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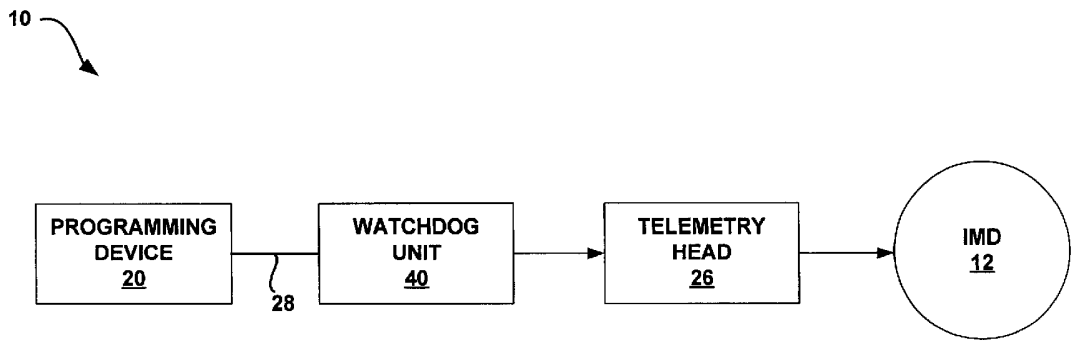

(57) Abstract: A watchdog unit receives stay-alive signals from a programming device during programming of an implantable medical device. The watchdog unit maintains a watchdog timer, and resets the timer upon receipt of each stay-alive signal. If the watchdog timer expires, the watchdog unit changes a mode of operation of the implantable device, e.g., places the implantable medical device into a known, safe state. For example, the watchdog unit may cause the implantable medical device to suspend delivery of therapy, perform a power-on reset, and/or recall a known, safe, therapy delivery program.

WO 2004/041359 A1

FAILSAFE PROGRAMMING OF IMPLANTABLE MEDICAL DEVICES

[0001] This application claims priority from U.S. Provisional Application Serial No. 60/422,259, filed October 31, 2002, and U.S. Provisional Application Serial No. 60/503,224, filed September 15, 2003.

[0002] The invention relates to medical devices, and more particularly, to programming of implantable medical devices.

[0003] A variety of types of implantable medical devices are used to deliver therapies to patients. For example, implantable pulse generators are used to deliver neurostimulation and cardiac pacing therapies to patients. As another example, implantable pumps are used to deliver therapeutic agents to patients.

[0004] Typically, a clinician uses a programming device, e.g., a clinician programmer, to program aspects of the operation of an implantable medical device after it has been implanted in a patient. Programming devices are computing devices capable of communicating with implantable medical devices through patient body tissue via device telemetry. To facilitate communication with an implantable medical device, a programming device may be coupled to a programming head that is placed on the surface of the patient at a position proximate to location of the implantable medical device within the patient.

[0005] A trend in the implantable medical device arts is the ever-increasing complexity of the devices themselves, and the firmware that controls the operation of the devices. For example, many modern implantable medical devices provide a variety of therapy delivery and/or patient monitoring modes, which may be selected and configured by the clinician during a programming session. During a programming session, the clinician may also need to select values for a variety of programmable parameters, threshold values, or the like, that control aspects the delivery of therapy.

[0006] Consequently, programming devices, and more particularly the software that allows a clinician to select modes and/or values for programmable parameters, have become increasingly complex. Programming sessions may involve trial-and-error testing of various modes and/or parameter values. In some cases, a programming session may be automated or semi-automated, e.g., conducted by a clinician or patient, with an algorithm executed by the programming device

controlling at least some of the selection of new modes and/or parameter values to test. Such testing requires frequent telemetry communication between the programming device and the implantable medical device as new modes and/or parameters selected by the clinician, the patient, or an algorithm are communicated from the programming device to the implantable medical device.

[0007] It is possible for the complex programming software executed by programming devices to have hidden failure modes that do not become apparent, even with extensive validation and testing. It is also possible for the physical cable between a programming device and a telemetry head, the telemetry head itself, or the RF telemetry link between the programming device and the implantable medical device to fail. If one or more such failures occur during a programming session, e.g., during communication of a new mode or new parameter values to the implantable medical device, the incomplete and/or inaccurate transfer of data may leave the implantable medical device operating in an undesirable and potentially unsafe configuration. Moreover, because of the failure of communication between the programming device and the implantable medical device, a clinician may be left with no immediate means to remove the implantable medical device from the unsafe condition.

[0008] In general, the invention is directed toward techniques for failsafe programming of implantable medical devices (IMDs). A watchdog unit receives stay-alive signals from a programming device during programming of an IMD. The watchdog unit maintains a watchdog timer, and resets the timer upon receipt of each stay-alive signal. If the watchdog timer expires, the watchdog unit changes a mode of operation of the implantable device, e.g., places the implantable medical device into a known, safe state, to avoid the IMD being left in an undesirable and potentially unsafe state with no immediate means to remove it from such a state. For example, the watchdog unit may cause the implantable medical device to suspend delivery of therapy, perform a power-on reset, and/or recall a known, safe, therapy delivery program.

[0009] The watchdog unit may be located on a cable that connects the programming device to a telemetry head used to communicate with the IMD, may couple the cable to the telemetry head, may be located within the telemetry head,

or may be located within the IMD. Consequently, in some embodiments, the stay-alive signals may be active transitions of a data line of the data cable, or wireless telemetry signals. The watchdog unit may be embodied as hardware, a software module, or a combination of hardware and software.

[0010] In one embodiment, the invention is directed to a method in which stay-alive signals are received from a programming device during the course of a wireless telemetry session between the programming device and an IMD, and a watchdog timer is reset in response to receipt of each of the stay-alive signals. A mode of operation of the IMD is changed in response to expiration of the watchdog timer.

[0011] In another embodiment, the invention is directed to a device that includes a telemetry circuit and a processor. The processor receives stay-alive signals from a programming device during the course of a wireless telemetry session between the programming device and an IMD, and resets a watchdog timer in response to receipt of each of the stay-alive signals. The processor sends a signal to the IMD via the telemetry circuit to change a mode of operation of the IMD in response to expiration of the watchdog timer.

[0012] In another embodiment, the invention is directed to an IMD that includes a telemetry circuit and a watchdog unit. The watchdog unit receives stay-alive signals from a programming device via the telemetry circuit during the course of a wireless telemetry session between the programming device and the IMD, and resets a watchdog timer in response to receipt of each of the stay-alive signals. The watchdog unit changes a mode of operation of the IMD in response to expiration of the watchdog timer.

[0013] In another embodiment, the invention is directed to a computer-readable medium containing instructions. The instructions cause a programmable processor to receive stay alive signals from a programming device during the course of a wireless telemetry session between the programming device and an IMD, reset a watchdog timer in response to receipt of each of the stay-alive signals, and change a mode of operation of the IMD in response to expiration of the watchdog timer.

[0014] In another embodiment, the invention is directed to a method in which programming signals that affect the operation of an IMD are sent to the IMD via

wireless telemetry during a programming operation, and stay-alive signals are sent to a watchdog unit during the programming operation to allow the watchdog unit to detect failure of a wireless telemetry session between a programming device and the IMD during the programming operation.

[0015] In another embodiment, the invention is directed to a programming device that includes a telemetry circuit and a processor. The processor sends programming signals that affect the operation of an IMD to the IMD via the telemetry circuit during a programming operation, and sends stay-alive signals to a watchdog unit during the programming operation to allow the watchdog unit to detect failure of a wireless telemetry session between the programming device and the IMD during the programming operation.

[0016] In another embodiment, the invention is directed to a computer-readable medium containing instructions. The instructions cause a programmable processor to send programming signals that affect operation of an IMD to the IMD via wireless telemetry during a programming operation, and send stay-alive signals to a watchdog unit during the programming operation to allow the watchdog unit to detect failure of a wireless telemetry session between a programming device and the IMD during the programming operation.

