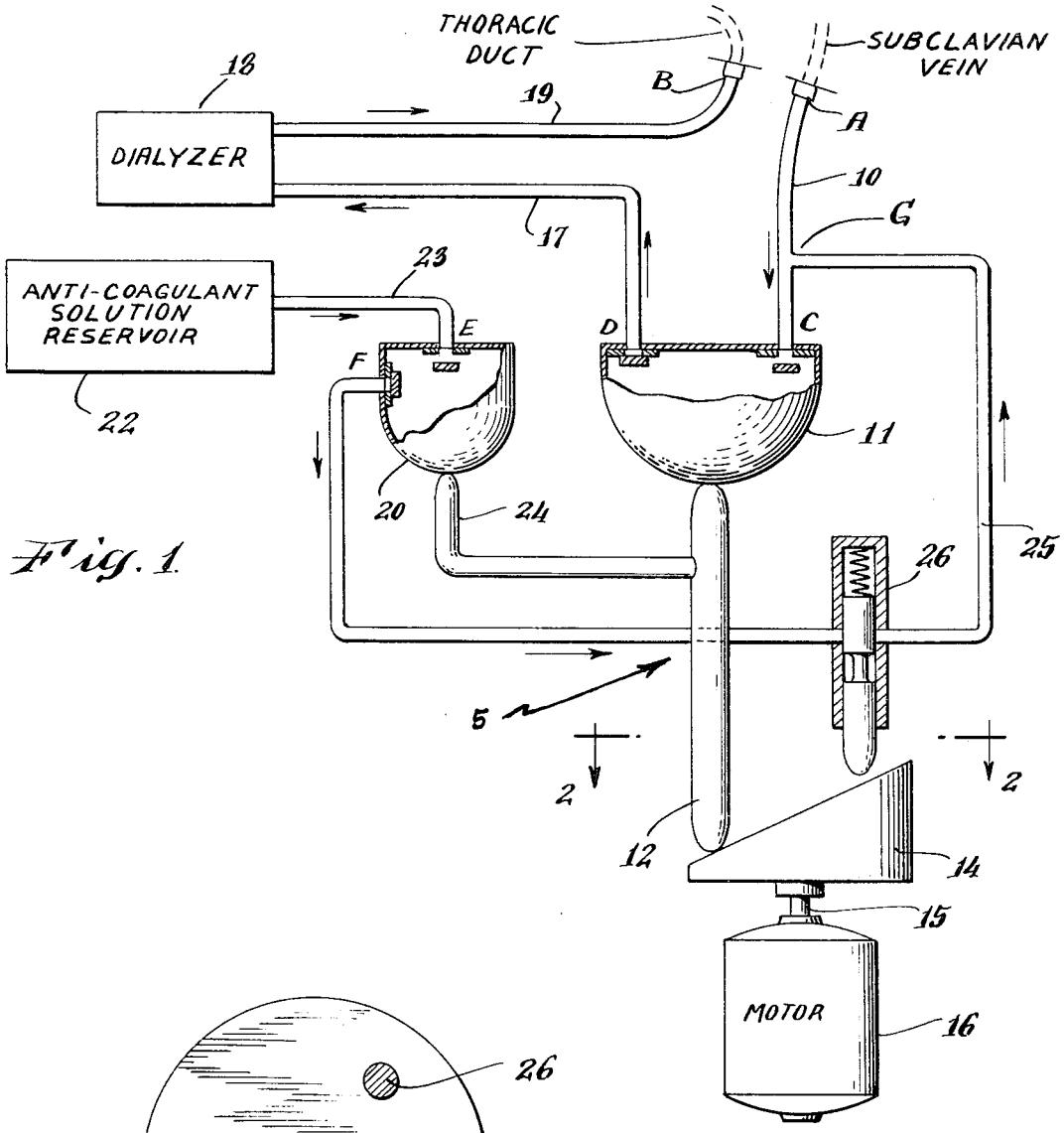

Fig. 1.

