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(54) Title: DEVICE TO BE USED IN COMBINATION WITH AN APPARATUS FOR THE EXTRACORPOREAL TREATMENT OF BLOOD

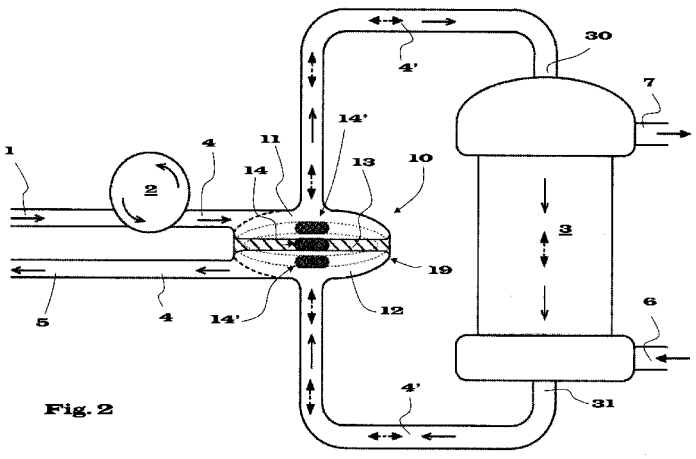

Fig. 2

(57) Abstract: A device for use in combination to an apparatus for the extracorporeal treatment of blood and comprising: a circuit (4) connectable to the patient by means of first (1) and second (5) connection means intended, respectively, to the collection of blood to be treated and to the return of the treated blood; a blood pump (2) arranged and acting on said circuit (4) so as to determine a flow towards the said second means of connection to the patient (5); an oxygenator (3), disposed and acting on said circuit (4) provided with a first input (30) for the blood to be treated and a first output (31) for the treated blood disposed downstream of said first inlet (30); the device (10) is characterized in that it comprises a first chamber (11) disposed on said circuit (4) upstream of said oxygenator (3), a second chamber (12) disposed downstream of said oxygenator (3), and a mobile wall (13) interposed between the said chambers (11, 12) and defining a wall or portion of the same chambers and provided with moving means (14; 18) adapted to move said wall (13) for generating an alternating flow of blood which crosses the said active element (3) and which is added to the flow generated by said pump (2).

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TITLE: DEVICE TO BE USED IN COMBINATION WITH AN APPARATUS FOR THE EXTRACORPOREAL TREATMENT OF BLOOD.

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DESCRIPTION

The present invention relates the technical field of the medical treatment of the blood by an extracorporeal veno-venous route and concerns a device inserted into a circuit usable in combination with a dedicated apparatus.

These treatments are performed with specific circuits and machine and are based on a basic pattern attributable to the following:

1) an access catheter inserted into a vein of the patient (for example, the femoral, jugular or the Subclavian);

2) a return catheter inserted into a patient's vein (for low flows and mini-invasive treatments is generally employed only a two-way catheter);

3) a line of tubes and junctions for the connection to and from the patient, often but not necessarily comprising additional elements such as pressure sensors or other chemical-physical quantities sensors, expansion devices, derivations for the infusion of drugs, air bubble detectors, clamps, etc.

4) a blood pump which provides the work required to overcome the resistances and to allow the extracorporeal blood circulation; this pump can be either occlusive (peristaltic or "roller" pumps) or non-occlusive (centrifugal pumps);

5) at least one active component that, in the case of the present invention is an oxygenator, that is, a component that allows the exchange of gases: it is a medical product of normal availability, composed of hollow fibers of suitable material, mainly polypropylene (PPP) or polymethylpentene (PMP), wound and/or stacked so as to be lapped externally by the blood flow while within the fibers is passing air, oxygen or a mixture of the two gases.

One embodiment of a known apparatus of this type is illustrated in Fig.1.

The efficiency of this type of treatment depends largely on the surface of the fibers that are in contact with the blood to be treated for a gas exchange that occurs, primarily, for the partial pressure difference: the greater the surface area, the more efficient is the treatment executed.

