A device (10) having a blood oxygenator (12) and heat exchanger (14) of the outside perfusion type. The blood oxygenator (12) employs a tightly packed, crisscrossing bundle of gas permeable hollow fibers (50). The heat exchanger (14) employs a bundle of polyurethane, liquid impermeable hollow tubes (96). A center divider (16) facilitates two separate compartments (30, 40) and allows control over pack densities within each compartment while allowing blood to move in a planar manner throughout the device (10).
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OXYGENATOR WEDGE CONFIGURATION

Field of the Invention

This invention relates to a blood oxygenator of
the outside perfusion type using hollow-fiber membranes
and to blood oxygenators having coextensive integral heat
exchanging units.
More particularly, the invention relates to an improved
apparatus and method of winding hollow fibers into a
blood oxygenator unit.

Description of the Prior Art

Blood Oxygenator

In known blood oxygenators, hollow fibers are
used as a means to bring blood into contact with oxygen
and provide a means for removal of carbon dioxide from
the blood. For simplicity, such gas exchange will be
referred to herein with regards to the oxygenation only,
it being understood that transfer of oxygen into and
carbon dioxide out of the blood is taking place. The
fibers are typically made of a homogeneous membrane of
gas-permeable material such as silicone or of hollow
fibers made of a microporous membrane of hydrophobic
polymeric material such as polyolefins.

There are two types of hollow fiber blood
oxygenators: the inside perfusion type in which blood is
passed through the bores of the hollow fibers while
oxygen is passed on the outside of the hollow fibers and
the outside perfusion type. Blood oxygenators of the
outside perfusion type pass oxygen through the bores of
the hollow fibers while blood is flowed past the outside
of the hollow fibers.

In blood oxygenators of the inside perfusion
type, no channeling of the blood occurs provided the
blood is uniformly distributed and fed to the interior of
the large number of hollow fibers involved. However, since the blood flowing through the bores of the hollow fibers moves in a virtually perfect laminar flow, the internal diameter of the hollow fibers needs to be reduced to a small diameter in order to increase the oxygenation rate (i.e., the oxygen transfer rate per unit volume of blood per unit area of membrane).

The laminar flow phenomenon of the blood passing through the hollow fibers presents many problems even when very fine hollow fibers are used. The result is that the oxygenation rate of a blood oxygenator of the inside perfusion type is not as beneficial as might be expected. Effectiveness of oxygen transfer is in part determined by the surface area contact of the blood with hollow fiber. Obviously, a much larger surface area contact results when blood is on the outside of the hollow fiber than when the blood is internal to the fiber.

If the oxygen is not distributed uniformly into the blood, the carbon dioxide desorption rate from the blood (i.e., the carbon dioxide transfer rate out of the blood per unit volume of blood per unit area of membrane) will be reduced.

In the common configuration for inside perfusion blood oxygenators, a cylindrical housing is simply packed with a large number of hollow fibers for gas exchange arranged so that the hollow fibers are parallel to the longitudinal axis of the cylindrical housing. Blood oxygenators of this construction have lower than desired gas exchange rate per unit area of the hollow fiber membrane.
In contrast, in blood oxygenators of the outside perfusion type the oxygen can be distributed uniformly through the spaces between adjacent fibers and the blood can be expected to move with better mixing. However, outside perfusion has had the disadvantage of being subject to less than the desired oxygenation of the blood because of regional channeling of the blood as it passes transversely to the outsides of the hollow fibers.

The known outside perfusion type blood oxygenators in which the hollow fibers are in perpendicular orientation to the direction of blood flow produces more mixing of the blood as the blood flows than inside perfusion constructions. This arrangement can bring about an improvement in oxygenation rate, as compared with those inside perfusion types or construction in which the hollow fibers are arranged to have their length parallel to the direction of blood flow. However, if the number of fibers used in such a blood oxygenator is large (as is desirable) and/or the flow rate of blood is increased in order to treat large volumes of blood, problems arise. For example, unacceptable pressure drop of the blood between inlet and outlets and/or channeling of the blood between groups of fibers may occur. By channeling it is to be understood that a significant flow of blood takes place through relatively large area voids between fibers so that there is little or no mixing. As the rate of oxygen transfer primarily takes place in a thin boundary layer adjacent the hollow fibers, the effectiveness of desired oxygenation is reduced.

Blood-side convective mixing is essential for efficient gas transfer in blood oxygenators. Without such mixing, sharply defined boundary layers of fully
oxygenated blood develop near the exchange surfaces and the fluxes of oxygen and carbon dioxide tend to be low. Low transport efficiency results in bulky devices with undesirably high blood priming volumes.

Other investigators have proposed constructions in attempts to reduce these problems. In United States to Takemura, Pat. No. 4,639,353, an oxygenator is shown in which a plurality of contact chambers are utilized each being limited in thickness as an attempt to discourage the undesired channeling.

Heat Exchanger

In prior art heat exchangers for blood oxygenator systems, the heat exchanger is typically made of a metal such as stainless steel tubing. Such materials are not as blood compatible as desired. Others have used polyethylene or polypropylene hollow fiber bundles in heat exchangers. However, potting compounds are less certain of seal than is desired. It is mandatory that there be no leakage of the cooling fluid used in the heat exchanger to the blood. If water or other heat exchange medium were to leak into the blood being treated, the impact to the patient could be serious.

Summary of the Invention

The present invention provides blood oxygenators of the outside perfusion type having high oxygen transfer rates, high carbon dioxide transfer rates, efficient heat exchange, and a construction which results in little or no stagnation of blood. Channeling of the blood is minimized. The devices of the invention provide very good oxygenation performance. As compared to prior devices having equal fiber surface area, the devices of the present invention provide superior
oxygenation. Thus, a desired oxygenation rate may be achieved while using less total quantities of the costly fibers.

When coupled with the heat exchanger of the invention, the unitary device results in a highly compact blood oxygenator capable of giving the needed gas transfer and temperature control. A further advantage of the construction of the invention lies in the parallel plane construction of the oxygenator and heat exchanger sections coupled with a means to have an uninterrupted, substantially planar flow pattern of blood transverse to both the oxygenator and heat exchanger without an interruption.

