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Stomberg et al.

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(54) **METHOD AND A SYSTEM FOR CONDUCTING FAILURE MODE RECOVERY IN AN IMPLANTED MEDICAL DEVICE**

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(57) **ABSTRACT**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 275 days.

A method and a system for conducting failure mode recovery of an implanted medical device. The embodiments described reduce the risk of leaving an IMD in an undesirable state when conditions during programming of the IMD unexpectedly change. In an example embodiment, failure mode recovery in an implanted device is facilitated when a communications link with a medical communications system having an application program is interrupted. The failure mode recovery method includes establishing a communications link between the medical communications system and an extender module configured to receive an application proxy from the application program. An application proxy is then loaded into the extender module via the application program. The application proxy is configured to transition the implanted device to a recovery state in response to a set of conditions. The implanted device then transitions to a completed state via the application program, while transitioning of the completed state is monitored. The implanted device is automatically restored by the application proxy to the recovery state when the set of conditions is detected while transitioning to the completed state.

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(51) **Int. Cl.**⁷ **A61N 1/362**

(52) **U.S. Cl.** **607/31**

(58) **Field of Search** 607/30-32, 59, 607/60; 128/903, 904, 899

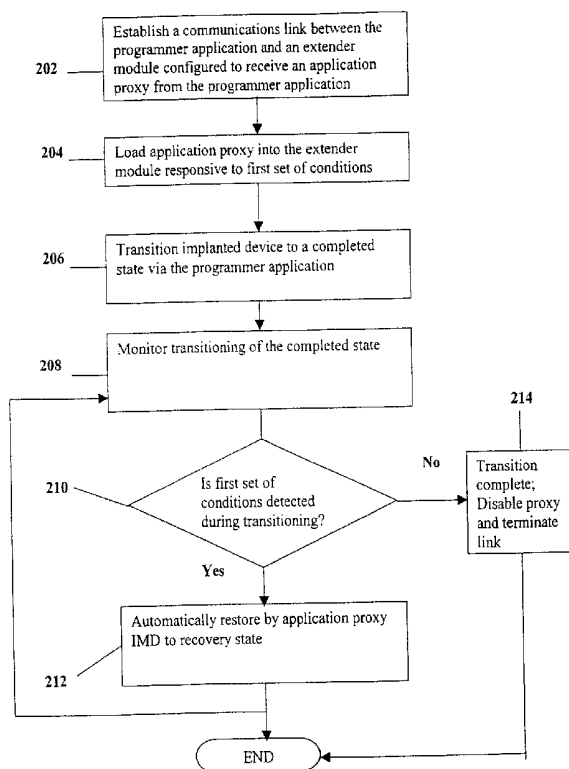
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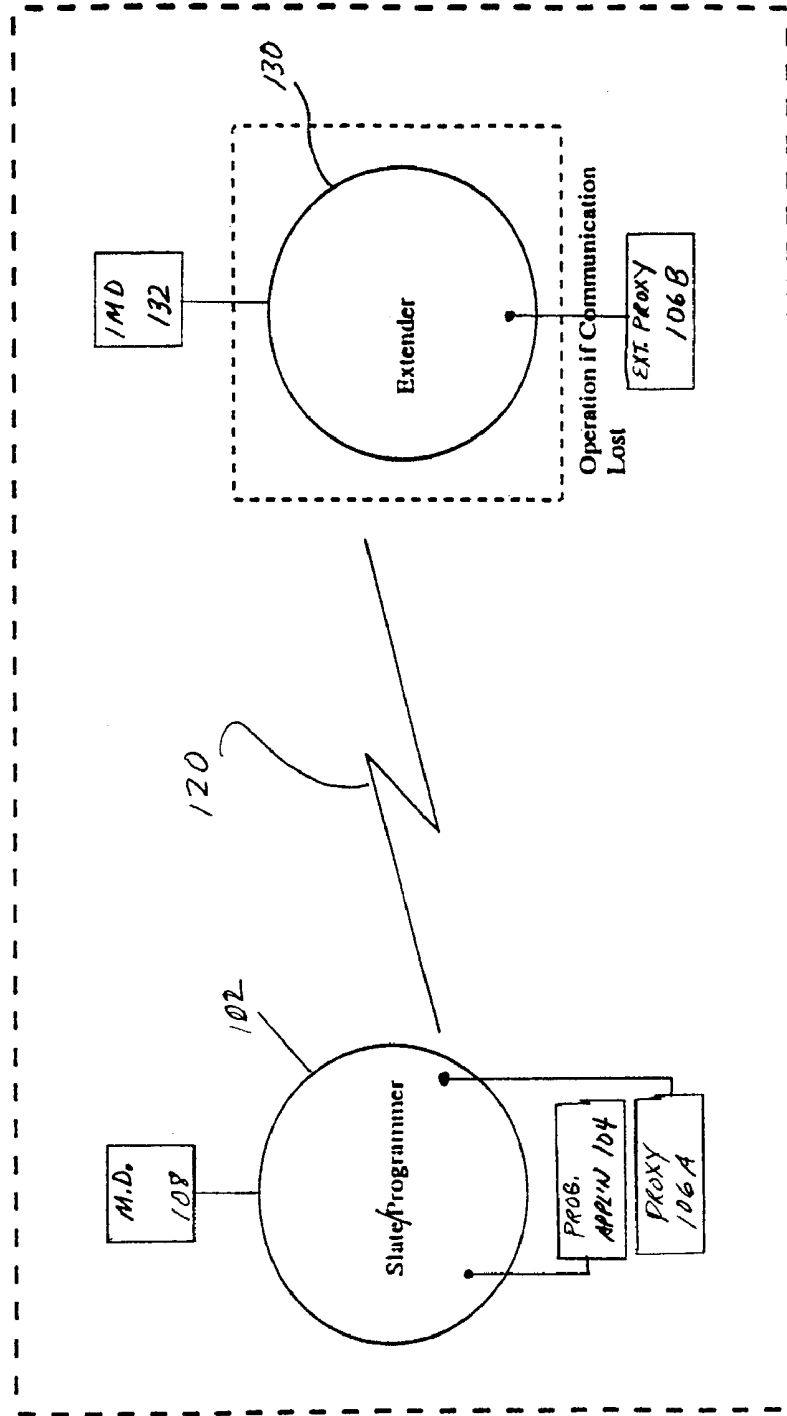
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24 Claims, 4 Drawing Sheets