In order to increase the efficiency of the treatment, the possible use of excessive surfaces with respect to the blood flow that laps would result in a slowing of the flow with a consequent increased risk of clotting, and with the increase of the risk of stagnation of ematic solid components and the possible creation of preferential circuits that would exploit only part of the fibers of the active component thereby reducing the efficiency. This would result in the need for further doses of anticoagulant drugs (i.e. Heparin) that, on the contrary, it would be preferable to reduce or, alternatively, the need to employ oxygenators with reduced exchange surfaces and therefore less efficient.

The needs are therefore contradicting each other and so far the mini-invasive treatments, i.e the treatments at low blood flow (<500 ml/min.), which are better tolerated by patients, are not very effective if carried out with oxygenators having small exchanging surface or are not properly practiced with oxygenators of the major surface.

The object of the present invention is to overcome the problem, allowing the use of oxygenators of relatively high surface area (also greater than 2 square meters) while allowing a blood flow to and from the patient reducible as desired, also below 50 ml / min (for possible pediatric use or other special needs).

In practice, the invention allows to generate an alternating flow of blood exclusively within the oxygenator. Said alternate flow is localized because it is limited to the portion of the circuit containing the oxygenator itself. The alternating flow of blood generated by the device of the present invention has added to the flow of the pump only at the inside of the oxygenator while the action of the pump is limited to the effective blood flow to and from the patient throughout the rest of the circuit.

In this way it will be possible the use of oxygenators made with materials of greater duration but less effective, simply by increasing the surface of contact with the blood to compensate for the lower efficiency, (as for example, in the case of oxygenators in polymethylpentene, of greater duration but of lesser efficiency, in place of those in Polypropylene, more efficient, but of short duration), without it being necessary to subject the patient to invasive practices necessary to maintain a high blood flow, such as a double catheterization or the use of large catheters needing surgical accesses or otherwise more traumatic and that, because of the high flows into play, require the use of highly specialized personnel.

Advantageously, with the present invention, it is possible to preserve the characteristic of mini-invasive treatment still allowing the use (and exploiting the efficiency) of high surface oxygenators.

In other words, the main advantage of the present invention resides in the possibility to perform very effectively, for example, the extracorporeal removal of CO2 maintaining reduced the real flow of blood to and from the patient (for example, within the value of 500 ml/min.) and adding to this real flow an alternating blood flow generated by the device of the present invention limited to the portion of the circuit containing the oxygenator. This greater flow being most suitable for the proper fluid dynamics of oxygenators of greater surface area, it allows to exploit the effectiveness and in the meantime reducing the risk of clotting and blood stagnation.

More particularly, the device of the invention is provided with means to generate an alternating flow of blood within the oxygenator, without altering the value of the main flow of the circuit, that is, the incoming and outgoing circuit connected to the patient. The alternating flux generated by the device limited to the oxygenator can be achieved with the means described

in the following.

More generally, the present invention allows to make independent the blood flow to and from the patient with respect to the circulating flow in contact with the surface of the active component. In this way can be used to surface components also relatively very high (even higher than 2 square meters) while allowing a blood flow to and from the patient reducible as desired, also below 50 ml / min. (for example, for pediatric uses).

At the same time, the possibility offered by the present invention to maintain a blood flow inside the oxygenator even in the case of pump stop, and then with a flow to and from the patient equal to zero, allows to avoid the coagulation problems that may occur in case of forced stop of treatment, for example, as a result of various kinds of alarms that force to stop temporarily the effective blood flow.

The invention will now be described with reference to the drawings which are provided by way of example and not limiting to other forms of embodiments not shown and / or described; in the accompanying drawings:

- Fig. 1 schematically illustrates a conventional circuit of the CO2 removal.
- Fig. 2 schematically shows a possible embodiment of the invention in which is visible the device which generates the alternating flow which, in this example, is a container of appropriate form divided into two halves by an elastic membrane to which a permanent magnet is fixed. The two halves of the device are not communicating but any movement of the membrane in the direction of the wall of a chamber will cause a decrease in volume of the same chamber and, at the same time, an identical variation of volume of opposite sign (in this case an increase) in the adjacent chamber. Inserting the container in a support capable of generating a magnetic alternating fields, the elastic membrane, dragged by the magnetic forces acting on the permanent magnet connected to it, it will undergo a controlled movement which results in an oscillation of the membrane and a consequent change in volume in phase opposition but identical in absolute value in the two adjacent chambers.
- Fig. 3 illustrates a bellows device consisting of two adjacent chambers separated by a central wall in which is inserted a bar that, moving alternately in one direction and in the opposite direction will cause a change in volume equal and opposite in the two halves of the bellows generating an oscillation in blood flow connected to it.

