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(54) Title: IMPLANTABLE MEDICAL DEVICE HAVING A CONTROLLED DIAGNOSTIC FUNCTION

(57) Abstract: Methods and systems for providing an implantable medical device with a controlled diagnostic function adapted to convert from a monitoring mode to a therapeutic mode upon sensing an actionable cardiovascular event are disclosed. A preferred embodiment uses an interactive control module to selectively control a plurality of gated circuits that turn the sensing, therapeutic and communications functions of the device on and off to conserve battery power and extend the life of the device. Some embodiments of a system disclosed herein also can be configured as a component of an Advanced Patient Management System that helps better monitor, predict and manage chronic diseases.

**IMPLANTABLE MEDICAL DEVICE HAVING A CONTROLLED
DIAGNOSTIC FUNCTION**

CARDIAC PACEMAKERS, INC., a United States national and resident, is filing
5 this application as a PCT application designating all countries except US, claiming prior to
US Patent Application No. 10/305,548 filed 26 November 2002.

Technical Field

10 The present device relates generally to implantable cardiovascular medical devices and particularly, but not by way of limitation, to such a device that can diagnose patient health by periodically monitoring patient health and converting from a monitoring mode to a therapeutic mode upon sensing a cardiovascular event.

Background

15 When functioning properly, the human heart maintains its own intrinsic rhythm based on physiologically-generated electrical impulses. It is capable of pumping adequate blood throughout the body's circulatory system. Each complete cycle of drawing blood into the heart and expelling it is referred to as a cardiac cycle.

20 However, some people have abnormal cardiac rhythms, referred to as cardiac arrhythmias. Such arrhythmias result in diminished blood circulation. Arrhythmias can occur in the upper chambers of the heart – the atria, or the lower chambers of the heart – the ventricles. However, ventricular arrhythmias present the most serious health risk as they can lead to rapid death from the lack of circulation. Arrhythmias
25 can be subdivided further into specific conditions of the heart that represent vastly different manifestations of abnormal cardiac rhythm. These conditions are bradycardia, or a slow heartbeat, and tachycardia, or a fast heart beat.

30 One mode of treating a cardiac arrhythmia uses an implantable medical device. Such implantable medical devices include pacemakers, also referred to as pacers, and defibrillators. The traditional use of a pacemaker is to treat a person with bradycardia. In other words, pacemakers help speed up the cardiac cycle of a person whose heart beats too slowly. Pacers accomplish this by delivering timed sequences of low energy electrical stimuli, called pace pulses, to the heart. Such stimuli are delivered via an intravascular lead wire or catheter (referred to as a
35 "lead") having one or more electrodes disposed in or about the heart.

In comparison to a pacemaker, an implanted defibrillator applies a much stronger electrical stimulus to the heart. This is sometimes referred to as a defibrillation countershock, also referred to simply as a “shock.” The shock changes ventricular fibrillation to an organized ventricular rhythm or changes a very rapid 5 and ineffective cardiac rhythm to a slower, more effective rhythm. Defibrillators help treat cardiac disorders that include ventricular fibrillation, ventricular tachycardia, atrial fibrillation, and atrial flutter. These inefficient or too rapid heartbeats reduce the pumping efficiency of the heart and thereby diminish blood circulation. The countershock delivered by the defibrillator interrupts the 10 tachyarrhythmia, allowing the heart to re-establish a normal rhythm for the efficient pumping of blood.

Another mode of treating a cardiac arrhythmia uses drug therapy. Drugs are often effective at restoring normal heart rhythms. Modern implantable medical devices can be configured to release drugs through specialized leads or a pumping 15 device. Steroids are commonly administered in this manner to suppress inflammation of the heart wall. However, with continuing advances in pharmaceutical research, powerful anti-arrhythmic drugs may also be administered through an implantable medical device.

An implantable medical device also can be configured to include an 20 accelerometer. A tiny crystal sensor inside the device detects body movement and signals the device to adjust pacing of the heart up or down according to the wearer’s activity. This technology has been further refined so that modern implantable medical devices can mimic the heart’s natural rhythm even more closely by adjusting the rhythm according to a person’s activity level. Modern implantable 25 medical devices also can separately sense and coordinate the contractility of both the upper (atria) and lower (ventricles) chambers of the heart and serve as dual pacer/defibrillators, drug delivery devices, and as a component of a comprehensive patient management system for predictive management of patients with chronic disease.

30 Modern implantable medical devices are becoming smaller (1/2 the size) and smarter than earlier devices and can last much longer. With the recent introduction of “mode switching,” modern devices can now, for example, recognize an abnormally fast heart rate in the upper chamber of the heart and react by automatically changing the therapy the device delivers. This feature allows the

device to deliver the most appropriate therapy. Modern implantable medical devices also can collect information and store it until the next clinic visit. Some devices also make follow-up easier by storing patient data directly into the memory of the device (such as name, diagnosis, doctor).

5 However, by tasking the implantable medical device to do more, the demands on the device's power supply, typically a lithium-iodine battery, increase, such that the device may need to be replaced more often. In order for an implantable medical device to serve multiple functions without having to be frequently replaced, the battery life, and hence, the useful life of the device, must be extended. This can
10 be accomplished by duty cycling the device's major subsystems. In other words, the device is on and using power only during specific periods to help conserve battery power.

15 Thus, for these and other reasons, there is a need for an implantable medical device that can serve multiple therapeutic purposes for many years without having to replace the device on more than a few occasions, if ever, during the patient's lifetime.

Summary

20 According to one aspect of the invention, there is provided a method and device for the controlled diagnosis and treatment of a cardiovascular event using a convertible implantable medical device with an extendable battery life. A cardiovascular event within the context of the invention comprises an arrhythmic event.

25 The convertible implantable medical device described herein comprises subsystems that perform specific functions. Those functions comprise a sensing function, a therapy function and a communications function. Each function can be selectively controlled by a separate control, or combined control and analysis module that opens and closes gated circuits. Gated circuit S controls an interactive sensing module that activates the sensing function. Gated circuit T controls an interactive therapy module that activates the therapy function, and gated circuit C controls an interactive communications module that activates the communications function. When a gated circuit is closed, it completes an electrical circuit with the power source and the module it controls and activates the function of that module.

In one embodiment, the device is configured to duty cycle from active (on) to inactive (off or dormant) states through the use of gated circuit S. When the control and analysis module closes gated circuit S, the circuit is complete and the sensing module is activated to perform the sensing function. When gated circuit S is 5 open (off), the sensing module is inactive. By way of non-limiting example only, a single duty cycle might be timed by gated circuit S being closed for 10 seconds out of every minute. When gated circuit S is closed, the sensing module monitors and 10 senses cardiovascular function. If the sensing module senses a cardiovascular event requiring intervention, the device converts from monitoring mode to therapeutic mode. Therapy can comprise electrical stimulation or chemotherapy. Duty cycling the device in this manner conserves power without compromising patient health. When the device is dormant, the power demand on the battery is minimal. However, 15 because the dormant state interval is relatively short, a sustained or persistent cardiovascular event that is sensed when the sensing module is activated would likely be diagnosed and treated before it becomes life threatening.

In another embodiment, the control and analysis module controls gated circuits S and T. When gated circuit T is closed (on), the circuit is complete and the therapy module is activated to perform the therapy function. When gated circuit T is open (off), the therapy module is inactive. By way of non-limiting example only, 20 gated circuit S can be permanently closed (on) to permanently activate the sensing module and function. When the sensing module senses an actionable cardiovascular event, gated circuit T switches on the therapy module temporarily. In this embodiment, the device can serve as a defibrillator and post-detection guardian by allowing the device to respond instantly to an acute event like cardiac fibrillation, 25 which is potentially life threatening.

