Aug. 6 1974 N. W. BURLIS 3,827,860

BLOOD OXYGENATION DEVICE

Filed June 15, 1972 2 Sheets-Sheet 1

FIG. 1

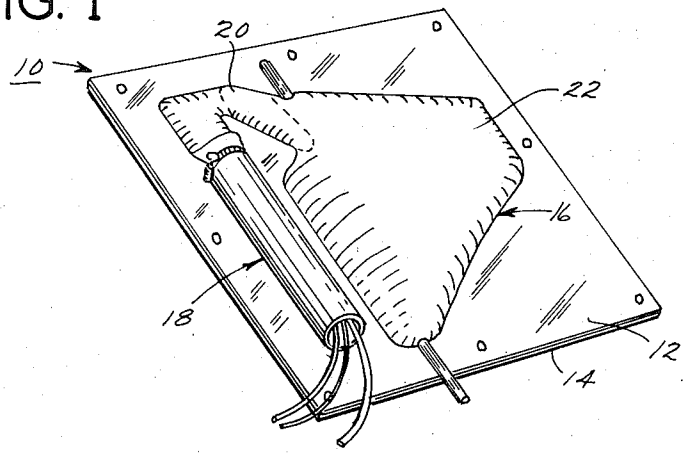
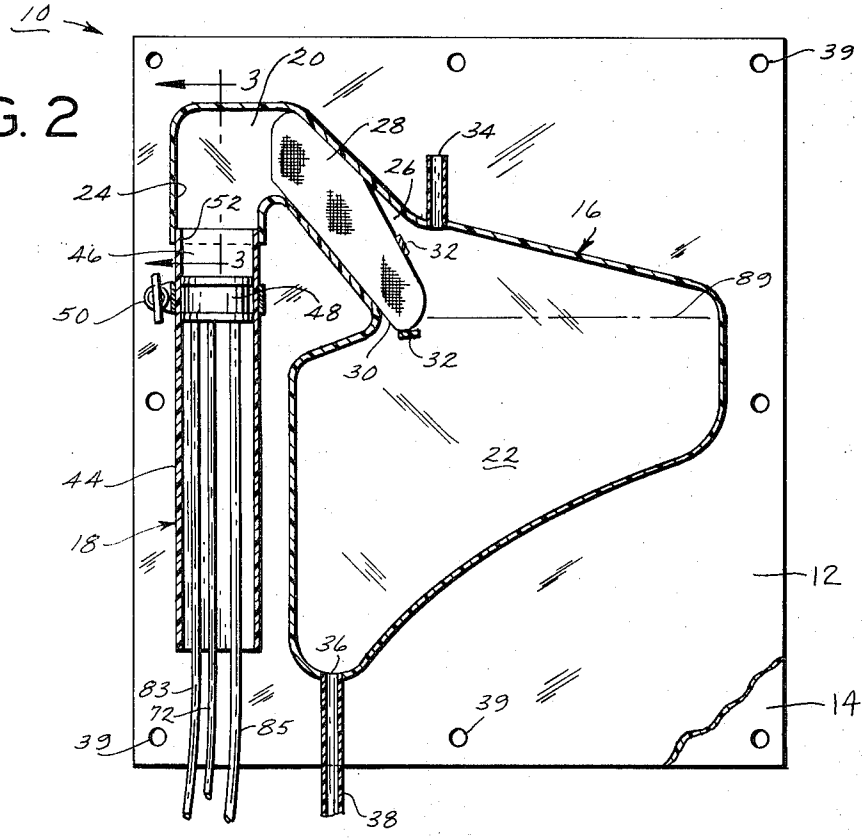


FIG. 2



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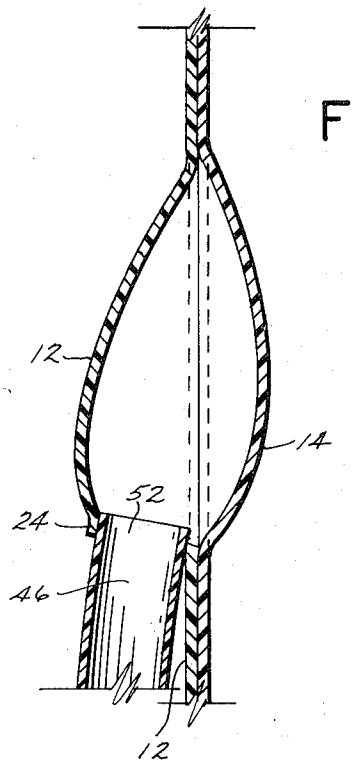
BLOOD OXYGENATION DEVICE

