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# (54) A heart monitoring device

Vorrichtung zur Überwachung des Herzens

Dispositif de surveillance du coeur

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## Description

BACKGROUND OF THE INVENTION

1. Field of the invention

**[0001]** The present invention relates to an implantable heart monitoring device comprising a control circuit. The control circuit is adapted to be connected to one or more sensor members suited to be positioned in or at the heart of a living being. At least a first of said sensor members is adapted to be positioned in the coronary sinus region of the heart and arranged to sense at least one constituent of blood. The control circuit is adapted to receive signals from said first sensor member, which received signals are related to said blood constituent. The control circuit is also arranged to sense the activity of the heart, via signals from said one or more sensor members, such that events signifying a heart cycle are detectable by said control circuit.

**[0002]** The invention also relates to a heart monitoring system including such a heart monitoring device.

2. Description of the prior art

**[0003]** Several different devices for monitoring the performance of a heart are known. Often these devices are also able to deliver stimulation pulses to the heart. The devices are often able to sense the electrical activity in the heart. It is also known to sense other physiological parameters, such as pressure, oxygen level, pH, nitric oxide, carbon dioxide, etc.

**[0004]** US-A-5 213 098 describes a cardiac stimulator with an oxygen saturation sensor positioned in the coronary sinus of the heart. This device is also able to sense the blood pressure and the electrical activity of the heart. The stimulator may be used to control the atrial stimulation in order to improve the filling of the ventricles.

**[0005]** US-A-5 199 428 describes a device for detecting myocardial ischemia. A pH sensor or an oxygen saturation sensor may be positioned in the coronary sinus. The device can be used to stimulate for example the left and/or right carotid sinus nerves in order to decrease cardiac workload.

**[0006]** US-A-6 236 873 B1 describes an electrochemical sensor for measuring the oxygen content in blood.

**[0007]** US-A-4 202 339 describes a sensor for measuring the oxygen saturation level in blood.

**[0008]** US-A-4 453 537 describes a device for sensing, inter alia, the carbon dioxide content in the blood.

**[0009]** US-A-5 582 170 describes a fibre optic sensor for sensing the nitric oxide content in blood.

**[0010]** US-A-5 720 768 describes different possible electrode positions in order to stimulate or sense the different chambers of the heart.

**[0011]** US-A-6 070 100 describes that electrodes may be positioned in both the left and the right atrium as well as in or at the left and the right ventricles. The document describes the possibility of sensing the impedance between different electrodes. The sensed impedance values may be used to improve the cardiac output.

**[0012]** US 5,156,147 describes a pacemaker which has a hemodynamic sensor which is arranged to provide a signal representing the pumping performance of the heart. The hemodynamic sensor may be a piezo-electric pressure sensor.

SUMMARY OF THE INVENTION

**[0013]** It is an object of the present invention to provide an implantable heart monitoring device, which in a relatively simple manner is able to monitor the heart condition. A further object is to provide such a device, which by means of a single sensor for a blood constituent is able to derive information about the heart condition. A still further object is to achieve an implantable heart monitoring system comprising such a device and to provide a use of such a system.

**[0014]** The above objects concerning the device are achieved by an implantable heart monitoring device of the kind defined in the first paragraph above and wherein the control circuit is also arranged to enable the following:

a) in response to signals from said first sensor member determine a first value related to said blood constituent during a first portion of a heart cycle, and
b) in response to signals from said first sensor member determine a second value related to said blood constituent during a second portion of a heart cycle.

**[0015]** With the heart monitoring device according to the invention, it is thus possible to obtain, from one and the same sensor member, different values for a blood constituent during different portions of a heart cycle. These values, and the relationship between these values, can provide important information about the condition of the heart. In particular, if the first sensor member is positioned in the coronary sinus of the heart, important information may be obtained. The blood in the coronary sinus is primarily the blood which comes from the cardiac venous system and exits into the right atrium. However, some blood may also enter from the right atrium into the coronary sinus. The blood in the right atrium normally represents the mixed venous blood of the body. By monitoring said blood constituent during different portions of a heart cycle, important information of the condition of the heart may be obtained, since these monitored blood constituent values may represent both cardiac venous blood and mixed venous blood. The advantages of the invention will become clear from the description below. The blood constituent that is sensed by the first sensor member will primarily be exemplified by the oxygen content in the blood, in particular by the partial pressure of oxygen in the blood. However, the invention is also applicable for sensing other blood constituents, such as the saturation level of oxygen, the carbon dioxide content,

the content of nitric oxide, the pH-level of the blood or the temperature etc. Since the heart monitoring device is also arranged to sense the activity of the heart, the control circuit can be arranged such that the blood constituent is measured during different well defined portions of the heart cycle.

**[0016]** According to one preferred embodiment of the invention, the control circuit is arranged such that the first portion of the heart cycle is during the diastolic portion of the heart cycle and the second portion of the heart cycle is during the systolic portion of the heart cycle. In particular, the second portion of the heart cycle can be within the later 70% of the systolic portion of the heart cycle. It will become clear from the following description that by selecting said first and second portions of the heart cycle in this manner, important information about the difference of said blood constituent in for example cardiac venous blood and mixed venous blood can be obtained.

**[0017]** According to one embodiment of the invention, the blood constituent in question is oxygen as has been explained above. The oxygen concentration in the cardiac venous blood and in the mixed venous blood carries important information about the heart condition. This will be explained later in this description.

**[0018]** According to one advantageous embodiment of the invention, the control circuit is arranged to monitor said first and second values over a plurality of heart cycles. It is thereby possible to monitor how said first and second values change with time.

**[0019]** According to one embodiment of the invention, the control circuit is arranged to trigger the heart monitoring device to carry out at least one measure if said first and second values and/or a relationship between said first and second values fulfil a predefined condition. The condition may for example be that the first value is lower than a first predefined level and the second value is higher than a second predefined level. The condition may also be that the first value has decreased more than a first predefined amount over a plurality of heart cycles while the second value has decreased less than a second predefined amount over the same heart cycles. The relationship between said first and second values and/or how said values change with time carry important information about the heart condition. The measure to be carried out may for example be to control the delivery of stimulation pulses to the heart. Another measure could be to deliver a drug in response to the monitored values. A still further measure could be to deliver a warning signal. These measures may thus be used to improve the heart condition or to warn a patient or a physician such that, for example, a suitable drug will be taken by the patient.

**[0020]** According to another embodiment of the invention, the device is also arranged to enable the sensing of the activity level of a living being into which the heart monitoring device is implanted, wherein the control circuit is arranged such that also the sensed activity level is taken into account when determining whether said measure should be carried out. The monitored values of said blood constituent may thereby be seen in relation to the activity level of the living being in question. This enables an improved basis for decisions concerning a possible measure to be carried out.

**[0021]** The invention also provides a heart monitoring system comprising a heart monitoring device according to any of the above embodiments and one or more leads connected to the heart monitoring device, wherein said one or more sensor members, including said first sensor member, are positioned on said leads. The invention thus provides a system which may be implanted into a living being.

**[0022]** According to a preferred embodiment of the system, the first sensor member and said control circuit are arranged to sense the amount of oxygen in the blood. Preferably, the first sensor member is located on a first lead, which is suited to be introduced into the coronary sinus of the heart such that the first sensor member can be positioned in the coronary sinus. Hereby, the above-mentioned advantages by positioning a sensor in the coronary sinus are obtained.

