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(54) **CONTACT-ACTIVATED EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR RECORDER**

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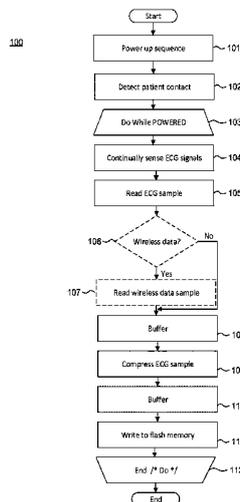
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(57) **ABSTRACT**

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 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) benefits extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. The wearable monitor can interoperate wirelessly with other physiology and activity sensors and mobile devices, and can include cellular phone capabilities. The power usage of the wireless communication can be reduced by using a low energy wireless transceiver in the monitor. The monitor detects that the monitor has been adhered to the patient and begin collecting physiological data after such detection, preserving battery power.

12 Claims, 11 Drawing Sheets



Related U.S. Application Data

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Fig. 1.

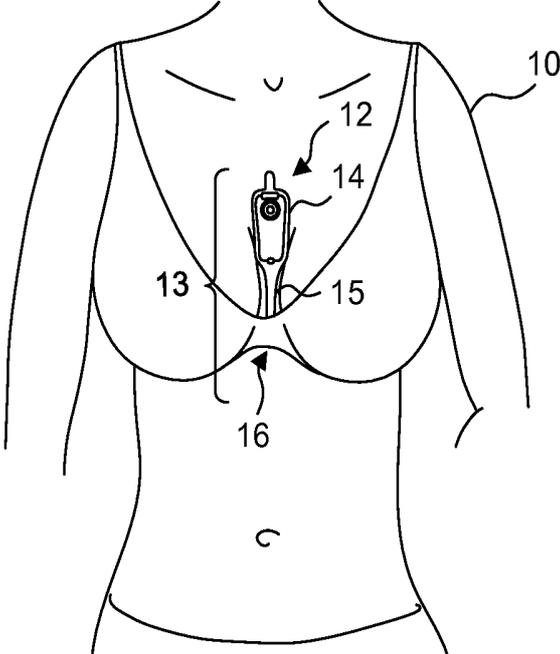


Fig. 2.

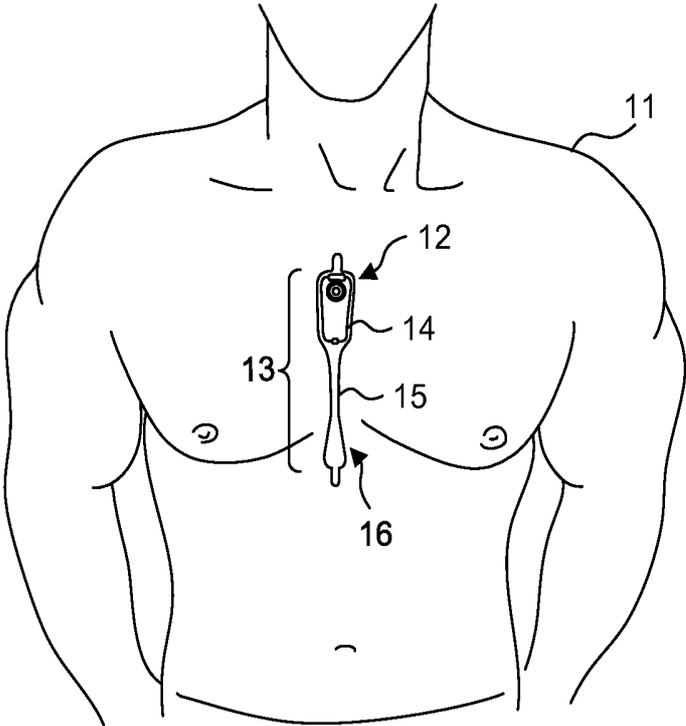


Fig. 4.

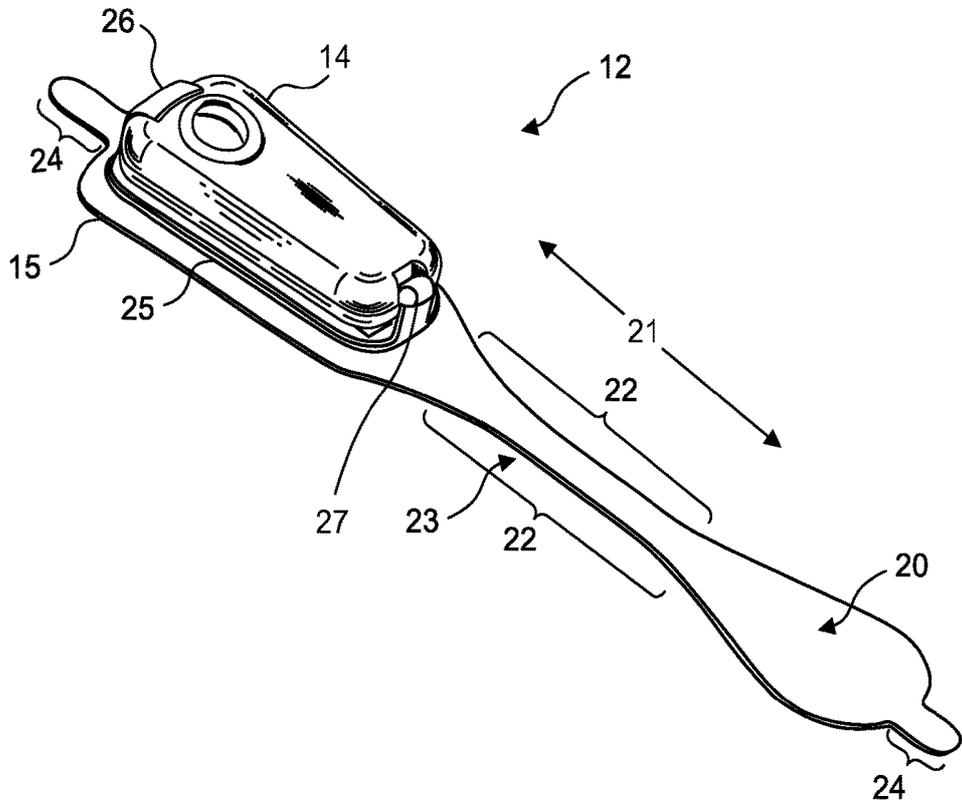


Fig. 5.

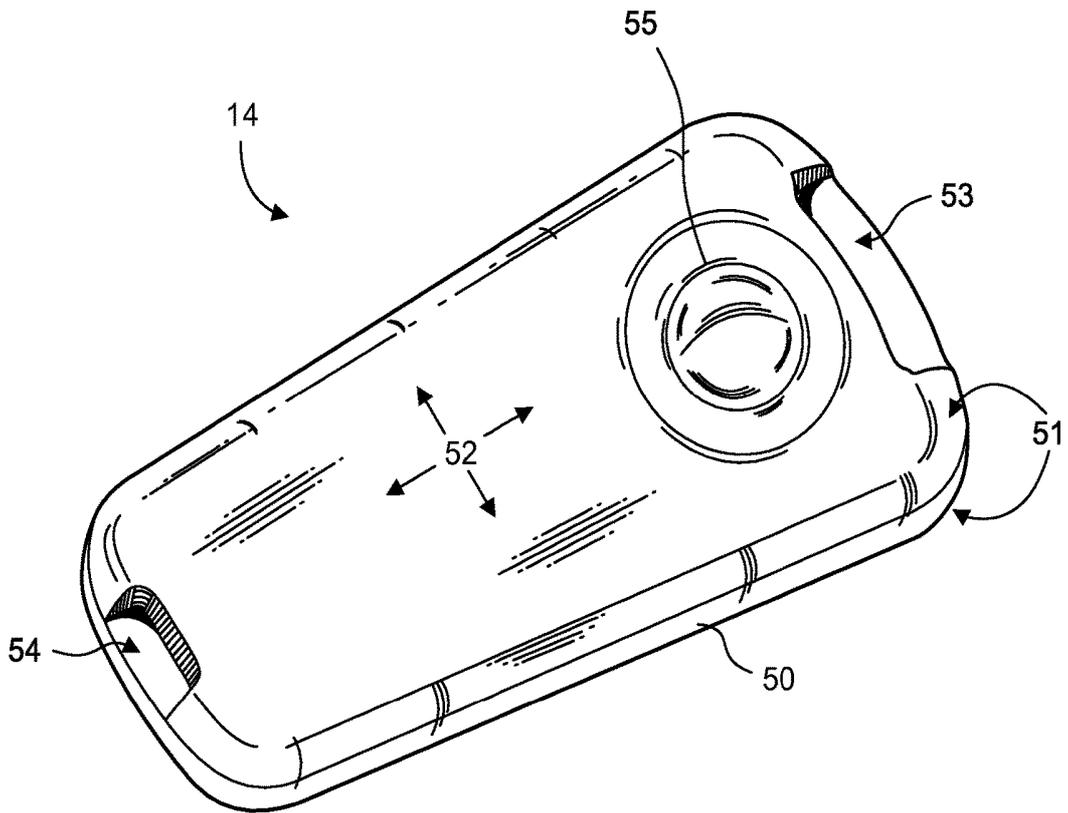


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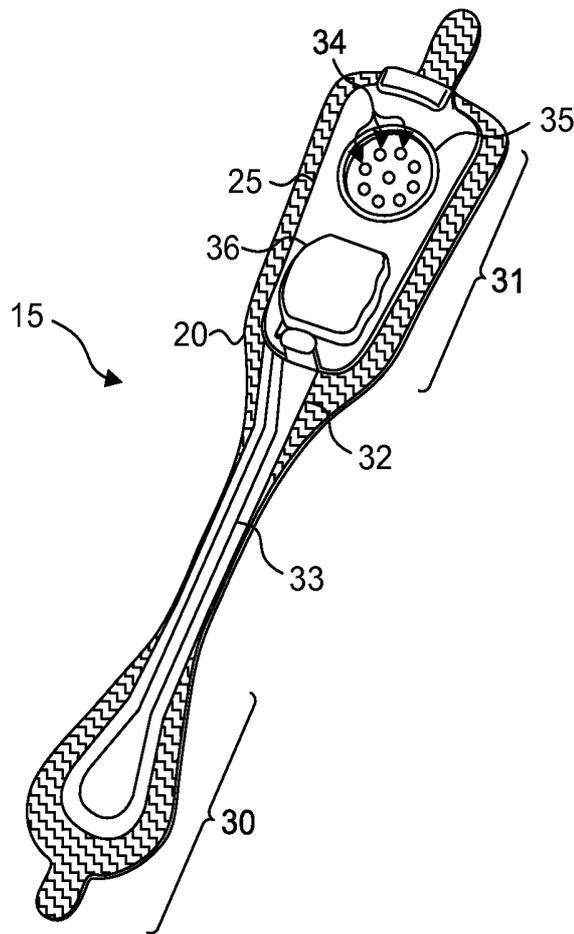


Fig. 7.

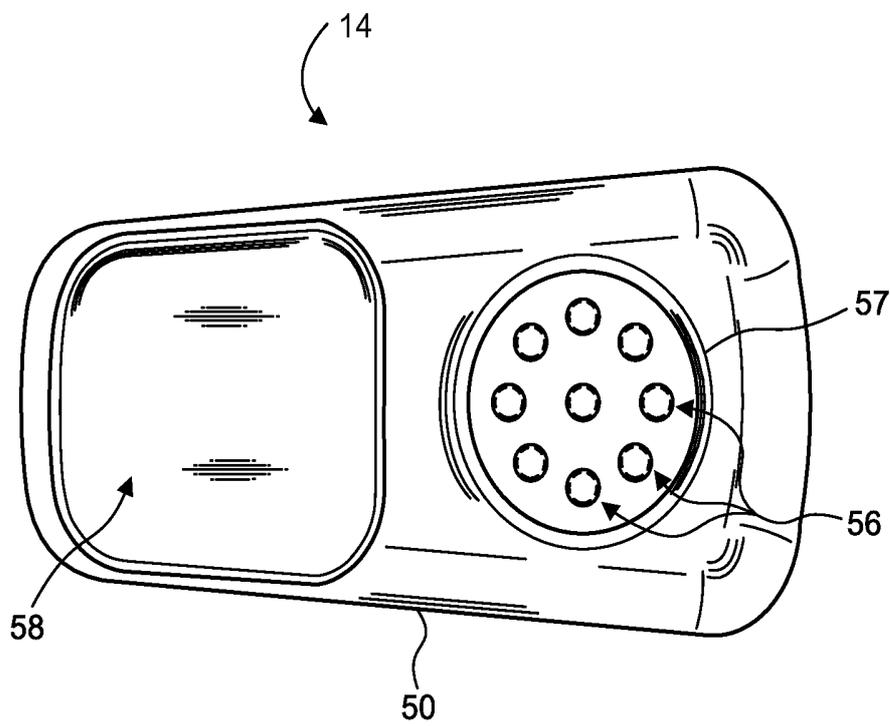


Fig. 8.

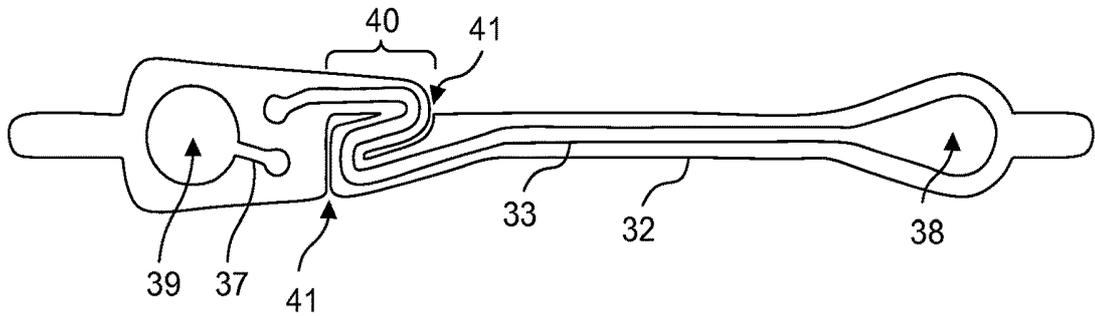


Fig. 9.

