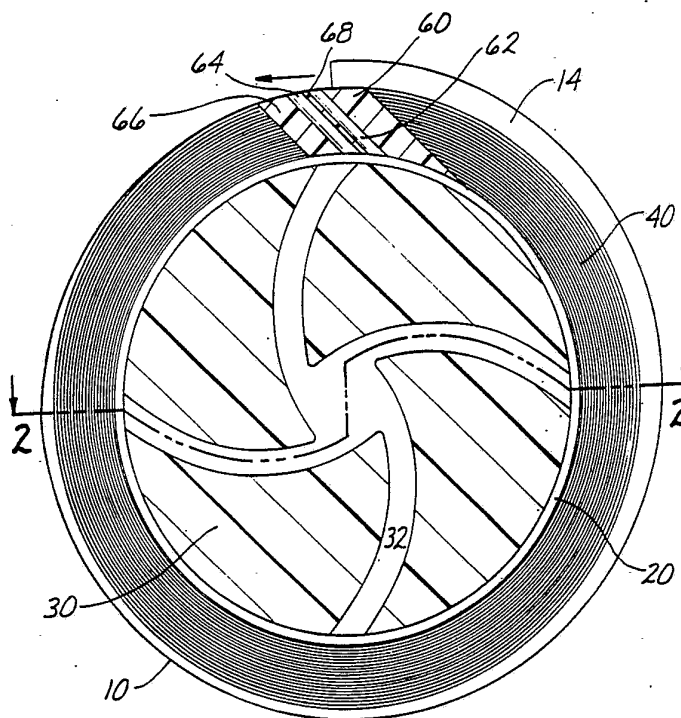




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 1/16	A2	(11) International Publication Number: WO 93/05828 (43) International Publication Date: 1 April 1993 (01.04.93)
(21) International Application Number: PCT/US92/07928 (22) International Filing Date: 18 September 1992 (18.09.92) (30) Priority data: 765,307 25 September 1991 (25.09.91) US (71)(72) Applicant and Inventor: MATHEWSON, Wilfred, F. [US/US]; 5420 Fairgreen Way, Bonsall, CA 92003 (US). (74) Agents: CANTER, Bruce, M. et al.; Baxter Healthcare Corporation, 2132 Michelson Drive, Irvine, CA 92715-1304 (US). (81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE).		Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: INTEGRATED CENTRIFUGAL PUMP AND MEMBRANE OXYGENATOR



(57) Abstract

A low priming volume integrated centrifugal pump and membrane oxygenator comprising a housing (10) containing a mass transfer bed (40) comprising gas permeable hollow membrane fibers (38) placed circumferentially in a ring around an impeller (30). The mass transfer bed (40) is formed by a multiple wrap of a fiber ribbon (42) comprising at least two layers of fibers (38) bonded in precise orientation with fibers in alternate layers positioned in line with the opening between fibers in the layers above and below. Adhesion means ensure precise orientation of the fibers (38). Priming volume is further reduced by a small impeller flow channel volume.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	MN	Mongolia
AU	Australia	FR	France	MR	Mauritania
BB	Barbados	GA	Gabon	MW	Malawi
BE	Belgium	GB	United Kingdom	NL	Netherlands
BF	Burkina Faso	GN	Guinea	NO	Norway
BG	Bulgaria	GR	Greece	NZ	New Zealand
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	PT	Portugal
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovak Republic
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CS	Czechoslovakia	LU	Luxembourg	SU	Soviet Union
CZ	Czech Republic	MC	Monaco	TD	Chad
DE	Germany	MG	Madagascar	TG	Togo
DK	Denmark	ML	Mali	UA	Ukraine
ES	Spain			US	United States of America

INTEGRATED CENTRIFUGAL PUMP AND MEMBRANE OXYGENATOR

FIELD OF THE INVENTION

The invention relates to extra corporeal device
5 technology for the support of patients during open heart
surgery and in emergency situations requiring
extracorporeal cardiopulmonary support. In particular, the
invention relates to new and useful improvements in
apparatus for the pumping and oxygenation of blood to
10 temporarily replace the cardiac and pulmonary functions of
a patient.

BACKGROUND OF THE INVENTION

During open heart surgery and in some emergency
15 cardiopulmonary situations, it is necessary to have some
means for pumping the blood and some means for oxygenating
the blood to replace or support the patient's
cardiopulmonary functions. Mechanical substitutes for
doing this can operate by taking blood from the patient's
20 venous system and oxygenating it by dispersing it over one
face of a membrane area and exposing the opposite face to
an atmosphere of pure or nearly pure oxygen. After the
blood absorbs oxygen in this environment, it is forced by
means of a pump into the arterial system of the patient.

