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(54) **INSERTABLE CARDIAC MONITOR FOR USE IN PERFORMING LONG TERM ELECTROCARDIOGRAPHIC MONITORING**

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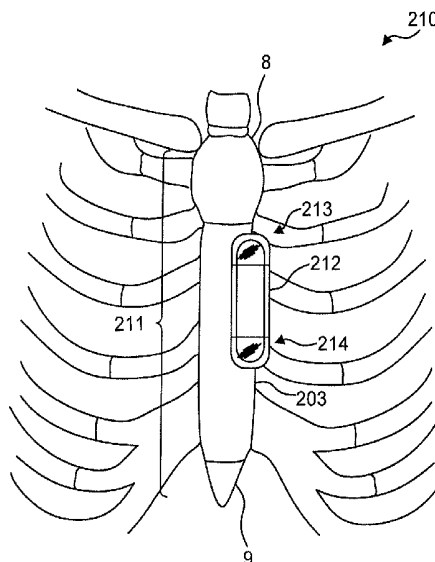
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(57) **ABSTRACT**

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 and storing samples of captured signals. In general, the ICM is intended to be implanted centrally and positioned axially and either over the sternum or slightly to either the left or right of the sternal midline in the parasternal region of the chest.

18 Claims, 10 Drawing Sheets



Related U.S. Application Data

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Fig. 1.

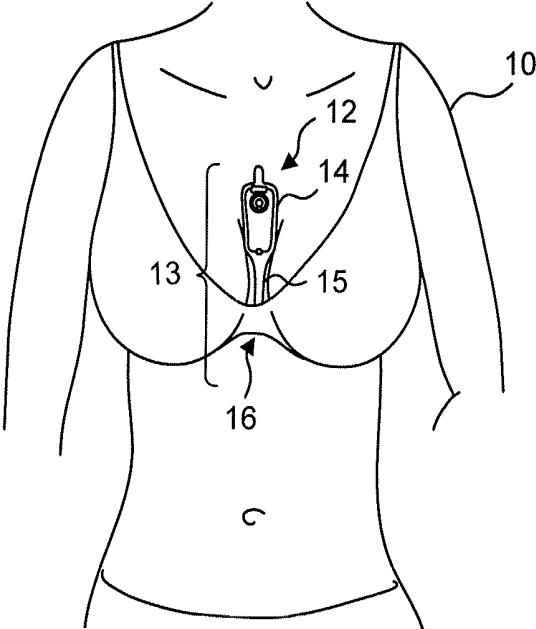


Fig. 2.

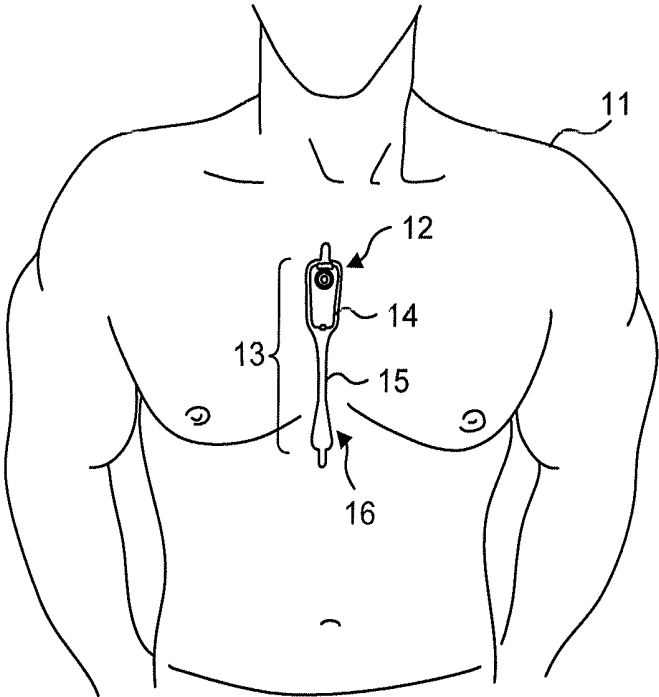


Fig. 3.

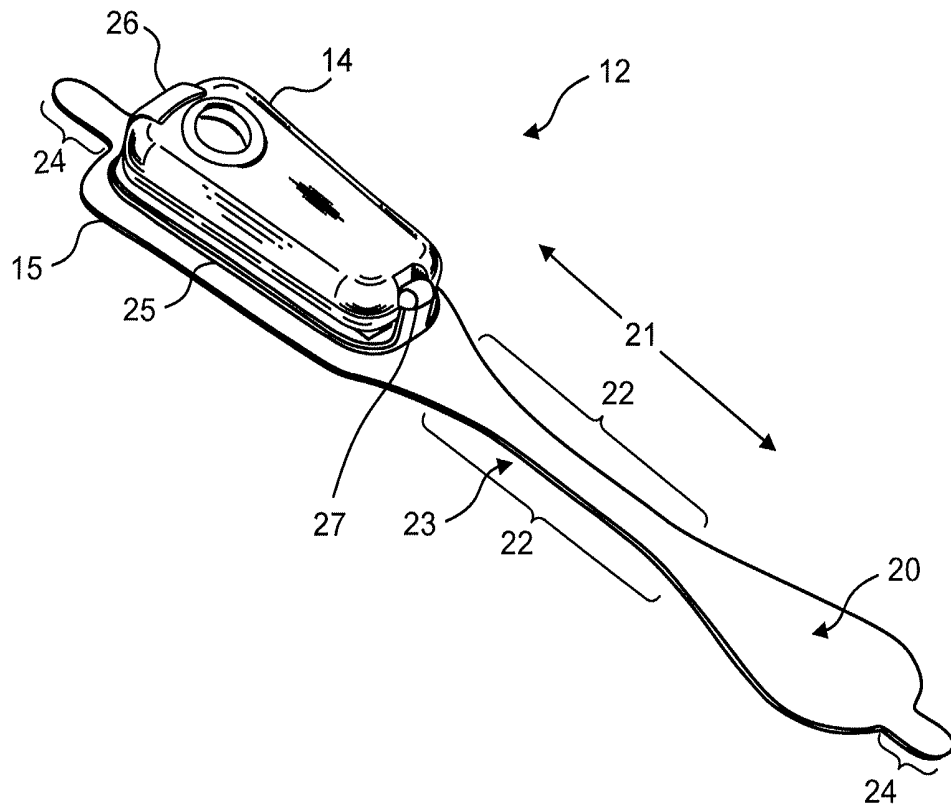


Fig. 4.

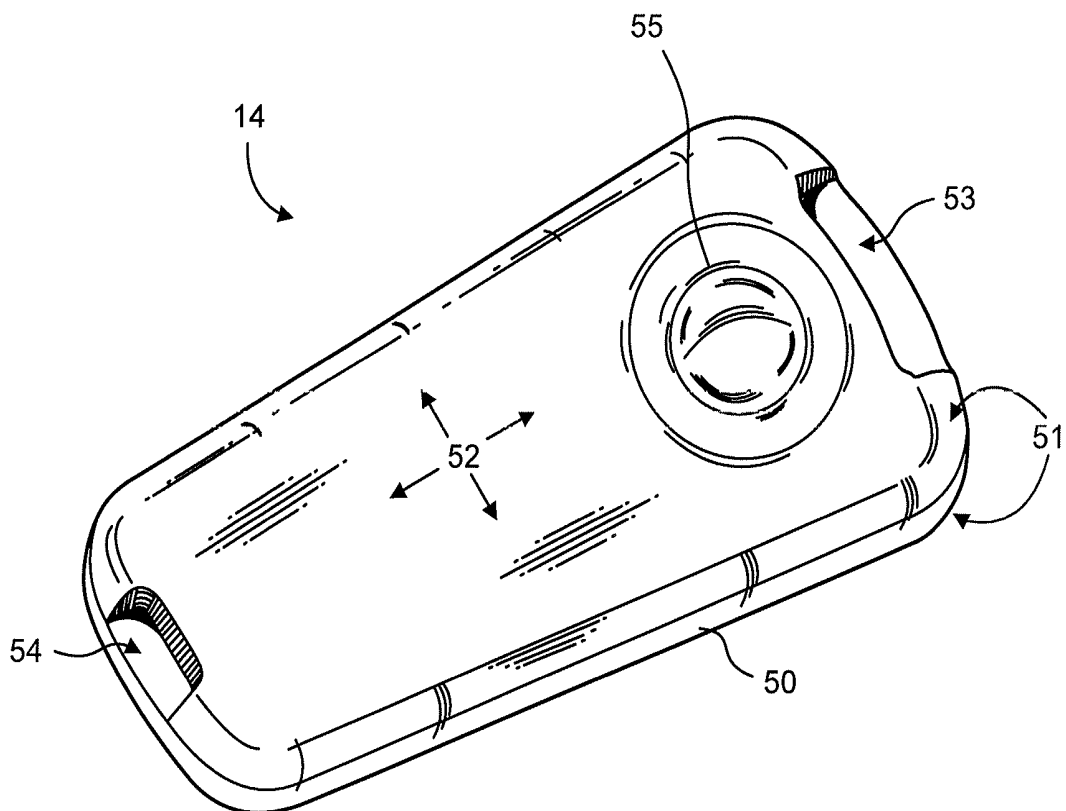


Fig. 5.

