RENAL PRESERVATION SYSTEM

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ABSTRACT

A cassette for use with a transport or an in-hospital support module to retain organs in viable condition that is generally boxed shaped and has side by side organ receiving chambers in fluid communication with venous reservoirs therebeneath, a flowmeter tank for each venous reservoir that is at a lower elevation than the venous reservoirs, a static membrane oxygenator fluidly connected to said tanks and mounted in an oxygenator chamber below the venous reservoirs, an arterial reservoir in gravity liquid flow communication with the oxygenator, a pulsatile pump head connected to the arterial reservoir, a heat exchanger fluidly connected between said pump head and a bubble trap, and conduits from the bubble trap to the organ chambers. The cassette is preferably made of a disposable material such as plexiglass. The modules have a pulsatile pump chamber, a gas source, a refrigeration source to furnish a cooling fluid to the heat exchanger, and pressure temperature and pump rate controls.

27 Claims, 11 Drawing Figures
RENAL PRESERVATION SYSTEM

BACKGROUND OF THE INVENTION

Apparatus for maintaining an organ in a viable state for transplantation.

In the prior art it is old to provide units for maintaining organs in a viable state, see for example U.S. Pat. Nos. 3,406,531 and 3,545,221. However, prior art units are large, bulky and expensive to manufacture. Further, in organ transplant procedures, frequently the donor organ, for example a kidney, is obtainable from a hospital a considerable distance from the location of the hospital where the transplant operation is to take place and it is necessary to transport the organ to the transplant hospital. Prior art organ preservation machines are so large that usually they are carried by special trucks and require a technician to monitor them continuously. In order to overcome problems such as mentioned above, as well as others, this invention has been made.

SUMMARY OF THE INVENTION

For use in combination with a transport or larger in-hospital support module containing a pump, gas under pressure and cooling apparatus, a cassette having an organ receiving chamber, a venous reservoir in gravity liquid flow communication with the organ chamber and in part defined thereby, an oxygenator chamber below the venous reservoir, a static membrane in the oxygenator chamber to have liquid flow by gravity through and having an inlet in gravity liquid communication with the venous reservoir and an outlet in gravity liquid flow communication with an arterial reservoir, and a pump tube and heat exchanger in series for conducting liquid from the arterial reservoir to the organ chambers.

One of the objects of the invention is to provide a new and novel disposable cassette having a complete circulatory system usable with a transport module or an in-hospital console for maintaining organs such as kidneys in a viable state. In furtherance of the above-mentioned object, it is a further object of the invention to provide a cassette that may be transferred between a transport module and in-hospital console without need to disturb the organ once placed in the circulatory system.

An additional object of this invention is to provide a new and novel cassette of a generally box like shape that has a membrane oxygenator, arterial and venous reservoirs, a heat exchanger, a pump head and a bubble trap that may be transferred between a transport module and an in-hospital console merely by disengagement and reengagement of the pump head with the respective pump chamber, changing connections for the cooling fluid of the heat exchanger and changing sources of oxygen and carbon dioxide. In furtherance of the above objects, it is a still further object to provide a cassette that is nearly entirely made of plastic materials.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a transport module having a cassette therein, portions of cover being broken away and the control panel closure being shown in an open condition;

FIG. 2 is a side view of the cassette of this invention, said view being generally taken along the line and in the direction of the arrows 2—2 of FIG. 3;

FIG. 3 is a transverse cross-sectional view generally taken along the line and in the direction of the arrows 3—3 of FIG. 2 and additional diagrammatically showing portions of a module used with the cassette;

FIG. 4 is an enlarged, fragmentary, transverse cross-sectional view generally taken along the line and in the direction of the arrows 4—4 of FIG. 2 to more clearly illustrate structural features of the organ receiving chambers and the venous reservoirs;

FIG. 5 is an enlarged, fragmentary horizontal cross-sectional view with portions of the organ support plates broken away, said view being generally taken along the line and in the direction of the arrows 5—5 of FIG. 4;

FIG. 6 is a horizontal cross-sectional view generally taken along the line and in the direction of the arrows 6—6 of FIG. 2;

FIG. 7 is a horizontal cross-sectional view generally taken along the line and in the direction of the arrows 7—7 of FIG. 2 with portions broken away to, in particular show the arterial reservoir;

FIG. 8 is an enlarged, fragmentary cross-sectional view generally taken along the line and in the direction of the arrows 8—8 of FIG. 6 to more fully show the mounting of the oxygenator;

FIG. 9 is a vertical cross-sectional view of a sample port member and adjacent line portions;

FIG. 10 is an enlarged fragmentary cross-sectional view of the membrane oxygenator that more clearly shows the filter therein; and

FIG. 11 is a perspective view of an in-hospital support unit having the cassette of this invention mounted thereon, said view schematically showing various component parts of said unit.

Referring in particular to FIGS. 2—5, the cassette of this invention includes end walls designated 11 and 12 respectively, and side walls generally designated 13 and 14 respectively which are joined together to form a generally rectangular box that is opened at the top and bottom. The upper part of the box is provided with organ receiving chambers 19 and 20. Chamber 19 is formed by a vertical partition 21 mounted in grooves 18 of side walls 13, 14 to be in parallel relationship to side walls 11 and 12, side wall portion 22 of side wall 14, side wall portion 23 of side wall portion 13, and upper wall portion 24 of end wall 11, a generally horizontal organ support plate 17 forming the bottom of the chamber, and a closure member 27 that is slidably mounted by horizontal grooves 15 in wall portion 22, 23 to be moved horizontally to provide access to the chamber. Horizontal ledges 16 are joined to the lower parts of wall portions 22, 23 to removeably support the bottom plate 17, it being understood that the bottom plate could be otherwise suitably mounted at the position it is mounted by the ledges. Chamber 20 advantageously is of the same size and shape as chamber 19 and is formed by top wall portions 22, 23 and 26 of walls 14, 13, and 12 respectively, a horizontal organ support plate 33 removably supported by ledges 16, vertical partition 21, and closure member 27. Organ support plates 17, 33 extend horizontally and advantageously are located in a common plane. Further, organ support plates 17, 33 have a plurality of drain apertures 36, 37 respectively and may be of slightly smaller dimensions than the spacing of partition 21 from the re-
spective end wall portions and the spacing of wall portions 22, 23 whereby liquid may drain from the organ support plates to the venous reservoirs 40 and 41 respectively that are vertically below the support plates.

