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Ayres

[11] **3,897,337**

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[54] **PLASMA SEPARATOR ASSEMBLY HAVING INTERFACE-SEEKING PISTON WITH CENTRIFUGAL VALVE**

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[*] Notice: The portion of the term of this patent subsequent to July 15, 1992, has been disclaimed.

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[21] Appl. No.: **446,370**

[52] **U.S. Cl.** **210/136;** 210/314; 210/359; 210/516; 210/DIG. 23

[51] **Int. Cl.** **B01d 21/26**

[58] **Field of Search** ..... 23/230 B, 258.5, 259, 292; 128/2 F, 214 R, 218 M, 272; 210/83, 84, 109, 131, 359, 514–518, DIG. 23, DIG. 24, 136, 314, 316; 233/1 A, 1 R, 26

[56] **References Cited**

UNITED STATES PATENTS

2,577,780	12/1951	Lockhart	128/272 X
3,539,300	11/1970	Stone	210/DIG. 24
3,647,070	3/1972	Adler	210/83
3,661,265	5/1972	Greenspan	210/359
3,741,400	6/1973	Dick	210/DIG. 23
3,782,548	1/1974	Bowen	210/DIG. 23

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Assistant Examiner—Robert H. Spitzer
Attorney, Agent, or Firm—Kane, Dalsimer, Kane, Sullivan and Kurucz

[57] **ABSTRACT**

A blood collection and separator assembly of the type suitable for centrifuging to separate the plasma or serum from the cellular phase of blood is disclosed. The assembly includes a collection container and an interface-seeking piston having a centrifugal valve associated therewith being slidably disposed therein for opening the valve during centrifugation and for sealing off the plasma or serum phase from the cellular or heavy phase of blood after centrifuging is terminated. The piston is formed having a specific gravity greater than the specific gravity of blood. The piston is provided with a valve assembly which automatically opens the valve when the assembly is subjected to centrifugal force. Disposed in tandem relationship with the valve means is a filter assembly to filter the plasma or serum as it passes through the valve means when the assembly is being centrifuged and the piston is moving downwardly into the container. The piston automatically stops at the plasma/serum-cellular interface by clogging the filter assembly with the cellular phase. When the centrifugal force is terminated the valve means is closed and the piston forms a barrier between the plasma or serum phase and the cellular phase.