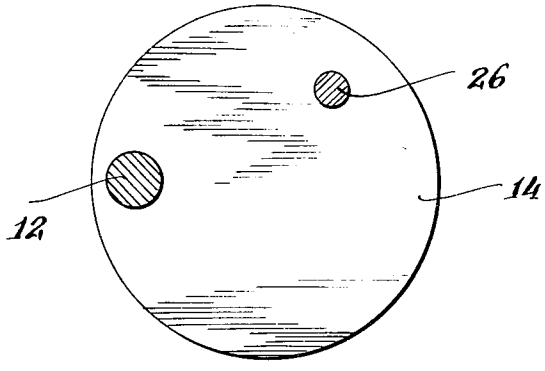

Fig. 2.

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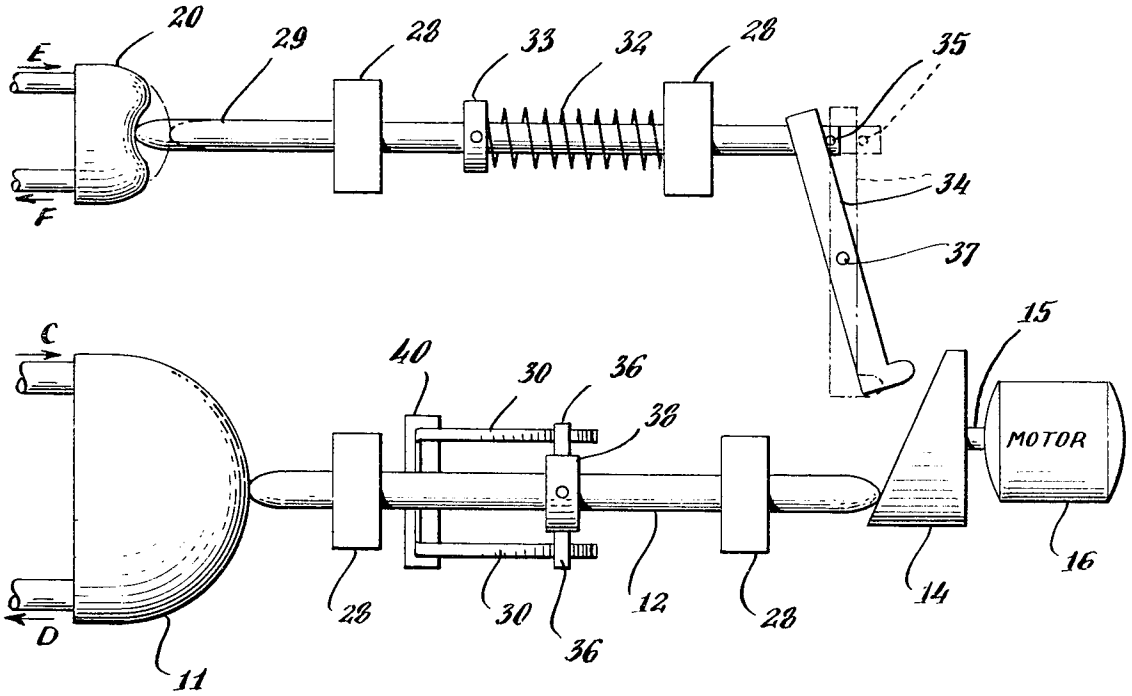
Fig. 3.



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SYSTEM FOR TRANSFERRING HUMAN FLUIDS WITHOUT CLOTTING THEREOF

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Int. Cl. A61m 5/00
U.S. Cl. 128—214 6 Claims

ABSTRACT OF THE DISCLOSURE

This invention provides an improved system for removing, treating and infusing a human fluid which must be prevented from clotting. Such system having a pumping apparatus to maintain the flow of the human fluid at a rate compatible with the natural body functions. The flow of the fluid occurring exterior of the body from a first removal position to a second infusion position. The pumping apparatus has an elastic collapsible chamber to hold a volume of the human fluid and compressing means to compress the chamber to expel the human fluid therefrom. The improvement therein includes a source of an anti-coagulant and a second elastic collapsible chamber positioned adjacent to the elastic chamber to remove and hold a volume of the anti-coagulant from its source. The second chamber having an inherent elasticity to expel the anti-coagulant when compressed and to create therein an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove the anti-coagulant solution from its source. The second chamber has an outlet conduit which is connected at one end to the discharge of the second chamber and at the other end to the flow of the human fluid at the first removal position. Means are provided to compress the second chamber in a predetermined relationship to the compression of the first elastic chamber, and to cause the anti-coagulant expelled from the second chamber to be injected into the flow of the human fluid being removed into the first elastic chamber.