[0017] The invention may provide advantages. For example, a watchdog unit according to the invention may quickly remove an IMD from an undesirable and unsafe state caused by a failure during programming of the IMD. By maintaining a watchdog timer and resetting the watchdog timer upon receipt of stay-alive signals, a watchdog unit according to the invention may detect hardware or software failures of the programming device, and failure of the cable that couples the programming device to the telemetry head. In embodiments where the watchdog unit is located within the IMD, which are preferred, the watchdog unit may additionally detect failure of the telemetry head, the radio-frequency telemetry connection between the telemetry head and the IMD, and telemetry circuitry of the IMD. However, embodiments wherein the watchdog unit is located outside the IMD may advantageously be used during programming of existing IMDs.

[0018] FIG. 1 is a conceptual diagram illustrating a system in which an example implantable medical device is programmed using failsafe programming techniques according to the invention.

[0019] FIG. 2 is a block diagram further illustrating the system of FIG. 1 according to an embodiment of the invention in which the system includes a watchdog unit that facilitates failsafe programming of the implantable medical device of FIG. 1.

[0020] FIG. 3 is a block diagram further illustrating the watchdog unit of FIG. 2 according to an embodiment of the invention.

[0021] FIG. 4 is a block diagram illustrating the implantable medical device of FIG. 1 according to an embodiment of the invention in which the implantable medical device includes a watchdog unit.

[0022] FIG. 5 is a block diagram illustrating an exemplary programming device that facilitates failsafe programming of the implantable medical device of FIG. 1.

[0023] FIG. 6 is a flow diagram illustrating exemplary operation of the programming device of FIG. 5 to facilitate failsafe programming of the implantable medical of FIG. 1.

[0024] FIG. 7 is a flow diagram illustrating exemplary operation of the watchdog unit of FIG. 3 to facilitate failsafe programming of the implantable medical device of FIG. 1.

[0025] FIG. 1 is a conceptual diagram illustrating a system 10 in which an example implantable medical device (IMD) 12 is programmed using failsafe programming techniques according to the invention. IMD 12 is shown in FIG. 1 implanted within a patient 14. In the illustrated embodiment, IMD 12 takes the form of an implantable neurostimulator (INS) that delivers neurostimulation therapy to patient 12 via leads 16A and 16B (hereinafter "leads 16").

[0026] Specifically, in the illustrated configuration, leads 16 are implanted proximate to the spinal cord 18 of patient 14, and IMD 12 delivers spinal cord stimulation (SCS) therapy to patient 14 in order to, for example, reduce pain experienced by patient 14. Leads 16 include electrodes (not shown in FIG. 1), and IMD 12 delivers neurostimulation to spinal cord 18 via the electrodes. IMD 12 may be an implantable pulse generator, and may deliver neurostimulation to spinal cord 18 in the form of electrical pulses.

[0027] IMD 12 delivers neurostimulation according to a program. The program may include values for a number of parameters, and the parameter values define the neurostimulation therapy delivered according to that program. In embodiments where IMD 12 delivers neurostimulation therapy in the form of electrical pulses, the parameters may include voltage or current pulse amplitudes, pulse widths, pulse rates, and the like. Further, the parameters for a program include information identifying which electrodes have been selected for delivery of pulses according to the program, and the polarities of the selected electrodes.

[0028] System 10 also includes a programming device 20. Programming device 20 may, as shown in FIG. 1, be a handheld computing device. Programming device 20 includes a display 22, such as a LCD or LED display, to display information to a user. Programming device 20 may also include a keypad 24, which may be used by a user to interact with programming device 20. In some embodiments, display 22 may be a touch screen display, and a user may interact with programming device 20 via display 22. A user may additionally or alternatively interact with clinician programmer 20 using peripheral pointing devices, such as a stylus or mouse. Keypad 24 may take the form of an alphanumeric keypad or a reduced set of keys associated with particular functions.

[0029] A clinician (not shown) may use programming device 20 to program neurostimulation therapy for patient 12. In some embodiments, the clinician specifies programs by selecting program parameter values, and tests the specified programs on patient 12. In other embodiments, programming device 20 provides an automated or semi-automated programming routine in which programming device 20 generates programs and tests the generated programs on patients. In such embodiments, either or both of the clinician and patient 14 may interact with programming device 20 during testing of the generated programs. Further, in such embodiments, the clinician may interact with programming device 20 to confirm programs generated by programming device 20 for testing, and/or to select programs from among those automatically tested by programming device. An exemplary programming device that provides a semi-automated programming routine is described in U.S. Patent No. 6,308,102, issued to Sieracki et al.

[0030] In either case, programming device 20 sends each of the programs to be tested to IMD 12 using radio-frequency telemetry techniques known in the art. For example, programming device 20 may send program parameters as commands, and may send other commands necessary to effect reprogramming of IMD 12 via device telemetry. IMD 12 receives and decodes the commands, and stores the program parameters in registers, or the like, for use in defining the neurostimulation delivered to patient 14 according to that program. Programming device 20 is coupled to a telemetry head 26 via cable 28, and head 26 is placed in proximity to IMD 12 to facilitate telemetry communication between programming device 20 and IMD 12.

[0031] Programming device 20 sends a number of commands to IMD 12 to reprogram IMD 12 for each program tested during the programming session. In conventional systems, if IMD 12, cable 28, or telemetry head 26 were to fail during the transmission of commands necessary to reprogram IMD 12 for testing of a program, IMD 12 could be left in an undesirable or potentially dangerous state, e.g., could deliver undesirable or potentially dangerous neurostimulation according to an incomplete program. Moreover, in conventional systems, because IMD 12, cable 28, or head 26 had failed, the clinician and/or patient 14 might be left with no immediate means to remove IMD 12 from the undesirable or potentially dangerous state.

[0032] System 10, in accordance with the invention, includes a watchdog unit (not shown). The watchdog unit and programming device 20 provide for failsafe programming of IMD 12, as will be described in greater detail below. The watchdog unit may be embodied as a hardware device, as a software algorithm stored within a computer-readable medium and executed by a processor, or as a combination of hardware and software.

[0033] The watchdog unit may be located, for example, within telemetry head 26 or along cable 28. In some embodiments, the watchdog unit may couple cable 28 to head 26. In other embodiments, the watchdog unit is located within or provided by IMD 12.

[0034] FIG. 2 is a block diagram further illustrating system 10 according to an embodiment of the invention. As discussed above, system 10 includes IMD 12,

and programming device 20 coupled to telemetry head 26 by cable 28. System 10 further includes a watchdog unit 40, which in the illustrated embodiment couples cable 28 to head 26.

[0035] During a programming session, watchdog unit 40 maintains a watchdog timer. Programming device 20 sends stay-alive signals to watchdog unit 40 via cable 28 to indicate that programming device 20 is functioning properly, and watchdog unit 40 resets the watchdog timer in response to each of the stay-alive signals. In the event that watchdog unit 40 fails to receive a stay-alive signal before the watchdog timer expires, watchdog unit 40 sends one or more commands to IMD 12 via telemetry head 26 to change a mode of operation of IMD 12, e.g., to place IMD 12 in a known, safe state.

[0036] For example, watchdog unit 40 may send a command to IMD 12 to cause IMD 12 to stop delivering therapy and/or perform a power-on reset (POR). In some embodiments, watchdog unit 40 or IMD 12 stores a known, safe neurostimulation therapy program. In such embodiments, watchdog unit 40 may provide the program to IMD 12, or send a command to IMD 12 to cause IMD 12 to recall the program for delivery of neurostimulation therapy according to the program.

