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(54) **DYNAMIC ANNOUNCING FOR CREATION
OF WIRELESS COMMUNICATION
CONNECTIONS**

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USPC **340/870.07**
See application file for complete search history.

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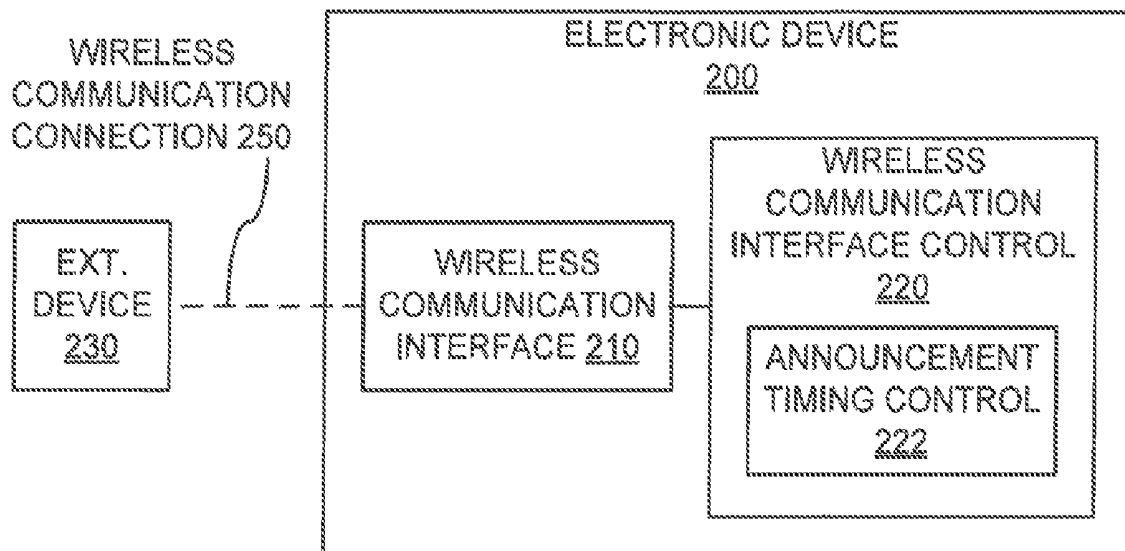
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(57) **ABSTRACT**

Example electronic devices, including but not limited to implantable medical devices, and methods employing dynamic announcing for creation of wireless communication connections are disclosed herein. In an example, an electronic device includes a wireless communication interface to transmit announcement signals for creating a wireless communication connection with the external device. The electronic device also includes a sensor to detect a characteristic of an environment external to the electronic device, and a control circuit including an announcement timing control module to dynamically control timing of the announcement signals based on the detected characteristic.

23 Claims, 8 Drawing Sheets



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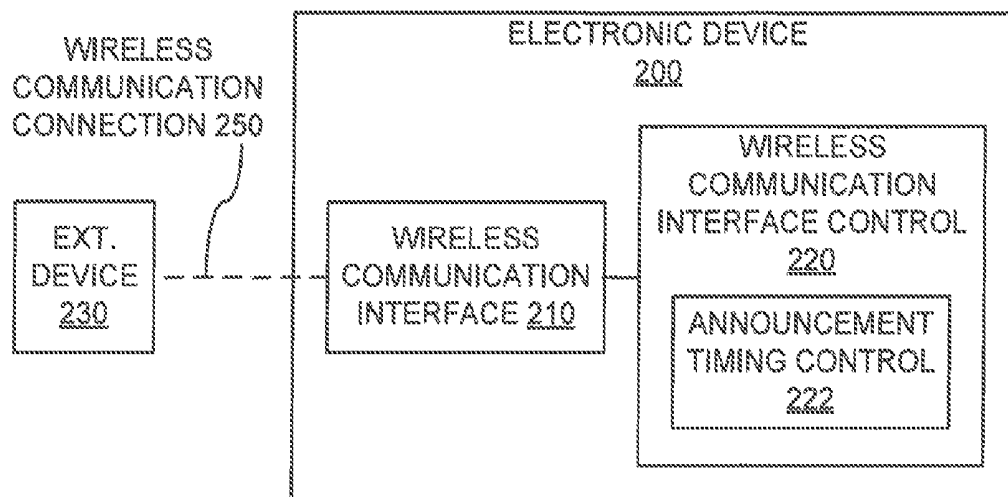


FIG. 1

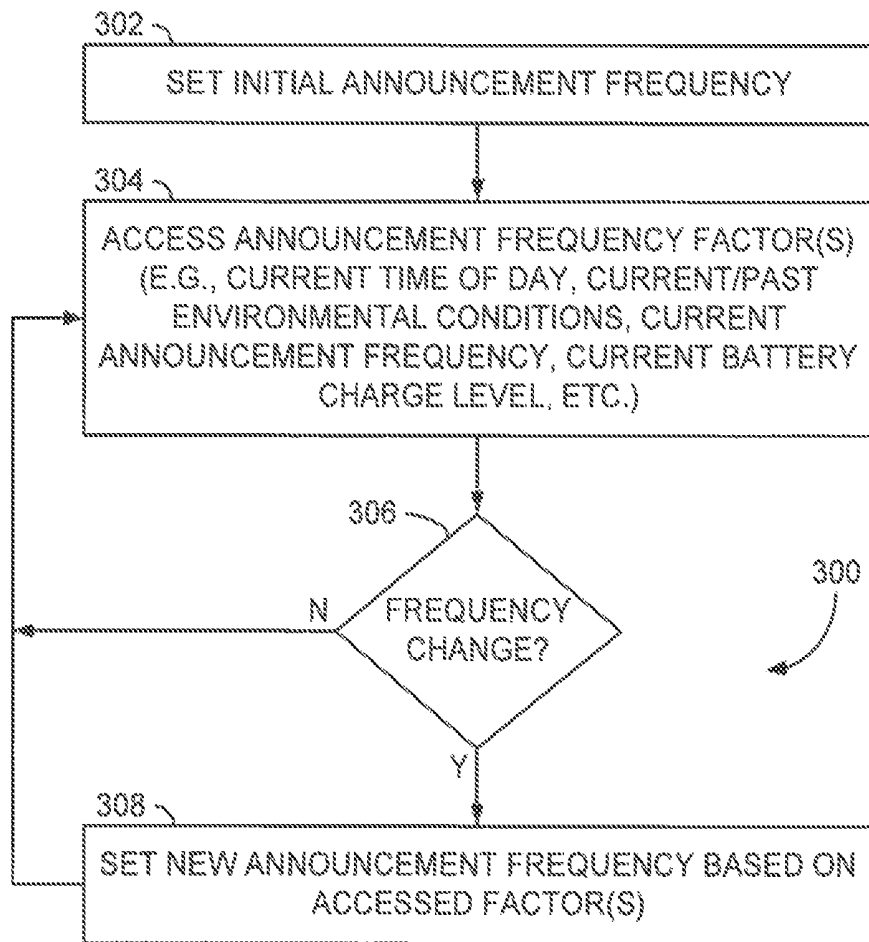


FIG. 2

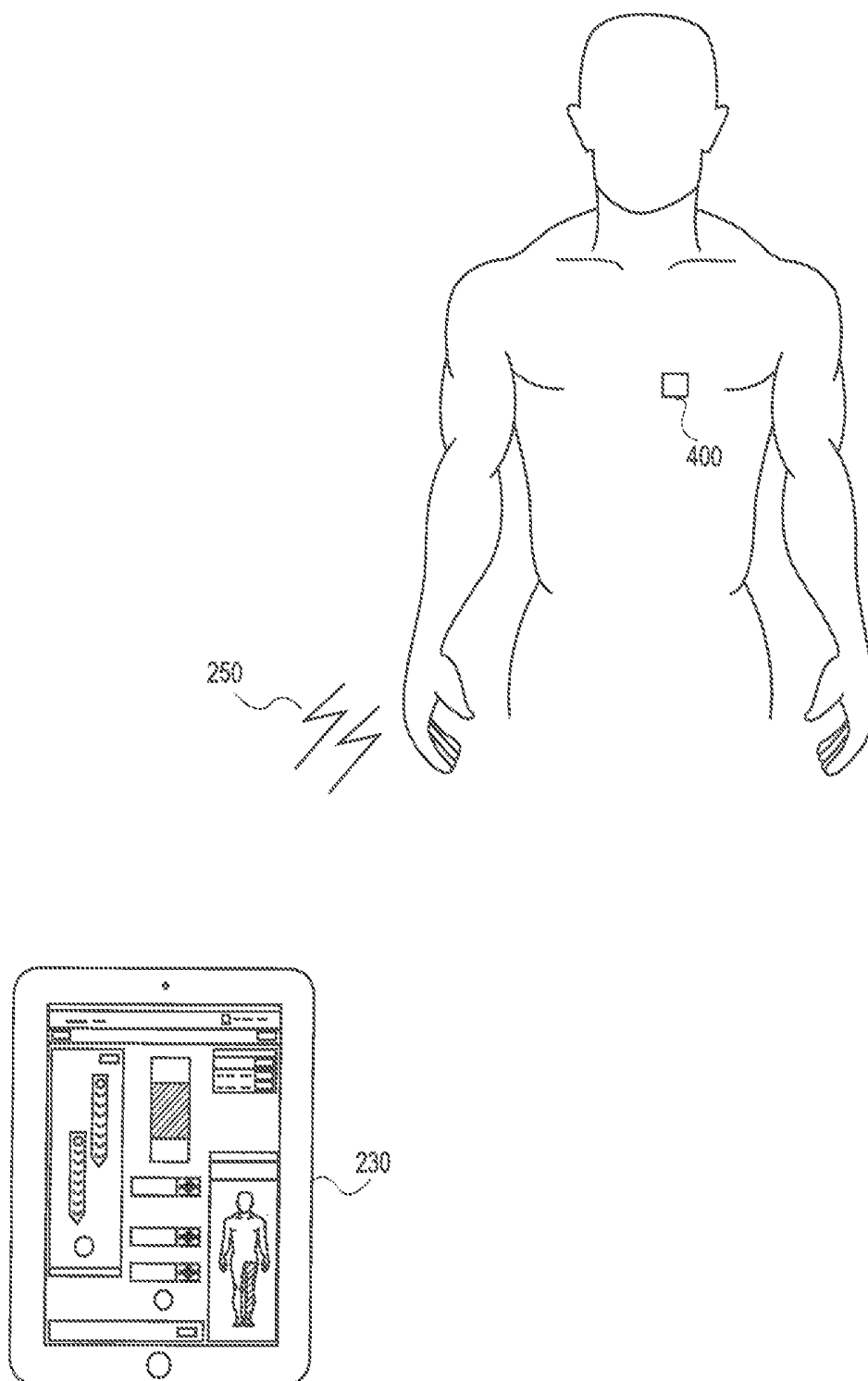
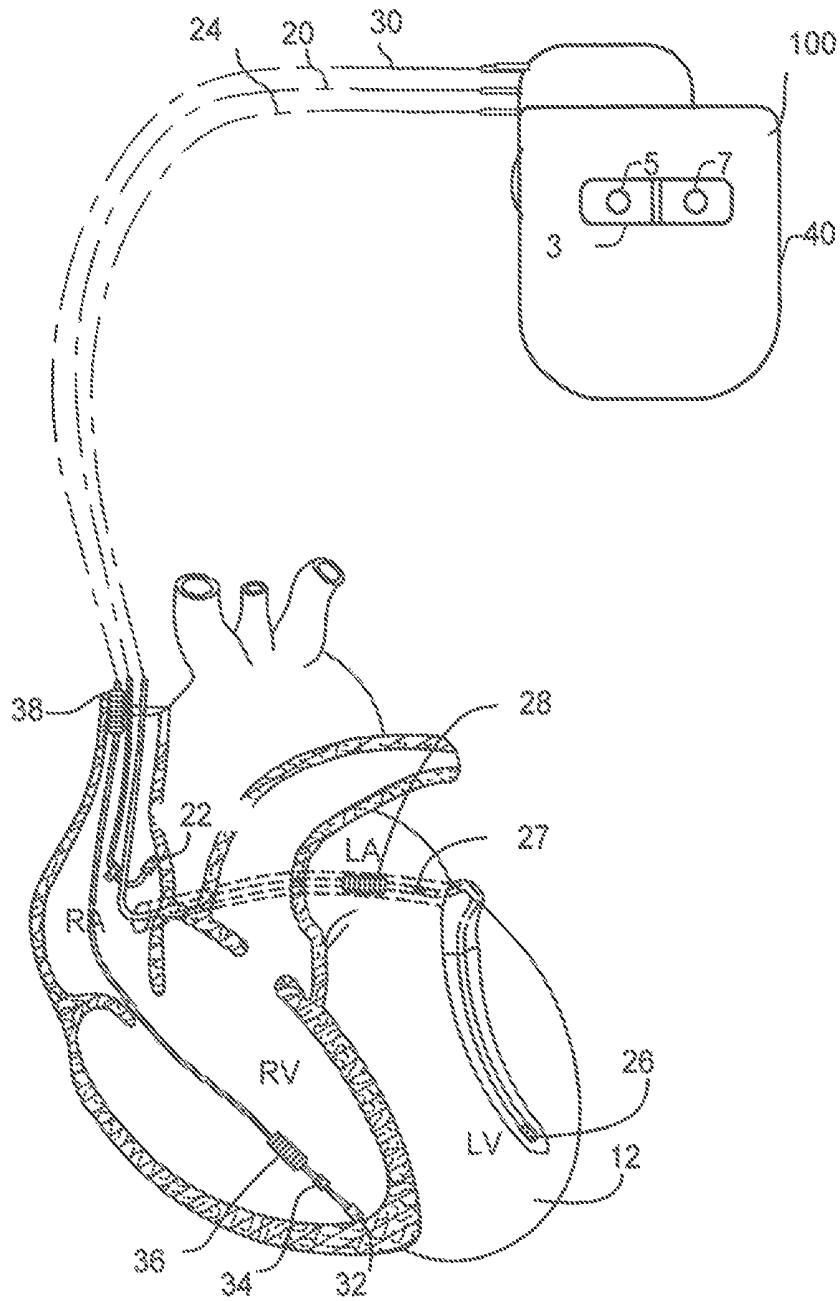


