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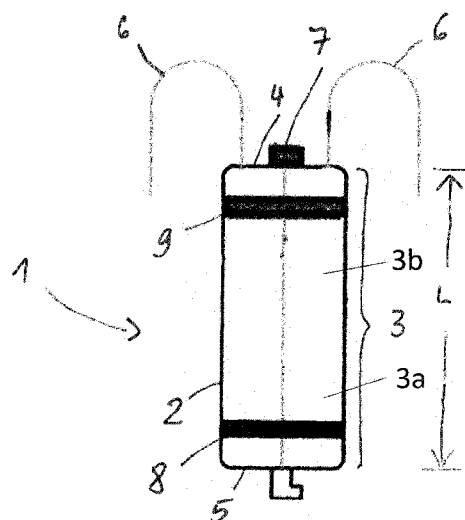


FIG. 1

(57) Abstract: A leadless pacemaker device (1) configured to provide for an intra-cardiac pacing is disclosed. The leadless pacemaker device (1) comprises a housing (2) having an elongated body (3) extending between a first end wall (4) and a second end wall (5); a processing circuitry arranged inside the housing (2) and configured to generate ventricular pacing signals for stimulating ventricular activity and to receive cardiac signals for evaluating cardiac activity; a first electrode (7) arranged at the first end wall (4) of the housing (2), the first electrode (7) having a first surface area and being configured to pace ventricular tissue and sense ventricular signals; a second electrode (8) arranged on the elongated body (3) of the housing (2) in an area that is closer to the second end wall (5) than to the first end wall (4), the second electrode (8) having a second surface area and being configured to serve as counter-electrode for the first electrode (7); and a third electrode (9) arranged on the elongated body (3) of the housing (2) in an area that is closer to the first end wall (4) than to the second end wall (5), the third electrode (9) having a third surface area and being configured to sense far-field signals.



LEADLESS PACEMAKER DEVICE WITH FAR-FIELD SIGNAL SENSING ELECTRODE

The instant invention generally relates to a leadless cardiac pacemaker device for providing an intra-cardiac pacing, in particular a ventricular pacing.

In recent years, leadless pacemakers have received increasing attention. Leadless pacemakers, in contrast to pacemakers implanted subcutaneously using leads extending transvenously into the heart, avoid leads in that the pacemaker device itself is implanted into the heart. Leadless pacemakers typically have the shape of a capsule for implantation into cardiac tissue, in particular the right ventricular wall of the right ventricle. Such leadless pacemakers exhibit the inherent advantage of not using leads, which can reduce risks for the patient involved with leads transvenously accessing the heart, such as the risk of pneumothorax, lead dislodgement, cardiac perforation, venous thrombosis and the like.

Leadless pacemakers may specifically be designed for implantation in the right ventricle and, in this case, during implantation are placed in or on the right ventricular wall. A ventricular pacing may for example be indicated in case a dysfunction at the AV node occurs, but the sinus node function is intact and appropriate. In such a case, in particular a so-called VDD pacing may be desired, involving a ventricular pacing with atrial tracking and hence requiring a sensing of atrial activity in order to pace at the ventricle based on intrinsic atrial contractions.

A pacing using atrial tracking is in particular motivated by patient hemodynamic benefits of atrioventricular (AV) synchrony by utilizing an appropriate sinus node function to trigger ventricular pacing, potentially allowing to maximize ventricular preload, to limit AV

valve regurgitation, to maintain low mean atrial pressure, and to regulate autonomic and neurohumoral reflexes.

However, the detection of atrial signals by leadless pacemaker implanted on or in the ventricular wall is often not easily possible. These atrial signals are typically low-frequency far-field signals.

Leadless pacemakers typically use the same signal path for detecting far-field signals as in case of detecting near field signals. Typically, the signal path extends from a tip electrode of the leadless pacemaker to a ring electrode of the leadless pacemaker.

It is an object of the present invention to provide a leadless pacemaker that is better suited to detect far-field signals, e.g. originating from the atrial chamber, than leadless pacemakers known from prior art.

