

[54] **METHOD OF TRANSPORTING AND STORING ORGANS WHILE RETAINING THE ORGANS IN A VIABLE CONDITION**

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[52] **U.S. Cl.** **195/1.7**
 [51] **Int. Cl.** **C12k 9/00**
 [58] **Field of Search** **195/1.7**

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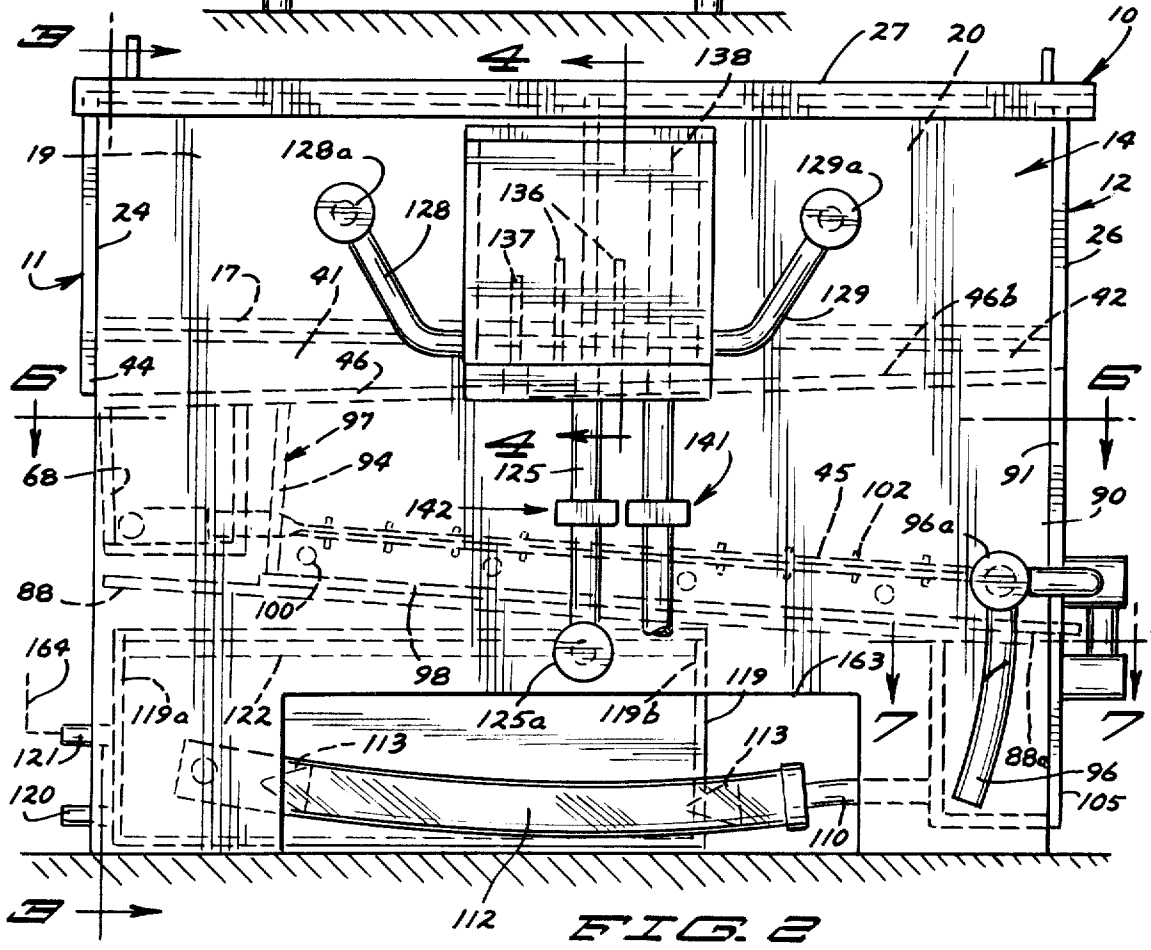
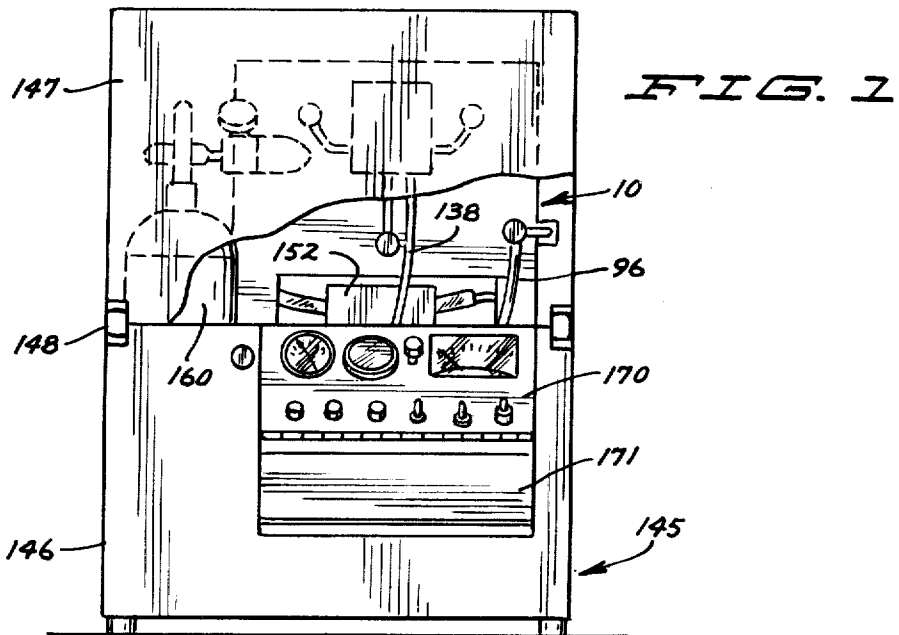
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Primary Examiner—Sam Rosen
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[57] **ABSTRACT**

