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Flow mixing machine and method according to a determined ratio of a biological fluid and a solution

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(71) Applicant(s)
Maco Pharma

(72) Inventor(s)
Behague, Maurice

(74) Agent / Attorney
Allens Arthur Robinson Patent & Trade Marks Attorneys, Level 27 530 Collins Street, Melbourne, VIC, 3000

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ABSTRACT

The invention concerns a flow mixing machine according to a determined ratio of a biological fluid and an anticoagulant and/or preservation solution, the aforementioned machine comprising a measurement device (7) for the volume of fluid that is collected by natural flow, a pumping device (8) for the anticoagulant and/or preservation solution and a control system (9) for the pumping device comprising a device to determine the volume of solution pumped and an automatic control device for the pump speed that comprises means able to:

- as a function of the determined ratio, calculate the theoretical volume of solution to mix with the volume of fluid collected;
- compare the theoretical volume of solution and the volume of solution pumped;
- adjust the pump speed according to the previous comparison.

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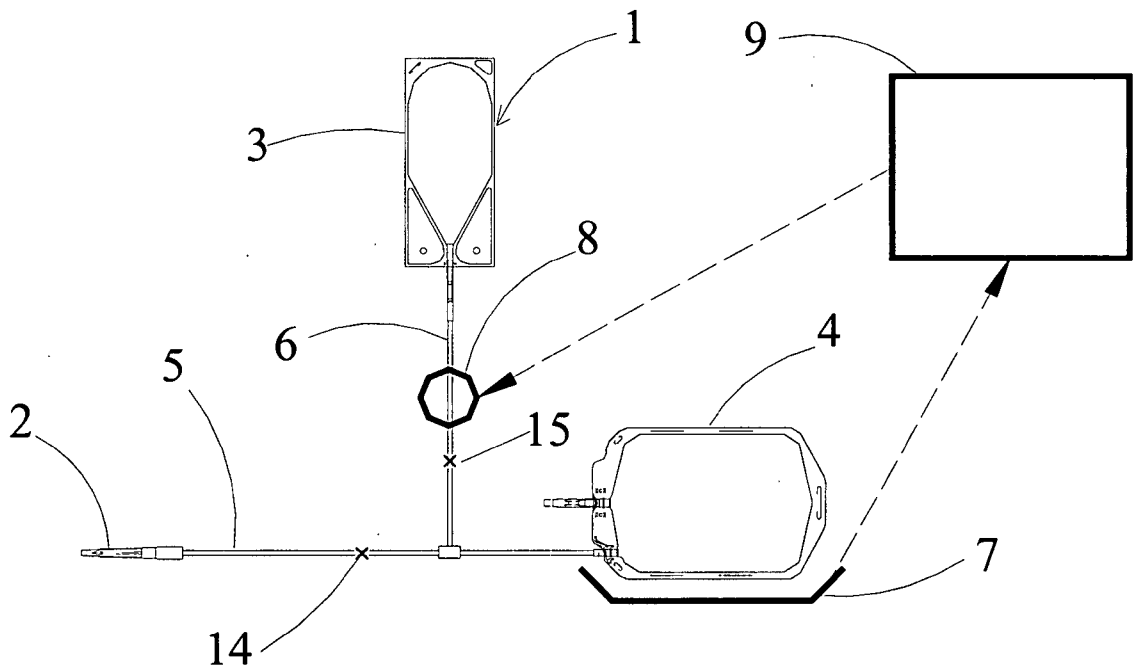

FIG. 1

AUSTRALIA

Patents Act 1990

ORIGINAL COMPLETE SPECIFICATION
STANDARD PATENT

Invention title: **FLOW MIXING MACHINE AND METHOD ACCORDING TO A DETERMINED RATIO OF A BIOLOGICAL FLUID AND A SOLUTION**

The following statement is a full description of this invention, including the best method of performing it known to us:

FLOW MIXING MACHINE AND METHOD ACCORDING TO A DETERMINED RATIO OF A BIOLOGICAL FLUID AND A SOLUTION

Field of the invention

The invention concerns a flow mixing machine according to a determined ratio of a biological fluid and an anticoagulant and/or preservation solution, as well as a mixing process by means of such a machine.

It typically applies to the case where the biological fluid is whole blood that has to be collected from a donor in a collection bag. In fact, it is recommended that the blood be collected in a sterile manner and be mixed with an anticoagulant and/or preservation solution at the time taken in order to enable subsequent use in optimum conditions of health safety.

