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Brumfield

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[54] **BLOOD OXYGENATOR AND THERMOREGULATOR APPARATUS**

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[51] **Int. Cl.** **A61m 1/03**

[58] **Field of Search** .... 23/258.5; 195/1.8; 128/DIG. 3, 400; 261/123, 124, DIG. 28; 55/255, 256

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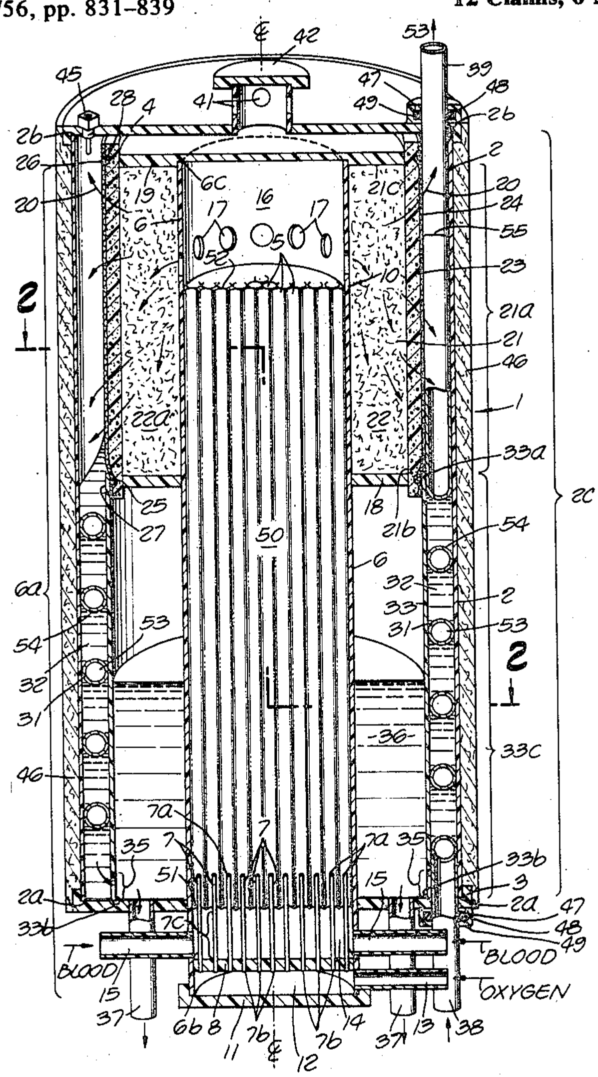
[57] **ABSTRACT**

Venous human blood flows into a base distributing manifold of a blood oxygenator, whose operating components are cooperatively vertically coaxially disposed. The blood is distributed into vertically aligned multiple, controlled small diameter oxygen exchange tubes, each exchange tube having a coaxial oxygen injection tube disposed at the exchange tube base. Oxygen gas flows through each injection tube, maintaining two-phase flow of oxygen-blood up through the exchange tubes. After oxygenation and separation of excess oxygen and exchanged carbon dioxide gas in a gas separator, the blood is further defoamed in an external coaxial defoamer bed. The defoamed blood then descends a coaxial annular ring in a spiral flow path over a spiral metal tube heat exchanger which contains temperature controlled circulating heat transfer fluid. The oxygenated defoamed blood is thermoregulated to the necessary temperature, exiting from the oxygenator base blood outlet conduit, returning to the patient's body.

