

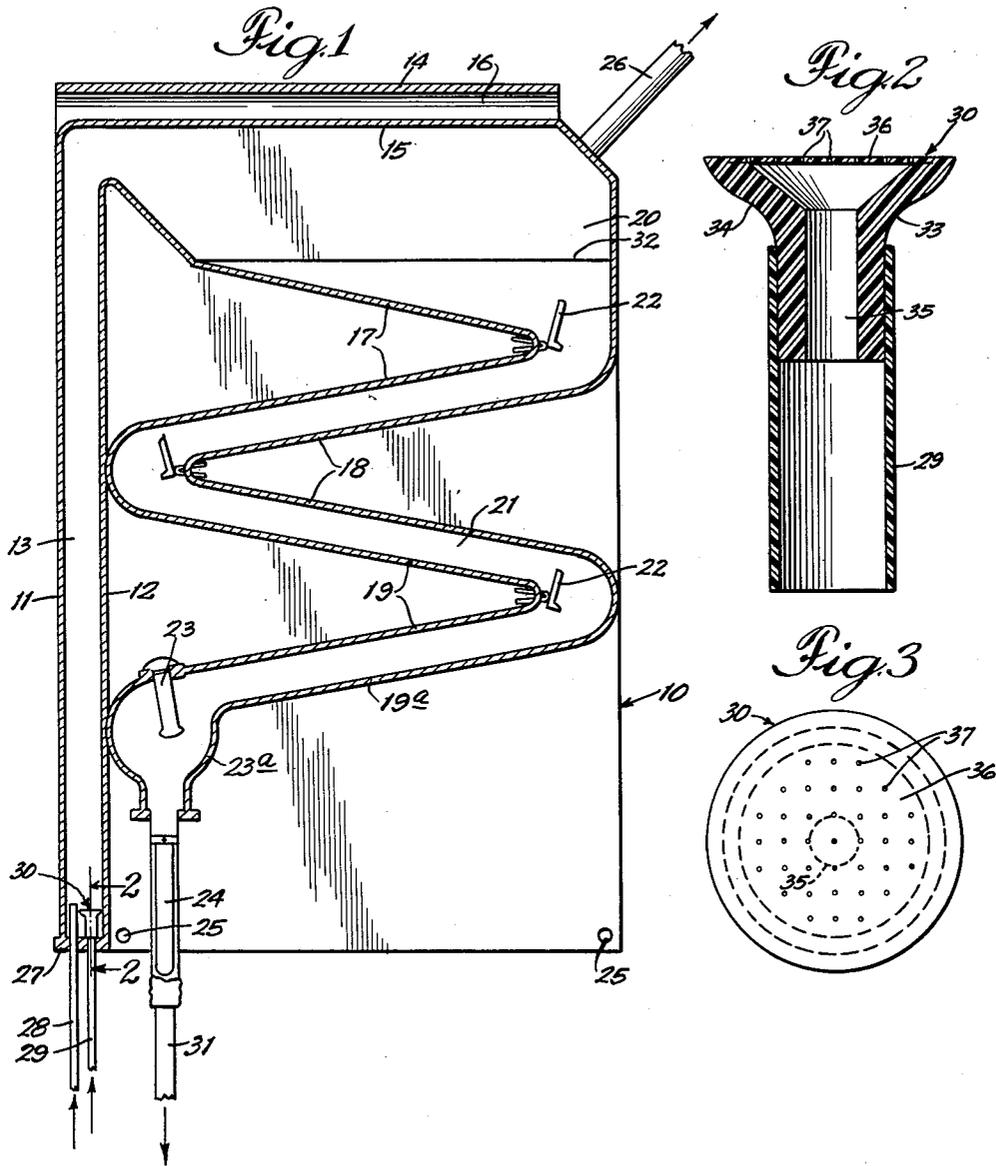
Oct. 16, 1962

C. R. BROMAN

3,058,464

OXYGENATOR

Filed April 22, 1957



INVENTOR:

Cyrus R. Broman,

BY *Dawson, Titton, Fallon & Kingman,*
ATTORNEYS.

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3,058,464

OXYGENATOR

Cyrus R. Broman, Evanston, Ill., assignor to Baxter Laboratories, Inc., Morton Grove, Ill., a corporation of Delaware

Filed Apr. 22, 1957, Ser. No. 654,161

3 Claims. (Cl. 128—214)

This invention relates to an improvement in an oxygenator, and more particularly to an oxygenator employed for treating human blood as a substitute for the human heart and lungs.

Reference is made hereby to the co-owned application of Theodore H. Gewecke and myself, Serial No. 610,605 filed September 18, 1956, which discloses an oxygenator on which this invention is an improvement.