Filed June 15, 1972 2 Sheets-Sheet 2

FIG. 3



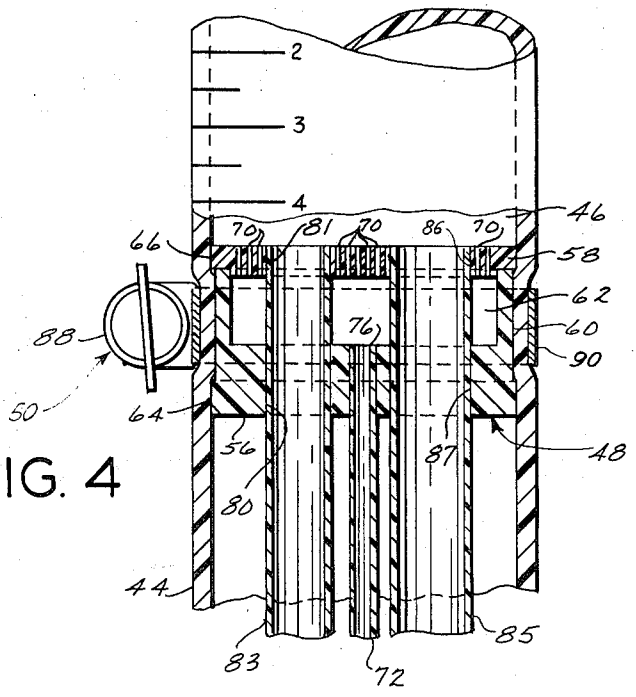


FIG. 4

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3,827,860

BLOOD OXYGENATION DEVICE

Norbert W. Burlis, University City, Mo., assignor to Sherwood Medical Industries Inc., St. Louis, Mo.

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U.S. Cl. 23—258.5 15 Claims

ABSTRACT OF THE DISCLOSURE

A bubble oxygenation device which includes a cylindrical oxygenator chamber connected in series with a defoaming chamber and a settling chamber, and an oxygen disperser member for delivering oxygen and venous blood to the oxygenator chamber, the disperser member being slidable in the oxygenator to control the oxygenation capacity thereof.

BACKGROUND OF THE INVENTION

This invention relates to blood oxygenation devices, and more particularly to blood oxygenators used to perform the function of the lungs during surgery, such as cardiac surgery.

Reference is hereby made to U.S. Patents, Nos. 2,854,002 and 3,112,746, which disclose blood oxygenation devices of the bubble type and a book by P. M. Galletti and G. A. Bocher, entitled "Heart-Lung Bypass" published by Grune & Stratton of New York, N.Y., which describes bubble-type as well as various other types of oxygenating devices.

Oxygenation devices of the bubble-type for use in extracorporeal circulation generally include an oxygenator chamber into which venous blood and gas bubles are introduced, a defoaming chamber for removing bubbles and filtering the blood, and a settling chamber for removing any remaining bubbles and serving as a reservoir for the oxygenated blood. Blood is pumped through the system at a flow rate determined primarily by the size of the human or other animal through which the blood is circulating.

There has been certain disadvantages or undesirable features associated with blood oxygenation devices in the past. For example, because of various design requirements, such as oxygenation capacity or adequate oxygenation at an adequate blood flow rate, avoidance or minimization of the destruction of blood elements due to the mechanics of the oxygenation device, gas pressures, bubble size, etc., it has been necessary to make oxygenation devices in different sizes, that is, with different oxygenation capacities. The cost of such devices is relatively high because it is, of course, relatively expensive to manufacture a variety of different sizes. Also, during surgery, blood monitoring devices may indicate that a change in oxygen content is required. Accordingly, the oxygenation or bubbling chamber of plastic bag type oxygenators is sometimes reduced in size, such as by pinching the chamber with external clamps. This is not a very precise manner of changing the oxygen content of the blood, and is not repeatable with accuracy. On the other hand, when the monitoring devices indicate that an increase in oxygenation level is desired, it is generally necessary to change the gas mixture since increasing the gas pressure might cause damage to the blood elements while not materially increasing the oxygen content due to the increased flow rate in the bubbling chamber. Changing the gas mixture, for example, to increase the ratio of oxygen to carbon dioxide, also of course has the effect of changing the carbon dioxide retention and elimination. In general, each oxygenator had certain design characteristics for providing optimum service that necessarily limit the degree of

variation in operating conditions or parameters, such as the blood flow rate.

