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(54) **SUBCUTANEOUS P-WAVE CENTRIC INSERTABLE CARDIAC MONITOR FOR LONG TERM ELECTROCARDIOGRAPHIC MONITORING**

(57) A P-wave centric subcutaneous insertable cardiac monitor (12, 30) for use in performing long term electrocardiographic (ECG) monitoring is disclosed. An implantable housing (15, 31) made of a biocompatible material is provided. At least one pair of ECG sensing electrodes (18, 19, 34, 35, 36) is provided on a ventral (or dorsal) surface and on opposite ends of the implantable housing (15, 31) operatively placed to facilitate sensing in closest proximity to the low amplitude, low frequency content cardiac action potentials that are generated during atrial activation. Electronic circuitry (80) is provided

within the housing assembly including a low power microcontroller (81) operable to execute under modular micro program control as specified in firmware (132), an ECG front end circuit (83) interfaced to the microcontroller (81) and configured to capture the cardiac action potentials sensed by the pair of ECG sensing electrodes 18, 19, 34, 35, 36) which are output as ECG signals, and non-volatile memory (82) electrically interfaced with the microcontroller (81) and operable to continuously store samples of the ECG signals.

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Description

FIELD

[0001] This application relates in general to electrocardiographic monitoring and, in particular, to a subcutaneous P-wave-centric insertable cardiac monitor (ICM) for long term electrocardiographic monitoring with special emphasis on reliably visualizing the P-wave.

BACKGROUND

[0002] The electrocardiogram (ECG) was invented by a Dutch physiologist, Willem Einthoven, in 1903. Physicians have since used ECGs to diagnose heart problems and other medical concerns. The medical and engineering principles underlying Einthoven's work are still applicable today, and although ECG machines have evolved to a broad array of different systems, over the past century, the fundamental role of an ECG machine remains the same: to record from the skin surface transmembrane ionic currents that are generated within the heart during cardiac activation and recovery.

[0003] Cardiac depolarization, which is the spread of electrical current throughout the heart, originates in the sinoatrial (SA) node in the right atrium and spreads leftward towards the left atrium and inferiorly towards the atrioventricular (AV) node. Thereafter a delay, occasioned by the AV node, allows atrial blood to enter the ventricles, prior to the continuation of the depolarization current proceeding down the Bundle of His and into the right and left bundle branches, then advancing to the Purkinje fibers, and finally spreading to activate the right and left ventricular muscle fibers themselves that lead to the heart muscle squeezing the blood supply forward.

[0004] During each cardiac cycle, the transmembrane ionic currents create an electrical field in and around the heart that can be detected by ECG electrodes either placed on the skin or implanted under the skin of the thorax to record far field electrical signals from the heart. These far field electrical signals are the captured ECG signals that can be visually depicted in an ECG trace as the PQRSTU waveforms, each letter of which represents a specific electrical activity in the heart well known to cardiologists. Within each cardiac cycle, these waveforms indicate key aspects of cardiac electrical activity. The critical P-wave component of each heartbeat represents atrial electrical activity, the electrical signal that is essential if one is to understand heart rhythm disorders. The QRS components represent ventricular electrical activity, equally critical to understanding heart rhythm disorders. The TU components represent ventricular cell voltages that are the result of resetting cellular currents in preparation for the next cardiac cycle. The TU components are generally of limited value for the purposes of understanding heart rhythm disorders and are rarely addressed in the analysis of heart rhythm disorders *per se*. (Note that the signals involved in the resetting of the atria

are so minuscule as to not be visible in an ECG trace or, even in a standard intra-cardiac recording.)

[0005] Practically, the QRS components of the ventricle electrical activity are often termed the "R-wave," in brief, as a shorthand way of identifying ventricular electrical activity in its entirety. (Henceforth, the shorthand version of "R-wave" will be used to indicate ventricular activity and "P-wave" will be used to indicate atrial activity.) These "waves" represent the two critical components of arrhythmia monitoring and diagnosis performed every day hundreds of thousands of times across the United States. Without a knowledge of the relationship of these two basic symbols, heart rhythm disorders cannot be reliably diagnosed. Visualizing both the P-wave and the R-wave allow for the specific identification of a variety of atrial tachyarrhythmias (also known as supraventricular tachyarrhythmias, or SVTs), ventricular tachyarrhythmias (VTs), and bradycardias related to sinus node and atrioventricular (AV) node dysfunction. These categories are well understood by cardiologists but only accurately diagnosable if the P-wave and the R-wave are visualized and their relationship and behavior are clear. Visualization of the R-wave is usually readily achievable, as the R-wave is a high voltage, high frequency signal easily recorded from the skin's surface. However, as the ECG bipole spacing and electrode surface area decreases, even the R-wave can be a challenge to visualize. To make matters of rhythm identification more complicated, surface P-waves can be much more difficult to visualize from the surface because of their much lower voltage and signal frequency content. P-wave visualization becomes exacerbated further when the recording bipole inter-electrode spacing decreases.

[0006] Subcutaneous ECG monitors, because of their small size, have greater problems of demonstrating a clear and dependable P-wave. The issues related to a tiny atrial voltage are exacerbated by the small size of insertable cardiac monitors (ICMs), the signal processing limits imposed upon them by virtue of their reduced electrode size, and restricted inter-electrode spacing. Conventional subcutaneous ICMs, as well as most conventional surface ECG monitors, are notorious for poor visualization of the P-wave, which remains the primary reason that heart rhythm disorders cannot precisely be identified today from ICMs. Furthermore, even when physiologically present, the P-wave may not actually appear on an ECG because the P-wave's visibility is strongly dependent upon the signal capturing ability of the ECG recording device's sensing circuitry. This situation is further influenced by several factors, including electrode configuration, electrode surface areas and shapes, inter-electrode spacing; where the electrodes are placed on or within the body relative to the heart's atria. Further, the presence or absence of ambient noise and the means to limit the ambient noise is a key aspect of whether the low amplitude atrial signal can be seen.

[0007] Conventional ICMs are generally capable of monitoring a patient's heart rhythm for up to three years

and are often used after diagnostic measures when dermal ECG monitors fail to identify a suspected arrhythmia. Consequently, when a physician is strongly suspicious of a serious cardiac rhythm disorder that may have caused loss of consciousness or stroke, for example, the physician will often proceed to the insertion of an ICM under the skin of the thorax. Although traditionally, the quality of the signal is limited with ICMs with respect to identifying the P-wave, the duration of monitoring is hoped to compensate for poor P-wave recording. This situation has led to a dependence on scrutiny of R-wave behavior, such as RR interval (R-wave-to-R-wave interval) behavior, often used as a surrogate for diagnosing atrial fibrillation, a potential cause of stroke. To a limited extent, this approach has some degree of value. Nevertheless, better recording of the P-wave would result in a significant diagnostic improvement, not only in the case of atrial fibrillation, but in a host of other rhythm disorders that can result in syncope or loss of consciousness, like VT or heart block.

[0008] The P-wave is the most difficult ECG signal to capture by virtue of originating in the low tissue mass atria and having both low voltage amplitude and relatively low frequency content. Notwithstanding these physiological constraints, ICMs are popular, albeit limited in their diagnostic yield. The few ICMs that are commercially available today, including the Reveal LINQ ICM, manufactured by Medtronic, Inc., Minneapolis, MN, the BioMonitor 2 (AF and S versions), manufactured by Biotronik SE & Co. KG, Berlin, Germany, and the Abbott Confirm Rx ICM, manufactured by Abbott Laboratories, Chicago, IL, all are uniformly limited in their abilities to clearly and consistently sense, record, and deliver the P-wave.

[0009] Typically, the current realm of ICM devices use a loop recorder where cumulative ECG data lasting for around an hour is continually overwritten unless an episode of pre-programmed interest occurs or a patient marker is manually triggered. The limited temporal window afforded by the recordation loop is yet another restriction on the evaluation of the P-wave, and related cardiac morphologies, and further compromises diagnostic opportunities.

[0010] For instance, Medtronic's Reveal LINQ ICM delivers long-term subcutaneous ECG monitoring for up to three years, depending on programming. The monitor is able to store up to 59 minutes of ECG data, include up to 30 minutes of patient-activated episodes, 27 minutes of automatically detected episodes, and two minutes of the longest atrial fibrillation (AF) episode stored since the last interrogation of the device. The focus of the device is more directed to recording duration and programming options for recording time and patient interactions rather than signal fidelity. The Reveal LINQ ICM is intended for general purpose ECG monitoring and lacks an engineering focus on P-wave visualization. Moreover, the device's recording circuitry is intended to secure the ventricular signal by capturing the R-wave, and is designed to accommodate placement over a broad range of subcuta-

neous implantation sites, which is usually sufficient if one is focused on the R-wave given its amplitude and frequency content, but of limited value in capturing the low-amplitude, low-frequency content P-wave. Finally, electrode spacing, surface areas, and shapes are dictated (and limited) by the physical size of the monitor's housing which is quite small, an aesthetic choice, but unrealistic with respect to capturing the P-wave.

[0011] Similar in design is the titanium housing of Biotronik's BioMonitor 2 but with a flexible silicone antenna to mount a distal electrode lead, albeit of a standardized length. This standardized length mollifies, in one parameter only, the concerns of limited inter-electrode spacing and its curbing effect on securing the P-wave. None of the other factors related to P-wave signal revelation are addressed. Therefore the quality of sensed P-waves reflects a compromise caused by closely-spaced poles that fail to consistently preserve P-wave fidelity, with the reality of the physics imposed problems of signal-to-noise ratio limitations remaining mostly unaddressed.

[0012] Therefore, a need remains for a continuously recording long-term ICM particularly attuned to capturing low amplitude cardiac action potential propagation from the atria, that is, the P-wave, for accurate arrhythmia event capture and subsequent diagnosis.

SUMMARY

[0013] Long-term electrocardiographic and physiological monitoring over a period lasting up to several years in duration can be provided through a continuously-recording subcutaneous insertable cardiac monitor (ICM). The sensing circuitry and the physical layout of the electrodes are specifically optimized to capture electrical signals from the propagation of low amplitude, relatively low frequency content cardiac action potentials, particularly the P-waves that are generated during atrial activation. In general, the ICM is intended to be implanted centrally and positioned axially and slightly to either the left or right of the sternal midline in the parasternal region of the chest.

[0014] One embodiment provides a P-wave centric subcutaneous insertable cardiac monitor for use in performing long term electrocardiographic (ECG) monitoring. An implantable housing made of a biocompatible material that is suitable for implantation within a living body is provided. At least one pair of ECG sensing electrodes is provided on a ventral (or dorsal) surface and on opposite ends of the implantable housing operatively placed to facilitate sensing in closest proximity to the low amplitude, low frequency content cardiac action potentials that are generated during atrial activation. Electronic circuitry is provided within the housing assembly including a low power microcontroller operable to execute under modular micro program control as specified in firmware, an ECG front end circuit interfaced to the microcontroller and configured to capture the cardiac action potentials sensed by the pair of ECG sensing electrodes which are

output as ECG signals, and non-volatile memory electrically interfaced with the microcontroller and operable to continuously store samples of the ECG signals.

