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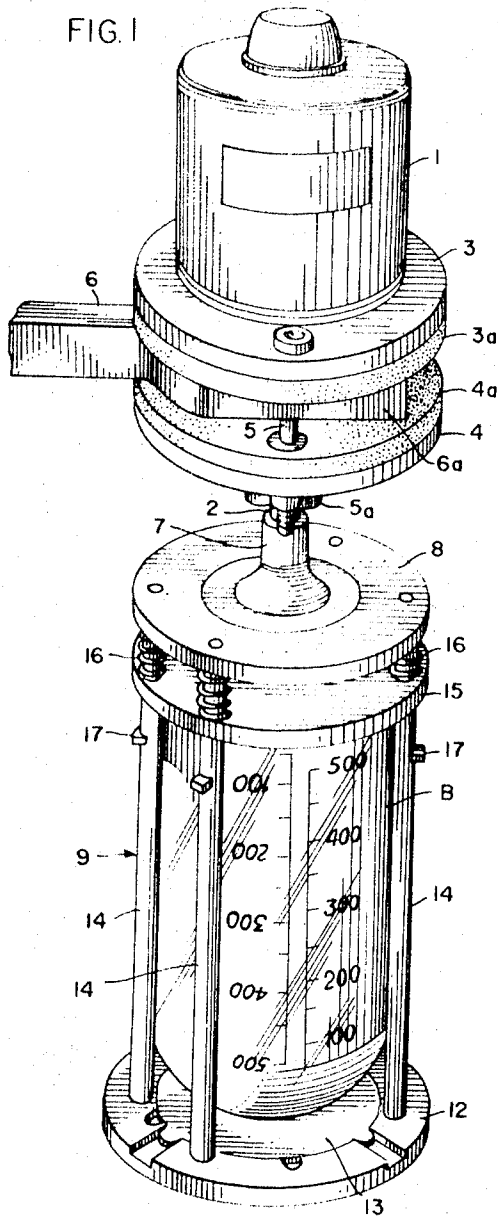
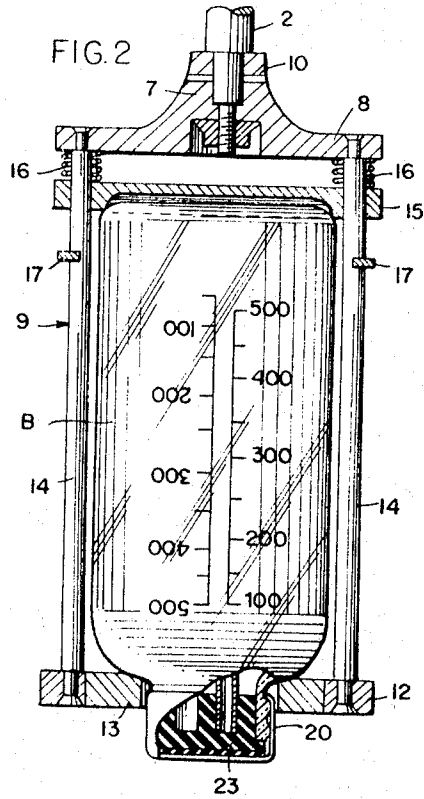
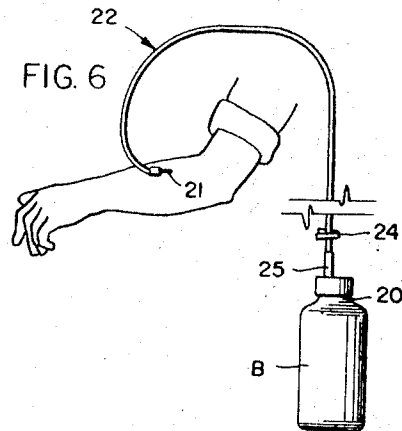
V. G. LUCAS

3,460,752

APPARATUS FOR PERFORMING PLASMAPHERESIS IN SITU

Original Filed Nov. 9, 1965

2 Sheets-Sheet 1



INVENTOR:

