



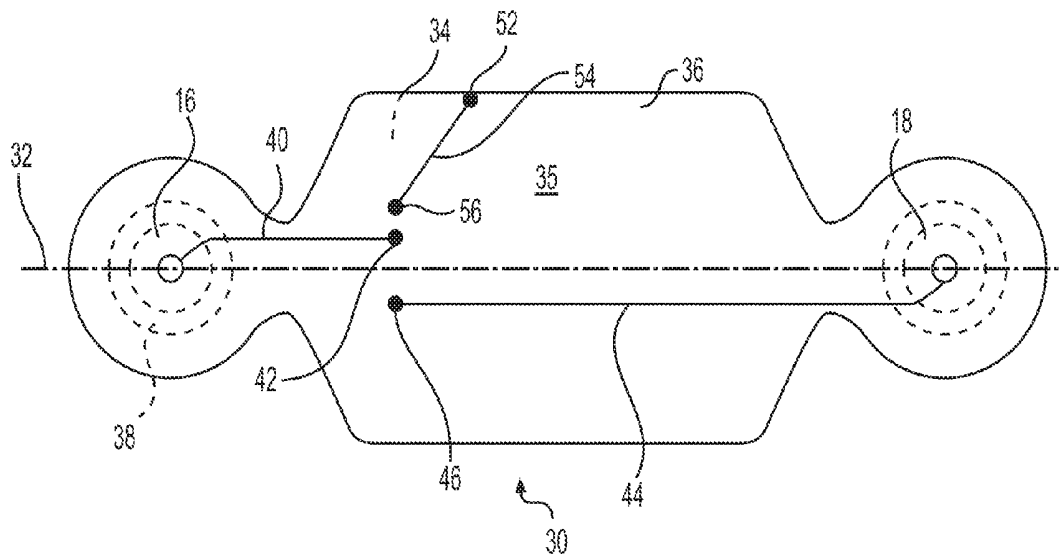
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(19) **United States**(12) **Patent Application Publication**
SPENCER et al.(10) **Pub. No.: US 2019/0320929 A1**(43) **Pub. Date: Oct. 24, 2019**(54) **ELECTRODE PATCH FOR HEALTH
MONITORING****Publication Classification**(51) **Int. Cl.***A61B 5/0408* (2006.01)*A61B 5/00* (2006.01)*A61B 5/0404* (2006.01)(52) **U.S. Cl.**CPC *A61B 5/04087* (2013.01); *A61B 5/0006*(2013.01); *A61B 5/044* (2013.01); *A61B**5/04085* (2013.01); *A61B 5/6823* (2013.01);*A61B 5/0404* (2013.01)(71) Applicant: **InfoBionic, Inc.**, Lowell, MA (US)(72) Inventors: **Darren SPENCER**, Fewcott (GB);
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Beach, CA (US)(73) Assignee: **InfoBionic, Inc.**, Lowell, MA (US)(21) Appl. No.: **16/409,951**(22) Filed: **May 13, 2019****Related U.S. Application Data**(63) Continuation of application No. 15/278,527, filed on
Sep. 28, 2016, now Pat. No. 10,327,657.(60) Provisional application No. 62/237,188, filed on Oct.
5, 2015.

(57)

ABSTRACT

A method of measuring bioelectric signals of a patient having an axis extending from the patient's head to the patient's feet includes attaching a patch to the patient's skin. The patch may include a first electrode and a second electrode spaced apart along a longitudinal axis of the patch. The patch may be attached such that the longitudinal axis of the patch is generally aligned with the axis of the patient. The method may also include attaching a third electrode to the patient's skin, and measuring bioelectric signals of the patient using the first electrode, the second electrode, and the third electrode.



