(12) STANDARD PATENT (11) Application No. **AU 2013254650 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Pulsatile blood pump

(51) International Patent Classification(s)
A61M 1/10 (2006.01)

(21) Application No: **2013254650** (22) Date of Filing: **2013.04.25**

(87) WIPO No: **WO13/160411**

(30) Priority Data

(31) Number	(32) Date	(33) Country
102012207042.7	**2012.04.27**	**DE**

(43) Publication Date: **2013.10.31**
(44) Accepted Journal Date: **2016.12.22**

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(56) Related Art
US 2010/0268333 A1

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
31. Oktober 2013 (31.10.2013)

WIPO | PCT

(10) Internationale Veröffentlichungsnummer
WO 2013/160411 A1

(51) Internationale Patentklassifikation:
A61M 1/10 (2006.01)

(21) Internationales Aktenzeichen: PCT/EP2013/058648

(22) Internationales Anmeldedatum:
25. April 2013 (25.04.2013)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
102012207042.7 27. April 2012 (27.04.2012) DE

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(84) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, RU, TJ, TM), europäisches (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, ML, MR, NE, SN, TD, TG).

Erklärungen gemäß Regel 4.17:

— *hinsichtlich der Berechtigung des Anmelders, ein Patent zu beantragen und zu erhalten (Regel 4.17 Ziffer ii)*

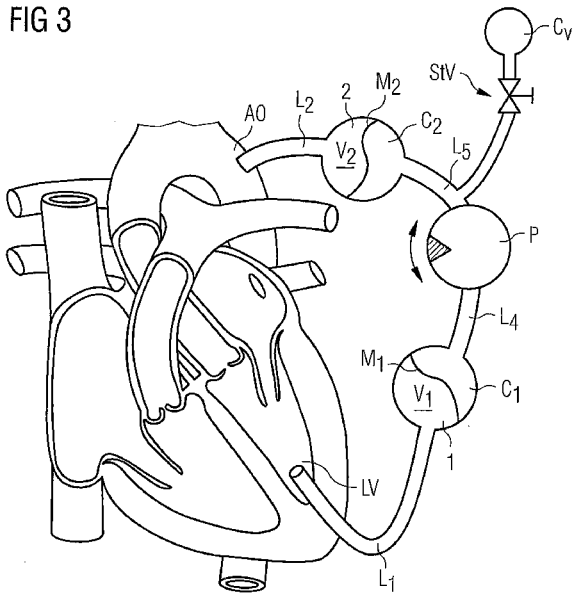
— *Erfindererklärung (Regel 4.17 Ziffer iv)*

[Fortsetzung auf der nächsten Seite]

(54) Title: PULSATILE BLOOD PUMP

(54) Bezeichnung : PULSATIONSBLUTPUMPE

FIG 3



(57) Abstract: The invention relates to an extra-vascular pulsatile blood pump comprising a bi-directionally active pump system (P, M) with a pump (P) which is connected via a first line (L_1) to the left ventricle (LV) and via a second line (L2) to the aorta (AO). A control (ST) enables a pump (P) to operate in accordance with a predetermined cardiac rhythm in alternate directions such that blood is taken in alternately by the first line (L_1) and simultaneously propelled out in the same amount by the other line (L_2), and is also taken in by the second line (L_2) and simultaneously propelled out by the first line (L_1). Said pulsatile blood pump combines the functions and advantages of an extravascular copulsatile pump with that of a extravascular counter pulsatile blood pump.

(57) Zusammenfassung: Eine extravasale Pulsationsblutpumpe besitzt ein bidirektional wirkendes Pumpsystem (P, M) mit einer Pumpe (P), die über eine erste Leitung (L_1) mit dem linken Ventrikel (LV) und über eine zweite Leitung (L_2) mit der Aorta (AO) verbunden ist. Mittels einer Steuerung (St) wird die Pumpe (P) entsprechend einem vorgegebenen Herzrythmus abwechselnd in die eine und die andere Richtung betrieben, so dass Blut abwechselnd einerseits durch die erste Leitung (L_1) angesaugt und gleichzeitig Blut im selben Maße durch die zweite Leitung (L_2) ausgestoßen wird und andererseits Blut durch die zweite Leitung (L_2) angesaugt und gleichzeitig Blut durch die erste Leitung (L_1) ausgestoßen wird. Die Pulsationsblutpumpe kombiniert die Funktionen und Vorteile einer extravasalen Copulsationspumpe mit denen einer extravasalen Gegenpulsationsblutpumpe.

WO 2013/160411 A1

Veröffentlicht:

— *mit internationalem Recherchenbericht (Artikel 21 Absatz 3)*

Pulsation blood pump

[0001] This invention relates to an extravascular pulsation blood pump and finds application in supporting the pulsation of the human heart.