200



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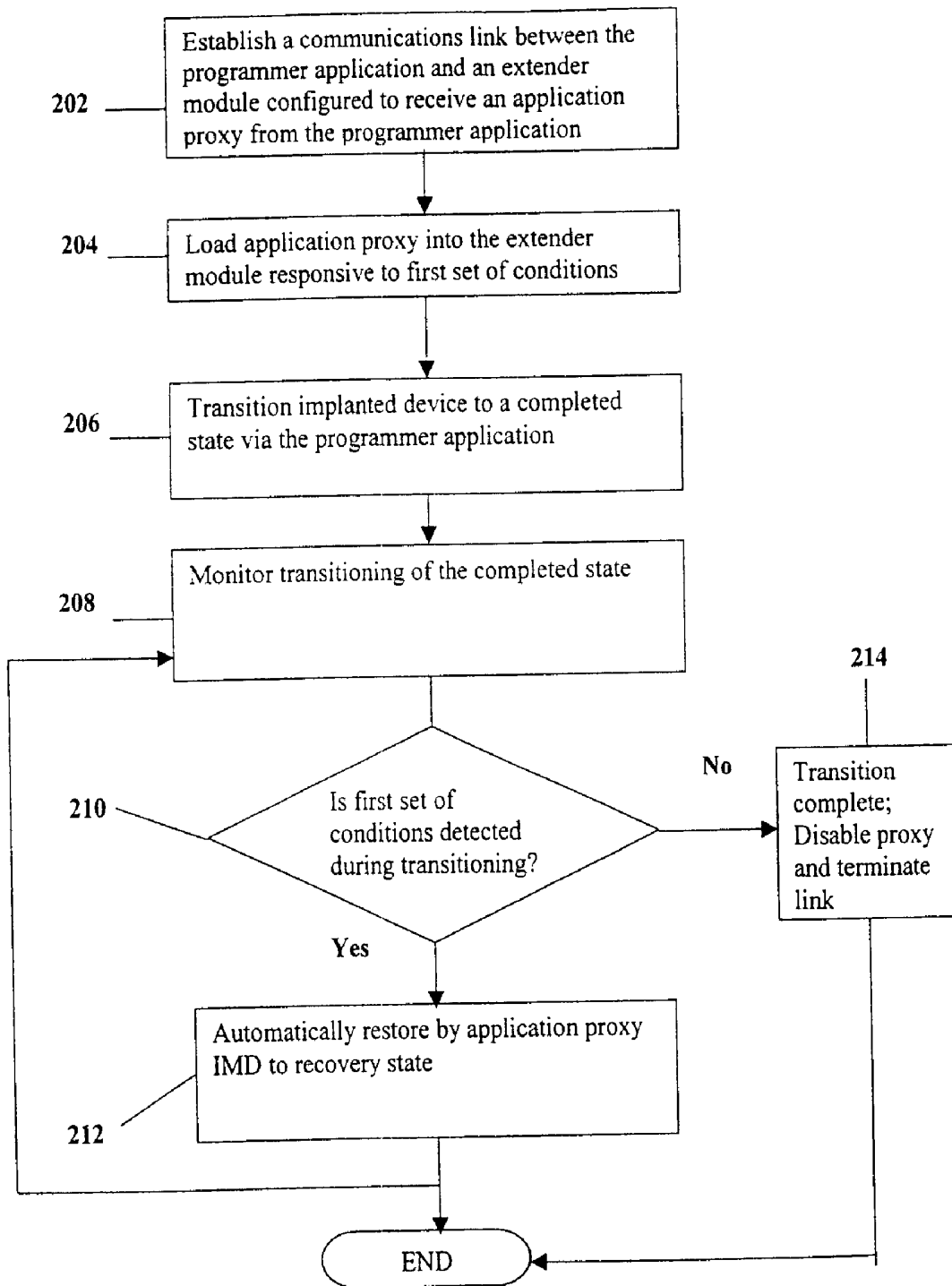