In yet another embodiment, gated circuit S and the sensing module can again be permanently on to sense a cardiovascular event requiring intervention. However, by way of non-limiting example only, when the sensing module senses an actionable cardiovascular event, gated circuit T and the therapy module is activated 30 permanently and is available to provide continuous therapy. In this embodiment, the device can serve as a pacer by allowing the device to provide continuous therapy for a chronic cardiac condition like bradycardia.

In a further embodiment, the device comprises a control and analysis module, a sensing module, a therapy module and a communications module. The

control and analysis module directs the closed and open states of gated circuits S, T and C, which in turn activate the sensing, therapy and communications modules respectively. The selective activation of the modules and their functions through the gated circuits controls the duty cycle of the device. By way of non-limiting example 5 only, when gated circuit S is closed, the sensing module is activated and monitors and senses patient health using predefined cardiovascular parameters. If the sensing module senses a cardiovascular event, it relays that information to the control and analysis module. The control and analysis module analyzes and diagnoses the cardiovascular event to determine if therapeutic intervention is necessary. If so, the 10 control and analysis module closes gated circuit T to activate the therapy module, which delivers an appropriate course of therapy. At any time, the control and analysis module may close gated circuit C, which activates the communications module. The communications module communicates the diagnosed and treated cardiovascular event to the control and analysis module to control further operation 15 of the device and/or to a data accessible patient management system. Such communicated cardiovascular data may be used as data points in post-myocardial infarction randomized controlled trials (RCTs).

In a preferred embodiment of the convertible, implantable medical device, the device has diagnostic and therapeutic functions and is powered by a battery 20 adapted to power operation of the device for at least 7 years. Lithium-based batteries may be employed to satisfy the embodiment wherein the device is powered for at least 7 years. As implantable medical device battery technology develops, batteries comprising other than lithium may be employed to satisfy the embodiment wherein the device is powered for at least 7 years. The device also comprises an 25 interactive control and analysis module adapted to analyze and diagnose an arrhythmic cardiovascular event and selectively control a plurality of gated circuits S, T and C that turn the functions of the device on and off by closing and opening the gated circuits. By selectively closing and opening the gated circuits, the operation of the device can be duty cycled between active, partially active or 30 inactive states to conserve power. When duty cycled in this manner, the device is adapted to monitor and assess patient health within ranges of nominal to maximal vigilance. In this embodiment, the interactive control and analysis module, which is always active, is coupled to the interactive sensing module that is adapted to sense an arrhythmic cardiovascular event. The interactive control and analysis module

also is coupled to the interactive therapy module adapted to deliver an appropriate course of therapy. Therapy can be in the form of electrical stimuli or chemotherapy or a combination of both. The interactive control and analysis module is further coupled to the interactive communications module that communicates data reflecting 5 the sensed, analyzed and diagnosed arrhythmic cardiovascular event and delivered therapy to control further operation of the device. The interactive communications module also may communicate data reflecting a record of the diagnosed and treated cardiovascular event to an externally accessible patient management system. In the preferred embodiment, the device offers the most flexibility in controlling the 10 diagnosis and treatment of a cardiovascular event in a prophylactic manner while simultaneously conserving battery power.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. Those skilled in the art will readily recognize various modifications and changes that may be made to 15 the present invention without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present invention, which is set forth in the following claims.

Brief Description of the Drawings

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In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not 25 by way of limitation, various embodiments discussed in the present document.

Figure 1 is a schematic/block diagram illustrating generally, among other things, the modular subsystems of the convertible, implantable cardiovascular medical device with a controlled diagnostic function of the present invention.

Figure 2 is a schematic/block diagram illustrating generally, among other 30 things, another embodiment of the modular subsystems of the convertible, implantable cardiovascular medical device with a controlled diagnostic function of the present invention.

Figure 3 is a schematic/block diagram illustrating generally, among other things, another embodiment of the convertible, implantable cardiovascular medical device with a controlled diagnostic function of the present invention.

Figure 4 is a state diagram illustrating generally, among other things, the 5 functions and activation sequences of the subsystems of the convertible, implantable cardiovascular medical device with a controlled diagnostic function of the present invention.

Figure 5 is a schematic/block diagram illustrating generally, among other things, another embodiment of the convertible, implantable cardiovascular medical 10 device with a controlled diagnostic function of the present invention.

Detailed Description

In the following detailed description, reference is made to the accompanying 15 drawings that form a part hereof, and in which are shown by way of illustration specific embodiments or examples. These embodiments may be combined, other embodiments may be utilized, and structural, logical, and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and 20 the scope of the present invention is defined by the appended claims and their equivalents.

The present method and device are described with respect to an implantable cardiovascular medical device that is adapted to periodically monitor patient health and convert from monitoring mode to therapeutic mode upon sensing a 25 cardiovascular event requiring medical intervention. In this way, the device's diagnostic function is controlled and the therapy it provides is initially prophylactic. The periodicity of monitoring and/or providing therapy is referred to as a duty cycle. The term "duty cycle" or "duty cycling" refers to the process of configuring the device to successively cycle from active (on) to inactive (off or dormant) states as a 30 way to effectively monitor patient health while simultaneously conserving battery power. The convertible, implantable medical device also can be integrated with an "Advanced Patient Management" system. The term "patient management" refers to the process of creating and collecting patient specific information, storing and collating the information, and generating actionable recommendations to enable the

predictive management of patients with chronic disease. The terms "gated" or "gated circuit" refer to the process of gating an electrical circuit so said circuit can be selectively powered.

Figure 1 is a schematic/block diagram illustrating generally the modular subsystems of a convertible, implantable medical device **100** having controlled diagnostic, therapeutic and communications functions. The device **100** is powered by a battery power source **101** adapted to power operation of the device for at least 7 years. In one embodiment, such a battery power source **101** may comprise a lithium-based battery. Those of skill in the art appreciate that other types of long-lasting batteries may be used to satisfy an embodiment of the device.

As further shown in Figure 1, the device also comprises an interactive control and analysis module **102** adapted to analyze and diagnose an arrhythmic cardiovascular event. The arrhythmic cardiovascular event can be a bradycardic or tachycardic event and can be localized in either the atria or the ventricles or both. The interactive control and analysis module **102** also controls a plurality of duty cycles that successively turn the functions of the device on and off. The duty cycles can be triggered by fixed or variable parameters.

In one embodiment, as generally illustrated in Figure 1, a fixed duty cycle can be set by timing gated circuit **S 103** to continuously cycle from active to inactive states in intervals less than 60 minutes. By way of non-limiting example only, gated circuit **S 103** may be closed for an interval of 5 seconds out of every minute – 5 seconds being roughly the time it takes for a human heart to complete 5 cardiac cycles. By way of further non-limiting example only, gated circuit **S 103** also may be timed to duty cycle to the off state for no more than 30 seconds. When gated circuit **S 103** is active, it activates sensing module **103a** to sense a cardiovascular event. If sensing module **103a** detects a cardiovascular event requiring intervention, sensing module **103a** communicates with the interactive control and analysis module **102**, which in turn closes gated circuit **T 104** to activate therapy module **104a** to deliver an appropriate course of therapy. At any time, the interactive control and analysis module **102** may close gated circuit **C 105** to activate communications module **105a** to communicate the sensed and analyzed cardiovascular event and delivered therapy data to the interactive control and analysis module **102** or an external system. By duty cycling the device in this manner, the battery life of the device is greatly conserved and can be predicted more accurately. This minimizes

the number of times the device needs to be replaced, if any, during the lifetime of the patient.

