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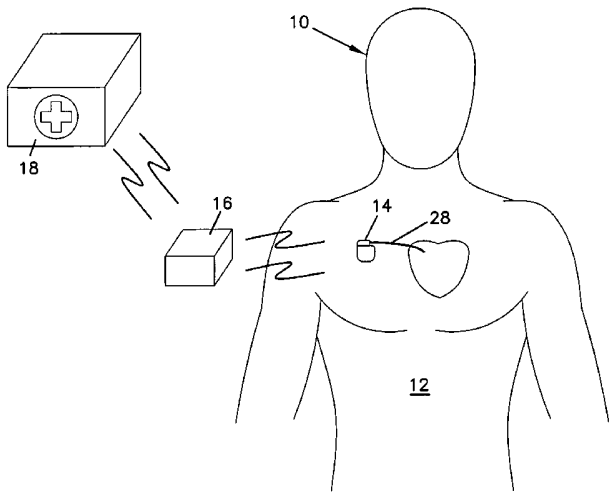
(54) **Title:** SYSTEM AND METHOD FOR TEMPORARY PROGRAMMING FOR IMPLANTED MEDICAL DEVICES



(57) **Abstract:** A system and method for temporary programming of an implantable medical device. The system and method include a repeater uploading temporary programming and instructions to a temporary memory of the device and then instructing the device to operate according to the temporary instructions. If during a first time period, the device is not in continuous periodic communication with the repeater, the device automatically reverts to operation under the normal operating instructions. At the end of the first time period, the caregiver or the patient may decide to revert to the normal programming. During a second time period, the device operates according to the temporary programming unless the caregiver or the patient instructs the device to revert to the normal programming, or the device fails to receive a periodic continuation signal from the repeater. Adverse health affects to the patient may also trigger the device to revert to the normal programming during either the first or second time period.

WO 2006/055131 A1

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SYSTEM AND METHOD FOR TEMPORARY PROGRAMMING FOR IMPLANTED MEDICAL DEVICES

This application is being filed as a PCT International Patent Application on 14 October 2005, in the name of Cardiac Pacemakers, Inc., a U.S. national corporation, applicant for the designation of all countries except the U.S. and Kenneth P. Hoyme, Alan H. Smythe, Howard D. Simms, Jr., Conrad L. Sowder, David Ternes, and Sylvia Quiles, all U.S. citizens, applicants for the designation of the U.S. only, and claims priority to U.S. Application Serial No. 10/993,699, filed 19 November 2004.

Technical Field

The present invention generally relates to implanted medical devices and external repeaters. More specifically, the present invention relates to devices and methods for temporary programming of implanted medical devices.

Background

Current medical technology utilizes a number of implanted medical devices to provide a wide-range of therapy for patients. Such implanted medical devices (IMDs) may provide rhythm altering electrical impulses to a patient's heart or other types and forms of electrical or neuro-muscular stimulus. These IMDs may also infuse a variety of therapeutic agents. Many of these IMDs are implanted beneath the skin of a patient and frequent physical access to the devices for alteration of the intensity, duration or other characteristics of the therapy is not desirable.

Current technology in the medical device industry allows for monitoring and communication with an implanted medical device without needing to directly access the IMD. Such access may even be accomplished remotely with telemetry tools capable of transmitting and receiving information via existing long-distance communication avenues, such as telephone, cellular communications or radio links. While these known techniques do permit remote alteration of the therapy delivered by an IMD, additional safety measures to guard against mistakes

in the programming of the new therapy or unexpected consequences of application of the new therapy are desirable.

Operation of an IMD based on a set of proposed or temporary operating parameters is also currently known. However, the current technology requires that a patient be physically present at a caregiver's location and within local telemetry range of the caregiver's programming equipment. In addition, once proper loading of the temporary parameters into the IMD has been verified, and IMD operation based on the temporary parameters has been verified, the caregiver's programming equipment is required to instruct the IMD to adopt the temporary parameters as normal operating parameters. Current IMD only permit operation in a temporary parameter mode when the IMD is proximate to and in continuous communication with the caregiver's programming equipment.

Summary

The present invention relates to a system for programming an implanted medical device. The system includes a medical device configured to be implanted within in a body of a patient. The medical device includes electrical circuitry to provide treatment to the patient, a first digital storage area for holding normal operation instructions and settings, a second digital storage area for holding temporary operating instructions and settings, a communications subsystem and a timing subsystem. The system also includes a repeater external of the patient's body, the repeater including a communication subsystem configured to communicate with the communications subsystem of the medical device.

The implanted medical device is configured to provide therapy to the patient using the normal operation instructions and settings stored in the first digital storage area. The repeater is configured to transmit temporary operation instructions and settings to the medical device for storage in the second digital storage area. The medical device may be instructed by the repeater to use the temporary operating instructions and settings to provide therapy to the patient. After the medical device has begun providing therapy using the temporary operation instructions and settings, the medical device will revert to the normal operation instructions and settings if a continuation signal is not received from the repeater within a first predetermined period of time.

The present invention further relates to a method of providing therapy to a patient with a programmable implantable device. The method includes providing the patient, the programmable implantable device and an external repeater remotely located from a caregiver treating the patient. The device delivers therapy to the patient based on normal operating instructions stored on the device. The caregiver communicates temporary operating instructions to the repeater. The repeater communicates the temporary operating instructions to the device and the device storing the temporary instructions in memory. The repeater communicates with the device to begin delivering therapy to the patient based on the temporary instructions. The device reverts to delivering therapy to the patient based on the normal instructions if the device does not maintain continuous periodic communication with repeater for a first predetermined period of time.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of the description, illustrate several aspects of the invention and together with the detailed description, serve to explain the principles of the invention. A brief description of the drawings is as follows:

FIG. 1 is a schematic view of an implantable medical device implanted within a patient's body, a repeater in proximity of the body to communicate with the device and a physician at a caregiver facility located remotely from the device and the repeater communicating with the repeater.

FIG. 2 is a schematic view of the implantable medical device of FIG. 1.

FIGS. 3A and 3B are a flow chart of a process for programming the implantable medical device of FIG. 2 with temporary operating instructions.

FIGS. 4A and 4B are a flow chart of an alternative process for programming the implantable medical device of FIG. 2 with temporary operating instructions.

Detailed Description of the Preferred Embodiment

Reference will now be made in detail to exemplary aspects of the present invention which are illustrated in the accompanying drawings. Wherever

possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

FIG. 1 shows a patient 10 within whose body 12 is implanted an implantable medical device 14 (shown as a cardiac rhythm management device) to provide therapy to the patient. The device includes communication circuitry to permit wireless communication with an external repeater 16. Repeater 16 may provide operating instructions to device 14 and may receive data from device 14 regarding therapy provided by device 14. Repeater 16 may also collect data from device 14 regarding the reaction of patient 10 to the therapy being provided by device 14.

