A second mode is configured to program electronic settings of the implantable monitoring device.


Agent: FINN in, J. Patrick; Fish & Richardson P.C., P.O. Box 1022, Minneapolis, Minnesota 55440-0122 (US).

Published: without international search report and to be republished upon receipt of that report.
IMPLANTABLE MONITORING DEVICE ACTIVATOR AND SYSTEM
INCLUDING MULTIPLE MODES

Background

Implantable devices are capable of sensing and recording various biological signals from the body, such as, for example, electrocardiogram (ECG) signals. Internal implantable devices offer advantages over external sensing devices that have at least one electrode attached externally to the patient. For example, internal implantable devices can provide a high degree of measurement sensitivity as they decrease the distance between the source of the signals and the sensing device. These highly sensitive measurements are recordable in the electronic components of the implantable device.

In some cases, telemetry is employed to transmit the measurements recorded by the implanted device to an external communication link that processes the data for subsequent analysis and diagnosis. In order to expand the diagnostic capabilities of the implantable device in some cases, there is a need to sense, record, and transmit significant volumes of information. Furthermore, in order to extend the life cycle of the implantable device, the implantable device should be as compact and should consume as little power as possible.

Summary

One embodiment provides an activator device configured to communicate with an implantable monitoring device. The activator device includes a first mode and a second mode different from the first mode. The first mode is configured to receive data of asymptomatic events passively recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of symptomatic events. The second mode is configured to program electronic settings of the implantable monitoring device.
Brief Description of the Drawings

The accompanying drawings are included to provide a further understanding of the present invention and are incorporated in and constitute a part of this specification. The drawings illustrate example embodiments and together with the description serve to explain principles of the invention. Other embodiments and many of the intended advantages of the embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

Figure 1 illustrates a block diagram of a telemetry system including an implantable device in accordance with one embodiment.

Figure 2 illustrates a block diagram of an implantable device in accordance with one embodiment.

Figure 3 illustrates a perspective view of an activator system including an activator device and a key according to one embodiment.

Figure 4 illustrates an exploded view of a spacer and the activator device of Figure 3 with a housing section removed according to one embodiment.

Figure 5 illustrates a top view of the spacer shown in Figure 4.

Figure 6 illustrates a plan view of the key shown in Figure 3 according to one embodiment.

Figure 7 illustrates a side view of the key shown in Figure 6.

Figure 8 illustrates a top end view of the key shown in Figure 6.

Figure 9 illustrates a bottom end view of the key shown in Figure 6.

Figure 10 illustrates an end view of the activator system showing the key inserted into an access slot of the activator device according to one embodiment.

Figure 11 illustrates a method employed by the activator device shown in Figure 3 according to one embodiment.

Figure 12 illustrates a modal diagram for the activator system according to one embodiment.
Figure 13A illustrates the activator system in a physician/programming mode according to one embodiment.

Figure 13B is another illustration of the activator system in the physician/programming mode.

Figure 14A illustrates the activator device in a patient/data receiving mode according to one embodiment.

Figure 14B is another illustration of the activator device in the patient/data receiving mode.

**Detailed Description**

In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as "top," "bottom," "front," "back," "leading," "trailing," etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

Embodiments relate to an implantable device configured with a signal monitoring system that is configured to continuously measure and selectively record biological signals, such as heart signals, and transmit the recorded biological signal information for subsequent analysis.

Figure 1 illustrates telemetry system 10 in accordance with one embodiment. Telemetry system 10 includes patient hub 12 and service hub 14. Patient hub 12 includes a patient 16 provided with an implantable monitoring device (IMD) 20 that is configured to collect biological data from patient 16, a programmable external
activator 22 configured to electronically communicate with (i.e., receive and transmit data from) IMD 20, and a base station 24 in telemetric communication with activator 22 that is configured to remotely transmit data collected by IMD 20 and activator 22. In one embodiment, IMD 20 and activator 22 are "paired" when manufactured by programming a unique IMD 20 identification number into a memory bank of activator 22. In this manner, activator 22 is configured to recognize and communicate with a single, specific, and identifiable IMD 20.

Service hub 14 includes service system 30 configured to remotely receive the data collected by IMD 20 that is uploaded to activator 22, and a service technician 32 and a physician or other medical personnel 34 that are enabled to access the data collected by IMD 20 after the data is transmitted to service system 30. Base station 24 of patient hub 12 is linked via a phone system or other communication system to service system 30 of service hub 14, for example by a land-based telephone line system, a wireless communication system, or the Internet, and service technician 32/medical personnel 34 have access to service system 30.

In one embodiment, IMD 20 is a surgically implanted electrocardiogram (ECG) monitoring device configured to continuously capture and selectively record both symptomatic (i.e., patient detected) and asymptomatic (i.e., non-patient detected, or IMD 20 detected) ECG events. In one embodiment, IMD 20 is configured to capture and record trending ECG waveform data based on periodic timed triggering of IMD 20. In this regard, ECG events and other biological signals are monitored and recorded within IMD 20, which is configured with transceiver capabilities for uploading data to activator 22. In one embodiment, activator 22 uploads the biological data from the patient 16 and is configured to wirelessly transmit the data to the base station 24 when the patient 16 is, for example, within wireless fidelity (WiFi) range of base station 24.

In one embodiment, activator 22 is rechargeable and sized to be worn externally or carried by patient 16. In one embodiment, activator 22 is a computational device including memory and programmable software that combine to enable activator 22 to program IMD 20, display waveforms of data collected by
IMD 20 on a real-time basis, respond to patient commands storing symptomatic data collected by IMD 20, store asymptomatic data collected by IMD 20, upload data from IMD 20, download data to IMD 20, and transmit data to service system 30 via base station 24.

