(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 May 2014 (15.05.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/072695 A1

(51) International Patent Classification:
A61M 1/12 (2006.01) *A61M 1/10* (2006.01)

(21) International Application Number:
PCT/GB2013/052889

(22) International Filing Date:
5 November 2013 (05.11.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1219958.4 6 November 2012 (06.11.2012) GB

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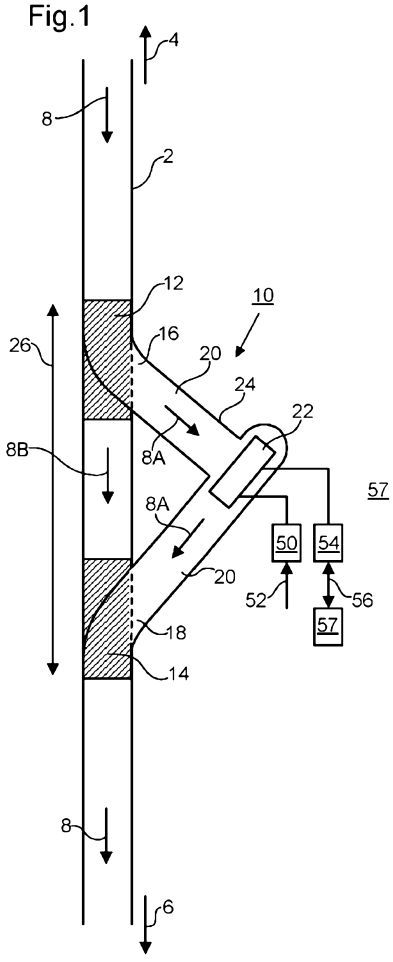
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,

[Continued on next page]

(54) Title: MECHANICAL CIRCULATORY SUPPORT

(57) Abstract: Mechanical circulatory supports configured to operate in series with the native heart are disclosed. In an embodiment, a centrifugal pump is used. In an embodiment, inlet and outlet ports are connected into the aorta and blood flow is diverted through a lumen and a centrifugal pump between the inlet and outlet ports.

Fig.1



WO 2014/072695 A1

MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

MECHANICAL CIRCULATORY SUPPORT

The present invention relates to a mechanical circulatory support (MCS) for assisting or replacing native heart function in cases of congestive heart failure (CHF).

Patients with CHF usually have a low cardiac output state as the native heart functions (pumps) poorly. This in turn leads to poor organ perfusion and the symptoms of heart failure including fatigue, breathlessness and feeling generally unwell. In heart failure the kidneys also suffer with poor perfusion and their function often deteriorates considerably (a condition called "the cardio-renal syndrome"). Poor kidney function means that patients feel more unwell, and important drugs have to be withdrawn as they can further adversely affect kidney function.

CHF is common and is a significant health care burden. It is graded from stage I-IV in severity. Stage IV patients are breathless at rest, candidates for heart transplantation, and medication is considered palliative. In the USA alone there are 5.7 million patients suffering from CHF and costs to treat this exceed $37.2 billion / year. In the Western world current supply of donor hearts only meets about 12% of demand. This percentage is higher than the actual number because most potential recipients are not included in the calculation; they are considered not suitable for a transplant because of co-morbidities or lack of a matched donor. This shortfall has resulted in the development of MCS devices as a transplant alternative. MCS devices are expensive and require invasive cardiac surgery (sternotomy or thoracotomy). Implantation carries a significant risk. Not all candidates are suitable for MCS because of co-morbidities.

Most permanent MCS devices assist the ventricle and are attached to it in use. These are called Ventricular Assist Devices (VADs), and are designed to drive a flow of blood that is in parallel with flow within the native heart, between the ventricle and the aorta. Such "in-parallel" configurations involve the device and heart sharing, and therefore competing, for inlet flow, which can disrupt normal functioning of the heart. Regeneration of heart muscle may be impeded and the heart is not able to pump to its best capacity.