[0037] Programming device 20 sends a stay-alive signal to watchdog unit 40 periodically such that watchdog unit 40 receives a stay-alive signal before the watchdog timer expires. In exemplary embodiments, the stay-alive signals comprise transitions on one or more data lines of cable 28 that couple programming device 20 to watchdog unit 40. By requiring stay-alive signals to be active transitions on one or more data lines rather than passive hardware handshaking lines, watchdog unit 40 may avoid erroneously resetting the watchdog timer in situations where programming device 20 has failed but continues to generate the passive signal, e.g. the signal is "locked in" by failure of programming device 20. Programming device 20 may provide stay-alive signals upon execution of instructions of control software of programming device 20 that is used for transmission of programming commands to IMD 12, rather than as part of an independent thread or process, so that programming device 20 does not continue to

signal that it is operating properly despite the fact that the control software has failed.

[0038] Watchdog unit 40 receives signals, e.g., programming commands, from programming device 20 via cable 28 during a programming operation, e.g., a reprogramming of IMD 12 with a new program to test during a programming session, that are provided to telemetry head 26 for transmission to IMD 12. In exemplary embodiments, the signals are transitions on one or more data lines of cable 28 that couple programming device 20 to watchdog unit 40. In some embodiments, watchdog unit 40 resets the watchdog timer upon receipt of both programming signals and stay-alive signals, and programming device 20 provides dedicated stay-alive signals such that watchdog unit 40 receives either a programming signal or stay-alive signal before the watchdog timer expires. Programming device 20 may send programming signals and stay-alive signals on common or separate data lines of cable 28.

[0039] As described above, a programming session may include multiple programming operations, e.g., IMD 12 may be reprogrammed a number of times to test a number of programs. Further, the programming session may include a period between programming operations where non-critical communication, or no communication, between programming device 20 and IMD 12 is taking place. In order to avoid delivery of stay-alive signals and maintenance of the watchdog timer during periods between programming operations, e.g., non-critical periods, programming device 20 may only deliver stay-alive signals during programming operations, and may signal the beginnings and ends of programming operations to watchdog unit 40 to cause watchdog unit to maintain the watchdog timer only during the programming operations.

[0040] As described above, watchdog unit 40 maintains the watchdog timer to detect hardware or software failures of programming device 20, and place IMD 12 in a safe state in response to such a failure. Further, because the watchdog timer will also expire if cable 28 fails, watchdog unit 40 will detect a failure of cable 28, and place IMD 12 in a safe state in response to such a failure.

[0041] FIG. 3 is a block diagram further illustrating watchdog unit 40 according to an embodiment of the invention. As illustrated in FIG. 3, watchdog unit 40

includes a processor 50 that controls watchdog unit 40 to provide the functionality attributed to watchdog unit 40 herein. Processor 50 maintains the watchdog timer as described above, and receives programming signals and stay-alive signals from programming device 20 via one or more data lines of cable 28.

[0042] Watchdog unit 40 may include a telemetry circuit 52 that enables communication between watchdog unit 40 and IMD 12 (FIG. 1). Upon expiration of the watchdog timer, processor 50 sends a command to IMD 12 via telemetry circuit 52 and telemetry head 26 (FIG. 1) to change a mode of operation of IMD 12, e.g., to place IMD 12 in a known, safe state. As described above, the command may cause IMD 12 to suspend delivery of therapy, perform a POR, and/or recall a stored program. In some embodiments, upon expiration of the watchdog timer, processor 50 sends a program stored in a memory 54 to IMD 12 via telemetry circuit 52 and head 26 to cause IMD 12 to deliver therapy according to the program. During "normal" operation, e.g., when the watchdog timer has not expired, processor 50 sends programming signals received from programming device 20 to IMD 12 via telemetry head 26.

[0043] In exemplary embodiments, watchdog unit 40 receives power for operation from programming device 20 via cable 28. In such embodiments, watchdog unit 40 may also include an auxiliary power source 56. In the event that processor 50 detects a failure in the delivery of power from programming device 20, which may be caused by a hardware failure of device 20 or a failure of cable 28, processor 50 may activate auxiliary power source 56 and send a command to IMD 12 via telemetry circuit 54 to change a mode of operation of IMD 12.

[0044] Auxiliary power source 56 may be, for example, a rechargeable battery or capacitive element. In some embodiments, auxiliary power source 56 need only store enough power to allow processor 50 to send a command to IMD 12 to place IMD 12 in a known, safe state. Further, the invention is not limited to embodiments where watchdog unit 40 receives primary power from programming device 20, but instead includes embodiments where watchdog unit 40 houses a primary power source, such as a rechargeable or non-rechargeable battery.

[0045] In some embodiments, watchdog unit 40 provides an emergency shutdown circuit 58, which may be activated by a user, such as the clinician or patient 14

(FIG. 1). Upon activation of emergency shutdown circuit 58, processor 50 sends a command to IMD 12 via telemetry circuit 52 to cause IMD 12 to, for example, suspend delivery of therapy. Emergency shutdown circuit 58 may include, for example, a switch that is activated by the user pressing a button located on a housing of watchdog unit 40.

[0046] Processor 50 may include one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or the like. Memory 54 may store program instructions that cause processor 50 to provide the functionality ascribed to it herein. Memory 54 may include one or more volatile, non-volatile, magnetic, optical, or electrical media, such as read-only memory (ROM), random access memory (RAM), electrically-erasable programmable ROM (EEPROM), non-volatile RAM (NVRAM), flash memory, or the like. Memory 54 may include both on-board and off-board components.

[0047] FIG. 4 is a block diagram illustrating IMD 12 according to an embodiment of the invention in which IMD 12 includes a watchdog unit 60. Like watchdog unit 40, watchdog unit 60 receives stay-alive signals from programming device 20, resets a watchdog timer in response to receipt of stay-alive signals, and changes a mode of operation of IMD 12 in response to expiration of the watchdog timer. Watchdog unit 60 located within IMD 12 may detect failure of telemetry head 26 (FIG. 1), loss of the RF telemetry link between programming device 20 and IMD 12, and failure of a telemetry circuit 62 of IMD 12 in addition to hardware or software failures of programming device 20 and failure of cable 28 (FIG. 1).

[0048] IMD 12 delivers neurostimulation therapy via electrodes 64A-D of lead 16A and electrodes 64E-H of lead 16B (collectively "electrodes 64"). Electrodes 64 may be ring electrodes. The configuration, type and number of electrodes 64 illustrated in FIG. 2 are merely exemplary.

[0049] Electrodes 64 are electrically coupled to a therapy delivery circuit 66 via leads 16. Therapy delivery circuit 66 may, for example, include one or more output pulse generators, e.g., capacitive elements and switches, coupled to a power source such as a battery. Therapy delivery circuit 66 delivers electrical pulses to patient 14 via two or more of electrodes 64 under the control of a processor 68.

[0050] As described above, processor 68 controls therapy delivery circuit 66 to deliver neurostimulation therapy according to a program. Specifically, processor 68 may control circuit 66 to deliver electrical pulses with the amplitudes and widths, and at the rates specified by the program. Processor 68 may also control circuit 66 to deliver the pulses via a selected combination of electrodes 64, as specified by the program.

[0051] As described above, IMD 12 may be reprogrammed a number of times during a programming session to test a number of programs. For each program tested, IMD 12 receives a number of commands, including the program parameters, from programming device 20 via telemetry circuit 62 and watchdog unit 60. The program parameters are stored within a memory 70 as the program used by processor 68 to control delivery of neurostimulation.

[0052] Programming device 20 also sends stay-alive signals via RF device telemetry, which are received by watchdog unit 60 via telemetry circuit 62. Watchdog unit 60 may reset the watchdog timer upon receipt of each stay-alive signal, and may also reset the watchdog timer upon receipt of programming commands from programming device 20. In some embodiments, watchdog unit 60 also receives signals indicating the beginning and ending of a programming operation from programming device 20, and maintains the watchdog timer only during the indicated programming operations.