BACKGROUND FOR THE INVENTION

This invention has particular application to the prevention of the clotting of human fluids in extra-corporeal flow. More particularly, it has particular application to the injection of an anti-coagulant solution into the flow of the human fluid as it is being removed from the body to prevent clotting thereof. In the systems for transferring human fluid outside the body as contemplated by the present invention, it is generally necessary to safeguard against any clotting which would obstruct the flow of the body fluid. In systems for treating human fluids outside the body, such as the system provided in the copending application, Ser. No. 630,942, filed Apr. 14, 1967, there is always a need for the assurance that the human fluid will not clot during its flow outside of the body. In that system a human fluid, such as lymph fluid, is removed from the body at one position, and then it is treated to have any impurities removed therefrom and eventually is infused into the body at a second position. The flow of the human fluid in the system is maintained by a pumping apparatus at a flow rate that is compatible with the natural body functions at both the removal and infused positions. However, even though due care is taken in the control of the flow of the human fluid outside the body, there is still the possibility that the fluid may clot. The clotting of a human fluid outside the body or even the obstruction of such must be prevented or some definite harm will result to the body. In case of blood clotting, death of the individual could easily result. Consequently,

there has been a need for some means to prevent such clotting of a human fluid in its transfer outside the body. Such means are provided by the present invention, whereby the clotting is prevented of a human fluid in its extra-corporeal flow by the injection of an anti-coagulant in the flow of the human fluid just as it is removed from the body. The present invention assures that a human fluid will not clot in its flow outside the body by means that are safe and effective.

According to the present invention, such human fluids as blood or lymph may be prevented from clotting by the injection of an anti-coagulant solution, such as heparin, into the flow of the fluid as it is removed from the body. A common mixture which has proven to be effective is about 50 milligrams of heparin and one liter of distilled water. The concentration of the solution may be varied as required. For example, in the dialysis of the lymph fluid the amount of heparin required is very small, generally about 10 ml. per liter of lymph fluid produced by the patient per day. Thus, if the patient is producing 3 liters of lymph fluid in twenty-four hours, he will require about 30 ml. of heparin solution added daily to his lymph flow. It must be noted that the concentration and the amount may be varied as required by the individual whose lymph fluid is being treated.

The location of the injection of the anti-coagulant solution, i.e., heparin solution, should be as close as possible to the exit of the human fluid from the body so that the anti-coagulant is effective from the moment the human fluid is removed from the body.

Also, it should be noted that it is necessary to inject small quantities of the anti-coagulant solution continually, in a proportional flow rate to that of the human fluid. Such is accomplished safely and effectively by the means provided by this invention.

SUMMARY OF THE INVENTION

According to my invention, an improved system is provided for removing, treating, and infusing a human fluid which must be prevented from clotting. Such system having a pumping apparatus to maintain the flow of the human fluid at a rate compatible with the natural body functions. The flow of the human fluid occurs outside of the body from a first removal position to a second infusion position. The pumping apparatus has an elastic collapsible chamber to hold a volume of the human fluid and compressing means to compress the elastic chamber to expel the human fluid therefrom. The improvement in the system comprises a source of an anti-coagulant solution and a second elastic collapsible chamber to remove and hold a volume of the anti-coagulant from its source. The second chamber has an inherent elasticity to expel the anti-coagulant when compressed and to create therein an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove the anti-coagulant from its source. Extended from the outlet of the second chamber is a conduit having one end connected to the discharge of the second chamber and the other end connected to the flow of the human fluid at the first removal position. Means are provided to compress the second chamber in a predetermined relationship to the compression of the first elastic chamber. Means are also provided to cause the anti-coagulant expelled from the second chamber to be injected into the flow of the human fluid being removed into the first elastic chamber.

