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(54) Title: APPARATUS FOR THE TREATMENT OF BLOOD

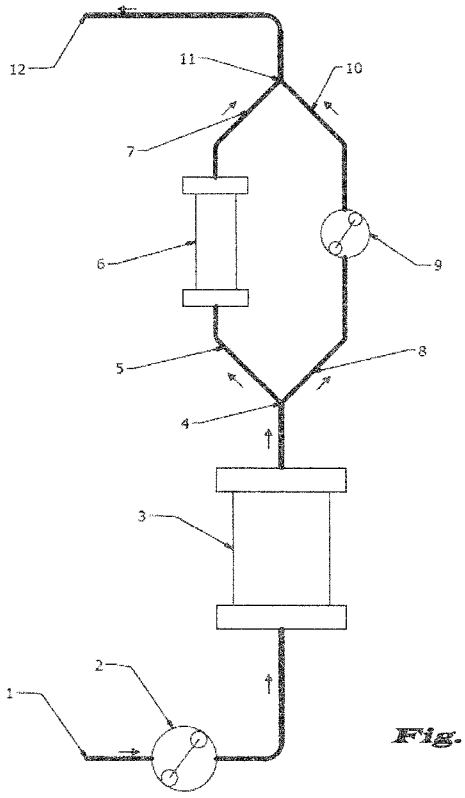

Fig. 1

(57) Abstract: An apparatus for the treatment of blood, of the type usable to perform a processing of the blood by passing the blood through a circuit comprising a first device (3) suitable to operate at a first flow value and a second device (6) suitable to operate at a second flow value, lower than the first; the apparatus is characterized in that it comprises a bifurcation (4) of said circuit which divides the same circuit in a first conduit (5, 7), on which said second device (6) is placed, and a second conduit (8, 10), on which is acting a means for regulating the flow (9), adapted to determine a flow value equal to the difference between the value of said first flow and the value of said second flow; said first conduit (5, 7) and said second conduit (8, 10) being joined together downstream of said second device (6) and of said means for regulating the flow (9).

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TITLE: APPARATUS FOR THE TREATMENT OF BLOOD

DESCRIPTION

The present invention relates to an apparatus for blood treatment.

The apparatus can be used for the extracorporeal removal of CO_2. Since several years there are on the market devices to remove the CO_2 from the blood by extracorporeal way, working similarly to the widespread treatments of dialysis, hemofiltration, etc., which remove by an extracorporeal way toxic or harmful waste products of metabolism that normally would be eliminated by the kidneys.

Among the purposes of the present invention there is to compensate, even if only partially, to the lung function when the lung itself is unable to do so due to different pathologies.

A known system for the aforementioned aim dates back more than forty years ago, and is known by the acronym "ECMO" (Extra Corporeal Membrane Oxygenation); it provides an access to larger vessels of the patient performed surgically with large diameter cannulas connected to a pump and to an oxygenator capable of handling high flows (even more than 5 liters per minute). This system, in its numerous variants, is able to completely replace the lung function and, in case, also the heart.

This technique has drawbacks of considerable importance. In fact, the management difficulties, the side effects and the inherent risks of this invasive method are high, as well as costs and the use of human resources in terms of continuous care. The survival of the treatment does not exceed 60% of the cases, and it is therefore generally considered a last resource.

In more recent times simpler ways are been tried, as systems without pump that use the pressure difference between the artery and vein for passing the blood through an oxygenator. Also these systems have side effects, primarily due to the need to draw blood from an artery, with consequent risks of bleeding, infection, and ischemia of the lower limbs.

The main action of such systems is to remove the excess CO_2 that accumulates in the blood while regarding the oxygenation is the portion of the lung tissue that still works with the aid of normal techniques of Mechanical Ventilation.

Assuming however, to maintain the patient under mechanical ventilation, recently minimally invasive systems have been developed; these systems remove a major part of CO_2 in the blood at low flows (lower than 500 ml / min) and with venous access. The documents EP-1415673 and EP-1698362 describe systems that reach very high levels of removal of CO_2 metabolically produced allowing a less traumatic adjustment of the parameters of the Mechanical Ventilation and thus promoting faster healing.