This object is achieved with a leadless pacemaker device having the features explained in the following. Such a leadless pacemaker device is configured to provide for an intra-cardiac pacing. It comprises a housing having an elongated body extending between a first end wall (also referred to as tip) and a second end wall (also referred to as bottom). The leadless pacemaker device further comprises a processing circuitry arranged inside the housing. The processing circuitry serves for generating ventricular pacing signals for stimulating ventricular activity. It further serves for receiving cardiac signals (e.g., ventricular signals and/or atrial signals) for evaluating cardiac activity.

Within the frame of this application the first end wall is to be understood as the end wall closest to the tip electrode, which is the distal wall with respect to the implantation catheter. The second end wall is opposite to the first end wall and therefore more proximal with respect to the implantation catheter. In the implanted state the first end wall is next to tissue of the implantation site. The second end wall is consequently the end wall which is most far away from the implantation site/from the tissue.

The leadless pacemaker device further comprises a first electrode, a second electrode, and a third electrode. The first electrode is arranged at the first end wall of the housing. The first electrode has a first surface area and is configured to pace ventricular tissue and sense ventricular signals. It is typically in direct contact with ventricular tissue, e.g., by implantation on or in the ventricular wall of the heart to be stimulated.

The second electrode is arranged, in particular in a planar manner, on the elongated body of the housing in an area that is closer to the second end wall than to the first end wall. Thus, the distance between the first electrode and the second electrode is comparatively big. The second electrode has a second surface area and is configured to serve as counter electrode for the first electrode. Expressed in other words, electrical signals applied to the cardiac tissue or sensed from the cardiac tissue are measured between the first electrode and the second electrode.

The third electrode is also arranged, in particular in a planar manner, on the elongated body of the housing, but in an area that is closer to the first end wall than to the second end wall. Thus, the third electrode is necessarily arranged closer to the first electrode than the second electrode is. The third electrode has a third surface area and is configured to sense far-field signals.

Due to the provision of this third electrode on the housing of the leadless pacemaker device, the presently described leadless pacemaker device is better suited to detect far-field signals than leadless pacemaker devices known from prior art. The third electrode accomplishes a higher fidelity and wider bandwidth signal detection to maximize signal detection of small low-frequency signals like an atrial p waves. Thus, the third electrode is particularly appropriate to better detect low-frequency far-field signals than the first electrode does. For performing such signal detection, the second electrode can also be used as counter electrode for the third electrode. The higher far-field signal sensing sensitivity of the third electrode than of the first electrode is mainly given by the arrangement of the third electrode on a lateral side of the elongated housing (instead of an arrangement on the first end wall like in case of the first electrode). By such an arrangement on a lateral side of the elongated body of the housing, in particular in a planar manner, a wider variety of shapes

of the third electrode is possible as in case of the first electrode. Furthermore, the third surface area can be adjusted to the special needs of far-field signal detection, i. e., it can be increased.

Furthermore, an arrangement of the third electrode on the lateral side of the elongated body circumvents a negative influence of regularly observed long-term tip electrode encapsulation due to scar tissue growth. Such scar tissue growth is less frequent in the area of the third electrode than in the area of the first electrode. Consequently, far-field signal strength loss due to electrode encapsulation is minimized by the chosen arrangement of the third electrode on the elongated body of the housing.

Summarizing, the leadless pacemaker device according to the present disclosure allows for better detection of far-field signals. This enables the device for an atrial-ventricular synchronous behavior and improves pacing therapy while minimizing negative side effects.

In an embodiment, the leadless pacemaker device is designed and operated as VDD implantable leadless pacemaker device (VDD-ILP).

In an embodiment, the second surface area is bigger than the first surface area. Such a design enhances the electric field quality of signals detected between the first electrode and the second electrode.

