(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 14 August 2003 (14.08.2003)

PCT

(10) International Publication Number WO 03/066163 A2

(51) International Patent Classification⁷: A61N 1/372

(21) International Application Number: PCT/US03/03748

(22) International Filing Date: 7 February 2003 (07.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/071,255 7 February 2002 (07.02.2002) US

- (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112 (US).
- (72) Inventors: VON ARX, Jeffrey, A.; 2115 Emerson Avenue South, Minneapolis, MN 55405 (US). YONCE, David, J.; 7580 Alden Way, Fridley, MN 55432 (US). MAZAR, Scott, T.; 6170 Brent Avenue East, Inver Grove Heights, MN 55076 (US). LENT, Karen, M.; 418 South 6th Street, Stillwater, MN 55082 (US). HARRIS, Thomas, J.; 3575 Owasso Street #201, Shoreview, MN 55126 (US).
- (74) Agents: STEFFEY, Charles, E. et al.; Schwegman, Lundberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402 (US).

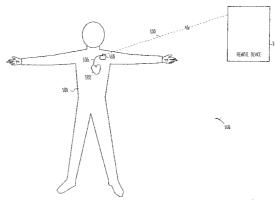
- (81) Designated States (national): AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

 without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: IMPLANTABLE MEDICAL DEVICE WITH TELEMETRY POWER MANAGEMENT



(57) Abstract: An implantable medical device includes a radio-frequency (RF) telemetry circuit and a power connection module through which the RF telemetry circuit is connected to an energy source such as a battery. The power connection module connects power from the energy source to at least one portion of the RF telemetry circuit when a user initiates an RF telemetry session. After the RF telemetry session is completed, the power connection module shuts off the at least one portion of the RF telemetry circuit. Power-on examples include a wireless telemetry activation signal received by a low power radio receiver in the implantable device, a physical motion detected by an activity sensor in the implantable device, an activation of an inductive telemetry circuit in the implantable device, a magnetic field detected by a magnetic field detector in the implantable device, and/or a telemetry activation signal detected by a sensing circuit included in the implantable device. Power-off examples include a wireless termination signal received by the implantable device, a delay timeout following the RF telemetry session, and/or a signal received by an inductive telemetry circuit in the implantable device.



03/066163

WO 03/066163 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

IMPLANTABLE MEDICAL DEVICE WITH TELEMETRY POWER MANAGEMENT

5 <u>Cross-Reference to Related Applications</u>

This application is related to co-pending, commonly assigned Von Arx et al. U.S. Patent Application Serial No. 10/025,223, entitled "A TELEMETRY DUTY CYCLE MANAGEMENT SYSTEM FOR AN IMPLANTABLE MEDICAL DEVICE," filed December 19, 2001 (Attorney Docket No. 279.366US1) and Von Arx et al. U.S. Patent Application Serial No. 10/025,183, entitled "AN IMPLANTABLE MEDICAL DEVICE WITH TWO OR MORE TELEMETRY SYSTEMS," filed December 19, 2001 (Attorney Docket No. 279.391US1), each of which is hereby incorporated by reference.

15 <u>Technical Field</u>

10

20

25

30

This document relates generally to implantable medical devices with telemetry.

Background

Medical devices are implanted in human bodies for monitoring physiological conditions, diagnosing diseases, treating diseases, or restoring functions of organs or tissues. Examples of such implantable medical devices include cardiac rhythm management systems, neurological stimulators, neuromuscular stimulators, and drug delivery systems. Because such a device may be implanted in a patient for a long time, the size and power consumption of the device are inherently constrained. Consequently, an implantable device may depend on an external system to perform certain functions. Communication between the implantable device and the external system is referred to as telemetry. Examples of specific telemetry functions include programming the implantable device to perform certain monitoring or therapeutic tasks, extracting an operational status of the implantable device, transmitting real-time physiological data acquired by the implantable device, and extracting physiological data acquired by and stored in the implantable device.

5

10

15

20

25

30

One particular example of implantable medical devices is a cardiac rhythm management device implanted in a patient to treat irregular or other abnormal cardiac rhythms by delivering electrical pulses to the patient's heart. Such rhythms result in diminished blood circulation. Implantable cardiac rhythm management devices include, among other things, pacemakers, also referred to as pacers. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly or irregularly. Such pacers may coordinate atrial and ventricular contractions to improve the heart's pumping efficiency. Implantable cardiac rhythm management devices also include devices providing cardiac resynchronization therapy (CRT), such as for patients with congestive heart failure (CHF). CHF patients have deteriorated heart muscles that display less contractility and cause poorly synchronized heart contraction patterns. By pacing multiple heart chambers or multiple sites within a single heart chamber, the CRT device restores a more synchronized contraction of the weakened heart muscle, thus increasing the heart's efficiency as a pump. Implantable cardiac management devices also include defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Such defibrillators may also include cardioverters, which synchronize the delivery of such stimuli to portions of sensed intrinsic heart activity signals. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. In addition to pacers, CRT devices, and defibrillators, implantable cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the functions of pacers and defibrillators, drug delivery devices, and any other implantable systems or devices for diagnosing or treating cardiac arrhythmias.

Typically, an implantable cardiac rhythm management device communicates, via telemetry, with an external device referred to as a programmer. One type of such telemetry is based on inductive coupling between two closely-placed coils using the mutual inductance between these coils. This type of telemetry is referred to as inductive telemetry or near-field telemetry because the coils must typically be closely situated for obtaining inductively coupled communication. One example of such an inductive telemetry is discussed in Brockway et al., U.S. Patent No. 4,562,841, entitled

"PROGRAMMABLE MULTI-MODE CARDIAC PACEMAKER," assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference in its entirety.

5

10

15

20

25

30

In one example, an implantable device includes a first coil and a telemetry circuit, both sealed in a metal housing (referred to as a "can"). The external programmer provides a second coil in a wand that is electrically connected to the programmer. During device implantation, a physician evaluates the patient's condition, such as by using the implanted device to acquire realtime physiological data from the patient and communicating the physiological data in real-time to the external programmer for processing and/or display. The physician may also program the implantable device, including selecting a pacing or defibrillation therapy mode, and parameters required by that mode, based on the patient's condition and needs. The data acquisition and device programming are both performed using the inductive telemetry. If the patient's condition is stable after implantation, he or she needs no attention from the physician or other caregiver until a scheduled routine follow-up. During a typical routine followup, the physician reviews the patient's history with the implantable device, reevaluates the patient's condition, and re-programs the implantable device if necessary.

One problem with inductive telemetry is its requirement that the two coils are closely placed. This typically requires placing the wand on the body surface over the implantable device. Because the wand is electrically connected to the programmer using a cable, the inductive telemetry limits the patient's mobility.

To improve communication range and patient mobility, a far-field radio-frequency (RF) telemetry may be used, in which an RF transceiver in the implantable device is used to communicate with an RF transceiver in the external programmer. With a far-field RF telemetry, the patient is typically free of any body surface attachment that limits mobility. However, RF telemetry may consume several thousand times more energy than inductive telemetry.

For these and other reasons, the present inventors have recognized an unmet need for long-range telemetry at reduced energy consumption from the implantable device.

Summary

An implantable medical device includes a radio-frequency (RF) telemetry circuit that includes a power switch through which the RF telemetry circuit is connected to an energy source such as a battery. The power switch is closed to connect power from the energy source to the RF telemetry circuit when a user initiates an RF telemetry session. After the RF telemetry session is completed, the power switch is opened to shut off at least a portion of the RF telemetry circuit.

5

10

15

20

25

30

In one example, the RF telemetry circuit is powered on by sending a telemetry activation signal from the remote device to the implantable device. A physician or other caregiver operating the remote device initiates an RF telemetry session. The power switch is closed when the telemetry activation signal is detected by the implantable device.

In another example, the RF telemetry circuit is powered on by a physical movement sensed by an accelerometer and detected by the implantable device. A patient with the implantable device initiates an RF telemetry session by tapping on the skin over the implantable device. The power switch is closed when the implantable device detects an acceleration resulted from the tapping.

In another example, the RF telemetry circuit is powered on by activating an inductive telemetry circuit included in the implantable device. A physician or other caregiver operating an external programmer initiates an inductive telemetry operation in order to initiate an RF telemetry session. The power switch is closed when an inductive telemetry circuit in the implantable device is activated.

In another example, the RF telemetry circuit is powered on by a magnetic field detected by the implantable device. A physician or other caregiver waves a magnet or a hand held device generating a magnetic field to initiate an RF telemetry session. The power switch is closed when the magnetic filed exceeds a predetermined level and is detected by the implantable device.

In another example, the RF telemetry circuit is powered on by introducing a telemetry activation signal into the patient through a surface electrocardiography (ECG) recording system. A physician or other caregiver operating the remote device including an ECG module initiates an RF telemetry

session. The power switch is closed when the telemetry activation signal is detected by a biopotential sensing circuit in the implantable device.

In another example, the RF telemetry circuit is powered on by introducing a telemetry activation signal into a patient through contacts between the patient and an external device adopted for telemetry activation. A patient initiates an RF telemetry session by contacting the external device. The power switch is closed when the telemetry activation signal is detected by a biopotential sensing circuit in the implantable device.

5

10

15

20

25

30

In one example, the RF telemetry circuit is shut off when a termination signal sent from the remote device through the RF telemetry is received by the implantable device. A physician or other caregiver operating the remote device may issue the termination signal. Alternatively, the termination signal may be sent when the remote device determines that the RF telemetry session is to be concluded. The power switch is opened when the implantable device receives the termination signal.

In another example, the RF telemetry circuit is shut off after a predetermined delay following an end of a data transmission session. A timer is started when the data transmission stops. The power switch is opened at the end of the predetermined delay if the data transmission has not resumed.

In another example, the RF telemetry circuit is shut off by activating an inductive telemetry circuit included in the implantable device. A physician or other caregiver operating an external programmer terminates an RF telemetry session. The power switch is closed immediately after the inductive telemetry circuit in the implantable device is activated.

Depending on a patient's needs for care and type of implantable device, one or more of the power-on methods and one or more of the power-off methods discussed in this document may be included in one implantable device. Using more than one method to connect/disconnect power from the energy source to the RF telemetry circuit increases the reliability of initiating and terminating the RF telemetry session in a timely manner to ensure patient safety and conserve energy and hence device longevity. Other aspects of the present systems, devices, and methods will become apparent upon reading the following Detailed Description and viewing the drawings that form a part thereof.

Brief Description of the Drawings

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

5

10

15

20

Figure 1 is a schematic illustration of an example of portions of an implantable system 100 and portions of an environment in which it is used.

Figure 2 is a schematic/block diagram illustrating one example of portions of a telemetry power management system for an implantable medical device.

Figure 3A is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-on by using a telemetry activation signal detector including a low power radio receiver.

Figure 3B is a schematic illustrating one example of the low power radio receiver.

Figure 4 is a flow chart illustrating one example of a method corresponding to the example of Figure 3A.

Figure 5 is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-on by detecting a physical activity.

Figure 6 is a flow chart illustrating one example of a method corresponding to the example of Figure 5.

Figure 7 is a schematic illustration of one example of portions of a telemetry power management system controlling power-on by activating inductive telemetry.

Figure 8 is a schematic/block diagram illustrating one example of portions of a telemetry power management system corresponding to the example of Figure 7.

Figure 9 is a flow chart illustrating one example of a method corresponding to the example of Figure 8.

Figure 10 is a schematic illustration of one example of portions of a telemetry power management system controlling power-on by creating a magnetic field near the implantable medical device.

Figure 11 is a schematic/block diagram illustrating one example of portions of a telemetry power management system corresponding to the example of Figure 10.

Figure 12 is a flow chart illustrating one example of a method corresponding to the example of Figure 11.

5

10

15

20

30

Figure 13 is a schematic illustration of one example of portions of a telemetry power management system controlling power-on by introducing a signal through an electrocardiograph (ECG) system.

Figure 14 is a circuit diagram illustrating one example of portions of the telemetry power management system of Figure 13.

Figure 15 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on by introducing a signal through an electrocardiograph (ECG) system.

Figure 16 is a circuit diagram illustrating one example of portions of the telemetry power management system of Figure 15.

Figure 17 is a schematic/block diagram illustrating one example of portions of a telemetry power management system corresponding to the examples of Figures 14 and 16.

Figure 18 is a schematic/block diagram illustrating one example of portions of a sensing amplifier.

Figure 19 is a schematic/block diagram illustrating another example of portions of a sensing amplifier.

Figure 20 is a flow chart illustrating one example of a method corresponding to the example of Figure 17.

Figure 21 is a schematic illustration of one example of portions of a telemetry power management system controlling power-on by using an external telemetry activation device.

Figure 22 is a schematic/block diagram illustrating one example of portions of telemetry power management system corresponding to the example of Figures 21.

Figure 23 is a flow chart illustrating one example of a method corresponding to the example of Figure 22.

Figure 24 is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-off by sending a command via RF telemetry.

Figure 25 is a flow chart illustrating one example of a method corresponding to the example of Figure 24.