One embodiment of activator 22 includes a patient interface 26 that is configured to enable patient 16 to send an activation signal to selectively activate IMD 20 to record a symptomatic ECG event (e.g., an anomalous cardiac event detected by patient 16) and, in one form of this embodiment, upload information from IMD 20 to activator 22, and then to service system 30 via base station 24 during the event. In one embodiment, activator 22 passively uploads ECG events recorded by IMD 20 at regular time intervals (e.g., daily) and transmits this data to service system 30 via base station 24. In one embodiment, activator 22 is configured to receive information, such as, for example, clock synchronization information transmitted from service system 30 through base station 24, for activator 22 and/or for downloading to IMD 20.

Base station 24 may be coupled to service system 30 in a variety of suitable ways. For example, base station 24 and service system 30 may be coupled by telephone lines, wireless communication, or the Internet. Other suitable communication links between base station 24 and service system 30 are also acceptable. Regardless of the communication link between base station 24 and service system 30, technician 32 has access to the patient 16 data measured by IMD 20.

Figure 2 illustrates a block diagram of IMD 20 in accordance with one embodiment. In one embodiment, IMD 20 includes a case 50, leads 52, a battery 54, a receiver 56, a transmitter 58, and an application specific integrated circuit (ASIC) 60 contained within case 50. In one embodiment, case 50 is a sealed titanium case sized to house various components of IMD 20, such as battery 54, receiver 56, transmitter 58, and ASIC 60. When implanted, IMD 20 can measure biological signals, such as ECG potentials, across leads 52 and store segments of the biological signal waveforms within ASIC 60. In one embodiment, one of leads 52
is coupled to an extending lead having a remote tip electrode, and the other of leads
52 is coupled to case 50, such that an ECG potential is measurable between the
remote tip electrode and case 50. In one embodiment, ASIC 60 is coupled to an
IMD memory device, such as a static random access memory (SRAM), which can
be configured to store segments of the signal waveforms for subsequent
transmission to activator 22.

Receiver 56 is configured to receive commands signals, for example, from
activator 22. In one embodiment, activator 22 sends an activation signal that
indicates that a segment of an ECG waveform should be recorded and then
transmitted. When such an activation signal is received, receiver 56 can be
configured to pass the activation signal to ASIC 60 so that segments of the ECG
waveform are recorded. In some embodiments, the waveform signals can be stored
in ASIC 60 and/or an IMD memory device external from ASIC 60. The recorded
segments of the ECG waveform can then be sent to transmitter 58 for transmission
to activator 22. In some embodiments, the signals can be transmitted directly to
activator 22 rather than first storing them in ASIC 60 and/or an IMD memory
device.

Once measured and transmitted, the data is available to service system 30
via the link between base station 24 and system 30. Thereafter, technician
32/medical personnel 34 have access to the measured signals. As such, the
information in the measured signals may be used by a physician to remotely
diagnose a condition of patient 16, to observe and record the measured signals,
and/or to further instruct IMD 20 based on the measured signals.

Figure 3 illustrates a perspective view of an activator system 200 according
to one embodiment configured to communicate with EVID 20 (Figure 1) in
continuously measuring and recording biological signals, such as heart signals, and
transmit the recorded biological signal information for subsequent analysis through
a multi-modal activator device 22. In particular, activator system 200 includes
activator device 22 and a key 202 that is insertable into the activator device 22 to
change a state of the activator device 22 from a data receiving mode (i.e., a "patient
mode" in which key 202 is not inserted) to a programming mode (i.e., a "physician mode" in which key 202 is inserted into activator 22).

In one embodiment, key 202 includes a head 204 and a shaft 206 extending from head 204 that provides redundant safety features that preclude changing the state of activator 22 from the patient mode unless at least two switches are closed. For example, in one embodiment shaft 206 includes a mechanical portion configured to mechanically close a micro-switch, and a magnetic portion configured to magnetically close a magnetic switch. In this regard, in one embodiment key 202 is a magnetic-mechanical key, or a key including mechanical and magnetic components.

In one embodiment, activator 22 includes a housing 210 enclosing electronic components (See Figure 4), a graphical user interface (GUI) 212 including a display panel 214, and a user control panel 216 electrically coupled to GUI 212 and display panel 214.

In one embodiment, housing 210 defines a first housing section 220 and a second housing section 222 that are sized to be reciprocally mated to one another to define an enclosure 224 that retains the electronic components of activator 22. Housing 210 is fabricated from suitable engineering plastics, including for example, thermoplastics, thermosets, curing resins and the like. One suitable resin for housing 210 includes high density polyethylene, although other suitable plastics are acceptable. In one embodiment, first housing section 220 forms a cover (or top) defining an access slot 226 and second housing section 222 forms a base (or bottom) defining a connector port 228, where access slot 226 and connector port 228 communicate with enclosure 224.

In general, access slot 226 defines an opening sized to receive key 202; inserting key 202 changes a communication state of activator device 22 from patient mode (described below) to physician mode (also described below). Connector port 228 is electrically configured to enable hardwire electrical recharging of activator device 22 battery stored within housing 210. In other embodiments, access slot 226 and connector port 228 are formed in other suitable locations of housing 210.
GUI 212 provides a data interface and display panel 214 to enable a user to view information and waveforms monitored by IMD 20 (Figure 1) and uploaded to activator 22. In one embodiment, display panel 214 is a liquid crystal display (LCD) screen and GUI 212 includes a separate bi-color amber/green, for example, light emitting diode (LED) light 230 or light guide 230. In one embodiment, LED light 230 is configured to illuminate to indicate an on/off status of activator 22, or a status of data uploading into activator 22 from IMD 20, or a status of data downloading from activator 22 to service center 30.