The heat exchanger is of an outside perfusion type construction utilizing a bundle of polyurethane hollow tubes. The large surface area provided for contact with the blood provides a very effective heat exchanger of the compact size even though polyurethane tube have a low heat transfer coefficient compared to stainless steel. Polyurethane hollow tubes, unlike the polyolefin heat exchange fiber materials previously used, are completely compatible with urethane potting compounds used to encapsulate the ends of both the oxygenator hollow fibers and of the heat exchanger hollow tubes. Therefore, the heat exchanger built in accordance with this invention substantially removes the possibility of leakage at the hollow fiber and hollow tube end potting interface. Such a possibility of leakage exists in the prior art.

The combination of oxygenator and heat exchanger provides an oxygenator which, as designed, meets the Draft Standard For Blood/Gas Exchange Devices (Oxygenators) of the Association for the Advancement of
Medical Instrumentation, February 1982 Revision.
(Commonly referred to in the industry as the A.A.M.I.
Standards).

The devices of the invention are arranged and
designed to be relatively simple to construct, thereby
lowering costs of manufacture over known prior art units.

According to the present invention, there is
provided a device comprising a blood oxygenator and an
integral heat exchanger. A housing divider-diffuser
plate with perforations separates the blood oxygenator
hollow fiber bundle from the heat exchange hollow tube
bundle. Access means are provided so that blood enters
the heat exchanger section through a port which opens
into a first chamber extending coextensive with the
length and width of the heat exchange hollow tube bundle.
Blood entering the first chamber passes through a first
perforated diffuser plate which acts to distribute blood
evenly over the surface of the heat exchange hollow tubes
and across the depth of the bundle of tubes.

The heated or cooled blood is then distributed,
without being recollected to a bulk quantity, to a
oxygenator bundle of hollow fibers by passage through the
housing divider diffuser plate. The oxygenator bundle of
hollow fibers consists of tightly packed hollow fibers.
The fiber and the tube ends are all potted in potting
compound in a single step at each end such that each
fiber and tube extends between end potting blocks.
Strong mixing of the blood is induced on the blood side
of the fibers by the tortuous path that the blood must
take in flowing past the fibers of the bundle.

The hollow fibers are laid into the device such
that the fibers cross over each immediately previously
laid adjacent fiber at an angle of between about 8 and
about 25 degrees. At the completion of laying down one
full layer of fibers across the housing-divider diffuser
plate, the pattern of laying down is shifted slightly out
of phase such that the next layer of fibers cross the
previously laid fibers adjacent fibers at a 8 to 25
degree angle but are shifted from the underlying layer.
This creates a relatively even pack density throughout
the bundle, increases the tortuous blood path and
therefore substantially reduces areas where shunting and
channeling may occur. However, in the preferred form of
the present invention, the hollow fibers for the
oxygenator portion are laid down on a specially
configured H-shaped member to further reduce the
possibility of undesired channeling.

The preferred angling of the fibers is at
angles of about 9 from the sides of the housing. A pack
density of about 50-55% of the available cross-sectional
area at the midpoint has been found to minimize
channeling and shunting without causing an unacceptable
pressure drop. A lower packing density may be used
within the potted ends of the fibers to facilitate fiber
end encapsulation. A substantial drop in oxygen transfer
is observed at a density of 45%. Channeling of blood
flow is found in devices packed at less than about 40%.
When the pack density is greater than about 55% the blood
pressure drop between entering and leaving rises to
unacceptable levels.

Blood, after traversing the oxygenation fibers,
exits the oxygenating bundle through a second perforated
diffuser plate while retaining its generally planar flow.
The blood then passes out of the housing through an
outlet which may open transversely to the length of the
oxygenator fibers. Both of the perforated diffuser plates are spaced from the exterior housing and provide support to the fiber and heat exchanger bundles.

The required packing density of the oxygenator fibers and heat exchange tubes may be easily maintained by virtue of the three diffuser plates. By the special configurations of the present invention, improvements in several respects are provided over the use of simple rectangular, cross-sectional regions for laying down the hollow fibers. The diffuser plates with the chamber and cover define a predetermined rigid cross-sectional area for the fibers and tubes.

The device is very compact which is an important feature of efficient oxygenators. The compactness may be achieved with a minimum of parts and manufacturing steps.

**Brief Description of the Drawings**

The detailed description of the invention, including its preferred embodiment, is hereinafter described with specific reference being made to the drawings in which:

- Figure 1 is an exploded pictorial view of the device of the invention;
- Figure 2 is a perspective view of the unexploded device of Figure 1 from the reverse side;
- Figure 3 is a cross-section taken along line 3-3 of Figure 2;
- Figure 4 is a top plan view of the device of Figure 2 with portions cut away to show the oxygenator fibers and diffuser plate;
- Figure 5 is a side plan of the device of Figure 2;
Figure 6 is a front plan view of the device of Figure 2;
Figure 7 is a photographic view of a partial first layer of oxygenation fibers within a core;
Figure 8 is a partial cross-section taken along line 8-8 of Figure 2.
Figure 9 is a cross-sectional view of the preferred form of the invention in cross-section showing the use of shaping members to produce the desired packing density;
Figure 10 is a perspective view of an insert member for use in the providing of a shaping, and Figure 11 is a cross-sectional view on lines 11-11 of Figure 10.

**Detailed Description of the Invention**

The device generally marked 10 of Figures 1-6 comprises an oxygenation section 12 and a heat exchanger section 14 which are separated by a common center divider 16. Preferably, the casing and divider elements are formed from biocompatible plastics capable of hermetically being bonded by potting compounds of the urethane type.

Device 10 includes an elongated rigid core member 20 of generally H-shaped cross-section which defines an upper channel shaped region 30 and lower channel shaped region 40. Each channel region is a longitudinally extending groove in the core member. Center divider 16 forms the web between the outside legs 42, 44 of the H of the core member 20.
Oxygenator section 12 includes the area defined by upper channel 30. Channel 30 is filled with hollow fibers 50 arranged longitudinally such that the hollow fibers generally are oriented in the direction roughly parallel to the legs 42, 44.