In another embodiment, as again generally illustrated in Figure 1, gated circuit **S 103** can be configured to continuously cycle from active to inactive states 5 based on a number of cardiac cycles. By way of non-limiting example only, the number of cardiac cycles that gated circuit **S 103** is closed, thereby activating sensing module **103a**, can be 3 cardiac cycles. In an alternative variation of this embodiment, gated circuit **S 103** is closed for a physiologically or technologically appropriate time interval. A technologically appropriate time may be the time it 10 takes the control and analysis module **102** or other analytical component to analyze and recognize a cardiovascular event requiring therapeutic intervention. Again, when gated circuit **S 103** is closed, it activates sensing module **103a**, which upon sensing a cardiovascular event requiring intervention, relays that information to the interactive control and analysis module **102**, which in turn activates therapy module 15 **104a** by closing gated circuit **T 104**. As always, the interactive control and analysis module **102** may activate the communications module **105a** by closing gated circuit **C 105**.

In yet another embodiment generally illustrated in Figure 1, a variable duty cycle of the therapeutic function might be accomplished by selectively controlling 20 gated circuits **S 103** and **T 104**. In this embodiment, gated circuit **S 103** is always closed to permanently activate sensing module **103a** for detection of a cardiovascular event. If sensing module **103a** senses a cardiovascular event requiring intervention, it relays that information to the control and analysis module 25 **102**, which in turn closes gated circuit **T 104** to activate therapy module **104a**. In this embodiment, gated circuit **T 104** and therapy module **104a** can be activated temporarily or permanently.

When gated circuit **T 104** is temporarily closed, it temporarily activates 30 therapy module **104a**. Therapy module **104a** is available to deliver appropriate therapy should sensing module **103** detect another cardiovascular event requiring intervention. In this embodiment, the implantable medical device can serve as a defibrillator and a post-detection guardian against a subsequent, but temporally proximate cardiovascular event.

When gated circuit **T 104** permanently activates therapy module **104a**, therapy module **104a** provides continuous therapy. In this embodiment, the implantable

medical device can serve as a pacer for treatment of post-implant heart block development or other chronic ailments requiring constant pacing of the heart. In either the temporary or permanent activation of therapy module 104a, the interactive control and analysis module 102 may activate the communications module 105a by 5 closing gated circuit C 105.

Figure 2 is a schematic/block diagram illustrating generally, among other things, another embodiment of the modular subsystems of a convertible, implantable medical device 100 having controlled diagnostic, therapeutic and communications functions. In this embodiment, which in most functional respects is identical to 10 Figure 1, the sensing module 103a not only performs the sensing function, but also the analysis function.

Figure 3 is a schematic/block diagram illustrating generally an embodiment of a convertible, implantable medical device 100 having controlled diagnostic and therapeutic functions implanted within a patient 200. The device 100 is powered by 15 a long-lasting battery power source 101 adapted to power operation of the device for at least 7 years. The implantable medical device 100 is adapted to electronically communicate 203 a record of a diagnosed cardiovascular event and delivered therapy to an external device like an Advanced Patient Management system 201 that is accessible by the patient 200 and/or a physician or other clinician 202. Those of 20 skill in the art appreciate that electronic communication with the APM may be accomplished by the use of various wired or wireless technologies.

Figure 4 is a state diagram illustrating generally, among other things, the functions and activation sequences of the subsystems of the convertible, implantable medical device 100 comprising a control and analysis function 102, a sensing function 103a, a therapeutic function 104a and a communications function 105a. The modules are coupled in such a manner that the specific functions of the modules can be selectively duty cycled to a variety of active and inactive states. The control and analysis module 102 controls the duty cycles and functions of the modules by 25 selectively closing gated circuits S 103, T 104 and C 105 as shown in Figure 1. 30 Gated circuit S 103 activates the sensing module 103a, which performs the sensing function. Gated circuit T 104 activates the therapy module 104a, which performs the function of delivering therapy. Gated circuit C 105 activates the communications module 105a, which performs the communications function. In an embodiment shown in Figure 3, when gated circuit S 103 is closed, the sensing

module **103a** monitors and senses patient health using predefined cardiovascular parameters. Those parameters can be indexed against standard population data or customized according to a patient's **200** unique health profile. If the sensing module **103a** senses a cardiovascular event, the control and analysis module **102** analyzes 5 and diagnoses the event to determine if therapeutic intervention is necessary. If so, the device converts to therapeutic mode, and the control and analysis module activates the therapy module **104a** for delivery of an appropriate course of therapy in the form of electrical stimulation or chemotherapy. At any or all times, the control and analysis module **102** may activate the communications module **105a** to 10 interactively communicate the diagnosed cardiovascular event and delivered therapy data to the control and analysis module **102**, which combines data received from the communications module to control further operation of the device. The control and analysis module **102** or communications module **105a** may also electronically communicate **203** the diagnosed cardiovascular event and delivered therapy to an 15 external device like an Advanced Patient Management (APM) system **201** accessible by the patient **200** and/or the physician **202**. In this embodiment, the device offers the most flexibility as both a duty cycled device and a device that can prophylactically treat a specific cardiovascular problem upon demand while simultaneously conserving power to extend the device's battery **101** life. By 20 maximizing the duty cycling of the entire device or a specific function of the device, the battery **101** life can be extended to at least 7 years without having to replace the device. Thus, a patient **200** may have to go through the implantation procedure only once during a lifetime.

Figure **5** is a schematic/block diagram illustrating generally another 25 embodiment of the convertible, implantable medical device **100** as a component of an APM system **201**. APM is a system that helps patients, their physicians and their families to better monitor, predict and manage chronic diseases. APM is particularly useful in maintaining long-term data continuity and combining information from medical devices, including the device with a controlled diagnostic function disclosed 30 herein, with patient information from other medical databases. In the embodiment shown in Figure **4**, the APM system **201** consists of three primary components: 1) a convertible, implantable medical device **100** including a sensing module **103a** adapted to monitor physiological functions, 2) a data management module **400** comprising a medical practice database, general practice data, patient data, and

patient population data, that processes the data collected from the sensing module, and 3) analyzers 401 that analyzes data from the data management module 400. APM is designed to support physicians and other clinicians in using a variety of different devices, patient-specific and non-specific data, along with medication 5 therapy, to provide the best possible care to patients.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. The above-described embodiments may be used in combination with each other. Those skilled in the art will readily recognize various modifications and changes that may be made 10 to the present invention without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present invention, which is set forth in the following claims and their equivalents. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and 15 "wherein."

What is claimed is:

1. A method for diagnosing a cardiovascular event and delivering therapy using a convertible implantable medical device, comprising the steps of:
 - 5 a. powering operation of the convertible medical device;
 - b. controlling a plurality of successive duty cycles of the implantable medical device to sense or treat or communicate a cardiovascular event;
 - c. sensing a cardiovascular event;
 - d. analyzing the sensed cardiovascular event;
 - e. diagnosing the analyzed cardiovascular event to deliver an appropriate course of therapy;
 - f. delivering the appropriate course of therapy; and
 - 10 g. communicating patient health data reflected by the sensed, analyzed and diagnosed cardiovascular event and delivered therapy to allow interactive communication with the convertible medical device.
- 15 2. The method of claim 1, wherein the step of powering operation of the convertible implantable medical device comprises the further step of powering the device with a battery.
- 20 3. The method of claim 2, wherein the step of powering operation of the convertible implantable medical device with a battery further comprises powering the device for at least 7 years.
- 25 4. The method of claim 2, wherein the step of powering operation of the convertible implantable medical device comprises the further step of powering the device with a battery comprising lithium.
- 30 5. The method of claim 4, wherein the step of powering operation of the convertible implantable medical device with a battery comprising lithium comprises the further step of powering the device for at least 7 years.

6. The method of claim 1, wherein the method comprises the further step of converting the convertible implantable medical device from a monitoring and communication mode to an intervention mode upon sensing a cardiovascular event requiring therapeutic intervention.

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7. The method of claim 6, wherein the method comprises the further step of communicating patient health to a control and analysis module.