Venous reservoir 40 is formed by the organ support plate 17, partition 29, and wall portions 42, 43 and 44 of walls 13, 14 and 11 respectively, plate portion 46a of a bottom planar plate 46 that inclines downwardly from wall 12 toward wall 11, a generally horizontal top wall 48 of a fluid passageway, generally designated 49 for the venous reservoir 41, and a vertical wall 50 of passageway 49. The venous reservoir 40 is located directly beneath the organ chamber 19, plate 46 having a drain aperture 51 in the corner portion thereof that is adjacent the juncture of wall portions 43 and 44. Wall 48, which is joined to wall portion 42, is vertically between support plate 17 and plate portion 46a, excluding from partition 29 to wall portion 44 and preferentially is inclined downwardly in a direction toward wall portions 43, 44 whereby any fluid draining onto said wall will drain onto plate portion 46a.

Partition 29 is joined to plate 46, wall portion 43 and the adjacent edge of wall 50, and is horizontally spaced from walls 11, 12 to be directly below partition 21. Although partition 29 does not extend up to the level of partition 21, it may, or could be formed integral therewith.

Passageway 49 opens through an opening 53 formed by partition 29, plate 46 and wall portion 56 to place the passageway in fluid communication with the venous reservoir 41. The venous passageway includes side wall portion 56 that is a part of wall 13 and a bottom wall 46c that is integrally joined to plate portion 46a to form a continuation thereof. Thus walls 48, 50, 56 and 46c form a passageway that is closed other than for opening 53 and a drain aperture 58 that is located in the portion 46c adjacent wall 11, the end of the passageway opposite opening 53 being closed by a portion of wall 11. The drain aperture 58 opens through the top wall of the flowmeter tank, generally designated 63, which is formed by parts of plate portions 46a, 46c (see FIGS. 3 and 6). Tank 63 has a side wall 66, a side wall 65, bottom wall 64, an end wall 67, and an end wall 68. Wall 68 could be formed by extending wall 11 further downwardly and wall 65 could be formed by part of wall 13. Drain aperture 51 drains through the top wall of a second flowmeter tank 74 which is formed by plate 46, tank 74 including side walls 65, 66, a bottom wall 64, and end walls 67, 68. Thus the tanks 63, 74 are located within the confines of walls 11-14 of the cassette or the downward extension thereof, the end walls 67 of the tanks being located substantially more closely adjacent the wall 11 then the horizontally spacing of the partition 21 from wall 11. A plurality of vertically spaced indicia (not shown) are provided on the walls 68 of the tanks to indicate the volume of fluid contained in the respective tank.

One end of a flexible plastic tube 80 opens through the lower part of walls 66 to the interior of tank 63 while the one end of a tube 81 opens through wall 66 of tank 74, the opposite ends of tube 80, 81 opening to the adjacent end portions of a T-coupling 82. Tubes 80, 81 are of sufficient flexibility that they may be readily clamped to block fluid flow therethrough when a flow rate measurement is to be taken. With the indicia provided on the tanks and the blocking of the respective tube 80, 81, the rate of flow into the respective tank can be determined by using a stopwatch.

A plastic tube 83 fluidly connects coupling 82 to the inlet 45a of a generally rectangular, generally flat, static membrane oxygenator 45 which is inclined downwardly in a direction toward wall 12 to have plasma flow therethrough by gravity flow. The outlet 45b of the membrane oxygenator (end adjacent wall 12) is fluidly connected to a conduit 84.

The oxygenator 45 has a top membrane wall 45c and a bottom membrane wall that are joined to edge members 45d. A reversely bent filter 179 is provided between the top and bottom membrane walls and has edges joined to edge members 45e whereby liquid entering port 45a has to flow through the filter prior to flowing through outlet port 45b. The filter is made of nylon or silk fabric of a mesh to filter out particulate particles in the liquid flowing through the oxygenator.

Located beneath the flowmeter tanks is an inclined planar plate 88 which is joined to the side walls to extend substantially the length thereof and is inclined downwardly in a direction from wall 11 toward wall 52 to provide the bottom of an oxygenator chamber 90. The top of chamber 90 is formed by wall 46, and the sides of the chamber are formed by wall portions 92, 93 of walls 13, 14. In this connection it is to be noted that inclined plate 88 is spaced from and in part directly beneath the flowmeter tanks.

A mounting member, generally designated 97, is provided for supporting the oxygenator membrane in a generally planar condition, member 97 having a bottom plate 98 that is slidable positioned on plate 88, an upstanding wall portion 91 joined to one end portion of plate 98 and an opposite upstanding wall portion 94 joined the opposite edge portion of plate 98. In a normal operating position, wall 94 forms one end of the oxygenator chamber and wall 91 the opposite end whereby the oxygenator chamber is closed other than for the gas discharge ports 95 in wall 94, the wall portion of wall 94 that defines a close fluid fit with the duct 83 that extends therethrough, and the wall portions of wall 91 that form a close fluid fit with the conduits 84 and 96 which extend therethrough. In the normal operating condition, wall 91 forms a openable portion of wall 12, i.e., located directly below wall portion 26 while wall 94 is horizontally between the tank walls and wall 91, spaced from the tank walls, and substantially more closely adjacent the tank walls than wall 91.