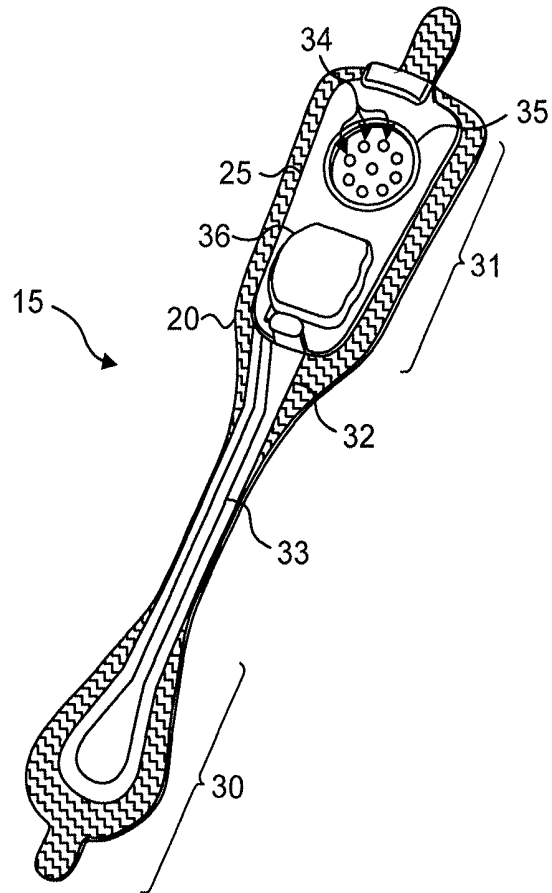


Fig. 6.

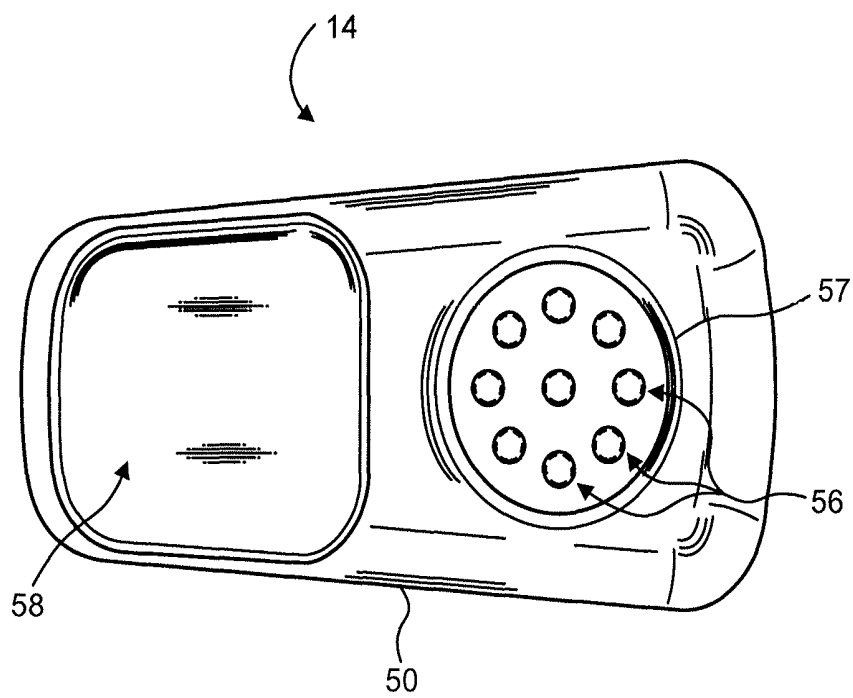


Fig. 7.

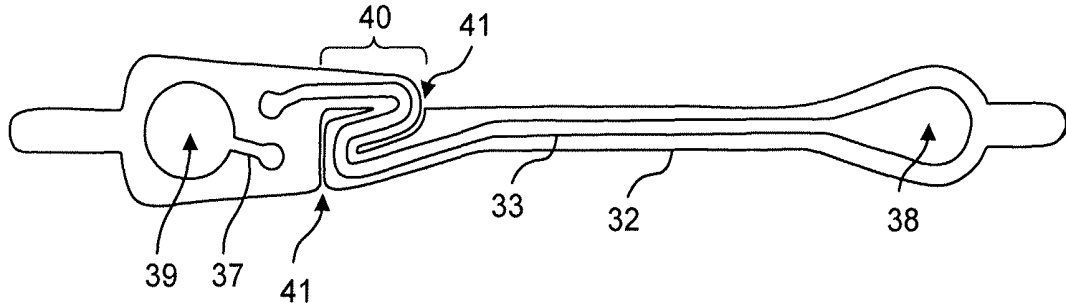


Fig. 8.

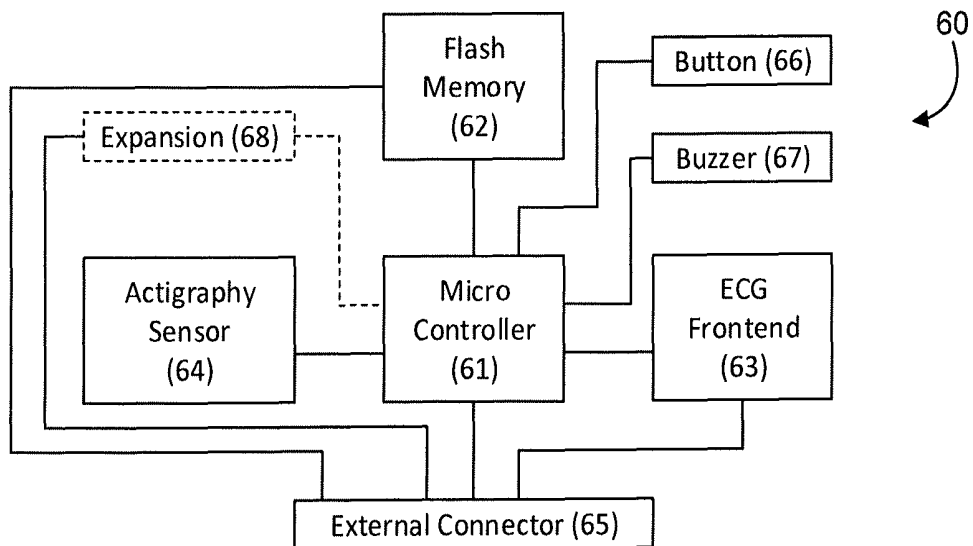


Fig. 9.

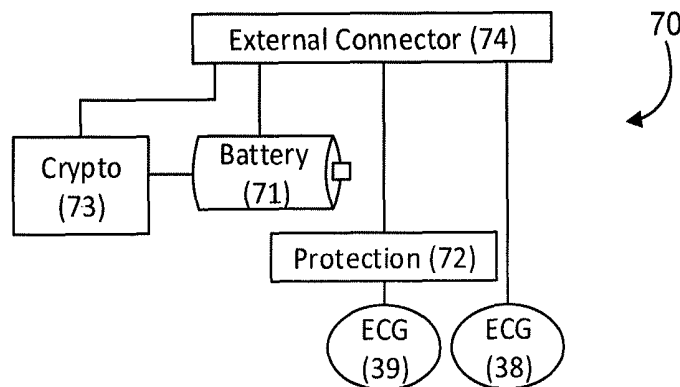


Fig. 10.