SUMMARY OF THE PRESENT INVENTION

It is therefore an object of the present invention to provide an improved blood oxygenation device wherein the above mentioned disadvantages are substantially obviated.

Another object is to provide an improved blood oxygenation device which is capable of efficient operation through a wide range of blood flow rates.

Another object is to provide an efficient blood oxygenation device which is especially simple, economical, highly efficient in operation, and which can be readily adjusted so that a single size can be used for humans or other animals of various sizes.

Still another object is to provide a novel oxygenator chamber and oxygenating gas disperser for use in an extracorporeal circulation system which readily permits stepless or minute, as well as relatively large, adjustments before and/or during use so as to provide efficient oxygenation of the blood for a wide range of blood flow rates.

Yet another object is to provide an economical oxygenator for use in an extracorporeal system wherein the oxygen content of the blood can be readily changed through a wide range of levels without undesirably affecting other characteristics of the oxygenation system.

In accordance with one form of the present invention, an oxygenation device is provided which includes a chamber for receiving blood to be oxygenated and an oxygenating gas, and a member for varying the location at which the gas is introduced into the chamber to control the time that the blood is in contact with the gas.

These and other objects and advantages of the present invention will be apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an oxygenation device in accordance with one embodiment of the present invention;

FIG. 2 is an elevational sectional view of the device of FIG. 1;

FIG. 3 is a cross-sectional view taken from line 3—3 of FIG. 2; and

FIG. 4 is an enlarged fragmentary view of the oxygenator chamber and gas disperser of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to FIGS. 1 and 2, there is shown a blood oxygenation device **10** of the bubble-type which can be used in an extracorporeal circulation system for simulating the function of the lungs during surgery, such as cardiac surgery. The oxygenation device **10** includes a pair of flat sheets **12** and **14** of a plastic material, for example, a thermoplastic material, such as polyvinyl chloride, united to form a series of compartments or chambers **16** through the sheet. An external oxygenator **18** is connected to the chambers.

The sheets **12** and **14** are united preferably by heat sealing along lines outlining or defining the chambers **16** illustrated in the drawing. Chamber **16** defines a deforming compartment or chamber **20** and a settling or reservoir compartment or chamber **22** between the sheets. The defoaming chamber **20** has an inlet **24** connected to the upper end of the oxygenator **18**, and a main defoaming portion **26** connected in fluid flow communication with the settling chamber **22**. The main defoaming portion **26** contains a defoaming member **28** disposed within a filter member **30**. The defoaming member **28** may be a suitable antifoaming material such as plastic fibers, metal

fibers, etc., which is coated with any well known suitable antifoam agent, such as conventional silicon fluids. Filter **30** is in the form of a sleeve which may be made of a porous material such as nylon. The defoaming member **28** is shown disposed within the filter sleeve **30** and positioned in the main defoaming portion **26** and held therein by uniting the sheets such as indicated at **32**. The device **10** is provided with a gas outlet or vent **34** for venting gas, including excess oxygen and carbon dioxide, from the blood. The vent **34** is above and in fluid communication with the defoaming chamber **20** and settling chamber **22** so that any bubbles or gas eminating from these chambers are vented to the atmosphere.

The settling chamber **22** is provided with an outlet indicated at **36** which has connected thereto an outlet tube indicated at **38** which may be connected thereto by cutting one layer, such as layer **12**, and heat sealing the plastic tube entirely around its periphery at the outlet so that tube **38** is sealed to sheets **12** and **14** and in fluid communication with chamber **22**.