[0053] Watchdog unit 60 changes a mode of operation of IMD 12, e.g., places IMD 12 into a known safe state, upon expiration of the watchdog timer. Watchdog unit 60 may, for example, cause IMD 12 to suspend delivery of therapy, perform a POR, and/or activate a known, safe program stored in memory 70. The functionality attributed to watchdog unit 60 herein may be provided by processor 68, or by a separate processor. Where watchdog unit 60 is embodied within a separate processor, watchdog unit 60 may signal expiration of the watchdog timer to processor 68 to cause processor 68 to change a mode of operation of IMD 12 in any of the above-identified ways.

[0054] Processor 68 and watchdog unit 60 may include one or more of a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like. Memory 70 may include program instructions that, when executed by

processor 68 and watchdog unit 60, cause processor 68 and watchdog unit 60to perform the functions ascribed to processor 68 and watchdog unit 60 herein. Memory 70 may include one or more volatile, non-volatile, magnetic, optical, or electrical media, such as RAM, ROM, NVRAM, EEPROM, flash memory, and the like. Memory 70 may include on-board and/or off-board components.

[0055] FIG. 5 is a block diagram illustrating programming device 20 in greater detail. Programming device 20 includes a processor 80 and a user interface 82 that allows a user, such as the clinician or patient 14, to interact with processor 80. User interface 82 may include display 22 and keypad 24 (FIG. 1), and allow the user to, for example, select programs to test during a programming session.

[0056] Processor 80 may transmit programming signals, e.g., commands, to IMD 12 via a telemetry circuit 84 and telemetry head 26 (FIG. 1). Processor 80 also provides stay-alive signals to a watchdog unit 40 via a data line of cable 28 (FIG. 1), or to a watchdog unit 60 via telemetry circuit 84 and telemetry head 26, as described above. Processor 80 sends the stay-alive signals periodically, such that the watchdog unit 40, 60 receives a stay-alive signal before the watchdog timer expires.

[0057] In some embodiments, as described above, the watchdog unit 40, 60 resets the watchdog timer upon receipt of both programming signals and stay-alive signals, and processor 80 provides dedicated stay-alive signals such that the watchdog unit 40, 60 receives with a programming signal or stay-alive signal before the watchdog timer expires. In exemplary embodiments, processor 80 provides stay-alive signals upon execution of instructions of control software of programming device 20. Further, in order to avoid delivery of stay-alive signals during period where there is no communication or non-critical communication with IMD 12, processor 80 may send signals to the watchdog unit 40, 60 indicating the beginning and end of programming operations within a programming session, and may send stay-alive signals only during the programming operations.

[0058] Processor 80 may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like. A memory 86 may include program instructions that, when executed by processor 80, cause programming device 20 to perform the functions ascribed to programming device 20 herein. Memory 86 may

include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0059] FIG. 6 is a flow diagram illustrating exemplary operation of programming device 20 to facilitate failsafe programming of IMD 12. Programming device 20 sends a signal indicating the beginning of a programming operation to a watchdog unit 40, 60 (90). During the programming operation, programming device 20 periodically sends stay-alive signals to the watchdog unit 40, 60 to cause the watchdog unit to reset a watchdog timer (92). In some embodiments, programming device 20 may only send dedicated stay-alive signals when no programming signal has been sent in time to cause the watchdog unit 40, 60 to reset the watchdog timer. When programming device 20 determines that the programming operation is done (94), programming device 20 sends a signal to the watchdog unit 40, 60 indicating the end of the programming operation (96).

[0060] FIG. 7 is a flow diagram illustrating exemplary operation of watchdog unit 40 to facilitate failsafe programming of IMD 12. Although FIG. 7 illustrates operation of watchdog unit 40, it is understood that watchdog unit 60, as described above, may perform many of the functions of watchdog unit 40.

[0061] Watchdog unit 40 receives a signal indicating the start of a programming operation from programming device 20 via one or more data lines of cable 28 (100), and initializes a watchdog timer in response to the signal (102). Watchdog unit 40 monitors for failure of power delivery from programming device 20 (104), activation of an emergency shutdown circuit 58 by a user (106), a signal indicating the end of the programming operation from programming device 20 (108), and stay-alive signals from programming device 20 (110) during the programming operation. Each time watchdog unit 40 receives a stay-alive signal, and in some embodiments a programming signal, from programming device 20 before the watchdog timer expires, watchdog unit 40 resets the watchdog timer (112).

[0062] If watchdog unit 40 does not receive a stay-alive signal or programming signal from programming device 20 before the watchdog timer expires (110), watchdog unit sends a signal to IMD 12 via telemetry head 26 to place IMD 12 in a known, safe state (116). The signal may cause IMD 12 to, for example, suspend

delivery of therapy, perform a POR, and/or recall a known, safe therapy program. Watchdog unit 40 also sends such a signal to IMD 12 (126) if a user activates the emergency shutdown circuit 58 (106). In embodiments wherein watchdog unit 40 receives primary power from programming device 20, watchdog unit 40 activates an auxiliary power source 56 (114) and sends the signal to IMD 12 (116) upon detection of a failure of power delivery by programming device 20 (104). When watchdog unit 40 receives a signal from programming device 20 indicating the end of the programming operation (108), watchdog unit 40 may stop maintaining the watchdog timer.

[0063] Various embodiments of the invention have been described. However, one skilled in the art will recognize the various modifications may be made to the described embodiments. For example, the invention is not limited to programming of spinal cord stimulation (SCS) therapy, or even to programming of neurostimulation therapy. The failsafe programming techniques described herein may be applied to the programming of any implantable medical device, such as pacemakers and implantable pumps. Moreover, the invention is not limited to failsafe programming of implantable medical devices that deliver therapy, but may include failsafe programming of implantable medical devices used to monitor patients, such as implantable hemodynamic monitors or loop recorders.

[0064] Further, although a programming device has been described herein primarily as a clinician programmer used to program therapy during a programming session, the invention is not so limited. A programming device that facilitates failsafe programming of an implantable medical device may a patient programmer used to control delivery of therapy by an implanted medical device in an ambulatory setting. For example, a patient programmer may be used to adjust program parameter for delivery of neurostimulation by an implantable medical device.

CLAIMS:

1. A method comprising:

receiving stay-alive signals from a programming device during the course of a wireless telemetry session between the programming device and an implantable medical device;

resetting a watchdog timer in response to receipt of each of the stay-alive signals; and

changing a mode of operation of the implantable medical device in response to expiration of the watchdog timer.

2. The method of claim 1, wherein receiving stay-alive signals comprises detecting transitions on a data line.

3. The method of claim 1, wherein receiving stay-alive signals comprises receiving stay-alive signals via wireless telemetry.

4. The method of claim 1, wherein receiving stay-alive signals comprises receiving programming signals and stay-alive signals, and resetting a watchdog timer comprises resetting the watchdog timer in response to each of the programming signals and stay-alive signals.

5. The method of claim 1, wherein changing a mode of operation of the implantable medical device comprises directing the implantable medical device to suspend delivery of therapy.

6. The method of claim 1, wherein changing a mode of operation of the implantable medical device comprises directing the implantable medical device to perform a power-on reset.

7. The method of claim 1, wherein changing a mode of operation of the implantable medical device comprises providing a program to the implantable

medical device, the program controlling delivery of therapy by the implantable medical device.

8. The method of claim 1, wherein changing a mode of operation of the implantable medical device includes causing the implantable medical device to revert to a previously stored program.

9. The method of claim 1, wherein changing a mode of operation of the implantable medical device comprises sending a signal to the implantable medical device via wireless telemetry.

10. The method of claim 1, further comprising:

receiving a signal from the programming device that indicates initiation of a programming operation; and

initializing the watchdog timer in response to the signal.

11. The method of claim 1, further comprising:

receiving power from the programming device;

detecting a failure of power delivery by the programming device;

activating an auxiliary power source in response to the detection; and

changing the mode of operation of the implantable medical device in response to the detection.