According to another aspect of my invention, an improved system is provided for removing, treating, and infusing a human fluid which must be prevented from clotting. Such system having a pumping apparatus to maintain the flow of the human fluid at a rate compatible with the natural body functions. The flow of the fluid occurs outside of the body from a first removal position

to a second infusion position. The pumping apparatus has an elastic collapsible chamber to hold a volume of the human fluid and a freely reciprocable push rod which is actuated by a rotatable nutating cam surface to compress the chamber to expel the human fluid therefrom. The improvement in the system comprises a source of an anti-coagulant solution and a second elastic collapsible chamber positioned adjacent to the first elastic chamber to remove and hold a volume of the anti-coagulant from its source. The second chamber having an inherent elasticity to expel the anti-coagulant when compressed and to create therein an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove the anti-coagulant solution from its source. Extended from the outlet of the second chamber is a conduit having one end connected to the discharge of the second chamber and the other end connected to the flow of the human fluid at the first removal position. Means are provided to compress the second elastic chamber to expel the anti-coagulant solution therefrom and inject the solution into the flow of the human fluid at the first removal position just after the first chamber has been compressed. The second elastic chamber being of a size relative to the first elastic chamber to cause the anti-coagulant to flow at a rate proportional to that of the human fluid to prevent clotting thereof.

In another aspect of my invention, the means to compress the second chamber may include in part a second push rod positioned parallel to the main push rod. The second rod being actuated by the rotatable nutating cam surface for only a small part of the rotation of the cam surface. There may also be included means for holding the second rod against the second chamber so that the second chamber is compressed during most of the rotation of the nutating cam surface so that the flow is controlled of the anti-coagulant into and from the second chamber.

According to another aspect of my invention, the outlet conduit has a volume equal to that of the second chamber. On the output of the conduit there may be an actuatable check valve arranged to supply the anti-coagulant expelled from the second chamber into the flow of the human fluid being removed into the first elastic chamber. Preferably, the check valve is angularly displaced from the position of the main push rod and is actuated by the rotatable nutating cam surface for only a small part of its rotation and is thereby open to supply the anti-coagulant for a brief interval.

Other features and advantages of the present invention will appear from the ensuing description of the best mode contemplated by me for carrying out my invention.

DESCRIPTION OF THE DRAWINGS

With reference to the accompanying drawings, I will describe the preferred embodiments of my invention. In the drawings:

FIG. 1 is a schematic view of a particular system embodying the present invention;

FIG. 2 is a plan view of the nutating cam surface taken along lines **2—2** in FIG. 1; and

FIG. 3 is a plan view of an alternate embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, the general system embodying the present invention is schematically shown. The system comprises a pumping apparatus, generally indicated here as **5**, which includes an elastic collapsible chamber **11** with a tubing **10** extended from its intake C to the body at position A from which a human fluid is removed and transferred into the chamber **11**. A freely reciprocable push rod **12** is provided to compress the chamber **11** to expel the human fluid therefrom through its output D and tubing **17** into a human fluid treating means **18**, shown here as a dialyzer. The treated fluid exits from the dialyzer **18** through tubing **19** and is infused into the body at position B at which the tubing **19** is connected. The push rod **12** is actuated by a rotatable nutating cam surface **14** which is driven by a motor **16** through shaft **15**.

The general description heretofore is of a system for treating human fluids disclosed in the said co-pending application. The description hereinafter will be of the improvement in the system for preventing the clotting of a human fluid in its extra-corporeal flow through the system described above.

As shown in FIGS. 1 and 3, a second elastic chamber **20** is positioned adjacent to the elastic chamber **11** to remove and hold a volume of anti-coagulant solution from a source thereof in FIG. 1. The solution is transferred from the reservoir **22** to the elastic chamber **20** through tubing **23** extending to the inlet E of the chamber **20**. This flow of the fluid is caused by the inflation of the chamber **20** after it has been compressed. That is, the inherent elasticity of the walls of the chamber **20** cause it to always take its normal shape as shown in FIG. 1. This, in turn, creates within the chamber **20** an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove the anti-coagulant from the reservoir **22**. Also, because of the inherent elasticity of chamber **20**, the anti-coagulant solution can be expelled therefrom when the chamber is compressed.