**[0023]** According to a further embodiment of the system, said first lead comprises at least a second sensor or electrode member, wherein said second sensor or electrode member is located closer to the distal end of said first lead than said first sensor member, and wherein said first lead is designed such that said second sensor or electrode member is arranged such that it can be introduced via the coronary sinus into a cardiac vein. Advantageously, the control circuit is arranged to enable the delivery of stimulation pulses to said second sensor or electrode member. Such a sensor or electrode member may be positioned via the great cardiac vein into for example the posterior, lateral or anterior vein of the left ventricle and may be used to stimulate the left ventricle of the heart.

**[0024]** According to a further embodiment, the system comprises, in addition to said first lead, at least a second lead, wherein said second lead comprises at least a third sensor or electrode member suited to be positioned in the right ventricle of the heart. Preferably, the control circuit is arranged to deliver stimulation pulses to both said second sensor or electrode member and to said third sensor or electrode member, so as to enable the delivery of stimulating pulses to both the ventricles of the heart. The third sensor or electrode member may of course also be used to sense events in the heart. According to one embodiment, it is thus possible to stimulate both the ventricles of the heart. This is advantageous for example when treating patients suffering from congestive heart failure.

**[0025]** The first and second portions of the heart cycle may thus be chosen such that the first value is related to the blood constituent in blood from the cardiac venous system and such that the second value is related to said blood constituent in mixed venous blood. The system

may for example be used to detect the state of ischemia in the heart. The system may, as has been explained above, for example be used to sense the blood constituent oxygen. The system may thereby be used to deliver a warning signal or to carry out a therapy if said first and second values and/or a relationship between said first and second values fulfil a predefined condition.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0026]**

Fig 1 shows schematically a heart monitoring system with a heart monitoring device connected to leads with sensor or electrode members positioned in a heart.

Fig 2 A shows schematically the coronary blood flow.

Fig 2 B shows schematically the aortic blood flow.

Fig 2 C shows schematically the blood flow in the coronary sinus.

Fig 2 D shows schematically the partial pressure of oxygen in the coronary sinus at rest.

Fig 2 E shows schematically an electrocardiogram.

Fig 3 shows a flow chart of the use of a heart monitoring system according to an embodiment of the invention.

Fig 4 shows a flow chart of the use of a heart monitoring system according to another embodiment of the invention.

## DESCRIPTION OF PREFERRED EMBODIMENTS

**[0027]** An embodiment of the invention will now first be described with reference to Fig 1. Fig 1 shows schematically a heart monitoring device 10. The device 10 comprises a housing 12. The device 10 is arranged such that it may be implanted in a human or animal being. A control circuit 14 is arranged within the housing 12. The device 10 may include an activity sensor 18 in order to enable the sensing of the activity level of a living being into which the heart monitoring device 10 is implanted. The device 10 comprises a connector portion 16 to which one or more leads 30, 40, 50 may be connected. In the shown embodiment, there are thus three leads 30, 40, 50. However, the number of leads may be more or less than three.

**[0028]** A first lead 30 comprises a first sensor member 33, which is adapted to be positioned in the coronary sinus region of the heart. The first sensor member 33 is arranged to sense at least one constituent of blood. The first lead 30 may also comprise a second sensor or electrode member 31, 32 located closer to the distal end of the first lead 30 than the first sensor member 33. The illustrated embodiment also shows a second lead 40 with at least a third sensor or electrode member 41, 42. Furthermore, a third lead 50 is shown with sensor or electrode members 51, 52. The sensor or electrode members 31, 41, 51 are located at the tip portion of the respective lead 30, 40, 50. These members may therefore be called tip electrodes. The electrodes 32, 42, 52 are located a little further up along the respective lead 30, 40, 50 and may be called ring electrodes. These sensors or electrode members 31, 32, 41, 42, 51, 52 are thus arranged as bipolar electrodes. It is of course possible that instead unipolar electrodes are used. The electrode members 31, 32, 41, 42, 51, 52 may be used to sense the activity of the heart and/or to deliver stimulation pulses to the heart.

**[0029]** At least one sensor member, in the shown embodiment the sensor member 33, is designed to sense a blood constituent. The blood constituent may for example be the partial pressure of oxygen in the blood. However, as has been mentioned above, the sensor member 33 may instead be designed to sense other blood constituents, such as the oxygen saturation level, carbon dioxide, nitric oxide, pH or temperature.

**[0030]** Fig 1 also schematically shows a heart with a right atrium RA, a right ventricle RV, a left atrium LA and a left ventricle LV. The first lead 30 with the first sensor member 33 is designed such that it can be introduced via the right atrium RA into the coronary sinus region of the heart. The first lead 30 may also be introduced further into the coronary venous system such that the second sensor or electrode member 31, 32 is introduced, for example, via the great cardiac vein into the posterior, lateral or anterior vein of the left ventricle. With such a position of the second sensor or electrode member 31, 32, it is for example possible to stimulate the left ventricle LV of the heart. The portion of the first lead 30 that is introduced into the cardiac venous system is here shown with a hatched line.

**[0031]** The second lead 40 is here shown to be introduced via the right atrium RA into the right ventricle RV such that the third sensor or electrode member 41, 42 is located close to the apex of the right ventricle RV. The third sensor or electrode member 41, 42 may be used to sense the electrical activity of the heart in the right ventricle RV and to deliver stimulation pulses to the right ventricle RV. A third lead 50 is here shown to be introduced into the right atrium RA and is thereby able to sense or deliver signals in this right atrium RA with the help of the sensor or electrode members 51, 52. The leads 30, 40, 50 suitably comprise electrical conductors, or other conductors, in order to conduct signals between the sensor or electrode members 31, 32, 33, 41, 42, 51, 52 and the control circuit 14, such as is well known to a person skilled in the art.

**[0032]** The device 10 may also be provided with means 60, which makes it possible to deliver a drug into the body

in which the device 10 is implanted. The device 10 may also be provided with means 70 for generating a warning signal. The warning signal may for example be communicated via wireless communication to an external device in the possession of the person into whom the device 10 is implanted or of a physician.

**[0033]** The control circuit 14 is thus adapted to receive signals from the first sensor member 33, which received signals are related to said blood constituent. The control circuit 14 is also arranged to sense the electrical activity of the heart, via signals from said one or more sensor members 31, 32, 33, 41, 42, 51, 52. Thereby, events signifying a heart cycle are detectable by the control circuit 14. The control circuit 14 is also arranged to enable the determination of a first value related to the blood constituent during a first portion of the heart cycle and to determine a second value related to the blood constituent during a second portion of the heart cycle. The different portions of the heart cycle may thus be detected by said one or more sensor members.

**[0034]** A heart monitoring system according to the invention comprises the heart monitoring device 10 together with one or more of the leads 30, 40, 50 and at least said first sensor member 33 positioned on the lead 30.

**[0035]** Fig 2 A-E show the variation of different parameters for corresponding parts of a heart cycle. The X-axis represents the time t and the Y-axis represents the different parameters. The systolic part of the heart cycle starts approximately at the hatched line 61 and ends at approximately the hatched line 62, where the diastolic portion of the heart cycle starts.

**[0036]** Fig 2 A shows schematically the blood flow in ml/min in the coronary artery.

**[0037]** Fig 2 B shows schematically the aortic blood flow in l/min.

**[0038]** Fig 2 C shows very schematically an example of the blood flow in the direction out from the coronary sinus in ml/min. It can be noted that during a portion of the heart cycle, primarily during the systolic portion, the blood flow is here negative. This means that blood during this portion flows in from the right atrium RA into the coronary sinus. This happens normally during the ventricular contraction.