Due to inefficiencies, existing MCS/VAD devices typically require significantly more input power than is necessary from a theoretical point of view purely to impart the desired momentum to the blood. The excess power is used to overcome the losses. The portion of the power that is used to overcome flow losses is imparted as unnecessary damage to the blood, leading to increased levels of haemolysis and/or thrombus formation that would be avoided with devices having higher fluid dynamic efficiency.

It is an object of the invention to provide a device that can be installed with less risk to the patient, which reduces disruption to normal functioning of the heart and/or which minimizes damage to the blood.

According to an aspect of the invention, there is provided a mechanical circulatory support, comprising: a body portion defining an internal lumen; an inlet port in fluid communication with the lumen; an outlet port in fluid communication with the lumen; and a pump for driving fluid flow from the inlet port towards the outlet port, wherein: the inlet port is arranged to provide a connection, or is in a state of

connection, into the aorta of a human body.

This arrangement does not require any connections to be made directly to the heart and can be installed using minimally invasive surgery, greatly reducing the risks associated with installation relative to arrangements that need to be connected directly to the heart. There is no need to perform a cardiopulmonary bypass for example. The reduced installation risk makes the device more suitable for treatment of earlier stage CHF than existing MCS/VAD devices, for example early stage IV CHF.

The outlet port may be connected to a downstream position in the aorta so as to be connected in series with the native heart. This type of connection is less disruptive to the normal functioning of the heart than systems which work in parallel with the heart and may help to promote regeneration of the heart muscle. Additionally or alternatively, by allowing the native heart to pump to its best capacity the additional pumping power required by the support may be reduced.

In an embodiment, the series connection is implemented by connecting the support in parallel with a small section of the descending aorta. In an alternative embodiment, the descending aorta is interrupted so that all of the blood flow passes through the support.

In other embodiments, the outlet port is connected at other positions in the vasculature, for example in the ascending aorta. In an embodiment, the support comprises one outlet port in the descending aorta and one outlet port in the ascending aorta. In this way, a proportion of the outflow is provided to the ascending aorta to support coronary flow more directly. In an embodiment, the inlet port is connected to one or more other strategic locations such as the ascending aorta, and the outlet port(s) connected as previously described into the descending aorta, the ascending aorta, or both. The descending aorta outlet has additional advantages for renal, splanchnic, and other organ perfusion without affecting brain flow.

In an embodiment, the pump is a centrifugal pump. The inventors have discovered that such pumps can provide particularly effective impetus to the circulating blood. In particular, unnecessary blood shear and fluid-dynamic diffusion (the effect of pressure rise as flow decelerates along the device passage) and turbulence can be minimized, which in turn minimizes the imposed shear stress to blood cells, thus minimizing blood cell lysis and thrombus formation. The improved pumping efficiency reduces power requirements, enabling the power supply to be made smaller and more comfortable to carry. In addition the pump itself can be made more compact. In an alternative embodiment, the pump is a mixed flow pump (e.g. a pump having characteristics intermediate between a centrifugal pump and an axial pump). In a still further embodiment, the pump is a helical pump. In a still further embodiment, the pump is an axial pump.

In an embodiment, the pump is configured to provide a continuous, rather than pulsatile flow. The inventors have realised that it is not necessary for the pump to mimic the pulsatile flow imparted by the native heart, particularly when installed so as to work in series with the heart. The pump can thus interact more smoothly with the blood flow, further minimizing damage to the blood. Additionally, the efficiency of a continuous pump can be optimized further than a pulsatile pump. Acceleration and deceleration of the

blood is reduced, which reduces the stresses that need to be applied to the blood. In alternative embodiments the pump is configured to provide a pulsatile flow (synchronous or asynchronous with the heart).

In an embodiment, the support comprises a power receiving member that is configured to receive power for driving the pump transcutaneously, for example by electromagnetic induction. Alternatively or additionally, power can be supplied percutaneously.

