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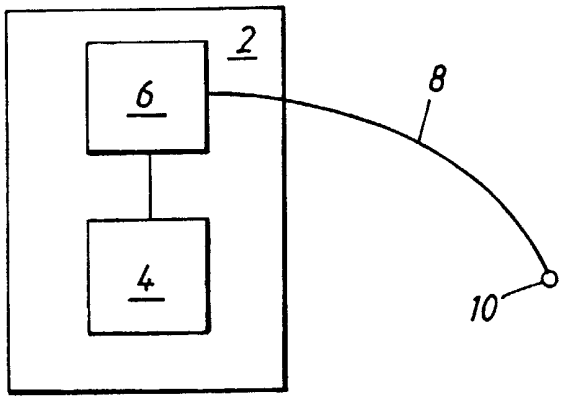
(54) Title: IMPLANTABLE HEART STIMULATOR



(57) Abstract: Implantable heart stimulator (2) comprising a control and detection means (4), a pulse generator (6) adapted to generate stimulation pulses to a heart via at least one electrode lead (8) adapted to be inserted into the heart of a patient. The electrode lead is provided with an electrode surface (10) intended to be in contact with heart tissue. A microinstability test is performed by the control means during a predetermined number of stimulation pulses, e.g. 15, where all pulses during the test have the same stimulation energy, and a microinstability test value is determined, wherein said value is a measure of the contact between the electrode surface and heart tissue.

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Title

Implantable heart stimulator

Field of the invention

The present invention relates to an implantable heart stimulator according to the preamble of the independent claim.

Background of the invention

Immediately after implantation of a heart stimulator and insertion of an heart electrode lead into the heart and attaching a stimulation electrode to heart tissue, the stimulation threshold, i.e. the least energy (pulse amplitude if the pulse width is constant) required to achieve heart contraction is relatively high. After the first months following implantation of a heart stimulator the stimulation threshold eventually stabilizes at a more or less constant value in the order of some Volts (2-5 Volts).

Natural fluctuations of the stimulation threshold occur due to e.g. the activity of the patient (awake or asleep), the intake of drugs, etc. These fluctuations might be considered as more or less predictable.

Another type of fluctuation, which is considered more unpredictable, might occur when the electrode surface of the electrode lead not is in good contact with heart tissue.

US-5,836,990 discloses a method and apparatus for determining electrode/tissue contact. The contact between an electrophysiology catheter electrode and cardiac tissue covered by blood is sensed by applying a constant voltage or current square wave signal to the electrode and then

monitoring the voltage or impedance or current at the electrode before, during and after the electrode contacts the tissue. In the apparatus disclosed in US-5,836,990 is a dedicated signal applied to the cardiac tissue in order to determine an electric parameter related to the contact between the electrode and the cardiac tissue. The electric parameter is then monitored and the contact is determined.

A drawback with the apparatus disclosed in the above referenced US-patent is that it requires a dedicated circuitry in order to determine the degree of contact between the electrode and the cardiac tissue.

The objects of the present invention is to achieve an improved implantable heart stimulator that avoids the above mentioned drawbacks with the apparatus disclosed in US-5,836,990 and that identifies varying stimulation thresholds due to microinstability.

Summary of the invention

The object of the invention is achieved by an implantable heart stimulator provided with the features set forth in the characterizing part of the dependent claim.
Preferred embodiments are set forth in the dependent claims.

Microinstability is as a term used to describe how stable the electrode surface, e.g. the electrode tip, is attached to the heart tissue. If the electrode surface not is properly attached to the heart tissue, movements of the electrode might then result in varying stimulation thresholds dependent on varying electrical conditions around the electrode. This in turn might result in more frequent delivery of back-up pulses which can be both unpleasant for

the patient and reduce the battery capacity of the heart stimulator.

The object of the present invention is thus achieved by performing a microinstablity test in order to identify varying stimulation thresholds and to increase the stimulation energy if so required to eliminate the influence of the varying threshold.

It is a further object of the invention to perform in addition to a stimulation threshold search a microinstability test in order to be able to adjust the stimulation energy to a level where the effects of microinstablity are reduced or eliminated.

Short description of the appended drawings

Figure 1 discloses a block diagram of the heart stimulator according to the present invention, and

Figure 2 discloses an IEGM illustrating the principles of a threshold search algorithm applicable in relation with the present invention.