FIG. 3A

**FIG. 3B**

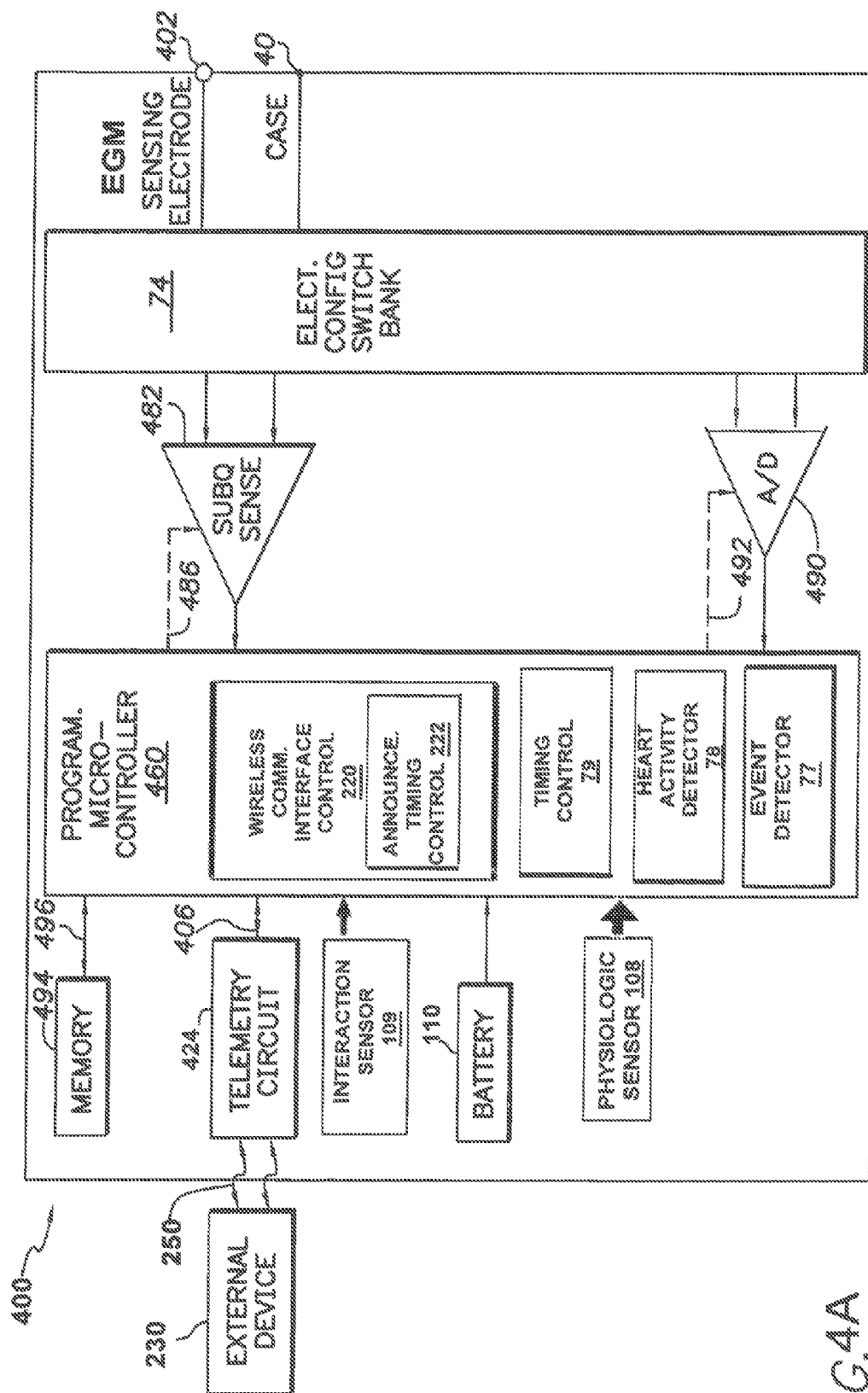


FIG. 4A

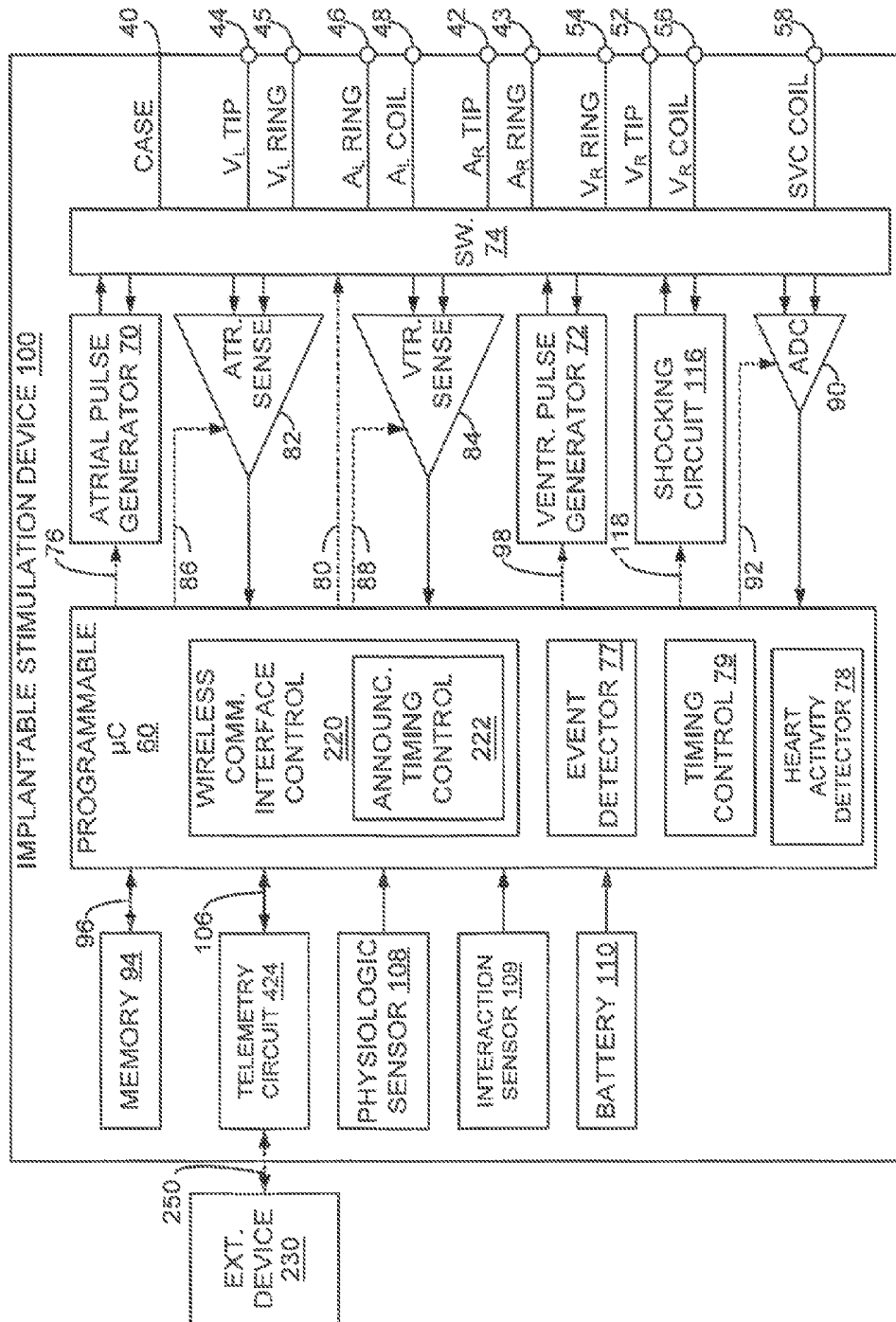


FIG. 4B

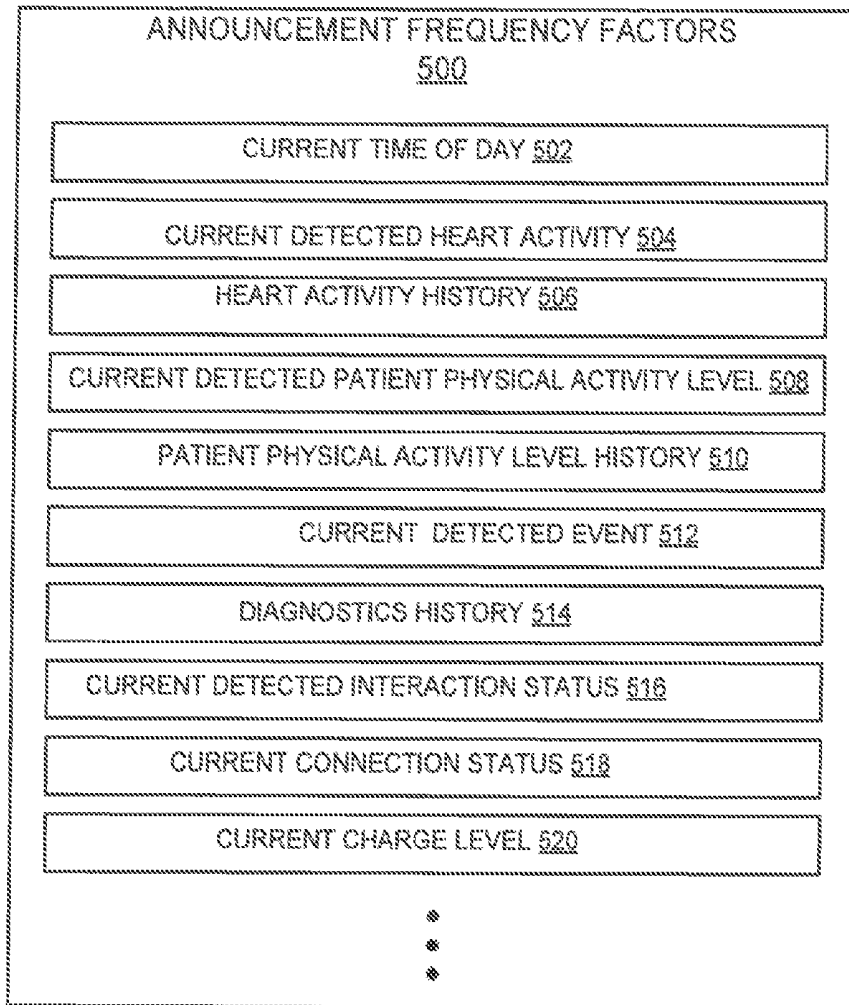


FIG. 5

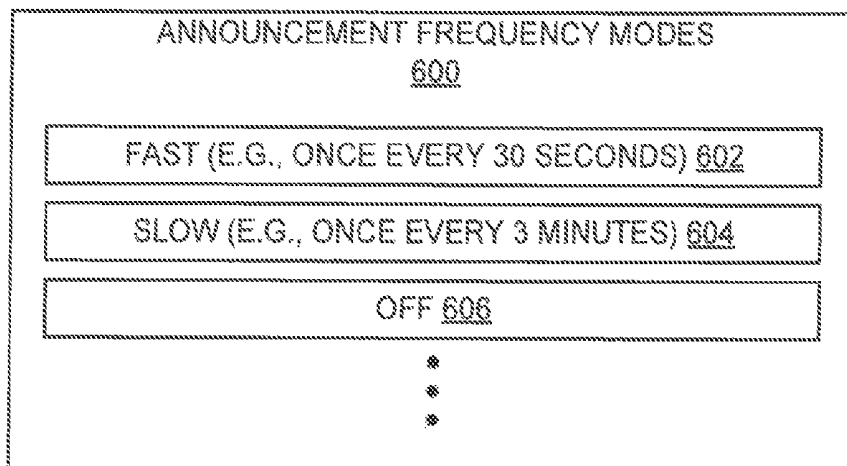


FIG. 6

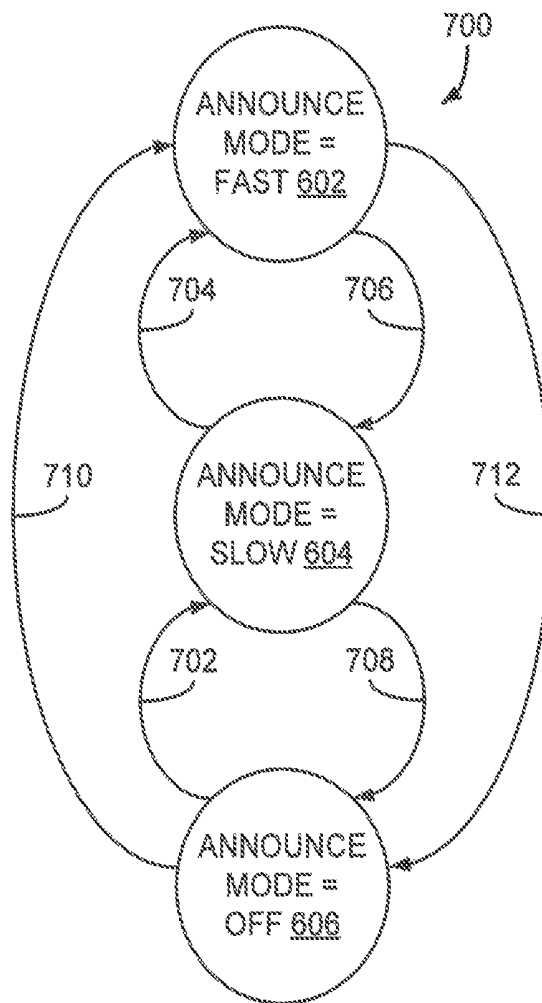


FIG. 7

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DYNAMIC ANNOUNCING FOR CREATION OF WIRELESS COMMUNICATION CONNECTIONS

PRIORITY CLAIM

The present application relates to and claims priority from U.S. provisional application Ser. No. 62/339,795, filed May 20, 2016, entitled "Dynamic Announcing For Creation Of Wireless Communication Connections," which is hereby expressly incorporated by reference in its entirety to provide continuity of disclosure.

FIELD OF THE INVENTION

The present invention relates to wireless communication technology. More specifically, the present invention relates to dynamically varying announcing frequency for creation of wireless communication connections.

BACKGROUND OF THE INVENTION

Many wireless communication technology standards, such as the original Bluetooth® standard and its variants (e.g., the Bluetooth® Low Energy, or BLE, standard), facilitate creation of communication connections between pairs of devices using announcement or advertising data packets, messages, or other signals. In some communication standards, for example, an electronic device may transmit such signals wirelessly while in an announcing or advertising mode (e.g., "discoverable" mode in the Bluetooth® standard) to make nearby devices aware of the presence of the announcing device. In response to those announcements or advertisements, another device may then attempt to create a communication connection with the announcing device by way of bidirectional exchange of device identities and/or capabilities, encryption/decryption keys, and other information with the electronic device to create a secure communication connection therebetween.

