

(19) World Intellectual Property
Organization
International Bureau



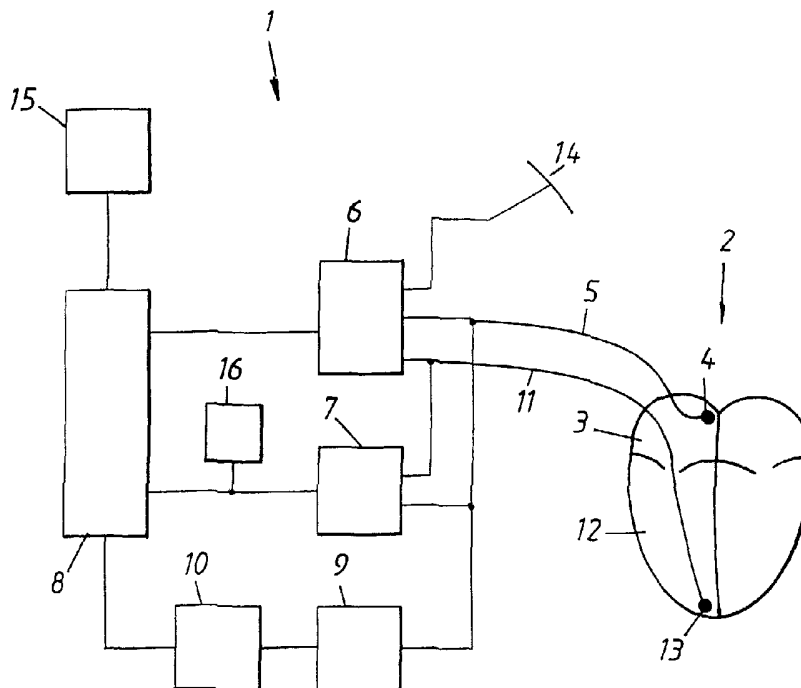
(43) International Publication Date
8 April 2004 (08.04.2004)

PCT

(10) International Publication Number
WO 2004/028629 A1

- (51) International Patent Classification⁷: **A61N 1/368**, 1/365, 1/37 // A61B 5/04
- (72) Inventor; and
(75) Inventor/Applicant (for US only): **HÖLJER, Carl-Johan** [SE/SE]; Mossavägen 10, S-247 32 Lund (SE).
- (21) International Application Number: PCT/SE2003/001289
- (74) Common Representative: **ST JUDE MEDICAL AB**; Patent Department, Veddestavägen 19, S-175 84 Järfälla (SE).
- (22) International Filing Date: 19 August 2003 (19.08.2003)
- (81) Designated State (national): US.
- (25) Filing Language: English
- (84) Designated States (regional): European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).
- (26) Publication Language: English
- (30) Priority Data: 0202882-7 30 September 2002 (30.09.2002) SE
- Published:
— with international search report
- (71) Applicant (for all designated States except US): **ST JUDE MEDICAL AB** [SE/SE]; Veddestavägen 19, S-175 84 Järfälla (SE).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HEART STIMULATOR DETECTING ATRIAL ARRHYTHMIA BY DETERMINING WALL DISTENSION BY IMPEDANCE MEASURING



(57) Abstract: An implantable dual chamber heart stimulator is comprising a mode switch for switching to a non P-wave synchronizing pacing mode when an atrial tachyarrhythmia is present. The pacing rate is adapted during atrial tachyarrhythmia to limit the atrial distension to a predetermined level. The atrial distension is measured during tachyarrhythmia through an impedance measurement that reflects the atrial volume.

Heart stimulator detecting atrial arrhythmia by determining wall distension by impedance measuring

Technical field of the invention

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

Background of the invention

10 Atrial fibrillation is a very common arrhythmia. During episodes of atrial fibrillation, the systolic function of the atria is lost. This results in distension of the atria which in turn makes it more difficult for the heart to return to sinus rhythm. Without regular systolic activity
15 the atria will only be passive mediators of volume to the ventricles. The degree of distension of the atria will reflect the venous return, i.e. preload.