VICTOR GRIFOLS LUCAS
BY

Dawson, Felton, Fallon & Lungman
ATT'YS

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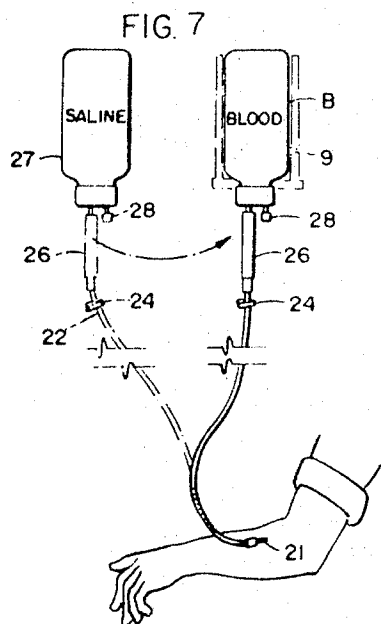
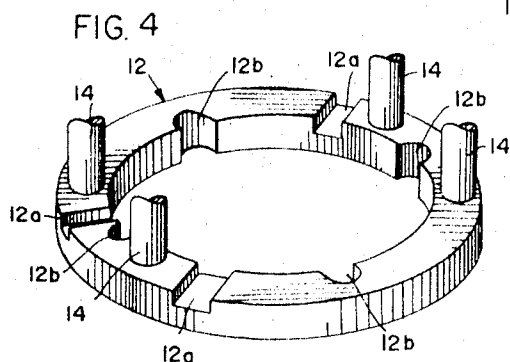
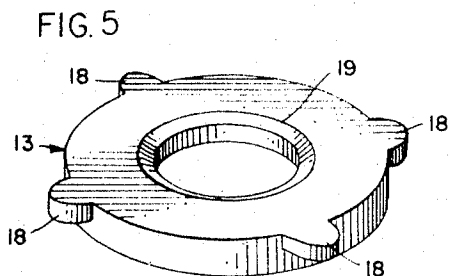
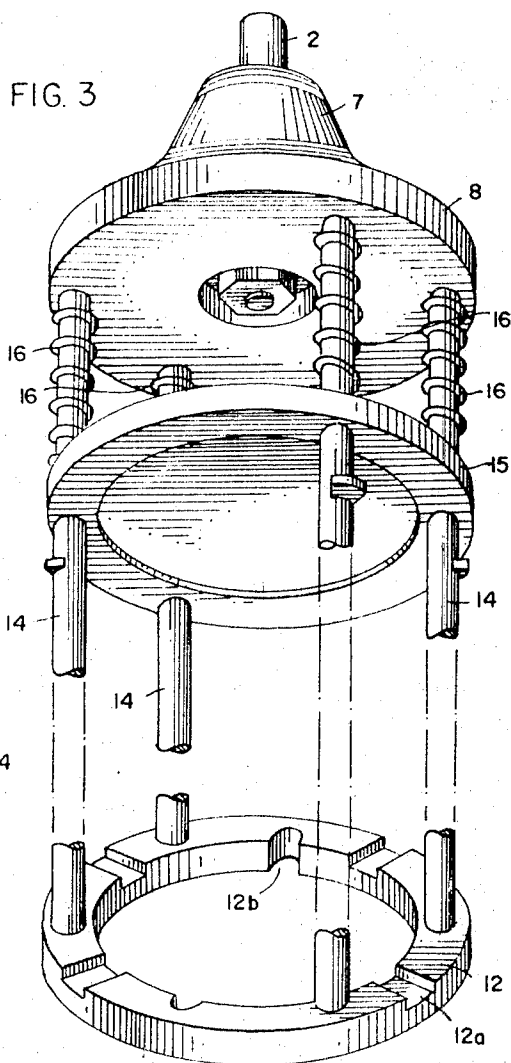
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Dawson, Filton, Fallon & Ljungman
ATT'YS

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APPARATUS FOR PERFORMING
PLASMAPHERESIS IN SITU

Victor Grifols Lucas, Barcelona, Spain, assignor, by mesne assignments, to American Hospital Supply Corporation, Evanston, Ill., a corporation of Illinois

Original application Nov. 9, 1965, Ser. No. 502,190, now Patent No. 3,407,812, dated Oct. 29, 1968. Divided and this application Sept. 12, 1968, Ser. No. 759,377

Int. Cl. B04b 9/12, 9/14; B01d 43/00

U.S. Cl. 233-26

7 Claims

ABSTRACT OF THE DISCLOSURE

An apparatus for performing plasmapheresis in situ including an inverted blood bottle, a bottle retainer secured to a driven shaft and equipped with means for holding the bottle in inverted position with the bottle's axis in alignment with the axis of the shaft, a motor for rotating the shaft and bottle at a predetermined rotational speed and for gradually reducing the speed of rotation of the bottle, and cushioning means associated with the motor and bottle for absorbing vibrations which might otherwise be transmitted to the bottle held by the retainer during operation of the centrifuge.

This application is a division of my co-pending application Ser. No. 502,190, filed Nov. 9, 1965, now Patent No. 3,407,812.

