PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : **A61M 1/36**

A1

(11) International Publication Number: **WO 97/46272**

(43) International Publication Date: 11 December 1997 (11.12.97)

(21) International Application Number: PCT/US97/09783

(22) International Filing Date: 5 June 1997 (05.06.97)

(30) Priority Data:
08/659,808 7 June 1996 (07.06.96) US

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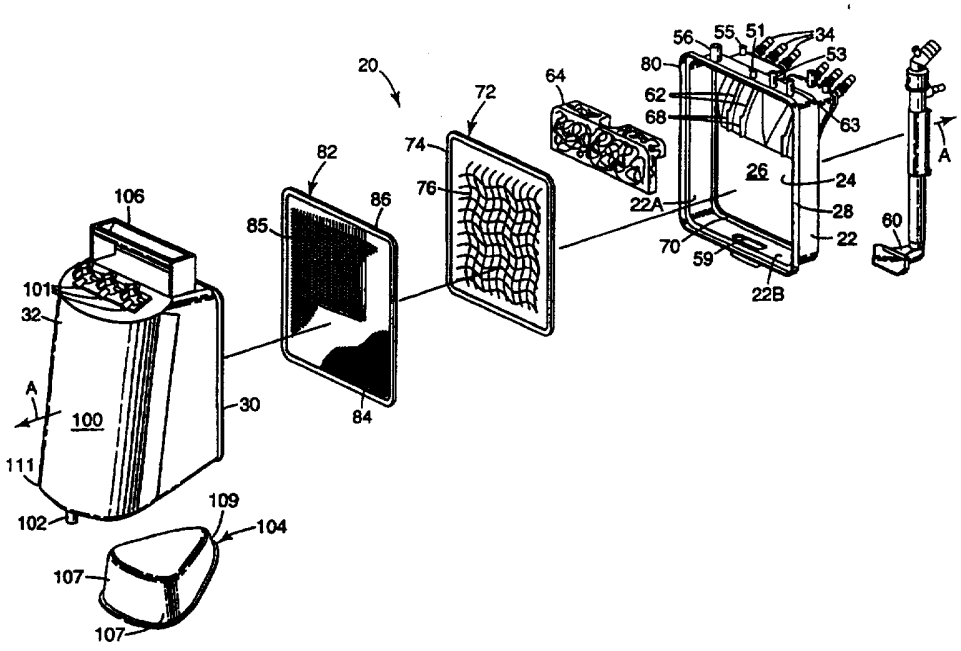
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: BLOOD TREATMENT SYSTEM



(57) Abstract

A blood treatment system (20; 120; 20') comprising a blood treatment cartridge (22) and a blood storage or outlet section (100). First and second planar blood treatment assemblies (70 and 80) can be inserted into the blood treatment cartridge (22) in spaced apart relationship along a single build axis (A), and the blood storage section (100) can be attached to the blood treatment cartridge along the single build axis (A), thus facilitating automated assembly of the system (20). The system (20) also facilitates observation of blood within its housing, in particular within the blood treatment cartridge (22).

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BLOOD TREATMENT SYSTEM

Field of the Invention

The invention relates to a blood treatment system and a method of assembling the same.

Background of the Invention

Various surgical procedures require interrupting the normal functioning of the heart and lungs of the patient. Some of the functions of these organs are temporarily replaced by an extracorporeal blood handling system. The main volume of the patient's blood, known as the venous return stream, is typically withdrawn from the patient through a venous cannula inserted into the right atrium. The blood handling system collects the volume of blood in a venous reservoir. The blood handling system serves to pump the blood, regulate the carbon dioxide and oxygen content, regulate the temperature, defoam and remove emboli and particulate matter using one or more filters. The blood is then returned to the patient through an aortic cannula inserted into the aorta distal to the heart.

Blood from the surgical field, known as cardiotomy blood, is typically drawn into a cardiotomy reservoir. The cardiotomy blood typically contains gas bubbles, fragments of tissue, bone chips, blood clots, surgical debris and other dangerous and undesirable contaminants. The cardiotomy reservoir defoams, filters and collects the cardiotomy blood prior to combining it with blood in the venous reservoir. The level of filtration required for cardiotomy blood is typically greater than that required for the relatively clean venous return stream.

The high level of filtration necessary for cardiotomy blood may cause damage to blood constituents, such as to due sheer stress. Consequently, cardiotomy blood filtration is preferably performed separately from filtration of the relatively clean venous return stream. Integrated cardiotomy reservoirs (ICR) combine the treatment of both cardiotomy and venous blood streams.

Turbulent flow may develop at various locations within the blood handling system. Turbulent flow can cause bubbles to form in the blood and can increase the blood-to-air contact. Blood to air contact causes hemolysis of red blood

cells. Hemolysis refers to the lysis or destruction of erythrocytes with the release of hemoglobin, resulting in a reduction in the ability of the blood to carry oxygen.

Blood handling systems can also have locations of blood stasis that can cause blood clotting or separation of blood components. Medical care providers are increasingly interested in viewing the condition of the blood throughout the entire blood circuit. Current blood treatment systems typically have internal regions that are not visible to the medical staff, such as the interior of cylindrically shaped filter media. Areas within the blood handling system that cannot be viewed by the medical staff may result in undetected blood stasis or clots.

Typical blood handling systems have a large number of discrete parts, requiring manual assembly, increasing the risk of assembly errors and increasing manufacturing costs. Manufacturing a variety of distinct extracorporeal blood handling systems with different blood treatment elements increases manufacturing and inventory costs. Variability between products also raises the risk of errors in assembly or marking of finished products, resulting in a potentially detrimental medical impact on the patient.

Summary of the Invention

This invention relates to blood treatment cartridge and a method of assembling the same. The blood treatment system utilizes a blood treatment cartridge with a two-dimensional assembly process (i.e., along a single build axis) that facilitates automated assembly and substitution of a variety of blood treatment media. The blood treatment system is provided with a high degree of biocompatibility and visibility.

Generally, a blood treatment system of the invention comprises a blood treatment cartridge having a chamber, and a blood-treatment-media-receiving opening defining an entrance to the chamber. A cardiotomy manifold (36) is provided in fluid communication with the chamber, with at least one cardiotomy blood sucker port in fluid communication with the cardiotomy manifold. A venous blood inlet is also provided in fluid communication with the chamber, with the venous blood inlet being spaced along the build axis from the cardiotomy manifold. A first generally planar blood treatment media is inserted along the build axis through the blood-treatment-media-receiving opening into the chamber. The first blood treatment media divides the chamber into first and second interior spaces, with the cardiotomy manifold in fluid

communication with the first interior space and the venous blood inlet in fluid communication with the second interior space. A second generally planar blood treatment media is inserted along the build axis through the blood-treatment-media-receiving opening of the blood treatment cartridge to enclose the second interior space. A blood outlet section is sealed to the blood treatment cartridge to form a housing enclosing the blood-treatment-media-receiving opening. The blood outlet section has an outlet port.

Preferably, the blood treatment cartridge and blood storage section form a housing comprising transparent plastic material, the housing being configured such that substantially the entire blood flow path is visible.

Also, preferably, the blood treatment cartridge includes a ledge in the chamber configured and positioned to engage the first blood treatment media to limit insertion of the first blood treatment media into the chamber. Most preferably, at least two ledges are provided, with the second ledge in the chamber between the blood-treatment-media-receiving opening and the first ledge. The second ledge is configured to engage the second blood treatment media to limit insertion of the second blood treatment media into the chamber. The second ledge defines a perimeter larger than the first ledge, and permits the first blood treatment media to be inserted into the chamber further than the second ledge.

Preferably, the first blood treatment media comprises a filtration media for filtering cardiotomy blood entering the system through the cardiotomy blood sucker port, and the second blood treatment media comprises a defoamer media for defoaming venous blood entering the system through the venous blood inlet and cardiotomy blood filtered by the filtration media. A pre-filter defoamer may also be provided for defoaming cardiotomy blood entering the first interior space from the cardiotomy blood sucker port before that blood is filtered by the filtration media. The filtration media may have, for example, an average pore size of about 20 to 40 microns.

Most preferably, a first frame extends around a perimeter of the filtration media, and a second frame extends around a perimeter of the defoamer media.

The blood-treatment-media-receiving opening of the blood treatment cartridge preferably has a perimeter forming means for snap-fit engagement with the blood outlet section.

Also, preferably, the blood outlet section (100) defines a blood storage chamber. A blood diverter may be provided within the blood storage chamber to form a pair of funnel-shaped blood flow channels diverging from one another as the channels extend from the blood-treatment-media-receiving opening toward the outlet port, and a pair of converging blood flow channels extending from the funnel-shaped blood flow channels to the outlet port. Most preferably, the funnel-shaped and converging blood flow channels define: (a) a first flow axis extending downwardly in the direction away from the blood-treatment-media-receiving opening at an angle of about 20 to 24 degrees with respect to horizontal; and (b) a pair of second flow axii converging downwardly toward one another in the direction perpendicular to the first flow axis at an angle of about 3 to 7 degrees to the horizontal.

The cardiotomy manifold preferably defines a downward curving ledge extending from the cardiotomy blood sucker port to the first interior space, with the downward curving ledge having a radius of about 2.5 to 7.6 cm. The cardiotomy blood sucker port extends along a tangent to the downward curving ledge. A plurality of support veins support a pre-filter defoamer in the cardiotomy manifold.

Also, preferably, the venous blood inlet includes a drop tube and a directionalized, velocity-reducing prime bowl downstream of the drop tube for directing a portion of the blood flow path outwardly toward the walls of the blood treatment cartridge and decelerating the blood flow. The prime bowl has a cross-section at least four times greater than the cross-section of the drop tube.