[0015] Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016]

FIGURE 1 is a diagram showing, by way of example, a subcutaneous P-wave centric insertable cardiac monitor (ICM) for long term electrocardiographic monitoring in accordance with one embodiment.

FIGURES 2 and 3 are respectively top and bottom perspective views showing the ICM of FIGURE 1.

FIGURE 4 is a bottom perspective view showing the ICM of FIGURE 1 in accordance with a further embodiment.

FIGURES 5 and 6 are respectively top and bottom perspective views showing an ICM in accordance with a still further embodiment.

FIGURE 7 is a plan view showing further electrode configurations.

FIGURE 8 is a functional block diagram showing the P-wave focused component architecture of the circuitry of the ICM of FIGURE 1.

FIGURE 9 is a functional block diagram showing a system for wirelessly interfacing with an ICM in accordance with one embodiment.

FIGURE 10 is a flow diagram showing an ICM-implemented method for monitoring ECG data.

FIGURE 11 is a functional block diagram showing the signal processing functionality of the microcontroller.

FIGURE 12 is a functional block diagram showing the operations performed by the download station.

DETAILED DESCRIPTION

[0017] Long-term electrocardiographic and physiological monitoring over a period lasting up to several years in duration can be provided through a continuously-recording subcutaneous insertable cardiac monitor (ICM). FIGURE 1 is a diagram showing, by way of example, a subcutaneous P-wave centric ICM 12 for long term electrocardiographic monitoring in accordance with one embodiment. The ICM 12 is implanted in the parasternal region 11 of a patient 10. The sensing circuitry and components, compression algorithms, and the physical lay-

out of the electrodes are specifically optimized to capture electrical signals from the propagation of low amplitude, relatively low frequency content cardiac action potentials, particularly the P-waves generated during atrial activation. The position and placement of the ICM 12 coupled to engineering considerations that optimize the ICM's sensing circuitry, discussed *infra*, aid in demonstrating the P-wave clearly.

[0018] Implantation of a P-wave centric ICM 12 in the proper subcutaneous site facilitates the recording of high quality ECG data with a good delineation of the P-wave. In general, the ICM 12 is intended to be implanted anteriorly and be positioned axially and slightly to either the right or left of the sternal midline in the parasternal region 11 of the chest, or if sufficient subcutaneous fat exists, directly over the sternum. Optimally, the ICM 12 is implanted in a location left parasternally to bridge the left atrial appendage. However, either location to the right or left of the sternal midline is acceptable; placement of the device, if possible, should bridge the vertical height of the heart, which lies underneath the sternum 7, thereby placing the ICM 12 in close proximity to the anterior right atrium and the left atrial appendage that lie immediately beneath.

[0019] The ICM 12 is shaped to fit comfortably within the body under the skin and to conform to the contours of the patient's parasternal region 11 when implanted immediately to either side of the sternum 7, but could be implanted in other locations of the body. In most adults, the proximal end 13 of the ICM 12 is generally positioned below the manubrium 8 but, depending upon patient's vertical build, the ICM 12 may actually straddle the region over the manubrium 8. The distal end 14 of the ICM 12 generally extends towards the xiphoid process 9 and lower sternum but, depending upon the patient's build, may actually straddle the region over or under the xiphoid process 9, lower sternum and upper abdomen.

[0020] Although internal tissues, body structures, and tissue boundaries can adversely affect the current strength and signal fidelity of all body surface potentials, subsurface low amplitude cardiac action potentials, particularly P-wave signals with a normative amplitude of less than 0.25 millivolts (mV) and a normative duration of less than 120 milliseconds (ms), are most apt to be negatively impacted by these factors. The atria, which generate the P wave, are mostly located posteriorly within the thoracic cavity (with the exception of the anterior right atrium, right atrial appendage and left atrial appendage). The majority of the left atrium constitutes the portion of the heart furthest away from the surface of the skin on the chest and harbors the atrial tissue most likely to be the source of serious arrhythmias, like atrial fibrillation. Conversely, the ventricles, which generate larger amplitude signals, are located anteriorly as in the case of the anterior right ventricle and most of the anterior left ventricle situated relatively close to the skin surface of the central and left anterior chest. These factors, together with larger size and more powerful impulse generation

from the ventricles, contribute to the relatively larger amplitudes of ventricular waveforms.

[0021] Nevertheless, as explained *supra*, both the P-wave and the R-wave are required for the physician to make a proper rhythm diagnosis from the dozens of arrhythmias that can occur. Yet, the quality of P-waves is more susceptible to weakening from distance and the intervening tissues and structures and from signal attenuation and signal processing than the high voltage waveforms associated with ventricular activation. The added value of avoiding further signal attenuation resulting from dermal impedance makes a subcutaneous P-wave centric ICM even more likely to match, or even outperform dermal ambulatory monitors designed to analogous engineering considerations and using similar sensing circuitry and components, compression algorithms, and physical layout of electrodes, such as described in U.S. Patent No. 9,545,204, issued January 17, 2017 to Bishay et al.; U.S. Patent No. 9,730,593, issued August 15, 2017 to Felix et al.; U.S. Patent No. 9,700,227, issued July 11, 2017 to Bishay et al.; U.S. Patent No. 9,717,433, issued August 1, 2017 to Felix et al.; and U.S. Patent No. 9,615,763, issued April 11, 2017 to Felix et al., the disclosures of which are incorporated by reference.

[0022] The ICM 12 can be implanted in the patient's chest using, for instance, a minimally invasive subcutaneous implantation instrument or other suitable surgical implement. The ICM 12 is positioned slightly to the right or left of midline, covering the center third of the chest, roughly between the second and sixth ribs, approximately spanning between the level of the manubrium 8 and the level of the xiphoid process 9 on the inferior border of the sternum 7, depending upon the vertical build of the patient 10.

[0023] During monitoring, the amplitude and strength of action potentials sensed by an ECG devices, including dermal ECG monitors and ICMs, can be affected to varying degrees by cardiac, cellular, extracellular, vector of current flow, and physical factors, like obesity, dermatitis, lung disease, large breasts, and high impedance skin, as can occur in dark-skinned individuals. Performing ECG sensing subcutaneously in the parasternal region 11 significantly improves the ability of the ICM 12 to counter some of the effects of these factors, particularly high skin impedance and impedance from subcutaneous fat. Thus, the ICM 12 exhibits superior performance when compared to conventional dermal ECG monitors to existing implantable loop recorders, ICMs, and other forms of implantable monitoring devices by virtue of its engineering and proven P-wave documentation above the skin, as discussed in W.M. Smith et al., "Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours," *Am. Heart J.*, Mar. 2017; 185:67-73, the disclosure of which is incorporated by reference.

[0024] Moreover, the sternal midline implantation location in the parasternal region 11 allows the ICM's elec-

trodes to record an ECG of optimal signal quality from a location immediately above the strongest signal-generating aspects of the atrial. Signal quality is improved further in part because cardiac action potential propagation travels simultaneously along a north-to-south and right-to-left vector, beginning high in the right atrium and ultimately ending in the posterior and lateral region of the left ventricle. Cardiac depolarization originates high in the right atrium in the SA node before concurrently spreading leftward towards the left atrium and inferiorly towards the atrioventricular (AV) node. On the proximal end 13, the ECG electrodes of the ICM 12 are subcutaneously positioned with the upper or superior pole (ECG electrode) slightly to the right or left of the sternal midline in the region of the manubrium 8 and, on the distal end 14, the lower or inferior pole (ECG electrode) is similarly situated slightly to the right or left of the sternal midline in the region of the xiphoid process 9 and lower sternum 7. The ECG electrodes of the ICM 12 are placed primarily in a north-to-south orientation along the sternum 7 that corresponds to the north-to-south waveform vector exhibited during atrial activation. This orientation corresponds to the aVF lead used in a conventional 12-lead ECG that is used to sense positive or upright P-waves. In addition, the electrode spacing and the electrodes' shapes and surface areas mimic the electrodes used in the ICM's dermal cousin, designed as part of the optimal P-wave sensing electrode configuration, such as provided with the dermal ambulatory monitors cited *supra*.

[0025] Despite the challenges faced in capturing low amplitude cardiac action potentials, the ICM 12 is able to operate effectively using only two electrodes that are strategically sized and placed in locations ideally suited to high fidelity P-wave signal acquisition. This approach has been shown to clinically outperform more typical multi-lead monitors because of the improved P-wave clarity, as discussed in W.M. Smith et al., cited *supra*. FIGURES 2 and 3 are respectively top and bottom perspective views showing the ICM 12 of FIGURE 1. Physically, the ICM 12 is constructed with a hermetically sealed implantable housing 15 with at least one ECG electrode forming a superior pole on the proximal end 13 and at least one ECG electrode forming an inferior pole on the distal end 14.

[0026] When implanted, the housing 15 is oriented most cephalad. The housing 15 is constructed of titanium, stainless steel or other biocompatible material. The housing 15 contains the sensing, recordation and interfacing circuitry of the ICM 12, plus a long life battery. A wireless antenna is integrated into or within the housing 15 and can be positioned to wrap around the housing's internal periphery or location suited to signal reception. Other wireless antenna placement or integrations are possible.

[0027] Physically, the ICM 12 has four ECG electrodes 16, 17, 18, 19. There could also be additional ECG electrodes, as discussed *infra*. The ECG electrodes include two ventral (or dorsal) ECG electrodes 18, 19 and two

wraparound ECG electrodes 16, 17. One ventral ECG electrode 18 is formed on the proximal end 13 and one ventral ECG electrode 19 is formed on the distal end 14. One wraparound ECG electrode 16 is formed circumferentially about the proximal end 13 and one wraparound ECG electrode 17 is formed circumferentially about the distal end 14. Each wraparound ECG electrode 16, 17 is electrically insulated from its respective ventral ECG electrode 18, 19 by a periphery 20, 21.

[0028] The four ECG electrodes 16, 17, 18, 19 are programmatically controlled by a microcontroller through on-board firmware programming to enable a physician to choose from several different electrode configurations that vary the electrode surface areas, shapes, and inter-electrode spacing. The sensing circuitry can be programmed, either pre-implant or *in situ*, to use different combinations of the available ECG electrodes (and thereby changing electrode surface areas, shapes, and inter-electrode spacing), including pairing the two ventral ECG electrodes 16, 17, the two wraparound ECG electrodes 18, 19, or one ventral ECG electrode 16, 17 with one wraparound ECG electrode 18, 19 located on the opposite end of the housing 15. In addition, the periphery 20, 21 can be programmatically controlled to logically combine the wraparound ECG electrode 16, 17 on one end of the ICM 12 with its corresponding ventral ECG electrode 18, 19 to form a single virtual ECG electrode with larger surface area and shape. (Although electronically possible, the two ECG electrodes that are only on one end of the ICM 12, for instance, wraparound ECG electrode 16 and ventral ECG electrode 18, could be paired; however, the minimal inter-electrode spacing would likely yield a signal of poor fidelity in most situations.)