Referring in particular to FIGS. 6 and 8, adjacent each side of plate 98 and joined thereto is an upright flange 99 that mounts a plurality of horizontal bolts 100 which in turn are threaded into a longitudinal bar 101, each bar being between flanges 99 and closely adjacent the respective flange. Bars 101, which are parallel to flanges 99 and spaced therefrom, mount a plurality of upright pins 102 that are extended through apertures in the adjacent side edge portion of the oxygenator that is above the bar to support the oxygenator in a generally flat condition vertically between plates 98, 46.

Bolts 100 may be rotated to varying the spacing of bars 101 and thereby the tautness in a side to side direction of the membrane oxygenator. The discharge end of conduit 96 is preferably bifurcated with one leg discharging beneath the oxygenator and the other leg above whereby the discharged gas can flow both above and below the oxygenator to wall 94.
It is to be understood that the structure for mounting the oxygenator may be varied. For example the plate 98, bars 99 and bolts 100 may be dispensed with. In such a case the wall 94 is joined to plate 88 and/or the side walls 13, 14; wall 91 integrally joined to wall portions 26, 105; and bars 101 secured to plate 98 to mount the oxygenator in spaced relationship to plate 98.

Referring in particular to FIGS. 6 and 7 located vertically below the discharge end portion of the membrane 45 is an arterial reservoir, generally designated 104, that other than set forth below is enclosed by wall portion 105 of wall 12, a bottom wall 106, an end wall 107 opposite wall portion 105, side wall portions 108, 109 of walls 12, 14 respectively and portion 88a of plate 88. Conduit 84 has an outlet port opening through wall portion 105 to the interior of the arterial reservoir while wall portion 107 in the lower part thereof has a discharge port 107a fluidly connected by a conduit 110 to one end of an elongated flexible pump tube 112. A bar 111 secured to wall 13 acts in combination therewith to provide a fluid passageway 111a that opens to the top of the arterial reservoir and to chamber 20 to maintain the same pressure in each.

Located in the pump tube are spaced, one-way valves 113, the valves advantageously being of the construction described in U. S. Pat. No. 3,525,356. The opposite end of the pump tube is fluidly connected to a transverse tube 115 that in turn opens to the inlet end of the heat exchange coil 117 of the heat exchanger generally designated 118. Coil 117 is coiled about a large diameter tube 122 that is located within the heat exchanger housing 119 and joined to one end wall 119a thereof to be supported in spaced relationship to the remaining walls of housing 119. The heat exchanger housing has a right angle bracket 116 secured thereto that in cooperation with the U-shaped bracket 114 secured to wall 13 removably mounts the heat exchanger adjacent wall 13 to extend beneath the oxygenator chamber. That is bracket 116 has a horizontal leg extended through the opening formed by bracket 114 and wall 13 to be supported by said bracket while permitting horizontal removal of the housing in one direction.

The heat exchanger includes an inlet port 121 that opens through wall 119a to the interior of tube 122 adjacent wall 119a and an outlet tube 120 that extends through wall 119a to terminate adjacent wall 119b and open to the space between tube 122 and the housing 119. The inlet port 121 is connectable to a suitable source of cooling fluid under pressure whereby the cooling fluid is forced through the housing in contact with the cooling coil to the outlet port 120.

The end of the cooling coil 117 remote from its inlet is fluidly connected by a conduit 124 that extends transversely from housing 119 and through sidewall 14 to have an outlet port that is fluidly connected to the lower end of the conduit 125. The upper end of the conduit 125 is fluidly connected to the inlet port in the bottom wall of the bubble trap generally designated 127 that is mounted on the exterior surface of wall 14. One end of conduits 128, 129 are connected to outlet ports in the lower part of the opposite end walls of the bubble trap. The opposite ends of the conduits 128, 129 extend through wall portion 22, of wall 14 to extend into chambers 19, 20 respectively for conducting plasma under pressure into kidneys 126 placed in the respective chamber.

Suitable divider walls 136 are provided in the lower portion of the bubble chamber to prevent direct flow of fluid from the inlet port of the chamber to the discharge ports thereof, whereby air in the liquid flowing into the bubble chamber is separated out of the liquid, i.e., flows into the space in the bubble chamber above the liquid in the chamber. A metal sheath 137 extends into the bubble chamber, the sheath being of a shape to have the probe (not shown) of a temperature sensing element mounted therein for continuously indicating the temperature of the liquid in the bubble chamber. Further, a pressure sensor tube 138 is in part mounted by the bubble chamber, one end of tube 138 being adapted for connection to a pressure sensor for continuously providing a pressure reading of the pressure in the chamber and the other end being located in the bubble chamber adjacent the top of the chamber to be located substantially above the normal level of liquid in the chamber.

At a location exterior of the chamber, tube 138 extends through a sample port member generally designated 141 (see FIG. 9). Member 141 includes a block 139 through which the tube extends, block 139 having a bore 139a that at one end opens to the ambient atmosphere and at the opposite end opens through an aperture in the tube to the interior of the tube (or the tube 138 could be two separate tube portions having adjacent ends mounted in block 139 in spaced relation). A Silicone rubber plug 140 is mounted in the bore 139a in compression to block fluid flow from the tube through said bore, but at the same time permit a syringe needle being extended through the plug whereby the contents of the syringe can be injected into the tube, or fluid in the tube can be withdrawn. Due to the plug being mounted in compression, upon withdrawing the needle, the plug material expands to close the opening made by the needle when it was extended through the plug.

As an example of an advantage of providing port member 141, in the event the liquid level in the bubble chamber drops beneath (or is below) a level desired, a syringe needle may be extended through plug 140 to withdraw air from conduit 138 and thereby reduce the gas volume in the chamber, or if the liquid level is too high, the syringe may be used to inject air into the tube and thereby increase the volume of gas above the liquid in the chamber.