Each of the hollow fibers 50 is a membrane designed for gas exchange. Each hollow fiber may comprise a porous resin capable of gas transfer such as polypropylene, polyethylene or other biocompatible suitable material which provides a gas exchange. The fibers are liquid impermeable. Suitable fibers for this purpose are well known and commercially available from a number of vendors including Mitsubishi Rayon Co., Ltd. of Tokyo, Japan and Celanese Chemical Co. of New York, New York.

A diffuser plate 60 as shown in Figures 1, 3, and 4 covers the upper layer of hollow fibers 50 and is attached to legs 42, 44 along its side edges. Diffuser plate 60 includes a plurality of orifices 62 which are spaced throughout the plate 60. Orifices 62 allow the passage of blood through plate 60 from within the upper channel shaped region 30. The plates adjacent the fibers are constructed such that each orifice border is chamfered to minimize sharp edges which might damage the hollow fibers.

The diffuser plate 60 bears against the hollow fiber bundle 64 within upper channel 30. The plate 60 assists in holding the hollow fibers at the desired pack density of fibers per unit area within the region 30. It is assisted in that purpose by cover 70. The orifices in plate 60 allow blood to pass through the bundle 64 from the plate 20 in a substantially planar manner. This provides optimum exposure of the blood to fiber surfaces.
and minimizes the pressure drop across the unit. It also aids in eliminating potential areas of stagnation which decreases efficiency and might give rise to clotting.

Orifices 62 (and 102, 140 described below) are preferably no greater than 1/2 inches (1.27cm) and preferably about 3/8 inches in diameter. Larger diameter orifices reduce the ability of the plate to provide pack density control and will allow the fibers to bulge into the orifices thereby potentially creating void spots in the fiber bundle therebelow. Another disadvantage in fibers bulging into the orifices is that pinching to close a fiber might occur.

An advantage in providing large diameter orifices of the preferred size is that the amount of plate surface area blocking fibers from gas exchange is reduced. By minimizing such fiber-plate contact area the overall efficiency of the device is improved. The number of orifices should, therefore, be maximized at the preferred size so long as the outlet plate and cover 70 remains sufficiently rigid to provide pack density control.

An outer cover member 70 further encloses the hollow fiber bundle as shown in Figures 1, 2, and 4. Cover 70 includes a blood outlet port 72 which preferably extends perpendicularly to the fibers across substantially the entire bundle as shown. Preferably, cover 70 also includes a vent port 74, temperature probe port 76 and a sample port 78. Sample port 78 may include a check valve/breather valve which allows a sample to be withdrawn without introducing air into chamber 80. As shown, cover member 70 defines a chamber 80 above diffuser plate 60. The spacing between outer cover 70 and diffuser plate 60 is provided for by spacer nodes 82.
and maintained in part due to the rigidity of diffuser plate 60. However, the force of maintaining the pack density of the fibers toward the diffuser plate tends to deform the highly perforated plate toward the cover. Therefore, a plurality of spacer nodes 82 are provided between the cover and outer plate as shown in Figures 1 and 3 to further stiffen diffuser plate 60 so as to maintain pack density while providing superior diffusion. Cover 70 is preferably provided with a grid of outer ribs to give it greater rigidity, as shown in the Figures. Because of blood pressure there is a tendency for Cover 70 and plate 60 to bow and thereby reduce packing density. Ribs 71 remove this tendency.

The packing density of hollow fiber bundle 64 is specified by the following formula:

packing density = \[ P(\%) = \left(\frac{d}{2}\right)^2 \frac{n}{ab \times 100} \]

Where "d" represents the outer diameter of the hollow fibers, "n" the number of hollow fibers enclosed within the housing, "a" the inner width of the housing and "b" the inner height of the housing between the diffuser plate 60 and center divider 16.

The preferred packing density is between about 50 and 55%. Pack densities below about 45% at this winding angle show a substantial drop in performance and densities as low as 40% will result in channeling of blood. Pack densities of only 40% at this winding angle often exhibited visible channels through which blood is preferentially shunted. Such shunting prevents that blood from being fully oxygenated and carbon dioxide removal is also decreased. If shunting is of a significant portion of the blood, stagnation of the
slower flowing blood is more likely. The preferred pack density described above will change with differences of fiber diameter and winding angle. This will be readily determined empirically by testing the angle of winding for pack density of various size fibers.

As shown in Graph 1 entitled "Outlet \( pO_2 \) vs. Pack Density," in order to obtain a blood outlet oxygen partial pressure of at least 200 mm Hg the pack density should be between about 50 and 55 percent. These results are for fibers and winding angles as described above.
Graph 2, entitled "Pressure Drop vs. Pack Density," shows that the pressure drop through the oxygenator bundle at a pack density between 50 and 55 percent is less than 150 mm Hg. Again these results are for fibers and winding angles as described above.
The hollow fibers within the oxygenator section are preferably laid in single fiber or in groups of fibers such that successive single fiber or group of fibers are laid at an angle to the previous fiber or group of fibers. After one complete layer is laid into upper channel 30, the pattern is shifted slightly. Each successive layer is laid such that the fibers within the layer cross each other as above. Each layer is slightly shifted in phase from the next. The overall effect is that a very uniform pack density is possible and channels are virtually eliminated. Figure 7 shows an incomplete first layer to illustrate the angles between each successive of another layer of fiber. The crossing fiber arrangement is preferable over parallel fiber packing since it forces the blood into effective, but gentle, transverse mixing without traumatizing the blood. Straight, uncrossed fibers packed to a 50 – 55% density may result in some shunting of blood and provide less mixing and therefore, less oxygen transfer.

