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3,207,156

HEART-LUNG MACHINE

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3 Sheets-Sheet 2

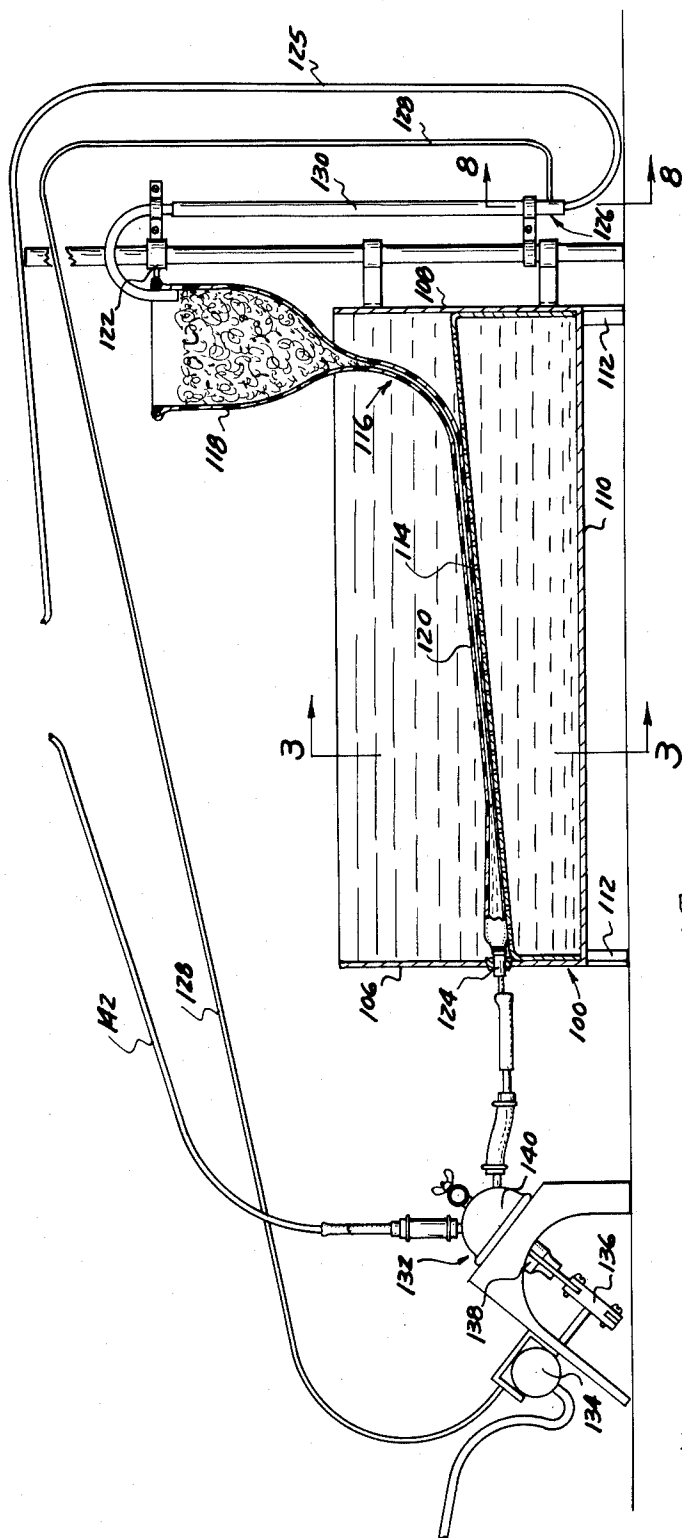


Fig. 2

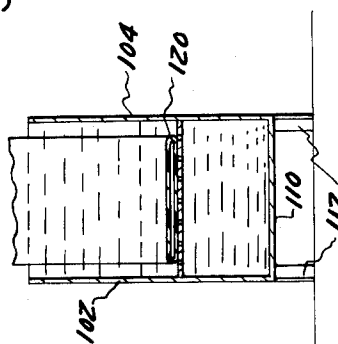


Fig. 3

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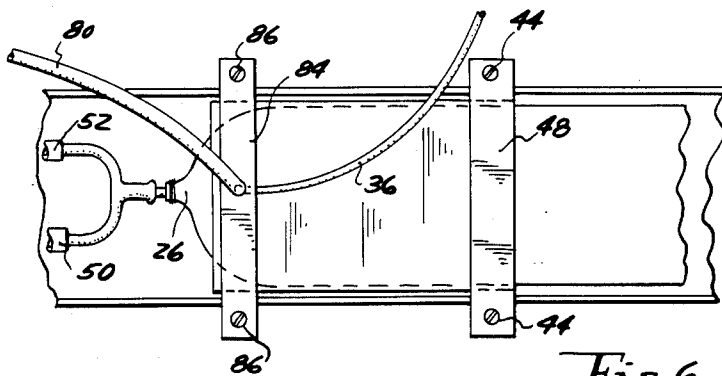


Fig. 6

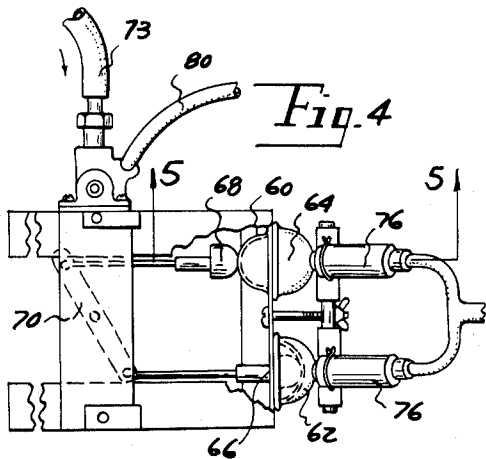


Fig. 4

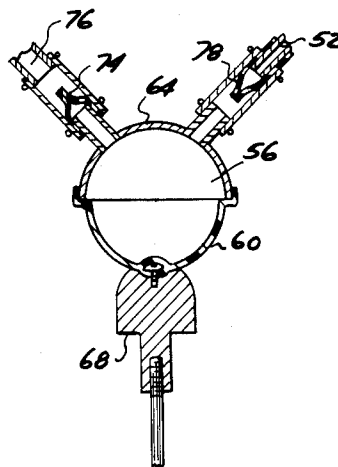