According to an aspect of the invention, there is provided a mechanical circulatory support, comprising: a pump configured to be installed, or in a state of installation, in a human body and configured to operate in series with the native heart; and a device for electromagnetically driving the pump that is configured to be mounted to the body. Thus, a support is provided that is suitable for "permanent" installation (e.g. so that the patient can leave the hospital with the support installed and operational) and which provides a pumping action that is in series, rather than in parallel, with the native heart.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which corresponding reference symbols indicate corresponding parts, and in which:

Figure 1 depicts a mechanical circulatory support connected to a section of vasculature and configured to drive fluid flow in parallel with a small portion of the native blood vessel;

Figure 2 depicts an alternative configuration for the mechanical circulatory support of Figure 1 in which the support drives blood flow that is entirely in series with the native blood vessel, bypassing a short portion of the native blood vessel;

Figure 3 depicts a mechanical circulatory support comprising multiple outlet ports and impedance setting members.

Figure 1 depicts a section of vasculature 2. In an embodiment, the section of vasculature 2 comprises a section of the descending aorta. In an embodiment, the section of the descending aorta is below the diaphragm (arrow 4). In an embodiment, the section of the descending aorta is upstream and/or above the renal arteries and/or splanchnic arteries (arrow 6). Blood flow is shown schematically by arrows 8, 8A and 8B.

A mechanical circulatory support 10 comprises connections into (i.e. through the wall of) the vasculature via inlet port 12 and outlet port 14. The inlet port 12 is in fluid communication with a first end 16 of a lumen 20 defined by body portion 24 of the support 10. The outlet port 14 is in fluid communication with a second end 18 of the lumen 20. A pump 22 is provided within the lumen 20 and configured for driving fluid flow in a direction away from the inlet port 12 and towards the outlet port 14.

In an embodiment, the pump 22 is a centrifugal pump. The geometry of centrifugal pumps appears at first sight to be less convenient than that of axial pumps, which are used in prior art MCS/VAD devices.

However, the inventors have recognised that efficiencies gained from the less aggressive interaction between the pump and the blood for a given level of pumping more than outweigh any difficulties imposed by the geometry. Levels of pumping that are required in the context of pumping blood can be provided with less input power and less damage to the blood. Operation at lower power levels makes it possible to reduce the dimensions of the pump. Reducing damage to blood reduces the risk of adverse side-effects during use.

In an embodiment, the pump 22 is configured to provide a continuous flow, rather than a pulsatile flow (such as that provided by the native heart). The resulting pump 22 is simpler and can be optimised more easily. The inventors have recognised that it is not necessary to mimic the pulsatile flow of the heart. This is particularly the case when the support 10 is provided in series with the heart because the extent to which the operation of the support disrupts the normal functioning of the heart is reduced in comparison to prior art arrangements that are connected directly to the heart and arranged to operate in parallel with the heart.

In the embodiment shown in Figure 1, the inlet port 12 is configured to divert a portion 8A of the blood flow within the blood vessel into the lumen 20 while allowing the remaining blood flow 8B to continue through the native blood vessel 2. The outlet port 14 is configured to allow the reintroduction of the diverted portion 8A of the blood flow back into the blood vessel 2 further downstream. In this embodiment, the support 10 therefore operates in parallel with a short portion 26 of the blood vessel 2. This approach minimises disruption to the existing vascular system and can be installed using minimally invasive surgery. In addition, the provision of a region having parallel flow paths increases the overall flow capacity of the vascular system, thereby reducing the load on the heart to a degree. The resistance and impedance of segment 8B may need to be adjusted to prevent recirculating flow between the outlet and the inlet of the pump.

In an embodiment, a device is provided for driving the pump electrically. In an embodiment, the device is configured to be mounted to the body (e.g. having components that are mounted inside the body, outside the body, or both). The support can thus be installed for long periods of time (e.g. multiple weeks, months or years). The patient is thus not required to remain within a hospital ward after the support is installed. In the embodiment shown in Figure 1, the device for driving the pump comprises a power receiving member 50, which receives power for driving the pump. The power receiving member 50 is configured to receive an input of power 52 from a power source located outside of the body (e.g. a battery mounted on the outside of the body) and/or a power source located inside the body (e.g. a battery mounted inside the body). In an embodiment, the connection between the power source and the power receiving member 50 is made wirelessly, for example using electromagnetic induction. In an embodiment, the power receiving member 50 comprises a coil. Where the wireless connection is made to a power source outside of the body, the connection may be referred to as a transcutaneous connection. In an embodiment, a wired connection is made between a power source located outside the body and the power receiving member 50.