One method of obtaining the preferred criss-crossing arrangement of fibers is to wind fibers into the oxygenator section of a plurality of cores 20 which are arranged around the periphery of a polygonal wheel. For example, such apparatus and procedures are described in U.S. patents 4,267,630, 4,276,687, 4,341,005 and 4,343,668. A reciprocating fiber guide assembly controls the angle that the fibers are laid into the cores while the wheel rotates. An optimum angle is about 9 measured between the fiber and edge of a core leg 42 or 44. Steeper angles create lower pack densities. Lower angles create higher pack densities.
During the winding process it is desirable to maintain an "as wound" pack density close to the desired finished pack density. Winding the fibers at a density substantially less than the finished density allows the fibers to move so that the center will have significant amount of undesired air space creating channels. Winding fibers in at a higher pack density than the finished density can create a void space between the top layer of fibers and the diffuser plate 60. As the bundles are removed from the winding wheel, the fibers can randomly move to fill the void space, again jeopardizing the precise spacings of the fiber layers.

The oxygenator diffuser plate 60 is then placed on top of the core and the fibers are cut with a knife. The perforated plate 60 is tacked onto legs 40, 42 such as by ultrasonic weld points 68. Plate 60 thereby holds the pack density at the desired value while allowing fluid to flow in the planar manner described previously. The fiber ends may be melted shut or otherwise sealed prior to end potting. The cores are then removed from the wheel for assembly of the outer jackets.

The currently preferred method is to wind the fibers onto a hexagonal wheel to which six cores 20 are attached such that the upper channel 30 may receive fiber windings. The actuator has a linear speed of 7.2432 inches per second and the wheel has a rotational speed of 50.25 rpm. The linear acceleration at reciprocating points is 147 inches per second. The winding width of upper channel 30 is 5.75 inches and the angle between fibers is 18.30 degrees. Each layer consists of 184 turns of the wheel. A 0.020 second linear actuator pause is made between each layer to slightly offset each layer.
After the required number of winds have been made, a side potting compound 84 is introduced along the contact of the hollow fibers and the face of legs 42, 44 of the core 20. Due to the winding angles employed, the packing density at the center of the contact face tends to be lower than desired and channeling is possible. Therefore, a urethane potting compound is introduced as a bead projecting several fibers deep along the contact edge to eliminate possible channels. An acceptable urethane side potting compound is available from Caschem, Inc. of Bayonne, N.J. and has a viscosity of about 90,000 cps, marketed as Vorite® 689 and Polycin® 943.

In the preferred form of the invention, using a potting compound in the manner described immediately above, is avoided. It has found that the use of a potting compound introduces variables that may adversely effect the entire product and does not necessarily accomplish the intended purposes of avoiding channeling as well as is desired. To overcome the potential drawbacks in using a potting system, the preferred form of the invention makes use of a construction as is shown in cross-section in Fig. 9. There it will be seen that insert members 84A either precast as part of the original "H" or alternately formed members that are prebonded to the vertical legs of the "H" have been placed into position as shown. By the use of such members, the winding as illustrated in Fig. 7 and Fig. 1 has a means for insuring a compacting adjacent the opposite edges of the channel in which the fibers are laid. This in effect provides less space in those edge regions than in the center of the channel, thereby bringing about the desired compacting without the necessity for using a potting compound. It will be readily apparent from Figure 7 that
due to the criss-crossing in winding there is a region
adjacent each leg or wall that has less density of fiber
if a simple rectangular trough is used.

As illustrated in Fig. 9 a generally triangular
configuration may be used for the leg or wall. Dependent
upon the amount of angle in the criss-crossing to produce
the oxygenation portion of the apparatus, one can
advantageously change the shape of the hypotenuse to
reflect a bulging area 84B as illustrated in Figs. 10 and
11 in any of a wide variety of configurations as dictated
by the winding configuration. Thus, one is able to
obtain the desired packing density and substantial
freedom from channeling as has been previously described
with respect to the use of a potting compound. This is
accomplished without the problem associated with use of
potting compounds.

Many configurations of the leg portion can be
utilized in accomplishing the advantages of the
invention. In essence, the cross-sectional profile of
channel 30 is modified to be incrementally smaller near
the legs than throughout the major part of the channel.

The need to avoid channeling is less severe in
the heat exchanger portion of the apparatus although,
even in this instance, the use of an insert member 132
preattached to the facing 120 can be advantageously
utilized to insure that with the desired number of winds
of heat exchange hollow tube, that a predetermined
packing density is also achieved with less channeling
than would be the case without such flexibility of
construction. In the instance of the heat exchanger
portion of the apparatus, channeling is of lesser
consequence to the operation of the finished unit than is
the case with the oxygenator portion. Therefore, the
more elaborate shaping such as illustrated in Fig. 9 is
not deemed necessary.

Following winding, the oxygenator diffuser
plate 60 is placed on top of the core and tack "welded"
to legs 40, 42 by ultrasonic welding. Then the fibers
are cut with a knife. Diffuser plate 60 thereby
maintains the pack density near or at the desired value.
The cores are then removed from the wheel for assembly of
the outer jackets. The fiber ends may be melted shut or
otherwise sealed prior to end potting.

The outer cover 70 is sealed onto the core.
Ribs 71 will aid in pressing the fibers to the ultimately
desired packing density. The hollow fiber bundle 64 will
ultimately be centrifugally end potted, as will be
described below along with the heat exchanger tubes. The
end potting region is shown in the drawings as reference
numeral 90. Because of the high packing density, the
ends of the fibers are preferably spread out manually
prior to potting to ensure that each fiber is encased
within the compound. This, of course, gives a reduction
in packing density within the potting compound region.

The heat exchange section 14 includes the
region defined by lower channel 40. Channel 40 is filled
with a plurality of substantially parallel, liquid
impermeable hollow tubes 96. The heat exchange hollow
tubes 96 are preferably formed from a polyurethane resin
such as B.F. Goodrich Estane 58091. The tubes are much
larger than the hollow fibers in the oxygenator,
typically being about 0.033 inches (840 microns) in
outside diameter with a wall thickness of about 0.004
inches (102 microns). In contrast, a typical oxygenator
fiber has an outside diameter of about 200 - 450 microns
and a wall thickness of less than 50 microns. The formation of heat exchanger tubes from polyurethane rather than the stainless steel, polyethylene, or polypropylene previously used represents a significant advance. While the efficiency of the heat exchanger is an important design consideration, it is vital that there must be no leakage. The end seals where polyurethane potting compounds are used with stainless steel tubes represent potential leakage areas of the cooling fluid into the blood.