25 Prior art extracorporeal device technology has used
individual devices for the functions of pumping blood and
oxygenating blood. For example, a pump would be used in
conjunction with an oxygenator. Typically, these devices
are connected together in an extracorporeal tubing loop to

receive venous blood from the patient and return arterial blood back to the patient. One of the problems with these types of devices, such as that shown in U.S. Patent No. 3,183,908, has been that large amounts of blood are
5 required to prime the oxygenator, the pump, and the tubing between the oxygenator and the pump.

Some attempts have been made to incorporate the pumping and oxygenation functions in a single device. For example, U.S. Patent No. 3,841,837 discloses a blood
10 oxygenator or dialyzer that achieves enhanced transfer through rotation of a cylindrically mounted membrane placed eccentrically inside a stator housing. Blood flows in the annular space between the rotor and the stator. Rotation causes a pumping action, thus causing pumping and
15 oxygenation to occur simultaneously. All of these prior art devices have required relatively large amounts of fluid to prime the pump and oxygenator. There have also been difficulties with the safety and ease of use by the perfusionist. Furthermore, these devices can be quite
20 costly to manufacture.

SUMMARY OF THE INVENTION

The present invention is directed to a low priming volume integrated centrifugal pump and membrane oxygenator
25 through which the blood is pumped then oxygenated. The integrated pump and oxygenator comprises a housing containing a mass transfer bed for oxygenating and an impeller for pumping. The fluid entering the housing is directed by the impeller through the mass transfer bed,

which is in the form of a fiber membrane ring surrounding the impeller. A gap is located between the impeller and ring to insure safe rotation of the impeller. The size or extent of the gap will depend upon the amount of secondary
5 flow desired to enhance oxygenation between the blood in the gap and the first fiber membrane layer or layers, while considering the added prime volume that occurs with increasing gap size.

The surface area requirements for mass transfer place
10 some design conditions on the height and diameter of the fiber membrane ring, which in turn, influences the design of the matching impeller. This could produce an unacceptably high prime volume if the impeller were designed in the conventional manner with relatively thin
15 vanes. This problem is overcome by use of an impeller with small volume flow channels in comparison with the total envelope volume of the impeller. The small impeller flow channel volume requires a greatly reduced priming volume and has the effect of reducing the amount of pump
20 turbulence.

The mass transfer bed comprises a ring of gas permeable hollow fibers running circumferentially around the impeller. This ring can be formed in any manner. A preferred embodiment is to create the fiber ring by using
25 a multiple wrap of a preformed fiber ribbon. This fiber ribbon can be constructed from at least two layers of fibers bonded together in precise orientation in an arrangement where the fibers in alternate layers are positioned in line with the opening between fibers in the

layers above or below. In a further embodiment, adhesive means can be used to achieve the precise orientation of the fibers in the ring.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic top plan view of the integrated centrifugal pump and membrane oxygenator of the present invention;

Fig. 2 is a sectional view taken on line 2-2 of Fig. 1;

10 Fig. 3 is an enlarged sectional view of a portion of one embodiment of the fiber tape used to make the mass transfer bed shown in Fig. 1;

15 Fig. 4 is an enlarged sectional view of a portion of another embodiment of the fiber tape used to make the mass transfer bed shown in Fig. 1; and

Fig. 5 is a graph depicting the discharge pressure/flow rate performance of the integrated pump and oxygenator of the present invention compared to another known pump.

20

DETAILED DESCRIPTION OF THE INVENTION

Referring to Figs. 1 and 2, the low priming volume integrated centrifugal pump and membrane oxygenator of the present invention comprises housing 10 containing impeller 30 surrounded by mass transfer bed 40. The top and bottom
25 of the mass transfer bed 40 are sealed to the upper and lower internal faces of housing 10. Fluid entering housing 10 through fluid inlet 12 is pumped by impeller 30 through mass transfer bed 40. In mass transfer bed 40 the fluid is oxygenated and the carbon dioxide is removed. The fluid is

then collected and discharged through a tapered exit manifold 14 located around the outer diameter of mass transfer bed 40.

The low priming volume of the integrated centrifugal pump and oxygenator of the present invention is a result of more than the mere housing integration of a pump and an oxygenator resulting from the reduction in the required manifolding and amount of tubing and connector priming volume. Priming volume is also reduced by other features of the present invention described below.

As shown in Fig. 1, impeller 30 has flow channels 32 that act to force the fluid through the mass transfer bed 40. As impeller 30 rotates, flow channels 32 deliver uniform radial flow to the mass transfer bed 40 in the course of its 360 degree rotation. This uniform radial flow enhances oxygenation by insuring that the mass transfer bed 40 is uniformly perfused with blood to be oxygenated. The rotation of the impeller 30 insures true and uniform radial flow over the entire circumference and height of the mass transfer bed 40. As the flow channel 32 passes a segment of the mass transfer bed 40, a local flow pulse is created followed by a quiescent period until the next flow channel 32 arrives. This pulse enhances mass transfer, in particular, oxygenation and carbon dioxide removal. Additionally, the rotation of impeller 30 causes fluid mixing to occur in the gap 20 between the outer diameter of the impeller 30 and the inner diameter of mass transfer bed 40. This fluid mixing has the effect of further enhancing mass transfer of the blood in the gap 20

and the first few layers of fibers 38 in mass transfer bed 40.

