United States Patent [19]

Brumfield

[11] **3,769,163**

[45] **Oct. 30, 1973**

[54] **BLOOD OXYGENATOR FLOW GUIDE**

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[52] **U.S. Cl.** **195/1.8,** 23/258.5, 55/255, 55/256, 128/DIG. 3, 261/122, 261/124

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

[58] **Field of Search** .... 22/258.5; 195/1.8; 128/DIG. 3, 400; 261/122, 123, 124, DIG. 28; 55/255,256

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Primary Examiner—Barry S. Richman
Attorney—J. L. Jones

[57] **ABSTRACT**

Venous patient blood flows into an oxygenator blood inlet container which is coaxially disposed above an oxygenating gas inlet container. The oxygenating gas enters the blood inlet container through multiple gas injection apertures in a gas distributing manifold plate disposed between the two containers. The above pair of containers are coaxially secured to the base terminus of a vertically aligned, multiple, small diameter aperture, tubular configuration of an oxygen exchange tubular array, the inlet blood container adjacent the base terminus of the exchange tubular array. The gas manifold plate has multiple apertures typically ranging from 120 to 500 microns in diameter, through which the oxygenating gas bubbles into the venous blood. The two-phase flow of blood and oxygenating gas flows upward through the multiple exchange tubular array, the aperture walls stabilizing the two phases. The large surface to volume ratio of gas to blood phase in the tubular array facilitates the rapid fixation of oxygen by the blood, and release of carbon dioxide into the gas phase exiting from the top terminus of the tubular array. The coaxial combination of the inlet oxygen container, the gas manifold plate, the inlet blood container, and the tubular array provide a flow guide useful in blood oxygenator apparatus.

3 Claims, 7 Drawing Figures

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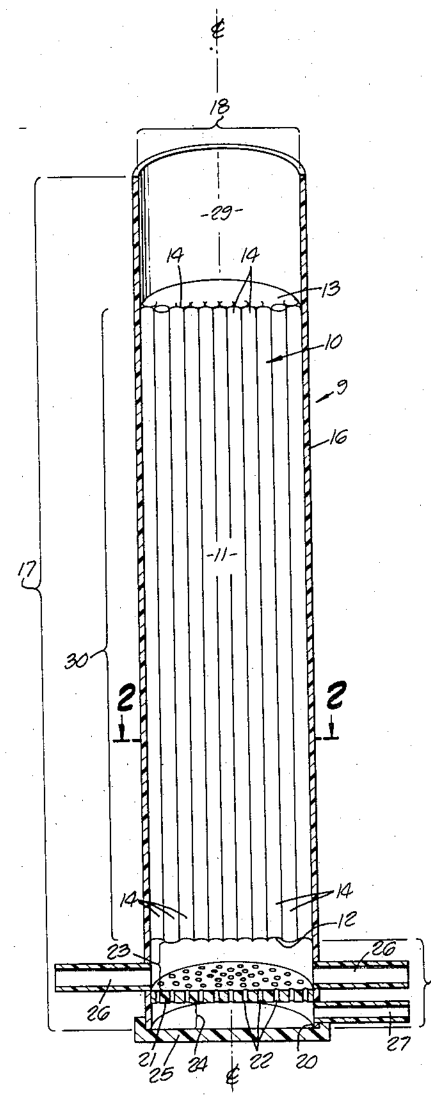

