

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
2 October 2008 (02.10.2008)

PCT

(10) International Publication Number
WO 2008/118045 A1

(51) International Patent Classification:

A61N 1/372 (2006.01)

(21) International Application Number:

PCT/SE2007/000296

(22) International Filing Date: 27 March 2007 (27.03.2007)

(25) Filing Language: English

(26) Publication Language: English

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: METHOD AND SYSTEM FOR INITIATING COMMUNICATION BETWEEN A HOME MONITORING DEVICE AND AN IMPLANTABLE MEDICAL DEVICE

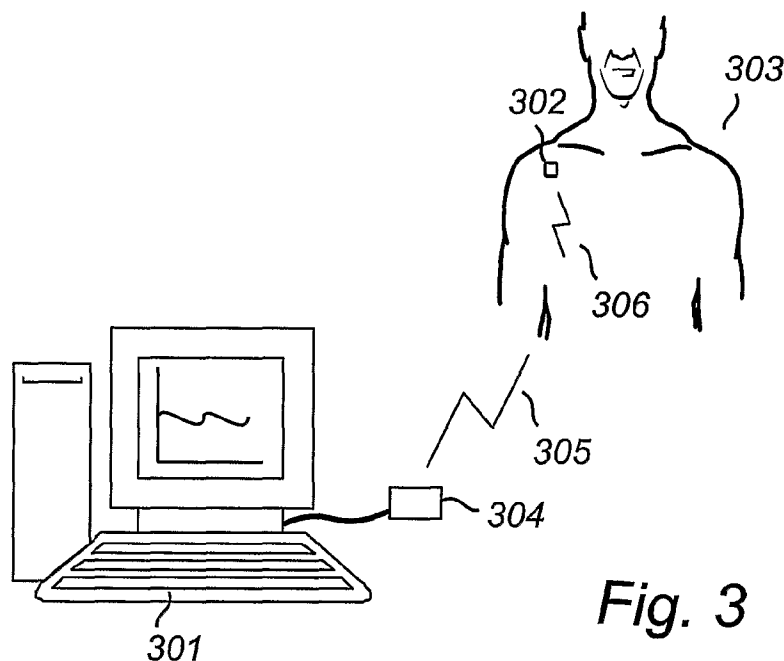


Fig. 3

(57) Abstract: The present invention relates to a method and system for establishing a wireless communication session between an implantable medical device IMD (302) and a home monitoring device (301). A basic idea of the invention is to have a home monitoring device frequently send communication-initiating signals to an IMD arranged within the body of a patient for establishing a communication session between the monitoring device and the IMD. In order to save energy, RF telemetry circuitry of the IMD is normally set in a low-power, idle mode. Occasionally, the RF circuitry will leave the low-power mode and enter an active mode in which it is able to detect a communication-initiating signal transmitted by the monitoring device. When a communication-initiating signal is detected, the IMD will respond accordingly to the monitoring

device and a communication session will be established. In the present invention, the telemetry circuitry of the IMD will be controlled to wake up from low-power mode and enter an active detection mode independently of the transmission of the communication-initiating signals from the monitoring device. Hence, the external monitoring device will frequently transmit communication-initiating signals, but the IMD will only detect a wake-up signal when leaving its low-power mode and entering active mode at a predetermined instant of time.



Published:

— *with international search report*

METHOD AND SYSTEM FOR INITIATING COMMUNICATION BETWEEN A
HOME MONITORING DEVICE AND AN IMPLANTABLE MEDICAL DEVICE

Technical field of the Invention

The present invention relates to a method and system for establishing a wireless communication session between
5 an implantable medical device and a home monitoring device.