The flow channel volume of flow channels 32 is relatively small compared with the envelope of the impeller 30. This is direct contrast to conventional radial impellers for centrifugal pumps. Conventional centrifugal pumps generally operate in a region of higher flow rates for a given required delivery pressure. Typical impellers have thin vanes with wide flow channels between the vanes to keep the flow channel volume as close to the maximum volume available as possible to create high flow rates. However, in extracorporeal cardiopulmonary support, relatively low flow and high pressure is required. Thus the impeller diameter and RPM requirements are dictated more by delivery pressure than flow demands. The small flow channel volume of the present invention results in high fluid delivery pressures at adequate flow rates, and thus allows the priming volume to be reduced. Another effect of the small flow channel volume is reduced turbulence in the pumping portion of the integrated pump and oxygenator.

The volume of flow channels 32 should be of a size to permit relatively laminar flow of the fluid in the impeller 30 so as to control friction losses and to minimize blood damage. Preferably the flow channel volume is from about 5% to about 60% of the total envelope volume. More preferably the flow channel volume is less than 50% of the total envelope volume. Most preferably the flow channel volume is from about 5% to about 30% of the total envelope

volume. The flow channel volume can be altered by any means such as adjusting the size, shape and number of the flow channels.

Impeller 30 should be of a size sufficient to force
5 the fluid through the mass transfer bed 40 and to return it to the patient without the need for an external pump. Preferably, the impeller 30 has a diameter of from about 2 inches to about 6 inches. The pump, including impeller and housing, can be made from any inert material that will not
10 react with the blood or the oxygen. For example, the pump, impeller and housing may be molded from plastic materials such as polycarbonate and the like.

The mass transfer bed 40 of the integrated pump membrane oxygenator is where the oxygenation of the fluid takes
15 place. The mass transfer bed 40 is preferably in the form of a ring of gas permeable, hollow fibers where the fibers run circumferentially around the ring. The mass transfer bed 40 can be constructed by any suitable means. The simplest construction is a plain winding of fiber.
20 Alternatively, a fiber mat, such as the commercially available Enka™ fiber mat, could be used. Preferably, the mass transfer bed 40 is formed from a multiple wrap of a preformed fiber ribbon 42 such as that depicted in Figs. 3 and 4. The fibers in the mass transfer bed 40 are held in
25 position relative to one another by any suitable means such as adhesive points or filaments. The mass transfer bed 40 has a gas inlet header 60 and gas inlet manifold 62 to allow the passage of a second fluid, the oxygen gas, into the lumens 46 of the fibers 38. The second fluid exits the

lumens 46 by means of gas outlet manifold 64 and gas outlet header 66, while maintaining separation of the second fluid from the first fluid. Manifold partition 68 separated the gas inlet header 60 and gas inlet manifold 62 from gas outlet header 66 and gas outlet manifold 64.

The gas inlet and outlet headers 60 and 66 may be formed by any conventional means. In a preferred embodiment, the gas inlet and outlet headers are created by potting a region with a urethane, a modified UV curable urethane, epoxy, or hot melt adhesive. The center portion of the potted region is then removed to expose the lumens and allow passage of a second fluid through them. A manifold partition 68 is placed in the open center portion to separate the gas inlet header 60 and gas inlet manifold 62 from the gas outlet header 66 and the gas outlet manifold 64. The gas inlet manifold 62 and the gas outlet manifold 64 communicate with appropriate inlet and outlet connectors in the housing 10. The header boundaries are selected for optimal flow and may range between tangential and radial.

The mass transfer bed 40 operates to oxygenate the first fluid, the patient's blood, by means of the lumen 46 of each fiber 38. The lumens 46 deliver the second fluid, the oxygenating gas, to the membrane wall 44 of the fiber 38. This membrane wall 44 is permeable to gas but not liquid. When liquid flows around the exterior of the fibers 38, the gas in the lumens 46 diffuse through membrane wall 44 into the liquid, thus resulting in oxygenation of the liquid. At the same time, carbon dioxide may be removed from the liquid by allowing the

carbon dioxide in the liquid to diffuse through membrane wall 44 into lumens 46 where it exits the housing 10 by means of gas outlet manifold 64 with any unused oxygenating gas. The membrane wall 44 may be formed from any suitable material that permits the diffusion of oxygen and carbon dioxide while preventing the diffusion of the liquid. Some suitable materials include microporous polypropylene, polyethylene, silicone rubber and its derivatives.

The mass transfer bed 40 is of a sufficient size to permit it to be sealed to the upper and lower internal faces of housing 10. Preferably, the mass transfer bed 40 has a radial thickness ranging from about 1/10 inch to about 1 inch. The mass transfer bed 40 may be bonded to the housing 10 using conventional materials such as polyurethane, epoxy and the like.