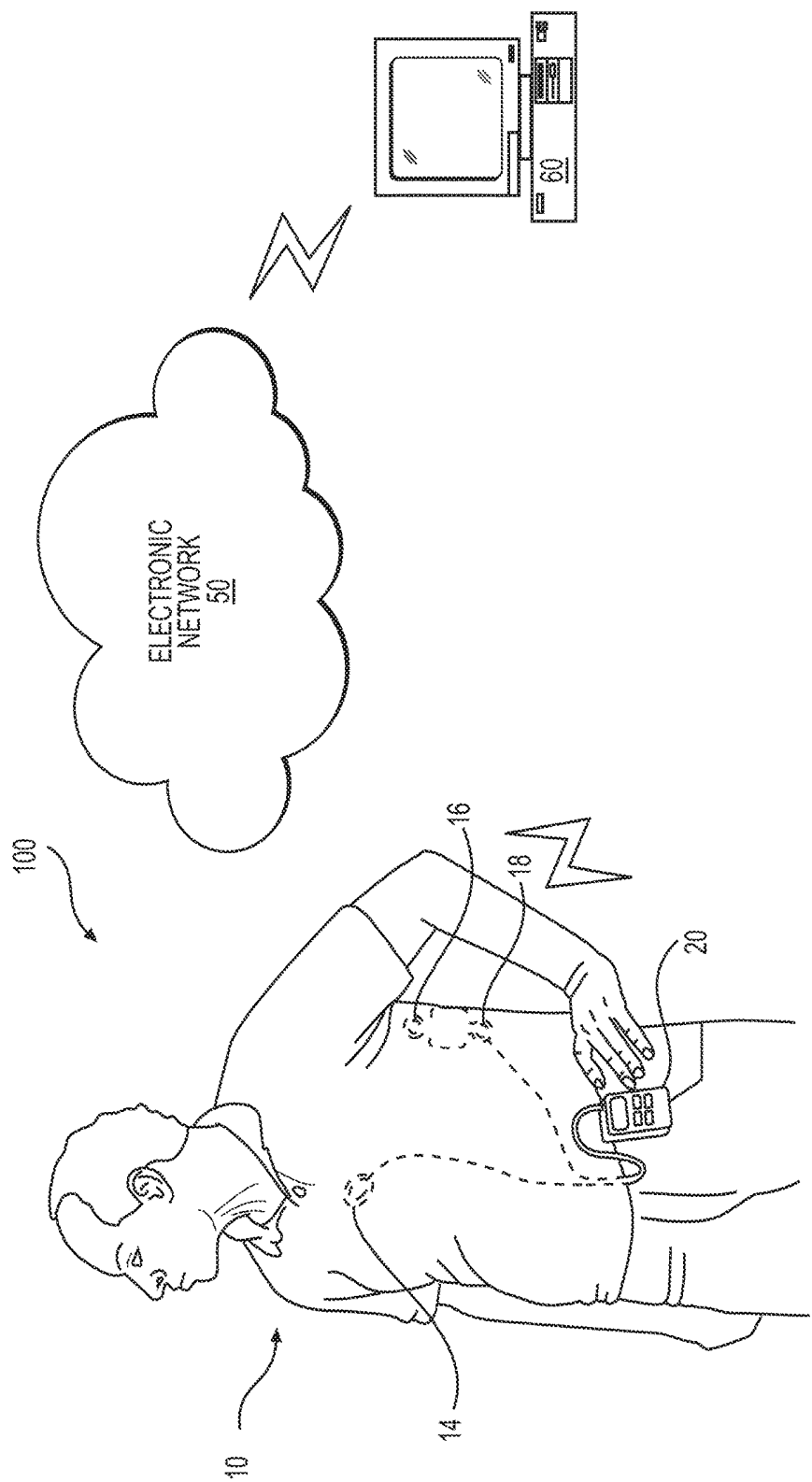


FIG. 1

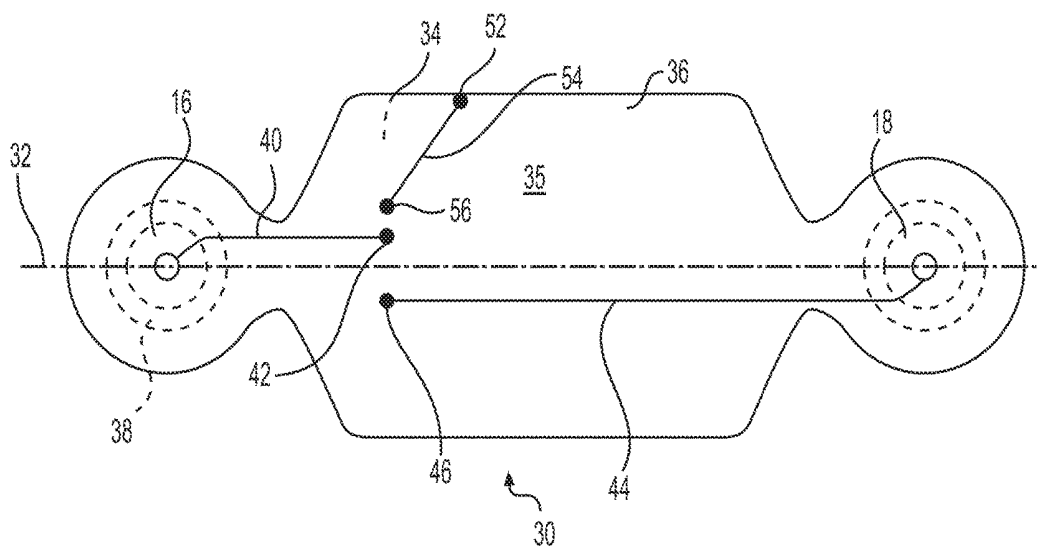


FIG. 2A

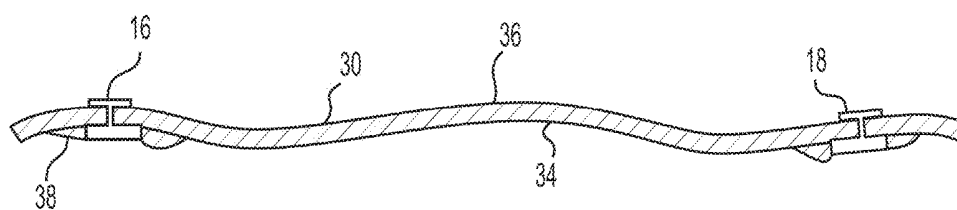


FIG. 2B

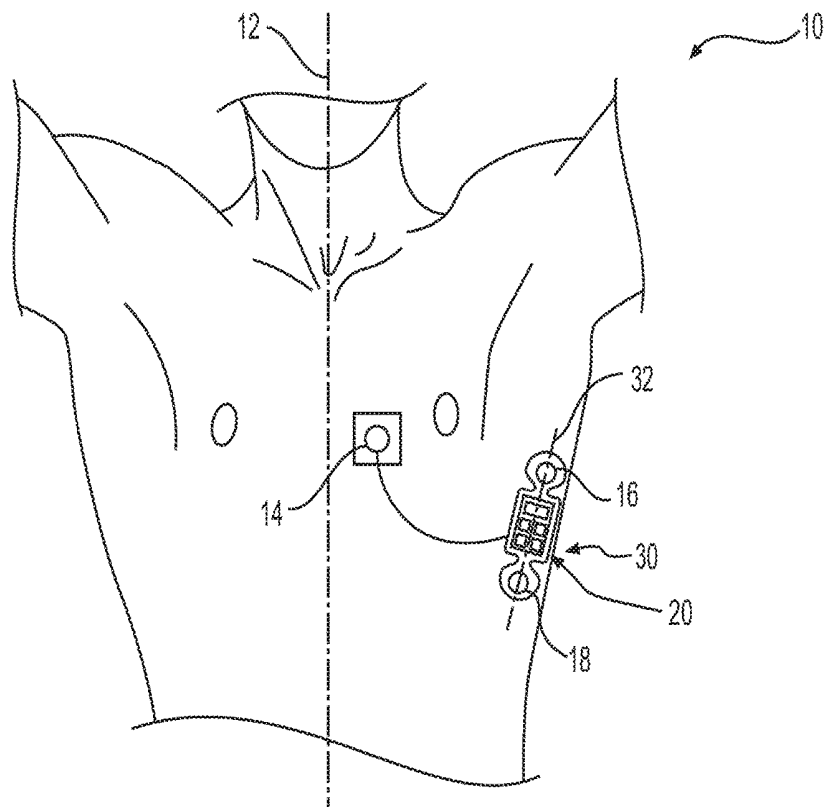


FIG. 3A

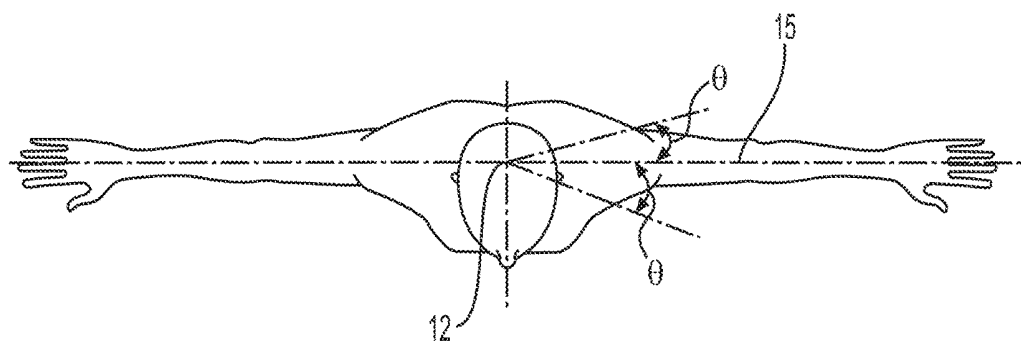


FIG. 3B

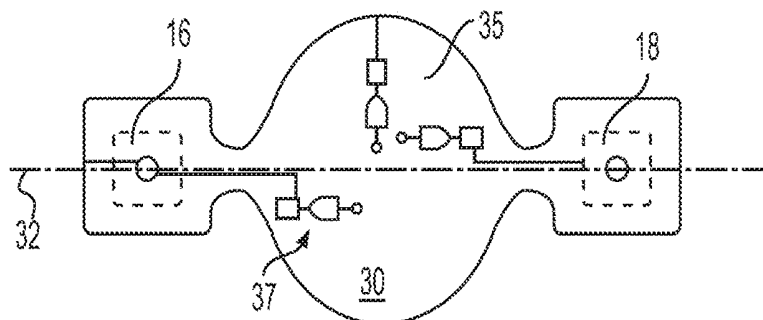


FIG. 4A

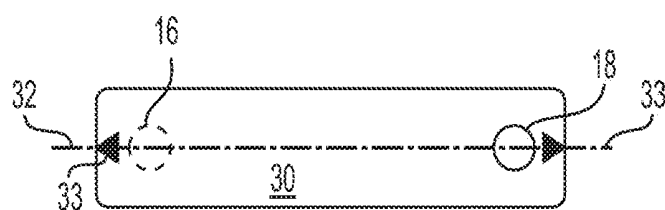


FIG. 4B

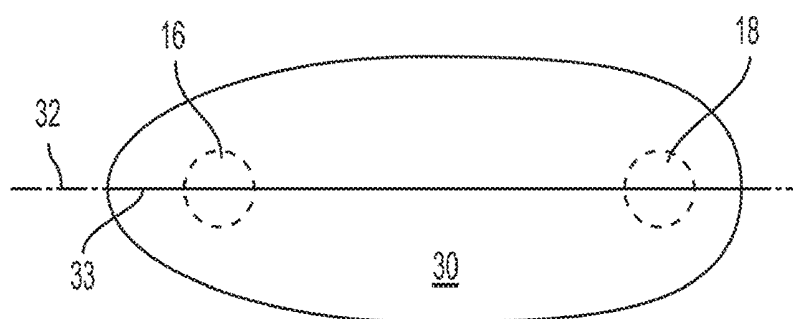


FIG. 4C

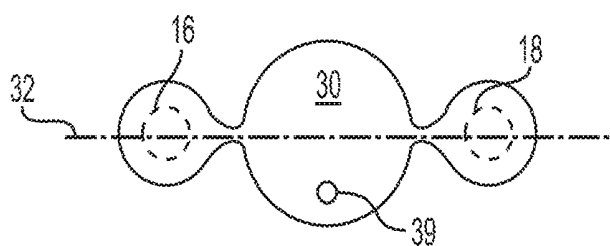


FIG. 4D

ELECTRODE PATCH FOR HEALTH MONITORING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefits of priority from U.S. Provisional Application No. 62/237,118, filed on Oct. 5, 2015, the disclosure of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] Various embodiments of the present disclosure relate to an electrode patch and systems and methods of using an electrode patch for health monitoring, and more particularly, to an electrode patch and systems and methods of using an electrode patch for physiologic data monitoring.

BACKGROUND

[0003] Physiologic data may be used to monitor the health of a patient. For example, bioelectric signals (e.g., electrocardiogram or ECG signals) from the patient's heart may be used to monitor cardiac health. ECG is a recording of the electrical activity of the heart. During ECG monitoring, electrodes attached to a patient's skin are used to detect electrical activity of the heart over a period of time. During ECG monitoring, electrical impulses generated by the heart during each heartbeat are detected and recorded and/or displayed on a device. Analysis of the data reveals the cardiac health (e.g., rate and regularity of heartbeats, size and position of the chambers, the presence of any damage to the heart, effects of drugs or devices used to regulate the heart, etc.) of the patient.

[0004] Multiple electrodes (e.g., left arm (LA), right arm (RA), and left leg (LL) electrodes) may be attached to the patient's skin for ECG measurement. These electrodes may be combined into a number of pairs (e.g., three pairs LA-RA, LA-LL, and RA-LL), and voltage signals may be recorded across each pair. Each pair is known as a lead. Each lead looks at the heart from a different angle. Different types of ECG measurements can be referred to by the number of leads that are recorded (e.g., 3-lead, 5-lead, 12-lead ECG, etc.).