Background Art

When communicating with an implantable medical
10 device (IMD) implanted in tissue of a human or animal body, a radio frequency (RF) transceiver is used for wireless communication of signals to/from RF communication circuitry comprised in the IMD. An IMD may be embodied in the form of an implantable cardioverter
15 defibrillator (ICD), a neural simulator, an implantable drug pump, an implantable cardiac monitor or health monitor, a pacemaker, etc. Communication may be established with the IMD for a number of reasons. For instance, medical personnel may want to monitor and/or
20 adjust parameters of the IMD, it may be desirable to perform medical or therapeutic treatment of the body via the IMD, e.g. defibrillation, restart of a stopped heart, injection of an insulin dose, etc. Needless to say, RF signaling enables establishment of a communication
25 channel without having to open up the patient surgically. In a home environment, the patient may have a monitoring device employed to establish RF communication with transceiver circuitry within an IMD. From a user's point of view, a home monitoring device may be viewed upon as a
30 computer arranged with an RF transceiver, a user interface for controlling the monitoring device and dedicated software designed for the purpose of communicating with an IMD. When establishing

communication with an IMD, the monitoring device broadcasts a wake-up signal to which the IMD responds before a communication session may be undertaken between the monitoring device and the IMD, i.e. before payload data is exchanged between the monitoring device and the IMD.

When an IMD detects a wake-up signal, initiates communication and engages in a communication session with the monitoring device, a significant amount of energy is consumed at the IMD, since its RF transceiver (and associated RF electronics) exits low-power mode and enters an active communication mode.

US 7,110,823 generally discloses establishment of communication between an implant device and an external device via an RF link. In order to conserve power, the RF telemetry system of the implant is only activated periodically with the period of activation being sufficiently short to allow a reasonably prompt response to a request for a communication session submitted by the external device. In particular, US 7,110,823 discloses that the external device sends an RF signal to the implant device to alert it that a communication cycle is desired. The implanted device periodically activates, e.g. once every 1-5 seconds, its RF telemetry receiver for a short period, e.g. during 10-200 milliseconds. If the external device transmits a communication session request during the period in which the receiver is active, the implant device detects the request and a session can be undertaken. The RF telemetry receiver of the implanted device is thus constantly going through a "sleep-listen" cycle when no communication request is detected.

A problem with US 7,110,823 is that the implant device still consumes quite an amount of power, constantly going through its sleep-listen cycles.

Summary of the Invention

An object of the present invention is thus to solve or at least mitigate the above mentioned problems in prior art and to provide a manner of establishing a communication session between a home monitoring device and an IMD in an efficient manner in terms of power consumption at the IMD.

This object is attained by a method of establishing a wireless communication session between an implantable medical device and a home monitoring device in accordance with claim 1 and a system comprising an implantable medical device and a home monitoring device, said system being arranged such that a communication session can be established between the implantable medical device and the home monitoring device in accordance with claim 12.

Preferred embodiments of the invention are defined in the dependent claims.

A basic idea of the invention is to have a home monitoring device frequently send communication-initiating signals to an IMD arranged within the body of a patient for establishing a communication session between the monitoring device and the IMD. In order to save energy, RF telemetry circuitry of the IMD is normally set in a low-power, idle mode. Occasionally, the RF circuitry will leave the low-power mode and enter an active mode in which it is able to detect a communication-initiating signal transmitted by the monitoring device. When a communication-initiating signal is detected, the IMD will respond accordingly to the monitoring device and a communication session will be established. In the present invention, the telemetry circuitry of the IMD will be controlled to wake up from low-power mode and enter an active detection mode independently of the transmission of the communication-initiating signals from the monitoring device. Hence, the external monitoring device will frequently transmit communication-initiating signals, but the IMD will only

detect a wake-up signal when leaving its low-power mode and entering active mode at a predetermined instant of time.