In an embodiment, the third surface area is bigger than the first surface area. Such a surface area difference between the first electrode and the third electrode is particularly appropriate to increase the sensitivity of the third electrode with respect to far-field signals in comparison to the sensitivity of the first electrode. In an embodiment, the third surface area corresponds to 1.1 to 10 times, in particular 1.2 to 9 times, in particular 1.3 to 8 times, in particular 1.4 to 7 times, in particular 1.5 to 6 times, in particular 1.6 to 5 times, in particular 1.7 to 4 times, in particular 1.8 to 3 times, in particular 1.9 to 2 times the first surface area.

In an embodiment, the third surface area is equal to or bigger than the second surface area. To give some examples, the third surface area may correspond to 1.1 to 5 times, in particu-

lar 1.2 to 4.5 times, in particular 1.3 to 4 times, in particular 1.4 to 3.5 times, in particular 1.5 to 3 times, in particular 1.6 to 2.5 times, in particular 1.7 to 2 times, in particular 1.8 to 1.9 times the second surface area.

In an embodiment, the second electrode is shaped in form of a ring electrode. Such a design as ring electrode is particularly appropriate for the second electrode to act as counter electrode for the first electrode and/or the third electrode.

In an embodiment, the third electrode is shaped in form of a ring electrode. The design of the third electrode as ring electrode makes it particularly easy to design the third electrode with a particularly big third surface area. Then, the third electrode is particularly appropriate to detect low-frequency far-field signals, e.g. atrial signals like atrial p waves. The shape of a ring electrode particularly facilitates to employ a big third surface area since the whole outer circumference can be used for forming the third electrode. Such a ring geometry of the third electrode provides a more uniform and spatially homogeneous detection of electrical signals and is thus particularly appropriate for detecting low-intensity far-field signals.

If both the second electrode and the third electrode are shaped in the form of a ring electrode, a broader antenna pattern is made possible than in case of a detection with the first electrode (tip electrode, not ring-shaped) and the second electrode.

In an embodiment, the ring electrode has a width in a direction extending along a longitudinal direction of extension of the housing that corresponds to 1% to 30, in particular 1% to 25%, 1 % to 20 %, in particular 2 % to 19 %, in particular 3 % to 18 %, in particular 4 % to 17 %, in particular 5 % to 16 %, in particular 6 % to 15 %, in particular 7 % to 14 %, in particular 8 % to 13 %, in particular 9 % to 12 %, in particular 10 % to 11 % of the total length of the housing. In this context, the total length of the housing is measured from the first end wall to the second end wall along the longitudinal direction of extension of the housing. It turned out that a width of the third electrode in the before-mentioned ranges is particularly appropriate for detecting cardiac (in particular atrial) far-field signals.

In an embodiment, the third electrode is arranged in the first third of the length of the housing. In this context, the length of the housing is measured from the first end wall to the second end wall along a longitudinal direction of extension of the housing. By such an arrangement, a sufficiently big distance between the third electrode and the second electrode can be achieved. Such a distance ameliorates the general sensing properties of the third electrode and assures proper functioning of the second electrode as counter electrode.

In an embodiment, the distance between the second electrode and the third electrode in a direction extending along a longitudinal direction of extension of the housing corresponds to at least 30 % of the length of the housing. In this context, the length of the housing is once again measured from the first end wall to the second end wall along the longitudinal direction of extension of the housing. In an embodiment, the distance between the second electrode and the third electrode corresponds to 30 % to 90 % of the length of the housing, in particular to 40 % to 80 %, in particular to 50 % to 70 %, in particular 55 % to 60 %.

In an embodiment, the third electrode comprises a surface coating. Such a surface coating can – in addition to an increased surface area of the third electrode – improve the tissue-to-electrode capacitance due to an improved electrode-to-tissue interface. An appropriate surface coating is a coating comprising at least one of one or more minerals, one or more organic materials, one or more ferroalloys, iron powder bound with sodium silicate potassium silicate, platinum, platinum-iridium alloys, carbon compounds as silicon carbide and conductive polymers.

In an embodiment the elongated body of the housing is made of a conductive material which is covered with an electrically insulating non-conductive coating. The second and the third electrode are formed by a recess in the insulating coating. The recess could be a window in the shape of a ring arranged along the circumference of the elongated body. A suitable material selected for the insulating non-conductive coating could be parylene, silicon and/or another suitable insulator.