Fiber ribbon 42 that makes up mass transfer bed 40 is formed from at least two layers of fibers 38 bonded together to form a ribbon of the appropriate height. The fibers 38 are spaced in an alternating arrangement as depicted in Figs. 3 and 4 so that the fibers in alternate layers are positioned in line with the opening between fibers in the layers above or below. Figs. 3 and 4 show only a portion of the fiber ribbon 42. This arrangement results good mixing of the blood between the layers. This precise orientation of the fibers 38 in the fiber ribbon 42 is achieved by fixing the fiber position with an adhesion means. The adhesion means may be in the form of point attachments 48 as depicted in Fig. 3 or in the form of adhesive filament 49 as shown in Fig. 4. Preferably the

lengthwise spacing pattern of these attachments 48 or filaments 49 is from about 0.050 inch to about 0.125 inch. Any conventional adhesive may be used such as an epoxy or a urethane or modified urethane cured by heat, catalyst or ultraviolet radiation. A hot melt adhesive may also be used. The use of such a precision orientation means allows optimum orientation of the fiber layers that simply cannot be achieved by use of single layer wraps.

For the simplicity of illustration, the fiber ribbon 42 is depicted schematically as a double layer ribbon in Figs. 3 and 4. The fiber ribbon 42 may consist of multiple layers. At least two layers should be used to ensure precise orientation of the fibers 38 relative to each other. Preferably, the fibers 38 used to construct fiber ribbon 42 have an outside diameter of from about 200 microns to about 600 microns and an inside diameter of from about 150 microns to about 500 microns. More preferably, the fibers 38 would have a uniform spacing, t , between the fibers of from about 25 microns to about 100 microns.

The fiber ribbon 42, because of the uniformly thin spacing between fibers, requires a significantly smaller priming volume than other known fiber membrane oxygenators. The thin uniform spacing t between the fibers 38 also results in highly efficient oxygenation, thus requiring less membrane surface area and thus less prime volume.

The fiber ribbon 42 is wound into a ring of appropriate thickness to fit into the housing 10 while allowing free rotation of impeller 30. Preferably, the height of the fiber ring 40 is about the height of the

impeller 30. Most preferably, the impeller 30 and fiber ring 40 have a height ranging from about 1/4 inch to about 2 inches.

As shown in Figs. 1 and 2, there is a gap 20 located between the outer edge of the impeller 30 and the innermost portion of fiber ring 42. The gap 20 is an open area that during operation is filled with the fluid to be oxygenated. Proper selection and control of gap 20 can result in enhancing oxygenation in the innermost layer or layers of the fiber ring 42. This is due to a secondary or eddy flow created in gap 20 by the tangential flow component created by impeller flow channel 32. Care must be taken to select a gap 20 of sufficient size to enhance oxygenation while making sure that gap 20 is not so large as to increase the priming volume required. Preferably gap 20 will be from about 0.010 inch to about 0.100 inch.

Preferably the gap 20 is a size that permits the creation of Taylor vortices in this region. Taylor vortices are a known hydrodynamic phenomena that appear in a viscous fluid when it is placed between an outer stationary cylinder and an inner rotating cylinder. As discussed by Schlichting in Boundary-Layer Theory 7th Ed., McGraw-Hill, 1979, instabilities in fluid flow between concentric cylinders where only the inner cylinder is in motion were first investigated by Lord Rayleigh, who performed calculations based on the assumption that the fluid was non-viscous. Taylor, using a framework of linear theory and considering viscous fluids, found that when a certain Taylor's number was exceeded, axially

circumferential vortices appear, which rotate in alternately opposite directions.

Taylor determined that there is a minimum condition for the establishment of such vortices, defined as the Taylor number (T_a). The Taylor number is dependent upon a number of factors and is defined as

$$T_a = \frac{\mu_{id}}{\nu} \sqrt{\frac{d}{R_i}} \geq 41.3$$

where d is the gap size, R_i is the radius of the inner rotating cylinder, ν is the kinematic viscosity of the fluid, and μ_{id} is the peripheral velocity of the inner rotating cylinder.

Taylor and others determined that turbulence would ensue if the Reynolds number (R_a) rose above about 1000. The Reynolds number is defined as

$$R_a = \frac{\omega (zd)}{\nu}$$

where ω is the axial velocity. More particularly, those skilled in hydrodynamics will appreciate that a time average velocity profile of fluid flow will generate a smooth curve, but an instantaneous velocity profile is very ragged. Thus, the Taylor vortices may be characterized as "main flow", but there will be a turbulent component of this, and as T_a rises, this instantaneous turbulent velocity will ultimately become more important.

Taylor vortices first will develop when the gap is in the range of from 0.010 to 0.020 inches depending on the speed and diameter of the impeller and the viscosity of the fluid. The Taylor number increases with increasing gap
5 dimension. As the gap increases beyond the desired range, the Taylor vortices will be replaced by turbulence which has the unwanted effect of increasing blood damage and increasing prime volume.