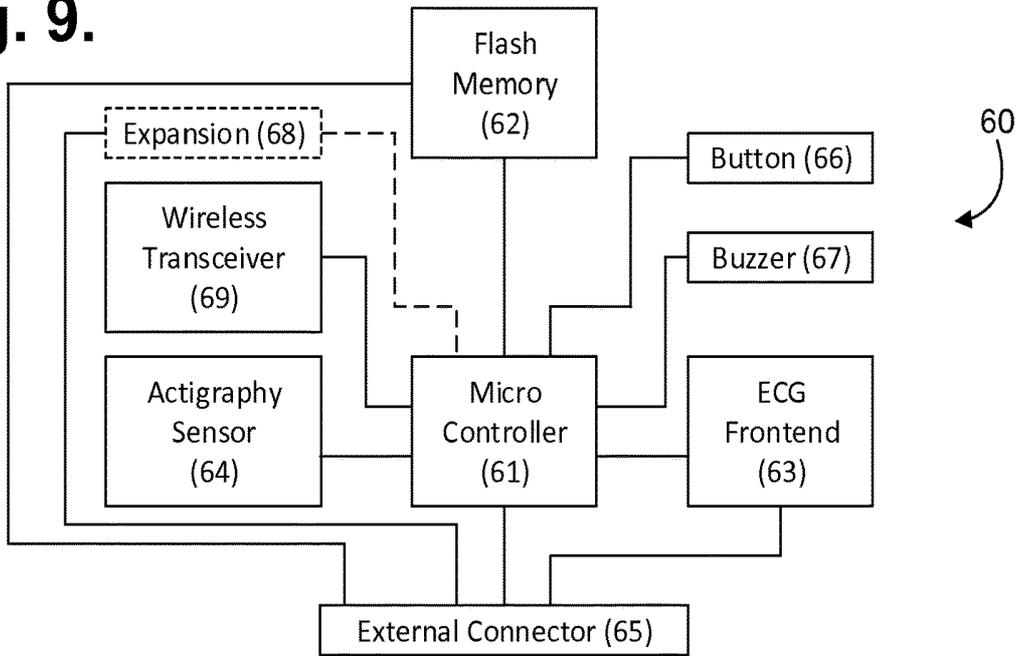


Fig. 10.

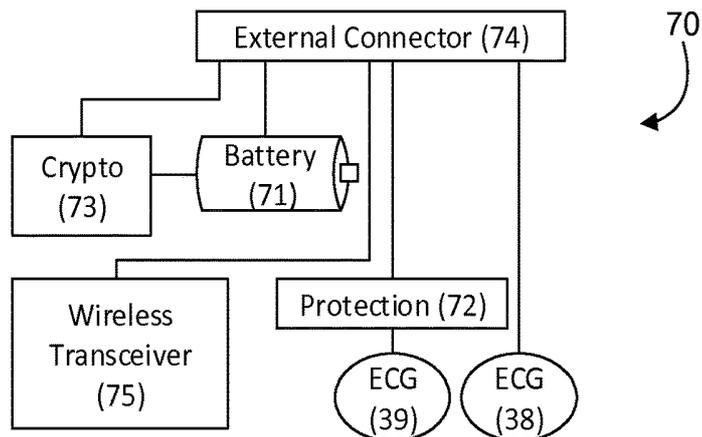


Fig. 11.

100

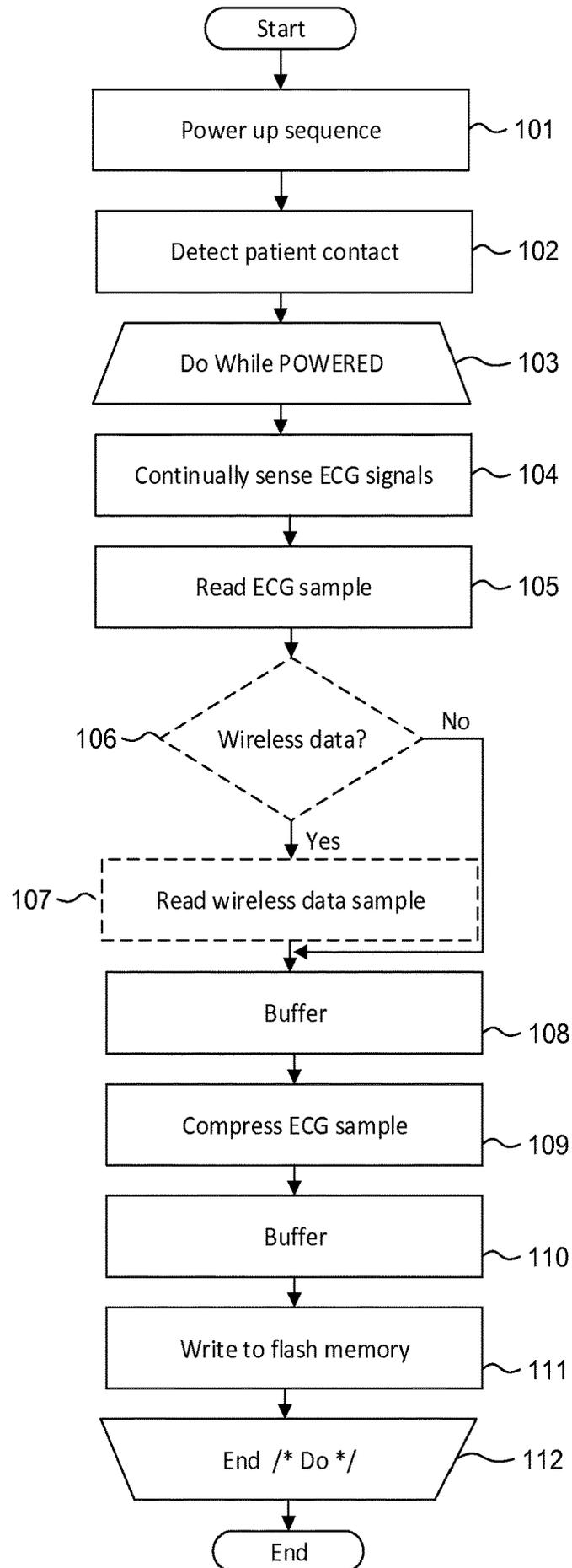


Fig. 12.

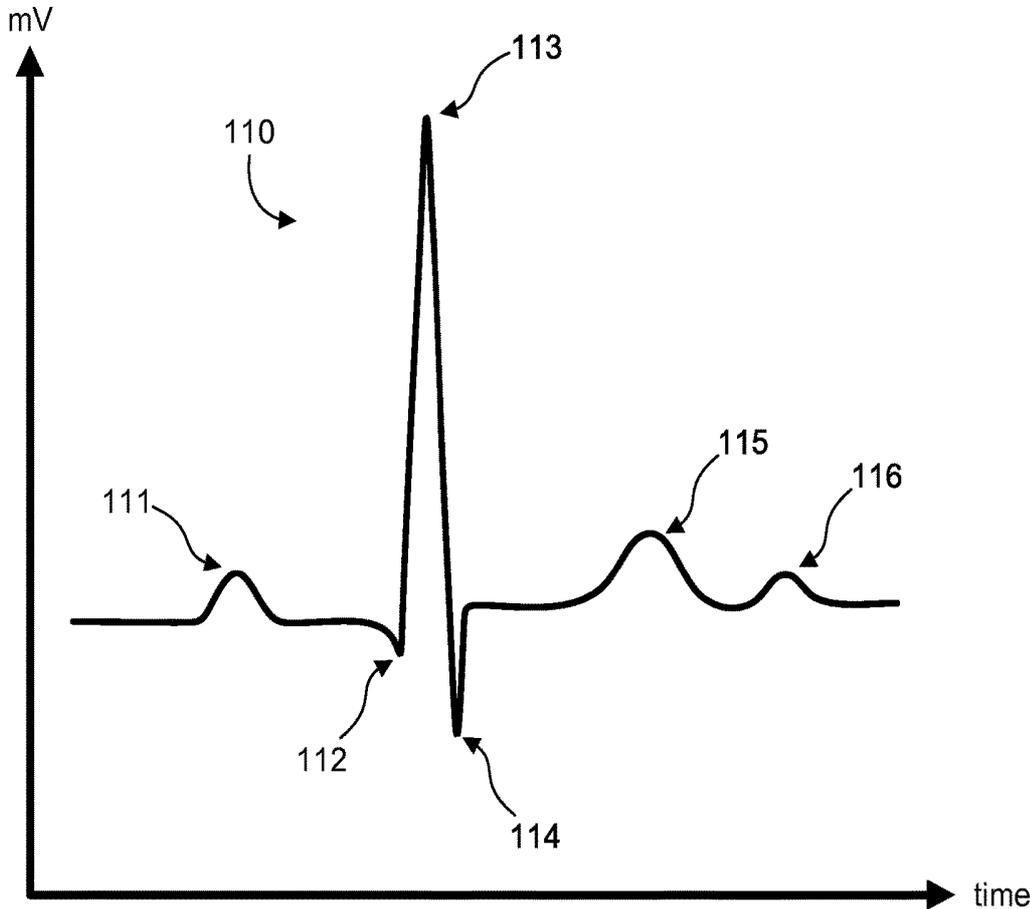


Fig. 13.

150

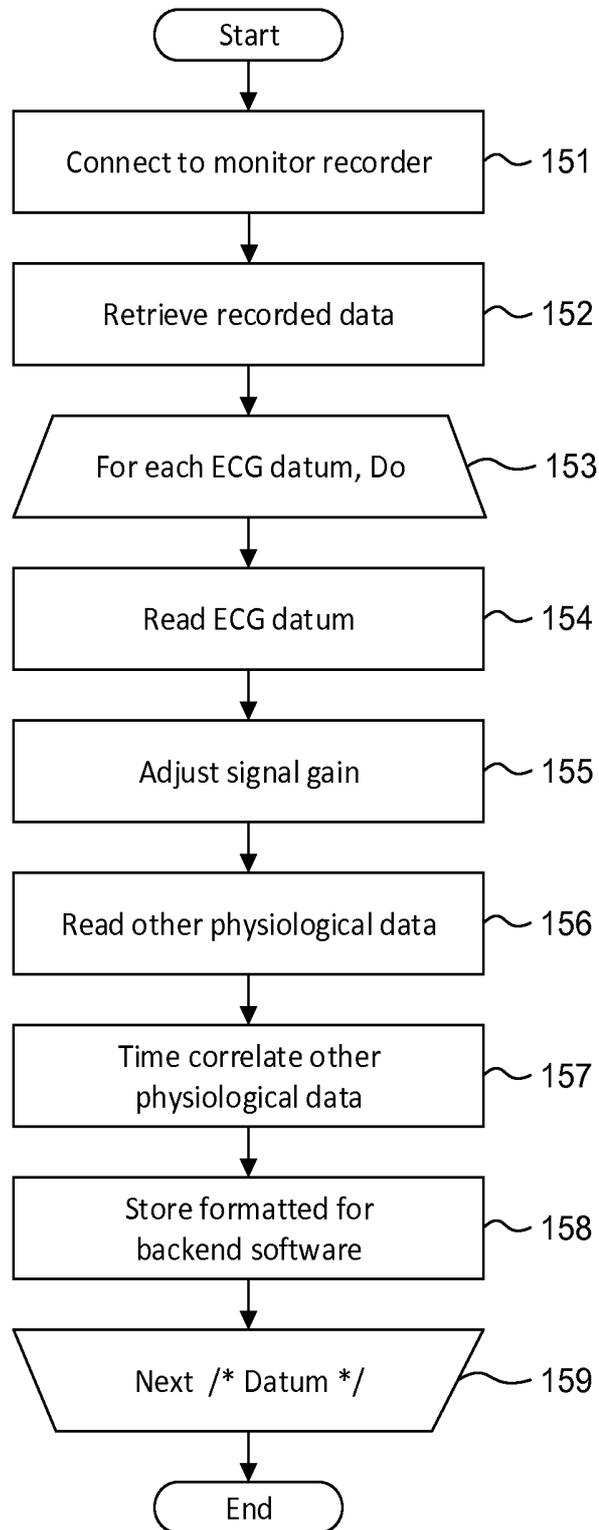


Fig. 14.