The housing further comprises an insulating component separating the elongated body of the housing in at least to parts, whereby the second electrode and the third electrode are

arranged on different parts of the elongated body separated by the insulating component. In other words, the elongated body of the housing could be made of two different parts made of conductive material, whereby the two parts are joined together via an insulating non-conductive component. The two windows in the insulating coating of the two different parts of the housing are forming the second electrode and the third electrode.

In an embodiment, the leadless pacemaker device comprises a memory unit, wherein the memory unit comprises a computer-readable program. This program causes the processing circuitry to perform the steps explained in the following when executed on the processing circuitry. First, an attempt is made with the first electrode to detect a cardiac far-field signal having an amplitude exceeding a predeterminable (or predetermined) amplitude. If this attempt has failed (i.e., if no sufficiently intense far-field signal could be sensed with the first electrode), the circuitry switches to a detection of a cardiac far-field signal with the third electrode. Such switching improves the low-frequency detection capabilities of the leadless pacemaker device to enable a reliable VDD operation mode of the device.

In an aspect, the present invention relates to a method of controlling the operation of the leadless pacemaker device according to the preceding explanations. As explained above, such a leadless pacemaker device comprises a housing having an elongated body extending between a first end wall and a second end wall. The leadless pacemaker device further comprises a processing circuitry arranged inside the housing. The processing circuitry serves for generating ventricular pacing signals for stimulating ventricular activity. It further serves for receiving cardiac signals for evaluating cardiac activity.

The leadless pacemaker device further comprises a first electrode, a second electrode, and a third electrode. The first electrode is arranged at the first end wall of the housing. The first electrode has a first surface area and is configured to pace ventricular tissue and sense ventricular signals.

The second electrode is arranged, in particular in a planar manner, on the elongated body of the housing in an area that is closer to the second end wall than to the first end wall. The

second electrode has a second surface area and is configured to serve as counter electrode for the first electrode.

The third electrode is also arranged, in particular in a planar manner, on the elongated body of the housing, but in an area that is closer to the first end wall than to the second end wall. The third electrode has a third surface area and is configured to sense far-field signals.

The second electrode and/or the third electrode could be formed as a recess or window in the insulating coating of two different conductive parts of the elongated body of the housing joined together by an insulating component.

The method comprises the steps explained in the following. First, a detection of cardiac far-field signals with the first electrode is allowed. If no cardiac far-field signals having an amplitude exceeding a predeterminable threshold could have been detected, the operational mode of the leadless pacemaker device is switched such to allow a detection of cardiac far-field signals with the third electrode.

In an aspect, the present invention relates to a method of detecting cardiac far-field signals of a patient in need of such detection with an implanted leadless pacemaker device according to the preceding explanations. As explained above, such a leadless pacemaker device comprises a housing having an elongated body extending between a first end wall and a second end wall. The leadless pacemaker device further comprises a processing circuitry arranged inside the housing. The processing circuitry serves for generating ventricular pacing signals for stimulating ventricular activity. It further serves for receiving cardiac signals for evaluating cardiac activity.

The leadless pacemaker device further comprises a first electrode, a second electrode, and a third electrode. The first electrode is arranged at the first end wall of the housing. The first electrode has a first surface area and is configured to pace ventricular tissue and sense ventricular signals.

The second electrode is arranged, in particular in a planar manner, on the elongated body of the housing in an area that is closer to the second end wall than to the first end wall. The second electrode has a second surface area and is configured to serve as counter electrode for the first electrode.

The third electrode is also arranged, in particular in a planar manner, on the elongated body of the housing, but in an area that is closer to the first end wall than to the second end wall. The third electrode has a third surface area and is configured to sense far-field signals.

The second electrode and/or the third electrode could be formed as a recess or window in the insulating coating of two different conductive parts of the elongated body of the housing joined together by an insulating component.