**[0039]** Fig 2 D shows very schematically an example of how the partial pressure of oxygen, in kPa, may vary in the coronary sinus during the heart cycle. During the systolic phase, in particular during the latter 70% or the latter half of the systolic portion of the heart cycle, the oxygen partial pressure represents the oxygen partial pressure in mixed venous blood, since, as explained above, the mixed venous blood from the right atrium RA tends to enter into the coronary sinus. Before the start of the systolic portion of the heart cycle, the partial pressure of oxygen in the coronary sinus represents the partial pressure of oxygen in the coronary venous blood.

**[0040]** Fig 2 E shows an electrocardiogram (ECG) during the heart cycle shown in the figures. P here represents the P-wave, R represents the QRS-complex and T represents the T-wave.

**[0041]** The concentration of different constituents of blood carries information about the heart condition. For example, the concentration of nitric oxide indicates the vasoconstriction-vasodilatation and may therefore, if measured in the cardiac venous blood, be used as an indication of biochemical events. The amount of lactic acid, and thereby the pH-value indicates whether anaerobic metabolism occurs. The different blood constituents may differ in cardiac venous blood as compared to in mixed venous blood. This fact is used according to the present invention in order to monitor the cardiac function and to detect if the heart does not function properly. In the description below, the partial pressure of oxygen will be used as an example of a blood constituent. It should be noted that the quantities mentioned are only given as examples. These quantities may vary between different living beings. The different quantities and the criteria for carrying out different measures should therefore be adapted to the particular living being using the invention.

**[0042]** When the living being is at rest, the partial pressure of oxygen in mixed venous blood may be about 5.3 kPa. The oxygen partial pressure in coronary venous blood in the coronary sinus may be about 2.3 kPa. When the living being in question is at a higher activity level (exercise), the oxygen partial pressure in mixed venous blood can decrease to about 2.0 kPa. However, the oxygen partial pressure in the cardiac venous blood normally does not decrease substantially during exercise but remains at approximately 2.3 kPa. However, at hard exercise, the partial pressure of oxygen in the cardiac venous blood may be reduced to about 2.0 kPa. These insights may be used to control a heart monitoring device according to the present invention.

**[0043]** Figs 3 and 4 show flow charts of the use of a heart monitoring system according to different embodiments of the invention. At the same time, these figures show how the heart monitoring device according to the invention operates. Fig 3 thus shows that a sensor, i.e. the mentioned first sensor member 33, is positioned in the coronary sinus of a living being. How to insert a lead into the coronary sinus is well known to a person skilled in the art and will therefore not be explained more closely here. The control circuit 14 is arranged to determine a first value of the blood constituent during a first portion of the heart cycle. Furthermore, the control circuit 14 is arranged to determine a second value related to the blood constituent during a second portion of the heart cycle. Of course, the first portion of the heart cycle is always different from the second portion of the heart cycle. The control circuit 14 can be arranged such that said first value of the blood constituent, in this example the partial pressure of oxygen, is measured during the diastolic portion of the heart cycle. The control circuit 14 may for example be arranged such that this first value is measured substantially around the P-wave. The control circuit is also arranged such that the second value of the blood constituent is measured during the systolic portion of the

heart cycle. Preferably, the second value is measured during the later 70% of the systolic portion of the heart cycle, for example substantially about the time of the occurrence of the T-wave. The first value is thus related to the oxygen partial pressure in coronary venous blood and the second value is related to the partial pressure of oxygen in primarily mixed venous blood.

**[0044]** Preferably, the control circuit 14 is arranged to monitor the first and second values over a plurality of heart cycles. In Fig 3, this is represented by the loop that is performed a number of times. This can be done in order to achieve a reliable value, for example by determining said first and second values as an average value over some heart cycles. It is also possible to monitor said first and second values over several heart cycles, or all the time, in order to monitor how these values change with time.

**[0045]** The control circuit 14 is arranged to trigger the heart monitoring device 10 to carry out at least one measure if the first and second values and/or a relationship between said first and second values fulfil a predefined condition. If the predefined condition is not fulfilled, then no particular measure is carried out, but the device 10 may directly or later be arranged to carry out a new determination of said first and second values. This is indicated by the hatched line starting at N. The predefined condition may be that the first value is lower than a first predefined level L1 and the second value is higher than a second predefined level L2. For example, in case the first value, i.e. the partial pressure of oxygen in the cardiac venous blood, is lower than for example 2.1 kPa while the second value, i.e. the partial pressure of oxygen in mixed venous blood, is higher than for example 3.0 kPa, then a measure can be carried out. The described situation means that the partial pressure of oxygen in mixed venous blood indicates that the living being in question is not under hard exercise although the partial pressure of oxygen in cardiac venous blood is quite low. This is an indication that the heart does not function properly, for example due to overload or due to an ischemic event. The measure to be carried out may for example be to control the delivery of stimulation pulses to the heart, for example by reducing the pacing rate, or to deliver a drug or to deliver a warning signal as has been described above.

**[0046]** Fig 4 shows another example of how the heart monitoring device according to the invention may operate. The first steps are here the same as in connection with Fig 3. The loop is performed a number of times. In this case, however, the predefined condition is that the first value has decreased more than a first predefined amount A1 over a plurality of heart cycles while the second value has decreased less than the second predefined amount A2 over said plurality of heart cycles. For example, the first predefined amount may be that the partial pressure of oxygen in the cardiac venous blood has fallen more than 0.2 kPa (or a certain percentage of the original value), while the partial pressure of oxygen in mixed venous blood has decreased less than for example 1.0 kPa (or a certain percentage of the original value). This, again, is an indication of the fact that the heart is not working properly. Also in this case, the measure can be that the delivery of stimulation pulses to the heart is controlled, that a drug is released or that a warning signal is delivered. It should be noted that it is of course possible to combine the two manners of operating the device disclosed in Figs 3 and 4.

**[0047]** Figs 3 and 4 thus also show manners of using the heart monitoring system according to the invention. The system may thus be used in order to detect a state of overload or ischemia in the heart. As has been mentioned above, the system may be arranged such that stimulating pulses may be delivered to both the ventricles RV, LV of the heart. The device 10 and the system may of course be arranged such that the delivery of the stimulation pulses is changed in an iterative process based on the detected and monitored first and second values. In this manner, the delivery of the stimulation pulses may be adjusted until a more normally operating heart condition is detected. As mentioned above, the control circuit 14 may be arranged also to sense the activity level of the living being into which the device 10 is implanted. In this manner, a further indication of the activity level of the living being in question is obtained. The control circuit 14 may thereby be arranged to detect whether said first and second values, or the change of said first and second values, correspond to that which is considered normal when the living being in question is at rest or is at a high activity level.

**[0048]** Although the invention has primarily been described in connection with sensing the partial pressure of oxygen, the invention is also applicable to other blood constituents like those mentioned above. For example, the half-time of nitric oxide is very short. This means that mixed venous blood will contain small amounts of nitric oxide while the level in the coronary venous blood is highly dependent on the intrinsic regulation of the cardiac perfusion. Therefore, similar conditions to those described above may be predefined for controlling the heart monitoring device also in response to the detection of first and second values concerning nitric oxide. Different predefined conditions may of course be set up for the different blood constituents.

**[0049]** Examples of different sensors that may be used are given in the documents cited above. For example, a sensor suitable for detecting the partial pressure of oxygen is given in the above cited US-A-6 236 873.

**[0050]** The invention is not limited to the described embodiments but may be varied and modified within the scope of the following claims.

