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(54) Title: MEDICAL DEVICE TELEMETRY ARBITRATION SYSTEM BASED UPON USER SELECTION
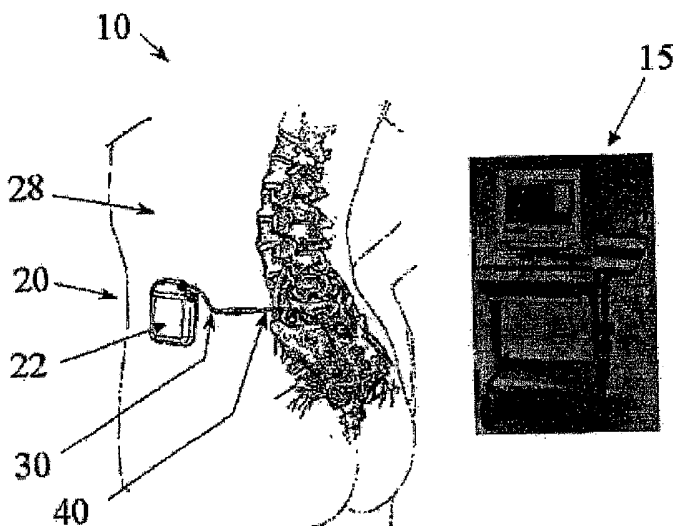
(57) Abstract: A medical system and method of establishing communication between a plurality of implantable medical devices and an external device. An identification command is sent transcutaneously to at least one of the plurality of implantable medical devices. The plurality of implantable medical devices respond to the identification command with an uplink response in one of a plurality of uplink time slots. The external device receives the uplink response from each of at least one of the plurality of implanted medical devices. The external device establishes transcutaneous communication to a selected one of the plurality of implanted medical devices based, at least in part, upon a user selection of one of said plurality of implanted medical devices.

MEDICAL DEVICE TELEMETRY ARBITRATION
SYSTEM BASED UPON USER SELECTION

TECHNICAL FIELD

[1]   This disclosure relates to medical device transcutaneous communication systems and methods and, more particularly, to a device arbitration system and method for transcutaneous communication with such medical devices.

BACKGROUND

[2]   Implantable medical devices for producing a therapeutic result in a patient are well known.   Examples of such implantable medical devices include implantable drug infusion pumps, implantable neurostimulators, implantable cardioverters, implantable cardiac pacemakers, implantable defibrillators and cochlear implants.   Some of these devices, if not all, and other devices either provide an electrical output or otherwise contain electrical circuitry to perform their intended function.

[3]   It is common for implantable medical devices, including implantable medical devices providing an electrical therapeutic output, to utilize transcutaneous telemetry to transfer information to and from the implanted medical device. Information typically transferred to an implanted medical device includes transferring instructions or programs to the implanted medical device from an external device such as an external programmer.   Information typically transferred from an implanted medical includes information regarding the status and/or performance of the implanted medical device.

[4]   As telemetry ranges increase, there is an increasing problem with communicating with multiple devices, as more than one device can be in the telemetry range of a programmer at once. If more than one implanted medical device responds to an identification command, the communication link may fail as uplink responses collide with one another.

SUMMARY

[5]   In order to efficiently select the desired one of a plurality of implanted medical devices, many or all of which may respond to an identification command issued by an external device, special techniques may be used.

[6]   In an embodiment, the present invention provides a medical device communication system having a plurality of implantable medical devices and an external device configured to transcutaneously send an identification command to at least one of the plurality of implantable medical devices. The plurality of implantable medical devices are configured to respond to the identification command with an uplink response in one of a plurality of uplink time slots. The external device is configured to receive the uplink response from each of the at least one of the plurality of implanted medical devices. The external device is configured to establish transcutaneous communication with a selected one of the plurality of implanted medical devices based, at least in part, upon a user selection of one of the plurality of implanted medical devices.

[7]   In another embodiment, the present invention provides a method of selecting one of a plurality of implanted medical devices with which to establish transcutaneous communication from an external device associated with at least one of the plurality of medical devices. An identification command is sent from the external device. At least one of the plurality of implanted medical devices responds to the identification command with an uplink response in one of a plurality of uplink time slots. The uplink response from each of the plurality of medical devices is received by the external device. One of the medical devices with which to establish communication is selected based, at least in part, upon a user selection of one of the plurality of implanted medical devices.

[8]   In a preferred embodiment, a list is developed of each of the at least one of the plurality of medical devices responding with the uplink response, to supply the list to the user; and to establish transcutaneous communication with one of the plurality of implanted medical devices selected from the list by the user.