The present invention is advantageous since the RF circuitry for the most part is set in the low-power mode, in which mode it consumes a negligible amount of power. It should be noted that power consumption is a critical factor in IMD applications. In a practical implementation, the monitoring device may constantly transmit communication-initiating signals, e.g. once every second, while the IMD may enter RF mode once every day and scan the RF channel for communication-initiating signals. Thus, the rate at which the IMD is activated is much lower than the rate at which communication-initiating telemetry signals are transmitted from the home monitoring device. Subsequently, when the IMD has detected a communication-initiating signal, the channel can be established and the monitoring device can read out any data of interest from the IMD. The amount of energy the IMD consumes due to being engaged in a communication session with the monitoring device is thus very small. The energy consumption of the home monitoring device is not a critical operating factor, since the home monitoring device is connected to a mains supply or powered by easily replacable or rechargeable batteries.

In contrast to prior art systems previously discussed, where establishment of communication between an implant device and an external device is effected by means of having the RF telemetry receiver of the implanted device constantly going through sleep-listen cycles, the present invention provides a system in which the monitoring device frequently transmits communication-initiating signals which the IMD occasionally can detect and respond to without constantly having to go through sleep-listen cycles.

The present invention is advantageously implemented in a home environment. In the home environment, it is

feasible to transmit communication-initiating signals at a relatively high frequency since it is likely that only a single IMD (or a small number of IMDs) exists that can respond to the numerous communication-initiating signals.

5 Regular monitoring of a patient in an automatic manner may advantageously take place at night, when the patient is asleep and unaware of the actual monitoring. Hence, there is no need for the patient herself to be active for a communication session to be initiated.

10 In general, the home monitoring device will read out the data from the IMD and terminate the communication session upon completion. When the session is terminated, the IMD will revert to its low-power mode. Possibly, the IMD will confirm to the monitoring device that it has
15 detected a communication-initiating signal before the monitoring device proceeds with the establishment of the communication session.

In an embodiment of the present invention, the transmission of communication-initiating telemetry
20 signals are controlled in such a manner that it is performed in a time interval that overlaps the instant of time at which the implanted medical device is activated from its low-power mode for detection. As a result, the monitoring device will, during a predetermined time
25 interval, frequently transmit wake-up signals which can be detected by the IMD. This embodiment enables a situation where a plurality of home monitoring units can be located in a medical service facility such as a nursing home. The different home monitoring units on the
30 premises of the nursing home can thus be synchronized to efficiently utilize the time and radio spectrum. For instance, a first monitoring unit can be programmed to transmit communication-initiating signals around the time instant when its associated IMD is controlled to wake up
35 from its low-power mode for signal detection, for instance between 10:00 and 10:05 am; a second monitoring

unit transmits communication-initiating to its associated IMD between 10:05 and 10:10 am, etc.

Advantageously, the patient in which the IMD is implanted is able to initiate communication by waking the
5 IMD up from low-power mode. For instance, the patient may wake up the IMD by means of a magnet or via communication methods such as inductive telemetry or by using another RF frequency than the one typically utilized when initiating a communication session with the home
10 monitoring device. In practice, the home monitoring device and the IMD may use a 402-405 MHz medical implant communication service (MICS) band for the communication-initiating signal and the subsequent communication session, while a 2.45 GHz industrial, scientific, and
15 medical (ISM) band may be used by the patient to wake up the telemetry circuitry of the IMD up from its low-power mode.

Consequently, the patient does not have to rely on preprogrammed communication-initiating time instants in
20 the IMD for transferring data to the monitoring device. Further, the IMD may be waken up from idle mode due to a specific condition of the patient in which the IMD is implanted, for instance, if the heart rate of the patient falls under, or exceeds, a predetermined level.

25 In another embodiment of the present invention, the selected instant of time at which the implantable medical device is activated is programmed into the implantable medical device. Further, the rate at which this selected instant of time occurs can be programmed into the
30 implantable medical device. This rate may be programmed to occur randomly.

In a further embodiment of the present invention, if the IMD is activated and a communication-initiating signal is not detected, the implantable medical device is
35 activated again after a predetermined instant of time to check for communication-initiating signal. This will overcome problems which may arise if the IMD cannot be

contacted due to temporarily unfavorable conditions of the radio channel. Since the home monitoring device frequently transmits communication-initiating signals, the IMD can assume that it will detected a signal once it wakes up from idle mode.