5

10

15

20

25

30

Figure 26 is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-off by using a timer.

Figure 27 is a flow chart illustrating one example of a method corresponding to the example of Figure 26.

Figure 28 is a flow chart illustrating one example of a method corresponding to one example of a telemetry power management system controlling power-off by using an inductive telemetry.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings that form a part hereof, and in which is shown, by way of illustration, specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

This document discusses, among other things, power management of telemetry circuit in an implantable medical device. The present methods and apparatuses will be described in applications involving implantable cardiac rhythm management systems such as pacemakers, CRT devices, cardioverter/defibrillators, and pacer/defibrillators. However, it is understood that the present methods and apparatuses may be employed in other types of

implantable medical devices, including, but not being limited to, neurological stimulators, neuromuscular stimulators, drug delivery systems, and various types of physiological signal monitoring devices.

5

10

15

20

25

30

Figure 1 is a schematic illustration of an example of portions of a medical system 100 and portions of an environment in which it is used. In this example, system 100 is a cardiac rhythm management system including, among other things, an implanted device 110 and a remote external device 140. Implanted device 110 is implanted within a patient's body 101 and coupled to the patient's heart 102 by a lead system 105. Examples of implanted device 110 include pacemakers, CRT devices, cardioverter/defibrillators, and pacer/defibrillators. Remote external device 140 provides a user interface for system 100. The user interface allows a physician or other caregiver to interact with implanted device 110 through a wireless telemetry link. In the example of Figure 1, the wireless telemetry link is a radio-frequency (RF) telemetry link 150 supported by RF transceivers residing in implanted device 110 and external device 140. RF telemetry link 150 provides for bi-directional data communication between implanted device 110 and remote device 140.

In one example, RF telemetry link 150 provides for data transmission from implanted device 110 to remote device 140. This may include, for example, transmitting real-time physiological data acquired by implanted device 110, extracting physiological data acquired by and stored in implanted device 110, extracting therapy history data stored in implanted device 110, and extracting data indicating an operational status of implanted device 110 (e.g., battery status and lead impedance). In a further example, RF telemetry link 150 transmits data from remote device 140 to implanted device 110. This may include, for example, programming implanted device 110 to acquire physiological data, programming implanted device 110 to perform at least one self-diagnostic test (such as for a device operational status), and programming implanted device 110 to deliver at least one therapy.

In one example, RF telemetry link 150 is a far-field telemetry link. A far-field, also referred to as the Fraunhofer zone, refers to the zone in which a component of an electromagnetic field produced by the transmitting electromagnetic radiation source decays substantially proportionally to 1/r,

where r is the distance between an observation point and the radiation source. Accordingly, far-field refers to the zone outside the boundary of $r = \lambda/2\pi$, where λ is the wavelength of the transmitted electromagnetic energy. In one example, a communication range of RF telemetry link 150 (a distance over which data is capable of being wirelessly communicated) is at least six feet but can be as long as allowed by the particular communication technology. Unlike an inductive telemetry link using a wand placed near implanted device 110, typically attached to the patient, and electrically connected to remote external device 140 with a cable, using RF telemetry link 150 frees the patient from any physical restraints caused by the wand and the cable. On the other hand, the power consumed by implanted device 110 to support a far-field RF telemetry can be as high as ten thousand times that of inductive telemetry. To reduce the energy consumption of implanted device 110, the present inventors have recognized the need for power management to reduce the energy drawn from implanted device 110 to support the RF telemetry link 150.

5

10

15

20

25

30

Figure 2 is a schematic/block diagram illustrating one example of portions of a telemetry power management system for implantable medical device. In this example, implantable medical system 100 includes implanted device 110, external remote device 140, and RF telemetry link 150. Remote device 140 includes a remote RF telemetry circuit 242 and a remote antenna 243. Implanted device 110 includes an energy source 211, an implanted RF telemetry circuit 212, an implanted antenna 213, and a switch controller 214. RF telemetry circuits 212 and 242, through antenna 213 and 243, respectively, communicate using RF telemetry link 150. A power switch 215, when closed, connects implanted RF telemetry circuit 212 to energy source 211 to draw energy therefrom. In many applications of system 100, data is being transmitted for a small fraction of the time when implanted device 110 is in use. Therefore, RF telemetry circuit 212 only needs to be powered during a data transmission (and for a short preceding power-up period). In this example, an output of switch controller 214 drives power switch 215. Switch controller 214 closes power switch 215 when implantable RF telemetry circuit 212 is powered to support the data transmission over RF telemetry link 150 and opens power switch 215 shortly after the data transmission is completed. This document presents several

specific illustrative examples of controlling the power-on and power-off status of RF telemetry circuit 212, such as by closing and opening power switch 215, respectively. The examples can be combined in any way.

In this document, "power switch" refers generally to any power connection module, not limited to an on/off switch, that, in one example controls an activation (or power-on) and deactivation (or power-off) of the RF telemetry. In one example, the RF telemetry circuit is powered on, or activated, when it enters an energization state that enables it to perform its intended telemetry function. In another example, the RF telemetry circuit is powered off, or deactivated, when it enters another energization state that maintains the circuit off or in a "sleep" or "barely awake" mode to conserve energy. In one example, the power switch connects/disconnects power from the energy source to one or more portions of the RF telemetry circuit.

In one example, power switch 215 connects/disconnects power from energy source 211 to portions of RF telemetry circuit 212. After the telemetry session is terminated, power switch 215 disconnects power from the portions of RF telemetry circuit 212 but maintains power connection to other portions of RF telemetry circuit 212, such that RF telemetry circuit 212 may be activated quickly when a new telemetry session is initiated.

20

25

30

5

10

15

Example of Power-On by Using a Low-Power Radio Receiver

Figure 3A is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry. In this example, power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212 when implanted device 110 receives an radio signal. Remote device 140 includes a telemetry activation signal generator 346 coupled to remote antenna 243. Switch controller 214 includes a telemetry activation signal detector 316 coupled to implanted antenna 213. Telemetry activation signal detector 316 includes a low power radio receiver 317. Low power radio receiver 317 is always awake to respond to telemetry activation signals. To initiate a data transmission over RF telemetry link 150, a telemetry activation signal is generated by telemetry activation signal generator 346 and emitted through

remote antenna 243. Upon receiving the telemetry activation signal through implanted antenna 213, telemetry activation signal detector 316 closes power switch 215 to operate implanted RF telemetry circuit 212. The telemetry activation signal is a radio signal having an amplitude and frequency in compliance with applicable government regulations. In one example, the telemetry activation signal is a high-power RF burst signal.

Figure 3B is a schematic illustrating one example of low power radio receiver 317. Low power radio receiver includes a tank circuit 318, a diode 319, a low-pass filter 320, and a low-power comparator 321. Tank circuit, coupled to antenna 213 to receive a signal including the telemetry activation signal, includes an inductor and a capacitor to form a high-Q resonant circuit that obtains a gain passively. Diode 319 is a non-linear element for rectifying the received signal. Low pass filter 320 includes a resistor and a capacitor to detect an envelope of the rectified signal. Low power comparator generates an output indicating a detection of the telemetry activation signal when at least a portion of the envelope exceed a predetermined detection threshold. In one example, low power radio receiver operates with a supply current of approximately 100 nA - 500 nA.

Figure 4 is a flow chart illustrating one example of a method corresponding to the example of Figure 3A. At 400, an RF telemetry session is initiated at remote device 140. In one example, the RF telemetry session is initiated by a physician or other caregiver. In another example, the RF telemetry session is initiated automatically by remote device 140, e.g., occasionally or periodically. In one example, the RF telemetry session is initiated for a regular check-up of a status of the device and conditions of the patient in whom the device is implanted. In one example, the RF telemetry session is initiated in response to a phone from a person, such as a caregiver or the patient, regarding a condition of the patient that needs immediate attention. At 410, remote device 140 sends out a telemetry activation signal. The telemetry activation signal is a radio signal having an amplitude and frequency in compliance with applicable government regulations. In one example, the telemetry activation signal is an RF burst. In a further example, the RF burst has a duration of up to five milliseconds and an amplitude sufficient to be received by implanted RF

5

10

15

20

25

30

telemetry circuit 212 up to a predetermined distance from remote device 140. Typically, the RF burst received at implanted RF telemetry circuit 212 has an amplitude of at least 1 mV. In one example, the RF burst amplitude used is determined based on an environmental noise and a signal-to-noise ratio that ensures reliable detection by diode detector 317. In one example, remote device sends a digital key that follows the telemetry activation signal. The digital key is a coded signal identifying a particular implantable device 110. If the telemetry activation signal is received by at least one implanted device 110 within the predetermined distance from remote device 140, power switch 215 in that particular implanted device 110 is closed at 430 for connecting RF telemetry circuit 212 and energy source 211 of that implanted device 110. At 440, telemetry device is activated to perform RF telemetry functions. At 450, if the particular implanted device 110 receives the digital key matching its identification code, it sends a responsive signal to remote device 140. In one example, implanted device 110 is prevented from sending out any signal after an end of the RF telemetry session until a matched digital key is received at the beginning of a new RF telemetry session. The reception of this responsive signal by remote device 140 indicates that RF telemetry has been successfully established, i.e., RF telemetry link 150 is ready for bi-directional data transmission. If the identification code fails to match the identification of the particular implanted device 110, its power switch 215 is opened at 455, and remote device 140 repeats the process at 410 after a predetermined delay 415. After the RF telemetry is established at 450, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140 at 460. The RF telemetry enters an idle state following an end of the RF telemetry session, when RF telemetry circuit 212 is powered but no data is being transmitted between implanted device 110 and remote device 140. After the RF telemetry enters an idle state, power switch 215 is opened at 470 to disconnect power to at least a portion of RF telemetry circuit 212. Examples of methods and apparatus controlling the opening of power switch 215 are described later in this document. At 480, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a message.

Example of Power-On by Physical Motion

5

10

15

20

25

30

Figure 5 is a schematic/block diagram illustrating another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry. In this example, power switch 215 is closed to connect power from energy source 211 to RF telemetry circuit 212 when a patient activity (e.g., a body motion) of a predetermined magnitude, duration, and/or pattern is detected. In this example, switch controller 214 includes accelerometer 520 and a sensor signal processing circuit 521. Accelerometer 520 senses acceleration of implanted device 110, resulted from body motion of the patient. In one example, sensor processing circuit 521 includes an amplifier and a filter to condition the activity signal sensed by accelerometer 520 and a comparator to compare the conditioned acceleration signal to a predetermined acceleration threshold. If the conditioned acceleration signal exceeds the predetermined acceleration threshold, sensor processing circuit 521 outputs a signal to close power switch 215. In an additional example, sensor processing circuit 521 further includes a pattern recognition module to detect a predetermined pattern of acceleration. One example of such pattern of acceleration includes three momentary acceleration impulses that are about one second apart from each other and all exceed the predetermined acceleration threshold.

Figure 6 is a flow chart illustrating one example of a method corresponding to the example of Figure 5. At 600, a physical movement of the patient in whom implanted device 110 is implanted initiates an RF telemetry session. In one example, the patient initiates an RF telemetry session to inform or alert a physician or caregiver of his recent or present condition. To initiate the telemetry operation at 610, the patient taps on his/her skin over implanted device 110. The movement resulted from the tapping is sensed by accelerometer 520. If the tapping results in an acceleration that exceeds a predetermined threshold acceleration level at 620, sensor processing circuit 521 outputs a signal that closes power switch 215 at 625. If the acceleration is below the threshold, the tapping does not initiate an RF telemetry session. In another example, in addition to requiring that acceleration exceeds a predetermined threshold

5

10

15

20

25

30

acceleration level, the tapping activity must also exhibit a predetermined pattern, and sensor processing circuit 521 outputs a signal to close power switch 215 at 625. One suitable predetermined pattern of movement results from tapping on the skin over the device three times in approximately one-second intervals. At 630, just after switch 215 is closed, RF telemetry circuit 212 is activated and ready for bi-directional communication with remote device 140 via RF telemetry link 150. In one example, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry. If the signal is received by remote device 140, and remote device 140 is available for communication, remote device 140 sends a response signal back to implanted device 110, and the RF telemetry is established at 640. If the RF telemetry cannot be established, because, for example, there is no available remote device 140 within the RF telemetry range, implanted RF telemetry circuit 212 will repeat 630 after a predetermined delay 645. In one example, delay 645 is a programmable constant. A suitable range of this constant is 0.5 to 2 seconds. In another example, delay 645 is a function of the number of unsuccessful attempts to establish the RF telemetry. This function represents a particular sequence of successive attempts to establish the RF telemetry. For example, if the first attempt fails, the next five attempts may be made in about one-minute intervals. If the RF telemetry is still not established, further attempts may be made in about 30-minute intervals. Other examples of successive attempts may include a time interval between consecutive attempts that increases linearly or exponentially. In another example, remote device 140 occasionally or periodically sends a signal including a digital key identifying a particular implantable device 110. In response to receiving this signal, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry at 640. In this example, implantable device 110 is prevented from starting RF telemetry communications without an authorization from remote device 140. Thus, implant device 110 need not make repeated attempts to establish RF telemetry, thereby saving energy. This also prevents the situation in which multiple implantable devices compete to establish RF telemetry with one remote device 140 by giving remote device 140 the control over which particular implantable device 110 to communicate with. Furthermore, preventing implantable device 110 from initiating signal transmission ensures

that implantable device 110 does not accidentally sent RF signals in violation of applicable government regulations when the patient travels to a different country. After the RF telemetry is established at 640, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140 at 650. After the RF telemetry enters an idle state, power switch 215 is opened at 660 to disconnect power from energy source 211 to at least a portion of RF telemetry circuit 212. Examples of methods and apparatus controlling the opening of power switch 215 are described later in this document. At 670, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a message.