This method comprises the steps explained in the following. In one option, first, an attempt is made to detect with the first electrode a cardiac far-field signal, in particular a cardiac far-field signal having an amplitude exceeding a predeterminable amplitude. If this attempt of detecting a far-field signal having a sufficiently high intensity was not successful, the leadless pacemaker device switches to a detection of the cardiac far-field signal with a third electrode. As explained above, the sensitivity of the third electrode with respect to a detection of far-field signals is much higher than the sensitivity of the first electrode so that even low-intensity far-field signals can be reliably detected with the third electrode. In another option, first, the leadless pacemaker device switches to a detection of the cardiac far-field signal to the third electrode without attempting to detect the far field signal with the first electrode first.

All embodiments of the leadless pacemaker device can be combined in any desired way and can be transferred either individually or in any arbitrary combination to any of the described methods. Likewise, embodiments of the methods can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the leadless pacemaker device or to a respective other method.

Further details of aspects of the present invention will be explained in the following making reference to an exemplary embodiment and an accompanying Figure. In the Figure:

Figure 1 shows an exemplary embodiment of a leadless pacemaker device.

Figure 1 shows a leadless pacemaker 1 comprising a housing 2 with an elongated body 3 extending between a first end wall 4 and a second end wall 5 and having a length L. Two anchoring wires 6 are arranged at the first end wall 4. These anchoring wires 6 serve for anchoring the leadless pacemaker 1 on or in ventricular tissue after implantation of the leadless pacemaker 1.

The leadless pacemaker 1 further comprises a first electrode 7 that is arranged at the first end wall 4. The first electrode 7 acts as cathode and serves for applying pacing pulses to ventricular tissue after implantation of the leadless pacemaker 1. The first end wall 4 is at least partially made of an insulating material to electrically separate the first electrode 7 and the elongated body 3 of the housing 2.

The leadless pacemaker 1 further comprises a second electrode 8 that serves as an anode and counter electrode for the first electrode 7. This second electrode 8 is arranged close to the second end wall 5, i.e. distant to the first electrode 7 and the first end wall 4. The second electrode 8 has the geometric shape of a ring electrode.

The leadless pacemaker 1 further comprises a third electrode 9 that is arranged close to the first end wall 4, i.e. distant to the second end wall 5 and distant to the second electrode 8. The third electrode 9 is also shaped in the form of a ring electrode and runs around the whole circumference of the elongated body 3 of the leadless pacemaker 1. The third electrode 9 serves for detecting low energy far-field signals, in particular far-field signals that are not or only hardly detectable by the first electrode 7 which stands in contact to ventricular tissue after implantation of the leadless pacemaker 1.

The elongated body 3 of the leadless pacemaker comprises two parts 3a, 3b made of a material which is an electrical conductor. The two parts are joined together by an insulating

component (not shown). The second electrode 8 and the third electrode 9 are formed by a recess or window in the insulating coating of the two parts 3a, 3b of the elongated body 3, whereby the windows are in the shape of a ring along the circumference of the elongated body 3. The two parts 3a and 3b of the elongated body 3 are made of a conductive material and coated with parylene as insulating coating.

Due to the shape of the third electrode 9, its surface area is much bigger than the surface area of the first electrode 7. This allows a much more sensitive detection of far-field signals. In addition, a ring shape of the third electrode 9 allows a spatially homogeneous detection of electrical signals. This is in particular true since the second electrode 8 is also designed as a ring electrode so that a particular homogeneous field between the third electrode 9 and the second electrode 8 can be formed for detection purposes. Thus, the second electrode 8 also serves as counter electrode for the third electrode 9.

During operation of the leadless pacemaker 1, the first electrode 7 may be used in a first step to try to detect far-field signals having a specified minimum amplitude. If this detection is successful, it would not be necessary to put the third electrode 9 into operation. However, if the detection was not successful, the leadless pacemaker 1 switches to a detection mode in which far-field signals are detected by the third electrode 9. Due to the increased surface area of the third electrode 9 and its planar arrangement on a lateral side of the elongated body 3 of the leadless pacemaker 1, the third electrode 9 is able to detect far-field signals in a much more sensitive way than the first electrode 7 does. Optionally, detection of the far field signal may be performed immediately with the third electrode 9 without attempting to use electrode 7 first.