The use of polyurethane heat exchange tubes with the polyurethane end potting compounds provides a positive seal which insures that no leakage will occur. This compatibility with the potting compound greatly increases the safety of the product.

The hollow tubes are packed into channel 40 such that channeling is minimized. However, performance of the heat exchanger is not greatly affected if some channeling is present. A pack density of between about 40% and 60% provides an efficient heat exchanger with an acceptable pressure drop. It is preferred to pack the polyurethane tubes at about a 45 - 55% pack density which provides an efficient unit, low pressure drop and low blood priming volume. The thin walled polyurethane hollow tubes provide good heat transfer. The efficiency desired is in ensuring that all of the blood is heated or cooled as desired, not in how much heat exchange fluid is required. The temperature differential between the blood and heat exchange fluid should be low to provide better control.

The heat exchanger tubes are preferably cut and then placed into the channel rather than wound into the channel. Winding is less preferable as it tends to cause
the hollow tubes to bend may cause cracks or breaks. Additionally, the curvature may allow some tubes ends to be too far inward after cutting which during end potting which may result in leakage in the device. The hollow tubes are then preferably melted shut at both ends simultaneously into a bundle or may be dipped in wax to close the tubes for end potting. Although it is preferred to use a leg shape that controls the cross-sectional area of channel 40, such as by use of rectangular wedges 132A, it is also acceptable to introduce side potting compound 132 along the interface of the heat exchanger tubes 96 with legs 42, 44 as shown. Side potting 132 may extend several tubes deep into the heat exchange bundle and decreases the likelihood of channeling within the heat exchanger.

A diffuser plate 100 is preferably attached to the core 20 along legs 42, 44 as shown by ultrasonic welding at points 108. Diffuser plate 100 includes a plurality of orifices 102 and may be identical to the diffuser plate 60. A cover 110 (preferably ribbed for rigidity) further encloses the heat exchanger bundle as shown in Figs. 1, 3, 5 and 6. Cover 110 includes a blood inlet port 114 and may include a temperature probe port 116 and sample port 118.

Although the heat exchanger described above will function adequately without the diffuser plate, the addition of the diffuser plate 100 lessens shunting and better maintains the desired pack density of the heat exchanger tubes. This increases the efficiency of the heat exchanger. As in the case of the oxygenator diffuser 60, the heat exchanger diffuser 100 is
preferably separated from cover 110 by a plurality of
nodes 120. Nodes 120 may be joined to cover 110 and
diffuser 100 thereby defining a chamber 130 therebetween.

Centrifugal end potting is well known in the
art and is, for example, shown in U.S. Pat. 4,389,363 to
Molthrop. Suitable potting compounds are available from
Caschem, Inc. of Bayonne, N.J. A polyurethane casting
system of Caschem, Inc. is described in U.S. Reissue Pat.
31,389. After potting, the hollow fibers are reopened by
conventional techniques such as by slicing through the
potted bundle with a sharp knife to expose the interior
of the fibers.

The heat exchanger and previously assembled
oxygenator bundle may then be end potted at each end with
a polyurethane potting compound. The hollow tubes are
reopened after potting such as by cutting with a sharp
knife. The end potting 135 provides a superior seal
which provides maximum assurance that the seal will not
leak.

The core 20 allows the end potting of the heat
exchange tubes 96 and the oxygenator fibers 50 to be
completed together in one potting. End potting tends to
be time consuming and eliminating the need for two
separate end potting procedures represents a very marked
improvement. Also, a single step potting reduces the
possibility of leakage around the potting edges. As
shown in Figure 8, the end potting 90 of the oxygenator
bundle and the end potting 135 of the heat exchanger
tubes 96 in one step results in a polyurethane dam 137
coextensive with potting 90 and 135. This dam 137
isolates the fibers 50 from the tubes 96 and encapsulates
the end 10 divider plate 16. It has been found that dam
137 prevents the possibility of leakage which might
otherwise occur in the absence of a dam extending in a
contiguous manner between the center divider and the
separate end potting areas.

As shown in Figs 1 - 5, blood outlet port 72
and blood inlet port 114 preferably are constructed and
arranged such that blood is directed across substantially
the width of the fiber and tube bundles in the respective
chambers.

As shown in Figs. 1 and 3, blood flows from the
heat exchanger section into the oxygenator section by
passing through perforations 140 in center divider 16.
Center divider 16 is preferably constructed and arranged
as described above for diffuser plate 60 and the same
considerations apply as to the number and size of
perforations 140. All three diffuser/dividers preferably
have about 62% of their surface area removed in the form
of perforations.

After the heat exchanger tube bundle and
oxygenator hollow fiber bundle have been end potted and
reopened, the device is completed by attaching end caps
160 and 170. Ends caps 160, 170 provide gas and heat
exchange media inlets and outlets to the open ends of the
hollow fiber and tube bundles.

End cap 160 is secured to perimeter of the the
cross-sectional end of core 20 and to outer jackets 70
and 110 and plastic strip 166. Plastic strip 166 has
projecting lugs 167 which aid in spacing and the forming
of dam 137. Alternate construction will have strip 166
formed as an integral part of center divider 16. In the
preferred form in which a dam 137 is formed during the
single end potting step, a seal is formed between a
plastic strip 166 which is adhered to dam 137 along the
width of the end potted region caps. A gas inlet 162 of
end cap 160 allows gas to contact all of the open oxygenator hollow fiber ends. A heat exchange outlet 164 allows heat exchange media leaving the interior of the heat exchanger hollow tubes to exit the device.