Detailed description of preferred embodiments

Figure 1 discloses an implantable heart stimulator 2 according to the invention comprising a control and detection means 4, a pulse generator 6 adapted to generate stimulation pulses to a heart via at least one electrode lead 8 adapted to be inserted into the heart of a patient. The electrode lead is provided with an electrode surface 10 intended to be in contact with heart tissue. The electrode surface is conventionally often arranged as a tip electrode but the invention is equally applicable on any electrode surface intended to be in contact with heart tissue, e.g. different kinds of ring electrodes.

The heart stimulator naturally also comprises energy source means and other means not further described herein as they have no significance for the present invention.

A microinstability test may be performed in many different ways.
According to a preferred embodiment of the invention is a microinstability test performed directly after that a stimulation threshold search has been performed.
According to an alternative embodiment of the invention is the microinstability test performed at regular intervals independently of any threshold search. The microinstability test may also be performed in relation to a heart stimulator not provided with threshold search means. The test need not be initiated at regular intervals but instead on demand, e.g. in response to an external signal, e.g. a magnetic signal, or in response to a sensing means detecting the occurrence of some specified event, e.g. if the threshold is varying irregularly.

The microinstability test is performed by the control and detection means 4 (comprising e.g a microprocessor) which supplies a control signal to the pulse generator to control the pulse generator to generate a predetermined number of stimulation pulses to the heart tissue via the electrode lead and which also detects capture, if any, for each of said stimulation pulses. The number of generated stimulation pulses is e.g. in the interval 10-20, preferably 15. All stimulation pulses during the microinstability test have the same stimulation energy. A typical stimulation pulse has an amplitude of some volts and a pulse width of 0,01 to 1,0 ms. A measure of the quality of the contact between the

electrode surface and heart tissue is given by a microinstability test value, a value being determined by the control and detection means 4 in accordance with an algorithm therefore, as the ratio between the number of stimulation pulses of the predetermined number that resulted in capture and the predetermined number. If one or more losses of capture are observed during the microinstability test, the test value is less than 1. The microinstability test is then repeated with slightly higher stimulation amplitude, typically 0,25 V, until 100 % capture is obtained during the microinstability test.

According to a further refinement of the invention is the microinstability test performed by a shortened relevant stimulation interval, e.g. AV-interval or VV-interval, to ensure that only stimulated heart events occur during the test. The interval is shortened with a predetermined time in the order of 5-100 ms.

According to a preferred embodiment of the invention and as indicated above is the microinstability test performed after that a stimulation threshold search has been completed.
In order to fully understand the advantages of the present invention is a threshold search algorithm illustrated in figure 2.
Figure 2 discloses an IEGM illustrating the principles of threshold search algorithms according to established standard prior art, see e.g. US-5,476,487, and applicable in relation with the present invention. A and V designate atrial and ventricular stimulation pulses, respectively. BU is a high output backup pulse delivered if loss of capture (LOC) occurs. As can be seen (complex 3) the pre-programmed

AV-interval is prolonged with Δ when a LOC occurs (complex 2). The reason for that is to await any intrinsic event if the first LOC was the result of a fusion beat. In this case there is no intrinsic activity and the LOC was not a result of a fusion beat but was due to a changed stimulation threshold of the heart tissue, and a stimulation threshold search is initiated.

In figure 2 during the threshold search the pre-programmed AV-interval is shortened to "AV-short" to override any intrinsic heart activity. The ventricular stimulation amplitude is successively stepped up by a predetermined amplitude step of e.g. 0,1-0,3 V and each unsuccessful ventricular stimulation pulse is followed by a back-up pulse. As an alternative the ventricular stimulation amplitude may start at an amplitude above the stimulation threshold and then successively be stepped down until non-capture occurs. This is performed until the stimulation threshold is detected, i.e. capture is detected from the ventricular stimulation pulse, and the stimulation pulse amplitude is then set to a value that equals the stimulation threshold plus a working margin, e.g. 0,3 V.

It should be noted that the threshold search according to the established technique disclosed in the above-mentioned US-5,476,487 is performed by using a pre-programmed AVI shortened to "AVI-short" as indicated above.

The microinstability test is then performed for a predetermined number of heart cycles, typically 15, with the shortened AVI used in the threshold search using the measured threshold as stimulation amplitude. If no loss of capture is observed during the predetermined number of heart cycles then the previously determined threshold is valid. If

one or more losses of capture are observed then the microinstability test is repeated with a slightly higher stimulation amplitude, typically 0,25 V. The test is repeated until 100 % capture is obtained during the microinstability test. The new stimulation amplitude valid for the period until the next threshold search is obtained after adding a working margin to the amplitude.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appendant claims.

