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OXYGENATOR

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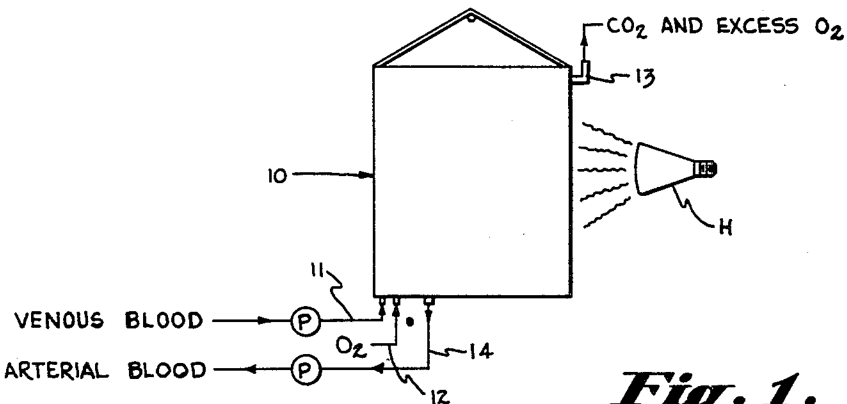

Fig. 1.

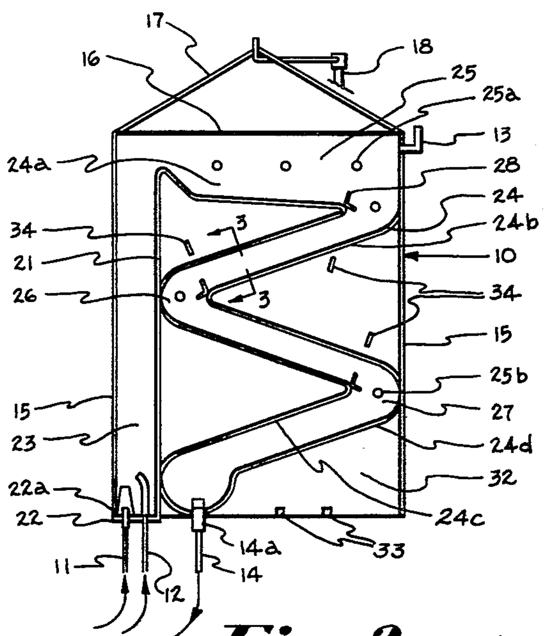

Fig. 2.

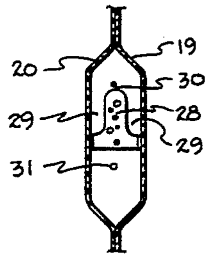

Fig. 3.

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OXYGENATOR

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This invention relates to an oxygenator and the method of producing the same, and more particularly, to an oxygenating device for treating human blood as a substitute for the human heart and lungs.

Although oxygenating devices for human bloods have been known and used for a considerable time, the recent work of Dr. C. Walton Lillehei at the University of Minnesota Medical Hospital and others has firmly established the role of inexpensive, disposable forms of such devices. The device of our invention is an improvement on the oxygenator described in an article by Dr. Lillehei in "Diseases of the Chest," volume XXIX, No. I, January 1956.

Our invention has several significant advantages over the oxygenator provided by those previous in the art. Of outstanding importance is its inexpensiveness of cost. Employing, as it does, heat-sealable thermoplastic material constructed into a unitary device, it is relatively inexpensive to produce. Thus, its use is immediately available to many more patients than the cumbersome, expensive arrangements previously described. Being of a flexible material, it is compactly transported and stored. Because of its unitary nature, it is immediately available for use without the need for making tedious connections.

It is to be appreciated that the role of an artificial heart-lung has by no means been fully investigated. Current usages are in cardiac surgery such as the renowned "blue baby" operations. Certain repairs on human hearts are now performed with the aid of artificial heart-lungs so as to render the heart immobile during the delicate surgical procedures followed. With the increasing awareness of the destructive character of heart ailments, it is entirely possible that usages now considered impractical may come into being. For example, post-cardiac stroke therapy may require immobilization of the heart so as to prevent complications and possibly death. For this purpose, our invention is eminently qualified.