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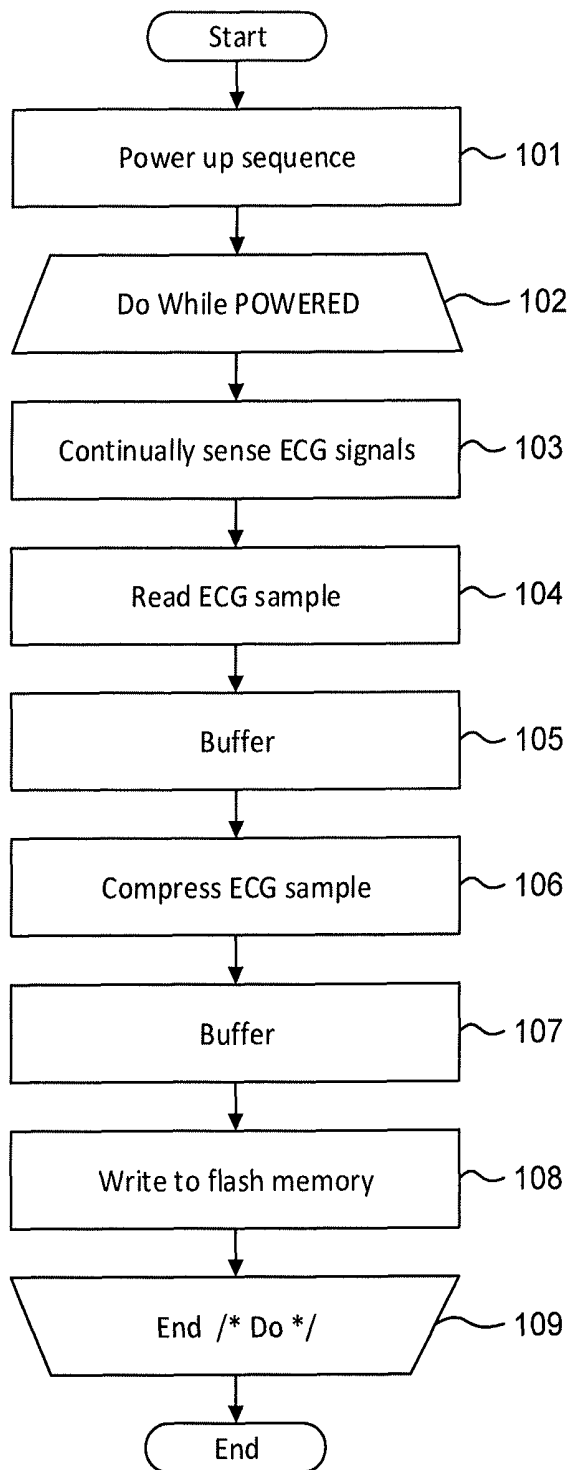


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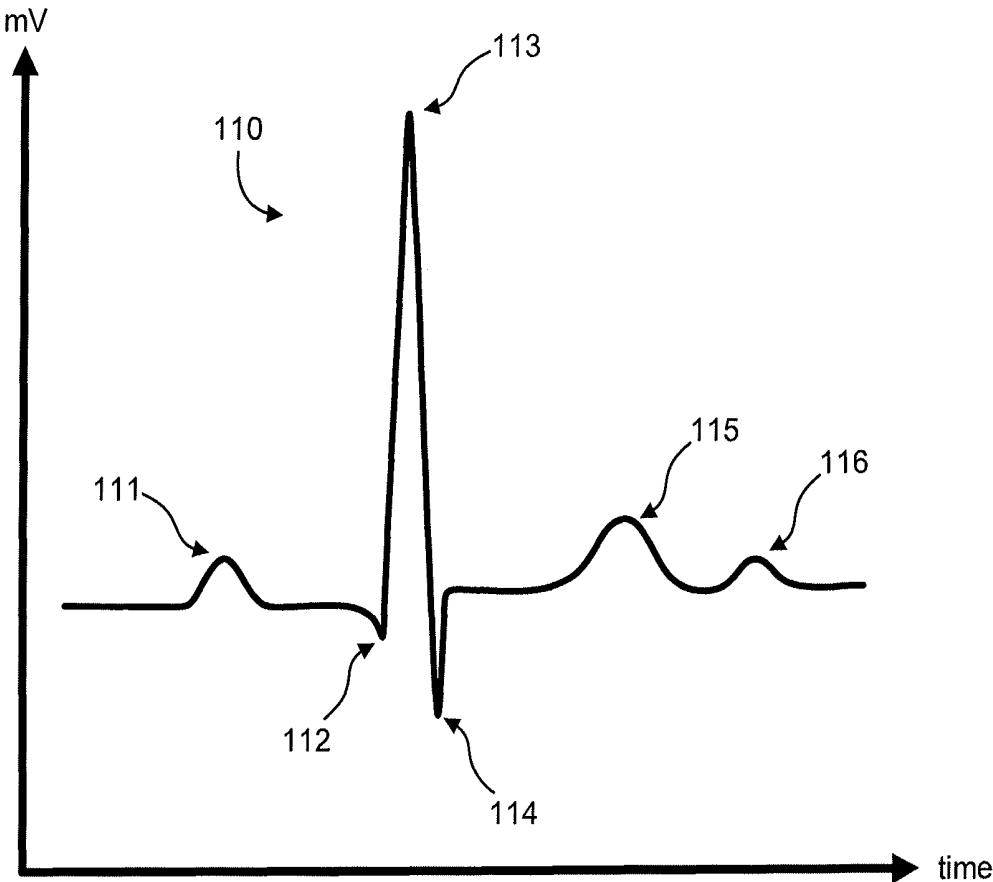


Fig. 12.

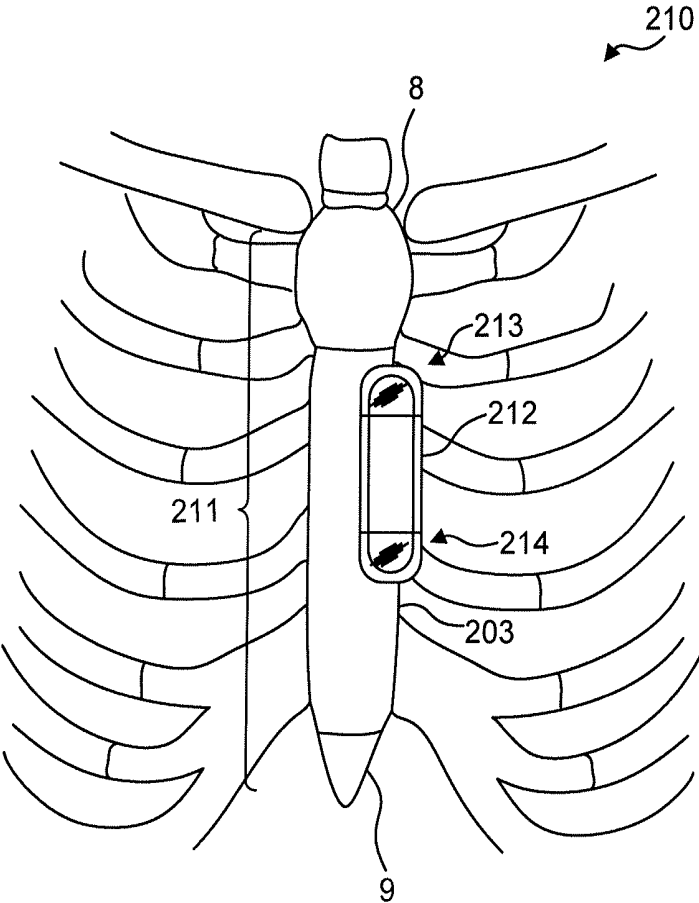


Fig. 13.

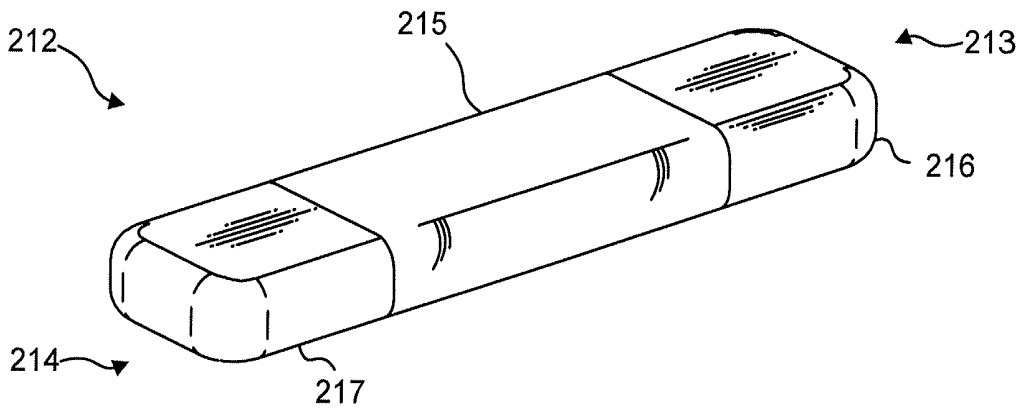


Fig. 14.