Typically, an electronic device is placed into its announcing or advertising mode in response to some user input received via a user interface, such as the press of a button or touch of an area on a touchscreen. However, some electronic devices that employ a wireless communication technology either do not provide a tactile user interface, or simply cannot be accessed physically during normal operation. One such class of device is the implantable medical device. Examples of implantable medical devices include, but are not limited to, automatic implantable cardioverter defibrillators (AICDs), cardiac pacemakers, spinal cord stimulation (SCS) devices, deep brain stimulation (DBS) devices, and implantable loop recorders (ILRs), such as implantable cardiac monitors (ICMs) and subcutaneous atrial fibrillation (AF) monitors. Such devices often employ wireless communication to connect with an external computer system to receive configuration information, commands, and so on, and to transmit operational status, logged events, and the like. Such devices, when implanted in a human body, are not physically accessible, and thus do not provide a tactile or physical interface to facilitate placing the device into an announcing or advertising mode to establish wireless communication with another device.

With the above aspects in mind, as well as others not explicitly discussed herein, various embodiments of an electronic device employing wireless communication, such

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as an implantable medical device, as well as methods of operating such a device, are disclosed herein.

SUMMARY

In one embodiment, an electronic device may include a wireless communication interface to transmit announcement signals for creating a wireless communication connection with an external device separate from the electronic device. The electronic device may also include a sensor to detect a characteristic of an environment external to the electronic device, and a control circuit including an announcement timing control module to dynamically control timing (e.g., frequency) of the announcement signals based on the detected characteristic. In some examples, the electronic device may be an implantable medical device.

While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which depicts and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various aspects, all without departing from the scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified block diagram of an example electronic device that employs dynamic announcing for creation of wireless communication connections.

FIG. 2 is a simplified flow diagram of an example method of operating the electronic device of FIG. 1 to employ dynamic announcing for creation of wireless communication connections.

FIG. 3A illustrates a system for the detection of environmental conditions in communication with an external device through a wireless communication connection.

FIG. 3B is a partly cut-away view of an example implantable cardiac stimulation device in electrical communication with at least three leads implanted into a patient's heart for delivering multi-chamber stimulation and shock therapy and for detecting environmental conditions.

FIG. 4A is a functional block diagram of selected components of a subcutaneous implantable monitor of 3A, including an announcement timing control module for dynamic announcing for creation of wireless communication connections.

FIG. 4B is a functional block diagram of the example implantable cardiac stimulation device of FIG. 3B, illustrating the basic elements providing pacing stimulation, cardioversion, and defibrillation in four chambers of the heart via one or more pulse generators, as well as an announcement timing control module for dynamic announcing for creation of wireless communication connections.

FIG. 5 is a list of example announcement frequency factors that may influence operation of the announcement timing control modules of FIGS. 4A and 4B.

FIG. 6 is a list of example announcement frequency modes that the announcement timing control modules of FIGS. 4A and 4B may provide based on the announcement frequency factors of FIG. 5.

FIG. 7 is an example state diagram of the example announcement frequency modes of FIG. 6.

DETAILED DESCRIPTION

This description is not to be taken in a limiting sense but is made merely to describe general principles of the inven-

tion. The scope of the invention should be ascertained with reference to the issued claims. In the description of the invention that follows, like numerals or reference designators are used to refer to like parts or elements throughout.

The following detailed description relates to electronic devices that employ a wireless communication interface. In one example, an electronic device may employ dynamic advertising (referred to herein as “announcing”) for creation of wireless communication connections with one or more other devices external to the electronic device via the wireless interface. In one example, the electronic device may alter the frequency of announcement messages, data packets, or other signals that are used to create a wireless communication connection. Alteration of the frequency may be based on one or more factors that may be accessed or sensed by the electronic device. In at least some examples, the electronic device may be an implantable medical device, such as an automatic implantable cardioverter defibrillator (AICD), pacemaker, spinal cord stimulation (SCS) system, deep brain stimulation (DBS) system, implantable loop recorder, or the like. In at least some examples, the external device may be a smartphone, smartwatch, personal digital assistant (PDA), tablet, laptop computer, desktop computer, bedside monitor, programmer, or the like.

As a result of at least some of the embodiments discussed in greater detail below, the electronic device may alter the frequency at which announcement messages or other signals are issued to balance overall power consumption of the device with the amount of time consumed in establishing a wireless communication connection when a physical user interface to the device (e.g., a button, a touchscreen, or the like) is non-existent or limited, thus at least restricting the ability of a user to place the device in an announcement mode explicitly. More specifically, announcement messages issued more often would reduce the amount of time to create a communication connection while increasing power consumption, whereas issuing such messages less often would tend to produce the opposite effects.

In some devices currently employing Bluetooth® technology, a user may initiate the formation of a connection between devices by making at least one of those devices “discoverable” by causing that device to transmit or broadcast one or more announcement or advertisement messages. Such initiation may be in the form of a press of a button, a touch of a touchscreen area, or other direct physical contact with the device. The announcement messages may include some identification information of the device, some encryption key information, and/or so forth. A nearby device, in response to receiving one of the announcements, may “pair” with the device providing the announcement messages to exchange further encryption information, data regarding capabilities of the two devices, and so on. Based on that exchange of information, the two devices may then be “bonded” to each other, facilitating one or more wireless communication connections between the devices over any arbitrary time period until the devices are unbonded.

Further, some devices provide a Bluetooth® pairing mechanism by way of the Near Field Communications (NFC) technology protocol. In such cases, a user may bring a Bluetooth® device into contact or near-contact with another Bluetooth® device to pair the devices without the use of an explicit announcement message phase.

In the situations described above, physical contact or near-contact with a device by way of a user or another device is utilized to initiate a process by which wireless communications are established between devices. In examples

described more fully below, however, wireless communication connections may be facilitated without such interaction.

FIG. 1 is a simplified block diagram of an example electronic device **200** that employs dynamic announcing for creation of wireless communication connections. In this example, the electronic device **200** includes a wireless communication interface **210** that may transmit wireless communication signals to, and/or receive wireless communication signals from, an external device **230**, such as by way of an established wireless communication connection **250**. The wireless communication interface **210** may include wireless signal transmitters, wireless signal receivers, and/or other circuitry for providing functionality. In one example, the wireless signals conform to a wireless communication standard, such as Bluetooth®, Bluetooth® Low Energy (BLE), ZigBee®, IEEE (Institute of Electrical and Electronics Engineers) 802.15.4, MICS (Medical Implant Communications Service), MedRadio (Medical Device Radiocommunications Service), or any other wireless communication standard that employs presence announcing or advertising to enable communication between at least two devices, such as by way of establishing a wireless communication connection between the electronic device **200** and the external device **230**. U.S. Pat. No. 9,288,614 (Young et. al) and U.S. Pub. No. 2015/0065047 (Wu et al.), each of which is incorporated herein by reference in its entirety, describe exemplary systems and methods that may be used in conjunction with the present invention to provide for initiating a bi-directional wireless communication connection **250** between electronic device **200** and external device **230**.

As depicted in FIG. 1, the electronic device **200** may also include a wireless communication interface control module **220** that may provide logic and control functions to operate the wireless communication interface **210** according to the protocols or standards being used to perform the desired wireless communications. For example, the wireless communication interface control module **220** may provide the logic for performing the announcement messages, pairing, bonding, and connection creation of the Bluetooth® standards, as described above. In some examples, the wireless communication interface control module **220** may include dedicated hardware circuitry to perform the desired functions. In other examples, the wireless communication interface control module **220** may include one or more hardware processors, such as microprocessors, microcontrollers, digital signal processors (DSPs), or other algorithmic processors, along with one or more memory devices containing instructions executable by the one or more hardware processors, to perform the functions ascribed to the wireless communication interface control module **220**. In yet other embodiments, the wireless communication interface control module **220** may include some combination of dedicated hardware circuitry and programmable hardware processor components.

Included within the wireless communication interface control module **220** may be an announcement timing control module **222**, which may access one or more factors or parameters that indicate one or more aspects of the environment in which the electronic device **200** operates to determine dynamically when or how often one or more announcing or advertising messages, data packets, or other signals are to be transmitted to facilitate creation of one or more wireless communication connections **250** between the electronic device **200** and the external device **230**.

External device **230** may include a patient activator to enable the user, such as a patient or caregiver, to manually trigger electronic device **200** either to trigger an alert or

trigger recording of EGM storage or other clinical episode, such as an episode of neuropathic pain, palpitations, or syncope.

FIG. 2 is a simplified flow diagram 300 of an example method 300 of operating an electronic device (e.g., the electronic device 200 of FIG. 1) to employ dynamic announcing for creation of wireless communication connections (e.g. the wireless communication connection 250 of FIG. 1). While the method 300 is described below within the context of the announcement timing control module 222 of the wireless communication interface control module 220 of the electronic device 200 of FIG. 1, other circuits or systems may employ the method 300 in other embodiments.

In the method 300, the announcement timing control module 222 may set an initial frequency for transmission of announcement messages, data packets, or other signals (operation 302). In some examples, the frequency may be once every so many seconds or minutes, or may be zero (e.g., no announcement messages) for at least some periods of time. However, in other examples, the announcement timing control module 222 may not set an initial transmission frequency for the announcements.

Thereafter, the announcement timing control module 222 may access one or more factors or parameters that are to influence dynamically the frequency of the announcements (operation 304). Examples of such factors may include, but are not limited to, the current time of day, current and/or past environmental and/or operational conditions in which the electronic device 200 is operating, the current announcement frequency, the current charge level of a battery or other energy source being employed by the electronic device 200 to perform its various functions, and so forth. Other factors, such as those that may be related to the specific operations performed by the electronic device 200, may be utilized in other embodiments. The announcement timing control module 222 may then determine whether a change in the announcement frequency is warranted based on the accessed factors (operation 306). If so, the announcement timing control module 222 sets a new, modified announcement frequency based on the accessed factors (operation 308). Such updating may be performed on a periodic or repetitive basis. The announcement timing control module 222 may then access the one or more factors (operation 304) to determine once again whether a new announcement frequency is warranted (operation 306), continuing in such a manner indefinitely.

While the operations 302-308 of the method 300 of FIG. 2 are illustrated in a particular order of performance, other orders for the operations 302-308, including simultaneous, concurrent, and/or overlapping of multiple operations 302-308 are possible. For example, the accessing of the one or more factors (operation 304) may occur on a more-or-less continual or repetitive basis, while the determining of the announcement frequency based on those factors may occur concurrently, but less often.

Implantable medical devices serving as the electronic device 200 of FIG. 1 will thus be described in conjunction with FIGS. 3A-B and 4A-B, in which the features included in various embodiments described hereafter could be implemented. However, numerous variations of such a device exist in which various circuits and methods discussed below can be implemented.

FIG. 3A illustrates a monitoring device 400, which may be implanted or external to the patient, and may dynamically communicate with an external device 230 using one or more wireless communication connections 250. In certain embodiments, monitoring device 400 is a device capable of

recording heart electrical activity such as an EGM-based monitor. In certain embodiments, monitoring device 400 is a subcutaneous EGM-based monitor, such as an implantable loop recorder (ILR) (e.g., an implantable cardiac monitor (ICM) or a subcutaneous atrial fibrillation (AF) monitor). In certain embodiments, the ILR is subcutaneously (i.e., just under the skin) implanted in the chest of a patient to the left of the breastbone. An ILR may include two or more electrodes attached to the casing or electrically connected to the device and spaced sufficiently far apart that cardiac events are sensed. An ILR that may be used with the invention is, e.g., a SJM Confirm™ Implantable Cardiac Monitor of St. Jude Medical. Examples of ILRs that may be used with the invention are described in U.S. Pat. No. 8,241,221 (Park), U.S. Pat. No. 8,467,884 (Park), and U.S. Pat. No. 7,294,108 (Bornzin et al.), each of which is incorporated herein by reference in its entirety.

An ILR may begin recording heart electrical activity in response to, for example, the ILR detecting electrical activity indicative of a heart-related problem, such as atrial fibrillation (AF), atrial tachycardia, ventricular tachycardia, asystole, syncope, and so on. In other examples, the ILR may begin such recording in response to receiving a signal from a patient-triggered external activator serving as the external device 230. Consequently, ILR operation may benefit from a dynamic increase in the announcement frequency to more quickly create a wireless communication connection 250 between the activator and the ILR to allow the ILR to receive the signal from the activator based on one or more of the factors described herein, such as detection of an elevated heart rate, an arrhythmia, an increased or decreased level of patient physical activity, change in posture, time of day and/or the like. As a result, the connection 250 may be established during times associated with a higher probability of the patient being symptomatic, and thus at times during which the signal from the activator is more likely to be received.

In certain embodiments, monitoring device 400 is also a cardiac stimulation device, such as a subcutaneous implantable cardioverter defibrillator (S-ICD) or a leadless pacemaker. An S-ICD may include multiple subcutaneous extracardiac electrodes (also referred to as remote sensing electrodes) for detecting electrical cardiac signals within the chest of the patient. The subcutaneous extracardiac electrodes are preferably extravascular and can be, e.g., paddle electrodes or coil electrodes mounted subcutaneously outside of the rib cage, but are not limited thereto. Exemplary locations of the subcutaneous extracardiac electrodes include near the bottom of the sternum (slightly to the left), below the left pectoral area, and below the clavicle and on the back left side (just below the shoulder blade). Of course, additional and/or alternative locations for subcutaneous electrodes are within the scope of the present invention.

Examples of S-ICDs that may be used with the invention are described in U.S. Pat. No. 7,970,473 (Nabutovsky, et al.), U.S. Pub. No. 2016/0030757 (Jacobson et al.), and U.S. Pat. No. 9,320,448 (Xi et al.), each of which is incorporated herein by reference in its entirety. Examples of leadless pacemakers that may be used with the invention are described in U.S. Pat. No. 9,278,218 (Karst et al.), U.S. Pat. No. 9,227,077 (Jacobson et al.) and U.S. Pat. No. 8,798,745 (Jacobson et al.), each of which is incorporated herein by reference in its entirety.

In certain embodiments, multiple monitoring devices 400 are used in conjunction with one another. In a system and may communicate through conductive communication, RF, or other wireless communication. In certain embodiments,

one of the monitoring devices **400** of a system of monitoring devices **400** is designated as a master device that gathers and, in some embodiments, processes communications from slave monitoring devices **400** and communicates with an external device **230** using one or more wireless communication connections **250**. For example, a master monitoring devices **400** may be a S-ICD that communicates with a slave monitoring device **400**, such as a leadless pacemaker, through conductive communication, as described in, e.g., U.S. Pub. No. 2016/0030757 (Jacobson et al.), incorporated herein by reference. The S-ICD may communicate with an external device **230** using a Bluetooth® interface or another wireless communication interface implementing some wireless communication protocol or standard.