Also shown in FIG. 1 is a caregiver facility 18. Caregivers at facility 18 may provide instructions to and receive information from repeater 16. While a caregiver at such a facility is preferably a physician who is treating patient 10 and familiar with the health situation of patient 10, the caregiver may also be a specialist in the particular device implanted in patient 10 who is working in conjunction with the patient's physician. It is anticipated that device 14 could include devices providing electrical impulses to some portion of a patient's body (such as defibrillators or pacemakers) or may deliver therapeutic agents (such as infusion pumps). While the actions performed by the device may differ depending on the application and medical condition being treated, the functions and features described below for altering therapy instructions or parameters are applicable to any similar implanted medical devices (IMDs). The caregiver may be using a programming device at the facility to develop and store instructions to be uploaded to repeater 16 for transmission to device 14. The programming device may also receive information from device 14 through repeater 16 to permit the caregiver to review and analyze the patient's response to therapy.

If the caregiver and patient 10 are both located at caregiver facility 18, the programming device may be integral with the repeater.

Referring now to FIG. 2, device 14 includes a communication subsystem 20 and a therapy delivery subsystem 22. Therapy delivery subsystem 22 via a conduit 28 to the portion of patient 10's body 12 where therapy is desired. In the example shown above in FIG. 1, conduit 28 is an electrical lead connecting device 14 (a pacemaker) to the patient's heart. Therapy delivery subsystem 22 may also include a patient status sensing capability which allows device 14 to sense and

record particular elements of patient 10's condition which might be affected by the therapy delivered by device 14. For example, subsystem 22 of the pacemaker of FIG. 1 may collect and record data on heart rhythm which may be used to determine if different therapy protocols may be desirable for patient 10. In another example, if device 14 were an infusion pump for delivering insulin, subsystem 22 may collect and record blood sugar levels.

Device 14 also may include an on-board memory 24 for storing and maintaining normal programming, such as operating instructions and parameters, on which the normal therapy provided to the patient is based. Normal memory 24 may also referred to as permanent memory, although, as will be discussed below, memory 24 may be subject to being overwritten with new instructions and parameters of operation to alter the therapy provided to patient 10 by device 14. Device 14 may also include a temporary on-board memory 26 for storing and maintaining new or temporary programming, such as operating instructions and parameters, for delivering therapy to patient 10. Within device 14 may be a switch 30 which is able to toggle operation of device 14 between the two different sets of operating instructions and parameters that may be stored in memories 24 and 26. Switch 30 may be a virtual or software switch which is operable based on instructions received by device 14 through repeater 16, or based on programming within device 14. Alternatively, switch 30 may also include a physical magnetic switch actuated by patient 10, or the caregiver or another person adjacent patient 10 using a magnetic wand.

Referring now to FIGS. 3A and 3B, uploading and testing of new operating instructions to device 14 includes a number of guards to prevent detrimental effects to patient 10 caused by alterations of the programming of device 10. While it is known to have a patient schedule an office visit with their caregiver to change or adjust the programming of the instructions used by an implanted medical device, such as device 10, such office visits are sometimes not possible or may be impractical or inconvenient. Remote programming of medical devices is also known as possible, but has not been a viable approach due to a lack of appropriate and necessary safeguards to protect against mistakes in reprogramming and/or new programming which does not have the desired effect on the patient's health. The procedures laid out in FIGS. 3A and 3B illustrates one embodiment of

remote programming of IMDs including adequate patient safeguards to permit secure and safe programming alterations.

To initiate the installation and testing of new programming for an IMD, patient 10 is in close proximity with repeater 16 so that repeater 16 may transmit signals to and receive signals from the IMD or device 14. Device 14 is delivering therapy to patient 10 based on a set of normal programming of instructions stored in memory 24 on-board device 14. At 100, the caregiver is located remotely from patient 10 and repeater 16 and establishes communication with the repeater and patient 10 to begin the loading and testing of new programming for device 14. "Remotely located" is defined to mean the caregiver and the patient (along with the IMD and the repeater) are not located at the same physical location. For example, the caregiver may be a physician at a hospital and the patient may be located at his or her home. On the other end of the spectrum, a patient (along with the IMD and the repeater) and caregiver located in the same room or treatment bay are not considered to be remotely located with respect to each other. The caregiver then uploads new programming to repeater 16 for communication to device 14 at 102. The new programming is then transferred from repeater 16 to device 14, which in turn stores the new programming in memory 26 on-board device 14 for temporary storage at 103.

Once the new programming has been uploaded from repeater 16 to device 14 and stored in memory 26, the caregiver, through repeater 16, instructs device 14 to begin delivering therapy to patient 10 based on the new programming for a first test period at 104. The first test period is relatively short (preferably ranging from a few seconds to a few minutes) to determine if there are any immediate ill effects to the health of patient 10. The first test period, at a minimum must extend long enough to verify that the new programming has been fully and correctly uploaded to memory 26. The first test period also may extend long enough to collect data regarding certain parameters of heart function and patient reaction to the new programming. The first test period may further extend to permit a caregiver to access the data regarding the certain parameters of heart function and patient reaction to the new programming via remote communication between repeater 16 and caregiver facility 18, so that the caregiver can verify that the new programming is initially functioning adequately.

During this first test period, at 106, patient 10 may remain within the immediate vicinity of repeater 16 so that repeater 16 is receiving a generally continuous stream of data regarding patient 10's reaction to the new therapy regime. The nature of the communication stream may be periodic, with polling and response required at certain regular intervals, and still be continuous communication as referred to herein. Such a continuous, periodic stream of communication enables device 14 to conserve battery life during the process. At 118, device 14 is configured at this stage to automatically revert to the prior normal programming if patient 10 moves away from the immediate vicinity of repeater 16. Thus, if patient 10 has a strong negative reaction to the new programming and collapses or falls away from repeater 16, device 14 will discontinue use of the new programming. As a safety measure, it is desirable that patient 10 remain near repeater 16 for the first test period so that data regarding the function of device 14 in response to the new programming can be verified. If patient 10 moves away from repeater 16 prior to completion of this first test period, device 14 will revert to the normal programming, even if no ill effects of the new programming have been detected.

During the first test period and once the first test period has been completed, the patient may be given an opportunity to critique the new programming of device 14 and the effect that therapy based on this new programming may have had upon the patient's perceived health and quality of life, at 108. If the patient's perception is that the therapy delivered by device 14 degrades comfort, interferes with the patient's normal daily activities, or otherwise has a deleterious impact on the patient, at 116, device 14 may be instructed to revert to providing therapy based on the normal programming held by memory 24. At 110, during the first test period and upon completion of the first test period, the caregiver may review the function of device 14 at 108 to determine if the new programming results in the desired function of device 14 and the desired response to the new therapy is detected in patient 10. If the caregiver determines that the level of function of device 14 is not having the desired results with regard to the patient's health, the caregiver may also, at 116, direct device 14 to revert back to providing therapy based on the normal programming within memory 24. At 116, the instruction to device 14 to revert to therapy based on the normal programming is communicated through repeater 16 by the caregiver in consultation with patient 10. Alternatively, repeater 16 may include

a button, switch or other feature permitting patient 10 to provide the instruction to device 14 to revert to normal programming within memory 24.