This invention relates to plasmapheresis, and more specifically, to an apparatus for performing plasmapheresis in situ.

In the past, whenever it has been desired to obtain human plasma by plasmapheresis, blood has first been withdrawn from the donor and has then been transmitted to a laboratory where it has been centrifuged to obtain separation of plasma from the red cells. Such a procedure has been characterized by the following disadvantages:

(1) The donor must suffer venipuncture twice; first for withdrawal of blood, and second, for re-injection of the red cells separated from his own blood, the re-injection of such cells serving to speed the process of recuperation so that more frequent donations may be feasible.

(2) Centrifugation of blood in the laboratory requires a detailed control in order to avoid mistakes that may produce shock in the donor if red cells from another person are administered to him.

(3) Repeated handling of the blood and its passage from one container to another, as well as recuperation of the red cells for re-injection, amount to a series of operations which require considerable time and increase the danger of infections and mistakes.

Accordingly, it is an object of the present invention to provide an apparatus for performing plasmapheresis in situ, thereby overcoming many of the important disadvantages and dangers in plasmapheresis as it is now practiced. Specifically, it is an object to provide an apparatus for practicing plasmapheresis in situ, thereby achieving important advantages in safety, asepsis and speed, to insure success with the least possible inconvenience and danger to the donor.

Another object is to provide an apparatus in which withdrawal of blood, and the centrifugation of such blood, are both carried out in the same container. In this connection, it is a specific object to provide an apparatus in which centrifugation is achieved by rotating the collection bottle on its own axis. A further object is to provide an apparatus in which a blood collection bottle is not only utilized directly in the centrifugation process,

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but is supported in such a way that re-injection of the red blood cells is greatly facilitated.

A still further object is to provide an apparatus in which a blood collection bottle is elastically suspended to avoid oscillations and vibrations, and thereby provide an automatic fixation of the spinning axis, during a centrifugation process.

Other objects and advantages will be apparent from the specification and drawings, in which:

FIGURE 1 is a perspective view of the complete apparatus embodying the present invention, such apparatus including an electric motor elastically suspending, and a carriage stand mounted for rotation by the motor and adapted to contain a collection bottle in inverted position; FIGURE 2 is a longitudinal sectional view of the carriage stand;

FIGURE 3 is an exploded perspective view illustrating structural details of the stand;

FIGURE 4 is a broken perspective view of the lower portion of the bottle retainer showing the lower retaining ring;

FIGURE 5 is a perspective view of a disk adapted to be mounted in the retainer's lower retaining ring;

FIGURE 6 is a view in reduced scale illustrating a first step in practicing the method of the present invention;

FIGURE 7 is another view in reduced scale illustrating subsequent steps in practicing such method.

Referring specifically to the drawings, I will now describe in detail the construction and functional characteristics of the apparatus, and the steps of the method, which permit practicing human plasmapheresis in the same place where blood is collected and which also allows immediate re-injection to the donor of his own red cells.

The apparatus shown in FIGURE 1 comprises an electric motor 1 disposed vertically with its shaft 2 projecting downwardly. At the lower end of the motor housing is a horizontal plate or clamping member 3 which is provided along its underside with a resilient pad or cushion 3a. A second clamping member 4, provided along its upper surface with a similar pad or cushion 4a, is spaced beneath member 3 and is detachably connected thereto by vertical bolts 5 or by any other suitable connecting means. By rotating wing nuts 5a, the distance between plates 3 and 4 may be reduced or increased to either clamp or release a supporting arm 6 having a Y-shaped end portion 6a disposed between the plates. The opposite end of the arm is firmly secured to a standard (not shown) or other appropriate stationary support means.

Motor shaft 2 extends downwardly through apertures in both clamping plates and is connected at its lower end to an adaptation neck 7 which constitutes a union between the shaft and the upper plate 8 of a bottle retainer or support 9. A pin 10 (FIGURE 2) extends through the lowermost end of the shaft and securely anchors the motor shaft and plate 8 for simultaneous rotation.

A collection bottle B, into which blood withdrawn from a donor is collected and in which centrifugation is thereafter immediately performed, is disposed in inverted position within the cage-like retainer 9. As shown in the drawings, retainer 9 comprises the upper disk 8, lower retaining ring 12 and disk 13, and parallel columns 14 extending between the upper disk 8 and the lower ring-disk assembly 12-13. The four columns are arranged in uniformly and circumferentially spaced relation. On the columns, another disk or plate 15 is slidably mounted and bears against the bottom of inverted bottle B. Disk 15 is urged downwardly by helicoidal expansion springs 16 concentrically mounted on the columns and interposed between upper plate 8 and disk 15. The extent of spring expansion is limited by lugs 17 connected to the respective columns. Lugs 17 therefore serve as stops to limit the

extent of downward movement of disk 15 under the influence of springs 16.

