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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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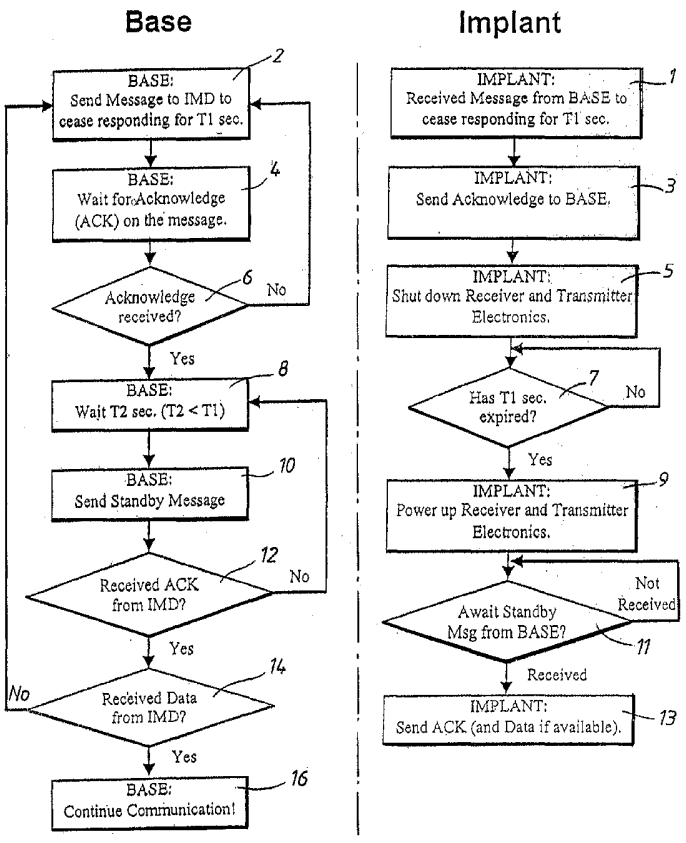
[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR RADIO COMMUNICATION BETWEEN AN IMPLANTABLE MEDICAL DEVICE AND AN EXTERNAL BASE UNIT



(57) Abstract: In a system for radio communication between an implantable medical device, IMD, and an external base unit the IMD comprises a transceiver for the communication with the external base unit. The external base unit is arranged to send, according to a predetermined criterion, a sleep message to the IMD transceiver requesting the IMD transceiver to switch to a sleep, power down mode of operation for a predetermined sleep time period. In a corresponding method of radio communication between an implantable medical device, IMD, and an external base unit, a sleep message is sent, according to a predetermined criterion, to the IMD transceiver requesting the IMD transceiver to switch to a sleep, power down mode of operation for a predetermined sleep time period.

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SYSTEM AND METHOD FOR RADIO COMMUNICATION BETWEEN AN IMPLANTABLE MEDICAL DEVICE AND AN EXTERNAL BASE UNIT.

Technical Field

The present invention relates to a system for radio communication between an implantable medical device, IMD, and an external base unit, said IMD comprising a transceiver for the communication with the external base unit, as well as to a corresponding method of radio communication.

Background

Systems for communication between an IMD and an external management device or base unit are well known, see e.g. US – A1 – 20040122488. In this way clinical and other data are retrieved from the IMD and the operation of the IMD is controlled from the outside of the patient.

In systems of this kind including an IMD communicating with an external base unit continuous efforts are made to save power in electrical IMDs to prolong the IMD battery life time.

The purpose of the present invention is to reduce the power consumption in the IMD for the radio communication with the external unit.

Disclosure of the Invention

This purpose is obtained by a system and a method of the kind defined in the introductory portion which have the characterizing features of claims 1 and 13 respectively.

Thus according to the invention power is saved by switching the IMD transceiver electronics to a sleep mode of operation for a predetermined sleep time period, in which the communication of information between external base unit and IMD is reduced. With the IMD in such a sleep mode it becomes very quickly operative at the expire of the sleep time period.