Fig. 5

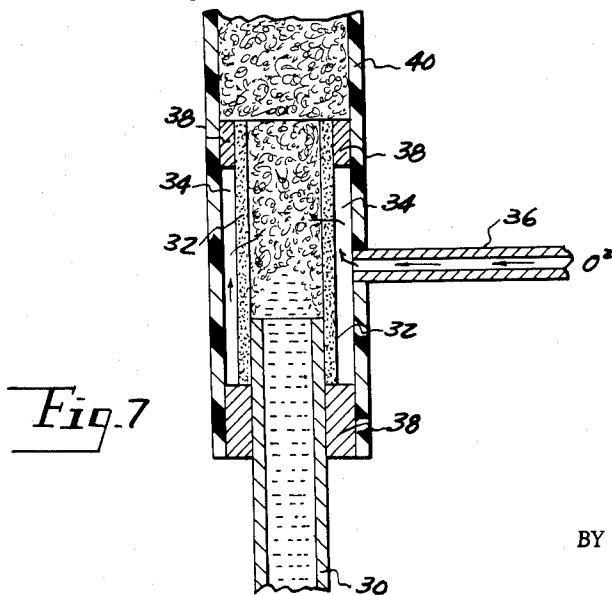


Fig. 7

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1

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HEART-LUNG MACHINE

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3 Claims. (Cl. 128—214)

This invention relates to a pump-oxygenator which may perform the functions of the heart and lungs of a patient for a short period of time during which surgery is performed.