Background of the invention

In this specification, where a document, act or item of knowledge is referred to or discussed, this reference or discussion is not an admission that the document, act or item of knowledge or any combination thereof was at the priority date:

(i) part of common general knowledge; or

(ii) known to be relevant to an attempt to solve any problem with which this specification is concerned.

A problem arises concerning obtaining a determined ratio between the quantity of fluid collected and the quantity of anticoagulant and/or preservation solution. In fact, in particular in the realm of blood collection, the quantity of anticoagulant and/or preservation solution found in the collection bag is set at a certain value so that the blood can be used medically.

From document EP-A-O 583 148, we know a device to introduce a flow of medical fluid in a flow of biological fluid that comprises a means of control designed to receive a volume signal, to calculate a speed of volume change and to adjust the flow of medical fluid according to the change in speed calculated.

This type of strategy to obtain a determined ratio of medical fluid in a biological fluid does not provide full satisfaction. In fact, the setting of the flow of the medical fluid is based on the measurement of a difference in volume that can not be satisfactorily obtained due to the overly low resolution of the useable measurement instruments.

Therefore, the operator has two possible options for this type of machine:

- use a big period of measurement to be able to obtain the variation in volume in a relatively exact manner, but then the adjustment of the flow of the medical fluid is not obtained in a frequent enough manner to be able to correspond with the flow of biological fluid in a satisfactory manner. In particular, if there is a high variation in the flow of the biological fluid, the adjustment of the flow of the medical fluid is too sudden, and the ratio is not preserved over time in a satisfactory manner;

- use a smaller period of measurement in order to try to better preserve the ratio over time, although the precision of the measurement of the variation in volume is too low to obtain a satisfactory adjustment of the flow of the medical fluid. In particular, the operator may then observe instabilities in the adjustment, which overly taxes the machine and, in fine, the ratio is not maintained over time.

Summary of the invention

According to a first aspect, the invention provides a mixing system comprising:

a measurement device operable to measure a volume of a biological fluid collected by natural flow from a patient without a pump;

a pumping device operable to measure an anticoagulant and/or preservation solution into the biological fluid and comprising a peristaltic pump having a head that is mobile in rotation at variable speeds; and

a control system operable to control the pumping device, the control system including a device operable to determine an actual volume of the anticoagulant and/or preservation solution previously pumped by the pumping device into the biological fluid comprising:

a component operable to determine the actual number of revolutions made by the head;

a component operable to calculate the actual volume based on the determined actual number of revolutions; and

an automatic control device operable to:

control a pumping speed of the pumping device;

calculate a theoretical volume of the anticoagulant and/or preservation solution to be mixed with the biological fluid collected by natural flow as a function of a determined ratio of the biological fluid collected and the anticoagulant and/or preservation solution pumped;

determine a theoretical number of revolutions of the pump head based at least on the calculated theoretical volume;

compare the theoretical volume to the actual volume by comparing the theoretical number of revolutions of the pump head with the determined actual number of revolutions made by the head to determine the difference between the theoretical volume and the actual volume; and

adjust the pumping speed of the pumping device as a direct function of the difference between the theoretical volume and the actual volume to approach the determined ratio, wherein, if the difference is positive, the pumping speed is increased and. If the difference is negative, the pumping speed is decreased or pumping is interrupted.

According to a second aspect, the invention provides a method for mixing a biological fluid and an anticoagulant and/or preservation fluid comprising:

collecting a biological fluid by natural flow collected from the patient without a pump;

measuring a volume of the biological fluid collected from the patient without a pump;

adding anticoagulant and/or preservation fluid to the biological fluid using a peristaltic pump having a head that is mobile in rotation at variable speeds;

calculating a theoretical volume of anticoagulant and/or preservation fluid to be added to the volume of biological fluid based on a determined ratio;

determining a theoretical number of revolutions of the head of the pump based at least on the calculated theoretical volume;

determining an actual number of revolutions made by head of the pump;

determining an actual volume of anticoagulant and/or preservation fluid added to the biological fluid collected based at least on the determined actual number of revolutions;

comparing the theoretical volume and actual volume comprising comparing the theoretical number of revolutions of the pump head with the number of revolutions actually carried out by the pump head to determine the difference between the theoretical volume and the actual volume; and

adjusting a pump speed of the pump based directly on the difference between the theoretical volume and the actual volume, so as to approach the determined ratio between the volume of biological fluid collected and the volume of anticoagulant and/or preservation solution added, wherein, if the difference is positive, the pump speed is increased and, if the difference is negative, the pump speed is decreased or pumping is interrupted.