In a second embodiment of the invention, the blood treatment system comprises a transparent housing defining a blood treatment chamber and a blood storage chamber downstream of the blood treatment chamber. A cardiotomy manifold is in fluid communication with the blood treatment chamber, and at least one cardiotomy blood sucker port is in fluid communication with the cardiotomy manifold. A venous blood inlet is in fluid communication with the blood treatment chamber, with the venous blood inlet being spaced from the cardiotomy manifold. An outlet port is provided in fluid communication with the blood storage chamber. A generally planar blood filtration media assembly has a periphery engaging the housing to divide the blood treatment chamber into first and second interior spaces that are visible through the transparent housing. The cardiotomy manifold is in fluid communication with the first interior

space, and the venous blood inlet is in fluid communication with the second interior space. A generally planar blood defoamer media assembly is provided generally parallel with and spaced apart from the blood filtration media assembly. The blood defoamer media assembly has a periphery engaging the housing to divide the second interior space from the blood storage chamber.

Preferably, a pre-filter defoamer is provided for defoaming cardiotomy blood entering the first interior space from the cardiotomy blood sucker port before that blood is filtered by the filtration media Most preferably, the blood filtration media assembly includes filtration media and a first frame extending around a perimeter of the filtration media, and the blood defoamer media includes a defoamer media and a second frame extending around a perimeter of the defoamer media.

In a third embodiment, the blood treatment system comprises a housing defining a blood treatment chamber and blood storage chamber downstream of the blood treatment chamber. A cardiotomy manifold is provided in fluid communication with the blood treatment chamber, with at least one cardiotomy blood sucker port in fluid communication with the cardiotomy manifold. A venous blood inlet is provided in fluid communication with the blood treatment chamber, and an outlet port is provided in fluid communication with the blood storage chamber. A blood filtration media assembly is provided for filtering blood entering the blood treatment chamber through the cardiotomy blood sucker port, and a blood defoamer media assembly is provided for defoaming blood entering the blood treatment chamber through the cardiotomy blood sucker port and venous blood inlet. A blood diverter is provided within the blood storage chamber. The diverter and the housing form a pair of funnel-shaped blood flow channels diverging from one another as the funnel-shaped blood flow channels extend from the blood-treatment-media-receiving opening toward the outlet port, and a pair of converging blood flow channels extending from the funnel-shaped blood flow channels to the outlet port. The funnel-shaped and converging blood flow channels define: (a) a first flow axis extending downwardly in the direction away from the blood-treatment-media-receiving opening at an angle of about 20 to 24 degrees with respect to horizontal; and (b) a pair of second flow axii converging downwardly toward one another in the direction perpendicular to the first flow axis at an angle of about 3 to 7 degrees to the horizontal.

Most preferably, the cardiotomy manifold defines a downward curving ledge extending from the cardiotomy blood sucker port to the first interior space. The downward curving ledge has a radius of about 2.5 to 7.6 cm, and the cardiotomy blood sucker port extends along a tangent to the downward curving ledge. A pre-filter defoamer defoams cardiotomy blood entering the first interior space from the cardiotomy blood sucker port before that blood is filtered by the filtration media. A plurality of support veins in the cardiotomy manifold supporting the pre-filter defoamer. The venous blood inlet includes drop tube, and a directionalized, velocity-reducing prime bowl downstream of the drop tube for directing a portion of the blood flow path outwardly toward the walls of the blood treatment cartridge and decelerating the blood flow. The prime bowl has a cross-section at least four times greater than the cross-section of the drop tube.

As used herein:

"Biocompatibility" refers to a low-turbulent flow path that minimizes hemolysis and blood-air contact.

"Initial Break Through Volume" refers to the volume of fluid required before the fluid penetrates the filter media and reaches the output port in the reservoir. Initial break through volume is typically most significant when priming the blood treatment system.

"Sucker Bypass" refers to a condition where both the venous return stream and the cardiotomy blood stream both pass through the cardiotomy filters.

Brief Description of the Drawing

Figure 1 is an exploded view of an exemplary blood treatment system;

Figure 2 is a top view of the blood treatment cartridge system of Figure 1;

Figure 3 is a side sectional view of the blood treatment system of Figure 1;

Figure 4 is an alternate side sectional view of the blood treatment system of Figure 1;

Figure 5 is a front view of the blood treatment system of Figure 1;

Figure 6 is a back view of the blood treatment system of Figure 1;

Figure 7 is an exploded view of an alternate blood treatment system for cardiotomy blood;

Figure 8 is a top view of an alternate cardiotomy blood treatment system;

Figure 9 is side sectional view of the cardiotomy blood treatment system of Figure 8;

Figure 10 is side view of the cardiotomy blood treatment system of Figure 8; and

Figure 11 is a schematic view of a method of assembling the blood treatment system.

Detailed Description of Preferred Embodiments

Figures 1-6 illustrate one embodiment of the blood treatment system 20. Blood treatment cartridge 22 has a blood treatment media receiving opening 24 defining an entrance to a chamber 26. A cartridge flange 28 extends around the perimeter of the blood treatment media opening 24 for engagement with a corresponding flange 30 on a front blood reservoir 32, as will be discussed in detail below.

A series of sucker ports 34 are located along a top edge of the blood treatment cartridge 22. The sucker ports 34 are preferably connected to one or more lines of tubing conducting cardiotomy blood from the surgical site to the blood treatment system 20 (not shown). As best seen in Figure 4, the blood sucker ports 34 are in fluid communication with a cardiotomy manifold 36 that leads to a separation chamber 37. The cardiotomy manifold 36 and sucker ports 34 define an arch 33 having a radius of curvature of about 3.8 cm (1.5 inches), and preferably in the range of 2.54 cm to 7.62 cm (1.0 inches to 3.0 inches). The bores for the sucker ports 34 are preferably tangent to the surface of the arch 33. The arch 33 directs the cardiotomy blood vertically downward into a first interior space 90 with minimal disturbance. The gradual shape of the arch 33 causes bubbles in the cardiotomy blood stream to rise to the surface. The bubbles may be broken when they contact pre-filter defoamer material 64 as the cardiotomy blood flows along the arch 33. Alternatively, the bubbles in the cardiotomy blood collect at the bottom of the separation chamber 37, where they are broken or popped by the pre-filter defoamer material 64. The cardiotomy blood preferably does not flow through the pre-filter defoamer material 64. The cardiotomy

manifold 36 can process at least six liters/minute (such as for example during sucker bypass) for an indefinite period of time.

Cardiotomy blood enters the blood treatment system 20 through the sucker ports 34 and cardiotomy manifold 36, and flows into the first interior space 90. The portion of the chamber 26 between the first blood treatment media assembly 72 and the second blood treatment media assembly 82 defines a second interior space 92. The venous blood stream and filtered cardiotomy blood stream are collected in the second interior space 92 prior to defoaming.

As best illustrated in Figure 3, a swiveling venous inlet connector 40 on a venous drop tube 42 is fluidly connected to the cartridge 22. A fluid line (not shown) carries the venous return stream from the patient to the inlet connector 40. A 30-70 durometer, silicone O-ring 31 is preferably interposed between the venous inlet connector 40 and the venous drop tube 42. The venous inlet connector 40 preferably is arranged at between 30 and 60 degrees with respect to the venous drop tube 42 and has an outside diameter of 12.6 mm. A venous sampling luer site 54 is located on the venous inlet connector 40. The venous inlet connector 40 preferably includes a connector flange 44 that engages with a semicircular ledge 46 on the back of the blood treatment cartridge 22. An opening 50 is provided in the venous drop tube 42 for receiving a temperature sensor 48. The stainless steel thimble 49 is preferably hermetically sealed across the opening 50 in fluid communication with the venous return stream. The temperature sensor 48 is preferably located within the thimble 49.

The venous drop tube 42 preferably includes a cuvette tube 52 with a sensor window 43 (see Figure 6). The sensor window 43 typically interfaces with an infrared sensor for measuring oxygen content and hematocrit in the venous return stream. A suitable cuvette tube 52 is available from Minnesota Mining and Manufacturing Company, St. Paul, Minnesota USA, under product designation CDI 100.

Turning to Figure 2, the blood treatment cartridge 22 preferably includes a series of ports along the top surface. A pair of filtered luer ports 55 provide access to the cardiotomy manifold 36. A 6.35 mm (0.25 inch) diameter prime port 58 in fluid communication with the cardiotomy manifold 36 is provided for priming the blood treatment system 20. A vent port 53 is provided for releasing excess pressure from the

chamber 26 during usage. The vent port 53 is preferably in fluid communication with the second interior space 92, although it will be understood that a series of vents may be provided for some applications. A recirculation port 63 allows priming fluid, such as saline, to be recirculated between the blood treatment system 20 and an oxygenator (not shown) during the prime cycle. Finally a drug inlet port 51 provides access to the interior space 92 containing the venous return stream and the filtered cardiotomy blood stream. An exemplary oxygenator is shown in U.S. Patent Nos. 5,149,318 (Lindsay) and 5,514,335 (Leonard et al.).

An auxiliary cardiotomy inlet 56 provides direct access to the chamber 92. In the event that the cardiotomy filter assembly 72 fails, a secondary filter assembly (not shown) for filtering the cardiotomy blood stream can be inserted into the blood circuit with minimal disruption to the surgery procedure. The filtered blood stream from the secondary filter assembly can then be directed to the chamber 92, thereby bypassing the failed filter assembly 72. An alternate system for handling medical fluids is shown in U.S. Patent No. 5,254,080 (Lindsay).

As shown best in Figures 1 and 3, a prime bowl 60 is located at the bottom of the venous drop tube 42 in fluid communication with the interior space 92 through an elongated inlet 59. Blood collects in the prime bowl 60 below chamber 26. In the event that the blood pumps fail, allowing blood in the drop tube 42 to travel backwards through the blood circuit, the prime bowl 60 operates as a trap to prevent air in the blood treatment system 20 from entering the venous blood stream. A blood trap is shown in U.S. Patent Nos. 5,282,783 (Lindsay) and 5,403,273 (Lindsay).