Operations on the heart ordinarily require the use of a mechanical pump which will assume the normal functions of the heart so that the blood circulatory path may be routed around the heart. This allows the surgeon to operate on the heart in a relatively blood-free field and to provide adequate blood circulation to the body during interruptions of the normal work of the heart. Although the surgery or medication may involve only the heart, the complexity inherent in an attempt to bypass only the patient's heart is great. Such a bypass involves carrying the blood to and from the lungs as well as connections to the vena cavae and aorta. The difficulty of making connections to and from the lungs has been found to be so substantial, that a bypass of both lungs and the heart is usually preferred.

The combined function of the heart and lungs in the normal human body is to receive blood from the great veins, combine it with sufficient oxygen, remove excess carbon dioxide, and pump the oxygenated blood at a suitable rate into the arterial tree for distribution throughout the body. Devices which perform these functions must be reliable, economical, and simple to operate. Adequate means must be provided to assure complete removal of all bubbles from the blood since bubbles or emboli may result in injury or death to the patient. In addition, means must be provided so as to allow easy sterilization of all parts in contact with the blood.

The present invention meets these objectives through the use of an inexpensive disposable flat bag disposed in a sloping orientation to allow the blood to move through the bag by gravity flow. The blood, after suitable introduction of oxygen, flows into a reservoir open to the atmosphere and thence by gravity flow down the sloping bag. Since the roof of the bag is pressed flat upon the surface of the liquid, the foam is trapped in the large reservoir where the liquid blood is allowed to drain out of the network of bubbles. The liquid blood flows in a shallow, broad stream down the bag which is of adequate breadth and length such that all remaining bubbles rise out of the stream.

At the bottom of the bag, a motor pumps the oxygenated blood into the patient's arteries at a flow rate equivalent to that normally pumped by the heart. In a preferred embodiment of the present invention which will be subsequently described in detail, the exhaust oxygen from an air motor is utilized to oxygenate the blood and the rate of pumping is automatically controlled by the level of blood in the bag. In addition, means are provided to stop the motor entirely when the blood in the reservoir decreases below a critical level, thus eliminating the possibility of pumping air into the arteries.

Another advantage of the present invention is that it comprises a primary structure which is so low in cost that it may be disposed of after its use and therefore does not involve the necessary complications and limitations imposed by the requirement that a device be sterilized after each use. By avoiding such sterilization and reuse, the present invention obviates the danger which might result from inadequate sterilization.

A further advantage of the present invention is that it requires no electrical connection since the motor is powered by the pressure of oxygen. Electrical connections

2

are undesirable due to the explosive characteristics of oxygen and anesthetics used during the operation, and due to the disastrous result of power failure at critical moments.

Other advantages of the present invention include low cost, light weight, and economy of operation and maintenance.

Other objects and advantages of the invention will more fully appear from the following description and drawings, wherein are disclosed two preferred embodiments of the invention. The description refers to the accompanying drawings in which:

FIGURE 1 is a side elevation view of one preferred embodiment of the present invention with parts broken away.

FIGURE 2 is a side elevation view of a second preferred embodiment of the present invention with parts broken away.

FIGURE 3 is a sectional view taken along the lines 3—3 of FIGURE 2.

FIGURE 4 is a sectional view taken along the lines 4—4 of FIGURE 1 with parts broken away.

FIGURE 5 is a fragmentary sectional view taken along the lines 5—5 of FIGURE 4.

FIGURE 6 is a fragmentary plane view of the embodiment shown in FIGURE 1.

FIGURE 7 is a sectional view taken through the bubbler which will be subsequently described in detail.