The invention therefore provides a flow mixing machine and, according to a determined ratio of a biological fluid and an anticoagulant and/or preservation solution, can provide a better maintenance of the ratio during the mixing, by using measurement instruments of standard resolution.

Other advantages of the invention will appear in the following description with reference to the appended drawings.

Brief description of the drawings

Figure 1 represents the operation of a mixing machine according to a first design in which only the collection bag is placed on a means of weight measurement.

Figure 2 represents the operation of a mixing machine according to another design in which the collection bags and anticoagulant and/or preservation solution bags are placed on a means for weight measurement.

Figure 3 is a perspective view of the mixing machine according to one design.

Detailed description of the drawings

Figures 1 and 2 represent the operating principle of a flow mixing machine according to a determined ratio of a biological fluid and an anticoagulant and/or preservation solution.

In particular, the biological fluid is a blood fluid such as whole blood taken from a donor and the anticoagulant and/or preservation solution is a solution of the CPD (citrate phosphate dextrose), CP2D (cirate phosphate 2 dextrose) or CDA (citrate dextrose acid) type. In general, the determined ratio between the quantity of anticoagulant and/or preservation solution and the quantity of whole blood is set to 1/7. However, this ratio varies according to the geographic regions in which the blood is collected.

According to figures 1 and 2, the fluid is collected from a donor by natural flow. The fluid and anticoagulant and/or preservation solution is mixed using a system with bags 1 comprising collecting means 2, a bag 3 containing an anticoagulant and/or preservation solution for the fluid collected, and a collection bag 4 intended to receive the fluid collected mixed with the anticoagulant and/or preservation solution. Collection bag 4 is in fluid communication with the collecting means 2 through a first soft tube 5 and with bag 3 containing the anticoagulant and/or preservation solution through a second soft tube 6.

The collecting means 2 in particular consist of a needle providing access to the donor's vein. In this case, the fluid is directly collected from the donor. The fluid is collected by natural flow, that is, based on the venous pressure and/or gravity. This means of collection provide greater comfort and safety for the donor.

In figures 1 and 2, all of the elements of the system with bags 1 are pre-connected so as to form a closed unit or closed circuit system. The system thereby formed is sterilised, packaged in sterile and ready-to-use packaging.

In a non shown variant, the biological fluid to be mixed is contained in a transfer bag. In this case, the collecting means 2 comprise a perforator that can be connected to an outlet valve in the transfer bag containing the biological fluid. The biological fluid is collected from the transfer bag by natural flow, for example by gravity.

According to figures 1 and 2, the mixing machine comprises a measurement device 7 of the volume of fluid that is collected by natural flow, a pumping device 8 for the anticoagulant and/or preservation solution and a control system 9 for the pumping device.

Measurement device 7 indicates, at all times, the total volume of the fluid collected by natural flow.

According to the design shown in figure 1, measurement device 7 of the volume of fluid collected comprises a means for measuring the weight of fluid collected such as a scale and a means for calculating the corresponding volume. The passage from the weight of the fluid to the volume of the fluid is calculated by means of the density of the fluid.

According to figure 2, the entire bag system 1 is placed on a scale. A tare is obtained after the bag system 1 is placed on the scale, in order to take into account the weight of the aforementioned bag system before mixing. Since the anticoagulant and/or preservation solution then moves from bag 3 of anticoagulant and/or preservation solution to collection bag 4, and these two bags are on the scale, only the weight of the fluid collected is measured.

If only collection bag 4 is placed on the scale (figure 1), it is necessary to take into account the tare normally obtained in addition to a constant which is the variation in weight related to the introduction of the anticoagulant and/or preservation solution in collection bag 4.

According to figure 2, the pumping device comprises a peristaltic pump 10 with a single head 11 that is mobile in rotation at variable speeds.

The mixing machine also comprises a placement device 12, around part of head 11, a flow loop 13 for the solution so as to allow the circulation of the solution by partial compression of a zone in the aforementioned loop.