In operation, the blood fluid from the patient is
10 directed with a cannula and tubing into flow inlet 12 of housing 10 so that the integrated pump and oxygenator is completely filled with fluid 40. No bubbles or air should be present. The fluid flows onto impeller 30, which is driven by drive shaft 18 causing the incoming fluid to flow
15 radially through flow channels 32. Drive shaft 18 may be driven by any conventional means. For example, a variable speed motor can be connected to the drive shaft. Alternatively, a sealed pump could be used such as that constructed by embedding magnets in the impeller and driven
20 by external magnets. The fluid from flow channels 32 is directed into gap 20 located between the outer edge of the impeller 30 and the innermost portion of mass transfer bed 40 creating a secondary or eddy flow by the tangential flow component coming from the impeller flow channel 32. The
25 net flow from impeller 30 is forced through mass transfer bed 40 where it comes in contact with the fibers 38. An oxygenating fluid is directed into gas inlet header 60 and gas inlet manifold 62 where it then enters lumens 46 of fibers 38. The fibers 38, which are made of a gas

permeable material, allow oxygen to flow through the fiber membrane wall 44 and into the blood, thus oxygenating it. The remainder of the oxygenating fluid is removed at the gas outlet header 66 and the gas outlet manifold 64.

5 Carbon dioxide may be removed by diffusing through the membrane wall 44 into lumen 46 where is removed through gas outlet header 66 and gas outlet manifold 64 with remaining oxygenating fluid. After the blood is oxygenated, it exits housing 10 at exit manifold 14 where it is then returned to

10 the patient.

The incoming flow rate to the integrated pump and membrane oxygenator of the present invention is determined by the patient's requirements for oxygenation and pumping. Preferably, the flow rates would range from about 1/2 liter

15 to about 8 liters per minute depending on patient size, with required discharge pressures not greater than about 500 mm Hg.

Utility of the invention is illustrated by the following specific examples.

20 An engineering model of the integrated pump and membrane oxygenator of the present invention was constructed to test the fluid dynamics. The inside of the housing was 6 inches in diameter and 1 1/2 inches high. The impeller had 4 grooved flow channels and was powered by means of a

25 drillpress motor. The engineering model had a ring constructed of screen material to simulate the fluid mechanics of a membrane bed. The screen material was about 1.5 inches high and 0.75 inches thick and was sealed against the upper and lower housing. Fluid was fed to the

housing inlet from a reservoir. The fluid pressure was measured by bordon tube pressure gauge and the flow was measured by timing the delivery of a specific quantity of fluid (water). The results are shown in Fig. 5.

5 The integrated pump membrane oxygenator of the present invention can be used for partial cardiopulmonary support in emergency situations or for total bypass in the operating room. Where the integrated pump membrane oxygenator is used for partial cardiopulmonary support, it
10 is not necessary to have a reservoir of heat exchanger. A small compliant section, which may be in the form of tubing, between the patient and the pump can be used to monitor the pressure of the fluid to control the speed of the pump motor as necessary. Modest heating and cooling of
15 blood can be accomplished by heating and cooling of the gas supply to the oxygenator. For total support, such as in the operating room, it is preferable to have a reservoir and good heat exchanger. This may be in the form of a combination/modular unit to be put on top of the integrated
20 pump membrane oxygenator when needed.

Since this integration eliminates high pressure connections between pump and oxygenator, the safe use of extracorporeal circulation is greatly improved. Furthermore, the present invention eases the burden of the
25 perfusionist through faster and easier setup, and easier priming and debubbling. And the cost benefit to the manufacturer, over separate pump and oxygenator units, is significant.

While the preferred embodiments of my invention have here been shown and described, it is to be understood that I do not limit myself to the precise construction herein disclosed and that various changes and modifications may be
5 made within the scope of the invention as defined in the appended claims.

CLAIMS

I claim:

1. A low priming volume integrated centrifugal pump and membrane oxygenator for pumping and oxygenating blood of a patient during open heart surgery or other emergency situations, said integrated pump and oxygenator comprising:
 - a housing, said housing containing a first fluid inlet, a first fluid exit, a second fluid inlet and a second fluid exit;
 - an impeller located in said housing, said impeller further comprising means for rotation;
 - a mass transfer bed located in said housing and surrounding said impeller, said mass transfer bed comprising a ring of hollow gas permeable membrane fibers running circumferentially around said impeller;wherein a fluid to be oxygenated is introduced into said housing by means of said first fluid inlet, is pumped by said impeller through said mass transfer bed and exits said housing by means of said first fluid exit, and an oxygenating fluid is directed through said second fluid inlet into the center of said hollow gas permeable membrane fibers and exits through said second fluid exit.
2. The integrated centrifugal pump and membrane oxygenator of claim 1 wherein said mass transfer bed is formed from a multiple wrap of a fiber ribbon.