FIG. 3B illustrates an implantable cardiac stimulation device **100** in electrical communication with a patient's heart **12** by way of three leads **20**, **24**, and **30** suitable for delivering multi-chamber stimulation and/or shock therapy. To sense atrial cardiac signals and to provide right atrial chamber stimulation therapy, the device **100** may be coupled to an implantable right atrial lead **20** including at least one right atrial tip electrode **22** that may be implanted in the patient's right atrial appendage. The right atrial lead **20** may also include a right atrial ring electrode to allow bipolar stimulation or sensing in combination with the atrial tip electrode **22**.

To sense the left atrial and left ventricular cardiac signals and to provide left-chamber stimulation therapy, the stimulation device **100** may be coupled to a "coronary sinus" lead **24** designed for placement in the "coronary sinus region" via the coronary sinus ostium in order to place a distal electrode adjacent to the left ventricle and additional one or more electrodes adjacent to the left atrium. As used herein, the phrase "coronary sinus region" refers to the venous vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible by the coronary sinus.

Accordingly, the coronary sinus lead **24** may be designed to receive atrial and/or ventricular cardiac signals, deliver left ventricular pacing therapy using at least one left ventricular tip electrode **26** for unipolar configurations or in combination with a left ventricular ring electrode for bipolar configurations, and/or deliver left atrial pacing therapy using at least one left atrial ring electrode **27** as well as shocking therapy using at least one left atrial coil electrode **28**.

The stimulation device **100** of FIG. 3B may also be in electrical communication with the patient's heart **12** by way of an implantable right ventricular lead **30** including, in this embodiment, a right ventricular (RV) tip electrode **32**, a right ventricular ring electrode **34**, a right ventricular coil electrode **36**, a superior vena cava (SVC) coil electrode **38**, and/or so on. The right ventricular lead **30** may be inserted transvenously into the heart **12** so as to place the right ventricular tip electrode **32** in the right ventricular apex such that the right ventricular coil electrode **36** is positioned in the right ventricle and the SVC coil electrode **38** will be positioned in the right atrium and/or superior vena cava. Accordingly, the right ventricular lead **30** may be capable of receiving cardiac signals, and delivering stimulation in the form of pacing and shock therapy to the right ventricle.

In certain embodiments, the implantable stimulation device **100** may incorporate one or more optical sensors **3** (also referred to as photoplethysmography (PPG) sensors) integrated with or attached to its housing **40**.

Optical sensors **3** may also be integrated with or attached to a monitoring device **400** (FIG. 3A) implanted in the pectoral region of a patient. In certain embodiments, optical sensor **3** may be used to detect patient interaction (as discussed in detail below). In certain embodiments, optical sensor **3** may be used to determine a person's heart activity, and these measurements may be used in lieu of, or in conjunction with, electrical activity measurements. Changes in the optical signal over time can be used to determine heart activity, even if the position of the optical sensor is far removed from the heart. In some embodiments, the monitoring device **400** may include both an optical sensor and an EGM-based monitor. Optical sensors that may be used with the current disclosure are disclosed in U.S. Pat. No. 8,328,728 (Schechter), U.S. Pat. No. 8,478,403 (Wenzel et al.), and U.S. Pat. No. 9,022,945 (Fayram et al.), each of which is incorporated herein in its entirety. In other embodiments, the monitoring device **400** may include an EGM-based monitor and an impedance measurement circuit. Impedance measurement circuits that may be used with the current disclosure are disclosed in U.S. Pat. No. 8,065,005 (Wong et al.) and U.S. Pat. No. 9,265,436 (Min, et al.), each of which is incorporated herein in its entirety.

The optical sensor, which can be used to obtain a PPG signal, includes a light source and a light detector. The light source **5** can include, e.g., at least one light-emitting diode (LED), laser, incandescent lamp or laser diode, but is not limited thereto. The light detector **7** can include, e.g., at least one photoresistor, photodiode, phototransistor, photodarlington or avalanche photodiode, but is not limited thereto. Light detectors are often also referred to as photodetectors or photocells.

The light source **5** outputs light that is reflected, absorbed and/or scattered by surrounding patient tissue, and reflected/scattered light is received by the light detector **7**. In this manner, changes in reflected light intensity are detected by the light detector **7**, which outputs a signal indicative of the changes in detected light. The output of the light detector **7** can be filtered and amplified. The signal can also be converted to a digital signal using an analog to digital converter, if the PPG signal is to be analyzed in the digital domain. A PPG sensor can use a single wavelength of light, multiple discrete wavelengths, or a broad spectrum of many wavelengths. If multiple wavelengths are used, the timing of the signals may be multiplexed to determine optical response of tissue at different wavelengths. Additional details of exemplary implantable PPG sensors that may be used in accordance with the present disclosure are disclosed in U.S. Pat. Nos. 6,409,675 and 6,491,639, both entitled "Extravascular Hemodynamic Sensor" (both Turcott), which are incorporated herein by reference.

It is generally the output of the photodetector that is used to produce a PPG signal. However, there exist techniques where the output of the photodetector is maintained relatively constant by modulating the drive signal used to drive the light source, in which case the PPG signal is produced using the drive signal, as explained in U.S. Pat. No. 6,731,967, entitled "Methods and Devices for Vascular Plethysmography via Modulation of Source Intensity," (Turcott), which is incorporated herein by reference.

Exemplary details of how to attach a sensor module to an electronic device **200** are described in U.S. Pat. No. 7,653,434, entitled "Autonomous Sensor Modules for Patient Monitoring" (Turcott et al.), which is incorporated herein by reference. It is also possible that the optical sensor **3** be integrally part of the implantable stimulation device **100** or a monitoring device **400**. For example, the optical sensor **3**

can be located within the housing **40** of an electronic device **200** that has a window through which light can be transmitted and detected. In a specific embodiment, the optical sensor **3** has a titanium frame with a light transparent quartz or sapphire window that can be welded into a corresponding slot cut in the housing of the implantable stimulation device **100** or monitoring device **400**. This will insure that the electronic device **200** enclosure with the welded optical sensor will maintain a hermetic condition.

Where the optical sensor is incorporated into or attached to an implanted electronic device, the light source and the light detector can be mounted adjacent to one another on the housing or header of the electronic device, or on the bottom of the device, or at any other location. The light source and the light detector can be placed on the side of an electronic device that, following implantation, faces the chest wall, and are configured such that light cannot pass directly from the source to the detector. The placement on the side of the electronic device that faces the chest wall maximizes the signal to noise ratio by directing the signal toward the highly vascularized musculature, and shielding the source and detector from ambient light that enters the body through the skin. Alternatively, at the risk of increasing susceptibility to ambient light, the light source and the light detector can be placed on the face of the electronic device that faces the skin of the patient. The light source and light detector may be positioned to face each other at a distance apart. Other variations are also possible.

FIG. **4A** is a functional block diagram of selected components of a monitoring device **400**. The particular monitoring device **400** shown in FIG. **4A** is for illustration purposes only, and one of ordinary skill in the pertinent art could readily duplicate, eliminate, or disable the appropriate circuitry in any desired combination to provide an ECG or EGM-based monitor.

Housing **40** (shown schematically) of monitoring device **400** includes a connector having one or more EGM sensor terminals **402** adapted for connection to subcutaneous (SubQ) EGM sensors mounted to (or connected to) the exterior housing of the device. Housing **40** (often referred to as the "can", "case" or "case electrode") can also act as the return (common) electrode, or anode, for any sensing electrodes implanted separately from the device. Only one EGM sensing electrode terminal is shown, but additional terminals can be provided to accommodate additional sensing electrodes or sensing leads.

At the core of monitoring device **400** is a programmable microcontroller **460**, which controls heart activity detection, such as heart rate, morphology, heart rate variability, and arrhythmia, and event detection, such as myocardial infarctions, strokes, cardiac ischemia, and pain (whether due to angina or another underlying condition being monitored and/or treated by the monitoring device **400** or another device in a system). The microcontroller **460** includes a microprocessor, or equivalent control circuitry, designed specifically for detecting heart activity and/or events and may further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. Typically, the microcontroller **460** includes the ability to process or monitor input signals (data) as controlled by a program code stored in a designated block of memory. The details of the design and operation of the microcontroller **460** are not critical to the invention. Rather, any suitable microcontroller **460** may be used that carries out the functions described herein. The use of microprocessor-based control circuits for performing timing and data analysis functions is well known in the art.

A switch bank **74** includes a plurality of switches for switchably connecting the EGM electrodes (assuming there is more than one) to the appropriate I/O circuits, thereby providing complete electrode programmability. A sense amplifier **482** is coupled to the EGM electrodes through switch bank **74** for sensing electrical cardiac activity. Sense amplifier **482** is capable of sensing signals in accordance with otherwise conventional techniques. The switch bank **74** determines the "sensing polarity" of the cardiac signal by selectively closing the appropriate switches, as is also known in the art. In this way, the clinician may program the sensing polarity. Sense amplifier **482** preferably employs a low power, precision amplifier with programmable gain and/or automatic gain control and/or automatic sensitivity control, bandpass filtering, and a threshold detection circuit, known in the art, to selectively sense electrical signals of interest. The automatic gain control, if implemented, enables the monitoring device **400** to deal effectively with the difficult problem of sensing any low frequency, low amplitude signal characteristics. The gain control is actuated by the programmable microcontroller **460**. The gains are controlled on sense amplifier **482** by the microcontroller using control line **486**. The outputs of the sense amplifier are connected to microcontroller **460**.

EGM signals and other sensed signals are also applied to the inputs of an analog to digital (A/D) data acquisition system **490**. The gain of the A/D converter **490** is controlled by the microprocessor **460** by signals along control line **492** in order to match the signal amplitude and/or the resolution to a range appropriate for the function of the A/D converter **490**. The data acquisition system **490** is configured to acquire EGM signals, convert the raw analog data into a digital signal, and store the digital signals for later processing and/or telemetric transmission to an external device **230**. The data acquisition system **490** is coupled to the EGM electrode **402** through switch bank **74** to sample cardiac signals. The microcontroller **460** is further coupled to a memory **494** by a suitable data/address bus **496**, wherein the programmable operating parameters used by the microcontroller **460** are stored and modified, as required, in order to customize the operation of monitoring device **400** to suit the needs of a particular patient. Such operating parameters define, for example, the particular parameters to be used to detect stroke or AF.

EGM-based heart activity detector unit **78** detects cardiac rhythm, including heart rate and heart variability, and cardiac morphology. The disclosure utilizes the sense amplifier **482** to sense electrical signals to determine whether a cardiac rhythm is physiologic or pathologic. As used herein, "sensing" is reserved for the noting of an electrical depolarization, and "detection" is the processing of sequential sensed depolarization signals potentially in conjunction with the sensor input to establish a diagnosis of an arrhythmia. The timing intervals between sensed events (e.g., P-P intervals or R-R intervals) are detected by a timing control unit **79** of microcontroller **460** and then classified by an EGM-based heart activity detector unit **78** by, for example, comparing the intervals to predefined rate zone limits indicative of, e.g., a tachycardia, bradycardia, AF, or asystole episode. Techniques for determining arrhythmias in an implantable device are described, for example, in U.S. Pat. No. 9,295,852 (Williamson), which is incorporated herein by reference. Techniques for measuring and quantifying HRV are described, for example, in U.S. Patent Pub. No. 20110066055 (Bharmi et al.), incorporated herein by reference. HRV is a measure of the variation in heart rate over time. Briefly, in one example described therein, HRV is

assessed based on an analysis of R-R intervals, including various frequency components thereof.

Event detector unit 77 may use the output of heart activity detector unit 78 and/or cardiac signals from an analog to digital (A/D) data acquisition system 490 to detect events, such as myocardial infarctions, cardiac ischemia, strokes, and pain. For example, HRV can be reduced by both stroke and cardiac ischemia. However, reductions in HRV may be more pronounced from stroke than when cardiac ischemia occurs and hence HRV can be used to discriminate stroke from cardiac ischemia, at least within some patients. One possible reason for this difference is that the efferent neural pathways involved in heart rate control are affected by stroke, but not necessarily from a site of cardiac ischemia. For a discussion of the effects of stroke on HRV see, for example, Tokgozoglu et al. "Effects of Stroke Localization on Cardiac Autonomic Balance and Sudden Death" Stroke 1999, 30, 1307-1311, incorporated herein by reference.

U.S. Pat. No. 8,241,221 (Park), incorporated herein by reference in its entirety, describes techniques that may be used in accordance with the present disclosure for detecting stroke within a patient using a subcutaneous monitor based on an analysis of features of an electrogram (EGM) sensed within the patient. Exemplary EGM features indicative of possible stroke include the onset of prominent U-waves, the onset of notched T-waves, and changes in ST segment duration or QT duration or dynamic trends in these parameters. ST segment variations may be caused by abnormalities in the polarizations of cardiac tissue during an acute myocardial infarction. ST segment variations may arise because of differences in the electric potential between cells that have become ischemic and those cells that are still receiving normal blood flow. ST segment variations may be an indication of injury to cardiac muscle, changes in the synchronization of ventricular muscle depolarization, drug or electrolyte influences, or the like.

U.S. Pat. No. 8,469,897 (Toren-Herrinton, et al.), incorporated herein by reference in its entirety, describes techniques that may be used in accordance with the present disclosure for determining the onset and determination of an ischemic or AMI condition based on a ST segment deviation. The cardiac cycle is composed of a P-wave, a Q-wave, an R-wave, an S-wave, and a T-wave. The portion of the signal between the S-wave and T-wave constitutes a ST segment. The ST segment may have a voltage level that aligns with the voltage level of a baseline heart rhythm. Alternatively, the ST segment may have a voltage level that is shifted above or shifted below the baseline. ST segment variations indicate a potential coronary episode. ST segment variations may include ST deviations or ST shifts. A ST deviation is determined by subtracting an average PQ segment (e.g., the isoelectric segment) voltage from the ST segment voltage for a heartbeat. The ST deviation provides a measure of the change in variability over a period of time. A ST shift is determined by changes in the ST deviation over a period of time. For examples a current ST shift may be calculated by subtracting a stored baseline ST deviation from a newly acquired ST deviation. ST deviations and ST shifts may be calculated as averages over multiple cardiac cycles as well.

The discrimination of ischemia related and non-ischemia related shifts in the ST segment may be determined by the event detector 77 by using a statistical determination of the variability of the ST segment shift. For example, a plurality of ST segment shifts may be collected to obtain a ST threshold. Then the ST threshold is used in a comparison with subsequently measured ST segment shifts to identify

the onset of a coronary episode. When the measured ST segment shift is less than a ST threshold, the termination of the coronary episode may be identified. Upon detecting the onset of a coronary episode, either an ischemic event or an AMI event, the cardiac signals are stored in memory 494.