User control panel 216 includes a plurality of buttons 240 including patient button 26. In one embodiment, buttons 240 are push-activated, for example by a user's thumb, and are configured to enable the user to signal IMD 20 to record a symptomatic event, or to toggle between display screens and other data screens displayed on display panel 214. In one embodiment, housing 210 includes a movable protective cover 242 that is hinged to one end 244 of housing 210. In this manner, cover 242 can be displaced away from user control panel 216 to provide access to buttons 240, or closed to protectively shield patient button 26 from inadvertent pressing and/or undesired data recording.

Figure 4 illustrates an exploded view of activator 22 with first housing section 220 (Figure 3) removed and enclosure 224 exposed. In particular, second housing section 222 forms a base configured to retain a printed circuit board 250 and a spacer 260 coupled with a portion of circuit board 250, where both printed circuit board 250 and spacer 260 are disposed within enclosure 224.

Printed circuit board 250 includes circuitry 252 having a variety of electronic components such as integrated circuits, memory cells, capacitors, diodes, antenna, etc. that enable activator 22 to electronically communicate with IMD 20 (Figure 1), and includes at least two mode switches 270, 272. For example, in one embodiment printed circuit board 250 includes a mechanical switch 270 and a magnetic switch 272 that are retained within enclosure 224 adjacent to access slot 226. In one embodiment, mechanical switch 270 is a micro-electronic switch configured to be shunted to a closed position when depressed, and magnetic switch
272 is a Hall effect sensor that is sensitive to the presence of a magnet (and more particularly, sensitive to the presence of magnetic flux density).

Figure 5 illustrates a top plan view of spacer 260 according to one embodiment. Spacer 260 includes a body 280 and a scaffold 282 extending from body 280. Body 280 is configured to mate with printed circuit board 250 (Figure 4) such that scaffold 282 aligns with access slot 226 (Figure 4).

In one embodiment, scaffold 282 defines a first flexible arm 290 spaced apart from a second flexible arm 292 to define a key slot 294 between arms 290, 292 that is sized to removably receive key 202. In one embodiment, first flexible arm 290 defines a prong 300, and second flexible arm 292 defines an opposing prong 302 that combine to retain key 202 (Figure 4) when key 202 is inserted into key slot 294. In particular, flexible arms 290, 292 are configured to flex and spread apart one from the other as key 202 is inserted into key slot 294, and when key 202 is fully seated within scaffold 282, prongs 300, 302 engage with detents formed in key 202 to securely retain and align key 202 in scaffold 282, as described below.

In one embodiment, spacer 260 is configured to be lightweight and rigid. In this regard, embodiments provide body 280 formed of a polymer to include one or more fenestrations that are compatible with electrical circuitry 252 of printed circuit board 250. In one embodiment, spacer 260 is formed of a molded polymer such as a polycarbonate, although other suitable polymer compositions are also acceptable.

Figure 6 illustrates a plan view of key 202 including head 204 and shaft 206 according to one embodiment. In one embodiment, head 204 defines a first major surface 310 opposite a second major surface 312, a peripheral ring 314 disposed at an outer circumference of the first and second major surfaces 310, 312, and an antenna 316. In one embodiment, peripheral ring 314 is a raised peripheral ring 314 and antenna 316 is disposed within the raised portion of peripheral ring 314.

In some embodiments, head 204 defines an optional key ring hole 320 extending between the first and second major surfaces 310, 312, and includes indicia 322 printed on at least one of the first and second major surfaces 310, 312. For example, in one embodiment "Physician Programming Key" is printed, or
molded, into first major surface 310 and "Not for Patient Use" is printed, or molded, into second major surface 312 to remind the user that key 202 is to be used by a trained professional to change a state of activator 22. In this regard, it is desired that key 202 be provided only to a trained clinician and not provided to patient 16 (Figure 1).

In general, shaft 206 extends from head 204 and defines a distal end 330 opposite a proximal end 332 that is adjacent and coupled to head 204. In one embodiment, shaft 206 includes a central longitudinal section 340, a first flange 342 coupled to a first side of central longitudinal section 340, a second flange 344 opposite first flange 342, and a magnet 346 integrally formed in central longitudinal section 340. In one embodiment, first flange 342 defines a first detent 352 and second flange 344 defines a second detent 354, where the detents 352, 354 are configured to be engaged by prongs 300, 302 (Figure 5) and securely retain key 202 when it is inserted into scaffold 282 (Figure 5). To this end, one embodiment provides magnet 346 integrally formed in central longitudinal section 340 adjacent to distal end 330 such that magnet 346 aligns with magnetic switch 272 when detents 352, 354 are engaged by prongs 300, 302, respectively.

In one embodiment, key 202 is molded or formed as an integral piece including head 204 connected to shaft 206, where antenna 316 is molded into head 204 and magnet 346 is molded into shaft 206. In other embodiments, magnet 346 is press fit into a suitable recess formed within shaft 206. In general, key 202 is molded from a suitably durable polymer such as a polycarbonate, or a blend of polycarbonate and another polymer. One suitable polymer for key 202 includes a Lexan™ polycarbonate thermoplastic resin. Another suitable polymer for key 202 includes a blend of Lexan™ and acrylonitrile butadiene styrene (ABS), although other suitable polymers and/or blends of polymers are also acceptable.