A sample port member, generally designated 142, of the same construction as member 141, is mounted by conduit 125 at a location exterior of the cassette and the bubble chamber in the same manner member 141 is mounted by conduit 139. By inserting a syringe needle through the plug of member 142, a sample of the perfusate may be withdrawn from conduit 125, or if an injectable drug is contained in the syringe, the drug may be injected into the conduit 125.

Advantageously the joints 96a, 125a, 128a, 129a of the conduits 96, 125, 128, 129 respectively may each have a bore opening to the fluid passageway of the respective conduit and a plug of silicone rubber in the bore whereby a liquid or fluid may be withdrawn from, or injected into the respective passageway.

The cassette of this invention is used in conjunction with a transport module, generally designated 145 (see FIG. 1), or an in-hospital support module (see FIG. 11). The transport module is of the size that may be manually carried and includes a main body 146 to
which there is removably secured a cover 147 that may be locked in a closed position by lock mechanism 148. Within the main body there is mounted a battery-motor driven pump 150 which has an elongated plate 151 and an adjustable, stationary plate 152 forming a pump chamber to have the pump tube extended therebetween when the cassette is mounted on the main body 146 in position of use. The plate 151 is cam driven, and through conventional adjustment mechanism, the stroke thereof is adjustable to control the perfusion pressure.

Further, within the main body 146 there is mounted a reservoir 155 for containing ice water, a battery operated, motor driven pump 156 for pumping the ice water from the reservoir through conduit 164 to the heat exchange cooling fluid inlet 121 and a return tube 157 for conducting cooling fluid from the heat exchange cooling fluid outlet to the reservoir. The motors for the pumps through appropriate electrical components (not shown) are optionally powered from a power cord connectable to a conventional AC power source, for example an electrical 110V socket in a building. Additionally within the main body there is provided a chamber for containing a cylinder 160 of a mixture of oxygen and carbon dioxide (preferably about 80 percent oxygen and 20 percent dioxide), and conduits and a valve (not shown) for fluidly connecting the cylinder to the gas inlet conduit 96 of the cassette and controlling the rate of flow thereof. The main body has a control panel 170 with control elements for the pumps, and gas flow, and pressure and temperature gauges, and a closure 171 that may be opened when the cover is latched in place on the main body there being provided latch mechanism (not shown) for releasably retaining closure 171 in a closed position.

The cassette is removably held in place on the main body by, for example, brackets 154 secured to the module frame, and the brackets being secured to the cassette by screws 153 extended through the brackets and threaded into the cassette walls to removably clamp the cassette to the main body. With the cover 147 open, the cassette may be readily detached from brackets 154, the couplings for the cooling fluid, oxygen and carbon dioxide mixture, and the pressure and temperature sensors disengaged and then the cassette lifted.

The cassette may be then readily positioned on the top wall 181 of an in-hospital support console, generally designated 180, that is provided with motor driven pulsating pump 182 of the same construction as pump 150, pump 182 having elongated plates extending above the top wall to form a pump chamber to receive the pump head of the cassette. Brackets are provided on the top wall for clamping the cassette thereto. Also console 180 has an electrically operated refrigeration unit 183 having lines 184, 185 that are adapted for connection to lines 120, 121 of the heat exchanger for supplying and circulating cooling media through the exchanger. Also within the console are carbon dioxide and oxygen cylinders 188, 187 that are connected through lines 189, 190 to a line 191 that is adapted for easy connection to line 96. Within lines 189, 190 there are provided shut off-flow control valves 192, 193 respectively. Additionally the console includes temperature and pressure sensors and gauges, controls for automatically controlling the operation of the refrigeration system to maintain the perfusate within the desired temperature range, and controls for the pulsatile pump.

On being placed on the support console, the cassette is clamped in place and the connections made for conducting the cooling fluid between the refrigeration unit and the heat exchanger inlet and outlet, carbon dioxide and oxygen under pressure from lines 192, 193 to conduit 96, and the pump head placed in position between the stationary and cam driven plate of the support console, i.e., the pump head 112 placed in the pump chamber. A rectangular cutout 163 is provided in wall 14 to facilitate placing the pump tube in the pump chamber. The support console is of much larger size than the transport unit and is of the construction to be used in the hospital.

In using the cassette when in place with either transport console 145 or a support console, the appropriate fluid connections made, including a cannula connected to conduit 128 and inserted in a blood vessel of the kidney 126, and the pumps operating to pressurize plasma in the bubble trap, the perfusate (plasma) is perfused through the kidney in chamber 19, flows through the apertures 36 into the venous reservoir 40, and under gravity flow, flows along plate portion 46b to drain through the aperture 51 into the flowmeter tank 74. Likewise, as to a kidney placed in chamber 20, the plasma flows under pressure through conduit 129 and is perfused through the kidney, drains through the drain apertures 37 to the venous chamber therebeneath and thence along plate portion 46b to the inlet 53, and thence to flow through the passageway 49 to drain through the aperture 58 into the flowmeter tank 63.

Assuming that neither of tubes 80, 81 are clamped off, the plasma in tanks 63, 74 flows through said tubes to and through tube 83 to the inlet of the membrane oxygenator. It is to be noted that a proper mixture of carbon dioxide and oxygen under pressure is discharged by conduit 96 into the oxygenator chamber and subsequently through the discharge openings 95 in wall 94. Since the membrane oxygenator is suspended in the oxygenator chamber, the gas mixture in the chamber flows in contact with the top and bottom surface of the oxygenator in a direction generally opposite to the direction of flow of fluid through the oxygenator. As a result the plasma in passing through the oxygenator gives off carbon dioxide and takes on oxygen. The plasma in flowing through the oxygenator under gravity flow, flows to conduit 84 and thence into the arterial reservoir 104. From the arterial reservoir, plasma is drawn into the pump tube 112 and thence pumped under pressure through the cooling coil, the rate of flow of cooling fluid through the heat exchanger being such to maintain the plasma exiting from the cooling coil at the desired temperature. From the cooling coil, the plasma is forced under pressure through conduit 124 and conduit 125 into the bottom of the bubble chamber. The pressure of the plasma in the bubble trap is controlled by controlling the stroke volume of the pump. Thus, the plasma in the chamber is forced under pressure through the conduits 128, 129. One of the conduits 128, 129 is clamped to block fluid flow from the bubble trap through the conduit that extends into the respective chamber 19, 20 in which no kidney is located.