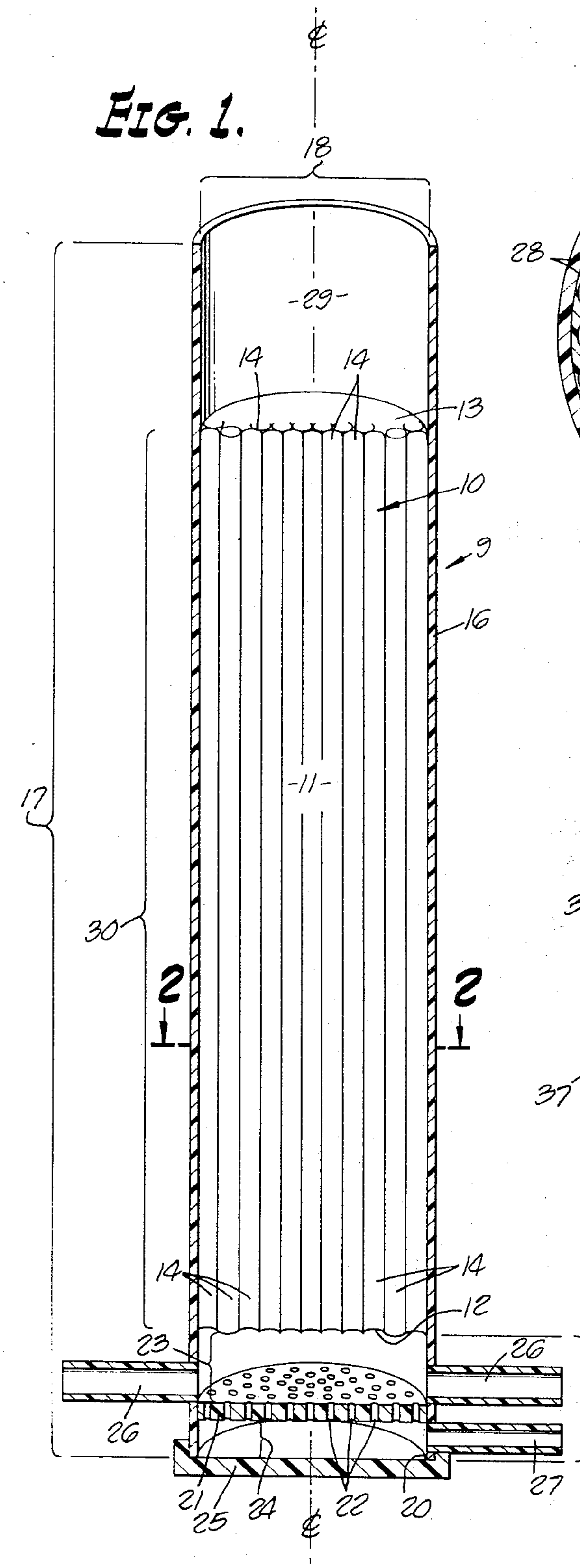

FIG. 1.

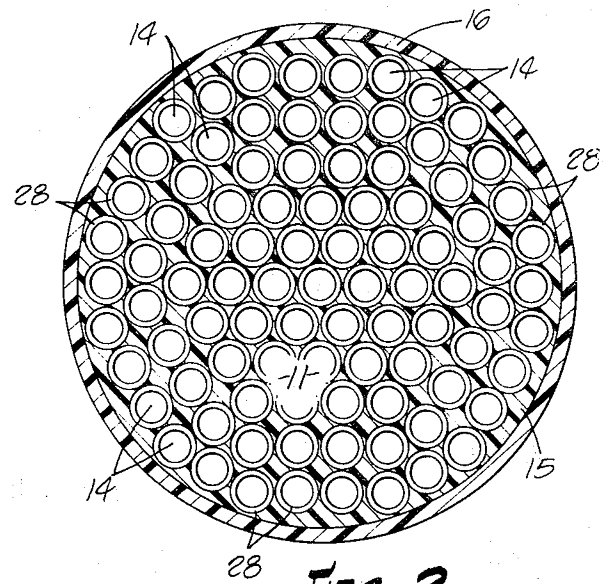

FIG. 2.

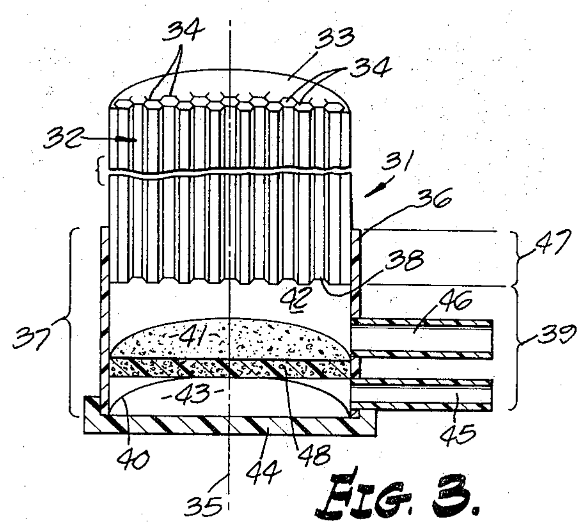

FIG. 3.