In maintaining organs in a viable condition during transport and subsequently in a hospital, the organ is placed in a cassette of a transport module, the cassette having an organ receiving chamber, a venous reservoir, an oxygenator, a pulsatile pump head and a heat exchanger. After transport the cassette is removed from the transport module and placed in an in-hospital support module. Each of the modules has a pulsatile pump chamber, a gas source for supplying oxygen, a cooling source to furnish a cooling fluid to the heat exchanger, and pressure, temperature and pump rate controls.

10 Claims, 11 Drawing Figures



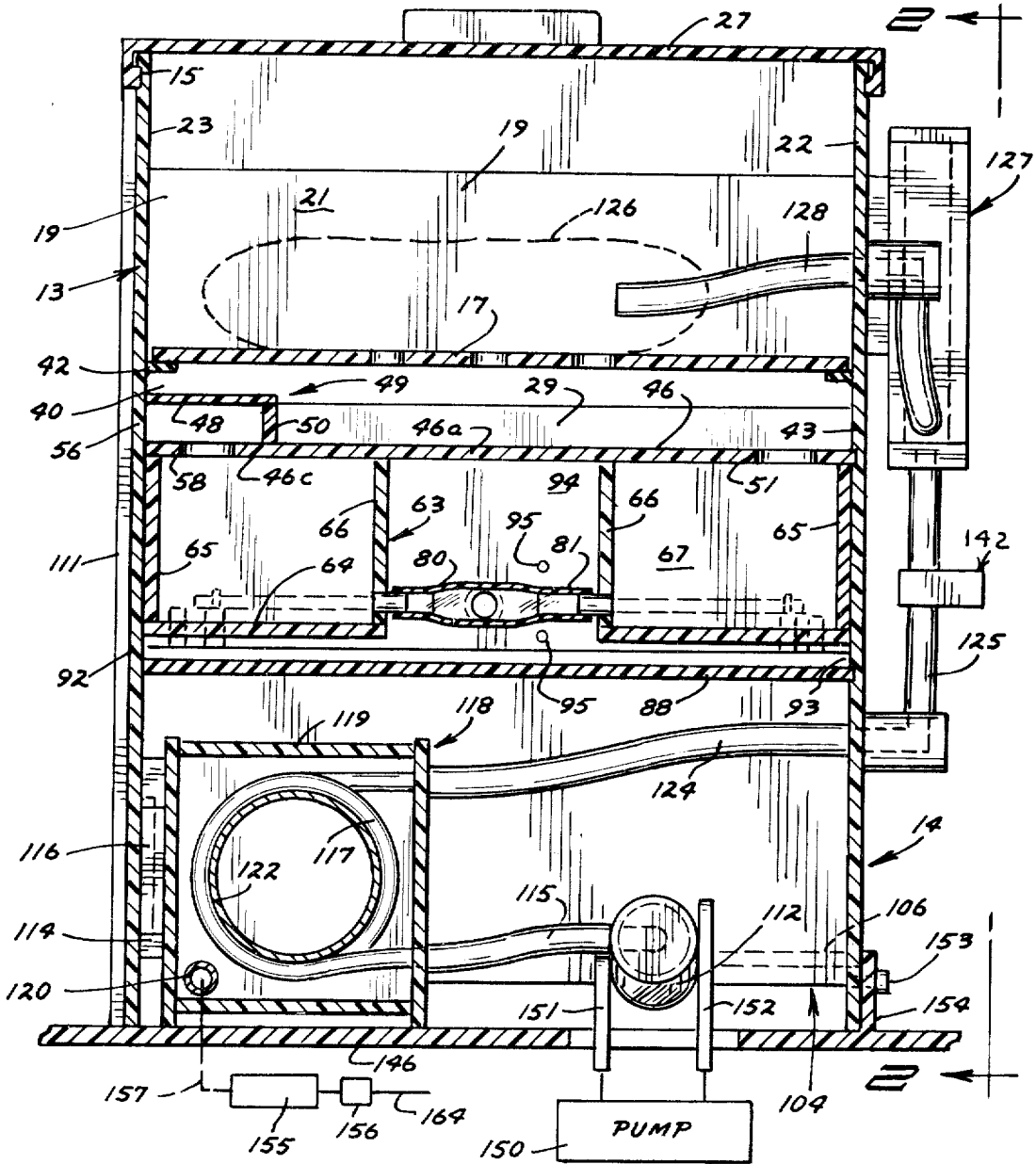


FIG. 9

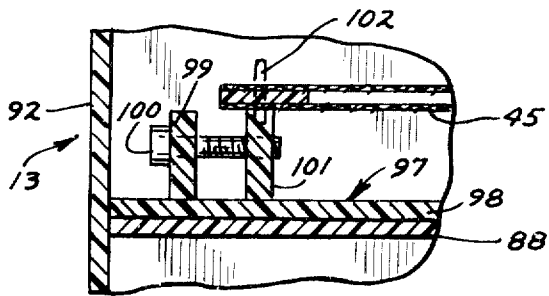