Claims

1. A leadless pacemaker device (1) configured to provide for an intra-cardiac pacing, the leadless pacemaker device (1) comprising:
 - a housing (2) having an elongated body (3) extending between a first end wall (4) and a second end wall (5);
 - a processing circuitry arranged inside the housing (2) and configured to generate ventricular pacing signals for stimulating ventricular activity and to receive cardiac signals for evaluating cardiac activity;
 - a first electrode (7) arranged at the first end wall (4) of the housing (2), the first electrode (7) having a first surface area and being configured to pace ventricular tissue and sense ventricular signals;
 - a second electrode (8) arranged on the elongated body (3) of the housing (2) in an area that is closer to the second end wall (5) than to the first end wall (4), the second electrode (8) having a second surface area and being configured to serve as counter-electrode for the first electrode (7); and
 - a third electrode (9) arranged on the elongated body (3) of the housing (2) in an area that is closer to the first end wall (4) than to the second end wall (5), the third electrode (9) having a third surface area and being configured to sense far-field signals.
2. The leadless pacemaker device according to claim 1, **wherein** the second surface area is bigger than the first surface area.
3. The leadless pacemaker device according to claim 1 or 2, **wherein** the third surface area is bigger than the first surface area.
4. The leadless pacemaker device according to any of the preceding claims, **wherein** the second electrode (8) is shaped in form of a ring electrode.
5. The leadless pacemaker device according to any of the preceding claims, **wherein** the third electrode (9) is shaped in form of a ring electrode.

6. The leadless pacemaker device according to claim 5, **wherein** the ring electrode has a width in a direction extending along a longitudinal direction of extension of the housing (2) that corresponds to 1 % to 30 % of a total length (L) of the housing (2), measured from the first end wall (4) to the second end wall (5) along the longitudinal direction of extension of the housing (2).
7. The leadless pacemaker device according to any of the preceding claims, **wherein** the third electrode (9) is arranged in a first third of a length (L) of the housing (2), measured from the first end wall (4) to the second end wall (5) along a longitudinal direction of extension of the housing (2).
7. The leadless pacemaker device according to any of the preceding claims, **wherein** a distance between the second electrode (8) and the third electrode (9) in a direction extending along a longitudinal direction of extension of the housing (2) corresponds to at least 30 % of a length (L) of the housing (2), measured from the first end wall (4) to the second end wall (5) along the longitudinal direction of extension of the housing (2).
8. The leadless pacemaker device according to any of the preceding claims, **wherein** the elongated body (3) is made of a conductive material which is covered with an electrically insulating non-conductive coating, and whereby the second (8) and/or the third electrode (9) are formed by a recess in the insulating coating.
9. The leadless pacemaker device according to any of the preceding claims, **wherein** the elongated body (3) comprises an insulating component separating the elongated body (3) of the housing in at least to parts (3a, 3b), whereby the second electrode (8) and the third electrode (9) are arranged on different parts of the elongated body (3) separated by the insulating component.
10. The leadless pacemaker device according to any of the preceding claims, **wherein** the insulating non-conductive coating comprises one or more of parylene and silicon.