## Claims

1. An implantable heart monitoring device (10) comprising:

a control circuit (14), one or more sensor members (31, 32, 33, 41, 42, 51, 52),
said control circuit (14) being adapted to be connected to one or more sensor members (31, 32, 33, 41, 42, 51, 52) suited to be positioned in or at the heart of a living being, at least a first (33) of said sensor members being adapted to be positioned in the coronary sinus of the heart and arranged to sense at least one constituent of blood, said control circuit (14) being adapted to receive signals from said first sensor member (33), which received signals are related to said blood constituent, said control circuit (14) also being arranged to sense the activity of the heart, via signals from said one or more sensor members (31, 32, 33, 41, 42, 51, 52), such that events signifying a heart cycle are detectable by said control circuit,

said control circuit (14) also being arranged to enable the following:

a) in response to signals from said first sensor member (33) determine a first value related to said blood constituent during a first portion of a heart cycle, and
b) in response to signals from said first sensor member (33) determine a second value related to said blood constituent during a second portion of a heart cycle.

**2.** An implantable heart monitoring device (10) according to claim 1, wherein said control circuit (14) is arranged such that said first portion of a heart cycle is during the diastolic portion of the heart cycle and said second portion of a heart cycle is during the systolic portion of a heart cycle.

**3.** An implantable heart monitoring device (10) according to claim 2, wherein said control circuit (14) is arranged such that said second portion of a heart cycle is within the later 70% of the systolic portion of a heart cycle.

**4.** An implantable heart monitoring device (10) according to any of the preceding claims, wherein said blood constituent is oxygen.

**5.** An implantable heart monitoring device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to monitor said first and second values over a plurality of heart cycles.

**6.** An implantable heart monitoring device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to trigger the heart monitoring device (10) to carry out at least one measure if said first and second values and/or a relationship between said first and second values fulfil a predefined condition,

**7.** An implantable heart monitoring device (10) according to claim 6, wherein said predefined condition is that said first value is lower than a first predefined level and said second value is higher than a second predefined level.

**8.** An implantable heart monitoring device (10) according to claim 5 in combination with claim 6. or 7, wherein said predefined condition is that said first value has decreased more than a first predefined amount over a plurality of heart cycles while said second value has decreased less than a second predefined amount over said plurality of heart cycles.

**9.** An implantable heart monitoring device (10) according to any of the claims 6-8, wherein the heart monitoring device (10) is arranged to also enable the delivery of stimulation pulses to the heart and wherein said measure is to control the delivery of said stimulation pulses to the heart.

**10.** An implantable heart monitoring device (10) according to any of the claims 6-9, wherein the heart monitoring device (10) is arranged to enable the delivery of a drug to the living being into which the heart monitoring device is implanted and wherein said measure is to control the delivery of said drug.

**11.** An implantable heart monitoring device (10) according to any of the claims 6-10, wherein the heart monitoring device (10) is arranged to enable the delivery of a warning signal and wherein said measure is to deliver said warning signal.

**12.** An implantable heart monitoring device (10) according to any of the claims 6-11, wherein said heart monitoring device (10) is arranged to enable the sensing of the activity level of a living being into which the heart monitoring device (10) is implanted, wherein said control circuit (14) is arranged such that also the sensed activity level is taken into account when determining whether said measure should be carried out.

**13.** An implantable heart monitoring system comprising:

a heart monitoring device (10) according to any of the preceding claims,
one or more leads (30, 40, 50) connected to said heart monitoring device (10), wherein said one or more sensor members (31, 32, 33, 41, 42, 51, 52) including said first sensor member (33), are positioned on said leads (30, 40, 50).

**14.** An implantable heart monitoring system according

to claim 13, wherein said first sensor member (33) and said control circuit (14) are arranged to sense the amount of oxygen in the blood.

**15.** An implantable heart monitoring system according to claim 13 or 14, wherein at least a first (30) of said leads is suited to be introduced into the coronary sinus of said heart and wherein said first sensor member (33) is positioned on said first lead (30) such that it can be positioned in the coronary sinus.

**16.** An implantable heart monitoring system according to claim 15, wherein said first lead (30) comprises at least a second sensor or electrode member (31, 32), wherein said second sensor or electrode member (31, 32) is located closer to the distal end of said first lead (30) than said first sensor member (33), and wherein said first lead (30) is designed such that said second sensor or electrode member (31, 32) is arranged such that it can be introduced via the coronary sinus into a cardiac vein.

**17.** An implantable heart monitoring system according to claim 16, wherein said control circuit (14) is arranged to enable the delivery of stimulation pulses to said second sensor or electrode member (31, 32).

**18.** An implantable heart monitoring system according to any of the claims 15-17, comprising, in addition to said first lead (30), at least a second lead (40), wherein said second lead (40) comprises at least a third sensor or electrode member (41, 42) suited to be positioned in the right ventricle (RV) of said heart.

**Patentansprüche**

**1.** Implantierbare Herzüberwachungsvorrichtung (10) enthaltend:

eine Steuerschaltung (14), ein Sensorteil oder mehrere Sensorteile (31, 32, 33, 41, 42, 51, 52) wobei die genannte Steuerschaltung (14) ausgelegt ist mit einem Sensorteil oder mit mehren Sensorteilen (31, 32, 33, 41, 42, 51, 52) verbunden zu werden, das beziehungsweise die geeignet ist beziehungsweise sind, im oder am Herzen eines Lebewesens positioniert zu werden, wenigstens ein erstes (33) der genannten Sensorteile ausgelegt ist im koronaren Sinus des Herzens positioniert zu werden und ausgebildet ist, wenigstens eine Blutkomponente abzufühlen, die genannte Steuerschaltung (14) ausgelegt ist, von dem genannten ersten Sensorteil (33) Signale zu empfangen, welche empfangenen Signale sich auf die genannte Blutkomponente beziehen, die genannte Steuerschaltung (14) außerdem ausgelegt ist, die Aktivität des Herzens über Signale aus dem genannten einen Sensorteil oder den mehreren Sensorteilen (31, 32, 33, 41, 42, 51, 52) abzufühlen, so dass durch die genannte Steuerschaltung Ereignisse, die einen Herzzyklus kennzeichnen, detektierbar sind,

die genannte Steuerschaltung (14) auch ausgebildet ist, das Folgende zu tun:

a) bestimme während eines ersten Abschnittes eines Herzzyklus in Reaktion auf Signale aus dem genannten ersten Sensorteil (33) einen ersten Wert, der sich auf die genannte Blutkomponente bezieht, und
b) bestimme während eines zweiten Abschnittes eines Herzzyklus in Reaktion auf Signale aus dem genannten ersten Sensorteil (33) einen zweiten Wert, der sich auf die genannte Blutkomponente bezieht.

**2.** Implantierbare Herzüberwachungsvorrichtung (10) nach Anspruch 1, bei der die genannte Steuerschaltung (14) so ausgebildet ist, dass der genannte erste Abschnitt eines Herzzyklus während des diastolischen Abschnittes des Herzzyklus vorhanden ist und der genannte zweite Abschnitt eines Herzzyklus während des systolischen Abschnittes eines Herzzyklus vorhanden ist.

**3.** Implantierbare Herzüberwachungsvorrichtung (10) nach Anspruch 2, bei der die genannte Steuerschaltung (14) so ausgebildet ist, dass der genannte zweite Abschnitt eines Herzzyklus innerhalb der späteren 70 % des systolischen Abschnittes eines Herzzyklus liegt.

**4.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der vorhergehenden Ansprüche, bei dem die genannte Blutkomponente Sauerstoff ist.

**5.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der vorhergehenden Ansprüche, bei der die genannte Steuerschaltung (14) ausgebildet ist den genannten ersten und den genannten zweiten Wert über eine Mehrzahl von Herzzyklen zu überwachen.

