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(54) **CAPACITIVE ELECTROCARDIOGRAPHY (ECG) PHYSIOLOGICAL MONITORING SYSTEMS**

(71) Applicant: **Medical Design Solutions, Inc.**, Milpitas, CA (US)

(72) Inventor: **Robert T. Stone**, Sunnyvale, CA (US)

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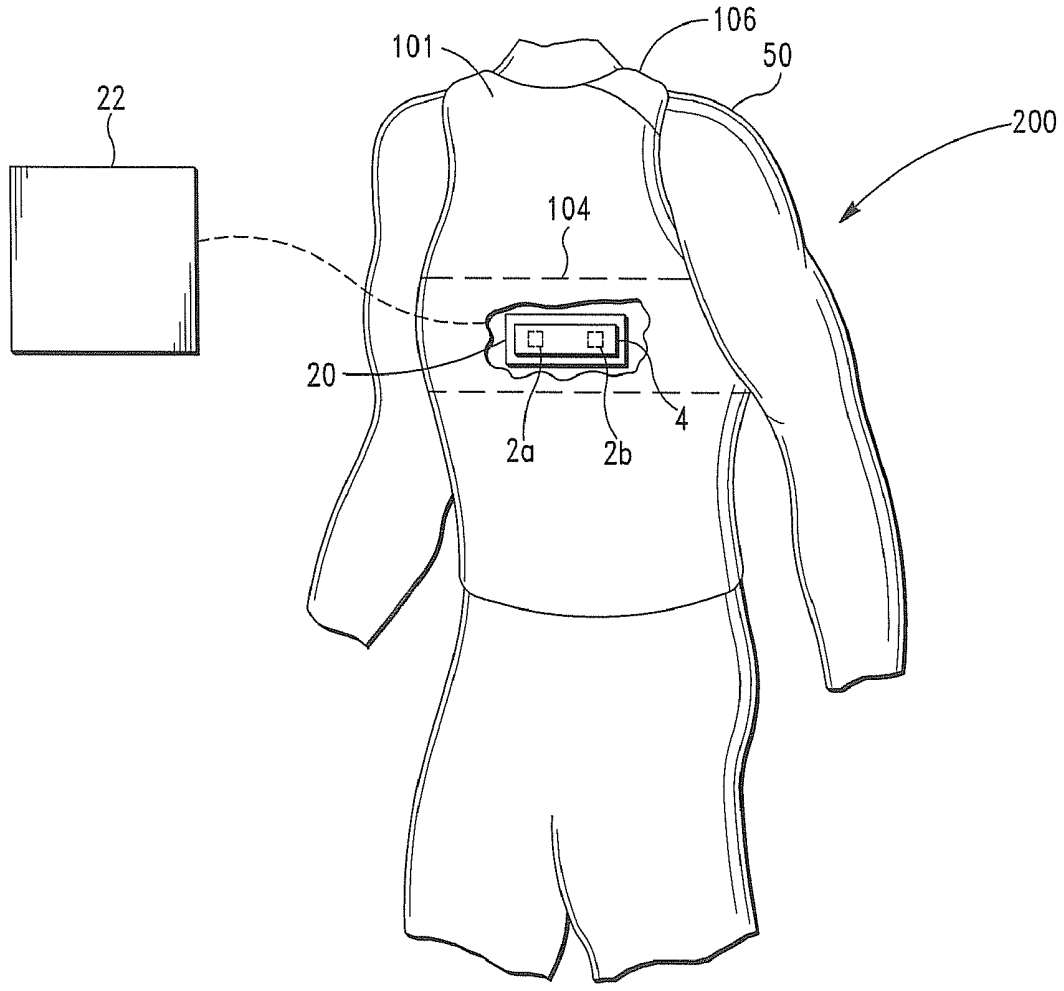
(57) **ABSTRACT**

An electrocardiography (ECG) physiological monitoring system that includes an ECG sensor assembly having first and second capacitive electrodes that are configured to electrically couple to a subject's skin and detect ECG signals, a reference electrode that is configured to average the capacitance potential of the first and second electrodes, an electronics module that is in direct communication with the ECG sensor assembly and programmed to control the ECG sensor assembly, process ECG signals therefrom, and wirelessly transmit the processed ECG signals, and transmission conductors that are configured to provide a signal communication path between the electronics module and the ECG sensor assembly.