The uploading of new programming and temporary operation of device 14 during the first test period have been described as remote from caregiver location 18. It is anticipated that the uploading new programming and the first test period could also occur at caregiver location 18.

If the patient and caregiver concur that the function of device 14 and the patient's response to the function of device based on the new programming are adequate and desirable, device 14 can be instructed to operate for a second test period, at 112. During this second test period, patient 10 and device 14 would not necessarily need to remain directly adjacent to repeater 16, as required during the first test period. During the second test period, patient 10 may be ambulatory and would only need to periodically return to the proximity of repeater 16 so that repeater 16 can download information from device 14 to monitor function of device 14. Patient 10 may need to have the repeater 16 query device 14 one or several times a day. Repeater 16 may then communicate the status information from device 14 and possibly from patient 10 regarding function of device 14 back to the caregiver. Device 14 may include a function which records when the periodic transfer of information from device 14 to repeater 16 occurs. If too great of a time gap exists since the last transfer, device 14 may be programmed to automatically revert to delivering therapy based on the normal programming in memory 24, at 118. The limit on the acceptable time gap prior to reversion to therapy delivery based on normal programming may be varied to meet the particular needs and circumstances of the patient.

Provided that repeater 16 and device 14 remain in periodic communication, the operation of device 14 delivering therapy based on the new programming is allowed to continue for the duration of the second test period, at 120. Upon completion of the second test period, at 122, patient 10 is again queried as the effectiveness and desirability of therapy based on the new programming. At this point or at any time during the second test period, if the patient finds the therapy produces undesirable results, the patient may request that device 14 be instructed by repeater 16 to revert to therapy delivery based on the normal programming. At 124, device 14 may be recording data regarding the health parameters of patient 10 which indicate the current or future health of the patient may be adversely affected, as

compared to desirable or acceptable health parameters programmed into device 14. If such adverse effects are sensed and/or recorded by device 14, device 14 may be programmed to automatically revert to delivering therapy based on the normal programming, at 132. Alternatively, repeater 16 may provide the analysis tools required to verify if the parameters sensed by device 14 are within pre-programmed acceptable parameters. If the parameters are determined by repeater 16 to be outside of an acceptable range, device 14 may be programmed to revert automatically to delivering therapy based on the normal programming, at 132.

At the completion of the second test period, or at any time during the second test period, the caregiver may also determine that the therapy delivered based on the new programming is acceptable or unacceptable, at 128. At the completion of the second test period or at any time during the second test period, if the caregiver decides that the therapy based on the new programming is not acceptable, at 134, the caregiver may communicate instructions to device 14 through repeater 16 to revert to delivering therapy based on the normal programming in memory 24. Alternatively, repeater 16 may include a button, switch or other feature permitting patient 10 to provide the instruction to device 14 to revert to normal programming within memory 24. Alternatively, patient 10 may be provided with a separate device, such as a hand-held device, to revert IMD to function according to the normal programming within memory 24.

If the caregiver determines the new programming and the therapy delivered based on the new programming are acceptable, at 130, device 14 may be instructed to write the new programming into memory 24, over-writing the existing normal programming. Once written into memory 24, the new programming can be relabeled the normal programming, and device 14 can deliver therapy based on the programming newly written in memory 24 without additional contact with repeater 16 being required.

FIGS. 4A and 4B illustrate the uploading and testing of the delivery of therapy by device 14 based on new programming. The process of FIGS. 4A and 4B is similar to the process detailed above, with regard to FIGS. 3A and 3B, with device 14 including a patient actuable switch 30 for reverting device 14 to therapy delivery based on the normal programming. At 108, if patient 10 determines that the therapy delivery based on the new programming is not acceptable, patient 10 may, at 136, deliver instructions to device 14 directly to revert to therapy based on the

normal programming. Patient 10 need not involve the caregiver in the reversion. Instructions to device 14 from patient 10 may be delivered by actuation of switch 30.

In FIG. 4B, during and following the second test period, the patient may also take the initiative to revert device 14 to delivering therapy based on the normal programming, at 126 and 138. Patient 10 may still report acceptable or non-acceptable function of device 14 at 122 and the caregiver may send instructions to revert device 14 to delivering therapy based on the normal programming. However, patient 10 may still have the ability to revert device 14 to normal programming, at 138. Instructions to device 14 from patient 10 may be delivered by actuation of switch 30.

The embodiments of the inventions disclosed herein have been discussed for the purpose of familiarizing the reader with novel aspects of the present invention. Although preferred embodiments have been shown and described, many changes, modifications, and substitutions may be made by one having skill in the art without unnecessarily departing from the spirit and scope of the present invention. Having described preferred aspects and embodiments of the present invention, modifications and equivalents of the disclosed concepts may readily occur to one skilled in the art. However, it is intended that such modifications and equivalents be included within the scope of the claims which are appended hereto.

What is claimed is:

1. A system for programming an implanted medical device comprising:

a medical device configured to be implanted within in a body of a patient;

the medical device including electrical circuitry to provide treatment to the patient, a first digital storage area for holding normal operation instructions and settings, a second digital storage area for holding temporary operating instructions and settings, a communications subsystem and a timing subsystem;

a repeater external of the patient's body, the repeater including a communication subsystem configured to communicate with the communications subsystem of the medical device;

the patient, the medical device and the repeater remotely located from a caregiver facility;

the medical device configured to provide therapy to the patient using the normal operation instructions and settings stored in the first digital storage area;

the repeater configured to transmit temporary operation instructions and settings to the medical device for storage in the second digital storage area;

the repeater configured to instruct the medical device to use the temporary operating instructions and settings to deliver therapy to the patient;

wherein after the medical device has begun delivering therapy using the temporary operation instructions and settings, the medical device will revert to the normal operation instructions and settings if the medical device fails to receive a generally continuous continuation signal from the repeater during a first predetermined period of time.

2. The system of claim 1, wherein the device is configured to revert to delivery of therapy to the patient based on the normal operation instructions if the device does not receive a periodic continuation signal from the repeater during a second predetermined period of time.

3. The system of claim 2, wherein the patient is ambulatory during the second predetermined period of time.

4. The system of claim 1, wherein the device is configured to replace the normal operation instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions after the second predetermined period of time.

5. The system of claim 1, wherein the device is configured to revert to delivery of therapy to the patient based on the normal operation instructions after the second predetermined period of time, unless instructed to replace the normal operation instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions.

6. The system of claim 1, wherein the repeater is configured to signal the device to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions.

7. The system of claim 1, wherein the repeater is configured to signal to the device to revert to delivery of therapy to the patient based on the normal operation instructions, and remove the temporary operation instructions from the second digital storage area.

8. The system of claim 1, wherein the device is configured to sense patient response to the therapy based on the temporary operation instructions and revert to delivering therapy based on the normal operation instructions if the device senses an adverse response to the therapy based on the temporary operation instructions.