Example of Power-On by Activating Inductive Telemetry

5

10

15

20

25

30

Figure 7 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry. In this example, system 100 includes an additional remote device, such as an external programmer 745. External programmer 745 and implanted device 110 include respective circuits providing an inductive telemetry link 755. Inductive telemetry link 755 uses mutual inductance between two closely placed coils, one at implanted device 110 and the other carried by a wand 746. Wand 746 is coupled to the external programmer 745 via a cable. When wand 746 is in place to form an adequate mutual inductance between the coils, external programmer 745 sends implanted device 110 a synchronization signal to establish inductive telemetry link 755. The establishment of inductive telemetry link 755 initiates the process of establishing the RF telemetry session. This process includes that the implanted device 110 powers up its RF telemetry circuit and sends a signal to remote device 140. The RF telemetry is established when implanted device 110 receives a response signal from remote device 140. In one example, remote device 140 and programmer 745 are physically integrated into one single device.

Figure 8 is a schematic/block diagram illustrating one example of portions of a telemetry power management system corresponding to the example of Figure 7. In this example, system 100 includes implanted device 110, remote device 140, and external programmer 745. In one example, remote device 140

and programmer 745 are physically integrated into one single device. Implanted device 110 communicates with remote device 140 via RF telemetry link 150, or with external programmer 745 via inductive telemetry link 755. External programmer 745 includes an external inductive telemetry circuit 847. Switch controller 214 in implanted device 110 includes an implantable inductive telemetry circuit 828 including an output that controls power switch 215. Inductive telemetry link 755 uses mutual inductance between coil 829 and another coil in wand 746. The coil in wand 746 is electrically connected to external inductive telemetry circuit 847. Switch 215 is closed to connect power from energy source 211 to RF telemetry circuit 212 after implanted inductive telemetry circuit 828 becomes active, i.e., after inductive telemetry link 755 is ready for bi-directional data communication. The inductive telemetry need not remain active after the RF telemetry is established.

5

10

15

20

25

30

Figure 9 is a flow chart illustrating one example of a method corresponding to the example of Figure 8. At 900, a physician or other caregiver initiates an RF telemetry session by placing or waving wand 746 near implanted device 110. In one example, the RF telemetry session is initiated for evaluating a patient's condition, and RF telemetry provides patient mobility after wand 746 is removed. In another example, the RF telemetry session is initiated just before implanted device 110 is implanted in a patient. The RF telemetry avoids bringing wand 746 into the sterile field of the operation. At 910, inductive telemetry link 755 is established. External programmer 745 indicates whether inductive telemetry link 755 was successfully established. If establishment of inductive telemetry link 755 was unsuccessful, the physician or other caregiver adjusts the position of wand 746 until such success is obtained. In one example, external programmer 745 sends a synchronization signal to implanted device 110. Upon receiving the synchronization signal, implanted inductive telemetry circuit 828 sends a return signal back to external programmer 745, and inductive link 755 is established at 910 when external inductive telemetry circuit 847 receives the return signal. At 920, power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212. At 930, RF telemetry circuit 212 is activated and ready for bi-directional communication with remote device 140 via RF telemetry link 150. In one example, implanted

RF telemetry circuit 212 sends a signal to remote device 140. If the signal is received by remote device 140, and remote device 140 is not busy with ongoing telemetry with other implantable device(s), remote device 140 sends a responsive signal back to implanted device 110, and the RF telemetry is 5 established at 940. If the RF telemetry cannot be established at 940, because, for example, there is no available remote device 140 within the RF telemetry range, RF telemetry circuit 212 will repeat 930 after a delay 945. In one example, delay 945 is a programmed constant. In another example, delay 945 is a function of the number of unsuccessful attempts to establish the RF telemetry. 10 This function represents a particular sequence of successive attempts to establish the RF telemetry. In another example, remote device 140 periodically sends a signal including a digital key identifying a particular implantable device 110. Only upon receiving this signal, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry at 940. At 950, external 15 programmer 745 indicates whether RF telemetry link 150 has been established. In one example, the physician or caregiver may then remove wand 746 from near implanted device 110 at 950, leaving the patient free of cable attachment. In another example, the physician or caregiver must remove wand 746 from near implanted device 110 at 950 before the RF telemetry can be established because 20 the inductive telemetry is given priority over the RF telemetry. At 960, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140. After the RF telemetry enters an idle state, power switch 215 is opened at 970 to disconnect power from energy source 211 to at least a portion of RF telemetry circuit 212. Examples of 25 methods and apparatuses controlling the opening of power switch 215 are described later in this document. At 980, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a

30 Example of Power-On by Magnetic Field

message.

Figure 10 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry. In this example, system 100 includes a magnetic field provider

1048. The RF telemetry session is initiated when implanted device 110 detects a magnet field. In one example, magnetic field provider 1048 includes a permanent magnet. In another example, magnetic field provider 1048 includes a hand-held, battery-powered magnetic field provider, such as a wireless, battery operated inductive wand. In another example, magnetic field provider 1048 is an external programmer including an inductive telemetry circuit or other circuit or other device generating a magnetic field.

5

10

15

20

25

30

Figure 11 is a schematic/block diagram illustrating one example of portions of a telemetry power management system corresponding to the example of Figure 10. In this example, system 100 includes implanted device 110, remote device 140, and magnetic field provider 1048. Switch controller 214 in implanted device 110 includes a reed switch or other magnetic field detector 1130 that controls power switch 215. Power switch 215 is closed to connect power from energy source 211 to RF telemetry circuit 212 when a magnetic field is detected by magnetic field detector 1130 exceeds a threshold.

Figure 12 is a flow chart illustrating one example of a method corresponding to the example of Figure 11. At 1200, a physician or other caregiver initiates an RF telemetry session by momentarily waving magnetic field provider 1048 near implanted device 110. In one example, the RF telemetry session allows evaluation of a patient's condition while providing patient mobility. At 1210, the magnetic field from magnetic field provider 1048 is detected by magnetic field detector 1130 when the field strength exceeds a threshold level. In response, at 1220, power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212. At 1230, RF telemetry circuit 212 is activated and ready for bi-directional communication with remote device 140 via RF telemetry link 150. In one example, implanted RF telemetry circuit 212 sends a signal to remote device 140. If the signal is received by remote device 140, and remote device 140 is not busy communicating with other implantable device(s), remote device 140 sends a responsive signal back to implanted device 110, establishing RF telemetry at 1240. If the RF telemetry cannot be established at 1240, because, for example, there is no available remote device 140 within the RF telemetry range, RF telemetry circuit 212 will repeat 1230 after a delay 1245. In one example, delay

1245 is a programmed constant. In another example, delay 1245 is a function of the number of unsuccessful attempts to establish the RF telemetry. This function represents a particular sequence of successive attempts to establish the RF telemetry. In another example, remote device 140 periodically sends a signal including a digital key identifying a particular implantable device 110. Only upon receiving this signal, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry at 1240. At 1250, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140. After the RF telemetry enters an idle state, power switch 215 is opened at 1260 to disconnect power from energy source 211 to at least a portion of RF telemetry circuit 212. Examples of methods and apparatus controlling the opening of power switch 215 are described later in this document. At 1270, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a message.

15

20

25

30

10

5

Example of Power-On by Using Signal Introduced via Surface ECG Electrodes

Figure 13 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry by using an electrocardiograph (ECG) monitoring or recording system. In this example, remote device 140 includes an ECG monitoring or recording module 1360. In one example, ECG module 1360 is used for assessing the behavior of implanted device 110 by observing the cardiac signals, such as through surface electrodes 1361A-D attached to a patient's skin. Once electrodes 1361A-D are electrically coupled to ECG module 1360, a low-amplitude electrical current signal is sent to the body from remote device 140, through two or more of electrodes 1361. This current signal is sensed by implanted device 110 as a telemetry power-on signal. In one example, the low-amplitude electrical current signal includes an encoded command that can be easily distinguished from noise that may be present on electrodes 1361. Once RF telemetry link 150 has been established, electrodes 1361 need not remain attached during the subsequent telemetry session.

Figure 14 is a circuit diagram illustrating one example of portions of the telemetry power management system of Figure 13. In this example, ECG

module 1360 is coupled to electrodes 1361, including three input electrodes 1361B-D and one right-leg negative feedback electrode 1351A. Right-leg negative feedback is a technique known in the art of ECG monitoring or recording for reducing noise pickup due to a common-mode voltage on electrodes 1361B-D while increasing patient safety. ECG module 1360 includes a telemetry activation signal generator 1465 and a signal summing circuit 1466. In one example, a physician or other caregiver initiates an RF telemetry session by providing an input at a user interface 1467. This input causes signal generator 1465 to issue a telemetry activation signal. In another example, signal generator 1465 automatically issues a telemetry activation signal upon a predetermined event. This signal is summed into the negative feedback circuit and introduced into the patient's body via electrode 1361A. In one example, the telemetry activation signal has a frequency much greater than 150 Hz. This allows the telemetry activation signal to be filtered out from the monitored ECG signal sensed by electrodes 1361B-D.

Figure 15 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry by using an electrocardiograph (ECG) system. In this example, ECG module 1360 is used for assessing the behavior of implanted device 110 by observing the cardiac signals through two input electrodes 1361C-D attached to the body surface. At least a portion of the telemetry circuit in implanted device 110 is powered on in response to a telemetry activation current signal injected into the body via electrodes 1361C-D.

Figure 16 is a circuit diagram illustrating one example of portions of the telemetry power management system of Figure 15. In this example, ECG module 1360 is configured to operate using input electrodes 1361B-D, without right-leg negative feedback electrode 1351A. One of input electrodes 1361C and 1361D is used as an output for telemetry activation signal generator 1465, such as by using a switch 1667. In the example shown in Figure 16, a physician or other caregiver initiates an RF telemetry session by providing an input to user interface 1467. This input causes remote device 140 to inject telemetry activation signal via input electrode 1361C.

5

10

15

20

25

30

Figure 17 is a schematic/block diagram illustrating one example of portions of system 100 corresponding in the examples of Figures 14 and 16. In this example, remote device 140 includes ECG module 1360, which is coupled to electrodes 1361 attached to the patient. Electrodes 1361 include four electrodes, 1361A-D, or alternatively, two electrodes, 1361C-D, as respectively discussed above for Figures 14 and 16. Switch controller 214 includes a sensing amplifier 1731 and detector 1732. In one example, in addition to sensing the telemetry activation signal, sensing amplifier 1731 is also used to sense a physiological signal. Examples of the sensed physiological signal include a cardiac signal, a respiration signal, and an acceleration signal. In one example, sensing amplifier 1731 is used to sense cardiac signals via electrodes 1733A and 1733B. Electrodes 1733A-B are both electrically coupled to sensing amplifier 1731, such as through lead wires. In one example, electrodes 1733A-B are disposed in close proximity to each other in or about a heart chamber. This is referred to as bipolar sensing. In an alternative example, electrode 1733A is disposed in or about a heart chamber, and electrode 1733B is located at or near a metal housing of implanted device 110 that houses switch controller 214, energy source 211, and implanted RF telemetry circuit 212. This is referred to as unipolar sensing. Sensing amplifier 1731 typically includes an amplifier and a filter. Detector 1732 includes a comparator having one input coupled to the output of the sensing amplifier 1731, another input representative of a predetermined comparison threshold, and an output indicating whether the signal sensed via electrodes 1733A-B exceeds the threshold. The output of detector 1732 is coupled to power switch 215 to close power switch 215 when the telemetry activation signal sensed through electrodes 1733A-B exceeds the threshold. This, in turn, connects power from energy source 211 to implanted RF telemetry circuit 212. In one example, detector 1732 further includes a binary code detector that detects a digital key, also sensed via electrodes 1733A-B. In one example, use of the digital key provides added noise immunity. In another example, the digital key also identifies a particular implantable device 110 with which RF telemetry link 150 is to be established. Power switch 215 is closed when the telemetry activation signal sensed through electrodes 1733A-B exceeds the threshold and a matching digital key is detected.