It is to be noted that with this invention, the cooling coil, arterial reservoir, oxygenator membrane, flowmeter tanks, venous reservoir, and organ receiving chambers are in a self-contained unit. Further, from the time
the liquid (perfusate) passes through the kidney until it flows into the arterial reservoir, the flow is gravity flow. Additionally, the overall size of the cassette is reduced in view of the general zigzag plasma flow path. That is, the plasma perfused through the kidney generally flows in a direction toward the end wall 11, then downwardly into the respective flowmeter tank, thence flows through the oxygenator membrane generally in a direction toward end wall 12 thence downwardly into the arterial reservoir, thereafter from the arterial reservoir it flows generally in a direction toward the downward extension of wall 11 to a location adjacent such downward extension, and then transversely to the inlet of the cooling coil. Thereafter it flows generally in the direction toward end wall 12 to the outlet of the cooling coil and thence upwardly to the bubble trap. It is to be noted that advantageously the bubble trap is located about midway between the walls 11 and 12. Even though this invention has been described with reference to perfusion of kidneys, it is to be understood that by using appropriate sized cassettes it can be used for perfusion of livers and hearts, or other organs of a body.

As one example of the cassette of this invention that is suitable for perfusing kidney weight up to 600 grams with effective oxygenation up to 600 ml./min. plasma flow, the height of the cassette from the top of closure 27 to the bottom edge of wall 13 is nearly 10 inches, the length dimension between the exterior surfaces of walls 11, 12 is approximately 12¼ inches and the width dimension between the exterior surfaces of walls 13, 14 is approximately 7½ inches. A transport module of the type illustrated in FIG. 1, including gas cylinder, cooling liquid and other elements thereof together with a cassette weighs about 80 pounds; and can be used to keep kidneys alive up to about 12 hours without recharging the batteries, provided the supply of ice is maintained; and with changing the gas cylinder, replenishing the ice supply and maintaining the source of power for about 48 hours. When the cassette is used with an in-hospital support console, it can keep a kidney alive for about 48 hours.

The walls 11–14 and the other walls and plates forming the various chamber, tanks and reservoirs, the heat exchanger housing and closure 27 are preferably made of a plastic material such as plexiglass.

Further, advantageously all other members of the cassette, other than the bolts 100 and pins 102 are made of plastic.

The transport module can be powered by batteries, a car or aircraft electrical system or the electrical system of a building. Further, it is small enough to fit in an airplane seat, and can be manually carried, for example, one model with the cassette therein weighs about 80 pounds. Thus the transport module may be readily transported to a donor organ site, have the donor organ placed in the cassette circulatory system and the module controls operated to keep the organ viable and then transported to a remote transplant site where the cassette is removed from the transport module. At the transplant site the cassette is clamped on the in-hospital support unit and connected to the unit sources of gases and cooling fluid and the unit pump actuated to pump plasma through the kidney or other organ without removing the organ from the cassette.

What is claimed is:

1. Apparatus for preserving and maintaining organs in a viable state comprising a cassette that includes means forming a first organ receiving chamber that has a bottom organ support plate, said support plate having a drain opening therethrough, means forming a first venous reservoir below the organ receiving chamber and in gravity flow liquid communication with the support plate drain opening, means forming an oxygenator chamber extending to a lower elevation than said venous reservoir means, a static membrane oxygenator stationarily mounted in the oxygenator chamber and having a liquid inlet and a liquid outlet at a lower elevation than the inlet to have liquid flow therebetween by gravity flow, first means for conducting liquid under gravity flow from the venous reservoir to the oxygenator inlet, means forming an arterial reservoir extending to a lower elevation than said outlet and fluidly connected to the outlet to receive liquid under gravity flow therefrom, a pump head having one end fluidly connected to the arterial reservoir to receive liquid therefrom and an opposite end, means fluidly connected to the pump head opposite end for conducting liquid under pressure from the pump head to an organ located in the organ chamber, and a generally vertical wall that in part defines portions of the organ chamber means, the venous reservoir means and the oxygenator chamber means.

2. Apparatus for preserving and maintaining organs in a viable state comprising a cassette that includes means forming a first organ receiving chamber that has a bottom organ support plate, said support plate having a drain opening therethrough, means forming a first venous reservoir below the organ receiving chamber and in gravity flow liquid communication with the support plate drain opening, means forming an oxygenator chamber extending to a lower elevation than said venous reservoir means, a static membrane oxygenator stationarily mounted in the oxygenator chamber and having a liquid inlet and a liquid outlet at a lower elevation than the inlet to have liquid flow therebetween by gravity flow, first means for conducting liquid under gravity flow flow from the venous reservoir to the oxygenator inlet, means forming an arterial reservoir extending to a lower elevation than said outlet and fluidly connected to the outlet to receive liquid under gravity flow therefrom, a pump head having one end fluidly connected to the arterial reservoir to receive liquid therefrom and an opposite end, and means fluidly connected to the pump head opposite end for conducting liquid under pressure from the pump head to an organ located in the organ chamber, the venous reservoir means and the organ chamber means including a plate that forms a top wall of the venous reservoir and a bottom wall of the organ chamber.