**6.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der vorhergehenden Ansprüche, bei der die genannte Steuerschaltung (14) ausgebildet ist, die Herzüberwachungsvorrichtung (10) zu veranlassen wenigstens eine Maßnahme auszuführen, wenn der genannte erste und der genannte zweite Wert und/oder die Beziehung zwischen dem genannten ersten und dem genannten zweiten Wert eine vorbestimmte Bedingung erfüllt.

**7.** Implantierbare Herzüberwachungsvorrichtung (10) nach Anspruch 6, bei der die genannte vorbestimmte Bedingung bedeutet, dass der genannte erste Wert kleiner als ein erster vorbestimmter Pegel ist und der genannte zweite Wert größer als ein zweiter vorbestimmter Pegel.

**8.** Implantierbare Herüberwachungsvorrichtung (10) nach Anspruch 5 in Kombination mit Anspruch 6 oder 7, bei der die genannte vorbestimmte Bedingung bedeutet, dass der genannte erste Wert mehr als einen vorbestimmten Betrag über eine Mehrzahl von Herzzyklen abgenommen hat während der genannte zweite Wert über die genannte Mehrzahl von Herzzyklen weniger als einen zweiten vorbestimmten Betrag abgenommen hat.

**9.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der Ansprüche 6 bis 8, bei der die Herzüberwachungsvorrichtung (10) ausgebildet ist auch die Abgabe von Stimulationsimpulsen zum Herzen zu aktivieren und bei der die genannte Maßnahme darin besteht, die Abgabe der genannten Stimulationsimpulse zum Herzen zu steuern.

**10.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der Ansprüche 6 bis 9, bei der die Herzüberwachungsvorrichtung (10) ausgebildet ist, die Abgabe eines Arzneimittels in das Lebewesen, in dem die Herzüberwachungsvorrichtung implantiert ist zu aktivieren und bei der die genannte Maßnahme darin besteht, die Abgabe des genannten Arzneimittels zu steuern.

**11.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der Ansprüche 6 bis 10, bei der die Herzüberwachungsvorrichtung (10) ausgebildet ist, die Abgabe eines Alarmsignals zu aktivieren und bei der die genannte Maßnahme darin besteht das genannte Alarmsignal auszugeben.

**12.** Implantierbare Herzüberwachungsvorrichtung (10) nach einem der Ansprüche 6 bis 11, bei der die genannte Herzüberwachungsvorrichtung (10) ausgebildet ist, das Abfühlen des Aktivitätspegels eines Lebewesens, in dem die Herzüberwachungsvorrichtung (10) implantiert ist, zu aktivieren, wobei die genannte Steuerschaltung (14) so ausgebildet ist, dass auch der abgefühlte Aktivitätspegel berücksichtigt wird, wenn bestimmt wird ob die genannte Maßnahme ausgeführt werden sollte.

**13.** Implantierbares Herzüberwachungssystem, enthaltend:

eine Herzüberwachungsvorrichtung (10) nach einem der vorhergehenden Ansprüche,
eine Leitung oder mehrere Leitungen (30, 40, 50), die mit der genannten Herzüberwachungsvorrichtung (10) verbunden ist beziehungsweise sind, wobei das genannte eine Sensorteil oder die genannten mehreren Sensorteile (31, 32, 33, 41, 42, 51, 52) einschließlich des genannten ersten Sensorteils (33) an den genannten Leitungen (30, 40, 50) positioniert sind.

**14.** Implantierbares Herzüberwachungssystem nach Anspruch 13, bei dem das genannte erste Sensorteil (33) und die genannte Steuerschaltung (14) ausgebildet sind den Sauerstoffgehalt des Blutes abzufühlen.

**15.** Implantierbares Herzüberwachungssystem nach Anspruch 13 oder 14, bei dem wenigstens eine erste (30) der genannten Leitungen geeignet ist, in den koronaren Sinus des genannten Herzens eingeführt zu werden und bei dem das genannte erste Sensorteil (33) an der genannten ersten Leitung (30) so positioniert ist, dass es im koronaren Sinus positioniert werden kann.

**16.** Implantierbares Herzüberwachungssystem nach Anspruch 15, bei dem die genannte erste Leitung (30) wenigstens einen zweiten Sensor oder ein Elektrodenteil (31, 32) enthält, wobei der genannte zweite Sensor oder das Elektrodenteil (31, 32) näher am distalen Ende der genannten ersten Leitung (30) angeordnet ist als das genannte erste Sensorteil (33) und wobei die genannte erste Leitung (30) so ausgebildet ist, dass der genannte zweite Sensor beziehungsweise das Elektrodenteil (31, 32) so positioniert ist, dass er beziehungsweise es über den koronaren Sinus in eine Herzvene einführbar ist.

**17.** Implantierbares Herzüberwachungssystem nach Anspruch 16, bei dem die genannte Steuerschaltung (14) ausgebildet ist, die Abgabe von Stimulationsimpulsen zum genannten zweiten Sensor oder Elektrodenteil (31, 32) zu aktivieren.

**18.** Implantierbares Herzüberwachungssystem nach einem der Ansprüche 15 bis 17, enthaltend zusätzlich zu der genannten ersten Leitung (30) wenigstens eine zweite Leitung (40), wobei die genannte zweite Leitung (40) wenigstens einen dritten Sensor oder ein Elektrodenteil (41, 42) enthält, der beziehungsweise das geeignet ist, im rechten Ventrikel (RV) des genannten Herzens positioniert zu werden.

**Revendications**

**1.** Dispositif (10) implantable de contrôle du coeur comprenant :

un circuit (14) de commande, un ou plusieurs

éléments (31, 32, 33, 41, 42, 51, 52) de capteur, le circuit (14) de commande étant conçu pour être relié à un ou plusieurs éléments (31, 32, 33, 41, 42, 51, 52) de capteur propres à être mis en position dans le coeur d'un être vivant ou sur son coeur, au moins un premier (33) des éléments de capteur étant conçu pour être mis en position dans le sinus coronaire du coeur et agencé de manière à détecter au moins un constituant du sang, le circuit (14) de commande étant conçu pour recevoir des signaux du premier élément (33) de capteur, ces signaux reçus se rapportant au constituant du sang, le circuit (14) de contrôle étant aussi agencé pour détecter l'activité du coeur par l'intermédiaire de signaux provenant d'un ou plusieurs éléments (31, 32, 33, 41, 42, 51, 52) de capteur, de façon à ce que des évènements signifiants un cycle cardiaque puissent être détectés par le circuit de commande,

le circuit de commande étant agencé aussi pour permettre ce qui suit :

a) en réaction à des signaux provenant du premier élément (33) de capteur, déterminer une première valeur reliée au constituant du sang pendant une première partie d'un cycle cardiaque, et
b) en réaction à des signaux provenant du premier élément (33) de capteur, déterminer une deuxième valeur reliée au constituant du sang pendant une deuxième partie d'un cycle cardiaque.

**2.** Dispositif (10) implantable de contrôle du coeur suivant la revendication 1, dans lequel le circuit (14) de commande est agencé de façon à ce que la première partie d'un cycle cardiaque se trouve pendant la partie diastolique du cycle cardiaque et la deuxième partie d'un cycle cardiaque se trouve pendant la partie systolique d'un cycle cardiaque.

**3.** Dispositif (10) implantable de contrôle du coeur suivant la revendication 2, dans lequel le circuit (14) de commande est agencé de façon à ce que la deuxième partie d'un cycle cardiaque se trouve dans les derniers 70% de la partie systolique d'un cycle cardiaque.

**4.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications précédentes, dans lequel le constituant du sang est l'oxygène.