9. The system of claim 1, wherein the device is configured to sense patient response to the therapy based on the temporary operation instructions and, if the response is acceptable, to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions.

10. The system of claim 1, wherein the repeater is configured to receive data from the device regarding patient response to therapy delivered based on the

temporary operation instructions and communicating to the device to revert to delivering therapy based on the normal operation instructions if the patient response to therapy based on the temporary operation instructions is adverse.

11. The system of claim 1, wherein the repeater is configured to receive data from the device regarding patient response to therapy delivered based on the temporary operation instructions and, if the response is acceptable, to signal the device to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions.

12. The system of claim 1, wherein the device is configured to respond to the patient signaling the device by reverting to delivering therapy based on the normal operation instructions if the temporary operation instructions do not provide acceptable patient response.

13. The system of claim 12, wherein the patient signals the device to revert to delivering therapy based on the normal operation instructions using a magnet.

14. The system of claim 12, wherein the patient signals the device to revert to delivering therapy based on the normal operation instructions using an electronic wand.

15. The system of claim 1, wherein the device is configured to respond to the patient signaling the device by replacing the normal operation instructions with the temporary operation instructions and normally delivering therapy to the patient based on the formerly temporary operation instructions.

16. The system of claim 15, wherein the patient signals the device to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions using a magnet.

17. The system of claim 15, wherein the patient signals the device to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions using an electronic wand.

18. The system of claim 1, wherein the device is configured to respond to the caregiver signaling the device by reverting to delivering therapy based on the normal operation instructions if the temporary operation instructions do not provide acceptable patient response.

19. The system of claim 18, wherein the caregiver signals the device to revert to delivering therapy based on the normal operation instructions using a magnet.

20. The system of claim 18, wherein the caregiver signals the device to revert to delivering therapy based on the normal operation instructions using an electronic wand.

21. A method of providing therapy to a patient with a programmable implantable medical device, the method comprising:

providing the patient, the programmable implantable medical device and an external repeater remotely located from a caregiver facility, the device delivering therapy to the patient based on normal operating instructions stored in a first memory of the device;

a physician at the caregiver facility communicating temporary operating instructions to the repeater;

the repeater communicating the temporary operating instructions to the device, and the device storing the temporary operating instructions in a second memory;

the repeater communicating with the device to begin delivering therapy to the patient based on the temporary operating instructions;

the device reverting to delivering therapy to the patient based on the normal operating instructions if the device does not receive a generally continuous continuation signal from the repeater during a first predetermined period of time.

22. The method of claim 21, further comprising the device reverting to delivering therapy to the patient based on the normal operating instructions if the device does not receive a periodic continuation signal from the repeater within a second predetermined period of time.

23. The method of claim 22, wherein the patient is ambulatory during the second predetermined period of time.

24. The method of claim 21, further comprising the device replacing the normal operating instructions with the temporary operating instructions and normally delivering therapy to the patient based on the formerly temporary operating instructions after the second predetermined period of time.

25. The method of claim 21, further comprising the device is not instructed to replace the normal operation instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions, and the device reverting to delivery of therapy to the patient based on the normal operation instructions after the second predetermined period of time.

26. The method of claim 21, further comprising the repeater signaling the device to replace the normal instructions with the temporary instructions and normally provide therapy to the patient based on the formerly temporary instructions.

27. The method of claim 21, further comprising the repeater signaling the device to revert to delivery of therapy to the patient based on the normal operation instructions, and remove the temporary operation instructions from the second digital storage area.

28. The method of claim 21, further comprising the device sensing patient response to the therapy based on the temporary instructions and reverting to delivering therapy based on the normal instructions if the device senses an adverse response to the therapy based on the temporary instructions.

29. The method of claim 21, further comprising the device sensing patient response to the therapy based on the temporary operation instructions and, if the response is acceptable, replacing the normal instructions with the temporary operation instructions and delivering therapy to the patient based on the formerly temporary operation instructions.

30. The method of claim 21, further comprising the repeater receiving data from the device regarding patient response to therapy delivered based on the temporary instructions and communicating to the device to revert to delivering therapy based on the normal instructions if the patient response to therapy based on the temporary instructions is adverse.

31. The method of claim 21, further comprising the repeater receiving data from the device regarding patient response to therapy delivered based on the temporary operation instructions and, if the response is acceptable, signaling the device to replace the normal instructions with the temporary operation instructions and deliver therapy to the patient based on the formerly temporary operation instructions.

32. The method of claim 21, further comprising the patient signaling the device to revert to delivering therapy based on the normal operation instructions if the temporary operation instructions do not provide acceptable patient response.

33. The method of claim 32, wherein the patient signals the device using a magnet.

34. The method of claim 32, wherein the patient signals the patient with an electronic wand.

35. The method of claim 21, further comprising the device responding to a signal from the patient by replacing the normal operation instructions with the temporary operation instructions and delivering therapy to the patient based on the formerly temporary operation instructions.

36. The method of claim 35, further comprising the patient signaling the device to replace the normal instructions with the temporary operation instructions and deliver therapy to the patient based on the formerly temporary operation instructions using a magnet.

37. The method of claim 35, further comprising the patient signaling the device to replace the normal instructions with the temporary operation instructions and deliver therapy to the patient based on the formerly temporary operation instructions using an electronic wand.

38. The method of claim 21, further comprising the device responding to a signal from the caregiver by reverting to delivering therapy based on the normal operation instructions if the temporary operation instructions do not provide acceptable patient response.

39. The method of claim 38, wherein the caregiver signals the device to revert to delivering therapy based on the normal operation instructions using a magnet.

40. The method of claim 38, wherein the caregiver signals the device to revert to delivering therapy based on the normal operation instructions using an electronic wand.

41. The method of claim 32, further comprising the patient instructing the repeater to signal the device to revert to delivering therapy based on the normal instructions if the temporary instructions do not provide acceptable patient response.

42. A system for programming an implanted medical device comprising:

a medical device implanted within in a body of a patient, the medical device including electrical circuitry to provide treatment to the patient, a first digital storage area for holding normal operation instructions and settings, a second digital storage area for holding temporary operating instructions and settings, a communications subsystem and a timing subsystem;

a repeater external of the patient's body, the repeater including a communication subsystem configured to communicate with the communications subsystem of the medical device;

the implanted medical device configured to provide therapy to the patient using the normal operation instructions and settings stored in the first digital storage area;

the repeater configured to transmit temporary operation instructions and settings to the medical device for storage in the second digital storage area;

the repeater configured to instruct the medical device to use the temporary operating instructions and settings to deliver therapy to the patient;

wherein after the medical device has begun delivering therapy using the temporary operation instructions and settings, the medical device is configured revert to delivering therapy using the normal operation instructions and settings if the medical device fails to receive a generally continuous continuation signal from the repeater during a first predetermined period of time;

wherein after the first predetermined period of time, the patient is ambulatory and the medical device is configured to revert back delivering therapy using the normal operation instructions and settings if the medical device fails to receive a periodic continuation signal from the repeater during a second predetermined period of time.