11. The leadless pacemaker device according to any of the preceding claims, **wherein** the third electrode (9) comprises a surface coating.
12. The leadless pacemaker device according to any of the preceding claims, **wherein** the leadless pacemaker device comprises a memory unit, the memory unit comprising a computer-readable program that causes the processing circuitry to perform the following steps when executed on the processing circuitry: a) attempting to detect, with the first electrode (7), a cardiac far-field signal; b) if step a) has not been accomplished successfully, switching to a detection of a cardiac far-field signal with the third electrode (9).
13. A method of controlling operation of a leadless pacemaker device according to any of the preceding claims, the leadless pacemaker device comprising:
 - a housing (2) having an elongated body (3) extending between a first end wall (4) and a second end wall (5);
 - a processing circuitry (15) arranged inside the housing (2) and configured to generate ventricular pacing signals for stimulating ventricular activity and to receive cardiac signals for evaluating cardiac activity;
 - a first electrode (7) arranged at the first end wall (4) of the housing (2), the first electrode (7) having a first surface area and being configured to pace ventricular tissue and sense ventricular signals;
 - a second electrode (8) arranged on the elongated body (3) of the housing (2) in an area that is closer to the second end wall (5) than to the first end wall (4), the second electrode (8) having a second surface area and being configured to serve as counter-electrode for the first electrode (7); and
 - a third electrode (9) arranged on the elongated body (3) of the housing (2) in an area that is closer to the first end wall (4) than to the second end wall (5), the third electrode (9) having a third surface area and being configured to sense far-field signals;

wherein the method comprises the following steps:

a) allowing a detection of a cardiac far-field signal with either the first electrode (7) or the third electrode (9),

b) if no cardiac far-field signal having an amplitude exceeding a predetermined amplitude has been detected, switching to allowing a detection of a cardiac far-field signal with the third electrode (9) or the first electrode (7) respectively.

14. A method of detecting cardiac far-field signals of a patient in need of such detection with an implanted leadless pacemaker device according to any of the preceding claims, the leadless pacemaker device comprising:

a housing (2) having an elongated body (3) extending between a first end wall (4) and a second end wall (5);

a processing circuitry (15) arranged inside the housing (2) and configured to generate ventricular pacing signals for stimulating ventricular activity and to receive cardiac signals for evaluating cardiac activity;

a first electrode (7) arranged at the first end wall (4) of the housing (2), the first electrode (7) having a first surface area and being configured to pace ventricular tissue and sense ventricular signals;

a second electrode (8) arranged on the elongated body (3) of the housing (2) in an area that is closer to the second end wall (5) than to the first end wall (4), the second electrode (8) having a second surface area and being configured to serve as counter-electrode for the first electrode (7); and

a third electrode (9) arranged on the elongated body (3) of the housing (2) in an area that is closer to the first end wall (4) than to the second end wall (5), the third electrode (9) having a third surface area and being configured to sense far-field signals;

wherein the method comprises the following steps:

a) attempting to detect, with either the first electrode (7) or the third electrode (9), a cardiac far-field signal having an amplitude exceeding a predetermined amplitude; and

b) if step a) has not been accomplished successfully, switching to a detection of a cardiac far-field signal with the third electrode (9) or the first electrode (7) respectively.