In one embodiment, antenna 316 is configured to receive electrical signals from a transmitter of activator 22 circuitry 252 and convert the signals to radio-frequency (RF) signals for transmission to EVID 20 (Figure 1). In this regard, antenna 316 is sized to have a length that matches or is proportional to the
wavelength of the transmitted RF signal. One suitable antenna 316 is a wire coiled antenna, although other suitable antenna configurations are also acceptable.

In one embodiment, magnet 346 is a rare earth magnet having a coercive force of greater than 14 kOe, although other suitable magnets are also acceptable.

In one embodiment, magnet 346 is a sintered NdFeB magnetized rare earth magnet identified as N40M and available from Applied Magnet Technology, Portage, IN.

Figure 7 illustrates a left side view of key 202. Proximal end 332 of shaft 206 is connected to head 204. Antenna 316 is not shown in this view for ease of illustration. Regarding shaft 206, detent 354 extends the full width of shaft 206, and magnet 346 extends between opposing surfaces of central longitudinal section 340.

Figure 8 illustrates a top end view of key 202. First and second major surfaces 310, 312 are substantially planar. In one embodiment, raised peripheral ring 314 defines a first concave curvature 351 relative to first major surface 310 and a second concave curvature 353 relative to second major surface 312. Concave curvatures 351, 353 of peripheral ring 314 combine to define opposing central concave troughs 355, 357, respectively, when key 202 is viewed along a longitudinal axis.

Figure 9 illustrates a front view of key 202. Central longitudinal section 340 defines a first major surface 360 opposite a second major surface 362. Magnet 346 extends between first major surface 360 and second major surface 362. In one embodiment, first and second flanges 342, 344 extend beyond first major surface 360 and beyond second major surface 362. In this regard, a lateral cross-sectional view of one embodiment of shaft 206 defines a substantially H-shaped cross-section. In one embodiment, central longitudinal section 340 is recessed relative to first and second flanges 342, 344.

Figure 10 illustrates an end view of activator system 200 showing key 202 inserted into access slot 226 of activator 22. In one embodiment, key 202 may be inserted such that first concave curvature 351 is oriented "up." Alternatively, key 202 may be inserted such that first concave curvature 351 is oriented "down." In this regard, shaft 206 may be inserted into access slot 226 in either orientation, and
key 202 is thus not orientation specific. When key 202 is inserted into activator 22, one of the concave curvatures 355, 357 of head 204 is oriented to provide clearance for the connection of a power cord, for example, into connector slot 228.

With reference to Figure 1, activator 22 includes a patient mode and is configured as a transceiver to upload data and/or information from IMD 20. Activator 22 is typically worn by the patient 16, or held by the patient 16, and is thus associated with the location of the patient 16 relative to base station 24. Throughout the day or the wearing cycle, activator 22 periodically uploads data from IMD 20 and downloads data and/or information to base station 24. In addition, during symptomatic events that the patient 16 senses, patient 16 can press patient button 26 on control panel 216 to signal IMD 20 to record biological data for subsequent uploading to activator 22 and eventual downloading to service system 30. In these embodiments, activator device 22 is maintained in a low-power patient mode when key 202 is not inserted into activator device 22.

With additional reference to Figure 4 and Figure 6, when key 202 is inserted into access slot 226, the state of activator device 22 changes from the patient mode state to a physician mode. In particular, when key 202 is fully inserted into access slot 226, central longitudinal section 340 contacts mechanical switch 270 and magnet 346 aligns with magnetic switch 272, and activator device 22 is enabled into the physician mode. The physician mode of activator 22 is characterized by activator 22 being configured as a transmitter that can wirelessly program IMD 20. In one embodiment, antenna 316 within head 204 of key 202 is configured to extend a telemetry range of activator 22. For example, in one embodiment inserting key 202 into activator 22 (i.e., when activator 22 is in physician mode) increases power to activator 22 and enables activator 22 to overcome potential nearby electrical interference, such as is present from other electronic devices in a surgical suite during implantation of IMD 20.

In one embodiment, and with reference to Figure 5, when key 202 is fully inserted into key slot 294, prong 300 seats into first detent 352 and prong 302 seats into detent 354 to retain and align magnet 346 over magnetic switch 272. In this
manner, shaft 206 of key 202 and scaffold 282 of spacer 260 combine to position key 202 such that both mechanical switch 270 and magnetic switch 272 are closed and activator device 22 changes state to the physician mode. In one embodiment, the state of activator device 22 changes only when both the mechanical switch 270 and the magnetic switch 272 are simultaneously closed.

Figure 11 illustrates a method 400 employed by activator device 22 in switching between modes according to one embodiment. At 402, activator device 22 is in the patient mode. As a point of reference, activator device 22 is in the patient mode during event monitoring in general, and whenever key 202 is not inserted into activator 22.

At 404, a program of activator device 22 queries whether activator device 22 senses the presence of magnet 346, and more specifically, whether switch 272 (Figure 4) is Hall effect coupled due to increased magnetic flux density from magnet 346. If activator device 22 does not sense the presence of the magnet 346, then activator device 22 remains in the patient mode indicated at 402.

At 406, if activator device 22 does sense the presence of magnet 346, a program of activator device 22 queries whether activator device 22 senses mechanical switch 270 having been depressed, as processed through circuitry 252 (Figure 4), for example. In this case, if magnetic switch 272 is closed but mechanical switch 270 is open, then activator device 22 remains in the patient mode. Otherwise, if both the magnetic switch 272 and the mechanical switch 270 are sensed and both are closed, then the activator device 22 is enabled to change state to the physician mode, as indicated at 408. In this manner, activator device 22 is provided with redundant safety features that assures that both mechanical switch 270 and magnetic switch 272 (Figure 4) are closed simultaneously before enabling the physician/programming mode of activator device.