3. The integrated centrifugal pump and membrane oxygenator of claim 2 wherein said fiber ribbon comprises at least two layers of fibers bonded together in an alternating arrangement.

5

4. The integrated centrifugal pump and membrane oxygenator of claim 3 wherein said layers of fibers are bonded together by adhesive point attachment means.

10

5. The integrated centrifugal pump and membrane oxygenator of claim 3 wherein said layers of fiber are bonded together by adhesive filament means.

15

6. An impeller for a low priming volume centrifugal pump, wherein said impeller has small flow channel volume relative to the total impeller envelope volume available.

20

7. The impeller of claim 6 wherein said flow channel volume is about 5% to about 60% of the total impeller envelope volume available.

25

8. The impeller of claim 7 wherein said flow channel volume is less than about 50% of the total impeller envelope volume available.

9. The impeller of claim 8 wherein said flow channel volume is less than about 30% of the total impeller envelope volume available.

10. A mass transfer bed comprising a ring of gas permeable, hollow fibers running circumferentially around said ring wherein said ring comprises a multiple wrap of fiber ribbon, said fiber ribbon comprising at least two
5 layers of fibers bonded together in an alternating arrangement.

11. The mass transfer bed of claim 10 wherein said fiber ring further comprises a potted region, said potted region
10 comprising a header to allow passage of second fluid through lumens of the fibers while maintaining separation of the second fluid from the first fluid.

12. A fiber ribbon constructed by bonding at least two
15 layers of fibers in an alternating arrangement so that the fibers in alternate layers are positioned in line with the opening between fibers in the layers above or below.

13. The fiber ribbon of claim 12 further comprising
20 precision orientation means for positioning said fibers in said alternating arrangement.

14. The fiber ribbon of claim 10 wherein the precision
orientation means comprises an adhesive bead or filament.
25

15. A fiber ribbon for a membrane oxygenator wherein said fiber ribbon comprises at least two layers of fibers positioned so that the fibers in alternate layers are

positioned in line with the opening between fibers in the layers above and below.

16. A method for making a mass transfer bed for a
5 membrane oxygenator, said mass transfer bed comprising a ring of fibers having a means for a fluid to be oxygenated to flow on the exterior of the fibers and the oxygenating gas to flow in the interior of the fibers, said method comprising:

- 10 forming a fiber ribbon by bonding at least two fiber layers in an alternating arrangement so that the fibers in alternate layers are positioned in line with the opening between fibers in the layers above and below;
- forming a fiber ring by making multiple wraps of said
15 fiber ribbon in a ring shaped form;
- potting a portion of said fiber ring;
- removing a part of said potted portion so as to expose the interior of said fibers to allow passage of an oxygenating gas therethrough; and
- 20 installing a header means to separate the fluid to be oxygenated from the oxygenating gas.