The prime bowl 60 also operates as a velocity reducer. The prime bowl 60 preferably has a cross-section about four to six times greater than the cross section of the drop tube 42. Consequently, the velocity of the venous return stream in the drop tube 42 is reduced to about 15-20% of its original velocity. For example, if the blood treatment system is operating at seven liters/min, the velocity of the venous return stream is reduced from 55 meters/min. to about 8.3 meters/min. The reduced velocity minimize splashing, foam-creating turbulent flow and contact with the air. The elongated shape of the elongated inlet 59 cause the venous return stream to exit the prime bowl 60 primarily laterally toward the edges 22A, 22B of the blood treatment cartridge 22 so that blood stasis in these regions is minimized.

A series of support veins 62 are formed along the chamber 26 proximate the cardiotomy manifold 36 for supporting the pre-filter defoamer material 64. The pre-filter defoamer material 64 serves to dissipate bubbles on the surface of the cardiotomy blood stream without directly interrupting the flow. Although the pre-filter defoamer material 64 is generally a planar sheet folded as shown best in Figure 4, it will be understood that a variety of shapes are possible, such as triangular a cross-section. A pre-filter ledge 68 is located on each of the support veins 62 for retaining the pre-filter defoamer material 64 proximate the sucker ports 34. The pre-filter defoamer material 64 is preferably inserted into the chamber 26 along a build axis "A".

A filter seal ledge 70 is located around the perimeter of the chamber 26 adjacent to the cardiotomy manifold 36. The filter seal ledge 70 is configured to receive a first blood treatment media assembly 72. The first blood treatment media assembly 72 is preferably a filtration media 76 supported by a media frame 74. The media frame 74 is preferably inserted into the chamber 26 along the build axis "A" to engage with the filter seal ledge 70 adjacent to the cardiotomy manifold 36. As discussed above, the first blood treatment media assembly 72 and cardiotomy manifold forms a first interior space 90 (see Figure 3).

A defoamer seal ledge 80 is located along the perimeter of the interior space 26 for receiving a second blood treatment media assembly 82. The second blood treatment media assembly 82 is preferably a defoamer media 84 retained in a media frame 86. A support screen 85 may optionally be positioned on one or both sides of the defoamer media 84. The media frame 86 is preferably configured to engage with the defoamer seal ledge 80. The filter seal ledge 70 preferably defines a smaller perimeter than the defoamer seal ledge 80 so that the blood treatment media assemblies 72, 82 can be easily inserted into the blood treatment cartridge 22 along the build axis "A." The media 76, 84 may be retained in the frames 74, 86 by a urethane potting resin, mechanical gasket, UV cured adhesive, or a variety of other methods. The first and second blood treatment media are preferably planar or some other discontinuous configuration that does not create enclosures that can not be viewed by the medical staff. Discontinuous configuration generally refers to media material that does not form a self-contained enclosure or pocket, such as a cylinder or pouch configuration.

It will be understood that additional seal ledges may be included along the perimeter of the chamber 26 for receiving additional blood treatment media. The perimeter of the seal ledges preferably increases in size closer to the cartridge flange 28 so that they can be automatically stacked in the chamber 26 along the build axis "A." In an alternate embodiment, a single seal ledge is provided proximate the cardiotomy manifold 36. Spacers may then provided along the perimeter of the chamber 26 to maintain the appropriate separation between the blood treatment media 72, 82.

The front blood reservoir 32 preferably includes a blood storage section 100 and a drain port 102. A handle 106 is preferably provided along the top of the front blood reservoir 32. A series of alternate sampling ports 101 may be provided along the top of the reservoir 32. It will be understood that the handle 106 may be located along any surface of the blood treatment system 20. The handle 106 may be used for carrying the blood treatment system 20, retaining sampling syringes or sampling lines during use. The blood storage section 100 preferably has a capacity of 2.0-4.0 liters. The treated blood exits the blood treatment system 20 via the drain port 102 prior to further handling and treatment, such as regulation of carbon dioxide content, oxygen content and temperature. The blood is ultimately returned to the patient through an aortic cannula inserted into the aorta distal to the heart.

A diverter dome 104 may optionally be included in the front blood reservoir 32. The diverter dome 104 reduces the volume retained in the storage section 100 proximate the outlet port 102. In the preferred embodiment, the volume of the storage section 100 below the level of the bottom of the second filter media assembly 82 is approximately 300 cc. The diverter dome 104 is configured to define funnel-shaped flow channels shown by arrows 105 on either side toward the outlet port 102 (see Figure 6). The diverter dome 104 preferably has a radius of curvature along a leading edge 109 of about 9.53 mm (.375 inches). The radius along the leading edge 109 blends into a radius of about 6.35 cm (2.5 inches) and then 7.62 cm (3.0 inches) along the sides toward the trailing edges 107. The radius of curvature for the trailing edges 107 is about 23.9 mm (0.94 inches). The portion of the diverter dome 104 about 22.6 mm (.89 inches) long between the two trailing edges 107 is straight. The diverter dome 104 has an overall length of about 12.6 cm (4.95 inches). The distance between the two trailing edges 107 is about 10.1 cm (4.0 inches).

As best seen in Figures 3 and 6, bottom surface 108 of the funnel-shaped flow channels 105 defines a first flow axis B extending downward at an angle α of about 20 to 24 degrees from horizontal toward the outlet port 102. The bottom surface 108 preferably defines a second flow axis C having a downward taper of approximately 3 to 7 degrees extending away from the diverter dome 104 and generally perpendicular to the first flow axis B. The resulting flow is away from the diverter dome 104 toward the curved edges 111 on either side of the outlet port 102. The compound curves along the bottom surface 108 results in a low-turbulent, sheet-flow of blood through the front blood reservoir 32.

Figure 7 is an exploded view of an alternate blood treatment system 120 for treating primarily cardiotomy blood. A front blood reservoir 122 seals the blood treatment media receiving opening 24' on the blood treatment cartridge 22'. The cartridge 22' is further discussed below in connection with Figures 8-10. It will be understood that the front blood reservoir 122 may be used with the cartridge 22 shown in Figures 1-6. The blood treatment system 120 is preferably assembled along the build axis A', as discussed herein.

The front blood reservoir 122 preferably has minimal volume for retaining blood. An outlet port 124 diverts the treated blood through a tubing 126 to a secondary blood storage reservoir 128, such as a flexible pouch or bag. The blood reservoir 128 preferably includes a pair of valves 130, 132 for venting air and adding drugs. The venous return stream is delivered directly to the blood reservoir 128 by a venous input line 134, thereby bypassing the blood treatment system 120. Check valves 131 may optionally be provided in the tubes 126, 134. A cap 136 is preferably located in the venous inlet to seal the chamber 26'. In the configuration of Figure 7, the blood treatment system 120 treats only the cardiotomy blood drawn in through the sucker ports 34'.

Figures 8-10 illustrate the cardiotomy blood treatment cartridge 22' of Figure 7 used with the front blood reservoir 32 of Figure 1. Since the venous return stream is not directed through the blood treatment system 20', the chamber 92' is significantly compressed as compared to the chamber 92 in Figure 4. The compressed chamber 90' reduces the initial break through volume to prime the system 20'. The operation of the cardiotomy manifold 36', the first and second blood treatment media

assemblies 72', 82' and the front blood reservoir 32' are substantially the same as discussed above.

The pre-filter defoamer material 64 is preferably constructed of an open cell, blood compatible, synthetic polymeric foam, such as a reticulated polyurethane foam, that collapses blood foam into liquid blood. The pre-filter defoamer material 64 preferably has 5-20 pores per inch (PPI) and most preferably 10 pores per inch. The pre-filters are preferably treated with an anti-foam compound such as silicone.

The filtration media may be constructed of fibrous polyester depth filter. Commercially available filtration media include Dacron polyester felt having a mean aperture size in the range of about 20 to 50 microns, and preferably 30 microns. The filtration media 76 is alternatively constructed of a pleated depth media with a pore size of about 20-40 microns and most preferably with pore size of 30 microns.

The defoamer media may be constructed from a woven screen of nylon, polyester or polypropylene. The defoamer media 84 is preferably a mesh with 10-40 pores per inch and most preferably 26 pores per inch. The defoamer media is preferably coated with silicone. The defoamer media 84 is preferably supported on the downstream side by a support screen 85 having pore sizes of about 300-400 microns. A suitable silicone coated, reticulated polyurethane foam with 26 PPI is available from Lydall Westex, Hamptonville, North Carolina USA.

The blood treatment systems 20, 20', 120 are preferably molded from a clear thermoplastic such as polycarbonate or PET-G (glycol modified polyethylene terephthalate). In a preferred embodiment, the components have a nominal wall thickness of about 2.16 mm to 2.29 mm (0.085 inches to 0.090 inches). The components of the blood treatment systems 20, 20', 120 are preferably treated with heparin. Heparin is an acid mucopolysaccharide that acts as an anti-thrombin, anti-thromboplastin, and an anti-platelet factor to prolong clotting time of whole blood.

The blood treatment systems 20, 20', 120 are designed so that the blood stream is easily visible to the medical staff at all times. Visibility of the blood stream is necessary to monitor for potential filter failure, blood stasis, debris, color and other factors. In particular, the drop tube 42, the blood treatment cartridge 22 and the front blood reservoir 32 are preferably constructed of a clear plastic material. Consequently, all sides of the pre-filter defoamer material are visible from either the top, back, bottom

or sides of the cartridge 22. The chambers 90, 90', 92, 92' are visible around the perimeter of the cartridges 22, 22' (see Figures 3, 4 and 9). The contents of the front blood reservoirs 32, 32', 122 are visible from the front or sides thereof.