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8. The method of claim 6, wherein the method comprises the further step of communicating patient health to a control module.

9. The method of claim 6, wherein the method comprises the further step of communicating patient health to a patient management system.

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10. The method of claim 1, wherein the step of controlling a plurality of successive duty cycles comprises the further step of selectively controlling gated circuits.

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11. The method of claim 10, wherein the step of selectively controlling gated circuits comprises the further step of controlling gated circuits S, T and C to open and closed states.

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12. The method of claim 11, wherein the step of selectively controlling gated circuits S, T and C to open and closed states comprises the further step of opening and closing gated circuits S, T and C in any combination of open and closed states relative to each other.

30

13. The method of claim 11, wherein the step of selectively controlling gated circuit S comprises the further step of closing gated circuit S to activate a sensing module to sense a cardiovascular event.

14. The method of claim 13, wherein the step of selectively controlling gated circuit T comprises the further step of closing gated circuit T to activate a therapy module to deliver therapy.

15. The method of claim 14, wherein the step of delivering therapy comprises the further step of delivering an electrical stimulus.
- 5 16. The method of claim 14, wherein the step of delivering therapy comprises the further step of delivering a chemotherapeutic agent.
- 10 17. The method of claim 13, wherein the step of selectively controlling gated circuit C comprises the further step of closing gated circuit C to activate a communications module to communicate the sensed cardiovascular event.
18. The method of claim 14, wherein the step of selectively controlling gated circuit C comprises the further step of closing gated circuit C to activate a communications module to communicate the delivered therapy.
- 15 19. The method of claim 11, wherein the step of selectively controlling gated circuit S comprises the further step of duty cycling gated circuit S to a closed state to activate the sensing module to sense a cardiovascular event and to an open state to deactivate the sensing module to conserve power if no cardiovascular event is sensed.
- 20 20. The method of claim 13, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a number of cardiac cycles.
- 25 21. The method of claim 20, wherein the step of gated circuit S being closed for a number of cardiac cycles comprises the further step of gated circuit S being closed for 1 cardiac cycle.
- 30 22. The method of claim 13, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a physiologically appropriate time interval.

23. The method of claim 13, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a technologically appropriate time interval.

5 24. The method of claim 11, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit S is closed, then gated circuit T is closed temporarily.

10 25. The method of claim 13, wherein the step of selectively controlling gated circuit S comprises the further step of when gated circuit S is closed, then gated circuit T is closed temporarily.

15 26. The method of claim 11, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit S is closed, then gated circuit T is closed permanently.

20 27. The method of claim 13, wherein the step of selectively controlling gated circuit S comprises the further step of when gated circuit S is closed, then gated circuit T is closed permanently.

25 28. The method of claim 19, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

30 29. The method of claim 20, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

30 30. The method of claim 21, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

31. The method of claim 22, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
- 5 32. The method of claim 23, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
- 10 33. The method of claim 24, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
- 15 34. The method of claim 25, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
35. The method of claim 26, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
- 20 36. The method of claim 27, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.
- 25 37. The method of claim 19, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.
- 30 38. The method of claim 20, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

39. The method of claim 21, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

5 40. The method of claim 22, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

10 41. The method of claim 23, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

15 42. The method of claim 24, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

43. The method of claim 25, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

20 44. The method of claim 26, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

25 45. The method of claim 27, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

30 46. The method of claim 1, wherein the step of controlling the plurality of duty cycles of the implantable medical device comprises the further step of timing a duty cycle for a time interval of less than 60 minutes.

47. The method of claim 46, wherein the step of timing the duty cycle comprises the further step of timing the duty cycle for a time interval of not more than 2 minutes.

5 48. The method of claim 47, wherein the step of timing the duty cycle comprises the further step of timing the duty cycle for a time interval of not less than 10 seconds.

10 49. The method of claim 11, wherein the step of selectively controlling gated circuit S comprises the further step of closing gated circuit S to activate a sensing module to sense and analyze a cardiovascular event.

15 50. The method of claim 49, wherein the step of selectively controlling gated circuit T comprises the further step of closing gated circuit T to activate a therapy module to deliver therapy.

51. The method of claim 50, wherein the step of delivering therapy comprises the further step of delivering an electrical stimulus.

20 52. The method of claim 50, wherein the step of delivering therapy comprises the further step of delivering a chemotherapeutic agent.

25 53. The method of claim 49, wherein the step of selectively controlling gated circuit C comprises the further step of closing gated circuit C to activate a communications module to communicate the sensed and analyzed cardiovascular event.

30 54. The method of claim 49, wherein the step of selectively controlling gated circuit C comprises the further step of closing gated circuit C to activate a communications module to communicate the delivered therapy.

55. The method of claim 11, wherein the step of selectively controlling gated circuit S comprises the further step of duty cycling gated circuit S to a closed state to activate the sensing module to sense a cardiovascular event and to an

open state to deactivate the sensing module to conserve power if no cardiovascular event is sensed.

5 56. The method of claim 49, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a number of cardiac cycles.

10 57. The method of claim 56, wherein the step of gated circuit S being closed for a number of cardiac cycles comprises the further step of gated circuit S being closed for 1 cardiac cycle.

15 58. The method of claim 49, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a physiologically appropriate time interval.

59. The method of claim 49, wherein the step of selectively controlling gated circuit S to the closed state comprises the further step of gated circuit S being closed for a technologically appropriate time interval.

20 60. The method of claim 49, wherein the step of selectively controlling gated circuit S comprises the further step of when gated circuit S is closed, then gated circuit T is closed temporarily.

25 61. The method of claim 49, wherein the step of selectively controlling gated circuit S comprises the further step of when gated circuit S is closed, then gated circuit T is closed permanently.

30 62. The method of claim 55, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

63. The method of claim 56, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

64. The method of claim 57, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

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65. The method of claim 58, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

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66. The method of claim 59, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

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67. The method of claim 60, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

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68. The method of claim 61, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed temporarily.

69. The method of claim 55, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

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70. The method of claim 56, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

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71. The method of claim 57, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

72. The method of claim 58, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

5 73. The method of claim 59, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

10 74. The method of claim 60, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

15 75. The method of claim 61, wherein the step of selectively controlling the gated circuits comprises the further step of when gated circuit T is closed, then gated circuit C is closed permanently.

20 76. The method of claim 1, wherein the step of controlling the plurality of duty cycles of the implantable medical device comprises the further step of timing a duty cycle for a time interval of less than 60 minutes.

77. The method of claim 76, wherein the step of timing the duty cycle comprises the further step of timing the duty cycle for a time interval of not more than 2 minutes.

25 78. The method of claim 77, wherein the step of timing the duty cycle comprises the further step of timing the duty cycle for a time interval of not less than 10 seconds.

30 79. The method of claim 1, wherein the step of sensing the cardiovascular event comprises the further step of sensing an arrhythmic event.

80. The method of claim 79, wherein the step of sensing the arrhythmic event comprises the further step of sensing a bradycardia event.

81. The method of claim 79, wherein the step of sensing the arrhythmic event comprises the further step of sensing a tachycardia event.
82. The method of claim 79, wherein the step of sensing the arrhythmic event comprises the further step of sensing a fibrillation event.
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83. The method of claim 1, wherein the step of analyzing the sensed cardiovascular event comprises the further step of using a pacemaker configured to analyze the cardiovascular event.
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84. The method of claim 1, wherein the step of diagnosing the analyzed cardiovascular event to deliver an appropriate course of therapy comprises the further step of using a pacemaker configured to diagnose the cardiovascular event.
15
85. The method of claim 1, wherein the step of delivering the appropriate course of therapy comprises the further step of using a pacemaker to deliver the therapy.
20
86. The method of claim 1, wherein the step of delivering therapy comprises the further step of delivering an electrical stimulus.
25
87. The method of claim 1, wherein the step of delivering therapy comprises the further step of delivering a chemotherapeutic agent.
30
88. The method of claim 1, wherein the step of communicating data reflecting the cardiovascular event and delivered therapy comprises the further step of communicating the cardiovascular event and delivered therapy data to a control and analysis module to control further operation of the device.
89. The method of claim 1, wherein the step of communicating data reflecting the cardiovascular event and delivered therapy comprises the further step of communicating the cardiovascular event and delivered therapy data to a control module to control further operation of the device.

