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(54) Title: IMPLANTABLE ELECTRODE LEAD WITH SWITCHING UNIT ADAPTED FOR SWITCHING ELECTRODE LEAD BETWEEN NORMAL PACING MODE AND LOCAL PACING MODE DURING MRI

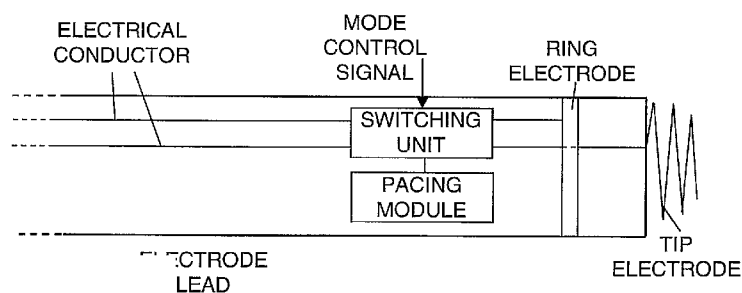


Fig. 2

(57) Abstract: Implantable electrode lead for tissue stimulation adapted to be attached to an implantable tissue stimulator provided with a pulse generator, the electrode lead comprises at least two stimulation electrodes to apply stimulation pulses to said tissue and arranged close to the distal end of the electrode lead, and at least two electrical conductors to connect said electrodes to said pulse generator. The electrode lead further comprises a switching unit arranged close to the distal end of the electrode lead and adapted to switch the electrode lead between a local pacing mode and a normal pacing mode, the switching unit being controlled by a mode control signal. Further, a pacing module is arranged close to the distal end of the electrode lead and in relation to the switching unit and being connectable to said at least two stimulation electrodes, the pacing module includes a pulse generating unit to generate stimulating pulses to be applied to the tissue by said stimulation electrodes. When the electrode lead is in the local pacing mode the electrical conductors are disconnected from said stimulation electrodes which instead are connected to the pacing module, and when the electrode lead is in the normal pacing mode the electrical conductors are connected to the stimulation electrodes.



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Implantable electrode lead with switching unit adapted for switching electrode lead between normal pacing mode and local pacing mode during MRI

Field of the invention

- 5 The present invention relates to an implantable electrode lead according to the preamble of the independent claim.

Background of the invention

- 10 Implantable pulse generator (IPG) systems are considered contraindicative to Magnetic Resonance Imaging (MRI). One concern discussed regarding compatibility of IPG systems and MRI scanning is heating at or close to the lead tip, caused by currents in the lead induced by the applied RF-field from the MRI system, i.e. the IPG lead is acting as an antenna picking up the RF field during the MRI scan.

- 15 If the heating is too high, there is a concern that there may be damages to the cardiac tissue.

The use of MRI scans for diagnostics is growing extensively and an increasing, already large number of IPG patients would benefit from MRI scans. It is thus desirable to reduce any heating at or close to the lead tip to acceptable and safe levels.

20

In the prior art a number of patents and patent applications exist related to different solutions of the above problem with MRI-scanning of IPG patients.

The solutions proposed in the prior art may be divided into two main groups.

25

The first group is essentially based upon filtering, insulating or compensation techniques to reduce effects of MRI.

See e.g. US-7,363,090 that includes a band stop filter arranged to attenuate a current flow through the lead wire along a range of selected frequencies.

- 30 In US-7,123,013 a tuneable compensation circuit is connected to the lead wire line. This circuit applies supplemental impedance to the wire line to cause the characteristic

impedance of the wire line to become unbalanced, thereby reducing the effects of induced voltages caused by the MRI field.

In US-2003/0204217 an electrode isolation system electrically isolates the lead electrodes from the voltage discharge unit during time intervals between the voltage pulses.

5 In US-2007/0238975 an MRI gradient magnetic field is sensed and the system switches from a first electrical signal processing mode to a second electrical signal processing mode based upon the sensed field.

US-2008/0079429 relates to an implantable medical device with two medical leads and a filter circuit coupled to the distal end of the first lead. A compensation circuit provides
10 compensation voltage to enable the filter to effectively block changing magnetic field induced current in the second lead from passing through a second electrode of the distal end of the second lead.