43. The system of claim 42, wherein the device is configured to replace the normal operation instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions after the second predetermined period of time.

44. The system of claim 42, wherein the repeater is configured to signal the device to replace the normal instructions with the temporary operation instructions and normally deliver therapy to the patient based on the formerly temporary operation instructions.

45. The system of claim 42, wherein the device is configured to sense patient response to the therapy based on the temporary operation instructions and revert to

delivering therapy based on the normal operation instructions if the device senses an adverse response to the therapy based on the temporary operation instructions.

46. The system of claim 42, wherein the repeater is configured to receive data from the device regarding patient response to therapy delivered based on the temporary operation instructions and communicating to the device to revert to delivering therapy based on the normal operation instructions if the patient response to therapy based on the temporary operation instructions is adverse.

47. The system of claim 42, wherein the device is configured to respond to the patient signaling the device by reverting to delivering therapy based on the normal operation instructions if the temporary operation instructions do not provide acceptable patient response.

48. The system of claim 47, wherein the patient signals the device to revert to delivering therapy based on the normal operation instructions using a magnet.

49. The system of claim 47, wherein the patient signals the device to revert to delivering therapy based on the normal operation instructions using an electronic wand.

50. A method of providing therapy to a patient with a programmable implantable medical device, the method comprising:

providing the patient, the programmable implantable medical device and an external repeater;

delivering therapy with the device to the patient based on normal operating instructions stored in a first memory of the device;

communicating temporary operating instructions to the repeater;

communicating the temporary operating instructions to the device with the repeater;

storing the temporary operating instructions in a second memory of the device;

communicating to the device with the repeater, instructing the device to begin delivering therapy to the patient based on the temporary operating instructions;

reverting the device to delivering therapy to the patient based on the normal operating instructions if the device does not receive a generally continuous continuation signal from the repeater during a first predetermined period of time;

while the patient is ambulatory, delivering therapy to the patient with the device based on the temporary operating instructions during a second predetermined period of time when the device receives a periodic continuation signal from the repeater;

while the patient is ambulatory during the second predetermined period of time, reverting the device to delivering therapy to the patient based on the normal operating instructions if the device does not receive a periodic continuation signal from the repeater during the second predetermined period of time.

51. The method of claim 50, further comprising the device replacing the normal operating instructions with the temporary operating instructions and normally delivering therapy to the patient based on the formerly temporary operating instructions after the second predetermined period of time.

52. The method of claim 50, further comprising the repeater signaling the device to replace the normal instructions with the temporary instructions and normally provide therapy to the patient based on the formerly temporary instructions.

53. The method of claim 50, further comprising the device sensing patient response to the therapy based on the temporary instructions and reverting to delivering therapy based on the normal instructions if the device senses an adverse response to the therapy based on the temporary instructions.

54. The method of claim 50, further comprising the repeater receiving data from the device regarding patient response to therapy delivered based on the temporary instructions and communicating to the device to revert to delivering therapy based on the normal instructions if the patient response to therapy based on the temporary instructions is adverse.

55. The method of claim 50, further comprising the patient signaling the device to revert to delivering therapy based on the normal instructions if the temporary instructions do not provide acceptable patient response.