The flow loop is formed by a part of the second tube 6 connecting bag 3 of anticoagulant and/or preservation solution to collection bag 4.

This loop may be pre-formed as in the system of bags described in European patent application EP-A-1 442 759.

According to the invention, the control system 9 comprises a device for determining the volume of the solution pumped and an automatic control device for the pumping speed.

The device for determining the volume provides, as of the beginning of the mixing, the total volume of the anticoagulant and/or preservation solution at all times.

According to figure 2, the device for determining the volume of solution pumped comprises a means for determining the number of revolutions carried out by head 11 of peristaltic pump 10 and a means for calculating the volume pumped corresponding to the aforementioned number of revolutions.

The device for measuring the volume of fluid collected or the device for determining the volume of solution pumped determines all parameters of the fluid or the solution from which a volume may be calculated by means of algorithm. For example, the device for measuring the volume or determining the volume detects a mass, a flow, a height in a bag, a pressure and/or a deformation.

Thereby, the device may include optical detectors, flow sensors, pressure sensors...

In particular, the device for measuring the volume of the fluid collected or the device for determining the volume of the solution pumped maintains the sterility of the system of bags.

Control system 9 according to the invention also comprises an automatic control device for the pumping speed, for example, in the form of a computer, that comprises means able to:

- as a function of the determined ratio, calculate the theoretical volume of the solution to be mixed with the volume of fluid collected;
- compare the theoretical volume of solution and the volume of solution pumped;
- adjust the pump speed as a function of the previous comparison so as to approach the ratio determined between the quantity of fluid collected and the quantity of anticoagulant and/or preservation solution mixed.

The automatic control device for the pump speed controls the speed of the pumping device according to the theoretical volume of the solution and the volume of the pumped solution. For example, the automatic control device controls the motor of pump 10.

Optical sensors 14 15 are added to the machine. A first optical sensor 14 is placed on the first tube 5. This sensor detects the presence of fluid, in order to verify that the fluid circulates suitably within the first tube 5. It also verifies that no air or anticoagulant and/or preservation solution rises up to the collecting means. Optical sensor 14 may, for example, be replaced or completed with an ultrasound sensor used to more finely detect inversions of flow.

A second optical sensor 15 may be placed on the second tube 6. This sensor detects the presence of anticoagulant and/or preservation solution in order to verify that the anticoagulant and/or preservation solution circulates suitably within second tube 6.

Figure 3 represents a view in perspective of a mixing machine for blood and anticoagulant and/or preservation solution. The mixing machine comprises a means to

measure the weight of the fluid collected in the form of scale 16, a peristaltic pump 10 and a control system for the peristaltic pump as described above.

The machine also includes an interface 17 for the user comprising a display 18 and a keyboard 19.

The machine also includes a placement device 12 around part of head 11, a flow loop for the solution so as to enable the circulation of the solution by partial constriction of a zone of the aforementioned loop.

According to a second aspect, the invention proposes a process to mix a biological fluid and an anticoagulant and/or preservation solution in a closed circuit and according to a determined ratio by means of a machine according to the first aspect of the invention.

The method foresees the use of a system of bags 1 such as described in relation with figure 1 comprising, in a closed circuit, means for collecting the fluid 2, a bag 3 containing an anticoagulant and/or preservation solution for the fluid collected, and a collection bag 4 intended to receive the fluid collected mixed with the anticoagulant and/or preservation solution. Collection bag 4 is in fluid communication with the sampling means of 2 through a first soft tube 5 and bag 3 containing the anticoagulant and/or preservation solution through a second soft tube 6.

The method comprises the following iterative stages:

- measurement of the volume collected in collection bag 4;
- determination of the volume of the solution pumped from bag 3 containing it;
- as a function of the determined ratio, calculation of the theoretical volume of the solution to be mixed with the volume of fluid collected;
- comparison of the theoretical volume of the solution and the volume of solution pumped;
- adjustment of the pump speed as a function of the previous comparison so as to approach the ratio determined between the quantity of fluid collected and the quantity of anticoagulant and/or preservation solution mixed.

The volume of fluid collected is measured by means of at least collection bag 4 on a means of weight measurement, then calculation of the volume of fluid corresponding to the weight measured.

Related to the mixing machine illustrated in figure 3, the collection bag and the anticoagulant and/or preservation solution bag are placed on scale 16. The scale thereby directly determines the weight of the fluid collected. The conversion of the weight of the fluid collected into volume of fluid collected is calculated by means of the density of the blood.