FIG. 8

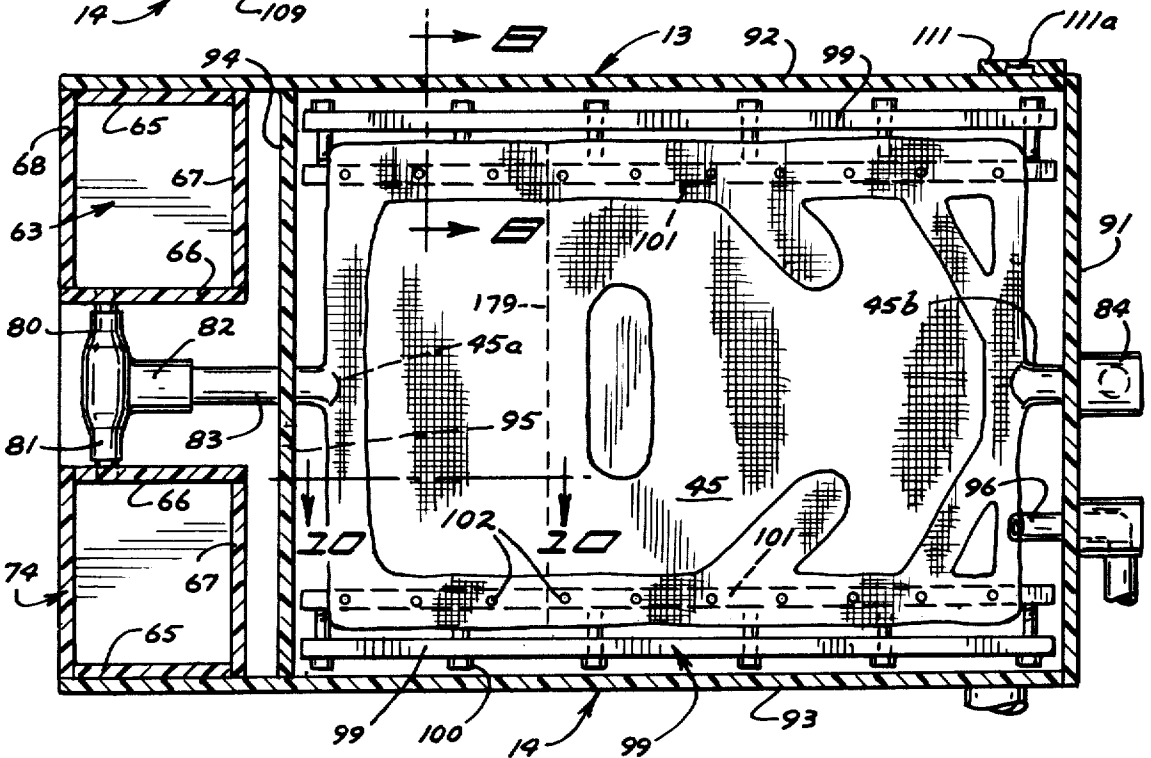
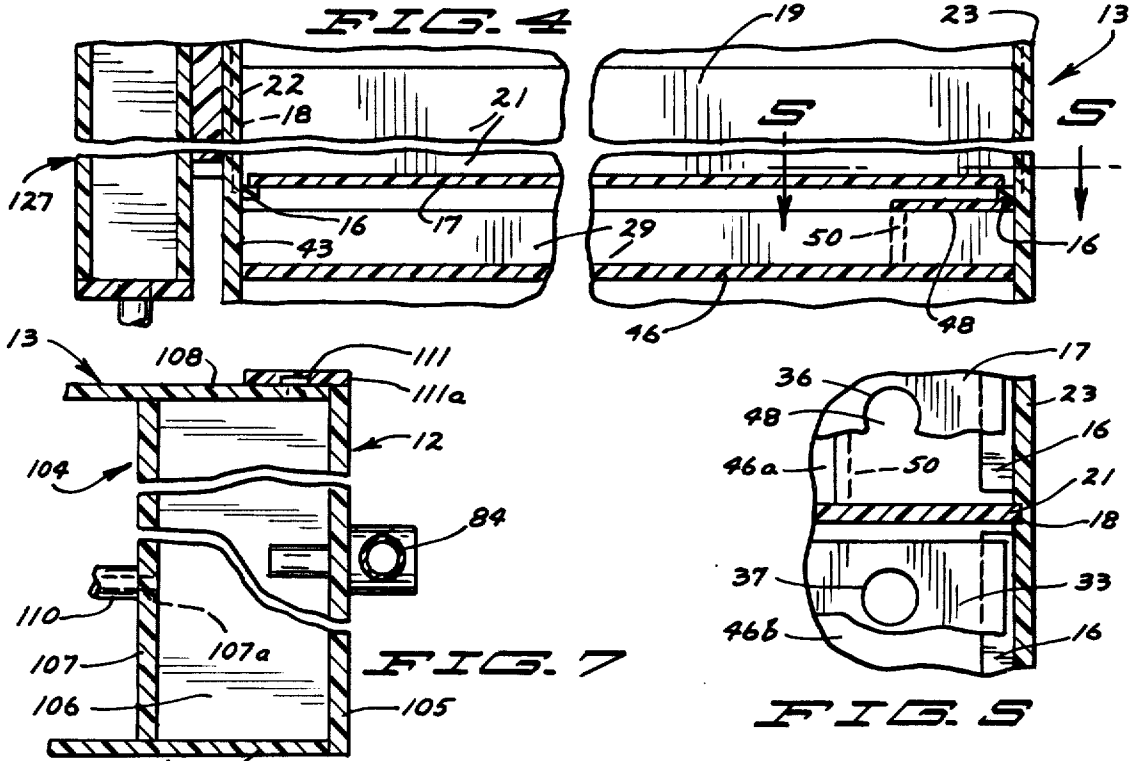
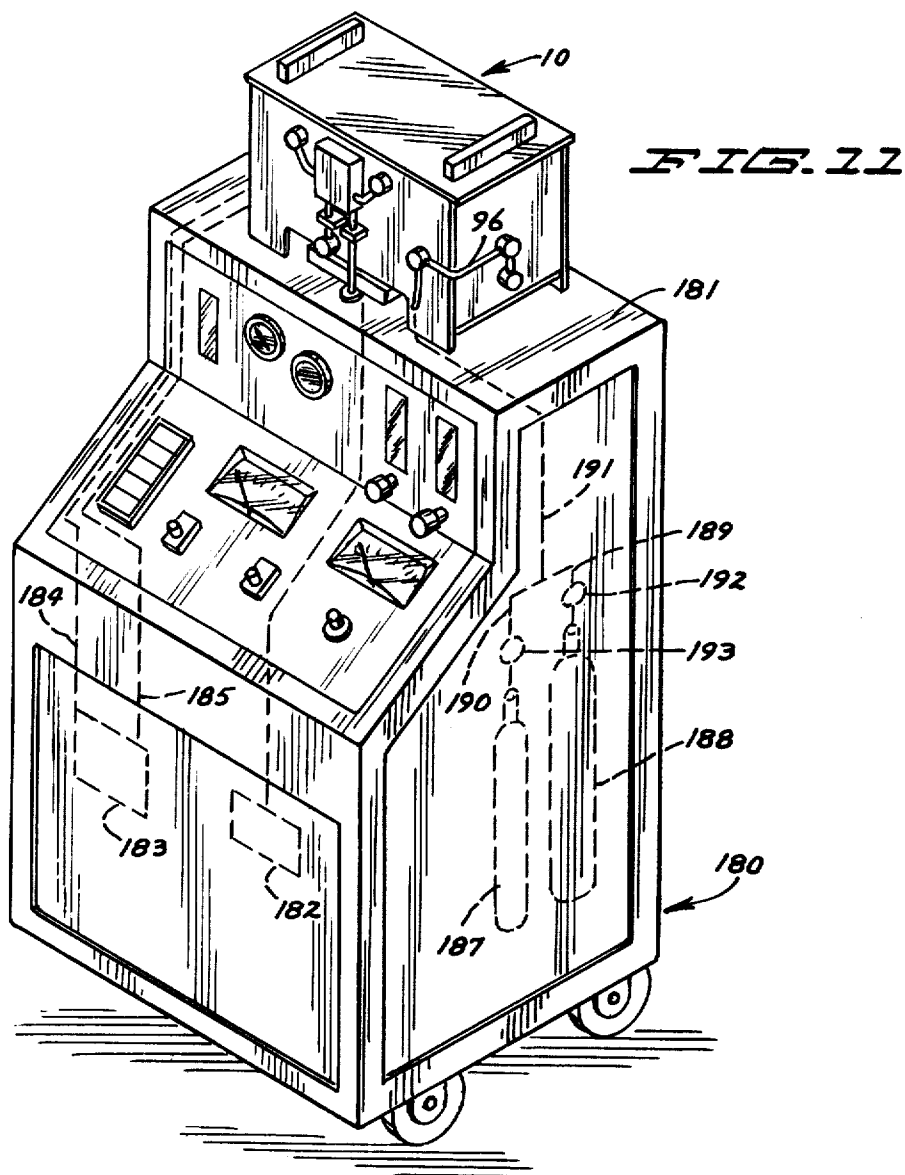
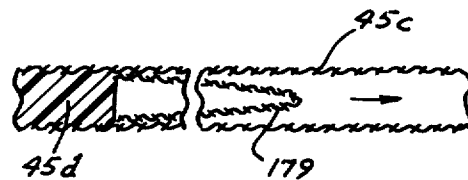
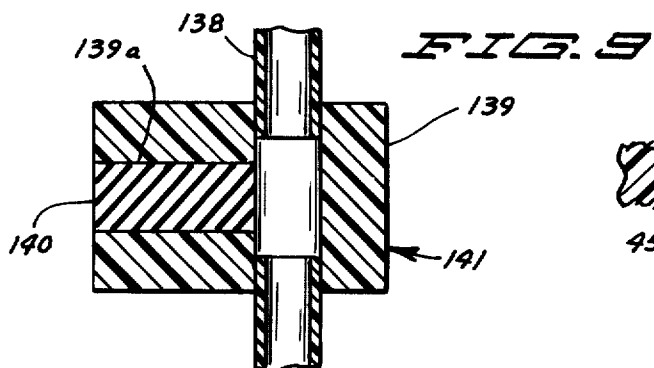