Referring now to the drawings in detail, a first embodiment of the invention is illustrated as comprising a sloping frame 10 having a circulation chamber 12 and supported, at one end by a vertical supporting member 14, and at the other by a support frame 16 of a pump indicated generally at 18. A flat bag 20, preferably constructed of disposable and inexpensive plastic film tubing, lies along the frame 10; the bag consists of a foam reservoir 22 at the upper part of the bag, and a flat section 24 at the lower portion of the bag terminating in a nozzle 26. The upper section of the bag is secured to the vertical support 14 by a clamp 28.

Venous blood from the patient flows by gravity down the venous line 30 and then upwards through a short section of microporous tubing 32 surrounded by an open space 34 into which oxygen is introduced through an oxygen feed tube 36. In this fashion, oxygen is forced through the pores into the rising current of blood in the form of bubbles. Since the size of the bubbles is a function of the density of the oxygen per unit area of the porous surface, the bubble size may be controlled by adjusting the rate of inflow of oxygen in the feed tube 36.

The porous tubing 32 and the venous line 30 are secured in position by gaskets 38 disposed in fluid-tight manner within a mixing tube 40. The oxygenated blood rises through the mixing tube 40, which is of wider dimension than the venous line 30, and pours over into the foam reservoir 22 of the blood bag 20. As the blood rises in the mixing tube 40, oxygen is dissolved into the blood while carbon dioxide is added to the gas within the larger bubbles.

The larger bubbles, in the form of foam, float above the blood and remain in the foam reservoir 22 while the liquid blood flows through the lower, flat portion 24 of the bag 20. Liquid blood drains out of the honeycombs of bubble films and into the flat portion 24 of the bag; as the bubble-walls grow thinner, they break spontaneously. To speed the elimination of the foam, a small amount of antifoam compound may be placed on the upper part of the inside walls of the reservoir. Possibly some of the well-drained dry foam may be permitted to overflow and be discarded.

The length and width of the flat section 24 of the bag are selected in accordance with the flow rates desired so as

to enable the smaller bubbles in the blood to rise to the surface as the blood moves down the bag. Through the proper selection of these critical dimensions, all bubbles will be removed before the blood reaches the bottom of the bag, thus eliminating the possibility of bubbles present in the blood entering the patient's system.

A plate 42 is connected by means of bolts 44 and nuts 46 to a bracket 48 which is fixed to the frame 10. The free end of the plate 42 is supported on the surface of the bag 20 so as to be raised or lowered as the level of the blood changes.

At the lower end of the bag 20, the nozzle 26 is connected to the inflow tubes 50 and 52. Each inflow tube is connected to a compression chamber 54 and 56 consisting of a flexible diaphragm 58 and 60 mounted in fluid-tight manner with a cup 62 and 64. The diaphragm is alternately pushed into the cup and pulled out by a piston 66 and 68 linked to an oscillating rocker arm 70 which is mounted on the shaft 71 of a reciprocating air motor 72. The reciprocating air motor, fed with oxygen through an air inlet hose 73, is actuated in a manner well known to the art.

On the compression stroke of the motor 72, the pressure of the compressed blood opens the exit pressure valve 74 and allows blood to be pushed into the blood return tube 76 and thence into the patient's arterial system (not shown). The compressed blood also closes the inlet pressure valve 78 preventing blood from entering the compression chamber 54 and 56 during the compression stroke. On the expansion stroke of the motor 72, the reduced pressure in the blood in the compression chamber will close the exit valve 74 and open the inlet valve 78, thus allowing blood to fill the compression chamber.

Exhaust oxygen from the motor 72 escapes through an exhaust tube 80 which terminates in a check valve 82 permanently affixed to the frame 10 by means of a bracket 84, bolts 86 and nuts 88. The check valve 82 has an exhaust chamber 90 positioned in a manner well known to the art so as to allow oxygen to enter the chamber 90 when the check valve 82 is opened. The check valve 82 is situated above the free end of the plate 42 so as to be opened when the blood level, and hence the plate, reach a predetermined level. The oxygen feed tube 36, connected to the exhaust chamber 90, allows the oxygen to be introduced into the porous tube 32 and bubbled into the blood.