In the second group, represented by US-2002/0116028, so-called photonic leads or
15 catheters are used where electrical pulses output by the pulse generator are converted into light energy and directed into the proximal end of the photonic catheter. The photonic catheter includes an optical conduction pathway and light entering the proximal end of the catheter is transmitted through the optical pathway, where it is collected and converted
20 back to electrical energy at the distal end of the photonic catheter. The optical pulses are then converted to electrical pulses and delivered to the heart electrodes.

In US-2002/0116029 a similar system is disclosed, differing in that a miniature pulse generator is arranged at the distal end of the photonic catheter that stores electrical energy received via the optical conductors and periodically releases that energy to deliver
25 electrical pulses to the bipolar heart electrodes. A similar device is also disclosed in US-2002/0116034.

Thus, the specific object of the present invention is to solve the problem of heat generation induced by the magnetic fields when performing MRI of a patient having an implantable
30 heart stimulator.

In addition to the above specific object of the invention the inventors have identified a more general object of the present invention which is to achieve an alternative stimulation mode in situations where the normal pacing mode of the implantable heart stimulator may not be possible or suitable to use.

5

Summary of the invention

The above-mentioned objects are achieved by the present invention according to the independent claim.

10 Preferred embodiments are set forth in the dependent claims.

Thus, the present invention solves the above problem by disconnecting the stimulating electrodes, e.g. the tip and the ring, from the rest of the lead (i.e. antenna) during MRI, or when another predefined situation occurs that motivates use of the local pacing mode.

15 According to the invention a pacing module is arranged close to the distal tip. In addition a switching unit is arranged close to the pacing module that during the normal pacing mode is closed, i.e. the stimulating electrodes are connected to the pulse generator of the heart stimulator. When the heart stimulator is put in local pacing mode (MRI mode) the tip and ring are disconnected from the rest of the lead, and the heart stimulator, and instead
20 connected to the pacing module. The pacing module includes a very simple pacemaker function that takes care of the pacemaker functionality during the MRI scan.

According to one embodiment of the present invention the local stimulation rate is set, during MRI, at an appropriate overdrive rate if the patient's intrinsic rate is low/none-
25 existent. If the patient's intrinsic rate is sufficient the switching unit only disconnects the electrical conductors from the stimulation electrodes.

According to another embodiment the local pacing module and the switching unit is energised by an energy unit being a battery or a capacitor, or by energy supplying
30 conductors going through the lead all the way up to the heart stimulator battery. These conductors are not directly connected to the tip and/or the ring so there is no problem if voltage is induced in them during MRI and they are heated. I.e. the thin conductors are

connected to the tip and/or ring via the pacing module and switching unit close to the tip of the lead and thus not directly connected to the tip/ring.

Short description of the appended drawings

5 Figure 1 is a schematic illustration of an implantable tissue stimulator provided with an electrode lead according to the present invention.

Figure 2 shows a schematic illustration of the distal part of an electrode lead according to the present invention.

10 Figure 3 shows a schematic illustration of the distal part of an electrode lead according to a preferred embodiment of the present invention.

Figure 4 shows a schematic illustration of the distal part of an electrode lead according to another preferred embodiment of the present invention.

Detailed description of preferred embodiments of the invention

15 With reference to figure 1 the present invention relates to an implantable electrode lead for tissue stimulation adapted to be attached to an implantable tissue stimulator provided with a pulse generator (not shown). The electrode lead comprises at least two stimulation electrodes to apply stimulation pulses to the tissue and arranged close to the distal end of the electrode lead, and at least two electrical conductors (not shown) to connect the
20 electrodes to the pulse generator.

In figure 2 the distal end of the electrode lead is schematically illustrated. The electrode lead comprises a switching unit arranged close to the distal end of the electrode lead and adapted to switch the electrode lead between a local pacing mode configuration and a
25 normal pacing mode configuration. The switching unit being controlled by a mode control signal. The electrode lead further comprises a pacing module arranged close to the distal end of the electrode lead and in relation to the switching unit and being connectable to the at least two stimulation electrodes. The pacing module includes a pulse generating unit to generate stimulating pulses to be applied to the tissue by the stimulation electrodes.