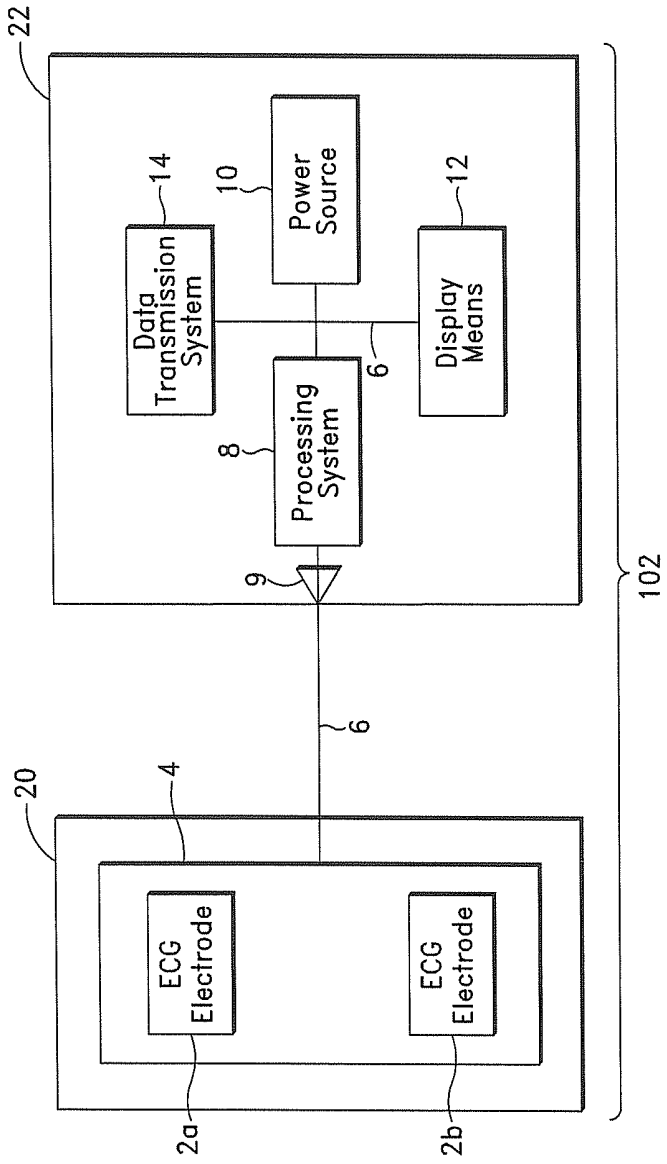

22
14
Data Transmission System
10
Power Source
12
Display Means
6
8
Processing System
9
6
102
20
4
ECG Electrode
ECG Electrode
2a
2b