The oxygenator of our invention is intended for use with conventional pumping equipment and tubular conduits connecting the device to a major heart vein and heart artery. Our oxygenator includes a pair of heat-sealable, thermoplastic materials in sheet form, heat sealed together to provide chambers for receiving oxygenation and defoaming of venous blood from a patient having an immobilized heart.

The oxygenator of our invention will be described in conjunction with the accompanying drawing in which FIG. 1 is a schematic view of an artificial heart-lung system; FIG. 2 is an elevational view of the oxygenator of our invention; and FIG. 3 is a cross-sectional view taken along the lines 3—3 of FIG. 2.

Referring now to the drawing, and in particular FIG. 1 wherein a schematic arrangement of an artificial heart-lung apparatus is pictured, the numeral 10 designates the oxygenator of our invention. Four conduits communicate with oxygenator 10. Conduit 11 connects a source of venous blood of a human being to oxygenator 10. Such a source might be the superior and inferior vena cavae. In the oxygenator, this carbon dioxide-bearing blood is intimately contacted with pure oxygen entering through conduit 12. After carbon dioxide-oxygen exchange has been achieved, the excess gases are vented from oxygenator 10 through vent 13. The oxygenated blood, now designated arterial blood, leaves oxygenator

10 through conduit 14 and returns to the patient's arterial system. This entry can be made through the aorta which is reached by making a small slit in the subclavian artery, the main channel to the left arm.

Aiding in the flow of blood to and from oxygenator 10 are pumps designated P which conveniently may take the form of a "finger" pump.

Also provided in the artificial heart-lung system is a source of heart to maintain the oxygenator and its associated blood at the proper temperature. Such a source is designated H in FIG. 1 and conveniently may assume the form of a heat lamp.

Referring now to FIG. 2, oxygenator 10 is shown in enlarged and detailed form. Also shown as communicating, flexible plastic tubes communicating with oxygenator 10 are conduits 11, 12 and 14 previously referred to in connection with FIG. 1. The oxygenator of our invention is essentially rectangular and is constructed of two flat sheets of heat-sealable, translucent plastic material arranged in face-to-face relation and heat sealed along the longer sides and one end thereof as indicated at 15 and 16. Also heat sealed to the sealed end of oxygenator 10 is a plastic hanger strap 17 which permits convenient supporting of oxygenator 10 from a vertical standard such as shown in partial form and designated 18. A modification employs the provision of a second heat seal parallel to and spaced from 16, the portions of side seals 15 being open between the two spaced seals, permitting the insertion of a rod so that the oxygenator is suspended like a curtain.

When the oxygenator of our invention is not filled with blood the two sheets comprising the main body portion of the oxygenator are disposed in face-to-face, lay-flat relationship as can be appreciated from a consideration of FIG. 3 wherein a portion of the oxygenator is shown in cross section. In FIG. 3 one sheet is designated 19 and the other sheet 20. Sheets 19 and 20 are heat sealed together along three of their sides as at 15 and 16, as indicated above. The sheets are additionally heat sealed along a longitudinal line parallel to seals 15 and located between the two sides, but closer to one of the side seals 15 as is designated 21 in FIG. 2. The longitudinal passage or chamber achieved by the cooperation of one seal 15 and seal 21 is used as an oxygenating or bubbling chamber. The end 22 of this chamber 23 opposite heat-sealed end 16 is closed by a lateral heat seal *22a*. Conduits 11 and 12 are heat sealed into this seal so as to communicate with chamber 23. The end of chamber 23 adjacent sealed end 16 communicates with the remaining portion of the envelope formed by heat sealing sheets 19 and 20 together. This major remaining portion of the envelope is provided with a series of heat seals along transverse lines, generally designated 24. One transverse line *24a*, along which sheets 19 and 20 are heat sealed together, is generally of a V configuration, one end of the V beginning at the end of heat seal 21. The trapezoidal chamber adjacent the top of chamber 23 and formed by heat seals 15, 16 and *24a*, is employed as a debubbling or defoaming chamber. The interior walls of the envelope are siliconized at this area to more readily cause oxygen and other entrapped gas such as carbon dioxide, to leave the blood. The freed gas then may issue through vent 13 provided in heat seal 15 at one side of the debubbling chamber 25.