WO 98/26839 discloses a pacemaker provided with a mode
20 switching feature adapted to stabilize ventricular heart rate during atrial fibrillation. In response to detection of atrial rhythm characteristics consistent with atrial fibrillation, the device swithes into a non-atrial synchronized, ventricular rate stabilization pacing mode.
25 The base ventricular pacing rate is modulated on a beat-by-beat basis based upon preceeding intrinsic or paced ventricular heart beat intervals to adjust the pacing interval towards a desired preset rate stabilization target pacing interval which is typically less than the programmed
30 base pacing interval of the device.

US 5,720,295 discloses a pacemaker comprising a mode switch for switching between a first mode wherein synchrony
between between the atrium and the ventricle is maintained
35 and a second mode wherein pacing is performed at a fixed rate or one determined by the metabolic indicator. This device further comprises means for monitoring the peak

amplitude of the atrial intrinsic signals. This information is used to generate short term and long term indicia indicative of the intrinsic signals' variability and deviation from normal sinus rhythm peak amplitudes. The two
5 indicia are combined to generate a single indicia which is then used to categorize the state of the atrium as one of several conditions such as flutter/flubber, coarse atrial fibrillation or fine atrial fibrillation. The categorization is used by a microcontroller for generating the proper
10 pacing pulses and may be also used as a criteria for mode switching.

In a dual chamber pacemaker it is common to include a mode switching feature that causes the pacemaker to switch to a
15 non P-wave synchronous mode if an atrial arrhythmia occurs. The pacing rate may be controlled by a an activity sensor or another more physiological sensor in the event of an atrial arrhythmia.

20 A problem with prior art mode switching pacemakers is that the atrial contribution is lost during atrial fibrillation and this will cause an increase of pressure of the venous return and thus increased atrial distension during atrial fibrillation. This will in turn make the return to normal
25 sinus rhythm more difficult. It may also increase the risk for future attacks of atrial fibrillation or other atrial tachyarrhythmia.

The object of the present invention is to achieve an
30 improved implantable heart stimulator adapted to limit the atrial distension, normally caused by atrial fibrillation because of increased atrial pressure, to a level which essentially eliminates atrial remodelling.

35 Short description of the inventive concept

The above mentioned object is achieved by an initially described implantable heart stimulator provided with the

characterizing features set forth in the characterizing portion of the independent claim.

Preferred embodiments are set forth in the dependent claims.

In a pacemaker according to the invention the atrial volume
5 is monitored through an impedance measurement in the right atrium when an atrial arrhythmia occurs. At the implantation or at a later point in time a reference value of the minimum atrial impedance during conditions when no atrial arrhythmia is present is measured. This minimum impedance corresponds
10 to the maximum atrial volume which also corresponds to atrial distension. The determined minimum impedance and its corresponding atrial distension is used by the pacemaker as a reference value (ZDIST) for the atrial distension. If the atrial volume increases during AF then the atrial distension
15 also increases. This is observed through the above mentioned impedance measurement. An increased atrial distension is detected as an atrial impedance having a lower value than the reference value ZDIST. If the atrial distension increases, the ventricular pacing rate is increased to allow
20 the atrial distension to decrease to an acceptable level. When the atrial distension measured as an atrial impedance has reached a level close to the reference value ZDIST then the ventricular pacing rate is decreased. In this fashion a closed loop rate responsive control of the ventricular
25 pacing rate during atrial arrhythmia is obtained. During conditions when no atrial arrhythmia is present the rate responsive control is obtained through synchronization to sensed P-waves or through an ordinary rate responsive sensor such as an activity sensor of the accelerometer type or any
30 type of physiological sensor such as a minute volume sensor. This has the advantage that the pacing rate will be adapted to the patient's needs regardless of if the patient has an atrial arrhythmia or not. Since, as mentioned above, the atrial contribution is lost during atrial fibrillation/
35 atrial arrhythmia the ventricular pacing rate may be increased above a rate responsive sensor indicated rate during atrial fibrillation or atrial arrhythmia in order to

avoid atrial distension which makes return to sinus rhythm more difficult.

Short description of the appended drawings

5

Figure 1 discloses a simplified block diagram of a dual chamber pacemaker according to the invention.

Figure 2 discloses a lead arrangement with a bipolar atrial electrode.