[0029] In a further embodiment, the housing 15 and contained circuitry can be provided as a standalone ICM core assembly to which a pair of compatible ECG electrodes can be operatively coupled to form a full implantable ICM device.

[0030] Other ECG electrode configurations are possible. For instance, additional ECG electrodes can be provided to increase the number of possible electrode configurations, all of which are to ensure better P-wave resolution. FIGURE 4 is a bottom perspective view showing the ICM 12 of FIGURE 1 in accordance with a further embodiment. An additional pair of ventral ECG electrodes 22, 23 are included on the housing's ventral surface. These ventral ECG electrodes 22, 23 are spaced closer together than the ventral ECG electrodes 18, 19 on the ends of the housing 15 and a physician can thus choose to pair the two inner ventral ECG electrodes 22, 23 by themselves to allow for minimal electrode-to-electrode spacing, or with the other ECG electrodes 16, 17, 18, 19 to vary electrode surface areas, shapes, and inter-electrode spacing even further to explore optimal configurations to acquire the P-wave.

[0031] Other housing configurations of the ICM are possible. For instance, the housing of the ICM can be structured to enhance long term comfort and fitment, and

to accommodate a larger long life battery or more circuitry or features, including physiologic sensors, to provide additional functionality. FIGURES 5 and 6 are respectively top and bottom perspective views showing an ICM 30 in accordance with a still further embodiment. The ICM 30 has a housing 31 with a tapered extension 32 that is terminated on the distal end with an electrode 34. On a proximal end, the housing 31 includes a pair of ECG electrodes electrically insulated by a periphery 37 that include a ventral ECG electrode 35 and a wraparound ECG electrode 33. In addition, a ventral ECG electrode 36 is oriented on the housing's distal end before the tapered extension 32. Still other housing structures and electrode configurations are possible.

[0032] In general, the basic electrode layout is sufficient to sense cardiac action potentials in a wide range of patients. Differences in thoracic tissue density and skeletal structure from patient to patient, though, can affect the ability of the sensing electrodes to efficaciously capture action potential signals, yet the degree to which signal acquisition is affected may not be apparent until after an ICM has been implanted and deployed, when the impacts of the patient's physical constitution and his patterns of mobility and physical movement on ICM monitoring can be fully assessed.

[0033] In further embodiments, the electrodes can be configured post-implant to allow the ICM to better adapt to a particular patient's physiology. For instance, electrode configurations having more than two sensing electrodes are possible. FIGURE 7 is a plan view showing further electrode configurations. Referring first to FIGURE 7(a), a single disc ECG electrode 40 could be bifurcated to form a pair of half-circle ECG electrodes 41, 42 that could be programmatically selected or combined to accommodate a particular patient's ECG signal characteristics post-ICM implant. Referring next to FIGURE 7(b), a single disc ECG electrode 45 could be divided into three sections, a pair of crescent-shaped ECG electrodes 46, 47 surrounding a central semicircular ECG electrode 48 that could similarly be programmatically selected or combined. Still other ECG electrode configurations are possible.

[0034] ECG monitoring and other functions performed by the ICM 12 are provided through a micro controlled architecture. FIGURE 8 is a functional block diagram showing the P-wave focused component architecture of the circuitry 80 of the ICM 12 of FIGURE 1. The circuitry 80 is powered through the long life battery 21 provided in the housing 15. Operation of the circuitry 80 of the ICM 12 is managed by a microcontroller 81, such as the EFM32 Tiny Gecko 32-bit microcontroller, manufactured by Silicon Laboratories Inc., Austin, TX. The microcontroller 81 has flexible energy management modes and includes a direct memory access controller and built-in analog-to-digital and digital-to-analog converters (ADC and DAC, respectively). The microcontroller 81 also includes a program memory unit containing internal flash memory (not shown) that is readable, writeable, and ex-

ternally programmable.

[0035] The microcontroller 81 operates under modular micro program control as specified in firmware stored in the internal flash memory. The functionality and firmware modules relating to signal processing by the microcontroller 81 are further described *infra* with reference to FIGURE 11. The microcontroller 81 draws power from the battery provided in the housing 15 and connects to the ECG front end circuit 83. In a further embodiment, the front end circuit 83 measures raw dermal electrical signals using a driven reference signal that eliminates common mode noise, as further described *infra*.

[0036] The circuitry 80 of the ICM 12 also includes a flash memory 82 external to the microcontroller 81, which the microcontroller 81 uses for continuously storing samples of ECG monitoring signal data and other physiology, such as respiratory rate, blood oxygen saturation level (SpO₂), blood pressure, temperature sensor, and physical activity, and device and related information. The flash memory 82 also draws power from the battery provided in the housing 15. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory 82 enables the microcontroller 81 to store digitized ECG data. The communications bus further enables the flash memory 82 to be directly accessed wirelessly through a transceiver 85 coupled to an antenna 17 built into (or provided with) the housing 15, as further described *infra* with reference to FIGURE 9. The transceiver 85 can be used for wirelessly interfacing over Bluetooth or other types of wireless technologies for exchanging data over a short distance with a paired mobile device, including smartphones and smart watches, that are designed to communicate over a public communications infrastructure, such as a cellular communications network, and, in a further embodiment, other wearable (or implantable) physiology monitors, such as activity trackers worn on the wrist or body. Other types of device pairings are possible, including with a desktop computer or purpose-built bedside monitor. The transceiver 85 can be used to offload stored ECG monitoring data and other physiology data and information and for device firmware reprogramming. In a further embodiment, the flash memory 82 can be accessed through an inductive coupling (not shown).

[0037] The microcontroller 81 includes functionality that enables the acquisition of samples of analog ECG signals, which are converted into a digital representation, as further described *infra* with reference to FIGURE 11. In one mode, the microcontroller 81 implements a loop recorder feature that will acquire, sample, digitize, signal process, and store digitized ECG data into available storage locations in the flash memory 82 until all memory storage locations are filled, after which existing stored digitized ECG data will either be overwritten through a sliding window protocol, albeit at the cost of potentially losing the stored data that was overwritten, if not previously downloaded, or transmitted wirelessly to an external receiver to unburden the flash memory. In another

mode, the stored digitized ECG data can be maintained permanently until downloaded or erased to restore memory capacity. Data download or erasure can also occur before all storage locations are filled, which would free up memory space sooner, albeit at the cost of possibly interrupting monitoring while downloading or erasure is performed. Still other modes of data storage and capacity recovery are possible.

[0038] The circuitry 80 of the ICM 12 can include functionality to programmatically select pairings of sensing electrodes when the ICM 12 is furnished with three or more electrodes. In a further embodiment, multiple sensing electrodes could be provided on the ICM 12 to provide a physician the option of fine-tuning the sensing dipole (or tripole or multipole) *in situ* by parking active electrodes and designating any remaining electrodes inert. The pairing selection can be made remotely through an inductive coupling or by the transceiver 85 via, for instance, a paired mobile device, as further described *infra*. Thus, the sensing electrode configuration, including number of electrodes, electrode-to-electrode spacing, and electrode size, shape, surface area, and placement, can be modified at any time during the implantation of the ICM 12.

[0039] In a further embodiment, the circuitry 80 of the ICM 12 can include an actigraphy sensor 84 implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller 81 by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the ICM 12 if, for instance, the ICM 12 has been inadvertently implanted upside down, that is, with the ICM's housing oriented caudally, as well as for other event occurrence analyses.

[0040] In a still further embodiment, the circuitry 80 of the ICM 12 can include one or more physiology sensors. For instance, a physiology sensor can be provided as part of the circuitry 80 of the ICM 12, or can be provided on the electrode assembly 14 with communication with the microcontroller 81 provided through a circuit trace. The physiology sensor can include an SpO₂ sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources.

[0041] In a yet further embodiment, firmware with programming instructions, including machine learning and other forms of artificial intelligence-originated instructions, can be downloaded into the microcontroller's internal flash memory. The firmware can include heuristics to signal patient and physician with alerts over health conditions or arrhythmias of selected medical concern, such as where a heart pattern particular to the patient is identified and the ICM 12 is thereby reprogrammed to watch for a reoccurrence of that pattern, after which an alert will be generated and sent to the physician (or other caregiv-

er) through the transceiver 85 via, for instance, a paired mobile device. Similarly, the firmware can include heuristics that can be downloaded to the ICM 12 to actively identify or narrow down a pattern (or even the underlying cause) of sporadic cardiac conditions, for instance, atrial tachycardia (AT), atrial fibrillation (AF), atrial flutter (AFL), AV node reciprocating tachycardia, ventricular tachycardia (VT), sinus bradycardia, asystole, complete heart block, and other cardiac arrhythmias, again, after which an alert will be generated and sent to the physician (or other caregiver) through the transceiver 85. For instance, an alert that includes a compressed ECG digitized sample can also be wirelessly transmitted by the ICM 12 upon the triggering of a preset condition, such as an abnormally low heart rate in excess of 170 beats per minute (bpm), an abnormally low heart rate falling below 30 bpm, or AF detected by onboard analysis of RR interval variability by the microcontroller 61. Finally, a similar methodology of creating firmware programming tailored to the monitoring and medical diagnostic needs of a specific patient (or patient group or general population) can be used for other conditions or symptoms, such as syncope, palpitations, dizziness and giddiness, unspecified convulsions, abnormal ECG, transient cerebral ischemic attacks and related syndromes, cerebral infarction, occlusion and stenosis of pre-cerebral and cerebral arteries not resulting in cerebral infarction personal history of transient ischemic attack, and cerebral infarction without residual deficits, to trigger an alert and involve the physician or initiate automated analysis and follow up back at the patient's clinic. Finally, in a still further embodiment, the circuitry 80 of the ICM 12 can accommodate patient-interfaceable components, including an external tactile feedback device (not shown) that wirelessly interfaces to the ICM 12 through the transceiver 85. A patient 10 can press the external tactile feedback device to mark events, such as a syncope episode, or to perform other functions. The circuitry 80 can also accommodate triggering an external buzzer 67, such as a speaker, magnetic resonator or piezoelectric buzzer, implemented as part of the external tactile feedback device or as a separate wirelessly-interfaceable component. The buzzer 67 can be used by the microcontroller 81 to indirectly output feedback to a patient 10, such as a low battery or other error condition or warning. Still other components, provided as either part of the circuitry 80 of the ICM 12 or as external wirelessly-interfaceable devices, are possible.

[0042] In a further embodiment, the ECG front end circuit 83 of the ICM 12 measures raw dermal electrical signals using a driven reference signal, such as described in U.S. Patent Nos. 9,700,227, 9,717,433, and 9,615,763, cited *supra*. The driven reference signal effectively reduces common mode noise, power supply noise and system noise, which is critical to preserving the characteristics of low amplitude cardiac action potentials, especially the P wave signals originating from the atria.