To strip the blood of any remaining gas, we provide a tortuous outlet passageway achieved by heat sealing a second V-type configuration as a *24b*, which is spaced from and opposed to seal at *24a*, and a third spaced V configuration heat seal as at *24c*, parallel to *24a*, but opposed to *24b*. An additional line heat seal is provided at *24d* to establish a regular passage for the blood to exit through conduit 14. The serpentine or zigzag passageway achieved by providing sheets 19 and 20 with the foregoing heat-sealing operations is enlarged at the points of change of passage direction especially at 26 and 27. The slowing up of blood flow at these points more readily enables any entrapped gas to become dissociated with the main body of blood.

To further enable the blood to rid itself of entrapped oxygen and carbon dioxide and to permit these gases to find their way to vent 13, we provide upwardly-extending tongue-like projections 28 which are heat-sealed to the inner walls of sheets 19 and 20 and can be better appreciated from FIG. 3. Projections 28 act like dams or weirs for the blood coursing through the zigzag passage, permitting the major portion of it to flow rapidly alongside of projection 28 as indicated at 29 in FIG. 3. The blood flowing over the top of projection 28 as at 30, flows more slowly and therefore, does not oppose the natural tendency of bubbles 31 to attempt to rise and pass into a higher branch of the zigzag passage. Without the provision of projections 28 the rapid flow of blood at the point of change in direction of zigzag passage might substantially prevent any entrapped gas from finding its way around the V configuration.

Referring again to FIG. 2, it is to be noted that a filter 14*a* is heat sealed into the exit portion of the zigzag passageway and communicates with conduit 14. Also referring to FIG. 2, it is to be noted that there is a portion of the envelope yet unheat-sealed into an enclosure as indicated at 32. This triangular-shaped portion provides a convenient storage space for conduits 11, 12 and 14 during transport and storage of the oxygenator of our invention. It is also possible to intermittently heat seal the portion of the open end of the envelope as at 33 to retain any equipment such as conduits within the confines of the envelope.

In the manufacture of our oxygenator, two sheets of thermoplastic material such as polyvinyl chloride are disposed in face-to-face relationship and trimmed to the proper shape. Short line seals are made at positions designated 34 which serve to define the change of direction points of the zigzag passage to be provided later. Aligned with and spaced from tack seals at positions 34 are tongue-like projections 28 which are then heat sealed into position by sealing the edges of projections 28 one to sheet 19 and the other to sheet 20. Projections 28 are constructed of the same material as sheets 19 and 20. The oxygenator is then completed by one heat-sealing operation wherein mating dies provide heat seals 15, 16, 21, 22*a* and include outlet connections for the three conduits and vent 13 as well as hanger 17.

It is to be noted that the operation of our oxygenator is significantly superior to prior devices in employing an oxygenating device wherein the walls defining a blood flow passage are in face-to-face relation, producing a film-type flow of blood. This promotes the stripping of a maximum amount of gas from the blood, which gas, if permitted to remain, might cause an embolism. To further achieve the flat type of blood passage found desirable, we spot heat seal together sheets 19 and 20 at a number of points in the blood passage, as at 25*a* in the defoaming chamber 25 and at 25*b* in the zigzag outlet passage.

By providing a flat type of outlet passage promoting film-like flow of blood, it is possible to discern at a glance whether all the entrapped gas has been scavenged from the outlet passage. This could be important in emergency situations where the flow of blood must be rapidly increased. With a thicker passageway, the opacity of the blood might mask any entrapped gas.

The foregoing detailed description has been given for clearness of understanding only and no unnecessary limitations are to be inferred therefrom.