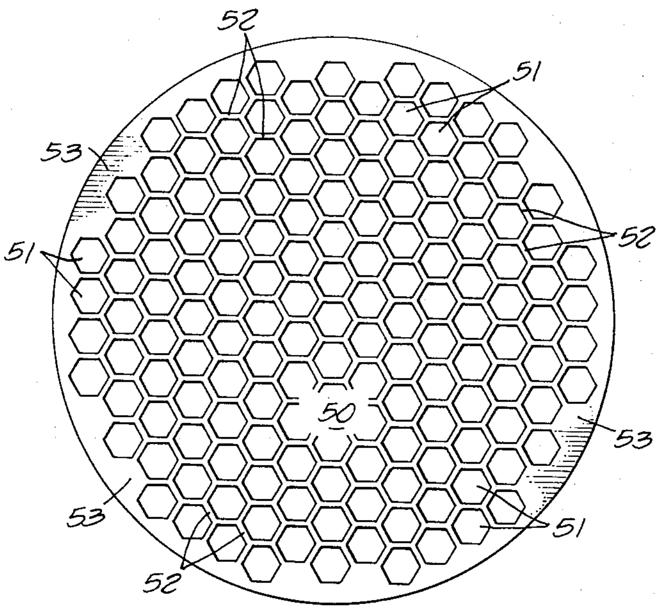

FIG. 4A.

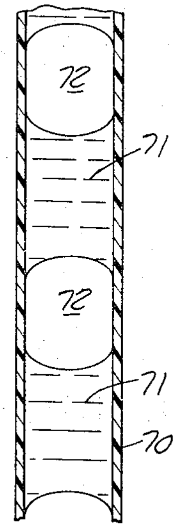

FIG. 5A.

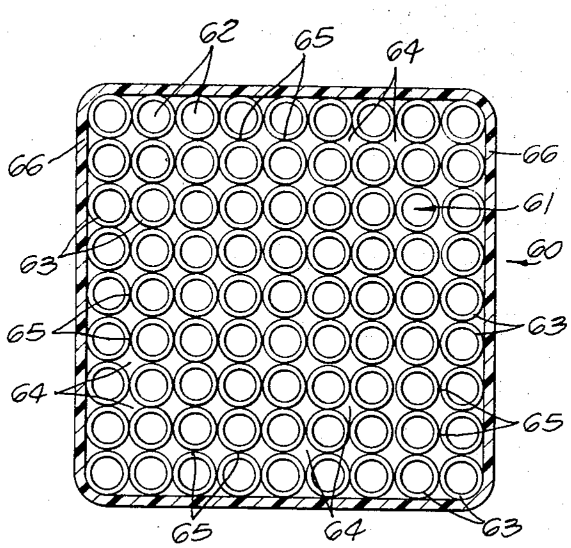

FIG. 4B.

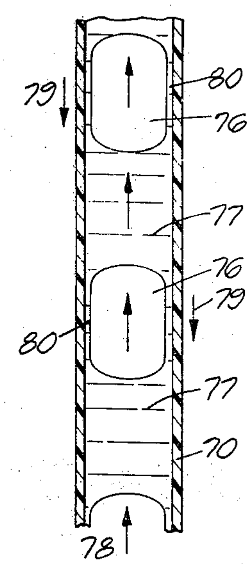

FIG. 5B.

BLOOD OXYGENATOR FLOW GUIDE

CROSS REFERENCES TO RELATED APPLICATIONS

This application is related to my copending application titled BLOOD OXYGENATOR AND THERMO-REGULATOR APPARATUS filed Aug. 26, 1971, Ser. No. 175,182.

BACKGROUND OF THE INVENTION

Blood oxygenators useful for treating patients blood are classified in Class 23 Subclass 258.5. The improvement taught in this invention is also so classified.

Typical of the blood oxygenators to which this invenion may be applied as an improvement is Rozhold et al., U.S. Pat. No. 3,545,937, Dec. 8, 1970. The tube 6 and the perforated plate 5 of Rozhold et al. can be effectively improved by application of the subject flow guide. Tompkins, U.S. Pat. No. 3,502,440, Mar. 24, 1970 represents another blood oxygenator 10, in which the main conduit 12 can be effectively improved by the application of the subject flow guide.