One or more physiologic sensors 108 may be mounted on or within monitoring device 400 or otherwise in communication with monitoring device 400. Event detector unit 77 may base the detection of events on the output of one or physiologic sensors 108. Various physiologic sensors that can be used in conjunction with the current invention are discussed in: U.S. patent application Ser. No. 11/856,443, of Zhao, filed Sep. 17, 2007, entitled "MEMS-Based Left Atrial Pressure Sensor for use with an Implantable Medical Device" and in U.S. patent application Ser. No. 11/623,663, filed Jan. 16, 2007, of Zou et al., entitled "Sensor/Lead Systems for use with Implantable Medical Devices," each of which is incorporated herein by reference in its entirety. Physiological sensors 108 may be one or more motion sensors, acceleration sensors such as an accelerometer, gyroscope, temperature sensors, minute ventilation sensors, posture sensors, impedance sensors, optical sensors, oxygen saturation sensors, and the like. The following patents, each of which is incorporated herein by reference in its entirety, describe exemplary activity sensors that may be used as a physiologic sensor 108: U.S. Pat. No. 6,658,292 to Kroll et al., entitled "Detection of Patient's Position and Activity Status using 3D Accelerometer-Based Position Sensor"; U.S. Pat. No. 6,625,493 (Kroll et al.), entitled "Orientation of Patient's Position Sensor using External Field"; U.S. Pat. No. 6,466,821 (Planca et al.), entitled "AC/DC Multi-Axis Accelerometer for Determining Patient Activity and Body Position"; U.S. Pub. No. 20150265839, entitled "Temperature Sensor for a Leadless Cardiac Pacemaker." An impedance sensor may be used to measure alterations of impedance through the chest cavity to determine changes in breathing. Respiration sensors such as impedance sensors may be used to monitor exertion and shortness of breath, which may be used by event detector unit 77 in conjunction with cardiac signals from A/D 490, as an indicator of a myocardial infarction. In certain embodiments, patient posture data is determined from sensed EGM data, as described in U.S. Pat. No. 7,636,599 (Koh et al.).

One or more interaction sensors 109 (discussed in further detail below) may be mounted on or within monitoring device 400 or otherwise in communication with monitoring device 400, in order to permit a user, such as the patient or a family member, to trigger a wireless communication connection 250 between monitoring device 400 and an external device 230. In certain embodiments, interaction sensors 109 may also be used to trigger activation of EGM storage.

The operating parameters of implantable monitoring device 400 may be non-invasively programmed into the memory 494 through telemetry circuit 424 in telemetric communication with external device 230 or other external device, such as a programmer, transtelephonic transceiver, or a diagnostic system analyzer. The telemetry circuit 424 is activated by the microcontroller 460 by a control signal 406. The telemetry circuit 424 advantageously allows SubQ EGM electrograms and status information relating to the operation of monitoring device 400 (as contained in the microcontroller 460 or memory 494) to be sent to external device 230 through an established communication link 250, and then on to a centralized processing system, where appropriate. The telemetry circuit 424 also allows an implantable monitoring device 400 to include a patient-

triggered activation option for EGM storage. The telemetry circuit **424** permits communication between monitoring device **400** and external physiologic sensor(s) **108** located in other location(s) and/or other devices (e.g., drug pumps or patient worn/carried electronic devices or sensors).

The Implantable monitor additionally includes a battery **110** that provides operating power to all of the circuits shown in FIG. 4A. The battery is capable of operating at low current drains for long periods of time for monitoring. The battery **110** also should have a predictable discharge characteristic so that elective replacement time can be detected.

In accordance with various embodiments disclosed below, the microcontroller **460** may also include a wireless communication control module **220**, which may operate as the wireless communication control module **220** of FIG. 1.

Moreover, the wireless communication control module **220** may include an announcement timing control module **222** serving as the announcement timing control module **222** of FIG. 1. In such examples, the telemetry circuit **424** may be operated as the wireless communication interface **210** of FIG. 1, such as a Bluetooth® interface or another wireless communication interface implementing some wireless communication protocol or standard. In some embodiments, the announcement timing control module **222** may receive information from the subcutaneous sensing circuit **482**, the data acquisition system **490** (e.g., when an arrhythmia occurs), and/or the like, as well as other information available within the monitoring device **400**, either directly or via stored data in the memory **494**, to determine a desired announcement frequency.

In addition to or in conjunction with increasing frequency of announcements, monitoring device **400** may also issue a patient alert when an event or potential event, such as acute myocardial infarction or stroke, is detected. The patient alert may direct external device **230** to call an emergency number, such as 911. The alert may also instruct the patient and/or caregiver to move within the external device's **230** connection range. The alert may also prompt the external device **230** to provide instructions to the user to, e.g., call 911 or their healthcare provider and/or provide a questionnaire (e.g., through an app) to confirm a detected event.

The microcontroller **460**, in one embodiment, may perform the functions of the heart activity detector **78**, event detector **77**, the timing control **79**, the wireless communication control module **220**, and/or other functions described herein by executing instructions stored in the memory **494**. Accordingly, the microcontroller **460** may operate as the heart activity detector **78** for periods of time, the event detector **77** for periods of time, the timing control **79** for other periods of time, and so on. In some examples, the microcontroller **460** may operate as these particular functional blocks in a concurrent or parallel manner.

In certain embodiments, an electronic device **200**, e.g., monitoring device **400** (FIG. 4A) or implantable stimulation device **100** (FIG. 4B), may include a neuromodulation implantable pulse generator (IPG) and a neuro stimulation pulse generator circuit to generate stimulation pulses for a brain or spinal cord nervous system, such as those used for spinal cord stimulation (SCS) or deep brain stimulation (DBS). The stimulation pulses may be delivered by a plurality of electrodes through a neuro output lead. The neuro stimulation pulse generator circuit may be controlled by a microcontroller via appropriate control signals to trigger or generate the stimulation pulses. Examples of EPGs that may be used with the current invention are disclosed in U.S. Pat. No. 9,288,614 and U.S. Pat. No. 8,983,604 (Keel et al.), each of which is incorporated herein

by reference in its entirety. For example, Keel et al. describe a neurostimulation system, which may be an SCS system, having a lead with various electrodes for implant within an epidural space of an upper thoracic region of the patient. The SCS device is equipped to sense both neural electrical signals and far-field cardiac electrical signals and to discriminate therebetween. In one specific example, the SCS device has a cardiac sense amplifier and a separate neural sense amplifier. In an example where a single wideband sense amplifier is instead provided, the SCS device selectively filters a frequency spectrum sensed by the wide-band amplifier to separate cardiac signals from neural signals. Still further, the SCS device may identify and distinguish various cardiac events such as atrial depolarization events (P-waves); ventricular depolarization events (R-waves); and ventricular repolarization events (T-waves) using one or more sensing vectors, i.e. a particular combination of electrodes with which signals are sensed. Different cardiac events can be distinguished based, for example, on signal amplitude, signal slope, signal morphology, sensing vector or sensing electrode spacing. For example, a vector spanning the atria of the heart will more readily sense P-waves; whereas a vector remote from the atria will typically not sense P-waves and so a comparison of far-field signals derived from those different vectors may be used to discriminate P-waves from R-waves. The relative spacing of electrode pairs can also provide a basis for distinguishing R-waves from P-waves, with relatively wider inter-electrode spacing providing signals that emphasize R-waves as opposed to P-waves. That is, the device may be equipped to record or obtain cardiac signals from a different electrode configuration (i.e. "vector") than used for the neural sensing electrode configuration to help distinguish cardiac signals from neural signals. For example, for an Octrode™ lead, the distal electrode to "Can" is a relatively large field vector that picks up the R-wave; whereas the distal to "Ring 8" is a narrower field vector that picks up atrial activity. An Octrode™ lead is a type of linear eight electrode percutaneous lead provided by St Jude Medical™.

An electronic device **200**, including monitoring device **400** and implantable stimulation device **100** and may uses P-waves, R-waves and other features of the cardiac signal to detect heart rate variability (HRV), atrial and ventricular arrhythmias, prolonged QT intervals, ST segment shifts or deviations, ischemia or other cardiac conditions or parameters. Insofar as HRV is concerned, the device may detect: high frequency (HF) components of HRV; low frequency (LF) components of HRV; and very low frequency (VLF) components of HRV, as well as a pNN50 statistical value.

The electronic device **200** device may detect myocardial infarctions based on shifts or deviations in ST segments. An elevation of ST segments may be used as an indicator of potentially life-threatening acute myocardial infarction requiring immediate intervention. An ST segment depression may be used as an indicator that the patient has partially occluded arteries, requiring monitoring and possibly therapeutic interventions, such as medication. The electronic device **200** may detect pain based on a combination of elevated heart rate and patient movement associated with pain.

FIG. 4B illustrates a simplified block diagram of the multi-chamber implantable cardiac stimulation device **100**, which may be capable of treating both fast arrhythmia and slow arrhythmia with stimulation therapy, including cardioversion, defibrillation, and pacing stimulation. The particular multi-chamber device **100** shown in FIG. 4B is for illustration purposes only, and one of ordinary skill in the

pertinent art could readily duplicate, eliminate, or disable the appropriate circuitry in any desired combination to provide a device capable of treating the appropriate one or more chambers with cardioversion, defibrillation, and/or pacing stimulation.

The stimulation device **100** may include a housing **40** which is often referred to as a “can,” “case,” or “case electrode,” and which may be programmably selected to act as the return electrode for all “unipolar” modes. The housing **40** may further be used as a return electrode alone or in combination with one or more of the coil electrodes **28**, **36**, or **38** (FIG. 3B), for defibrillation shocking purposes. The housing **40** may further include a connector having a plurality of terminals **42**, **43**, **44**, **45**, **46**, **48**, **52**, **54**, **56**, and **58** (shown schematically and, for convenience, the names of the electrodes to which they are connected are shown next to corresponding terminals). As such, in order to achieve right atrial sensing and stimulation, the connector may include at least one right atrial tip terminal (A_R TIP) **42** adapted for connection to the atrial tip electrode **22**. The connector may also include a right atrial ring terminal (A_R RING) **43** for connection to the right atrial ring electrode.

To achieve left chamber sensing, pacing, and/or shocking, such a connector may include a left ventricular tip terminal (V_L TIP) **44**, a left ventricular ring terminal (V_L RING) **45**, a left atrial ring terminal (A_L RING) **46**, and a left atrial shocking coil terminal (A_L COIL) **48**, that are adapted for connection to the left ventricular tip electrode **26**, a left ventricular ring electrode (not shown), the left atrial ring electrode **27**, and the left atrial coil electrode **28**, respectively (FIG. 3B).

To support right ventricular sensing, pacing, and/or shocking, the connector may further include a right ventricular tip terminal (V_R TIP) **52**, a right ventricular ring terminal (V_R RING) **54**, a right ventricular shocking coil terminal (R_V COIL) **56**, and an SVC shocking coil terminal (SVC COIL) **58**, which are adapted for connection to the right ventricular (RV) tip electrode **32**, the RV ring electrode **34**, the RV coil electrode **36**, and the SVC coil electrode **38**, respectively.

At the core of the stimulation device **100** is a programmable microcontroller **60** that may control the various modes of stimulation therapy. The microcontroller **60** may include a microprocessor or equivalent control circuitry designed specifically for controlling the delivery of stimulation therapy, and may include random access memory (RAM) and/or read-only memory (ROM), logic and timing circuitry, state machine circuitry, and/or input/output (I/O) circuitry. Further, the microcontroller **60** may have the ability to process or monitor various input signals (data) as controlled by a program code stored in a designated block of memory. Exemplary types of control circuitry that may be used with the invention include the microprocessor-based control system of U.S. Pat. No. 4,940,052 (Mann et al.) and the state-machines of U.S. Pat. No. 4,712,555 (Thomander et al.) and U.S. Pat. No. 4,944,298 (Sholder), each of which is incorporated herein by reference in its entirety.

In the embodiment of FIG. 4B, the stimulation device **100** includes an atrial pulse generator **70** and a ventricular pulse generator **72** that may generate stimulation pulses for delivery by the right atrial lead **20**, the right ventricular lead **30**, and/or the coronary sinus lead **24** via an electrically configurable switch **74**. To provide the stimulation therapy in each of the four chambers of the heart **12**, the atrial pulse generator **70** and the ventricular pulse generator **72** may include, for example, dedicated pulse generators, independent pulse generators, multiplexed pulse generators, and/or

shared pulse generators. The atrial pulse generator **70** and the ventricular pulse generator **72** may be generally controlled by the microcontroller **60** via appropriate control signals **76** and **98**, respectively, to trigger or inhibit the stimulation pulses.

The microcontroller **60** may further include timing control circuitry **79**, which may be used to control timing of the stimulation pulses such as, for example, pacing rate, atrio-ventricular (AV) delay, atrial interchamber (A-A) delay, and/or ventricular interchamber (V-V) delay. Such timing control circuitry **79** may also be used to keep track of the timing of refractory periods, noise detection windows, evoked response windows, alert intervals, marker channel timing, and so on.

The switch **74** may include a plurality of switches for connecting the desired electrodes to the appropriate I/O circuits, thereby providing complete electrode programmability. Accordingly, the switch **74**, in response to a control signal **80** from the microcontroller **60**, may determine the polarity of the stimulation pulses (e.g., unipolar, bipolar, cross-chamber, and the like) by selectively opening and closing the appropriate combination of switches. Atrial sensing circuits **82** and ventricular sensing circuits **84** may also be selectively coupled to the right atrial lead **20**, coronary sinus lead **24**, and the right ventricular lead **30** through the switch **74** for detecting the presence of cardiac activity in each of the four chambers of the heart **12**.

Accordingly, the atrial sensing circuit **82** and the ventricular sensing circuit **84** may include dedicated sense amplifiers, multiplexed amplifiers, and/or shared amplifiers. The switch **74** determines the “sensing polarity” of the cardiac signal by selectively closing the appropriate switches of the switch **74**. In this way, the clinician may program the sensing polarity independent of the stimulation polarity.

Each of the atrial and ventricular sensing circuits **82**, **84** may employ one or more low-power precision amplifiers with programmable gain, automatic gain, and/or sensitivity control, one or more band-pass filters, and/or a threshold detection circuit, to selectively sense the cardiac signal of interest. The automatic sensitivity control may enable the stimulation device **100** to deal effectively with the difficult problem of sensing the low amplitude signal characteristics of atrial or ventricular fibrillation.