The sheets **12** and **14** are shown provided with a plurality of holes **39** for the purpose of supporting the oxygenation device **10**, as well as attaching other apparatus thereto during use. The oxygenation device is positioned such that the outlet **36** of the settling chamber is at the bottom and the defoaming chamber **20** is at the top, for example, as seen in FIG. 2 of the drawings.

The oxygenator **18** includes a hollow member **44**, shown cylindrical, which provides an oxygenator chamber or column **46**, and a movable oxygenation gas disperser or diffusion member **48**. The device **18** is shown also including a releasable holding member **50**, illustrated as a releasable clamp, disposed externally of the chamber **46** which may be used where desired or required for holding or clamping the movable disperser **48** in a desired position within chamber **46**.

The oxygenator member **44** is shown formed of a plastic material, for example, from plastic tubing, which is preferably flexible but may be rigid if desired. Preferably the member **44** is formed of a suitable flexible plastic, such as polyvinyl chloride, or polyurethane, and such that it is circular in cross-section when not collapsed or stretched and is, furthermore, preferably formed as a separate member distinct from the plastic sheets **12** and **14**, as seen in the drawing. The member **44** is also preferably formed seamless, such as by producing it by extrusion, to provide a smooth surface to readily obtain a fluid tight seal with member **48**. The upper end or outlet of oxygenator chamber **46**, indicated at **52**, is connected, as seen in FIG. 3, to the inlet **24** of the defoaming chamber **20** by cutting the layer **12**, inserting the end **52** into the opening formed thereby and securing such as by cementing or heat sealing entirely around the tubular member **44** to form a fluid tight connection between the oxygenator chamber **46** and the defoaming chamber **20**. In the drawing, the oxygenator chamber **46** is shown extending vertically and the defoaming chamber **20** connected thereto is shown extending angularly downwardly therefrom.

The oxygenation gas disperser **48** is slidable in oxygenator chamber **46** and is in fluid tight sealing engagement with the walls of the chamber. As seen in greater detail in FIG. 4, the disperser **48** is in the form of a hollow piston-type member formed of suitable plastic material such as acrylic. The disperser is shown including a lower circular housing member **56** connected, such as by cement or by heat fusing, to an upper circular gas dispersing plate **58**. Housing **56** has a cylindrical side wall **60** defining with the plate **58** an internal gas chamber **62**. The outer surfaces of members **56** and **58**, which are indicated respectively at **64** and **66**, are in sealing slidable engagement with the walls of the oxygenator chamber **46** to seal and prevent blood above the disperser member **48** from flowing downwardly past the disperser member.

The upper disperser plate **58** includes a plurality of holes **70** which are of small diameter, for example, .006 of an inch, for efficiently distributing gas introduced into the disperser chamber **62** into the oxygenator chamber **46**. Gas is introduced into chamber **62** by means of a plastic tube **72** connected such as by cement in an opening **76** in the housing **56**.

The disperser member **48** is also provided with a pair of openings **80** and **81** disposed respectively in the housing **56** and upper plate **58** in aligned relation with each other to receive a conduit or tube, such as a plastic tube **83** adapted to be connected so as to supply venous blood through the disperser member **48** to the oxygenator chamber **46**. The upper end of tube **83** may be connected to members **56** and **58** such as by a suitable plastic cement. The opposite end of tube **83**, which is not shown, is connected to a body source of venous blood. Disperser member **48** is also shown provided with another conduit or tube **85** which is similarly connected in fluid communication with chamber **46** through the member **48**. Tube **85** may be of plastic and is shown connected through aligned openings **86** and **87** in the disperser member. Tube **85** may also be used to deliver blood to the oxygenator chamber **46** for certain operative procedures.

The releasable holding device **50** is shown surrounding the tubular member **44** and the disperser **48** for releasably securing the member **48** within the chamber **46**. Holding device **50** is shown as including a clamping band **90** and an adjustable screw-type ratchet or take-up **88** for tightening the band around the members **44** and **48**. The holding device **50** may be of any suitable type for holding member **48** in a desired location, for example, it may include an elastic member or a conventional hose clamp, or the like. In some cases, the member **48** may be made of a size such that the clamping device is necessary to effect sealing engagement between the inner chamber **46** and the member **48**. The member **48** and chamber **46** may be sized to effect a sliding, fluid tight friction fit therebetween so that a clamping or holding device such as device **50** is not required.