[0002] To enable a previously damaged human heart to recover, the pulsation of the heart is supported by means of artificial pumps. So-called intraaortic balloon pumps (IABPs) find wide application. A balloon is thus placed in the aorta and filled with helium and emptied alternately, according to the cardiac rhythm, through a relatively long catheter from outside the body. Emptying is effected shortly before the onset of systole to thereby significantly lower the blood pressure in the aorta, so that the heart can eject its blood volume into the aorta against a low aortic pressure. At the onset of diastole the balloon is filled again, thereby increasing the pressure in the aorta and thus driving the blood into the organs and peripheral blood vessels. This method is also known as the counterpulsation or aortic counterpulsation method.

[0003] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

[0004] US 2005/0096496 A1 points out various disadvantages of intraaortic balloon pumps. Among other things, they involve the risk of infection due to the indwelling catheter, and do not allow the patient to get out of bed. Hence, they are normally only used for one or two days, although chronically weak hearts actually require long-term support. Moreover, the catheter hinders blood flow in the blood vessel. Hence, it is proposed therein to connect a subcutaneously implanted pump to an arterial blood vessel via a conduit and to suck blood out of the artery when the heart contracts (systole) and pump it back into the artery again when the heart relaxes (diastole). In this manner a counterpulsation is obtained without a balloon closing the blood vessel itself or a catheter extending within the blood vessel. The pump can be configured as a bladder, sack or diaphragm pump. It is also proposed to supplement the extravascular counterpulsation pump by a second extravascular pump with which blood is continuously sucked directly out of the heart via a first conduit and fed via a second conduit directly to that artery to which the extravascular counterpulsation pump is also connected.

[0005] Extravascular counterpulsation blood pumps can attain substantially higher volume flows than conventional aortic balloon pumps, namely up to 2.4 l per minute instead of 0.7 l per minute. Such counterpulsation systems can furthermore be replaced or supplemented by

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copulsation systems in which the conduit of the extravascular blood pump is connected directly to a ventricle of the heart. The pump then sucks blood out of the ventricle into a chamber temporarily during diastole to thereby minimize the blood volume in the ventricle and prevent a dilatation of the heart, and pumps this blood during the following systole back into the ventricle, from where it flows into the arterial blood vessel through the open cardiac valve.

[0006] Both counterpulsation and copulsation by means of an extravascular blood pump fully implanted in the body involve the problem that the blood sucked by means of the pump must be stored temporarily in a reservoir. For this purpose, the blood pump possesses a so-called compliance chamber whose volume accordingly decreases upon filling of the blood pump. Compliance chambers are relatively voluminous. This applies in particular to gas-filled compliance chambers, because in the case of a small gas-filled compliance chamber the pump would require a great deal of energy to accordingly compress the gas volume of the compliance chamber during the suction phase. This problem doubles when both a counterpulsation pump and a copulsation pump are implanted simultaneously.

[0007] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

[0008] According to a first aspect, the invention provides an extravascular pulsation blood pump, comprising

- a first conduit for connecting the pulsation blood pump to a heart chamber(,
- a second conduit for connecting the pulsation blood pump to a blood vessel,
- a bidirectional pumping system which is arranged for alternately sucking blood through the first conduit and simultaneously ejecting blood through the second conduit, on the one hand, and sucking blood through the second conduit and simultaneously ejecting blood through the first conduit, on the other hand, and
- a control means which is provided for operating the pumping system alternately in one and the other direction according to a given cardiac rhythm.

[0009] Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to”.

[0010] Advantageously the pulsation blood pump according to the invention combines the functions of counterpulsation and copulsation and possesses for this purpose a bidirectionally

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acting pumping system which is connected via two conduits to a blood vessel, for example the aorta, on the one hand, and to a heart chamber, for example the left ventricle, on the other hand. Preferably, between the heart and the blood vessel there is a valve, which is normally formed by a cardiac valve. The bidirectional pumping system is arranged for removing a first quantity of blood from the heart during diastole of the heart and substantially simultaneously bringing a second quantity of blood into the blood vessel. On the other hand, preferably the pumping system is arranged for removing a quantity of blood corresponding to the second quantity from the blood vessel again during the heart's systole following the diastole and substantially simultaneously in turn bringing a quantity of blood corresponding to the first quantity into the heart. The first and second quantities can be identical, but this is not necessary, for the pumping system can be configured as a differential pumping system.