Figure 12 illustrates a modal diagram for activator system 200 (Figure 3) according to one embodiment. The modal diagram illustrates various modes and/or states of activator device 22. For example, in one embodiment modal diagram includes that following states of activator system 200: a shipping mode 502 of
activator device 22 after it is manufactured and prior to activation by a trained clinician; a paired operational mode 504 that includes a programming mode 510 and a data receiving mode 512; a streaming mode 520 associated with programming mode 510; a battery depleted mode 522 associated with data receiving mode 512; and a standby mode 532.

With additional reference to Figure 3, when activator device 22 is manufactured it is configured with a factory-only interface to occupy shipping mode 502. In one embodiment, when activator device 22 is in shipping mode 502 its functionality is suspended with the exception of a clock or timing function. In this regard, shipping mode 502 is configured to conserve activator device 22 power by diminishing its functionality, and shipping mode 502 power conservation will continue until activator device 22 is programmed or configured to occupy a different state. In one embodiment, activator device 22 is configured to enter program mode 510 from shipping mode 502 when key 202 is inserted into access slot 226. In one embodiment, for example upon return of activator device 22 to the manufacturer, activator device 22 is configured to return to shipping mode 502 from program mode 510 through the use of a factory-only interface.

In general, activator device 22 is in program mode 510 when key 202 is inserted into activator device 22 and the plural redundant safety devices described in Figure 11 are satisfied. Alternatively, when key 202 is withdrawn from activator device 22, activator device 22 is configured to exit program mode 510 and occupy data receiving mode 512. Embodiments of activator device 22 when in programming mode 510 or data receiving mode 512 are described in greater detail in Figures 13A-14B below.

In one embodiment, activator device 22 is configured to transition from programming mode 510 to streaming mode 520 when an appropriate menu choice is inputted into control panel 216 (Figure 3). Recall, programming mode 510 is enabled when key 202 is correctly inserted into activator device 22. In this Specification, programming mode 510 is referred to as a physician mode, or a clinician mode, these terms being used interchangeably. It is to be understood that
changing a state of activator device 22 to programming mode 510 is desirably conducted by a physician or other qualified clinician and is not intended to be conducted by a patient or other unauthorized user. In any regard, programming mode 510 is configured to enable activator device 22 to program or electronically change a setting of IMD 20 and/or a setting of activator device 22.

With the above in mind, and with reference to Figure 3, activator device 22 is configured to transition from programming mode 510 to streaming mode 520 when key 202 is inserted into activator device 22 and an appropriate menu choice is made on control panel 216. When activator device 22 is in streaming mode 520, embodiments provide for activator device 22 to signal IMD 20 to stream continuous ECG waveform data for reception by activator device 22, which is particularly useful during implantation of IMD 20. In one embodiment, activator device 22 is configured to be in a data-ready state to receive and display ECG waveform data within about three seconds after signaling IMD 20 to begin streaming such data.

Activator device 22 is configured to display ECG waveform data on display panel 214. In one embodiment, streaming waveform data scrolls across display panel 214 and can include heart rate output, and heart rate data determined from an R-R interval, for example. Other waveform data may also be displayed on panel 214. In one embodiment, heart rate data is displayed on panel 214 in a three-second average and is updated about every three seconds, pursuant to ANSI/AAMI EC13:2002 section 4.1.2.1(d). In this regard, in one embodiment activator device 22 is configured to identify R-waves and compute the R-R interval of a beating heart.

In one embodiment, when activator device 22 is in streaming mode 520 it is configured to "freeze" the waveform data displayed on panel 214 and resume scrolling in response to an appropriate menu choice entered into control panel 216. In one embodiment, when waveform data is "frozen," heart rate data is not updated on display 214. In certain cases, streaming ECG signals can be interfered with and/or lost for more than about three seconds, for example when activator device 22 experiences strong electrical interference or is moved beyond telemetry range of
IMD 20. Embodiments of activator device 22 provide for the display of text messages on display panel 214 to instruct the clinician to move activator device 22 closer to IMD 20 in response to such temporary interruptions to the ECG signals. In other embodiments, activator device 22 is configured to display an informative message on display panel 214 and flash LED 230 if battery of IMD 20 is near the end of its life, for example.

In one embodiment, when activator device 22 is in streaming mode 520 it is configured to not permit the transmission of signals to IMD 20. For example, when activator device 22 is in streaming mode 520, activator device 22 is precluded from signaling IMD 20 to upload data. In this regard, in one embodiment activator device 22 is configured to de-activate patient button 26 during streaming mode 520. In another embodiment, activator device 22 is configured to signal IMD 20 to exit streaming mode 520, for example when a clinician enters such an affirmative command into control panel 216 instructing IMD 20 to discontinue streaming of ECG waveform data. In a related embodiment, activator device 22 is configured to automatically return to program mode 510 after occupying streaming mode 520 continuously for about 30 minutes.

Embodiments of activator device 22 provide a battery depleted mode 522 that is configured to ensure that activator device 22 does not transition to standby mode 532 when the battery inside of activator device 22 is depleted. Upon depletion of the battery, activator device 22 is configured to occupy battery depleted mode 522, for example when the voltage of activator device 22 battery has dropped below a pre-set threshold.