Further features of, and advantages with, the present invention will become apparent when studying the appended claims and the following description. Those skilled in the art realize that different features of the present invention can be combined to create embodiments other than those explicitly described in the following.

Brief Description of the Drawings

A detailed description of preferred embodiments of the present invention will be given in the following with reference made to the accompanying drawings, in which:

Fig. 1 is a schematic view of a patient's body showing a pacemaker implanted in the body;

Fig. 2 illustrates functional blocks of an IMD in the form of a pacemaker, to which the present invention may be applied; and

Fig. 3 shows an IMD telemetry device in accordance with an embodiment of the invention.

Detailed Description of Embodiments of the Invention

Fig. 1 illustrates an implantable medical device (IMD) in the form of a pacemaker 3 implanted in a patient's body. A lead 2 connects the pacemaker 3 to the heart 1, thereby allowing stimulation of the heart 1 and control of the heart rhythm. In order to transmit and receive RF signals, the pacemaker 3 comprises a transceiver and an antenna (not shown in Fig. 1).

Fig. 2 illustrates functional blocks of a pacemaker (in this particular case a bi-ventricular pacemaker) in more detail. The pacemaker 20 comprises a housing (not shown) being hermetically sealed and biologically inert. Typically, the housing is conductive and may thus serve

as an electrode. The pacemaker 20 is connectable to one or more pacemaker leads, where only two are shown in Fig. 2; namely a ventricular lead 21' implanted in the right ventricle of the heart and an atrial lead 21'' implanted in the right atrium of the heart. The leads 21', 21'' comprise one or more electrodes, such as a tip electrode or a ring electrode, arranged to, inter alia, measure impedance or transmit pacing pulses for causing depolarization of cardiac tissue adjacent to the electrodes generated by a pace pulse generator 22 under influence of a controller or controlling circuit 23 including a microprocessor for e.g. signal processing. The controller 23 controls, inter alia, pace pulse parameters such as output voltage and pulse duration.

Further, storage means 25 is connected to the controller 23, which storage means 25 may include a random access memory (RAM) and/or a non-volatile memory such as a read-only memory (ROM). Detected signals from the patient's heart are processed in an input circuit 24 and are forwarded to the controller 23 for use in logic timing determination in known manner. The pacemaker 20 is powered by a battery 26, which supplies electrical power to all active electrical components of the pacemaker. The pacemaker 20 also comprises an RF transceiver 27 for wireless communication of signals to/from a home monitoring device. Medical personnel or the patient herself may e.g. want to monitor and/or adjust parameters of the pacemaker 20 or to perform reprogramming. The transceiver is connected to an antenna 28 via which the wireless communication occurs. The pacemaker 20 is typically arranged such that it can register an IEGM and provide it to the monitoring device via the RF transceiver 27.

A telemetry system in accordance with an embodiment of the invention is shown in Fig. 3. A home monitoring device 301 is employed to communicate with transceiver circuitry in an IMD 302 implanted into a patient 303 as

is described in more detail in Fig. 2. In principle, a home monitoring device is a computer arranged with an RF transceiver 304 connected to the computer via an appropriate connection such as USB, a user interface for controlling the home monitoring device and dedicated software designed for the purpose of communicating with an IMD. Even though not shown in Fig. 3, the RF transceiver 304 may be arranged to conduct wireless transmissions with the monitoring device 301. When establishing communication with an IMD, the home monitoring device broadcasts a communication-initiating signal 305 before a communication session can be undertaken with the concerned IMD. The home monitoring device frequently transmits communication-initiating signals such that the IMD can detect them when waking up from low-power mode.

If the telemetry circuitry of the IMD 302 is activated from its low-power, idle mode, it will detect the communication-initiating signal 305 and reply to the communication-initiating signal by means of transmitting a response signal 306. Then, a communication session can be established between the monitoring device and the IMD. Possibly, the monitoring device terminates the communication session when a requested data set has been received at the monitoring device from the IMD. When the communication session is completed, the IMD reverts to the low-power mode.