12 Claims, 6 Drawing Figures



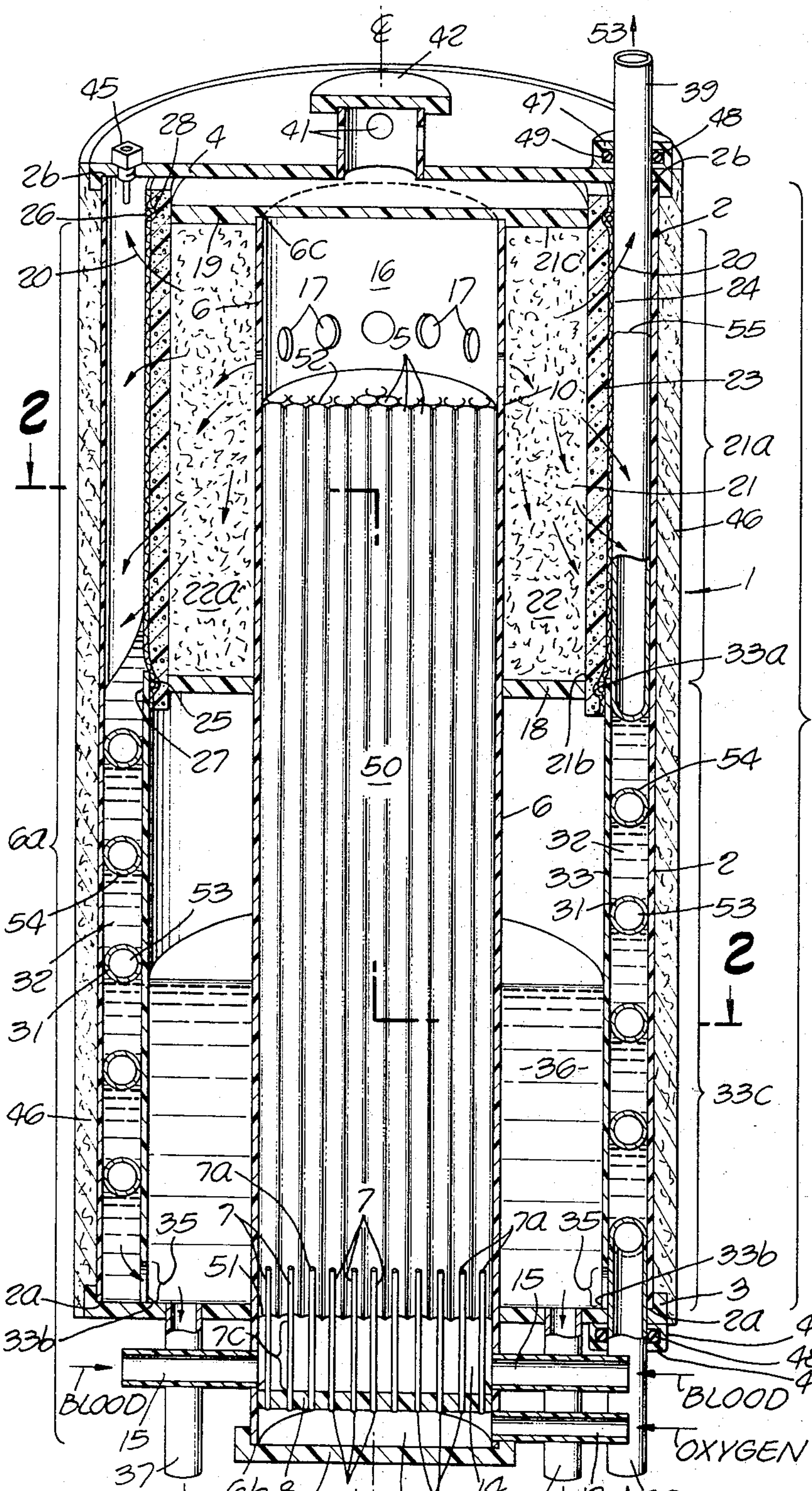


FIG. 1.

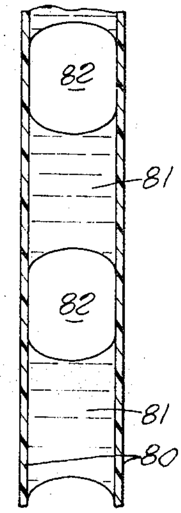


FIG. 4A.

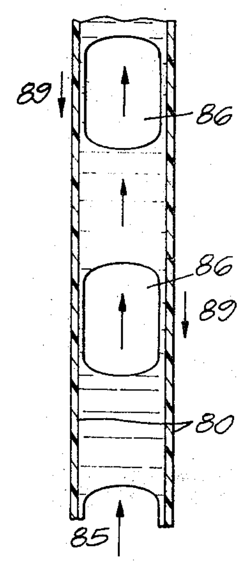


FIG. 4B.

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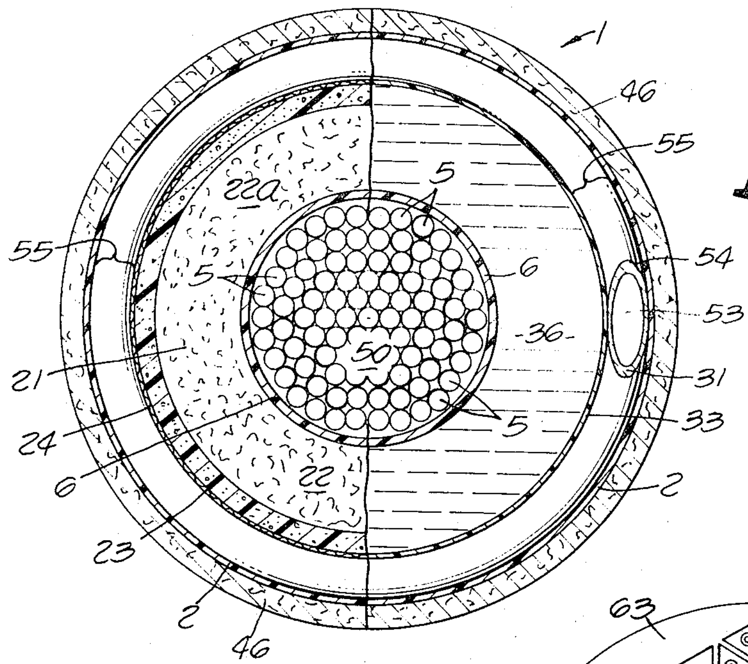

FIG. 2.

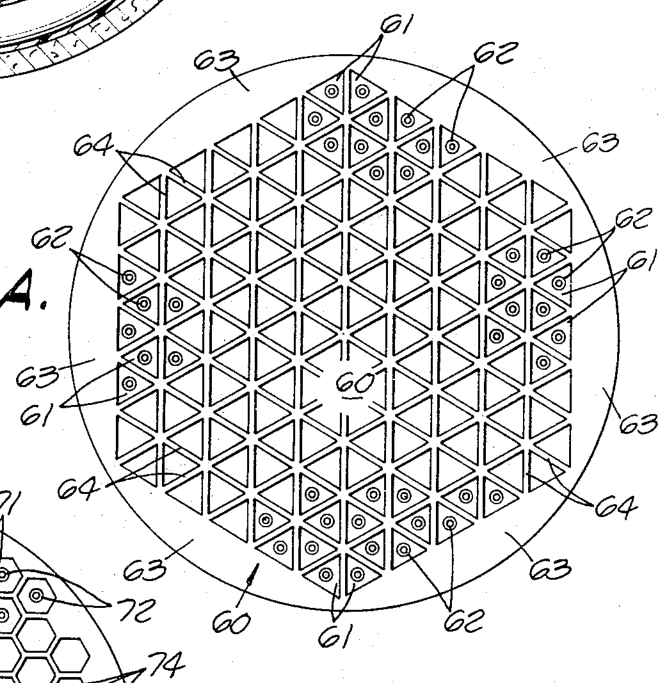

FIG. 3A.

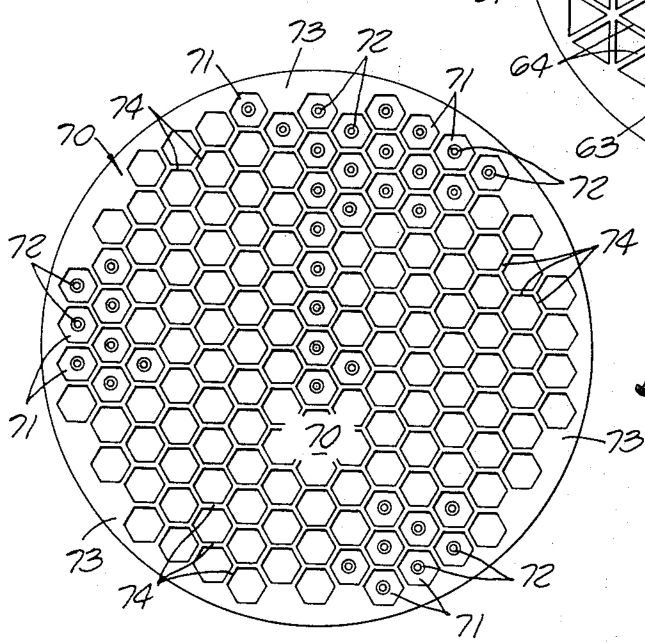

FIG. 3B.