Figure 18 is a schematic/block diagram illustrating one example of portions of sensing amplifier 1731. In this example, amplifier 1834A is a low-frequency amplifier used to amplify the physiological signal. Amplifier 1834B is a high-frequency amplifier used to amplify the telemetry activation signal. A filter 1835A attenuates signals that are not at the physiological signal frequency. This configuration is suitable when a telemetry activation signal has a frequency that is significantly different from the physiological signal frequency, avoiding the use of a wideband amplifier that may expose implantable device 110 to a wide range of noises. In one example, the physiological signal is a cardiac signal, and filter 1835A includes a bandpass filter having a bandwidth of 150 Hz. Filter 1835B passes the telemetry activation signal to detector 1732, and attenuates signals at other frequencies. This example uses a telemetry activation signal frequency that is different, and therefore distinguishable, from that of the cardiac or other physiological signal.

Figure 19 is a schematic/block diagram illustrating another example of portions of sensing amplifier 1731. In this example, sensing amplifier 1731 includes a shared amplifier 1834A and two filters 1835A-B, both coupled to the output of amplifier 1834A. This configuration is alternative implementation to that of Figure 18, eliminating components, however, the implementation of Figure 18 allows more design flexibility in the signal processing. In one example, the physiological signal sensed during particular time periods and the telemetry activation signal is sensed during other times. For example, a respiration signal is monitored by periodically sensing body impedance. A telemetry activation signal is injected into the body when the body impedance is not being sensed.

Figure 20 is a flow chart illustrating one example of a method corresponding to the example of Figure 17. At 2000, a physician or other caregiver initiates an RF telemetry session by providing input at a user interface. In response, a telemetry activation signal is introduced into a patient's body through ECG electrodes 1361. The telemetry activation signal is a short-duration electrical current signal flowing into the body when a switch in remote device 140 is momentarily closed. In one example, the telemetry activation signal includes a digital key identifying a particular implantable device 110 with

5

10

15

20

25

30

which RF telemetry link 150 is to be established. In one example, the RF telemetry session is initiated for an evaluation of a patient's conditions. At 2010, the telemetry activation signal is detected by implanted device 110. In response, at 2020, power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212. At 2030, RF telemetry circuit 212 is activated and ready for bi-directional communication with remote device 140 via RF telemetry link 150. In one example, implanted RF telemetry circuit 212 sends a signal to remote device 140. If the signal is received by remote device 140, and remote device 140 is not busy communicating with other implantable device(s), remote device 140 sends a responsive signal back to implanted device 110, and the RF telemetry is established. If, at 2040, the RF telemetry is not established, because of excessive environmental noises or other reasons, RF telemetry circuit 212 will repeat 2030 after a delay 2045. In one example, delay 2045 is a programmed constant. In another example, delay 2045 is a function of the number of failed attempts to establish the RF telemetry. This function represents a particular sequence of successive attempts to establish the RF telemetry. In another example, remote device 140 periodically sends a signal including a digital key identifying a particular implantable device 110. Only upon receiving this signal, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry at 2040. At 2050, remote device 140 indicates that RF telemetry link 150 has been established. The physician or caregiver may remove ECG electrodes 1361 so that the patient's mobility is no longer limited by their connecting cable. At 2060, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140. In an idle state, after the data transmission is complete, power switch 215 is opened at 2070. This disconnects power from energy source 211 to at least a portion of RF telemetry circuit 212. Examples of methods and apparatus controlling the opening of power switch 215 are described later in this document. At 2080, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a message.

Example of Power-On by Momentary Contacting An External Device

5

10

15

20

25

30

Figure 21 is a schematic illustration of another example of portions of a telemetry power management system controlling power-on of at least a portion of the telemetry by using an external telemetry activation device. In this example, system 100 includes a telemetry activation device 2170 that introduces a telemetry activation signal into a patient's body to be received by implanted device 110 for activating telemetry. In one example, the telemetry activation signal includes an encoded command that is distinguishable from noise that may be present on electrodes 2171. In one example, device 2170 is dedicated to telemetry activation. In another example, device 2170 is a monitoring device, or a therapy device, or any medical device or non-medical device incorporating a telemetry activation system. In one example, device 2170 includes a user input and/or output interface such as to accept commands and display telemetry activity or other status information regarding implanted device 110. Telemetry activation device 2170 includes a pair of conductive structures 2171 for contact with the patient. A small electrical current flows into the patient's body when the patient contacts both conductive structures. In the example of Figure 21, the conductive structures include a pair of conductive joysticks. The patient holds one joystick in each hand to initiate an RF telemetry session for data transmission between implanted device 110 and remote device 140. In an alternative example, conductive structure 2171 includes two conductive patches incorporated onto a bar, a handle, or any portion of the housing of telemetry activation device 2170. In one example, the patient initiates telemetry sessions periodically to transfer acquired physiological data and/or therapy history to a physician or other caregiver. In another example, the patient initiates a telemetry session when attention of the physician or other caregiver is needed.

Figure 22 is a schematic/block diagram illustrating one example of portions of telemetry power management system corresponding to the example of Figure 21. In this example, system 100 includes a telemetry activation device 2170 having conductive structures 2171. Switch controller 214 includes sensing amplifier 1731 and detector 1732. In one example, sensing amplifier 1731 is also used to sense a physiological signal via electrodes 1733A-B that are electrically coupled to sensing amplifier 1731. In one example, the sensed physiological signal is a cardiac signal. Electrodes 1733A-B are configured for

either bipolar sensing or unipolar sensing. Power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212 in response to the telemetry activation signal being sensed by sensing amplifier 1731 and detected by detector 1732.

5

10

15

20

25

30

Figure 23 is a flow chart illustrating one example of a method corresponding to the example of Figure 22. At 2300, a user initiates an RF telemetry session as scheduled or needed. In one example, the user is a patient. In another example, the user is a physician or other caregiver who is supervising or examining the patient. At 2310, the user selects an operation. In the example of Figure 23, the user may elect to transfer data from implanted device 110 to remote device 140 immediately or after a delay. If the user elects to transfer data after a delay, then at 2315, telemetry activation device 2170 prompts the user to enter a time for the data transfer. At 2320, telemetry activation device 2170 prompts the user to contact conductive structures 2171. In the example of Figure 23, telemetry activation device 2170 prompts the user to grab the conductive joysticks on the device. In response, at 2330, power switch 215 is closed to connect power from energy source 211 to implanted RF telemetry circuit 212. At 2340, RF telemetry circuit 212 is activated and ready for bi-directional communication with remote device 140 via RF telemetry link 150. In one example, implanted RF telemetry circuit 212 sends a signal to remote device 140. If the signal is received by remote device 140, and remote device 140 is available to communicate with an implantable device, remote device 140 sends a responsive signal back to implanted device 110, and the RF telemetry is established at 2350. If the RF telemetry cannot be established at 2350, because of excessive environmental noise or other reasons, RF telemetry circuit 212 will repeat 2340 after a delay 2355. In one example, delay 2355 is a programmed constant. In another example, delay 2355 is a function of the number of failed attempts to establish the RF telemetry. This function represents a particular sequence of successive attempts to establish the RF telemetry. In another example, remote device 140 periodically sends a signal including a digital key identifying a particular implantable device 110. Only upon receiving this signal, RF telemetry circuit 212 sends out a signal to remote device 140 to establish RF telemetry at 2350. At 2360, remote device 140 indicates whether RF telemetry

link 150 has been established. If so, the user may then remove hands from conductive structures 1371. At 2370, data is transmitted from remote device 140 to implanted device 110 and/or from implanted device 110 to remote device 140. After data communication is complete, the RF telemetry enters an idle state.

Power switch 215 is then opened at 2380 to disconnect power from energy source 211 to at least a portion of RF telemetry circuit 212. Examples of methods and apparatuses controlling the opening of power switch 215 are described later in this document. At 2390, remote device 140 indicates whether the telemetry session was successful, such as by logging or displaying a message.

Example of Power-Off by Sending Command via RF Telemetry

5

10

15

20

25

30

Figure 24 is a schematic/block diagram illustrating one example of portions of a telemetry power management system controlling power-off of at least a portion of the telemetry. In this example, once RF telemetry link 150 has been established by using one or more of the approaches discussed above, a telemetry power-off signal is sent to implanted device 110 via RF telemetry link 150. The telemetry power-off signal is an encoded command, such as a unique digital code. In this example, switch controller 214 includes a power-off signal detector 2480 coupled to antenna 213. Upon detection of the power-off signal, detector 2480 opens power switch 215 to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211. In a further example, detector 2480 opens power switch 215 upon detection of the power-off signal and determination that RF telemetry has entered an idle state.

Figure 25 is a flow chart illustrating one example of a method corresponding to the example of Figure 24. At 2500, remote device 140 sends a power-off signal to implanted device 110 to terminate a previously-established RF telemetry session. In one example, a physician or other caregiver provides a user input at a user-interface that triggers the power-off signal. In another example, remote device 140 sends the power-off signal automatically when it determines that an RF telemetry session should end. For example, remote device 140 determines that an RF telemetry session should end when no data is transmitted via RF telemetry link 150 for a predetermined duration, such as ten

minutes. At 2520, implanted device 110 receives the telemetry power-off signal. At 2530, power-off signal detector 2480 determines whether the RF telemetry is in an idle state, in which no data is being transferred between implanted device 110 and remote device 140. In one example, if data is being transferred, or is about to be transferred, power-off signal detector 2480 repeats a step 2530 of determining whether the RF telemetry is in an idle state after a predetermined delay 2532. At 2540, after the RF telemetry is determined to be in an idle state, implanted device 110 sends a termination signal to remote device 140 to inform remote device 140 of the completion of the RF telemetry session. Then, at 2550, power switch 215 is opened to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211. Upon receiving the termination signal from implanted device 110, remote device 140 indicates a successful completion of the RF telemetry session at 2560, such as by logging or displaying a message.

15

20

25

30

5

10

Example of Power-Off by Timing

Figure 26 is a schematic/block diagram illustrating another example of portions of a telemetry power management system controlling power-off of at least a portion of the telemetry. In this example, switch controller 214 includes a timer 2682 coupled to implantable RF telemetry circuit 212. Timer 2682 starts timing an interval when the RF telemetry enters an idle state. If data transmission via the RF telemetry resumes during the predetermined delay, timer 2682 is reset and does not restart until the RF telemetry enters another idle state. If the delay expires during the idle state, timer 2682 opens power switch 215 to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211.

Figure 27 is a flow chart illustrating one example of a method corresponding to the example of Figure 26. In this example, an idle state of the RF telemetry, during which no data is transmitted between implanted device 110 and remote device 140, terminates RF telemetry session at 2700. At 2710, when the RF telemetry enters an idle state, timer 2682 is then started at 2720 to measure a time spent in the idle state. If data transmission via RF telemetry link 150 resumes at 2730, before the time value exceeds a predetermined delay, timer

2682 is reset (re-zeroed) and is to be restarted upon reentering the idle state. If data transmission via RF telemetry link 150 does not resume before the time value exceeds the predetermined delay at 2740, implanted device 110 then sends a termination signal to remote device 140 to inform remote device 140 of the completion of the RF telemetry session. At 2760, power switch 215 is opened to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211. At 2770, if the termination signal from implanted device 110 is received, remote device 140 indicates a successful completion of the RF telemetry session, such as by logging or displaying a message.

10

15

20

25

30

5

Example of Power-Off by Using Inductive telemetry

In one example, once RF telemetry link 150 has been established, a physician or other caregiver uses the inductive telemetry link 755 of Figures 7 or 8, to end the RF telemetry session. This allows immediate shutoff of RF telemetry link 150 regardless of whether the RF telemetry is in the idle state. An encoded RF telemetry power-off signal is sent from external programmer 745 to implanted device 110 through inductive telemetry link 755. Upon detection of the RF telemetry power-off signal, implanted inductive telemetry circuit opens power switch 215 to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211. Figure 28 is a flow chart illustrating one example of a method corresponding to this example.

In the example of Figure 28, at 2800, a physician or other caregiver provides input to a user interface that causes external programmer 745 to terminate a previously-established RF telemetry session. In one example, the physician or other caregiver wants to terminate RF telemetry because a checkup, diagnosis, or treatment session has been completed, and the RF telemetry is no longer needed. In another example, physician or other caregiver want to establish RF telemetry with a different implanted device. Upon receiving the RF telemetry termination command, external programmer 745 sends the encoded RF telemetry power-off signal to implanted device 110 at 2810. At 2820, implanted device 110 receives the RF telemetry power-off signal. At 2830, implanted device 110 sends a responsive termination signal to remote device 140 to inform remote device 140 and external programmer 745 of the completion of the RF

telemetry session. At 2840, power switch 215 is opened to disconnect the power to at least a portion of implanted RF telemetry circuit 212 from energy source 211. At 2850, upon receiving the termination signal, external programmer 745 indicates termination of the RF telemetry session. At 2860, if the termination signal from implanted device 110 is received, remote device 140 indicates the termination RF telemetry session, such as by logging or displaying a message.