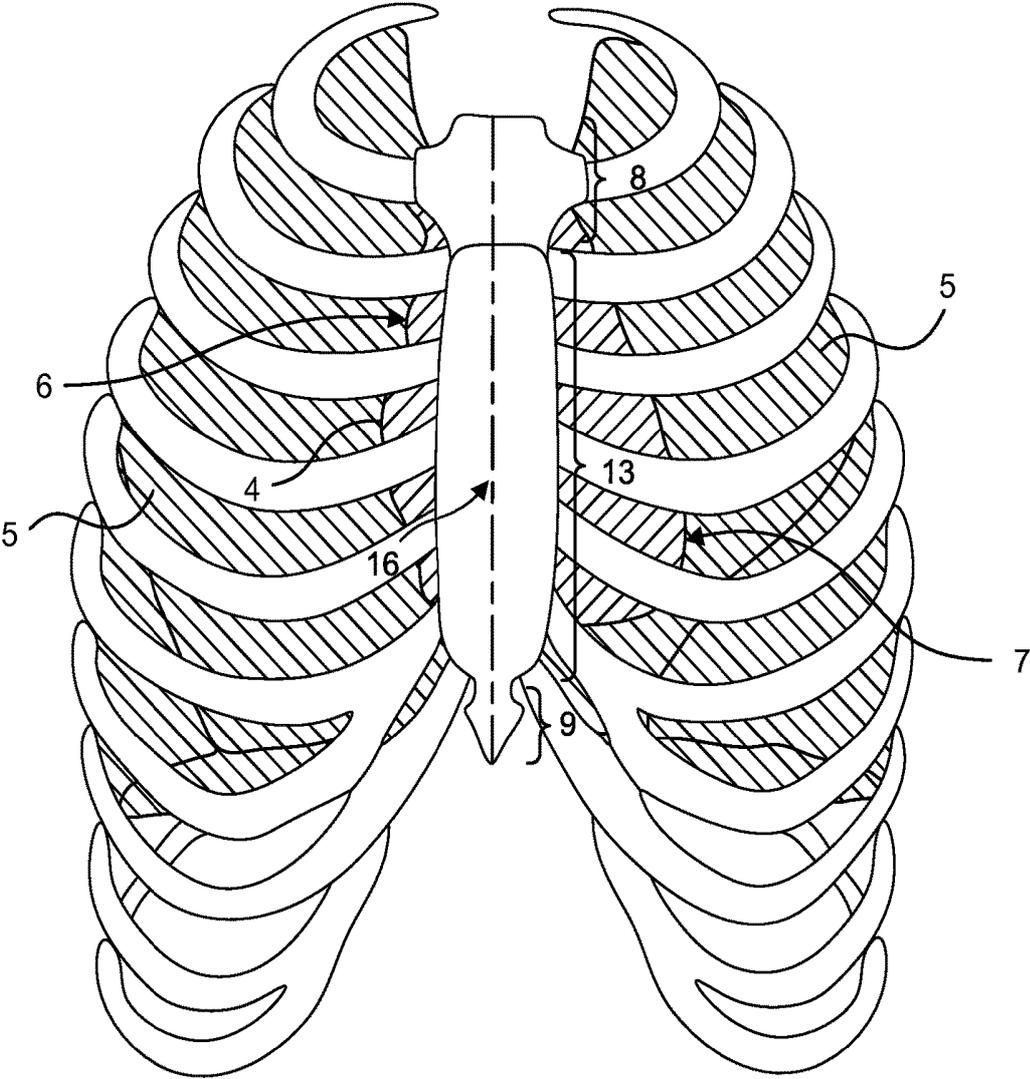


Fig. 15.

80

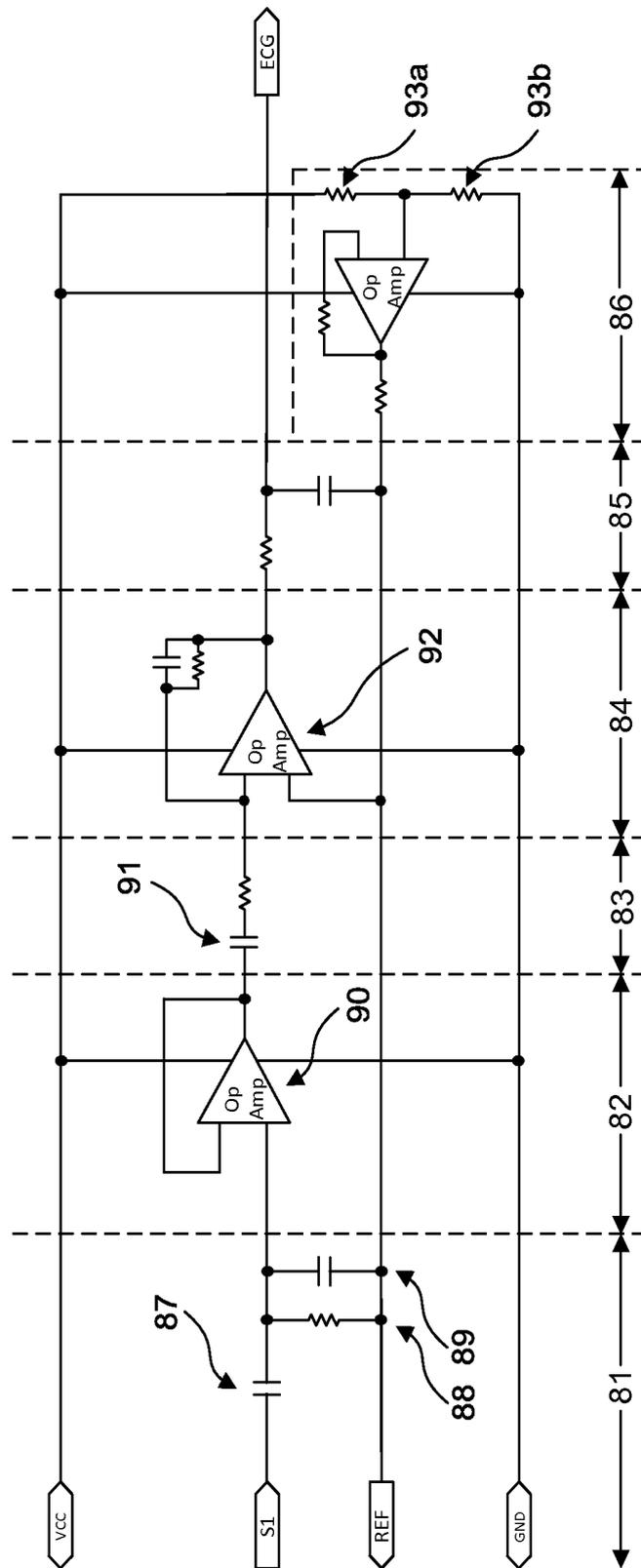


Fig. 16.

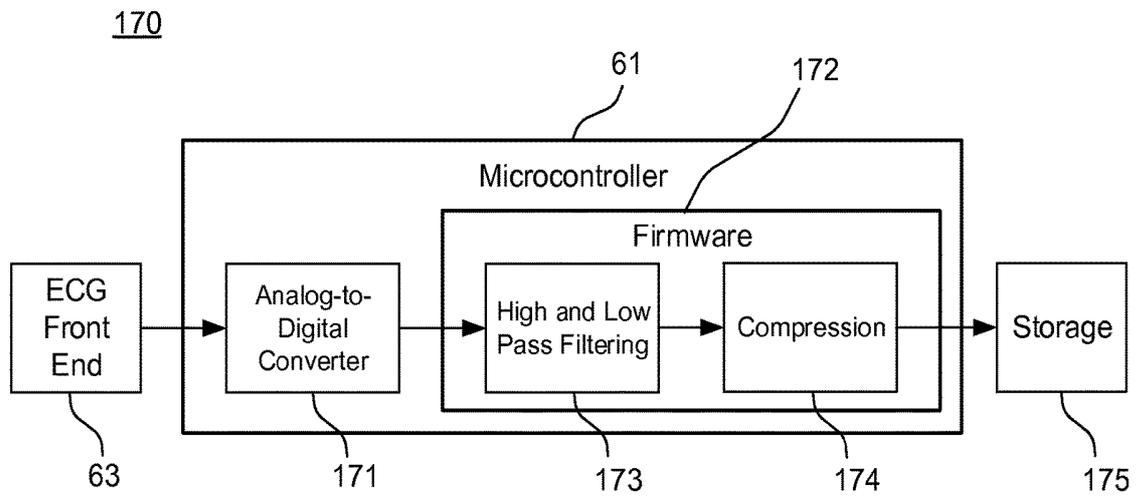
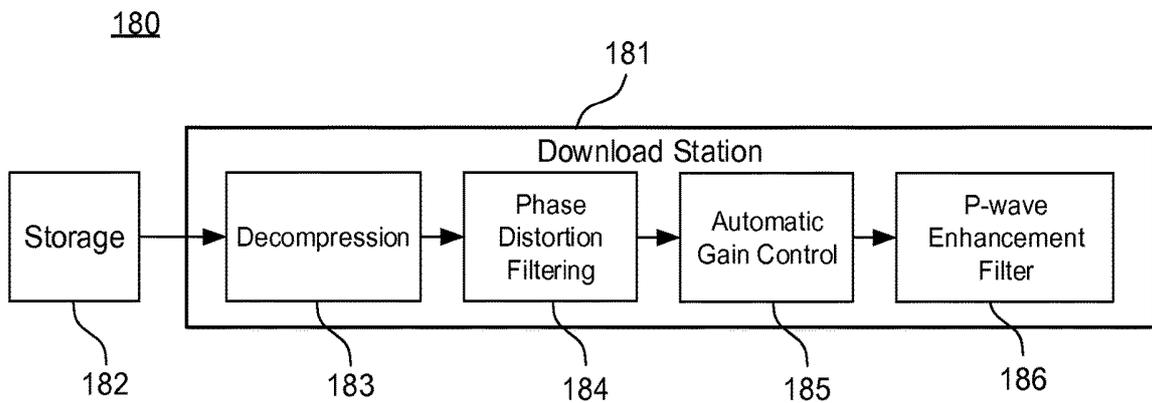


Fig. 17.



**CONTACT-ACTIVATED EXTENDED WEAR
ELECTROCARDIOGRAPHY AND
PHYSIOLOGICAL SENSOR MONITOR
RECORDER**

CROSS-REFERENCE TO RELATED
APPLICATION

This present non-provisional patent application is a continuation-in-part of U.S. Pat. No. 10,165,946, issued Jan. 1, 2018; which is a continuation-in-part of U.S. Pat. No. 9,433,367, issued Sep. 6, 2016; which is a continuation-in-part of U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, and a continuation-in-part of U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, and which 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 disclosures of which are incorporated by reference; this present non-provisional patent application is also a continuation-in-part of U.S. Pat. No. 9,700,227, issued Jul. 11, 2007, which is a continuation-in-part 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 disclosures of which are incorporated by reference.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to a contact-activated extended wear electrocardiography and physiological sensor monitor recorder.

BACKGROUND

The first electrocardiogram (ECG) was invented by a Dutch physiologist, Willem Einthoven, in 1903, who used a string galvanometer to measure the electrical activity of the heart. Generations of physicians around the world have since used ECGs, in various forms, to diagnose heart problems and other potential medical concerns. Although the basic principles underlying Dr. Einthoven's original work, including his naming of various waveform deflections (Einthoven's triangle), are still applicable today, ECG machines have evolved from his original three-lead ECG, to ECGs with unipolar leads connected to a central reference terminal starting in 1934, to augmented unipolar leads beginning in 1942, and finally to the 12-lead ECG standardized by the American Heart Association in 1954 and still in use today. Further advances in portability and computerized interpretation have been made, yet the electronic design of the ECG recording apparatuses has remained fundamentally the same for much of the past 40 years.

Essentially, an ECG measures the electrical signals emitted by the heart as generated by the propagation of the action potentials that trigger depolarization of heart fibers. Physiologically, transmembrane ionic currents are generated within the heart during cardiac activation and recovery sequences. Cardiac depolarization originates high in the right atrium in the sinoatrial (SA) node before spreading leftward towards the left atrium and inferiorly towards the atrioventricular (AV) node. After a delay occasioned by the AV node, the depolarization impulse transits the Bundle of His and moves into the right and left bundle branches and Purkinje fibers to activate the right and left ventricles.

During each cardiac cycle, the ionic currents create an electrical field in and around the heart that can be detected

by ECG electrodes placed on the skin. Cardiac electrical activity is then visually represented in an ECG trace by PQRSTU-waveforms. The P-wave represents atrial electrical activity, and the QRSTU components represent ventricular electrical activity. Specifically, a P-wave represents atrial depolarization, which causes atrial contraction.

P-wave analysis based on ECG monitoring is critical to accurate cardiac rhythm diagnosis and focuses on localizing the sites of origin and pathways of arrhythmic conditions. P-wave analysis is also used in the diagnosis of other medical disorders, including imbalance of blood chemistry. Cardiac arrhythmias are defined by the morphology of P-waves and their relationship to QRS intervals. For instance, atrial fibrillation (AF), an abnormally rapid heart rhythm, can be confirmed by the presence of erratic atrial activity or the absence of distinct P-waves and an irregular ventricular rate. Atrial flutter can be diagnosed with characteristic "sawtooth" P-waves often occurring twice for each QRS wave. Some congenital supraventricular tachycardias, like AV node re-entry and atrioventricular reentrant tachycardia using a concealed bypass tract, are characterized by an inverted P-wave occurring shortly after the QRS wave. Similarly, sinoatrial block is characterized by a delay in the onset of P-waves, while junctional rhythm, an abnormal heart rhythm resulting from impulses coming from a locus of tissue in the area of the AV node, usually presents without P-waves or with inverted P-waves within or shortly before or after the QRS wave. Also, the amplitudes of P-waves are valuable for diagnosis. The presence of broad, notched P-waves can indicate left atrial enlargement or disease. Conversely, the presence of tall, peaked P-waves, especially in the initial half, can indicate right atrial enlargement. Finally, P-waves with increased amplitude can indicate hypokalemia, caused by low blood potassium, whereas P-waves with decreased amplitude can indicate hyperkalemia, caused by elevated blood potassium.