Normal Operation

Fig. 1

FIG. 2

200



300

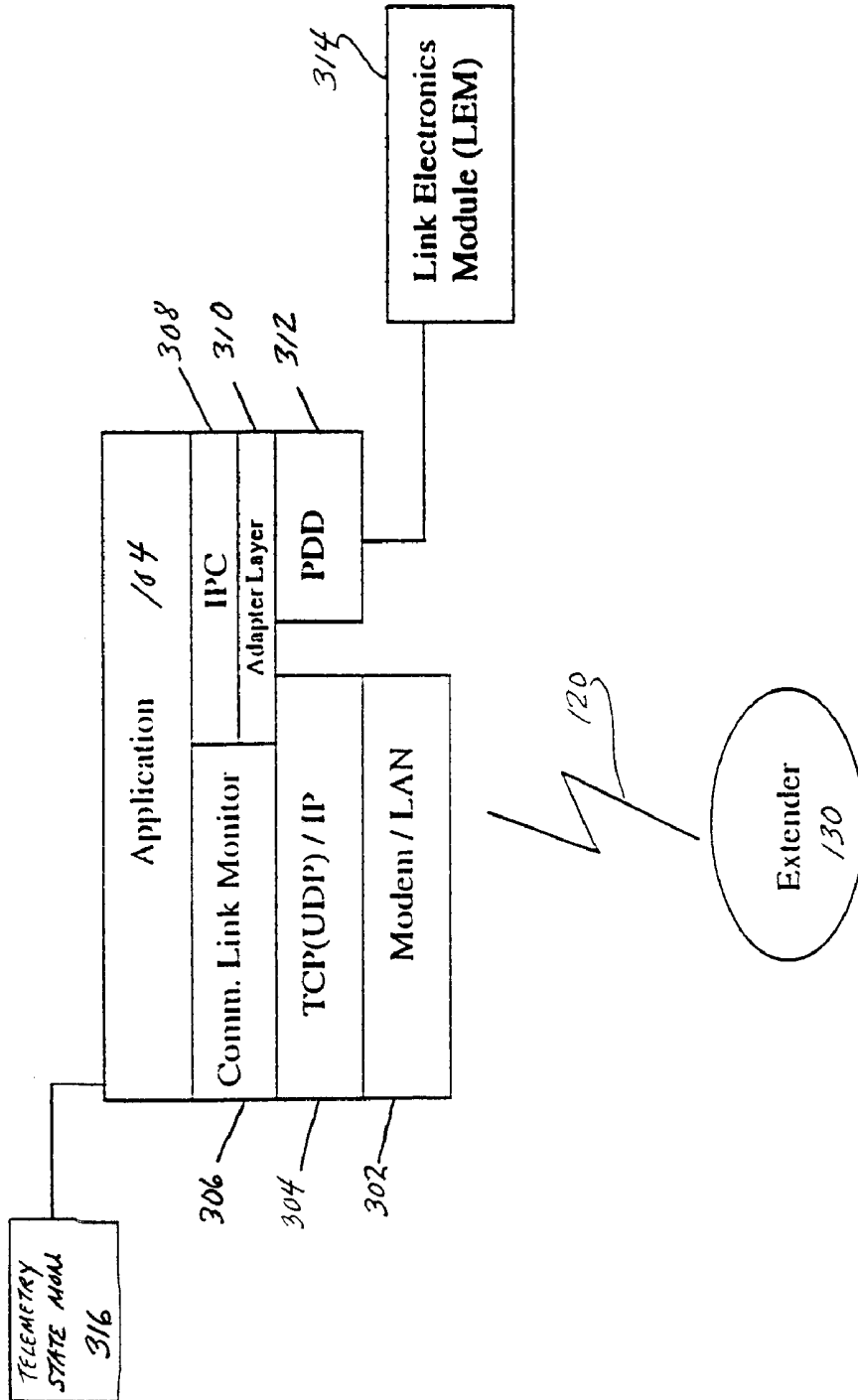


Fig. 3

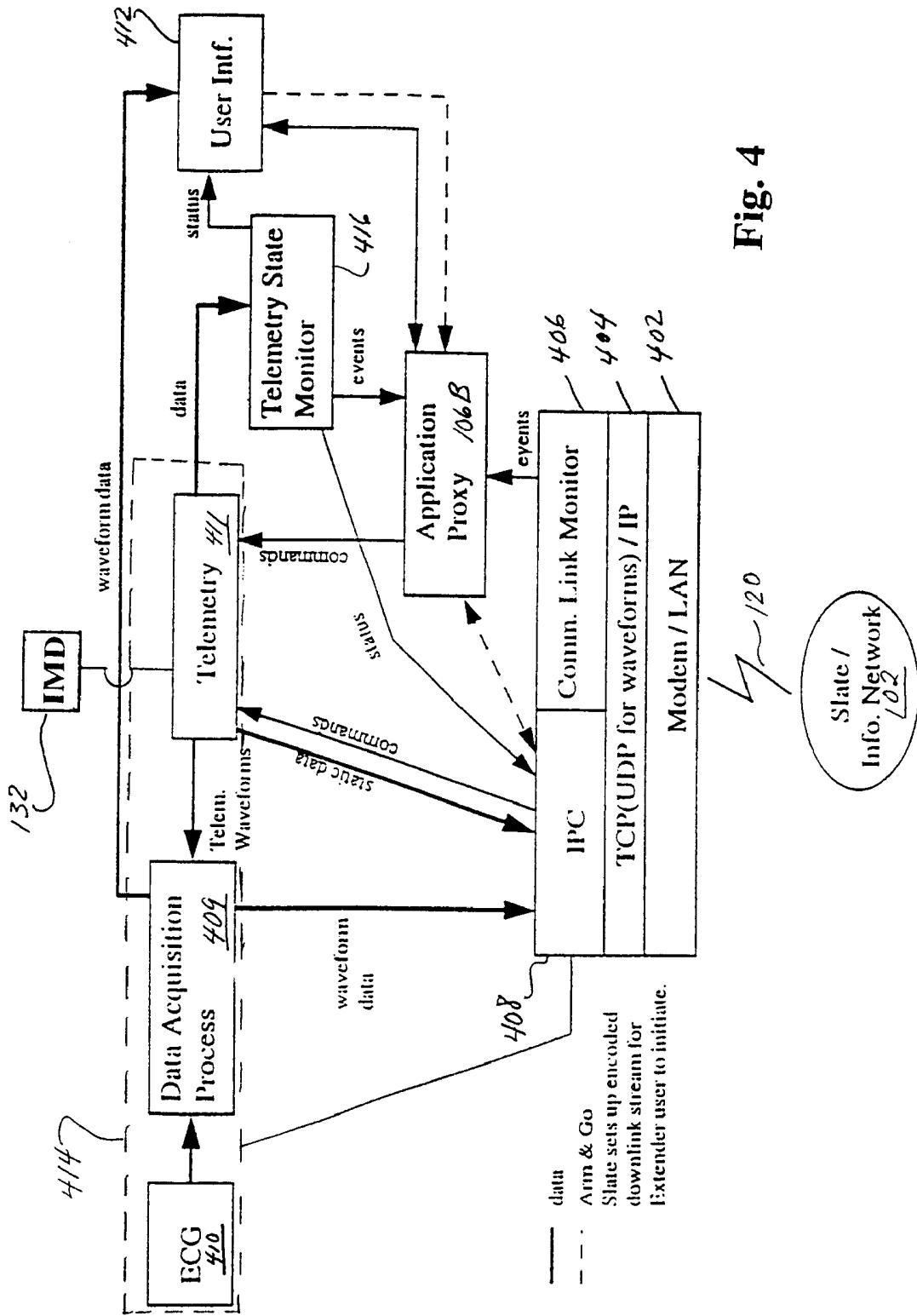


Fig. 4

**METHOD AND A SYSTEM FOR
CONDUCTING FAILURE MODE RECOVERY
IN AN IMPLANTED MEDICAL DEVICE**

RELATED PATENT DOCUMENTS

This application claims priority of U.S. Provisional Application Ser. No. 60/173,081, filed on Dec. 24, 1999 (P-8745.00), entitled "Application Proxy for Telecommunication-Enabled Remote Medical Devices Access Instruments." The disclosure and drawings of the Provisional Application are specifically incorporated herein by reference.

FIELD OF THE INVENTION

The present invention generally relates to medical devices. Specifically, the invention relates to a method and a system for monitoring the reliability and integrity of a remote communication link between a programming unit and an implanted medical device.

BACKGROUND OF THE INVENTION

In recent years, implantable electronic device technology has rapidly advanced. Sizes and weights have decreased, while functionality has increased. These advances have created a corresponding demand for two-way communication or telemetry between the implantable medical device and an external device, for example, a programmer device. In a pacemaker system, for example, a programmer device downloads to an implanted pacemaker data such as operating parameters. Likewise, data may flow from the implanted device to the programmer device. Modern pacemakers are capable of storing significant amounts of data about the patient, for example, the average heart rate, and information pertaining to the pacemaker itself, for example, battery voltage level. This data may need to be transmitted to the programmer device for evaluation by a physician.

Currently implanted medical device programmers typically include an extendible head portion that includes an antenna. The antenna is connected to other circuitry in the programmer device via a stretchable coil cable. Thus, the head portion can be positioned over the patient's implanted device site for programming or telemetry interrogation of the implanted device. Command instructions or data that are downloaded to the implanted device are referred to as downlink transmissions, and data transmitted from the implanted device to the programmer device are referred to as uplink transmissions.

A technology-based health care system that fully integrates the technical and social aspects of patient care and therapy should be able to flawlessly connect the patient with care providers irrespective of separation distance or location of the participants. While clinicians will continue to treat patients in accordance with accepted modem medical practice, developments in communications technology are making it ever more possible to provide medical services in a time and place independent manner.