In operation, after the oxygenation device **10** has been primed by the introduction of a suitable amount of priming blood into the system, one or both of the plastic tubes **83** and **85** may be connected with a body source of venous blood to by oxygenated. Also, the plastic tube **72** is connected with a source of oxygenating gas which may be pure oxygen or oxygen with a relatively small percentage of carbon dioxide; preferably the gas is about 97% oxygen and 3% carbon dioxide. The plastic tube **83** is connected to the patient's arterial system. The extracorporeal circulation system, of course, includes a suitable blood pump for maintaining a flow of blood through the system.

Depending upon the size of the patient, the disperser member **48** will be moved to a predetermined position within the oxygenator chamber **46** to set the oxygenator for efficient oxygenation at a desired blood flow rate. As seen in FIG. 4, the outer surface of the tubular member **44** may be calibrated, for example, in litres per minute. In this regard, it should be noted that the oxygenation device may be shipped from the manufacturer with the disperser member **48** in its uppermost position within the oxygenator chamber **46**, for example, in its pediatric position, so that the disperser member may be withdrawn to a desired position within chamber **46** by loosening clamp **50** where used, and pulling the disperser downwardly by tubes **72**, **83** and **85**. If desired, however, a rigid plunger rod (not shown) may be provided to assist in locating or repositioning disperser **48** within chamber **46**. Also, the member **48** may be moved in some cases, in either direction by hand manipulating the exterior of member **44** adjacent the member **48**. After the disperser member **48** is positioned for the desired flow rate or oxygenation capacity required by the particular patient, the clamp **50**, where used, is adjusted to tighten the clamp

around the outer periphery of member 44 and member 48 to secure the member 48 in the desired position, and, where required, to effect sealing engagement between the slidable disperser member 48 and the chamber 46.

The oxygenation gas flowing into the chamber 62 (FIG. 4) through the tube 72 flows through the small passages 70 in the dispersing plate 58 and produces bubbles in the venous blood which is flowing into chamber 46 by way of tubes 83 and/or 85. The venous blood flows over the top of disperser plate 58 and the bubbles flow through the blood and cause the blood and gas mixture to rise and flow upwardly in the chamber 46 and then into the defoaming chamber 20. The blood and gas bubbles produce a foam which flows into the anti-foaming material 28 and through the filter 30 and the excess gas and carbon dioxide are vented to atmosphere by vent 34. As seen in FIG. 2, the filtering and anti-foam members extend slightly below the operating level of the settling chamber which is indicated by a line 89 in FIG. 2. Thus, the blood will not fall or splash into the settling chamber 22 to cause bubbling and this aids in removing and preventing the trapping of gas bubbles. The oxygenated or arterial blood in the settling chamber, after any further bubbles are removed, flows into tube 38 and back into the arterial system of the patient.

During continued operation, should it be desired to change the oxygen content of the blood, the releasable holding means 50 is loosened and the disperser 46 is moved in the desired direction to effect the desired change in oxygen content. For example, if body monitoring devices indicate that an increase in oxygen content of the blood is desired, then the disperser member 48 is moved downwardly in the oxygenator chamber 46 to increase the effective length of chamber 46 so that blood flowing in the chamber 46 is subjected to the oxygenating gas for a longer time, that is, the blood will be travelling a longer distance in the oxygenator chamber 46 and therefore be subjected to the gas bubbles over a longer period of time. On the other hand, if it is desired to decrease the oxygen content of the blood, for example, to avoid oxygen poisoning or for any other reason, the disperser member 48 is moved upwardly in the chamber 46 to thereby decrease the effective length of the oxygenator chamber and decrease the length of time that venous blood remains in the oxygenator chamber.

The oxygenator 18 is preferably of sufficient capacity to handle the greatest flow rate of blood expected to be required for a human being or for an animal. In this way, when the disperser member 48 is, for example, near the lower end of the tube 44 it will provide a sufficient oxygenation capacity for the largest person or animal with which it is to be used. As the disperser member 48 is moved to the upper end of the sleeve 46, it, of course, provides effective oxygenation for very small blood flow rates, for example, for pediatric patients.