56. The method of claim 55, wherein the patient signals the device using a magnet.

57. The method of claim 55, wherein the patient signals the patient with an electronic wand.

FIG.1

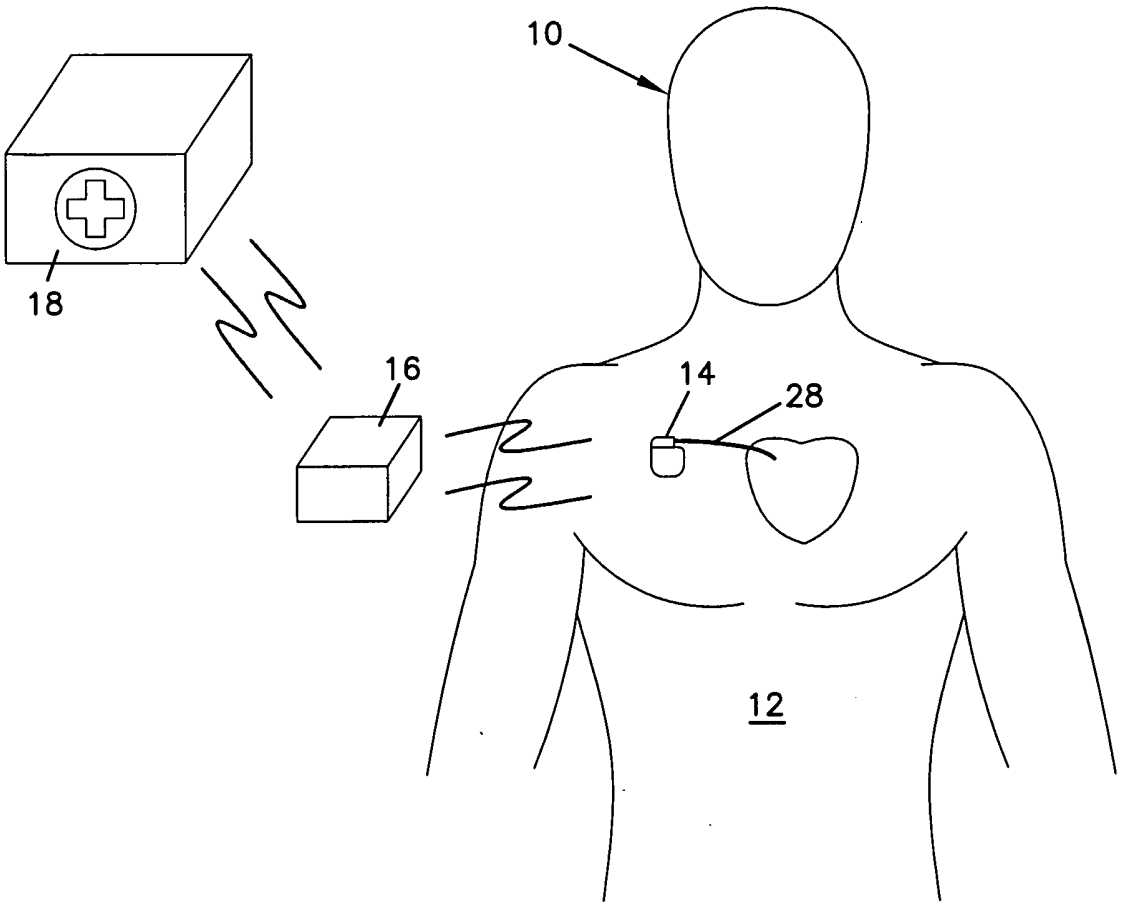


FIG.2

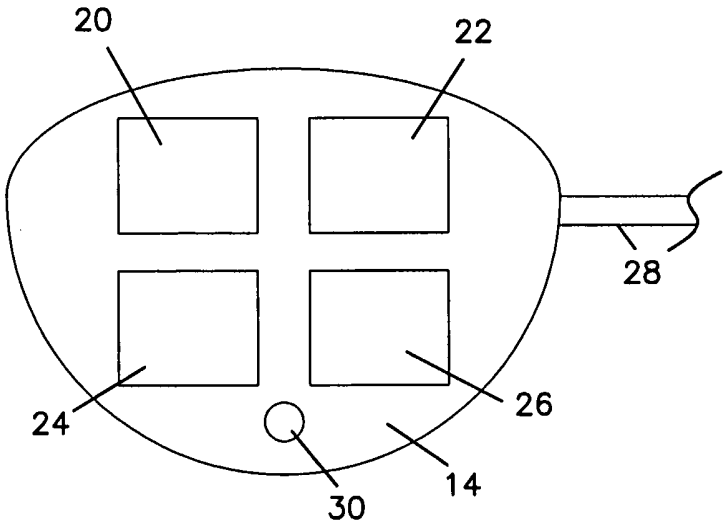


FIG. 3A

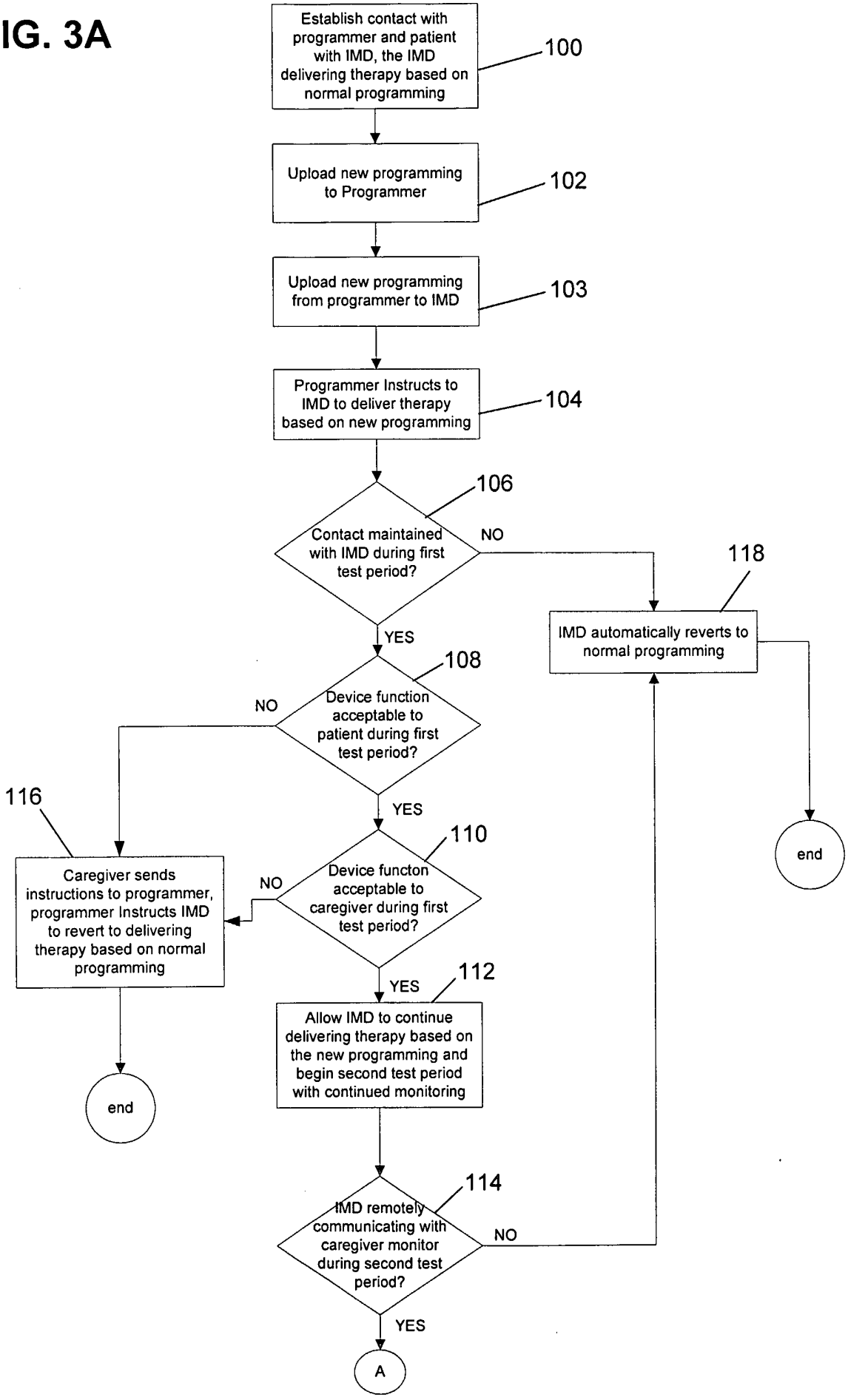

Establish contact with programmer and patient with IMD, the IMD delivering therapy based on normal programming
100
Upload new programming to Programmer
102
Upload new programming from programmer to IMD
103
Programmer Instructs to IMD to deliver therapy based on new programming
104
106
Contact maintained with IMD during first test period?
NO
YES
118
IMD automatically reverts to normal programming
end
108
Device function acceptable to patient during first test period?
NO
YES
116
Caregiver sends instructions to programmer, programmer Instructs IMD to revert to delivering therapy based on normal programming
110
Device functon acceptable to caregiver during first test period?
NO
YES
112
Allow IMD to continue delivering therapy based on the new programming and begin second test period with continued monitoring
end
114
IMD remotely communicating with caregiver monitor during second test period?
NO
YES
A