[9]   In a preferred embodiment, the external device is further configured to identify each of the plurality of medical devices based, at least in part, on the uplink signal received.

[10]   In a preferred embodiment, if at least two of the plurality of medical devices respond with the uplink signal in one of the plurality uplink time slots, to instruct known ones of the plurality of medical devices to cease responding to the identification command, to resend the identification command and receiving the uplink signal is repeated.

[11]   In a preferred embodiment, the external device continues to resend identification commands until no two of the plurality of medical devices respond with the uplink signal in one of the plurality of uplink time slots.

[12]   In a preferred embodiment, known ones of the plurality of medical devices cease responding, for a predetermined period of time, to the identification command as a result of being instructed to cease responding.

[13]   In a preferred embodiment, known ones of the plurality of medical devices cease responding, until instructed otherwise, to the identification command as a result of being instructed to cease responding.

[14]   In a preferred embodiment, the external device supplies a list of the plurality of medical devices identified to a user, and establishes transcutaneous communication with one of the plurality of implanted medical devices selected from the list by the user.

[15]   In a preferred embodiment, transcutaneous communication is maintained with the selected one of the plurality of medical devices for a remainder of a communication session.

BRIEF DESCRIPTION OF THE DRAWINGS

[16]   **Figure 1** shows a general environmental view 10 for an implantable neurostimulation system (INS) embodiment of the present invention.

[17]   **Figure 2** illustrates an implantable medical device implanted in a patient with an external device for transcutaneous communication with such implanted medical device.

[18]   **Figure 3** shows an external device for transcutaneous communication with an implanted medical device with two implanted medical devices within range of the external device.

[19]   **Figure 4** is a timing diagram illustrating timing of issuance of an identification command and response of acknowledgements in a plurality of time slots.

[20]   **Figure 5** is an exemplary representation of a presentation of alternative medical devices to be presented to a user.

[21]   **Figure 6** is a timing diagram illustrating timing of issuance of an identification command and response of acknowledgements in a plurality of time slots with issuance of a further silence command and the re-issuance of another identification command.

DETAILED DESCRIPTION

[22]   The following exemplary embodiments are described, for the most part, in the context of a implantable neurostimulator having a rechargeable power source, although use of the various device arbitration system with other implantable medical devices, such as pacemakers, implantable cardiac defibrillators, defibrillators, therapeutic agent infusion devices (e.g., drug pumps), is contemplated.

[23]   **Figure 1** shows a general environmental view 10 for an implantable neurostimulation system (INS) embodiment. Neurostimulation systems are used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions. Neurostimulation system 20 includes a neurostimulator 22, a stimulation lead extension 30 and a stimulation lead 40. Neurostimulator 22 is typically implanted subcutaneously in the patient's body 28 at a location selected by a clinician. Stimulation lead 40 is typically fixed in place near the location

selected by the clinician using a well known device such as an adjustable anchor.

[24]   External device 15 may be used to transcutaneously communicate with implantable neurostimulator 22 as discussed below.

[25]   **Figure 2** shows an implantable neurostimulator 22, a stimulation lead 40, and a lead extension 30. Implantable neurostimulator 22 has a housing 24, a power supply carried in housing 24, and stimulation electronics coupled to the battery and coupled to connector block 26, which is also known as a terminal block. Stimulation lead 40 has a lead proximal end, a lead distal end and a lead body. The lead proximal end has at least one electrical connector (also known as electrical terminals) and the lead distal end has at least one stimulation electrode. There is at least one lead conductor contained in the lead body that is electrically connecting the electrical connector to the stimulation lead 40.

[26]   Neurostimulation system 20 includes an external communication device such as a physician programmer usually operable by a medical practitioner, such as a physician, and/or a patient programmer usually operable by the patient. Neurostimulation system 20 may also include or be used with various other medical devices and computer-based platforms, such as PCs, notebooks, servers, etc.

[27]   A physician programmer is typically used by a physician, clinician or other medical professional to control or set all available parameters of the implantable medical device and to set parameters and limits under which a patient may be able to control or adjust the implanted medical device.

[28]   A patient programmer is typically used by a patient, or another person caring for such patient, into whom the implantable medical device has been implanted for control of medical device parameters over which the patient typically has control. As an example, the patient could use the control to turn the implantable medical on or off or to adjust the therapy level or therapy type

provided by the implanted medical device within constraints previously set by the physician programmer.

[29]   It is to be recognized and understood that the present invention may be found useful with other types of external devices, other than specifically physician programmers or patient programmers, in transcutaneous communication with implanted medical devices.