[0043] The ECG front end circuit 83 is organized into a passive input filter stage, a unity gain voltage follower stage, a passive high pass filtering stage, a voltage amplification and active filtering stage, and an anti-aliasing passive filter stage, plus a reference generator. The passive input filter stage passively shifts the frequency response poles downward to counter the high electrode impedance from the patient on the signal lead and reference lead, which reduces high frequency noise. The unity gain voltage follower stage allows the circuit to accommodate a very high input impedance, so as not to disrupt the subcutaneous potentials or the filtering effect of the previous stage. The passive high pass filtering stage includes a high pass filter that removes baseline wander and any offset generated from the previous stage. As necessary, the voltage amplification and active filtering stage amplifies or de-amplifies (or allows to pass-through) the voltage of the input signal, while applying a low pass filter. The anti-aliasing passive filter stage 75 provides an anti-aliasing low pass filter. The reference generator drives a driven reference signal containing power supply noise and system noise to the reference lead and is connected directly to the patient, thereby avoiding the thermal noise of the protection resistor that is included as part of the protection circuit 72.

[0044] When operated standalone, the recording circuitry of the ICM 12 senses and records the patient's ECG data into an onboard memory. The ICM 12 can interoperate with other devices wirelessly through the transceiver 85. FIGURE 9 is a functional block diagram showing a system 90 for wirelessly interfacing with an ICM 12 in accordance with one embodiment. The ICM 12 is designed for long-term electrocardiographic and physiological monitoring lasting up to several years in duration. During that time, stored data ECG monitoring data and other physiology and information will need to be offloaded and the ICM's firmware may need to be reprogrammed, and the transceiver 85 enables the ICM 12 to communicate with external devices to facilitate these functions.

[0045] In one embodiment, the ICM 12 can be wirelessly connected to a download station 92 executing data link software ("DL") 93 that permits the secure remote retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the ICM 12, or performance of other functions. The ICM 12 connects to the download station 92 over a wireless network 91 via the transceiver 85. In turn, the download station 92 executes the data link software 93 or similar program that wirelessly interacts with the ICM 12 to retrieve the stored ECG monitoring data or perform other function. The download station 92 could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a ICM 12. Still other forms of download station 92 are possible.

[0046] Upon retrieving stored ECG monitoring data from a ICM 12, middleware (not shown) executing on the

download station 92 first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described *infra* with reference to FIGURE 12. The formatted data can then be retrieved from the download station 92. The middleware could alternatively be executed by a separate device other than the download station 92.

[0047] A client-server model could be used to employ a server 94 to remotely interface with the download station 92 over the network 91 and retrieve the formatted data or other information. The server 94 executes a patient management program 95 ("Mgt") or similar application that stores the retrieved formatted data, recorded physiology, and other information in a secure database 96 cataloged in that patient's electronic medical records (EMRs) 97, along with tracking and correlating patient symptoms. In addition, the patient management program 95 could manage a subscription service that authorizes a ICM 12 to operate for a set period of time or under predefined operational parameters.

[0048] The patient management program 95, or other trusted application, also maintains and safeguards the secure database 96 to limit access to patient EMRs 97 to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database 96.

[0049] Physician and other authorized healthcare personnel are able to securely access the retrieved formatted data and other information stored in the EMRs 97 in the secure database 96 by executing an application program ("MD") 98, such as a post-monitoring ECG analysis program, on a personal computer 99 or other connectable computing device, and, through the application program 98, coordinate access to his patient's EMRs 97 with the patient management program 95 and perform other functions. The application program 98 can include the capability to actively or interactively diagnose or narrow down the underlying cause of sporadic cardiac conditions, for instance, atrial tachycardia (AT), AF, atrial flutter, AV node reciprocating tachycardia, ventricular tachycardia (VT), sinus bradycardia, asystole, complete heart block, and other cardiac arrhythmias. Other diagnoses are possible.

[0050] In a further embodiment, RR interval data can be extracted from the retrieved formatted data and be presented to physicians in a format that includes views of relevant near field and far field ECG data, which together provide contextual information that improves diagnostic accuracy, such as described in U.S. Patent No. 9,408,551, issued August 9, 2016 to Bardy et al., the disclosure of which is incorporated by reference. Both near field and far field ECG data views are temporally

keyed to an extended duration RR interval data view. The durations of the classical "pinpoint" view, the pre- and post-event "intermediate" view, and the RR interval plot are flexible and adjustable. Thus, the pinpoint "snapshot" and intermediate views of ECG data with the extended term RR interval data allow a physician to comparatively view heart rate context and patterns of behavior prior to and after a clinically meaningful arrhythmia, patient concern or other indicia, thereby enhancing diagnostic specificity of cardiac rhythm disorders and providing physiological context to improve diagnostic ability.

[0051] As a result, with the assistance of the server 94, a complete end-to-end closed loop of patient care can be provided, with the ICM 12 providing long-term ECG and physiology monitoring and data reporting, the patient management program 95 managing ECG and physiology data retrieval and patient symptom tracking and correlation, the application program 98 empowering physicians with the ability to effectively identify the underlying cause of sporadic cardiac conditions, particularly cardiac rhythm disorders, and the ICM 12 again facilitating patient following upon diagnosis and throughout treatment.

[0052] In a further embodiment, the ICM 12 can interoperate wirelessly with other physiology monitors and activity sensors 104, whether implanted or dermal, such as activity trackers worn on the wrist or body, and with mobile devices 102, including smartphones and smart watches, that are designed to communicate over a public communications infrastructure, such as a cellular communications network. Wearable physiology monitors and activity sensors 104 encompass a wide range of wirelessly interconnectable devices that measure or monitor a patient's physiological data, such as heart rate, temperature, blood pressure, respiratory rate, blood pressure, blood sugar (with appropriate subcutaneous probe), oxygen saturation, minute ventilation, and so on; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level.

[0053] The physiology sensors in non-wearable mobile devices 102, particularly smartphones, are generally not meant for continuous tracking and do not provide medically precise and actionable data sufficient for a physician to prescribe a surgical, catheter or serious drug intervention; such data can be considered screening information that something may be wrong, but not data that provides the highly precise information that may allow for a surgery, such as implantation of a pacemaker for heart block or a defibrillator for ventricular tachycardia, or the application of serious medications, like blood thinners for atrial fibrillation or a cardiac ablation procedure. Such devices, like smartphones, are better suited to pre- and post-exercise monitoring or as devices that can provide a signal that something is wrong, but not in the sufficient detail and FDA approved, legally meaningful validation to allow for medical action. Conversely, medically actionable wearable sensors and devices sometimes provide continuous recording for relatively short time periods, up to

80 days, but do not span years and, further, must be paired with a smartphone or computer to offload and evaluate the recorded data, especially if the data is of urgent concern.

[0054] Wearable physiology monitors and activity sensors 104, also known as "activity monitors," and to a lesser extent, "fitness" sensor-equipped mobile devices 102, can trace their life-tracking origins to ambulatory devices used within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests. Data is typically tracked by the wearable physiology monitors or activity sensors 104 and mobile device 102 for only the personal use of the wearer. The physiological monitoring is strictly informational, even where a device originated within the medical community, and the data is generally not time-correlated to physician-supervised monitoring. Importantly, medically-significant events, such as cardiac rhythm disorders, including tachyarrhythmias, like ventricular tachycardia or atrial fibrillation, and bradyarrhythmias, like heart block, while potentially detectable with the appropriate diagnostic heuristics, are neither identified nor acted upon by the wearable physiology monitors and activity sensors 104 and the mobile device 102.

[0055] Frequently, wearable physiology monitors and activity sensors 104 are capable of wirelessly interfacing with mobile devices 102, particularly smart mobile devices, including so-called "smartphones" and "smart watches," as well as with personal computers and tablet or handheld computers, to download monitoring data either in real-time or in batches. The wireless interfacing of such activity monitors is generally achieved using transceivers that provide low-power, short-range wireless communications, such as Bluetooth, although some wearable physiology monitors and activity sensors 104, like their mobile device cohorts, have transceivers that provide true wireless communications services, including 4G or better mobile telecommunications, over a telecommunications network. Other types of wireless and wired interfacing are possible.

[0056] In a further embodiment, where the wearable physiology monitors and activity sensors 104 are paired with a mobile device 102, the mobile device 102 executes an application ("App") 103 that can retrieve the data collected by the wearable physiology monitor and activity sensor 104 and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Where the wearable physiology monitors and activity sensors 104 has sufficient onboard computational resources, the activity monitor itself executes an app without the need to relay data to a mobile device 102. The app can include or be supplemented by downloadable programming instructions, including machine learning and other forms

of artificial intelligence-originated instructions. The app can include heuristics to signal patient and physician with alerts over health conditions or arrhythmias of selected medical concern, such as where a heart pattern particular to the patient is identified and the mobile device 102, in collaboration with the ICM 12, is thereby reprogrammed to watch for a reoccurrence of that pattern, after which an alert will be generated and sent to the physician (or other caregiver). Similarly, the app can include heuristics that can actively identify or narrow down a pattern (or even the underlying cause) of sporadic cardiac conditions, for instance, atrial tachycardia (AT), atrial fibrillation (AF), atrial flutter (AFL), AV node reciprocating tachycardia, ventricular tachycardia (VT), sinus bradycardia, asystole, complete heart block, and other cardiac arrhythmias, again, after which an alert will be generated and sent to the physician (or other caregiver). For instance, an alert that includes a compressed ECG digitized sample can also be wirelessly transmitted by the app upon the triggering of a preset condition, such as an abnormally low heart rate in excess of 170 beats per minute (bpm), an abnormally low heart rate falling below 30 bpm, or AF detected by onboard analysis of RR interval variability by the app. Finally, a similar methodology of creating app programming tailored to the monitoring and medical diagnostic needs of a specific patient (or patient group or general population) can be used for other conditions or symptoms, such as syncope, palpitations, dizziness and giddiness, unspecified convulsions, abnormal ECG, transient cerebral ischemic attacks and related syndromes, cerebral infarction, occlusion and stenosis of pre-cerebral and cerebral arteries not resulting in cerebral infarction personal history of transient ischemic attack, and cerebral infarction without residual deficits, to trigger an alert and involve the physician or initiate automated analysis and follow up back at the patient's clinic. Still other activity monitor and mobile device functions on the collected data are possible.

[0057] In a yet further embodiment, a wearable physiology monitor, activity sensor 104, or mobile device 102 worn or held by the patient 10, or otherwise be used proximal to the patient's body, can be used to first obtain and then work collaboratively with the more definitive and capable ICM 12 to enable the collection of physiology by the ICM 12 before, during, and after potentially medically-significant events. The wearable physiology monitor, activity sensor 104, or mobile device 102 must be capable of sensing cardiac activity, particularly heart rate or rhythm, or other types of physiology or measures, either directly or upon review of relayed data. Where the wearable physiology monitor or activity sensor 104 is paired with a mobile device 102, the mobile device 102 serves as a relay device to trigger a medical alert upon detecting potentially medically-significant events in the data provided by the paired activity monitor, such as cardiac rhythm disorders, including tachyarrhythmias and bradyarrhythmias. Finally, if the wearable physiology monitor or activity sensor 104 has sufficient onboard computa-

tional resources and also is equipped with a wireless communications services transceiver, the wearable physiology monitor or activity sensor 104 effectively becomes the mobile device and executes an application (not shown) that will trigger the medical alert directly. Still other configurations of the detection app are possible.