Figure 11 is a schematic illustration of a preferred method 200 of assembling the blood treatment systems 20, 20', 120. A pick and place robot 202 locates a blood treatment cartridge on an assembly carousel 204. The carousel 204 rotates to a second station 205 where a pick and place robot 206 installs a pre-filter foam material in the blood treatment cartridge along the build axis "A." A glue dispenser arm 208 applies a bead of glue along the filter seal ledge at station 207 in preparation for insertion of the first blood treatment media. The carousel moves the assembly to station 209 where pick and place robot 210 inserts the first blood treatment media into the chamber along the build axes A or A'. The glue is then cured at a UV curing station 212. The carousel 204 then moves the partially assembled blood treatment system to an unload cart 213 where a pick and place robot 214 transfers the assembly to a second carousel 216.

A glue dispenser arm 218 at station 217 applies a bead of glue along the defoamer seal ledge in preparation for insertion of the second blood treatment media. A pick and place robot 220 at station 219 installs the second blood treatment media along a build axes A or A' into the chamber. The glue is cured at a UV curing station 222. The carousel 216 then rotates to a second glue dispenser arm 224 at station 223 where glue is applied along the cartridge flange in preparation for installation of the front blood reservoir 32. A pick and place robot 226 at station 225 installs the front blood reservoir along a build axis A or A'. The glue is cured by a UV cure robot arm 228. The carousel 216 then rotates to station 230 where a pick and place robot 232 removes the blood treatment system 20, where it is forwarded for inspection and packaging.

The structure of the blood treatment system permits each of the components to be inter-engaged along a single build axis, thus facilitating automated assembly. Additionally, the minimal number of components renders automated assembly a cost-effective alternative. Automated assembly provides a number of key advantages for medical devices of this type. First, assembly is extremely accurate and repeatable. Secondly, the nature of the blood treatment system permits a variety of blood treatment media to be substituted automatically during the assembly process. The automated

assembly process permits the type of blood treatment media installed in a particular blood treatment system to be accurately tracked and recorded.

The invention has now been described with reference to several embodiments described herein. It will be apparent to those skilled in the art that many changes can be made in the embodiments without departing from the scope of the invention as defined by the claims.

CLAIMS:

1. A blood treatment system (20; 120; 20') assembled along a single build axis (A; A'), the system (20; 120; 20') comprising:

a blood treatment cartridge (22; 22') having a chamber (26; 26'), a blood-treatment-media-receiving opening (24; 24') defining an entrance to the chamber (26; 26'), a cardiotomy manifold (36; 36') in fluid communication with the chamber (26; 26'), and at least one cardiotomy blood sucker port (34; 34') in fluid communication with the cardiotomy manifold (36; 36');

a first generally planar blood treatment media (76) inserted along the build axis (A; A') through the blood-treatment-media-receiving opening (24; 24') into the chamber (26; 26'), the first blood treatment media (76) dividing the chamber (26; 26') into first and second interior spaces (90 and 92; 90' and 92'), with the cardiotomy manifold (36; 36') in fluid communication with the first interior space (90; 90');

a second generally planar blood treatment media (84) inserted along the build axis (A; A') through the blood-treatment-media-receiving opening (24; 24') of the blood treatment cartridge (22; 22') to enclose the second interior space (92; 92'); and

a blood outlet section (100; 122) sealed to the blood treatment cartridge (22; 22') to form a housing enclosing the blood-treatment-media-receiving opening (24; 24'), the blood outlet section (100; 122) having an outlet port (102; 124).

2. A blood treatment system (20; 120; 20') according to claim 1 further characterized the blood treatment cartridge (22; 22') and blood storage section (100; 122) form a housing comprising transparent plastic material, the housing being configured such that substantially the entire blood flow path is visible.

3. A blood treatment system (20; 120; 20') according to claim 1 or 2 further characterized in that the blood treatment cartridge (22; 22') includes at least one ledge (72) in the chamber (26; 26') configured and positioned to engage the first blood treatment media (76) to limit insertion of the first blood treatment media (76) into the chamber (26).

4. A blood treatment system (20; 120; 20') according to claim 3 further characterized in that the ledge (70) constitutes a first ledge (70), the blood treatment cartridge (22) further including a second ledge (80) in the chamber (26) between the blood-treatment-media-receiving opening (24) and the first ledge (70) and configured to engage the second blood treatment media (82) to limit insertion of the second blood treatment media (82) into the chamber (26), the second ledge (80) defining a perimeter larger than the first ledge (70) and permitting the first blood treatment media (72) to be inserted into the chamber (26) further than the second ledge (80).

5. A blood treatment system (20) according to any of claims 1-4 further characterized in that a venous blood inlet (40) is provided in fluid communication with the second interior space (92) of the chamber (26), with the venous blood inlet (40) being spaced along the build axis (A) from the cardiotomy manifold (36).

6. A blood treatment system (20) according to any of claims 1-5 further characterized in that:

the first blood treatment media (70) comprises a filtration media (76) for filtering cardiotomy blood entering the system (20) through the cardiotomy blood sucker port (34);

the second blood treatment media (80) comprises a defoamer media (84) for defoaming venous blood entering the system (20) through the venous blood inlet (40) and cardiotomy blood filtered by the filtration media (76); and

the system (20) further includes a pre-filter defoamer (64) for defoaming cardiotomy blood entering the first interior space (90) from the cardiotomy blood sucker port (34) before that blood is filtered by the filtration media (76).

7. A blood treatment system (20) according to claim 6 further characterized in that the filtration media (76) has an average pore size of about 20 to 40 microns.

8. A blood treatment system (20) according to claim 6 or 7 further characterized in that a first frame (74) extends around a perimeter of the filtration media (76), and a second frame (86) extends around a perimeter of the defoamer media (84).

9. A blood treatment system (20) according to any of claims 5-8 further characterized in that:

the cardiotomy manifold (36) defines a downward curving ledge (68) extending from the cardiotomy blood sucker port (34) to the first interior space (90), the downward curving ledge (68) having a radius of about 2.5 to 7.6 cm, the cardiotomy blood sucker port (34) extending along a tangent to the downward curving ledge (68);

the cardiotomy manifold (36) further including a plurality of support veins (62) supporting a pre-filter defoamer (64); and

the venous blood inlet includes drop tube (42) and a directionalized, velocity-reducing prime bowl (60) downstream of the drop tube (42) for directing a portion of the blood flow path outwardly toward the walls of the blood treatment cartridge (22) and decelerating the blood flow, the prime bowl (60) having a cross-section at least four times greater than the cross-section of the drop tube (42).

10. A blood treatment system (20; 120; 20') according to any of claims 1-9 further characterized in that the blood-treatment-media-receiving opening (24) of the blood treatment cartridge (22) has a perimeter forming means for snap-fit engagement with the blood outlet section (100).

11. A blood treatment system (20; 120; 20') according to any of claims 1-10 further characterized in that the blood outlet section (100) defines a blood storage chamber.

12. A blood treatment system (20; 120; 20') according to claim 11 further characterized in that the blood outlet section (100) further includes a blood diverter (104) within the blood storage chamber forming a pair of funnel-shaped blood flow channels (105) diverging from one another as the channels (105) extend from the blood-treatment-media-receiving opening (24) toward the outlet port (102), and a pair

of converging blood flow channels (108) extending from the funnel-shaped blood flow channels (105) to the outlet port (102).

13. A blood treatment system (20; 120; 20') according to claim 12 further characterized in that the funnel-shaped and converging blood flow channels (105 and 108) define:

a first flow axis extending downwardly in the direction away from the blood-treatment-media-receiving opening (24) at an angle (α) of about 20 to 24 degrees with respect to horizontal; and

a pair of second flow axii (C) converging downwardly toward one another in the direction perpendicular to the first flow axis at an angle of about 3 to 7 degrees to the horizontal.

14. A blood treatment system (20) comprising:

a transparent housing defining a blood treatment chamber (26) and blood storage chamber downstream of the blood treatment chamber (26), a cardiotomy manifold (36) in fluid communication with the blood treatment chamber (26), at least one cardiotomy blood sucker port (34) in fluid communication with the cardiotomy manifold (36), a venous blood inlet (40) in fluid communication with the blood treatment chamber (26), with the venous blood inlet (40) being spaced from the cardiotomy manifold (36), and an outlet port (102) in fluid communication with the blood storage chamber;

a generally planar blood filtration media assembly (70) having a periphery engaging the housing to divide the blood treatment chamber (26) into first and second interior spaces (90 and 92) that are visible through the transparent housing, with the cardiotomy manifold (36) in fluid communication with the first interior space (90) and the venous blood inlet (40) in fluid communication with the second interior space (92);

a generally planar blood defoamer media assembly (80) generally parallel with and spaced apart from the blood filtration media assembly (70), the blood defoamer media assembly (80) having a periphery engaging the housing to divide the second interior space (92) from the blood storage chamber.

15. A blood treatment system (20) according to claim 14 further characterized in that a pre-filter defoamer (64) is provided for defoaming cardiotomy blood entering the first interior space (90) from the cardiotomy blood sucker port (34) before that blood is filtered by the filtration media (76).

16. A blood treatment system (20) according to claim 14 or 15 further characterized in that the blood filtration media assembly (70) includes filtration media (76) and a first frame (74) extending around a perimeter of the filtration media (76), and the blood defoamer media (80) includes a defoamer media (84) and a second frame (86) extending around a perimeter of the defoamer media (84).

17. A blood treatment system (20) according to claim 16 further characterized in that the filtration media (76) having an average pore size of about 20 to 40 microns.