[30]   An external device typically uses well known wireless communication techniques to transcutaneously communicate with an implanted medical device. Such transcutaneous communication is typically referred to as telemetry. Many well known telemetry techniques are available to provide such transcutaneous communication.

[31]   A problem may arise, however, when an external device, such as a physician programmer or a patient programmer, attempts to communicate with an implanted medical device in a physical location which is somewhat in the proximity of a second implantable or implanted medical device. Such a situation may occur, for example, if a patient has more than one medical device implanted, if a second patient also having an implanted medical device is nearby, e.g., in an emergency ward or a hospital or other medical setting, or if another implantable medical awaiting implant, for example, is located nearby.

[32]   In a typical transcutaneous communication situation involving an external device and an implanted medical device, the external device will send a wireless communication request, such as an identification command. An implanted medical will receive the identification request and will send back an acknowledgement, perhaps including information about the implanted medical device. This procedure works well as long as only one implantable or implantable medical device is within wireless range of the communication request. For example, in **Figure 3** a first patient has a first neurostimulator 22A implanted in their body 28A. A second patient is located nearby, e.g., in an adjacent treatment location in a medical facility. The second patient also has an implanted medical device, in this case neurostimulator 22B, implanted

in their body 28B. If both neurostimulator 22A and neurostimulator 22B operate under the same or similar telemetry protocol, both neurostimulator 22A and neurostimulator 22B may respond to the communication request with an acknowledgement. If these acknowledgements occurs at the same time or near in time such as with an overlap in time, then the acknowledgement from neurostimulator 22A may collide with the acknowledgement from neurostimulator 22B and cause corruption of communication for both implanted medical devices.

[33]   Partly for this reason, some delay is designed into the timing of the acknowledgement for an implanted medical device. A reply period may be divided into a plurality of time slots. An individual medical device, such as neurostimulator 22A or neurostimulator 22B may reply to the communication request (identification command) in one of the plurality of time slots. This is illustrated schematically in the timing diagram of **Figure 4** in which time increases from left to right in the diagram. Identification request 50 is sent by external device 15. In one of a plurality of time slots (52, 54, 56, 58, 60, 62, 64 and 66), implanted medical device 15 can respond.

[34]   If implanted medical device 15 randomly picks one of the plurality of time slots in which to respond, the chance of two or more medical devices responding in the same time slot (52, 54, 56, 58, 60, 62, 64 and 66) is reduced. If two or more medical devices do respond in the same time slot, e.g., time slot 52, then a collision occurs and communication is not established. In this case, external device 15 may reissue an identification command and repeat the process. The probability that the two or more medical devices will again randomly pick the same time slot to respond on consecutive iterations of issuance of identification commands is reduced.

[35]   However, even if communication is successful on a second or subsequent issuance of an identification command, the establishment of transcutaneous communication is delayed due to the time required to reissue the identification command and to reprocess acknowledgements. Since, in many instances, transcutaneous communication will not or can not occur during the delivery of

therapy to the patient, the time periods between therapies, e.g., between electrical stimulation pulses, is in short supply. Thus, increasing the time required to establish transcutaneous communication is significant.

[36]   Even if two or more medical devices respond in different time slots, external device 15 must still determine which of the medical devices 22 with which to establish communication. This can be done by building a list of medical devices 22 responding to the identification request and allowing a user of the external device 15, e.g., a physician or the patient, to select the appropriate medical device 22. For example, a table, list or other presentation of information such as that illustrated in **Figure 5** could be presented to the user. As examples of information that could be presented in such a presentation, the multiple medical devices 22 identified could be listed by serial number since the serial number could have been included in the acknowledgement sent back to external device 15 by medical device 22. Similarly, the presentation could include the patient's name, again if that information was included in the acknowledgement sent back to external device 15 by medical device 22. Also, it is contemplated that the type of medical device 22 could also be presented such as whether the medical device 22 is a neurostimulator, a drug pump and a cardiac defibrillator or other medical device. It is to recognized and understood that these are merely examples of the kinds and type of information which could be presented to a user, either together, individually or selectively, enabling the user of external device 15 to make an informed decision on the selection of the medical device 15 with which to establish transcutaneous communication. It is also to be recognized and understood that other forms of presentation, other than the tabular format illustrated in **Figure 5**, could be used as a presentation format, such as an iconic display, visual representations by color or shape, auditory or tactile sensory presentations.

[37]   Other techniques to establish transcutaneous communication between an external device 15 and one of a plurality of medical devices 22 are contemplated.