FIG. 1

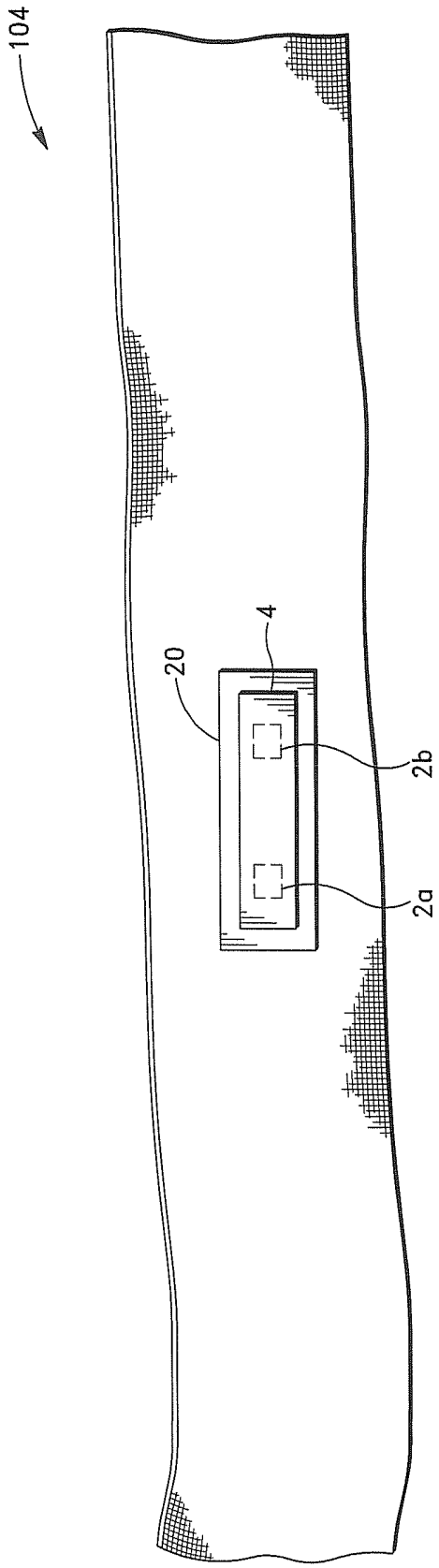


FIG. 2

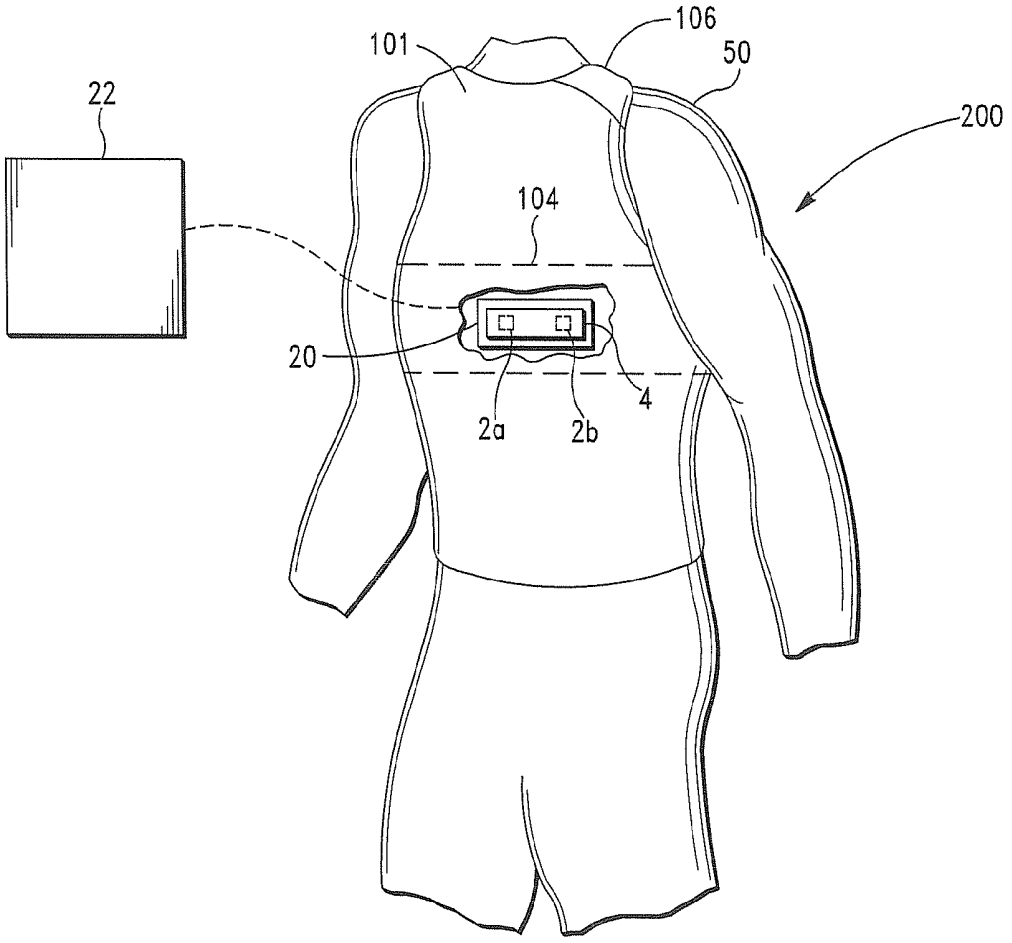


FIG. 3

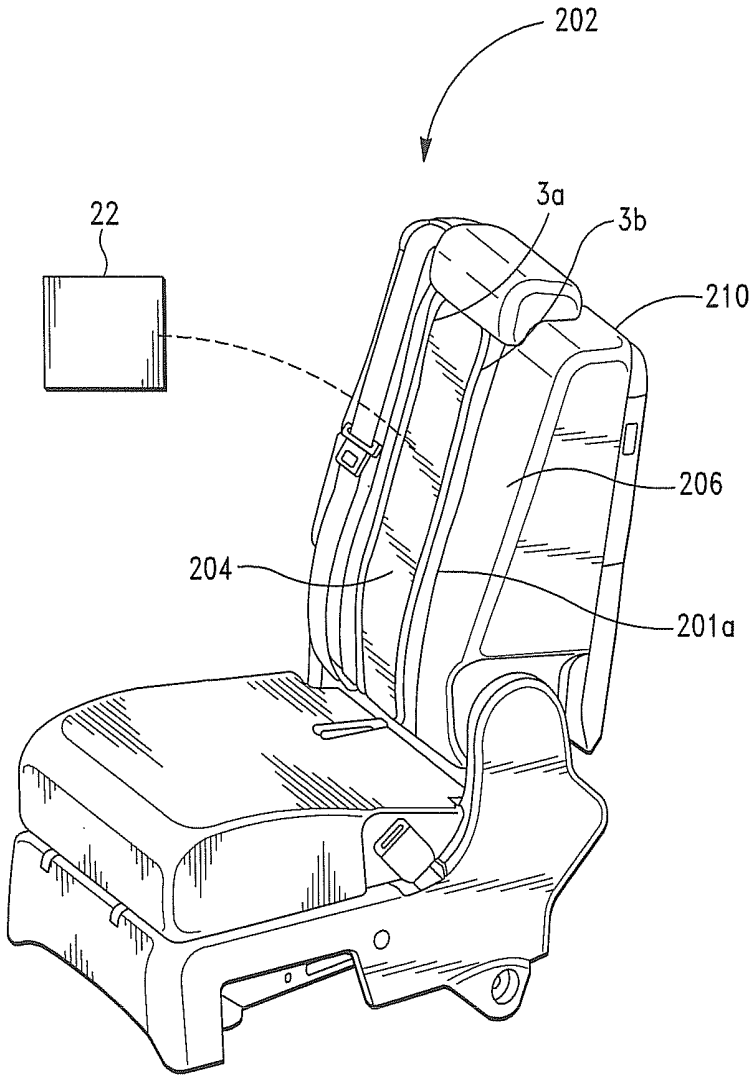


FIG. 4

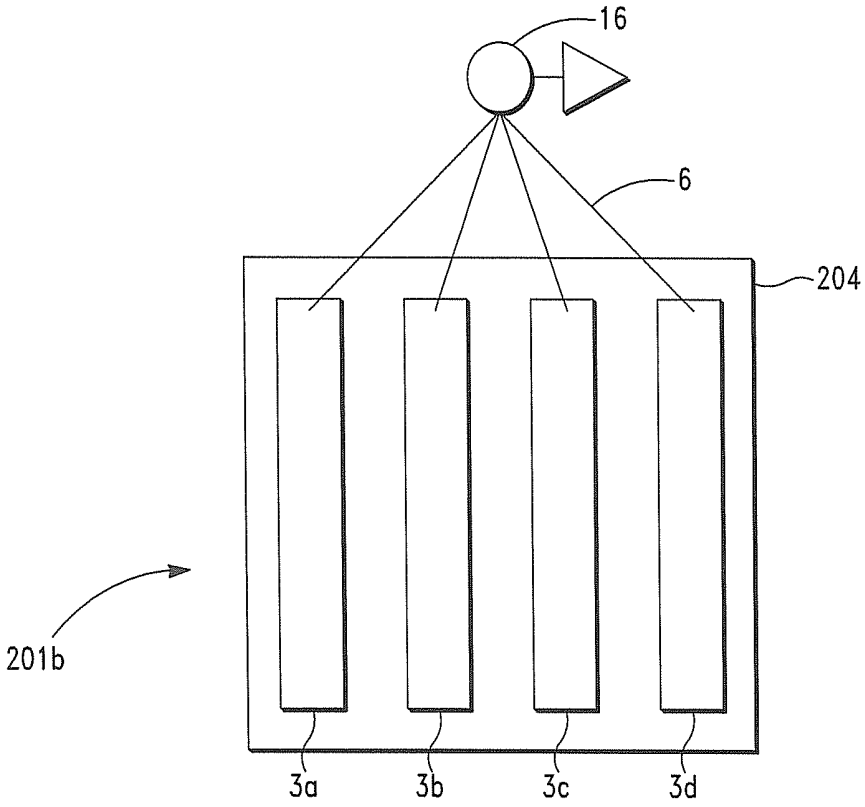


FIG. 5A

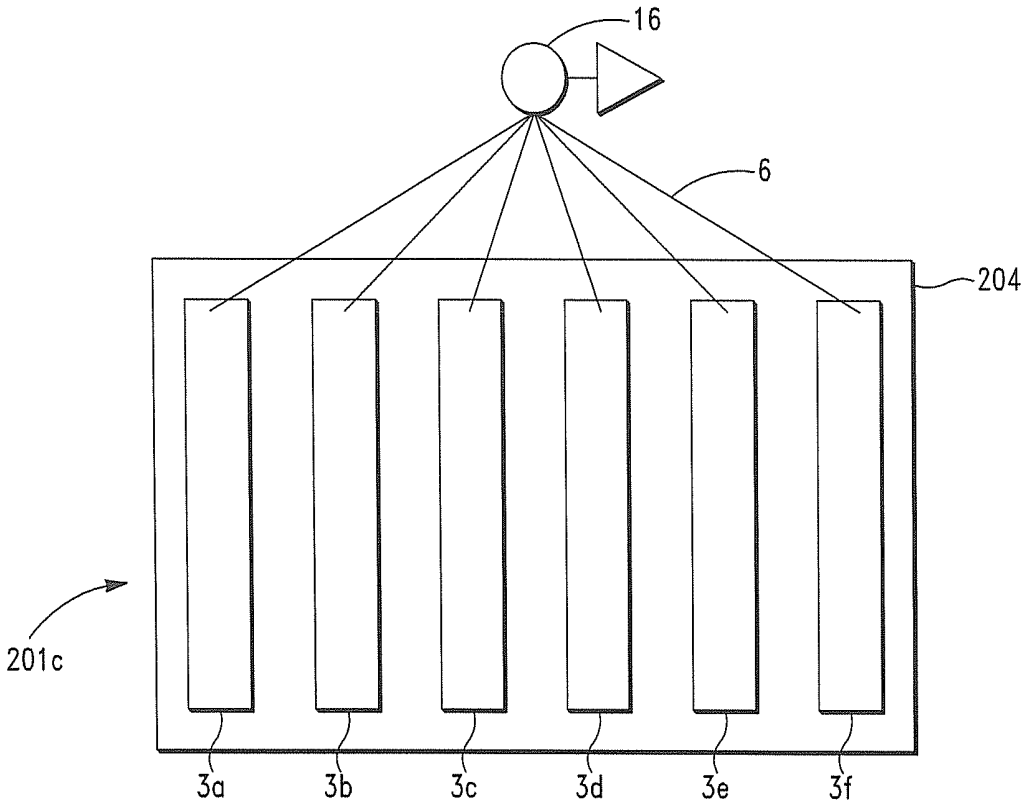


FIG. 5B

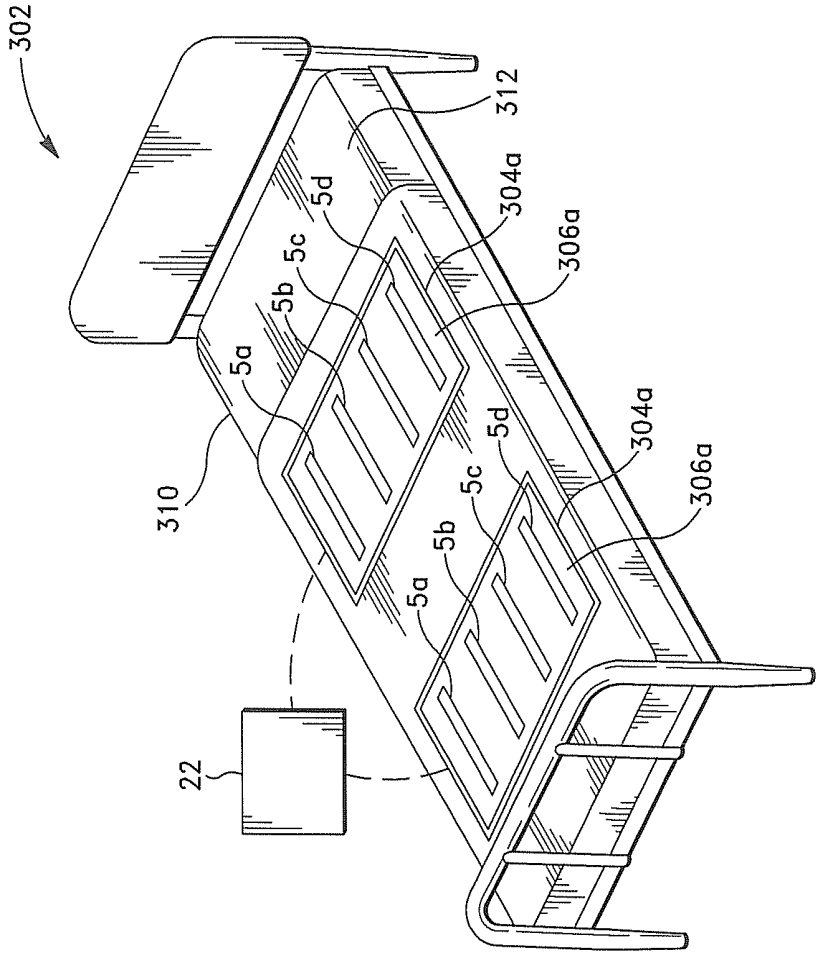


FIG. 6

CAPACITIVE ELECTROCARDIOGRAPHY (ECG) PHYSIOLOGICAL MONITORING SYSTEMS

FIELD OF THE INVENTION

[0001] The present invention relates to systems and methods for monitoring physiological characteristics of a subject. More particularly, the present invention relates to systems and methods for determining