Prior art methods of clinical services are generally limited to in-hospital operations. For example, if a physician needs to review the performance parameters of an implanted device, the patient will likely visit the clinic. If the medical condition of the patient with the implanted device warrants a continuous monitoring or adjustment of the device, the patient will have to stay in the hospital for an extended period of time. Such continuous treatment plans pose both economic and social hardship on patients. Depending on the

frequency of data collection this procedure may seriously inconvenience patients that live in rural areas or have limited physical mobility. The need for upgrading the software of an implanted medical device also requires another trip to the hospital to have the upgrade installed. Further, as the segment of the population with implanted medical devices increases many more hospitals, clinics and service personnel will be needed to provide in-hospital care to patients, thus escalating the cost of healthcare.

Updating operating parameters and upgrading software in an implanted device are two examples where the state of an implanted device is changed. If the process of changing the state of an implanted device is interrupted, the physician must restore the device to a known state to ensure proper operability. If state changes to an implanted device are directed from a remote location, the process must also address possible interruptions.

SUMMARY OF THE INVENTION

Various embodiments of the present invention are directed to addressing various needs in connection with programming an IMD. Accordingly, the present invention provides a method and system that reduces the risk of leaving an IMD in an undesirable state when conditions unexpectedly change during programming of the IMD.

In various embodiments the present invention supports a communications system for transferring information between an IMD and a remote expert data center capable of dispensing therapy and clinical care on real-time basis. The present invention provides a method that improves the degree of patient safety while providing access to a remote expert data system. The capability provided by the present invention reduces the burden of the IMD patient of having to travel to a specific hospital or clinic for program upgrades, physician follow up evaluations and adjustments that need to be made to the IMD(s).