The oxygenator 18 when made for use on humans, is preferably made to provide efficient oxygenation for blood flow rates from about ¼ litre per minute to 6 litres per minute so that it is useful for both adults and children. This is accomplished in one design by forming the oxygenator chamber with an inner diameter of 2 inches and having a length of 6–18 inches and with the conventional gas flow rate of about 2–3 times blood flow rate.

Movement of the disperser member 48 longitudinally in the oxygenator chamber 46, as previously mentioned herein, varies the effective length of the chamber, that is, the distance between the member 48 and upper end portion of the chamber 46. In this way, the time that the blood is in contact with the oxygenating gas and, hence, the oxygen content in the blood is thereby controlled or varied. Thus, the oxygenation capacity or rate of blood flow during which effective oxygenation is accomplished can be readily varied or controlled. Not only does the oxygenator permit a single size to be used on patients or animals of highly different sizes to obtain the economies thereof, but it provides means for readily varying the oxygen content of blood during surgery. The disperser member 48 provides for adjustment in the oxygen content, in a stepless manner by merely sliding member 48 in the oxygenator chamber, and such adjustment can be relatively large or very small, as desired or required. By having the capability of varying the oxygen content of the blood in this manner during surgery, the physician is provided with a very precise manner of changing the oxygen content which can be repeated easily since the tube 44 is preferably provided with graduations or other calibration indicia. Use of a single size oxygenator avoids the chance of error in choosing a properly sized device of the prior art type after surgery has begun. Also, varying the effective length of the oxygenator chamber 46 by varying the position of the member 48 to vary the oxygenation capacity does not generally require a change in the ratio of oxygen to carbon dioxide used or in other mechanical features of the apparatus. In addition, reducing the effective length of the oxygenation chamber when it is desired to employ it for use with a smaller person or child, also reduces the volumn of priming fluid required.

The design of the defoaming and settling chambers vary greatly and may include various types of filters, bubble traps, vents, and so forth, as is well known to those skilled in the art. The oxygenator 18 may of course be used with various types of defoaming and settling chambers.

It should be understood that, although this invention has been described with reference to the illustrated preferred embodiment, modifications thereto may be made without departing from the true spirt and scope of the invention.

What is claimed is:

1. A blood oxygenation device comprising an oxygenator chamber adapted to receive blood to be oxygenated and an oxygenating gas, said oxygenator chamber including a seamless plastic elongate tubular member normally circular in cross-section, and means for introducing oxygenation gas and blood into said oxygenator chamber to produce a mixture of rising blood and gas bubbles and for selectively varying the location at which said oxygenating gas is introduced into said chamber to control the length of time that blood introduced into said chamber is subjected to said gas to adjust the effective oxygenation capacity of the device in accordance with the oxygenation requirements of the patient, said means including a member selectively slidably connected in said oxygenator chamber and having passage means therein for transmitting said gas from a supply to said chamber to produce said gas bubbles.

2. A blood oxygenation device for use in an extracorporeal blood circulating system comprising a pair of flexible plastic sheets, said sheets being preselectively united to provide a blood defoaming chamber and a blood reservoir connected in fluid communication with said defoaming chamber for receiving oxygenated blood, anti-foam means in said defoaming chamber for removing excess gas from the blood, and an oxygenator comprising a plastic tubular member defining an oxygenator chamber having an upper end portion connected in fluid communication with said defoaming chamber, and means for introducing oxygenation gas and venous blood into said oxygenator chamber to produce a mixture of rising blood and gas bubbles including a gas disperser member selectively slidably connected in said oxygenator chamber to selectively vary the distance between said disperser member and said upper end portion for varying the effective length of said oxygenator chamber to adjust the effective oxygenation capacity of the device in accordance with the oxygenation requirements of the patient, said disperser member including upper and lower members defining a gas chamber adapted for connection with a supply of oxygenation gas, said upper member having a plurality of relatively small openings therein for dispersing said gas and producing relatively small gas bubbles in the blood in said

oxygenator chamber, and means extending through said disperser member for connection with a source of venous blood to supply said venous blood to said oxygenator chamber.