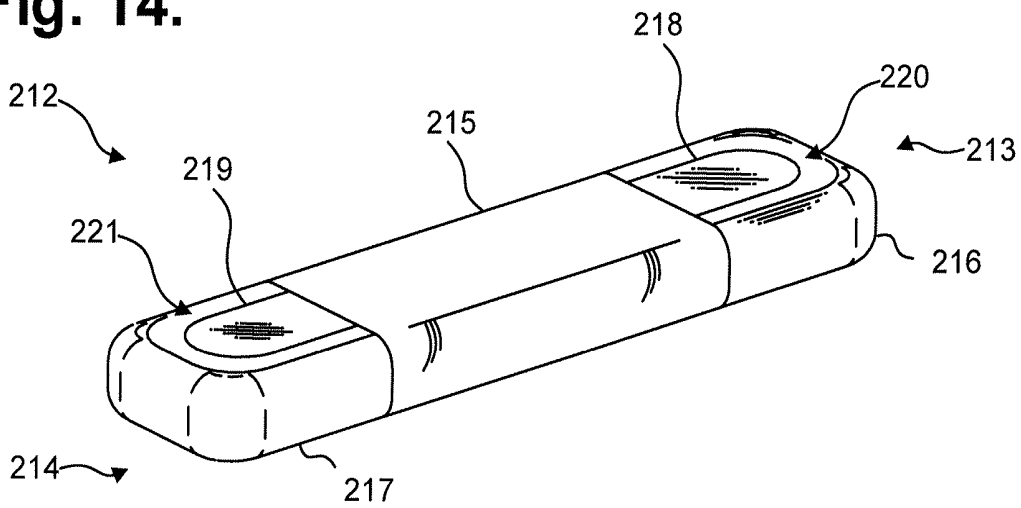


Fig. 15.

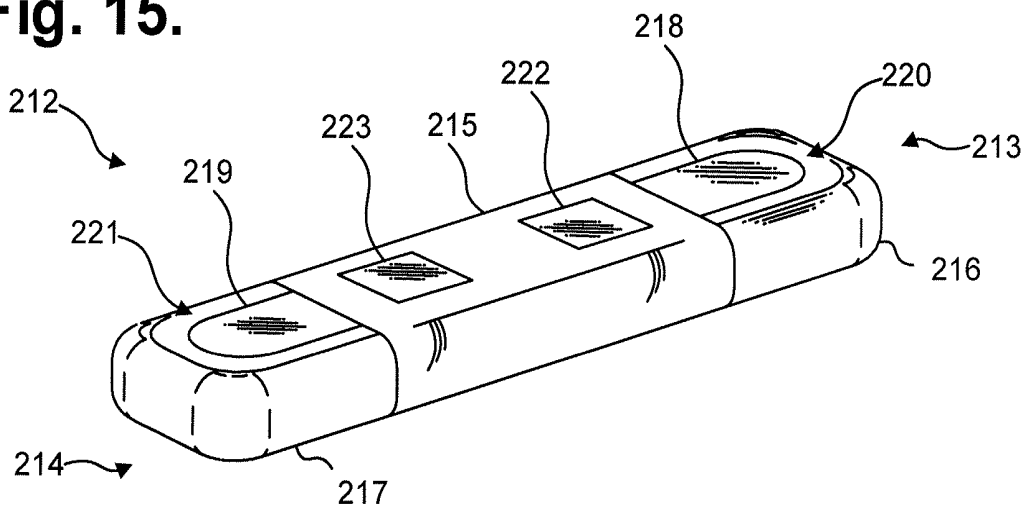


Fig. 16.

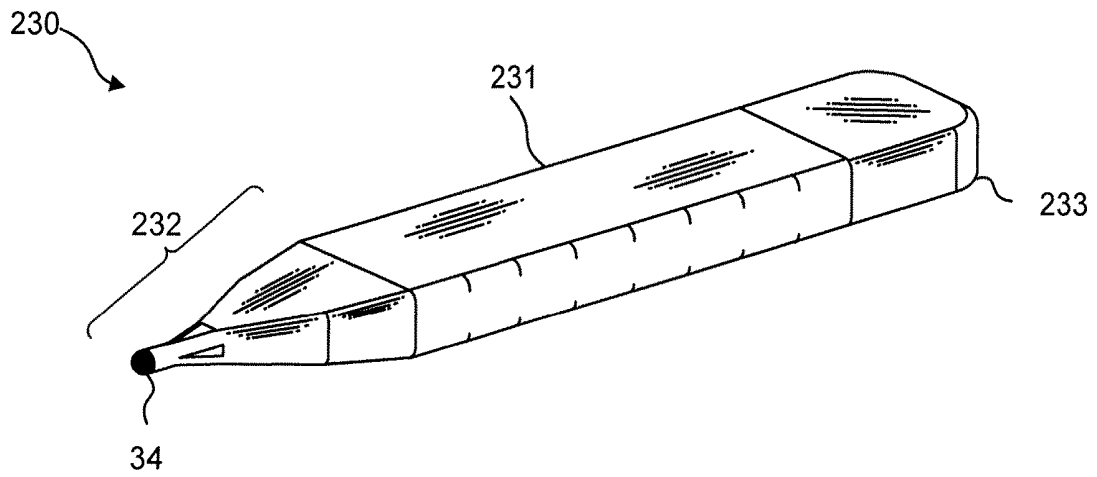


Fig. 17.

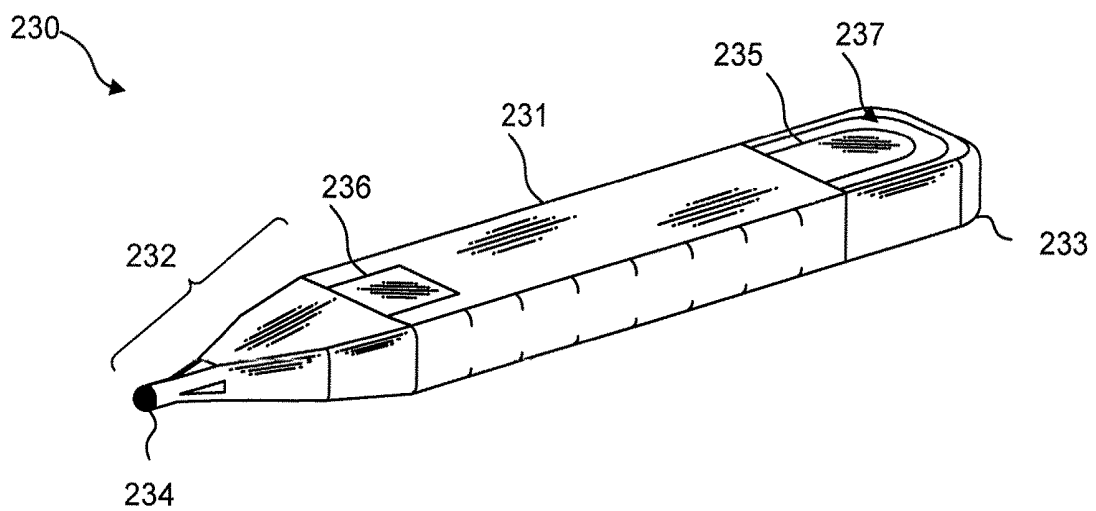


Fig. 18.