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BLOOD OXYGENATOR AND THERMOREGULATOR APPARATUS

BACKGROUND OF THE INVENTION

This invention relates to a blood oxygenator and a thermoregulator apparatus particularly suitable for saturating venous blood with oxygen and releasing the carbon dioxide contained in the blood, together with regulating the temperature of the oxygenated blood prior to returning the blood to the patient's body. The advent of more advanced patient treatment and of radical cardiopulmonary surgery has increased the need for a disposable oxygenator and thermoregulator apparatus. The apparatus should require a minimum of priming with blood, plasma, or the like, and the flow of the blood through the apparatus should produce a minimum trauma to the circulating blood, so that hazards to the patient are reduced.

Apparatus for treating blood, human and animal are now classified in Class 23-Subclass 258.5. Blood oxygenators are specifically listed in the class.

SUMMARY OF THE INVENTION

A blood oxygenator and thermoregulator apparatus is disposed in a vertical tubular casing, having cooperative operating components. In the apparatus suitably disposed below the patient, the venous blood of the patient is distributed through a multiplicity of small diameter oxygen exchange tubes, coadjacently disposed in a solidly packed parallel equal length tube array. A first cylindrical tube case means permanently coaxially closely secures the vertical tube array the required spaced distance from the first tube case means terminuses. A multiplicity of short oxygenator tubes equal in number to the number of multiple gas exchange tubes are each singly disposed inside and adjacent a single exchange tube terminus in the exchange tube array. A second terminus of each one of said multiplicity of injection tubes terminate in an injection tube manifold plate, the manifold plate being planarly disposed normal to the first case means axis of symmetry and completely sealing the first tube case means. The manifold plate is disposed a residual injection tube length from the tube array first terminus, providing an inlet blood reservoir volume. An oxygen inlet reservoir volume is provided in said first tube case means between said manifold plate and a first closure means for said first tube case means. At least one foamed blood escape aperture means is provided in the first tube case means adjacent said tube array second terminus, and a gas separation chamber is disposed above the blood escape aperture means, with at least one gas escape aperture means provided adjacent to the gas separation chamber.

Separate blood inlet conduit means and oxygen inlet conduit means are disposed in the first case means providing the respective conduction of blood and oxygen to said tube array. An annular defoamer bed is concentrically disposed around said first tube case means extending from a bed base annular closure, disposed substantially below said foamed blood escape aperture means, to the top of said gas separation chamber, forming a thin annular shell blood filter surrounding both the defoamer bed and the gas separation chamber. An annular tube second case means is concentrically disposed around said first tube case means, the second case means having a first terminus supportively securing said bed base annular closure. The annular tube second case means has a second terminus securing a first annular oxygenator case closure plate, and the second case means has a length required to provide the necessary oxygenated blood reservoir in the annular volume between the first and second case means.

A tubular heat exchange means is snugly concentrically disposed around the second case means and contains a circulating heat transfer fluid, providing a controlled temperature range of 50° to 108°F for the oxygenated blood flowing from the blood filter over the exchange means. A tubular exterior third case means is snugly concentrically disposed around the heat exchange means providing an exterior boundary surface for the annulus in which blood circulates.

The third case means has a length at least equal to the combined length of the second case means and the blood filter. A first terminus of the third case means is permanently completely secured to the first oxygenator case closure base plate and the second terminus is sealed to the second oxygenator case closure plate, the second closure plate having gas escape aperture means disposed therein. Heat exchange means fluid inlet and outlet conduits are conductively disposed therein. At least one oxygenated blood outlet conduit is disposed from the first oxygenator case closure base plate.

Included in the objects of this invention are:

To provide a simple, relatively inexpensive, disposable blood oxygenator and defoamer apparatus, with blood thermoregulation control.

To provide a disposable blood oxygenator and thermoregulator apparatus which can be quickly placed in operation and which can be sterilized prior to use.

To provide a blood oxygenator and thermoregulator apparatus which is substantially transparent, adapting it to constant visual observation during use with patients.

To provide a blood oxygenator and thermoregulator apparatus requiring a minimum volume of blood fluid extenders to place the apparatus in operative condition.

To provide a blood oxygenator and thermoregulator means for controlling the temperature of oxygenated blood exiting therefrom.

To provide a blood oxygenator and thermoregulator apparatus which functionally operates with a minimum damage to the blood circulating therein.

Other objects and advantages of this invention are taught in the following description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The description of this invention is to be read in conjunction with the following drawings.

FIG. 1 is an elevational perspective partial sectional view of the blood oxygenator and thermoregulator apparatus.

FIG. 2 is a sectional view through 2—2 of FIG. 1.

FIG. 3A is another cross sectional view similar to FIG. 2, illustrating a further modification of an oxygen exchange tube array cross sectional configuration with the oxygen injection tubes disposed therein.

FIG. 3B is still another cross sectional view illustrating the cross sectional geometry of another oxygen exchange tube array configuration having gas injection tubes disposed therein.