[0058] In a still further embodiment, the monitoring data recorded by the ICM 12 can be uploaded directly into the patient's EMRs 97, either by using a mobile device 102 as a conduit for communications with the secure database 96 via the server 94, or directly to the server 94, if the ICM 12 is appropriately equipped with a wireless transceiver or similar external data communications interface. Thus, the data recorded by the ICM 12 would directly feed into the patient's EMRs 97, thereby allowing the data to be made certifiable for immediate use by a physician or authorized healthcare provider. No intermediate steps would be necessary when going from subcutaneously sensing cardiac electric signals and collecting the patient's physiology using a ICM 12 to presenting that recorded data to a physician or healthcare provider for medical diagnosis and care. The direct feeding of data from the ICM 12 to the EMRs 97 clearly establishes the relationship of the data, as recorded by the ICM 12, to the patient 10 that the physician is seeing and appropriately identifies any potentially medically-significant event recorded in the data as originating in the patient 10 and nobody else. Based on the monitoring data, physicians and healthcare providers can rely on the data as certifiable and can directly proceed with determining the appropriate course of treatment for the patient 10, including undertaking further medical interventions as appropriate.

[0059] In a yet further embodiment, the server 94 can evaluate the recorded data, as fed into the patient's EMRs 97, to refer the patient 10 for medical care to a general practice physician or medical specialist, for instance, a cardiac electrophysiologist referral from a cardiologist when the recorded data indicates an event of sufficient potential severity to warrant the possible implantation of a pacemaker for heart block or a defibrillator for ventricular tachycardia. Other uses of the data recorded by the ICM 12 are possible. For instance, a patient 10 who has previously suffered heart failure is particularly susceptible to ventricular tachycardia following a period of exercise or strenuous physical activity. A wearable sensor 104 or device 102 that includes a heart rate monitor would be able to timely detect an irregularity in heart rhythm. The application executed by the sensor 104 or device 102 allows those devices to take action by triggering the dispatch of a ICM 12 to the patient 10, even though the data recorded by the sensor 104 or device 102 is itself generally medically-insufficient for purposes of diagnosis and care. Thus, rather than passively recording patient data, the sensor 104 or device 102 takes on an active role in initiating the provisioning of medical care to the patient 10 and starts a cascade of appropriate medical interventions under the tutelage of and followed by physicians and trained healthcare professionals.

[0060] In a still further embodiment, based upon machine learning instructions executed by the ICM 12 that generates alerts over health conditions or arrhythmias of selected medical concern, the ICM 12 could upload an event detection application to the sensor 104 or device 102 to enable those devices to detect those types of potentially medically-significant events. Alternatively, the event detection application could be downloaded to the sensor 104 or device 102 from an online application store or similar online application repository. Finally, the ICM 12 could use the sensor 104 or device 102 to generate an appropriate alert, including contacting the patient's physician or healthcare services, via wireless (or wired) communications, upon detecting a potentially medically-significant event or in response to a patient prompting.

[0061] The mobile device 102 could also serve as a conduit for providing the data collected by the wearable physiology monitor or activity sensor 104 to a server 122, or, similarly, the wearable physiology monitor or activity sensor 104 could itself directly provide the collected data to the server 122. The server 122 could then merge the collected data into the wearer's EMRs 134 in the secure database 124, if appropriate (and permissible), or the server 122 could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology monitor or activity sensor 104. Still other server 122 functions on the collected data are possible.

[0062] Finally, in a yet further embodiment, the ICM 12 can be interrogated using a conventional inductive programmer 100, which could be interfaced to the application program 98 executing on a physician's device, or in a standalone fashion. Inductive interfacing may be necessary where the transceiver 85 has suffered an error condition or is otherwise unable to communicate externally.

[0063] The ICM 12 continuously monitors the patient's ECG, heart rate and physiology over a long period of time lasting up to several years in duration. FIGURE 10 is a flow diagram showing an ICM-implemented method 110 for monitoring ECG data. Initially, upon successful implantation, the microcontroller 61 executes a power up sequence (step 111). During the power up sequence, the voltage of the battery is checked, the state of the flash memory 62 is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed.

[0064] Following satisfactory completion of the power up sequence, an iterative processing loop (steps 112-121) is continually executed by the microcontroller 61. During each iteration (step 112) of the processing loop, the ECG frontend 63 (shown in FIGURE 11) continually senses the dermal ECG electrical signals (step 113, FIGURE 10) via the ECG electrodes 16 and 17 and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step 114) by the microcontroller 61 by sampling the analog ECG signal that is output by the ECG front end circuit 63. Each sampled

ECG signal, in quantized and digitized form, is processed by signal processing modules as specified in firmware (step 115), as described *infra*, and temporarily staged in a buffer (step 116), pending compression preparatory to storage in the flash memory 62 (step 117). Following compression, the compressed ECG digitized sample is again buffered (step 118), then written to the flash memory 62 (step 119) using the communications bus. In a further embodiment, an alert that includes the compressed ECG digitized sample can also be wirelessly transmitted upon the triggering of a preset condition (step 120), such as an abnormally low heart rate in excess of 170 beats per minute (bpm), an abnormally low heart rate falling below 30 bpm, or AF detected by onboard analysis of RR interval variability by the microcontroller 61. Processing continues for an indefinite duration (step 121). Still other operations and steps are possible.

[0065] The microcontroller 61 operates under modular micro program control that includes processing of raw analog ECG signals. FIGURE 11 is a functional block diagram showing the signal processing functionality 130 of the microcontroller 61. The microcontroller 61 operates under modular micro program control as specified in firmware 132. The firmware modules 132 include high and low pass filtering 133, and compression 134. Other modules are possible. The microcontroller 61 has a built-in ADC, although ADC functionality could also be provided in the firmware 132.

[0066] The ECG front end circuit 63 first outputs an analog ECG signal, which the ADC 131 acquires, samples and converts into an uncompressed digital representation. The microcontroller 61 includes one or more firmware modules 133 that perform filtering. In one embodiment, three low pass filters and two high pass filters are used. Following filtering, the digital representation of the cardiac activation wave front amplitudes are compressed by a compression module 134 before being written out to storage 135.

[0067] The download station 92 (shown in FIGURE 9) executes a data link program ("DL") 93 or similar program that wirelessly interfaces with the ILR 12 to retrieve the stored ECG monitoring data and perform other functions. FIGURE 12 is a functional block diagram showing the operations 140 performed by the download station 141. The download station 141 could be a server, personal computer (as shown), tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of wirelessly interfacing with a ICM 12. Still other forms of download station are possible, including download stations connected through indirect wireless interfacing using, for instance, a smart phone connected to the ICM 12 through Bluetooth or Wi-Fi, or over an inductive coupling.

[0068] The download station 141 is responsible for off-loading stored ECG monitoring data from a ICM 12. The download station 141 operates under programmable control as specified in software. The stored ECG monitoring data remotely retrieved from storage 142 on a ICM

12 is first decompressed by a decompression module 143, which converts the stored ECG monitoring data back into an uncompressed digital representation more suited to signal processing than a compressed signal.

5 The retrieved ECG monitoring data may be stored into local storage (not shown) for archival purposes, either in original compressed form, or as uncompressed.

[0069] The download station 141 can include an array of filtering modules. For instance, a set of phase distortion filtering tools 144 may be provided, where corresponding software filters can be provided for each filter implemented in the firmware executed by the microcontroller 61. The digital signals are run through the software filters in a reverse direction to remove phase distortion. For instance, a 45 Hertz high pass filter in firmware may have a matching reverse 45 Hertz high pass filter in software. Most of the phase distortion is corrected, that is, canceled to eliminate noise at the set frequency, but data at other frequencies in the waveform remain unaltered. As well, bidirectional impulse infinite response (IIR) high pass filters and reverse direction (symmetric) IIR low pass filters can be provided. Data is run through these filters first in a forward direction, then in a reverse direction, which generates a square of the response and cancels out any phase distortion. This type of signal processing is particularly helpful with improving the display of the ST-segment by removing low frequency noise.

[0070] An automatic gain control (AGC) module 145 can also be provided to adjust the digital signals to a usable level based on peak or average signal level or other metric. AGC is particularly critical to single-lead ECG monitors, where physical factors, such as the tilt of the heart, can affect the electrical field generated. On three-lead Holter monitors, the leads are oriented in vertical, horizontal and diagonal directions. As a result, the horizontal and diagonal leads may be higher amplitude and ECG interpretation will be based on one or both of the higher amplitude leads. In contrast, the ICM 12 has only a single lead that is oriented in the vertical direction, so variations in amplitude will be wider than available with multi-lead monitors, which have alternate leads to fall back upon.

[0071] In addition, AGC may be necessary to maintain compatibility with existing ECG interpretation software, which is typically calibrated for multi-lead ECG monitors for viewing signals over a narrow range of amplitudes. Through the AGC module 145, the gain of signals recorded by the ICM 12 of the electrocardiography monitor 12 can be attenuated up (or down) to work with FDA-approved commercially available ECG interpretation.

[0072] AGC can be implemented in a fixed fashion that is uniformly applied to all signals in an ECG recording, adjusted as appropriate on a recording-by-recording basis. Typically, a fixed AGC value is calculated based on how an ECG recording is received to preserve the amplitude relationship between the signals. Alternatively, AGC can be varied dynamically throughout an ECG recording, where signals in different segments of an ECG

recording are amplified up (or down) by differing amounts of gain.

[0073] Typically, the ICM 12 will record a high resolution, low frequency signal for the P-wave segment similar to the ICM's dermal cousin, such as provided with the dermal ambulatory monitors cited *supra*. However, for some patients, the result may still be a visually small signal. Although high resolution is present, the unaided eye will normally be unable to discern the P-wave segment. Therefore, gaining the signal is critical to visually depicting P-wave detail. This technique works most efficaciously with a raw signal with low noise and high resolution, as typically generated by the ICM 12. Automatic gain control applied to a high noise signal will only exacerbate noise content and be self-defeating.

[0074] Finally, the download station can include filtering modules specifically intended to enhance P-wave content. For instance, a P-wave based boost filter 146, which is a form of a preemphasis filter, can be applied to the signal to restore missing frequency content or to correct phase distortion. Still other filters and types of signal processing are possible.

[0075] In one embodiment, the ICM 12 can simply be inserted with a small surgical incision that is the width of the widest part of the ICM, typically the transverse cross section of the thickest aspect of the housing 15. Blunt dissection thereafter under local anesthesia can be used to create the subcutaneous space to receive the ICM 12, which would generally be inserted into the implantation site, proximal (housing) end first, followed by the distal (electrode assembly) end. In a further embodiment, the ICM 12 can be implanted in the patient's chest using, for instance, a minimally invasive subcutaneous implantation instrument, such as described in U.S. Patent No. 6,436,068, issued August 20, 2002 to Bardy, the disclosure of which is incorporated by reference.

[0076] While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the scope.