30 When the electrode lead is in the local pacing mode the electrical conductors are disconnected, by the switching unit, from the stimulation electrodes which instead are

connected to the pacing module, and when the electrode lead is in the normal pacing mode the electrical conductors are connected to the stimulation electrodes.

5 According to a preferred embodiment, which is illustrated by the schematic block diagram in figure 3, the electrode lead further comprises a control module arranged close to the distal end of the lead and in relation to the switching unit, the control module is adapted to generate the mode control signal.

10 According to an embodiment of the present invention the local pacing mode is applicable when certain predefined criteria are fulfilled and the mode control signal is generated in dependence thereto.

15 According to a preferred embodiment the mode control signal is generated by the implantable tissue stimulator and supplied to the switching unit via an electrical connection in the electrode lead. In this case the normal situation is probably that the tissue stimulator has received information via telemetry that the local pacing mode should be applied because an MRI scan is to be performed.

20 According to a preferred embodiment the electrode lead further comprises a magnetic resonance (MR) detector, which is schematically illustrated in figure 3, adapted to detect a magnetic resonance (MR) field of predetermined field strength, and in response of such detection to generate the mode control signal. The predetermined field strength is 0,1 Tesla or higher.

25 Preferably, the MR detector is a Hall element sensor. As an alternative the MR detector is a Giant Magnetic Resistance (GMR) sensor.

30 According to another preferred embodiment the electrode lead comprises a radio frequency (RF) sensor adapted to detect a radio frequency field of predetermined field strength, and in response of such detection generate the mode control signal.

According to still another predetermined embodiment the electrode lead comprises a temperature sensor adapted to detect an increased temperature in the distal end of the lead, and in response of such detection generate the mode control signal.

- 5 The electrode lead further comprises an energy unit, e.g. a battery or a capacitor, arranged close to the distal end of the lead and used to energize said switching unit and pacing module.

10 The required energy needed for the circuitry in the distal end of the electrode lead, the pacing module, the switching unit, and other optional circuitry may as an alternative be supplied via energy supplying conductors arranged in the electrode lead. These conductors are connected to the implantable tissue stimulator.

15 Preferably, when the electrode lead is in the local pacing mode the electrodes are also used to sense heart events.

The stimulating pulses generated by the pacing module, during the local pacing mode, may be varied with regard to stimulation rate and stimulation energy as will be further outlined in the following, and when discussing figure 4.

20

According to one preferred embodiment, when in the local pacing mode, the pacing module generates stimulating pulses at a fixed rate being the stimulation rate used in the normal pacing mode prior switching to the local pacing mode. As an alternative, the fixed rate is set to a specific value, e.g. 70 or 80 stimulations per minute.

25

As a further alternative, when in the local pacing mode, the pacing module generates stimulating pulses at a variable rate starting at the stimulation rate used in the normal pacing mode prior switching to the local pacing mode and then varied in dependence of sensed heart events.

30

During normal pacing mode (no MRI scan) the switching unit connect the respective electrical conductor to the connection to the stimulation electrodes which in figure 3 is achieved by setting the switching unit in the horizontal direction.

For safety reasons this connection is maintained if the available energy, e.g. the battery,
5 for the pacing module is too low.

Before or at the start of an MRI scan the pacemaker system goes into the local pacing mode, either automatically, e.g. a sensed RF-field detected by detector initiates mode change, or via programming from an external programming device. During MRI mode the
10 switching unit instead connect the pacing module to the respective stimulation electrodes. In figure 3 the mode control signal is generated by the control module. As an alternative the mode control signal is generated by the tissue stimulator, lead to the distal end of the electrode lead via a thin wire (not shown) and applied to the switching unit.

15 In the local pacing mode only a small part of the lead is connected to the stimulating electrodes resulting in an insignificant heating of the parts of the lead connected to the tissue/blood (tip and ring).