In the accompanying drawings is schematically illustrated an apparatus for the removal of CO_2 from the blood which comprises, in its usual form shown in Fig.1, the following component parts:

- first means of connection to the patient for the taking of blood through an access line (typically a venous catheter), marked with the reference (1) in the drawings,
- a blood pump (2);
- an oxygenator (3), provided with a first inlet (30) for the entrance of the blood to be treated, a

first output (31) for the treated blood, and to a second input (6) for the entrance of air/oxygen and a respective second output (7) for the removed air and the CO_2;

- second connecting means (5) to the patient for the return of the blood to the patient through a return line (4) that generally terminates in a catheter inserted into a patient's vessel. The connecting means in the inlet and outlet may be combined into a single two-way catheter.

The invention relates to a device (10) that determines an alternate flow within the active component (3).

Said alternate flow, which, advantageously, can be generated by the oscillation of a membrane that separates the two cavities of a casing (this solution ensures that there is exact correspondence between the volume subtracted to a compartment and the volume added to the linked compartment, namely it is guaranteed the exact phase opposition and amplitude) or by a pair of equal bellows that share a movable wall (similar to the previous example, the movement of the bellows in a common movable direction of the wall will cause an identical, albeit of sign opposite, blood displacement in the two different compartments). The two compartments, or sections, are connected both upstream and downstream of the oxygenator (each maintained separate compartment for which there is no mixing between the two incoming streams and output from the oxygenator).

The movements determined by the device (10) generate an alternating flow of blood within the oxygenator (3), prevents the stagnation and keep elevated the speed along the walls of the fibers of the oxygenator itself.

It is important to note the total absence of single or bi-directional valves that would adversely have hemolytic effects and would be useless for purposes of the invention.

Advantageously, moreover, in accordance with the present invention (and as also detectable by means of the examples of Figs. 2 and 3) the proposed solution is not occlusive and therefore does not significantly increase the mechanical damage to the solid components of the blood. In other words, the moving means (hereinafter better described) adapted to move a movable wall of the device determine an action on the blood of non-occlusive type, not causing contact between the same wall and other parts of the device (10) and / or of the blood circuit.

It is provided, for explanatory and not limiting purpose, a blood volume value put in alternate motion of about 1000/2000 ml/min, which corresponds, with oscillations at 4 Hz frequency (always as an example) to volumes of about 2/4 ml per hemicycle.

The above-mentioned oscillations do not interfere with the flow of blood to and from the patient. This flow is controlled by the blood pump (2) which, in this case, is preferable, but not essential, to be of occlusive type to better limit the oscillations to the circuit section comprising the oxygenator.

In Fig. 2 is schematically shown an embodiment of a circuit provided with the device of the

invention. Even in this case, the same reference numerals of Fig.1 have been used to indicate similar components. The example of Figure 2 is provided with an oxygenator (3). This oxygenator, as previously specified, can be differently constituted, in function of the relevant blood treatment apparatus.

Again in Fig. 2, the reference (10) marks the device which comprises a compartment (19) divided into two chambers or sections (11, 12) through a flexible septum or wall (13). A section (11) is arranged and acts upstream of the oxygenator (3), while the other section (12) is arranged and acts downstream and in phase opposition with respect to the first (11). It is important, for the purposes of the better operation of the invention, that the tubes or connection ducts (4'), placed between the chambers (11, 12) that are part of the device (10) and the oxygenator (3), have the greatest diameter possible (to reduce the resistances and pressure drops), have the shortest possible length (for the same reasons previously described) and are rigid (to avoid response delays due to the elastic deformation of the connections that would make less linear the oscillation of the blood flow and may impact with undesired pulsations in the flow that reaches the patient). The tubes (4 ') that connect the device (10) to the oxygenator (3) are therefore rigid and of greater diameter than the tubes (4) forming the remaining part of the blood circuit.