6 Claims, 2 Drawing Figures

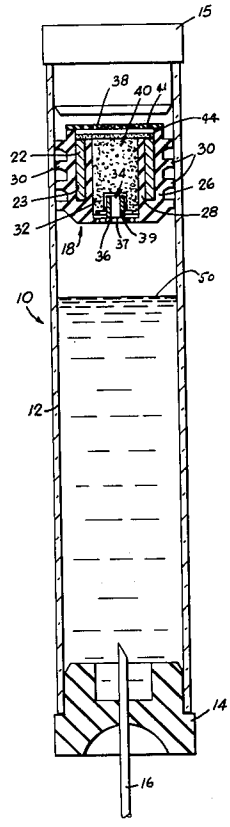

Fig. 1

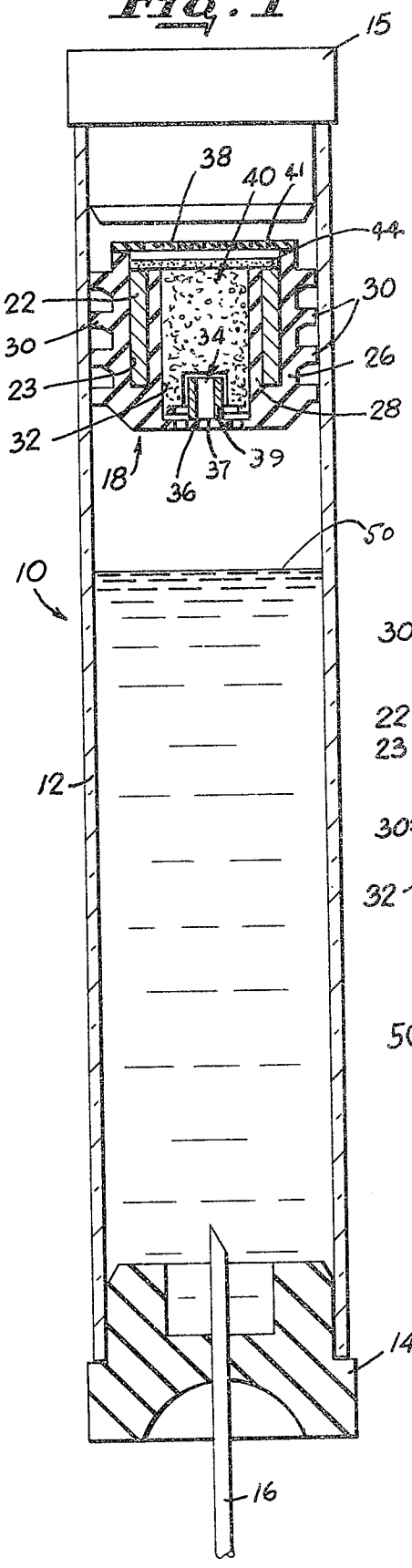
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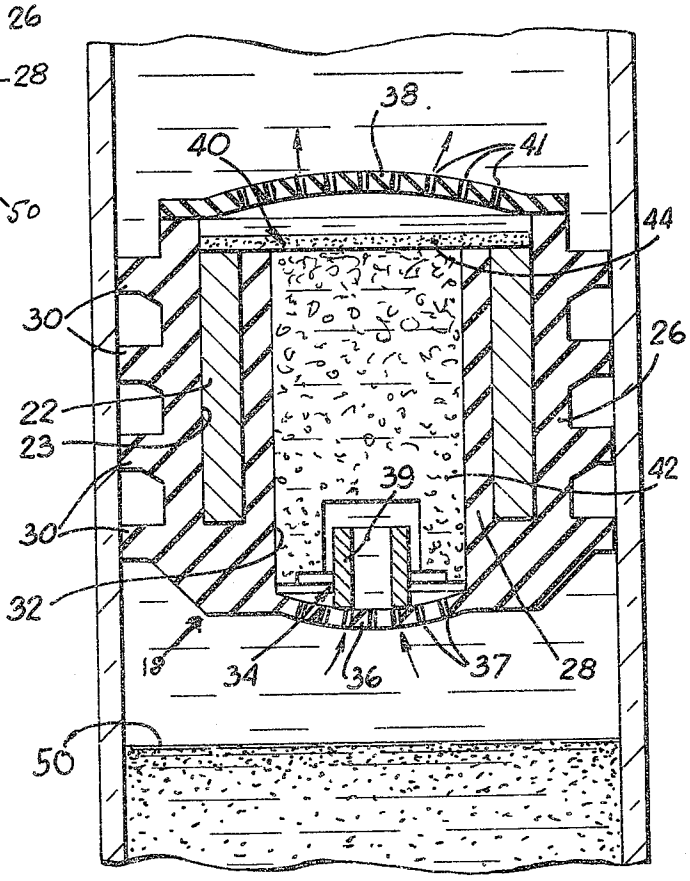
Fig. 2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PLASMA SEPARATOR ASSEMBLY HAVING INTERFACE-SEEKING PISTON WITH CENTRIFUGAL VALVE

BACKGROUND OF THE INVENTION

This invention plasma/serum generally to plasma/-serum separator assemblies and particularly to a plasma/serving separator having an interface-seeking piston with a centrifugal valve assembly. The piston is slidably disposed in a collection container for receiving blood. The piston includes valve means which is normally closed but which will automatically open when the assembly is subjected to centrifugal force. The piston also includes a filter means disposed in fluid communication with the valve means so that as the plasma or serum passes through the valve means it is filtered to remove any solid materials that may be present in the plasma or serum phase and which provides means for stopping the piston at the interface between the serum/plasma and cellular phase.

DESCRIPTION OF THE PRIOR ART

It is known to separate blood into its component parts by centrifugation, for example, the assembly disclosed in U.S. Pat. No. 2,460,641. However, this particular assembly does not employ a means for sealing the separated plasma or serum phase from the cellular phase.

It is also known to provide assemblies for manually separating the plasma or serum phase from the cellular phase, for example, as disclosed in U.S. Pat. Nos. 3,586,064; 3,661,265; 3,355,098; 3,481,477; 3,512,940 and 3,693,804. In all of these devices the serum is collected in a blood collection container and means are provided for separating the plasma or serum phase from the cellular phase employing filters, valves, transfer tubes or the like.