For a pacemaker dependent patient (very low or non-existent intrinsic heart rate) the
20 pacing module now takes over the pacing of the patient. This can for instance be done in the following way. The pacing module includes an oscillator that generates a clock signal to a charge pump in the pacing module where the programmed pace pulse amplitude is generated over an output capacitor. The pacing module then signals to the output stage to put out a pace pulse by connecting the output capacitor to the stimulating electrodes.

25 Preferably, the output capacitor has a capacitance in the range of μF . Today there are 4,7 μF capacitors available in 1,6 x 0,8 mm size (or even smaller) on the market.

If the patient has a sufficient intrinsic rate no pacing is needed and it is enough to disconnect the electrical conductors of the electrode lead from the tissue stimulator via the
30 switching unit.

Figure 4 illustrates a schematic block diagram of still another embodiment of the present invention.

In this embodiment four stimulation electrodes are included, being e.g. tip-electrodes, ring
5 electrodes, and/or coronary sinus electrodes.

The electrical conductors are connected to an implantable tissue stimulator (not shown) responsible for pulse generation during the normal pacing mode. In that mode the switching unit is switched such that the stimulation electrodes receive stimulation energy
10 from the tissue stimulator via the dotted line.

When the electrode lead is set to work in the local pacing mode the switching unit is switched such that the stimulation electrodes receive, via the dashed line, stimulation energy from the local energy unit B, being e.g. a battery, a capacitor having large
15 capacitance, or a "super-capacitor". The requirements of the local energy unit B is that it can generate the required energy during a minimum time period, e.g. related to the time it takes to perform an MRI procedure.

According to this embodiment a resistor R is arranged at one of the electrical conductors close to the tip circuitry. The resistor has a resistance of 2 – 20 kOhm to limit current
20 induced by RF. The voltage drop is then minimized for currents in the interval of 1 -20 μ A, while RF is effectively suppressed.

In this embodiment the switching unit has two purposes, the first is to ensure switching
25 between the normal and local pacing mode and the second is to control between which of electrodes the stimulation pulse is applied.

The bi-directional arrow between the switching unit and the control and pacing module indicates a system of communication channels for control signals to control the switching
30 unit, and to receive sensed heart signals.

In the following the mode control will be further discussed.

When the electrode lead is in the normal pacing mode the control unit of the heart stimulator passively stores information regarding stimulation rate, sensed heart activity etc.

5

According to a preferred embodiment the mode control is different dependent upon where the electrode lead is positioned. During implantation it is set, preferably in the control unit, the position of the electrode lead, e.g. if it is positioned in the atrium, ventricle or in the coronary sinus.

10

Preferably, if the electrode lead is positioned in the atrium no local pacing mode is available; instead the switching unit only disconnects the electrodes from the electrical conductors without connecting them to the pacing module.

15 If the electrode lead is positioned in the ventricle a number of different situations must be analyzed prior the local pacing mode is applied.

The analysis is based upon measured stimulation pulse interval lengths in an undisturbed environment. These are measured by a control unit of the heart stimulator.

20 In addition normal heart sensing is performed by the heart stimulator. The stimulation pulse interval lengths and marker pulses representing sensed heart events are communicated to the control module at the electrode lead tip.

In the following four essentially different situations are described resulting in different therapy modes.

25

1) Only stimulation pulses and no sensed heart events are detected. The stimulation interval length may have a preset interval length or may be varied in the dependence of a rate responsive function.

30 In the local pacing mode a preset stimulation rate is then used. The preset stimulation rate may be the last measured rate or a previous rate that may be slightly higher, but the normal

rate is preferred, e.g. 70 pulses/min. Preferably, the stimulation pulses are set to a slightly higher amplitude than during normal stimulation.