In a circuit for extracorporeal medical treatments, when there are more than one component in series on the same line, for instance an oxygenator and a hemofilter, it is necessary to employ different flows for each of the components or devices.

In order to avoid parallel connections that would require a total flow corresponding to the total amount of two flows, it is considered advantageous for many reasons to limit the total flow to that of the component that requires it to a greater extent by regulating and limiting the flow in the other component.

An object of the present invention is to determine the correct and suitable flow for the treatment, by means of a bifurcation that allows the desired flow to pass in the component with a lower flow and which allows the excess flow to pass freely into a parallel section of conduit.

According to the present solution, at once after, downstream, another bifurcation rejoins the two flows in a single tube.

The present invention provides an apparatus for blood treatment, of the type usable to execute a processing of the blood by passing the blood through a circuit comprising a first device suitable to operate at a first flow value and a second device suitable to operate at a second flux value, lower than the first; the apparatus is characterized in that it comprises a bifurcation of said circuit which divides the same circuit in a first conduit, on which is arranged said second device, and a second duct, on which is acting a means for regulating the flow, act to determine a flow value equal to the difference between the value of said first flow and the value of said second flow; said first conduit and said second conduit being gathered between them downstream of said second device and said means for regulating the flow.

According to the invention the said bifurcation may be located downstream or upstream of said first device.

The first device can be an oxygenator, the second device can be a hemofilter and the means for regulating the flow can be a pump or other suitable device to vary the flow such as, for example, a device adapted to vary the section of the duct on which it is agent so as to adjust consequently its flow-through.

These and other results have been achieved in accordance with the invention by adopting the idea of making an apparatus having the features disclosed in claim 1. Other features are described in the dependent claims.

These and other advantages and features of this invention will be best understood by anyone skilled in the art from the following description and with the help of the attached drawings

given as a practical exemplification of the invention, but not to be considered in a limitative sense, wherein:

- Figs 1, 2 and 3 are diagrams concerning possible examples of embodiment of an apparatus in accordance with the invention, in which the details are presented schematically and not to scale.

In the specific case but not limitative example illustrated in Fig.1, the apparatus comprises a circuit adapted to the extracorporeal removal of CO_2 by means of a device called oxygenator (3) which takes advantage of the maximum blood flow available and of a hemofilter (6) for CVVH treatments (continuous dialysis) that generally requires (or is planned for) lower flows. In the circuit the arrows indicate the direction of blood.

Via a catheter inserted into a blood vessel of the patient connected to an end (1) of the circuit, the blood is drawn through the action of a pump (2) which in this specific but not limitative case generates a flow of 500 ml / min.

The aforementioned flow transits entirely within the oxygenator (3) to reach a first bifurcation (4) where it is divided.

A part of this flow is adjusted by a pump (9), or by other means described below, which allows the passage of a flow of 300 ml / min, while the remaining fraction (in the described case, 500-300 = 200 ml / min.) flows through the hemofilter (6) obtaining, by difference, the desired flow of 200 ml / min.

Downstream from the first bifurcation, i.e. downstream of both the hemofilter (6) and the pump (9), a second bifurcation (11) brings together the two streams into a single pipe which at the end (12) is connected to the catheter for returning the treated blood to the patient.

The pump (9) or the flow regulator device is advantageously positioned between the portions of the tube (8) and (10) so that the excess flow encounters the resistance of the hemofilter (6) in the other branch of the bifurcation and thereby increases the pressure of the blood within the oxygenator (3); this phenomenon limits advantageously the formation of not dissolved oxygen bubbles.

In other words, thanks to the bifurcation (4) presented by the circuit and to the subdivision of a part of the same circuit into two branches, all devices or components of the apparatus operate with an optimal flow of blood to be treated.