90. The method of claim 1, wherein the step of communicating data reflecting the cardiovascular event and delivered therapy comprises the further step of communicating the cardiovascular event and delivered therapy data to an externally accessible patient management system.

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91. The method of claim 1, wherein the step of communicating data reflecting the cardiovascular event and delivered therapy comprises the further step of communicating the cardiovascular event and delivered therapy data for the purposes of a post-myocardial infarction randomized controlled trial.

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92. A method for diagnosing a cardiovascular event and delivering therapy using a convertible implantable medical device, comprising the steps of:

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- a. powering the device using a lithium iodine battery;
- b. controlling a plurality of successive duty cycles of the implantable medical device to sense a cardiovascular event using selectively controlled gates S, T and C selectively switched to open and closed states;
- c. sensing an arrhythmic cardiovascular event;
- d. analyzing the sensed arrhythmic cardiovascular event;
- e. diagnosing the analyzed arrhythmic cardiovascular event to deliver an appropriate course of prophylactic therapy;
- f. delivering the appropriate course of prophylactic therapy using an electrical stimulus; and
- 20
- g. communicating data reflecting the sensed, analyzed and diagnosed arrhythmic cardiovascular event and delivered electrical stimulus therapy to control further operation of the convertible implantable medical device.

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93. The method of claim 92, wherein the step of communicating data reflecting the sensed, analyzed and diagnosed arrhythmic cardiovascular event and delivered electrical stimulus therapy comprises the further step of communicating the cardiovascular event and delivered therapy data to an externally accessible patient management system.

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94. The method of claim 92, wherein the step of communicating data reflecting the sensed, analyzed and diagnosed arrhythmic cardiovascular event and delivered electrical stimulus therapy comprises the further step of 5 communicating the cardiovascular event and delivered therapy data for the purposes of a post-myocardial infarction randomized controlled trial.

95. The method of claim 92, wherein the step of selectively controlling gated 10 circuits S, T and C by switching circuits S, T and C to open and closed states comprises the further step of switching gated circuits S, T and C to any combination of open and closed states relative to each other.

96. A convertible implantable medical device having diagnostic and therapeutic functions comprising:

- 15 a. an interactive control module adapted to selectively control a plurality of duty cycles that successively turn the functions of the device on and off through the use of gated circuits;
- b. an interactive sensing module coupled to the interactive control module to sense a cardiovascular event;
- c. an interactive analysis module integrated with the interactive control module to analyze and diagnose a cardiovascular event sensed by the interactive sensing module;
- d. an interactive therapeutic module coupled to the interactive control module to deliver an appropriate course of therapy; and
- e. an interactive communications module coupled to the interactive control module to communicate patient health data reflected by the sensed, analyzed and diagnosed cardiovascular event and delivered therapy to allow interactive inquiry of the operation of the convertible 25 medical device.

30 97. The convertible implantable medical device of claim 96, wherein the device further comprises a power source adapted to power operation of the convertible implantable medical device.

98. The power source of claim 97, wherein the power source further comprises a battery.
99. The battery of claim 98, wherein the battery is capable of powering 5 operation of the convertible implantable medical device for at least 7 years.
100. The battery of claim 99, wherein the battery further comprises a lithium-based battery.
101. The battery of claim 100, wherein the lithium-based battery is capable of 10 powering operation of the convertible implantable medical device for at least 7 years.
102. The convertible implantable medical device of claim 96, wherein the 15 device converts from a mode of monitoring and communicating patient health to an intervention mode upon sensing a cardiovascular event requiring therapeutic intervention.
103. The interactive control module of claim 96, wherein the analysis and 20 diagnosis of the cardiovascular event uses a pacemaker configured to analyze and diagnose the cardiovascular event.
104. The interactive control module of claim 96, when the delivery of an appropriate course of therapy uses a pacemaker configured to deliver the 25 therapy.
105. The interactive control module of claim 96, wherein the controlled plurality of duty cycles is controlled by selectively opening and closing gated circuits.
106. The selectively controlled gated circuits of claim 105, wherein the 30 selectively controlled gated circuits comprise gated circuits S, T and C.

107. The selectively controlled gated circuits claim 106, wherein the selectively controlled gated circuits S, T and C are selectively controlled to any combination of open and closed states relative to each other.
- 5 108. The selectively controlled gated circuit S of claim 106, wherein the control module opens gated circuit S to deactivate the interactive sensing module and closes gated circuit S to activate the interactive sensing module.
- 10 109. The selectively controlled gated circuit T of claim 106, wherein the control module opens gated circuit T to deactivate the interactive therapy module and closes gated circuit T to activate the interactive therapy module.
- 15 110. The selectively controlled gated circuit C of claim 106, wherein the control module opens gated circuit C to deactivate the interactive communications module and closes gated circuit C to activate the interactive communications module.
- 20 111. The gated circuit S of claim 108, wherein the interactive sensing module is active to sense a cardiovascular event.
112. The gated circuit S of claim 108, wherein the interactive sensing module is adapted to duty cycle to an active state to sense a cardiovascular event and to an inactive state to save power if no cardiovascular event is sensed.
- 25 113. The gated circuit S of claim 108, wherein the interactive sensing module is active for a number of cardiac cycles.
114. The gated circuit S of claim 113, wherein the number of cardiac cycles is 3.
- 30 115. The gated circuit S of claim 108, wherein the interactive sensing module is active for a physiologically appropriate time interval.
116. The gated circuit S of claim 108, wherein the interactive sensing module is active for a technologically appropriate time interval.

117. The selectively controlled gated circuits of claim 106, wherein when gated circuit S is closed, then gated circuit T is closed temporarily.
- 5 118. The selectively controlled gated circuits of claim 106, wherein when gated circuit S is closed, then gated circuit T is closed permanently.
119. The selectively controlled gated circuits of claim 106, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 10 120. The selectively controlled gated circuits of claim 111, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
121. The selectively controlled gated circuits of claim 112, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 15 122. The selectively controlled gated circuits of claim 113, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 20 123. The selectively controlled gated circuits of claim 114, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
124. The selectively controlled gated circuits of claim 115, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 25 125. The selectively controlled gated circuits of claim 116, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
126. The selectively controlled gated circuits of claim 117, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 30 127. The selectively controlled gated circuits of claim 118, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.