FIG. 3B

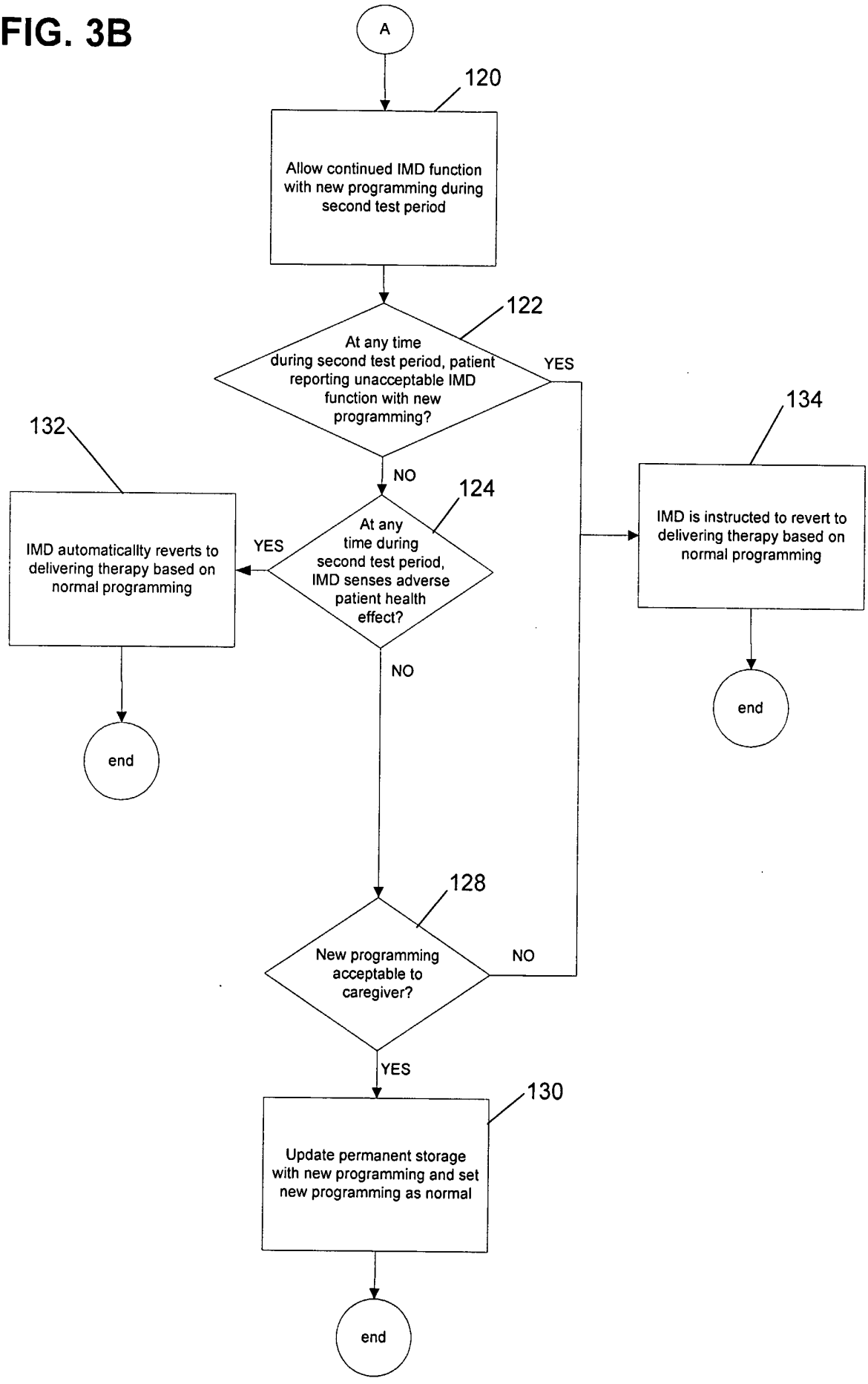

A
120
Allow continued IMD function with new programming during second test period
122
At any time during second test period, patient reporting unacceptable IMD function with new programming?
YES
NO
132
IMD automaticallty reverts to delivering therapy based on normal programming
124
At any time during second test period, IMD senses adverse patient health effect?
YES
NO
134
IMD is instructed to revert to delivering therapy based on normal programming
end
end
128
New programming acceptable to caregiver?
NO
YES
130
Update permanent storage with new programming and set new programming as normal
end

FIG. 4A

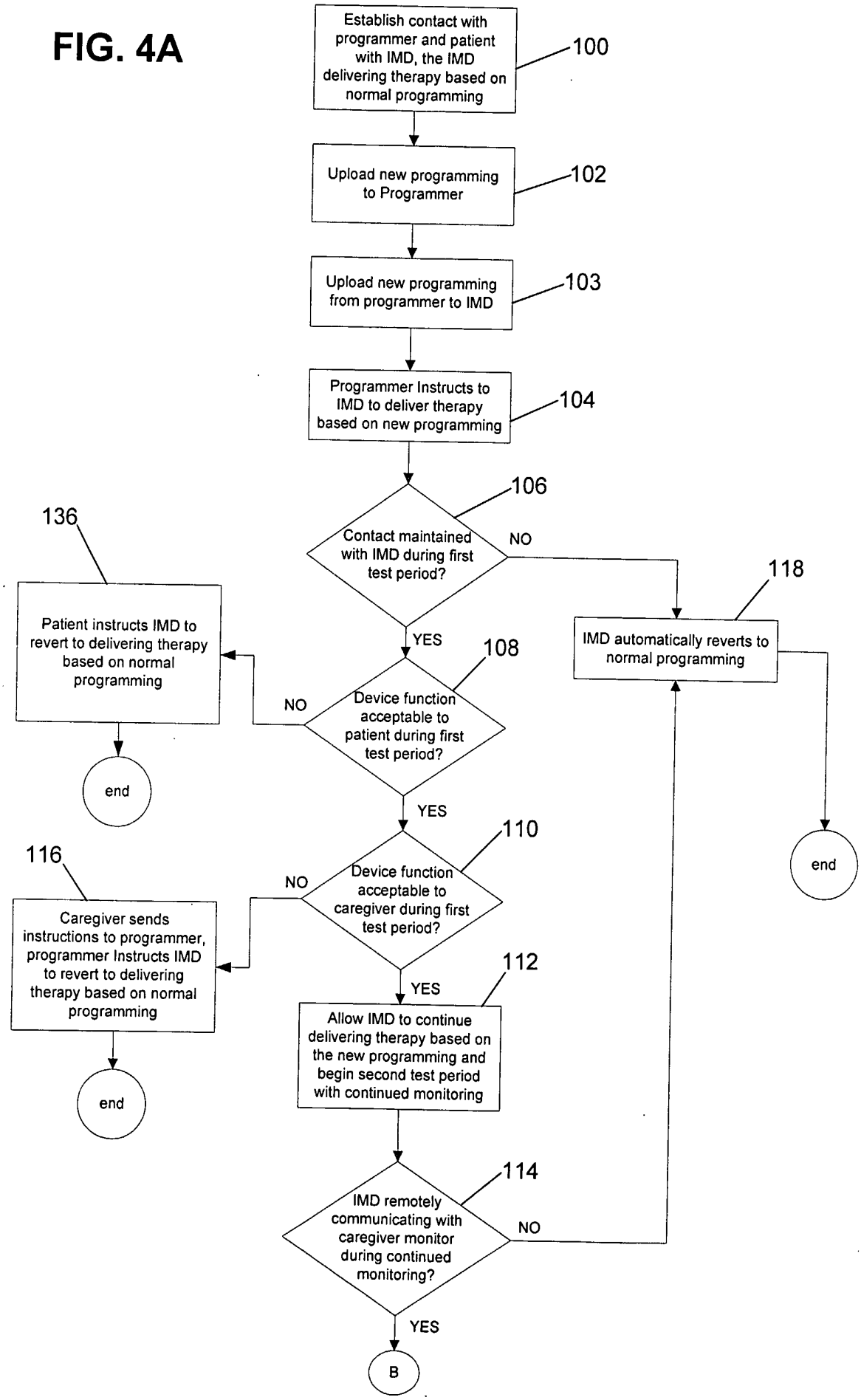
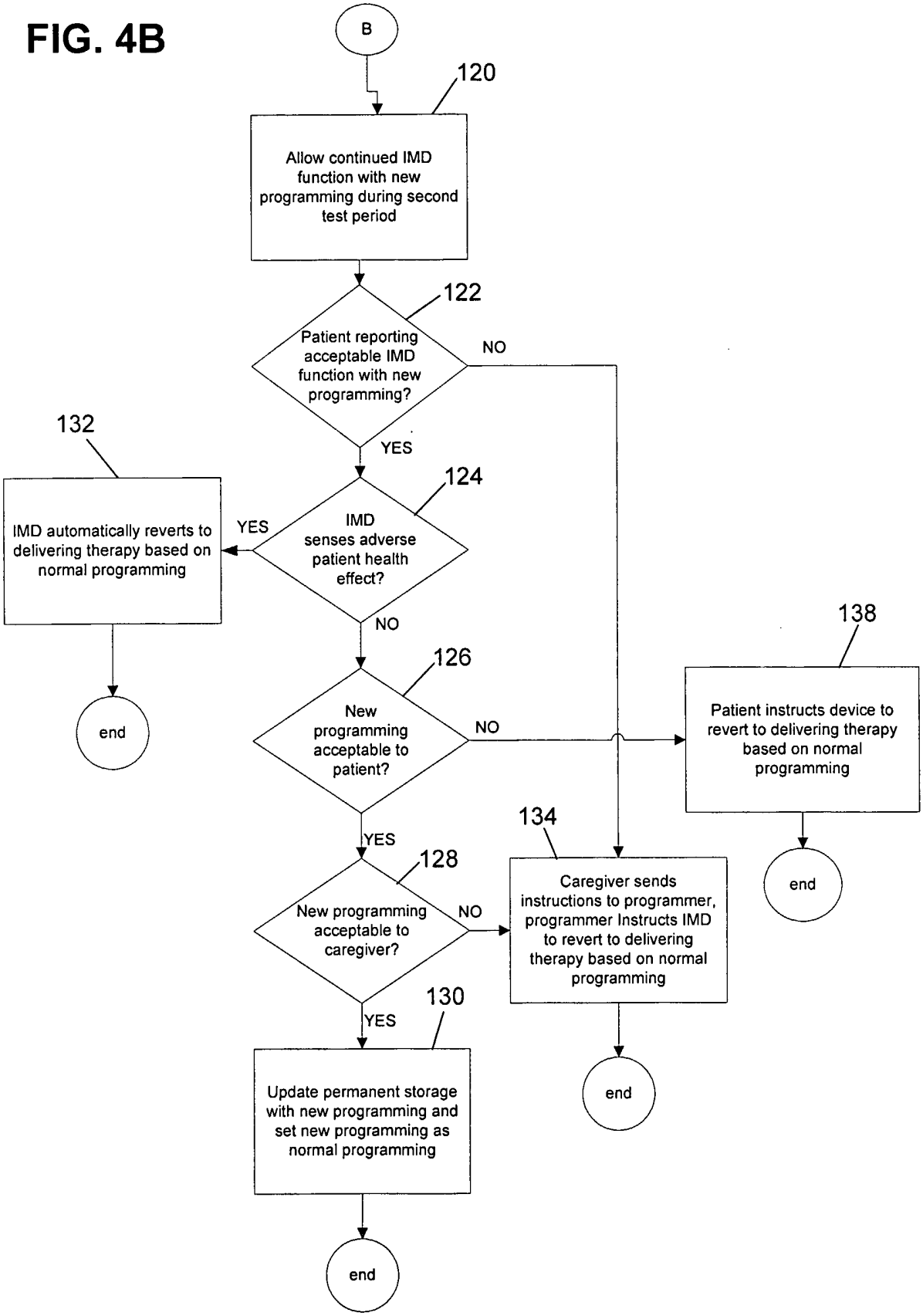