This volume of fluid collected is used to calculate a theoretical volume of solution as a function of the determined ratio.

In parallel, the volume of solution pumped is determined by the determination device and, in particular, the number of revolutions of the head of pump 11 of peristaltic pump 10.

The difference between the theoretical volume of solution and the volume of solution pumped is calculated and the pump speed is adjusted by application of a pump speed that is a function of this difference.

For example, if the difference is negative, this means that too much solution was pumped with respect to the quantity of fluid collected. The pumping is then interrupted.

If the difference is positive, this means that not enough solution was pumped and pumping takes place. The pumping speed is determined as a function of this difference. The greater the difference, the more the speed is increased to make up for the lack of anticoagulant and/or preservation solution in the collection bag with respect to the fluid collected.

In one variant, the theoretical volume of the solution calculated from the volume of fluid collected is transcribed in theoretical number of revolutions of the head of the peristaltic pump.

The number of revolutions actually carried out by the pump head is compared with this theoretical number of revolutions of the pump head and the pump speed is adjusted as a function of the previous comparison.

These iterative stages are carried out with a sampling period ranging from 1 and 5 seconds, in particular 3 seconds.

This sampling period is sufficiently long for a sufficient variation in the volume of the fluid collected to be detected in a precise manner and sufficiently short to obtain quasi continuously the determined ratio between the quantity of anticoagulant and/or preservation solution mixed.

Therefore, even if the mixture is interrupted for any reason before the end of the procedure, the determined ratio is respected. In the case of blood collection, the loss of this ratio leads to a drop in the quality of the blood by lysis of the erythrocytes and a deterioration of the functionality of the platelets, resulting in the impossibility of using the blood.

The machine and the associated method are especially adapted for the collection of blood from a donor in which the volume of fluid collected increases in an increasing manner with a limited flow, as is the case when whole blood is collected by natural flow.

The method described avoids fast changes in the pumping speed.

It will be appreciated that the invention is not to be restricted to the details described above with reference to the preferred embodiments but that numerous modifications and variations can be made without departing from the spirit or scope of the invention as defined in the following claims.

The word 'comprising' or forms of the word 'comprising' as used in this description and in the claims do not limit the invention claimed to exclude any variants or additions.

The claims defining the invention are as follows:

1. A mixing system comprising:

a measurement device operable to measure a volume of a biological fluid collected by natural flow from a patient without a pump;

a pumping device operable to measure an anticoagulant and/or preservation solution into the biological fluid and comprising a peristaltic pump having a head that is mobile in rotation at variable speeds; and

a control system operable to control the pumping device, the control system including:

a device operable to determine an actual volume of the anticoagulant and/or preservation solution previously pumped by the pumping device into the biological fluid comprising:

a component operable to determine the actual number of revolutions made by the head;

a component operable to calculate the actual volume based on the determined actual number of revolutions; and

an automatic control device operable to:

control a pumping speed of the pumping device;

calculate a theoretical volume of the anticoagulant and/or preservation solution to be mixed with the biological fluid collected by natural flow as a function of a determined ratio of the biological fluid collected and the anticoagulant and/or preservation solution pumped;

determine a theoretical number of revolutions of the pump head based at least on the calculated theoretical volume;

compare the theoretical volume to the actual volume by comparing the theoretical number of revolutions of the pump head with the determined actual number of revolutions made by the head to determine the difference between the theoretical volume and the actual volume; and

adjust the pumping speed of the pumping device as a direct function of the difference between the theoretical volume and the actual volume to approach the determined ratio, wherein, if the difference is positive, the pumping speed is increased and. If the difference is negative, the pumping speed is decreased or pumping is interrupted.

2. A mixing system according to Claim 1, wherein the measurement device comprises a device operable to weigh the biological fluid.

3. A mixing system according to Claim 1, wherein the measurement device comprises a device operable to calculate the volume of a biological fluid collected by natural flow based on weight.

4. A mixing system according to any preceding claim, wherein the pumping device comprises a peristaltic pump having a single head that is mobile in rotation at variable speeds.

5. A mixing system according to Claim 4, wherein the automatic control device comprises:

a component operable to determine the number of revolutions made by the head; and

a component operable to calculate the actual volume based on the number of revolutions.