[0005] Many cardiac problems become noticeable only during physical activity (walking, exercise, etc.). An ambulatory electrocardiogram (ECG) continuously monitors the electrical activity of the heart while a patient does normal activities. Typically, a 12-lead or a 5-lead ECG is used for periodic ECG monitoring (e.g., at a doctor's office, etc.) and a 3-lead ECG is used for continuous ambulatory monitoring. In 3-lead monitoring, ECG data is collected using three electrodes attached to the patient. The collected data is recorded in a monitor operatively coupled to the electrodes. The stored data is analyzed by a health care provider. In some cases, the monitor may transmit ECG data to a health care provider for analysis. Several types of monitors (e.g., Holter monitor, event monitors, mobile cardiovascular telemetry monitors, etc.) are known in the art. Some of these monitors store the data for subsequent analysis by a health care provider, while others transmit (real-time, periodically, or on demand) the collected ECG data to a remote site where it is analyzed.

[0006] Regardless of the type of ECG measurement, the quality of the measurement depends on the attachment

quality and positioning of the electrodes on the body. Typically, electrodes are positioned to obtain good signals from all regions of the heart. Organizations such as American Heart Association (AHA) and International Electrotechnical Commission (IEC) provide guidelines for electrode positions for ECG measurements. While these recommended electrode positions result in acceptable ECG data, there remains a need for improved ECG measurement systems and methods.

BRIEF DESCRIPTION OF THE FIGURES

[0007] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various exemplary embodiments and together with the description, serve to explain the principles of the disclosed embodiments.

[0008] FIG. 1 illustrates an exemplary system for measuring ECG of a patient.

[0009] FIGS. 2A and 2B illustrate top and side views respectively of an exemplary adhesive patch used in the ECG measurement system of FIG. 1.

[0010] FIG. 3A illustrates a front view of a patient with an exemplary adhesive patch attached.

[0011] FIG. 3B illustrates a top view of a patient with arms outstretched.

[0012] FIGS. 4A-4D illustrate other exemplary embodiments of an adhesive patch which may be used in the ECG measurement system of FIG. 1.

SUMMARY

[0013] In one aspect, a method of measuring bioelectric signals of a patient having an axis extending from the patient's head to the patient's feet is disclosed. The method may include attaching a patch to the patient's skin. The patch may include a first electrode and a second electrode spaced apart along a longitudinal axis of the patch. The patch may be attached such that the longitudinal axis of the patch is generally aligned with the axis of the patient. The method may also include attaching a third electrode to the patient's skin, and measuring bioelectric signals of the patient using the first electrode, the second electrode, and the third electrode.

[0014] Additionally or alternatively, the method may include one or more of the following aspects: the bioelectric signals may include ECG signals; attaching the patch may include attaching the patch under an arm pit of the patient; attaching the third electrode may include attaching the third electrode above the right atrium of the patient's heart; the method may further include electrically connecting the first electrode, the second electrode, and the third electrode to a portable monitor, and using the monitor to measure the bioelectric signals; and attaching the monitor to the patch; attaching the patch to the patient's skin includes attaching the patch to a thoracic region spanning about 15° on either side of a linear axis extending through the patient's outstretched arms.

[0015] In another aspect, a method of measuring ECG signals of a patient including an axis extending from the patient's head to the patient's feet, is disclosed. The method may include attaching a patch under the left armpit in the patient's thoracic region. The patch may include a first electrode and a second electrode spaced apart along a longitudinal axis of the patch, the patch being attached such

that the longitudinal axis is generally aligned with the axis of the patient. The method may also include attaching a third electrode to a chest of the patient, and measuring ECG signals using the first electrode, the second electrode, and the third electrode.

[0016] Additionally or alternatively, the method may include one or more of the following aspects: electrically connecting the first electrode, the second electrode, and the third electrode to a portable monitor, and using the monitor to measure the ECG signals; further include attaching the monitor to the patch; the monitor is attached to the patch between the first electrode and the second electrode; attaching the patch includes attaching the patch to a thoracic region spanning about 15° on either side of a linear axis extending through the patient's outstretched arms; electrically connecting the third electrode to the portable monitor includes directing measured signals from the third electrode to the patch; wherein the patch includes an adhesive layer on a surface covered by a protective strip, and the method further includes removing the protective strip prior to attaching the patch.

[0017] In another aspect, an adhesive electrode patch for measuring bioelectric signals from a patient is disclosed. The patch may include an elongated flexible strip extending along a longitudinal axis from a first end region to a second end region. The patch may also include a first electrode on the first end region, and a second electrode on the second end region; and a central region located between the first end region and the second end region. A width of the central region in a direction transverse to the longitudinal axis is greater than a width of the first and second end regions.

[0018] Additionally or alternatively, the patch may include one or more of the following aspects: a skin-facing surface and an exposed surface opposite the skin-facing surface, the skin-facing surface may include an adhesive layer covered by a protective strip; the exposed surface of the strip may include markings to assist a patient in aligning the strip on the patient's body; the strip may include conductive traces extending from the first electrode and the second electrode to the central region; and the strip may be made of a fabric material, and the first electrode and second the electrodes include silver.

DETAILED DESCRIPTION

[0019] Reference will be made in detail to exemplary embodiments of the disclosure, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0020] Embodiments of the present disclosure may include methods and systems for monitoring physiologic data of a patient. Various aspects of the present disclosure may be used in combination with, or include, one or more features disclosed in U.S. Pat. No. 8,478,418 (issued Jul. 2, 2013) and U.S. Pat. No. 8,620,418 (issued Dec. 31, 2013), each of which are incorporated by reference herein in their entireties. While an exemplary embodiment of measuring ECG data is described below, it should be noted that, the current disclosure may be applied to the measurement of any physiologic data. For example, the disclosed systems and methods may be used to measure signals indicative of heart rate, activity level (e.g., physical mobility or movement), respiration rate, blood pressure (e.g., systolic and/or diastolic), blood oxygen saturation (SpO₂), blood glucose or

insulin level, pulse oximetry, impedance, body temperature, etc. It is also contemplated that, in some embodiments, the measured physiologic data may be used to determine a cardiac safety indicator such as QT prolongation, ST elevation, etc.