- 2) Intrinsic heart events occur frequently, with no stimulation pulses. If some stimulation pulses occur, there are never two consecutive pulses. In this case the local pacing mode is not activated.
- 3) Stimulation pulses and heart events occur together, having intervals never shorter than a measured minimum value. The measured minimum interval must not be physiologically inadequate, e.g. must not be shorter than the interval length that corresponds to 110/min, or a preset threshold value adapted to the patient. The local pacing module then stimulates in an overdrive mode, i.e. uses set stimulation rate with an interval length slightly shorter than the measured minimum value. As in the first case the stimulation pulses may have slightly higher amplitude than during normal stimulation.
- 4) Stimulation pulses and heart events occur together having measured intervals where the shortest intervals are too short, e.g. shorter than a preset proportion of the corresponding length interval of the maximum tracking rate (MTR). The control unit of the heart stimulator must then further analyse the situation and prepare communication information via telemetry to the external programmer that no safe stimulation mode exists. A decision regarding relevant therapy must then be taken of a physician having all information of the patient's status.
- The recommendation is then based upon some of, or all of the following items a-d:
- a) give a rate reducing heart drug, b) give an arrhythmia controlling drug, c) apply a relevant overdrive stimulation rate, d) a physician performs constant monitoring of the patient's ECG in relation to the functionality of the implanted heart stimulator.

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 appending claims.

Claims

1. Implantable electrode lead for tissue stimulation adapted to be attached to an implantable tissue stimulator provided with a pulse generator, the electrode lead comprises at least two stimulation electrodes to apply stimulation pulses to said tissue and arranged close to the distal end of the electrode lead, and at least two electrical conductors to connect said electrodes to said pulse generator,
5 characterized in that the electrode lead further comprises a switching unit arranged close to the distal end of the electrode lead and adapted to switch the electrode lead between a local pacing mode and a normal pacing mode, said switching unit being controlled by a mode control signal,
10 a pacing module arranged close to the distal end of the electrode lead and in relation to said switching unit and being connectable to said at least two stimulation electrodes, said pacing module includes a pulse generating unit to generate stimulating pulses to be applied to the tissue by said stimulation electrodes,
15 wherein, when the electrode lead is in the local pacing mode the electrical conductors are disconnected from said stimulation electrodes which instead are connected to the pacing module, and when the electrode lead is in the normal pacing mode the electrical conductors are connected to said stimulation electrodes.
- 20 2. Implantable electrode lead according to claim 1, wherein said electrode lead further comprises a control module arranged close to the distal end of the lead and in relation to said switching unit, the control module is adapted to generate said mode control signal.
- 25 3. Implantable electrode lead according to claim 1 or 2, wherein said local pacing mode is applicable when certain predefined criteria are fulfilled and the mode control signal is generated in dependence thereto.
- 30 4. Implantable electrode lead according to claim 1, wherein said mode control signal is generated by said implantable tissue stimulator and supplied to the switching unit via an electrical connection in said electrode lead.

5. Implantable electrode lead according to claim 1, wherein the electrode lead further comprises an magnetic resonance (MR) detector adapted to detect a magnetic resonance (MR) field of a predetermined field strength, and in response of such detection to generate said mode control signal.
- 5 6. Implantable electrode lead according to claim 5, wherein predetermined strength is 0,1 Tesla or higher.
7. Implantable electrode lead according to claim 5 or 6, wherein said MR
10 detector is a Hall element sensor.
8. Implantable electrode lead according to claim 5 or 6, wherein said MR detector is a Giant Magnetic Resistance (GMR) sensor.
- 15 9. Implantable electrode lead according to claim 1, wherein said electrode lead further comprises a radio frequency (RF) sensor adapted to detect a radio frequency field of predetermined field strength, and in response of such detection generate said mode control signal.
- 20 10. Implantable electrode lead according to claim 1, wherein said electrode lead further comprises a temperature sensor adapted to detect an increased temperature in the distal end of the lead, and in response of such detection generate said mode control signal.
11. Implantable electrode lead according to any preceding claim, wherein said
25 electrode lead further comprises an energy unit, e.g. a battery or a capacitor, arranged close to the distal end of the lead and used to energize said switching unit and pacing module.
12. Implantable electrode lead according to any of claims 1-10, wherein said
30 electrode lead further comprises energy supplying conductors arranged to supply energy from the implantable tissue stimulator to said control module and pacing module.