Other blood oxygenator apparatus can usefully apply the subject invention.

SUMMARY OF THE INVENTION

Venous patient blood flows into a blood inlet container which is disposed above an oxygenating gas inlet container. The oxygenating gas enters the gas inlet container through a gas inlet conduit. The gas is distributed into the blood inlet container through multiple apertures in a gas distributing manifold plate, which is contiguously disposed between the gas inlet container and the blood inlet container. The pair of containers are coaxially secured to the base terminus of an oxygen exchange tubular array. The tubular array has a multiple small diameter aperture, equal length tubular configuration disposed in said array, the tubular apertures being disposed normal to the manifold plate. The tubular array includes a boundary case. The blood inlet container is secured to and adjacent the base terminus of the tubular array. The oxygen exchange tubular array can have an integral tubular configuration, or it can be a packed tubular configuration. The integral tubular configuration has a multiplicity of small diameter oxygen exchange tubular apertures coaxially adjacently disposed in a solid equal length upstanding tubular matrix having a boundary case, a base terminus and a top terminus. The packed tubular configuration comprises a multiplicity of small diameter, thin wall plastic tubes coadjacently disposed, contiguously packed in a parallel, equal length tubular pattern and having a boundary case. A boundary case can have a case length substantially longer than the tubular array. The base terminus of the tubular array can be secured a required case length first value from the boundary case base terminus. The gas manifold plate has multiple apertures, typically ranging from 120 to 500 microns in diameter, through which the oxygenating gas bubbles into the venous blood. The two-phase mixture of blood and oxygenating gas formed in the blood inlet container, flows upward through the oxygen exchange tubular array, the aperture walls stabilizing the two-phase flow. The large surface/volume ratio of gas phase to blood phase in the tubular array facilitates the rapid fixation of oxygen by the blood and the concurrent release of carbon dioxide gas into the gas phase exiting from the top terminus of the tubular array. The combination of the inlet oxygen container, the gas manifold plate, the inlet blood container, and the oxygen exchange tubular array provide a blood oxygenator flow guide extremely useful in blood oxygenator apparatus. The wall stabilized flow of blood during the oxygenating process speeds the blood oxygenation with a minimum of damage to the formed blood elements, platelets, erythrocytes, and the like.

Included in the objects of this invention are:

To provide a simple, relatively inexpensive blood oxygenator flow guide.

To provide an oxygen exchange tubular array.

To provide a blood oxygenator flow guide efficient in the gas exchange process, producing minimum damage to formed blood elemznts. elements.

To provide an oxygen exchange tubular array which minimizes coalescence of oxygenating gas bubbles during its operation.

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 flow guide.

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

FIG. 3 is an elevational, perspective partial sectional view of another modification of the blood oxygenator flow guide apparatus.

FIG. 4A is another cross sectional view illustrating the cross sectional geometry of a hexagonal aperture tubular configuration.

FIG. 4B is still another cross sectional view similar to the cross sectional view of **FIG. 2,** illustrating multiple thin wall tubes packed in a pattern in a boundary case.

FIG. 5A schematically illustrates a static slug mixture of blood and oxygenating gas vertically disposed in a two-phase mixture of gas and blood in a single aperture of an oxygen exchange tubular array.