FIG. 4A schematically illustrates a slug mixture of blood and oxygen gas vertically disposed before two-phase slug flow begins in an oxygen exchange tube. FIG. 4B is an enlarged schematic illustration of a flowing mixture of a two-phased slug flow of blood and oxygen gas in a single oxygen exchange tube.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the elevational perspective partial section view of FIG. 1 in detail, the blood oxygenator 1 has a multiplicity of small diameter oxygen exchange tubes 5 coadjacently disposed in a solidly packed parallel equal length tube array 50. Typically the tube array 50 ranges from 4 to 24 inches long, and each single tube 5 ranges from one-sixteenth to five-sixteenths inches in a single internal tube diameter. The tube array 50 is vertically disposed in the oxygenator apparatus 1. The multiple tubes 5 are closely packed, preferably being a solidly bonded mass with no interstices between the tube walls, typically being an extruded plastic tube array, as 50 or the like. A first cylindrical tube case means 6 permanently coaxially closely secures the tube array 50, the first case means 6 having a case length 6a, longer than the tube array 50. The tube array 50 is coaxially disposed inside the case means 6, spaced the required distances from each of the first case means terminus 6*b* and second case means terminus 6*c*. A multiplicity of short oxygen injection tubes 7 have clear internal gas passages, the injection tubes being equal in number to the number of multiple oxygen gas exchange tubes 5. A first terminus 7*a* of each one of the multiplicity of the oxygen injection tubes 7 is disposed inside and closely adjacent to a single exchange tube 5 terminus 51 in the exchange tube array 50. A second terminus 7*b* of each one of the multiplicity of oxygen injection tubes 7 terminates in an injection tube manifold plate 8. The manifold plate 8 is planarly disposed normal to the first case means 6 axis of symmetry and the manifold plate area completely seals the first tube case means 6. The manifold plate 8 is disposed the residual injection tube length 7*c* from the tube array first terminus 51 providing an inlet blood reservoir volume 14 between the tube array first terminus 51 and the manifold plate 8. A first closure means 11 permanently completely seals the first tube case means 6 at the case means first terminus 6*b*, providing an oxygen inlet reservoir volume 12 between the first closure means 11 and the manifold plate 8.

Multiple foamed blood escape aperture means 17 are provided in the first case tube means 6 adjacent to the tube array 50 second terminus 52. A gase separation chamber 16 is disposed above the multiple foam blood escape aperture means 17 extending to the first case means 6 second terminus 6*c*. At least one blood inlet conduit means 15 is disposed in the first case means 6, providing direct conduction of blood into the blood reservoir volume 14. At least one oxygen inlet conduit means 13 is disposed in the first case means 6 providing direct conduction of oxygen into the oxygen reservoir volume 12.

An annular blood defoamer bed 21 is concentrically disposed around the first tube case means 6 having a bed depth 21*a* required to defoam the oxygenated blood flowing from the foamed blood escape aperture means 17. The blood defoamer bed 21 has a bed base annular closure 18 supportively externally sealed around the first case means 6 at a bed 21 first terminus 21*b*, securing the bed 21 to the first case means 6. The annular defoamer bed 21 has a second terminus 21*c* almost coplanar with the first case means terminus 6*c*. The defoamer bed 21 has a first open cell plastic foam packing 22 disposed in the defoamer bed, the packing surface having a silicone defoaming composition thin film 22*a* disposed on the foam packing. The silicone defoaming composition is selected to be compatible with blood and to accelerate the separation of gas phase from the liquid blood phase, thereby defoaming blood.

A thin annular shell blood filter is a combination of a thin filter medium 23 coaxially surrounding the defoamer bed 21 and the gas separation chamber 16, and a covering filter cloth 24. The annular blood filter medium 23 is a dense, open cell, plastic foam composition filter medium. A thin, fine weave filter cloth 24 is exteriorly disposed as a thin layer over all of the exterior face of filter medium 23. The blood filter medium length is not less than the defoamer bed depth 21*a*. The filter cloth 24 is permanently secured to the foam filter medium 23, and the combination of 23 and 24 are snugly secured by a nylon cord means 25 to the bed base annular closure 18 at 27. A shell filter closure plate 19 is internally supportively disposed in and snugly secured to the blood filter medium 23 and filter cloth 24 combination at the filter terminus 21*c* which is opposed to the filter terminus 21*b* secured to the bed face annular closure 18. In this apparatus the filter closure plate 19 is supportively bonded to the case means. The oxygen and carbon dioxide gases 20 escape from the defoamer bed 21 and gas separation chamber 16 through the thin annular shell blood filter combination of filter medium 23 and filter cloth 24. The cord means 26 secures the combination of filter medium 23 and cloth 24 to closure 19, at 28.

An annular tube second case means 33 is concentrically disposed around the first tube case means 6 having an internal tube diameter substantially equal to the shell blood filter medium 23 and filter cloth 24 combination external diameter. The second case means 33 has a first terminus 33*a* supportively securing the bed base annular closure 18 and the annular shell blood filter, and a second terminus 33*b* secures a first annular oxygenator case closure plate 3, and is hermetically bonded to the plate 3. The second case means 33 has a length 33*c* required to provide the necessary oxygenated blood reservoir 36 in the annular volume between the first case means 6 and the second case means 33. At least one blood reservoir aperture 35 is disposed in the wall of second case means 33 contiguous to the second case means 33 second terminus 33*b*, providing an aperture for blood to flow into the blood reservoir 36.

A tubular heat exchange means 31 is snugly concentrically disposed around the second case means 33. A heat exchange thermoregulating fluid 53 circlates through the heat exchange means 31. In this specific example, the heat exchange means 31 comprises multiple spiral turns of an aluminum tube heat exchanger coil 31, the aluminum coil being completely externally coated with a thin polyurethane film 54 which is chemically and physically compatible with circulating blood. The spiral turns of the heat exchanger coil 31 provide an annular blood flow helical path 32 for the blood exiting from the blood filter shell 23 and cloth filter 24. The tubular heat exchange means 31 can control the circulating blood temperature in a typical range of 50° to 108°F as the blood descends the spiral path 32. A tubular exterior third case means 2 is snugly concentrically disposed around the tubular heat exchange means 31, providing an exterior boundary surface for the blood circulating annulus 55 enclosing the heat exchanger means 31. The third case means 2 has a length 2c at least equal to the combined lengths 33*c* and 21*a* of the second case means 33 and the defoamer bed 21. A first terminus 2*a* of the third case means 2 is permanently completely sealed by the first oxygenator case closure plate 3 and the second terminus 2*b* of the third case means 2 is sealed by the second oxygenator closure plate 4. The second oxygenator closure plate 4 has gas escape aperture means 41, covered by cap 42 disposed therein, allowing escape of carbon dioxide gas exchanged in the circulating blood, as well as the excess oxygen gas. The heat exchange means 31 has a fluid inlet conduit 38 and a fluid outlet conduit 39 conductively disposed outside of the blood circulating annulus 55. Seals 47 hermetically secure the inlet conduit 38 and the outlet conduit 39 into the apparatus 1, utilizing an O-ring 48 disposed in O-ring groove 49.