According to one embodiment of the invention, failure mode recovery in an implanted device is facilitated when a communications link with a medical communications system having an application program is interrupted. The method includes establishing a communications link between the medical communications system and an extender module configured to receive an application proxy from the application program. The application proxy, which is configured to transition the implanted device to a recovery state in response to a set of conditions, is then loaded into the extender module via the application program. The application program then transitions the implanted device to a completed state, and the transition process is monitored. The implanted device is automatically restored by the application proxy to the recovery state if the set of conditions is detected while transitioning to the completed state.

According to another embodiment of the invention, failure mode recovery in an implanted device is facilitated when a communications link with a medical communications system is interrupted. The method includes loading the application proxy from the application program into the extender module. The application proxy is configured to transition the implanted device to a recovery state in response to a set of conditions. A communications link is then established between the implanted device and the medical communications system via the extender module. The implanted device then transitions to a completed state via the application program, while the transition to the completed state is monitored. The implanted device is automatically restored by the application proxy to the recovery

ery state if the set of conditions is detected while transitioning to the completed state.

The above summary of the present invention is not intended to describe each illustrated embodiment or every implementation of the present invention. The figures in the detailed description that follow more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIG. 1 illustrates a block diagram of an IMD programming and failure recovery mode system in accordance with an example embodiment of the invention;

FIG. 2 is a flowchart illustrating the manner of configuring an IMD programming system for conducting failure mode recovery of an IMD when programming is interrupted in accordance with an example embodiment of the invention;

FIG. 3 is a block diagram of an example programming unit of the IMD programming and failure recovery mode system in accordance with an example embodiment of the invention; and

FIG. 4 is a block diagram of an example of an extender module of the IMD programming and failure recovery mode system in accordance with an example embodiment of the invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

The present invention is generally directed to a method and system for conducting failure mode recovery of an IMD that encounters an interruption in IMD programming that would leave the IMD in an undesirable state. While the present invention is not necessarily limited to such an application, the invention will be better appreciated using a discussion of example embodiments in such a specific context.

Referring now to the figures, FIG. 1 illustrates a block diagram of an IMD programming and failure recovery mode system **100** in accordance with an example embodiment of the invention. System **100** includes a programmer or programming unit **102**, that is part of a medical communications system, having a programmer application **104** and an application extender proxy program **106A**. Programmer **102** is used by a physician **108** (or any other medical professional) to communicate with and program an IMD **132**. System **100** also includes an extender module **130**, communicatively coupled via communications link **120** to programmer **102**, which interfaces more directly with IMD **132**. Extender module **130** includes a processor and memory arrangement configured to provide failure mode recovery capabilities upon receiving the application extender proxy program **106A**, which is designated as **106B** when loaded into extender module **130**. In one example, a patient with IMD

132 is remote from a hospital or clinic but is in need of an IMD evaluation or programming. With the present invention, extender module **130** extends the programming capabilities of programmer **102** to the patient, with control of the programming being directed from the facility where the physician is located. An interruption in programming may leave IMD **132** in an unknown state that may endanger the patient. With the aid of application proxy **106B**, any interruption in communications or changes in programming conditions will allow system **100** to recover the IMD to a normal operating state. The failure mode recovery is transparent to the patient.

Referring now to FIG. 2, a flowchart **200** illustrates an example process for returning an IMD to a known operating state when IMD programming is interrupted (or when certain conditions occur) in accordance with an example embodiment of the invention. The method of the present invention facilitates failure mode recovery of an implanted device when a communications link with a medical communications system having a programmer application program is interrupted. Flowchart **200** is an example description of at least a single programming of device transition; however the IMD device may move through several transitions before the programming session is complete. At step **202**, a communications link is first established between the medical communications system, which includes programmer **102**, and extender module **130** that is configured to receive an application proxy **106A** from the application program **104**. At step **204**, application proxy **106A** is loaded into extender module **130** via application program **104**. The application proxy **106A** is configured to transition implanted device **132** to a recovery state in response to a set of conditions. The set of conditions include, but are not limited to, interruption in the communications link between the medical communications system and extender module **130**; misalignment of the programming head of the extender module in detecting ECG readings or in conducting telemetry with the IMD; loss of telemetry connection with the IMD; a failure of programmer **102**; poor placement of the programming head proximate the IMD and the patient's heart; and a poor connection between the extender module and the programming unit.

At this point, the extender performs the programming function proximate to the patient even though the actual programming unit may be remotely located from the patient. When the extender is in communication with the programming unit, the normal programming session can commence. At step **206**, implanted device **132** transitions to a completed state under control of the programmer application program. In one example, transitioning to a completed state includes opening the read switch, programming and closing the read switch, thereby returning the IMD to its normal operating state. At the programmer during programming, a physician or healthcare specialist provides remote analysis of the data and approves changes in therapy, for example. At step **208**, the transition to the completed state is monitored for various conditions. A communications interruption between the IMD and the programmer during a state transition could leave the IMD in an unstable state, thereby endangering the patient. In addition, stray radio frequency signals or electroreared switchic waves can disrupt programming of the IMD also leaving the IMD in an unstable state. In view of the foregoing, at step **210** a determination is made whether a set of conditions has been detected during the transition to the completed state. If so, at step **212** the implanted device is automatically restored by the application proxy **106B** to a known, stable state. Restoring the IMD to the stable state includes, for example, backing out of a programming mode

or cease performing upgrades. The process can end after step 212 or can return to monitoring step 208 to monitor any additional state transitions prompted by additional programming efforts after communications have been re-established. In order to re-establish communications with the IMD and resume the programming session, the application proxy would need to be downloaded or pre-loaded into the extender again.