As provided by this invention, the chamber **20** is compressed in a predetermined relationship to the compression of elastic chamber **11**. Alternate means for compressing the chamber **20** are illustrated in FIGS. 1 and 3. According to the embodiment illustrated in FIG. 1, the second chamber **20** is compressed simultaneously with chamber **11**, by an appendage **24** mounted on the main push rod **12** which is actuated by the nutating cam surface **14**.

In the alternate embodiment illustrated in FIG. 3, chamber **20** is compressed by a separately actuated push rod **29** just after the first chamber **11** has been compressed. The rod **29** in its normal position (shown by the solid lines) is held against the second chamber **20** by a spring **32** bearing against a collar **33** mounted thereon. The push rod is actuated by the interaction of a rocker arm **34** and the cam surface **14**, together with the spring **32**. As the nutating cam **14** is rotated through one revolution, the rocker arm **34** is displaced a small amount. This motion momentarily moves the push rod **29** away from chamber **20**, thus allowing the chamber **20** to draw the anti-coagulant from the reservoir **22**. As soon as the cam **14** has rotated further, the spring pushes the rod **29** back against the chamber **20**, thus compressing it and expelling therefrom the anti-coagulant. In this particular embodiment (FIG. 3), the expelled anti-coagulant by the compression of chamber **20**, is injected into the flow of the human fluid solely by the compression of chamber **20**. As shown in FIG. 1, the expelled solution is carried through an outlet conduit **25** and injected into the flow of the human fluid at point G in tubing **10**.

In the embodiment illustrated in FIG. 1, the expelled fluid is injected into the flow of the human fluid by the combined action of the compression of chamber **20** and the actuation of a check valve **26** which is placed in the outlet conduit **25** to supply the anti-coagulant into the flow of the human fluid. In this particular embodiment (FIG. 1), the conduit **25** preferably has a volume equal to that of the second chamber **20**. The reason being that since the flow of the solution expelled from the chamber **20** is monitored by the check valve **26** and remains in the conduit **25** before it is injected into the flow of human fluid at point G.

As shown in FIG. 2, the check valve **26** is angularly displaced from the position of the main reciprocating rod **12**. The check valve **26** is only actuated for a small part of the rotation of the cam surface **14** and is thereby

open for a brief interval after the elastic chamber **11** and the second chamber **20** have been simultaneously compressed respectively by the main push rod **12** and the appendage **24**.

In operation (as shown in FIG. 1), when the motor driven nutating cam **14** makes one rotation it drives the main push rod with the appendage **24** forward and both the anti-coagulant chamber **20** and the human fluid chamber **11** are compressed in phase. The compression of the small chamber **20** pumps the anti-coagulant to the check valve **26** which is also actuated by the nutating cam **14** in such as manner that the valve **26** is always closed except for a brief interval immediately after completion of the compression stroke. Thus, there is a positive pressure on the anti-coagulant solution forcing it to pass through the check valve **26** and then through the outlet conduit **25** into the flow of the human fluid being removed from the body. The check valve **26** is closed very soon after being opened, however, to prevent the suction pressure, developed by the chamber **20** due to its elastic recovery force, from drawing the heparin solution immediately into the human fluid input tubing **10**. Thus, with the check valve **26** closed, the human fluid chamber **11** can recover by its elastic memory from a compressed position to its normal position only as allowed by the flow of human fluid flow pressure in the body.