3. A blood oxygenation device for use in an extracorporeal blood circulating system comprising a pair of flexible plastic sheets, said sheets being preselectively united to provide a blood defoaming chamber and a blood reservoir connected in fluid communication with said defoaming chamber for receiving oxygenated blood, anti-foam means in said defoaming chamber for removing excess gas from the blood, and an oxygenator comprising a plastic tubular member defining an oxygenator chamber having an upper end portion connected in fluid communication with said defoaming chamber, and means for introducing oxygenation gas and venous blood into said oxygenator chamber to produce a mixture of rising blood and gas bubbles including a gas disperser member selectively slidably connected in said oxygenator chamber to vary the distance between said disperser member and said upper end portion for varying the effective oxygenation capacity of the device in accordance with the oxygenation requirements of the patient, said oxygenator chamber being transparent and having indicia thereon to indicate the relative position of said disperser member therein.

4. A blood oxygenation device for use in an extracorporeal blood circulating system comprising a tubular oxygenator chamber having upper and lower portions, means for introducing venous blood and an oxygenating gas into said oxygenator chamber to produce a rising mixture of blood and gas bubbles therein including a gas disperser member disposed within said oxygenator chamber in sealing slidable engagement with the interior walls of said oxygenator chamber and slidable between said upper and lower portions in a stepless manner by the user for varying the oxygenation capacity of the oxygenation device in accordance with the oxygenation requirements of the patient, said disperser member including a gas dispersing wall having a plurality of gas dispersing passages therethrough disposed within said oxygenator chamber, and means for connecting said gas dispersing passages with a source of oxygenating gas, a defoaming chamber connected to said upper portion of said oxygenator chamber to receive said mixture and release gas therefrom, and a reservoir chamber connected to said defoaming chamber to receive oxygenated blood from said defoaming chamber and having outlet means for discharging oxygenated blood therefrom.

5. The blood oxygenation device according to claim 4 wherein said oxygenator chamber is of transparent material and said disperser member can be viewed therethrough.

6. The blood oxygenation device according to claim 4 further comprising means including indicia on the device to indicate the position of said disperser member along the length of said oxygenator chamber for indicating the setting of the effective oxygenation capacity of the device.

7. The blood oxygenation device according to claim 4 wherein said oxygenator chamber is sized so that said movement of said disperser member between said upper and lower portions changes the effective oxygenation capacity of the device through a range of between about ¼ litre of blood per minute to about 6 litres of blood per minute.

8. The blood oxygenation device according to claim 4 wherein said gas disperser member has a bottom wall and a gas chamber between said gas dispersing wall and said bottom wall, said means for connecting said gas dispersing passages with a source of oxygenating gas including tube means connected with said bottom wall and communicating with said gas chamber.

9. The blood oxygenation device according to claim 8 wherein said means for introducing venous blood and an oxygenating gas into said oxygenator chamber further includes an opening in said gas dispersing wall, an opening in said bottom wall, and second tube means connectable to a source of venous blood and passing through said bottom wall opening and said gas chamber, and into said gas dispersing wall opening to communicate with said oxygenator chamber.

10. The blood oxygenation device according to claim 9 wherein said second tube means terminates at the upper end thereof substantially in the upper plane of said disperser wall so that venous blood enters said oxygenator chamber at the upper surface of said disperser wall.

11. The blood oxygenation device according to claim 4 wherein said gas disperser member is slidable along a longitudinal straight line over at least a major portion of the length of said oxygenator chamber.

12. The blood oxygenation device according to claim 11 wherein said oxygenator chamber is of transparent material, and the device has indicia thereon for indicating the position of said disperser member in said oxygenator chamber and thereby the effective oxygenation capacity of the device.

13. The blood oxygenation device according to claim 12 wherein said indicia are disposed on said oxygenation chamber.

14. The blood oxygenation device according to claim 11 wherein said means for introducing venous blood into said oxygenator chamber includes tube means connected to said disperser member for movement therewith, said disperser member being slidable in said oxygenator chamber along a longitudinal straight line in either direction to increase or decrease the oxygenation capacity of the device.

15. The blood oxygenation device according to claim 14 further including releasable clamping means exteriorly of said oxygenation chamber clamping the interior walls of said oxygenator chamber against said disperser member to releasably secure the same in a selected location.

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BARRY S. RICHMAN, Primary Examiner

U.S. Cl. X.R.

55—255, 256; 128—DIG. 3; 195—1.8; 261—122, DIG. 28