[38]   A first exemplary technique implanted medical devices respond to an identification command (sent by an external unit) with various random delays to prevent the uplink response from multiple implanted medical devices from overlapping and thereby corrupting the signal. The user of the external device can then look at each time slot, identify and record each implanted medical device that responds, i.e., sends an uplink response, and telemeter the identified implanted medical devices to stop communicating to an identification command from that external device for a period of time, and then reissue the identification command. After repeated attempts, all implanted medical devices within range can be found and silenced. When no further implanted medical devices respond to the identification command, a complete list of implanted medical devices within range is obtained. The user may select from the list of devices based on knowledge of how the devices are named or identified in order to uniquely select an individual implanted medical device.

[39]   This is illustrated in the timing diagram of **Figure 6** in which time increases to the right. External device 15 sends an identification command 50A. Two or more medical devices 22 respond with varying delays, each in one of time slots 52A through 66A. Any medical device 22 responding in a time slot (52A, 54A, 56A, 58A, 60A, 62A, 64A or 66A) that does not collide with the response of another medical device 22 can be identified by external device 15 and instructs with command 68A to cease responding to further identification commands, e.g., for a predetermined period of time or until another specified event or signal. External device 15 may then issue a second identification command 50B and await responses from remaining medical devices 22 in one of time slots 52B, 54B, 56B, 58B, 60B, 62B, 64B or 66B. Again any responses that do not collide identify another medical device or other medical devices 22. This process may be repeated until, eventually, no medical devices respond within any of the time slots indicating that all medical devices 22 within range have been identified. The particular medical device 22 with which external device 15 communicates may than be selected through conventional, e.g., picked from a list, or other means.

[40]   A second exemplary technique uses a pseudo-random system that is based on downlink telemetry strength. Implanted medical devices that receive a strong downlink signal reply to an identification command in a first time slot, or in a first few time slots, during device arbitration. Implanted medical devices that receive a weaker downlink signal reply to the identification command in a later time slot or in later time slots. The user can then select the implanted medical device that first responds to the identification command, which typically is the implanted medical device closest to the external device operated by the user and that received the strongest downlink signal, i.e., the strongest identification command. The user not need select the particular implanted medical device from a list of devices that are in the telemetry range of the external device. The arbitration is faster than the first exemplary technique, since it doesn't need to find and identify every implanted medical device within range, but only needs to find the closest implanted medical device, which responds in one of the earliest timeslots. Multiple command attempts are typically not needed.

[41]   In **Figure 3**, medical devices receiving an identification command having a strong or stronger downlink signal, i.e., an identification command, may respond in one of the first four time slots, namely time slots (52, 54, 56 and 58) and medical devices receiving an identification command having a weak or weaker downlink signal, i.e., an identification command, may respond in one the last four time slot, namely time slots (60, 62, 64 and 66). Relative downlink signal strength may be approximated without reference to the knowledge of the downlink signal strength of another medical device, for example, by a predetermined threshold. A signal strength of an identification command above a predetermined threshold is treated as strong downlink signal while an identification command having a signal strength below the predetermined threshold is treated as a weak downlink signal.

[42]   This technique works well when external device 15 is located significantly closer to the medical device 22 with which communication is intended than other medical devices within communication range. An additional benefit of

this technique is that if only one medical device 22 responds in a time slot indicative of a strong downlink signal, and perhaps if the user is confident that external device 15 is positioned closest to the intended medical device 22, then communication may be established with that medical device 22 without the necessity of identifying or listing all responding medical devices 22.

[43]   External device 15 will start a transcutaneous communication session with the first implanted medical device 22A recognized after broadcasting an identification command is sent. As noted above, the uplink time slots (52, 54, 56, 58, 60, 62, 64 and 66) may be grouped according to detected downlink strength.

[44]   External device 15 may send an identification command 50 to find a medical device 22 on the first button pressed by a user that requires telemetry. The delayed uplinks from the medical device 22 may be grouped so that the medical device 22 that receives the identification command 50 with high downlink strength (for example, data strength of 7), it will send an uplink response randomized in the first four timeslots (52, 54, 56 and 58) (100-400 milliseconds of delay) and if the medical device 22 receives the identification command 50 with medium or low downlink strength (for example, data strength of 3 or 1), it will respond with a randomized uplink in the last four timeslots (60, 62, 64 and 66) (500-800 milliseconds of delay).

[45]   A medical device 22 detects a high strength downlink if an external device 22 is positioned properly over the medical device 22. Another medical device 22 that is sitting right next to the first medical device 22 will get a strength indicator of medium or low. This dramatically increases the odds of selecting the medical device 22 that is closest to the external device and can shorten the amount of time (up to 400 milliseconds) for determining which medical device 22 to talk to for a properly located external device 15.