In one embodiment, the pre-set voltage threshold that indicates a depleted battery is selected to be a lower than the voltage that triggers a low battery warning on display panel 214. That is to say, activator device 22 does not transition to battery depleted mode 522 when the battery is at the "low battery" voltage. In one embodiment, battery depleted mode 522 is configured to conserve power by suspending bi-directional telemetry of activator device 22. In another embodiment, the functionality of patient button 26 is suspended when activator device 22 is in
battery depleted mode 522. In another embodiment, activator device 22 includes an audible alarm, and battery depleted mode 522 is configured to sound the alarm prior to suspending LED, LCD, and alarm capabilities of activator device 22.

In one embodiment, activator device 22 is configured to return directly to data receiving mode 512 when battery is recharged. In a related embodiment, activator device 22 is configured to maintain functionality of all of its features while connected to a power supply cord, for example a power supply cord connected to port 228.

Embodiments of activator device 22 provide a standby mode 532. In one embodiment, standby mode 532 is configured to be patient-initiated. In one embodiment, standby mode 532 is configured to disable RF transmission of activator device 22, which is desirable when patient 16 carries activator device 22 onto a commercial airliner. In another embodiment, standby mode 532 is configured to disable the sound card in circuitry 252 (Figure 4) to silence auditory output of activator device 22. In one embodiment, when activator device 22 is in standby mode 532, RF transmission between activator device 22 and base station 24 (Figure 1) is terminated within two minutes, and any newly initiated RF transmission is suspended. In one embodiment, display panel 214 is configured to text an informative message indicating that activator device 22 occupies standby mode 532.

In one embodiment, a patient-initiated command is employed to return activator device 22 to data receiving mode 512 from standby mode 532. Embodiments of standby mode 532 provide for the display of informative messages on display panel 214 whenever patient button 26 is inadvertently depressed while activator device 22 occupies standby mode 532.

Embodiments of activator device 22 programming mode 510 are described with reference to Figures 13A and 13B. Figure 13A illustrates key 202 inserted into activator device 22 to configure program mode 510. Program mode 510 enables activator device 22 to electronically communicate with IMD 20 in programming settings of IMD 20. With this in mind, it is to be understood that protective cover
242 would typically be opened in the program mode 510 to provide an authorized clinician access to buttons 240 on control panel 216.

Figure 13B illustrates an authorized clinician or physician 34 using activator system 200 to program a setting of IMD 20. It is to be understood that activator device 22 is typically oriented toward the authorized clinician during programming to permit the physician 34 to view the control panel of activator device 22.

Programming mode 510 is a separate and distinct mode different from any other mode of activator device 22. In one embodiment, activator device 22 is a stand-alone separately programmable device including memory and programming logic within circuitry 252 (Figure 4) that enables activator device 22 to be a "smart" computer programming device for IMD 20. In particular, programming mode 510 enables activator device 22 to program a setting of IMD 20, and/or program data collection settings of activator device 22. For example, embodiments of program mode 510 enable a clinician to program a user language of device 22, view real-time ECG signals on display panel 214, set heart rate limits for monitoring by IMD 20, and set threshold heart rates of IMD 20.

When activator device 22 is in program mode 510, it is configured to do a self-check of battery level and display text on display panel 214 if the battery charge is low. Upon completion of the battery check, program mode 510 is configured to enable activator device 22 to transmit a signal to IMD 20 communicating that activator device 22 is ready to receive data from IMD 20. In one embodiment, one or more redundant safety checks are completed at this stage. For example, program mode 510 is configured to enable activator device 22 to check and display the identification number of IMD 20 on display panel 214 to confirm that activator device 22 and IMD 20 are properly paired.

In one embodiment, when in program mode 510, activator device 22 is configured to display a range of menu choices on display panel 214 upon initiating or entering into program mode 510. In one embodiment, when activator device 22 is in program mode 510, activator device 22 is configured to not transmit upload
commands to IMD 20 and to not transmit signals if patient button 26 is inadvertently depressed.

Embodiments of program mode 510 are configured to enable activator device 22 to program IMD 20 with a range of physician-defined settings. For example, one embodiment of program mode 510 enables activator device 22 to program IMD 20 for the smallest R-R interval (in milliseconds) that the physician desires before IMD 20 triggers event detection. Another embodiment of program mode 510 enables activator device 22 to be configured to program IMD 20 with the largest time intervals (in milliseconds) from the last valid R-wave before IMD 20 automatically triggers event detection.

In one embodiment, as activator device 22 enters program mode 510 it checks (via signaling) to see if IMD 20 is within telemetric communication range. Embodiments of program mode 510 are configured to provide a text display on panel 214 to instruct the authorized clinician to move activator device 22 closer to IMD 20 if necessary. In one embodiment, if no response is received from IMD 20 program mode 510 is configured to enable activator device 22 to broadcast an electronic message to all other implantable monitoring devices within RF range. Monitoring devices that are located in this manner have their identification number displayed on panel 214 for confirmation by the authorized clinician. If there is no response from an implantable monitoring device to the activator device 22 signal, or if multiple implantable monitoring devices respond, an appropriate error message is displayed on panel 214 and amber LED 230 flashes.

The authorized clinician is presented with a start up menu as activator device 22 enters program mode 510. The start up menu offers various menu options including a choice of language, viewing formats for ECG data, a display of IMD 20 information, and programming options for IMD 20. Menu options include: setting a low R-R rate, setting a high R-R rate, and/or setting a beats-per-minute (BPM) appropriate to one of the low or high R-R rate settings.