End cap 170 is constructed in a similar manner to end cap 160. End cap 170 includes a gas outlet 172 which collects gas leaving the open ends of the oxygenator hollow fibers such that gas is exhausted through gas outlet 172. Outlet 172 is preferably sized to accept either a 1/2" (1.27 cm) I.D. tubing set or a 1/4" (0.63 cm) I.D. tubing set inserted into the lumen of outlet 172. Vent port 178 may also be provided as shown. Port 172 may be connected to a vacuum source in order to prevent anesthesia gas from escaping into the operating room. A heat exchanger inlet 174 provides heat exchange media to each of the heat exchanger hollow tubes through their open ends. As in end cap 160, end cap 170 may be sealed to plastic strip 166 such that the open ends of the heat exchanger hollow tubes are isolated from the open ends of the oxygenator hollow fibers.

One may achieve even greater assurance against the possibility of leakage between the spaces that are desired communication with open ends of the tube bundle and the open ends of the hollow fiber bundle and other undesired regions in the following manner. During the end potting of the hollow fibers and heat exchange tubes, a mold is used, configured to shape the perimeter region of the potting compound 90 and 35 to a shoulder 200 around the outer ends of hollow fiber bundle 64 and around the outer ends of hollow tube bundle 96. This is illustrated in Figure 8. Prior to placing end cap 160 as a closure, O-rings 201 are placed onto shoulder 200. The tapered walls of end cap 160 press against O-rings 201
and effectively seal the space communication
respectively with the interior of hollow fibers 50 and
tubes 96 from each other as well as scaling the blood
flow regions from either the gas passing through hollow
fibers 50 or from the fluid used for heat exchange.

Of course, the seals described previously of
the potting compound 90 and 35 also prevent undesired
leakage.

Blood entering inlet 114 sweeps through chamber
130 and more uniformly contacts the heat exchanger bundle
after passing through the diffuser 100. Chamber 130, in
conjunction with diffuser 100 provides excellent blood
flow distribution to the heat exchanger tubes.
Observation of the blood through the outer jacket shows
that it swirls in the chamber 130.

The oxygenator construction described above
provides an even resistance to blood flow throughout the
oxygenator section 12. Flow vectors are substantially
equal throughout the fiber bundle 64 which maximizes
oxygen transfer by minimizing shunting. The inventive
outside perfusion design provides a greater surface area
for gas transfer and provides better mixing. With the
invention, it is possible by the mixing action of the
blood in flowing around the fibers to get more red blood
cells closer to blood plasma adhering to the fibers such
that oxygen dissolved in the plasma may reach individual
the red blood cells.

At the Association Advancement Medical
Instrumentation (AAMI) Standard condition (blood flow
rate = 6L/min., inlet gas = 100% O₂, venous hemoglobin
saturation = 65%, hemoglobin concentration = 12 gm%)
modified to a hemoglobin saturation = 55%, a unit having
only 3.8 square meters of hollow fiber surface area
provides oxygen transfer at 450 ml/minute. Utilization
of the fibers is maximized while pressure drop and blood
prime volumes are kept at low values.

The design allows the mass production of
oxygenators having excellent gas transfer rates with
reduced production costs. The heat transfer efficiency
is well within the recommendations of the AAMI Standards.

Through the use of the unique oxygenation
section design, it is possible to maximize utilization of
hollow fibers while minimizing the surface area of the
hollow fibers. Since hollow fiber stock is expensive,
the cost savings alone is an important advantage of the
invention. The lower overall surface area of fibers also
decreases the likelihood of platelet and fibrinogen
aggregation on the fiber surface. A lower hemolysis rate
is also found with the decrease in fiber surface area.

The case, diffuser plates, outer jackets and
end caps are all preferably formed from a non-toxic,
biocompatible plastic polycarbonate resins. Suitable for
the purpose are the Lexan brand resins of General
Electric Co. Polymers Product Department of Pittsfield,
Massachusetts. Lexan 144 grade polycarbonate resins are
currently preferred.

Oxygenators

If heat exchange is not needed in an integrated
unit, the oxygenator features of the invention may be
utilized by providing a core having a U-shaped
cross-section. Center divider 16 becomes a replacement
for diffuser plate 100 and is supported in spaced
relationship to the outer case by projection. The outer
jacket would then be secured to the center divider. Of
course, the end caps would only need gas inlets and
outlets. The oxygenator thus described provides all of
the advantages found in the oxygenator section of the
device. It may be used in conjunction with systems
having their own separate heat exchange units if desired.

**Heat Exchanger**

The heat exchanger section described above for
the device may be produced without an oxygenating
section. A heat exchanger may be constructed by
utilizing a core having a U-shaped cross-section such
that center divider 16 is enclosed within outer jacket
70. As above, the end caps would be modified, in this
case to provide heat exchanger inlets and outlets only.

Any application needing heat exchange with the
advantages of using the polyurethane hollow tubes
described above may be satisfied by following the
teachings of the invention. A bundle of polyurethane
hollow tubes may be placed in a case and end potted with
a polyurethane end potting compound. After end caps are
secured a heat exchanger is formed in which the interior
of the hollow tubes are isolated from the flow paths
along the outside of the tubes. Heat exchange media may
be passed through the lumens or outside the lumens as
desired by the application. The heat exchanger may
include diffuser plates to increase the distribution of
fluid over the tubes. The unique combination of
polyurethane hollow tubes with the polyurethane end
potting compound provides maximal security that there
will not be leakage in the device.

Although the device is shown in the figures
with a core having an H-shaped cross-section, the
advantages of the invention may also be attained with a
device in which the heat exchange tubes are generally
perpendicular to rather than parallel to the oxygenator
fibers. Such a device may be made by moving the lower
portions of legs 42, 44 below the center divider to the other edges of the center divider. In such a construction the end caps would need to be separate and two separate end potting would be required. A somewhat less efficient method of assembly would result.