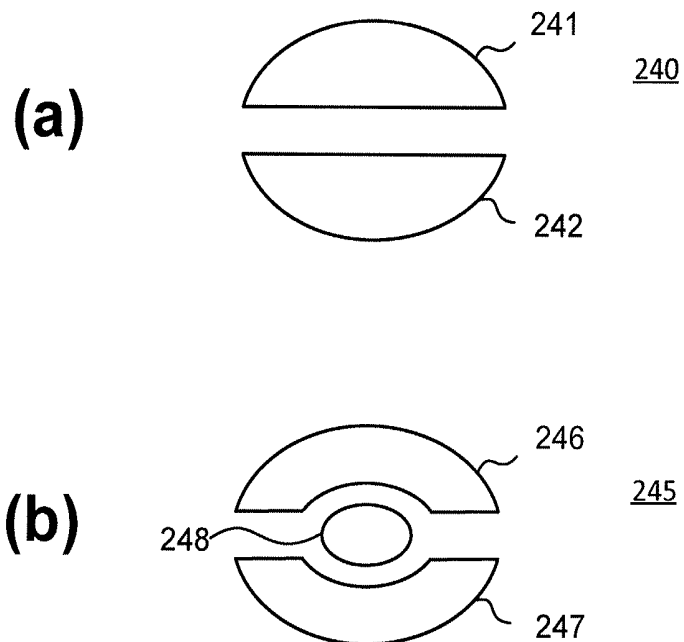
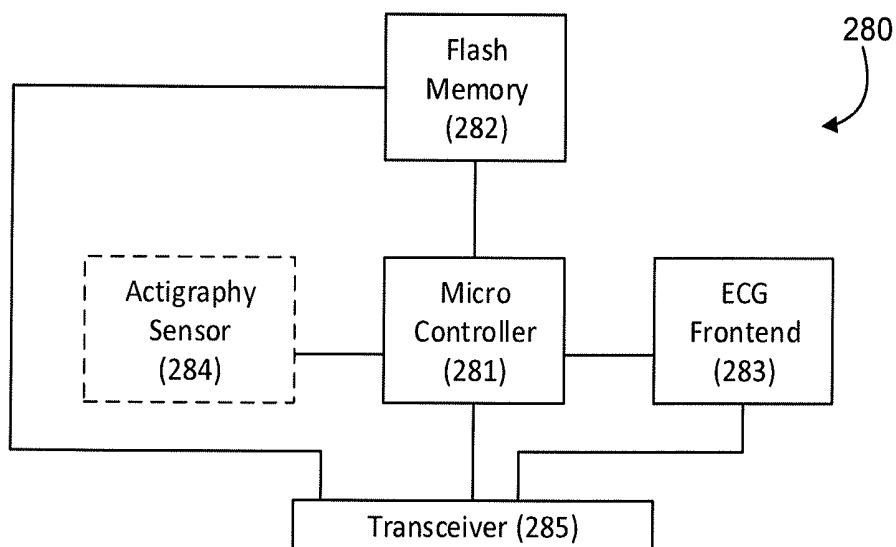


Fig. 19.



**INSERTABLE CARDIAC MONITOR FOR
USE IN PERFORMING LONG TERM
ELECTROCARDIOGRAPHIC MONITORING**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This non-provisional patent application is a continuation-in-part of U.S. Pat. No. 10,478,083, issued Nov. 19, 2019, which is continuation of U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, and further claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent application, Ser. No. 61/882,403, filed Sep. 25, 2013, the filing dates of which are claimed and the disclosures of which are incorporated by reference; this present non-provisional patent application is also a continuation-in-part of U.S. patent application Ser. No. 15/832,385, filed Dec. 5, 2017, pending, the disclosure of which is incorporated by reference.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an insertable cardiac monitor for use in performing long term electrocardiographic monitoring.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG, that is of a quality sufficient to be useful in arrhythmia diagnosis, and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern.

A 30-day observation day period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of dermal ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Notwithstanding the cause of electrode dislodgment, depending upon the type of ECG monitor employed, precise re-placement of a dislodged ECG electrode maybe essential to ensuring signal capture at the same fidelity. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

While subcutaneous ECG monitors can perform monitoring for an extended period of time, up to three years, such 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.

Conventional ICMs 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.

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, Minn., 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, Ill., all are uniformly limited in their abilities to clearly and consistently sense, record, and deliver the P-wave.

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.

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 subcutaneous 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.

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.

Therefore, a need remains for a continuously recording ECG monitor practicably capable of being worn capable of recording atrial signals reliably and that is designed for atrial activity recording.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum. In addition, power is provided through a battery provided on the electrode patch, which avoids having to either periodically open the housing of the monitor recorder for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder off line for hours at a time. In addition, the electrode patch is intended to be disposable, while the monitor recorder is a reusable component. Thus, each time that the electrode patch is replaced, a fresh battery is provided for the use of the monitor recorder.

Further, 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), such as one described in commonly-owned U.S. patent application Ser. No. 15/832,385, filed Dec. 5, 2017, pending, the disclosure of which is incorporated by reference. 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.

In one embodiment, an insertable cardiac monitor (ICM) for use in performing long term electrocardiographic (ECG) monitoring is provided. The monitor includes; an implantable housing included of a biocompatible material that is suitable for implantation within a living body; at least one pair of ECG sensing electrodes provided on a ventral 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; and electronic circuitry provided within the housing assembly. The electronic circuitry includes an ECG front end circuit interfaced to a low-power microcontroller and configured to capture

the cardiac action potentials sensed by the pair of ECG sensing electrodes which are output as ECG signals; the low power microcontroller operable to execute under modular micro program control as specified in firmware, the microcontroller operable to read samples of the ECG signals, buffer the samples of the ECG signals, compress the buffered samples of the ECG signals, buffer the compressed samples of the ECG signals, and write the buffered samples into a non-volatile flash memory; and the non-volatile memory electrically interfaced with the microcontroller and operable to store the written samples of the ECG signals.

In a further embodiment, a subcutaneous implantable loop recorder for long term electrocardiographic (ECG) monitoring is provided. The recorder includes an implantable housing included of a biocompatible material that is suitable for implantation within a living body; an implantable electrode assembly included of a biocompatible substrate that is suitable for implantation within the living body and which extends distally outwards from the housing along a narrow profile with a rounded end; an upper ECG electrode formed on a posterior surface of the housing; a lower ECG electrode formed on a posterior surface at a distal aspect of the electrode assembly and electrically coupled to a circuit trace provided along the electrode assembly and connecting into the housing; and electronic circuitry provided within the housing. The electronic circuitry includes an ECG front end circuit interfaced to a low-power microcontroller and configured to capture the cardiac action potentials sensed by the pair of ECG sensing electrodes which are output as ECG signals; the low power microcontroller operable to execute under modular micro program control as specified in firmware, the microcontroller operable to read samples of the ECG signals, buffer the samples of the ECG signals, compress the buffered samples of the ECG signals, buffer the compressed samples of the ECG signals, and write the buffered samples into a non-volatile flash memory; and the non-volatile memory electrically interfaced with the microcontroller and operable to store the written samples of the ECG signals.

The foregoing aspects enhance ECG monitoring performance and quality facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

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

FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor, including a monitor recorder in accordance with one embodiment, respectively fitted to the sternal region of a female patient and a male patient.

FIG. 3 is a perspective view showing an extended wear electrode patch with a monitor recorder in accordance with one embodiment inserted.

FIG. 4 is a perspective view showing the monitor recorder of FIG. 3.

FIG. 5 is a perspective view showing the extended wear electrode patch of FIG. 3 without a monitor recorder inserted.

FIG. 6 is a bottom plan view of the monitor recorder of FIG. 3.

FIG. 7 is a top view showing the flexible circuit of the extended wear electrode patch of FIG. 3 when mounted above the flexible backing.

FIG. 8 is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. 3.

FIG. 9 is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. 3.

FIG. 10 is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. 3.

FIG. 11 is a graph showing, by way of example, a typical ECG waveform.

FIG. 12 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.

FIGS. 13 and 14 are respectively top and bottom perspective views showing the ICM of FIG. 12.

FIG. 15 is a bottom perspective view showing the ICM of FIG. 12 in accordance with a further embodiment.

FIGS. 16 and 17 are respectively top and bottom perspective views showing an ICM in accordance with a still further embodiment.

FIG. 18(a) and FIG. 18(b) are plan views showing further electrode configurations.

FIG. 19 is a functional block diagram showing the P-wave focused component architecture of the circuitry 280 of the ICM 212 of FIG. 12.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor 12, including a monitor recorder 14 in accordance with one embodiment, respectively fitted to the sternal region of a female patient 10 and a male patient 11. The wearable monitor 12 sits centrally (in the midline) on the patient's chest along the sternum 13 oriented top-to-bottom with the monitor recorder 14 preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor 12 can be corrected post-monitoring, as further described infra. The electrode patch 15 is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline 16 (or immediately to either side of the sternum 13). The distal end of the electrode patch 15 extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch 15, located under the monitor recorder 14, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor 12 in a location at the sternal midline 16 (or immediately to either side of the sternum 13) significantly improves the ability of the wearable monitor 12 to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG wave-

forms that indicate ventricular activity. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of right ventricular activity and provides superior recordation of the QRS interval.

During use, the electrode patch **15** is first adhered to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **3** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal ends of the electrode patch **15** create a narrow longitudinal midsection **23** or “isthmus” and defines an elongated “hour-glass”-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torquing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled “Extended Wear Electrocardiography Patch,” U.S. Pat. No. 9,545,204, issued on Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusable snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient’s electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, as further described infra beginning with reference to FIG. **8**. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **4** is a perspective view showing the monitor recorder **14** of FIG. **3**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in com-

monly-assigned U.S. Design Patent, entitled “Electrocardiography Monitor,” No. D717955, issued on Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button’s top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient’s skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **5** is a perspective view showing the extended wear electrode patch **15** of FIG. **3** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **6** is a bottom plan view of the monitor recorder **14** of FIG. **3**. A cavity **58** is

formed on the bottom surface of the sealed housing 50 to accommodate the upward projection of the battery compartment 36 from the bottom surface of the non-conductive receptacle 25, when the monitor recorder 14 is secured in place on the non-conductive receptacle 25. A set of electrical contacts 56 protrude from the bottom surface of the sealed housing 50 and are arranged in alignment with the electrical pads 34 provided on the bottom surface of the non-conductive receptacle 25 to establish electrical connections between the electrode patch 15 and the monitor recorder 14. In addition, a seal coupling 57 circumferentially surrounds the set of electrical contacts 56 and securely mates with the moisture-resistant seal 35 formed on the bottom surface of the non-conductive receptacle 25.