It is also known to provide assemblies for the sealed separation of blood in which a piston is actuated by centrifugal force such as is disclosed in U.S. Pat. Nos. 3,508,653 and 3,779,383. These devices use either a deformable piston made of a resilient material or valve means associated with the piston to effect a sealed separation after centrifugation.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a plasma/serum separator assembly in which an interface-seeking piston automatically stops when centrifuged at the plasma/serum-cellular interface.

It is another object of the invention to provide a piston having a centrifugal valve means that will not be accidentally opened when the container is being filled with blood by the pressure difference of blood at atmospheric pressure and the vacuum on the other side of the valve. It is also an object of the invention to provide a piston having a filter assembly which will prevent cellular materials contained in the blood from passing into the separated plasma or serum phase.

It is another object of the invention to provide a plasma/serum separator assembly which is economical to manufacture and can be used in conjunction with standard blood collecting equipment.

My invention generally contemplates the provision of a separator assembly which includes a blood collection container for receiving blood, the container having at least one open end which is adapted to receive a closure for sealing the end of the container. An interface-seeking piston is formed having a specific gravity greater than the specific gravity of blood and having a centrifugal valve means which automatically opens when the assembly is subjected to centrifugal force. A filter assembly is disposed in the piston in fluid communication with the valve means so that the plasma and/or serum after passing through the valve means is filtered to remove any solid materials contained therein. The piston automatically stops when the filter assembly becomes clogged with the heavy phase at the plasma/-serum-cellular interface.

DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention reference is had to the drawings which illustrate a preferred embodiment of the invention herein.

FIG. 1 is a sectional, elevational view of the plasma/-serum separator assembly illustrating a pointed cannula penetrating one of the stoppered ends of the container through which blood is introduced into the container prior to its separation.

FIG. 2 is an enlarged sectional, elevational view partly broken away illustrating the position of the piston approaching the plasma/serum-cellular interface while the assembly is being centrifuged.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For a better understanding of the invention herein a description of the preferred embodiment is had which is illustrated in FIGS. 1 and 2.

In FIG. 1 separator assembly **10** comprises a tubular member or container **12** which is sealed at its open ends by closure members **14** and **15.** Closure members **14** and **15** are preferably made of elastomeric material, for example, rubber, and are capable of being penetrated by a cannula **16** so that blood can be transferred from a blood source into the container under aseptic conditions. Closures **14** and **15** should be self-sealing so that when the cannula is removed from closure **14** there will be no loss of blood passing through the penetration portion of closure **14.** As depicted in FIG. **1,** blood is being conducted through cannula **16** and is shown filling container **12** to about the point where piston **18** is positioned adjacent closure member **15.** Thereafter, cannula **16** is removed and assembly **10** is ready for centrifuging for subsequent separation of the collected blood into the plasma or serum phase and the cellular phase. In this connection, apertures **37** of diaphragm **36** remain closed while blood is filling container **12** and will not accidentally open by the pressure differential between blood at atmospheric pressure and the vacuum that is present in the filter **40** and at the top surface of diaphragm **36.**

Disposed in container **12** is piston **18** which includes a tubular metal insert **22** which is mounted in the annular recess **23** of piston **18.** Metal insert **22** is preferably made of stainless steel or other rigid chemically inert material having a specific gravity substantially greater than blood. The body of piston **18** is preferably formed of elastomeric material and is provided with annular recess **23** which is dimensioned to receive tubular member **22** in an interference fit so that no air space remains in annular recess **23.**

The elastomeric portion of piston **18** comprises an outer wall **26** and spaced therefrom is inner wall **28** in

which their respective wall surfaces define annular recess 23. Formed integrally with wall 26 is a plurality of radially spaced resilient sealing rings 30 which contact the inner wall surface of container 12 in sealing liquid-tight engagement. Piston 18 when mounted in the container will maintain a liquid-tight sealing contact with the inner wall of container 12 throughout the piston's path of travel within the container during centrifuging. A longitudinally extending bore 32 provides a chamber for housing filter assembly 40. Valve means 34 includes a resilient diaphragm 36 and weighted mass 39. Diaphragm 36 is formed across the lower end of piston 18 to provide a barrier or closure for bore 32 and is made of a suitable elastomer, for example rubber. Also, positioned adjacent valve means 34, in bore 32, is filter assembly 40. Positioned within bore 32 and contacting the inner face of diaphragm 36 is a weighted mass or tubular insert 39 preferably cylindrical and having a diameter substantially less than the diameter of bore 32 which provides centrifugal valve opening means for diaphragm 36. Mass 39 has a loose fit relative to filter assembly 40. When the blood separator assembly is centrifuged to effect separation of the cellular phase from the plasma or serum phase, mass 39 presses against diaphragm 36 with sufficient force to stretch diaphragm 36 downwardly to thereby open apertures 37.