**5.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications précédentes, dans lequel le circuit (14) de commande est agencé pour contrôler les premières et deuxièmes valeurs sur une pluralité de cycles cardiaques.

**6.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications précédentes, dans lequel le circuit (14) de commande est agencé pour déclencher le dispositif (10) de contrôle du coeur pour effectuer au moins une mesure si la première et la deuxième valeurs et/ou une relation entre la première et la deuxième valeurs satisfait à une condition définie à l'avance.

**7.** Dispositif (10) implantable de contrôle du coeur suivant la revendication 6, dans lequel la condition définie à l'avance est que la première valeur est inférieure à un premier niveau défini à l'avance et que la deuxième valeur est supérieure à un deuxième niveau défini à l'avance.

**8.** Dispositif (10) implantable de contrôle du coeur suivant la revendication 5 en combinaison avec la revendication 6 ou 7, dans lequel la condition définie à l'avance est que la première valeur a diminué de plus d'une première quantité définie à l'avance sur une pluralité de cycles cardiaques, tandis que la deuxième valeur a diminué de moins qu'une deuxième quantité définie à l'avance sur cette pluralité de cycles cardiaques.

**9.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications 6 à 8, dans lequel le dispositif (10) de contrôle du coeur est agencé pour permettre aussi l'envoi d'impulsions de stimulation au coeur et dans lequel la mesure consiste à commander l'envoi des impulsions de stimulation au coeur.

**10.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications 6 à 9, dans lequel le dispositif (10) de contrôle du coeur est agencé pour permettre l'envoi d'un médicament à l'être vivant, dans lequel le dispositif de contrôle du coeur est implanté, et dans lequel la mesure consiste à régler l'envoi du médicament.

**11.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications 6 à 10, dans lequel le dispositif (10) de contrôle du coeur est agencé pour permettre l'envoi d'un signal d'avertissement et dans lequel la mesure consiste à envoyer le signal d'avertissement.

**12.** Dispositif (10) implantable de contrôle du coeur suivant l'une quelconque des revendications 6 à 11, dans lequel le dispositif (10) de contrôle du coeur est agencé pour permettre la détection du niveau d'activité d'un être vivant, dans lequel le dispositif (10) de contrôle du coeur est implanté, le circuit (14) de commande étant agencé de manière à ce que le

niveau d'activité détecté soit aussi pris en compte lors de la détermination du point de savoir si ladite mesure doit être effectuée.

**13.** Système implantable de contrôle du cour comprenant :

un dispositif (10) de contrôle du coeur suivant l'une quelconque des revendications précédentes,
une ou plusieurs dérivations (30, 40, 50) reliées au dispositif (10) de contrôle du coeur, l'un ou les plusieurs éléments (31, 32, 33, 41, 42, 51, 52) de capteur, y compris le premier élément (33) de capteur, étant mis en position sur les dérivations (30, 40, 50).

**14.** Système implantable de contrôle du coeur suivant la revendication 13, dans lequel le premier élément (33) de capteur et le circuit (14) de commande sont agencés pour détecter la quantité d'oxygène dans le sang.

**15.** Système implantable de contrôle du coeur suivant la revendication 13 ou 14, dans lequel au moins une première tranche de dérivation est propre à être introduite dans le sinus coronaire du coeur et dans lequel le premier élément (33) de capteur est mis en position sur la première dérivation (30) de façon à pouvoir être mis en position dans le sinus coronaire.

**16.** Système implantable de contrôle du coeur suivant la revendication 15, dans lequel la première dérivation (30) comprend au moins un deuxième capteur ou élément (31, 32) à électrode, dans lequel le deuxième capteur ou élément (31, 32) à électrode est placé plus près de l'extrémité distale de la première dérivation (30) que le premier élément (33) de capteur et dans lequel la première dérivation (30) est conçue de façon à ce que le deuxième détecteur ou élément (31, 32) à électrode soit agencé de façon à ce qu'il puisse être introduit par l'intermédiaire du sinus coronaire dans une veine cardiaque.

**17.** Système implantable de contrôle du coeur suivant la revendication 13, dans lequel le circuit (14) de commande est agencé pour permettre l'envoi d'impulsions de stimulation au deuxième détecteur ou élément (31, 32) à électrode.

**18.** Système implantable de contrôle du coeur suivant l'une quelconque des revendications 15 à 17, comprenant, en plus de la première dérivation (30), au moins une dérivation (40), la deuxième dérivation (40) comprenant au moins un troisième capteur ou élément (41, 42) à électrode propre à être mis en position dans le ventricule (RV) droit du coeur.