The outputs of the atrial sensing circuit **82** and ventricular sensing circuits **84** may be connected to the microcontroller **60** for triggering or inhibiting the atrial and ventricular pulse generators **70** and **72**, respectively, in a demand fashion in response to the absence or presence of cardiac activity, respectively, in the appropriate chambers of the heart **12**. The atrial and ventricular sensing circuits **82** and **84**, in turn, may receive control signals over signal lines **86** and **88** from the microcontroller **60** for controlling the gain, threshold, polarization charge removal circuitry, and the timing of any blocking circuitry coupled to the inputs of the atrial and ventricular sensing circuits **82** and **84**.

For arrhythmia detection, the stimulation device **100** may include a heart activity detector **78** that utilizes the atrial and ventricular sensing circuits **82** and **84** to sense cardiac signals for determining whether a rhythm may be physiologic or pathologic. As used herein, “sensing” generally refers to the process of noting an electrical signal, while “detection” generally refers to the step of confirming the sensed electrical signal as the signal being sought by the detector. As an example, “detection” applies to the detection of both proper rhythms (i.e., “P wave” or “R wave”) as well

as improper dysrhythmias including arrhythmia and bradycardia (e.g., detection of the absence of a proper rhythm).

The timing intervals between sensed events (e.g., P-waves, R-waves, and/or depolarization signals associated with fibrillation which are sometimes referred to as “F-waves” or “Fib-waves”) may then be classified by the heart activity detector **78** by comparing them to a predefined rate zone limit (e.g., bradycardia, normal, low-rate ventricular tachycardia, high-rate ventricular tachycardia, fibrillation rate zones, and so on) and various other characteristics (e.g., sudden onset, stability, morphology, information from one or more physiologic sensors **108**, and so on) to determine the type of remedial therapy required (e.g., bradycardia pacing, anti-tachycardia stimulation, cardioversion shocks, and/or defibrillation shocks, collectively referred to as “tiered therapy”).

Physiologic sensors **108** may be mounted on a lead or mounted on or within stimulation device **100** or otherwise in communication with stimulation device **100**. Various physiologic sensors that can be used in conjunction with the current invention are discussed in: U.S. patent application Ser. No. 11/856,443, of Zhao, filed Sep. 17, 2007, entitled “MEMS-Based Left Atrial Pressure Sensor for use with an Implantable Medical Device” and In U.S. patent application Ser. No. 11/623,663, filed Jan. 16, 2007, of Zou et al., entitled “Sensor/Lead Systems for use with Implantable Medical Devices,” each of which is incorporated herein by reference in its entirety. Physiological sensors **108** may be one or more motion sensors, accelerometers, gyroscopes, temperature sensors, minute ventilation sensors, posture sensors, impedance sensors, optical sensors, oxygen saturation sensors, and the like. The following patents, each of which is incorporated herein by reference in its entirety, describe exemplary activity sensors that can be used to determine patient activity: U.S. Pat. No. 6,658,292 to Kroll et al., entitled “Detection of Patient’s Position and Activity Status using 3D Accelerometer-Based Position Sensor”; U.S. Pat. No. 6,625,493 to Kroll et al., entitled “Orientation of Patient’s Position Sensor using External Field”; U.S. Pat. No. 6,466,821 to Pianca et al., entitled “AC/DC Multi-Axis Accelerometer for Determining Patient Activity and Body Position;” U.S. Pub. No. 20150265839, entitled “Temperature Sensor for a Leadless Cardiac Pacemaker.” An impedance sensor may be used to measure alterations of impedance through the chest cavity to determine changes in breathing. Respiration sensors such as impedance sensors may be used to monitor exertion and shortness of breath, which may be indicative of a myocardial infarction.

One or more interaction sensors **109** (discussed in further detail below) may be mounted on or within stimulation device **100** or otherwise in communication with stimulation device **100**, in order to permit a user, such as the patient or a family member, to trigger a wireless communication connection **250** between stimulation device **100** and an external device **230**. In certain embodiments, interaction sensors **109** may also be used to trigger activation of EGM storage.

Cardiac signals and other sensed signals may also be applied to the inputs of a data acquisition system **90** which is depicted as an analog-to-digital converter (ADC) for simplicity of illustration. EGM signals and other sensed signals are also applied to the inputs of an analog to digital (A/D) data acquisition system **490**. The gain of the ADC converter **90** is controlled by the microprocessor **60** by signals along control line **92** in order to match the signal amplitude and/or the resolution to a range appropriate for the function of the ADC converter **90**. The data acquisition

system **90** may be configured to acquire intracardiac electrogram (EGM) signals, convert the raw analog data into digital signals, and store the digital signals for later processing and/or telemetric transmission (e.g., via wireless signals **250**) to an external device **230** by way of telemetry circuit **424**. Such a data acquisition system **90** may be coupled to the right atrial lead **20**, the coronary sinus lead **24**, and/or the right ventricular lead **30** through the switch **74** to sample the cardiac signals across any pair of desired electrodes.

The microcontroller **60** may further be coupled to a memory **94** by a suitable data/address bus **96**, wherein the programmable operating parameters used by the microcontroller **60** may be stored and modified, as required, so as to customize the operation of the stimulation device **100** to suit the needs of particular patients. Such operating parameters may define, for example, stimulation pulse amplitude, pulse duration, polarity of electrodes, rate, sensitivity, automatic features, arrhythmia detection criteria, and/or the amplitude, shape of waves, and/or vector of each stimulation pulse to be delivered to the patient’s heart **12** within each respective tier of therapy. The telemetry circuit **424** is activated by the microcontroller **60** by a control signal **106**.

The operating parameters of implantable stimulation device **100** may be non-invasively programmed into the memory **94** through telemetry circuit **424** in telemetric communication with external device **230** or other external device, such as a programmer, transtelephonic transceiver, or a diagnostic system analyzer. The telemetry circuit **424** is activated by the microcontroller **60** by a control signal **106**. The telemetry circuit **424** advantageously allows electrograms and status information relating to the operation of stimulation device **100** (as contained in the microcontroller **60** or memory **94**) to be sent to external device **230** through an established communication link **250**, and then on to a centralized processing system, where appropriate. The telemetry circuit **424** also allows a stimulation device **100** to include a patient-triggered activation option for electrogram storage. The telemetry circuit **424** permits communication between stimulation device **100** and external physiologic sensor(s) **108** located in other location(s) and/or other devices (e.g., drug pumps or patient worn/carried electronic devices or sensors).

The stimulation device **100** may additionally include a power source that may be illustrated as a battery **110** for providing operating power to all the circuits of FIG. 4B. For the stimulation device **100** employing shocking therapy, the battery **110** may be capable of operating at low current drains for long periods of time, such as, for example, less than 10 microamps (μA), and may also be capable of providing high-current pulses using shocking circuit **116** controlled by the microcontroller **60** via control signals **118** when the patient requires a shock pulse (e.g., in excess of 2 A at voltages above 2 volts (V) for periods of 10 seconds (s) or more).

In accordance with various embodiments disclosed below, the microcontroller **60** may also include a wireless communication control module **220**, which may operate as the wireless communication control module **220** of FIG. 1.

Moreover, the wireless communication control module **220** may include an announcement timing control module **222** serving as the announcement timing control module **222** of FIG. 1. In such examples, the telemetry circuit **424** may be operated as the wireless communication interface **210** of FIG. 1, such as a Bluetooth® interface or another wireless communication interface implementing some wireless communication protocol or standard. In some embodiments, the announcement timing control module **222** may receive

information from the atrial and ventricular sensing circuits **82**, **84**, the data acquisition system **90** (e.g., when an arrhythmia occurs), and/or the like, as well as other information available within the implantable stimulation device **100**, either directly or via stored data in the memory **94**, to determine a desired announcement frequency.

The microcontroller **60**, in one embodiment, may perform the functions of the event detector **77**, the timing control **79**, the wireless communication control module **220**, and/or other functions described herein by executing instructions stored in the memory **94**. Accordingly, the microcontroller **60** may operate as the event detector **77** for periods of time, the timing control **79** for other periods of time, and so on. In some examples, the microcontroller **60** may operate as these particular functional blocks in a concurrent or parallel manner.

Additional and alternative details of implantable stimulation device **100** can be found in U.S. Pat. No. 5,405,363 (Kroll et al.) and U.S. Pat. No. 5,040,534 (Mann et al.), each of which are incorporated herein by reference in its entirety.

Event detector **77** may detect a preliminary indication of stroke based on an analysis of the output of heart activity detector **78**, e.g., T-waves, U-waves (if present), ST segments, and QT segments, as described in U.S. Pat. No. 8,241,211 (Park), incorporated herein by reference.

U.S. Pat. No. 8,989,852 (Gill, et al.), incorporated herein by reference in its entirety, describes techniques that may be used in accordance with the present disclosure for detecting and distinguishing stroke and cardiac ischemia based on electrocardiac signals. In one example, the device senses atrial and ventricular signals within the patient along a set of unipolar sensing vectors and identifies certain morphological features within the signals such as PR intervals, ST intervals, QT intervals, T-waves, etc. The device detects changes, if any, within the morphological features such as significant shifts in ST interval elevation or an inversion in T-wave shape, which are indicative of stroke or cardiac ischemia. By selectively comparing changes detected along different unipolar sensing vectors, the device distinguishes or discriminates stroke from cardiac ischemia within the patient. The discrimination may be corroborated using various physiological and hemodynamic parameters.

FIG. **5** is a list of example announcement frequency factors **500** that may influence operation of the announcement timing control module **222** of FIGS. **1**, **4A** and **4B**. Examples of the announcement frequency factors **500** may include, but are not limited to, a current time of day **502**, a current detected heart activity **504** (e.g., heart rate, HRV or HRT, morphology, sinus rhythm, tachycardia, bradycardia, atrial fibrillation, ventricular fibrillation, asystole), a heart activity history **506**, a current detected patient body position and/or physical activity level **508**, a patient body position and/or physical activity level history **510**, a current detected event **512** (e.g., myocardial infarction, stroke, cardiac ischemia, angina, neuropathic pain), a diagnostics history **514** (detected by an electronic device **200** or and/or programmed by a user), a current detected interaction status **516**, a current wireless communication connection status **518**, and a current battery charge level **520**. Other factors **500** not listed in FIG. **5** (e.g., body temperature) may be employed, and some factors **500** depicted in FIG. **5** may not be employed when determining an appropriate announcement frequency.

The announcement timing control module **222** advantageously minimizes over-advertising by the electronic device **200** during periods when external device **230** is unlikely trying to connect, while improving the user experience during the connection process by increasing advertising/

announcement frequency at times when a user is likely to initiate such a connection. In addition, announcement timing control module **222** advantageously increases connection speed between the electronic device **200** and external device **230** during critical periods, such as when the patient is experiencing an acute myocardial infarction or stroke, in order to enhance patient safety and clinical outcome.

In an embodiment, the announcement timing control module **222** may base the announcement frequency at least in part on the current time of day **502**. In one example, the electronic device **200** may include a real-time clock from which the current time of day **502** may be determined. In one example, a lower frequency may be used during times when the patient in which the electronic device **200** is implanted is expected to be asleep, such as approximately 10 PM to 6 AM, while a higher frequency may be utilized during times when the patient is expected to be awake. An expected time of sleep (e.g., 10 PM to 6 AM) and an expected time of wakefulness (e.g., 6:01 AM to 9:59 PM) may be programmed parameters entered by a user using an external device **230** and telemetry circuit **424** of electronic device **200**. An expected time of sleep and an expected time of wakefulness may also be “learned” or modified by the electronic device **200**, as discussed in more detail below. The particular times of day and their associated announcement frequencies may be configured by way of the telemetry circuit **424**, or via other means. Also, the time of day **502** may be synchronized with the local time zone based on information received at the electronic device **200**, such as information received via the wireless communication interface **201**, such as telemetry circuit **424**.

In certain embodiments, the announcement timing control module **222** may use current detected body position and/or physical activity level **508**, such as posture, to confirm or corroborate a determination of announcement frequency based on current time of day. For example, a physiological sensor **108**, such as an acceleration sensor, e.g., an accelerometer, may detect a patient’s posture based on the acceleration of electronic device **200**. If the patient is lying down, this may corroborate that a lower frequency may be used based on a current time of day **502** when the patient in which the electronic device **200** is implanted is expected to be asleep. If the patient is, however, not lying down based on, e.g., the accelerometer’s reading, the announcement timing control module **222** may determine that a higher frequency of announcement should be used regardless of the current time of day **502**. In this way posture, and/or other activity level data, may be used in conjunction with time of day in order to decrease the frequency of announcements at times when the patient is likely to be asleep, and thus unlikely to attempt communication with an external device.

In certain embodiments, the announcement timing control module **222** determines an expected time of sleep and an expected time of wakefulness by monitoring a patient over a baseline period of time, e.g., weeks or months, using physiological sensors **108** to log physical activity data with time of day into memory.

In certain embodiments, the announcement timing control module **222** keeps a log of the time of day **502** at which a user attempts to initiate a connection between the electronic device **200** and external device **230**. Announcement timing control module **222** may use the log to determine trend information regarding the time of day that a user typically attempts to initiate such a connection. The announcement frequency may then be adjusted based on the trend data.

In some implementations, the announcement timing control module **222** may base the announcement frequency at

least in part on the current detected heart activity **504** and/or the heart activity history **506**. The announcement frequency control module **222** may interpret heart activity **504** such as a heart rate exceeding some threshold, tachycardia, HRV or HRT less than a threshold, certain morphologies, ST segment shifts less than a ST shift threshold, atrial fibrillation, ventricular fibrillation, and asystole, as conditions warranting increasing the announcement frequency to support faster creation of a wireless communication connection between the implantable stimulation device **100** and/or monitoring device **400** and the external device **230**. In some examples, an abnormally low heart rate, such as one that falls below some threshold (e.g., indicative of Bradycardia, Sick Sinus Syndrome or profound long pauses), may also be considered pathological and/or unstable, prompting the announcement frequency control module **222** to increase the announcement frequency for at least some period of time after initial detection. Oppositely, a relatively normal or stable heart rate may influence the announcement frequency control module **222** to lower the current announcement frequency such as to conserve the electronic device's battery.

In certain embodiments, the announcement frequency may be dependent on duration of the detected heart activity **504**. Announcement frequency may not be altered until the detected heart activity **504** has a duration longer than a threshold and announcement frequency may be increased in increments (in some embodiments, up to a limit) dependent on the duration of the detected heart activity **504** being longer than incrementally longer thresholds. For example, an AF lasting less than 5 minutes may not trigger an increase in announcement frequency. An AF lasting one hour or more may trigger a higher announcement frequency than an AF lasting between 5 minutes and an hour. In certain embodiments, an AF lasting more than an hour will not trigger any further increase in announcement frequency, unless other factors (either detected or programmed) are present.