Example Choice of Power On/Off Methods

5

10

15

20

25

30

Each power-on or power-off method discussed above offers advantages, which are discussed herein by way as example, and not by way of limitation. Power-on by RF burst signal allows an RF telemetry session to be initiated at remote device 140. This allows a physician or other caregiver to provide care to a patient from a remote location. An examination of the patient may be performed with or without the patient's knowledge. In one example, the patient's routine check-up is performed through the RF telemetry and telephone, so that the patient saves a trip to a physician's office. In another example, the patient who needs close monitoring is frequently checked by the physician or other caregiver through the RF telemetry, so that the patient need not be hospitalized to receive similar care. Power-on by physical activity allows an RF telemetry session to be initiated by a patient or a person with the patient. No additional external device is required. In one example, implanted device 110 already includes an accelerometer as an activity or metabolic need sensor employed in a therapy algorithm. The same accelerometer may be used for telemetry power management by modifying only software. Power-on of RF telemetry using inductive telemetry is convenient when implanted device 110 includes an inductive telemetry system. Having external programmer 745 available during an RF telemetry session also provides an alternative communications modality if RF telemetry is lost because of RF interference or other reasons. Power-on by magnetic field allows RF telemetry power management using a magnet or a hand-held device. This is likely more convenient to handle than external programmer 745. In one example, implanted device 110 already includes a function activated or suppressed by an external magnet. For example, holding a magnet near implanted device 110 may cause it

to pace at a fixed pacing rate, overriding any therapy algorithm that would be otherwise effective. Using a magnetic field for RF telemetry power management in this example may be implemented by modifying only software. Power-on by introducing a signal via surface ECG electrodes is convenient when remote device 140 includes an ECG module. During a patient's follow-up visit to a physician, the physician typically attaches ECG electrodes to the patient to diagnose the patient's condition. By automatically detecting when the cables from such ECG electrodes are connected to the programmer, telemetry is seamlessly automatically activated without requiring physician intervention. In another example, using RF telemetry provides for a higher rate of data transmission as compared with inductive telemetry, reducing the duration of a telemetry session. Power-on by momentarily contacting an external device allows a patient to initiate and/or schedule an RF telemetry session and is convenient for patients who regularly use a medical device such as a monitor.

5

10

15

20

25

30

Power-off by sending a command via RF telemetry deactivates implanted RF telemetry circuit 212 without wasting power by keeping the RF telemetry power on longer than necessary. However, under some circumstances RF telemetry link 150 may be interrupted before the power-off signal is sent to implanted device 110. Examples of such circumstances include a strong RF noise or a patient moving beyond a range of the RF telemetry. Under such circumstances, power-off using a timer ensures that implanted RF telemetry circuit is shut off after the RF telemetry has been idle for a predetermined period of time. Power-off using inductive telemetry permits the physician or other caregiver to immediately terminate the RF telemetry at any time. In one example, the physician or other caregiver terminates an RF telemetry that is accidentally established with an unintended implantable device. An inductive telemetry is less likely to be accidentally established because it often requires the wand to be closely (within a few inches) coupled to the implantable device. In another example, the physician or other caregiver may terminate the RF telemetry by using the inductive telemetry, such as when one or more other power-off methods fail. In a further example, the one or more other power-off methods fail because of the presence of a noise, such as a cellular phone signal.

Depending on the patient's needs for care and type of implantable device, one or more of the power-on methods and one or more of the power-off methods discussed above may be included in one implantable device. Using more than one method to connect/disconnect power from energy source 211 to implanted RF telemetry circuit 212, or at least portions thereof, increases the reliability of initiating and terminating the RF telemetry session in a timely manner. This ensures patient safety, conserves energy, and hence increases device longevity. If one method fails, another available method may be automatically or manually applied. In one example, implanted device 110 employs one power-on method but several power-off methods, such as all three discussed above. This decreases energy waste and patient risks by ensuring that implanted RF telemetry circuit 212 is deactivated as soon as the RF telemetry session ends.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the implantable device can be any implantable medical device having an active electronic circuit. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein."

WHAT IS CLAIMED IS:

5

10

15

20

25

1. A system including an implantable medical device, the implantable medical device including a far-field radio-frequency (RF) first telemetry circuit, the implantable medical device also including a power connection module, coupled to the first telemetry circuit, to connect/disconnect power to at least a portion of the first telemetry circuit, and the system characterized in that it includes, coupled to the power connection module to control a conductivity state of the power connection module, at least one of:

a wireless signal detector, controlling the conductivity state of the power connection upon detecting at least one of predetermined wireless signal, a demodulated or decoded predetermined wireless signal, or a magnetic field present near the implantable medical device;

an activity sensor;

a telemetry activation sensing circuit, controlling the conductivity state of the power connection upon a detection of a predetermined telemetry activation signal; or

a timer, changing the conductivity state of the power connection module after waiting a predetermined period of time after the first telemetry circuit enters a predetermined state that includes at least one of a data transmission idle state or a telemetry establishment failure state.

- 2. The system of claim 1, in which the implantable medical device includes an implantable cardiac rhythm management device, and the first telemetry circuit provides at least a six-foot telemetry range.
- 3. The system of claim 1, in which the wireless signal detector includes a near-field inductive second telemetry circuit.
- 30 4. The system of claim 3, in which the second telemetry circuit includes a receiver adapted to receive the predetermined wireless signal, and in which the predetermined wireless signal includes a command for changing the conductivity state of the power connection module.

5. The system of claim 3, in which the second telemetry circuit includes a receiver adapted to detect a magnetic field having a predetermined frequency and to change the conductivity state of the power connection module when the magnetic field is detected.

- 6. The system of claim 3, in which the second telemetry circuit includes a receiver adapted to detect a near-field inductive telemetry communication and to change the conductivity state of the power connection module when the near-field inductive telemetry communication is detected.
- 7. The system of claim 3, further including:

5

10

15

20

a first remote device, electromagnetically coupled to the first telemetry circuit, the first remote device including a far-field RF third telemetry circuit to provide communication with the implantable medical device for at least a six-foot range; and

a second remote device, magnetically coupled to the second telemetry circuit, the second remote device including a near-field inductive fourth telemetry circuit to provide near-field communication with the implantable medical device.

- 8. The system of claim 7, in which the first and second remote devices are physically integrated.
- 25 9. The system of claim 1, in which the wireless signal detector includes a low power radio detector adapted to detect a predetermined telemetry activation signal.
- 10. The system of claim 9, in which the predetermined telemetry activation30 signal includes an RF burst and a digital key adapted to identify a particular implantable medical device.

11. The system of claim 9, further including a remote device including a telemetry activation signal generator configured to be electromagnetically coupled to the low power radio detector.

- 5 12. The system of claim 1, in which the wireless signal detector includes a magnetic field detector adapted to detect a magnetic field having a magnetic field strength that exceeds a predetermined threshold.
- 13. The system of claim 12, further including a magnetic field provider
 separate from the implantable medical device.
 - 14 The system of claim 13, in which the magnetic field provider includes at least one of a magnet and a battery powered portable magnetic field provider.
- 15 15. The system of claim 1, further including a remote device far-field RF second telemetry circuit, electromagnetically coupled to the first telemetry circuit, to provide long-range communications with the implantable medical device.
- 20 16. The system of claim 1, in which the activity sensor includes an accelerometer.

25

- 17. The system of claim 16, further including a pattern recognition module, coupled to the accelerometer, to detect at least one predetermined pattern of acceleration.
- 18. The system of claim 1, further including a cardiac sensing lead, coupled to the telemetry activation sensing circuit, and in which the telemetry activation sensing circuit includes:
- an amplifier having an input and an output, the input coupled to the cardiac sensing lead; and
 - a filter, coupled to the output of the amplifier.

19. The system of claim 1, further including:

5

a cardiac signal sensing amplifier having an input and output, the output coupled to the telemetry activation sensing circuitry, the telemetry activation sensing circuitry including a filter coupled to the output of the sensing amplifier; and

a cardiac sensing lead, coupled to the input of the cardiac sensing amplifier.

- 20. The system of claim 1, further including a minute ventilation sensor circuit, coupled to the telemetry activation sensing circuit.
- 21. The system of claim 1, further including an external interface device adapted to be communicatively coupled to the implantable medical device, the external interface device including an electrical current generator adapted to introduce an electrical current into a body to be received by the telemetry activation sensing circuit to connect power to at least a portion of the first telemetry circuit.
- The system of claim 21, in which the external device further includes a
 surface electrocardiograph (ECG) electrode to introduce the electrical current into the body.
- 23. The system of claim 21, in which the external device further includes at least two conductive surfaces, coupled to the electrical current generator, to
 25 introduce the electrical current into the body through contacts between the metal surfaces and the body.

24. A method including:

30

connecting at least one portion of a far-field radio-frequency (RF) first telemetry circuit in an implantable device to an energy source through a power connection module;

detecting a control signal that includes at least one of a predetermined wireless signal, a demodulated or decoded predetermined wireless signal, an

activity level signal exceeding a predetermined threshold, a predetermined electrical current signal introduced into a body, or a first telemetry circuit data transmission activity signal,

and

5

20

25

- changing a conductivity state of the power connection module, when the control signal is detected, to couple or decouple power to the at least one portion of the first telemetry circuit.
- The method of claim 24, further including transmitting data from the first
 telemetry circuit across at least a six-foot telemetry range.
 - 26. The method of claim 24, in which detecting the control signal including detecting a near-field inductive predetermined wireless signal that includes at least one of:
- a magnetic signal having a predetermined frequency;
 - a code initiating communication activity of the first near-field inductive telemetry circuit;
 - a command code, the command code including a command for changing the conductivity state of the power connection module;
 - an RF burst signal for changing the conductivity state of the power connection module by connecting power to the at least one portion of the first telemetry circuit;
 - a termination code for changing the conductivity state of the power connection module by disconnecting power to the at least one portion of the first telemetry circuit; or
 - a magnetic field strength signal for changing the conductivity state of the power connection module when the strength of the magnetic field exceeds a predetermined threshold for at least a predetermined period of time.
- 30 27. The method of claim 24, in which the detecting the control signal includes monitoring an acceleration level or pattern.

28. The method of claim 24, further including introducing the predetermined electrical current into the body through a plurality of surface electrocardiograph (ECG) electrodes or a plurality of conductive contacts of an external device.

- 5 29. The method of claim 24, in which the predetermined electrical current signal is an approximately sinusoidal signal having a frequency of about 30 kilohertz.
- 30. The method of claim 24, in which the changing the conductivity state of the power conduction module includes disconnecting power to the at least one portion of the first telemetry circuit when the first telemetry circuit exists in an idle state for a predetermined period of time.
- 31. The method of claim 24, in which the changing the conductivity state of
 the power connection module includes connecting power to the at least one portion of the first telemetry circuit.
 - 32. The method of claim 31, further including: attempting to establish communication between the first RF telemetry
- 20 circuit and an external device; and

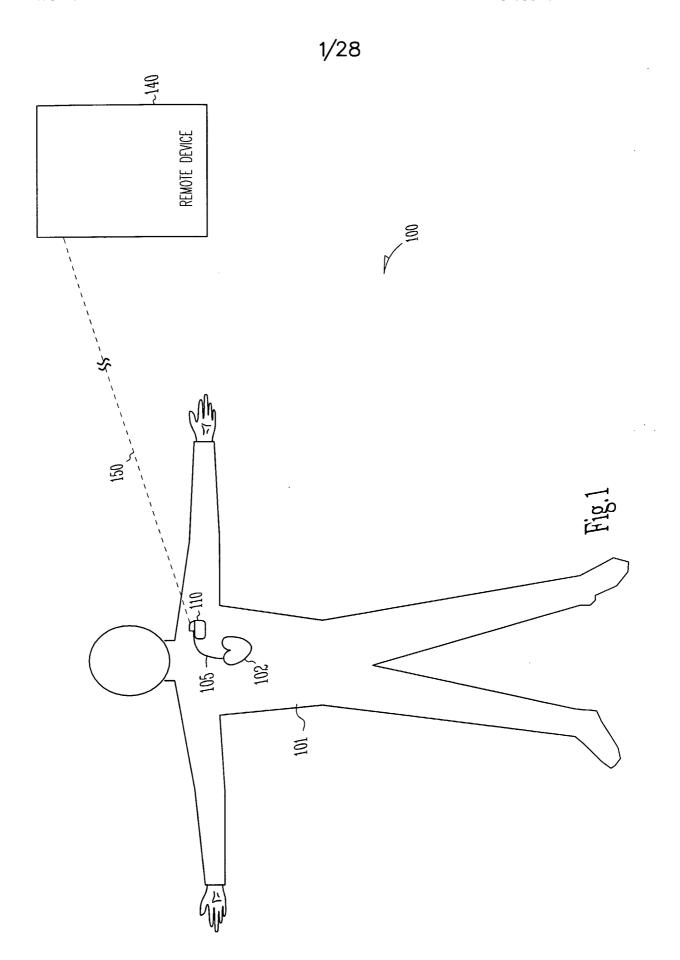
if the attempt to establish communication fails:

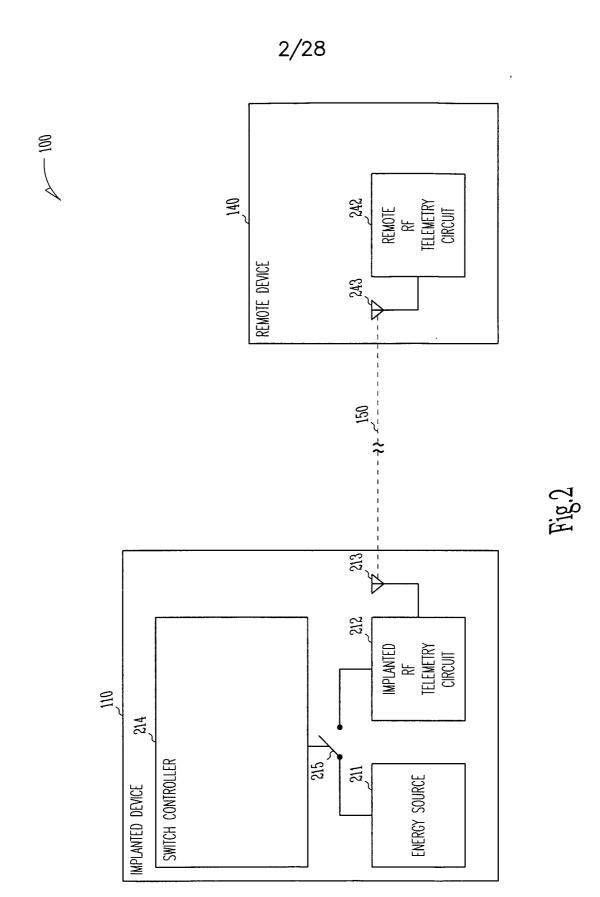
changing the conductivity state of the power connection module to disconnect power to the at least one portion of the first telemetry circuit; and

- repeating the attempt to establish the communication after waiting for a predetermined period of time.
- 33. The method of claim 31, further including:

 detecting a predetermined second telemetry activation signal; and
 starting data transmission using the first telemetry circuit when the
 second telemetry activation signal is detected.