128. The selectively controlled gated circuits of claim 106, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
129. The selectively controlled gated circuits of claim 111, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
5
130. The selectively controlled gated circuits of claim 112, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
131. The selectively controlled gated circuits of claim 113, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
10
132. The selectively controlled gated circuits of claim 114, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
133. The selectively controlled gated circuits of claim 115, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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134. The selectively controlled gated circuits of claim 116, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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135. The selectively controlled gated circuits of claim 117, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
136. The selectively controlled gated circuits of claim 118, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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137. The convertible implantable medical device having diagnostic and therapeutic functions of claim 96, wherein the selectively controlled plurality of duty cycles of the implantable medical device that successively turn the functions of the device on and off is measured in time intervals of less than 60 minutes.
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138. The selectively controlled plurality of duty cycles of claim 137, wherein the controlled plurality of duty cycles of the implantable medical device is measured in time intervals of not more than 2 minutes.
- 5 139. The selectively controlled plurality of duty cycles of claim 138, wherein the controlled plurality of duty cycles of the implantable medical device is measured in time intervals of not less than 30 seconds.
- 10 140. The interactive sensing module of claim 96, wherein the sensed cardiovascular event is an arrhythmic event.
141. The sensed cardiovascular event of claim 140, wherein the arrhythmic event is a bradycardia event.
- 15 142. The sensed cardiovascular event of claim 140, wherein the arrhythmic event is a tachycardia event.
143. The sensed cardiovascular event of claim 140, wherein the arrhythmic event is a fibrillation event.
- 20 144. The interactive therapeutic module of claim 96, wherein the therapeutic module delivers an electrical stimulus.
145. The interactive therapeutic module of claim 96, wherein the therapeutic module delivers a chemotherapeutic agent.
- 25 146. The interactive communications module of claim 96, wherein the communications module communicates data reflecting the sensed, analyzed and diagnosed cardiovascular event and delivered therapy to a control and analysis module to control further operation of the device.
- 30 147. The interactive communications module of claim 96, wherein the communications module communicates data reflecting the sensed,

analyzed and diagnosed cardiovascular event and delivered therapy to a control module to control further operation of the device.

148. The interactive communications module of claim 96, wherein the
5 communications module communicates data reflecting the sensed,
analyzed and diagnosed cardiovascular event and delivered therapy to an
Advanced Patient Management system.

149. The interactive communications module of claim 96, wherein the
10 communications module communicates data reflecting the sensed,
analyzed and diagnosed cardiovascular event and delivered therapy for the
purposes of a post-myocardial infarction randomized controlled trial.

150. A convertible implantable medical device having diagnostic and
15 therapeutic functions comprising:
a. an interactive control module adapted to selectively control a
plurality of duty cycles that successively turn the functions of the
device on and off through the use of gated circuits;
b. an interactive sensing module coupled to the interactive control
module to sense a cardiovascular event;
c. an interactive analysis module integrated with the interactive sensing
module to analyze and diagnose a cardiovascular event sensed by the
interactive sensing module;
d. an interactive therapeutic module coupled to the interactive control
module to deliver an appropriate course of therapy; and
e. an interactive communications module coupled to the interactive
control module to communicate patient health data reflected by the
sensed, analyzed and diagnosed cardiovascular event and delivered
therapy to allow interactive inquiry of the operation of the convertible
20 medical device.

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151. The convertible implantable medical device of claim 150, wherein the
device further comprises a power source adapted to power operation of the
convertible implantable medical device.

152. The power source of claim 151, wherein the power source further comprises a battery.
- 5 153. The battery of claim 152, wherein the battery is capable of powering operation of the convertible implantable medical device for at least 7 years.
154. The battery of claim 152, wherein the battery further comprises a lithium-based battery.
- 10 155. The battery of claim 154, wherein the lithium-based battery is capable of powering operation of the convertible implantable medical device for at least 7 years.
- 15 156. The convertible implantable medical device of claim 150, wherein the device converts from a mode of monitoring and communicating patient health to an intervention mode upon sensing a cardiovascular event requiring therapeutic intervention.
- 20 157. The interactive sensing module of claim 150, wherein the analysis and diagnosis of the cardiovascular event uses a pacemaker configured to analyze and diagnose the cardiovascular event.
- 25 158. The interactive therapy module of claim 150, when the delivery of an appropriate course of therapy uses a pacemaker configured to deliver the therapy.
- 30 159. The interactive control module of claim 150, wherein the controlled plurality of duty cycles is controlled by selectively opening and closing gated circuits.
160. The selectively controlled gated circuits of claim 159, wherein the selectively controlled gated circuits comprise gated circuits S, T and C.

161. The selectively controlled gated circuits of claim 160, wherein the selectively controlled gated circuits S, T and C are selectively controlled to any combination of open and closed states relative to each other.
- 5 162. The selectively controlled gated circuit S of claim 160, wherein the control module opens gated circuit S to deactivate the interactive sensing module and closes gated circuit S to activate the interactive sensing module.
- 10 163. The selectively controlled gated circuit T of claim 160, wherein the control module opens gated circuit T to deactivate the interactive therapy module and closes gated circuit T to activate the interactive therapy module.
- 15 164. The selectively controlled gated circuit C of claim 160, wherein the control module opens gated circuit C to deactivate the interactive communications module and closes gated circuit C to activate the interactive communications module.
- 20 165. The gated circuit S of claim 162, wherein the interactive sensing module is active to sense a cardiovascular event.
166. The gated circuit S of claim 160, wherein the interactive sensing module is adapted to duty cycle to an active state to sense a cardiovascular event and to an inactive state to save power if no cardiovascular event is sensed.
- 25 167. The gated circuit S of claim 162, wherein the interactive sensing module is active for a number of cardiac cycles.
168. The gated circuit S of claim 167, wherein the number of cardiac cycles is 3.
- 30 169. The gated circuit S of claim 162, wherein the interactive sensing module is active for a physiologically appropriate time interval.
170. The gated circuit S of claim 162, wherein the interactive sensing module is active for a technologically appropriate time interval.

171. The selectively controlled gated circuits of claim 160, wherein when gated circuit S is closed, then gated circuit T is closed temporarily.
- 5 172. The selectively controlled gated circuits of claim 160, wherein when gated circuit S is closed, then gated circuit T is closed permanently.
173. The selectively controlled gated circuits of claim 160, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 10 174. The selectively controlled gated circuits of claim 165, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
175. The selectively controlled gated circuits of claim 166, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 15 176. The selectively controlled gated circuits of claim 167, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 20 177. The selectively controlled gated circuits of claim 168, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
178. The selectively controlled gated circuits of claim 169, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 25 179. The selectively controlled gated circuits of claim 170, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
180. The selectively controlled gated circuits of claim 171, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.
- 30 181. The selectively controlled gated circuits of claim 172, wherein when gated circuit T is closed, then gated circuit C is closed temporarily.

182. The selectively controlled gated circuits of claim 160, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
183. The selectively controlled gated circuits of claim 165, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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184. The selectively controlled gated circuits of claim 166, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
185. The selectively controlled gated circuits of claim 167, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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186. The selectively controlled gated circuits of claim 168, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
187. The selectively controlled gated circuits of claim 169, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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188. The selectively controlled gated circuits of claim 170, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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189. The selectively controlled gated circuits of claim 171, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
190. The selectively controlled gated circuits of claim 172, wherein when gated circuit T is closed, then gated circuit C is closed permanently.
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191. The convertible implantable medical device having diagnostic and therapeutic functions of claim 150, wherein the selectively controlled plurality of duty cycles of the implantable medical device that successively turn the functions of the device on and off is measured in time intervals of less than 60 minutes.
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192. The selectively controlled plurality of duty cycles of claim 191, wherein the controlled plurality of duty cycles of the implantable medical device is measured in time intervals of not more than 2 minutes.
- 5 193. The selectively controlled plurality of duty cycles of claim 192, wherein the controlled plurality of duty cycles of the implantable medical device is measured in time intervals of not less than 30 seconds.
- 10 194. The interactive sensing module of claim 150, wherein the sensed cardiovascular event is an arrhythmic event.
195. The sensed cardiovascular event of claim 194, wherein the arrhythmic event is a bradycardia event.
- 15 196. The sensed cardiovascular event of claim 194, wherein the arrhythmic event is a tachycardia event.
197. The sensed cardiovascular event of claim 194, wherein the arrhythmic event is a fibrillation event.
- 20 198. The interactive therapeutic module of claim 150, wherein the therapeutic module delivers an electrical stimulus.
199. The interactive therapeutic module of claim 150, wherein the therapeutic module delivers a chemotherapeutic agent.
- 25 200. The interactive communications module of claim 150, wherein the communications module communicates data reflecting the sensed, analyzed and diagnosed cardiovascular event and delivered therapy to a control and analysis module to control further operation of the device.
- 30 201. The interactive communications module of claim 150, wherein the communications module communicates data reflecting the sensed,

analyzed and diagnosed cardiovascular event and delivered therapy to a control module to control further operation of the device.