FIG 1

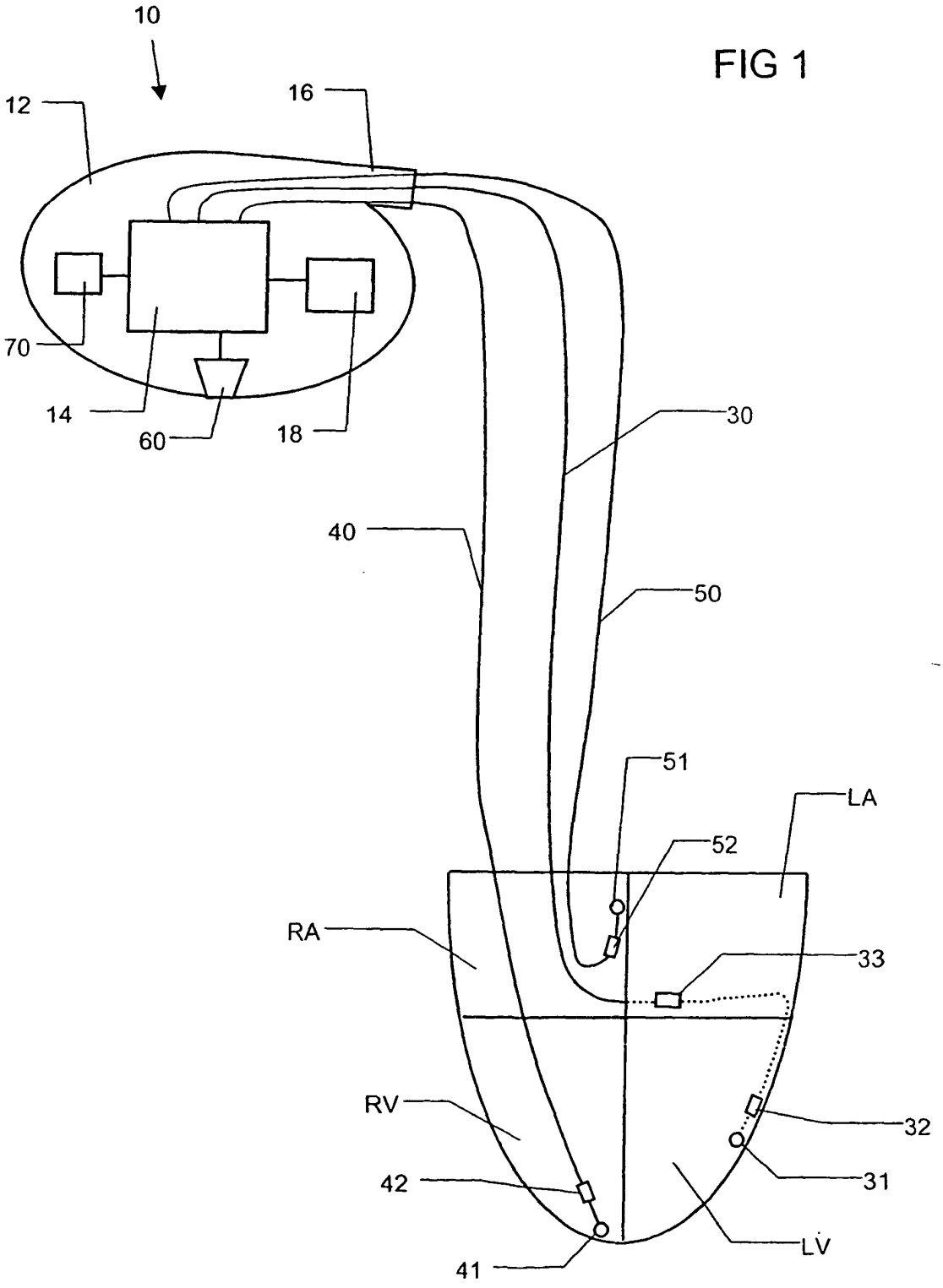


FIG 2 A

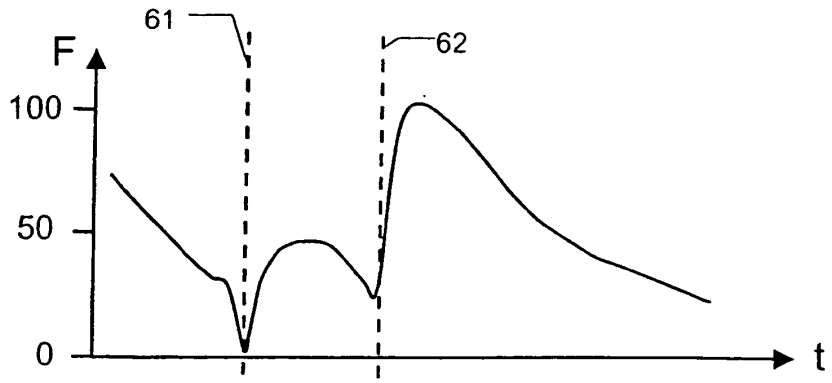



FIG 2 B

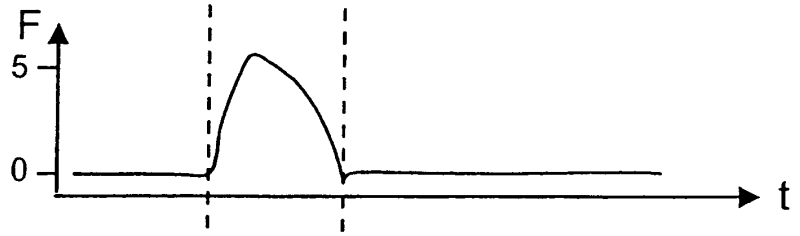



FIG 2 C

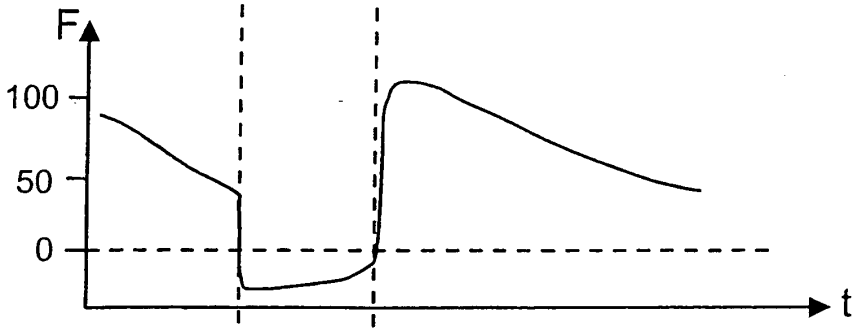



FIG 2 D

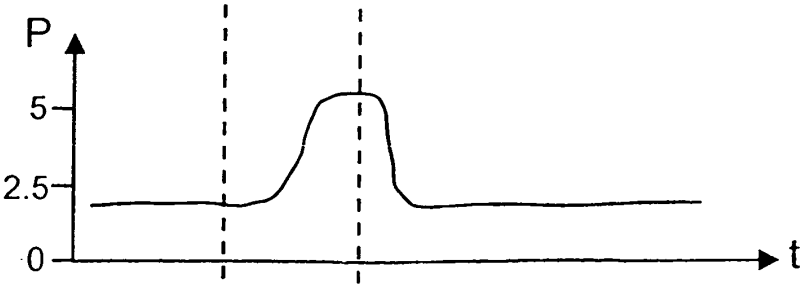



FIG 2 E

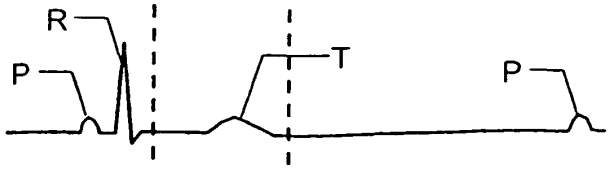


FIG 3

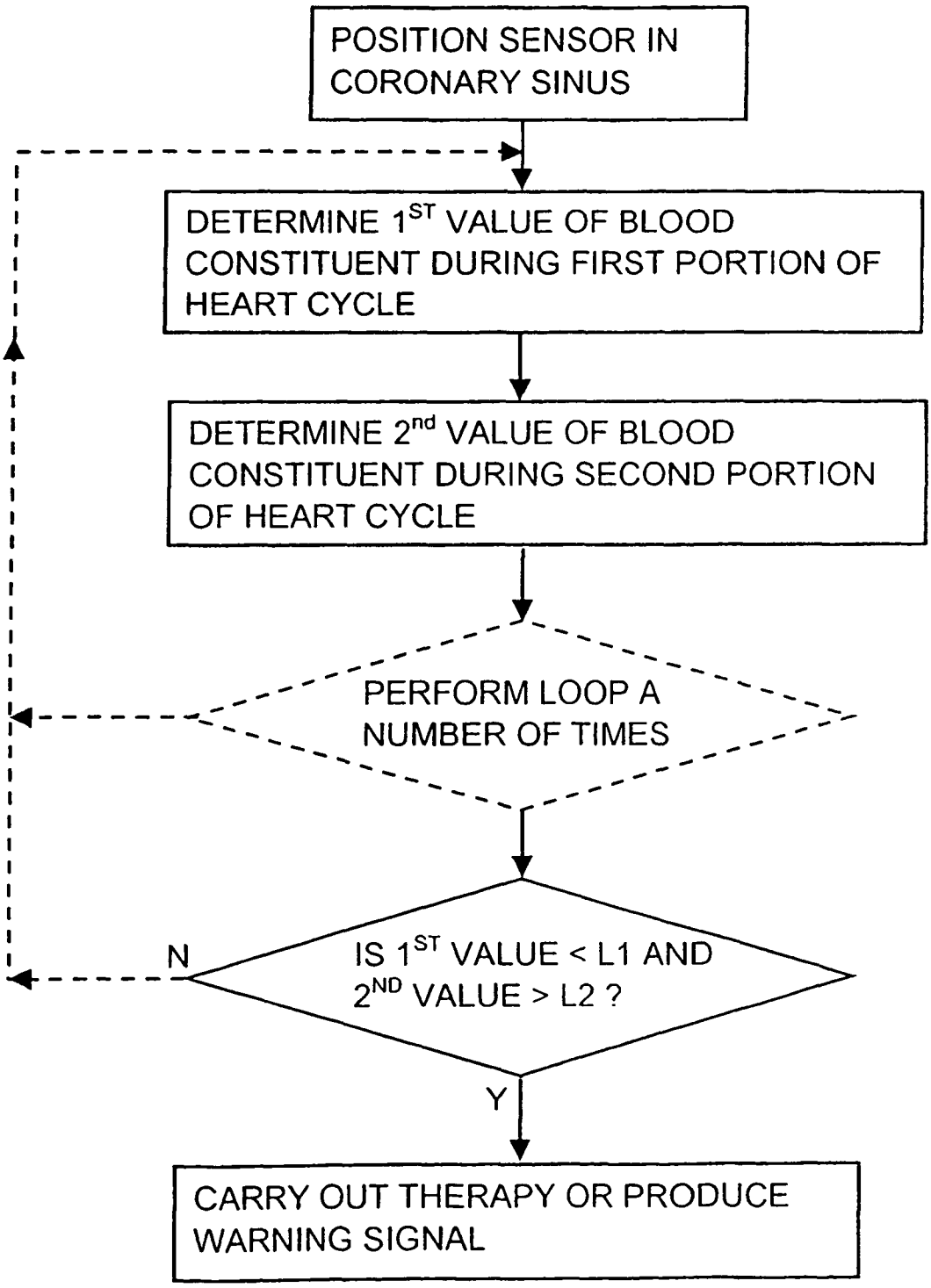
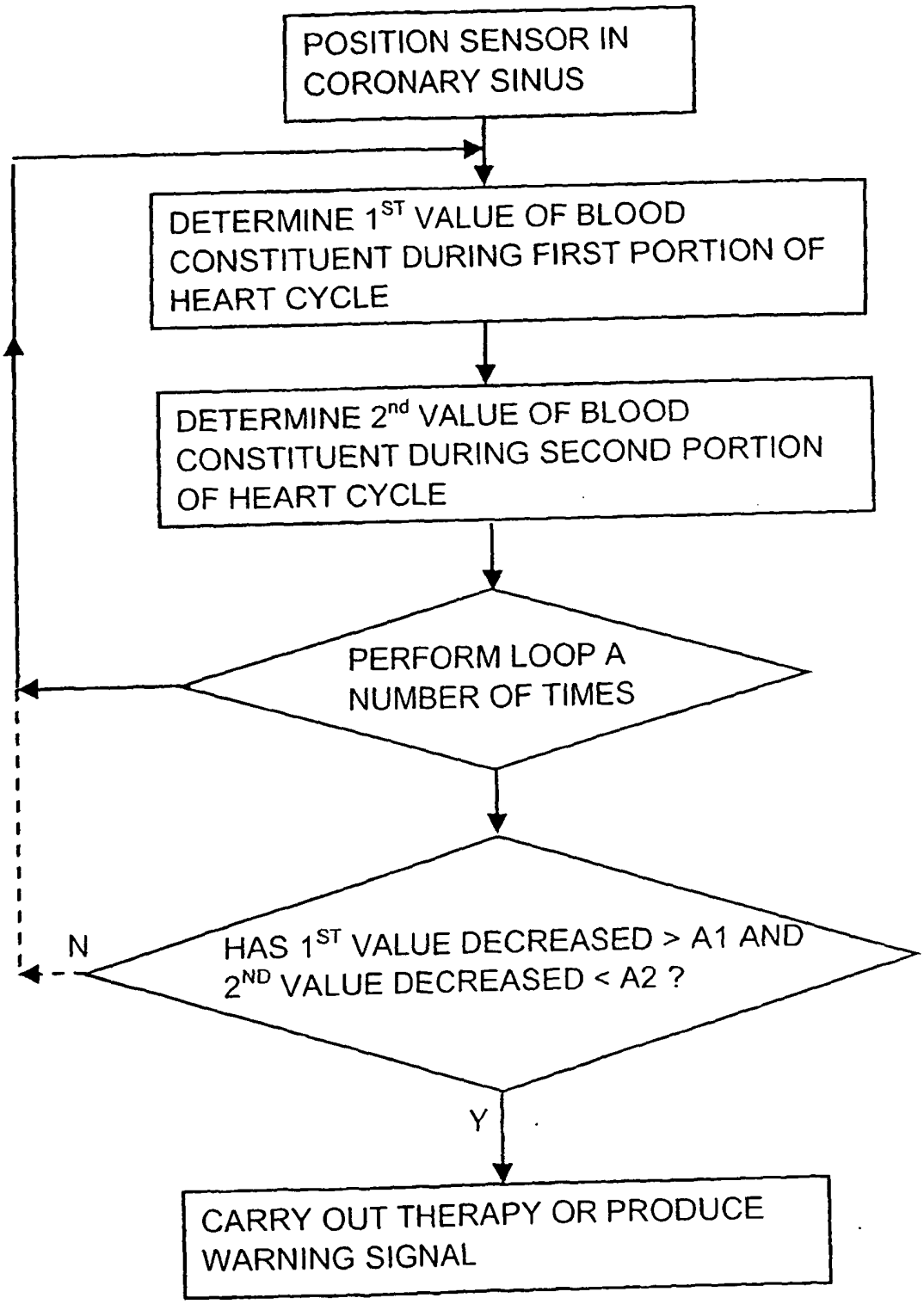

POSITION SENSOR IN CORONARY SINUS
DETERMINE 1ST VALUE OF BLOOD CONSTITUENT DURING FIRST PORTION OF HEART CYCLE
DETERMINE 2nd VALUE OF BLOOD CONSTITUENT DURING SECOND PORTION OF HEART CYCLE
PERFORM LOOP A NUMBER OF TIMES
N
IS 1ST VALUE < L1 AND 2ND VALUE > L2 ?
Y
CARRY OUT THERAPY OR PRODUCE WARNING SIGNAL

FIG 4


POSITION SENSOR IN CORONARY SINUS
DETERMINE 1ST VALUE OF BLOOD CONSTITUENT DURING FIRST PORTION OF HEART CYCLE
DETERMINE 2nd VALUE OF BLOOD CONSTITUENT DURING SECOND PORTION OF HEART CYCLE
PERFORM LOOP A NUMBER OF TIMES