In Figs. 1 and 2 the means for regulating the flow (9) is schematically represented with a symbol that reproduces a rotors pump. In accordance with the invention can be used different types of pumps of other devices capable of determining the value of the desired flow, suitable for the related device that is crossed.

For example, it may be employed a device that allows to reduce the internal section of the tube in order to adjust the relative flow.

For other extracorporeal applications, the pump (or the flow restrictor device) (9) can advantageously be positioned also in correspondence of the branch (5) or in the branch (7) of the circuit, as shown schematically in Fig.3. In Fig. 3 are represented three of the possible different positions that can assume the device (9).

In particular, with the continuous line has been represented the positioning corresponding to that of Fig.1, while a broken line represents the other two possible positions in which the flow regulator (9) is located in the branch on which acts the hemofilter (6), respectively downstream and upstream of the same.

In the examples of Figs. 1 and 3, the portion of the circuit with the subdivision in the two branches (5, 7) and (8, 10) is positioned downstream of the component having a greater flow, which can be an oxygenator (3); the portion with the subdivision can also be placed upstream of this device (3), as shown in the example of Fig.2.

In the circuits of the drawings the possible components not directly affected by the invention are not represented; in fact, a circuit of the type described may comprise, for example, means for collecting the ultrafiltrate, means for infusing substances in the blood, means for controlling the presence of bubbles, means for adjusting the temperature, connections to sources or oxygen tanks, etc. ..

With the present invention all devices are able to operate on the blood at a flow rate considered optimal flow.

With reference to Figs 1 and 3, under conditions of use, the blood, which is drawn from the patient through a catheter in correspondence of the end (1) of the circuit, is pushed downstream by the first pump (2) to the oxygenator (3), which is traversed by a flow which is suitable to its optimal operation because the pump (2) determines a flow equal to the optimum value expected for the oxygenator (3). Located downstream of the oxygenator there is the bifurcation (4) which divides the circuit into two branches. In the branch (8, 10), arranged on the right in the drawing, the value of the blood flow passing through is regulated by the pump (9) and, therefore, in the other branch (5, 7) the value of the blood flow is equal to the difference between the upstream flow, the one passing through the oxygenator (3), and the flow of the right branch, so as to also the second device (6) operates at the optimum flow, even when this is different from the flow of the first device (3). Taking an example, if the optimum flow of the oxygenator (3) is 500 ml / min (milliliters per minute), the first pump (2) imparts to the blood a flow of this value so as to optimize the operation of the

oxygenator (3). Located downstream of the oxygenator, the action of the second pump (9) (or of another suitable flow regulator) which determines a flow of 300ml / min into the right branch lowers the value of the flow in the left branch (5, 7) up to the optimal value for the hemofilter (6), in this case 200ml / min. Downstream from the branch, after the point (11), the circuit is joined and the blood returns to the patient through the end (12) at the same flow that it had initially.

In the example of Fig. 2, the regulation of the flow for the second device (6) takes place upstream of the first device (3). The values of the flows of the blood in the part of the circuit with the branch are the same as the previous example, and the flow of blood downstream is received by the first device (3) with a flow equal to the output from the first pump (2) arranged upstream.

As expressed earlier, and with reference to the accompanying drawings, the present invention relates to an apparatus for the treatment of the blood of the type usable to execute a processing of the blood by passing the blood through a circuit comprising a first device (3) capable of working a first flow value, a first flow-adjusting means (2) adapted to determine a blood flow having said first value, and a second device (6) suitable to operate at a second flow value, lower than the first. The apparatus comprises a bifurcation (4) of the circuit which divides the same circuit in a first conduit (5, 7), which comprises said second device (6), and a second conduit (8, 10), on which is acting a second flow regulator means (9), adapted to determine a flow value equal to the difference between the value of said first flow and the value of said second flow; said first conduit (5, 7) and said second conduit (8, 10) being joined between them downstream of said second device (6) and of said flow regulator means (9).

The first means for regulating the flow (2), as well as the second means for regulating the flow (9) may be pumps.