Cardiac rhythm disorders may present with lightheadedness, fainting, chest pain, hypoxia, syncope, palpitations, and congestive heart failure (CHF), yet rhythm disorders are often sporadic in occurrence and may not show up in-clinic during a conventional 12-second ECG. Some atrial rhythm disorders, like atrial fibrillation, are known to cause stroke, even when intermittent. Continuous ECG monitoring with P-wave-centric action potential acquisition over an extended period is more apt to capture sporadic cardiac events that can be specifically identified and diagnosed. However, recording sufficient ECG and related physiological data over an extended period remains a significant challenge, despite an over 40-year history of ambulatory ECG monitoring efforts combined with no appreciable improvement in P-wave acquisition techniques since Dr. Einthoven's original pioneering work over a 110 years ago.

Electrocardiographic monitoring over an extended period provides a physician with the kinds of data essential to identifying the underlying cause of sporadic cardiac conditions, especially rhythm disorders, and other physiological events of potential concern. A 30-day observation period is considered the "gold standard" of monitoring by some, yet a 14-day observation period is currently deemed more achievable by conventional ECG monitoring approaches. Realizing a 30-day observation period has proven unworkable with existing ECG monitoring systems, which are arduous to employ; cumbersome, uncomfortable and not user-friendly to the patient; and costly to manufacture and deploy. An intractable problem is the inability to have the monitoring electrodes adhere to the skin for periods of time exceeding 5-14 days, let alone 30 days. Still, if a patient's

ECG could be recorded in an ambulatory setting over a prolonged time periods, particularly for more than 14 days, the chances of acquiring meaningful medical information and capturing an abnormal event while the patient is engaged in normal activities are greatly improved.

The location of the atria and their low amplitude, low frequency content electrical signals make P-waves difficult to sense, particularly through ambulatory ECG monitoring. The atria are located either immediately behind the mid sternum (upper anterior right atrium) or posteriorly within the chest (left atrium), and their physical distance from the skin surface, especially when standard ECG monitoring locations are used, adversely affects current strength and signal fidelity. Cardiac electrical potentials measured from the classical dermal locations have an amplitude of only one-percent of the amplitude of transmembrane electrical potentials. The distance between the heart and ECG electrodes reduces the magnitude of electrical potentials in proportion to the square of change in distance, which compounds the problem of sensing low amplitude P-waves. Moreover, the tissues and structures that lie between the activation regions within the heart and the body's surface further attenuate the cardiac electrical field due to changes in the electrical resistivity of adjacent tissues. Thus, surface electrical potentials, when even capable of being accurately detected, are smoothed over in aspect and bear only a general spatial relationship to actual underlying cardiac events, thereby complicating diagnosis. Conventional 12-lead ECGs attempt to compensate for weak P-wave signals by monitoring the heart from multiple perspectives and angles, while conventional ambulatory ECGs primarily focus on monitoring higher amplitude ventricular activity, i.e., the R-wave, that, comparatively, can be readily sensed. Both approaches are relatively unsatisfactory with respect to the P-wave and related need for the accurate acquisition of the P and R-wave medically actionable data of the myriad cardiac rhythm disorders that exist.

Additionally, maintaining continual contact between ECG electrodes and the skin after a day or two of ambulatory ECG monitoring has been a problem. 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's non-conductive adhesive and the skin's surface. These factors adversely affect electrode adhesion which in turn adversely affects the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, bending, 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 or unattached. Moreover, subtle dislodgment may occur and be 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.

Conventionally, multi-week or multi-month monitoring can be performed by implantable ECG monitors, such as the Reveal LINQ insertable cardiac monitor, manufactured by

Medtronic, Inc., Minneapolis, Minn. This monitor can detect and record paroxysmal or asymptomatic arrhythmias for up to three years. However, like all forms of implantable medical device (IMD), use of this monitor requires invasive surgical implantation, which significantly increases costs; requires ongoing follow up by a physician throughout the period of implantation; requires specialized equipment to retrieve monitoring data; and carries complications attendant to all surgery, including risks of infection, injury or death. Finally, such devices do not necessarily avoid the problem of signal noise and recording high quality signals.

Holter monitors are widely used for ambulatory ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that includes cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The leads are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine using electrode locations that are not specifically intended for optimal P-wave capture but more to identify events in the ventricles by capturing the R-wave. The duration of monitoring depends on the sensing and storage capabilities of the monitor. A "looping" Holter (or event) monitor can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest precludes a patient from replacing or removing the sensing leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

U.S. Pat. No. 8,460,189, to Libbus et al. ("Libbus") discloses an adherent wearable cardiac monitor that includes at least two measurement electrodes and an accelerometer. The device includes a reusable electronics module and a disposable adherent patch that includes the electrodes. ECG monitoring can be conducted using multiple disposable patches adhered to different locations on the patient's body. The device includes a processor configured to control collection and transmission of data from ECG circuitry, including generating and processing of ECG signals and data acquired from two or more electrodes. The ECG circuitry can be coupled to the electrodes in many ways to define an ECG vector, and the orientation of the ECG vector can be determined in response to the polarity of the measurement electrodes and orientation of the electrode measurement axis. The accelerometer can be used to determine the orientation of the measurement electrodes in each of the locations. The ECG signals measured at different locations can be rotated based on the accelerometer data to modify amplitude and direction of the ECG features to approximate a standard ECG vector. The signals recorded at different locations can be combined by summing a scaled version of each signal. Libbus further discloses that inner ECG electrodes may be positioned near outer electrodes to increase the voltage of measured ECG signals. However, Libbus treats ECG signal acquisition as the measurement of a simple aggregate directional data signal without differentiating between the distinct kinds of cardiac electrical activities presented with an ECG waveform, particularly atrial (P-wave) activity.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, Calif., are wearable monitoring devices that are typically worn on the

upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors, but without specifically enhancing P-wave capture. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period and to resist disadherence from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring. Neither is designed for a female-friendly fit or for recording of the atrial (P-wave) signals.

Personal ambulatory monitoring, both with smartphones or via adjuncts to smartphones, such as with a wirelessly-connected monitor or activity tracker, of varying degrees of sophistication and interoperability, have become increasingly available. For instance, McManus et al., "A Novel Application for the Detection of an Irregular Pulse using an iPhone 4S in Patients with Atrial Fibrillation," Vol. 10(3), pp. 315-319 (March 2013), the disclosure of which is incorporated by reference, discloses obtaining pulsatile time series recordings before and after cardioversion using the digital camera built into a smartphone. An algorithm implemented as an app executed by the smartphone analyzed recorded signals to accurately distinguish pulse recordings during atrial fibrillation from sinus rhythm, although such a smartphone-based approach provides non-continuous observation and would be impracticable for long term physiological monitoring. Further, the smartphone-implemented app does not provide continuous recordings, including the provision of pre-event and post-event context, both of which are critical for an accurate medical diagnosis that might trigger a meaningful and serious medical intervention. In addition, a physician would be loath to undertake a surgical or serious drug intervention without confirmatory evidence that the wearer in question was indeed the subject of the presumed rhythm abnormality. Validation of authenticity of the rhythm disorder for a specified patient takes on critical legal and medical importance.

The AliveCor heart monitor, manufactured by AliveCor, Inc., San Francisco, Calif., provides a non-continuous, patient-triggered event monitor, which is worn on the fingertip. Heart rate is sensed over a single lead (comparable to Lead I on a conventional ECG) and recorded by an app running on a smartphone, such as an iOS operating system-based smartphone, such as the iPhone, manufactured by Apple Inc., Cupertino, Calif., or an Android operating system-based smartphone, manufactured and offered by various companies, including Google Inc., Mountain View, Calif.; Samsung Electronics Co., Ltd., Suwon, S. Korea; Motorola Mobility LLC, a subsidiary of Google Inc., Libertyville, Ill.; and LG Electronics Inc., Seoul, S. Korea. The Android operating system is also licensed by Google Inc. The app can send the data recorded by an AliveCor heart monitor from the smartphone to healthcare providers, who ultimately decide whether to use the data for screening or diagnostic purposes. Furthermore, as explained supra with respect to

the McManus reference, none of these devices provides the context of the arrhythmia, as well as the medico-legal confirmation that would otherwise allow for a genuine medical intervention.

Similarly, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives. The Fitbit Tracker, manufactured by Fitbit Inc., San Francisco, Calif.; the Jawbone UP, manufactured by Jawbone, San Francisco, Calif.; the Polar Loop, manufactured by Polar Electro, Kempele, Finland; and the Nike+FuelBand, manufactured by Nike Inc., Beaverton, Oreg., for instance, provide activity trackers worn on the wrist or body with integrated fitness tracking features, such as a heart rate monitor and pedometer to temporally track the number of steps taken each day with an estimation calories burned. The activity tracker can interface with a smartphone or computer to allow a wearer to monitor their progress towards a fitness goal. These activity trackers are accessories to smartphones, including iOS operating system-based smartphones, Android operating system-based smartphones, and Windows Phone operating-system based smartphones, such as manufactured by Microsoft Corporation, Redmond, Wash., to which recorded data must be offloaded for storage and viewing.

The features of activity trackers can also be increasingly found in so-called "smart" watches that combine many of the features of activity trackers with smartphones. Entire product lines are beginning to be offered to provide a range of fitness- and health-tracking solutions. As one example, Samsung Electronics Co., Ltd., offers a line of mobile products with fitness-oriented features, including the Galaxy S5 smartphone, which incorporates a biometric fingerprint reader and heart rate monitor; the Gear 2 smart watch, which also incorporates a heart rate monitor; and the Gear Fit wearable device, which incorporates a heart rate monitor, real time fitness coaching, and activity tracker. The Galaxy S5 smartphone's heart rate monitor is not meant for continuous tracking, while the both the Gear 2 smart watch and Gear Fit wearable device must be paired with a smartphone or computer to offload and view the recorded data. Such a pairing requires the devices to be close to each other and makes data offload challenging when a smartphone or a computer are not at hand.

With all manner of conventional "fitness-oriented" devices, whether smartphone, smart watch, or activity tracker, quantified physiology is typically tracked for only the personal use of the wearer. Monitoring can be either continuous or non-continuous. The wearer must take extra steps to route recorded data to a health care provider; thus, with rare exception, the data is not time-correlated to physician-supervised monitoring nor validated. Furthermore, the monitoring is strictly informational and medically-significant events, such as serious cardiac rhythm disorders, including tachyarrhythmias and bradyarrhythmias, while potentially detectable, are neither identified nor acted upon.

In today's medical and legal environment, a mobile device, such as a smartphone, provides information that seldom can be translated into data that triggers surgery or drug therapy by a physician. In the case of a smartphone detecting a fast heartbeat, for example, such a detection and the information on the smartphone would neither be identified as truly related to the patient in question or would be deemed sufficient for subjecting a patient to surgery or potentially toxic drug therapy. Thus, such data that is available today is not actionable in a medically therapeutic relevant way. To make such data actionable, one must have recorded data that allows a specific rhythm diagnosis, and a

vague recording hinting that something may be wrong with the heart will not suffice. Further, the recorded data must not only identify the heart-related event of concern, but the signals before and after the event, which provides critical medical information for a physician to diagnose the disorder specifically. Finally, the recorded data must be made certifiable, so that the relationship of the recorded data to the patient that the physician is seeing is clear and appropriately identifiable as an event originating in the patient being examined. Establishing this relationship of data-to-patient has become a legally mandatory step in providing medical care, which heretofore has been impracticable insofar as one cannot merely rely upon a smartphone to provide legally sufficient identification of an abnormality with actionable data such that a patient undergoes a serious medical or surgical intervention commonly used in the management of heart rhythm disorders.

Further, conventional wearable sensors are generally poorly-suited for continuous long-term monitoring due to inadequate power management and because of poor skin contact. Such devices can start trying to record physiological data, using up battery power, regardless of whether they are currently being worn by a person whose physiological data the sensors are intended to gather. As a result of this battery power drain, the effective monitoring time for which these sensors can be used is reduced. The power drain can further be exacerbated by the wearable devices performing functions other than physiological monitoring, such as interfacing with other devices and transferring collected data to these devices. For multi-purpose devices especially, such as smartphones, these additional activities can use up the majority of the battery power, leaving insufficient power for continuous long-term monitoring.

Therefore, a need remains for a low cost extended wear continuously recording ECG monitor attuned to conserving power and capturing low amplitude cardiac action potential propagation for arrhythmia diagnosis, particularly atrial activation P-waves, and practicably capable of being worn for a long period of time, especially in patient's whose breast anatomy or size can interfere with signal quality in both women and men.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring coupled with an onboard ability to cascade into the medical records and to the medical authorities appropriate medical interventions upon detection of a condition of potential medical concern.

A still further need remains for a low cost extended wear continuously recording ECG monitor attuned to capturing low amplitude cardiac action potential propagation for arrhythmia diagnosis, particularly atrial activation P-waves, practicably capable of being worn for a long period of time, especially in patient's whose breast anatomy or size can interfere with signal quality in both women and men, and that is able to interface with other devices that are distant from the monitor.

SUMMARY

Physiological monitoring can be provided through a lightweight wearable monitor that includes two components, a flexible extended wear electrode patch and a reusable monitor recorder that removably snaps into a receptacle on the electrode patch. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The ECG electrodes on the electrode patch

are tailored to be positioned axially along the midline of the sternum for capturing action potential propagation in an orientation that corresponds to the aVF lead used in a conventional 12-lead ECG that is used to sense positive or upright P-waves. 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 and significantly improves the ability of the wearable monitor to cutaneously sense cardiac electrical potential signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals indicating ventricular activity in the ECG waveforms. The patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. Moreover, the wearable monitor is worn in such a location that is comfortable to woman and allows wear during activity.