FIG. 6



METHOD OF TRANSPORTING AND STORING ORGANS WHILE RETAINING THE ORGANS IN A VIABLE CONDITION

CROSS REFERENCE TO RELATED APPLICATION

This application is a Divisional Application of our co-pending U.S. Pat. Application Ser. No. 201739, filed Nov. 24, 1971, now U.S. Pat. No. 3,777,507, granted Dec. 11, 1973.

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 therethrough 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 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 a 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 removably 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 respective 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, extends from partition 29 to wall portion 44 and preferably 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 than 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 tubes 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 member 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 12 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 is 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 slidably 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 an 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 13, 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 106 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 parts 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 sensor 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 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% oxygen and 20% carbon 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 **152**, 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 **46a** 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 therethrough 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.

5 What is claimed is:

1. In the method of preserving and maintaining an organ in a viable state in a cassette that has a perfusate circulatory system that includes an organ chamber, a venous reservoir, an oxygenator, a heat exchanger, and an arterial reservoir, placing the cassette in a manually portable transport module that has a cooling fluid source for supplying cooling fluid to the cassette heat exchanger and an oxygen source for supplying oxygen to the cassette, transporting the combination of the cassette and transport module to the site of a donor organ, placing the donor organ in the organ chamber, and connecting the organ in the circulatory system to perfuse the organ, transporting the combination of the cassette and transport module to an organ transplant site that is remote from said site of the donor organ, removing the cassette with the organ therein from the transport module at the transplant site, and while the organ is connected in the circulatory system, manually transferring the cassette from the transport module to an in-hospital support unit that has sources for supplying cooling fluid and oxygen to the heat exchanger and oxygenator respectively.

2. The method of claim 1 further characterized in the step of pumping perfusate to the organ during the transport step from the donor site to the transplant site, discontinuing pumping perfusate during the transfer step and resume pumping perfusate to the organ in the cassette after the cassette has been transferred from the transport module to the in-hospital unit.

3. The method of claim 1 further characterized in that during the step of transporting said combination from the donor site to the transplant site, the step of supplying a mixture of carbon dioxide and oxygen in contact with the oxygenator from a single source of a mixture of carbon dioxide and oxygen in the transport module.

4. In the method of maintaining an organ in a viable state, placing an organ in a cassette at an organ donor site including connecting the organ in the cassette perfusate circulatory system that includes a venous reservoir, an oxygenator and an arterial reservoir, transporting the cassette with the organ therein in a manually transportable transport module that has sources for supplying oxygen and cooling fluid to the cassette from the donor site to a remote in-hospital transplant site and at the transplant site transferring the cassette from the transport module to an in-hospital support unit that has a source for supplying cooling fluid to the cassette and a source for supplying oxygen to the cassette including supplying cooling fluid and oxygen to the cassette from said unit sources, the last mentioned transferring step including retaining the organ connected in said circulatory system.

5. The method of claim 4 further characterized in that the transporting step includes applying a pump pressure to the perfusate in the circulatory system from a source contained in the transport module and supplying oxygen and cooling fluid to the cassette from the transport unit, and that after the transferring step, applying a pump pressure to the perfusate in the circulatory system from a source in the in-hospital unit.

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6. The method of claim 1 further characterized in the steps of conducting oxygen from the transport module oxygen source to the oxygenator and cooling fluid from the transport module cooling fluid source to the heat exchanger while the organ is in the circulatory system and the cassette is in the transport module; discontinuing the conduction of oxygen and cooling fluid from the respective transport module source to the oxygenator and heat exchanger prior to the transfer step, and after the transfer step conducting oxygen and cooling fluid from the respective support unit source to the oxygenator and heat exchanger respectively.

7. In the method of maintaining an organ in a viable state in a cassette that has an organ perfusate circulatory system, including an organ chamber; at an organ donor site, placing the organ in the organ chamber including connecting the organ in the circulatory system, transporting the cassette with the organ connected in the circulatory system in a manually transportable transport unit from the donor site to a remote in-hospital transplant site, including circulating an oxygenated liquid through the circulatory system to the organ; and supplying oxygen from the transport module to the circulatory system to replenish the oxygen in the system; at the transplant site while the organ is still con-

nected in the circulatory system, transferring the cassette from the transport unit to an in-hospital support unit; and while the cassette is in the support unit, circulating an oxygenated liquid through the circulatory system to the organ and supplying oxygen to the circulatory system to replenish the oxygen in the system.

8. The method of claim 7 further characterized in that the transporting step includes cooling the liquid in the circulatory system by using a source of cooling medium external to the cassette and in the transport unit, and that while the cassette is in the support unit, cooling the liquid in the circulatory system by using a source of cooling medium external to the cassette and in the support unit.

9. The method of claim 7 further characterized in that the transporting step includes applying a pumping pressure to the circulatory system from a source external to the cassette and in the transport unit to force liquid to flow through the system to the organ; and after the transferring step, applying a pumping pressure from a source external to the cassette and in the support unit to force liquid to flow through the system to the organ.

10. The method of claim 7 wherein the support unit is of a much larger size than the transport module.

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