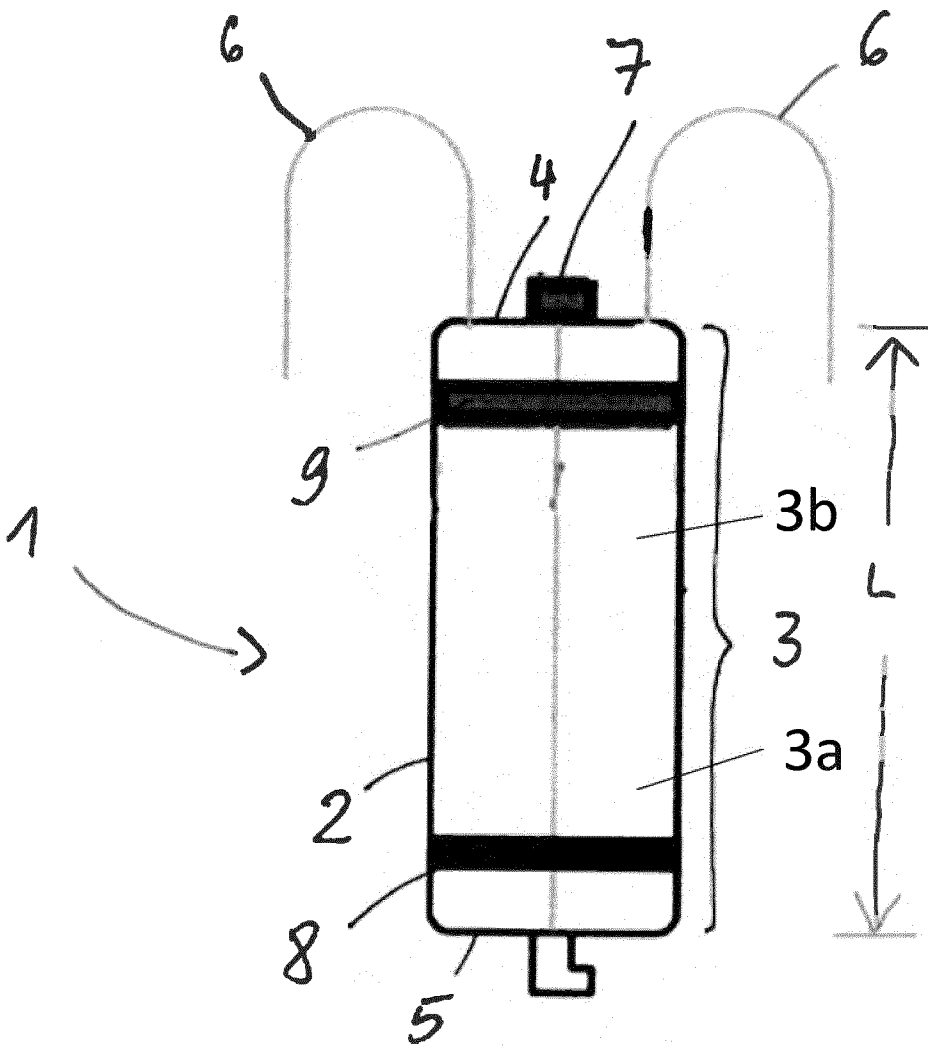


FIG. 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2022/079365

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **14, 15**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2022/079365

A. CLASSIFICATION OF SUBJECT MATTER**INV. A61N1/375****ADD. A61N1/365**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 3 744 390 A1 (PACESETTER INC [US]) 2 December 2020 (2020-12-02)	1-12
Y	paragraphs [0080], [0097], [0099], [0107] - [0110], [0119]; figures 5A, 5B -----	13
Y	EP 3 789 081 A1 (BIOTRONIK SE & CO KG [DE]) 10 March 2021 (2021-03-10) paragraph [0066] -----	13
A	US 2019/168007 A1 (STAHMANN JEFFREY E [US] ET AL) 6 June 2019 (2019-06-06) paragraph [0062]; figure 1 -----	1-13



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20 January 2023

Date of mailing of the international search report

30/01/2023

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2022/079365

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			EP	3717063 A1		07-10-2020
			US	2019168007 A1		06-06-2019
			WO	2019108482 A1		06-06-2019

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 14, 15

Claim 14 (appearing as claim 13, see Item VII) defines a method of "controlling operation of a leadless pacemaker device". The "operation" of said device implicitly involves pacing of the heart, by providing electrical pulses. In consequence, claim 13 relates to therapeutical treatment of the human or animal body. Thus, it is covered by the provisions of Article 17(2)(a)(i) PCT and Rule 39.1 (iv) PCT, i.e. the International Search Authority cannot be required to perform the search on its subject-matter. Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1 (iv) PCT, no examination is required to be carried out on this claim. Claim 15 (appearing as claim 14, see Item VII) refers to "of detecting cardiac far-field signals of a patient in need of such detection with an implanted leadless pacemaker device according to any of the preceding claims". Said device comprises i.a. an electrode "configured to pace ventricular tissue and sense ventricular signals" (see claim 1) and it is immediately apparent from the description that the pacing actually take place. Thus, claim 14 implicitly comprises the step of pacing and also falls under the provisions of Article 17(2)(a)(i) PCT and Rule 39.1 (iv) PCT, i.e. the International Search Authority cannot be required to perform the search on its subject-matter. Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1 (iv) PCT, no examination is required to be carried out on this claim.