Moreover, the electrocardiography monitor offers superior patient comfort, convenience and user-friendliness. The electrode patch is specifically designed for ease of use by a patient (or caregiver); assistance by professional medical personnel is not required. The patient is free to replace the electrode patch at any time and need not wait for a doctor's appointment to have a new electrode patch placed. Patients can easily be taught to find the familiar physical landmarks on the body necessary for proper placement of the electrode patch. Empowering patients with the knowledge to place the electrode patch in the right place ensures that the ECG electrodes will be correctly positioned on the skin, no matter the number of times that the electrode patch is replaced. In addition, the monitor recorder operates automatically and the patient only need snap the monitor recorder into place on the electrode patch to initiate ECG monitoring. Thus, the synergistic combination of the electrode patch and monitor recorder makes the use of the electrocardiography monitor a reliable and virtually foolproof way to monitor a patient's ECG and physiology for an extended, or even open-ended, period of time.

Further, the electrocardiography monitor is able to detect when the monitor is adhered to the patient and initiate the monitoring upon detecting the adherence, thus conserving battery power when compared to conventional monitors that go through monitoring steps regardless of whether they are attached to the patient. The detection can be accomplished based on the electrocardiographic signals sensed by the electrodes, using techniques such as measuring and analyzing voltage using the electrographic electrodes that adhere to the patient's chest. In a further embodiment, the detection of the contact can be accomplished by measuring impedance of the electrocardiographic electrodes that adhere to the patient's chest. The detection of the contact can be initiated based on receiving actigraphy data indicating attachment to a patient, based on an expiration of a time interval, or based on both factors.

In a further embodiment, the wearable monitor can interoperate wirelessly with other wearable physiology monitors and activity sensors and with mobile devices, including so-called "smartphones," as well as with personal computers and tablet or handheld computers, to download monitoring data either in real-time or in batches. The interoperation can be accomplished by using a low energy wireless transceiver as part of the monitor, which can conserve battery power and allow for a longer monitoring period. Also, the wireless transceiver can be implemented using a standard that allows

the transceiver to have cellular phone capabilities such as connecting to telecommunications networks, such as the Internet or a cellular network, and interfacing with devices via the networks, extending the distance over which the interfacing can be accomplished. Where a wearable physiology monitor, activity sensor, or mobile device worn or held by the patient includes the capability to sense cardiac activity, particularly heart rate, or other physiology, an application executed by the monitor, sensor, or device can trigger the dispatch of a medically-actionable wearable monitor to the patient upon detecting potentially medically-significant events, such as cardiac rhythm disorders, including tachyarrhythmias and bradyarrhythmias. Upon receipt of the wearable monitor, the patient can use the sensor or device, if appropriately equipped with photographic, fingerprint or thumbprint, voice, or other recording features, to physically record the placement and use of the wearable monitor, thereby facilitating the authentication of the data recorded by the wearable monitor. Finally, the monitor wireless transceiver can also be used to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology monitor, activity sensor, or mobile device for relay to an external system or further device, such as a server, analysis, or for further legal validation of the relationship of the monitor to the patient, or for other purpose.

One embodiment provides a contact-activated extended wear electrocardiography and physiological sensor monitor recorder. The recorder includes a sealed housing adapted to be removably secured into a non-conductive receptacle on a disposable extended wear electrode patch and an electronic circuitry comprised within the sealed housing. The electronic circuitry includes an electrocardiographic front end circuit electrically interfaced to the microcontroller and operable to sense electrocardiographic signals through electrocardiographic electrodes provided on the disposable extended wear electrode patch, each of the electrocardiographic electrodes adapted to be positioned axially along the midline of the sternum for capturing action potential propagation; an externally-powered microcontroller electrically interfaced to the front end and operable to execute under micro programmable control through firmware that is stored in a program memory unit of the microcontroller, the microcontroller operable to detect the electrodes being adhered to the sternum based on the sensed electrographic signals and to start an execution of a monitoring sequence stored as part of the firmware based on the detected adherence; and an externally-powered flash memory electrically interfaced with the microcontroller and operable to store samples of the electrocardiographic signals collected during the execution of the monitoring sequence.

A further embodiment provides a contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation. The monitoring patch includes a disposable extended wear electrode patch and an ambulatory electrocardiography monitor. The disposable extended wear electrode patch includes a flexible backing including stretchable material defined as an elongated strip with a narrow longitudinal midsection, each end of the flexible backing comprising an adhesive contact surface adapted to serve as a crimp relief; a pair of electrocardiographic electrodes included on the contact surface of each end of the flexible backing, each electrocardiographic electrode conductively exposed for dermal adhesion and adapted to be positioned axially along the midline of the sternum for capturing action potential propagation; a non-conductive receptacle affixed to a non-

contacting surface of the flexible backing and including an electro mechanical docking interface; and a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to the docking interface, at least one of the circuit traces adapted to extend along the narrow longitudinal midsection to serve as a strain relief. The ambulatory electrocardiography monitor includes a wearable housing adapted to securely fit into the receptacle and electronic circuitry provided within the wearable housing and including an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface. The circuitry further includes an electrocardiographic front end circuit adapted to sense cardiac electrical potential differentials through the electrocardiographic electrodes; a low power microcontroller in control of the front end and operable to execute over an extended period under modular micro program control as specified in firmware, the microcontroller further operable to receive the sensed cardiac potential differentials as electrocardiographic signals representative of amplitudes of the action potential propagation, to detect the electrodes adhered to the sternum based on the received electrocardiographic signals and to start an execution of a monitoring sequence stored as part of the firmware based on the detection of the adherence; and a non-volatile memory electrically interfaced with the microcontroller and operable to continuously store samples of the electrocardiographic signals collected during the execution of the monitoring sequence throughout the extended period.

In a further embodiment, a wireless transceiver may also be attached to the microcontroller to facilitate upload of data to monitoring device, or to receive data from additional sensors. The transceiver can be configured to connect to a telecommunications network, allowing to increase a range over which the transceiver can interact with other devices.

The foregoing aspects enhance ECG monitoring performance and quality by facilitating long-term ECG recording, which is critical to accurate diagnosis of cardiac rhythm disorders.

The monitoring patch is especially suited to the female anatomy, although also easily used over the male sternum. The narrow longitudinal isthmus or midsection can fit nicely within the inter-mammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhered between the breasts, would cause chafing, irritation, discomfort, and annoyance, leading to low patient compliance.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, particularly P-waves, which is another feature critical to proper cardiac rhythm disorder diagnoses.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological data, such as heart rate, temperature, blood pressure, respiratory rate, blood pressure, blood sugar (with appropriate subcutaneous probe), oxygen saturation, minute ventilation, as well as other measures of body chemistry and physiology.

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 respectively fitted to the sternal region of a female patient and a male patient.

FIG. 3 is a functional block diagram showing a system for remote interfacing of a contact-activated extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. 4 is a perspective view showing a contact-activated extended wear electrode patch with a monitor recorder inserted.

FIG. 5 is a perspective view showing the monitor recorder of FIG. 4.

FIG. 6 is a perspective view showing the extended wear electrode patch of FIG. 4 without a monitor recorder inserted.

FIG. 7 is a bottom plan view of the monitor recorder of FIG. 4.

FIG. 8 is a top view showing the flexible circuit of the extended wear electrode patch of FIG. 4 when mounted above the flexible backing.

FIG. 9 is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. 4.

FIG. 10 is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. 4.

FIG. 11 is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. 4.

FIG. 12 is a graph showing, by way of example, a typical ECG waveform.

FIG. 13 is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. 14 is a front anatomical view showing, by way of illustration, the locations of the heart and lungs within the rib cage of an adult human.

FIG. 15 is a schematic diagram showing the ECG front end circuit of the circuitry of the monitor recorder of FIG. 9 in accordance with one embodiment.

FIG. 16 is a functional block diagram showing the signal processing functionality of the microcontroller in accordance with one embodiment.

FIG. 17 is a functional block diagram showing operations performed by the download station in accordance with one embodiment.

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. Both the electrode patch and the monitor recorder are 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. FIGS. 1 and 2 are diagrams showing, by way of example, 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.

During ECG monitoring, the amplitude and strength of action potentials sensed on the body's surface are affected to varying degrees by cardiac, cellular, extracellular, vector of current flow, and physical factors, like obesity, dermatitis, large breasts, and high impedance skin, as can occur in dark-skinned individuals. Sensing along 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 waveforms that indicate ventricular activity by countering some of the effects of these factors.

The ability to sense low amplitude, low frequency content body surface potentials is directly related to the location of ECG electrodes on the skin's surface and the ability of the sensing circuitry to capture these electrical signals. FIG. 14 is a front anatomical view showing, by way of illustration, the locations of the heart 4 and lungs 5 within the rib cage of an adult human. Depending upon their placement locations on the chest, ECG electrodes may be separated from activation regions within the heart 4 by differing combinations of internal tissues and body structures, including heart muscle, intracardiac blood, the pericardium, intrathoracic blood and fluids, the lungs 5, skeletal muscle, bone structure, subcutaneous fat, and the skin, plus any contaminants present between the skin's surface and electrode signal pickups. The degree of amplitude degradation of cardiac transmembrane potentials increases with the number of tissue boundaries between the heart 4 and the skin's surface that are encountered. The cardiac electrical field is degraded each time the transmembrane potentials encounter a physical boundary separating adjoining tissues due to differences in the respective tissues' electrical resistances. In addition, other non-spatial factors, such as pericardial effusion, emphysema or fluid accumulation in the lungs, as further explained infra, can further degrade body surface potentials.

Internal tissues and body structures can adversely affect the current strength and signal fidelity of all body surface potentials, yet low amplitude cardiac action potentials, particularly the P-wave with a normative amplitude of less than 0.25 microvolts (mV) and a normative duration of less than 120 milliseconds (ms), are most apt to be negatively impacted. The atria 6 are generally located posteriorly within the thoracic cavity (with the exception of the anterior right atrium and right atrial appendage), and, physically, the left atrium constitutes the portion of the heart 4 furthest away from the surface of the skin on the anterior chest. Conversely, the ventricles 7, which generate larger amplitude signals, generally are located anteriorly with the ante-

rior right ventricle and most of the left ventricle situated relatively close to the skin surface on the anterior chest, which contributes to the relatively stronger amplitudes of ventricular waveforms. Thus, the quality of P-waves (and other already-low amplitude action potential signals) is more susceptible to weakening from intervening tissues and structures than the waveforms associated with ventricular activation.

The importance of the positioning of ECG electrodes along the sternal midline **15** has largely been overlooked by conventional approaches to ECG monitoring, in part due to the inability of their sensing circuitry to reliably detect low amplitude, low frequency content electrical signals, particularly in P-waves. In turn, that inability to keenly sense P-waves has motivated ECG electrode placement in other non-sternal midline thoracic locations, where the QRSTU components of the ECG that represent ventricular electrical activity are more readily detectable by their sensing circuitry than P-waves. In addition, ECG electrode placement along the sternal midline **15** presents major patient wearability challenges, such as fitting a monitoring ensemble within the narrow confines of the inter-mammary cleft between the breasts, that to large extent drive physical packaging concerns, which can be incompatible with ECG monitors intended for placement, say, in the upper pectoral region or other non-sternal midline thoracic locations. In contrast, the wearable monitor **12** uses an electrode patch **15** that is specifically intended for extended wear placement in a location at the sternal midline **16** (or immediately to either side of the sternum **13**). When combined with a monitor recorder **14** that uses sensing circuitry optimized to preserve the characteristics of low amplitude cardiac action potentials, especially those signals from the atria, as further described infra with reference to FIG. **15**, the electrode patch **15** helps to significantly improve atrial activation (P-wave) sensing through placement in a body location that robustly minimizes the effects of tissue and body structure.

Referring back to FIGS. **1** and **2**, 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 locations better adapted to sensing and recording low amplitude cardiac action potentials during atrial propagation (P-wave signals) than placement in other locations, such as the upper left pectoral region, as commonly seen in most conventional ambulatory ECG monitors. The sternum **13** overlies the right atrium of the heart **4**. As a result, action potential signals have to travel through fewer layers of tissue and structure to reach the ECG electrodes of the electrode patch **15** on the body's surface along the sternal midline **13** when compared to other monitoring locations, a distinction that is of critical importance when capturing low frequency content electrical signals, such as P-waves.

Moreover, 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 AV node. The ECG electrodes of the electrode patch **15** are placed with the upper or superior pole (ECG electrode) along the sternal midline **13** beneath the manubrium and the lower or inferior pole (ECG electrode) along the sternal midline **13** in the region of the Xiphoid process **9** and lower sternum. The ECG electrodes are placed primarily in a head-to-foot orientation along the sternum **13** that corresponds to the head-to-foot waveform vector exhibited during atrial acti-

vation. This orientation corresponds to the aVF lead used in a conventional 12-lead ECG that is used to sense positive or upright P-waves.

Furthermore, the thoracic region underlying the sternum **13** along the midline **16** between the manubrium **8** and Xiphoid process **9** is relatively free of lung tissue, musculature, and other internal body structures that could occlude the electrical signal path between the heart **4**, particularly the atria, and ECG electrodes placed on the surface of the skin. Fewer obstructions means that cardiac electrical potentials encounter fewer boundaries between different tissues. As a result, when compared to other thoracic ECG sensing locations, the cardiac electrical field is less altered when sensed dermally along the sternal midline **13**. As well, the proximity of the sternal midline **16** to the ventricles **7** facilitates sensing of right ventricular activity and provides superior recordation of the QRS interval, again, in part due to the relatively clear electrical path between the heart **4** and the skin surface.