[0021] FIG. 1 is a schematic illustration of an exemplary system 100 for measuring ECG of a patient 10. A plurality of electrodes 14, 16, 18 may be attached to the patient 10 to detect ECG signals. The electrodes 14, 16, 18 detect (and in some cases amplify) tiny electrical changes on the skin that are caused when heart muscles depolarize during each heartbeat. At rest, each heart muscle cell has a negative charge (called the membrane potential) across its cell membrane. Decreasing this negative charge toward zero, via the influx of the positive cations (Na⁺ and Ca⁺⁺) is called depolarization. Depolarization activates mechanisms in the cell that cause it to contract. During each heartbeat, a healthy heart will have an orderly progression of a wave of depolarization that is triggered by the cells in the sinoatrial node, spreads out through the atrium, passes through the atrioventricular node and then spreads all over the ventricles. The depolarization wave (or ECG data) is indicative of the overall rhythm of the heart and is detected as variations in voltage between the electrode pairs (e.g., between electrodes 14-16, 14-18, and 16-18).

[0022] System 100 may include a monitor 20 operatively coupled to the electrodes 14, 16, 18. Monitor 20 may be adapted to receive and store the ECG data from the electrodes 14, 16, 18. Monitor 20 may be coupled to electrodes 14, 16, 18 wirelessly or using a wired connection. In embodiments where the ECG data is transmitted to monitor 20 wirelessly, some or all of electrodes 14, 16, 18 may include a transceiver to transmit the measured ECG data to monitor 20. In some embodiments, monitor 20 may transfer at least a portion of the measured ECG data to a remote analysis station 60 for analysis. Although analysis station 60 is illustrated as a computer, in general, analysis station 60 may include any collection of computational devices and personnel (e.g., one or more servers, databases, and computers networked together).

[0023] The ECG data from monitor 20 may be transferred to remote analysis station 60 over a wired connection, using a portable storage medium (transferable memory device, etc.), or transferred wirelessly over an electronic network 50 (e.g., the internet). Rather than transferring data directly to analysis station 60, in some embodiments, monitor 20 may transfer the data to analysis station 60 through an intermediate device (e.g., cellular phone, PDA, etc.). That is, the ECG data from monitor 20 may be first sent to an intermediate device such as a cellular phone using Bluetooth or other similar technologies (HomeRF, IrDA, etc.), when monitor 20 is close to the cellular phone. The ECG data from the cellular phone may then be sent to the analysis station 60 over the phone's cellular communication network or the electronic network 50.

[0024] Analysis station 60 may analyze the ECG data to check the cardiac health of patient 10. Any analysis methodology known in the art may be used to analyze the received data (e.g., a methodology described by Philip de Chazal, et al., in "Automatic Classification of Heartbeats Using ECG Morphology and Heartbeat Interval Features," IEEE Transactions on Biomedical Engineering, Vol. 51, No. 7, July, 2004). Since methods and algorithms for analyzing ECG data are well known in the art, they are not described

herein. In some embodiments, monitor **20** may at least partially analyze the collected ECG data before it is transferred to analysis station **60**.

[0025] In some embodiments, monitor **20** may store the collected ECG data, and continuously transmit (directly or through an intermediate device) a subset of the data (e.g., data at a lower resolution, etc.) to the analysis station **60**. The analysis station **60** may analyze the received data to determine if it indicates an anomaly (e.g., an arrhythmia, an unexpected trend in the data, etc.). If an anomaly is indicated, analysis station **60** may request (i.e. transmit instructions) the monitor **20** for more data (e.g., data from the same time frame at a higher resolution, etc.). Upon receipt of this request, the monitor **20** may retrieve the requested data from memory and transmit it to the analysis station **60**. The analysis station **60** may then analyze the data (e.g., using a more rigorous analysis methodology) to confirm or refute the anomaly detected during the previous analysis. This analysis methodology is described in more detail in U.S. Pat. No. 8,478,418, which is incorporated by reference herein.

[0026] Monitor **20** may be any type of portable monitor known in the art (e.g., Holter monitor, event monitor, mobile cardiovascular telemetry (MCT) monitor, etc.). Monitor **20** may include integrated circuits (microprocessor, memory, communication devices, etc.), visual displays (LED, LCD, etc.), and/or buttons that can be activated by the patient **10**. The integrated circuits of monitor **20** may enable processing of collected ECG data, and communication between monitor **20**, the intermediate device (if any), and the analysis station **60**. The user activatable buttons may enable the patient **10** to trigger an activity (data collection, communication with analysis station **60**, etc.) when the patient **10** feels uncomfortable (e.g., experiences chest pains, etc.), and the display may enable the monitor **20** and analysis station **60** to communicate with patient **10** (e.g., using text messages).

[0027] Monitor **20** may be a portable device, sized and adapted to be kept in the possession (strapped, attached, placed in the pocket, etc.) of patient **10**. Such a portable monitor **20** may enable the patient **10** to go about the patient's daily activities while the monitor **20** records (and/or transfers) ECG data. In the exemplary embodiment illustrated in FIG. 1, monitor **20** is shown as a device attached (e.g., clipped) to the patient's belt. However, this is only exemplary, and other configurations are possible. For example, in some embodiments, monitor **20** may be combined with, or incorporated into a cellular phone (or another device, such as, watch, etc.). In embodiments where electrodes **14**, **16**, **18** are connected by a wire to the monitor, monitor **20** may include a connector to receive the connecting wire. In embodiments where electrodes **14**, **16**, **18** are coupled wirelessly, monitor **20** may include a transceiver to communicate with a transceiver of electrodes **14**, **16**, **18**.