13. Implantable electrode lead according to claim 1, wherein when the electrode lead is in the local pacing mode said electrodes are also arranged to sense heart events.
14. Implantable electrode lead according to claim 1, wherein, in the local mode
5 said pacing module is arranged to generate stimulating pulses at a fixed rate being the stimulation rate used in the normal pacing mode prior switching to the local pacing mode.
15. Implantable electrode lead according to claim 13, wherein in the local mode
10 said pacing module is arranged to generate stimulating pulses at a variable rate starting at the stimulation rate used in the normal pacing mode prior to switching to the local pacing mode and then varied in dependence of sensed heart events.

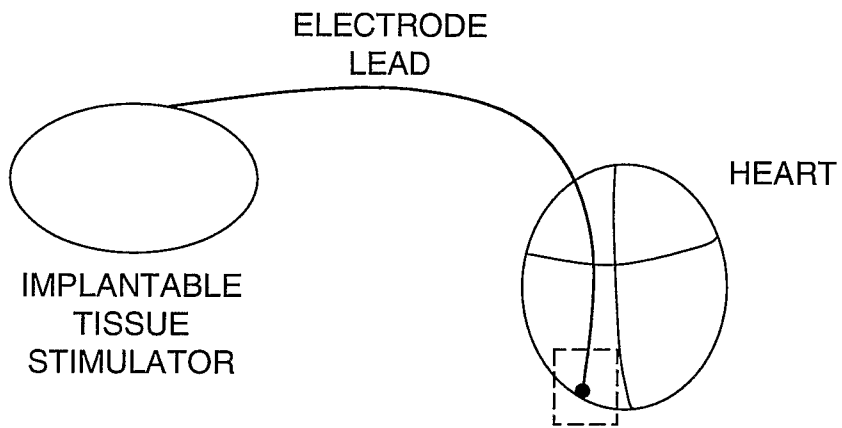


Fig. 1

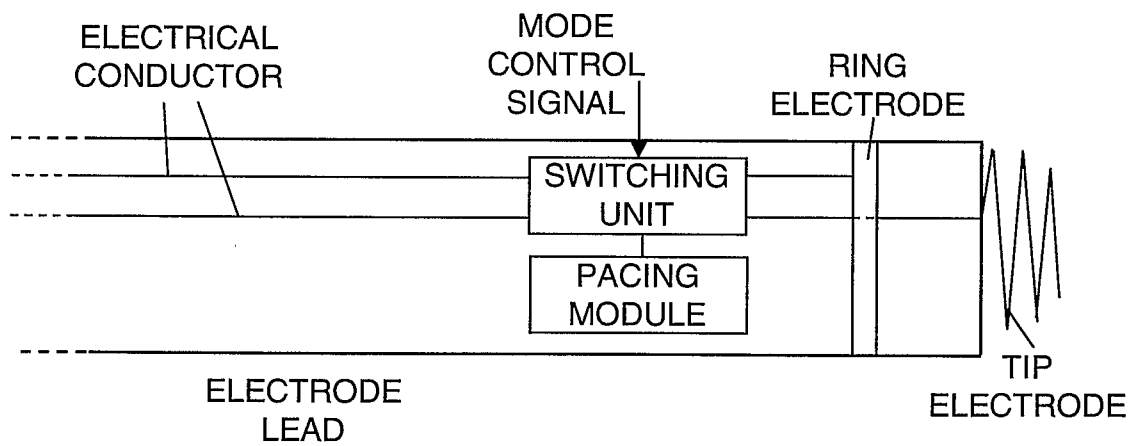


Fig. 2

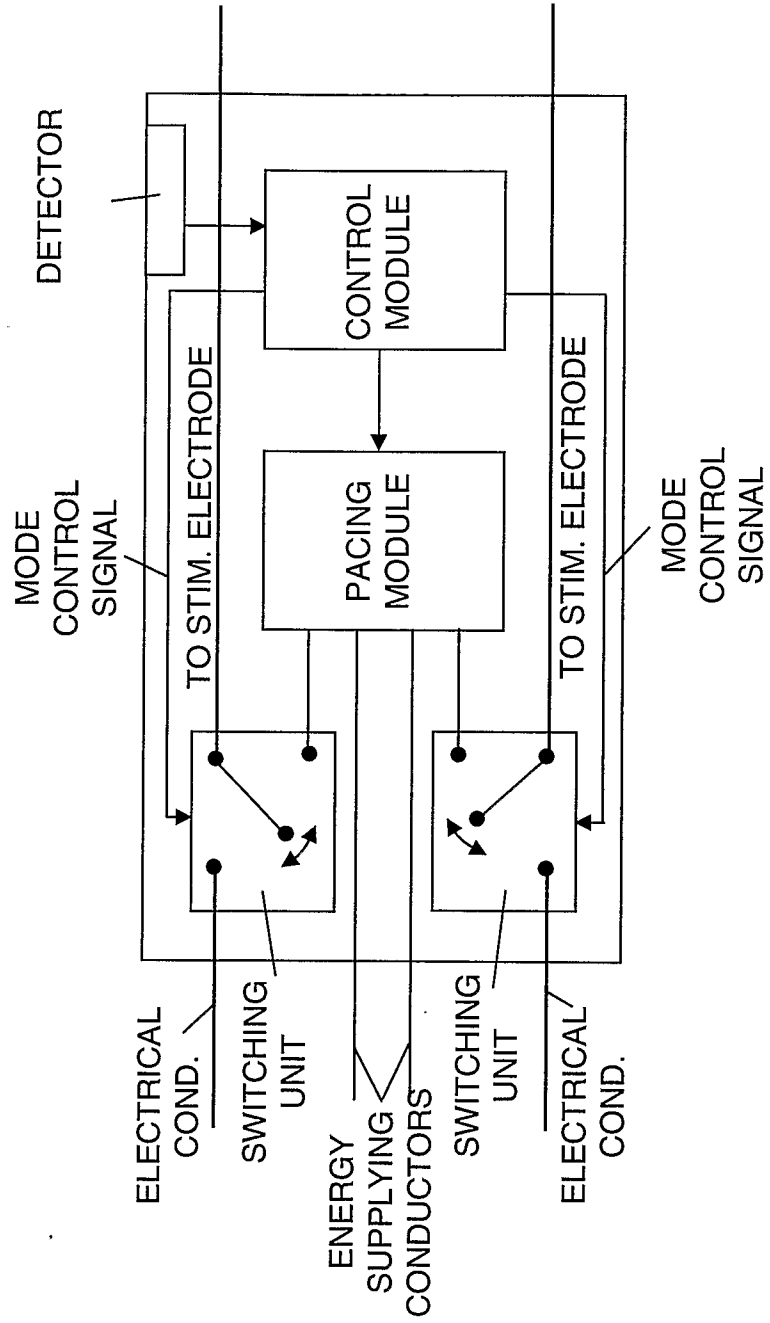


Fig. 3

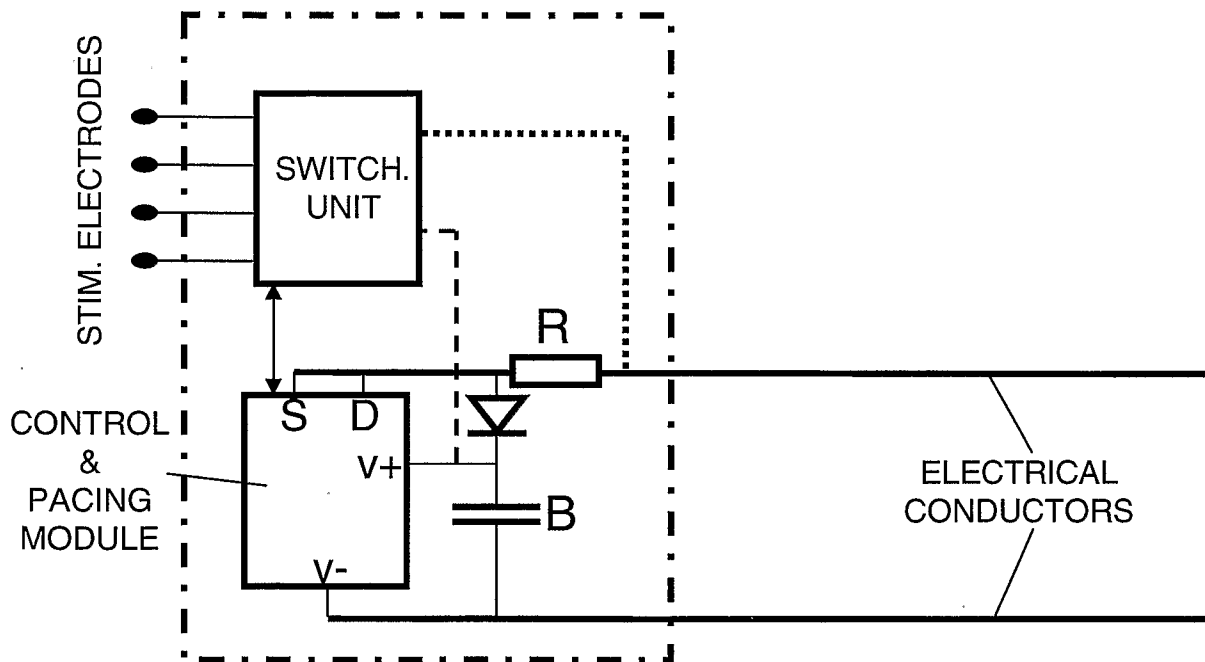


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2008/000728

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

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)

IPC: A61N, A61B, G01R