Finally, non-spatial factors can affect transmembrane action potential shape and conductivity. For instance, myocardial ischemia, an acute cardiac condition, can cause a transient increase in blood perfusion in the lungs **5**. The perfused blood can significantly increase electrical resistance across the lungs **5** and therefore degrade transmission of the cardiac electrical field to the skin's surface. However, the placement of the wearable monitor **12** along the sternal midline **16** in the inter-mammary cleft between the breasts is relatively resilient to the adverse effects to cardiac action potential degradation caused by ischemic conditions as the body surface potentials from a location relatively clear of underlying lung tissue and fat help compensate for the loss of signal amplitude and content. The monitor recorder **14** is thus able to record the P-wave morphology that may be compromised by myocardial ischemia and therefore make diagnosis of the specific arrhythmias that can be associated with myocardial ischemia more difficult.

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 waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. 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 or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides excellent recordation of the QRS interval as the Xiphoid process overlies the apical region of the ventricles.

When operated standalone, the monitor recorder **14** of the extended wear electrocardiography and physiological sensor monitor **12** senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor **12** can interoperate with other devices. FIG. **3** is a functional block diagram showing a system **120** for remote interfacing of a contact-activated extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The monitor recorder **14** is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch

15, as further described infra with reference to FIG. 4, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder 14 can then be connected to a download station 125, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder 14, or performance of other functions. The monitor recorder 14 has a set of electrical contacts (not shown) that enable the monitor recorder 14 to physically interface to a set of terminals 128 on a paired receptacle 127 of the download station 125. In turn, the download station 125 executes a communications or offload program 126 ("Offload") or similar program that interacts with the monitor recorder 14 via the physical interface to retrieve the stored ECG monitoring data. The download station 125 could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built device designed specific to the task of interfacing with a monitor recorder 14. Still other forms of download station 125 are possible. Also, as mentioned below, the data from the monitor 12 can be offloaded wirelessly and the monitor 12 can interface with the download station 125 wirelessly.

FIG. 17 is a functional block diagram showing the operations 180 performed by the download station 125. The download station 125 is responsible for offloading stored ECG monitoring data from a monitor recorder 14 and includes an electro mechanical docking interface by which the monitor recorder 14 is connected at the external connector 65. The download station operates under programmable control as specified in software 181. The stored ECG monitoring data retrieved from storage 182 on a monitor recorder 14 is first decompressed by a decompression module 183, which converts the stored ECG monitoring data back into an uncompressed digital representation more suited to signal processing than a compressed signal. The retrieved ECG monitoring data may be stored into local storage for archival purposes, either in original compressed form, or as uncompressed.

The download station can include an array of filtering modules. For instance, a set of phase distortion filtering tools 184 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.

An automatic gain control (AGC) module 185 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 electrocardiography monitor 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.

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 185, the gain of signals recorded by the monitor recorder 14 of the electrocardiography monitor 12 can be attenuated up (or down) to work with FDA-approved commercially available ECG interpretation.

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.

Typically, the monitor recorder 14 will record a high resolution, low frequency signal for the P-wave segment. 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 generated by the monitor recorder 14. Automatic gain control applied to a high noise signal will only exacerbate noise content and be self-defeating.

Finally, the download station can include filtering modules specifically intended to enhance P-wave content. For instance, a P-wave enhancement filter 186, which is a form of pre-emphasis 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.

In addition to the processing described above, the download station can also convert retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described below with reference to FIG. 13. Referring back to FIG. 3, the data processed by the download station 125 can then be retrieved from the download station 125 over a hard link 135 using a control program 137 ("Ctl") or analogous application executing on a personal computer 136 or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer 136 or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. 13. Note that formatted data stored on the personal computer 136 would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) 134 in the secure database 124, as further discussed infra. In a further embodiment, the download station 125 is able to directly interface with other devices over a computer communications network 121, which could be some combination of a local area network and a wide area network, including the Internet or another telecommunications network, over a wired or wireless connection.

A client-server model could be used to employ a server 122 to remotely interface with the download station 125 over the network 121 and retrieve the formatted data or other

information. The server **122** executes a patient management program **123** (“Mgt”) or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient’s EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** 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 **124**. The physician would execute an application program **130** (“Pgm”), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient’s EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology monitors and activity sensors **131**, such as activity trackers worn on the wrist or body, and with mobile devices **132**, including smart watches and smartphones. Wearable physiology monitors and activity sensors **131** 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. The physiology sensors in non-wearable mobile devices, 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 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 validation to allow for medical action. Conversely, medically actionable wearable sensors and devices sometimes provide continuous recording for relatively short time periods, but must be paired with a smartphone or computer to offload and evaluate the recorded data, especially if the data is of urgent concern.

Wearable physiology monitors and activity sensors **131**, also known as “activity monitors,” and to a lesser extent, “fitness” sensor-equipped mobile devices **132**, 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 **131** and mobile device **132** 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 **131** and the mobile device **132**.

Frequently, wearable physiology monitors and activity sensors **131** are capable of wirelessly interfacing with mobile devices **132**, 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 **131**, 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.

Where the wearable physiology monitors and activity sensors **131** are paired with a mobile device **132**, the mobile device **132** executes an application (“App”) that can retrieve the data collected by the wearable physiology monitor and activity sensor **131** 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 **131** has sufficient onboard computational resources, the activity monitor itself executes an app without the need to relay data to a mobile device **132**. Generally, such more computationally-capable wearable physiology monitors and activity sensors are also equipped with wireless communications services transceivers, such as found in some smart watches that combine the features of activity monitors with mobile devices. Still other activity monitor and mobile device functions on the collected data are possible.

In a further embodiment, a wearable physiology monitor, activity sensor **131**, or mobile device **132** 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 a more definitive monitor recorder **14** to enable the collection of physiology by the monitor recorder **14** before, during, and after potentially medically-significant events. The wearable physiology monitor, activity sensor **131**, or mobile device **132** 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 **131** is paired with a mobile device **132**, the mobile device **132** serves as a relay device and executes an application that will trigger the dispatch of a monitor recorder **14** to the patient **10** upon detecting potentially medically-significant events in the data provided by the paired activity monitor, such as cardiac rhythm disorders, including tachyarrhythmias and bradyarrhythmias. If the mobile device **132** is itself performing the monitoring of the patient’s physiology, the mobile device **132** executes an

application that will trigger the dispatch of a monitor recorder 14 to the patient 10 in near-real time upon detecting potentially medically-significant events, thereby avoiding the delay incurred by data relay from an activity monitor. Finally, if the wearable physiology monitor or activity sensor 131 has sufficient onboard computational resources and also is equipped with a wireless communications services transceiver, the wearable physiology monitor or activity sensor 131 effectively becomes the mobile device 132 and executes an application that will trigger the dispatch of a monitor recorder 14 to the patient 10 in near-real time upon detecting potentially medically-significant events without the need to first interface with a mobile device 132. Still other configurations of the detection app are possible.

The act of triggering the dispatch of a monitor recorder 14 represents the first step in a cascade of possible medical interventions of potentially increasing seriousness and urgency. Sensors 131 and devices 133 are generally not capable of detecting and recording medically precise and actionable data, whereas, as a device designed for extended wear, the monitor recorder 14 continually monitors the patient's physiology over a long time period and will capture any medically-actionable data leading up to, throughout the occurrence of, and following an event of potential medical concern.

The monitoring data recorded by the monitor recorder 14 can be uploaded directly into the patient's EMRs 134, either by using a mobile device 132 as a conduit for communications with a server 122 coupled to a secure database 124 within which the patient's EMRs 134 are stored, or directly to the server 122, if the monitor recorder 14 is appropriately equipped with a wireless transceiver or similar external data communications interface, as further described infra. Thus, the data recorded by the monitor recorder 14 would directly feed into the patient's EMRs 134, thereby allowing the data to be made certifiable for immediate use by a physician or healthcare provider. No intermediate steps would be necessary when going from cutaneously sensing cardiac electric signals and collecting the patient's physiology using a monitor recorder 14 to presenting that recorded data to a physician or healthcare provider for medical diagnosis and care. The direct feeding of data from the monitor recorder 14 to the EMRs 134 clearly establishes the relationship of the data, as recorded by the monitor recorder 14, 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. In a further embodiment, the server 122 can evaluate the recorded data, as fed into the patient's EMRs 134, 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 monitor recorder 14 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 131 or device 133 that includes a heart rate monitor would be able to timely detect an irregularity in heart rhythm. The application executed by the

sensor 131 or device 133 allows those devices to take action by triggering the dispatch of a monitor recorder 14 to the patient 10, even though the data recorded by the sensor 131 or device 133 is itself generally medically-insufficient for purposes of diagnosis and care. Thus, rather than passively recording patient data, the sensor 131 or device 133 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.

In a still further embodiment, the monitor recorder 14 could upload an event detection application to the sensor 131 or device 133 to enable those devices to detect those types of potentially medically-significant events, which would trigger the dispatch of a monitor recorder 14 to the patient 10. Alternatively, the event detection application could be downloaded to the sensor 131 or device 133 from an online application store or similar online application repository. Finally, the monitor recorder 14 could use the sensor 131 or device 133 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.

The patient 10 could be notified by the sensor 131 or device 133, through the sensor's or device's user interface, that an event of potential medical concern has been detected coupled with an offer to have a monitor recorder 14 sent out to the patient 10, assuming that the patient 10 is not already wearing a monitor recorder 14. Alternatively, the sensor 131 or device 133 could unilaterally send out a request for a monitor recorder 14. The request for a monitor recorder 14 could be sent via wireless (or wired) communications to the patient's physician, a medical service provider organization, a pharmacy, an emergency medical service, or other appropriate healthcare entity that would, in turn, physically provide the patient with a monitor recorder 14. The patient 10 could also be told to pick up a monitor recorder 14 directly from one of the above-identified sources.

Conventional Holter monitors, as well as the ZIO XT Patch and ZIO Event Card devices, described supra, are currently available only by a physician's prescription for a specific patient 10. As a result, the physiological data recorded by these monitors and devices are assumed by healthcare professional to belong to the patient 10. In this prescriptive medicine context, grave questions as to the authenticity of the patient's identity and the data recorded do not generally arise, although current medical practice still favors requesting affirmative patient and caregiver identification at every step of healthcare provisioning. As a device intended for adoption and usage broader than prescriptive medicine, the monitor recorder 14 carries the potential to be used by more than one individual, which can raise concerns as to the veracity of the data recorded.

In a still further embodiment, the mobile device 132, or, if properly equipped, the activity monitor, can be used to help authenticate the patient 10 at the outset of and throughout the monitoring period. The mobile device 132 (or activity monitor) must be appropriately equipped with a digital camera or other feature capable of recording physical indicia located within the proximity of the mobile device 132. For instance, the Samsung Galaxy S5 smartphone has both a biometric fingerprint reader and autofocus digital camera built in. Upon receipt of a monitor recorder 14, the patient 10 can use the photographic or other recording features of the mobile device 132 (or activity monitor) to physically record the placement and use of the monitor

recorder 14. For instance, the patient 10 could take a picture or make a video of the monitor recorder 14 using as applied to the chest using the built-in digital camera. The patient 10 could also swipe a finger over the biometric fingerprint reader. Preferably, the patient 10 would include both his or her face or similar uniquely-identifying marks or indicia, such as a scar, tattoo, body piercing, or RFID chip, plus any visible or electronic indicia on the outside of the monitor recorder's housing, as further described infra with reference to FIG. 5, in the physical recording. The physical recording would then be sent by the mobile device 132 (or activity monitor) via wireless (or wired) communications to the patient's physician's office or other appropriate caregiver, thereby facilitating the authentication of the data recorded by the monitor recorder 14. Alternatively, the physical recording could be securely stored by the monitor recorder 14 as part of the monitoring data set.

The mobile device 132 could also serve as a conduit for providing the data collected by the wearable physiology monitor or activity sensor 131 to a server 122, or, similarly, the wearable physiology monitor or activity sensor 131 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 131. Still other server 122 functions on the collected data are possible.

Finally, the monitor recorder 14 can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. 9 and 10. Thus, when wireless-enabled, both wearable physiology monitors, activity sensors 131, and mobile devices 132 can wirelessly interface with the monitor recorder 14, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server 122, analysis, or other purpose. In addition, the monitor recorder 14 could wirelessly interface directly with the server 122, personal computer 129, or other computing device connectable over the network 121, when the monitor recorder 14 is appropriately equipped for interfacing with such devices. In one embodiment, network 121 can be a telecommunications network, such as the Internet or a cellular network, and the wireless transceiver can have at least some cellular phone capabilities, such as by being able to connect to the telecommunications networks. For example, if implemented using the standard such as Bluetooth® 4.2 standard or a Wi-Fi standard, the transceiver can connect to the Internet. Similarly, if implemented using a cellular standard and including a cellular chipset, the transceiver can connect to a cellular network as further described below. Once connected, the monitor recorder 14 can interface with the above-described devices via connecting to the telecommunications network. Still other types of remote interfacing of the monitor recorder 14 are possible.

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, with the monitoring being initiated upon the recorder 14 detecting contact with the patient 10, 11. FIG. 4 is a perspective view showing a contact-activated 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 midsection 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 "hourglass"-like shape, when viewed from above. The upper part of the "hourglass" is sized to allow an electrically non-conductive receptacle 25, sits on top of the outward-facing surface of the electrode patch 15, to be affixed to the electrode patch 15 with an ECG electrode placed underneath on the patient-facing underside, or contact, surface of the electrode patch 15; the upper part of the "hourglass" has a longer and wider profile (but still rounded and tapered to fit comfortably between the breasts) than the lower part of the "hourglass," which is sized primarily to allow just the placement of an ECG electrode of appropriate shape and surface area to record the P-wave and the QRS signals sufficiently given the inter-electrode spacing.