[0028] Electrodes **14**, **16**, **18** may be any type of electrodes that may be attached to the skin of patient **10**. In some embodiments, at least two of the electrodes **16**, **18** may be configured as an adhesive patch **30**. FIGS. 2A and 2B illustrate an exemplary embodiment of an adhesive patch **30**. FIG. 2A illustrates a top view of patch **30**, and FIG. 2B illustrates its side view. In the description that follows, reference will be made to both FIGS. 2A and 2B. Adhesive patch **30** may be made of a flexible material (tape, fabric, etc.) that is adapted to conform to the contours of the patient's skin. Adhesive patch **30** may be configured as a reusable patch or a disposable patch. In some embodiments,

the material of adhesive patch may have pores (or otherwise breathable) or other features to enhance patient comfort. One side (skin-facing side **34**) of the adhesive patch **30** may include an adhesive. Any type of adhesive (e.g., acrylates, silicones, hydrogels, hydrocolloids, polyurethanes, etc.) that can attach the adhesive patch **30** to the skin of the patient may be used. In some embodiments, the adhesive may be coated to the skin-facing side **34** of the adhesive patch **10**. In some embodiments, the adhesive may be covered by a strip of removable protective material (e.g., similar to adhesive bandages such as Band-Aid). After removing this protective strip, the adhesive patch **30** may be attached on the patient by pressing the skin-facing side **34** to the patient's skin. In this configuration, the side of patch **30** opposite to the skin-facing side (i.e., exposed side **36**) is exposed to the atmosphere. Although patch **30** is described as being attached to the patient's skin using an adhesive layer, it is also contemplated that in some embodiments, patch **30** may be attached using other attachment mechanisms (e.g., adhesive tape, sutures, clips, etc.).

[0029] In general, adhesive patch **30** may have any size and shape. In some embodiments, adhesive patch **30** may have an elongated shape (e.g., oval, elliptical, rectangular, dumbbell shaped, hour-glass shaped etc.) with an axis (longitudinal axis **32**) extending along its length. Electrodes **16**, **18** may be spaced apart along the longitudinal axis **32** of adhesive patch **30**. In an exemplary embodiment, as illustrated in FIG. 2A, the elongated shape of patch **30** may include circular regions at its two ends, the sides of which converge to form narrower neck regions that further expand to a wider central region **35**. In the embodiment of FIG. 2A, electrodes **16**, **18** are placed on the circular regions and spaced apart by the wider central region **35**. The wider central region **35** and the circular end regions may have any dimensions suitable for its purpose. In some embodiments (see FIG. 2A), the central region **35** may be sized to attach a monitor **20** thereon.

[0030] Electrodes **16**, **18** may include any material and configuration (size and shape) that are currently used for, or are suitable for, bioelectric measurements. See, Neuman, M. R., Chapter 40: Biopotential Electrodes, "Biopotential Electrodes," The Biomedical Engineering Handbook: Second Edition, Ed. Joseph D. Bronzino, Boca Raton, CRC Press LLC, 2000, which is incorporated by reference herein. In some embodiments, electrodes **16**, **18** may have a substantially circular cross-sectional shape and be made of silver with a surface layer of silver chloride. However, other shapes (square, rectangular, polygonal, etc.) are also contemplated. Electrodes **16**, **18** may be attached to the adhesive patch **30** in any manner (e.g., adhesives, etc.). In some embodiments, the electrodes **16**, **18** may be stitched or weaved into the material of the adhesive patch **30**. In some embodiments, the material of electrodes **16**, **18** may be deposited or coated on the patch **30**. In some embodiments, as illustrated in FIG. 2B, electrodes **16**, **18** may have a region of reduced diameter along its thickness (in a direction perpendicular to the plane of the paper), and may be attached to patch **30** like a button.

[0031] In some embodiments, adhesive patch **30** may also include an electrically conductive gel **38**. The conductive gel **38** may be provided in a region adjacent the electrodes **16**, **18**. Conductive gel **38** may be a viscous conductive medium that fills any gap between the electrodes **16**, **18** and the patient's skin to improve detectability of electrical activity

under the skin. Any type of commercial or specially formulated gel known in the art may be used as conductive gel **38**.

[0032] In some embodiments, conductive patch **30** may include conductive traces **40**, **44** that extend from the electrodes **16**, **18** to terminals **42**, **46** of patch **30**. These traces **40**, **44** may include any conductive material and may be provided by any known additive and/or subtractive processes (masking and plating/deposition, plating/depositing and etching, etc.). These traces **40**, **44** may extend along the skin-facing surface **34** or the exposed surface **36** of patch **30**. The conductive traces **40**, **44** may direct the measured bioelectric signals from electrodes **16**, **18** to the terminals **42**, **46**. The terminals **42**, **46** may be the ends of traces **40**, **44** positioned on the exposed surface **36** of the patch **30**. In embodiments where the traces **40**, **44** extend along the skin-facing surface **34**, a through-hole via may electrically connect ends of the traces **40**, **44** to the terminals **42**, **46**. In general, the terminals **42**, **46** may be positioned anywhere on patch **30**. In some embodiments, the terminals **42**, **46** may be positioned on an edge of patch **30**. In such embodiments, an external wire attached to (e.g., clipped, etc.) the terminals **42**, **46** may retrieve the measured bioelectric signals from the patch **30**. In some embodiments, as illustrated in FIG. 2A, the terminals **42**, **46** may be positioned on the central region **35** of patch **30**. In some such embodiments, patch **30** may also include a trace **54** that extends from a terminal **52** at an edge of the patch **30** to a terminal **56** at the central region **35**. An external wire attached to terminal **52** may direct measured signals from electrode **14** to terminal **56**. In some such embodiments, a monitor **20** attached to central region **35** may receive the measured signals from terminals **42**, **46**, and **56**.

[0033] In some embodiments, adhesive patch **30** may also include circuitry (not shown) to process (amplify, filter, etc.) the bioelectric signals measured by the electrodes **16**, **18** (and, in some embodiments, electrode **14**). In some embodiments, the circuitry may be formed directly on the material of patch **30** using fabrication techniques known in the art (e.g., using IC fabrication techniques). In some embodiments, the circuitry may be formed on a discrete component (integrated circuit chip, printed circuit board, etc.) which is attached to the patch **30**. The circuitry may be positioned anywhere on patch **30**. In some embodiments, the circuitry may be positioned on the central region **35** such that the measured signals are processed by the included circuitry on its way from an electrode to its corresponding terminal. In embodiments where the bioelectric signals are wirelessly transmitted to monitor **20**, the circuitry may also include a transmitter (or transceiver) circuit to transmit the signals to monitor **20**.