The placement of the flexible backing 20 on the sternal midline 16 (or immediately to either side of the sternum 13) also helps to minimize the side-to-side movement of the wearable monitor 12 in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing 20 due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact surface of the flexible backing 20, but only on the distal end 30 and the proximal end 31. As a result, the underside, or contact surface of the longitudinal midsection 23 does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection 23 forms a crimp relief that respectively facilitates compression and twisting of the flexible backing 20 in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing 20, the flexible circuit 32 is only able to bend and cannot stretch in a planar direction. The flexible circuit 32 can be provided either above or below the flexible backing 20. FIG. 7 is a top view showing the flexible circuit 32 of the extended wear electrode patch 15 of FIG. 3 when mounted above the flexible backing 20. A distal ECG electrode 38 and proximal ECG electrode 39 are respectively coupled to the distal and proximal ends of the flexible circuit 32. A strain relief 40 is defined in the flexible circuit 32 at a location that is partially underneath the battery compartment 36 when the flexible circuit 32 is affixed to the flexible backing 20. The strain relief 40 is laterally extendable to counter dislodgment of the ECG electrodes 38, 39 due to tensile and torsional forces. A pair of strain relief cutouts 41 partially extend transversely from each opposite side of the flexible circuit 32 and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit 32 in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder 14 are provided through a micro controlled architecture. FIG. 8 is a functional block diagram showing the component architecture of the circuitry 60 of the monitor recorder 14 of FIG. 3. The circuitry 60 is externally powered through a battery provided in the non-conductive receptacle 25 (shown in FIG. 5). Both power and raw ECG signals, which originate in the pair of ECG electrodes 38, 39 (shown in FIG. 7) on the distal and proximal ends of the electrode patch 15, are received through an external connector 65 that mates with a corresponding physical connector on the electrode patch 15. The external connector 65 includes the set of electrical contacts 56 that protrude from the bottom surface of the sealed housing 50 and which physically and electrically interface with the set of pads 34 provided on the

bottom surface of the non-conductive receptacle 25. The external connector includes electrical contacts 56 for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector 65 of the monitor recorder 14 and the device into which the monitor recorder 14 is attached, whether an electrode patch 15 or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector 65 also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder 14, and performance of other functions.

Operation of the circuitry 60 of the monitor recorder 14 is managed by a microcontroller 61. The micro-controller 61 includes a program memory unit containing internal flash memory that is readable and writable. The internal flash memory can also be programmed externally. The microcontroller 61 draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The microcontroller 61 connects to the ECG front end circuit 63 that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry 60 of the monitor recorder 14 also includes a flash memory 62, which the micro-controller 61 uses for storing ECG monitoring data and other physiology and information. The flash memory 62 also draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory 62 enables the microcontroller 61 to store digitized ECG data. The communications bus further enables the flash memory 62 to be directly accessed externally over the external connector 65 when the monitor recorder 14 is interfaced to a download station.

The circuitry 60 of the monitor recorder 14 further includes an actigraphy sensor 64 implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller 61 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 monitor recorder 14 if, for instance, the monitor recorder 14 has been inadvertently installed upside down, that is, with the monitor recorder 14 oriented on the electrode patch 15 towards the patient's feet, as well as for other event occurrence analyses.

The microcontroller 61 includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch 15 or other source, can interface to the microcontroller 61 over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry 60 of the monitor recorder 14, or can be provided on the electrode patch 15 with communication with the micro-controller 61 provided over one of the electrical contacts 56. 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. In a further embodiment, a wireless interface for interfacing with other wearable (or implantable) physiology monitors, as well as data offload and programming, can be provided as part of the circuitry 60 of the monitor recorder 14, or can be provided on the

electrode patch 15 with communication with the microcontroller 61 provided over one of the electrical contacts 56.

Finally, the circuitry 60 of the monitor recorder 14 includes patient-interfaceable components, including a tactile feedback button 66, which a patient can press to mark events or to perform other functions, and a buzzer 67, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer 67 can be used by the microcontroller 61 to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry 60 of the monitor recorder 14 are possible.

While the monitor recorder 14 operates under micro control, most of the electrical components of the electrode patch 15 operate passively. FIG. 9 is a functional block diagram showing the circuitry 70 of the extended wear electrode patch 15 of FIG. 3. The circuitry 70 of the electrode patch 15 is electrically coupled with the circuitry 60 of the monitor recorder 14 through an external connector 74. The external connector 74 is terminated through the set of pads 34 provided on the bottom of the non-conductive receptacle 25, which electrically mate to corresponding electrical contacts 56 protruding from the bottom surface of the sealed housing 50 to electrically interface the monitor recorder 14 to the electrode patch 15.

The circuitry 70 of the electrode patch 15 performs three primary functions. First, a battery 71 is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle 25. The battery 71 is electrically interfaced to the circuitry 60 of the monitor recorder 14 as a source of external power. The unique provisioning of the battery 71 on the electrode patch 15 provides several advantages. First, the locating of the battery 71 physically on the electrode patch 15 lowers the center of gravity of the overall wearable monitor 12 and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing 50 of the monitor recorder 14 is sealed against moisture and providing power externally avoids having to either periodically open the housing 50 for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder 14 off line for hours at a time. In addition, the electrode patch 15 is intended to be disposable, while the monitor recorder 14 is a reusable component. Each time that the electrode patch 15 is replaced, a fresh battery is provided for the use of the monitor recorder 14, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder 14 is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller 61. Requiring those additional sensors or components to draw power from a source external to the monitor recorder 14 keeps power considerations independent of the monitor recorder 14. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry 60.

Second, the pair of ECG electrodes 38, 39 respectively provided on the distal and proximal ends of the flexible circuit 32 are electrically coupled to the set of pads 34 provided on the bottom of the non-conductive receptacle 25 by way of their respective circuit traces 33, 37. The signal ECG electrode 39 includes a protection circuit 72, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry 70 of the electrode patch 15 includes a cryptographic circuit 73 to authenticate an electrode patch 15 for use with a monitor

recorder 14. The cryptographic circuit 73 includes a device capable of secure authentication and validation. The cryptographic device 73 ensures that only genuine, non-expired, safe, and authenticated electrode patches 15 are permitted to provide monitoring data to a monitor recorder 14.

The monitor recorder 14 continuously monitors the patient's heart rate and physiology. FIG. 10 is a flow diagram showing a monitor recorder-implemented method 100 for monitoring ECG data for use in the monitor recorder 14 of FIG. 3. Initially, upon being connected to the set of pads 34 provided with the non-conductive receptacle 25 when the monitor recorder 14 is snapped into place, the microcontroller 61 executes a power up sequence (step 101). During the power up sequence, the voltage of the battery 71 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. In a further embodiment, an authentication procedure between the microcontroller 61 and the electrode patch 15 are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps 102-109) is continually executed by the microcontroller 61. During each iteration (step 102) of the processing loop, the ECG frontend 63 (shown in FIG. 8) continually senses the cutaneous ECG electrical signals (step 103) via the ECG electrodes 38, 29 and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step 104) by the microcontroller 61 by sampling the analog ECG signal output front end 63. FIG. 11 is a graph showing, by way of example, a typical ECG waveform 110. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave 111 has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave 112, followed by a larger upward deflection of an R-wave 113, and terminated with a downward waveform of the S wave 114, collectively representative of ventricular depolarization. The T wave 115 is normally a modest upward waveform, representative of ventricular depolarization, while the U wave 116, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor 12, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step 105), pending compression preparatory to storage in the flash memory 62 (step 106). Following compression, the compressed ECG digitized sample is again buffered (step 107), then written to the flash memory 62 (step 108) using the communications bus. Processing continues (step 109), so long as the monitoring recorder 14 remains connected to the electrode patch 15 (and storage space remains available in the flash memory

62), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the method 100 described above with reference to FIG. 10 can also be implemented by a continuously-recording subcutaneous insertable cardiac monitor (ICM), such as one described in commonly-owned U.S. patent application Ser. No. 15/832,385, filed Dec. 5, 2017, pending, the disclosure of which is incorporated by reference. The ICM can be used for conducting a long-term electrocardiographic and physiological monitoring over a period lasting up to several years in duration. FIG. 12 is a diagram showing, by way of example, a subcutaneous P-wave centric ICM 212 for long term electrocardiographic monitoring in accordance with one embodiment. The ICM 212 is implanted in the parasternal region 211 of a patient 10. The sensing circuitry and components, compression algorithms, 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 generated during atrial activation. The position and placement of the ICM 212 coupled to engineering considerations that optimize the ICM's sensing circuitry, discussed infra, aid in demonstrating the P-wave clearly.