With reference to step 210, if the set of conditions is not detected during the transition, then the transition to the completed state continues until completion. Once transition is complete the IMD is ready for the next transition. Where additional state transitions (or programming) are not expected and a message is sent from programmer 102 to the extender module 130, at step 214, to disable application proxy 106B and to terminate communications link 120.

In another embodiment, the extender module is the programming head of programmer 102 that is communicatively coupled to programmer 102. Prior to collecting ECG data and coupling the programmer with the IMD, the application proxy is downloaded automatically into the memory of the extender module. Since the extender module has a processor and a memory circuit arrangement, it is capable of receiving and storing the application proxy. If during the programming session with the patient, programmer 102 crashes or becomes disabled, the extender module is capable of automatically restoring the IMD to a known state. The extender module also includes a link electronics module (LEM, FIG. 3) that senses whether communications have been lost with programmer 102. Prior systems required that the application proxy be manually loaded into the extender module (programming head) and that the application proxy or emergency programming be initialized by actuating a button on the programming head by the medical professional. One of the advantages to the present system is that the application proxy with the emergency programming is automatically pre-loaded at programmer start-up and the application proxy automatically restores the IMD to the recovery state upon the LEM sensing an interruption in communications from the programmer.

Referring now to FIG. 3, a block diagram 300 illustrates an example programming unit 102 of the IMD programming and failure mode recovery system 100 in accordance with an example embodiment of the invention. Extender module 130 is coupled to programming unit 102 via communications link 120, which include, for example, a local area network, wide area network, and a public service telecommunications network (wired and wireless). A link can also be provided to the Internet via a PC or a wireless link to a global satellite communications network. A more detailed discussion of the methods of communicating remotely with an IMD is provided in U.S. Pat. No. 5,752,976 to Duffin et al, which is assigned to the assignee of the present invention and is incorporated herein by reference.

Programming unit 102, in this example embodiment, includes a modem/LAN module 302 coupled to a TCP (UDP)/IP module 304 for communications with various networks. A communications link monitor (CLM) 306 that monitors the integrity of the communications link with extender module 130 is coupled to module 304 and to programmer application 104. In particular, CLM 306 monitors the state of connection with the extender, generates events to application 104 that include notification of availability of voice communications after communications link is interrupted, and generates a message for display of an expected application proxy response to a particular event or condition that occurs. CLM 306 also provides the following

functions: validating the modem connection to the programmer/information network to ensure that there is sufficient data throughput; and enabling feature availability on the programmer and information network, such as ECG data, uplink telemetry waveform data, non-hazardous downlink data (e.g., diagnostics, interrogations) and hazardous downlink data (e.g., disable tachycardia detection). CLM 306 also validates initialization steps (e.g., connected to IN, patient is monitored, ready to begin session) and monitors communications on the programming side of system 100 continuously. An IPC (Interprocessor Communications) module 308 is coupled to application 104 and communicates with the link electronics module 314 of the programmer through PDD 312 (peripheral device driver) or alternatively communicates with extender module 130 through TCP/EP module 304 and modem 302. An adapter layer 310 is interposed between IPC 308 and PDD 312 and serves as an intermediary between the two modules in directing data to either a local LEM 314 or to the remote extender module 130. A telemetry state monitor 316 is also coupled to programmer application 104 for monitoring telemetry waveforms that are generated by the IMD. Any irregularities are immediately reported to application 104. The telemetry state monitor also sends status messages to the extender and to the programmer and determines the status of the IMD read switch.

Referring now to FIG. 4, a block diagram 400 illustrates an example of an extender module 130 side of the IMD programming system 100 in accordance with an example embodiment of the invention. As shown, programming unit 102 is coupled to extender module 130 via communications link 120. Extender module 130 includes a modem/LAN module 402 coupled to a TCP(UDP)/IP module 404 for communications with various networks and a communications link monitor (CLM) 406 that monitors the integrity of the communications link between programmer 102 and extender module 130. CLM 406 provides similar functions to the extender module as CLM 306 provides to the programmer. In addition, CLM 406 advises proxy 106B when there is a communications breakdown or when another condition has occurred that requires enabling the application proxy.

An IPC module 408 is coupled to application proxy 106B and communicates with the link electronics module (LEM) 414. LEM 414 includes a data acquisition process module 409, an ECG module 410 and a telemetry module 411. In this example, IMD 132 is coupled to the telemetry module 411 that sends telemetry waveforms that are generated by the IMD to the telemetry state monitor 416 and to the data acquisition process module (DAP) 409. DAP module 409 also gathers ECG waveform data via ECG module 410 from the patient having IMD 132. DAP 409 proceeds to link the telemetry data from the IMD with the ECG data and then bundles the data for transmission in regular intervals back to programming unit 102. Programming unit 102 receives and displays the data to the physician and to the user via a user interface 412 (through extender 130). User interface 412 provides regular status updates to the medical personnel using the extender to re-position the programming head or is used to display messages coming from the application proxy (e.g., cancel read switch) if a communications breakdown occurs. In an example embodiment, the user interface is used to input data or commands to the application proxy.

The telemetry state monitor (TSM) 416 is coupled to application proxy 106B and monitors telemetry waveforms that are generated by the IMD. In addition, the telemetry state monitor regularly samples waveform data from the

IMD to determine if the telemetry link is still valid and determines the status of the read switch. The TSM then decides whether it is necessary to notify the application proxy **106B** that a condition of concern has occurred or if any irregularities are identified. The TSM also sends status messages to extender **130**, user interface **412** and to programmer **102**.