Figures 14A and 14B illustrate activator device 22 in data receiving mode 512. As a point of reference, in data receiving mode 512, key 202 of activator
system 200 (Figure 13A) is not inserted into activator device 22. Figure 14A illustrates activator device 22 as it would appear to patient 16 (Figure 1) during use when in data receiving mode 512. When in data receiving mode 512, activator device 22 is configured to receive data that IMD 20 has recorded. Recall, IMD 20 (Figure 1) is configured to passively record data of asymptomatic events (events not detected by the patient 16), and selectively record data of symptomatic events (events sensed or detected by patient 16) after patient button 26 is depressed; and activator device 22 is configured to receive each of these uploaded data sets when in data receiving mode 512.

Figure 14B illustrates activator device 22 near the person of patient 16 (either carried, or more typically, worn on a belt). When activator device 22 is in data receiving mode 512 it is configured to upload data from IMD 20 (Figure 1). For example, in one embodiment activator device 22 signals IMD 20 to transmit data to activator device 22 about every 20 hours. In one embodiment, activator device 22 is configured to connect with base station 24 about every 30 minutes to transfer data from the memory of activator device 22 to base station 24 for subsequent transmission to service system 30 (Figure 1). In one embodiment, if memory of activator device 22 is full, activator device 22 is configured to attempt a data connection with base station 24 about once every 5 minutes to download data and subsequently clear its memory.

In one embodiment, activator device 22 includes a class 1 Bluetooth RF communication protocol and is configured to wirelessly communicate with base station 24. With this in mind, embodiments of activator device 22 in data receiving mode 512 provide for wireless data-secure connection with base station 24. In this regard, the Bluetooth technology configures activator device 22 to be a proximity device wirelessly operable through a Pico net established dynamically and automatically as the Bluetooth-enabled activator device 22 enters and leaves radio proximity of base station 24. In one embodiment, when in data receiving mode 512, activator device 22 is configured to include an adaptive frequency hopping (AFH) capability that is configured to reduce interference between other wireless
technologies sharing the 2.4 GHz spectrum. In one embodiment, the AFH capability of activator device 22 includes signal hopping across 79 frequencies at 1 MHz intervals, although other signal hopping intervals are also acceptable.

In general, data receiving mode 512 is the standard mode of operation during patient use. Data receiving mode 512 is configured to enable telemetry transmission between IMD 20 and activator device 22 and disable the programming capability of activator device 22. The data receiving mode 512 enables activator device 22 to signal IMD 20 to initiate recording and periodic uploading of data for subsequent transmission to base station 24 and service system 30 (Figure 1). In one embodiment, data receiving mode 512 is configured to enable patient 16 to manually signal IMD 20 to begin recording data (for example during a symptomatic event) through the touch of patient button 26.

Data receiving mode 512 is configured to enable activator device 22 to automatically signal IMD 20 to upload the memory contents of its main data buffer, for example, in the event that patient 16 has not initiated an upload command manually through button 26 within a 20-hour period. In one embodiment, after 20 hours from the last successful data upload from IMD 20 to activator device 22 (either patient activated or otherwise) activator device 22 is configured to signal IMD 20 to upload data up to every 30 minutes for a period of 24 hours.

In one embodiment, data receiving mode 512 is configured to enable activator device 22 to audibly alarm periodically (e.g., for 10 seconds every hour) if no upload acknowledgement occurs in a 24 hour period. Other embodiments include activator device 22 flashing LED 230 and/or displaying information on display panel 214 in the event an upload acknowledgement has not occurred in a 24 hour period. In one embodiment, buttons 240 are provided to enable patient 16 to silence alarms.

Activator device 22 signals IMD 20 to begin recording data when patient button 26 is pressed in the data receiving mode 512. In one embodiment, activator device 22 attempts to re-send the activation signal every 5 seconds if the activation signal from activator device 22 is not acknowledged by IMD 20.
In another embodiment, activator device 22 is configured to automatically send an upload command to EVID 20 on a periodic basis (e.g., within 150 seconds) when patient button 26 is depressed. In one embodiment, when data uploaded from IMD 20 to activator device 22 is complete, activator device 22 is configured to automatically transfer the data to base station 24.

In other embodiments, activator device 22 is configured when in data receiving mode 512 to include a non-volatile data buffer that enables the storage of waveform data (e.g., 630 minutes of waveform data) along with associated time stamps for the waveform data. In one embodiment, memory (or space) occupied by data in the buffer of activator device 22 is cleared (or erased) after successful transmission of data to base station 24.

In other embodiments, activator device 22 is configured to readjust DVID 20 clock at least one time a week. Embodiments of data receiving mode 512 include configuring activator device 22 to receive readjustment clock signals from service system 30 (Figure 1), for example via base station 24 (Figure 1), and transmit the readjustment clock signals to DVID 20. In one embodiment, time adjustment to IMD 20 clock is coordinated to not occur while activator device 22 and IMD 20 are in programming mode 510, streaming mode 520, or battery depleted mode 522.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that a variety of alternate and/or equivalent implementations may be substituted for the specific embodiments shown and described without departing from the scope of the present invention. This application is intended to cover any adaptations or variations of the specific embodiments discussed herein. Therefore, it is intended that this invention be limited only by the claims and the equivalents thereof.
WHAT IS CLAIMED IS:

1. An activator device configured to communicate with an implantable monitoring device, the activator device comprising:
   a first mode configured to receive data of asymptomatic events passively recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of symptomatic events; and
   a second mode different from the first mode, the second mode configured to program electronic settings of the implantable monitoring device.