18. A blood treatment system (20) comprising:

a housing defining a blood treatment chamber (26) and blood storage chamber downstream of the blood treatment chamber (26), a cardiotomy manifold (36) in fluid communication with the blood treatment chamber (26), at least one cardiotomy blood sucker port (34) in fluid communication with the cardiotomy manifold (36), a venous blood inlet (40) in fluid communication with the blood treatment chamber (26), and an outlet port (102) in fluid communication with the blood storage chamber;

a blood filtration media assembly (70) for filtering blood entering the blood treatment chamber (26) through the cardiotomy blood sucker port (34);

a blood defoamer media assembly (84) for defoaming blood entering the blood treatment chamber (26) through the cardiotomy blood sucker port (34) and venous blood inlet (40);

a blood diverter (104) within the blood storage chamber forming, together with the housing, a pair of funnel-shaped blood flow channels (105) diverging from one another as the channels (105) extend from the blood-treatment-media-receiving opening (24) toward the outlet port (102), and a pair of converging blood flow channels (108) extending from the funnel-shaped blood flow channels (105) to the outlet

port (102), the funnel-shaped and converging blood flow channels (105 and 108) defining:

a first flow axis extending downwardly in the direction away from the blood-treatment-media-receiving opening (24) at an angle (α) of about 20 to 24 degrees with respect to horizontal; and

a pair of second flow axii (C) converging downwardly toward one another in the direction perpendicular to the first flow axis at an angle of about 3 to 7 degrees to the horizontal.

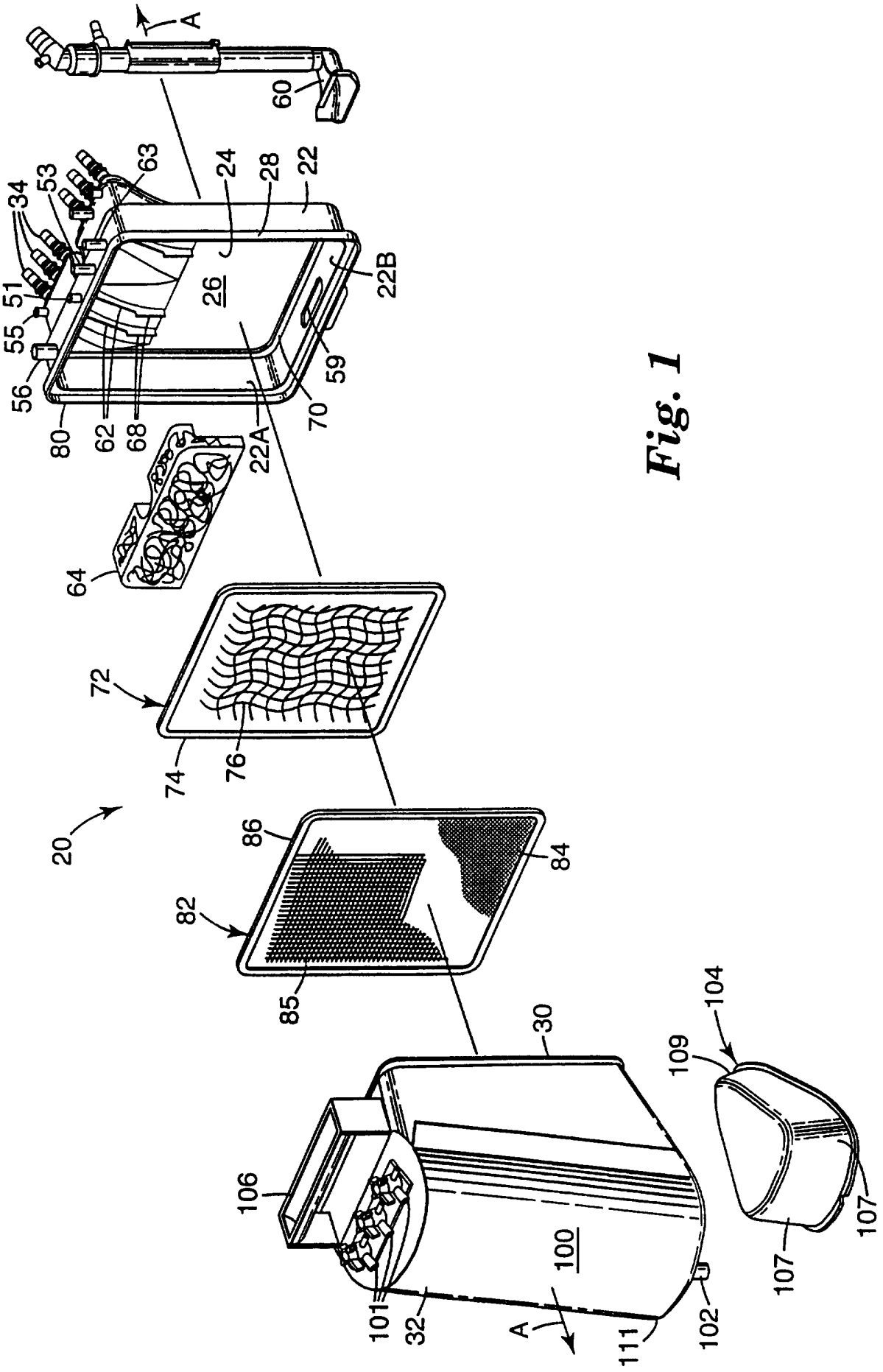
19. A blood treatment system (20) according to claim 18 further characterized in that:

the cardiotomy manifold (36) defines a downward curving ledge (68) extending from the cardiotomy blood sucker port (34) to the first interior space (90), the downward curving ledge (68) having a radius of about 2.5 to 7.6 cm, the cardiotomy blood sucker port (34) extending along a tangent to the downward curving ledge (68);

the system (20) further includes a pre-filter defoamer (64) for defoaming cardiotomy blood entering the first interior space (90) from the cardiotomy blood sucker port (34) before that blood is filtered by the filtration media (76);

the cardiotomy manifold (36) further including a plurality of support veins (62) supporting the pre-filter defoamer (64); and

the venous blood inlet includes drop tube (42) and a directionalized, velocity-reducing prime bowl (60) downstream of the drop tube (42) for directing a portion of the blood flow path outwardly toward the walls of the blood treatment cartridge (22) and decelerating the blood flow, the prime bowl (60) having a cross-section at least four times greater than the cross-section of the drop tube (42).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107
107

Fig. 1

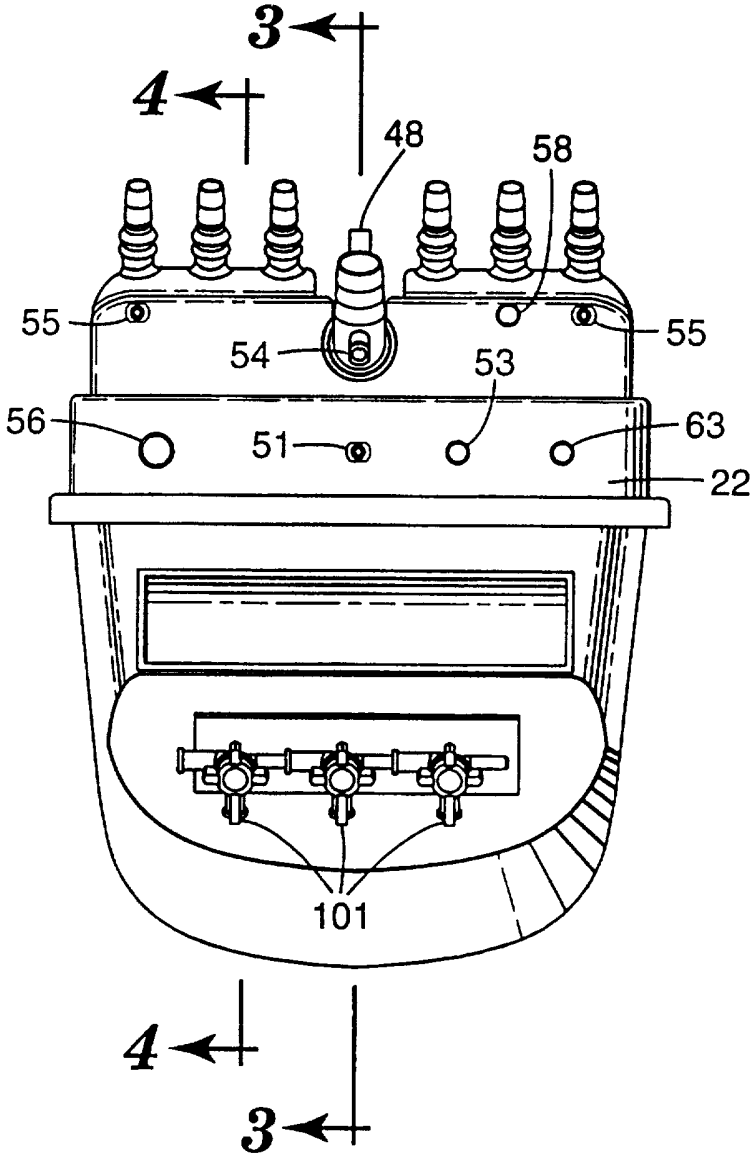
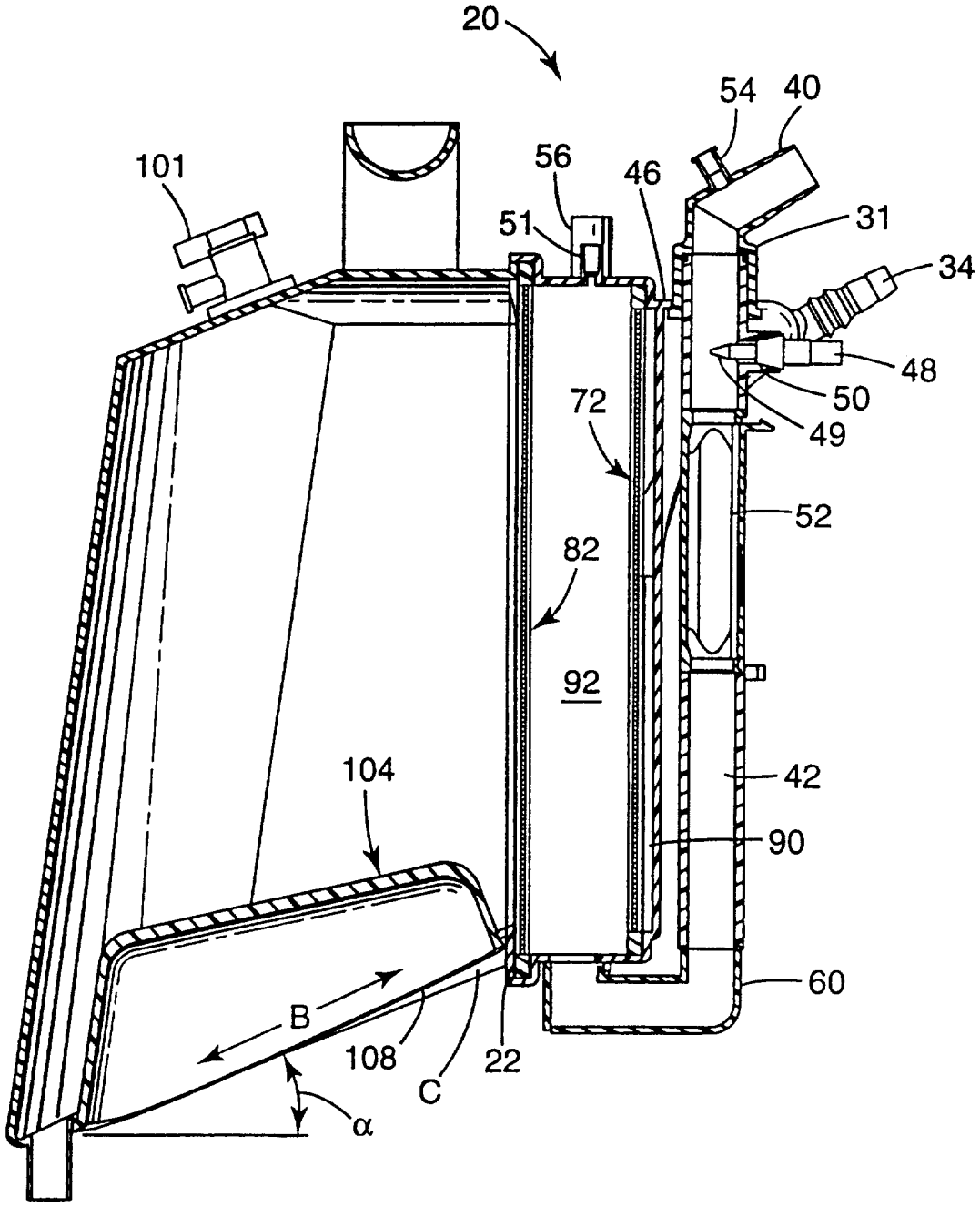