N
HAS 1ST VALUE DECREASED > A1 AND 2ND VALUE DECREASED < A2 ?
Y
CARRY OUT THERAPY OR PRODUCE WARNING SIGNAL

## REFERENCES CITED IN THE DESCRIPTION

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|---|---|---|---|
| 专利名称(译) | 心脏监测设备 | | |
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| 申请号 | EP2003012265 | 申请日 | 2003-06-11 |
| 申请(专利权)人(译) | ST.犹达医疗用品AB | | |
| 当前申请(专利权)人(译) | ST.犹达医疗用品AB | | |
| [标]发明人 | HOLMSTROM NILS | | |
| 发明人 | HOLMSTRÖM, NILS | | |
| IPC分类号 | A61N1/365 A61B5/00 | | |
| CPC分类号 | A61N1/36557 A61N1/365 | | |
| 优先权 | 0202347 2002-07-30 SE | | |
| 其他公开文献 | EP1386637A1 | | |
| 外部链接 | Espacenet | | |


摘要(译)

本发明涉及一种可植入心脏监测装置（10），其包括适于连接到一个或多个传感器构件（31,32,33,41,42,51,52）的控制电路（14）。第一传感器构件（33）适于定位在心脏的冠状窦区域中并且布置成感测至少一种血液成分。控制电路（14）布置成感测心脏的活动并且还使得能够实现以下：a）响应于来自所述第一传感器构件（33）的信号确定与第一部分期间的所述血液成分相关的第一值。心动周期，和b）响应来自所述第一传感器构件（33）的信号，确定在心动周期的第二部分期间与所述血液成分相关的第二值。本发明还涉及一种包括这种心脏监测装置的系统以及这种系统的用途。