physiological characteristics as a function of electrocardiography (ECG) characteristics signals.

BACKGROUND OF THE INVENTION

[0002] As is well known in the art, ECG signals provide an effective means for determining one or more physiological characteristics of a mammalian subject. By monitoring the ECG signals of a subject, any deviation in a seminal physiological characteristic, e.g. heart rate, can be detected and immediately transmitted to a physician for analysis and prompt preventative action(s). ECG is thus one of the most widely used means for monitoring the health status of a subject.

[0003] Conventional clinical ECG systems typically employ 12-15 silver-silver chloride (Ag—AgCl) electrodes, i.e. wet ECG electrodes, which are affixed to specific regions of the chest, arms, or hands and legs. Wet ECG electrodes provide a wet conducting medium for charge transfer between the electrodes and the body. Adhesive tape is also often applied to keep the wet ECG electrodes in place.

[0004] There are, however, several drawbacks and disadvantages associated with wet ECG electrodes and, hence, ECG systems employing same. A major drawback is that wet electrode ECG systems often require cleaning of the attachment site on the body and, in some instances, also shaving hair off the attachment site. Cleaning of the attachment site is inconvenient and can cause skin irritation, allergic reactions, and inflammation due to toxicological issues of the electrode gels in long-term treatments.

[0005] Additionally, the quality of the signal will be compromised as the electrode gel dehydrates during prolonged use.

[0006] Further, since it is difficult to keep the electrode gel and/or adhesives entirely separate from each other over the long term. Cross-coupling between neighboring electrode sites can thus occur through leakage current.