3. Apparatus for preserving and maintaining organs in a viable state comprising a cassette that includes means forming a first organ receiving chamber that has a bottom organ support plate, said support plate having a drain opening therethrough, means forming a first venous reservoir below the organ receiving chamber and in gravity flow liquid communication with the support plate drain opening, means forming an oxygenator chamber extending to a lower elevation than said venous reservoir means, a static membrane oxygenator stationarily mounted in the oxygenator chamber and having a liquid inlet and a liquid outlet at a lower elevation than the inlet to have liquid flow therebetween by
gravity flow, first means for conducting liquid under gravity flow from the venous reservoir to the oxygenator inlet, means forming an arterial reservoir extending to a lower elevation than said outlet and fluidly connected to the outlet to receive liquid under gravity flow therefrom, a pump head having one end fluidly connected to the arterial reservoir to receive liquid therefrom and an opposite end, and means fluidly connected to the pump head opposite end for conducting liquid under pressure from the pump head to an organ located in the organ chamber, the first means including flowmeter tank means for receiving liquid under gravity flow from the venous reservoir, said tank means having vertically spaced indicia defining volumetric graduations, and means for conducting liquid under gravity flow from the tank means to the oxygenator inlet.

4. The apparatus of claim 3 further characterized in that said cassette has a vertical wall that forms part of each of the organ chamber means, the venous reservoir means, and the oxygenator chamber means.

5. The apparatus of claim 4 further characterized in that said oxygenator chamber means has a wall having an outlet port permitting the exhaust of gas from the oxygenator chamber, said oxygenator inlet being substantially more closely adjacent the last mentioned wall than the oxygenator outlet.

6. Apparatus for use in combination with a unit having a source of gas under pressure, a pulsatile pump and a source of cooling fluid, to preserve and maintain organs in a viable state, comprising a cassette having a vertical side wall, a vertical end wall joined to said side wall, first wall means acting in cooperation with said side and end walls to define an openable and closeable organ receiving chamber including a bottom wall having a first drain opening, second wall means acting in cooperation with the above mentioned walls to define a venous chamber extending beneath the first drain opening to receive liquid from the organ receiving chamber under gravity flow, said second wall means including an inclined venous chamber bottom wall over which fluid will flow under gravity in the direction of downward inclination, third wall means acting in cooperation with said inclined wall and at least one of the side and end walls to define an oxygenator chamber extending at least in part beneath said venous reservoir, a static membrane oxygenator mounted in the oxygenator chamber and having a liquid inlet and a liquid outlet at a lower elevation than the oxygenator inlet, said liquid inlet being connected in fluid communication with the venous reservoir to receive liquid under gravity from the lower part of the inclined plate, elongated pulsatile pump tube means having an inlet and an outlet adapted for being acted on by the unit pump to force liquid under pressure from the tube means inlet to the tube means outlet, fifth means for defining the arterial reservoir extending to a lower elevation than the oxygenator outlet, sixth means for conducting liquid under gravity flow from the oxygenator to the arterial reservoir, and seventh means for conducting liquid under pressure from the tube means outlet to the interior of the organ chamber.

7. The apparatus of claim 6 further characterized in that there is provided a second end wall that defines portions of the oxygenator chamber means and the arterial reservoir means, at least part of said second end wall forming a portion of the oxygenator chamber means constituting a removable closure for the oxygenator chamber, that said oxygenator chamber means includes a bottom wall, and that there is provided means attached to said second wall closure portion for movement therewith for mounting said oxygenator.

8. The apparatus of claim 6 further characterized in that the seventh means includes a heat exchanger adapted for receiving cooling fluid from the unit source of cooling fluid.

9. The apparatus of claim 8 further characterized in that the seventh means includes a bubble trap connected in series with the heat exchanger.

10. The apparatus of claim 9 further characterized in that the bubble trap is mounted on one of said walls externally of said organ chamber, and that the seventh means includes conduit means connected to the lower part of the bubble trap and extending through the last mentioned wall into the organ chamber.

11. The apparatus of claim 8 further characterized in that the connection of the liquid inlet to the venous reservoir includes a flowmeter tank, said tank having a wall that is a portion of said inclined wall.

12. The apparatus of claim 11 further characterized in that there is provided a second end wall that forms part of the oxygenator chamber means and the arterial reservoir means, and that said liquid inlet is located more closely adjacent the first end wall than the second end wall and that the liquid outlet is located more closely adjacent second end wall than the first end wall.

13. The apparatus of claim 12 further characterized in that the oxygenator is generally flat and of a maximum vertical thickness many times smaller than the dimension between its inlet and its outlet, and that the oxygenator is at a higher elevation than the pump tube means.

14. In apparatus for preserving and maintaining organs in a viable state, a cassette having vertical side and end walls joined together in a generally rectangular box formation, a vertical partition plate mounted by the upper portions of said side walls to form in cooperation with the side and end walls portions of a first and a second organ receiving chamber, openable closure means mounted by the side and end walls to form the tops of the organ receiving chambers, a first and a second organ support plate mounted to at least one of the above mentioned walls for forming the bottom of the respective organ chamber, said organ support plates having drain openings therethrough, a vertical partition wall, an inclined first wall portion vertically beneath the first organ support plate and joined to one end wall, the partition wall and the side walls to form in cooperation therewith and with the first support plate a first venous reservoir, an inclined second wall portion vertically beneath the second support plate and joined to the other end wall, the partition wall and the side walls to form in cooperation therewith and with the second support plate a second venous reservoir, an elongated static membrane oxygenator having a liquid inlet and a liquid outlet, first means opening into the venous reservoirs for conducting liquid under gravity flow to the oxygenator liquid inlet, first wall means including a bottom wall portion vertically below the venous reservoirs for acting in cooperation with the inclined wall portions, the side walls and at least one of the end walls to form an oxygenator chamber having a gas inlet and a gas discharge outlet remote from the gas inlet, said oxygenator being mounted in the oxygenator chamber with the liquid inlet at a higher elevation than the liquid out-
let to permit liquid to flow therethrough by gravity flow, the liquid inlet being substantially more closely adjacent the gas outlet than the gas inlet and the liquid outlet being substantially more closely adjacent the gas inlet than the gas outlet. Second wall means acting in cooperation with at least one of the above mentioned walls to form an arterial reservoir at a lower elevation than the liquid outlet and means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir.