Implantation of a P-wave centric ICM 212 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 212 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 211 of the chest, or if sufficient subcutaneous fat exists, directly over the sternum. Optimally, the ICM 212 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 203, thereby placing the ICM 212 in close proximity to the anterior right atrium and the left atrial appendage that lie immediately beneath.

The ICM 212 is shaped to fit comfortably within the body under the skin and to conform to the contours of the patient's parasternal region 211 when implanted immediately to either side of the sternum 203, but could be implanted in other locations of the body. In most adults, the proximal end 213 of the ICM 212 is generally positioned below the manubrium 8 but, depending upon patient's vertical build, the ICM 212 may actually straddle the region over the manubrium 8. The distal end 214 of the ICM 212 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.

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.

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. Pat. No. 9,545,204, issued January 21, 2021 to Bishay et al.; U.S. Pat. No. 9,730,593, issued Aug. 15, 2021 to Felix et al.; U.S. Pat. No. 9,700,227, issued Jul. 11, 2021 to Bishay et al.; U.S. Pat. No. 9,7217,433, issued Aug. 1, 2021 to Felix et al.; and U.S. Pat. No. 9,615,763, issued Apr. 11, 2021 to Felix et al., the disclosures of which are incorporated by reference.

The ICM 212 can be implanted in the patient's chest using, for instance, a minimally invasive subcutaneous implantation instrument or other suitable surgical implement. The ICM 212 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 203, depending upon the vertical build of the patient 210.

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 211 significantly improves the ability of the ICM 212 to counter some of the effects of these factors, particularly high skin impedance and impedance from subcutaneous fat. Thus, the ICM 212 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.*, March 2021; 2185:67-73, the disclosure of which is incorporated by reference.

Moreover, the sternal midline implantation location in the parasternal region 211 allows the ICM's electrodes 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 depolar-

ization 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 **213**, the ECG electrodes of the ICM **212** 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 **214**, 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 **203**. The ECG electrodes of the ICM **212** are placed primarily in a north-to-south orientation along the sternum **203** 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.

Despite the challenges faced in capturing low amplitude cardiac action potentials, the ICM **212** 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. FIGS. **13** and **14** are respectively top and bottom perspective views showing the ICM **212** of FIG. **1**. Physically, the ICM **212** is constructed with a hermetically sealed implantable housing **215** with at least one ECG electrode forming a superior pole on the proximal end **213** and at least one ECG electrode forming an inferior pole on the distal end **214**.

When implanted, the housing **215** is oriented most cephalad. The housing **215** is constructed of titanium, stainless steel or other biocompatible material. The housing **215** contains the sensing, recordation and interfacing circuitry of the ICM **212**, plus a long life battery. A wireless antenna is integrated into or within the housing **215** 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.

Physically, the ICM **212** has four ECG electrodes **216**, **217**, **218**, **219**. There could also be additional ECG electrodes, as discussed infra. The ECG electrodes include two ventral (or dorsal) ECG electrodes **218**, **219** and two wrap-around ECG electrodes **216**, **217**. One ventral ECG electrode **218** is formed on the proximal end **213** and one ventral ECG electrode **219** is formed on the distal end **214**. One wrap-around ECG electrode **216** is formed circumferentially about the proximal end **213** and one wrap-around ECG electrode **217** is formed circumferentially about the distal end **214**. Each wrap-around ECG electrode **216**, **217** is electrically insulated from its respective ventral ECG electrode **218**, **219** by a periphery **220**, **221**.

The four ECG electrodes **216**, **217**, **218**, **219** are programmatically controlled by a microcontroller through onboard 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 **216**, **217**, the two wrap-around

ECG electrodes **218**, **219**, or one ventral ECG electrode **216**, **217** with one wrap-around ECG electrode **218**, **219** located on the opposite end of the housing **215**. In addition, the periphery **220**, **221** can be programmatically controlled to logically combine the wrap-around ECG electrode **216**, **217** on one end of the ICM **212** with its corresponding ventral ECG electrode **218**, **219** 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 **212**, for instance, wrap-around ECG electrode **216** and ventral ECG electrode **218**, could be paired; however, the minimal inter-electrode spacing would likely yield a signal of poor fidelity in most situations.)

In a further embodiment, the housing **215** 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.

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. FIG. **15** is a bottom perspective view showing the ICM **212** of FIG. **12** in accordance with a further embodiment. An additional pair of ventral ECG electrodes **222**, **223** are included on the housing's ventral surface. These ventral ECG electrodes **222**, **223** are spaced closer together than the ventral ECG electrodes **218**, **219** on the ends of the housing **215** and a physician can thus choose to pair the two inner ventral ECG electrodes **222**, **223** by themselves to allow for minimal electrode-to-electrode spacing, or with the other ECG electrodes **216**, **217**, **218**, **219** to vary electrode surface areas, shapes, and inter-electrode spacing even further to explore optimal configurations to acquire the P-wave.

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. FIGS. **16** and **17** are respectively top and bottom perspective views showing an ICM **230** in accordance with a still further embodiment. The ICM **230** has a housing **231** with a tapered extension **232** that is terminated on the distal end with an electrode **234**. On a proximal end, the housing **231** includes a pair of ECG electrodes electrically insulated by a periphery **237** that include a ventral ECG electrode **233** and a wrap-around ECG electrode **234**. In addition, a ventral ECG electrode **236** is oriented on the housing's distal end before the tapered extension **232**. Still other housing structures and electrode configurations are possible.

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.

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. FIGS. **18(a)** and **18(b)** are plan views showing further electrode configurations. Referring first to FIG. **18(a)**, a single disc ECG electrode **240** could be bifurcated to form a pair of half-circle ECG electrodes **241**, **242** that could be program-

matically selected or combined to accommodate a particular patient's ECG signal characteristics post-ICM implant. Referring next to FIG. 18(b), a single disc ECG electrode 245 could be divided into three sections, a pair of crescent-shaped ECG electrodes 246, 247 surrounding a central semicircular ECG electrode 248 that could similarly be programmatically selected or combined. Still other ECG electrode configurations are possible.

ECG monitoring and other functions performed by the ICM 212 are provided through a micro controlled architecture. FIG. 19 is a functional block diagram showing a system for wirelessly interfacing with an ICM in accordance with one embodiment.

The circuitry 280 is powered through the long life battery 21 provided in the housing 215, which can be a direct current battery. Operation of the circuitry 280 of the ICM 212 is managed by a microcontroller 281, such as the EFM32 Tiny Gecko 32-bit microcontroller, manufactured by Silicon Laboratories Inc., Austin, Tex. The microcontroller 281 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 281 also includes a program memory unit containing internal flash memory (not shown) that is readable, writeable, and externally programmable.

The microcontroller 281 operates under modular micro program control as specified in firmware stored in the internal flash memory. The microcontroller 281 draws power from the battery provided in the housing 215 and connects to the ECG front end circuit 63. The front end circuit 63 measures raw subcutaneous electrical signals using a driven reference signal that eliminates common mode noise, as further described infra.

The circuitry 280 of the ICM 212 also includes a flash memory 282 external to the microcontroller 281, which the microcontroller 281 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 282 also draws power from the battery provided in the housing 215. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory 282 enables the microcontroller 281 to store digitized ECG data. The communications bus further enables the flash memory 282 to be directly accessed wirelessly through a transceiver 285 coupled to an antenna 217 built into (or provided with) the housing 215. The transceiver 285 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 285 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 282 can be accessed through an inductive coupling (not shown).

The microcontroller 281 includes functionality that enables the acquisition of samples of analog ECG signals, which are converted into a digital representation, implementing the method 100 described supra with reference to

FIG. 10. In one mode, the microcontroller 281 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 282 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.

The circuitry 280 of the ICM 212 can include functionality to programmatically select pairings of sensing electrodes when the ICM 212 is furnished with three or more electrodes. In a further embodiment, multiple sensing electrodes could be provided on the ICM 212 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 285 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 212.