In addition, IPC **408** sends commands to telemetry module **411** coming from the programmer and receives static data from telemetry module **411** that is sent to the programmer along with status data from telemetry state monitor **416**. IPC **408** also serves as an intermediary in directing data to either LEM **414** or to the extender module **130**. Application proxy **106B** provides the following functions that can be grouped together in different ways depending on the conditions that are being responded to. The application proxy acts on behalf of the programming application (or programmer) to respond to unexpected events that may occur in programming an IMD and implements certain downlink transmission commands, such as canceling read switch, performing emergency programming, canceling temporary settings and storing last known permanent values. The application proxy also maps events to the downlink transmissions; coordinates device interactions with the programming application; and notifies the user interface (UI) of changes in communications status with the actions to be taken in connection with the changes. I

In another related application, the present invention is useful in training medical personnel in remote locations on the aspects of programming IMDs. A voice communications link would first be established with an IMD operator, located proximate the patient with the IMD to be interrogated, that will be moving the programming head or wand coupled to the extender module. If the communications link with the extender module is interrupted, the IMD operator is advised by immediately over the voice communications link the status of the programming during the training session by the training physician located at the programming location. The voice communications link can be established via a telephone, a video conference call, a cellular telephone, via a separate Internet connection or other related communications formats.

Some of the advantages provided by the various embodiments of the present invention include enhanced patient availability for regular IMD and ECG evaluations; increased accuracy of data being communicated between the implanted device and the medical communications system due to the monitoring of the telemetry link with the implanted device. In addition, the present invention provides for a comfortable programming or interrogation session in a patient's home or familiar environment and eliminates the necessity of traveling to the hospital.

The present invention is compatible with a number of techniques for interrogating and programming implanted medical devices, such as drug pumps, neurological implants, nerve stimulators, various cardiac implants and equivalent medical devices. In addition, the embodiments described are compatible with remote patient management systems that interact with remote data and expert data centers and compatible with a data communication system that enables the transfer of clinical data from the patient to a remote location for evaluation, analysis, data reposition, and clinical evaluation.

Various modifications, equivalent processes, as well as numerous structures to which the present invention may be applicable will be readily apparent to those of skill in the art

to which the present invention is directed upon review of the present specification. The claims are intended to cover such modifications and devices.

We claim:

1. A method for conducting failure mode recovery in an implantable medical device upon interruption of communications with the implantable medical device, the method comprising:

- (a) establishing a communications link between a remote medical communications system having a programming application program and a programming extender module configured to receive an application proxy from the application program;
- (b) loading the application proxy into the programming extender module;
- (c) transitioning the implantable medical device to a known recovery state in response to an interruption of a communications with the implantable medical device;
- (d) transitioning the implantable medical device to a predetermined completed state;
- (e) monitoring transition of the implantable medical device to the predetermined completed state; and
- (f) automatically restoring the implantable medical device to the known recovery state by the application proxy if an interruption of communications with the implantable medical device is detected while transitioning to the completed state.

2. The method of claim **1**, further comprising the step of automatically re-establishing the communications link with the implantable medical device by repeating steps (a) and (b) after an interruption of communications with the implantable medical device has been detected.

3. The method of claim **2**, further comprising the step of establishing a voice communications link with a patient having the implantable medical device at the programming extender module before step (a).

4. The method of claim **1**, wherein the restoring step includes the steps of:

- performing downlink transmission commands that transition the implanted device out of a programming mode;
- monitoring the communications link for changes in status; and
- reporting changes in status of the communications link via a user Interface.

5. The method of claim **4**, further comprising the step of displaying messages via the user interface on actions performed by the application proxy.

6. The method of claim **4**, further comprising the step of reconfiguring the application proxy via the user interface.

7. The method of claim **1**, wherein the monitoring step includes the steps of:

- validating a communications connection with the remote medical communications system;
- validating a set of initialization steps for programming the implantable medical device; and
- monitoring the communications link between the implantable medical device and the remote medical communications system.

8. The method of claim **1**, wherein step (e) includes collecting a set of ECG and telemetry waveform data as a data set and transmitting the data set to the remote medical communications system.

9. The method of claim **8**, wherein collecting telemetry waveform data includes sampling data to validate integrity of a telemetry communications link.

10. The method of claim 9, further comprising the step of transmitting a telemetry communications link status code to the application program and to the extender module.

11. The method of claim 1, further comprising the step of disabling the application proxy and terminating the communications link when an interruption of communications with the implantable medical device is not detected after step (e).

12. A system for conducting failure mode recovery in an implantable medical device upon interruption of with the implanted medical device, the system comprising:

- (a) a remote medical communications system having an implantable medical device programming application program;
- (b) a programming extender module interfacing the medical communications system to the implantable medical device and being, configured to receive an application proxy from the application program;
- (c) means for establishing a communications link between the medical communications system and the programming extender module;
- (d) means for loading an application proxy into the programming extender module and transitioning the implantable medical device to a known recovery state in response to an interruption in communications between the medical communications system and the implantable medical device;
- (e) means for transitioning the implantable medical device to a predetermined completed state;
- (f) means for monitoring transition of the implantable medical device to the completed state; and
- (g) the application proxy being configured to automatically restore the implantable medical device to the recovery state when an interruption in communications between the medical communications system and the implantable medical device is detected while the implantable medical device is transitioning to the completed state.

13. A method for collecting waveform data from a patient's heart, the method comprising:

- (a) establishing a communications link between a remote medical communications system having an application program and an extender module configured to receive an application proxy from the application program;
- (b) loading the application proxy into the extender module via the application program, the extender module being proximate the patient's heart, the application proxy being configured to execute the application program and to re-establish the communications link in response to a loss of communications;
- (c) collecting waveform data from the patient's heart; and
- (d) monitoring the communications link between the remote medical communications system and the extender module for a loss of communications and advising the application proxy if a loss of communications is detected.