34. The method of claim 33, in which the detecting second telemetry activation signal includes detecting a digital key adapted to identify a particular implantable medical device.





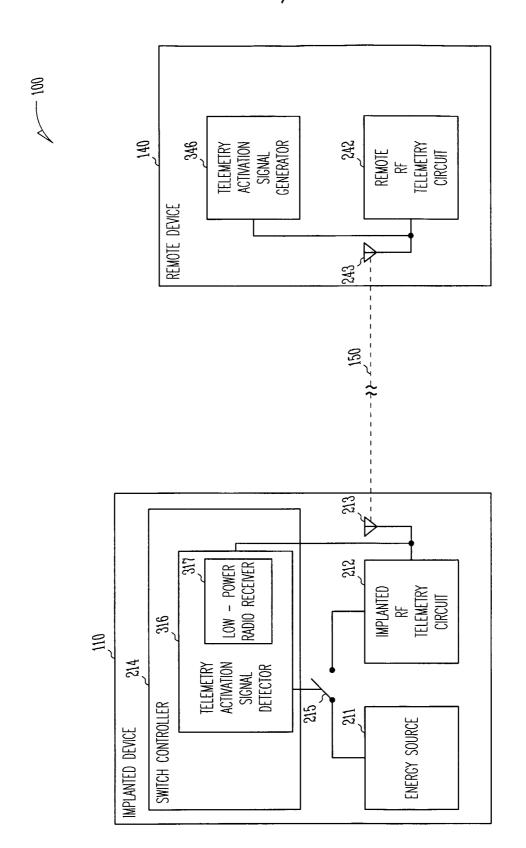
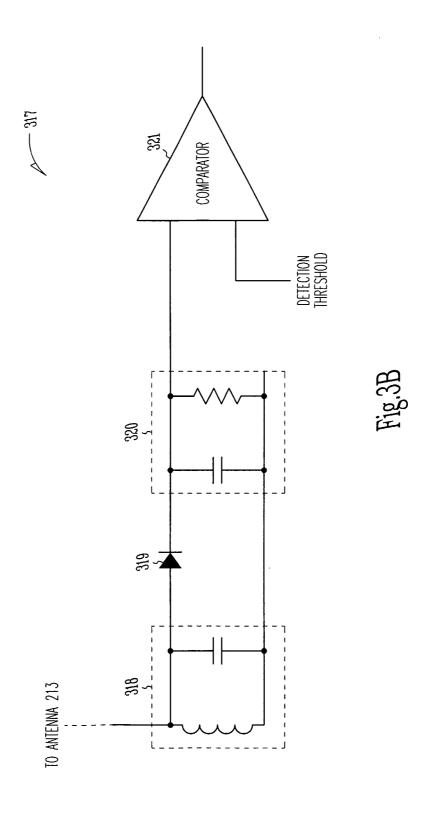


Fig.3A



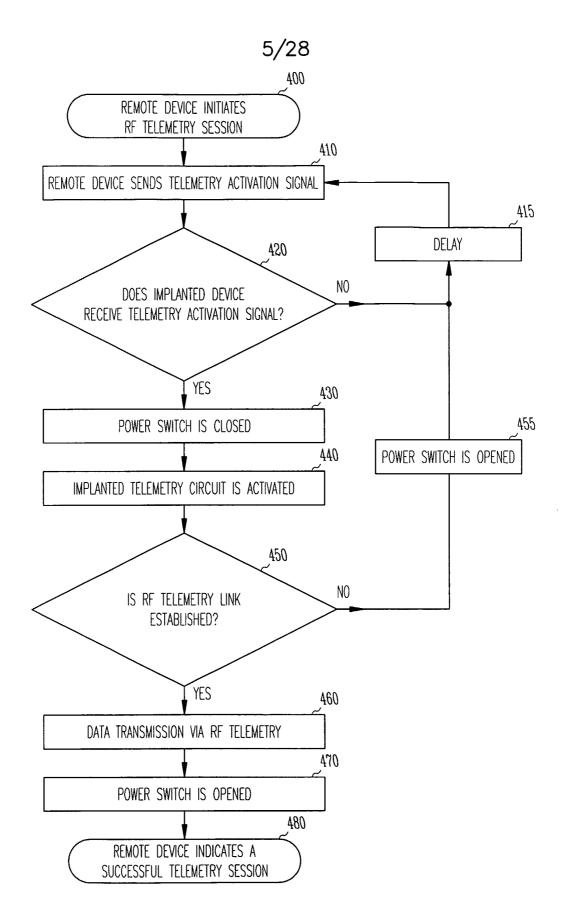


Fig.4



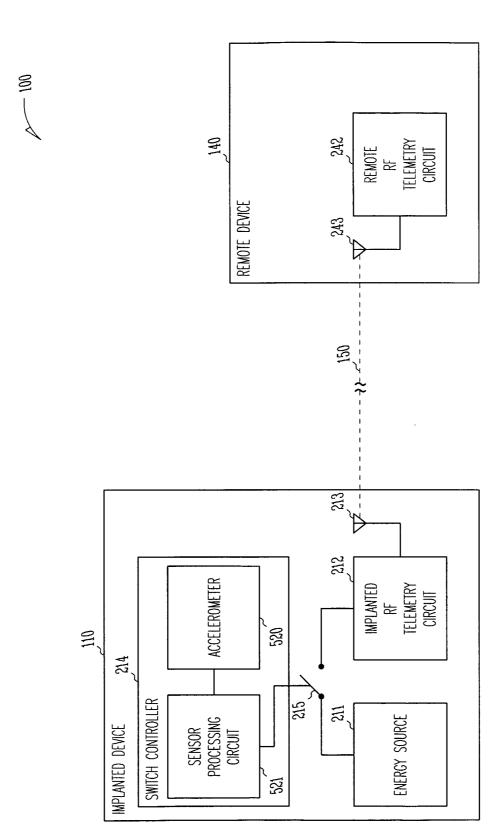


Fig.5

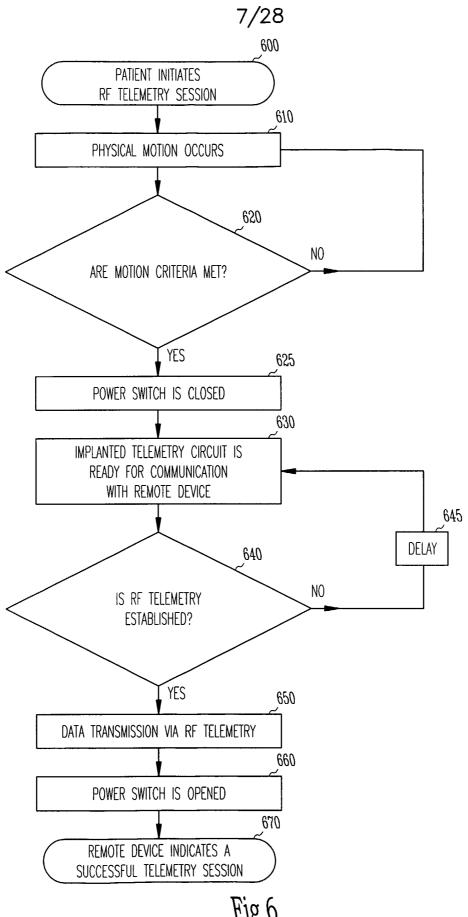
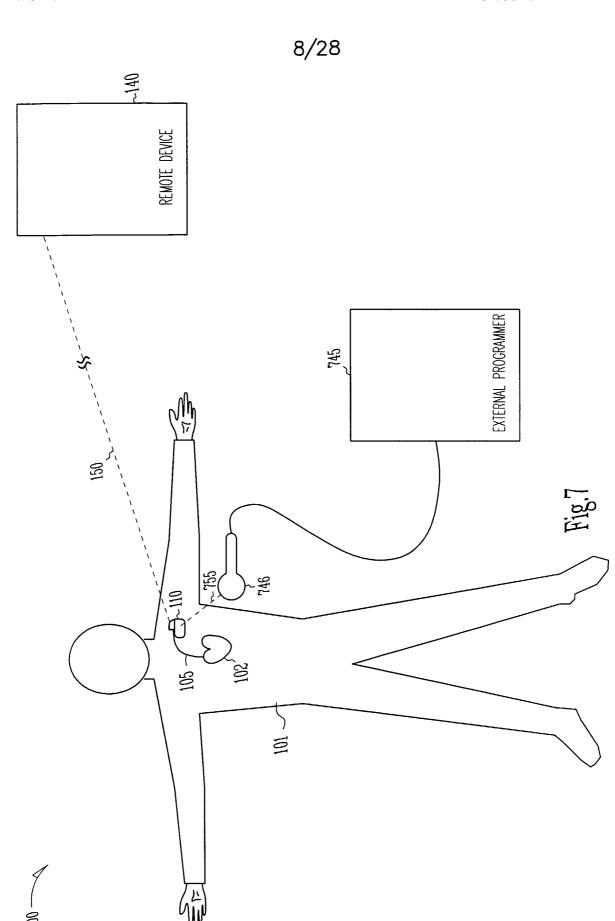
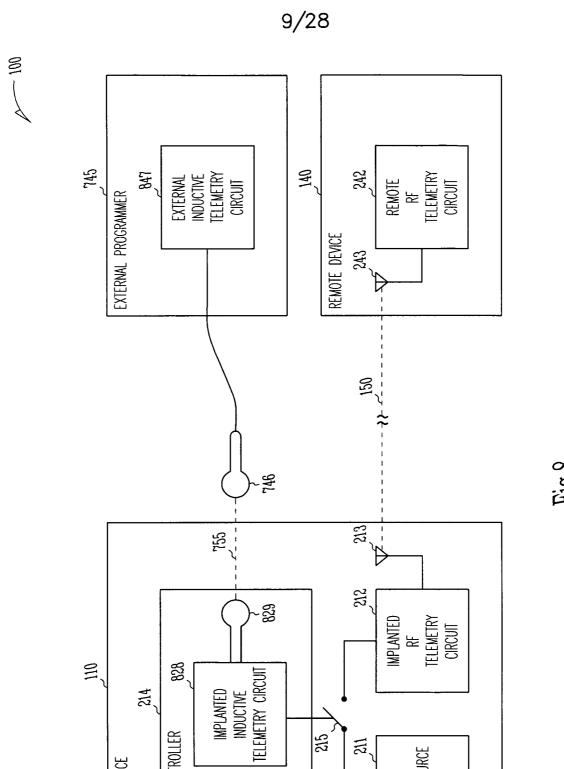