Certain communication standards prescribe that a radio communication channel of an Medical Implant Communication Systems, MICS, is to be regarded as free to use if no communication activity is detected within a prescribed silent time period. To obtain a reliable system for communication between an IMD and an external base unit based on these standards messages must be sent from the base unit to the IMD sufficiently frequent to avoid loosing the right to the channel

and sent messages must result in immediate responses from the IMD. However, to maintain the communication channel between the base unit and the IMD also during the sleep time period of the IMD transceiver, according to advantageous embodiments of the invention, said base unit is arranged to start sending, in absence of communication activity on the communication channel, a radio signal in the form of standby messages on the communication channel before the expire of said silent time period. The IMD is adapted to acknowledge to the base unit receipt of said sleep message but not acknowledge receipt of any messages received in the sleep mode of operation. Thus, in this way the communication channel is maintained in the absence of communication on the channel by the base unit sending standby messages with sufficiently high frequency without consuming current from the IMD battery for IMD acknowledgements of the standby messages.

According to another advantageous embodiment of the system according to the invention said standby messages comprise empty data packets sent with intervals shorter than the silent time period.

Brief Description of the Drawings

To explain the invention in greater details an embodiment of the invention, chosen as an example, will now be described with reference to the enclosed drawing, on which figure 1 shows flow charts illustrating the function in the base unit and the implant, IMD, respectively of the present invention, and figure 2 a corresponding time sequence diagram.

Detailed Description of a Preferred Embodiment

Figure 1 shows flow charts illustrating the function of the base unit, Base, and the IMD, Implant, respectively of the present invention.

When it is suitable according to a predetermined criterion, e.g. when the flow of data on the communication channel between base unit and IMD is reduced, the base unit sends a sleep message to the IMD requesting the IMD transceiver to switch to a sleep power down mode for a predetermined sleep time period of length T1 in order to save power of the IMD battery . This sleep message instructs the IMD transceiver to cease responding to messages from the base unit for the time period T1. This is illustrated at step 2 in figure 1.

Receipt of this sleep message is illustrated at step 1 of the flow chart illustrating the function of the implant, IMD, and an acknowledgement of this sleep message is sent by the IMD, at step 3 in the implant flow chart. The base unit is waiting for this acknowledgement, at step 4 in figure 1, to know that this sleep message is received and understood.

If the base unit does not receive such an acknowledgement from the IMD, cf. step 6 in figure 1, another sleep message is sent by the base unit to the IMD.

Upon receipt of the sleep message the IMD transceiver electronics are shut down to a sleep mode of operation, at step 5 if the IMD flow chart, and a timer of the IMD is started to count the time period T1, cf. step 7 in the IMD flow chart.

According to the communications standards FCC MICS, Federal Communication Commission Medical Communication System/Service, and ETSI ULP-AMI, European Telecommunications Standards Institute Ultra Low Power – Active Medical Implant, a MICS radio communication channel is to be regarded as free to use if no activity is detected within a 10 msec period. To make a telemetry system between an IMD and an external base unit reliable, messages sent from the base unit result in an immediate response from the IMD. This must occur at least once per 10 msec to secure that the right to the communication is not lost.

When the acknowledgement of the receipt of the sleep message is received by the base unit, at step 6 of the base unit flow chart in figure 1, the base unit starts sending, after a time interval T2 which is shorter than 10 msec, a radio signal on the communication channel in the form of standby messages or empty data packets just having a header. These standby messages or empty data packets are sent with the time interval T2 to comply with the mentioned MICS standard for maintaining the communication channel to the IMD, see steps 8 and 10 in the base unit flow chart. In this sleep mode of the IMD the base unit is prepared that the standby messages are not acknowledged by the IMD.

The IMD is in the power saving sleep mode for the time period T1, cf. step 7 in the IMD flow chart in figure 1. When the time period T1 has expired the IMD receiver and transmitter are powered up, in step 9 in the IMD flow chart. This powering up can be performed in two alternative ways.

According to a first alternative the IMD transmitter is powered up at the end of the time period T1 and sends an acknowledgement to the base unit. As a second alternative the IMD powers up its receiver at the end of time period T1 and

waits for the next standby message or empty data packet from the base unit. When this next standby message or empty data packet is received by the IMD receiver, the IMD transmitter is powered up and an acknowledgement is sent to the base unit.