In an embodiment, the wired connection is established percutaneously.

In an embodiment, the support 10 further comprises a data transmitter/receiver 54 for transmitting/receiving data 56 to/from a controller 57 outside of the body. In an alternative embodiment, the controller 57, or a part of the controller 57, is configured to be installed within the body (i.e. under the skin). In an embodiment of this type, the controller 57 is sealed in a manner suitable for installation within the body and/or comprises a housing made from a material that is suitable for being in contact with tissue within the body for a prolonged period of time (e.g. a biocompatible material). In an embodiment, the controller 57 comprises a housing made from the same biocompatible material as a housing for an internal power source (e.g. internal batteries) for powering part or all of the support 10.

In an embodiment, the controller 57 is configured to interact with one or more sensors for monitoring one or more operating characteristics of the pump 22. For example, speed sensors can be used to measure the rotational speed of an impeller of the pump 22. In one embodiment three (3) Hall-effect sensors are used to measure impeller rotational speed. Alternatively or additionally, the pressure rise across the impeller is measured, for instance with two pressure transducers, one upstream and one downstream of the impeller. In an embodiment, the flow rate is measured, or calibrated as a function of other measured parameters. In an embodiment the set of measurements output from the sensors, or any subset of the measurements (e.g. impeller rotational speed and pressure rise) are used (for example by the controller 57) to adaptively control the rotational velocity of the impeller and therefore also the power input to the pump motor in order to achieve the required perfusion. In other embodiments, other operational characteristics are adaptively controlled in response to one or more sensor measurements.

In one embodiment, performance data, such as impeller rotational speed and/or pressure rise and/or flow rate is/are transmitted to an internal or external unit (e.g. the controller 57 or a part of the controller 57) that is configured to sound an alarm in case of acute conditions developing, or in case of a system malfunction. In an embodiment, the performance data is transmitted wirelessly to an external unit that collects the data in an application installed in a smartphone or similar device by the patient's bedside, and for example sends them electronically to a monitoring station. In an embodiment, the monitoring station is set up to send an alarm to the patient's guardian or physician, or to emergency services. Alternatively or additionally, the system may be set up to intelligently tune operation of the pump to improve performance.

Figure 2 illustrates an alternative embodiment in which the mechanical circulatory support 10 is configured to bypass a portion of the blood vessel 2, rather than operate in parallel with this portion of the blood vessel 2, as in the embodiment of Figure 1. The inlet port 12 in this embodiment diverts all of the flow 8 within the blood vessel 2 into the lumen 20 of the support 10. Similarly, the outlet port 14 is configured to reintroduce all of the flow 8 back into the native blood vessel 2.

In the embodiments described with reference to Figures 1 and 2, the support 10 has a single inlet port 12 and a single outlet port 14. However, this is not essential. In alternative embodiments, the support 10

may comprise two or more inlet ports 12 and/or two or more outlet ports 14. In an embodiment, the support 10 comprises a single inlet port 12 within the descending aorta and two outlet ports 14. In an embodiment, the first outlet port 14 is configured to be connected into the descending aorta and the second outlet port 14 is configured to be connected into the ascending aorta. In an embodiment, the support 10 has a single inlet port 12 connected into the descending aorta and a single outlet port 14 connected into the ascending aorta. Providing an outlet to the ascending aorta may be useful for example to provide additional support to the brain, or to 'prime' the pump. Other configurations are possible according to clinical need.