Fig.6



PCT/US03/03748 WO 03/066163



215

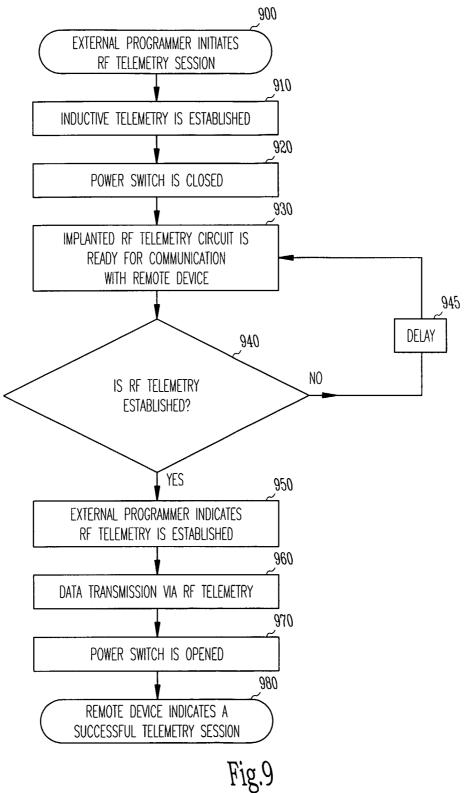
311

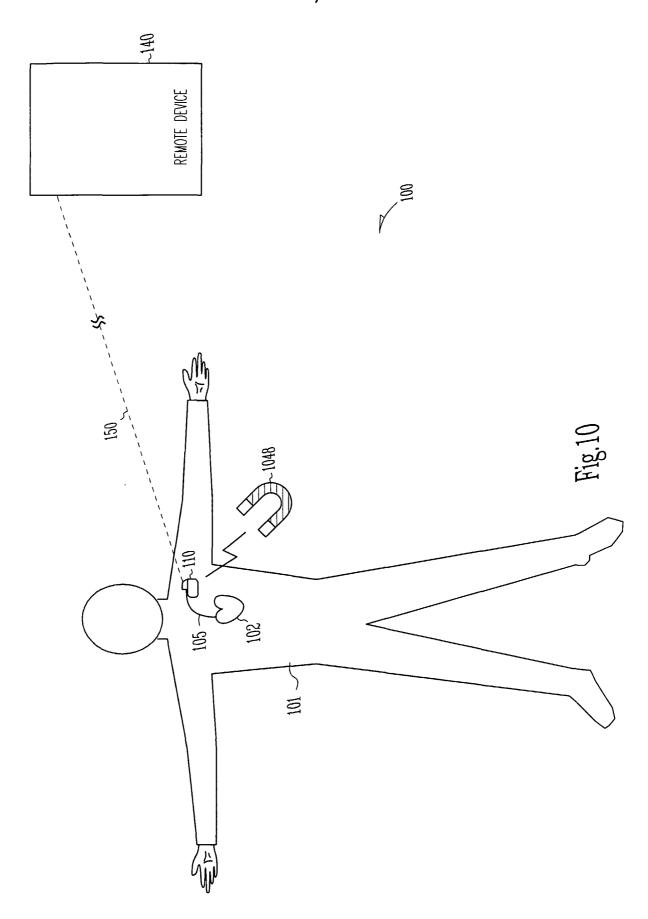
ENERGY SOURCE

214

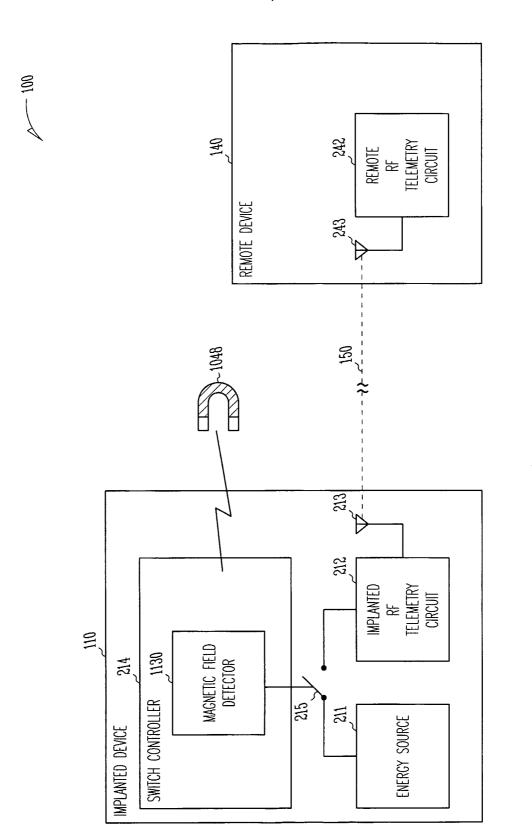
IMPLANTED DEVICE

SWITCH CONTROLLER









F16.11

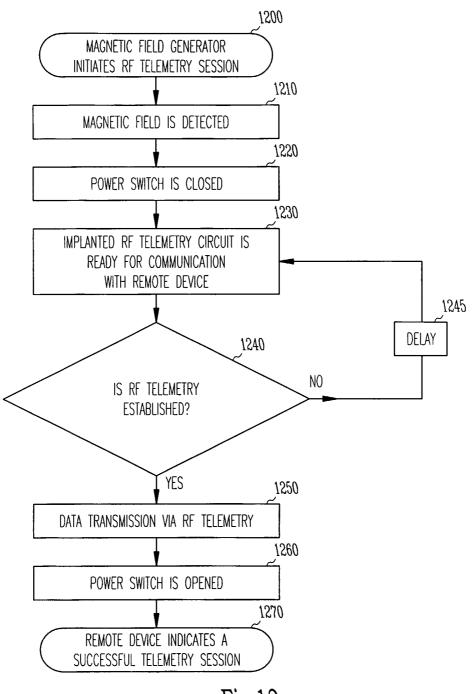
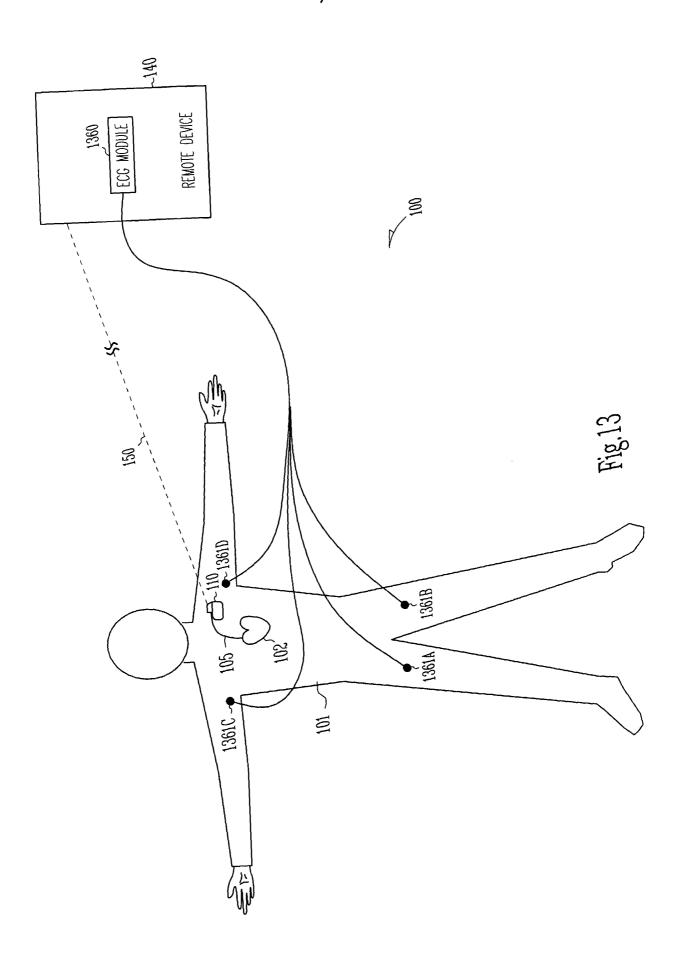


Fig.12

14/28



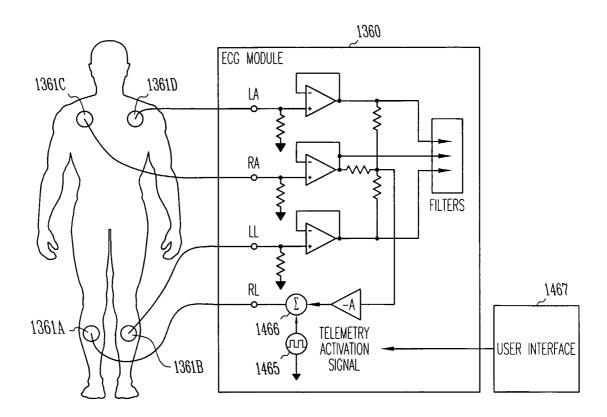
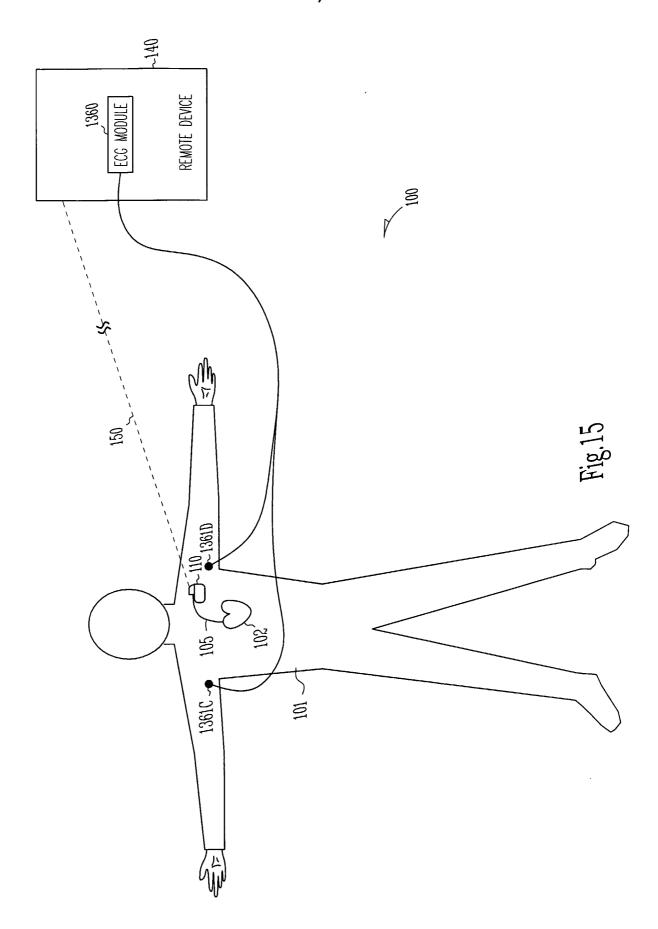


Fig.14



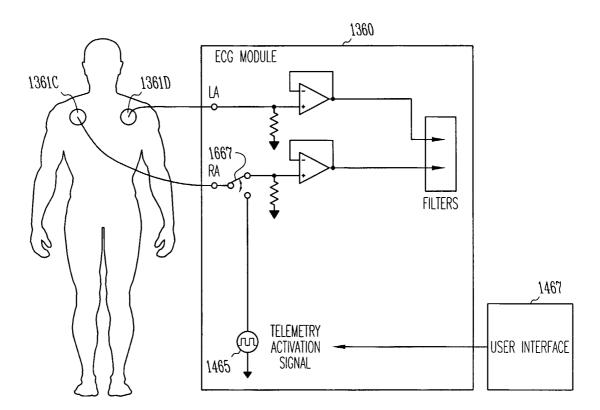
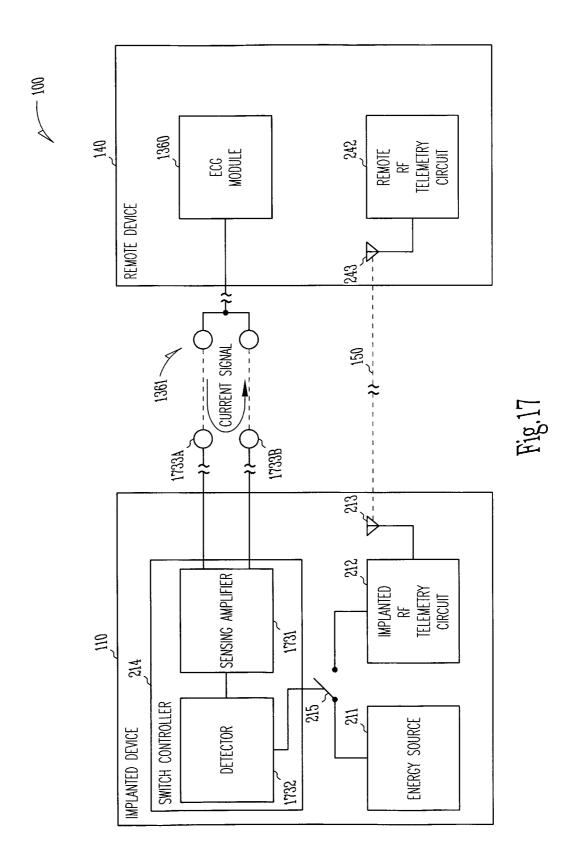
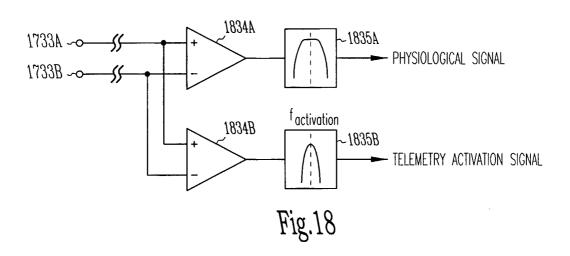