The device (10) adapted to determine the oscillation is provided with a means for imparting motion. In this case may be provided, in alternative or in addition to the solutions shown in Fig. 2 and Fig. 3, two tube segments, a double bellows or a double elastic expansion box driven by mechanical means which alternately compress them, or pistons, oscillating membranes, piezoelectric oscillators, syringes with alternate electrified motion.

In practice, a device in accordance with the present invention is usable in combination with an apparatus for treatment of blood arranged to operate the removal of CO_2 from the blood; the device is provided with means to exclusively increase the blood flow that passes through said oxygenator (3). The term increase of the flow through the oxygenator means the sum of the flows in both directions inside the oxygenator itself.

For greater clarity, the following example is proposed: 10 ml are pushed upstream of the oxygenator while at the same time, downstream of the same are aspirated 10 ml, and subsequently reversing the process we will have made to pass through the oxygenator 20 ml. By repeating this cycle once per second, every second pass 20 ml (10 in one direction and 10 in the opposite direction), this flow keeps moving the blood within the oxygenator even if the actual flow, to and from the patient it remains stationary and blocked by the pump (2), which in this example and for convenience is of occlusive type. In this case the total flow in the oxygenator (pump stationary) will be of (20 x 60 =) 1200 ml / min. If the pump (2) pushes the blood at a flow rate of 500 ml / min, the flow inside the oxygenator will be 1200 + 500 = 1700 ml / min, while the flow collected and returned to the patient will be only 500 ml / min.

This feature is particularly useful also in the case of temporary stop of the blood pump due to the occurrence of various kinds of alarms (very frequent case). With the use of the present invention, even if the blood pump stops, a considerable flow inside the oxygenator such as to avert the danger of coagulation is ensured.

According to a first embodiment of the invention (schematically illustrated in Figure 2) the device comprises means adapted to determine an oscillation on the blood flow through an oxygenator (3). In this case, the means adapted to determine the oscillation comprise an elastic wall (13) supporting a body (14) subject to magnetic attraction which, thanks to unrepresented electromagnetic control means, can be moved towards one or the other of the two chambers (11, 12) and thereby reducing the volume and thereby increasing the volume of the other chamber.

In the drawing of Fig. 2 are represented with a discontinuous line some of the possible configurations assumed by the wall (13) within the chambers (11) and (12), with (14') is shown the possible corresponding position of the body (14).

In the example of Fig.3, the device (3) comprises two chambers (11, 12) shaped as a bellows and separated by a common wall (13). The common wall (13) is connected to an electric motor (18) able to move alternately in the direction indicated by the double arrow. In practice, the wall displacement (13) determines, cyclically and alternately, the change of volume in the two chambers (11, 12), with the bellows structure of a chamber which expands while that of the other chamber is contracted.

The forms and movement mode of the wall (13) may be different from those described and illustrated. By way of example, may be provided piezoelectric actuating means, pairs of syringes arranged upstream and downstream of the oxygenator, equipped with related plungers driven in phase opposition, mechanical compression means, etc.. ..

Advantageously, the blood pump (2) can be of occlusive type.

A process according to the present invention can therefore be used to improve the extracorporeal treatment of blood. A treatment of this type provides to pass the blood taken from the patient in a first circuit (4) connectable to the patient by means of first (1) and second connection means (5) intended, respectively, to the collection of blood to be treated and to the return of the treated blood. On the first circuit a blood pump (2) is arranged and acting on the circuit (4) so as to determine a flow to said second connection means to the patient (5). In addition, the process provides the passage of blood in an oxygenator disposed and acting on the circuit (4) and provided with a first input (30) for the blood to be treated and a first output (31) for the treated blood disposed downstream of the first input (30). The innovative process provides for increasing the amount of blood flow through the said component (3), without affecting the remaining part of said circuit (4) connectable to the patient. In particular, the blood can be subjected to the action of means adapted to determine an oscillation, that is, a

reciprocating motion on the flow of blood that passes through said oxygenator (3). Some examples of such oscillator means have been described previously, but could be used for that purpose also other means able to cause an increase of blood flow summing the unidirectional flow of blood pump which passes through said component (3) to an alternating flow that it remains confined to its interior or in any case does not reach the patient.