In the aforesaid conduits therefore circulates the blood, and the bifurcation divides the circuit into two ducts in which blood circulates..

The devices described, oxygenator (3) and hemofilter (6), are components of the apparatus and not machines linked together. These devices are, in practice, individual components that are part of a circuit preassembled to work aboard of a machine specifically intended.

The invention also describes a process for the treatment of the blood. A process in accordance with the invention involves the following operative steps:

- realizing a blood circuit connected in input and in output to a patient to draw blood form the patient and to return the treated blood to the same patient;

- passing the blood through the circuit in a first device (3) suitable to operate at a first flow value and in a second device (6) suitable to operate at a second flow value, lower than the first;

- forming a bifurcation of said circuit which divides the same circuit in a first conduit (5, 7), on which said second device (6) is disposed, and a second duct (8, 10), comprising means for regulating the flow (9), adapted to determine a flow value equal to the difference between the value of said first flow and the value of said second flow; said first conduit (5, 7) and said second conduit (8, 10) being joined between them downstream of said second device (6) and of said flow regulator means (9).

The first device (3) being an oxygenator and the second device (6) being a hemofilter.

In practice, the process comprises the use of an apparatus made as described above.

It is understood that the details of execution may vary in any equivalent way as in the shape, dimensions, elements disposition, nature of the materials used, without however leaving the scope of the adopted solution idea and, thereby, remaining within the limits of the protection granted to the present patent .

CLAIMS

1. Apparatus for the treatment of blood, of the type usable to perform a processing of the blood by passing the blood through a circuit comprising a first device (3) suitable to operate at a first flow value and a second device (6) suitable to operate at a second flow value, lower than the first, apparatus characterized in that it comprises a bifurcation (4) of said circuit which divides the same circuit in a first conduit (5, 7), on which said second device (6) is placed, and a second conduit (8, 10), on which is acting a means for regulating the flow (9), adapted to determine a flow value equal to the difference between the value of said first flow and the value of said second flow; said first conduit (5, 7) and said second conduit (8, 10) being joined together downstream of said second device (6) and of said means for regulating the flow (9).

2. Apparatus according to claim 1 characterized in that said bifurcation (4) is located downstream of said first device (3).

3. Apparatus according to claim 1, characterized in that said bifurcation (4) is positioned upstream of said first device (3).

4. Apparatus according to one of the preceding claims, characterized in that said first device (3) is an oxygenator.

5. Apparatus according to one of the preceding claims, characterized in that said second device (6) it is a hemofilter.

6. Apparatus according to one of the preceding claims, characterized in that said flow regulator means (9) is a pump.

7. Apparatus according to one of claims 1 to 5, characterized in that said flow regulator means (9) is a device adapted to vary the section of the conduit (8, 10) on which is acting so as to adjust accordingly the relative flow-through.

8. Apparatus according to one of the preceding claims, characterized in that said first value is equal to about 500 ml/min and said second flow is approximately 200 ml/min.