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

SE,DK,FI,NO classes as above

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

EPO-INTERNAL, WPI DATA, PAJ, BIOSIS, MEDLINE, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20080154342 A1 (DIGBY, DENNIS ET AL), 26 June 2008 (26.06.2008), claim 1, abstract, paragraphs [0008]-[0011], [0054]-[0056] --	1-15
A	WO 0180940 A1 (GREATBIO TECHNOLOGIES, INC.), 1 November 2001 (01.11.2001), page 4, line 19 - page 6, line 29, figure 1, claim 1, abstract --	1-15
A	US 20060142813 A1 (MASCHKE, MICHAEL), 29 June 2006 (29.06.2006), figures 3,4, paragraphs [0007]-[0010], [0024] --	1-15

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Date of the actual completion of the international search

10 July 2009

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International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20040088012 A1 (KROLL, MARK W. ET AL), 6 May 2004 (06.05.2004), claim 1, abstract, paragraphs [0011]-[0013] --	1-15
A	US 7369898 B1 (KROLL, MARK W. ET AL), 6 May 2008 (06.05.2008), claim 1, abstract --	1-15
A	US 20080154348 A1 (ATALAR, ERGIN ET AL), 26 June 2008 (26.06.2008), claim 1, abstract --	1-15
A	WO 03095022 A2 (MEDTRONIC, INC.), 20 November 2003 (20.11.2003), page 5, line 27 - page 8, line 13, claim 1 --	1-15
A	US 20060167496 A1 (NELSON, SHANNON D. ET AL), 27 July 2006 (27.07.2006), abstract --	1-15
A	US 20030088303 A1 (GOODE, PAUL V.), 8 May 2003 (08.05.2003), figure 9, claim 1, paragraph [0041] --	1-15
A	WO 9943381 A1 (PACESETTER AB), 2 Sept 1999 (02.09.1999), page 4, line 25 - page 6, line 6, figures 2,3, claim 1 --	1-15
A	US 5843135 A (WEIJAND, KOEN J. ET AL), 1 December 1998 (01.12.1998), claims 1, 5 --	1-15
E	US 20090149906 A1 (AMERI, MASOUD ET AL), 11 June 2009 (11.06.2009), claims 1, 7, 8, abstract, paragraphs [0005]-[0006] --	1-15

INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	US 20090149909 A1 (AMERI, MASOUD), 11 June 2009 (11.06.2009), figures 2, 8, claim 1, abstract, paragraph [0005] -----	1-15

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G01R 33/28 (2006.01)

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Cited literature, if any, will be enclosed in paper form.

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US	20080154342	A1	26/06/2008	NONE		
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