Oxygenating devices for human blood have been well known to the medical art for centuries. As such they have taken many forms. Despite the variety of forms available, ranging from the most simple to the very complex, such devices have found relatively little use. Since these devices deal with one of the most delicate parts of the human anatomy, there is always the fear that they will not prove to be perfectly operative. The fears of doctors in the use of oxygenating devices have, to a very large extent, been focused on the oxygen dispersing mechanism itself. This particular structural element, i.e., the oxygen dispersing means, must be the equivalent of the human lungs. The human lungs operate to provide the proper amount and distribution of oxygen to achieve carbon dioxide exchange.

Finding a full and operative structural equivalent of the human lungs has been an important problem facing those working in the art of artificial oxygenation of blood. The amount of oxygen, contacted with the blood is critical. Too much oxygenation in an artificial oxygenator causes excessive foaming of the blood which may persist even when the blood is reinfused into the patient, giving rise to the danger of an embolism. Even if the oxygenator is provided with adequate means for defoaming, the presence of excess foam necessarily restricts the efficiency of the oxygenating device and, more importantly, its capacity. On the other hand, an insufficient quantity of oxygen coming in contact with the blood gives rise to an insufficient carbon dioxide exchange so that the blood is not properly revived.

Even though the amount of oxygen brought in contact with the blood is proper, i.e., not promotive of excessive foaming but yet sufficient to fully oxygenate the quantity of blood passed through the oxygenating device it is further necessary and equally important that the distribution of the oxygen quantity be proper. Generally, an improper distribution of oxygen increases the turbulence of the blood and increases the rate of hemolysis of red blood cells.

It is therefore a general object of this invention to provide an oxygen dispersing device for a blood oxygenator which overcomes the problems outlined above. Another object is to provide a device for dispersing oxygen wherein the undesirable effects of blood turbulence are substantially avoided. Still another object is to provide an oxygen dispersing device for introducing oxygen into a vertically disposed, blood filled chamber. Yet another object is to provide a device for introducing oxygen into a vertical column of blood wherein a large number of small bubbles of oxygen are provided. A further object is to provide an oxygen dispersing device capable of introducing a large number of small but uniformly sized bubbles into the bottom of a column of blood. Other objects and advantages of my invention will be seen as this specification proceeds.

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This invention will be described, in an illustrated embodiment, in conjunction with the accompanying drawing, in which—

FIGURE 1 is an elevational view of a disposable blood oxygenator incorporating the improved features of this invention; FIGURE 2 is an enlarged cross sectional view taken along the line 2—2 of FIGURE 1; and FIGURE 3 is a top plan view of the oxygen dispersing device shown in cross section in FIGURE 2.

Referring now to the drawing, an illustration is given of a disposable blood oxygenator in FIGURE 1. The oxygenator in FIGURE 1 is designated generally by the numeral 10. Oxygenator 10 includes two substantially rectangular flat sheets of a plastic material of a thermo plastic character, such as polyvinyl chloride. Two such sheets are arranged in face-to-face, lay flat relation and are heat-sealed along a number of lines to form a unitary structure, the details of which are set forth more particularly in the above identified application of Theodore H. Gewecke and Cyrus R. Broman. The sheets making up oxygenator 10 are heat sealed along two, spaced, longitudinally disposed, parallel lines 11 and 12 to form an oxygenation or bubbling chamber or column, designated 13. The sheets are additionally heat sealed along two, horizontally disposed, spaced, parallel lines 14 and 15 adjacent one end thereof (ultimately providing the top of the oxygenator) to provide a slot 16 adapted to receive a slip metal rod (not shown) which provides a convenient suspending means for the oxygenator.

In the illustration given, the sheets making up oxygenator 10 are additionally heat sealed together along a series of line (conveniently identified as V configurations). For example one V configuration of heat sealing designated by the numeral 17 has its apex laterally disposed and directed away from oxygenation chamber 13. A second V heat seal configuration 18 is oppositely oriented to configuration 17 while a third configuration 19 is disposed similarly to configuration 17. Thus, a defoaming chamber 20 is provided in the topmost portion of oxygenator 10 which communicates with oxygenation chamber 13. The spaced heat seals designated by the numerals 17, 18 and 19 provide a zig-zag or serpentine outlet passage from the bottom of defoaming chamber 20, the outlet passage being designated by the numeral 21.

A series of bubble baffles or weirs 22 are provided in passage 21 at the points where the outflow or blood changes direction. Oxygenator 10 is also provided with a thermostat element pocket 23 extending into passage 21 which is adapted to receive a suitable thermostatic element (not shown).

The extreme end portion of the outlet passage 21 is provided with a blood filter 24. The last leg of the serpentine passage 21 is defined by one leg of V configuration 19 and an additional linear heat seal 19a. Oxygenator 10 is provided with a pair of holes extending therethrough and designated 25 which provide convenient means for tying the oxygenator in place so as to maintain it in a substantially flat condition during use. The upper end of the oxygenator is provided with a gas outlet port 26 which serves to vent excess oxygen and carbon dioxide to the atmosphere.