2. The activator device of claim 1, wherein the first mode is a patient mode and the second mode is a physician mode.

3. The activator device of claim 1, wherein the activator device is configured in the first mode to periodically signal the implantable monitoring device to upload recorded data of asymptomatic and symptomatic events to the activator device for storage.

4. The activator device of claim 3, wherein the activator device is configured in the first mode to periodically download stored data of asymptomatic and symptomatic events via a base station for transmission to a third party.

5. The activator device of claim 4, wherein the activator device is configured in the first mode to signal daily the implantable monitoring device to upload recorded data and to hourly download stored data of asymptomatic and symptomatic events to the base station for transmission to a third party.

6. The activator device of claim 4, wherein the activator device is configured in the first mode to wirelessly download stored data of asymptomatic and symptomatic events to the base station.
7. The activator device of claim 4, wherein the activator device is configured in the first mode to include adaptive frequency hopping that is configured to reduce wireless interference of data transmission to the base station.

8. The activator device of claim 4, wherein the activator device is configured in the first mode to erase its memory after downloading stored data to the base station.

9. The activator device of claim 1, wherein the activator device is configured in the second mode to enable an authorized user to program a user language of the activator device.

10. The activator device of claim 1, wherein the activator device is configured in the second mode to program the implantable monitoring device for a heart rate range to be monitored.

11. The activator device of claim 10, wherein the activator device is configured in the second mode to signal the implantable monitoring device to record and store all waveform data outside of the programmed heart rate range.

12. The activator device of claim 1, wherein the activator device is configured in the second mode to display real-time ECG waveforms on a graphical user interface.

13. The activator device of claim 1, wherein the activator device is configured in the second mode to signal the implantable monitoring device to continuously stream telemetry data to the activator device.

14. The activator device of claim 1, wherein the activator device is configured in the second mode to signal the implantable monitoring device to report an identification number to the activator device.
15. The activator device of claim 1, wherein the activator device is configured in the second mode to broadcast a signal to one or more other monitoring devices when data connection is interrupted between the activator device and the implantable monitoring device.

16. The activator device of claim 1, further comprising:
   a shipping mode and a standby mode that are each different from the first and second modes, the first mode including a battery depleted mode and the second mode including a streaming mode.

17. The activator device of claim 1, wherein the activator device is configured in the second mode to provide a data view option not available in the first mode.

18. An activator device configured to communicate with an implantable monitoring device, the activator device comprising:
   a first mode configured to receive data of first biologic events passively recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of second biologic events; and
   means for selectively changing a mode of the activator device to a second mode different from the first mode, the second mode configured to program electronic settings of the implantable monitoring device.

19. The activator device of claim 18, wherein the activator device is configured in the first mode to receive data of asymptomatic biologic events passively recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of symptomatic biologic events.
20. The activator device of claim 18, wherein the means for selectively changing a mode of the activator device comprises a separate device that is insertable into a housing of the activator device.

21. An activator system configured to communicate with an implantable monitoring device, the activator system comprising:
   an activator device including a first mode configured to receive data of asymptomatic events recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of symptomatic events, and a second mode configured to program electronic settings of the implantable monitoring device; and
   a key configured to insert into the activator device, and when inserted to change a state of the activator device from the first mode to the second mode.

22. The activator system of claim 21, wherein the first mode is different from the second mode.

23. The activator system of claim 21, wherein the activator device is configured in the first mode to upload at least daily the asymptomatic and symptomatic event data.

24. The activator system of claim 21, wherein the activator device is configured in the first mode to download at least hourly the asymptomatic and symptomatic event data to a service system.

25. The activator system of claim 24, wherein the activator device is configured in the first mode to communicate wirelessly with the service system and to frequency hop to reduce wireless interference of data transmission to the service system.
26. The activator system of claim 21, wherein the activator device is configured in the second mode to display real-time ECG waveforms on a graphical user interface.

27. The activator system of claim 21, wherein the activator device is configured in the second mode to signal the implantable monitoring device to continuously stream telemetry data to the activator device.

28. The activator system of claim 21, further comprising:
   a shipping mode and a standby mode that are each different from the first and second modes;
   a battery depleted mode associated with the first mode; and
   a streaming mode associated with the second mode.

29. A monitoring system comprising:
   an implantable monitoring device;
   an activator device including a first mode configured to receive data of asymptomatic events recorded by the implantable monitoring device and enable manual signaling of the implantable monitoring device to record data of symptomatic events, a second mode configured to program electronic settings of the implantable monitoring device; and
   a base station in electrical communication with the activator device that is configured to receive data from the activator device and transmit the data to another system.

30. The monitoring system of claim 29, further comprising:
   a key configured to insert into the activator device, and when inserted to change a state of the activator device from the first mode to the second mode.
31. A handheld device configured to wirelessly communicate with an implantable monitoring device, the handheld device comprising:

   a first operating mode that configures the handheld device to receive, at predetermined intervals from the implantable monitoring device, data associated with a physiologic signal measured and transmitted by the implantable monitoring device; and

   a second operating mode, different from the first operating mode, that configures the handheld device to program one or more parameters of the implantable monitoring device, and to continuously receive real-time data associated with the physiologic signal measured and transmitted by the implantable monitoring device and display the received real-time data on a display of the handheld device.
ACTIVATOR DEVICE IS IN PATIENT MODE

DOES ACTIVATOR DEVICE SENSE THE PRESENCE OF THE MAGNET IN THE KEY?

NO

YES

DOES ACTIVATOR DEVICE SENSE THAT THE MECHANICAL MICRO-SWITCH IS CLOSED?

NO

YES

ACTIVATOR DEVICE IS IN PHYSICIAN MODE

Fig. 11