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. Pat. No. 9,545,204, issued 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, such as described in commonly-assigned U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. 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. 5 is a perspective view showing the monitor recorder 14 of FIG. 4. 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 commonly-assigned U.S. Design Pat. No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. In addition, a label, barcode, QR code, or other visible or electronic indicia is printed on the outside of, applied to the outside of, or integrated into the sealed housing 50 to uniquely identify the monitor recorder 14 and can include a serial number, manufacturing lot number, date of manufac-

ture, and so forth. 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. 6 is a perspective view showing the extended wear electrode patch **15** of FIG. 4 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. 7 is a bottom plan view of the monitor recorder **14** of FIG. 4. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compart-

ment **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. 8 is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. 4 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 an '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. Other forms of the patch **15** are also possible. For example, in a further embodiment, the distal and proximal circuit traces are replaced with interlaced or sewn-in flexible wires, as further described in commonly-assigned U.S. Pat. No. 9,717,432, issued Aug. 1, 2017, the disclosure of which is incorporated by reference.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. 9 is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. 4. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. 6). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. 8) 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 microcontroller **61** includes a program memory unit containing internal flash memory that is readable and writeable. 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 microcontroller **61** operates under modular micro program control as specified in firmware, and the program control includes processing of the analog ECG signal output by the ECG front end circuit **63**. FIG. **16** is a functional block diagram showing the signal processing functionality **170** of the microcontroller **61** in accordance with one embodiment. The microcontroller **61** operates under modular micro program control as specified in firmware **172**. The firmware modules **172** may include high and low pass filtering **173**, and compression **174**. Other modules are possible. The microcontroller **61** has a built-in ADC, although ADC functionality could also be provided in an external chip **172**.

The ECG front end circuit **63** first outputs an analog ECG signal, which the ADC **171** acquires, samples and converts into an uncompressed digital representation. The microcontroller **61** includes one or more firmware modules **173** that perform filtering. In one embodiment, a high pass smoothing filter is used for the filtering; other filters and combinations of high pass and low pass filters are possible in a further embodiment. Following filtering, the digital representation of the cardiac activation wave front amplitudes are compressed by one or more compression modules **174** before being written out to storage **175**.

As further described below with reference to FIG. **11**, the microcontroller **61** can check for whether electrodes **38, 39** (and thus the monitor **12** as a whole) are adhered to a patient **10, 11**, prior to beginning collecting physiological data. The microcontroller **61** can determine the adherence based on the action potentials sensed by the front end **63** through the electrodes **38, 39**. When the monitor **12** is adhered to the patient's **10, 11** body, and in particular the sternum **13**, the front end can sense **63** body surface potentials through the electrodes **38, 39**. The microcontroller **61** can distinguish the signals sensed by the front end **63** through the electrodes **38, 39** that are due to the cardiac action potentials from other kinds of electrical signals that are not indicative of the monitor **12** being in contact with the sternum **13**. For example, the front end **63** can measure voltage through the electrodes **38, 39**, and the microcontroller **61** can process the

measured voltage to determine if the electrodes **38, 39** are sensing cardiac action potentials. For example, if an ECG waveform that results from the processing of the measured voltage is a flatline, the electrodes **38, 39** are likely covered by a release liner; in this case, the microcontroller **61** determines that the electrodes **38, 39** are not in contact with the sternum **13**. On the other hand, if processing of the measured voltage detects at least that the electrodes **38, 39** have sensed at least a portion of a typical ECG waveform, such as the one shown below with reference to FIG. **12**, the microcontroller **61** can determine that the monitor **12** is adhered to the sternum **13**. For instance, an R wave is distinctly different from noise and can be easily detected by an R-wave detection algorithm that can be implemented by the microprocessor **61**; upon detecting that the electrodes **38, 39** sensed an R-wave based on the measured voltage, the microcontroller **61** can determine that the monitor **12** is adhered to the patient **10, 11**.

In a further embodiment, the contact with the sternum **13** can also be determined by the front end **63** or another circuit interfaced to the microcontroller **61** by measuring the impedance of the electrodes **38, 39**. Once the electrodes **38, 39** are adhered to the patient's **10, 11** skin and are measuring voltage of the body surface potentials, the impedance of the electrodes **38, 39** differs from the impedance when the electrodes **38, 39** are not in contact with the skin, with the electrodes **38, 39** having a higher impedance when not adhered to the patient's skin. By comparing the predetermined impedance of the electrodes **38, 39** when the electrodes **38, 39** are not in contact with the patient's skin to a measured impedance, the microcontroller **61** can detect that the contact between the sternum **13** and the electrodes **38, 39** has been established. In a further embodiment, the microcontroller **61** can determine that the electrodes **38, 39** are connected to the sternum **13** when the measured impedance falls into a predetermined value range. Other ways to determine the adherence are possible. Multiple sensors and input sources can be used by the microcontroller **61** to best determine if the monitor **12** is in use and should start recording. For example, as further described below, in one embodiment, the microcontroller **61** starts checking for the contact of the electrodes **38, 39** with the sternum **13** only after receiving actigraphy data indicating that the monitor **12** is being worn by the patient **10, 11**.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the microcontroller **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, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

In addition, the actigraphy sensor 64 can be used to determine whether the monitor 12 is attached to the patient 10, 11. The actigraphy data collected by the actigraphy sensor 64 can be identified as indicative of the monitor 12 being worn by the patient based on the data satisfying one or more of certain thresholds of acceleration and deceleration, the frequency with which the actigraphy data is generated, and a duration of time during which the data is generated. For example, walking can be recognized by a variance of over 0.02 g (g-force) in the vertical acceleration within a frequency range of 1-3 Hz. Actigraphy data indicative of walking can be set as indicative of the monitor 12 being worn by the patient 12. Other kinds of actigraphy data, based on other thresholds, can also be set as the monitor being attached. Following the receipt of such data from the actigraphy sensor 34, the microcontroller 61 can begin to check whether the electrodes 38, 39 are connected to the patient 10, 11. The circuitry 60 of the monitor recorder 14 includes a wireless transceiver 69 that can provides wireless interfacing capabilities. The wireless transceiver 69 also draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The wireless transceiver 69 can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile standard; the Bluetooth® data exchange standard; or other wireless communications or data exchange standards and protocols.

The wireless transceiver used 69 can minimize the drain on the battery provided on the electrode patch 15 or another source that is used to power the monitor 12 by being implemented using a low energy communication standard. For example, one such standard is the Bluetooth® 4.0 standard. While the Bluetooth® 4.0 standard does not have a similar communication range to previous versions of the standard, the Bluetooth® 4.0 standard significantly reduces the power consumption during wireless communication when compared to the other standards. Further, the standard is optimized for sending small packets of data, which can be used to communicate collected ECG data in near-real time; in one embodiment, the wireless transceiver can send data packets that include physiological data once every four seconds, allowing for continuous transfer of the collected electrocardiographic and other kinds of data. Thus, implementing the wireless transceiver 69 using the Bluetooth® 4.0 standard to communicate with other devices compatible with the standard, such as the mobile device 132, minimizes the consumption of power such communication requires, extending the time that the monitor 12 can continuously conduct physiological monitoring.

Further, while many communication standards require communicating devices to be within a short range of each other, the range within which the wireless transceiver 69 can communicate with devices can be extended by implementing the transceiver 69 using standards that allow the transceiver 69 to have cellular phone capabilities such as accessing a telecommunications network, such as the Internet or a cellular network. For example, the standards such as the Bluetooth® 4.2 and the Wi-Fi® standards allow the transceiver 69 to connect to the Internet, though other standards can also be used to establish the Internet connection. When implemented using the Bluetooth 4.2 or the Wi-Fi® stan-

dards, the wireless transceiver 69 can communicate with other phones as well as other kinds of devices, such as activity sensors 131, mobile devices 132, the server 122, personal computer 129, or other computing device connectable over the network 121, to download and offload data over a great distance via the Internet. Similarly, the wireless transceiver 69 can include a cellular chipset that uses a cellular protocol, such as High Speed Packet Access Protocol (HSPA), though other protocols can be used, to access a cellular network and interface with devices such as other phones via the cellular network. Other standards allowing the wireless transceiver 69 have cellular phone capabilities are possible.

In one embodiment, a part of the functions required by the Bluetooth 4.0 or another wireless standard is carried out by the microcontroller 61 interfaced to the wireless transceiver 69. In a further embodiment, a separate chip carrying out these functions can be also interfaced to the microcontroller 61.

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 microcontroller 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. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

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. 10 is a functional block diagram showing the circuitry 70 of the extended wear electrode patch 15 of FIG. 4. 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**, such as described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

The ECG front end circuit **63** measures raw cutaneous electrical signals using a driven reference that 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 those signals from the atria. FIG. **15** is a schematic diagram **80** showing the ECG front end circuit **63** of the circuitry **60** of the monitor recorder **14** of FIG. **9** in accordance with one embodiment. The ECG front end circuit **63** senses body surface potentials through a signal lead (“S1”) and reference lead (“REF”) that are respectively connected to the ECG electrodes of the electrode patch **15**. Power is provided to the ECG front end circuit **63** through a pair of DC power leads (“VCC” and “GND”). An analog ECG signal (“ECG”) representative of the electrical activity of the patient’s heart over time is output, which the micro controller **11** converts to digital representation and filters, as further described infra.

The ECG front end circuit **63** is organized into five stages, a passive input filter stage **81**, a unity gain voltage follower stage **82**, a passive high pass filtering stage **83**, a voltage amplification and active filtering stage **84**, and an anti-aliasing passive filter stage **85**, plus a reference generator. Each of these stages and the reference generator will now be described.

The passive input filter stage **81** includes the parasitic impedance of the ECG electrodes **38**, **39** (shown in FIG. **8**), the protection resistor that is included as part of the protection circuit **72** of the ECG electrode **39** (shown in FIG. **10**), an AC coupling capacitor **87**, a termination resistor **88**, and filter capacitor **89**. This stage passively shifts the frequency response poles downward there is a high electrode impedance from the patient on the signal lead S1 and reference lead REF, which reduces high frequency noise.

The unity gain voltage follower stage **82** provides a unity voltage gain that allows current amplification by an Operational Amplifier (“Op Amp”) **90**. In this stage, the voltage stays the same as the input, but more current is available to feed additional stages. This configuration allows a very high input impedance, so as not to disrupt the body surface potentials or the filtering effect of the previous stage.

The passive high pass filtering stage **83** is a high pass filter that removes baseline wander and any offset generated from the previous stage. Adding an AC coupling capacitor **91** after the Op Amp **90** allows the use of lower cost components, while increasing signal fidelity.

The voltage amplification and active filtering stage **84** amplifies the voltage of the input signal through Op Amp **91**, while applying a low pass filter. The DC bias of the input signal is automatically centered in the highest performance input region of the Op Amp **91** because of the AC coupling capacitor **91**.

The anti-aliasing passive filter stage **85** provides an anti-aliasing low pass filter. When the microcontroller **61** acquires a sample of the analog input signal, a disruption in the signal occurs as a sample and hold capacitor that is internal to the microcontroller **61** is charged to supply the signal for acquisition. The anti-aliasing low pass filter minimizes the disruption to the input signal.

The reference generator in subcircuit **86** drives a driven reference containing power supply noise and system noise to the reference lead REF. A coupling capacitor **87** is included on the signal lead S1 and a pair of resistors **93a**, **93b** inject system noise into the reference lead REF. The reference generator 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**.

In contrast, conventional ECG lead configurations try to balance signal and reference lead connections. The conventional approach suffers from the introduction of differential thermal noise, lower input common mode rejection, increased power supply noise, increased system noise, and differential voltages between the patient reference and the reference used on the device that can obscure, at times, extremely, low amplitude body surface potentials.

Here, the parasitic impedance of the ECG electrodes **38**, **39**, the protection resistor that is included as part of the protection circuit **72** and the coupling capacitor **87** allow the reference lead REF to be connected directly to the skin’s surface without any further components. As a result, the differential thermal noise problem caused by pairing protection resistors to signal and reference leads, as used in conventional approaches, is avoided.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu of including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller’s expansion port via the external connector **74**. Similarly to the wireless transceiver **69**, the wireless transceiver **75** can be implemented using a standard that allows to conserve battery power, such as the Bluetooth® 4.0 standard, though other standards are

possible. Further, similarly to the wireless transceiver 69, the wireless transceiver 75 can be implemented using a standard that allows the transceiver 75 to have cellular phone capabilities such as accessing a telecommunications network such as the Internet or a cellular network using the standards described above with reference to the wireless transceiver 69, such as the Bluetooth® 4.2 standard, a Wi-Fi standard, or a cellular standard.

The monitor recorder 14 continuously monitors the patient's heart rate and physiology. FIG. 11 is a flow diagram showing a monitor recorder-implemented method 100 for monitoring ECG data for use in the monitor recorder 14 of FIG. 4. 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.