As shown in FIG. 2, filter assembly 40 includes coarse filter 42 which is mounted in bore 32 of piston 18 and fine filter 44 which is secured with a suitable adhesive on to piston 18 so that it covers the upper opening of bore 32. Filter 42 has an interference fit relative to bore 32 so that filter 42 remains in fixed position. Diaphragm 38 is also made of a suitable elastomer, for example rubber, and is cemented or otherwise secured to the top of wall 26 of piston 18. Diaphragm 38 is formed having one or more apertures or slits which are normally closed but which are opened when plasma/serum is passing through piston 18 as illustrated by the direction of the arrows in FIG. 2.

Fine filter 44 has average pore openings less than the average diameter of the red blood cells so that any plasma or serum containing solid materials of the diameter of a red blood cell or larger will be removed by filter 44 before passing through apertures 39 of diaphragm 38. Coarse filter 42 has an average pore size greater than the cellular phase of blood and serves as a prefilter to take out larger particles such as fibrin strands or clots from the plasma or serum before it reaches fine filter 44.

FIG. 2, which is an enlarged sectional view partly broken away, illustrates the position of piston 18 approaching the plasma/serum-cellular interface 50 during centrifugation and before the cells pass through coarse filter 42 and clog fine filter 44 thereby stopping the descent of piston 18 at the interface. It should be noted that apertures 37 and 41 of diaphragms 36 and 38 are open during the descent of piston 18 in container 12 but apertures 41 will automatically close when fine filter 44 clogs with red cells while apertures 37 of diaphragm 36 remain open even though centrifuging continues. When centrifuging ceases apertures 37 of diaphragm 36 will automatically close. It should be noted that piston 18 has a specific gravity substantially greater than the specific gravity of blood. However, piston 18 will automatically stop at the plasma/serum-cellular interface 50 when filter 44 of piston 18 becomes clogged with the heavy cellular phase, such as the red blood cells, thereby separating the light phase plasma or serum from the heavy phase cellular material of blood and will form a barrier between the two phases when centrifuging is completed.

When using the assembly illustrated in FIGS. 1 and 2 after the blood has been collected, assembly 10 is placed in a centrifuge and, at first, is subjected to a spin speed which is suitable to cause the heavy or cellular phase material to pass downwardly in the container toward stopper 14 but the spin speed is insufficient to cause the piston 18 to slide downwardly through the plasma/serum phase. Then, the assembly is subjected to a higher spin speed which causes mass 39 to press downwardly on diaphragm 36 additionally to open apertures 37 in piston 18. Piston 18 then starts its movement downwardly in the container and separated plasma or serum pass through apertures 37 and through coarse filter 42 and fine filter 44. The hydrostatic pressure of the plasma/serum exerted against diaphragm 38 causes it to stretch upwardly thereby opening valve apertures 41 to permit the passage of separated plasma or serum to the top side of piston 18. When piston 18 reaches the plasma/serum-cellular interface, red cells and other portions of the cellular phase pass through coarse filter 42 and are stopped by fine filter 44 thereby causing filter 44 to become clogged and effectively stop piston 18 at the plasma/serum-cellular interface 50. Thereafter, even though centrifuging continues diaphragm 38 returns to its normal relaxed position as in FIG. 1 with apertures 41 closed. However, until centrifuging ceases apertures 37 of diaphragm 36 remain open due to mass 39 exerting a force against diaphragm 36. When centrifuging ceases, resilient diaphragm 36 moves mass 39 to its normal position thereby automatically closing apertures 37. When centrifuging is completed the piston is established as a sealed barrier at the interface between the serum/plasma phase and the cellular phase.