Claims

1. A P-wave centric subcutaneous insertable cardiac monitor (ICM) (12, 30) for use in performing long term electrocardiographic (ECG) monitoring, comprising:

- an implantable housing (15, 31) comprised of a biocompatible material that is suitable for implantation within a living body (10);
- at least one pair of ECG sensing electrodes (18, 19, 34, 35, 36) provided on a ventral surface and on opposite ends of the implantable housing (15, 31) operatively placed to facilitate sensing in closest proximity to the low amplitude, low fre-

quency content cardiac action potentials that are generated during atrial activation; and electronic circuitry (80) provided within the housing assembly (15, 31) comprising a low power microcontroller (81) operable to execute under modular micro program control as specified in firmware (132), an ECG front end circuit (83) interfaced to the microcontroller (81) and configured to capture the cardiac action potentials sensed by the pair of ECG sensing electrodes (18, 19, 34, 35, 36) which are output as ECG signals, and non-volatile memory (82) electrically interfaced with the microcontroller (81) and operable to continuously store samples of the ECG signals.

2. A subcutaneous insertable cardiac monitor (12) in accordance with Claim 1, further comprising:

- at least one further ECG sensing electrode (22, 23) further provided on the ventral surface of the implantable housing assembly (15), wherein the firmware (132) comprises programmatic selection of one or more pairings of the ECG sensing electrodes (18, 19, 22, 23).

3. A subcutaneous insertable cardiac monitor (12) in accordance with Claim 1, further comprising:

- at least one further ECG sensing electrode (16, 17, 33) further provided to wraparound an end of the implantable housing (15) circumferentially about one of the pair of ECG sensing electrodes (18, 19, 35), continue around the sides and ends of the implantable housing (15), and over the planar surface of the implantable housing (15), wherein the firmware (132) comprises programmatic selection of one or more pairings of the ECG sensing electrodes (16, 17, 18, 19, 33, 34, 35, 36).

4. A subcutaneous insertable cardiac monitor (12) in accordance with Claim 3, further comprising:

- a periphery (20, 21, 37) interposed between the at least one further ECG sensing electrode (16, 17, 35) and the ECG sensing electrode (18, 19, 35) about which the at least one further ECG sensing electrode (16, 17, 33) is circumferentially provided, wherein the firmware (132) comprises programmatic control over the electrically insulative properties of the periphery.

5. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, wherein at least one of the ECG sensing electrodes (18, 19, 34, 35, 36), is dissimilar from the other ECG sensing

electrode (18, 19, 35, 36) with respect to one or more of electrode size, shape, surface area, and placement.

6. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, wherein the ECG front end circuit (83) is optimized to sense P-wave signals in the cardiac action potentials.

7. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, the electronic circuitry (80) further comprising:

a transceiver (85) operable to wirelessly interface to an external device (92) through which to at least one of provide the samples of the ECG signals from the non-volatile memory (82) and receive modular micro program control into the firmware (132).

8. A subcutaneous insertable cardiac monitor (12, 30) in accordance with Claim 7, wherein the firmware (132) comprises instructions operable to program the microcontroller (81) to perform the steps comprising:

monitoring the cardiac action potentials sensed by the pair of ECG sensing electrodes (18, 19, 34, 35 36) for arrhythmias of selected medical concern and wirelessly sending an alert via the transceiver (85) upon the occurrence of one of the arrhythmias of selected medical concern; executing heuristics to actively identify or narrow down a pattern or underlying cause of sporadic cardiac conditions and wirelessly sending an alert via the transceiver (85) upon the occurrence of one of the pattern and the underlying cause; executing programming tailored to the monitoring and medical diagnostic needs of at least one of a specific patient, patient group or general patient population of conditions or symptoms of medical concern and wirelessly sending an alert via the transceiver (85) upon the occurrence of one of the conditions or symptoms of medical concern.

9. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, further comprising:

a patient-interfaceable component (67) selected from the group comprising an external tactile feedback device that wirelessly interfaces to the ICM through the transceiver and an external buzzer (67) implemented as part of the external tactile feedback device or as a separate wirelessly-interfaceable component.

10. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, the pair of ECG sensing electrodes (18, 19, 34, 35, 36) further comprising:

an electrode configuration defining an electrode-to-electrode spacing of between 20 mm to 200 mm.

11. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, the pair of ECG sensing electrodes further comprising:

an electrode shape comprising a round disc from 2 mm to 10 mm in diameter.

12. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, the pair of ECG sensing electrodes (18, 19, 35, 36) further comprising:

an electrode shape selected from the group comprising circumferentially-shaped and asymmetrically-shaped electrodes.

13. A subcutaneous insertable cardiac monitor (12) in accordance with any preceding claim, wherein the housing assembly comprises (15) a hermetically sealed implantable housing defining a rectangular shape with rounded edges.

14. A subcutaneous insertable cardiac monitor (30) according to claim 13, wherein the rectangular shape has a tapered extension (32) that is terminated on the distal end with one of the pair of ECG sensing electrodes (34).

15. A subcutaneous insertable cardiac monitor (12, 30) in accordance with any preceding claim, further comprising:

a physiology sensor comprised within the housing assembly and electrically coupled to the circuitry with the physiological sensor operable to sense physiology of the living body; and the non-volatile memory (82) further operable to store samples of the physiology sensed by the physiology sensor.

Fig. 1.

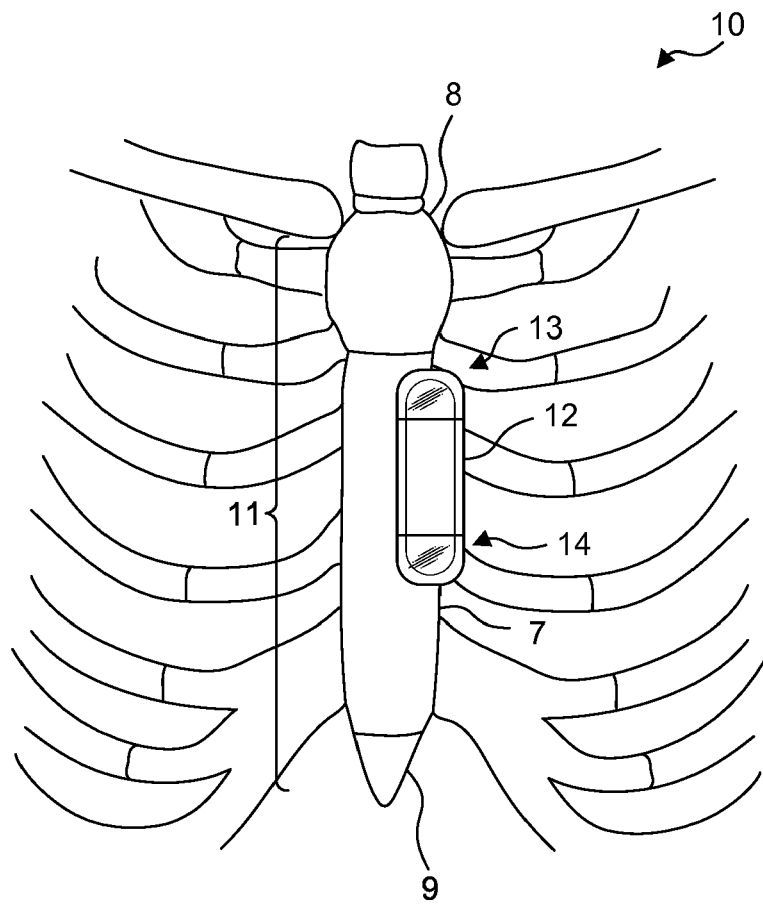


Fig. 2.

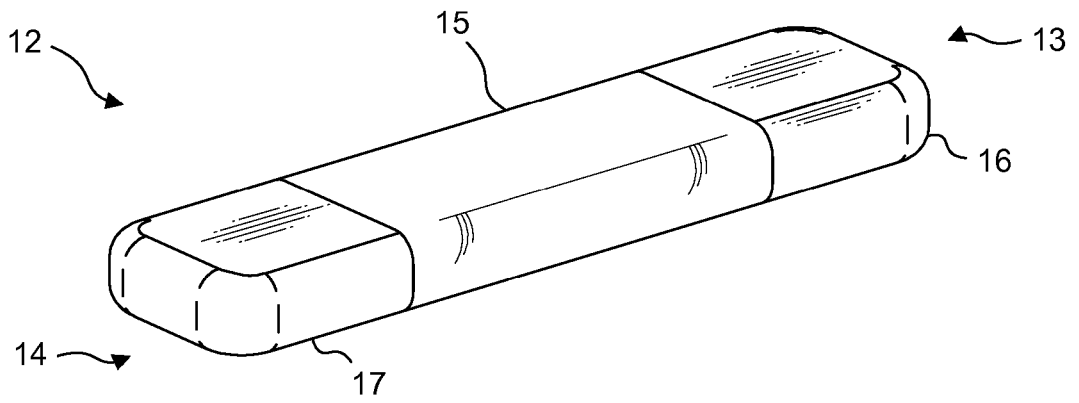


Fig. 3.

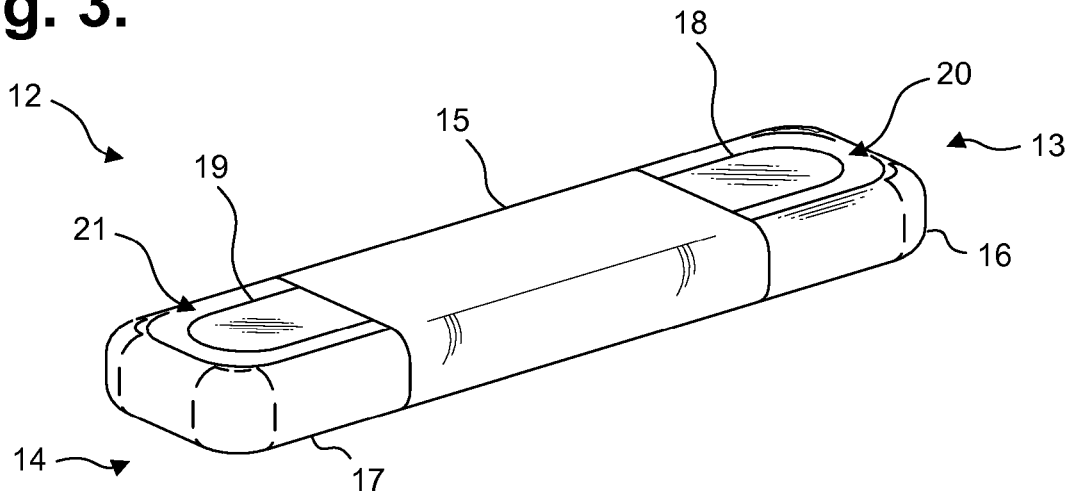


Fig. 4.