However, if the telemetry circuitry of the IMD remains in its low-power mode, no detection of communication-initiating signals will take place, and the monitoring device will proceed with its continuous transmission of signals. Possibly, should the IMD wake up from its low-power mode without detecting a communication-initiating signal, it can be programmed to make further attempts to detect such a signal within a predetermined period of time. This alleviates the situation where the radio channel is inferior and a

signal temporarily cannot be detected. A number of parameters may be programmed into the IMD, such as the selected instant of time at which the implantable medical device is activated and the rate at which this selected
5 instant of time occurs. However, in an embodiment of the invention, the transmission of communication-initiating signals are controlled at the monitoring device in such a manner that it is performed in a time interval that overlaps the instant of time at which the implanted
10 medical device is activated from its low-power mode for detection. As a result, the monitoring device will, during a predetermined time interval, frequently transmit wake-up signals which can be detected by the IMD. In such an embodiment, is it not necessary to implement a "fall
15 back" mechanism of making further attempts to detect a communication-initiating signal, as described in the above.

The home monitoring device (and thus an eventual operator of the monitoring device) may be located
20 remotely from the patient 306, for example in another room. It is also possible that signals to be processed by the monitoring device are transmitted to it via a network such as the Internet. As can be seen, the present invention is particularly advantageous in a home
25 environment where it is unlikely that a plurality of monitoring devices are utilizing the same RF band simultaneously. It should be noted that the patient 303 may have a plurality of IMDs implanted with which the monitoring device 301 is able to communicate. A number of
30 situations are possible, for instance

- a) *broadcasting*, where any IMD may initiate communication;
- b) *pointcasting*, where only one IMD may initiate communication;
- 35 c) *multicasting*, where any number of predefined IMDs may initiate communication.

The home monitoring device and its RF transceiver shown throughout the drawings typically employs the 402-405 MHz MICS band for bidirectional communication with the IMD. The MICS standard allows 10 channels, each 300 kHz, to be used in the 402-405 MHz band. Maximum output power is restrained to 25 μ W. If the MICS band exclusively is used for communication between the home monitoring device and the IMD, the IMD need not be equipped with 2.45 GHz telemetry circuitry. However, as previously mentioned, the 2.45 GHz band may advantageously be employed by a patient to wake up the IMD from idle mode. In the 2.45 GHz ISM band, it is easy to design a low power receiver that can be used to wake up the device for a MICS communication session. However it is observed that the attenuation of 2.45 GHz signals in body tissue is significant and thus 2.45 GHz wake-up must be done with a short distance between patient and home monitoring device. The MICS band support wireless communication having ranges of 2 meters or more.

Even though the invention has been described with reference to specific exemplifying embodiments thereof, many different alterations, modifications and the like will become apparent for those skilled in the art. The described embodiments are therefore not intended to limit the scope of the invention, as defined by the appended claims.

CLAIMS

1. A method of establishing a wireless communication session between an implantable medical device and a home monitoring device, the method comprising the steps of:
- 5 frequently transmitting communication-initiating telemetry signals from said home monitoring device;
- activating telemetry circuitry of the implantable medical device from a low-power mode independently of the transmission of the communication-initiating telemetry signals, wherein a rate at which said telemetry circuitry is activated is lower than a rate at which communication-initiating telemetry signals are transmitted;
- 10 detecting at least one of the communication-initiating telemetry signals at the implantable medical device; and
- establishing a communication session between the implantable medical device and the monitoring device.
- 20 2. The method according to claim 1, wherein the step of detecting a communication-initiating telemetry signal further comprises the step of:
- sending, from the implantable medical device to the monitoring device, a confirmation signal that the communication-initiating telemetry signal was detected.
- 25 3. The method according to any one of claims 1 or 2, further comprising the steps of:
- terminating, at said monitoring device, the communication session when a requested data set has been received at the monitoring device from the implantable medical device; and
- 30 setting the telemetry circuitry of the implantable medical device in the low-power mode when the communication session is terminated.
- 35

4. The method according to any one of claims 1-3,
wherein the frequent transmission of communication-
initiating telemetry signals from said monitoring device
are controlled to occur in a time interval that overlaps
5 an instant of time at which the telemetry circuitry of
the implanted medical device is activated from its low-
power mode for detection.