Water at desired temperatures is introduced into the circulation chamber 12 by means of a water inlet hose 92 and is removed from the chamber 12 through a water discharge hose 94. Thus the blood passing through the bag 20 may be maintained at desired temperatures simply by adjusting the temperature of the circulating water.

In operation, the device of the present invention is placed below the patient so as to allow venous blood to flow by gravity down the venous line 30 and into the porous tube oxygenator 32 where exhaust oxygen from the air motor 72 is bubbled into the stream of blood. The blood flows over into the bag 20 where the foam is trapped in the foam reservoir 22; due to the breadth and shallowness of the stream of blood in the lay-flat portion of the bag, bubbles readily arise out of the stream. When sufficient blood distends the bag 20, it raises the lower end of the hinged plate 42 opening the valve 82 which directs the exhaust oxygen from the air motor 72 into the porous tube oxygenator 32. If the blood level falls, the plate drops, closing the valve 82 proportionately and slowing the motor. If the blood level reaches a critical low level, the valve closes completely, stopping the motor and thus eliminating the possibility of pumping air into the arteries.

The reciprocating action of the motor 72 causes the blood to be pumped alternately from each compression chamber 60, thus providing a steady flow of blood into

the arterial line 76 and then into the arteries of the patient.

FIGURES 2 and 3 illustrate a second embodiment of the present invention. An open tank 100 having side-walls 102 and 104, endwalls 106 and 108, bottom 110, legs 112, and a sloping shelf 114, is filled with fluid. A bag 116 consisting of an open foam reservoir 118 situated above the fluid surface, and a lay-flat section 120 of smaller cross-section supported by the shelf 114 below the fluid surface, is held in place at its upper end by a clamp 122. At its lower end the bag terminates in a nozzle 124 which protrudes through the end wall 106.

The tank 100 is placed below the level of the patient so that venous blood flows down the venous line 125 through an oxygenator 126 identical to that described in conjunction with the first embodiment of this invention. Oxygen enters through a feed tube 128 through porous tubing, bubbling into the blood as it flows up through a mixing tube 130.

The foam floating on the surface of the blood is trapped in the foam reservoir 118, while the liquid blood flows down into the lay-flat section 120. The blood, being of greater density than the surrounding fluid gravitates to the lower end of the bag.

The presence of bubbles in the blood will lower the density of the blood; the pressure of the surrounding fluid will then decrease the thickness of the layer of blood flowing down the bag. Since the rate at which bubbles rise out of the stream is a function of the thickness of the layer of blood, proper selection of fluid and fluid depth will assure the removal of all bubbles from the blood before the blood reaches the lower end of the bag while at the same time regulating the blood temperature as desired.

The blood passes through the nozzle 124 into a pump 132 identical to that described in conjunction with the first embodiment of the present invention. An air motor 134 drives an oscillating rocker arm 136 connected to two pistons 138 so as to alternately invaginate two hemispheres 140 which receive blood from the bag. Blood is thus forced alternately from each of the hemispheres 140 through a blood return tube 142 back into the patient's arterial system.

Exhaust oxygen from the motor 134 is transported through the feed tube 128 to the porous tube oxygenator 126. The rate of flow of blood from the patient's system may be measured by suitable gage means, this information being utilized to control the pumping rate, and thus the rate at which oxygen is introduced into the blood.

The blood flowing through the bag may be maintained at desired temperatures by controlling the temperature of the surrounding fluid in the tank 100. This embodiment provides a very large surface for heat exchange, thus insuring accurate control of the blood temperature.

Although the present invention has been illustrated solely in conjunction with one variety of pump, it should be noted that any type of blood pump may provide the pumping action. The use of exhaust oxygen from the motor to oxygenate the blood is not necessary to the present invention; alternatively, power means other than an air motor may be employed to drive the pump, and oxygen may be supplied to the oxygenator from a separate source.