14. A system for collecting waveform data from a patient's heart, the system comprising:

- (a) a remote medical communications system having an implantable medical device programming application program;
- (b) a programming extender module interfacing the medical communications system to the implantable medical device and being configured to receive an application proxy from the application program, the programming extender module being located proximate the patient's heart;

(c) means for establishing a communications link between the medical communications system and the programming extender module;

(d) means for loading the application proxy into the programming extender module to re-establish an interrupted communications link;

(e) means for collecting waveform data from the patient's heart; and

(f) means for monitoring the communications link between the medical communications system and the programming extender module and advising the application proxy if an interruption of the communications link is detected.

15. A method for conducting failure mode recovery in an implantable medical device upon loss of communications with a remote medical communications system, the method comprising:

(a) loading an application proxy from a programming application program resident on the remote medical communications system into a programming extender module, the application proxy being configured to transition the implantable medical device to a known recovery state in response to a loss of communications;

(b) establishing a communications link between the implantable medical device and the remote medical communications system via the programming extender module;

(c) transitioning the implantable medical device to a completed state via the programming application program;

(d) monitoring transition of the implantable medical device to the completed state; and

(e) automatically restoring the implantable medical device to the known recovery state by the application proxy if a loss of communications is detected while transitioning the implantable medical device to the completed state.

16. The method of claim 15, wherein the restoring step includes the steps of implementing downlink transmission commands; monitoring the communications link for changes in status; and reporting changes in the communications link status via a user interface.

17. The method of claim 16, wherein the restoring step further includes the steps of mapping events to downlink transmissions and coordinating implantable medical device interactions with the application program.

18. The method of claim 15, wherein the monitoring step includes the step of monitoring the communications link between the implantable medical device and the remote medical communications system.

19. A system for conducting failure mode recovery in an implantable medical device upon loss of communications with a remote medical communications system having an application program for programming the implantable medical device, the system comprising:

(a) a programming extender module interfacing the implantable medical device with the remote medical communications system;

(b) means for loading an application proxy from the application program into the programming extender module, the application proxy configured to transition the implanted device to a known recovery state in response to a loss of communications;

(c) means for establishing a communications link between the implantable medical device and the medical com-

munications system via the extender module after a loss of communications;

- (d) means for transitioning the implantable medical device to a completed state via the application program;
- (e) means for monitoring transition of the implantable medical device to the completed state; and
- (f) means for automatically restoring the implantable medical device to the known recovery state if a loss of communications is detected while the implantable medical device is transitioning to the completed state.

20. A method for conducting failure mode recovery in an implantable medical device upon loss of communications with a remote medical communications system, the method comprising:

- (a) establishing a first communications link between the remote medical communications system and an extender module;
- (b) loading an application proxy from a programming application program resident on the remote medical communications system into the extender module, the application proxy being configured to transition the implantable medical device to a known recovery state in response to a loss of communications;
- (c) establishing a second communications link between the implantable medical device and the remote medical communications system via the extender module;
- (d) transitioning the implantable medical device to a completed state via the application program;
- (e) monitoring transition of the implantable medical device to the completed state; and
- (f) automatically restoring the implantable medical device to the known recovery state by the application proxy if a loss of communications is detected while transitioning the implantable medical device to the completed state.

21. The method of claim 20, wherein the restoring step includes the steps of implementing downlink transmission commands; monitoring the communications link for

changes in status; and reporting changes in the communications link status via a user interface.

22. The method of claim 20, wherein the restoring step further includes the steps of mapping events to downlink transmissions and coordinating implantable medical device interactions with the application program.

23. The method of claim 20, wherein the monitoring step includes the step of monitoring the communications link between the implantable medical device and the remote medical communications system.

24. A system for conducting failure mode recovery in an implantable medical device upon loss of communications with a remote medical communications system, the system comprising:

- (a) a programming extender module;
- (b) means for establishing a first communications link between the remote medical communications system and the programming extender module;
- (c) means for loading a application proxy from a programming application program resident on the remote medical communications system into the programming extender module, the application proxy being configured to transition the implantable medical device to a known recovery state in response to a loss of communications;
- (d) means for establishing a second communications link between the implantable medical device and the remote medical communications system via the programming extender module;
- (e) means for transitioning the implantable medical device to a completed state via the application program;
- (f) means for monitoring transition of the implantable medical device to the completed state; and
- (g) an application proxy configured to automatically restore the implantable medical device to the known recovery state if a loss of communications is detected while transitioning the implantable medical device to the completed state.

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专利名称(译)	用于在植入的医疗设备中进行故障模式恢复的方法和系统		
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摘要(译)

一种用于进行植入式医疗设备的故障模式恢复的方法和系统。当IMD的编程期间的条件意外地改变时, 所描述的实施例降低了使IMD处于不期望状态的风险。在示例实施例中, 当与具有应用程序的医疗通信系统的通信链路被中断时, 便于植入设备中的故障模式恢复。故障模式恢复方法包括在医疗通信系统和扩展器模块之间建立通信链路, 扩展器模块被配置为从应用程序接收应用代理。然后通过应用程序将应用程序代理加载到扩展器模块中。应用代理被配置为响应于一组条件将植入设备转换到恢复状态。然后, 植入的设备通过应用程序转换到完成状态, 同时监视完成状态的转换。当转换到完成状态时检测到一组条件时, 应用代理自动将植入设备恢复到恢复状态。