The acknowledgement from the IMD is received by the base unit, at step 12 of the base unit flow chart, together with possible data which can be appended to the acknowledgment, at step 14 in the base unit flow chart of figure 1.

After the power up of the IMD transceiver the IMD is waiting for the next standby message, step 11 in the IMD flow chart, from the base unit, and is sending an acknowledgment of receipt of this next message together with possible available data to the base unit, at step 13 in the IMD flow chart.

If the base unit receives data from the IMD the communication between base unit and IMD continues, at step 16 in the base unit flow chart. If no data are received by the base unit from the IMD, and no more data is expected, the above described procedure is started again by the base unit sending a sleep message to the IMD transceiver requesting the IMD transceiver to switch to the sleep mode for the time period T1.

The above described procedure starting by the base unit sending a sleep message to the IMD can also be restarted in response to other predetermined criteria.

Figure 2 illustrates an example of a time sequence of messages or data packets exchanged between the base unit and the IMD in the procedure described above with reference to figure 1.

As appears from figure 2 the base unit is sending standby messages, StdBy in the figure, with an interval of T2 to the IMD, and the IMD is returning an acknowledgement, ACK, to the base unit, at 20 in figure 2. After a time T0 after this acknowledgement 20 the base unit is sending a sleep message to the IMD, requesting the IMD to power down its transmitter Tx and receiver Rx to the sleep mode wherein answering of any messages from the base unit is stopped, at 22 in the figure. The base unit continues to send standby messages StdBy at 24, 26,....28 to maintain the communication channel to the IMD as described above, but to save power no acknowledgments are sent by the IMD in the sleep time period T1. At the end of the sleep mode the IMD transceiver Tx/Rx is powered up, and the first standby message StdBy received thereafter is acknowledged, at 30 in

figure 2. After possible data exchange between base unit and IMD, or in response to another predetermined criterion, this procedure is restarted.

As appears from the description above and figure 2 the time period T1 is longer than the time T2. According to the standards discussed above the time T2 must be less than 10 msec, whereas the time period T1 can typically be of the order of 0.05 – 1.0 sec.

In the embodiment described above it is assumed that the base unit initiates the data flow but, according to another embodiment of the invention, an equivalent data flow can be controlled by the IMD.

There are at least two ways to implement the basic data flow depending on the amount of hardware support available in the system according to the invention. These two ways can be characterized as software or hardware oriented embodiments of the invention. In a software oriented embodiment messages are sent between the application software in the base unit and the application software in the IMD. Each application performs actions necessary on their radio units to control sleep, wait and wakeup behaviour. In a hardware oriented embodiment of the invention one side, preferably the external base unit, can control the opposite side, IMD, by means of a special set of radio messages operating directly on the remote radio control unit to set timers and power down the radio transceiver.

CLAIMS

1. System for radio communication between an implantable medical device, IMD, and an external base unit, said IMD comprising a transceiver for the communication with the external base unit, **characterized in** that said external base unit is arranged to send, according to a predetermined criterion, a sleep message to the IMD transceiver requesting the IMD transceiver to switch to a sleep, power down mode of operation for a predetermined sleep time period.

2. System according to claim 1, said communication between IMD and external base unit taking place on a communication channel which is disconnected in the absence of communication activity on the channel during a silent time period of predetermined length, **characterized in** that, in the absence of communication activity on said communication channel, said base unit is arranged to start sending a radio signal in the form of standby messages on the communication channel before the expiry of said silent time period in order to maintain said communication channel between base unit and IMD in the absence of communication activity.

3. System according to claim 1 or 2, **characterized in** that the IMD is adapted to acknowledge to the base unit receipt of said sleep message but not acknowledge receipt of any messages received in the sleep mode of operation.

4. System according to claim 2 or 3, **characterized in** that said standby messages comprise empty data packets sent with intervals shorter than said silent time period.

5. System according to any one of the preceding claims, **characterized in** that said base unit is arranged to send said sleep message to the IMD immediately after termination of sending information to or receiving information from the IMD.

6. System according to any one of the preceding claims, **characterized in** that the IMD comprises a timer for keeping the IMD in the sleep mode for said sleep time period of predetermined length.