The bottom portion of oxygenator 10 is partially heat sealed along a horizontal line as designated by the numeral 27 to close-off the bottom portion of oxygenation chamber 13. Heat sealed into seal 27 is blood inlet tube 28 and oxygen inlet tube 29, oxygen inlet 29 terminating in an oxygen dispersing device generally designated 30 and shown more particularly in FIGURES 2 and 3. Also associated with oxygenator 10 during operation thereof, but not shown herein, are suitable

pumps and tubing communicating oxygenator 10 with the body of a patient whose blood is undergoing oxygenation.

For placing the oxygenator 10 in use certain additional materials are needed. These include a rod and suitable stand for supporting oxygenator 10 by means of sleeve or chamber 16. Two pumps are required for inducing flow to and from oxygenator 10. One pump is for the venous line which terminates in blood inlet 28 and another pump is required for the arterial line which is attached to the oxygenated blood outlet designated 31. Additional tubing for connecting oxygenator 10 with the patient is also required. A source of heat such as a bank of three 150 watt heat lamps placed about 12 to 18 inches from the unit is required. These lamps are operated by a suitable thermostat and relay which can be associated with oxygenator 10 as by insertion into pocket 23.

The use of oxygenator 10 can be further appreciated from a consideration of a typical operating procedure such as is set forth immediately below.

Operation

Inasmuch as oxygenator 10 is intended for single use, a quick set-up procedure is contemplated. First, oxygenator 10 is suitably suspended by a rod extending through chamber or sleeve 16 and tied down by laces extending through holes 25 at the bottom of oxygenator 10. Thereafter and 125 cc. of 0.9% sodium chloride solution (normal saline) is introduced upwardly into oxygenator 10 through arterial line 31, thereby filling an enlarged chamber 32 which serves as a slowdown chamber. Thereafter any bubbles are removed from the saline solution as by gentle manipulation. Outlet passage 21 is subjected to heat for about two or three minutes and about 1,000 cc. of heparinized blood is introduced into bubbling chamber 13 through venous line 28 to fill oxygenator 10 to blood operating level 32 which exists in defoaming chamber 20. Previous to the introduction of the heparinized blood, oxygen from a source not shown is introduced into chamber 13 by means of oxygenation tube 29. The arterial and venous lines 31 and 28 respectively are now connected to suitable pumps (not shown) and further communicated to the blood vessels of a patient as by cannulation. The patient has been administered 150 U.S.P. heparin units per kilogram of body weight. The priming blood contains about 4000 U.S.P. heparin units.

When the pumps are started after proper connection, venous blood flows from the venous pump through the venous inlet tube and into the bubbling chamber. Oxygen from an outside source flows through the oxygen inlet tube 29 and mixes with the blood in the oxygenation chamber 13. Thereafter, chamber 13 is gradually filled with a gentle, uninterrupted, rising column of bubbles. As the bubbles reach the top of chamber 13, they flow into the defoaming chamber 20. There the bubbles come in contact with the siliconized walls of chamber 20 and are gradually dispelled. Carbon dioxide and excess oxygen through vent 25 at the upper corner of chamber 20. Oxygenated blood falls into the pool defined by operating level 32 and the top leg of V configuration heat seal 17. Thereafter, blood exists from the pool, traveling slowly down the zig-zag outlet passage 21 toward the arterial line 31. Any remaining bubbles coming from the blood in passage 21 rise in passage 21 and eventually exist through vent 26. Baffles 22 provide for bubbles to transfer from one leg of passage 21 to another without being swept back down with blood flow, thus facilitating complete stripping of blood of any occluded bubbles. The descending channel of passage 21 widens just above filter chamber 24, as designated 23a, to permit any pinpoint bubbles to aggregate, if any have proceeded this far. The oxygenated blood then flows downward to filter 24 where clots or particulate matter are eliminated. The blood continues through the filter 24, out through arterial

line 31 to the arterial pump and then to the subject. After completion of surgery involving the use of oxygenator 10, any residual blood in oxygenator 10 can be pumped out for reuse.

In order to provide the not only desirable but critical distribution of oxygen bubbles, oxygen defusing device 30 is employed. In FIGURE 2 device 30 is seen to include a tubular member 33 which is connected at one end thereof to venous line 29. The connection between tubular element 33 and line 29 can be readily achieved by heat sealing since preferably element 33 is also constructed of polyvinyl chloride, as is the tubing defining venous line 29.