[46]   If two implanted medical devices are at an approximately equal distance from the external device, special provision may need to be made since collision of uplink responses from the multiple implanted medical devices is likely. First, the system may still pick the first implanted medical device that communicates

with it, since there still can be timeslots within each downlink strength that are still randomly sorted, or sorted by serial number, for example, so uplink responses from equally spaced implanted medical device do not collide. Second, the user may by alerted to move the external device closer to the implanted medical device with which communication is desired, in the event of collision of uplink responses from more than one implanted medical device. Third, all of the implanted medical devices may be listed as in the first exemplary technique described above and the user may select the implanted medical device with which communication is desired.

[47]   In a third exemplary technique, the user may look at the strength of the uplink signal from each of the plurality of implanted medical devices.   In this exemplary embodiment, time-slot arbitration would be used with many different time slots to minimize and, hopefully, prevent uplink response collisions. The user may receive uplink response from all of the implanted medical devices using the arbitration techniques as described above in the first exemplary technique and then look to see which implanted medical device replied with the strongest uplink signal.   The user may then select the implanted device having the strongest uplink response signal, which is usually the implanted medical device that is closest to the external device issuing the identification command.

[48]   It is to be recognized and understood that the above described techniques are primarily intended to arbitrate between two or more implanted medical devices in the establishment and/or identification of such devices by an external device desiring to communicate with one or more such devices. It should be recognized that once each, or one of, the implanted medical are identified such that an identifier associated with the implanted medical device is known to the external device, that the external device may communicate with any such known implanted medical device simply by specifying the identifier or address of that device without the necessity to further resort to arbitration techniques.

[49]   After the communication session starts, the ID medical device 22 selected is set in the external device 15 and the external device 15 will only communicate to the initial medical device 22 found until the communication session is ended.

[50]   Thus, embodiments of the medical device telemetry arbitration system are disclosed. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

What is claimed is:

1.   A medical device communication system, comprising:

a plurality of implantable medical devices;

an external device being configured to transcutaneously send an identification command to at least one of said plurality of implantable medical devices;

said plurality of implantable medical devices being configured to respond to said identification command with an uplink response in one of a plurality of uplink time slots;

said external device being configured to receive said uplink response from each of said at least one of said plurality of implanted medical devices;

characterized in that said external device is configured to establish transcutaneous communication with a selected one of said plurality of implanted medical devices based, at least in part, upon a user selection of one of said plurality of implanted medical devices.

2.   A medical device communication system as in claim 1 wherein said external device is configured to develop a list of each of said at least one of said plurality of medical devices responding with said uplink response, to supply said list to said user; and to establish transcutaneous communication with one of said plurality of implanted medical devices selected from said list by said user.

3.   A medical device communication system as in claim 1 wherein said external device is further configured to identify each of said plurality of medical devices based, at least in part, on said uplink signal received; if at least two of said plurality of medical devices respond with said uplink signal in one of said plurality uplink time slots, to instruct known ones of said plurality of medical devices to cease

responding to said identification command; and to repeat sending said identification command and to repeat receiving said uplink signal.

4.   A medical device communication system as in claim 3 wherein said external device is configured to continue to resend identification commands until no two of said plurality of medical devices respond with said uplink signal in one of said plurality of uplink time slots.

5.   A medical device communication system as in claim 3 wherein said known ones of said plurality of medical devices cease responding, for a predetermined period of time, to said identification command as a result of being instructed to cease responding.

6.   A medical device communication system as in claim 3 wherein said known ones of said plurality of medical devices cease responding, until instructed otherwise, to said identification command as a result of being instructed to cease responding to said identification command.

7.   A medical device communication system as in claim 3 wherein said external device is configured to supply a list said plurality of medical devices identified in said identifying step to a user, and to establish transcutaneous communication with one of said plurality of implanted medical devices selected from said list by said user.

8.   A medical device communication system as in claim 1 which maintains transcutaneous communication with said selected one of said plurality of medical devices for a remainder of a communication session.

9.   A method of selecting one of a plurality of implanted medical devices with which to establish transcutaneous communication from an external device associated with at least one of said plurality of medical devices, comprising the steps of:

   sending an identification command from said external device;

at least one of said plurality of implanted medical devices responding to said identification command with an uplink response in one of a plurality of uplink time slots;

receiving said uplink response from each of said at least one of said plurality of implanted medical devices with said external device;

selecting one said plurality of implanted medical devices to establish transcutaneous communication based, at least in part, upon a user selection of one of said plurality of implanted medical devices.