7. System according to any one of the preceding claims, **characterized in** that the IMD is adapted to power up its transmitter at the expiry of said sleep time period and send an acknowledge to the base unit.

8. System according to any one of the claims 1 - 6, **characterized in** that the IMD is adapted to power up its receiver at the expiry of said sleeping time period and in response to the receipt of a next standby message thereafter power up its transmitter to send to the base unit an acknowledgment of receipt of this standby message.

9. System according to any one of the preceding claims, **characterized in** that the length of said sleep period is of the order of 0.05 to 1.0 sec.

10. System according to any one of the preceding claims, **characterized in** that the communication on said communication channel is based on FCC MICS communication standard.

11. System according to any one of the claims 1 – 9, **characterized in** that the communication on said communication channel is based on ETSI ULP-AMI communication standard.

12. System according to any one of the preceding claims, **characterized in** that the IMD is a heart stimulator and the external base unit a programmer, said IMD and base unit comprising telemetry means to establish said communication channel in the form of a telemetry link.

13. Method of radio communication between an implantable medical device, IMD, and an external base unit, said IMD comprising a transceiver for the communication with the external base unit, **characterized in** that a sleep message is sent, according to a predetermined criterion, to the IMD transceiver requesting the IMD transceiver to switch to a sleep, power down mode of operation for a predetermined sleep time period.

14. Method according to claim 13, wherein said communication between IMD and external base unit is done on a communication channel which is disconnected if no communication activity is detected on the channel during a silent time period of predetermined length, **characterized in** that, in the absence of communication activity on said communication channel, said base unit starts sending a radio signal in the form of standby messages on the communication channel before the expiry of said silent time period in order to maintain said communication channel between base unit and IMD in the absence of communication activity.

15. Method according to claim 14, **characterized in** that said standby messages comprise empty data packets sent with intervals shorter than said silent time period, the first empty data packet being sent before the expiry of said silent time period.

16. Method according to any one of the claims 13 – 15, **characterized in** that said sleep message is sent by the base unit to the IMD immediately after termination of sending information to or receiving information from the IMD.

17. Method according to any one of the claims 13 - 16, **characterized in** that receipt of said sleep message is acknowledged to the base unit by the IMD, whereas no acknowledgments are sent by the IMD in the sleep mode.

18 Method according to any one of the claims 13 - 17, **characterized in** that an acknowledgment is sent by the IMD to the base unit at the expiry of said sleep time period.

19. Method according to claim 13 - 18, **characterized in** that an acknowledgment of receipt of the first message after the expiry of said sleep time period is sent by the IMD to the base unit.