The end of element 33 opposite the end connected to line 29 is provided with an enlarged portion 34 and the flow passage existing within tubular element 33 generally conforms to the outside configuration of element 33, the flow passage being designated 35. The enlarged portion of tubular element 33 is closed by a diaphragm 36 extending across passage 35 at the end of tubular element 33. Diaphragm 36 is provided with a plurality of holes 37 (best seen in FIGURE 3) which are uniformly distributed in diaphragm 36 and which are of uniform size. Oxygen diffusing device 30 is so constructed that it can be heat sealed into seal 27 so as to maintain diaphragm 36 in substantially horizontal condition.

Excellent results have been obtained when diaphragm 36 is also constructed of polyvinyl chloride, thereby permitting connection of diaphragm 36 to tubular element 33 by heat sealing. Where diaphragm 36 is attempted to be connected to element 33 by solvent sealing, a greater thickness of diaphragm is required since a portion of the diaphragm is dissolved in order to effectuate the seal. The greater thickness of diaphragm makes substantially more difficult the provision of uniform sized holes 37 therein. Optimum results have been obtained by using a thickness of polyvinyl chloride of about 4 mils as diaphragm 36.

For the flow rates generally required in oxygenation of blood of human patients, which range from about 2½ to 4 liters of oxygen for each liter of blood, and enlargement of flow passage 35 of a diameter of about ⅝ of an inch has proved desirable. Across this opening, diaphragm 36 is provided with openings of about 10 mils diameter disposed on ⅜ inch centers.

I have found that the horizontal disposition of diaphragm 36 is important in minimizing blood hemolysis. Also important is the provision of uniform sized openings 37 in diaphragm 36. Where openings are non-uniform, the presence of larger openings causes increased hemolysis due to excessive turbulence and uneven distribution of O₂. Also, oversized openings where the openings are non-uniform reduces the oxygen pressure applied to the under surface of diaphragm 36 so that blood may run back into oxygen tube 29. It is to be appreciated that this cannot be conveniently overcome by increasing the pressure of oxygen since this would provide a flow rate higher than the desired flow rate and thereby increase turbulence and hence hemolysis. On the other hand, if the openings are too small, an intermittent flow of bubbles is provided which results in "jetting," resulting not only in turbulence but in inadequate oxygenation of blood.

With the increased usage of blood oxygenators under the influence of workers such as Dr. C. Walton Lillehei of the University of Minnesota Medical School, and others, the problem of controlling oxygen-blood contact has become even more acute. With greater numbers of heart operations in prospect, it is mandatory that the artificial heart-lungs employed be free of any structural defects. As pointed out above, these defects have been considered essentially to relate to the phase of oxygenator operation dealing with oxygen-blood contact. Improvements have been presented that deal with the phase of contact wherein gases have been stripped from the blood after contact but it is to be appreciated that an equally important problem

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exists with respect to the initiation of contact and the diffusion of oxygen in the blood.

In this connection it is to be further appreciated that with the increased number of heart operations that are being performed, it is necessary to provide oxygenators that are not only foolproof in operation but which are easily and reasonably constructed. Many heart surgical operations would not be performed if the oxygenator apparatus is too costly or too complicated to employ since hospitals may feel it undesirable to stock expensive devices. The improvement presented herein eminently fills this need by making available an oxygenator which can be reasonably and quickly constructed. An important operative element of oxygenator 10, is oxygen dispersing device 30 which can be readily and quickly assembled by heat sealing to provide a unit capable of foolproof operation.

While in the foregoing specification an embodiment of the invention has been set out in considerable detail for purposes of illustration, it will be apparent to those skilled in the art that considerable deviation in these details may be made without departing from the spirit and principles of the invention.

I claim:

1. In combination with a disposable oxygenator constructed of a pair of thermoplastic sheets arranged in face-to-face relation and united together to form a vertical oxygenation chamber therein when the united sheets are disposed vertically, a tubular member secured in the base of said chamber and providing a conduit for oxygen to enter said chamber, said tubular member having ends internal and external of said chamber, said external end being adapted to be connected to an oxygen source, the said internal end being enlarged, a diaphragm extending across the said internal end to close the same, said diaphragm being provided with a plurality of uniformly

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sized openings extending therethrough, said openings being uniformly distributed in said diaphragm.

2. In an oxygenator, a vertically-extending oxygenating chamber defined by a pair of thermoplastic sheets perimetrically united along the sides and bottom, the bottom union being interrupted at two spaced points, a conduit extending through said union at each of said points to deliver blood and oxygen to said chamber, the oxygen delivery conduit being equipped internally of said chamber with an upwardly-flared fitting, and a diaphragm secured to the upper end of said fitting, said diaphragm being equipped with a plurality of uniformly sized openings extending therethrough, said openings being uniformly distributed in said diaphragm.

3. The oxygenator of claim 2 in which said diaphragm is constructed of thermoplastic material.

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