In certain embodiments, electronic device **200** may tier the seriousness of the detected heart activity **504** and provide different announcement frequencies depending on the relative seriousness, e.g., the mode of advertising for a VF may be very faster (e.g., every 1-10 seconds) than an VT (e.g., every 20-30 seconds) and the mode of advertising for a VT may be faster than an AF (e.g., every 30-40 seconds). The ranking may also be dependent on other factors, such as those detected by physiological sensor **108** that may herald an acute episode or the patient's diagnostic history **514** (which may either be detected by the electronic device **200** or programmed by a user, e.g. prior stroke, myocardial infarction, ischemia, age CHADS2 score, etc.).

In some examples, the electronic device **200** (e.g., monitoring device **400** (FIG. 4A) and/or implantable stimulation device **100** (FIG. 4B)) may store previously sensed heart activities, such as heart rates, heartbeat waveforms, arrhythmias, and the like as heart activity history **506** in memory **494** (FIG. 4A) or **94** (FIG. 4B), and use this data to "learn" or predict times during the day when there is a higher probability of an abnormal heart activity to occur. The electronic device **200** may then increase the announcement frequency to support faster creation of a wireless communication connection between the electronic device **200** and the external device **230** during the periods when there is a higher chance of an abnormal heart activity so that the patient activator (external device **230**) can be used immediately. Conversely, the electronic device **200** may decrease the announcement frequency to support slower creation of a wireless communication connection between the electronic

device **200** and the external device **230** when there is a lower probability of an abnormal heart activity, e.g., to preserve battery function.

In some implementations, the announcement timing control module **222** may base the announcement frequency at least in part on the current detected patient physical activity level **508** and/or the patient physical activity level history **510**. The patient physical activity level **508** (which may include positional data, e.g., prone or standing, blood pressure, and physical exertion data) may be determined by one or more factors sensed via one or more physiological sensors **108**, which may be a motion sensor, accelerometer, gyroscope, temperature sensor, minute ventilation sensor, posture sensor, impedance sensors, optical sensors, oxygen saturation sensors, and the like. The possible presence of exercise-induced arrhythmia and/or other signs of relatively strenuous patient physical activity (e.g., fast walking, jogging, etc.), as indicated via the current detected patient physical activity level **508**, may cause the announcement frequency control module **222** to increase the announcement frequency to support faster creation of a wireless communication connection between the electronic device **200** and the external device **230**. More moderate indications of activity (e.g., slow walking) may lead the announcement control module **222** to determine that the announcement frequency should be relatively slow or moderate to conserve electrical power. Moreover, even lower levels of patient physical activity history (e.g., resting, reclining, sleeping for extended periods of time, and so on) may influence the announcement timing control module **222** to turn off announcements altogether for the time being. (For methods of detecting rest and sleep states using an activity sensor that may be used in accordance with the present disclosure, see U.S. Pat. No. 5,476,483, entitled "System and method for modulating the base rate during sleep for a rate-responsive cardiac pacemaker" (Bornzin et al.) which is hereby incorporated herein by reference.) Ceasing announcements under such circumstances may be seen as an automatic implementation of an "airplane mode" often provided in other wireless communication equipment.

In some embodiments, the electronic device **200** may store previously detected patient physical activity level history **510**, against which the current detected patient physical activity level **508** data may be compared to ascertain whether the current patient physical activity level **508** is relatively high or low for the patient, thus providing some indication to the announcement timing control module **222** as to whether the current announcement frequency should be maintained or altered.

In another example, the announcement timing control module **222** may base the announcement frequency at least in part on a current detected event **512** and/or the diagnostics history **514**. The current detected event **512** may be determined by one or more factors sensed via the subcutaneous sensing circuits **482**, the atrial sensing circuits **82**, the ventricular sensing circuits **84**, one or more physiologic sensors **108**, and/or from the output of the heart activity detector **78**. Upon detection of a life-threatening event, such as an acute myocardial infarction or a stroke, the electronic device **200** increases the announcement frequency via the announcement timing control module **222** in response to such an episode.

In some examples, the external device **230** of FIGS. 1, 3A, 4A, and 4B may be a device that may be manually activated by the patient when the patient believes or feels that a heart-related clinical episode or pain-related episode has occurred. An indication of that activation may then be

transmitted via a wireless communication connection **250** between the external device **230** and the electronic device **200**. In some cases, the creation of a wireless communication connection **250** between the external device **230** and the electronic device **200** may be delayed due to the lack of an announcement message from the electronic device **200**, such as due to a low announcement message frequency. Such a delay may thus cause an associated delay in the indication of patient activation being received at the electronic device **200**. However, if the announcement timing control module **222** dynamically increases the announcement frequency in response to detecting the same clinical episode, generation of the wireless communication connection **250** may occur more quickly, thus reducing the delay in receiving the patient indication from the external device **230**, thereby rendering the indication as a more effective patient confirmation of the clinical episode.

Additionally, the announcement timing control module **222** may access the diagnostics history **514** maintained by the monitoring device **400** and/or implantable stimulation device **100** to anticipate when next to advertise more frequently. The announcement timing control module **222** may compare the current heart activity status with previous detected heart clinical conditions to verify and/or accelerate announcement frequency. The announcement timing control module **222** may also store time of day **502** when a pathological heart activity is detected as part of the diagnostics history **514** in order to determine a trend in the data that may be used by announcement timing control module **222** to modulate advertisement frequency based on time of day.

In another example, the announcement timing control module **222** may base the announcement frequency at least in part on the current detected interaction status **516** of the electronic device **200**. In one example, the electronic device **200** may include an interaction sensor **109** (FIGS. 4A and 4B), such as an accelerometer, that measures instantaneous acceleration of electronic device **200**. In some embodiments, the announcement timing control module **222** may interpret high accelerations of short duration as a physical attempt by the patient or another person (e.g., a physical "tap" of the body near the electronic device **200**) to increase the announcement frequency. In some examples, an increase in the announcement frequency may be initiated only upon the receipt of a predetermined sequence of taps detected via the interaction sensor **109** over some period of time. In other embodiments, the announcement frequency may be decreased by a different tap sequence.

In yet other examples, the physical tapping interaction between the patient or other person and the electronic device **200** may be detected using other sensors or transducers. For example, Interaction sensor **109** may include an impedance monitor that may measure a voltage response to an induced current to determine if the impedance of a particular portion of the patient skin has been altered due to contact of the patient's hand with an area near the electronic device **200**.

In yet another example, interaction sensor **109** may include an audio microphone or other sensor may be employed within the electronic device **200** to detect audible patient taps near the device **200**. In yet another example, the announcement frequency may change based on the physical change of body position, such as from supine to upright.

In yet another embodiment, interaction sensor **109** may include a PPG sensor. For example, the implantable stimulation device **100** may incorporate one or more light sources, such as light-emitting diodes (LEDs) that emit light to a photo-detector. In this example, a change in the amount of light from the LEDs detected at the photo-detector may be

interpreted as a patient tap of an area close to the device **100**. A rhythmic tap will create a fluid shift that causes a rapid change in the optical absorption of the local tissue that is unlikely to occur for any reason other than patient initiation of the device.

In yet another embodiment, interaction sensor **109** may include one or more magnets employed to detect interaction between the patient and the implantable stimulation device **100**.

The announcement timing control module **222** may base the announcement frequency at least in part on the current connection status **518** of the implantable stimulation device **100** in at least some embodiments. For example, if the current connection status **518** indicates that a wireless communication connection **250** is currently coupling the implantable stimulation device **100** with the external device **230**, the announcement timing control module **222** may reduce the announcement frequency, or set the frequency to zero, at least while the wireless communication connection is active. In some embodiments, the announcement timing control module **222** may increase the announcement frequency for some determinable period of time following a disconnection of a wireless communication connection **250** to facilitate reconnection.

In addition, the announcement timing control module **222** may base the announcement frequency at least in part on the current charge level **520** of the battery **110** of the monitoring device **400** or implantable stimulation device **100** in some implementations. For example, relatively or extremely low charge levels of the battery **110** may cause the announcement timing control module **222** to reduce the frequency of the announcement messages, possibly to zero, for at least some period of time to conserve battery charge.

According to some embodiments, the announcement timing control module **222** may take into account a combination of the above factors **500** to determine an appropriate announcement frequency. For example, based on any or all of the heart activity history **506**, the patient physical activity level history **510**, and/or the diagnostics history **514**, the announcement timing control module **222** may determine one or more times during the day that the patient is typically more active, as well as times during the day that the patient is more likely to experience a clinical episode, and increase the announcement frequency during at least some of those times of day, as indicated by the current time of day **502**.

Various physiological parameters, hemodynamic parameters or cardiac rhythm parameters detected by the device can be used to confirm or corroborate the determination of whether the condition is stroke or cardiac ischemia, and also to confirm or corroborate changes in announcement frequency. For example, the heart rate can be monitored. An increase in heart rate is typically associated with stroke but not cardiac ischemia. As another example, heart rate variability (HRV) can be monitored. Reductions in HRV may be more pronounced from stroke than when cardiac ischemia occurs. Other parameters that can be monitored include signals representative of one or more of: blood volume; blood pressure; pre-ejection interval; heart rate turbulence (HRT), evoked response; capture threshold; kidney function; heart rate alternans, stroke volume and contractility. For example, a sudden increase in blood pressure may be due to cardiac ischemia and hence would tend to corroborate a diagnosis of ischemia. Pre-ejection intervals tend to become longer during cardiac ischemia but become shorter during stroke. Capture thresholds tend to increase due to cardiac ischemia, at least in the vicinity of the ischemia. Alternans tends to occur in conjunction with cardiac ischemia but not

stroke. A variety of these parameters can be evaluated and then combined to yield a "score," which is then used to corroborate the determination of stroke vs. cardiac ischemia and may similarly be used by announcement timing control module 122 to corroborate whether announcement frequency should be modified and at what frequency.

Different days of the week, such as Monday through Friday versus Saturday and Sunday, may be distinguished such that the announcement frequency schedule may be different on weekdays versus weekends. For example, the heart activity level history 506, the patient physical activity level history 510, and/or the diagnostics history 514 may indicate that on the weekend the patient (a "weekend warrior") is exercising, which is inducing tachyarrhythmias, but on the weekdays the patient is relatively sedentary, corresponding to periods of normal heart activity. Rather than treating all days equally and producing a weekly average based on time of day, the announcement timing control module 222 may distinguish between days of the week that could benefit from more or less frequent communication.

In other examples, an indication of elevated heart activity level or patient physical activity (e.g., by way of the current detected heart activity 504 and/or the current detected patient physical activity level 508), and/or an indication of an cardiac ischemia, myocardial infarction, stroke, angina, or episode of pain (e.g., via the current detected event 512) may cause the announcement timing control module 222 to increase the announcement frequency, even though the current time of day 502 would otherwise dictate a relatively lower announcement frequency. In some implementations, a physical tap by a patient, as indicated via the current detected interaction status 516, may also cause an increase in the announcement frequency despite a current time of day 502 indicating a lower frequency and a lack of any elevated heart or patient physical activity and an absence of any event, as described above (e.g. when the patient has vasovagal symptoms that are not associated with abnormal cardiac rhythms). Thus, one or more announcement frequency factors 500 may override another one or more of the announcement frequency factors 500, thus implementing a hierarchy among the factors 500.

In another specific example, one or more physiological sensors 108 (shown in FIGS. 4A and 4B) acquires a current detected patient physical activity level 508 over a predetermined period of time (e.g., an hour, four hours, eight hours, a day and the like). For instance, an accelerometer or an activity sensor may be used to sense body movements of the patient. Alternatively, the activity sensor may be a workload sensor or any other type of sensor that senses metabolic changes, such as nutrition and oxygen consumption of the patient. Current detected patient physical activity level 508 data is analyzed to determine whether a state of sustained exercise has been achieved. The state of sustained exercise is declared when the level of activity is greater than a predetermined exercise threshold value (e.g., greater than 130% of at rest level) warranting modulation of announcement frequency. Alternatively, the sustained exercise state may be described when the current detected patient physical activity level 508 is less than the predetermined exercise threshold value, but the activity level remains at an intermediate threshold level for a predetermined length of time (e.g., at 75% of the exercise threshold value for a sustained duration of five minutes, 20 minutes and the like). As a further alternative, the sustained exercise state may be declared when the activity level increases by a large incremental amount in a short period of time. The current detected patient physical activity level 508 may be stored in

memory 94 for later retrieval and processing and/or may be used by announcement timing control unit 222 to trigger an increase in announcement frequency.

Optionally, the current detected patient physical activity level 508 may be compared to an activity level baseline value. The baseline of the activity level data may be determined over a predetermined period of time (e.g., one hour). The activity level data, to determine the baseline, may be collected when the patient is minimally exerting herself. For example, a patient may be walking at a non-exercise pace for the baseline predetermined period of time. The baseline may be an average of multiple values of a patient's activity over multiple predetermined periods of time (e.g., one hour periods measured weekly). Alternatively, the baseline activity may be acquired only once in a longer period of time (e.g., once every six months) while the activity level data is acquired more often.

In an embodiment, as the patient exercises, current detected heart activity 504 data, which includes, e.g., ST segments, arrhythmias, heart rate, etc. is acquired. The current detected heart activity 504 data is collected over a series of cardiac cycles for a predetermined period of time. For instance, the current detected heart activity 504 data may be collected over a ten minute or one hour sample interval. The current detected heart activity 504 data may be a series of intrinsic heartbeats. Alternatively, the current detected heart activity 504 data may be a series of paced heartbeats, which are stimulated by either an atrial pulse generator or a ventricular pulse generator. Further, the current detected heart activity 504 data may be collected before, concurrently with, or after the current detected patient physical activity level 508.

In an embodiment, an ST baseline may be determined based on the ST segment variations in the cardiac data. The ST baseline may be determined by collecting cardiac data when the patient is resting and not moving (e.g., sitting or lying down). The baseline may be based on data collected over a baseline predetermined period of time (e.g., an hour, four hours, a day and the like).

When detected patient physical activity level 508 is above a threshold, microcontroller 460 (FIG. 4A) or 60 (FIG. 4B) may monitor the cardiac data (which may take more battery energy to detect) for, e.g., ST segment variations, such as ST shifts and ST deviations, as described above, and event detector 77 determines a current detected event 512, such as ischemic episodes (e.g., Ischemia, demand ischemia, acute myocardial infarction, stroke, an inconsistent physiology, and the like). Depending on the seriousness of the ischemic episode detected by event detector 77, the frequency of announcements may be increased and/or the patient physical activity level that induced the ischemia may be recorded in memory 94. Alternatively, a detected patient physical activity level that is a running average of activity level data from the time of beginning exercise or from the time of the last ischemic episode may be recorded. Further heart activity and patient physical activity level data may be recorded at the time of the ischemic episode, such as, heart rate, pacing rate, blood pressure, respiratory rate, oxygen consumption, carbon-dioxide production, body motion, and the like that may corroborate the detected event and modulate announcement frequency.