2/4

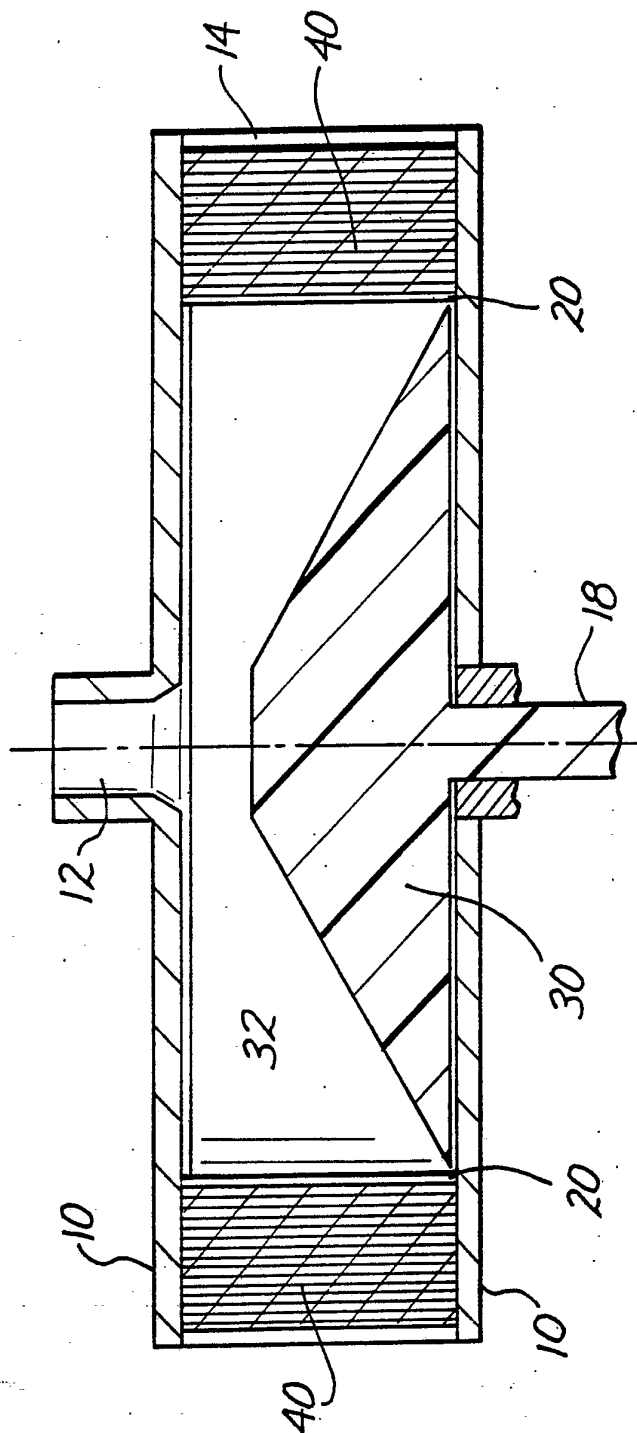


Fig. 2

3/4

Fig. 3

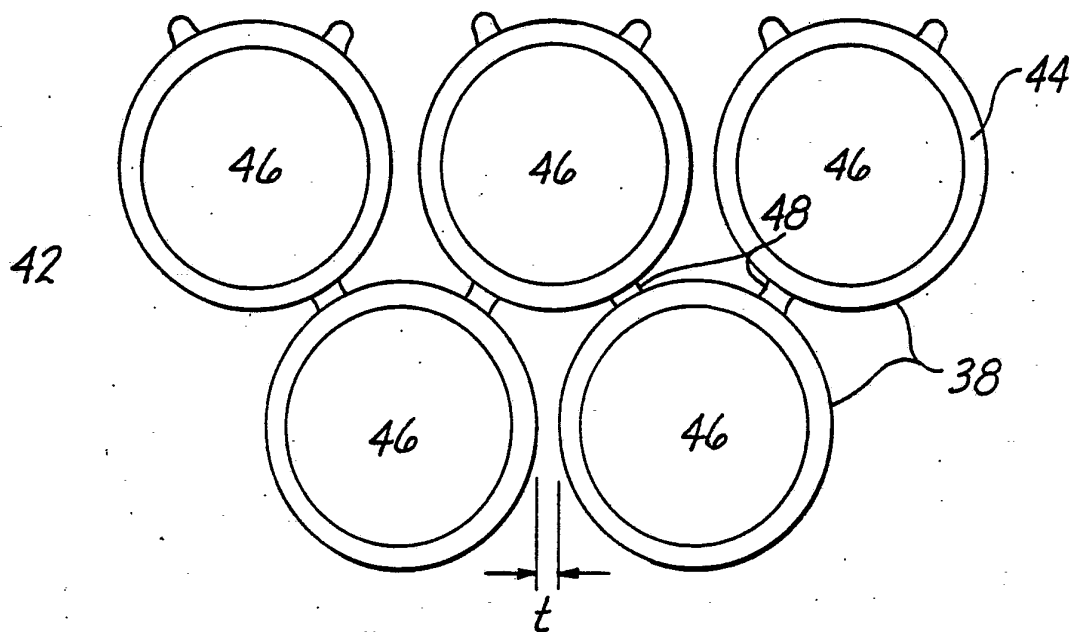
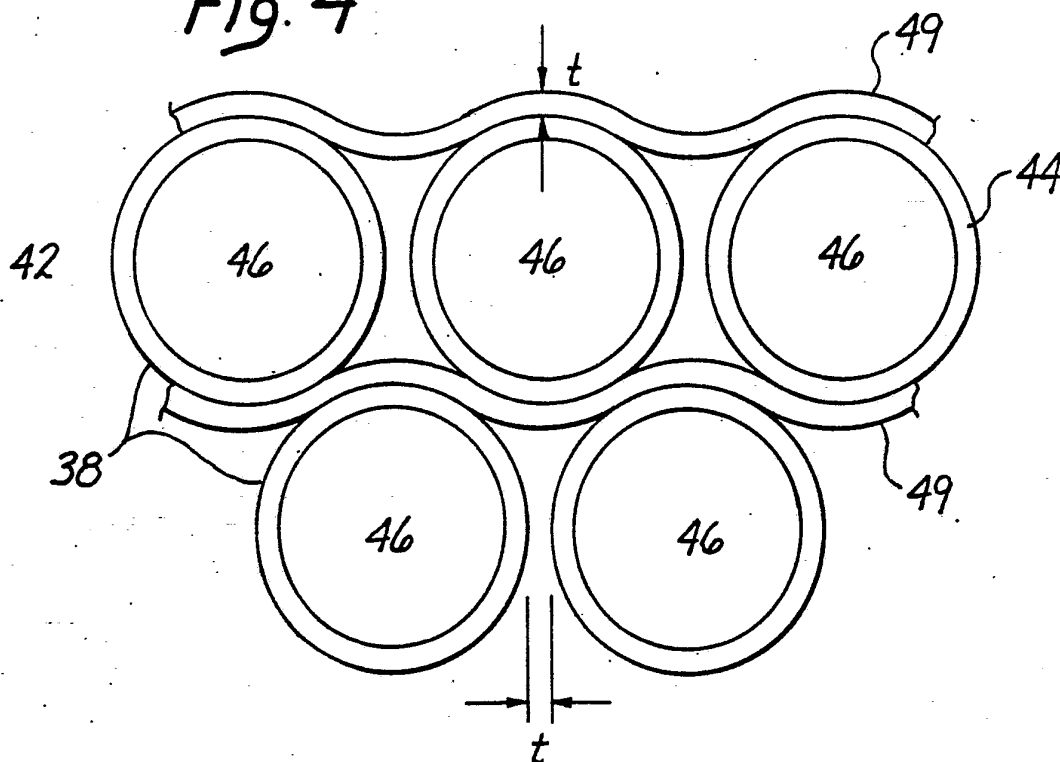