202. The interactive communications module of claim 150, wherein the
5 communications module communicates data reflecting the sensed,
analyzed and diagnosed cardiovascular event and delivered therapy to an
Advanced Patient Management system.

203. The interactive communications module of claim 150, wherein the
10 communications module communicates data reflecting the sensed,
analyzed and diagnosed cardiovascular event and delivered therapy for the
purposes of a post-myocardial infarction randomized controlled trial.

204. A convertible implantable medical device having diagnostic and
15 therapeutic functions comprising:
a. an interactive control module adapted to analyze and diagnose an
arrhythmic cardiovascular event and control a plurality of duty cycles
that successively turn the functions of the device on and off through
the use of selectively controlled gated circuits S, T and C;
b. an interactive sensing module coupled to the interactive control
module to sense an arrhythmic cardiovascular event;
c. an interactive analysis module integrated with the interactive control
module to analyze and diagnose an arrhythmic cardiovascular event
sensed by the interactive sensing module;
d. an interactive therapeutic module coupled to the interactive control
module to deliver an appropriate course of prophylactic therapy in the
form of an electrical stimulus; and
e. an interactive communications module coupled to the interactive
control module to communicate data reflecting the analyzed and
30 diagnosed arrhythmic cardiovascular event and delivered therapy to
control further operation of the implantable medical device.

205. The implantable medical device of claim 204, wherein the device further comprises a lithium iodine battery power source adapted to power operation of the convertible implantable medical device.

5 206. The implantable medical device of claim 204, wherein the interactive communications module is further coupled to an externally accessible patent management system.

10 207. The implantable medical device of claim 204, wherein the interactive communications module is further coupled to an externally accessible patent management system for the purposes of a post-myocardial infarction randomized controlled trial.

15 208. A convertible implantable medical device having diagnostic and therapeutic functions comprising:

20 a. an interactive control module adapted to analyze and diagnose an arrhythmic cardiovascular event and control a plurality of duty cycles that successively turn the functions of the device on and off through the use of selectively controlled gated circuits S, T and C;

b. an interactive sensing module coupled to the interactive control module to sense an arrhythmic cardiovascular event;

c. an interactive analysis module integrated with the interactive sensing module to analyze and diagnose an arrhythmic cardiovascular event sensed by the interactive sensing module;

25 d. an interactive therapeutic module coupled to the interactive control module to deliver an appropriate course of prophylactic therapy in the form of an electrical stimulus; and

e. an interactive communications module coupled to the interactive control module to communicate data reflecting the analyzed and diagnosed arrhythmic cardiovascular event and delivered therapy to control further operation of the implantable medical device.

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209. The implantable medical device of claim 208, wherein the device further comprises a lithium iodine battery power source adapted to power operation of the convertible implantable medical device.

5 210. The implantable medical device of claim 208, wherein the interactive communications module is further coupled to an externally accessible patent management system.

10 211. The implantable medical device of claim 208, wherein the interactive communications module is further coupled to an externally accessible patent management system for the purposes of a post-myocardial infarction randomized controlled trial.

15 212. A convertible implantable medical device having diagnostic and therapeutic functions, wherein the device is a component of an Advanced Patient Management system and comprises:

20 a. an interactive, electronically accessible data management module adapted to store patient and medical data;

b. an interactive control module adapted to selectively control a plurality of duty cycles that successively turn the functions of the device on and off through the use of gated circuits S, T and C;

c. an interactive sensing module coupled to the interactive control module adapted to sense physiological functions;

d. an interactive analysis module integrated with the interactive control module to analyze and diagnose a physiological function sensed by the interactive sensing module;

e. an interactive therapeutic module coupled to the interactive control module to deliver an appropriate course of therapy; and

f. an interactive communications module coupled to the interactive control module and data management module adapted to communicate patient health data reflected by the sensed, analyzed and diagnosed physiological function, medical data and delivered therapy to allow interactive inquiry of the operation of the convertible medical device.

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213. A convertible implantable medical device having diagnostic and therapeutic functions, wherein the device is a component of an Advanced Patient Management system and comprises:

- 5 a. an interactive, electronically accessible data management module adapted to store patient and medical data;
- b. an interactive control module adapted to selectively control a plurality of duty cycles that successively turn the functions of the device on and off through the use of gated circuits S, T and C;
- 10 c. an interactive sensing module coupled to the interactive control module adapted to sense physiological functions;
- d. an interactive analysis module integrated with the interactive sensing module to analyze and diagnose a physiological function sensed by the interactive sensing module;
- 15 e. an interactive therapeutic module coupled to the interactive control module to deliver an appropriate course of therapy; and
- f. an interactive communications module coupled to the interactive control module and data management module adapted to communicate patient health data reflected by the sensed, analyzed and diagnosed physiological function, medical data and delivered therapy to allow interactive inquiry of the operation of the convertible medical device.

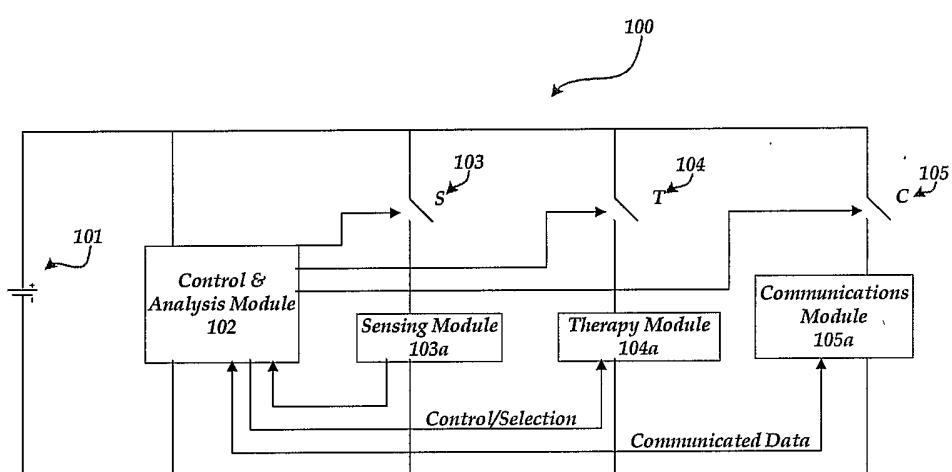


Fig.1.

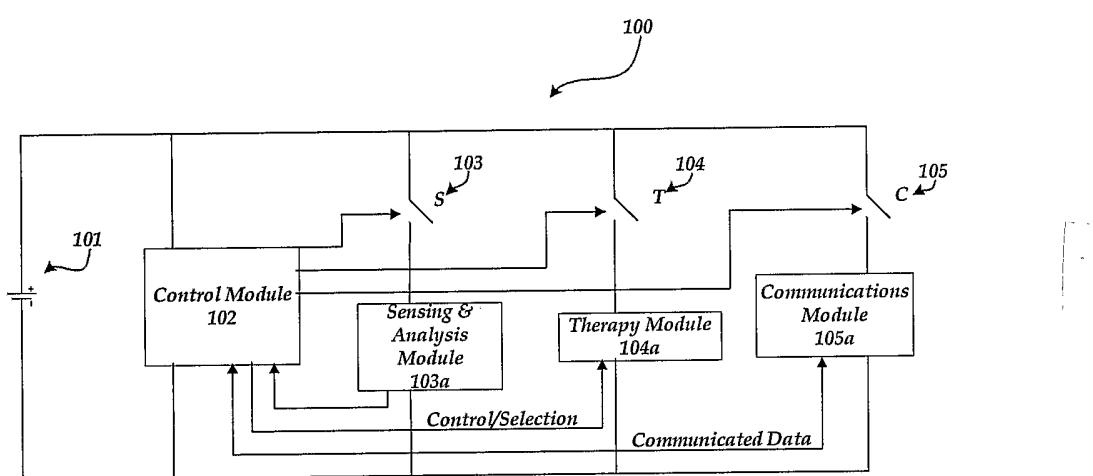


Fig.2.