12. The method of claim 1, further comprising:

receiving an emergency-off signal from a user; and

changing the mode of operation of the implantable medical device in response receipt of the signal.

13. A device to perform any of the methods of claims 1, 2 and 5-10, comprising:

a telemetry circuit; and

a processor to receive stay-alive signals from a programming device during the course of a wireless telemetry session between the programming device and an implantable medical device, reset a watchdog timer in response to receipt of each of the stay-alive signals, and send a signal to the implantable medical device via the telemetry circuit to change a mode of operation of the implantable medical device in response to expiration of the watchdog timer.

14. The device of claim 13, wherein the device receives power from the programming device, the device further comprising an auxiliary power source, and

wherein the processor detects a failure of power delivery by the programming device, activates the auxiliary power source in response to the detection, and sends a signal to the implantable medical device via the telemetry circuit to change the mode of operation of the implantable medical device in response to the detection.

15. The device of claim 13, further comprising a user interface, wherein the processor receives an emergency-off signal in response to interaction of a user with the user interface, and sends a signal to the implantable medical device via the telemetry circuit to change the mode of operation of the implantable medical device in response to receipt of the signal.

16. The device of claim 13, wherein the programming device is coupled to a programming head by a cable, and the device is located within the programming head.

17. The device of claim 13, wherein the programming device is coupled to a programming head by a cable, and device couples the cable to the programming head.

18. An implantable medical device to perform any of the methods of claims 1 and 3-10 comprising:

a telemetry circuit; and

the programming device and the implantable medical device, reset a watchdog timer in response to receipt of each of the stay-alive signals, and change a mode of operation of the implantable medical device in response to expiration of the watchdog timer.

19. The implantable medical device of claim 18, wherein the watchdog unit comprises a processor.

20. The implantable medical device of claim 19, wherein the processor comprises a processor that controls operation of the implantable medical device.

21. The implantable medical device of claim 18, wherein the implantable medical device comprises an implantable neurostimulator.

22. A computer-readable medium comprising instructions that cause a programmable processor to perform any of the method of claims 1-12.

23. A method comprising:

sending programming signals that affect operation of an implantable medical device to the implantable medical device via wireless telemetry during a programming operation; and

sending stay-alive signals to a watchdog unit during the programming operation to allow the watchdog unit to detect failure of a wireless telemetry session between a programming device and the implantable medical device during the programming operation.

24. The method of claim 23, further comprising sending signals to the watchdog unit to indicate the beginning and ending of the programming operation.

25. The method of claim 23, wherein sending stay-alive signals comprises generating transitions on a data line.

26. The method of claim 23, wherein sending stay-alive signals comprises sending stay-alive signals via wireless telemetry.

27. The method of claim 23, wherein sending stay-alive signals comprises:
resetting a timer upon delivery of a programming signal; and
sending a stay-alive signal upon expiration of the timer.

28. A programming device to perform any of the methods of claims 23-27 comprising:
a telemetry circuit; and
a processor to send programming signals that affect operation of an implantable medical device to the implantable medical device via the telemetry circuit during a programming operation, and send stay-alive signals to a watchdog unit during the programming operation to allow the watchdog unit to detect failure of a wireless telemetry session between the programming device and the implantable medical device during the programming operation.

29. A computer-readable medium comprising instructions that cause a programmable processor to perform any of the methods of claims 23-27.