Where a multiplicity of outlet ports 14 are provided, flow characteristics associated with each of the different outlet ports 14 and/or flow paths leading to the outlet ports 14, may be chosen so as to control the distribution of blood flow provided by the pump 22 according to clinical need. The flow characteristics may include the flow resistance, flow compliance and/or flow inductance. For example, where only a small contribution to the flow is required at a particular outlet port 14, the flow resistance associated with that outlet port 14 may be arranged to be relatively high. Conversely, where a relatively high flow output from the outlet port 14 is required, the flow resistance associated with that outlet port 14 may be arranged to be relatively low. Figure 3 illustrates, highly schematically, such a configuration. Here, support 10 comprises a single inlet port 12 and three different outlet ports 14A, 14B, 14C. Outlet port 14A is positioned downstream of the inlet port 12 in the same section of vasculature 2. The other outlet ports 14B and 14C are located elsewhere in the vascular system and are not shown in Figure 3. Flow characteristic setting members 28A, 28B, 28C, which may be valves for example or sections of tubing of controlled diameter, are positioned on respective flow paths between the pump 22 and each of the three outlet ports 14A, 14B, 14C. By varying the flow characteristics using the flow characteristic setting members 28A, 28B, 28C, it is possible to define the proportion of the total flow output by the pump 22 that will be present in the respective flow paths 30A, 30B and 30C.

In an embodiment, the pump is configured to provide a pumping output that is equivalent to or greater than the total pumping requirement of the body within which the support is installed, so that no additional pumping from the native heart is required. In an embodiment, the pump 22,34 is configured to provide a pressure of at least 125 mmHg and/or flow rates equivalent to the normal cardiac output of 5 litres per minute. The centrifugal pump approach of the present invention allows such pressure and flow rates to be achieved in a compact device with minimum damage to the blood. In another embodiment, the pumping output is lower than the total pumping requirement of the body. In such an embodiment the pump assists the native heart, which must provide a portion of the total pumping power.

CLAIMS

1. A mechanical circulatory support, comprising:
a body portion defining an internal lumen;
an inlet port in fluid communication with the lumen;
an outlet port in fluid communication with the lumen; and
a pump for driving fluid flow from the inlet port towards the outlet port, wherein:
the inlet port is arranged to provide a connection, or is in a state of connection, into the aorta of a human body.

2. A supporting according to claim 1, wherein the inlet port is arranged to provide the connection, or is in the state of connection, into the descending aorta of the human body.

3. A support according to claim 2, wherein:
the outlet port is arranged to provide a connection, or is in a state of connection, into the vascular system at a position other than the descending aorta.

4. A support according to claim 3, wherein:
the position other than the descending aorta comprises a position in the ascending aorta.

5. A support according to any of claims 2-4, wherein:
the outlet port is arranged to provide a connection, or is in a state of connection, into the descending aorta, downstream of the inlet port.

6. A support according to any of the preceding claims, wherein the inlet port is arranged to provide the connection, or be in the state of connection, at a position below the diaphragm.

7. A support according to any of the preceding claims, wherein the outlet port is arranged to provide the connection, or be in the state of connection, at a position upstream of the renal arteries or the splanchnic arteries.

8. A support according to any of the preceding claims, wherein:
the inlet and outlet ports are arranged to provide connections, or be in states of connection, at respective upstream and downstream positions in a section of vasculature such that, when connected, blood flows between the upstream and downstream positions partly through the aorta and partly through the

internal lumen of the support.

9. A support according to any of claims 1 to 7, wherein:

the inlet and outlet ports are arranged to provide connections, or be in states of connection, at respective upstream and downstream positions in a section of vasculature such that, when connected, blood is diverted so as to flow entirely through the internal lumen of the support between the upstream and downstream positions.

10. A support according to claim 8 or 9, wherein the section of the vasculature is the aorta.

11. A support according to claim 10, wherein the section of the vasculature is the descending aorta.

12. A support according to any of the preceding claims, comprising:

a plurality of the outlet ports, each outlet port being arranged to provide a connection, or be in a state of connection, into the vascular system at a different position; and

one or more flow characteristic setting members for controlling the distribution of flow between the pump and each of the outlet ports.