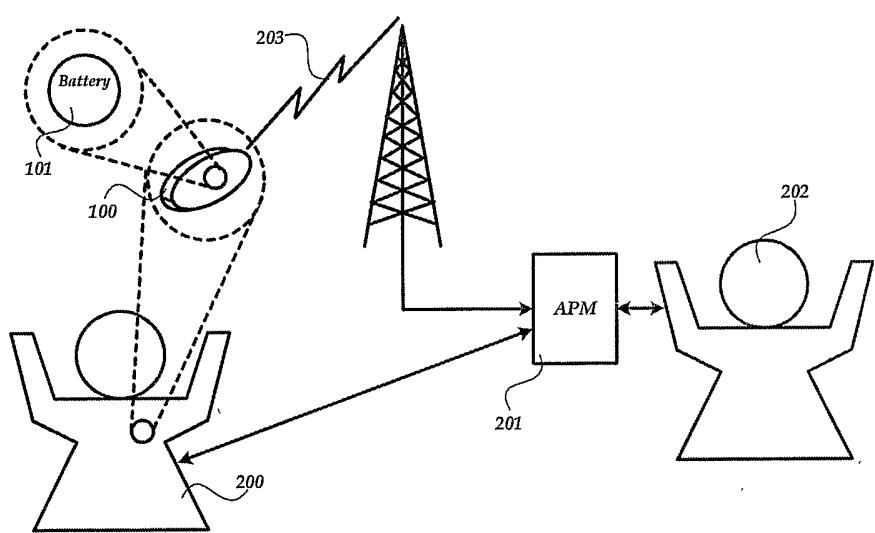
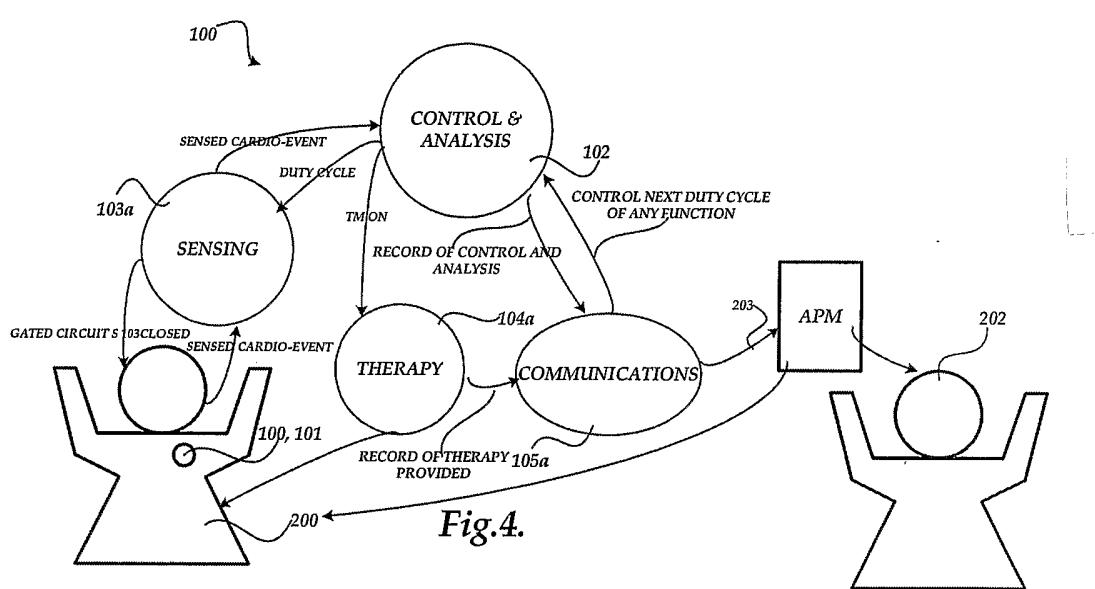


Fig.3.



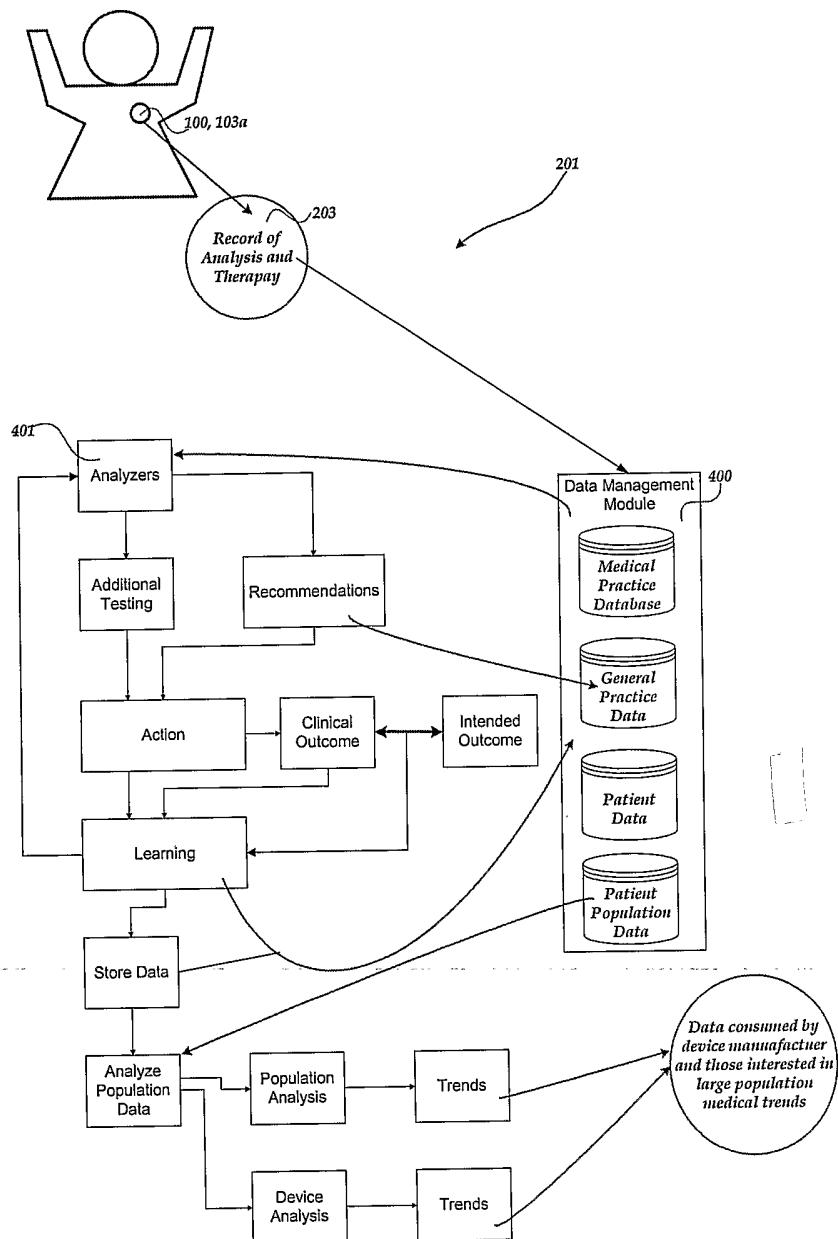


Fig.5.