At least one oxygenated blood outlet conduit 37 is exteriorly secured to and exits from the first oxygenator closure plate 3.

In this apparatus a hypodermic needle fastening means 45 is disposed through the closure plate 4, providing for the introduction of required dosage of medication through a syringe means during the operation of the blood oxygenator 1.

A foam insulating layer 46 is exteriorly secured on the third case means 2 providing additional temperature regulation means, as is necessary.

FIG. 2 is an illustration of the cross sectional view through the apparatus 1 at two levels in a cross sectional structure of the apparatus. The left side of FIG. 2 is an illustration of the cross section of apparatus 1 through the annular shell blood filter, the defoamer bed, and the tube array. The third case means 2 has a foam insulating layer 46 exteriorly disposed around the case member 2. The blood circulating annulus 55 is shown disposed on both halves of the sectional view. The left half portion of the view illustrates the filter cloth 24 exteriorly disposed over the exterior face of the filter medium 23. The defoamer bed 21 has the open cell plastic foam packing 22 disposed in the bed 21, the packing surface of 22 having a thin film silicone defoaming composition 22*a* disposed thereon. The tubular first case means 6 forms the inner structure member of the defoamer bed and the outer structure of the tube array 50 disposed in case member 6. The individual oxygen exchange tubes 5 are disposed in the tube array 50 as integral exchange tube apertures. The right hand side of FIG. 2 illustrates the cross section structure of the apparatus 1 at a lower level in the apparatus, wherein the blood reservoir 36 is formed between the case member 6 and the case member 33. Again the blood circulating annulus 55 is shown disposed between case member 33 and case member 2. A cross sectional view of the tubular heat exchange means 31 is shown having circulating heat transfer fluid 53 disposed in tube 31. A thin polyurethane film 54 is shown disposed exteriorly on the tube 31 preventing physical and chemical reaction of the circulating blood with the aluminum tubing. The foam insulating layer 46 is shown exteriorly secured on the third case means 2.

FIG. 3A illustrates in cross sectional view a multiple oxygen exchange tube array 60 formed in one piece. Each single oxygen exchange tube 61 is triangular in cross section, having a common wall 64 with the adjacent oxygen exchange tubes 61. The solid, integral tube array can be provided by extruding a suitable plastic composition, providing parallel tube arrays of the desired length. Integral solid plastic tube array exterior wall spacer 63 provides a circular cross section for the tube array 60, enabling the tube array 60 to be tightly and securely disposed in a first cylindrical tube 6 case means as taught above. The multiplicity of short oxygen injection tubes 62 are shown coaxially disposed, equal in number to the number of multiple oxygen exchange tubes 6

FIG. 3B further illustrates another cross sectional configuration which is equivalent to the cross sectional configuration of FIG. 3A. In this second configuration the small diameter oxygen exchange tubes 71 are also coadjacently disposed in a solid, integral tube array configuration 70, a single oxygen exchange tube 71 being hexagonally in cross section. Again, a multiplicity of short oxygen injection tubes 72 having internally clear gas passages are shown disposed equal in number to the number of multiple oxygen gas exchange tubes 71. An external solid plastic spacer 73 is shown integrally disposed around the regular hexagonal shaped oxygen exchange tubes providing a circular perimeter for the tube array configuration so that it may be disposed in a first cylindrical tube case means. The oxygen exchange tube can have a wide variety of cross sectional shapes, preferably being regular symmetrical shapes adapted to close packing and providing a large cross sectional area for flow of fluid. The thin wall 74 is disposed around the hexagonal tubes 72.

The blood oxygenating apparatus of this invention is operated in a concurrent two-phase flow of gasesous oxygen and circulating blood. The mass transport of blood and oxygen and the exchanged carbon dioxide gas is upward through the apparatus 1. The oxygen exchange tube array 50 or the like can be designed for blood circulating flows ranging from that of newborn infants to adults undergoing radical cardio-pulmonary surgery. In order to avoid massive blood trauma during the oxygenating process, it is desirable that the circulating blood be oxygenated with as little blood turbulence as possible. To this end blood transport should be through an optimal number of oxygen exchange tubes, providing a maximum amount of blood oxygenating exchange surface. In the mass transport of blood upward through the tube array 50, or the like, local fluid circulation occurs in each oxygen exchange tube. The local circulation of the blood during this transport process is wall stabilized, providing constantly renewed blood fluid surface as the blood is pumped up by the oxygen bubbles. The oxygen gas may flow in true bubble flow, or in slug flow as the gas velocity through the oxygen exchange tube is increased.

Typically, the blood flow rate through the oxygenator and thermoregulator apparatus 1 can vary from 500 ml/min to 7,500 ml/min. This wide variation in flow rate in the apparatus 1 can be produced by varying the number of oxygen exchange tubes disposed in a solidly packed tube array. Typically, a tube array 50 for the low flow rate can contain 85 tubes, each one-fourth inch in diameter. At the other end of the flow rate range an apparatus requiring a flow rate of 7,500 mililiters/min. can have 1,360 oxygen exchange tubes disposed in a tube array 50, each single tube having a diameter of one-sixteenth inch. The gas-blood flow ratio can vary over the range of 1–4 times the blood flow rate. The oxygenating gas typically contains 98 percent oxygen and 2 percent carbon dioxide.

Comparative studies have shown that blood trauma can be produced in bubble oxygenators and conventional disc oxygenators. In order to minimize the blood trauma during the oxygenation process, the oxygen flow rate should be the minimum value required to maintain the oxygen transfer rate required. This invention minimizes the blood trauma by minimizing the turbulence in the oxygenating process and minimizing the external work done on the circulating blood during the flow through the oxygen tube exchange array. In this apparatus compressed oxygen gas forms a two-phase mixture of blood and oxygen gas within the single oxygen gas exchange tube. The oxygen gas reduces the density of the mixture of blood and gas and the mixture is pumped upward through the exchange tube. Bubble flow occurs at the lowest gas superficial velocity and slug flow occurs at the next higher range of gas velocity. During both bubble and slug flow a thin film of blood is exposed to oxygen gas, maximizing the rate of oxygen transfer into the blood, with the concurrent release of carbon dioxide gas. The bubbles flowing up the exchange tube crowd against one another and against the tube wall, exposing a large ratio of surface to gas volume as the bubbles rise. Slugs tend to form at higher gas flow rates, the gas slugs moving at higher velocity than the liquid, slip through the liquid, constantly exposing fresh blood surface for oxygen-carbon dioxide exchange. The blood fluid transported by the slugs and the bubbles tend to flow laminarly due to the thin film structure. The apparatus is operable and flow is stable over a wide range of liquid and gas flow rates, providing safety in patient treatment. The apparatus can be operated disposed at angles to the vertical, and can be even operated disposed horizontally, in an emergency. By simply varying the number of oxygen exchange tubes disposed in a tube array, one can easily vary the capacity of the apparatus for oxygen exchange capacity. As the alternate slugs of gas and blood ascend an exchange tube during upflow, there is considerable slippage between the liquid and the gas phase.