It is understood that the described inventive concept is applicable to other solutions, also different from those described and illustrated remaining within the scope of the inventive idea of the present invention.

CLAIMS

1. A device for use in combination to an apparatus for the extracorporeal treatment of blood and comprising:

- a circuit (4) connectable to the patient by means of first (1) and second (5) connection means intended, respectively, to the collection of blood to be treated and to the return of the treated blood;

- a blood pump (2) arranged and acting on said circuit (4) so as to determine a flow towards the said second means of connection to the patient (5);

- an oxygenator (3), disposed and acting on said circuit (4) provided with a first input (30) for the blood to be treated and a first output (31) for the treated blood disposed downstream of said first inlet (30);

device (10) characterized in that it comprises a first chamber (11) disposed on said circuit (4) upstream of said oxygenator (3), a second chamber (12) disposed downstream of said oxygenator (3), and a mobile wall (13) interposed between the said chambers (11, 12) and defining a wall or portion of the same chambers and provided with moving means (14; 18) adapted to move said wall (13) for generating an alternating flow of blood which crosses the said active element (3) and which is added to the flow generated by said pump (2).

2. Device according to claim 1, characterized in that the movement of said wall (13) with respect to said chambers (11, 12) determines a change in volume differentiated in the two chambers (11, 12), with a volume increase of a chamber corresponding to an identical volume decrease in the other chamber.

3. Device according to claim 1 and/or 2, characterized in that said wall (13) is provided with a body subject to magnetic attraction (14) which, thanks to electromagnetic control means, can be moved to one of the two chambers (11, 12) and thereby reducing the volume in that chamber and thereby increasing the volume of the other chamber.

4. Device according to claim 1 and/or 2, characterized in that said first chamber (11) and second chamber (12) are bellow-shaped and are separated by said movable wall (13) which is connected and conducted by moving means shaped so as to move it alternately towards one or the other of the two chambers (11, 12) and thereby reducing the volume in this chamber and thereby increasing the volume of the other chamber of identical value.

5. Device according to one of the preceding claims, characterized in that the connecting tubes (4') between said chambers (11, 12) and the oxygenator (3) are rigid, non-deformable by the action of said pump (2) and of said device (10).

6. Device according to one of the preceding claims, characterized in that the connecting tubes (4') between said chambers (11, 12) and the oxygenator (3) are of larger diameter than the tubes (4) of the rest of the circuit.

7. Device according to one of the preceding claims, characterized in that the means for moving said movable wall (13) are independent from those of said pump (2), so as to ensure a flow inside the oxygenator (3) in conditions of stopped pump (2).

8. Device according to one of the preceding claims, characterized in that it is devoid of valves.

9. Device according to one of the preceding claims, characterized in that said handling means (14; 18) adapted to move said wall (13) determine a non-occlusive action on the blood, not causing contact between the same wall (13) and other parts of the device (10) and / or of the blood circuit.