Lower ring 12 is provided on its upper surface with a plurality of uniformly and circumferentially spaced notches or recesses 12a. In addition, the inner surface of the ring is provided with a like number of recesses or openings 12b, such recesses being uniformly spaced from each other and preferably being disposed substantially equal distances circumferentially between notches 12a. Disk 13 is adapted to fit within the large central opening of ring 12 and, as shown clearly in FIGURE 5, has a plurality of uniformly and circumferentially spaced ears 18. The ears project outwardly and are of semicircular shape, as are the recesses or openings 12b of ring 12, and the two parts (disk 13 and ring 12) are so mated that the disk may be moved upwardly into the large central opening of the ring with its ears 18 slidably received within opening or recesses 12b. Disk 13 is also provided with a central opening 19 for receiving the neck 20 of bottle B.

It is to be noted that the diameter of the large central opening of ring 12 is greater than the diameter of bottle B. Therefore, the bottle may be introduced into the cage-like retainer by inserting it upwardly in inverted position until its base engages the undersurface of spring-loaded plate 15. Disk 13 is fitted onto the inverted neck of the bottle, and the plate and bottle are then urged upwardly to compress springs 16 and to permit the ears 18 of the disk to pass upwardly through openings 12b. Thereafter, disk 13 is rotated until ears 18 seat within notches or recesses 12a. The weight of the bottle B, combined with the downward force exerted by springs 16, hold the ears 18 in position within recesses 12a during the centrifugation step.

It will be observed that when the apparatus is assembled as shown in FIGURE 1, stationary arm 6 supports the unit at a point or zone between motor 1 and bottle retainer 9. This arrangement, coupled with the cushioning effect of padded clamping members 3 and 4, substantially eliminates or dampens vibrations which might otherwise occur during centrifugation. As will be brought out later, it is important that vibrations which might produce turbulence of blood during centrifugation, and during the gradual reduction in rotational speed of the retainer following a period of centrifugation, be avoided.

Preferably, the motor is constructed to rotate shaft 2 and retainer 9 at a speed of between 1500 to 3000 revolutions per minute. It is imperative that the motor be constructed and arranged, or controlled in its operation, so that deceleration of the retainer 9 and the blood-containing bottle B, following a period of centrifugation, occur gradually over an interval in excess of 3 minutes. Such gradual deceleration is necessary to prevent turbulence in the blood and to permit a substantially complete separation of plasma and red cells. The gradual and uniform deceleration may be easily achieved by constructing the rotating parts to spin with minimum friction and also to possess, by virtue of their mass, sufficient momentum to spin for a period in excess of 3 minutes and preferably for a period in excess of 4 minutes, after the electric motor has been deenergized. In practice, a deceleration period in the range of 4 to 10 minutes, with an optimum period of approximately 7 to 8 minutes, has been found particularly effective. Periods in excess of 10 minutes are not desirable because they unduly extend the plasmapheresis procedure without any appreciable increase in the degree of red cell and plasma separation.

While gradual deceleration may be achieved as described above, it is to be understood that similar results may be obtained with rotating parts having greater friction and less mass by simply gradually reducing the electric power supplied to the motor over an interval in excess of 3 minutes and, preferably, in excess of 4 minutes.

To practice plasmapheresis in situ, using the apparatus

just described, venipuncture is first performed with the needle 21 of a conventional blood collection set 22, and then collecting the blood in a sterile, partially-evacuated bottle B (FIGURE 6). Bottle B is a standard blood-collection bottle, having its neck 20 closed with a self-sealing rubber stopper 23. Blood flows through the collection set into the bottle and, after a predetermined amount of blood (normally 500 ccs.) has been collected, standard clamp 24 is manipulated to close the blood-collection tube and the filling needle 25 is withdrawn from the self-sealing stopper 23 and, as indicated in broken lines in FIGURE 7, is inserted into the drip tube assembly 26 connected to a suspended bottle 27 containing sterile physiological saline. The sterile saline is allowed to flow along the tube 22 which connects to the donor's vein. This allows (1) some degree of replenishment of the total fluid lost by the donor during the withdrawal of blood and (2) the maintenance of patency of the needle which was previously inserted into the donor's vein and which has not been removed therefrom. Failure to maintain a slow flow of physiologically compatible liquid through this needle would result in the formation of a clot within the needle.

Blood bottle B is entirely conventional and contains standard amounts of an approved anti coagulant substance such as, for example, citrate, heparin, or EDTA.