In a further embodiment, the circuitry 280 of the ICM 212 can include an actigraphy sensor 284 implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller 281 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 212 if, for instance, the ICM 212 has been inadvertently implanted upside down, that is, with the ICM's housing oriented caudally, as well as for other event occurrence analyses.

In a still further embodiment, the circuitry 280 of the ICM 212 can include one or more physiology sensors. For instance, a physiology sensor can be provided as part of the circuitry 280 of the ICM 212, or can be provided on the electrode assembly 214 with communication with the microcontroller 281 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.

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 212 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) through the transceiver 285 via, for instance, a paired mobile device. Similarly, the firmware can include heuristics that can be downloaded to the ICM 212 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 **285**. For instance, an alert that includes a compressed ECG digitized sample can also be wirelessly transmitted by the ICM **212** 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 **281**. 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 **280** of the ICM **212** can accommodate patient-interfaceable components, including an external tactile feedback device (not shown) that wirelessly interfaces to the ICM **212** through the transceiver **285**. A patient **210** can press the external tactile feedback device to mark events, such as a syncope episode, or to perform other functions. The circuitry **280** 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 **281** to indirectly output feedback to a patient **210**, such as a low battery or other error condition or warning. Still other components, provided as either part of the circuitry **280** of the ICM **212** or as external wirelessly-interfaceable devices, are possible.

The ECG front end circuit **283** of the ICM **12** measures raw subcutaneous electrical signals using a driven reference signal, such as described in U.S. Pat. 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.

The ECG front end circuit **283** 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 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.

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 spirit and scope.

What is claimed is:

1. An insertable cardiac monitor (ICM) for use in performing long term electrocardiographic (ECG) monitoring, comprising:

an implantable housing comprised of a biocompatible material that is suitable for implantation within a living body;

at least one pair of ECG sensing electrodes provided on a ventral surface and on opposite ends of the implantable housing; and

electronic circuitry provided within the housing, comprising:

an ECG front end circuit interfaced to a low-power microcontroller and configured to capture cardiac action potentials sensed by the at least one pair of ECG sensing electrodes which are output as ECG signals;

the low power microcontroller configured to execute under modular micro program control as specified in firmware, the microcontroller configured to read samples of the ECG signals, buffer the samples of the ECG signals, compress the buffered samples of the ECG signals, buffer the compressed samples of the ECG signals, and write the compressed buffered samples into a non-volatile flash memory; and

the non-volatile memory electrically interfaced with the microcontroller and configured to store the written samples of the ECG signals.

2. A monitor according to claim 1, further comprising: a power up sequence stored as part of the firmware, wherein the microcontroller is configured to execute the power up sequence upon the monitor being implanted into the body.

3. A monitor according to claim 2, the power up sequence comprising one or more of a battery voltage checking procedure, a flash memory state checking procedure, and a microcontroller diagnostic procedure.

4. A monitor according to claim 1, further comprising: an actigraphy sensor electrically interfaced with the microcontroller and configured to sense actigraphy event occurrences based on movement of the sensor using an actigraphy event occurrence criteria and to send an interrupt signal to the micro-controller upon sensing each of the actigraphy event occurrences.

5. A monitor according to claim 4, wherein the actigraphy sensor comprises a 3-axis accelerometer.

6. A monitor according to claim 4, wherein the actigraphy event occurrences comprise at least one of a fall and a postural change.

7. A monitor according to claim 1, further comprising: a battery comprised within the implantable housing and which powers the electronic circuitry.

8. A monitor according to claim 1, further comprising: one or more memory storage locations comprised in the non-volatile memory in which the written samples of the ECG signals are stored,

wherein, upon all of the memory storage locations being filled, the microcontroller is configured to overwrite the written samples of the ECG signals stored in one of the memory storage locations to store the written samples of the ECG signals acquired after the written samples being overwritten. 5

9. A monitor according to claim 1, further comprising: one or more memory storage locations comprised in the non-volatile memory in which the written samples of the ECG signals are stored; and 10

a transceiver interfaced to the microcontroller and configured to wirelessly interface to an external device and provide the stored written samples of the ECG signals from the non-volatile memory upon all of the memory storage locations being filled. 15

10. A subcutaneous implantable loop recorder for long term electrocardiographic (ECG) monitoring, comprising: a hermetically sealed implantable housing defining a rectangular shape with rounded edges and comprised of a biocompatible material that is suitable for implantation within a living body of a patient; 20

at least one pair of ECG sensing electrodes provided on a ventral surface and on opposite ends of the implantable housing; 25

electronic circuitry provided within the housing, the electronic circuitry comprising:

an ECG front end circuit interfaced to a low-power microcontroller and configured to capture cardiac action potentials sensed by the at least one pair of ECG sensing electrodes which are output as ECG signals; 30

the low power microcontroller configured to execute under modular micro program control as specified in firmware, the microcontroller configured to read samples of the ECG signals, buffer the samples of the ECG signals, compress the buffered samples of the ECG signals, buffer the compressed samples of the ECG signals, and write the compressed buffered samples into a non-volatile flash memory; and 40

the non-volatile memory electrically interfaced with the microcontroller and configured to store the written samples of the ECG signals.

11. A recorder according to claim 10, further comprising: a power up sequence stored as part of the firmware, wherein the microcontroller is configured to execute the power up sequence upon the monitor being implanted into the body.

12. A recorder according to claim 11, the power up sequence comprising one or more of a battery voltage checking procedure, a flash memory state checking procedure, and a microcontroller diagnostic procedure.

13. A recorder according to claim 10, further comprising: an actigraphy sensor electrically interfaced with the microcontroller and configured to sense actigraphy event occurrences based on movement of the sensor using an actigraphy event occurrence criteria and to send an interrupt signal to the micro-controller upon sensing each of the actigraphy event occurrences.

14. A recorder according to claim 13, wherein the actigraphy sensor comprises a 3-axis accelerometer.

15. A recorder according to claim 13, wherein the actigraphy event occurrences comprise at least one of a fall and a postural change.

16. A recorder according to claim 10, further comprising: a battery comprised within the implantable housing and which powers the electronic circuitry.

17. A recorder according to claim 10, further comprising: one or more memory storage locations comprised in the non-volatile memory in which the written samples of the ECG signals are stored, 5

wherein, upon all of the memory storage locations being filled, the microcontroller is configured to overwrite the written samples of the ECG signals stored in one of the memory storage locations to store the written samples of the ECG signals acquired after the written samples being overwritten.

18. A recorder according to claim 10, further comprising: one or more memory storage locations comprised in the non-volatile memory in which the written samples of the ECG signals are stored; and 10

a transceiver interfaced to the microcontroller and configured to wirelessly interface to an external device and provide the stored written samples of the ECG signals from the non-volatile memory upon all of the memory storage locations being filled.

* * * * *

专利名称(译)	可插入式心脏监护仪，用于执行长期心电图监护		
公开(公告)号	US10624551	公开(公告)日	2020-04-21
申请号	US16/178455	申请日	2018-11-01
[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 FELIX JASON		
发明人	BARDY, GUST H. FELIX, JASON		
IPC分类号	A61B5/0408 A61B5/0432 A61B5/11 A61B5/0452 A61B5/0205 A61B5/145 A61B5/00 G01N27/30 A61B5/021 A61B5/08 A61B5/091 A61B5/01 A61B5/04 A61B5/1455 A61B5/087		
CPC分类号	A61B5/04085 A61B5/04325 A61B5/0452 A61B5/6823 A61B5/14532 A61B5/1117 A61B5/6801 A61B5/1118 A61B5/4809 A61B5/6833 A61B5/04087 A61B5/1116 A61B5/02055 A61B5/0006 A61B5/0022 A61B5/04525 A61B2560/0412 G01N27/307 A61B5/021 A61B5/14551 A61B5/091 A61B2505/07 A61B2560/045 A61B2560/0271 A61B5/01 A61B5/14542 A61B5/7455 A61B2562/0219 A61B5/0816 A61B5/04017 A61B5/087 A61B2562/164 G16H40/67		
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外部链接	Espacenet		

摘要(译)

通过连续记录皮下可插入心脏监护仪 (ICM) ，可以提供长达数年的长期心电图和生理监护。 电极的传感电路和物理布局经过专门优化，可从低振幅，相对低频含量的心脏动作电位的传播中捕获电信号，特别是在心房激活过程中产生的P波并存储捕获信号的样本。 通常，ICM的目的是在胸骨旁区域的胸骨上方或胸骨中线的左侧或右侧稍稍向胸骨中央或轴向植入。