[0011] As a result, advantageously the heart is considerably relieved both during systole and during diastole. For the heart pumps against a lower arterial pressure during systole because blood is simultaneously being removed from the blood vessel into which the heart is pumping. During the subsequent diastole the heart is relieved by a part of the filling volume being removed from the relevant heart chamber by means of the blood pump and brought into the heart chamber again only during the following systole. The heart chamber thus expands less, thereby preventing or reducing a dilatation or widening of the heart chamber. Even when the heart chamber widens to its normal extent and fills with blood during diastole, it is at least achieved by means of the pulsation blood pump according to the invention that the filling volume of the relevant heart chamber "increases" by the quantity of blood removed from the heart chamber by means of the bidirectional pumping system, because this very quantity is returned to the heart chamber again during the following systole and this quantity of blood is ejected into the connected vascular system at the same time as the heart activity. While the heart is relieved and/or extended in capacity during diastole in this manner, the pressure in the appurtenant blood vessel, for example the aorta, is increased due to the blood quantity simultaneously brought into the blood vessel, so that the organs and adjacent blood vessels are supplied with more blood due to the increased blood pressure in the relevant blood vessel. The pulsation blood pump according to the invention having a bidirectionally acting pumping system thus combines the functions and advantages of a copulsating extravascular blood pump with those of a counterpulsating extravascular blood pump.

[0012] One preferred advantage of the pulsation blood pump according to the inventionis that it is not necessary to provide a separate compliance chamber for each of these two functions. Instead, the pumping system can have for example a first pumping chamber with variable volume which is attached for example to the heart chamber, and a second pumping

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chamber with variable volume which is then attached to the corresponding blood vessel, the two pumping chambers being so coupled with each other that to the same extent as blood is sucked into the first pumping chamber, blood is ejected from the second pumping chamber, and vice versa. Accordingly, the two pumping chambers respectively act as a compliance chamber for the other pumping chamber. This can be illustrated by comparison with a double-acting cylinder piston. While displacement of the piston within a cylinder reduces the volume before the piston in the moving direction, it increases the volume behind the piston. The decreasing volume before the piston is comparable to a compliance chamber for the increasing volume behind the piston. In the reverse moving direction of the piston this functionality is accordingly reversed. That is to say, the pressurized chamber of the piston cylinder always acts simultaneously as a pumping chamber out of which something is pumped, and as a compliance chamber for the chamber located on the other side of the piston.

[0013] This basic principle can be modified in different ways. In particular, there can be realized by means of a differential piston a differential pumping system which pumps different volume flows in one and the other direction, the piston stroke being identical in absolute terms.

[0014] According to the invention, the respective pressures on the suction side of the pump help to minimize the required energy for displacing the piston or the hydraulic liquid. This is crucial in particular for a fully implantable system in order to minimize battery size.

[0015] Another modification of the above-described basic principle provides for separate compliance chambers. That is to say, while the volume on one side of the piston acts as a pumping chamber and as a compliance chamber simultaneously with the above-described double-acting cylinder piston, these two functions are mutually separate in this modified embodiment. Thus, the bidirectional pumping system can possess a first pumping chamber with variable volume and a first compliance chamber with variable volume which together form a first double chamber, and a second pumping chamber with variable volume can form together with a second compliance chamber with variable volume a second double chamber. The compliance chambers are separated from the respective appurtenant pumping chamber here by a variable partition, which can be configured for example as a flexible membrane or at least comprise a flexible membrane. By means of a pump a fluid is now pumped back and forth between the two compliance chambers, so that, depending on the pumping direction, blood is ejected from the one appurtenant pumping chamber while blood is simultaneously sucked into the other appurtenant pumping chamber, and vice versa.

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[0016] Advantageously this last-mentioned modification of the basic principle over conventional systems provides that the compliance chambers may be filled with a liquid instead of a gas, so that the compliance chambers do not have to be greater than the blood volume to be received by the pumping chambers. This advantageously makes the system especially efficient and furthermore safer in comparison to gas-filled compliance chambers. The liquid to be used may be any liquid. A further advantage of this modification over the double-acting cylinder piston is that the pump is decoupled from the blood, that is to say, the pump only pumps liquid between the two compliance chambers, and not blood.

[0017] The pulsation blood pump according to the invention may be implanted completely into a patient's body. But at least the pumping system is provided and arranged for being implanted. An energy supply means for the pump or, if the pump is driven by means of a separate motor, for this motor, can likewise be implantable and be charged from time to time or continuously for example transcutaneously either using physical contacts or preferably contactlessly.

[0018] The pulsation blood pump according to the invention of course comprises a control means which is provided and arranged for operating the bidirectional pumping system alternately in one and the other direction according to a given cardiac rhythm. The cardiac rhythm can be captured in different ways using suitable sensor means, and the thus established cardiac rhythm data transmitted to the control means. In particular, the pulsation blood pump can be controlled by means of the same cardiac rhythm data that are also employed for controlling conventional synchronous heart-support systems, such as e.g. intraaortic blood pumps.