6. A mixing system according to Claim 4 or Claim 5, comprising:

a placement device around part of the head; and

a flow loop operable with the head and placement device to move the solution through the loop by constriction of a zone of the flow loop.

7. A mixing system according to any preceding claim, wherein the biological fluid comprises blood or a blood component.

8. A method for mixing a biological fluid and an anticoagulant and/or preservation fluid comprising:

collecting a biological fluid by natural flow collected from the patient without a pump;

measuring a volume of the biological fluid collected from the patient without a pump;

adding anticoagulant and/or preservation fluid to the biological fluid using a peristaltic pump having a head that is mobile in rotation at variable speeds;

calculating a theoretical volume of anticoagulant and/or preservation fluid to be added to the volume of biological fluid based on a determined ratio;

determining a theoretical number of revolutions of the head of the pump based at least on the calculated theoretical volume;

determining an actual number of revolutions made by head of the pump;

determining an actual volume of anticoagulant and/or preservation fluid added to the biological fluid collected based at least on the determined actual number of revolutions;

comparing the theoretical volume and actual volume comprising comparing the theoretical number of revolutions of the pump head with the number of revolutions actually carried out by the pump head to determine the difference between the theoretical volume and the actual volume; and

adjusting a pump speed of the pump based directly on the difference between the theoretical volume and the actual volume, so as to approach the determined ratio between the volume of biological fluid collected and the volume of anticoagulant and/or

preservation solution added, wherein, if the difference is positive, the pump speed is increased and, if the difference is negative, the pump speed is decreased or pumping is interrupted.

9. A method according to Claim 8, further comprising:

using a collection device in a closed circuit collection system to obtain the biological fluid;

collecting the biological fluid in a collection bag in the closed circuit collection system; and

removing the anticoagulant and/or preservation solution from a solution bag in the closed circuit collection system using the pump.

10. A method according to Claim 9, wherein measuring a volume of the biological fluid collected comprises:

placing the collection bag on a weight measurement device; and

calculating the volume of fluid corresponding to the weight measured.

11. A method according to any one of Claims 8 to 10, wherein comparing comprises determining a difference between the theoretical volume and the actual volume.

12. A method according to any one of Claims 8 to 11, comprising repeating the steps in multiple iterations.

13. A method according to Claim 12, wherein each iteration lasts between 1 and 5 seconds.

14. A method according to any one of Claims 8 to 13, wherein the biological fluid comprises blood or a blood component.

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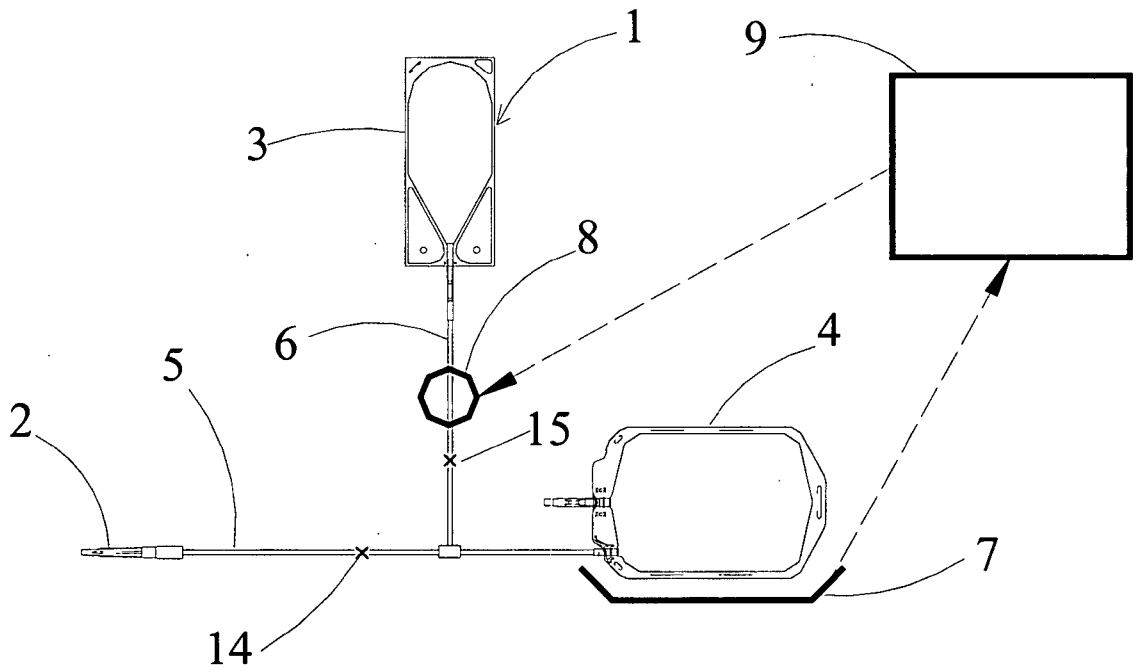