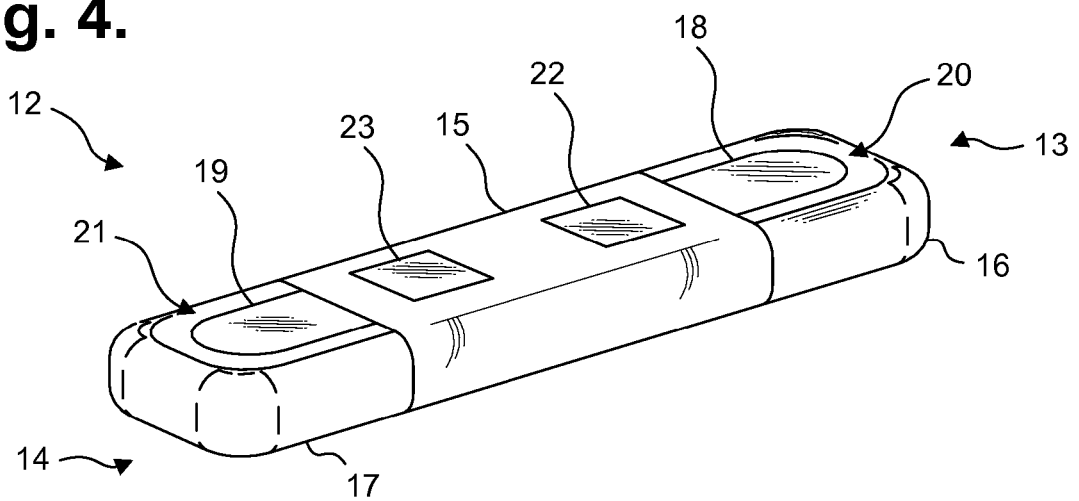


Fig. 5.

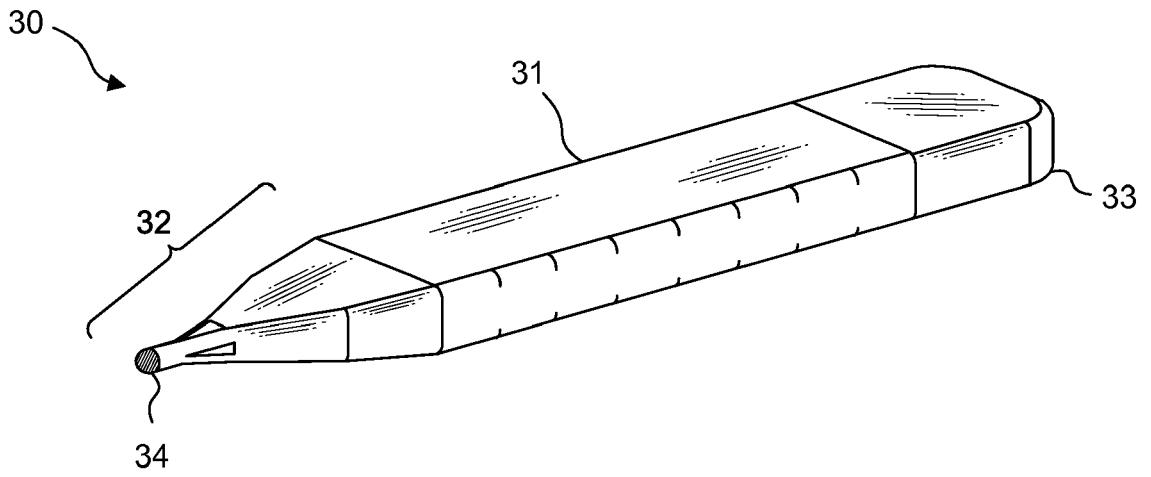


Fig. 6.

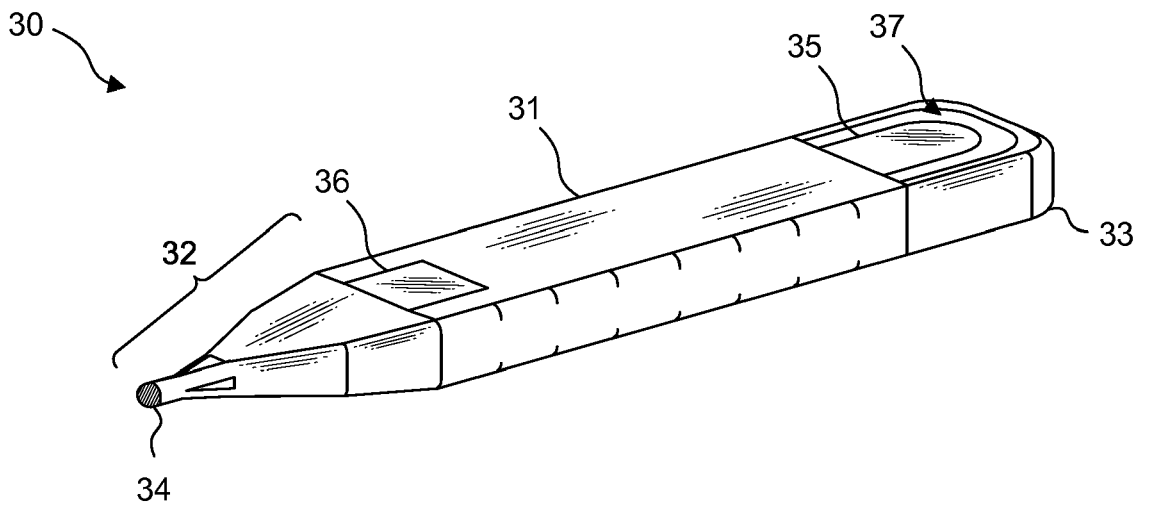


Fig. 7.

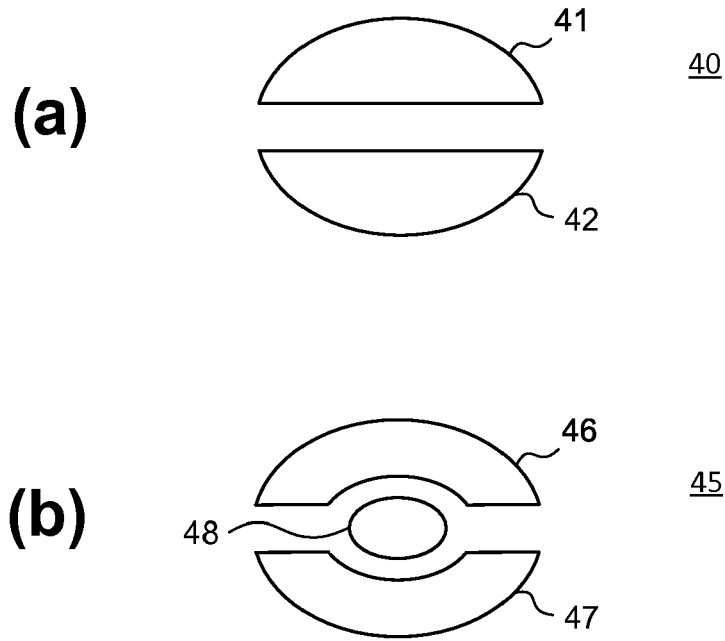


Fig. 8.

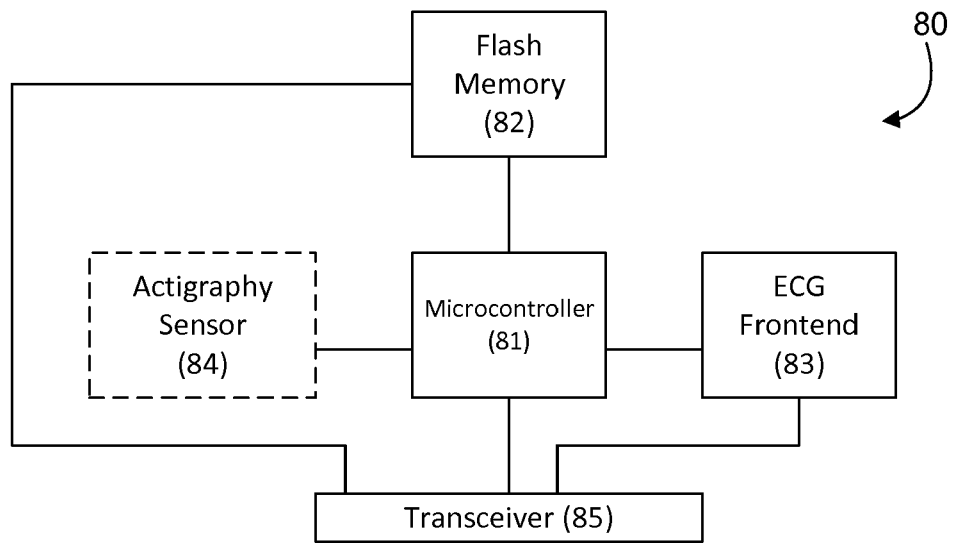


Fig. 9.

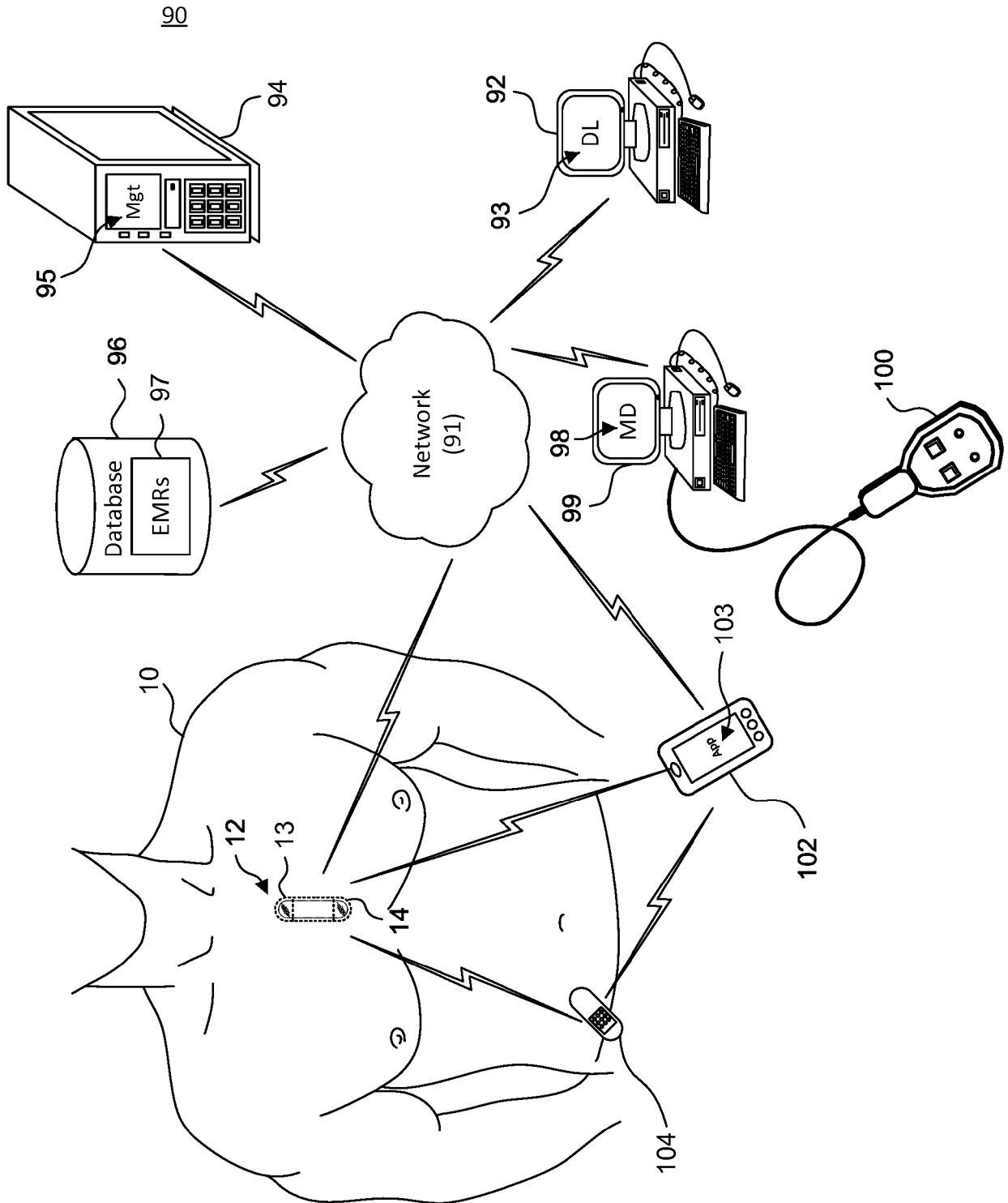


Fig. 10.