In addition, the sloping bag of the present invention need not be used solely in conjunction with the bubbler type of oxygenator; it may be used with any apparatus where bubbles need be removed from the blood; such as cardiotomy suction devices.

Having described the invention in its simplest terms, it is to be understood that the features of construction may be changed and varied in greater or lesser degree without departing from the essence of the invention defined in the appended claims.

I claim:

1. A heart-lung machine, comprising:

tube means for diverting blood from the heart of a patient, said tube means having input and output ends, 5
oxygenating means for introducing oxygen into the blood in the form of bubbles connected to the output of said tube means,
said oxygenating means being provided with outlet means, 10
a flexible bag receiving said oxygenating outlet means and having an upper reservoir portion adapted to receive blood and froth from said oxygenating means, said bag having a lower section extending laterally from said upper portion at an inclination with respect to the horizontal and supported so as to form a shallow, flat broad flow area, 15
said lower section having a lower exit opening,
pumping means for pumping the blood into said patient's arterial system connected to the lower opening of said bag, 20
an air motor operatively connected to and actuating said pumping means,
said air motor being provided with exhaust means communicating with said oxygenating means, 25
whereby oxygen gas exhausted from said air motor may be employed as the oxygen supply for the oxygenating means,
gaging means for measuring the amount of blood in said bag operatively associated therewith, 30
means for controlling the exhaust oxygen flow from said motor to said oxygenating means as a function of said amount of blood in said bag,
and second tube means connected to said pump means for returning blood to the patient's arterial system. 35

2. A heart-lung machine, comprising:

tube means for diverting blood from the heart of a patient,
said tube means having input and output ends, 40
oxygenating means for introducing oxygen into the blood in the form of bubbles connected to the output of said tube means,
said oxygenating means being provided with outlet means, 45
a flexible bag receiving said oxygenating outlet means and having an upper reservoir portion adapted to receive blood and froth from said oxygenating means, said bag having a lower section extending from said upper section forming a shallow, flat broad flow area, said lower section being provided with a lower exit opening, 50
a tank of fluid having a sloping frame therein,
said flexible bag being situated on said frame with the upper reservoir portion exterior of said fluid and the lower section immersed therein resting on the frame, 55
pumping means for pumping blood into said patient's arterial system connected to said lower opening of the bag,
gaging means for measuring the depth of flow of blood in said bag operatively associated therewith, 60
means contacting said bag for controlling the pumping rate of said pump as a function of said depth of flow,
means coacting with said pump control means for controlling the rate of oxygenation as a function of said depth of flow,
and second tube means connected to said pump means for returning blood to the patient's arterial system.

3. A heart-lung machine, comprising:

tube means for diverting blood from the heart of a patient,
said tube having input and output ends,

oxygenating means for introducing oxygen into the blood in the form of bubbles connected to the output of said tube means,
said oxygenating means being provided with outlet means, 5
a flexible bag receiving said oxygenating outlet means and having an upper reservoir portion adapted to receive blood and froth from said oxygenating means, said bag having a lower section extending from said upper section forming a shallow, flat broad flow area, said lower section being provided with a lower exit opening, 10
a tank of fluid having a sloping frame therein,
said flexible bag being situated on said frame with the upper reservoir portion exterior of said fluid and the lower section immersed therein resting on the frame, 15
pumping means for pumping blood into said patient's arterial system connected to said lower opening of the bag, 20
an air motor connected to said pumping means operative to actuate said pumping means,
said air motor also being provided with exhaust means communicating with said oxygenating means, 25
whereby oxygen gas exhausted from the air motor may be employed as the oxygen supply for the oxygenating means,
gaging means for measuring the depth of flow of blood in said bag operatively associated therewith, 30
said exhaust means having means for controlling the exhausted gas flow from said air motor as a function of the depth of blood flow in said bag,
and second tube means connected to said pumping means for returning blood to the patient's arterial system. 35

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