In considering the invention it must be remembered that the disclosure is illustrative only and that the scope of the invention is to be determined by the appended claims.
WHAT IS CLAIMED IS

1. A device comprising:
   a) a housing including an elongated rigid core of generally H-shaped cross-section, the core including opposing side walls, joined to a web, the web of said core being perforated with a plurality of orifices substantially throughout the width and length of the web, said core defining with said side walls upper and lower longitudinally extending channels, the opposing side walls of said upper channel being interiorly configured to provide a variable cross-sectional profile of channel width between said side walls;
   b) a bundle of gas exchange hollow fibers of a composition suitable for gas exchange and being disposed substantially longitudinally in said upper chamber;
   c) a bundle of heat exchange hollow tubes impervious to liquid, said heat exchange bundle being disposed substantially longitudinally in said lower chamber;
   d) first and second closure members joined to the opposing side walls at the upper edges of said channels and defining with said channels inlet and outlet manifold chamber space means outwardly of the outermost layers of said gas exchange fibers and outwardly of the outermost layers of said heat exchange tubes;
   e) the remote end regions of said tubes and said fibers being encapsulated with a polymeric material which bonds to said side walls and said closure members to define a gas exchange cavity and a heat exchange cavity;
   f) outlet means in fluid communication with said outlet space means;
g) inlet means in fluid communication with said inlet space means;

h) said inlet and outlet chamber space means being constructed and arranged such that fluid flowing through said housing will flow in a directly generally transverse to the longitudinal direction of the gas exchange hollow fibers and heat exchange tubes;

i) heat exchange fluid inlet means in fluid communication with the interior of the heat exchange hollow tubes at a first end thereof;

j) heat exchange fluid outlet means in fluid communication with the interior of the heat exchange hollow tubes and disposed at the opposite end of the heat exchange tubes;

k) gas exchange inlet means for providing a gas inlet to the interior of the gas exchange hollow fibers at a first end thereof; and

l) gas exchange outlet means for providing a gas outlet for the interior of the gas exchange hollow fibers, said outlet means being disposed at the opposite end of the hollow fibers from the inlet means.

2. The device of Claim 1 wherein first and second diffuser plates are positioned within said manifold space means and in contact with and extending across the outermost layer of said hollow fibers and said tubes in each respective channel, said diffuser plates defining a plurality of orifices extending therethrough substantially throughout the diffuser plates, each of said diffuser plates being respectively spaced from said closure members.
3. The device of Claim 1 wherein the interior configuration of said side walls has a generally triangular cross-section with the hypotenuse of said triangle having a concave shape with a radius of about 1.25 inches.

4. The device of claim 1 wherein said gas exchange hollow fibers are arranged within said upper channel in layers of fibers such that each fiber is generally laid at an angle of between about 8 and 25 degrees from the side wall and each succeeding fiber crosses the underlying fiber at an angle of about 18 degrees with the cross-points of the fibers being offset from each other.

5. The device of Claim 4 wherein the angle is about 9 degrees.

6. The device of claim 4 wherein said hollow fibers are packed within said channel to a pack density of between about 50 and about 55%.

7. The device of claim 1 wherein said heat exchanger inlet means and outlet means comprise separate manifolds providing fluid communication to the lumens of the heat exchange hollow tubes and wherein said gas inlet means and outlet means comprise separate manifolds providing fluid communication to the lumens of the gas exchange hollow fibers, said manifolds being constructed and arranged such that fluid may not flow between the gas exchange hollow fiber lumens and the heat exchange hollow tube lumens.
8. The device of claim 7 wherein the encapsulation of the end region of said hollow fibers and said tubes includes a unitary bonding to the encircling walls to give a gas-tight enclosure.

9. The device of claim 8 wherein the encapsulating polymeric material surfaces at each end of said tubes and said hollow fibers supports resilient O-rings encircling the outermost regions of each end of said encapsulated fibers and said tubes and wherein said gas inlet and outlet means and said fluid inlet and fluid outlet means each are constructed and arranged to sealingly engage the respective O-rings to provide a gas and liquid-tight seal.

10. The device of claim 2 wherein said diffuser plates are constructed and arranged such that the liquid to undergo gas exchange flowing through said device is distributed across substantially the entire surface of an inlet side diffuser plate and the liquid to undergo gas exchange moves through said heat exchange bundle and said gas exchange bundle substantially in a planar flow until exiting through the outlet side diffuser plate.

11. A blood oxygenator comprising:
   a) an elongated housing defining first and second opposite end openings, said housing having first and second opposing sides and a top and a bottom and first and second closure members over said end openings; said opposing sides being interiorly configured to provide a variable cross-sectional profile of channel width between said side walls;
b) a bundle of hollow fibers for gas exchange being disposed inside said housing and having the ends of said fibers spaced from said end closure members, each fiber having an inlet and an outlet end, each of said fiber inlet ends and each of said fiber outlet ends being respectively in fluid communication with spaces defined by said first and second closure member and the ends of said fibers;

c) sealant means encapsulating the exterior end portions of said hollow fibers adjacent the fiber inlets and outlets respectively and joined to the walls, top and bottom to define a blood chamber cavity, the ends of the fibers being open to expose the interior of said fibers to the spaces defined by said end closure member;

d) blood inlet means communicating with said blood chamber cavity through said housing bottom;

e) blood outlet means communicating with said blood chamber cavity through said housing top;

f) gas inlet means communicating with the interior of said hollow fibers at the hollow fiber inlet ends;

g) gas outlet means communicating with the interior of said hollow fibers at the hollow fiber outlet ends; and

12. The device of claim 11 wherein the sealant means includes a surface at each end of said hollow fibers supports resilient O-rings encircling the outermost ends and wherein said gas inlet and said gas outlet means are each constructed and arranged to sealingly engage the respective O-rings.
13. The oxygenator of claim 11 wherein said hollow fibers are arranged within said housing in a migrating pattern of crossing layers of hollow fibers, said crossed layers of fibers thereby reinforcing each other against a tendency to move under the hydraulic pressure of flowing blood and wherein said hollow fibers are packed within said housing at a density of about 50 to about 55%.

14. The oxygenator of claim 11 wherein the interior configuration of said side walls has a generally triangular cross-section wherein the hypotenuse of said triangles has regions adjacent each end thereof with convex cross-section.