From the foregoing, it is readily observed that a plasma/serum separator assembly in which an interface-seeking piston with a centrifugal valve is disclosed the assembly is described in which blood can be collected, centrifuged, separated into its component phases and is capable of being shipped through the mail for further analytical determinations without the plasma or serum mixing with the cellular phase even though the assembly is inverted and handled roughly.

While variations of the invention herein may be had the objectives of the invention have been illustrated and described and it is contemplated that changes in design can be made without departing from the spirit of the invention described herein.

What is claimed is:

1. A separator assembly capable of separating blood into a plasma/serum or light phase and a cellular or heavy phase comprising:

a container having at least one open end which is adapted to receive blood for subsequent separation into a light phase and a heavy phase;

a closure sealing the open end of the container, the closure being formed of a self-sealing, elastomeric material which is penetrable by a cannula through which blood to be separated is conducted into the container;

an interface-seeking piston having a specific gravity relatively greater than blood and slidably mounted in the container adjacent one end thereof and

being movable downwardly in said container due to the influence of centrifugal force and having means on an outer surface for providing sealing engagement with an inner surface of the container;

a valve assembly mounted on the piston and disposed at the lower end thereof, said assembly comprises a lower resilient diaphragm mounted on the lower end of said piston and having apertures formed therein, said apertures being normally closed and adapted to open during the downward movement of the piston; an upper resilient diaphragm mounted on the upper end of said piston, having apertures formed therein, said apertures being normally closed and adapted to open during the downward movement of the piston;

a filter assembly mounted between said valve assembly and said upper diaphragm and being in fluid communication with the valve assembly, said filter assembly including a lower coarse filter having an average pore opening larger than the diameter of blood cells, disposed adjacent said valve assembly and an upper fine filter having an average pore opening smaller than the diameter of blood cells, said fine filter disposed between the upper diaphragm and said coarse filter, said filter assembly being capable of removing substantially all solid material from the separated plasma/serum phase; and

said fine filter providing piston stop means when said piston is at the plasma/serum-cellular interface whereby the cellular phase clogs the fine filter to prevent further upward flow of fluid through the fine filter so that the piston automatically stops at said interface and the upper diaphragm apertures close.

2. The separator assembly of claim **1** wherein the valve assembly includes a weight mass disposed on the upper surface of said lower diaphragm, said mass being forced downward against the lower resilient diaphragm when the assembly is subjected to centrifugal force whereby said lower diaphragm is stretched and the apertures therein are opened.

3. The separator assembly of claim **1** wherein said filter assembly is disposed in a passage formed through said piston, the upper and lower ends of said passage being closed by said upper and lower resilient diaphragms respectively.

4. An interface-seeking piston adapted for use for separating the serum or plasma phase from the cellular phase of blood in a separator assembly including a container, said piston having a specific gravity relatively greater than blood and adapted to be slidably mounted adjacent one end of the container and movable downwardly in said container due to the influence of centrifugal force and having means on an outer surface thereof for providing sealing engagement with an inner surface of the container;

a valve assembly mounted on the piston and disposed at the lower end thereof, said assembly comprises a lower resilient diaphragm mounted on the lower end of said piston and having apertures therein, said apertures being normally closed and adapted to open during the downward movement of the piston;

a resilient upper diaphragm having apertures formed therein and mounted at the upper end of said piston with said apertures being normally closed and adapted to open during the downward movement of the piston;

a filter assembly mounted between said valve assembly and said upper diaphragm and being in fluid communication with the valve assembly, said filter assembly including a lower coarse filter having an average pore opening larger than the cellular phase, disposed adjacent said valve assembly and an upper fine filter having an average pore opening smaller than cellular phase; said fine filter disposed between said upper diaphragm and said coarse filter, said filter assembly being capable of removing substantially all solid material from the separated plasma/serum phase and said fine filter being adapted to provide piston stop means when said piston is at the plasma/serum-cellular interface.

5. The piston of claim **4** wherein the valve assembly includes a weight-mass disposed on the upper surface of said lower diaphragm, said mass being forced downward against the resilient lower diaphragm when the piston is subjected to centrifugal force whereby said lower diaphragm is stretched and the apertures therein are opened.

6. The piston of claim **4** wherein said filter assembly is disposed in a passage formed through said piston, the upper and lower ends of said passage being closed by said upper and lower resilient diaphragms respectively.

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