FIG. 4A illustrates in vertical cross sectional view a static mixture of blood and oxygen gas disposed in an oxygen exchange tube. The liquid **81** is alternately interphased with the oxygen gas bubble **82** in the exchange tube **80**.

In FIG. 4B the upward flowing mixture of blood **85** is shown with interphased oxygen gas bubbles **86** disposed in the oxygen exchange tube **80**. The slippage between gas and liquid is illustrated by the arrows **89** indicating local relative downward flow of blood film on the side of the tube **80** while the gas bubbles **86** are ascending the tube. It is this laminar phenomenon in blood flow which accelerates the exchange of oxygen gas solution in the blood and the rapid evolution of carbon dioxide from the blood during this rapid gas exchange process.

The integral heat exchange means provides temperature control of the perfused blood, providing precise control of an important medical variable during a medical treatment. Thus the perfused blood can be varied in the range of 50° to 108°F as is required for the optimum treatment condition for the patient. The blood can be medicated routinely as required prior to the final temperature regulation of the blood and its return to the patient's circulatory system.

In operation, the apparatus **1** is disposed below the patient and the heat transfer fluid **53** is programmed for the scheduled temperature. Prior to the induction of the patient's circulating blood, the apparatus **1** may be primed with transfusion blood, plasma, saline solution, or the like, as is required. The patient's blood or the alternate substitute fluid is saturated with oxygen flowing through inlet conduit **13** into the oxygen reservoir **12**, then up through the oxygen injection tube **7**. Venous blood flows through the blood inlet conduits **15** into the blood reservoir **14** and up through the oxygen exchange tube array **50**. The oxygen saturated blood fluid exits the tube array **50** at **52** and flows through the aperture **17** into the defoamer bed **21**. A heat exchange means **31** helically disposed provides a spiral descending flow path **32** for the blood, provides heat transfer for the blood, and equilibrates the the blood to the desired exit temperature. The blood exits from the annulus **55** through the apertures **35** to the blood reservoir **36**. The blood collected in the annular blood reservoir **36** exits through the blood exit conduit **37**, thence through the means required to place the blood back in the patient's circulating system.

For the patient's safety it is necessary that the chemical composition and the physical structure of the components of the blood oxygenator apparatus of this invention be compatible with the patient's circulating blood. Consistent with the above requirements for the defoamer bed composition, the open cell elastic plastic foam medium can typically be selected from polyurethane foam of the open cell reticulated modification, polyester fiber felts, silicone rubber foam of the open cell type, and polypropylene fiber foam of the open cell construction. These foams can contain in the expanded state, prior to compression, up to 80 pores per linear inch of foam. Likewise, for the filter function of the annular shell filter **23**, the foam can contain open cell pore openings ranging typically from 25 to 150 microns in diameter. The mechanical structure of the rigid oxygenator components can be rigid polyvinyl chloride, high density polyethylene, polypropylene, polycarbonate, and other rigid plastic compositions which meet the required chemical and physical compatibility requirements. The fine weave filter cloth required for filter cloth **23**, or the like, can be a nylon knit or woven cloth of the required porosity. Silicone defoaming agents are well known, one which is compatible with the defoaming requirement for the defoamer bed is a Dow-Corning silicone no. 2003, applied as a very thin coating to the foam structure disposed in the defoamer bed.

The oxygenator apparatus of this invention is precisely assembled and the joints carefully bonded to minimize blood leakage problems both within components of the apparatus as well as external leakage from the apparatus as a whole. Hermetic sealing of the external case, as well as for selected internal components, is necessary. The bonding can be accomplished by well known cementing procedures, ultrasonic sealing, dielectric sealing, or conductive heat sealing, as are applicable and necessary. In conformance with well known principles, the plastic components selected for sealing together must be chemically and physically compatible. It is desirable that the selected components be chemically and physically stable under standard medical steam sterilization conditions, or other medically accepted sterilization conditions.

Many modifications and variations in the improvement in a disposable blood oxygenator and thermoregulator apparatus can be made in the light of my teaching. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

I claim:

1. In a process suitable for exchanging oxygen for carbon dioxide in patient extra corporeal circulating blood, the improvement combination comprising:

flowing a pro rata volume portion of said blood into a first terminus of each one of a multiplicity of small diameter blood-gas exchange tubes coadjacently disposed in a tube array, said tube array ranging from 4 to 24 inches long and said tubes ranging from one-sixteenth to five-sixteenths inches in a single internal tube diameter, said tube array disposed in a blood oxygenator apparatus, each one of said first terminus secured adjacent the apparatus base end,

separately injecting into each said flowing pro rata volume portion of blood from one to four volumes of oxygen gas, forming a two-phase bubble dispersion of said gas and blood in each one of said blood-gas exchange tubes, providing absorption of said oxygen by said blood and release of said carbon dioxide gas by said blood, and,

flowing said two-phase bubble dispersion from the second terminus of each one of said blood-gas exchange tubes into a single common gas separation chamber disposed adjacent the multiplicity of said second terminus.