Fig. 2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C
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α

Fig. 3

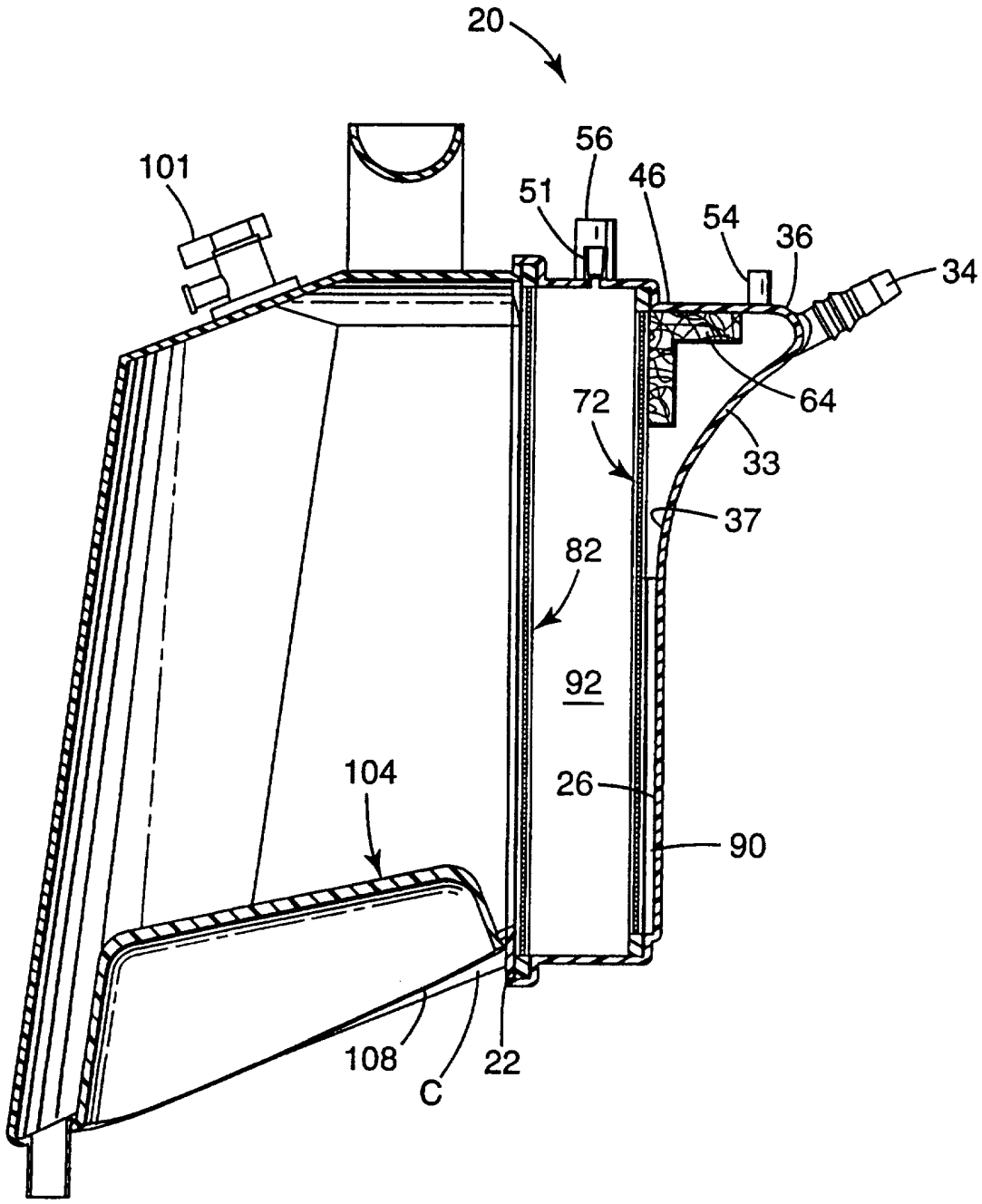


Fig. 4

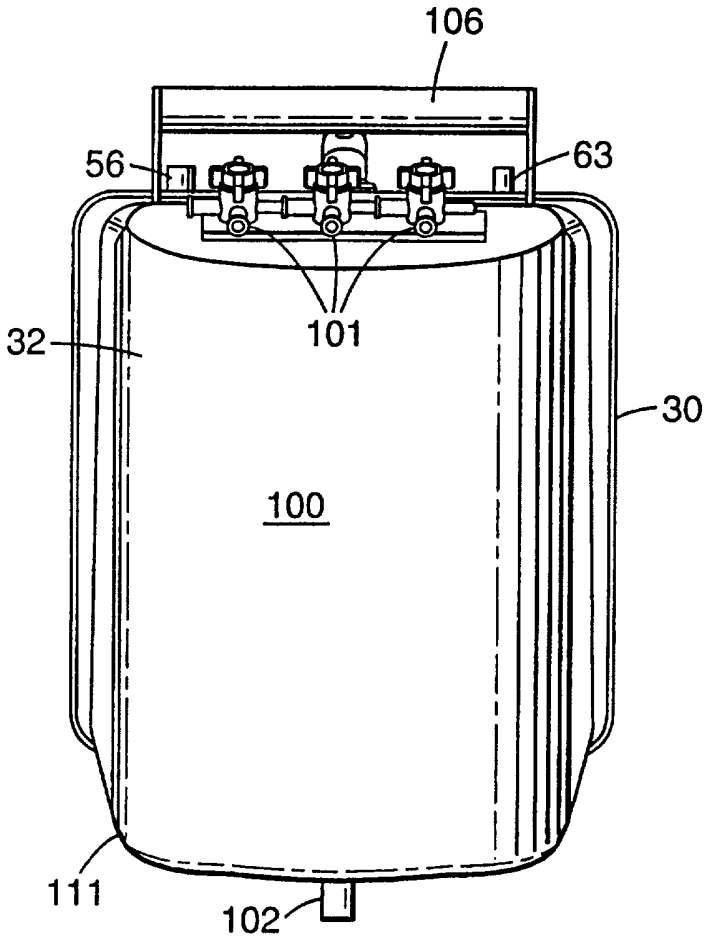
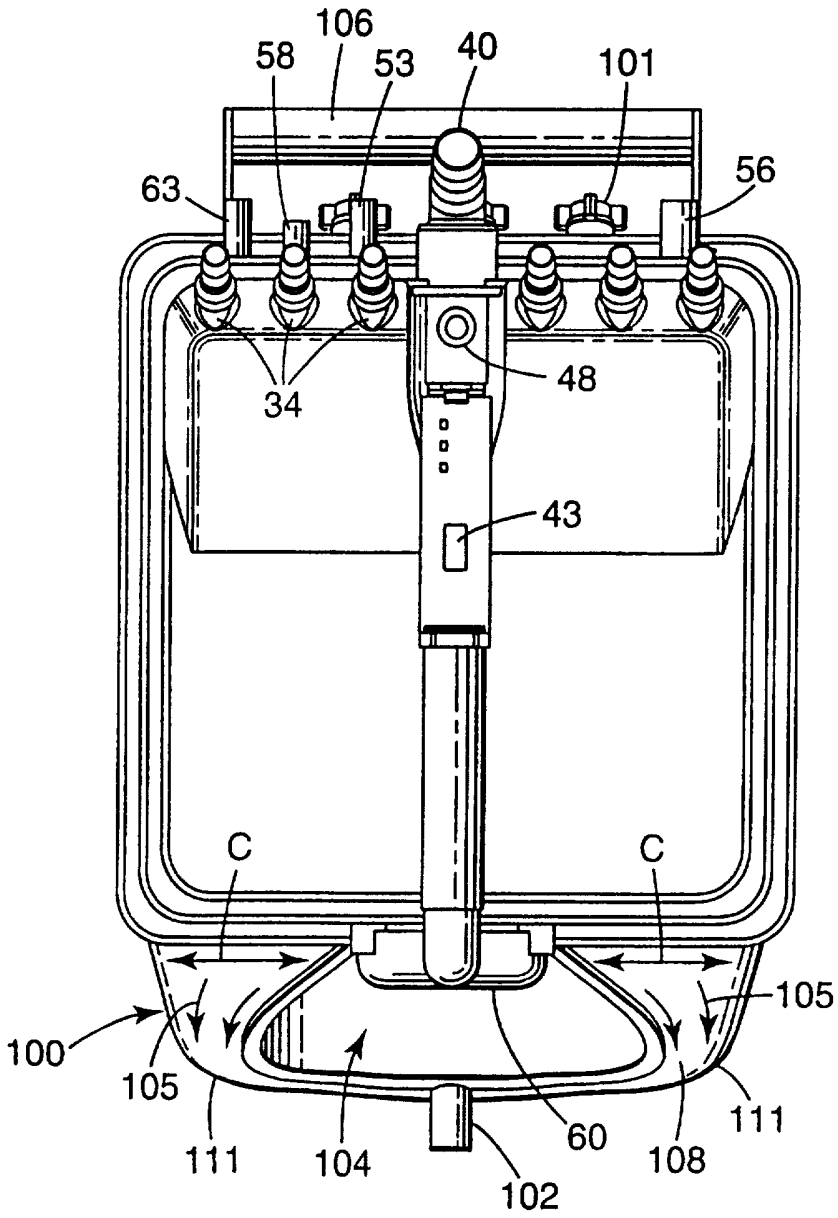