[0034] FIG. 3A illustrates an adhesive patch **30** attached to patient **10**. FIG. 3A depicts the front view of a patient's thoracic region, and FIG. 3B illustrates a top view of the patient with arms outstretched. In the description that follows, reference will be made to both FIGS. 3A and 3B. Patient **10** may have a vertical axis **12** extending from the patient's head to the patient's feet and a horizontal axis **15**, perpendicular to the vertical axis **12**, and extending along the patient's outstretched arms. In general, patch **30** may be attached anywhere on the patient's body in any orientation. In some embodiments, adhesive patch **30** is attached to the thoracic region of the patient's torso with its longitudinal axis **32** in a generally vertical orientation (i.e. head-feet). In this orientation, longitudinal axis **32** of patch **30** may be

generally aligned with the vertical axis **12** of patient **10**. It should be noted that, because of different contours (curved, sloped, etc.) on different regions of the patient's body, general alignment of longitudinal axis **32** with vertical axis **12** (as used herein), does not necessarily mean that the longitudinal axis **32** is parallel to the vertical axis **12**. Instead, as illustrated in FIG. 3, the longitudinal axis **32** may extend in the same direction as the vertical axis **12**.

[0035] Adhesive patch **30** may be attached in a vertical orientation anywhere in the thoracic region of patient **10**. As is known to a person of ordinary skill in the art, the thoracic region is the area above the diaphragm and includes the sternal region, the pectoral region, and the axillary region. The sternal region lies over the sternum or the breastbone, the pectoral region includes the region of the chest muscles on either side of the sternum, and the axillary region is the area proximate the armpits. In the exemplary embodiment illustrated in FIG. 3A, patch **30** is attached to a region under the left arm with its longitudinal axis **32** generally aligned with the vertical axis **12**. In this disclosure, a region that spans the axillary region and the pectoral region near the axillary region is considered to be under an arm. That is, a region spanning an angle θ of about 15° on either side of the horizontal axis **15** (see FIG. 3B) extending over the thoracic region is considered to be under an arm.

[0036] Electrode **14** may be any type of electrode used in bioelectric signal measurement and may be attached anywhere in the patient's thoracic region. In some embodiments, electrode **14** may be attached at any location where any one of V_1 to V_6 electrode is commonly positioned during 12 lead ECG measurement. In some embodiments, electrode **14** may be attached to the sternal region or in the left pectoral region proximate the sternal region. In some embodiments, electrode **14** may be positioned at a region above the right atrium of the patient's heart. After attaching the electrode **14** at the desired location, it is connected to the monitor **20**. In some embodiments, electrode **14** may be connected to terminal **52** of patch **30** using an external wire.

[0037] After the adhesive patch **30** is attached to the patient's skin, the electrodes **16** and **18** are connected to the monitor **20**. In embodiments where the monitor **20** is positioned remote from the patch **30**, external wires (e.g., from terminals **42**, **46**) may connect the electrodes **16**, **18** to the monitor **20** (see FIG. 1). In other embodiments, the signal from the electrodes **16**, **18** may be wirelessly transmitted to the monitor **20**. In some such embodiments, the measured signals from electrode **14** may be directed to the patch **30** (through terminal **52**) and signals from all the electrodes **14**, **16**, **18** transmitted wirelessly to the monitor **20**.

[0038] In some embodiments, as illustrated in FIG. 3A, the monitor **20** may be attached to the patch **30**. The monitor **20** may be attached to the patch **30** at any location and by any method (adhesive, mechanical fastener, strap, etc.). In some embodiments, the monitor **20** may be detachably clipped (e.g., using a clip) to the central region **35** of patch **30**. In some embodiments, a hook and loop system (e.g., Velcro fasteners) may attach monitor **20** to the patch **30**. In some embodiments, a strap may couple the monitor **20** to the patch **30**. It is also contemplated that, in some embodiments, the patch **30** may have a recess that securely receives the monitor **20** therein. The terminals **42**, **46**, and **56** may also be connected to the monitor **20** to receive the measured signals from the electrodes **14**, **16**, **18**. In some embodiments, when the monitor **20** is attached to the patch **30**, the

terminals 42, 46, and 56 of the patch 30 may mate with corresponding terminals of the monitor 20 to direct the signals into the monitor 20.

[0039] As described above, these electrode measured signals may be stored, processed, and/or transmitted from the patch 30 to a remote analysis station 60 directly or through an intermediate device. The analysis station 60 may analyze the measured data to identify an anomaly.

[0040] It should be noted that the shape and configuration of the adhesive patch 30 illustrated in FIG. 2A is only exemplary. In general, patch 30 may have any shape suitable for its purpose. FIGS. 4A-4D illustrate some exemplary shapes of patch 30 with two electrodes 16, 18 spaced apart along a longitudinal axis 32. As illustrated in FIG. 4A, in some embodiments, the end portions of the patch 30 may have a generally square or a rectangular configuration and the central region 35 may have a generally circular configuration. The central region 35 may include some circuit elements 37 (filter, A/D converter, etc.) formed thereon to at least partially process the measured bioelectric signals from the electrodes 16, 18. These processed signals may be received by a monitor 20 attached to central region 35 or positioned elsewhere on the patient 10.

[0041] FIG. 4B illustrates an exemplary patch 30 having a generally rectangular shape, and FIG. 4C illustrates an exemplary patch 30 having a generally elliptical shape. As illustrated in FIGS. 4B and 4C, in some embodiments, patch 30 may have markings 33 thereon, for example, arrows or a line. These markings 33 may assist in generally aligning the longitudinal axis 32 of the patch 30 with the vertical axis 12 of the patient 10. FIG. 4D illustrates an exemplary patch 30 in which the end portions and the central region 35 is configured to be substantially circular. As illustrated in FIG. 4D, in some embodiments, patch 30 may include an indicator 39 that alerts the patient 10 when it is time to replace the patch 30. For example, indicator 39 may change color with time, and the patient may be advised to change the patch 30 when the indicator 39 becomes a particular color (red, etc.).