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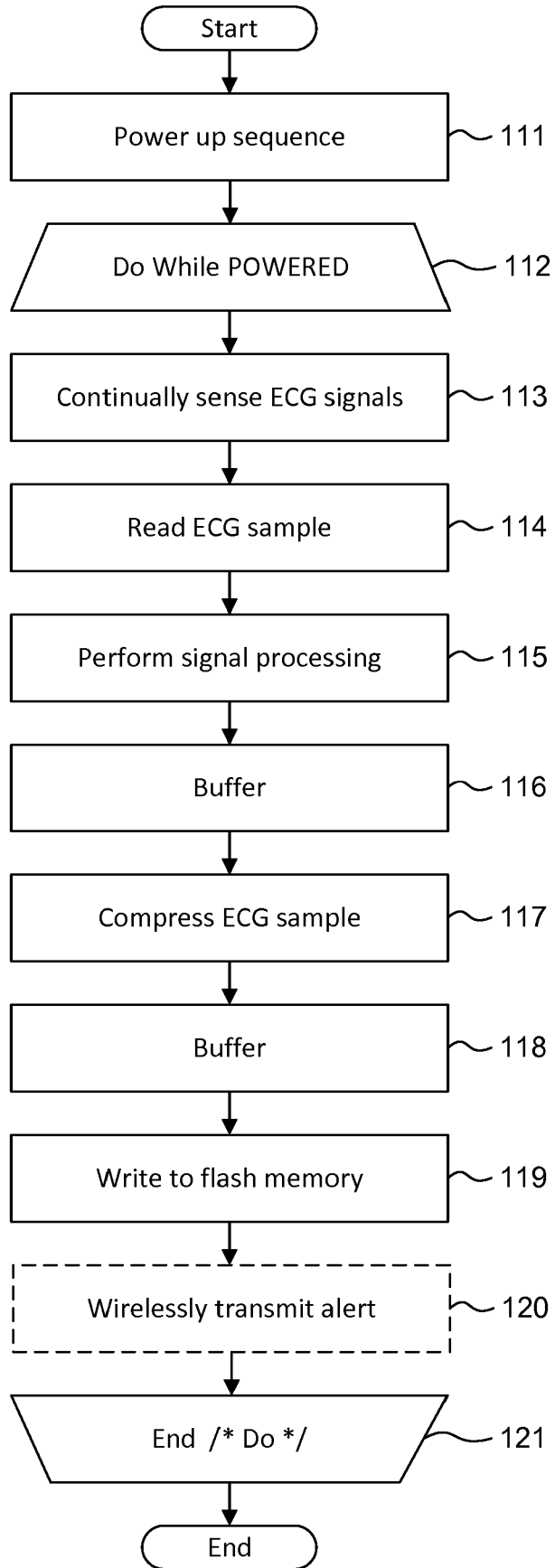


Fig. 11.

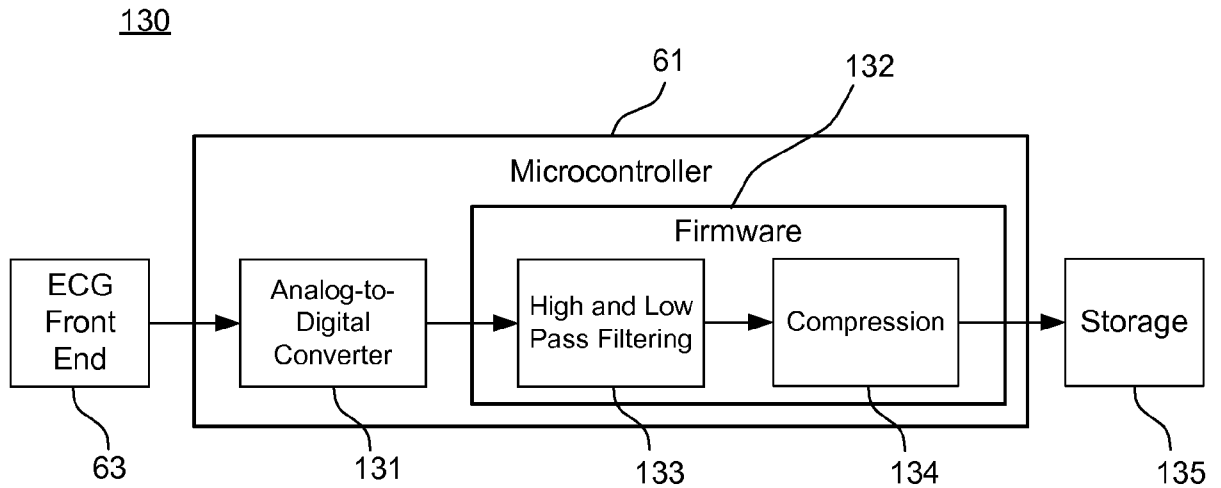
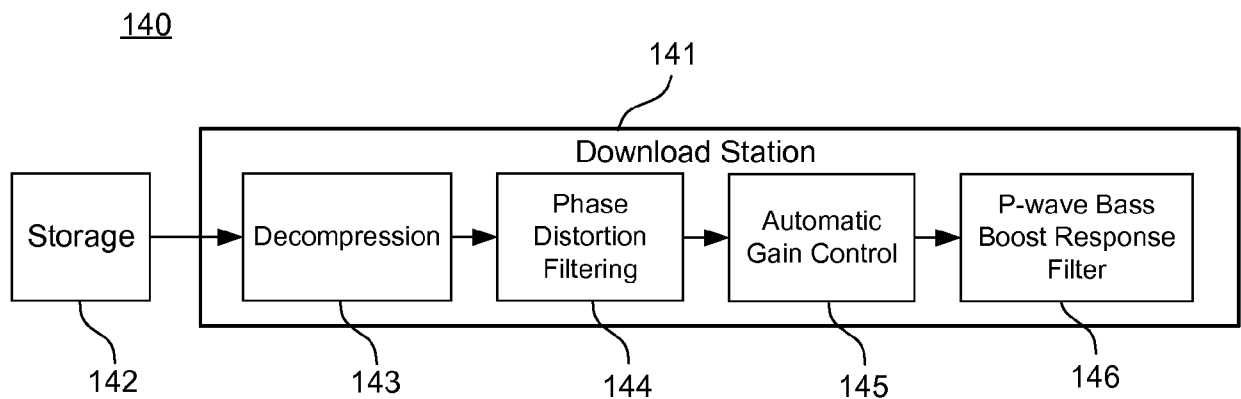


Fig. 12.





EUROPEAN SEARCH REPORT

Application Number
EP 18 20 9920

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2016/144190 A1 (CAO JIAN [US] ET AL) 26 May 2016 (2016-05-26) * abstract; figures 1-4, 7-11 * * paragraphs [0005] - [0009], [0025] - [0069], [0097] - [0130] * -----	1-15	INV. A61B5/00 A61B5/042 A61B5/0428 A61B5/0452 A61B5/0205
X	US 2016/235318 A1 (SARKAR SHANTANU [US]) 18 August 2016 (2016-08-18) * abstract; figures 1-9 * * paragraphs [0016] - [0075] * -----	1,6-9, 11-15	
X	US 2009/270747 A1 (VAN DAM PETER [NL] ET AL) 29 October 2009 (2009-10-29) * abstract; figures 1-4 * * paragraphs [0011] - [0036] * -----	1-15	
X	US 2013/325081 A1 (KARST EDWARD [US] ET AL) 5 December 2013 (2013-12-05) * abstract; figures 1-13 * * paragraphs [0021] - [0022], [0042] - [0120] * -----	1-15	
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (IPC) A61B A61N
Place of search The Hague		Date of completion of the search 26 February 2019	Examiner Carta, Riccardo
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

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5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

26-02-2019

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专利名称(译)	皮下p波中心可插入式心脏监护仪，用于长期心电图监测		
公开(公告)号	EP3494871A1	公开(公告)日	2019-06-12
申请号	EP2018209920	申请日	2018-12-03
[标]申请(专利权)人(译)	BARDY诊断		
申请(专利权)人(译)	BARDY诊断，INC.		
当前申请(专利权)人(译)	BARDY诊断，INC.		
[标]发明人	BARDY GUST H		
发明人	BARDY, GUST H.		
IPC分类号	A61B5/00 A61B5/042 A61B5/0428 A61B5/0452 A61B5/0205		
CPC分类号	A61B5/0006 A61B5/0031 A61B5/0205 A61B5/042 A61B5/0428 A61B5/0452 A61B5/686 A61B2560/0209 A61B2560/0481 A61B2562/162 A61B5/02055 A61B5/0215 A61B5/0422 A61B5/04325 A61B5/076 A61B5/0816 A61B5/14532 A61B5/14542 A61B5/746		
代理机构(译)	HANNA MOORE + CURLEY		
优先权	15/832385 2017-12-05 US		
外部链接	Espacenet		

摘要(译)

公开了一种用于执行长期心电图 (ECG) 监测的P波中心皮下可插入心脏监测器 (12,30)。提供了由生物相容性材料制成的可植入壳体 (15,31)。至少一对ECG感测电极 (18,19,34,35,36) 设置在腹侧 (或背侧) 表面上，并且位于可植入壳体 (15,31) 的相对端上，可操作地放置以便于在最接近的附近进行感测。在心房激动期间产生的低振幅，低频含量的心脏动作电位。电子电路 (80) 设置在壳体组件内，包括低功率微控制器 (81)，其可操作以在固件 (132) 中指定的模块化微程序控制下执行，ECG前端电路 (83) 连接到微控制器 (81)。并且被配置为捕获由作为ECG信号输出的ECG感测电极对18,19,34,35,36感测到的心脏动作电位，以及与微控制器 (81) 电连接的非易失性存储器 (82) 和可操作以连续存储ECG信号的样本。

Fig. 1.