Claims

1. Implantable heart stimulator (2) comprising a control and detection means (4), a pulse generator (6) adapted to generate stimulation pulses to a heart via at least one electrode lead (8) adapted to be inserted into the heart of a patient, said electrode lead being provided with an electrode surface (10) intended to be in contact with heart tissue, characterized in that a microinstability test is performed by said control and detection means (4) on a predetermined number of stimulation pulses where all pulses during the test have the same stimulation energy, such that a microinstability test value is determined as the ratio between the number of stimulation pulses of the predetermined number for which capture was detected and the predetermined number, said value being a measure of the contact between the electrode surface and heart tissue.

2. Heart stimulator according to claim 1, characterized in that if one or more losses of capture are observed during the test then the microinstability test is repeated with a slightly higher stimulation amplitude, typically 0,25 V, until 100 % capture is obtained during the microinstability test.

3. Heart stimulator according to any preceding claim, characterized in that said predetermined number is in the interval 10-20, preferably 15.

4. Heart stimulator according to any preceding claim, characterized in that said microinstability test is performed after that a stimulation threshold search has been

performed.

5. Heart stimulator according to any preceding claim, characterized in that a relevant stimulation interval, e.g. AV-interval or VV-interval, is shortened with a predetermined time in the order of 5-100 ms during the microinstability test.

6. Heart stimulator according to any preceding claim, characterized in that the microinstability test is performed at regular intervals, preferably every 8 hours.

Fig. 1

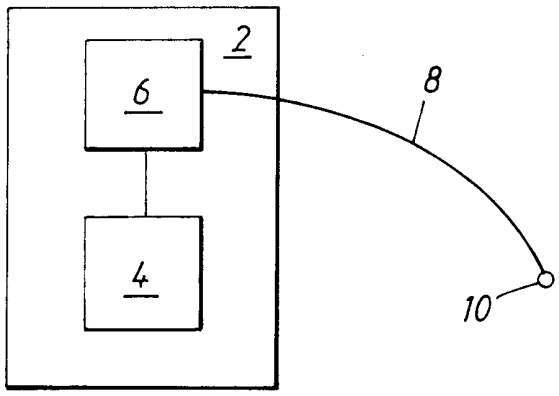
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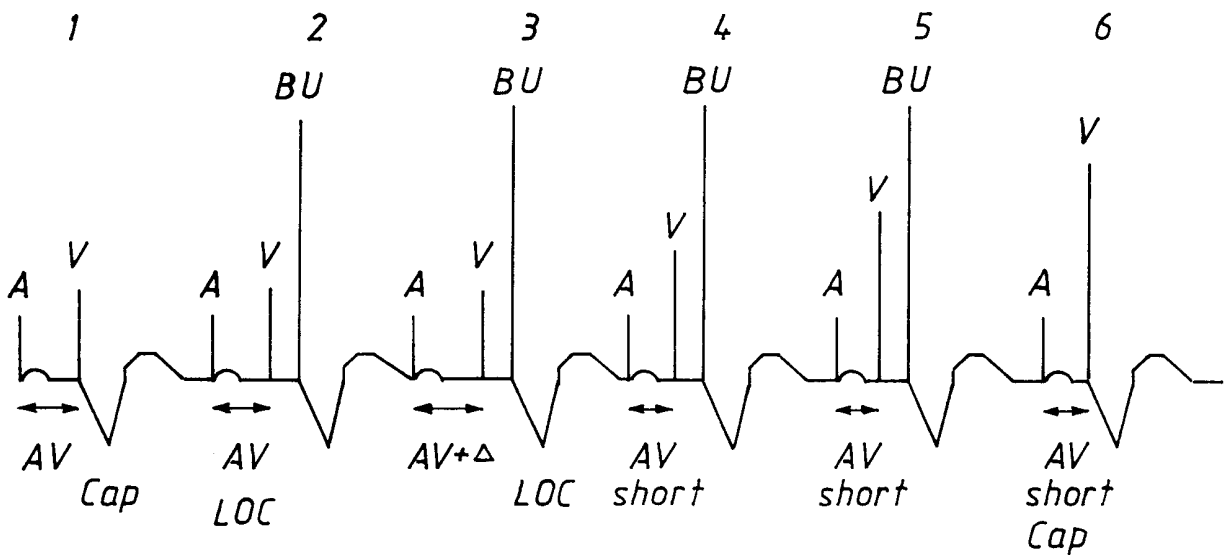
Fig. 2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