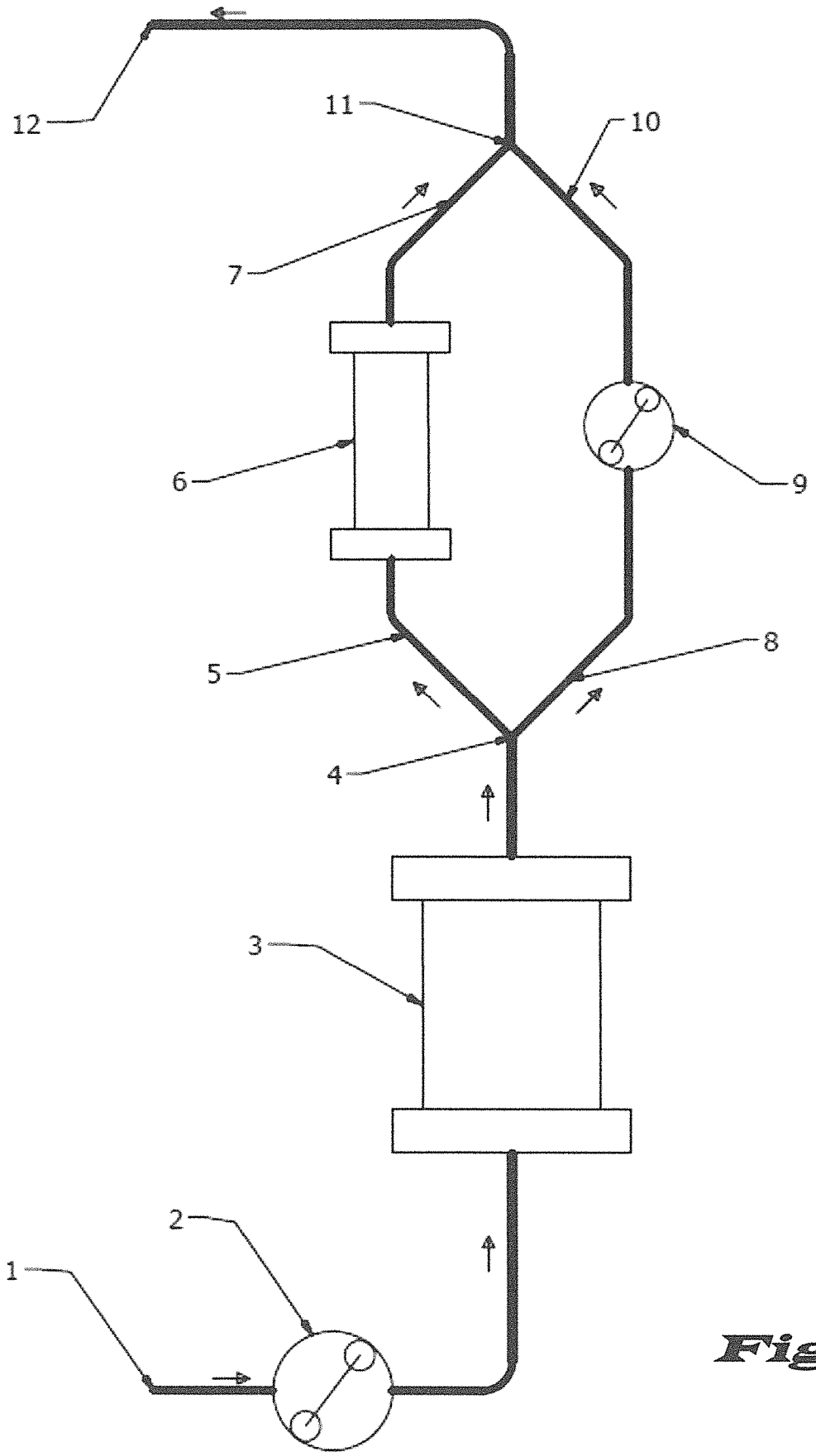

Fig. 1

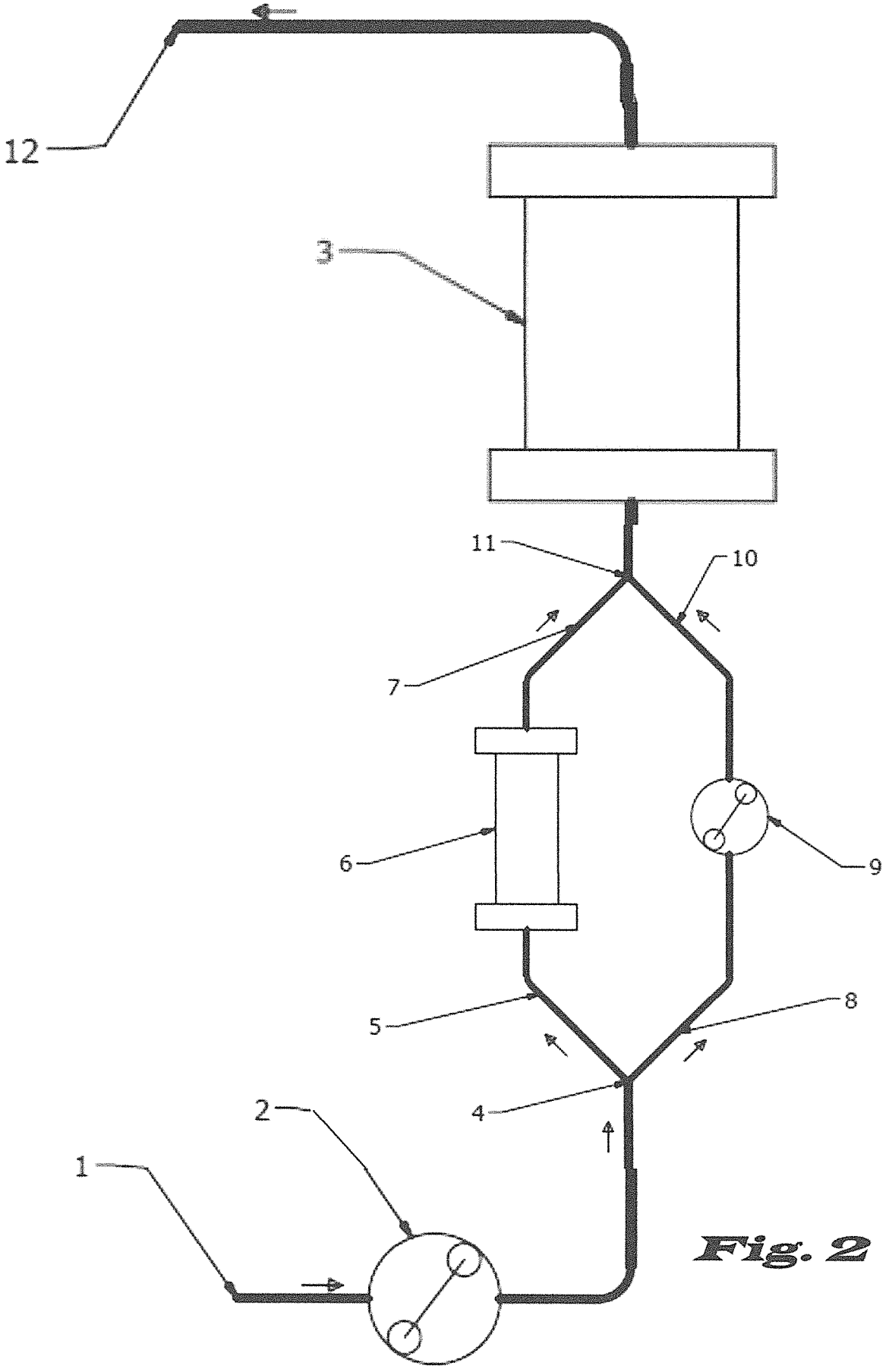

Fig. 2

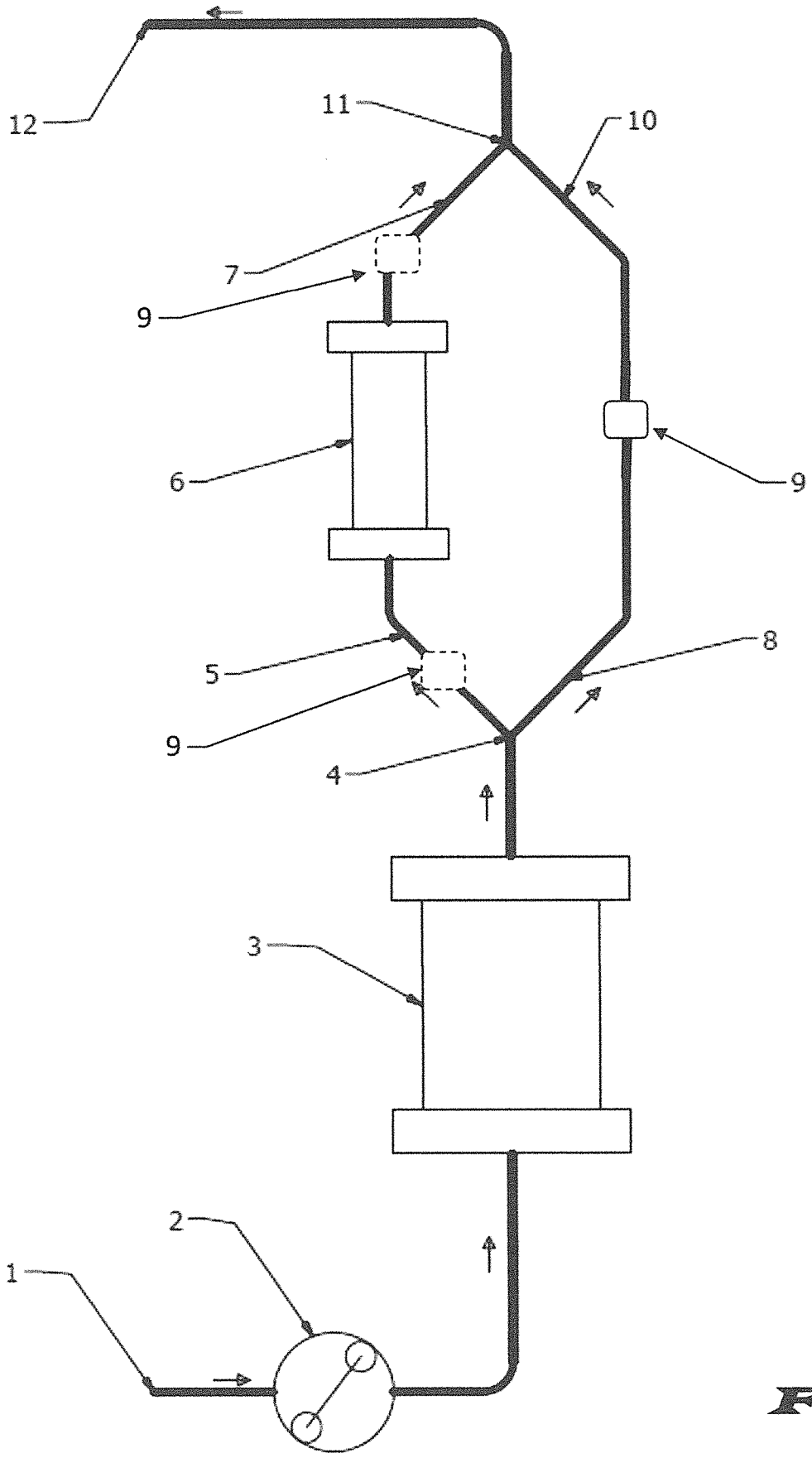

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2015/000316

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/16 A61M1/32 A61M1/34
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	CN 202 270 211 U (WENKUI YU) 13 June 2012 (2012-06-13) paragraphs [0015], [0016], [0018], [0019]; figures 1,2	1-6 7,8
X Y	EP 2 238 995 A1 (GAZZANO MICHELE [IT]) 13 October 2010 (2010-10-13) paragraphs [0016] - [0030]; figures 2,3,4	1-6 7,8
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Y	US 2007/066928 A1 (LANNOY JEAN-MICHEL [FR]) 22 March 2007 (2007-03-22) paragraphs [0010], [0111]	8

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

[X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 May 2016	12/05/2016

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

International application No
PCT/IT2015/000316

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2011/106233 A2 (UNIV MICHIGAN [US]; MUELLER BRUCE A [US]) 1 September 2011 (2011-09-01) paragraphs [0042], [0045]	8
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Y	GB 1 437 345 A (BRUMFIELD R C) 26 May 1976 (1976-05-26) page 1, column 1, lines 11-12 page 4, column 1, lines 45-47	8

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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