10 Figure 3 discloses a lead arrangement with a tripolar atrial electrode.

Detailed description of preferred embodiments of the invention

15 Figure 1 discloses a simplified block diagram of a dual chamber pacemaker according to the invention. The patients' heart 2 is connected via atrial electrode 4 and atrial lead body 5 to the pacemaker 1. The patient's heart 2 is also connected via ventricular electrode 13 and ventricular lead
20 body 11 to the pacemaker 1. The pacemaker 1 comprises the following functional blocks: pacing pulse generating means 6, cardiac signal detecting means 7, pacemaker controller 8, impedance measurement means 9, impedance analysis means 10, activity sensor 15 and pacemaker encapsulation 14. In normal
25 operation the pacemaker controller 8 orders pacing pulse generating means 6 to deliver an atrial pacing pulse via atrial lead 4,5 if no intrinsic P-wave has occurred before the end of the atrial escape interval. The paced or sensed atrial event starts a paced or sensed AV-delay in the
30 pacemaker controller 8. The sensed AV-delay is typically slightly shorter than the paced AV-delay in order to obtain the same delay between the atrial mechanical contraction and the ventricular mechanical contraction irrespective of if it is triggered by a paced or sensed atrial event. If no
35 intrinsic ventricular sensed event occurs before the end of the AV-delay then a ventricular pacing pulse is delivered by pacing pulse generating means 6 to the ventricle 12 via

ventricular lead comprising ventricular lead body 11 and ventricular electrode 13. The rate at which the pacemaker controller 8 is operating the pacemaker is modulated by the sensor 15 if the rate responsive function is enabled. If the heart's intrinsic rate is lower than the sensormodulated rate then the patient will be paced. If the heart's intrinsic rate is higher than the sensormodulated rate then the pacemaker will be inhibited and no pacing occurs. If an atrial arrhythmia/atrial fibrillation occurs then the arrhythmia will be detected by arrhythmia detecting means 16. In response to the atrial arrhythmia the controller initiates a pacing mode change to a non P-wave synchronous pacing mode and further activates impedance measurement means 9 and impedance analysis means 10. The impedance measurement current is injected to the heart via atrial lead 5,4 with the pacemaker encapsulation 14 used as return electrode. If the voltage measured between atrial electrode 4 and pacemaker encapsulation 14 has been lowered this indicates that the atrial impedance has been lowered. If the atrial impedance has been lowered this indicates that the atrial volume has increased and that the atrial distension has increased. In response to the increased atrial distension the controller will increase the pacing rate until the atrial distension reaches a lower value similar to that preceeding the atrial arrhythmia. During the atrial arrhythmia/fibrillation the pacing rate is controlled in a closed loop system with the atrial distension measured as atrial impedance as feedback parameter. This makes it possible to limit the atrial distension which will minimize negative effects such as atrial tissue remodelling and it will further increase the probability of spontaneous reversion to normal sinus rhythm.

Figure 2 discloses an alternative current path which uses a bipolar atrial lead comprising electrode 4, atrial lead body 5 and ring electrode 17. The impedance measurement means 9 injects an impedance measurement current via said atrial

lead to the atrium 3. The pacemaker encapsulation 14 is used as return electrode. The voltage used as impedance measurement is measured between an atrial ring electrode 17 and pacemaker encapsulation 14.

5 Figure 3 discloses a further improved current path which is specifically advantageous in that it provides improved sensitivity to volume changes of the right atrium 3. The impedance measurement means 9 injects an impedance measurement current via an atrial lead comprising an atrial
10 electrode 4, an atrial lead body 5, a first atrial ring electrode 17, a second atrial ring electrode 18. The measurement current is injected to the atrium by electrode 4 and the pacemaker encapsulation 14 is used as return elctrode. The voltage between ring electrodes 17 and 18 is
15 measured and this voltage represents a measure of the atrial impedance which reflects the atrial volume. A higher volume is indicated by a lowered impedance which in turn indicates increased atrial distension.

20 The atrial impedance can be monitored in many alternative ways. One possibility is to use the pacing pulses for impedance measurement in the atrium 3. This is particularly suitable when the patient suffers from atrial fibrillation since pacing pulses will not capture the atrium 3 under
25 those circumstances.

The invention can also be used for monitoring the degree of atrial distension over an extended period of time to be able to follow the disease development and to enable the physisician to adapt therapy accordingly. In that case the
30 end diastolic atrial impedance would be measured several times per day. The result may be presented as average values of atrial impedance or atrial distension. The averaging period may range from 3 hours up to approximately 200 hours. This monitoring method can also be used when the heart is in
35 atrial fibrillation in which case the average atrial impedance is monitored.