5. The method according to any one of the preceding
10 claims, wherein a patient in which the medical device is
implanted herself can select an instant of time at which
the telemetry circuitry of the implantable medical device
is activated for detection.

15 6. The method according to any one of the preceding
claims, wherein the selected instant of time at which the
telemetry circuitry of the implantable medical device is
activated is programmed into the implantable medical
device.

20

7. The method according to any one of the preceding
claims, wherein the rate at which the selected instant of
time occurs is programmed into the implantable medical
device.

25

8. The method according to claim 7, wherein a random
rate for selecting the instant of time is programmed into
the implantable medical device.

30 9. The method according to any one of the preceding
claims, wherein, if the telemetry circuitry of the
implantable medical device is activated and a
communication-initiating telemetry signal is not
detected, said telemetry circuitry is activated again
35 after a predetermined instant of time.

10. The method according to any one of the preceding claims, wherein the transmission of communication-initiating telemetry signals and the subsequent communication session is undertaken in the medical
5 implant communication service (MICS) band.

11. The method according to claim 5, wherein the activation of the telemetry circuitry by the patient is undertaken in the industrial, scientific, and medical
10 (ISM) band.

12. A system comprising an implantable medical device (302) and a home monitoring device (301), said system being arranged such that a communication session
15 can be established between the implantable medical device and the home monitoring device, wherein

the home monitoring device is arranged with at transceiver (304) for frequently transmitting communication-initiating telemetry signals to the
20 implantable medical device;

the implantable medical device is arranged with telemetry circuitry (27) which is configured to be activated from a low-power mode independently of the transmission of the communication-initiating telemetry
25 signals, wherein a rate at which said telemetry circuitry is activated is lower than a rate at which communication-initiating telemetry signals are transmitted, said telemetry circuitry further being configured to detect at least one of the communication-initiating telemetry
30 signals, wherein a communication session can be established between the implantable medical device and the monitoring device.

13. The system according to claim 12, wherein the
35 implantable medical device (302) further is arranged to send a confirmation signal that the communication-initiating telemetry signal has been detected.

14. The system according to any one of claims 12 or 13, wherein

5 the home monitoring device (301) further is arranged to terminate the communication session when a requested data set has been received from the implantable medical device; and

10 the implantable medical device (302) further is arranged with a controller (24) for setting the telemetry circuitry (27) in the low-power mode when the communication session is terminated.

15 15. The system according to any one of claims 12-14, wherein said home monitoring device (301) is arranged to control the frequent transmission of communication-initiating telemetry signals to occur in a time interval that overlaps an instant of time at which the telemetry circuitry (27) of the implanted medical device (302) is activated from its low-power mode for detection.

20

16. The system according to any one of claims 12-15, wherein the implantable medical device (302) is arranged with storage means (25) in which the selected instant of time at which the telemetry circuitry (27) is activated
25 can be programmed, and/or the rate at which the selected instant of time occurs.