10.   A method as in claim 9 wherein said selecting step comprises:

developing a list of each of said at least one of said plurality of medical devices responding with said uplink response;

supplying said list to a user; and

establishing transcutaneous communication with one of said plurality of implanted medical devices selected from said list by said user.

11.   A method as in claim 9 further comprising the steps of:

identifying each of said plurality of medical devices based, at least in part, on said uplink signal received;

if at least two of said plurality of medical devices respond with said uplink signal in one of said plurality uplink time slots, instructing known ones of said plurality of medical devices to cease responding to said identification command; and

repeating said sending step, said responding step and said receiving step.

12.   A method as in claim 11 wherein said repeating step occurs until no two of said plurality of medical devices respond with said uplink signal in one of said plurality of uplink time slots.

13. A method as in claim 11 wherein said known ones of said plurality of medical devices cease responding to said identification command as a result of instructing step for a predetermined period of time.

14. A method as in claim 11 wherein said known ones of said plurality of medical devices cease responding to said identification command as a result of instructing step until instructed otherwise.

15. A method as in claim 11 wherein said selecting step comprises:

supplying a list said plurality of medical devices identified in said identifying step to a user; and

establishing transcutaneous communication with one of said plurality of implanted medical devices selected from said list by said user.

16. A method as in claim 9 further comprising the step of maintaining transcutaneous communication with said selected one of said plurality of medical devices for a remainder of a communication session.
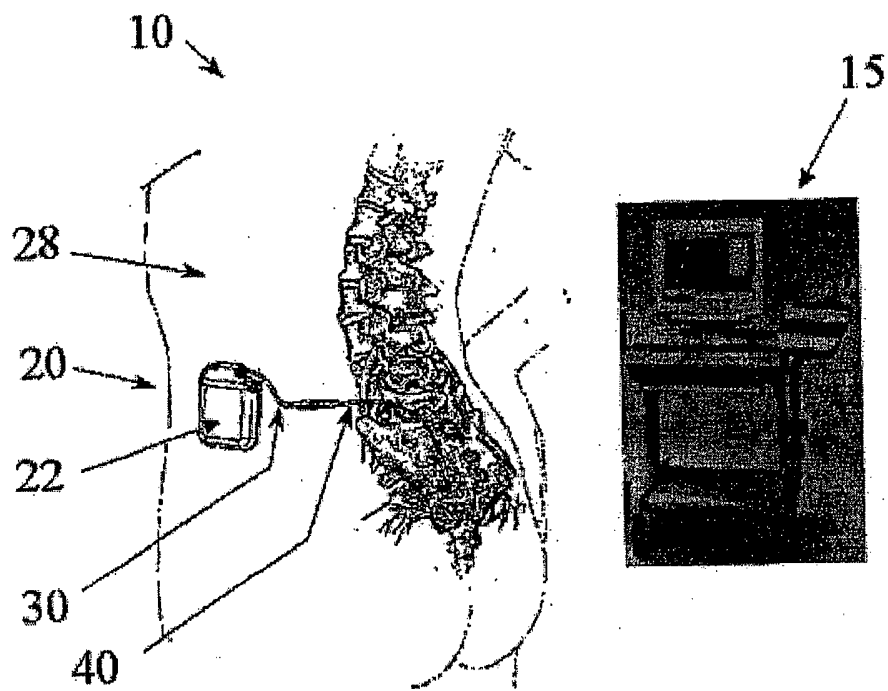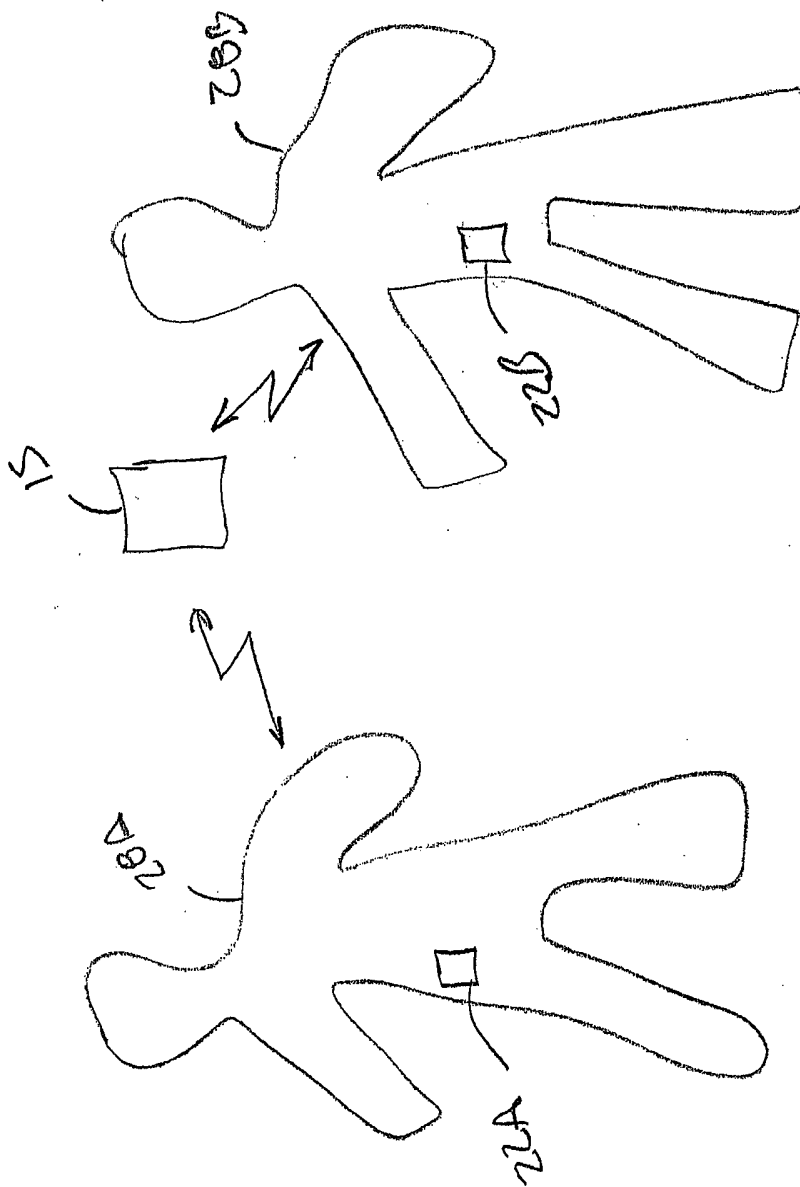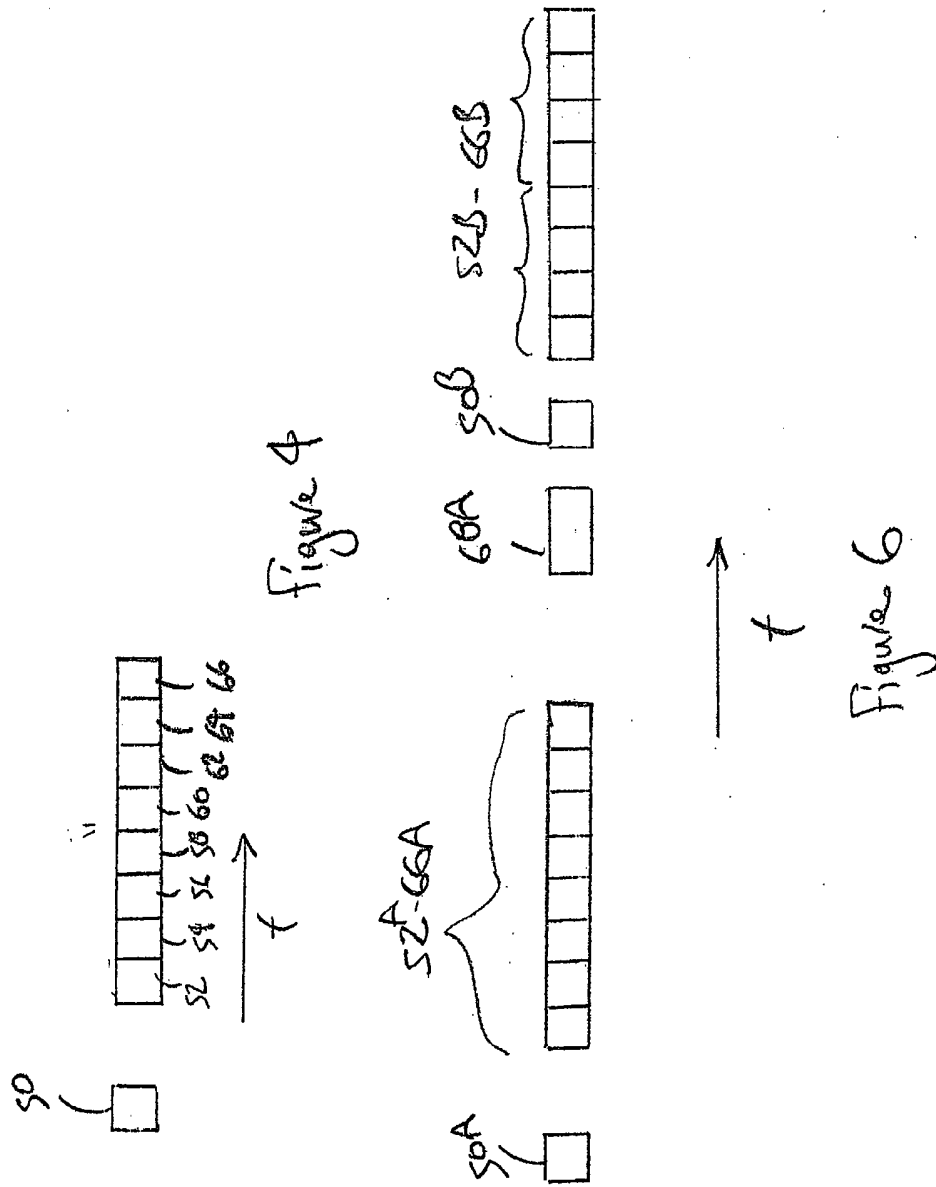
Fig. 1
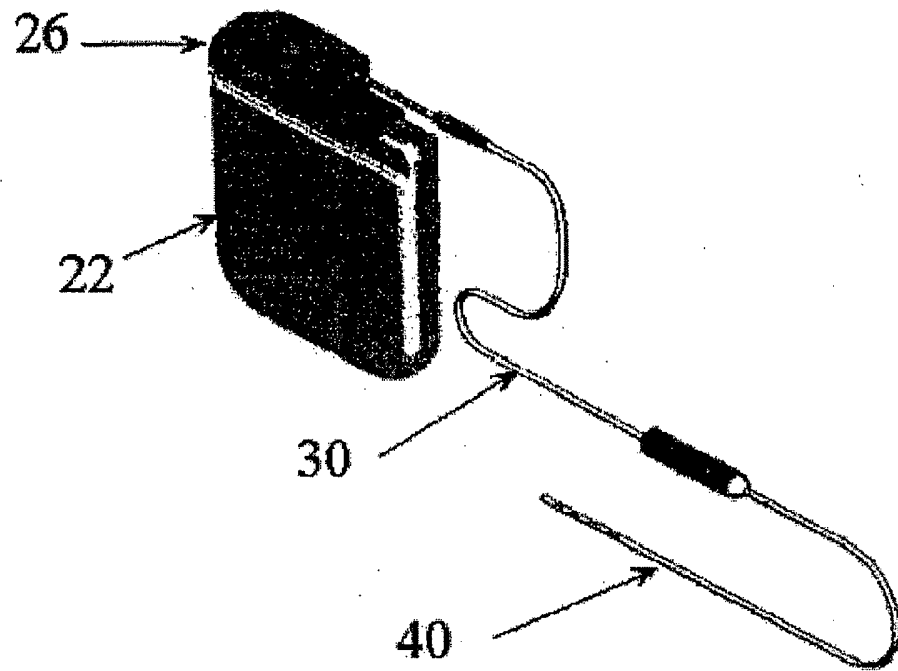
Fig. 2