[0019] According to another aspect the invention provides a method for supporting the pulsation of a heart, comprising the following steps:

a) removing a first quantity of blood from the heart and bringing a second quantity of blood into a blood vessel substantially during a diastole of the heart,

b) removing a quantity of blood corresponding to the second quantity from the blood vessel and bringing a quantity of blood corresponding to the first quantity into the heart substantially during a systole of the heart following the diastole, and

c) repeating the steps a) and b) a plurality of times,

wherein the first and second quantities of blood are removed and brought in by means of the same pumping system.

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[0020] Advantageously the present invention improves the support of the heart's pulsation by means of extravascular pulsation blood pumps, and in particular advantageously propose a pulsation blood pump that is optimized with respect to its functionality and overall size in comparison to the previously described extravascular pulsation blood pump.

[0021] Hereinafter the invention will be explained by way of example with reference to the accompanying drawings. Therein are shown:

[0022] Figure 1 the basic principle of a pulsation blood pump according to the invention by the example of support for the left ventricle,

[0023] Figure 2 a first modification of the basic principle,

[0024] Figure 3 a second modification of the basic principle, and

[0025] Figure 4 the basic principle by the example of supporting the right ventricle.

[0026] With reference to the schematic representation according to Figure 1, the basic principle of the pulsation blood pump according to the invention will be explained hereinafter. The pulsation blood pump consists substantially of a bidirectional pumping system which is connected via a first conduit L1 and a second conduit L2 to a blood vessel, here the aorta AO, on the one hand, and to a heart chamber, here the left ventricle LV, on the other hand. The bidirectional pumping system consists substantially of a pump P and a motor M driving the pump P. How the pump and/or the motor are concretely constituted and coupled with each other in the particular case is of minor importance to the invention. What is essential to the basic principle represented in Figure 1 is that the pump P is configured in the manner of a double-acting piston-cylinder arrangement wherein the piston K is moved in a direction back and forth within a cylinder Z. This changes the volumes V1 and V2 in the mutually opposing pumping chambers 1 and 2 separated by the piston K.

[0027] The motor M and thus the pump P is operated alternately in one and the other direction according to a given cardiac rhythm via a control means St. The cardiac rhythm data for controlling the pumping system (e.g. pressure, ECG, contraction, PPS, etc.) can be captured by means of a sensor means S coupled with the control means St and be transmitted to the control means St. This is indicated in Figure 1 only schematically by a sensor S lying in the atrium of the left ventricle LV, which may be a pressure sensor.

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[0028] The energy necessary for operating the pumping system can be made available from an energy storage device E, which is accordingly charged for example contactlessly either continually or preferably temporarily via a transmitter T.

[0029] Employing this energy and with consideration of the cardiac rhythm data processed by the control means St, the piston K is now displaced according to the cardiac rhythm such that during systole the volume V1 of the pumping chamber 1 is reduced and blood is accordingly pumped out of the pumping chamber 1 via the conduit L1 into the left ventricle LV. Thus, blood is simultaneously sucked out of the aorta AO through the conduit L2 into the increasing volume V2 of the second pumping chamber 2. The left ventricle LV thus works against a reduced aortic pressure, and also the blood volume displaced out of the pumping chamber 1 flows through the left ventricle LV and the aortic valve into the aorta AO. During the following diastole the piston K is moved in the opposite direction, so that blood is sucked out of the left ventricle LV through the conduit L1 into the pumping chamber 1, and simultaneously a corresponding quantity of blood is pumped out of the second pumping chamber 2 through the conduit L2 into the aorta AO. This minimizes the expansion of the left ventricle LV and counteracts a dilatation of the heart, so that the heart can recover. Simultaneously, the blood pumped into the aorta AO so increases the blood pressure in the aorta AO that the blood flows reliably into the organs, i.e. also in the heart, and the peripheral blood vessels. Reduction of the diastolic ventricular size enables the wall stress of the myocardium to be minimized and thus the heart to be supplied with blood more efficiently.

[0030] Figure 2 shows a first modification of this basic principle. The piston K is configured here as a differential piston with two piston areas of different size. Accordingly, the volumes V1 and V2 do not change to the same extent upon a motion of the piston K in the direction R. In the concretely represented exemplary embodiment, a smaller quantity of blood is pumped back and forth between the left ventricle LV and the pumping chamber 1 due to the differential piston K than between the aorta AO and the second pumping chamber 2. Depending on which heart function is to be mainly supported by the pulsation blood pump, the greater piston area of the differential piston can lie on the side of either the heart or the blood vessel. However, the differential piston K requires on the side of the smaller piston area an additional compliance chamber C, which is connected to the pump P via a conduit L3. The compliance chamber C takes up the difference resulting from the volume displacement V2 and V1, which is positive or negative depending on the displacement direction of the differential piston K. The compliance chamber C is placed at a location within the patient where it is only subjected to low ambient pressure, for example in the abdomen, and is connected to the pump P via a

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conduit L3. In the conduit L3 and the compliance chamber C there is preferably located a liquid, i.e. in particular no blood.