[0042] Adhesive patches 30 may also include other features not described with reference to the figures. For instance, patch 30 may include markings (e.g., to identify the name of the manufacturer) and text to assist (e.g., directions of use) the patient in use of the patch 30. It is also contemplated that other sensors (e.g., temperature sensor, accelerometer, sensor to analyze sweat, etc.) may be incorporated into patch 30. For example, in some embodiments, indicator 39 of FIG. 4D may be a sensor that changes color with temperature, in the presence of a constituent in sweat, etc. It should be noted that while certain features (e.g., markings 33, indicator 39) have been described in connection with various embodiments, it is to be understood that any feature described in conjunction with any embodiment disclosed herein may be used with any other embodiment disclosed herein.

[0043] While the current disclosure describes using an adhesive patch for ECG monitoring, it should be understood that the disclosure is not limited thereto. Rather, the principles of the systems and methods described herein may be employed for the measurement of any physiologic data of a patient. Those having ordinary skill in the art and access to the teachings provided herein will recognize additional

modifications, applications, embodiments, and substitution of equivalents all fall within the scope of the embodiments described herein.

1-20. (canceled)

21. A system for measuring bioelectric signals from a user, comprising:

- a patch configured to be attached under the user's arm such that a longitudinal axis of the patch is generally aligned with an axis that extends from the user's head to the user's feet, the patch including a first electrode and a second electrode spaced apart along the longitudinal axis;
- a third electrode spaced apart from the patch and configured to be attached to the user's chest; and
- a monitor operatively coupled to the first electrode, the second electrode, and the third electrode, the monitor being configured to measure bioelectric signals of the user using the first electrode, the second electrode, and the third electrode.

22. The system of claim 21, wherein the bioelectric signals include ECG signals.

23. The system of claim 21, wherein the third electrode is configured to be attached to (a) a sternal region or (b) a left pectoral region proximate the sternal region of the user.

24. The system of claim 21, wherein the third electrode is configured to be attached above a right atrium of the user's heart.

25. The system of claim 21, wherein the monitor is configured to be physically attached to the patch.

26. The system of claim 21, wherein the patch is configured to be attached to the user's thoracic region at an area spanning about 15° on either side of a linear axis that extends through the user's outstretched arms.

27. The system of claim 21, wherein the monitor is configured to (a) store the measured bioelectric signals, and/or (b) transmit at least a portion of the measured bioelectric signals to a remotely located analysis device.

28. The system of claim 21, wherein the system further includes an analysis device positioned remote from the monitor and the patch, and wherein

- (a) the monitor is configured to transmit a first portion of the measured bioelectric signals to the analysis device,
- (c) the analysis device is configured to analyze the first portion of the bioelectric signals received from the monitor to determine if an anomaly is indicated,
- (d) the analysis device is configured to send a request to the monitor for additional data if analysis of the first portion indicates the anomaly, and
- (e) the monitor is configured to transmit a second portion of the measured bioelectric signals to the analysis device in response to the request from the analysis device for additional data, and
- (f) the analysis device is configured to analyze the second portion of the bioelectric signals received from the monitor to confirm the indicated anomaly.

29. The system of claim 21, wherein the patch is an adhesive patch that includes a flexible material adapted to conform to contours of the user's body and signal processing circuitry formed in the flexible material.

30. The system of claim 21, wherein a shape of the adhesive patch is one of oval, elliptical, rectangular, dumb-bell shaped, and hour-glass shaped.

31. The system of claim 21, wherein the patch is configured to be attached under the user's left arm.

32. The system of claim **21**, wherein the patch is a disposable patch, and wherein the patch includes an indicator configured to alert the user when it is time to replace the patch.

33. A method of measuring bioelectric signals of a user, comprising:

attaching a patch under the user's arm such that a longitudinal axis of the patch is generally aligned with an axis that extends from the user's head to the user's feet, the patch including a first electrode and a second electrode spaced apart along the longitudinal axis;

attaching a third electrode to the user's chest, wherein the third electrode is separate from the patch;

operatively coupling a monitor to the first electrode, second electrode, and the third electrode; and

measuring bioelectric signals using the monitor.

34. The method of claim **33**, further including attaching the monitor to the patch.

35. The method of claim **34**, wherein attaching the monitor to the adhesive patch includes attaching the monitor between the first electrode and the second electrode.

36. The method of claim **33**, wherein attaching the patch under the user's arm includes attaching the patch to the user's thoracic region in an area spanning about 15° on either side of a linear axis that extends through the user's outstretched arms.

37. The method of claim **33**, wherein attaching the third electrode includes attaching the third electrode above a right atrium of the user's heart.

38. The method of claim **33**, further including transmitting at least a portion of the measured bioelectric signals from the monitor to a remote device.

39. The method of claim **33**, wherein the measuring bioelectric signals includes measuring ECG signals.

40. The method of claim **33**, further including storing at least a portion of the measured bioelectric signals in the monitor.

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专利名称(译)	用于健康监测的电极贴片		
公开(公告)号	US20190320929A1	公开(公告)日	2019-10-24
申请号	US16/409951	申请日	2019-05-13
申请(专利权)人(译)	INFOBIONIC INC.		
当前申请(专利权)人(译)	INFOBIONIC INC.		
[标]发明人	VAN DER SLUIS PETER		
发明人	SPENCER, DARREN VAN DER SLUIS, PETER		
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摘要(译)

一种测量具有从患者的头部延伸到患者的脚的轴线的患者的生物电信号的方法，该方法包括将贴片附接到患者的皮肤上。贴片可包括沿着贴片的纵轴间隔开的第一电极和第二电极。贴片可以被附接成使得贴片的纵轴大体上与患者的轴对准。该方法还可以包括将第三电极附接到患者的皮肤，并且使用第一电极，第二电极和第三电极来测量患者的生物电信号。