After the filling needle 25 has been removed from the self-sealing stopper of the blood bottle, the substantially filled bottle is placed within retainer 9, in the position shown in FIGURES 1 and 2, and motor 1 is energized to centrifuge the collected blood for a period of 15 to 20 minutes, including deceleration time. Centrifugation causes the red cells to migrate outwardly against the inside wall surfaces of the bottle, thereby separating the cells from the plasma which remains in the bottle's axial zone. Following centrifugation, the bottle is allowed to remain undisturbed in the stationary retainer 9 for a further period of 1 to 3 minutes, at which time the red cells which have been driven to the wall of the bottle during centrifugation slide downwardly and occupy the lower portion of the inverted bottle.

As indicated by the solid lines in FIGURE 7, a typical airway needle 28 is then inserted into self-sealing stopper 23 and into communication with the air tube (not shown) within the blood bottle. Thereafter, drip tube assembly 26 is withdrawn from the stopper of the saline bottle 27 and the needle of that assembly is inserted into the stopper of the inverted blood bottle. The contents of the bottle are allowed to flow through the tube system 22 into the donor's vein until exactly half the contents of the blood bottle (approximately 250 ccs.) have been so administered. The administration procedure is then discontinued by closing clamp 24, and needle 21 is withdrawn from the donor's vein.

The residual contents of the blood bottle will consist of plasma contaminated by a certain small proportion of red cells. In practice, this contamination amounts to between 2 to 5% of the 250 ccs. residual volume. The contaminating red cells are subsequently removed from the plasma by the use of a conventional centrifuge. This degree of red cell loss is quite insignificant and is considered to be small enough to permit a healthy individual to be subjected to the plasmapheresis procedure disclosed herein several times in a week.

It will be noted that throughout the plasmapheresis procedure, needle 21 remains in position in the donor's vein. Only a single venipuncture occurs and, since the entire procedure is conducted at the donor's bedside, there is no danger that the red cells returned to the donor may have been taken from someone else. The entire procedure is performed safely and relatively quickly, in 25 minutes or less, with no discomfort to the donor except possibly for that occasioned by the single venipuncture.

While in the foregoing I have disclosed the method

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and apparatus of the invention in considerable detail for purposes of illustration, it will be understood that many of these details may be varied without departing from the spirit and scope of the invention.

I claim:

1. An apparatus for performing plasmapheresis in situ, comprising an inverted cylindrical bottle disposed with its axis oriented vertically, said bottle having a downwardly tapered neck portion terminating in a stoppered opening, a bottle retainer supporting said bottle for rotational movement about the vertical axis thereof, an electric motor operatively connected to said retainer for rotating and supporting the same, and supporting means for supporting said motor, said supporting means including cushioning means for resiliently supporting said motor and thereby absorbing vibrations which might otherwise be transmitted to said bottle during operation of said motor.

2. The structure of claim 1 in which said motor has an operating speed within the range of approximately 1500 to 3000 revolutions per minute, the frictional resistance to rotation and the mass of the rotatable parts being such that upon de-energization of said motor the full deceleration of said retainer and fluid-containing bottle carried thereby will occur over an interval in excess of three minutes.

3. The structure of claim 1 in which said bottle is detachably supported by said retainer.

4. In an apparatus for practicing plasmapheresis in situ, an electric motor oriented with its shaft extending vertically, a bottle retainer of generally cylindrical configuration having the longitudinal axis thereof extending vertically and having one end thereof secured to said

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motor shaft for rotation of said retainer about said axis when said motor is operated, said bottle retainer defining a chamber for supporting an inverted blood-containing bottle having a downwardly tapered neck portion terminating in an axially-oriented stoppered opening, and support means for supporting said motor, said support means including cushioning means for resiliently supporting said motor and thereby absorbing vibrations which might otherwise be transmitted to said blood bottle during operation of said motor.

5. The structure of claim 4 in which said motor shaft has a rotational speed within the range of approximately 1500 to 3000 revolutions per minute, the fractional resistance to rotation and the mass of the rotatable parts being such that upon de-energization of said motor the full deceleration of said retainer and a blood bottle carried thereby will occur gradually over an interval in excess of three minutes.

6. The structure of claim 4 in which said bottle retainer is provided with means for resiliently supporting said bottle.

7. The structure of claim 4 in which said bottle retainer is adapted for releasably supporting said bottle.

References Cited

German printed application, 1,128,180, Lennart, Apr. 19, 1962.

WILLIAM I. PRICE, Primary Examiner

U.S. Cl. X.R.

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