[0031] Figure 3 shows a second modification of the basic principle. Here, the first pumping chamber 1 forms with a first compliance chamber C1 a first double chamber, and the second pumping chamber 2 with a second compliance chamber C2 a second double chamber. The pumping chambers 1 and 2 are separated from the compliance chambers C1 and C2 by a respective membrane M1 and M2, so that the volume V1 and V2 of the pumping chambers 1 and 2 is respectively variable. By means of a pump P, which is rendered here only schematically and may be a bidirectional rotation pump by way of example, a fluid is then pumped back and forth between the compliance chambers C1 and C2 according to the cardiac rhythm such that the variable volumes V1 and V2 of the two pumping chambers 1 and 2 change in the manner described hereinabove with reference to Figure 1. For this purpose, the pump P is connected to the compliance chambers C1 and C2 via the conduits L4 and L5. In the conduits L4, L5 and the compliance chambers C1, C2 there is located a hydraulic fluid, i.e. in particular no blood. The pump P is thus reliably shielded from the blood circulation by means of the membranes M1 and M2. This is favorable for the structure and the effectiveness of the pumps P usable for the pumping system. Likewise, it considerably improves the fatigue strength of the pumping system.

[0032] An additional compliance chamber CV can be provided to take up volume fluctuations when the blood quantities V1 and V2 vary in size. Figure 3 shows such an additional compliance chamber CV for taking up a part of the fluid pumped between the compliance chambers C1 and C2. This additional compliance chamber CV is optional and preferably adjustable variably with regard to its compliance properties. For adjusting the compliance properties, the control valve StV is used. The adjustment can be effected either prior to implantation or preferably for example by remote control also after implantation either as needed or continually. This enables the blood volumes received in the pumping chambers 1 and 2 to be varied, also dynamically, where applicable. A reason for such a measure may be for example that problems arise upon filling of one or the other of the two pumping chambers 1 and 2, or that the available volumes of the pumping chambers 1 and 2 are to be varied intentionally. Thus, it is possible that different volumes are pumped between the appurtenant compliance chambers C1 and C2 in spite of the common pump P for both pumping chambers 1 and 2, with the differential volume being taken up by the additional compliance chamber CV. By means of the control valve StV it is thus possible to control the suction volumes and ejection volumes of the pumping chambers 1 and 2 variably. However, the volume reduction

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must not have the result that so much blood continually remains in one of the pumping chambers that successive agglutination of the blood is to be feared.

[0033] Instead of the additional compliance chamber CV being attaching to the conduit L5, it can also be attached to the conduit L4.

[0034] Figure 4 finally shows yet a further modification of the basic principle represented in Figure 1. Here, the conduits L1 and L2 of the pulsation blood pump are not connected to the left ventricle LV and the aorta AO, but instead to the right ventricle RV and the pulmonary arteries PA.

[0035] There is also the possibility to operate two separate pulsation blood pumps of the above-described type simultaneously for the left half of the heart, on the one hand, and for the right half of the heart, on the other hand.

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Claims

1. An extravascular pulsation blood pump, comprising

- a first conduit for connecting the pulsation blood pump to a heart chamber(,
- a second conduit for connecting the pulsation blood pump to a blood vessel,
- a bidirectional pumping system which is arranged for alternately sucking blood through the first conduit and simultaneously ejecting blood through the second conduit, on the one hand, and sucking blood through the second conduit and simultaneously ejecting blood through the first conduit, on the other hand, and
- a control means which is provided for operating the pumping system alternately in one and the other direction according to a given cardiac rhythm.

2. A pulsation blood pump according to claim 1, comprising a sensor means coupled with the control means for capturing and transmitting cardiac rhythm data to the control means.

3. A pulsation blood pump according to claim 1 or 2, wherein the pumping system has a first pumping chamber with variable volume which is attached to the first conduit, and a second pumping chamber with variable volume which is attached to the second conduit, wherein the first and second pumping chambers are so coupled with each other that when blood is sucked into the first pumping chamber through the first conduit blood is ejected from the second pumping chamber into the second conduit, and vice versa.