15. The apparatus of claim 14 further characterized in that cassette includes an elongated pump pulsatile tube having one end connected to the arterial reservoir and an opposite end and means for conducting liquid from the tube opposite end to the organ receiving chambers.

16. The apparatus of claim 15 further characterized in that the last mentioned means includes a heat exchanger, said tube and heat exchanger being at least partially located beneath the oxygenator chamber.

17. Apparatus for preserving and maintaining organs in a viable state comprising a general box like shaped cassette having an organ receiving chamber, an oxygenator chamber and a liquid circuit that includes a venous reservoir, an oxygenator in said chamber, an arterial reservoir and a pump member in liquid communication with one another for receiving perfusate from the organ receiving chamber, oxygenating the received perfusate and returning the oxygenated perfusate under pressure to the organ receiving chamber means, a transport module having means for receiving and removable supporting the cassette, gas cylinder means removably connectable to the oxygenator chamber for conducting oxygen to the oxygenator chamber and pump means for cooperating with the pump member to draw perfusate into the pump member and force perfusate therethrough in one liquid flow direction, said member being removably disengageable from the pump means when the cassette is removed from the transport module, and means for removably clamping the cassette to the transport module.

18. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having first means including a bottom wall organ support plate forming an organ receiving chamber, second means vertically below the organ plate and cooperating therewith for forming a venous reservoir that is in liquid communication with the organ receiving chamber to receive liquid drained onto the bottom plate by gravity flow, third means vertically below the venous chamber and acting in cooperation with the second means for receiving liquid from the venous reservoir and oxygenating the received liquid, said third means including a static membrane oxygenator having a liquid outlet and a liquid inlet that is substantially horizontally offset from the liquid outlet and at a higher elevation than the liquid outlet to permit liquid gravity flow therethrough, a gas inlet port remote from the liquid inlet and a gas outlet port remote from the liquid outlet, the third means including fourth means acting in cooperation with the venous reservoir means for forming an oxygenator chamber having said gas inlet and gas outlet and conducting liquid from the venous reservoir to the liquid inlet, said oxygenator being mounted in said oxygenator chamber to have gas flow from the gas inlet to the gas outlet on either side thereof and in contact therewith, fifth means acting in cooperation with the third means vertically beneath the third means and horizontally offset from the liquid inlet to form an arterial reservoir, means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir, sixth means for receiving liquid from the arterial reservoir and conducting liquid under pressure to the organ receiving chamber, and a first vertical end wall having a first and second portion that form parts of the oxygenator chamber means and fifth means respectively.

19. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having first means that includes a bottom wall organ support plate forming an organ receiving chamber, second means vertically below the organ plate and cooperating therewith for forming a venous reservoir that is in liquid communication with the organ receiving chamber to receive liquid drained onto the bottom plate by gravity flow, third means vertically below the venous chamber and acting in cooperation with the second means for receiving liquid from the venous reservoir and oxygenating the received liquid, said third means including a static membrane oxygenator having a liquid outlet and a liquid inlet that is substantially horizontally offset from the liquid outlet and at a higher elevation than the liquid outlet to permit liquid gravity flow therethrough, a gas inlet port remote from the liquid inlet and a gas outlet port remote from the liquid outlet, the third means including fourth means acting in cooperation with the venous reservoir means for forming an oxygenator chamber having said gas inlet and gas outlet and conducting liquid from the venous reservoir to the liquid inlet, said oxygenator being mounted in said oxygenator chamber to have gas flow from the gas inlet to the gas outlet on either side thereof and in contact therewith, the second means including an inclined wall beneath the organ receiving chamber that forms at least part of the bottom of the venous reservoir and at least part of the top of the oxygenator chamber, fifth means acting in cooperation with the third means vertically beneath the third means and horizontally offset from the liquid inlet to form an arterial reservoir, means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir, and sixth means for receiving liquid from the arterial reservoir and conducting liquid under pressure to the organ receiving chamber.

20. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having first means that includes a bottom wall organ support plate forming an organ receiving chamber, second means vertically below the organ plate and cooperating therewith for forming a venous reservoir that is in liquid communication with the organ receiving chamber to receive liquid drained onto the bottom plate by gravity flow, third means vertically below the venous chamber and acting in cooperation with the second means for receiving liquid from the venous reservoir and oxygenating the received liquid, said third means including a static membrane oxygenator having a liquid outlet and a liquid inlet that is substantially horizontally offset from the liquid outlet and at a higher elevation than the liquid outlet to permit liquid gravity flow therethrough, a gas inlet port remote from the liquid inlet and a gas outlet port remote from the liquid outlet, the third means including fourth means acting in cooperation with the venous reservoir means for forming an oxygenator chamber having said gas inlet and gas outlet and
conducting liquid from the venous reservoir to the liquid inlet, said oxygenator being mounted in said oxygenator chamber to have gas flow from the gas inlet to the gas outlet on either side thereof and in contact therewith, fifth means acting in cooperation with the third means vertically beneath the third means and horizontally offset from the liquid inlet to form an arterial reservoir, means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir, and sixth means for receiving liquid from the arterial reservoir and conducting liquid under pressure to the organ receiving chamber, the sixth means including a bubble trap having a temperature sensor member, said bubble trap being fluidly connected to the organ receiving chamber, a heat exchanger fluidly connected to the bubble trap and a pump member fluidly connected to the heat exchanger and the arterial reservoir, and a manually movable transport module for receiving the cassette and enclosing the cassette, said module having pump means for removably receiving the pump member and cooperating therewith for pressurizing liquid in the pump member and means for circulating cooling fluid through the heat exchanger.

21. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having an organ receiving chamber, an oxygenator chamber and a liquid circuit that includes a venous reservoir, an oxygenator in said chamber, an arterial reservoir and a pump member in liquid communication with one another for receiving perfusate from the organ receiving chamber, oxygenating the received perfusate and returning the oxygenated perfusate under pressure to the organ receiving chamber means and a transport module having a main body for removably mounting the cassette, gas cylinder means removably connectable to the oxygenator chamber for conducting oxygen to the oxygenator chamber, pump means for cooperating with the pump member to draw perfusate into the pump member and force perfusate therethrough in one liquid flow direction, and cover means cooperating with the main body for enclosing the cassette when it is mounted on the main body.

22. Apparatus for preserving and maintaining organs in a viable state comprising a manually portable cassette having an organ receiving chamber, an oxygenator chamber and a liquid circuit that includes a venous reservoir, an oxygenator in said chamber, an arterial reservoir and a pump member in liquid communication with one another for receiving perfusate from the organ receiving chamber, oxygenating the received perfusate and returning the oxygenated perfusate under pressure to the organ receiving chamber means, a support unit having a wall for removably receiving and supporting the cassette, gas cylinder means removably connectable to the oxygenator chamber for conducting oxygen to the oxygenator chamber and pump means for cooperating with the pump member to draw perfusate into the pump member and force perfusate therethrough in one liquid flow direction, said pump member being removably disengagable from the pump means, and means for removably clamping the cassette on said wall.

23. The apparatus of claim 22 further characterized in that said pump member comprises an elongated pulsatile pump tube, and that said pump means comprises a pair of pump plates extending above said wall to have the pump tube extend between said plates.

24. The apparatus of claim 22 further characterized in that said cassette is of a generally box like shape.

25. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having first means including a bottom wall organ support plate forming an organ receiving chamber, second means vertically below the organ plate and cooperating therewith for forming a venous reservoir that is in liquid communication with the organ receiving chamber to receive liquid drained onto the bottom plate by gravity flow, third means vertically below the venous chamber and acting in cooperation with the second means for receiving liquid from the venous reservoir and oxygenating the received liquid, said third means including an oxygenator having a liquid outlet and a liquid inlet that is substantially horizontally offset from the liquid outlet and at a higher elevation than the liquid outlet to permit liquid gravity flow therethrough, and fourth means acting in cooperation with the venous reservoir means for forming an oxygenator chamber and conducting liquid from the venous reservoir to the liquid inlet, said oxygenator being mounted in said oxygenator chamber, the second means including an inclined wall beneath the organ receiving chamber that forms at least part of the bottom of the venous reservoir and at least part of the top of the oxygenator chamber, fifth means acting in cooperation with the third means vertically beneath the third means and horizontally offset from the liquid inlet to form an arterial reservoir, means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir, and sixth means for receiving liquid from the arterial reservoir and conducting liquid under pressure to the organ receiving chamber.

26. Apparatus for preserving and maintaining organs in a viable state comprising a cassette having first means including a bottom wall organ support plate forming an organ receiving chamber, second means vertically below the organ plate and cooperating therewith for forming a venous reservoir that is in liquid communication with the organ receiving chamber to receive liquid drained onto the bottom plate by gravity flow, third means vertically below the venous chamber and acting in cooperation with the second means for receiving liquid from the venous reservoir and oxygenating the received liquid, said third means including an oxygenator having a liquid outlet and a liquid inlet that is substantially horizontally offset from the liquid outlet and at a higher elevation than the liquid outlet to permit liquid gravity flow therethrough, fourth means acting in cooperation with the third means vertically beneath the third means and horizontally offset from the liquid inlet to form an arterial reservoir, means for conducting liquid under gravity flow from the liquid outlet to the arterial reservoir, and fifth means for receiving liquid from the arterial reservoir and conducting liquid under pressure to the organ receiving chamber, said third means including a wall that forms at least a part of the bottom of oxygenator chamber and the top of the arterial reservoir.

27. Apparatus for preserving and maintaining organs in a viable state comprising a cassette that includes means forming a first organ receiving chamber that has a bottom organ support plate, said support plate having a drain opening therethrough, means forming a first venous reservoir below the organ receiving chamber and in gravity flow liquid communication with the support
plate drain opening, means forming an oxygenator chamber extending to a lower elevation than said venous reservoir means, a static membrane oxygenator stationarily mounted in the oxygenator chamber and having a liquid inlet and a liquid outlet at a lower elevation than the inlet to have liquid flow therethrough by gravity flow, said inlet being spaced from the venous reservoir, first means for conducting liquid under gravity flow from the first venous reservoir to the oxygenator inlet, means forming an arterial reservoir extending to a lower elevation than said outlet and fluidly connected to the outlet to receive liquid under gravity flow therefrom, a pump head having one end fluidly connected to the arterial reservoir to receive liquid therefrom and an opposite end, means fluidly connected to the pump head opposite end for conducting liquid under pressure from the pump head to an organ located in the organ chamber, means defining a second organ receiving chamber in side by side relationship with the first organ receiving chamber and that has a bottom plate having a drain opening therethrough, a second venous reservoir extending vertically beneath the second organ chamber to receive liquid draining through the last mentioned drain opening, means defining a fluid passageway having an inlet opening to the second venous reservoir, an intermediate portion extending horizontally below the first organ receiving chamber and an outlet, and means for conducting liquid under gravity flow from the passageway outlet to the first means at a location spaced from the venous reservoirs.

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