Fig 1

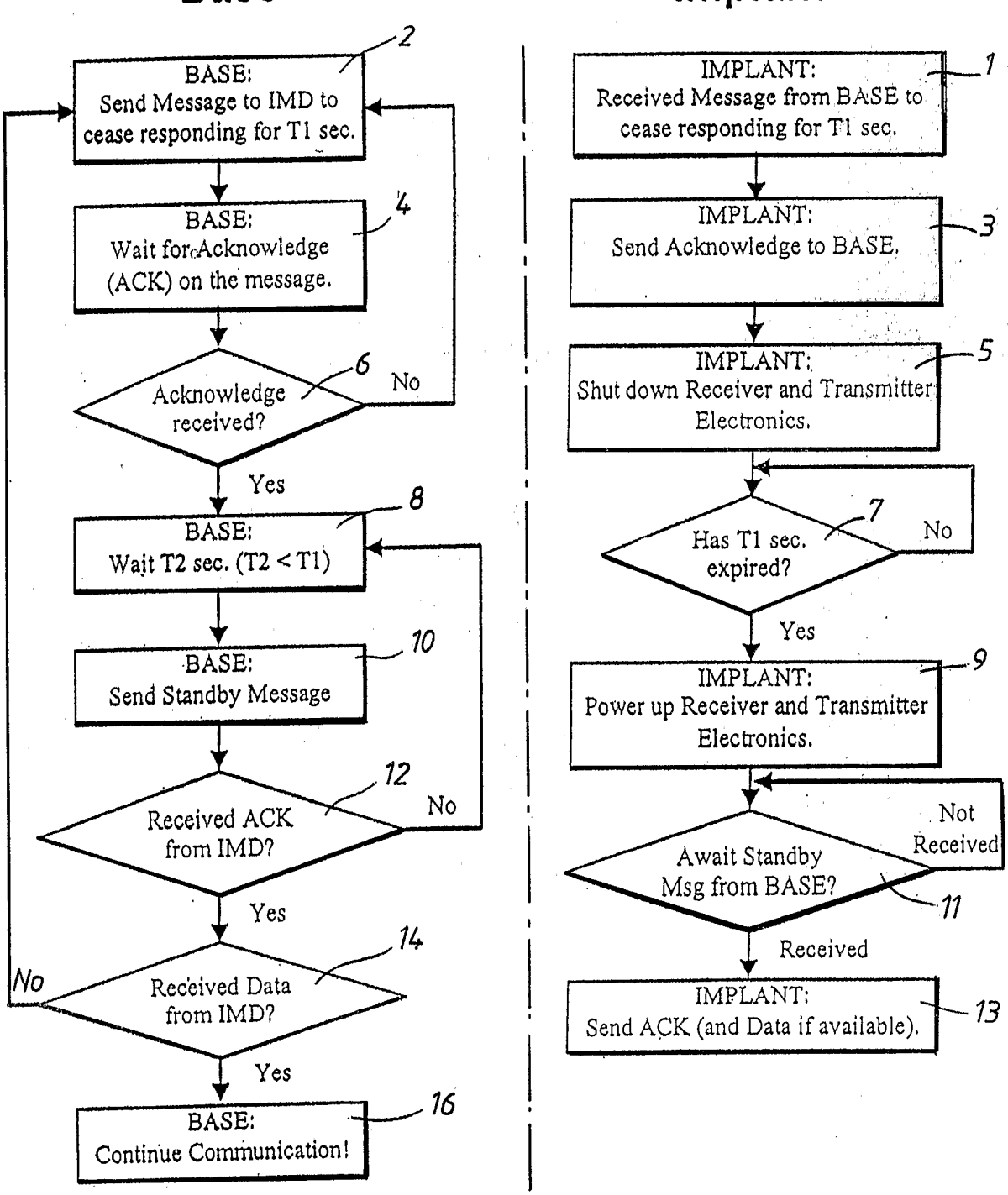
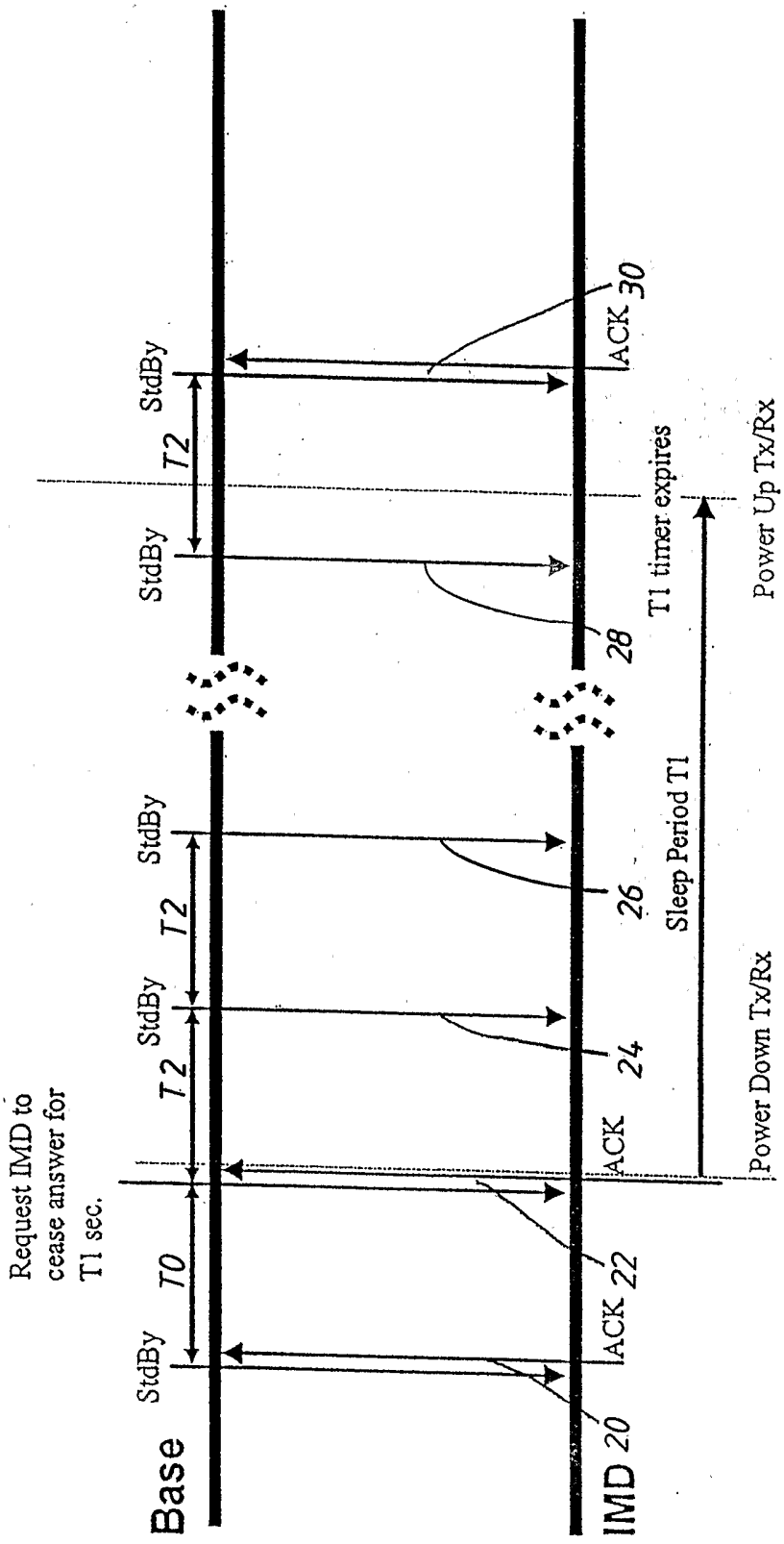