Fig. 4



4/4

PERFORMANCE OF PUMP/MEMBRANE
OXYGENATOR ENGINEERING MODEL

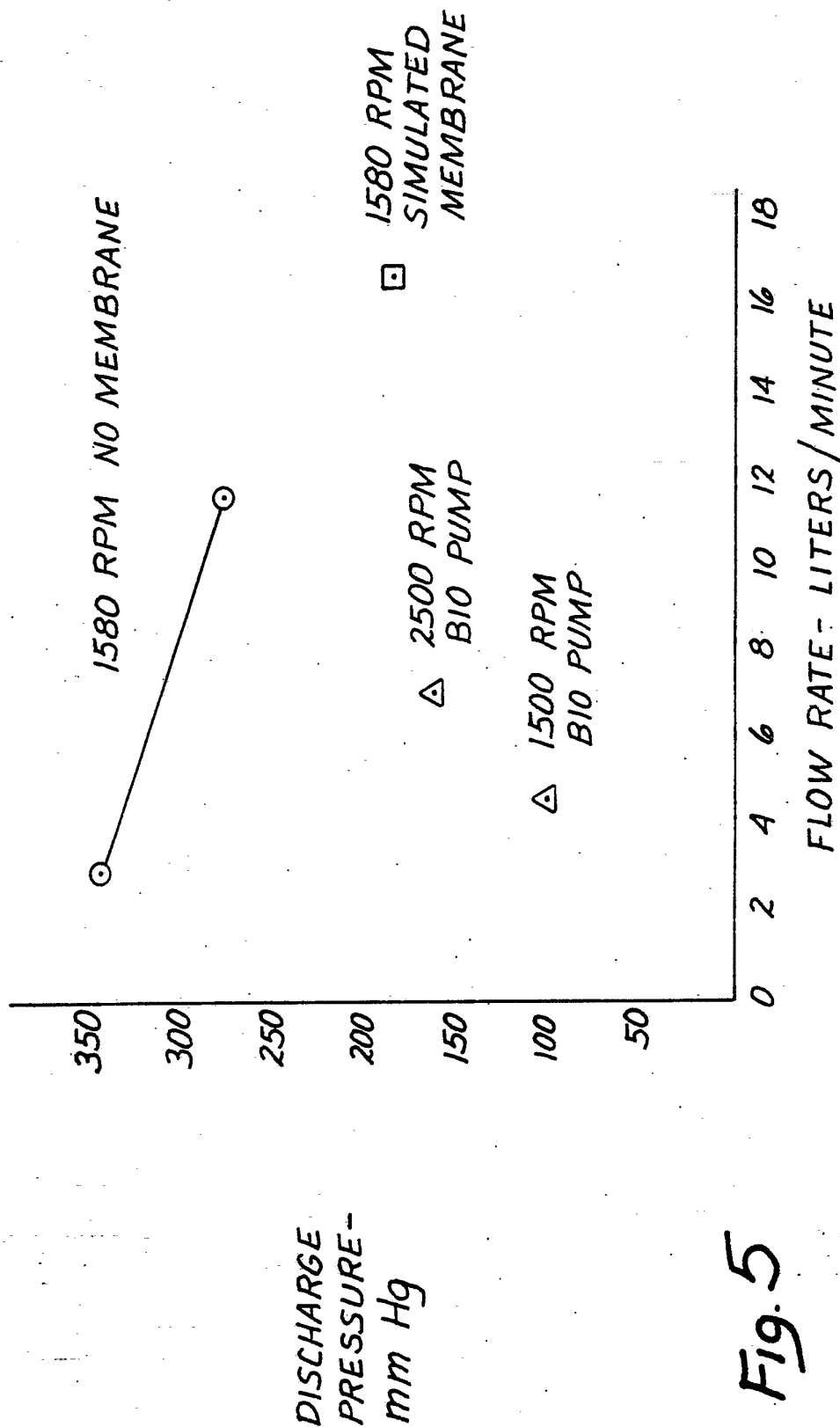


Fig. 5