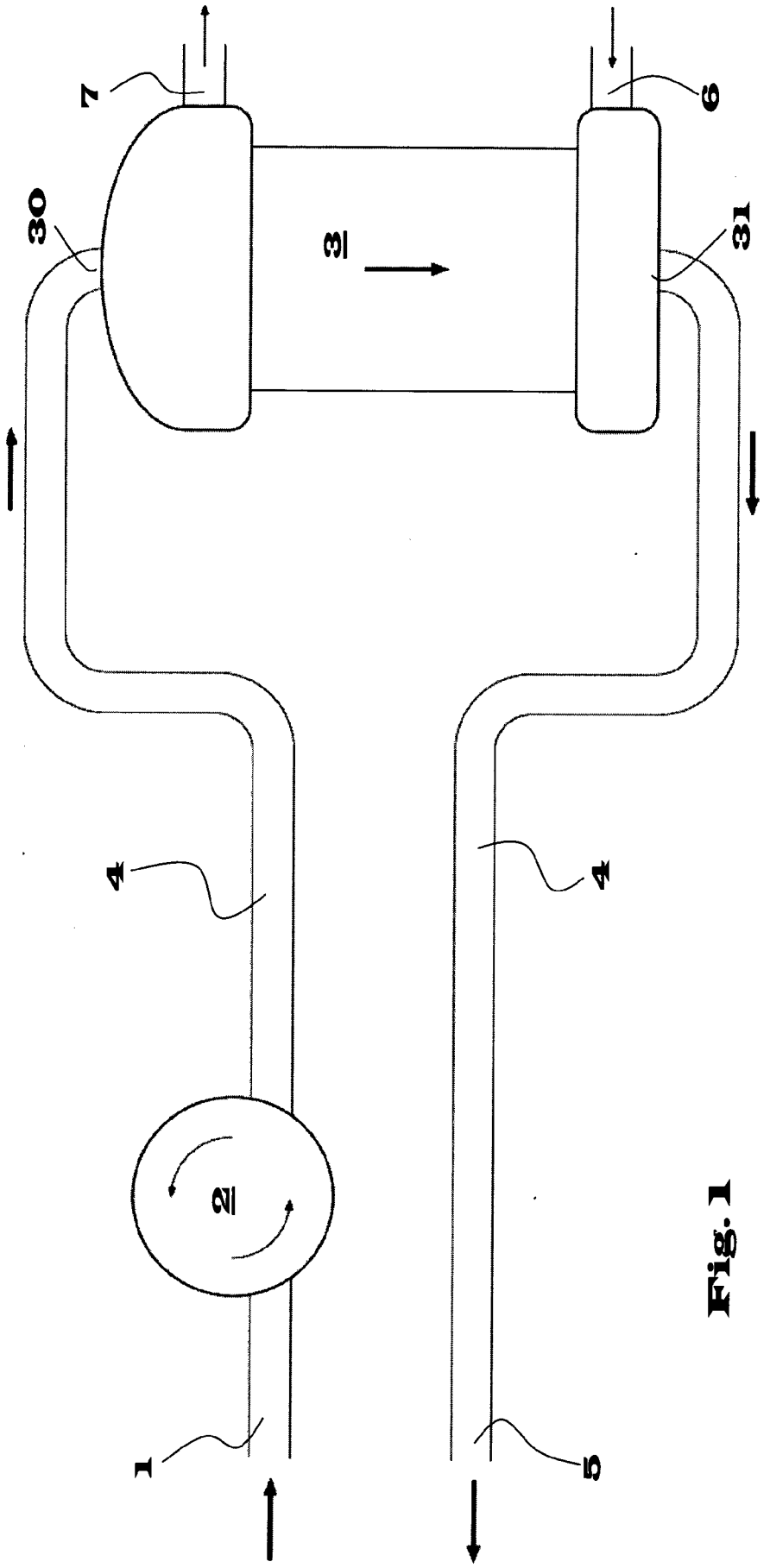

Fig. 1

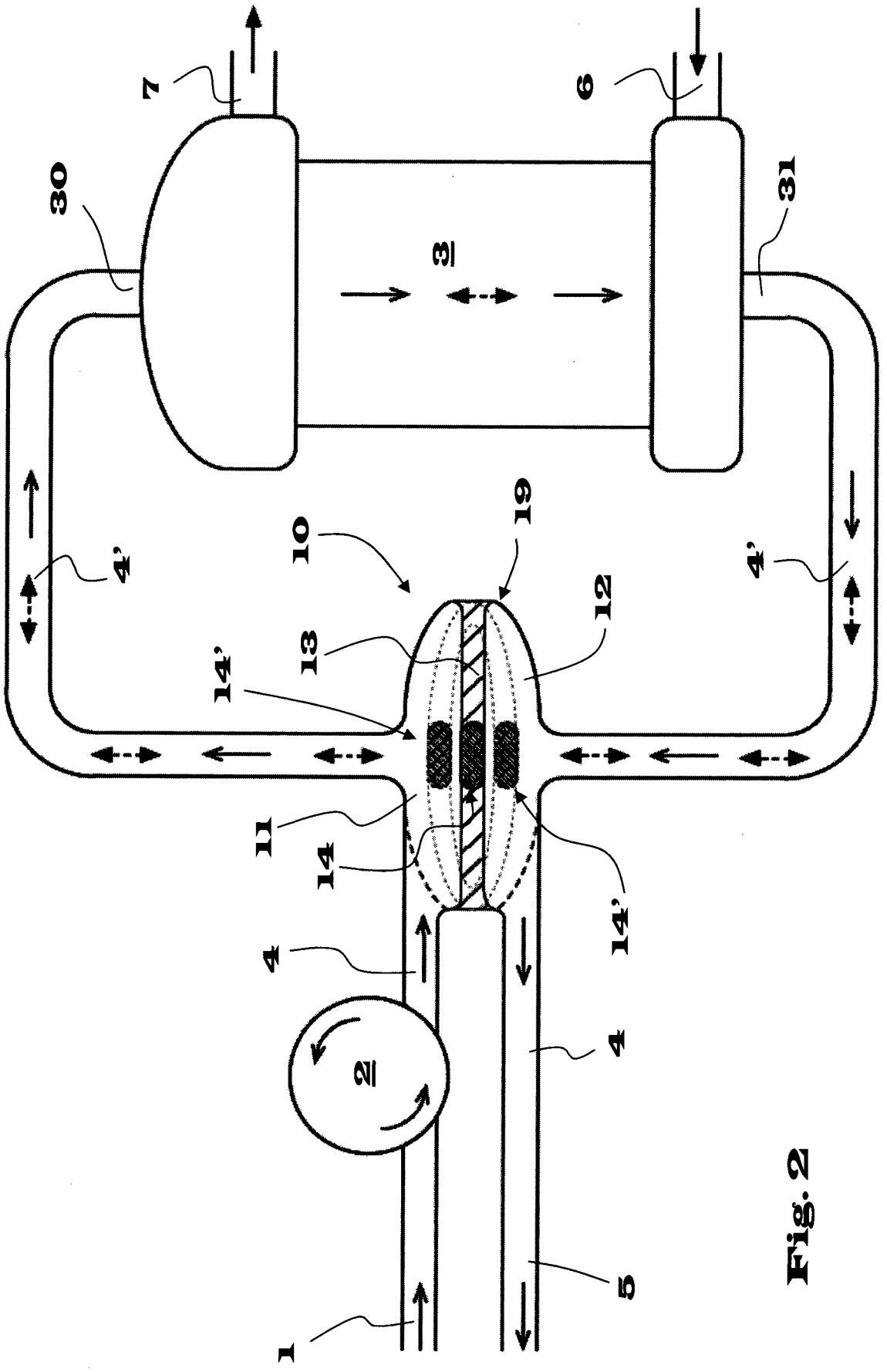

Fig. 2

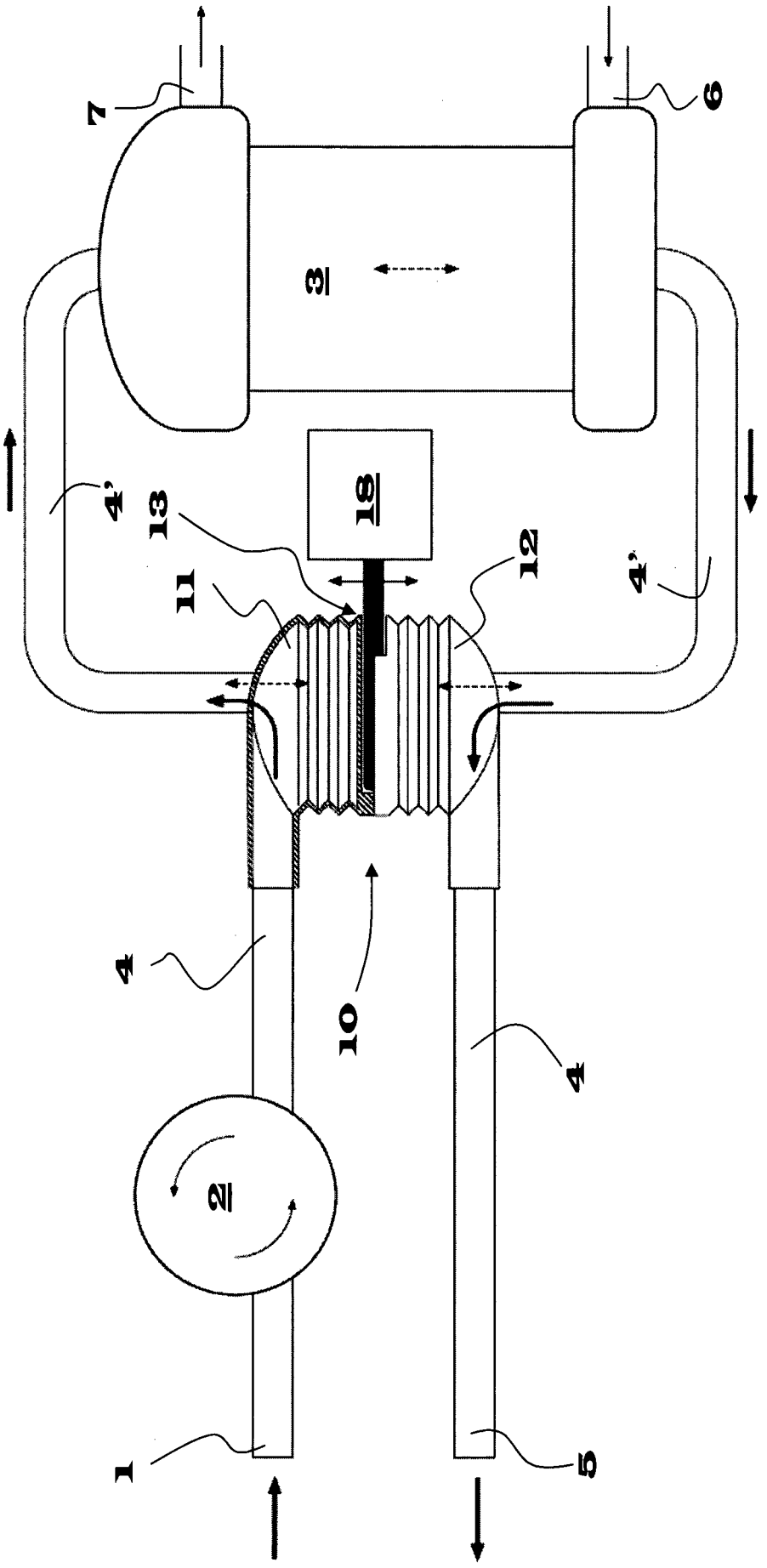

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/001672

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/16 A61M1/10 A61M1/26 A61M1/36
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 383 921 A (BELLHOUSE BRIAN J [GB] ET AL) 17 May 1983 (1983-05-17) column 1, line 4 - line 19 column 2, line 59 - column 3, line 63 figure 4 -----	1-7,9
Y	JP S55 167009 A (NIKKISO CO LTD) 26 December 1980 (1980-12-26) abstract figure 7 -----	1-7,9
A	US 5 626 759 A (KRANTZ WILLIAM B [US] ET AL) 6 May 1997 (1997-05-06) column 1, line 5 - line 10 column 5, line 39 - column 6, line 49 column 8, line 36 - column 9, line 29 ----- -/--	1

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
2 February 2017	09/02/2017

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/001672

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 729 829 A (DUGGINS RAY B [US]) 8 March 1988 (1988-03-08) column 3, line 2 - line 18 column 5, line 1 - column 6, line 18 figures 1,3,4 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2016/001672

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4383921	A	17-05-1983	NONE	
JP S55167009	A	26-12-1980	NONE	
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