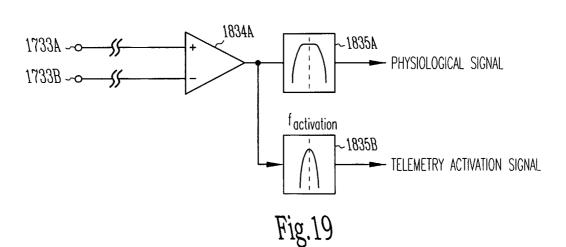
Fig.16











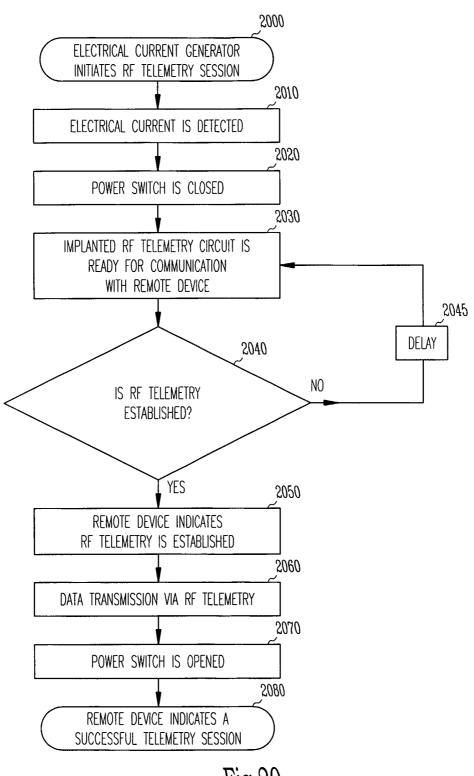
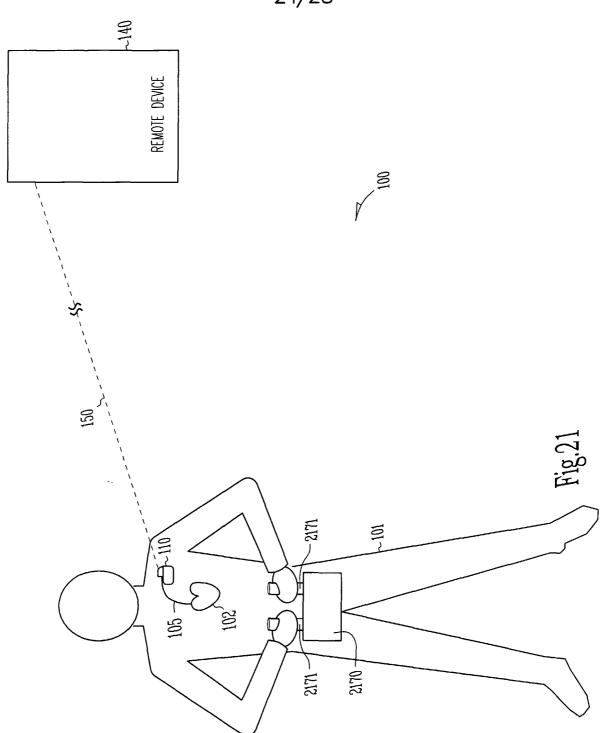


Fig.20





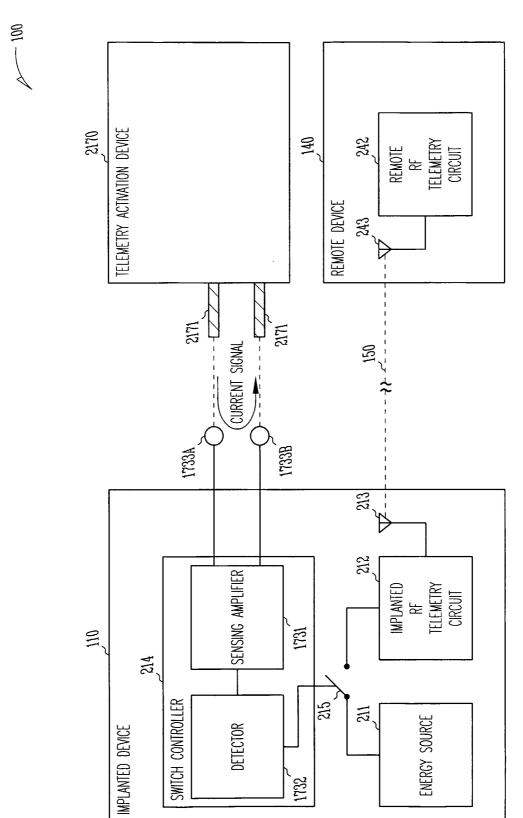
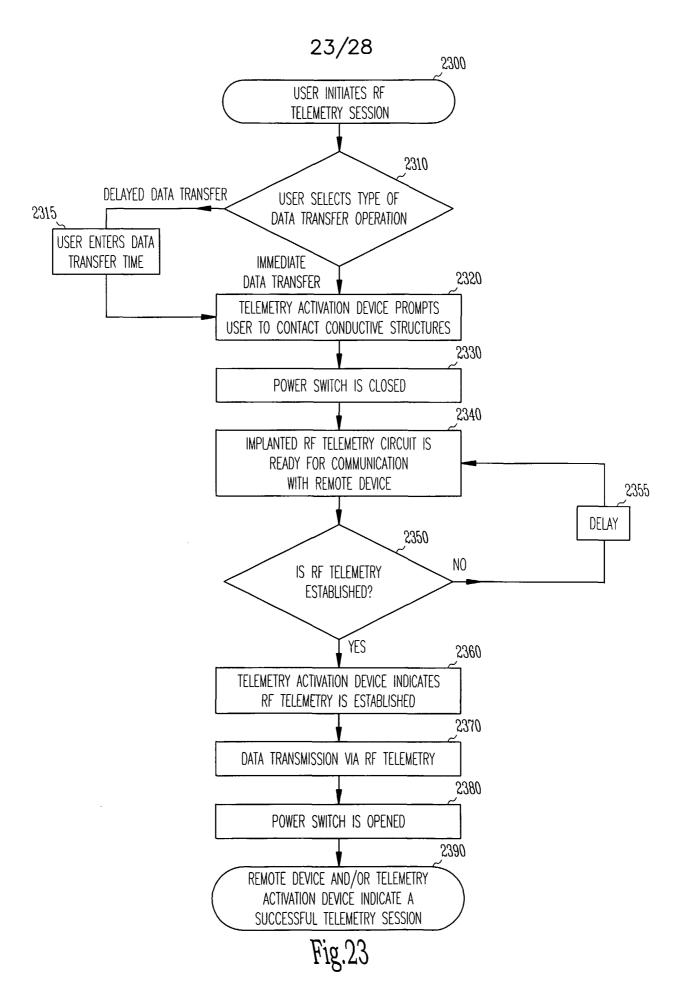
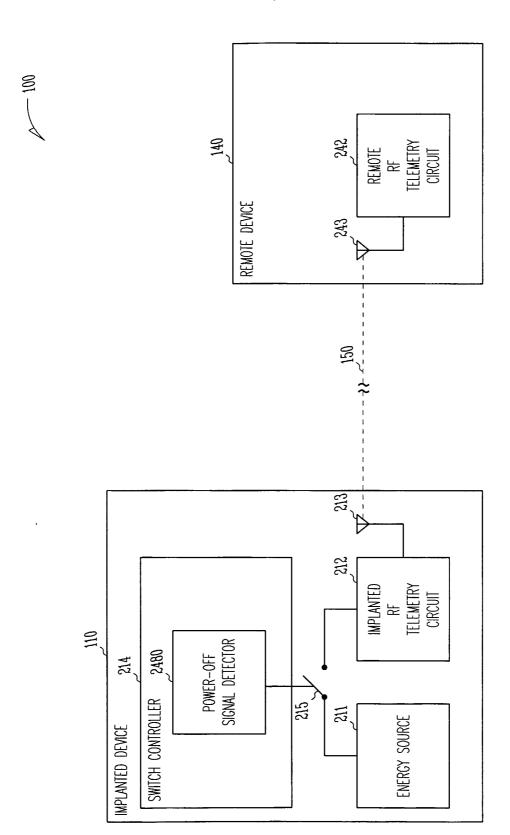


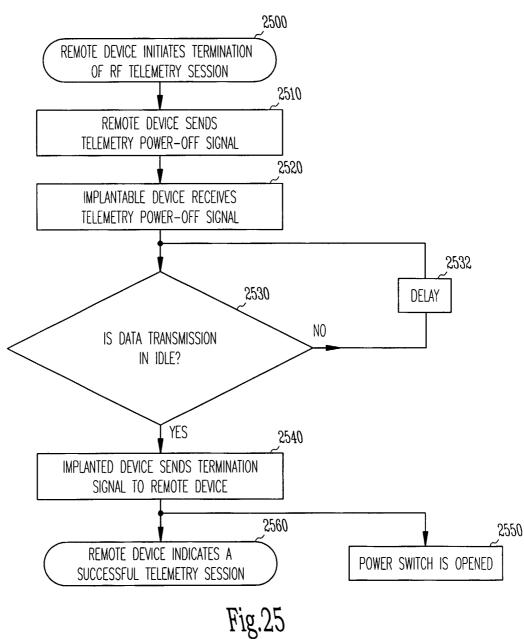
Fig.22



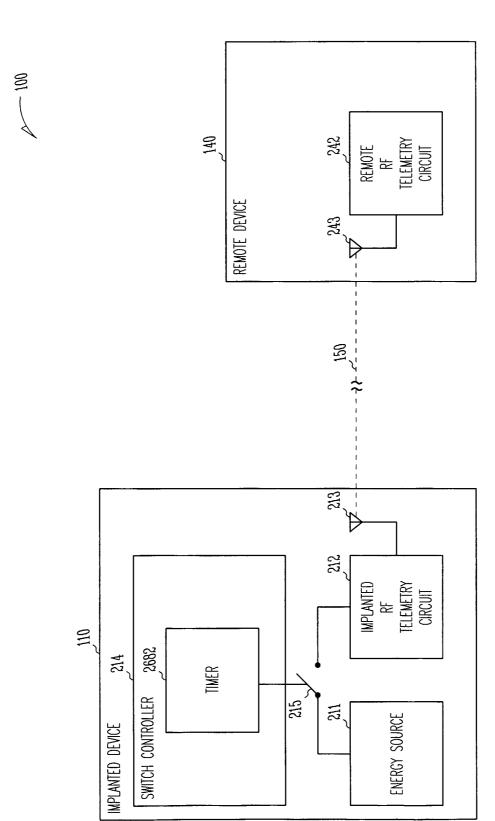




F18.24







F1g.26

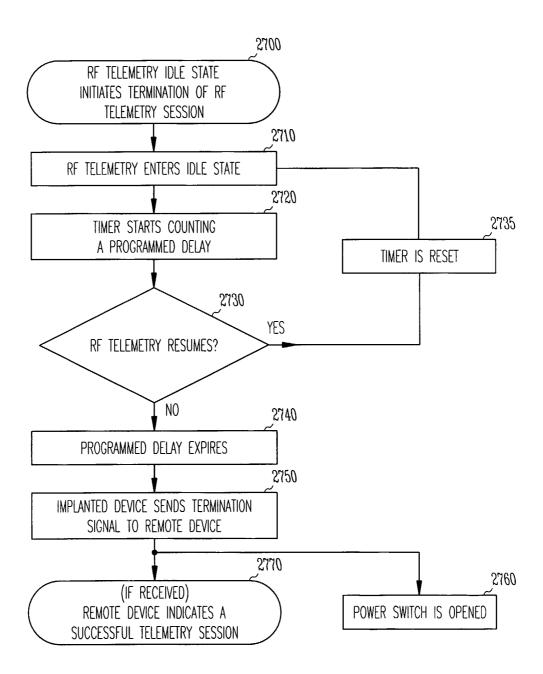


Fig.27

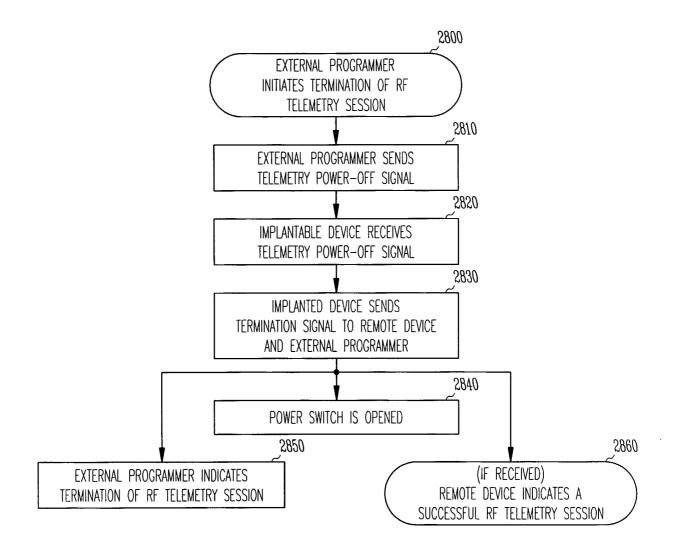


Fig.28