Base
Implant
BASE: Send Message to IMD to cease responding for T1 sec.
2
BASE: Wait for Acknowledge (ACK) on the message.
4
Acknowledge received?
6
No
Yes
BASE: Wait T2 sec. (T2 < T1)
8
BASE: Send Standby Message
10
Received ACK from IMD?
12
No
Yes
Received Data from IMD?
14
No
Yes
BASE: Continue Communication!
16
IMPLANT: Received Message from BASE to cease responding for T1 sec.
1
IMPLANT: Send Acknowledge to BASE.
3
IMPLANT: Shut down Receiver and Transmitter Electronics.
5
Has T1 sec. expired?
7
No
Yes
IMPLANT: Power up Receiver and Transmitter Electronics.
9
Await Standby Msg from BASE?
11
Not Received
Received
IMPLANT: Send ACK (and Data if available).
13

Fig. 2


Base
IMD
StdBy
T0
T2
ACK
20
22
24
26
28
30
Request IMD to cease answer for T1 sec.
Sleep Period T1
T1 timer expires
Power Down Tx/Rx
Power Up Tx/Rx

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000509

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/08
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, H04L

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20030114898 A1 (JEFFREY A. VON ARX ET AL), 19 June 2003 (19.06.2003), abstract, paragraph (0002),(0052),(0064),(0075),(0080) --	1-19
X	WO 03066163 A2 (CARDIAC PACEMAKERS, INC.), 14 August 2003 (14.08.2003), page 2, line 4 - line 6; page 5, line 9 - line 11; page 27, line 15 - line 18, abstract --	1,12,13
A	US 6738670 B1 (ALLEN DALE ALMENDINGER ET AL), 18 May 2004 (18.05.2004), column 2, line 51 - line 57; column 4, line 66 - column 5, line 9; column 5, line 58 - column 6, line 11, column 6, line 46 - line 48; abstract --	1-19

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"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	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/000509

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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