Figure 3

Figure 4

Figure 6

No.	S/N	Patient	Type
1	1234	Susan	INS
2	5678	Bob	Drug Pump
3	3478	Joe	Defibrillator
~	~	~	~
N	7812	Sally	—

figure 5

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
A61N1/372   A61B5/00

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)
A61N   A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, 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 2002/065509 A1 (LEBEL RONALD J ET AL) 30 May 2002 (2002-05-30) paragraphs '0002!, '0010!, '0157!, '0312!	1-16
X	US 2003/220673 A1 (SNELL JEFFREY D) 27 November 2003 (2003-11-27) paragraphs '0001!, '0033!, '0039!, '0045!, '0051!	1-16
X	US 6 482 154 B1 (HAUBRICH GREGORY JOHN ET AL) 19 November 2002 (2002-11-19) column 1, lines 7-14 column 1, line 52 - column 2, line 33 column 12, lines 38-53	1,2, 8-10,16
X	US 2001/031997 A1 (LEE MICHAEL THOMAS) 18 October 2001 (2001-10-18) paragraphs '0002!, '0022!, '0041!	1,2, 8-10,16

[ ] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
24 November 2005	02/12/2005

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2002065509	A1	30-05-2002	NONE	
US 2003220673	A1	27-11-2003	NONE	
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