13. A support according to claim 12, wherein the one or more flow characteristic setting members are each configured to control one or more of the following: flow resistance, flow compliance, flow inductance.

14. A mechanical circulatory support, comprising:

a pump configured to be installed, or in a state of installation, in a human body and configured to operate in series with the native heart; and

a device for electrically driving the pump that is configured to be mounted to the body.

15. A support according to claim 14, wherein the pump is configured to be installed, or is in a state of installation, within the aorta.

16. A support according to claim 15, wherein the pump is configured to be installed, or is in a state of installation, within the descending aorta.

17. A support according to any of the preceding claims, further comprising a controller for controlling operation of the pump.

18. A support according to claim 17, wherein the controller is configured to be installed under the skin.

19. A support according to claim 17 or 18, wherein the controller comprises a biocompatible housing so as to be suitable for installation under the skin.

20. A support according to any of the preceding claims, configured to provide a pumping output equivalent to or greater than that required by the body, so that no additional pumping from the native heart is required.

21. A support according to any of claims 1 to 19, configured to provide a pumping output less than the total required by the body, so as to supplement pumping provided by the native heart.

22. A support according to any of the preceding claims, further comprising:
a power receiving member configured to receive power for driving the pump transcutaneously.

23. A support according to claim 22, wherein the power receiving member is configured also to receive power for driving the pump percutaneously.

24. A support according to any of claims 1 to 21, further comprising:
a power receiving member configured to receive power for driving the pump percutaneously.

25. A support according to any of the preceding claims, wherein the pump is configured to provide a continuous flow.

26. A support according to any of claims 1-24, wherein the pump is configured to provide a pulsatile flow.

27. A support according to any of claims 1-26, wherein the pump is a centrifugal pump.

28. A support according to any of claims 1-26, wherein the pump is a mixed flow pump.

29. A support according to any of claims 1-26, wherein the pump is a helical pump.

30. A support according to any of claims 1-26, wherein the pump is an axial pump.

31. A support configured and arranged to operate substantially as hereinbefore described with reference to and/or as illustrated in the accompanying drawings.