We claim:

1. A unitary, disposable blood oxygenator comprising a flexible envelope constructed of a pair of plastic sheets in face-to-face relationship, with the side and upper edges thereof united by a heat seal, further heat seal lines connecting the sheets within the periphery of the envelope defining a passageway through the envelope, a pair of inlets at one end of the passageway, one inlet being connected to an oxygen source and the other inlet adapted to be connected to a supply of venous blood, at least one aperture through the upper portion of the envelope for connecting the passageway with the atmosphere, and an outlet at the other end of the passageway for discharging the oxygenated blood.

2. In an oxygenation system for the oxygenation of blood comprising a source of oxygen, a source of blood, and an oxygenation device, the improved oxygenation device which comprises a unitary disposable plastic blood oxygenator comprising a flexible envelope constructed of a pair of plastic sheets in face-to-face relationship with the side and upper edges thereof united by a seal, further seals connecting the sheets within the periphery of the envelope thus defining a passageway through the envelope, a pair of inlets at one end of the passageway, one inlet being adapted for connection to an oxygen source and the other inlet adapted to be connected to a supply of blood, at least one aperture through the upper portion of the envelope for connecting the passageway with the atmosphere and an outlet at the other end of the passageway for discharging the oxygenated blood.

3. In an oxygenation system comprised of a source of blood, a source of oxygen and an oxygenator, the improved oxygenator which comprises a unitary, disposable blood oxygenator, comprising a pair of substantially rectangular sheets of thermoplastic material disposed in face-to-face, lay-flat relation and joined together along the two longer sides and an end to form an open-ended envelope, said envelope sheets being additionally joined together along a line parallel to and intermediate said sides to form a narrow, elongated oxygenating chamber, the intermediate joint extending from the open end of said envelope to a point spaced from the closed end of said envelope, the end of said oxygenating chamber adjacent the open end of said envelope being closed except for passages for introduction of venous blood and oxygen into said chamber, said envelope sheets being additionally joined together along a transverse line to provide with the envelope end joint a de-foaming chamber adjacent the end of said oxygenating chamber adjacent the closed end of said envelope, and said sheets being additionally joined together along spaced pairs of transverse lines to provide a zigzag passage communicating with said de-foaming chamber and extending to the open end of said envelope, and gas vent means in one of the joints defining said de-foaming chamber.

4. The oxygenator of claim 3 in which said zigzag passage is equipped with weir means at the areas thereof where blood flowing therein changes its direction of flow.

5. The oxygenator of claim 3 in which said zigzag passage is enlarged at the areas thereof where blood flowing therein changes its direction of flow.

6. In an oxygenation system comprised of a source of blood, a source of oxygen and an oxygenator, the improved oxygenator which comprises a pair of generally rectangular thermoplastic sheets arranged in face-to-face, vertical relation, said sheets being united together along the upper end and two vertical sides thereof, hanger means associated with said upper end to support said device, said sheets being united together along a vertically-extending line adjacent one of said vertical sides, said vertically-extending line terminating a spaced distance from said upper end, the space between said vertically-extending line and said adjacent one vertical side providing an oxygenating chamber with the lower end thereof being closed except for entrance means for blood and oxygen, said sheets being additionally united along

a second line extending generally transversely and downwardly from the upper end of said vertically-extending line and terminating adjacent to but spaced from the vertical side remote from said vertically-extending line to provide a de-foaming chamber, said de-foaming chamber being provided with gas venting means to vent excess gases to the atmosphere, said sheets being still further united along a pair of generally parallel, inclined lines, one of which is connected with the end of said second line adjacent said remote vertical side and the other of which is connected to said remote vertical side to provide an outlet.

7. The structure of claim 6, in which an upwardly-

extending tongue-like projection is united to said sheets at the connection of said one of said pair of inclined lines with said second line.

References Cited in the file of this patent

UNITED STATES PATENTS

2,784,716	Broman	Mar. 12, 1957
2,848,995	Ryan	Aug. 26, 1958
2,854,002	De Wall et al.	Sept. 30, 1958

OTHER REFERENCES

"Silicones and Blood Coagulation," by Jaques et al.; Canadian M.A.J., July 1946, vol. 55, pages 26–31.