FIG. 5B schematically illustrates the flowing mixture of two-phase slug flow of blood and oxygenating gas in a single aperture of an oxygen exchange tubular array.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the elevational perspective partial sectional view of **FIG. 1** in detail, together with the sectional view of **FIG. 2,** the blood oxygenator flow guide **9** has an oxygen exchange tubular array **10** disposed therein. The combination of the small diameter aperture, tubular matrix configuration **11** and the boundary case **16** comprise the oxygen exchange tubular array **10.** The length **30** portion boundary case **16** coincides with the base terminus **12** and the top terminus **13** of the small diameter aperture tubular matrix configuration **11.** A single tubular aperture **14** of the aperture tubular matrix configuration **11** is illustrated in **FIG. 1** and **FIG. 2.** The single tubular aperture **14** is individually formed by the single tube walls **28.** The tube walls **28** are in turn enclosed in a plastic matrix **15** forming a securing matrix for the tube walls **28.** The aperture tubular configuration **11** consists of the subcombination of the multiple tube walls **28** adjacently disposed in a plastic matrix **15,** providing multiple, small diameter apertures **14.** The boundary case **16** has a diameter **18,** and a case length first value **19** is disposed between the base terminus 12 of the configuration 11 and the case base terminus 20. The gas distributing manifold plate 21 has multiple apertures 22 disposed therein which are porous to the oxygenating gas. The gas distributing manifold plate 21 is shown normally disposed to the line of center of the boundary case 16. The blood inlet container 23 is formed between the base terminus of the tubular matrix configuration 11 and the manifold plate 21, having a pair of blood inlet conduits 26 7 integrally secured to the tube case 16. The oxygenating gas inlet container 24 is disposed between the gas manifold plate 21 and the case closure 25. The boundary case closure 25 is integrally secured to the case base terminus 20 by cement, or the like. A gas inlet conduit 27 conducts oxygenating gas into the gas inlet container 24. The defoaming chamber 29 is shown disposed above the top terminus 13 of the tubular matrix configuration 11, the chamber 29 being suitably disposed for defoaming the oxygenated blood.

FIGS. 3 and 4A together illustrate a still further modification of the improved blood oxygenator flow guide 31. The oxygen exchange tube array 32 comprises a multiple, small diameter aperture tubular matrix configuration 33 formed in a one piece plastic extrusion. The configuration 33 has multiple, controlled diameter hexagonal cross section tubular apertures 34 disposed parallel to the line of center 35 of the array 32. A tube case 36 has a tube case length 37. The oxygen exchange tube array 32 is tightly secured to the case 36, the array base terminus 38 limiting a tube case length first value 39 between the base terminus 38 and the case base terminus 40. A manifold plate 41 is disposed in the case 36 normal to the cylindrical axis 35. The manifold plate 41 has multiple microscopic random appertures 48 disposed therein, providing for the flow of oxygenating gas through the plate. The blood inlet container 42 and the gas inlet container 43 are formed in the tube case length first value 39 by the manifold plate 41 foring a partition therebetween. A case closure 44 integrally secures the case base terminus 40. A gas inlet conduit 45 is conductively secured to the gas inlet container 43, and a blood inlet conduit 46 is conductively secured to the blood inlet container 42.

The oxygen exchange tubular array 32 of FIG. 3 is equivalently shown in enlarged sectional detail as the oxygen exchange tubular array 50 in FIG. 4A. The apertures 51 are shown to be hexagonal in cross section with the walls 52 disposed between the apertures 51. An integral exterior matrix boundary case 53 provides a structural boundary case equivalent for its required length to the boundary case 16. Thus it becomes unnecessary to use a long boundary case 16 having a length 17, and one can use a short case 36, essentially the length required to form a blood inlet container 42 and the gas inlet container 43. A securing length value 47 of the case 36 secures the case 36 to the array base terminus 38.

A still further modification of this invention is illustrated in FIG. 4B wherein the cross sectional view is equivalent to the cross sectional views of FIG. 2 and FIG. 4A. The oxygen exchange tubular array 60 has the multiple tubular configuration 61. The individual tubular apertures 62 are formed by individual tube walls 63 disposed in a line of contact 65 between the individual tubes. The open interstices 64 formed between the contacting individual tube walls 63 are equivalent apertures to the circular apertures 62. Thus two-phase flow of blood and oxygenating gas flow upward through the circular apertures 62 and also the interstices apertures 64. The multiple aperture tubular configuration 61 can be formed by cementing the lines of contact 65 with a suitable adhesive, and the lines of contact 65 can also be heat sealed together, to form a coherent tubular configuration 61 suitable for insertion in the boundary case 66. The array 60 consisting of the combination of the tubular configuration 61 and the case 66 is thus equivalent in structure to the combination of the tubular matrix configuration 11 and the tube case 16 of FIGS. 1 and 2, as well as the tubular array 32 of FIG. 3 and the tubular array 50 of FIG. 4A. All of the above listed structures are equivalent in providing tube walls which stabilize a two-phase flow of blood and oxygenating gas flowing through the multiple apertures of the tubular array.