15. A hollow fiber-type device having an integral heat exchanger, said device comprising:
   a) an oxygenator section, said oxygenator section including:
      an elongated rigid core of H-shaped cross section defining an upper and lower longitudinally extending groove in said core, the side walls of the upper groove having a generally interior triangular cross-section, the core including a center divider between opposing side walls of the core, which together define said grooves, said center divider being perforated with a plurality of orifices substantially throughout the width and length of the center divider,
      a plurality of oxygenation hollow fibers arranged longitudinally in said upper groove, said fibers being arranged in layers, each fiber crossing over the next at an angle of from about 4 to about 13 degrees from the longitudinal axis of the core;
first and second walls in supportive relationship to the ends of said hollow fibers at the remote ends thereof with said ends of said hollow fibers left open to the interiors thereof, said first and second walls being secured to said core, closure means defining with said first and second walls manifold chamber space means at the inlet and outlet ends of said fibers; oxygen inlet means communicating with the open ends of said hollow fibers at the inlet ends thereof; gas outlet means communicating with the open ends of said hollow fibers at the outlet ends thereof; a first cover means enclosing said upper groove side walls and end walls, said first cover means defining a chamber above the top most layer of hollow fibers, said first cover means further including an outlet plate constructed and arranged so as to contact substantially the entire top most layer of hollow fibers, said outlet plate including a plurality of orifices substantially throughout the width and length of the outlet plate, said first cover means and outlet plate being constructed and arranged such that fluid within said chamber between the first cover means and outlet plate may pass to said hollow fibers only through said outlet plate orifices; a blood outlet passage provided in the first cover means, said passage being constructed and arranged so as to allow passage of blood from said chamber to the exterior of said device; said hollow fibers within the space defined by said core, first and second walls and inlet plate being packed to a density of about 50 to about 55 percent;
b) a heat exchanger section, said heat exchanger section including a plurality of polymeric hollow tubes arranged side by side longitudinally in said lower groove of said elongated rigid core;

third and fourth walls in supportive relationship to the ends of said heat exchanger hollow tubes at the remote ends thereof, with said end portions of said hollow tubes left open to the interior thereof, said third and fourth walls being secured to said core;

heat exchange closure means defining with said walls heat exchanger manifold chambers at the inlet and outlet ends of said heat exchanger tubes, a heat exchange medium inlet means communicating with the open ends of said heat exchange hollow tubes;

a heat exchange medium outlet means communicating with the opposite open ends of said hollow tubes;

a second cover means enclosing said lower groove side walls and third and fourth walls, said second cover means defining a second chamber between the outermost heat exchanger hollow tubes from said center divider and said second jacket, said second cover means further including an inlet plate constructed and arranged so as to contact substantially the entire outermost heat exchanger hollow tube layer, said inlet plate including a plurality of orifices, substantially throughout the width and length of the inlet plate, said second cover means and outlet plate being, constructed and arranged such that fluid surrounding said heat exchanger hollow tubes may pass into said second chamber only through said inlet plate orifices;
a blood inlet passage provided in the second
cover means, said outlet passage being constructed and
arranged so as to allow passage of blood into said second
chamber.

16. The device of claim 15 wherein said first and
second walls include a surface at each end thereof
supporting resilient O-rings encircling the outermost
ends and wherein said closure means at said oxygen inlet
means and said gas outlet means are constructed and
arranged to sealingly engage the respective O-rings.

17. The device of claim 16 wherein said third and
fourth walls include a surface at each end thereof
supporting resilient O-rings encircling the outermost and
wherein said closure means at each end are constructed
and arranged to sealingly engage the respective O-rings.

18. The device of claim 1 wherein said gas exchange
hollow fibers are arranged such that each succeeding
layer of fibers generally crisscrosses the next adjacent
layer of fibers at an angle of about 9 degrees from
the longitudinal axis of the core.

19. The device of claim 15 wherein said core,
walls, jackets and inlet and outlet plates are formed
from a biocompatible polycarbonate polymer.

20. The device of claim 15 wherein said inlet plate
is held in a spaced relationship from said second cover
means by a plurality of spacing nodes and said outlet
plate is held in a spaced relationship from said first
cover means by a plurality of spacing nodes.
21. The device of claim 1 wherein said gas exchange hollow fibers and said heat exchange hollow tubes are arrayed with their longitudinal axis generally parallel to each other.

22. The device of claim 21 wherein the remote end portions of said hollow fibers and said hollow tubes are encapsulated in a polymeric material to provide a gas tight seal to the interior chambers and to one another.

23. The device of claim 1 wherein said first and second closure means are held spaced from cover means having a ribbed outer surface for stiffness.
**INTERNATIONAL SEARCH REPORT**

I. CLASSIFICATION OF \( \text{INTERNATIONAL} \) APPLICATION (if several classification symbols apply, indicate):

According to International Patent Classification (IPC) or to both National Classification and IPC:

- IPC(4): A61M 1/14
- U.S. Cl.: 422/46,48; 55/16,158; 210/321.64, 321.79, 321.88

II. FIELDS SEARCHED

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<td>U.S.</td>
<td>422/46,48; 55/16,158; 210/321.64, 321.79, 321.88</td>
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched:

III. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of Document, with indication where appropriate, of the relevant passages</th>
<th>Relevant to Claim No.</th>
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<tr>
<td>Y</td>
<td>US, A, 4,624,778 (CLERMONT ET AL) 25 November 1986</td>
<td>1-23</td>
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<tr>
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<td>US, A, 4,639,353 (TAKEMURA ET AL) 27 January 1987</td>
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<tr>
<td>Y</td>
<td>US, A, 4,749,551 (BORGIONE) 07 June 1988</td>
<td>1-23</td>
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* Special categories of cited documents:

- "Y" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

*"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

*"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

*"A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search: 25 JULY 1989

Date of Mailing of this International Search Report: 12 FEB 1990

International Searching Authority: ISA/US

Signature of Authorized Officer: L. Kummert