Claims

1. An implantable pacemaker (1) comprising a pacemaker controller (8) for controlling at least operating mode and pacing rate of said pacemaker, pulse generating means (6) for pacing at least a patient's ventricle, a cardiac signal detecting means (7) for detecting signals originating from at least a patient's atrium (3), an impedance measuring means (9) for measuring an atrial impedance, an arrhythmia detecting means 16, a mode switch algorithm within said controller (8) for switching the pacing mode to a non P-wave synchronous mode if an atrial arrhythmia is detected by arrhythmia detecting means 16 characterized in that atrial distension is measured through said atrial impedance measurement; and that the ventricular pacing rate is increased so as to decrease said atrial distension when an atrial arrhythmia is present.
2. An implantable pacemaker (1) according to claim 1 characterized in that said atrial impedance measurement is made using said impedance measurement means (9) and that said pulse generating means (6) form a part of said impedance measurement means.
3. An implantable pacemaker (1) according to claim 1 characterized in that a bipolar atrial lead comprising an atrial electrode (4), an atrial lead body (5) and a ring electrode (17) is utilized; and the atrial impedance measurement current is injected at the atrial electrode (4) with the pacemaker encapsulation (14) as return node; and that the voltage reflecting the atrial impedance is measured between the atrial electrode (4) and the pacemaker encapsulation (14).
4. An implantable pacemaker according to claim 1

characterized in that a tripolar atrial lead comprising an electrode (4), an atrial lead body (5), a first ring electrode (17), a second ring electrode (18) is utilized; and

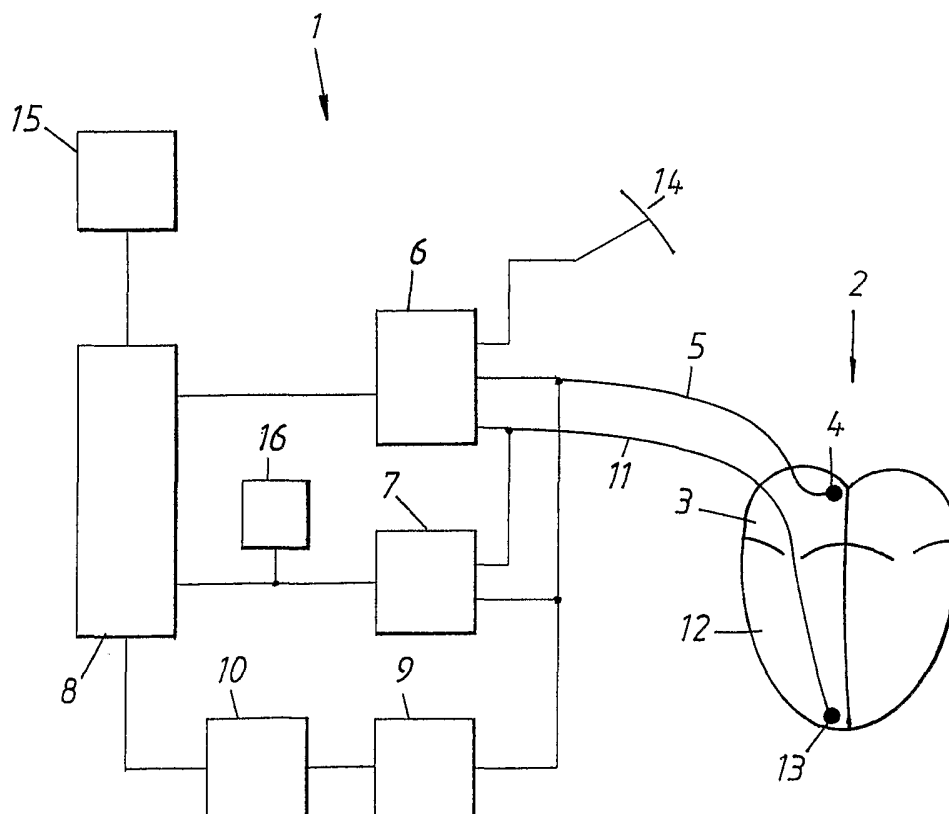
5 the atrial impedance measurement current is injected at the atrial electrode (4) with the pacemaker encapsulation (14) as return node; and the voltage reflecting the atrial impedance is measured between two ring electrodes (17,18) located in the right
10 atrium (3).