Medical studies have shown that blood trauma occurs in bubble oxygenators and disc oxygenators, resulting in destruction of the formed blood elements of platelets and erythrocytes. This invention minimizes blood trauma by minimizing the turbulence in the oxygenating process and minimizing the external work done on the circulating blood during flow through the oxygen exchange tubular array. In this apparatus oxygenating gas forms a two-phase mixture of blood and gas within a single oxygen exchange tube. The oxygen gas reduces the average density of the mixture of blood and gas, and the lowered density mixture is pumped upward through the tubular aperture. 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 oxygenating gas, maximizing the rate of oxygen gas transferred into the blood, with the concurrent release of carbon dioxide into the gas bubbles. The bubbles flowing up the exchange wall expose a large ratio of surface to gas volume as the bubbles rise, maximizing the gas exchange process.

FIG. 5A illustrates in vertical cross sectional view a static mixture of blood and oxygenating gas disposed in an oxygen exchange tube aperture. The blood 71 is alternatively interposed with the oxygenating gas bubble 72 in the exchange tube aperture having walls 70.

In FIG. 5B the upward flowing direction 78 of the mixture of blood slugs 77 and oxygenating gas slugs 76 are shown disposed in the same tube walls 70 of the aperture. The slippage between oxygenating gas and blood liquid is illustrated by the arrow 79, indicating local relative downward flow of the laminar blood film adjacent to the wall 70, as the low density gas slug moves upward in the aperture more rapidly than the blood slug 77. The relatively rapid upward flow of the gas slug 76 as compared to the flow of the blood slug 77 provide a continuously renewed laminar blood film 80 which undergoes rapid absorption of oxygen gas and concurrent evolution of carbon dioxide gas from the blood as it ascends the wall 70. It is the relatively nonturbulent two-phase flow of blood and oxygenating gas upward through the multiple exchange tube array that provides the minimum blood trauma and destruction of formed elements in the blood.

The manifold plates 21 and 41 can range in multiple aperture configuration from the parallel aligned multiple apertures 22 of plate 21 to the microscopic random multiple apertures 48 of the plate 41. The multiple apertures 22 can range in cylindrical diameter from typically 500 microns down to the microscopic random multiple apertures **48** having air permeability values equivalent to an average of 100 microns aperture. The thickness of the manifold plate are typically those values required to be self-supporting or the like.

For the patient's safety it is necessary that the chemical composition and the physical structure of the components of the blood oxygenator flow guides be compatible with the patient's circulating blood, preventing clotting and the like. The mechanical structure of the flow guide 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 apparatus of this invention is precisely assembled and the joints carefully bonded to minimize blood leakage problems both within the components of the apparatus as well as external leakage from the apparatus as a whole. 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 established 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 procedures.

In operation, the blood oxygenation flow guides **39** and **31**, or the like, can be suitably incorporated in a complete blood oxygenator having a blood defoaming component and a blood thermoregulating component secured thereto. As mentioned above, the improvements of this invention can be applied to the blood oxygenator of Rozhold et al and to the blood oxygenator of Tompkins. Other blood oxygenator apparatus can also incorporate the blood oxygenator flow guide of this invention. In operation the blood oxygenator flow guide of this invention, together with the collateral blood defoaming component and blood temperature thermoregulator component are disposed in an apparatus below the patient. A heat transfer fluid, as is necessary for the thermoregulator, is programmed for the scheduled temperature. Prior to the induction of the patient's circulating blood, the blood oxygenator flow guide **10** of this invention primed with transfusion blood, plasma, saline solution, or the like, as is required. The priming fluid is circulated into the apparatus through the blood inlet conduit **26** and the oxygenating gas flow rate is initiated through the gas inlet conduit **27**. The relative flow rates of oxygenating gas to blood flow is stabilized as required. Typically, the blood flow rate through the blood oxygenating flow guide can vary from 500 ml/min to 7500 ml/min. This wide variation in flow rate in the blood oxygenator flow guide can be produced by varying the number of apertures in the tubular array. Typically an array for the low flow rate can contain **95** tubular apertures, each 0.20 inch in circular diameter. The blood oxygenator flow guide can typically have tubular apertures ranging from 0.10 to 0.20 inch diameter disposed in a tubular array. The gas flow rate can vary from 1 to 4 times the blood flow rate. The oxygenating gas typically contains 98 percent oxygen and 2 percent carbon dioxide. Other medically acceptable gases can be introduced. The two-phase flow of blood and oxygenating gas flow upward through the flow guide through the apertures as earlier described, the blood absorbing oxygen and concurrently evolving carbon dioxide, which mixes into the gas bubble. After oxygenation is completed at the top of the tubular array, the blood foam is then separated in a defoaming chamber into fluid blood free from entrained gas bubbles. The blood can be regulated at temperature as required, prior to return to the patient's body.