The microcontroller 61 further checks whether the electrodes 38, 39 are in contact with the patient's 10, 11 sternum 13—whether the monitor 12 has been adhered to the patient 10, 11 (step 102). As mentioned above, microcontroller 61 can use the front end 63 to detect when the electrodes 38, 39 are adhered to the skin of the patient's sternum 13 based on the ECG signals measured by the front end 63 through the electrodes 38, 39. In one embodiment, following the power-up sequence, the microcontroller 61 can continually check for the adherence such as by having the front end 63 measure voltage through the electrodes 38, 39 and determining whether the measured voltage was due to cardiac action potentials, such as by detecting that an R-wave was sensed by the electrodes 38, 39. Alternatively, or in addition to the detection based on the sensed electrocardiographic signals, the contact can be determined by measuring impedance of the electrodes 38, 39. The contact determination can also be performed after an expiration of a certain time intervals as determined by a timer. For example, the microcontroller 61 can check the presence of the contact every several minutes after the monitor 12 has been powered on. In one embodiment, the timer can be a part of the firmware implemented by the microcontroller 61. In a further embodiment, the timer can be a separate component of the circuitries 60 or 70. In a further embodiment, the microcontroller 61 does not start checking for the contact change until receiving actigraphy data from the actigraphy sensor 64 that satisfies one or more predetermined criteria and indicates that the monitor 12 has been attached to a patient 10, 11. For example, actigraphy data whose frequency and magnitude fits indicates the patient 10, 11 walking can be set as data indicative of the monitor 12 being attached to the patient. After receiving the data, the microcontroller 61 can check for the contact through the front end 63 once or repetitively, upon expiration of successive time intervals as measured by the timer. Making sure that the monitor 12 is adhered to the patient 10, 11 before initiating collection of ECG data allows to conserve battery power and thus extend the length of monitoring using a single power source. In one embodiment, electrocardiographic signals sensed during this step recorded, as further described below; in a further embodiment, the signals can be discarded upon the determination by the microcontroller 61 that the monitor 12 is adhered to the patient 10, 11.

Upon detecting that the electrodes 38, 39 are adhered to the patient (step 102), the microcontroller 61 proceeds to continually execute a monitoring sequence defined by the firmware of the microcontroller 61, the sequence including the iterative processing loop (steps 103-112) executed by the microcontroller 61. During each iteration (step 103) of the processing loop, the ECG front end 63 (shown in FIGS. 9 and 15) continually senses the cutaneous ECG electrical signals (step 104) via the ECG electrodes 38, 39 and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step 105) by the microcontroller 61 by sampling the analog ECG signal output front end 63. FIG. 12 is a graph showing, by way of example, a typical ECG waveform 190. 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 191 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 192, followed by a larger upward deflection of an R-wave 193, and terminated with a downward waveform of the S wave 194, collectively representative of ventricular depolarization. The T wave 195 is normally a modest upward waveform, representative of ventricular depolarization, while the U wave 196, 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 within the AV node or the His-Purkinje fibers or even metabolic 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.

Returning to FIG. 11, in a further embodiment, optionally, the monitor recorder 14 also continuously receives data from wearable physiology monitors or activity sensors 131 and mobile devices 132 (shown in FIG. 3). Optionally, If wireless data is available (step 106), a sample of the wireless is read (step 107) by the microcontroller 61. If wireless data is not available (step 106), the method 100 moves to step 108.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step 108), pending compression preparatory to storage in the flash memory 62 (step 109). If wireless data sample was read in step 106, the wireless data sample, in quantized and digitized form, is temporarily staged in the buffer (step 108), pending compression preparatory to storage in the flash memory 62 (step 109). Following compression, the compressed ECG digitized sample, and if present, the wireless data sample, is again buffered (step 110), then written to the flash memory 62 (step 111) using the communications bus. Processing continues (step 112), 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. In a further embodiment, the microcontroller 61 can periodically check, such as upon expiration of time intervals maintained by the timer, whether the monitor 61 remains attached to the

patient **10, 11** based on impedance of the electrodes **38, 39** and terminates the processing upon detecting that the monitor **12** has been disconnected from the patient **10, 11**. Still other operations and steps are possible. In a further embodiment, the reading and storage of the wireless data takes place, in a conceptually-separate execution thread, such as described in commonly-assigned U.S. Pat. No. 10,165,946, issued Jan. 1, 2019, to Bardy et al., the disclosure of which is incorporated by reference.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first be converted into a format suitable for use by third party post-monitoring analysis software. FIG. **13** is a flow diagram showing a method **150** for offloading and converting ECG and other physiological data from a contact-activated extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The method **150** can be implemented in software and execution of the software can be performed on a download station **125**, which could be a programmer or other device, or a computer system, including a server **122** or personal computer **129**, such as further described supra with reference to FIG. **3**, as a series of process or method modules or steps. For convenience, the method **150** will be described in the context of being performed by a personal computer **136** or other connectable computing device (shown in FIG. **3**) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method **150** by a computer system would be analogous mutatis mutandis.

Initially, the download station **125** is connected to the monitor recorder **14** (step **151**), such as by physically interfacing to a set of terminals **128** on a paired receptacle **127** or by wireless connection, if available. The data stored on the monitor recorder **14**, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step **152**) over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device.

The data retrieved from the monitor recorder **14** is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps **153-159**) in an iterative processing loop. During each iteration (step **153**), the ECG datum is read (step **154**) and, if necessary, the gain of the ECG signal is adjusted (step **155**) to compensate, for instance, for relocation or replacement of the electrode patch **15** during the monitoring period. Filtering described above with reference to FIG. **17** can also optionally take place during step **155**.

In addition, depending upon the configuration of the wearable monitor **12**, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor **64** based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder **14** will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory **62** by the microcontroller

61. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step **156**) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information) was noted (step **157**). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step **158**) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder **14**, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder **14**, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step **159**) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

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. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder, comprising:
 - a sealed housing adapted to be removably secured into a non-conductive receptacle on a disposable extended wear electrode patch; and
 - an electronic circuitry comprised within the sealed housing, comprising:
 - an electrocardiographic front end circuit electrically interfaced to an externally-powered microcontroller and operable to sense voltage comprising electrocardiographic signals through electrocardiographic electrodes provided on the disposable extended wear electrode patch once a removable release liner is removed from the electrocardiographic electrodes, each of the electrocardiographic electrodes adapted to be positioned axially along the midline of the sternum for capturing action potential propagation;
 - an actigraphy sensor electrically interfaced with the externally-powered microcontroller, the actigraphy sensor operable to collect movement data when the sealed housing is worn by the patient and to provide

the movement data collected when the sealed housing is worn by the patient to the externally-powered micro-controller;

a timer operable to measure one or more time intervals following an execution of a power-up sequence by the externally-powered microcontroller and a receipt of the movement data collected when the sealed housing is worn by the patient by the externally-powered microcontroller;

the externally-powered microcontroller electrically interfaced to the electrographic front end circuit and operable to execute under micro programmable control through firmware that is stored in a program memory unit of the microcontroller, the microcontroller operable to execute the power-up sequence upon the sealed housing being secured into the non-conductive receptacle, to receive the movement data collected when the sealed housing is worn by the patient, to measure the voltage via the front end following an expiration of each of the time intervals and to process the sensed voltage following the measurement, determine the sensed voltage to be representative of one of the portion of the electrocardiographic waveform and the release liner being attached to the electrocardiographic electrodes during the processing, to detect an adherence of the electrodes to a patient upon determining the sensed voltage to be representative of the at least the portion of the electrocardiographic waveform and not the release liner being attached to the electrocardiographic electrodes, and to start for a first time during a monitoring period an execution of a monitoring sequence stored as part of the firmware upon detecting the adherence, the monitoring sequence comprising sampling the electrocardiographic signals over the monitoring period and storing all of the sampled electrocardiographic signals, wherein the timer initiates the measurement of another one of the time intervals upon the determination of the sensed voltage being representative of the release liner being attached to the electrocardiographic electrodes;

an externally-powered flash memory electrically interfaced with the microcontroller and operable to store the samples of the electrocardiographic signals collected during the execution of the monitoring sequence; and

a wireless transceiver interfaced with the externally-powered microcontroller and the externally-powered flash memory, the wireless transceiver comprising a cellular chipset operable to receive additional data associated with the patient from one or more cellular phones over a cellular network and to transmit the stored samples of the electrocardiographic signals and the additional data over the cellular network.

2. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder according to claim 1, wherein the wireless transceiver is further operable to wirelessly interface with one or more further external wireless-enabled devices.

3. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder according to claim 2, wherein the wireless transceiver communicates to the one or more further external wireless-enabled devices an alert generated based on the samples.

4. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder according to

claim 1, wherein the patient is referred for medical care based on the transmitted samples.

5. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder according to claim 1, the disposable extended wear electrode patch further comprising:

- a flexible backing formed of an elongated strip of stretchable material with a narrow longitudinal midsection and, on each end, a contact surface at least partially coated with an adhesive dressing provided as a crimp relief;
- the pair of the electrocardiographic electrodes conductively exposed on the contact surface of each end of the elongated strip;
- a non-conductive receptacle adhered to an outward-facing surface of the elongated strip and comprising electrical pads; and
- a flexible circuit affixed on each end of the elongated strip as a strain relief and comprising a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads, at least one of the circuit traces adapted to extend along the narrow longitudinal midsection to serve as the strain relief.

6. A contact-activated extended wear electrocardiography and physiological sensor monitor recorder according to claim 1, wherein the timer is one of interfaced to the externally-powered micro-controller or implemented by the externally-powered microcontroller.

7. A contact-activated ambulatory electrocardiography monitor optimized for capturing low amplitude cardiac action potential propagation, comprising:

- a disposable extended wear electrode patch comprising:
 - a flexible backing comprising stretchable material defined as an elongated strip with a narrow longitudinal midsection, each end of the flexible backing comprising an adhesive contact surface adapted to serve as a crimp relief;
 - a pair of electrocardiographic electrodes comprised on the contact surface of each end of the flexible backing, each electrocardiographic electrode conductively exposed for dermal adhesion and adapted to be positioned axially along the midline of the sternum for capturing action potential propagation;
 - a release liner removably attached to the electrocardiographic electrodes;
 - a non-conductive receptacle affixed to a non-contacting surface of the flexible backing and comprising an electro mechanical docking interface; and
 - a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to the docking interface, at least one of the circuit traces adapted to extend along the narrow longitudinal midsection to serve as a strain relief; and
- an ambulatory electrocardiography monitor recorder comprising:
 - a wearable housing adapted to securely fit into the receptacle; and
 - electronic circuitry provided within the wearable housing and comprising an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface, further comprising:
 - an electrocardiographic front end circuit adapted to sense voltage comprising cardiac electrical potential differentials through the electrocardiographic

electrodes when the release liner is removed from the electrocardiographic electrodes;

an actigraphy sensor electrically interfaced with a low-power microcontroller, the actigraphy sensor operable to collect movement data when the sealed housing is worn by the patient and to provide the movement data collected when the sealed housing is worn by the patient to the micro-controller;

a timer operable to measure one or more time intervals following an execution of a power-up sequence by the low-power microcontroller and a receipt of the movement data collected when the sealed housing is worn by the patient by the low-power microcontroller;

the low power microcontroller in control of the electrographic front end circuit and operable to execute over an extended monitoring period under modular micro program control as specified in firmware, the microcontroller further operable to execute the power-up sequence upon the sealed housing being secured into the non-conductive receptacle, to receive the movement data collected when the sealed housing is worn by the patient, to measure the voltage via the electrocardiographic front end following an expiration of each of the time intervals, to process the sensed voltage, to determine the sensed voltage to be representative of one of the portion of the electrocardiographic waveform and the release liner being attached to the electrocardiographic electrodes during the processing, to detect an adherence of the electrodes to a patient upon the determination that the sensed voltage represents the at least the portion of the electrocardiographic waveform and not the release liner being attached to the electrocardiographic electrodes, and to start for a first time during the extended monitoring period an execution of a monitoring sequence stored as part of the firmware upon detecting the adherence, the monitoring sequence comprising sampling the electrocardiographic signals over the extended monitoring period and storing all of the sampled electrocardiographic signals, wherein the timer initiates the measurement of another one of the time intervals upon the determination of the sensed voltage

being representative of the release liner being attached to the electrocardiographic electrodes;

a non-volatile memory electrically interfaced with the microcontroller and operable to continuously store the samples of the electrocardiographic signals collected during the execution of the monitoring sequence throughout the extended monitoring period; and

a wireless transceiver interfaced with the low power microcontroller and the non-volatile memory, the wireless transceiver comprising a cellular chipset configured to receive additional data associated with the patient from one or more cellular phones over a cellular network and to transmit the stored samples of the electrocardiographic signals and the additional data over the cellular network.

8. A contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation according to claim 7, wherein the electrocardiographic front end circuit is optimized to sense P-wave signals in the electrocardiographic signals.

9. A contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation according to claim 7, wherein the wireless transceiver is further operable to wirelessly interface with one or more further external wireless-enabled devices.

10. A contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation according to claim 9, wherein the wireless transceiver communicates to the one or more further external wireless-enabled devices an alert generated based on the samples.

11. A contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation according to claim 7, wherein the patient is referred for medical care based on the transmitted samples.

12. A contact-activated ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation according to claim 7, wherein the timer is one of interfaced to the low-power microcontroller or implemented by the low-power microcontroller.

* * * * *

专利名称(译)	接触激活式延长磨损心电图和生理传感器监护仪		
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摘要(译)

生理监测可通过可穿戴的监测器提供，该监测器包括两个组件，一个灵活的扩展磨损电极贴片和一个可移动的可重复使用的监测记录器。可穿戴式监护仪沿胸骨自上而下的位置位于患者胸部中央。将可穿戴式监护仪放置在胸骨中线处（或紧靠胸骨的任一侧）会增加磨损，因为消除了在整个监护期间将ECG电极连续放置在皮肤上相同位置的要求。可穿戴式监视器可以与其他生理和活动传感器以及移动设备进行无线互操作，并且可以包括蜂窝电话功能。通过在监视器中使用低能耗无线收发器，可以减少无线通信的功耗。监护仪检测到监护仪已贴在患者身上，并在检测后开始收集生理数据，从而节省了电池电量。

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