4. A pulsation blood pump according to claim 3, wherein the first pumping chamber forms with a first compliance chamber with variable volume a first double chamber, and the second pumping chamber with a second compliance chamber with variable volume a second double chamber, wherein the first pumping chamber is separated from the first compliance chamber and the second pumping chamber from the second compliance chamber by a respective variable partition, and wherein the pumping system comprises a pump which is arranged for pumping a fluid back and forth between the first compliance chamber and the second compliance chamber.

5. A pulsation blood pump according to claim 4, wherein the partitions respectively comprise a flexible membrane.

6. A pulsation blood pump according to either of claims 4 to 5, wherein the fluid is a liquid.

7. A pulsation pump according to any one of claims 1 to 6, wherein the pumping system is a differential pumping system.

8. A pulsation blood pump according to any one of claims 1 to 7, wherein the pumping system is arranged for being implanted into a patient's body.

9. A method for supporting the pulsation of a heart, comprising the following steps:

a) removing a first quantity of blood from the heart and bringing a second quantity of blood into a blood vessel substantially during a diastole of the heart,

b) removing a quantity of blood corresponding to the second quantity from the blood vessel and bringing a quantity of blood corresponding to the first quantity into the heart substantially during a systole of the heart following the diastole, and

c) repeating the steps a) and b) a plurality of times,

wherein the first and second quantities of blood are removed and brought in by means of the same pumping system.

10. A method according to claim 9, wherein the blood removed from the heart and the blood vessel is stored temporarily in separate pumping chambers of the pumping system, and the same blood is brought into the heart or blood vessel again with the next systole or diastole.

11. A method according to claim 10, wherein the first pumping chamber is coupled with a first compliance chamber, and the second pumping chamber with a second compliance chamber, and wherein blood flow is effected from the first pumping chamber into the heart and from the second pumping chamber into the blood vessel by alternatingly filling and emptying the first and second compliance chambers .

12. A method according to any one of claims 9 to 11, wherein the blood is removed from the heart from the left half of the heart, in particular the left ventricle, and the blood from the blood vessel from the aorta.

13. A method according to anyone of claims 9 to 11, wherein the blood is removed from the heart from the right half of the heart, in particular the right ventricle, and the blood from the blood vessel from the pulmonary arteries.

14. A method according to any one of claims 9 to 13, wherein a greater quantity of blood is removed from the heart than from the blood vessel.

15. A method according to any one of claims 9 to 13, wherein a greater quantity of blood is removed from the blood vessel than from the heart.