2. In an extra corporeal blood oxygenator apparatus suitable for oxygenating venous blood and removing carbon dioxide therefrom, the combination comprising:

a. a plurality of elongated oxygen exchange small diameter tubes disposed in a closely juxtaposed array, each exchange tube having an open venous blood inlet base end and an open arterial blood outlet top end, and being of substantially uniform cross section between said ends,

a first common manifold encompassing and communicating with all said tubes inlet base ends, for delivering venous blood thereto,

c. an oxygen supply tube extending into the inlet end of each exchange tube having a terminal discharge orifice disposed inwardly from the inlet base end thereof, adapted to discharge oxygen gas in the direction of the blood flow,

d. a second common manifold encompassing and communicating with all the oxygen supply tubes for delivering oxygen gas thereto,

e. an annular defoaming chamber disposed above and in flow communication with said array and axially coaligned therewith and,

f. an annular blood filter surrounding and in flow communication with the aforesaid defoaming chamber.

3. Apparatus in accordance with claim 2 wherein said array has an integral single connecting tube array wall.

4. Apparatus in further accordance with claim 2 wherein said tubes in said array are uniformly spaced through the tube array cross section; an annular volume surrounding said array; a helical heat exchange tube disposed within aforesaid annular volume, providing a helical flow channel between its convolutions, the arterial blood adapted to flow through the helical flow channel.

5. Apparatus in further accordance with claim 4 including an annular blood reservoir surrounding said array, the lower end of the helical flow channel communicating with said reservoir.

6. Apparatus in further accordance with claim 3 wherein the helical flow channel surrounds said blood reservoir.

7. A disposable blood oxygenator apparatus suitable for exchanging oxygen for carbon dioxide in patient extra corporeal circulating blood, wherein the improvement combination comprises:

a multiplicity of small diameter oxygen exchange tubes coadjacently disposed in a closely packed, parallel, equal length upstanding tube array, said tube array disposed in an oxygenator apparatus, the tube array first terminus secured adjacent the apparatus base end,

a first tube case means permanently coaxially closely securing said tube array, said first case means having a case length longer than said tube array, said tube array coaxially disposed relative to said first case means the required spaced distance from said case means first terminus,

a multiplicity of short oxygen gas injection tubes having internal gas passages therein, said injection tubes equal in number to the number of multiple oxygen gas exchange tubes, a first terminus of each one of said multiplicity of injection tubes disposed inside and adjacent a single exchange tube terminus in said exchange tube array first terminus, a second terminus of each one of said multiplicity of injection tubes terminating in an injection tube manifold plate, said manifold plate disposed the residual injection tube length from said tube array first terminus, providing therebetween an inlet blood reservoir volume,

an annular defoamer bed concentrically disposed around said first tube case means, having a bed depth required to defoam oxygenated blood, said bed having foamed blood escape aperture means adjacently disposed in aforesaid case means, said bed having a bed base annular closure supportively externally sealed around said first case means at a bed first terminus, and the second bed means terminus coplanar with said first case means second terminus, said defoamer bed having a first open cell plastic foam packing disposed therein, the packing surface having a silicone defoaming composition thin film disposed thereon, thereby accelerating the separation of oxygenated blood and gas,

a thin annular shell blood filter means coaxially surrounding said defoamer bed and a gas separation chamber disposed above said tube array, said annular shell blood filter having a dense open cell plastic foam composition filter meedium cylindrically disposed therein and a thin fine weave filter cloth disposed over the filter medium exterior, the blood filter means length being not less than the defoamer bed depth, said filter cloth permanently exteriorly secured to said foam filter medium, said shell blood filter snugly secured to said bed base annular closure, and,

a shell filter closure plate internally supportively disposed in and snugly secured to said shell blood filter at the second terminus of aforesaid filter opposed to the filter terminus secured to the bed base annular closure.

8. An apparatus as set forth in claim **7** wherein the further improvement combination comprises:

an annular tube second case means concentrically disposed around said first tube case means having an internal tube diameter substantially equal to the shell blood filter external diameter, said second case means having a first terminus supportively securing said bed base annular closure, and said annular shell blood filter, and a second terminus securing a first annular oxygenator case closure plate, said second case means having a length required to provide the necessary oxygenated blood reservoir in the annular volume between said first and second case means, said second case means having at least one blood reservoir aperture disposed in the tube wall thereof contiguous said second case means second terminus.

a tubular heat exchange means snugly concentrically disposed around said second case means, a heat exchange thermoregulating fluid circulating through said heat exchange means, said exchange means having a blood circulating path externally disposed thereon providing a controlled temperature range of 50° to 108°F for the oxygenated blood flowing from said blood filter over said exchange means, said tubular means having a fluid inlet conduit and a fluid outlet conduit,

a tubular exterior third case means snugly concentrically disposed around said heat exchange means, providing an exterior boundary surface for the blood circulating annulus enclosing said heat exchange means, said third case means having a length at least equal to the combined lengths of said second case means and said blood filter, a first terminus of said third case means permanently completely sealed by said first oxygenator case closure plate and the second terminus of said third case means sealed by said second oxygenator closure plate, said second oxygenator closure plate having gas escape aperture means disposed therein, said heat exchange means fluid inlet conduit and said fluid outlet conduit conductively disposed outside of said blood circulating annulus, to the blood oxygenator exterior, and

at least one oxygenated, temperature regulated blood outlet conduit exteriorly disposed from said first oxygenator case closure plate.

9. A combination as set forth in claim **8** wherein said tubular heat exchange means further comprises a spirally wound tubular coil snugly concentrically disposed around said second case means.

10. In a disposable blood oxygenator apparatus suitable for exchanging oxygen for carbon dioxide in patient extra corporeal circulating blood, the combination comprising:

a multiplicity of small diameter oxygen exchange tubes coadjacently disposed in a solidly packed, parallel, equal length tube array, said tube array ranging from 4 to 24 inches long and said tubes ranging from one-sixteenth to five-sixteenths inches in a single internal tube diameter, said tube array vertically disposed in an oxygenator apparatus, the tube array first terminus secured adjacent the apparatus base end,

a first tube case means permanently coaxially closely securing said tube array, said first case means having a case length substantially longer than said tube array, said tube array coaxially disposed inside said first case means the required spaced distances from each of the first and second case means terminus,