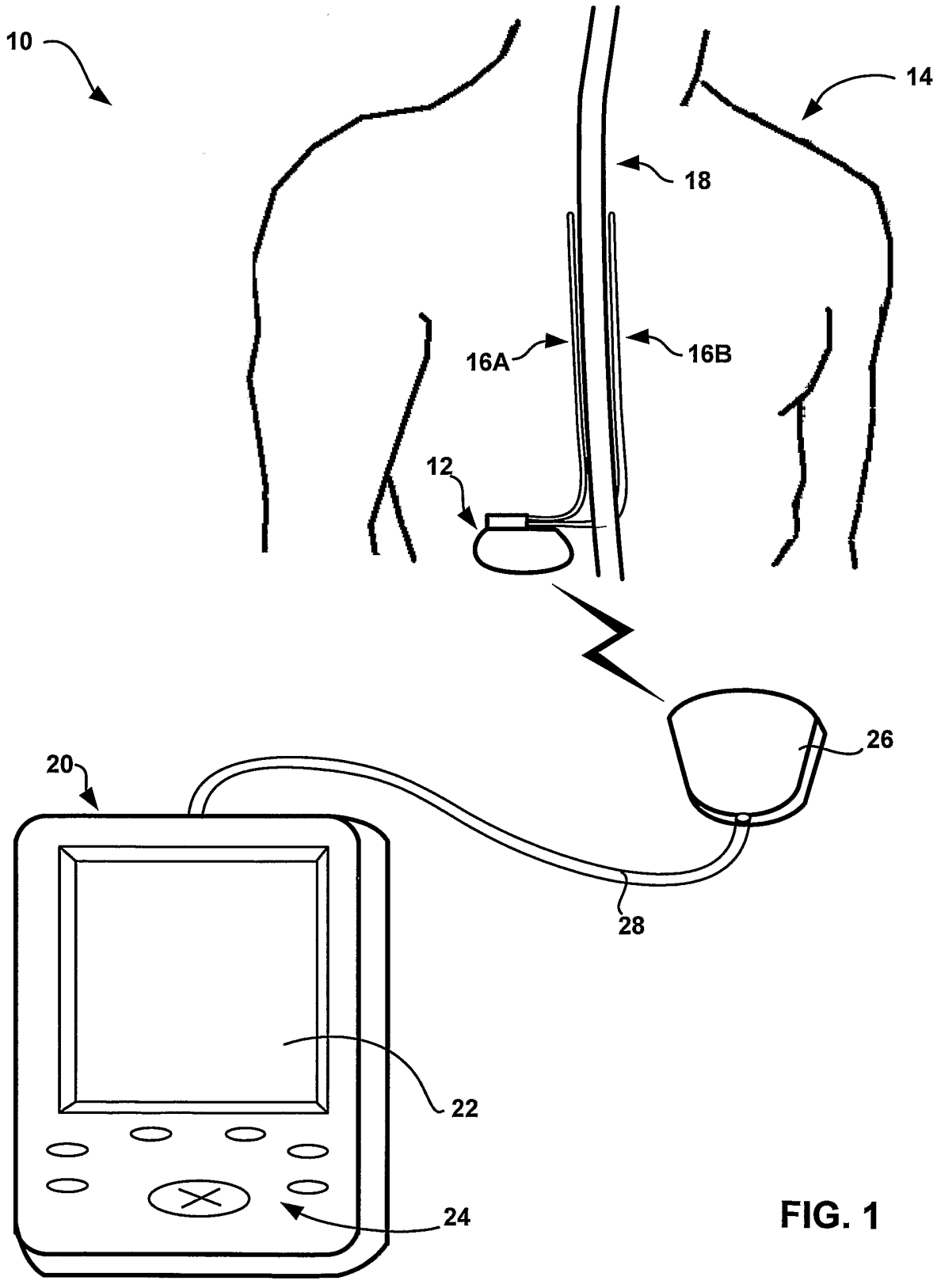

FIG. 1

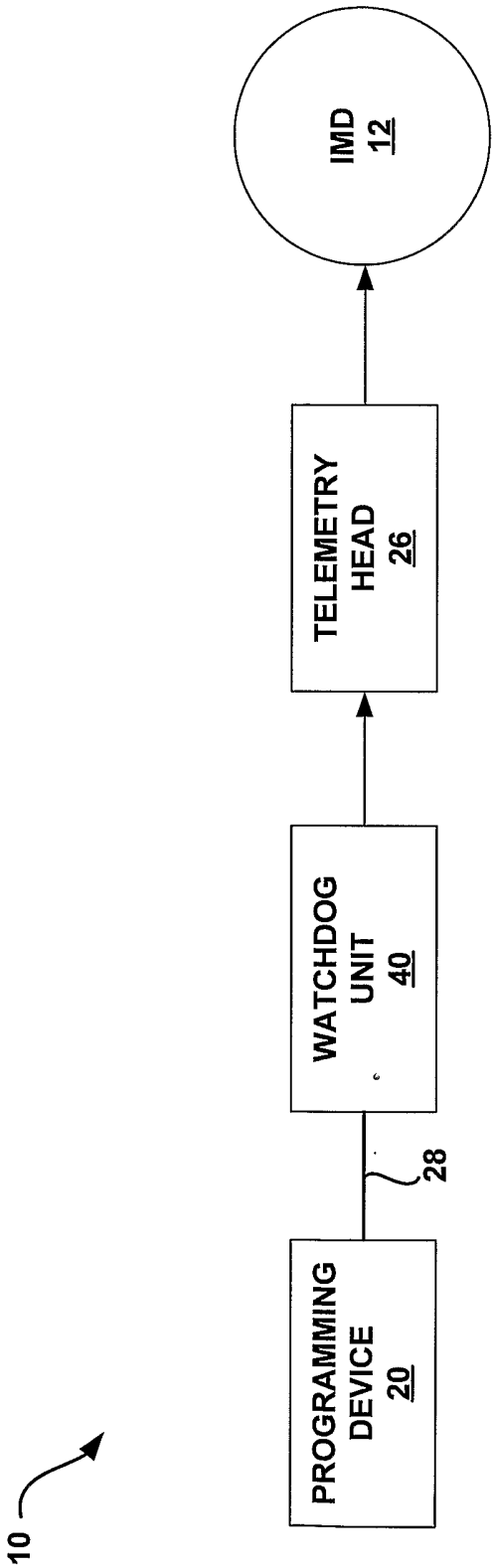
IMD
12
TELEMETRY
HEAD
26
WATCHDOG
UNIT
40
28
PROGRAMMING
DEVICE
20
10

FIG. 2

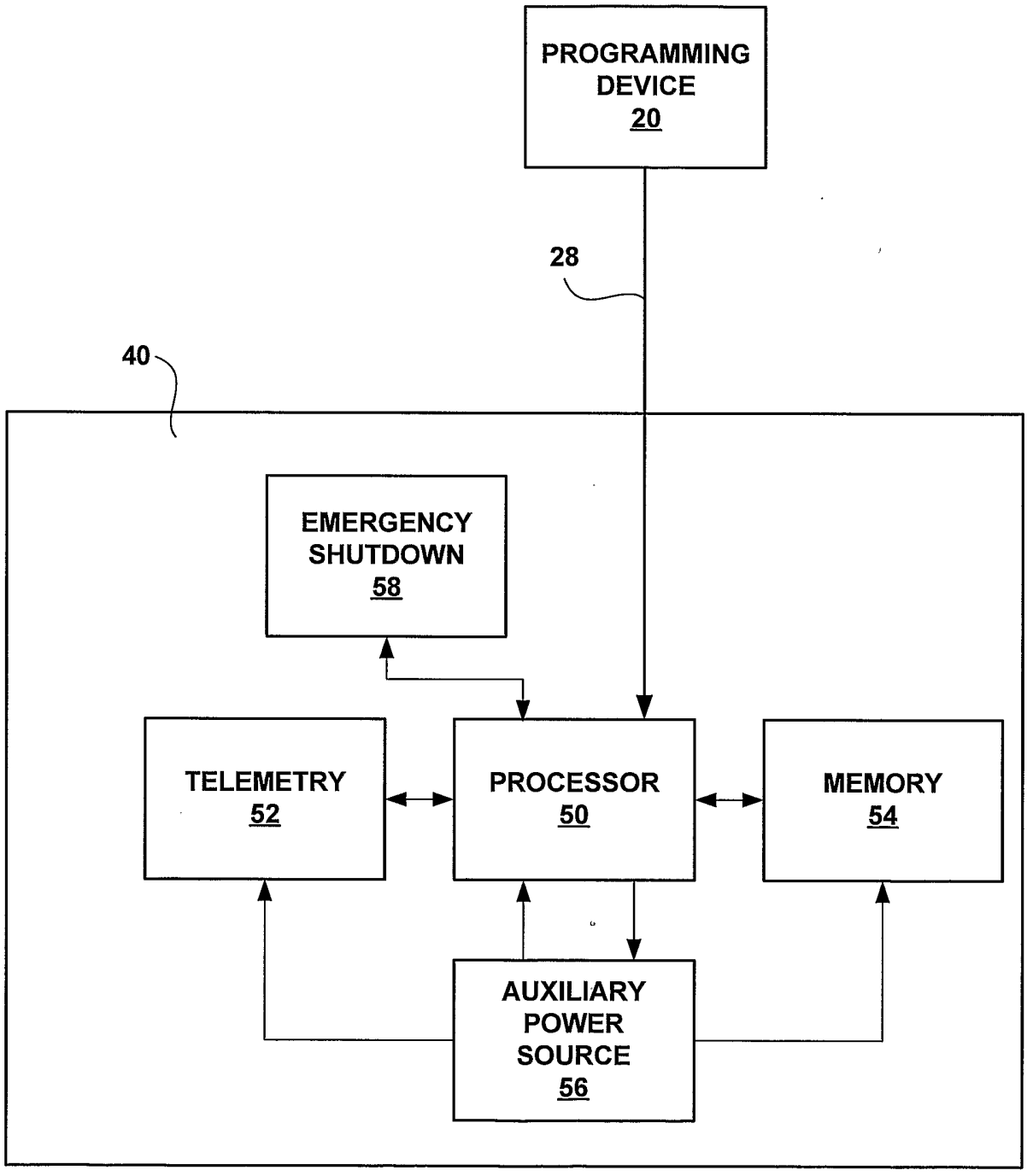
PROGRAMMING DEVICE 20
28
40
EMERGENCY SHUTDOWN 58
TELEMETRY 52
PROCESSOR 50
MEMORY 54
AUXILIARY POWER SOURCE 56