For example, microcontroller 460 or 60 may determine whether the patient abruptly stopped exercising. For example, microcontroller 460 or 60 monitors the physiologic sensor 108 (e.g., accelerometer) for any significant measurement drop over a predetermined window of time (e.g., the measurement drop may be based on a percentage

drop). For instance, the patient may have stopped exercising immediately upon having the ischemic episode because of anginal pain (e.g., a change in body posture immediately following an ischemic episode). In the case where the electronic device **200** is a neurostimulator, the patient may have stopped exercising based upon neurogenic pain, and the device will record these instances as well in order to determine trends, as discussed in further detail below. Alternatively, the patient may indicate an amount of anginal pain (or neurogenic pain) by tapping their body proximate to the electronic device **200** location. Microcontroller **460** or **60** may also monitor for a sudden increase in heart rate or other change in the patient's movement characteristic of acute pain. If the patient stopped exercising after the ischemic episode or there is a similar indication, the event detector **77** may detect pain and increase advertisement frequency in anticipation of the patient triggering connection of the external device with the electronic device.

Microcontroller **460** or **60** may also log whether or not the patient attempted such a connection even in the absence of device detected anginal or neurogenic pain. Also, the external device (e.g., through an app) may prompt the patient to enter the reason why the patient triggered the device (e.g., angina pain, neurogenic pain, palpitations, syncope, etc.) and this information may be programmed into the electronic device **200** and logged with the detected heart activity and/or detected patient physical activity and stored in memory **494** (FIG. 4A) or **94** (FIG. 4B). In this way, electronic device **200** records in memory (e.g., **94** or **494**) that a detected heart activity and/or detected patient physical activity level is accompanied by an event, e.g., that an ST shift is accompanied by anginal pain. Microcontroller **460** or **60** may also log the time of day **502** at which a detected heart activity and/or detected patient physical activity level is accompanied by an event. However, if the patient did not stop exercising during an ischemic episode and there is no other indication of an episode, such as angina, the electronic device **200** records in memory **94** or **494** that the heart activity, e.g., ST shift, is not accompanied by anginal pain or other episode.

The microcontroller **60** and/or **460** may determine current detected patient physical activity level **508** based on the activity level value at the occurrence of the ischemic episode or other event **512**. Alternatively, the current detected patient physical activity level **508** may represent a running average of the activity level when the ischemic episode or other event occurred. Over a predetermined period of time (e.g., several weeks or months), trends may be determined based on the heart activity history **506**, the patient physical activity level history **510**, the time of day **502** at which a detected heart activity and/or detected patient physical activity level is accompanied by an event, diagnostic history **514** and/or history of interaction/connection requests. These trends may indicate heart activities and patient physical activity level that are either likely to trigger an event or prompt a patient to try establish a connection between devices and time of day when events are more likely to occur or a patient is more likely to attempt a connection between devices.

The announcement timing control module **222** may also access configuration data, such as in the memory **94** and/or **494**, that indicates preferences regarding, for example, which announcement frequency factors **500** override other factors **500**, what levels detected by the interaction sensor **109** are to be interpreted as a physical tap by the patient, what levels of patient or heart activity are to be attained

before the announcement frequency is increased, how many different announcement frequencies are to be employed, and so on.

FIG. **6** is a list of example announcement frequency modes **600** or states that the announcement timing control module **222** of FIGS. **1**, **4A**, and/or **4B** may provide based on the announcement frequency factors **500** of FIG. **5**. As shown in this particular example, three separate modes are utilized: a "fast" frequency mode **602**, a "slow" frequency mode **604**, and an "off" mode **606**. In one implementation, the fast frequency mode **602** may result in an announcement message, data packet, or other signal being transmitted via the telemetry circuit **424** once every 30 seconds, and the slow frequency mode **604** may result in an announcement frequency of three minutes. In other embodiments, greater or fewer numbers of announcement frequency modes **600** may be employed, as well as different announcement frequencies for each of the modes **600**. Moreover, some examples may not implement the off mode **606** (during which no announcement messages, data packets, or other signals are transmitted) unless an override mechanism, such as by way of a physical tap by the patient, as described above, is available to initiate the wireless communication connection **250** in the absence of an announcement.

FIG. **7** is an example state diagram **700** of the example announcement frequency modes **600** of FIG. **6**. In an example, the state diagram **700** represents a state machine implemented within the announcement timing control module **222**. In the example of FIG. **7**, the state machine may be a Moore state machine, in which the current announcement frequency is dictated by the current state or mode **602**, **604**, and **606**. In other examples, a Mealy state machine may be implemented, in which the current announcement frequency associated with a specific state or mode **602**, **604**, or **606** may be altered based on values of the announcement frequency factors **500**.

The state diagram **700** includes several state transitions **702**, **704**, **706**, **708**, **710**, and **712** from one of the states **602**, **604**, and **606** to another based on current values of the announcement frequency factors **500**. In other embodiments, one or more of the transitions **702-712** may be omitted. Also, in some embodiments, a transition from the off mode **606** may be to either the slow mode **604** by way of transition **702** or to the fast mode **602** via transition **710**, depending on the current state of one or more of the announcement frequency factors **500**. For example, the occurrence of a clinical episode, as indicated by the current detected event **512**, or the detection of a physical tap via the current detected interaction status **516**, may cause the announcement timing control module **222** to use transition **710** from the off mode **606** to the fast mode **602**, or to use transition **704** from the slow mode **604** to the fast mode **602**, to create a wireless communication connection **250** quickly. Similarly, a transition from the fast mode **602** may be to either the slow mode **604** by way of transition **706** or the off mode **606** via transition **712**.

While the embodiments described in detail above focus on implantable medical devices, other medical electronic devices that are not implantable, such as a "wearable" medical device that may monitor for heart rate, arrhythmia and/or other medical conditions, may serve as the electronic device **200**, and may incorporate any of the aspects of the embodiments discussed above. Moreover, in some examples, the electronic device **200** may not be a medical device, whether implantable or not, but may still incorporate one or more of the aspects of the embodiments described herein.

Those skilled in the art will understand and appreciate that various modifications not explicitly described above may be made to the present disclosure and still remain within the scope of the present invention. Moreover, although the present invention has been described with reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the scope of the present invention.

What is claimed is:

1. An electronic device configured to communicate wirelessly with an external device separate from the electronic device, the electronic device comprising:

a wireless communication interface configured to transmit announcement signals for creating a wireless communication connection with the external device, the announcement signals comprising announcement messages configured to dynamically vary the discovery opportunities of the electronic device by the external device in a manner that will reduce current drain;

a sensor configured to detect a characteristic of an environment external to the electronic device; and

a control circuit comprising an announcement timing control module configured to dynamically control timing of the announcement signals based on the detected characteristic by dynamically setting a frequency at which the announcement messages are repeatedly transmitted based on at least the detected characteristic, the announcement timing control module further configured to dynamically transition the frequency from a first frequency to a second frequency slower than the first frequency.

2. The electronic device of claim 1, the electronic device comprising at least one of an automatic implantable cardioverter defibrillator, an artificial cardiac pacemaker, or an implantable loop recorder, and the detected characteristic comprising an electrical signal produced by a heart of a patient.

3. The electronic device of claim 1, wherein the detected characteristic comprises a signal indicative of a patient's heart activity.

4. The electronic device of claim 1, further comprising a real-time clock configured to provide a current time of day, the announcement timing control module further configured to dynamically set the frequency at which announcement messages are repeatedly transmitted based on both the detected characteristic and the current time of day.

5. The electronic device of claim 4, wherein the sensor is at least one of an accelerometer or a gyroscope.

6. The electronic device of claim 4, wherein the detected characteristic is a signal indicative of an activity level of a human.

7. The electronic device of claim 6, wherein the announcement timing control module is further configured to lower the frequency at which the announcement messages are repeatedly transmitted when the current time of day is an expected time of sleep and the activity level is indicative of a supine posture.

8. An implantable medical device for monitoring physiology of a person, the implantable medical device capable of wirelessly communicating with an external device located external to the person, the implantable medical device comprising:

a wireless communication interface configured to transmit announcement signals for creating a wireless communication connection with the external device;

at least one sensor configured to detect a characteristic of an environment external to the implantable medical device; and

a control circuit comprising an announcement timing control module configured to dynamically control timing of the announcement signals based on at least the detected characteristic, the announcement signals comprising announcement messages configured to dynamically vary the discovery opportunities of the implantable medical device by the external device in a manner that will reduce current drain, the announcement timing control module further configured to dynamically control the timing of the announcement messages by dynamically setting a frequency at which the announcement messages are repeatedly transmitted based on at least the detected characteristic, the announcement timing control module further configured to dynamically set the frequency to at least one of a first frequency, or a second frequency slower than the first frequency.

9. The implantable medical device of claim 8, further comprising a heart activity detector configured to determine a heart activity of the person based on the detected characteristic, wherein the announcement timing control module is configured to dynamically increase or decrease the frequency of the announcement messages based on the heart activity.

10. The implantable medical device of claim 8, the implantable medical device configured to determine a heart rate of the person based on the detected characteristic, wherein the announcement timing control module is configured to increase the frequency of the announcement messages in response to the determined heart rate exceeding a first threshold or falling below a second threshold.

11. The implantable medical device of claim 8, the implantable medical device configured to determine, at least one of:

a body position, or

a physical activity level of the person and whether the physical activity level of the person exceeds a threshold, wherein the announcement timing control module is configured to increase the frequency of the announcement messages in response to, at least one: the determined body position being an upright position, or the determined physical activity level of the person exceeding a threshold.

12. The implantable medical device of claim 8, the implantable medical device configured to determine, at least one of:

a body position, or

a physical activity level of the person, wherein the announcement timing control module is configured to cease transmission of the announcement messages in response to, at least one:

the determined body position, or

the determined physical activity level of the person indicating that the person is sleeping.

13. The implantable medical device of claim 8, wherein: the heart activity detector is further configured to detect an arrhythmia,

the implantable device is configured to determine at least one of a body position or a physical activity level of the person, and

the announcement timing control module is further configured to determine whether the arrhythmia and the, at least one body position or physical activity level of the person indicate an exercise-induced arrhythmia and

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increase the frequency of the announcement messages when the exercise-induced arrhythmia is determined.

14. The implantable medical device of claim 8, further comprising:

a real-time clock configured to provide a current time of day, the announcement timing control module further configured to dynamically set the frequency of the announcement messages based on the current time of day.

15. The implantable medical device of claim 8, further comprising:

a heart activity detector configured to determine a heart activity of the person based on the detected characteristic;

a memory configured to store the heart activity together with the time of day at which the heart activity was detected; and

a microcontroller configured to determine a trend in the time of day at which a pathological heart activity is detected, wherein the announcement timing control module is further configured to dynamically set the frequency of the announcement messages based the trend.

16. The implantable medical device of claim 8, further comprising:

a heart activity detector configured to determine a heart activity of the person and determine whether the heart activity is a pathological heart activity based on the detected characteristic;

an event detector configured to detect a cardiac event;

a memory configured to store at least one of the pathological heart activity or the cardiac event together with the time of day at which at least one of the pathological heart activity or the cardiac event was detected; and

a microcontroller configured to determine a trend in the time of day at which at least one of the pathological heart activity or the cardiac event is detected, wherein the announcement timing control module is further configured to dynamically set the frequency of the announcement messages based on the trend.

17. The implantable medical device of claim 8, further comprising:

a heart activity detector configured to determine a heart activity of the person based on the detected characteristic;

an event detector configured to detect cardiac events;

a memory configured to store at least one of the heart activity or cardiac events when the person triggers the implantable medical device to connect with the external device;

a microcontroller configured to determine a trend in at least one of the heart activity or the cardiac events

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occurring when the person triggers the implantable medical device to connect with the external device, wherein the announcement timing control module is further configured to increase the frequency of the announcement messages when at least one of a current detected heart activity or a current detected cardiac event satisfies the trend.

18. The implantable medical device of claim 8, further comprising:

a sensor configured to detect a level of acceleration imparted upon the implantable medical device, the announcement timing control module further configured to increase the frequency of the announcement messages based on the detected level of acceleration exceeding a threshold.

19. A method for dynamically controlling a frequency of advertising messages transmitted by an electronic device to dynamically vary the discovery opportunities of the electronic device by the external device in a manner that will reduce current drain, the method comprising:

detecting a characteristic of an environment external to the electronic device;

accessing an advertising frequency factor employable to set the frequency of advertising messages, wherein the advertising frequency factor is based on the detected characteristic;

dynamically transitioning the frequency of the advertising messages from a first frequency to a second frequency slower than the first frequency based at least in part on the advertising frequency factor; and

transmitting the advertising messages using at least one of the first or second frequencies.

20. The method of claim 19, the announcement frequency factor comprising a heart rate of a patient.

21. The method of claim 19, the announcement frequency factor comprising at least one of a cardiac or a neurogenic event of a patient.

22. The method of claim 19, the announcement frequency factor comprising at least one of a body position or a physical activity level of a patient.

23. The method of claim 22, further comprising providing a current time of day using a real-time clock, wherein dynamically transitioning the frequency of the advertising messages from the first frequency to the second frequency slower than the first frequency based at least in part on the advertising frequency factor comprises transitioning the frequency of the advertising messages based on the current time of day and the at least one of the body position or the physical activity level of the patient.

* * * * *

专利名称(译)	动态通知创建无线通信连接		
公开(公告)号	US9907486	公开(公告)日	2018-03-06
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[标]申请(专利权)人(译)	标兵		
申请(专利权)人(译)	PACESETTER , INC.		
当前申请(专利权)人(译)	PACESETTER , INC.		
[标]发明人	PFLUGH TIMOTHY QU FUJIAN COPPOLA BENJAMIN KARST EDWARD WEINBERG LISA P		
发明人	PFLUGH, TIMOTHY QU, FUJIAN COPPOLA, BENJAMIN KARST, EDWARD WEINBERG, LISA P.		
IPC分类号	A61B5/07 A61B5/00 A61B5/0255 A61B5/0402 A61B5/11		
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其他公开文献	US20170332942A1		
外部链接	Espacenet USPTO		

摘要(译)

本文公开了示例电子设备，包括但不限于可植入医疗设备，以及采用动态通知来创建无线通信连接的方法。在示例中，电子设备包括无线通信接口，用于发送用于与外部设备建立无线通信连接的通告信号。电子设备还包括：传感器，用于检测电子设备外部的环境的特性；以及控制电路，包括通告定时控制模块，用于基于检测到的特性动态地控制通告信号的定时。