a multiplicity of short oxygen injection tubes having clear internal gas passages therein, said injection tubes equal in number to the number of multiple oxygen gas exchange tubes, a first terminus of each one of said multiplicity of injection tubes disposed inside and adjacent a single exchange tube terminus in said exchange tube array first terminus, a second terminus of each one of said multiplicity of injection tubes terminating in an injection tube manifold plate, said manifold plate planarly disposed normal to the first case means axis of symmetry and the manifold planar area completely sealing said first tube case means, said manifold plate disposed the residual injection tube length from said tube array first terminus, providing there between an inlet blood reservoir volume,

an annular defoamer bed concentrically disposed around said first tube case means, having a bed depth required to defoam oxygenated blood, said bed having foamed blood escape aperture means adjacently disposed in aforesaid case means, said bed having a bed base annular closure supportively externally sealed around said first case means at a bed first terminus, and the second bed means terminus coplanar with said first case means second terminus, said defoamer bed having a first open cell plastic foam packing disposed therein, the packing surface having a silicone defoaming composition thin film disposed thereon, accelerating the separation of oxygenated blood and gas,

a thin annular shell blood filter means coaxially surrounding said defoamer bed and a gas separation chamber disposed above said tube array, said annular shell blood filter having a dense open cell plastic foam composition filter medium cylindrically disposed therein and a thin fine weave filter cloth disposed over the filter medium exterior, the blood filter means length being not less than the defoamer bed depth, said filter cloth permanently exteriorly secured to said foam filter medium, said shell blood filter snugly secured to said bed base annular closure, and,

a shell filter closure plate internally supportively disposed in and snugly secured to said shell blood filter at the second terminus of aforesaid filter opposed to the filter terminus secured to the bed base annular closure.

11. In a disposable blood oxygenator apparatus suitable for exchanging oxygen for carbon dioxide in patient circulating blood, and for regulating the blood temperature, the combination comprising:

a multiplicity of small diameter oxygen exchange tubes coadjacently disposed in a solidly packed, parallel, equal length tube array, said tube array ranging from 4 to 24 inches long and said tubes ranging from one-sixteenth to five-sixteenths inches in a single internal tube diameter, said tube array vertically disposed in an oxygenator apparatus, the tube array first terminus secured adjacent the apparatus base end,

a first cylindrical tube case means permanently coaxially closely securing said tube array, said first case means having a case length substantially longer than said tube array, said tube array coaxially disposed inside said first case means the required spaced distances from each of the first and second case means terminus,

a multiplicity of short oxygen injection tubes having clear internal gas passages therein, said injection tubes equal in number to the number of multiple oxygen gas exchange tubes, a first terminus of each one of said multiplicity of injection tubes disposed inside and adjacent a single exchange tube terminus in said exchange tube array first terminus, a second terminus of each one of said multiplcity of injection tubes terminating in an injection tube manifold plate, said manifold plate planarly disposed normal to the first case means axis of symmetry and the manifold planar area completely sealing said first tube case means, said manifold plate disposed the residual injection tube length from said tube array first terminus, providing there between an inlet blood reservoir volume,

a first closure means, permanently completely sealing said first tube case means at said case means first terminus, providing an oxygen inlet reservoir volume between said first closure means and said manifold plate,

at least one foamed blood escape aperture means provided in said first case tube means adjacent the second terminus of said tube array,

a gas separation chamber means disposed in said first case means above said at least one foamed blood escape aperture means, extending to said first case means second terminus,

at least one blood inlet conduit means disposed in said first case means providing direct conduction of blood into said blood reservoir volume,

at least one oxygen inlet conduit means disposed in said first case means providing direct conduction of oxygen into said oxygen reservoir volume,

an annular defoamer bed means concentrically disposed around said first tube case means, having a bed depth required to defoam oxygenated blood flowing from said foamed blood escape aperture means, said bed means having a bed base annular closure means supportively externally sealed around said first case means at a bed means first terminus supportively securing said bed means to said first case means, and the second bed means terminus coplanar with said first case means second terminus, said defoamer bed having a first open cell plastic foam packing means disposed therein, the packing surface having a silicone defoaming composition thin film means disposed thereon accelerating the separation of oxygenated blood and gas,

a thin annular shell blood filter means coaxially surrounding said defoamer bed and aforesaid gas separation chamber, said annular shell blood filter having a dense open cell plastic foam composition filter medium means cylindrically disposed therein and a thin fine weave filter cloth disposed over the filter medium means exterior, the blood filter length being not less than the defoamer bed depth, said filter cloth permanently secured to said foam filter medium means, said shell blood filter snugly secured to said bed base annular closure,

a shell filter closure plate means internally supportively disposed in and snugly secured to said shell blood filter at the filter second terminus opposed to the filter terminus secured to the bed base annular closure means,

an annular tube second case means concentrically disposed around said first tube case means having an internal tube diameter substantially equal to the shell blood filter external diameter, said second case means having a first terminus supportively securing said bed base annular closure, and said annular shell blood filter, and a second terminus securing a first annular oxygenator case closure plate, said second case means having a length required to provide the necessary oxygenated blood reservoir in the annular volume between said first and second case means, said second case means having at least one blood reservoir aperture disposed in the tube wall thereof contiguous said second case means second terminus,

a tubular heat exchange means snugly concentrically disposed around said second case means, a heat exchange thermoregulating fluid circulating through said heat exchange means, said exchange means having a blood circulating path externally disposed thereon providing a controlled temperature range of 50° to 108°for the oxygenated blood flowing from said blood filter over said exchange means, said tubular means having a fluid inlet conduit and a fluid outlet conduit,

a tubular exterior third case means snugly concentrically disposed around said heat exchange means, providing an exterior boundary surface for the blood circulating annulus enclosing said heat exchange means, said third case means having a length at least equal to the combined lengths of said second case means and said blood filter, a first terminus of said third case means permanently completely sealed by said first oxygenator case closure plate and the second terminus of said third case means sealed by said second oxygenator closure plate, said second oxygenator closure plate having gas escape aperture means disposed therein, said heat exchange means fluid inlet conduit and said fluid outlet conduit conductively disposed outside of said blood circulating annulus, to the blood oxygenator exterior, and

at least one oxygenated, temperature regulated blood outlet conduit means exteriorly disposed from said first oxygenator case closure plate.

12. A combination as set forth in claim **11** wherein said tubular heat exchange menas is a spirally wound tubular coil snugly concentrically disposed around said second case means.

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