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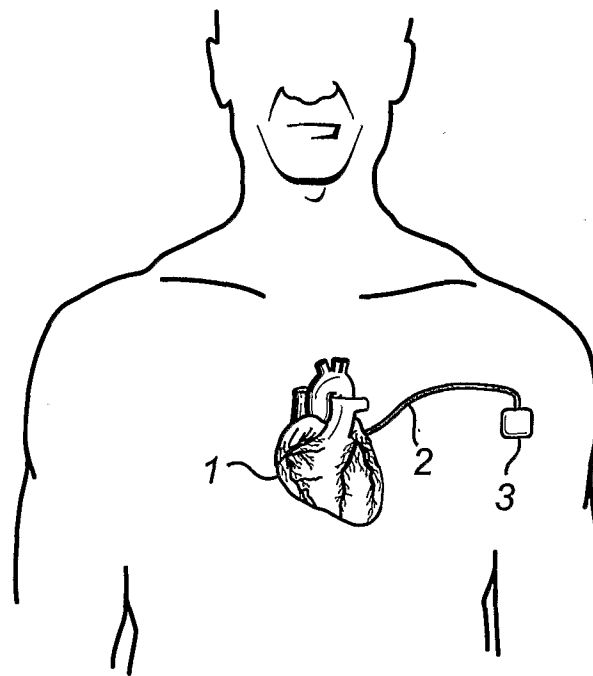


Fig. 1

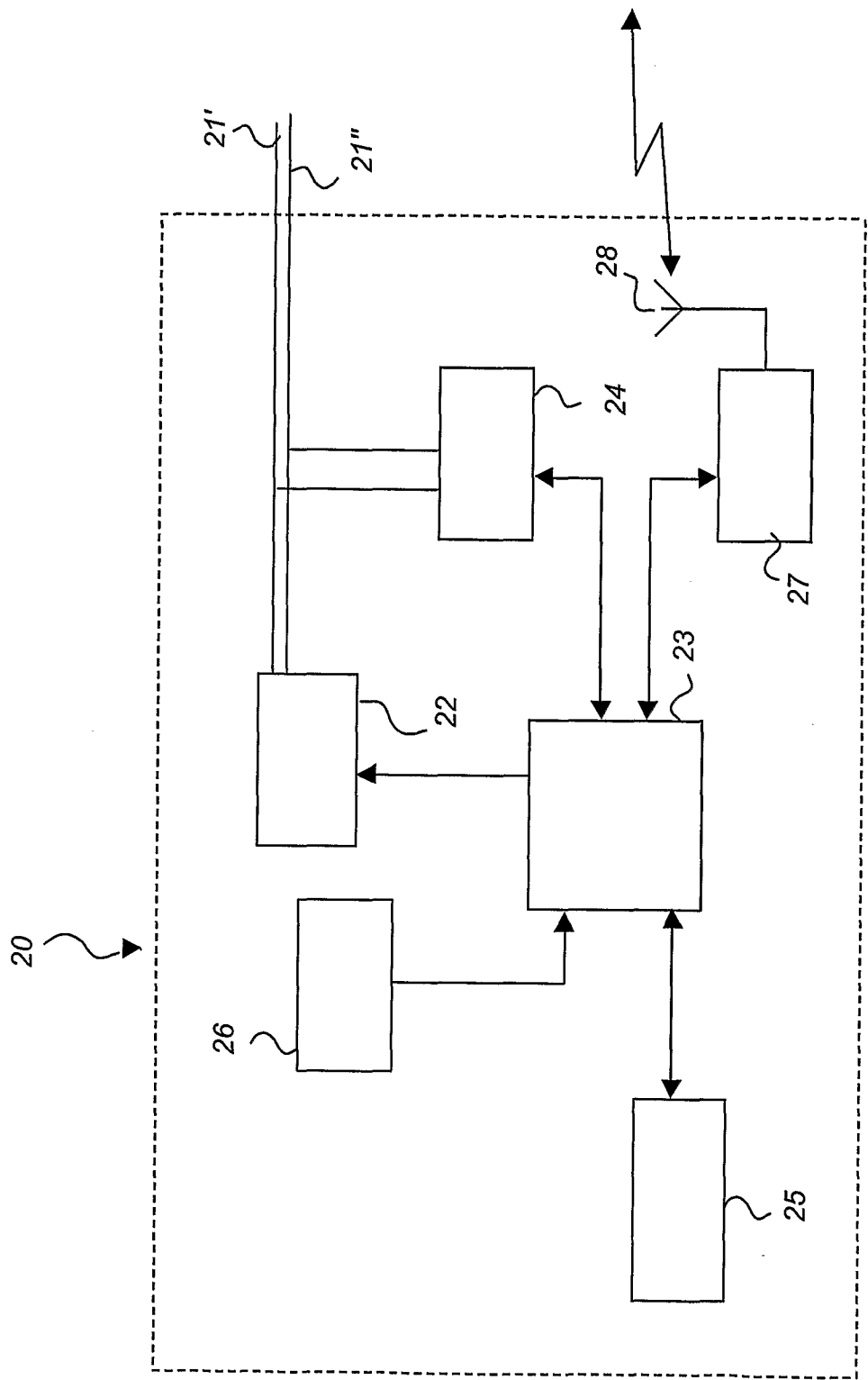
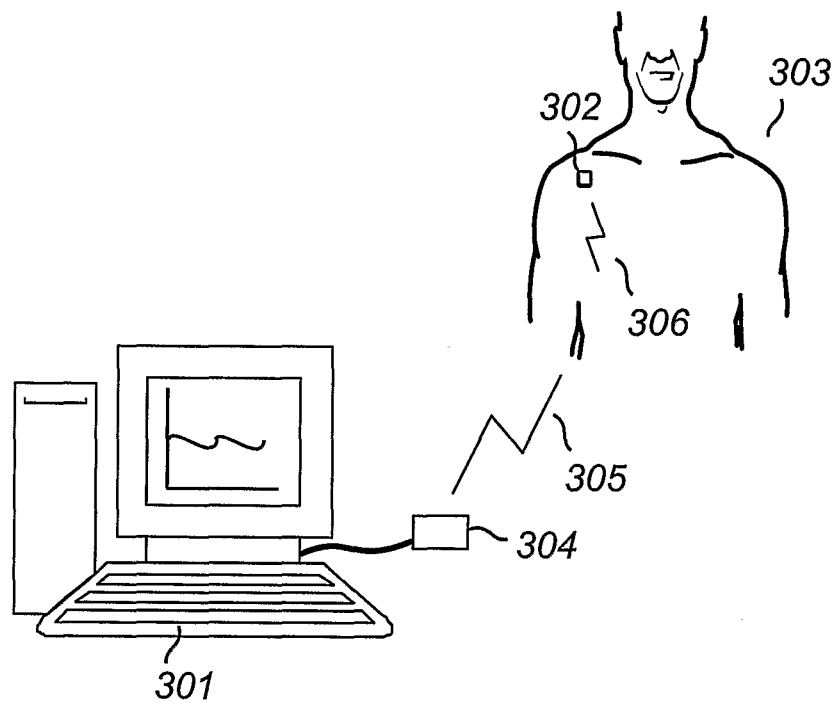


Fig. 2

3/3

*Fig. 3*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2007/000296

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

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, INSPEC, BIOSI, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 20050099817 A1 (CARDIAC PACEMAKERS, INC.), 27 October 2005 (27.10.2005), page 3, line 4 - page 7, line 25, abstract --	1-16
A	US 20030114898 A1 (VON ARX, J A ET AL), 19 June 2003 (19.06.2003), paragraph [0037], [0040], [0047] - [0048] --	1-16
A	US 20030229383 A1 (WHITEHURST, T K), 11 December 2003 (11.12.2003), Whole document -- -----	1-16

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 ☒ See patent family annex.

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Date of the actual completion of the international search

26 November 2007

Date of mailing of the international search report

29 -11- 2007

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International patent classification (IPC)**A61N 1/372** (2006.01)**Download your patent documents at www.prv.se**

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/09/2007

International application No.

PCT/SE2007/000296

WO 20050099817 A1 27/10/2005 NONE

US 20030114898 A1 19/06/2003 US 6993393 B 31/01/2006
US 20060116744 A 01/06/2006

US 20030229383 A1 11/12/2003 US 7110823 B 19/09/2006
BR 0407421 A 24/01/2006
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