Fig.1

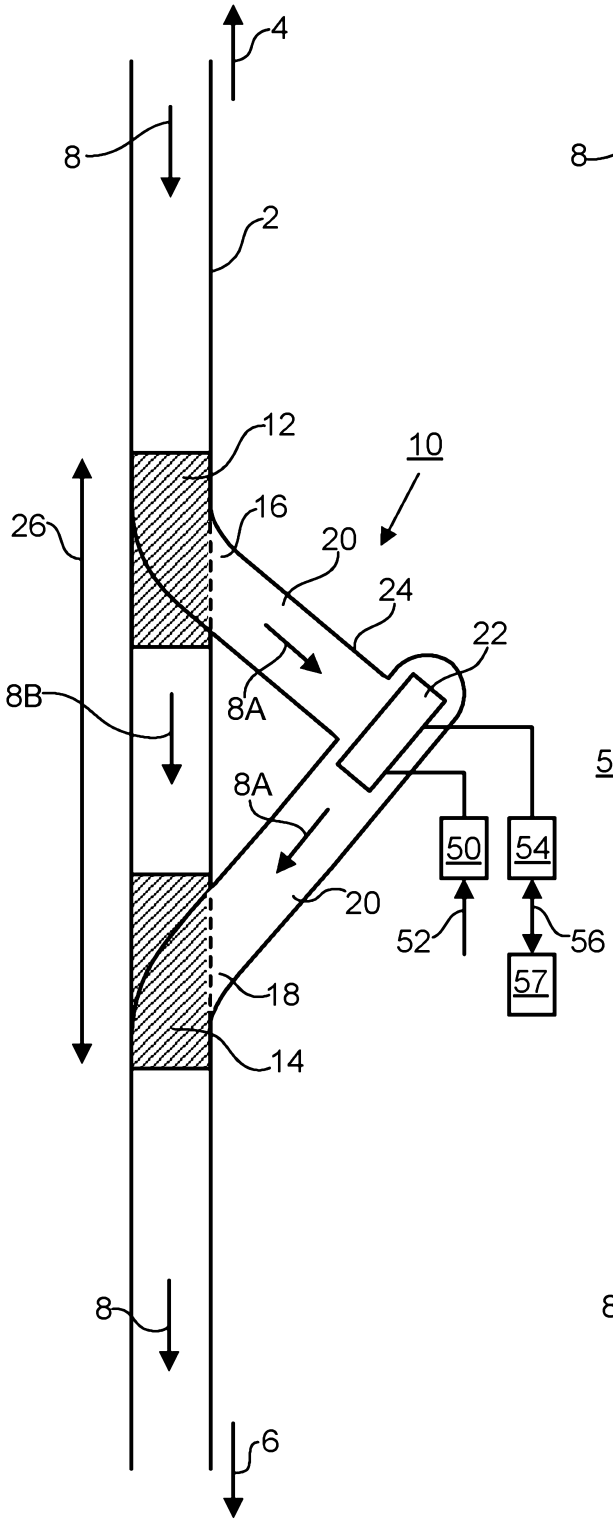

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Fig.2

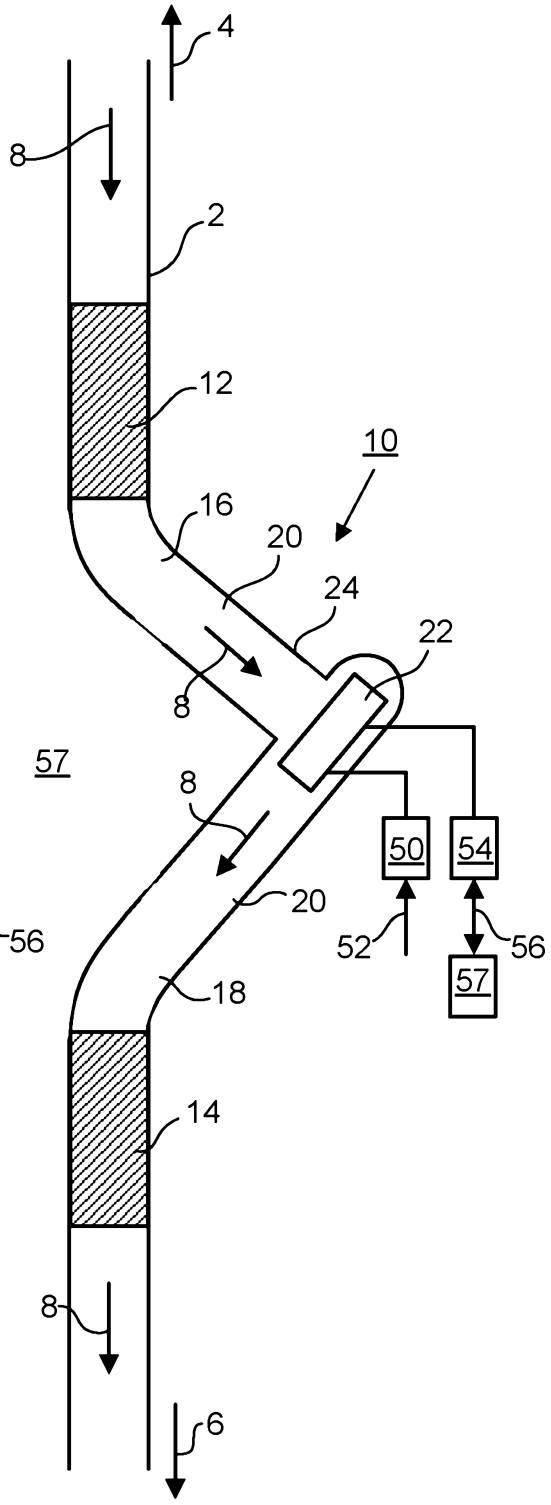
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Fig.3