According to the embodiment illustrated in FIG. 1, the amount of heparin solution that is injected into the human fluid is controlled by the stroke of the main push rod **12**. There are several ways in which the stroke of the main push rod may be varied to effectively regulate the amount of heparin that is injected into the human fluid. One way is that the heparin chamber **20** may be replaced by one which is larger or smaller to provide more or less displacement per stroke as may be required for the particular human fluid being transferred. A second way is by making the diameter of the appendage **24** larger or smaller. The larger the diameter of the appendage **24**, the more the chamber **20** is displaced per stroke, and accordingly more heparin solution is injected into the flow of the human fluid. A third way is by adjusting the length of the stroke of the push rod **12** to be longer or shorter. That is, the longer the stroke, the more the chamber **20** is displaced per stroke and therefore more heparin solution is injected into the human fluid. Another way is by adjusting the length of the check valve **26** stroke to make it longer or shorter to vary the time interval and the degree to which the check valve **26** is open. This may be varied from fully opened for a relatively long interval to partially opened for a relatively short interval or even from continuously fully opened to continuously fully closed. As can be seen, the amount of heparin solution that is required to prevent the clotting of any particular human fluid may be provided by an adjustment or modification of the component parts of the apparatus used according to this invention.

Referring to FIG. 3, the alternate mechanism for compressing chamber **20** and injecting the anti-coagulant into the human fluid flow is shown. In this embodiment, the push rod **29**, is slidably mounted on supports **28**, as is the main push rod **12**. The main rod **12** is held against the human fluid chamber **11** by a U-shaped spring **30**, which two legs are pressed against a pair of rollers **36** mounted in a sliding block **38** secured to the rod **12**. The spring **38** is mounted on a block **42** below the rod **12**. As described before, the small rod **29** is held against chamber **20** by the spring **32** bearing against the collar **33** mounted thereon. Pivotally mounted on a pin **37** is the rocker arm **34** which is in contact with the pin **35** on the rod. As shown, the rocker arm **34** is extended in the area of the rotation of the cam **14**. As the nutating cam **14** is rotated through one revolution, the rocker arm **34** is displaced a small amount. This motion momentarily carries the push rod **29** away from the chamber (as shown by dotted lines) allowing it to draw the anti-coagulant from the reservoir **22**, FIG. 1. As soon as the cam **22** has rotated further, the spring **32** pushes the push rod **29** against the diaphragm **20** until the next short stroke, so that almost all the time the chamber **20** is compressed and therefore the anti-coagulant cannot flow in or out of the chamber **20**. Only small amounts of the anti-coagulant can be injected during each short stroke once per cycle.

It is noted that the chamber **20** in the embodiment shown in FIG. 3, combines the functions of both the chamber and the check valve **26** (FIG. 1). Thus, the check valve is eliminated. The function of the check valve **26** is accomplished by having the chamber **20** under compression most of the time due to the spring force on the push rod **29**.

The length of the stroke of the rod **29** can be adjusted by changing the position of the pin **35** on the rod **29**. For example, if the pin **35** is positioned further to the left (FIG. 3), the stroke of the rod will be lengthened. Also, the spring force on the rod **29** can be adjusted by moving the collar **33** against which the spring bears. That is, if the collar **33** is moved to the left, the force of the spring will be decreased.

The mechanism shown in FIG. 3 may be further modified so that a third fluid can be pumped into the human fluid flow in proportional flow rates to that of the human fluid. This can be accomplished by extending the rocker arm **34** and installing a duplicate parallel push rod. For example, the primary fluid may be lymph, the second fluid may be an anti-coolant heparin solution and the third fluid may be a glucose magnesium additive which will add a color to the fluid upon having certain characteristics.

Various anti-coagulants may be used according to this invention including a sodium and potassium solution, a solution of fluorides and citrates, and a heparin solution. The heparin solution which is based on the substance of heparin found in the liver and blood of humans, has proved to be quite effective and may be used as a suitable anti-coagulant in the present invention.

From the foregoing it is readily acknowledged that the invention as described herein and illustrated in the drawings, very effectively achieves the desired result of preventing a human fluid from clotting in its flow outside of the body.

Although the various features of the invention have been shown as apply to several embodiments of the invention, it will be evident that changes may be made in such detail that certain features may be used without departing from the principles of the invention described herein and claimed in the appended claims.