Fig. 5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58
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C
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108
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102

Fig. 6

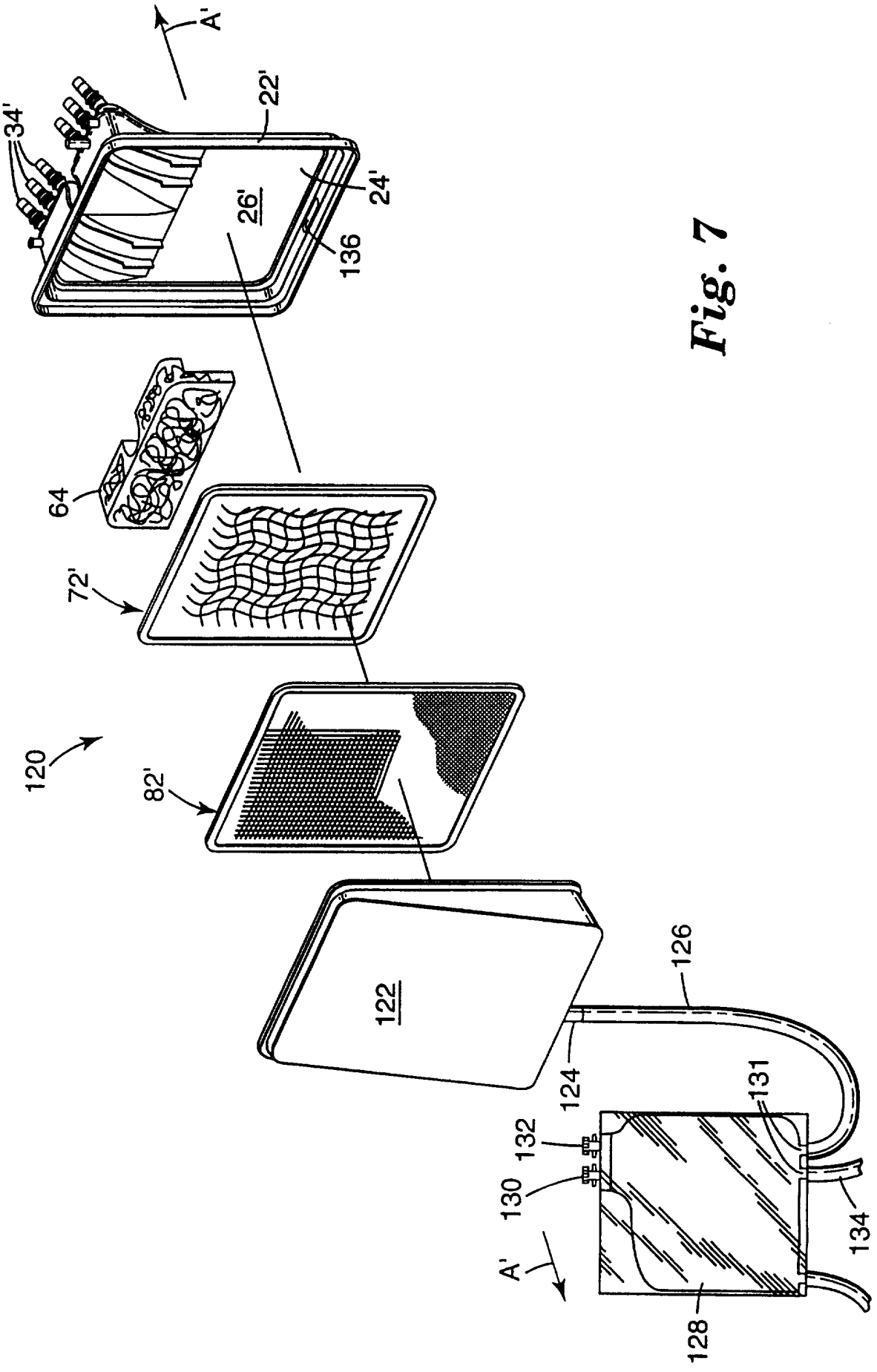


Fig. 7

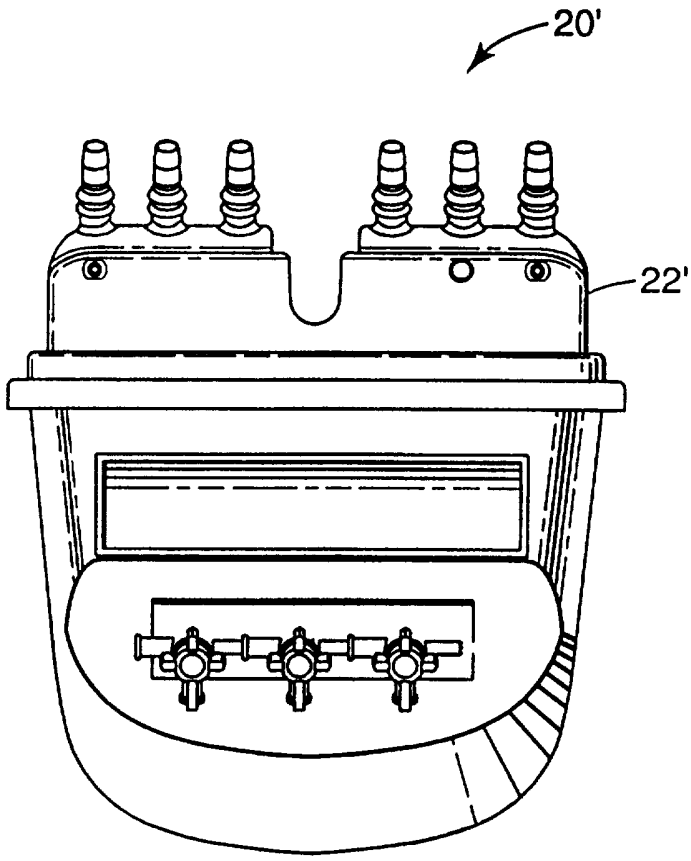


Fig. 8

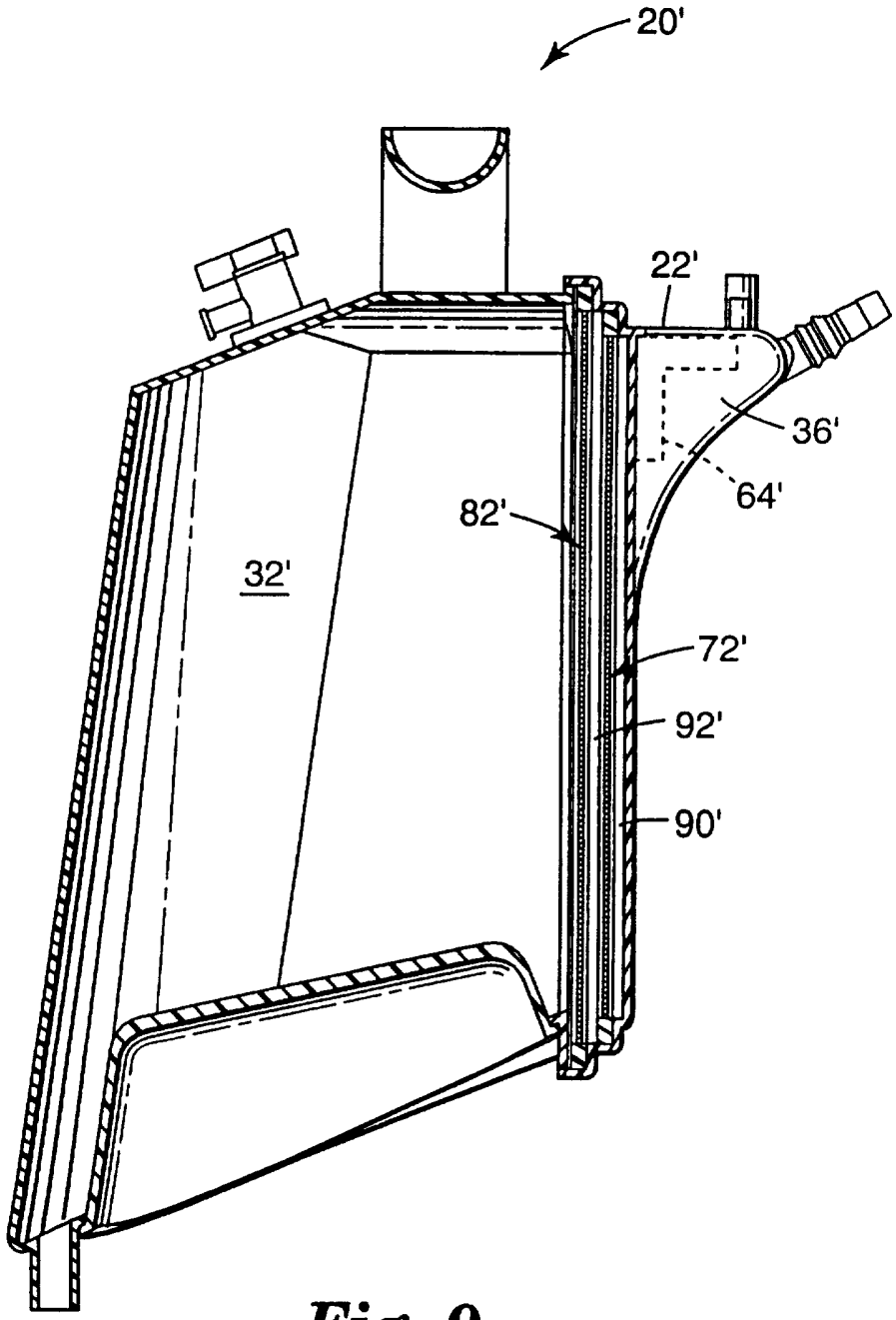


Fig. 9

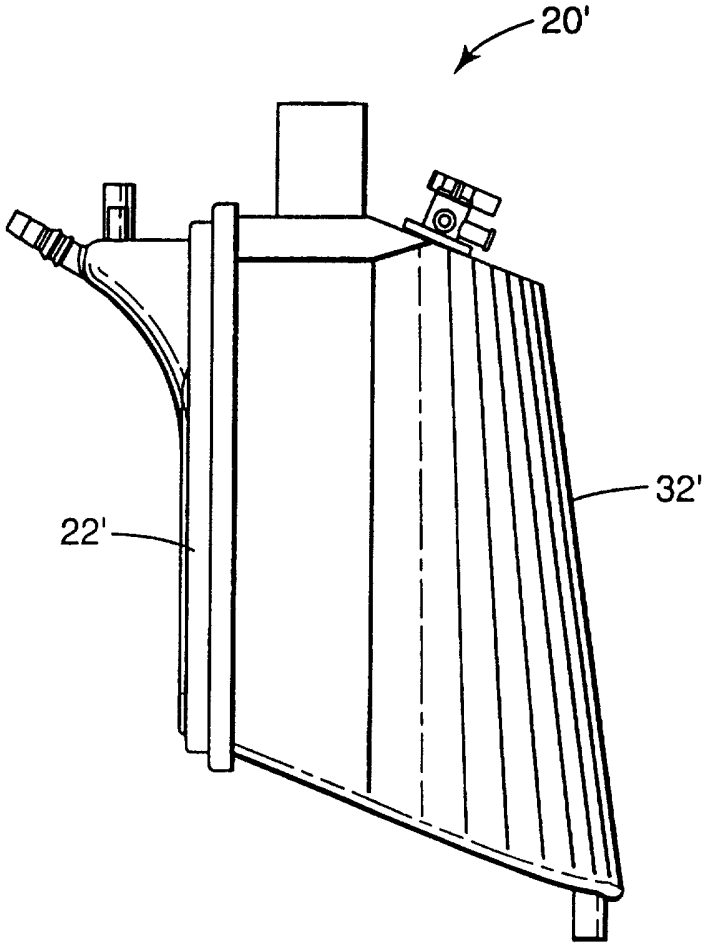
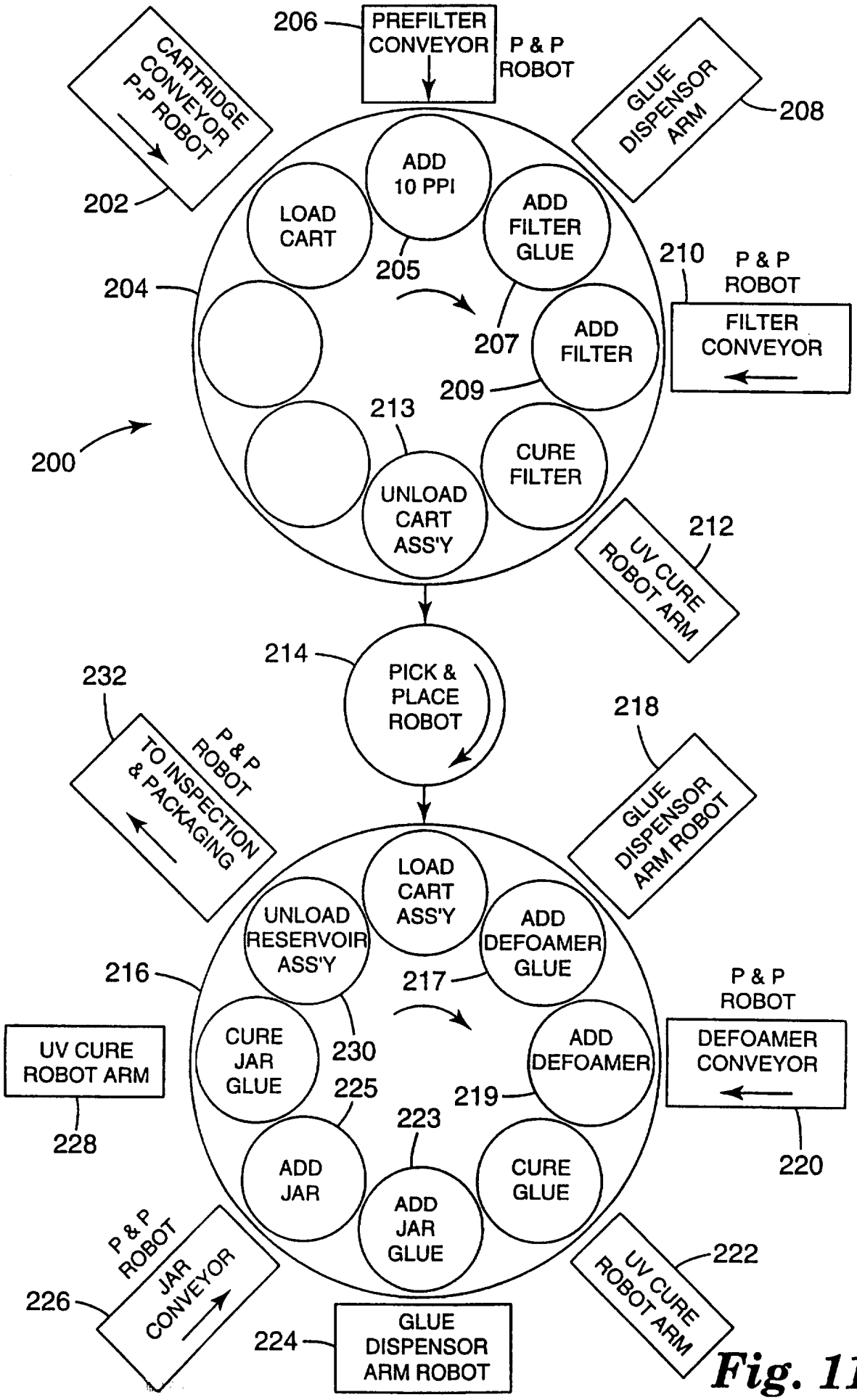


Fig. 10


206
PREFILTER CONVEYOR
P & P ROBOT
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202
GLUE DISPENSOR ARM
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ADD 10 PPI
LOAD CART
ADD FILTER GLUE
205
204
210
P & P ROBOT
FILTER CONVEYOR
207
ADD FILTER
209
213
CURE FILTER
UNLOAD CART ASS'Y
200
212
UV CURE ROBOT ARM
214
PICK & PLACE ROBOT
232
P & P ROBOT TO INSPECTION & PACKAGING
218
GLUE DISPENSOR ARM ROBOT
LOAD CART ASS'Y
UNLOAD RESERVOIR ASS'Y
ADD DEFOAMER GLUE
216
217
P & P ROBOT
DEFOAMER CONVEYOR
UV CURE ROBOT ARM
CURE JAR GLUE
230
ADD DEFOAMER
225
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223
228
ADD JAR
CURE GLUE
220
ADD JAR GLUE
P & P ROBOT JAR CONVEYOR
222
UV CURE ROBOT ARM
226
224
GLUE DISPENSOR ARM ROBOT

Fig. 11

INTERNATIONAL SEARCH REPORT

Interna...onal Application No
PCT/US 97/09783

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 158 533 A (STRAUSS BRIAN ET AL) 27 October 1992 see abstract; figure 4 see column 5, line 32 - column 7, line 34 see column 9, line 62 - column 10, line 21 ---	18 1-9, 11-17,19
Y	EP 0 355 785 A (TERUMO CORP) 28 February 1990 see abstract; figures 4,5 see column 6, line 35 - column 7, line 32 ---	1,2,5-9, 11-17,19
Y A	WO 96 00593 A (POLYSTAN HOLDING AS) 11 January 1996 see abstract; figures 3,4 see page 4, line 31 - page 5, line 29 --- -/--	3,4 9

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 1997	05. 11. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zeinstra, H

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INTERNATIONAL SEARCH REPORT

Intern. ional Application No
PCT/US 97/09783

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intern. ..nal Application No
PCT/US 97/09783

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