FIG 1

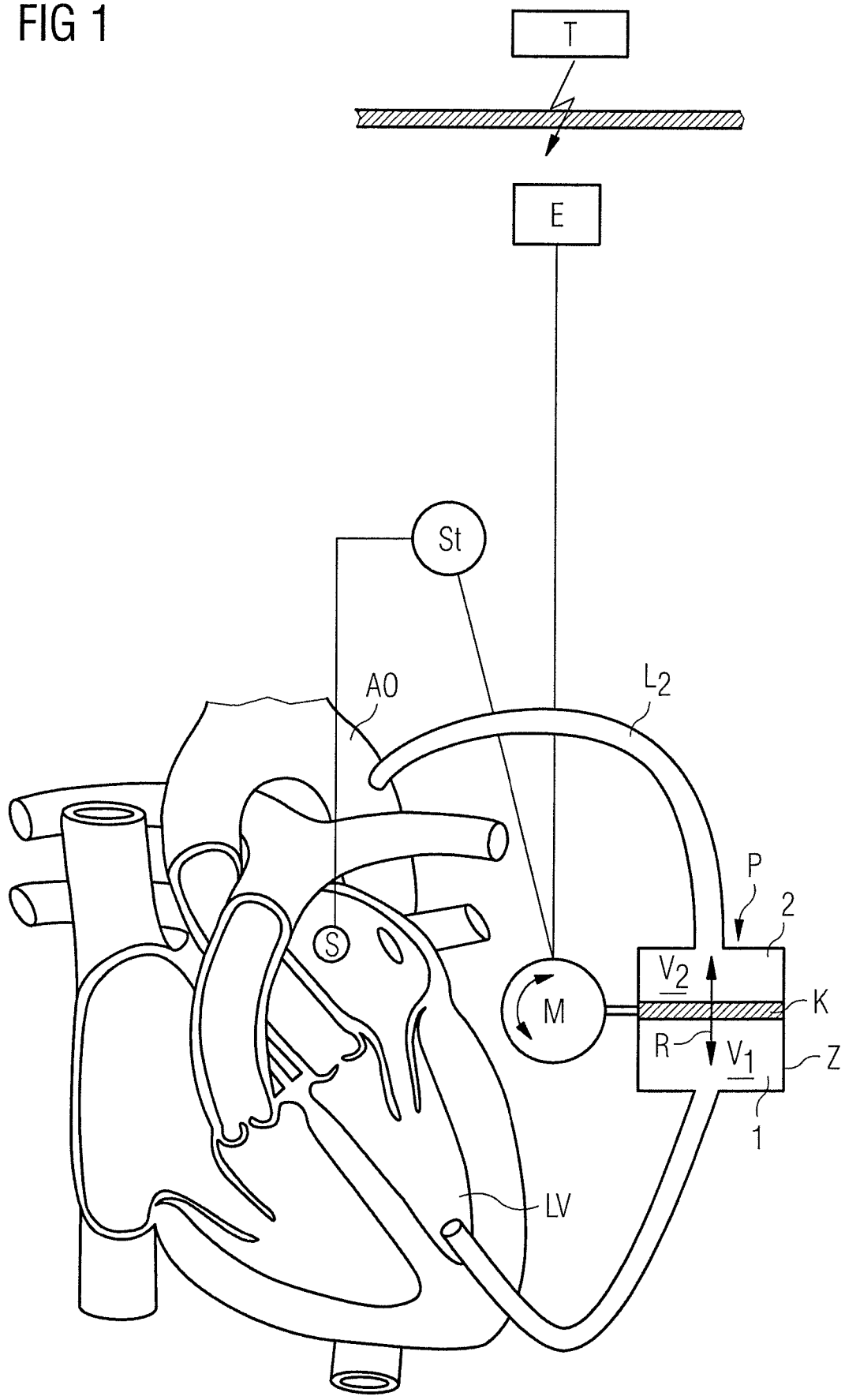

FIG 2