I claim:

1. An improved system for removing, treating and infusing a human fluid which must be prevented from clotting, such system having a pumping apparatus to maintain the flow of the human fluid at a rate compatible with the natural body functions, said flow occurring exterior of said body, said pumping apparatus having an elastic collapsible chamber to hold a volume of said human fluid and compressing means to compress said chamber to expel said human fluid therefrom; and wherein the improvement comprises:

(a) a source of an anti-coagulant solution;

(b) a second elastic collapsible chamber positioned adjacent to said first elastic-chamber to remove and hold a volume of said anti-coagulant from said source, said second chamber having an inherent elasticity to expel said anti-coagulation solution when compressed and to create therein an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove said anti-coagulant solution from said source;

(c) an outlet conduit from said second chamber having one end connected to the discharge of said second chamber and the other end connected to the flow of said human fluid at said first removal position;

(d) means to compress said second chamber in a predetermined relationship to the compression of said first elastic chamber; and

(e) means to cause the anti-coagulant expelled from the second chamber to be injected into the flow of said human fluid being removed into the first elastic chamber.

2. An improved system for removing, treating and infusing a human fluid which must be prevented from clotting, such system having a pumping apparatus to maintain the flow of the human fluid at a rate compatible with the natural body functions, said flow occurring exterior of said body from a first removal position to a second infusion position, said pumping apparatus having an elastic collapsible chamber to hold a volume of said human fluid and a freely reciprocable push rod which is actuated by a rotatable nutating cam surface to compress said chamber to expel said human fluid therefrom; and wherein the improvement comprises:

(a) a source of an anti-coagulant solution;

(b) a second elastic collapsible chamber positioned adjacent to said first elastic chamber to remove and hold a volume of said anti-coagulant from said source, said second chamber having an inherent elasticity to expel said anti-coagulant solution when compressed and to create therein an elastic force sufficient to inflate the chamber to cause a pressure to induce flow thereinto and remove said anti-coagulant from said source;

(c) an outlet conduit from said second chamber having one end connected to the discharge of said second chamber and the other end connected to the flow of said human fluid at said removal position;

(d) means to compress said second elastic chamber to expel said anti-coagulant solution therefrom and to inject said solution into the flow of said human fluid at said first removal position just after said first chamber has been compressed; and

(e) said second chamber being of a size relative to said first elastic chamber to cause said anti-coagulant to flow at a rate proportional to that of said human fluid to prevent clotting thereof.

3. An improved system according to claim 2, wherein said means to compress said second chamber includes in part a second push rod positioned parallel to said main push rod, said second rod being actuated by said rotatable nutating cam surface for only a small part of the rotation of said cam surface.

4. An improved system according to claims 2 and 3, wherein there is included means for holding said second push rod against said second elastic chamber so that said second chamber is compressed during most of the rotation of said nutating cam surface so that flow is controlled of said anti-coagulant into and from said second chamber.

5. An improved system according to claim 2, wherein said outlet conduit has a volume equal to that of said second chamber and on the output of said conduit is an actuatable check valve arranged to supply said anti-coagulant expelled from said second chamber into the flow of said human fluid being removed into said first elastic chamber.

6. An improved system according to claims 2 and 5, wherein said check valve is angularly displaced from the position of said main push rod and is actuated by the rotatable nutating cam surface for only a small part of its rotation and is thereby opened to supply said anti-coagulant for a brief interval.

References Cited

UNITED STATES PATENTS

3,140,714	7/1964	Murphy et al.	128—214
3,145,713	8/1964	Latham	128—214
3,382,811	5/1968	Chastang et al.	103—152
3,384,080	5/1968	Muller	128—214
3,410,263	11/1968	McGinnis	128—214 X
3,411,448	11/1968	Von Wrangell et al.	103—148 X

OTHER REFERENCES

Sarles et al.: Trans. Amer. Soc. Artif. Inter. Org. 11:165, 1965.

Sarles et al.: Trans. Amer. Soc. Artif. Inter. Org. 12:33, 1966.

Hargest et al.: Trans Amer. Soc. Artif. Inter. Org. 13:341, 1967.

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U.S. Cl. X.R.

23—285.5; 103—5, 152; 210—321