FIG. 1

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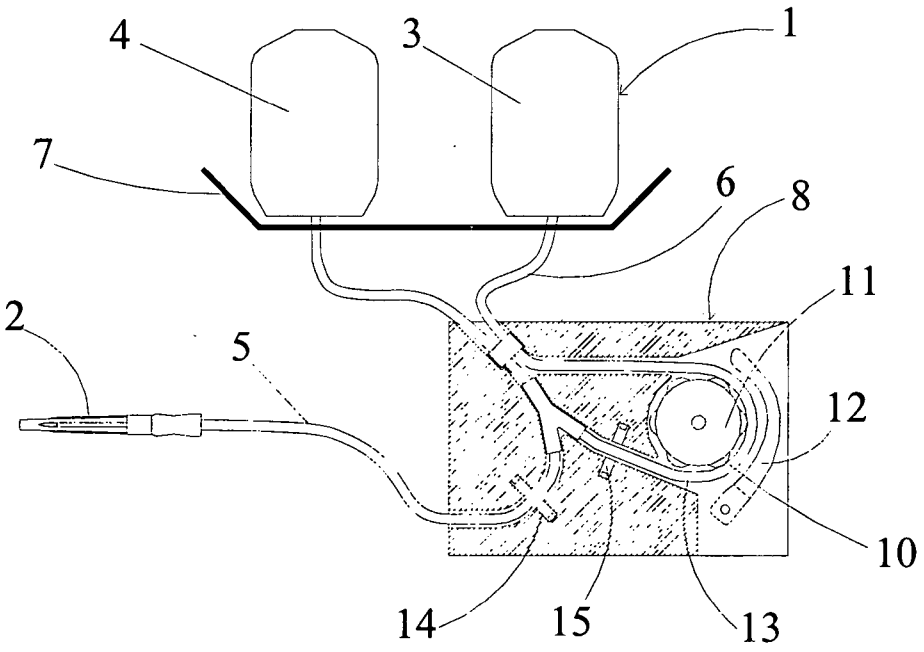

FIG. 2

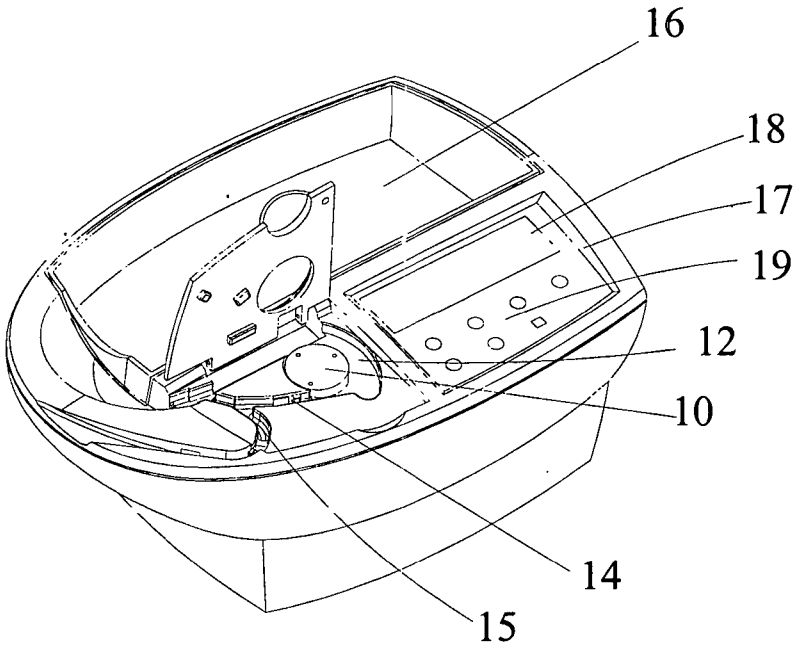

FIG. 3