5. An implantable pacemaker according to claim 1 characterized in that said ventricular pacing rate
15 during an atrial arrhythmia is controlled in a closed loop fashion by varying said ventricular pacing rate to keep said atrial impedance close to a reference value ZDIST.

20 6. An implantable pacemaker according to claim 1 characterized in that the pacemaker repetitively stores measured values of atrial distension; and that measured values can be displayed as average values
25 over a predetermined period.

1 / 2

Fig. 1



2/2

Fig. 2

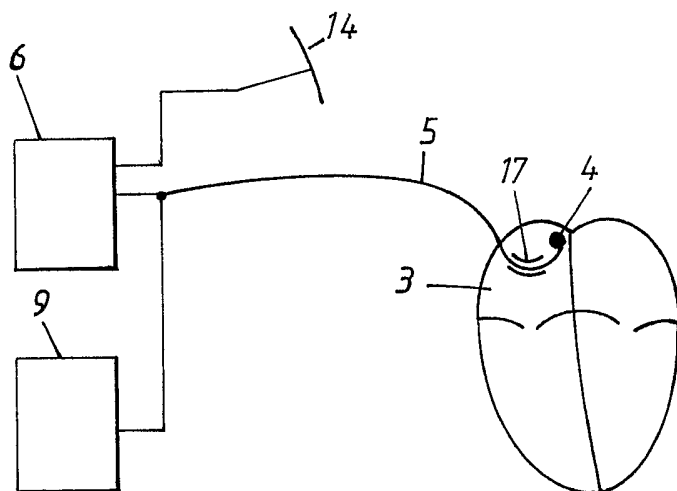
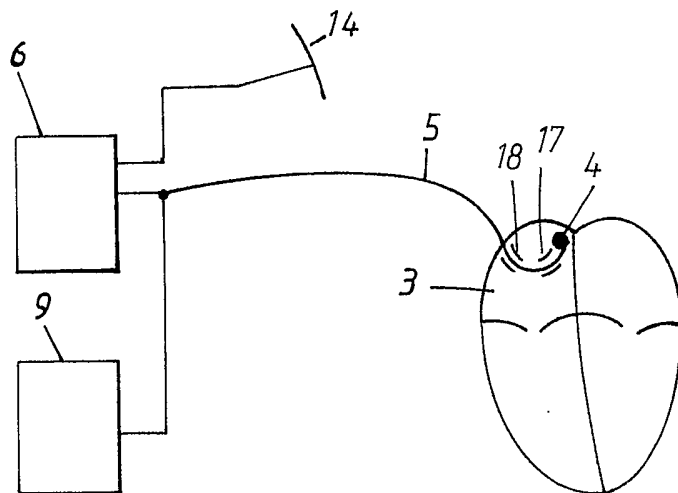


Fig. 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/01289

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/368, A61N 1/365, A61N 1/37 // A61B 5/04
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)

IPC7: A61N, A61B

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, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0904802 A2 (PACESETTER INC.), 31 March 1999 (31.03.99), figure 6, abstract --	1-6
A	EP 0473070 A2 (FEREK-PETRIC, BOZIDAR), 4 March 1992 (04.03.92), figure 1, abstract --	1-6
D,A	US 5720295 A (SAUL E. GREENHUTET AL), 24 February 1998 (24.02.98), figure 4, abstract --	1-6
D,A	WO 9826839 A1 (MEDTRONIC, INC.), 25 June 1998 (25.06.98), figure 1, abstract --	1-6

☐ 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

24 November 2003

Date of mailing of the international search report

27 -11- 2003

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Patrik Blidefalk /OGU
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

06/09/03

International application No.

PCT/SE 03/01289

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
EP	0904802	A2	31/03/99	US	5951593 A	14/09/99
EP	0473070	A2	04/03/92	DE	69114948 D	00/00/00
				US	5261418 A	16/11/93
				US	5271392 A	21/12/93
US	5720295	A	24/02/98	EP	0836866 A	22/04/98
WO	9826839	A1	25/06/98	AU	5530098 A	15/07/98
				DE	69720058 D	00/00/00
				EP	0957984 A,B	24/11/99
				US	5893882 A	13/04/99