FIG. 3

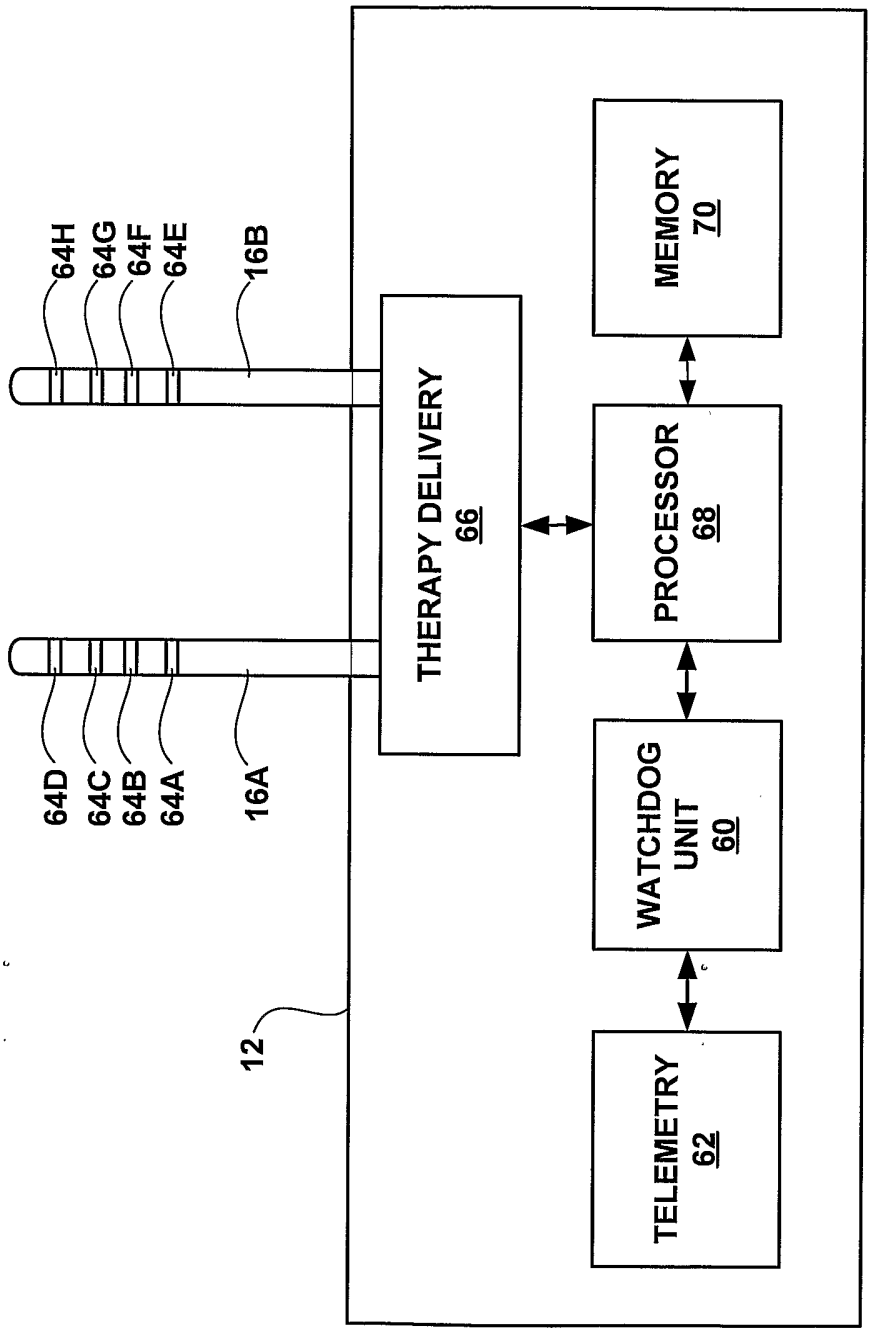
64H
64G
64F
64E
16B
64D
64C
64B
64A
16A
12
THERAPY DELIVERY
66
MEMORY
70
PROCESSOR
68
WATCHDOG
UNIT
60
TELEMETRY
62

FIG. 4

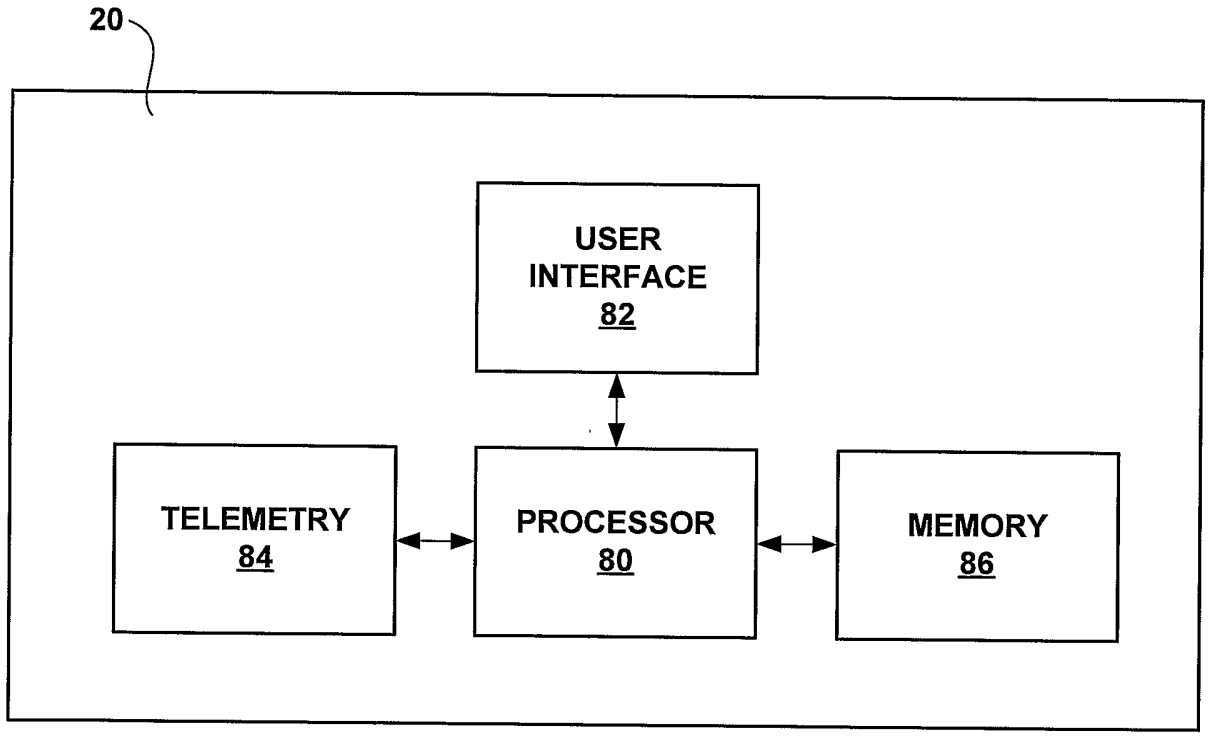

FIG. 5

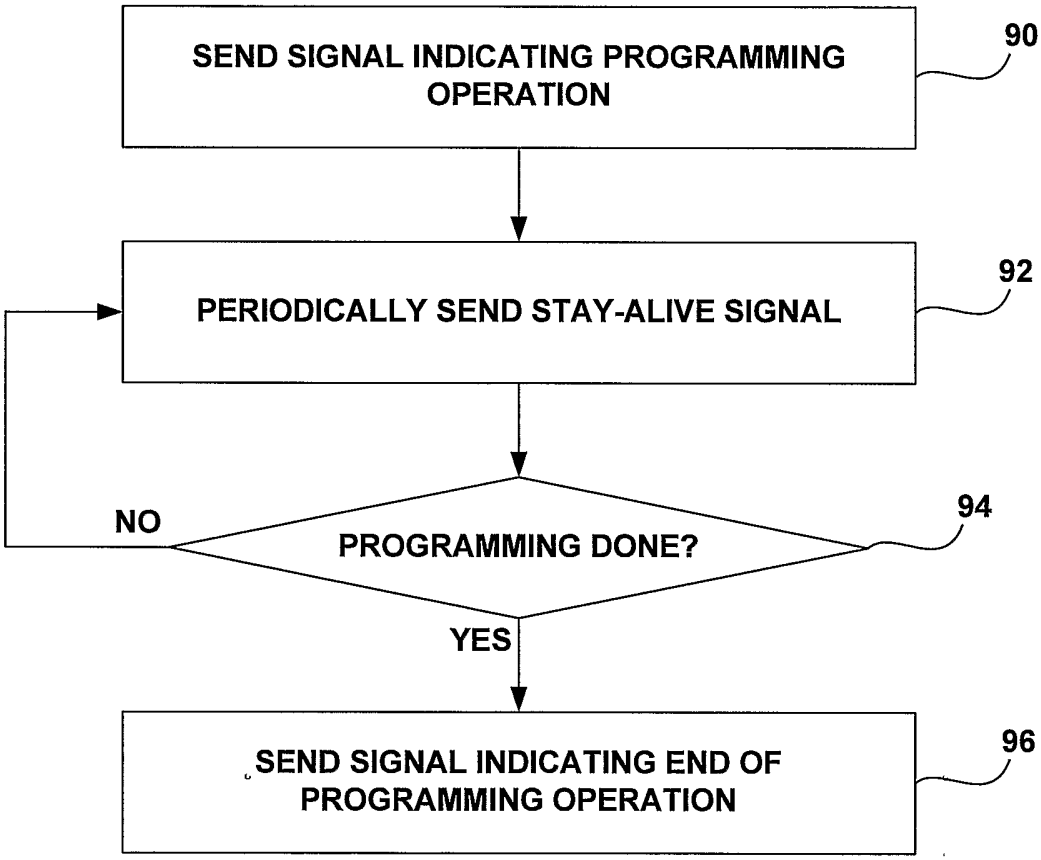
SEND SIGNAL INDICATING PROGRAMMING OPERATION
90
PERIODICALLY SEND STAY-ALIVE SIGNAL
92
NO
PROGRAMMING DONE?
94
YES
SEND SIGNAL INDICATING END OF PROGRAMMING OPERATION
96