Many modifications and variations in the improvement in a blood oxygenator flow guide can be made in the light of my teachings. 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, wherein all of the required flowing blood volume is formed into a flowing volume of two-phame gas-blood dispersion, by contiguously flowing said blood volume above a gas distribution manifold plate and by flowing oxygen gas through multiple apertures disposed through said plate, said gas flowing from below said plate into said blood volume, the further improvement combination which comprises:

maintaining the volumetric ratio of said oxygen gas flow to said blood flow in the range of 1 to 4,

partitioning said flowing volume of said two-phase dispersion pro rata between the first terminus of each one of a multiplicity of small diameter gas exchange tubes coadjacently disposed in a tube array, said tube array ranging from 4 to 24 inches long and said tubes ranging from 1/16 to 5/16 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;

said multiple apertures of said gas distribution manifold plate having an average pore diameter permeability value of from 120 to 300 microns

flowing the volume of two-phase dispersion disposed in each one of said gas-blood exchange tubes to the tube array top second terminus, said second terminus disposed adjacent to a blood defoaming chamber;

and,

flowing said two-phase dispersion into said blood defoaming chamber and separating the blood and gas phases.

2. A disposable blood oxygenator flow guide for extra-corporeally oxygenating patient blood and removing carbon dioxide therefrom, comprising:

a multiple, tubular aperture configuration having a multiplicity of small diameter apertures coadjacently disposed parallel in equal tubular length in an integral matrix, said apertures ranging from 1/16 to 5/16 inches in a single internal aperture diameter and being from 4 to 24 inches long, forming a tubular array having a base terminus and a top terminus, said array having an open blood inlet end and an open blood outlet end, and being of substantially uniform cross section between said ends,

a single blood inlet container directly communicating with said array blood inlet end delivering venous blood thereto,

a single gas inlet container communicating with an oxygenating gas supply, receiving gas therefrom, a single porous manifold plate having gas injection apertures of an average pore diameter permeability value ranging from 120 to 300 microns separating said blood inlet container and said gas inlet container, disposed to deliver oxygenating gas into said blood inlet container and discharging bubbles into the blood

and,

a blood defoaming chamber conductively disposed adjacent said tube array top terminus.

3. In a disposable extra-corporeal blood oxygenator flow guide suitable for exchanging oxygen for carbon dioxide in patient extra-corporeal circulating blood, the combination comprising:

a multiplicity of small diameter aperture, thin wall, oxygen exchange tubes coadjacently disposed in a contiguously packed, parallel, equal length tubular configuration, said exchange tubes ranging from 1/16 to 5/16 inches in a single internal tube diameter and being from 4 to 24 inches long, the packed configuration having a base terminus and a top terminus,

a boundary case permanently coaxially contiguously completely securing said configuration, said case having a case length substantially longer than said tubular configuration, said configuration coaxially disposed inside said case, the base terminus of said tubular configuration secured the required case length value from the case base terminus,

a multiplicity of gas injection apertures disposed through a single manifold plate, said gas injection apertures having an average pore diameter permeability value ranging from 120 to 300 microns, said manifold plate secured in said boundary case normal to the case length symmetry axis a case length value from said configuration base terminus, providing a single inlet blood container between said base terminus and said manifold plate,

a closure, permanently sealing said boundary case at said case base terminus, providing an oxygenating gas inlet container between said closure and said manifold plate.

and,

a blood defoaming chamber conductively disposed adjacent said tube array top terminus.

* * * * *