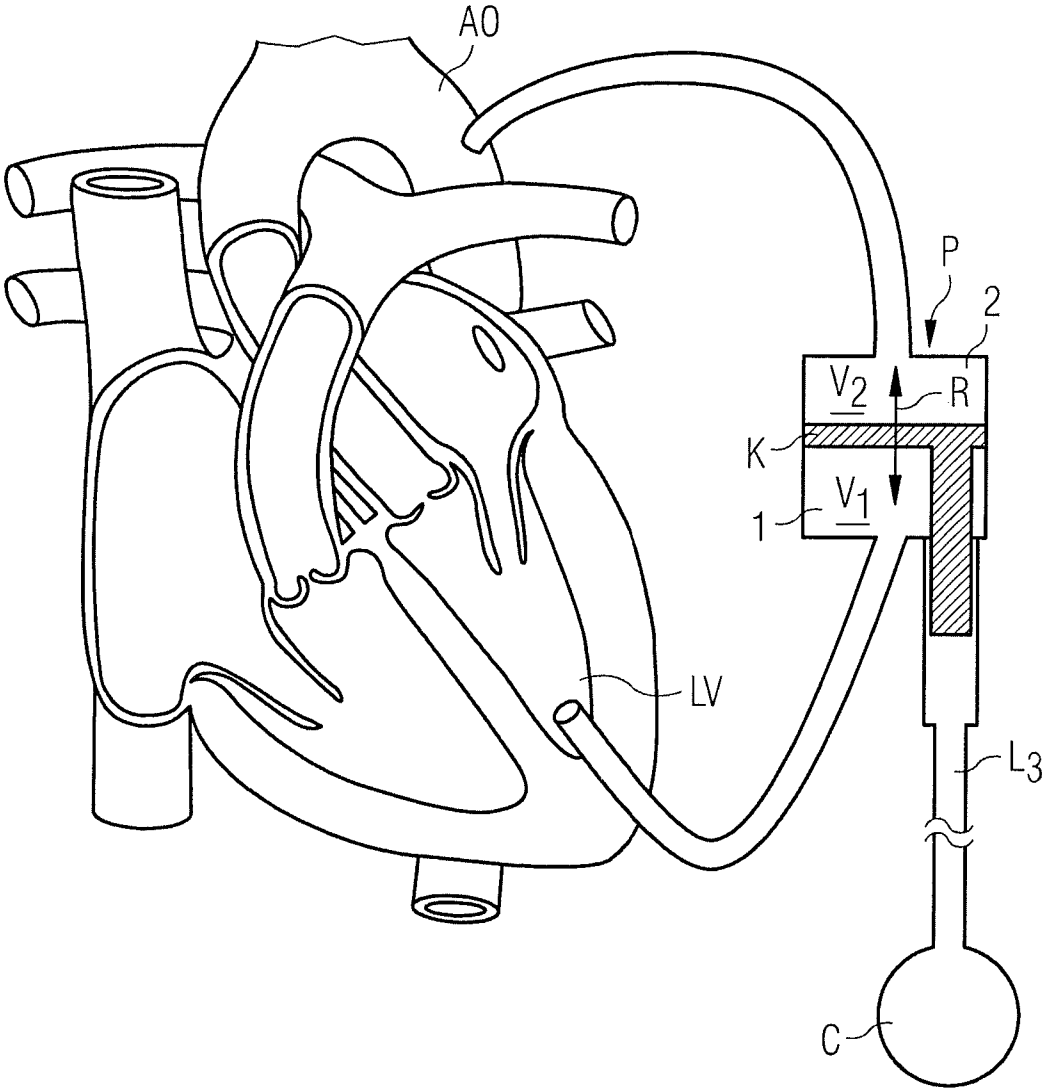

FIG 3

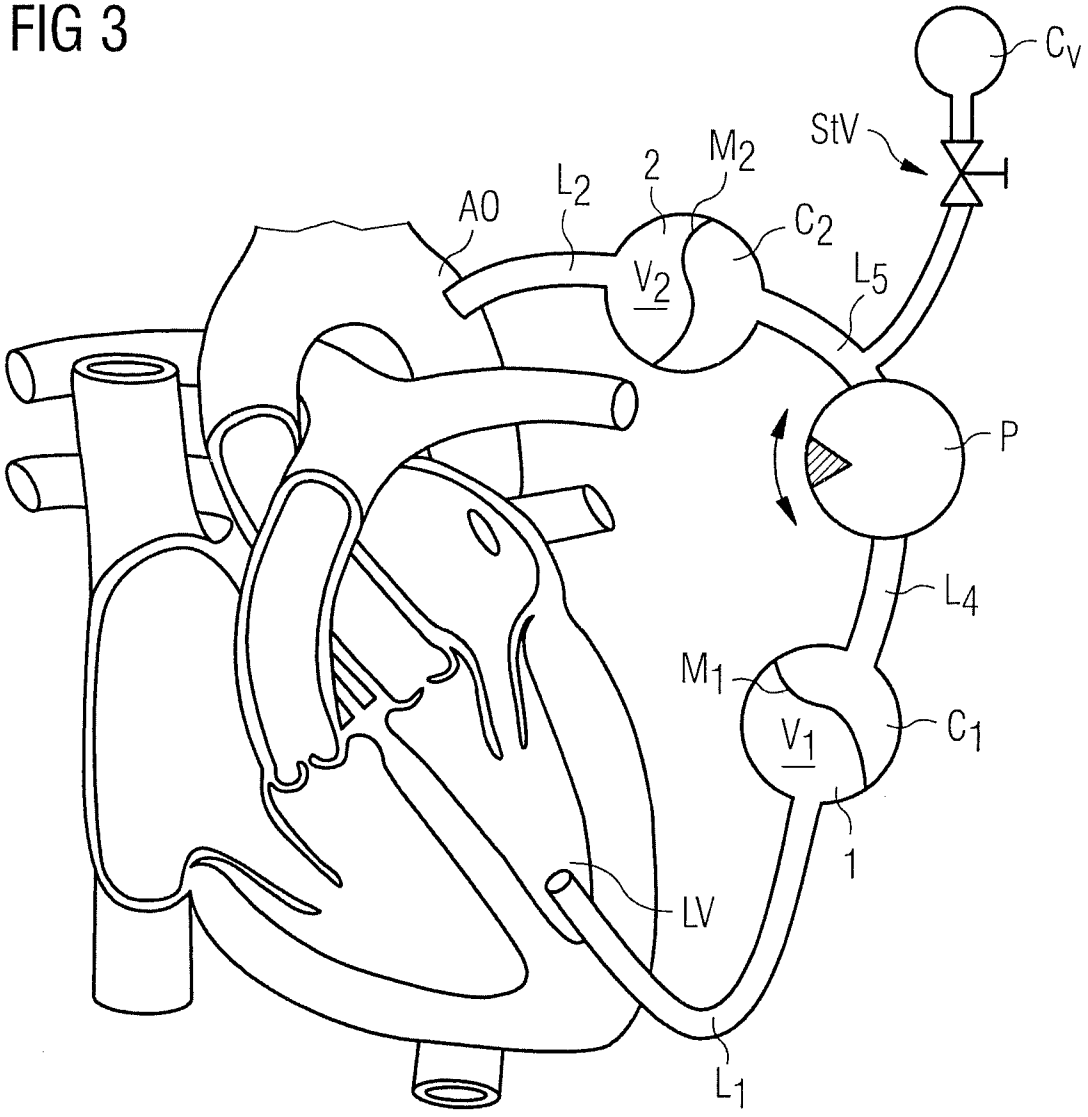

FIG 4