Establish contact with programmer and patient with IMD, the IMD delivering therapy based on normal programming
100
Upload new programming to Programmer
102
Upload new programming from programmer to IMD
103
Programmer Instructs to IMD to deliver therapy based on new programming
104
106
Contact maintained with IMD during first test period?
NO
YES
118
IMD automatically reverts to normal programming
end
136
Patient instructs IMD to revert to delivering therapy based on normal programming
end
108
Device function acceptable to patient during first test period?
NO
YES
110
Device function acceptable to caregiver during first test period?
116
Caregiver sends instructions to programmer, programmer Instructs IMD to revert to delivering therapy based on normal programming
end
NO
YES
112
Allow IMD to continue delivering therapy based on the new programming and begin second test period with continued monitoring
114
IMD remotely communicating with caregiver monitor during continued monitoring?
NO
YES
B

FIG. 4B


B
120
Allow continued IMD function with new programming during second test period
122
Patient reporting acceptable IMD function with new programming?
NO
YES
132
IMD automatically reverts to delivering therapy based on normal programming
YES
124
IMD senses adverse patient health effect?
NO
end
126
New programming acceptable to patient?
NO
138
Patient instructs device to revert to delivering therapy based on normal programming
end
YES
134
128
New programming acceptable to caregiver?
NO
Caregiver sends instructions to programmer, programmer Instructs IMD to revert to delivering therapy based on normal programming
YES
130
Update permanent storage with new programming and set new programming as normal programming
end
end

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/036811

A. CLASSIFICATION OF SUBJECT MATTER
A61N1/372

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 G06F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	US 2006/030904 A1 (QUILES SYLVIA) 9 February 2006 (2006-02-09) p. 2, [0022] - p. 3, [0029]; p. 6, [0056] - p. 8, [0070]; figures 1-2B,5A-6	1-20, 42-49
X	US 4 253 466 A (HARTLAUB ET AL) 3 March 1981 (1981-03-03)	1,2,42
A	column 3, line 5 - column 6, line 8 column 16, line 44 - column 18, line 22; claim 14; figures 1,3-5C	3-20, 43-49

-/--

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

[X] 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 document 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	Date of mailing of the international search report
7 March 2006	20/03/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Fischer, O

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 515 160 A (KEIMEL ET AL) 7 May 1985 (1985-05-07)	1
A	column 1, line 63 - column 2, line 53; claim 1; figures 1-3	2-20, 42-49
A	US 5 456 692 A (SMITH, JR. ET AL) 10 October 1995 (1995-10-10) column 12, line 66 - column 13, line 17; figures 1-4	1-20, 42-49
A	US 2001/037220 A1 (MERRY RANDY L ET AL) 1 November 2001 (2001-11-01) abstract; figures 1-3	1-20, 42-49

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/036811

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-41,50-57
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy and surgery: method claims 21 and 50 include the step of delivering therapy to the patient unsing a surgically implanted medical device.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2005/036811

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006030904 A1	09-02-2006	NONE	
US 4253466 A	03-03-1981	NONE	
US 4515160 A	07-05-1985	NONE	
US 5456692 A	10-10-1995	NONE	
US 2001037220 A1	01-11-2001	NONE	