FIG. 6

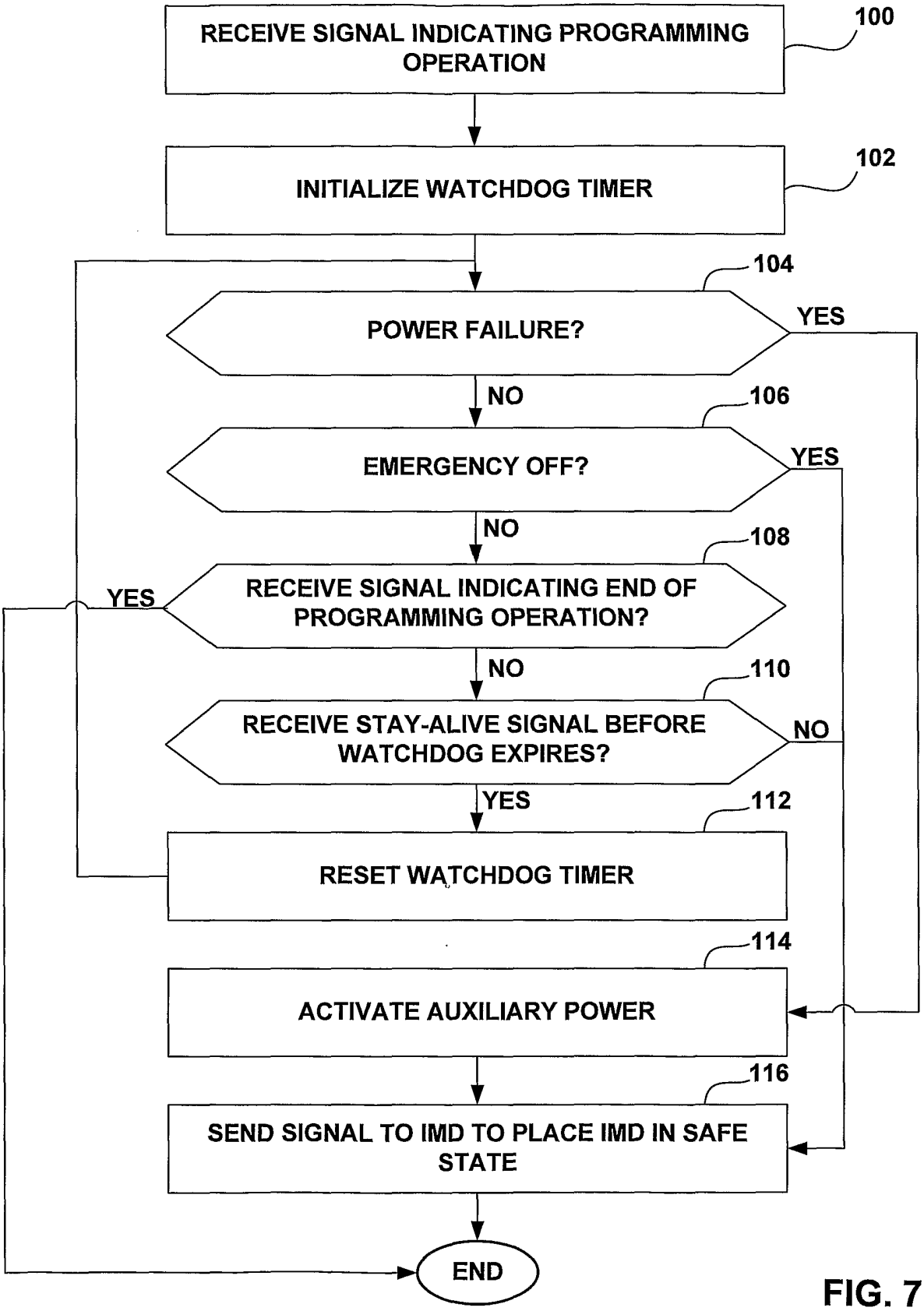
RECEIVE SIGNAL INDICATING PROGRAMMING OPERATION
100
INITIALIZE WATCHDOG TIMER
102
104
POWER FAILURE?
YES
NO
106
EMERGENCY OFF?
YES
NO
108
RECEIVE SIGNAL INDICATING END OF PROGRAMMING OPERATION?
YES
NO
110
RECEIVE STAY-ALIVE SIGNAL BEFORE WATCHDOG EXPIRES?
NO
YES
112
RESET WATCHDOG TIMER
114
ACTIVATE AUXILIARY POWER
116
SEND SIGNAL TO IMD TO PLACE IMD IN SAFE STATE
END

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/34325

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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)
IPC 7 A61N

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 2002/133207 A1 (BIRKHOLZ DOUG M ET AL) 19 September 2002 (2002-09-19) paragraph '0009! - paragraph '0020!; figure 2 ---	1-10,12, 13,15, 22-29
X	US 5 792 201 A (YANG MIN-YAUG ET AL) 11 August 1998 (1998-08-11) column 2, line 65 -column 15, line 59; figures 2-10 ---	1-10,12, 13,15, 22-29
A	EP 0 750 921 A (PACESETTER INC) 2 January 1997 (1997-01-02) page 3, line 20 -page 12, line 38; figures 1-4 --- -/--	1-16, 22-29

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

[X] Patent family members are listed in 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
25 March 2004	02/04/2004

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	Kurze, V

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/34325

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 753 327 A (PACESETTER INC) 15 January 1997 (1997-01-15) column 1, line 55 -column 19, line 58; figures 1-10	1-16, 22-29
A	US 5 350 407 A (MCCLURE LAWRENCE C ET AL) 27 September 1994 (1994-09-27) column 2, line 57 -column 28, line 46; figures 2,3	1-16, 22-29

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 17-21

The phrase after the second comma of claim 17 attempts to define the device using the unclear term "device couples", which cannot be understood.
The grammar of those parts of claim 18 which start at the top of page 19 is grammatically so unclear and appears to refer to certain devices ("the programming device", and "the medical device") which have not been defined or mentioned earlier in the claim, that the sense of the claim cannot be understood. Furthermore, it appears that the part starting at the top of page 18 belongs to a method claim, rather than a device claim, as defined on page 18. Therefore, the scope of the inteded protection cannot be identified.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/34325

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 17-21
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:

see FURTHER INFORMATION sheet PCT/ISA/210

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 II Observations where unity of invention is lacking (Continuation of item 2 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

International Application No
PCT/US 03/34325

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002133207 A1	19-09-2002	NONE	
US 5792201 A	11-08-1998	US 5607458 A	04-03-1997
		DE 69630993 D1	22-01-2004
		EP 0753327 A2	15-01-1997
		JP 9028815 A	04-02-1997
EP 0750921 A	02-01-1997	US 5653735 A	05-08-1997
		EP 0750921 A2	02-01-1997
		JP 9010323 A	14-01-1997
EP 0753327 A	15-01-1997	US 5607458 A	04-03-1997
		DE 69630993 D1	22-01-2004
		EP 0753327 A2	15-01-1997
		JP 9028815 A	04-02-1997
		US 5792201 A	11-08-1998
US 5350407 A	27-09-1994	NONE	