[0007] In an effort to overcome the drawbacks associated with wet electrode ECG systems, gel-less, i.e. dry, ECG electrode systems have been developed. Dry electrode ECG systems typically employ 4-12 capacitive electrodes and a reference electrode.

[0008] There are, however, similarly several drawbacks and disadvantages associated with dry ECG electrodes and, hence, ECG systems employing same.

[0009] A major drawback associated with dry ECG electrode systems is that the amplitude levels of ECG signals detected by a dry electrode are typically very low. Thus, detecting spontaneous changes in ECG signals is very difficult.

[0010] Further, the high impedance exhibited by dry ECG electrodes necessitates an on-site amplifier with ultra-high impedance. Since the level of electrical noise introduced by the on-site amplifier is proportional to the magnitude of the impedances, signal quality of the amplifier output is degraded.

[0011] Dry ECG electrode systems also often exhibit poor signal quality due to external signal interference; particularly, electromagnetic radiation.

[0012] Dry electrode systems are also subject to internal signal interference that is generated by changes in the displacement of the electrode-to-skin distance and friction between the electrodes and the medium that the electrodes are attached to, e.g. fabric of a garment.

[0013] A further drawback associated with dry ECG electrode systems is that the systems typically employ a remote reference electrode that is positioned in such a manner that the body of a subject is disposed between the dry ECG electrode(s) and reference electrode.

[0014] By way of example, one conventional ECG system, known as the Electric Potential Integrated Circuit (EPIC) sensor system, which is produced by Plessey Semiconductors Ltd. (Application Note 291566, Issue No. 1), is designed and configured to be employed in a seat. The Plessey EPIC sensor system employs a large reference electrode that is incorporated into the seat and two ECG sensors that are incorporated into the clothing of an individual. To receive ECG signals with the Plessey EPIC sensor system, a subject must be positioned in the signal path between the reference electrode and the two ECG sensors.

[0015] Although the Plessey EPIC sensor system reduces external signal interference, internal signal interference is amplified.

[0016] Another major drawback of the EPIC sensor system is that the system only utilizes the "best" or "cleanest" ECG signal that is detected by one of the ECG sensors, while discarding the ECG signal that is detected by the other ECG electrode. As a result, the EPIC sensor system provides an ECG signal having substantially reduced accuracy due to the inherent subjectivity of the signal processing method.

[0017] It would thus be desirable to provide an improved ECG physiological monitoring system and method that (i) accurately monitors ECG signals representing one or more physiological characteristics associated with a user or wearer, (ii) does not require the use of any conductive gels, (iii) is suitable for long term monitoring of physiological characteristics, (iv) substantially reduces or abates external electromagnetic interference and (v) substantially reduces or abates internal interference.

[0018] It is therefore an object of the present invention to provide an improved ECG physiological monitoring system and method that (i) accurately monitors ECG signals representing one or more physiological characteristics associated with a user or wearer, (ii) does not require the use of any conductive gels, (iii) is suitable for long term monitoring of physiological characteristics, (iv) substantially reduces or abates external electromagnetic interference and (v) substantially reduces or abates internal interference.

[0019] It is another object of the present invention to provide an ECG physiological monitoring system and method that is suitable for long term monitoring of physiological characteristics.

[0020] It is another object of the present invention to provide an ECG physiological monitoring system and method that includes reliable and effective means to connect external modules, e.g. processing units.

SUMMARY OF THE INVENTION

[0021] The present invention is directed to an improved system and method for determining physiological characteristics as a function of electrocardiography (ECG) characteristics signals.

[0022] In one embodiment of the invention, the ECG physiological monitoring system includes an ECG sensor system, signal transmission conductors and an electronics module.

[0023] In some embodiments, the ECG sensor system further includes first and second ECG electrodes and a reference electrode.

[0024] In a preferred embodiment, the first and second ECG electrodes comprise capacitive electrodes that are designed and configured to detect ECG signals without direct physical communication with the skin of a subject.

[0025] According to the invention, the reference electrode provides a capacitive reference as a function of the capacitance potential of the first and second ECG electrodes. In a preferred embodiment, the capacitive reference comprises the average of the capacitance potential of the first and second ECG electrodes (C_{Avg}).

[0026] In some embodiments, the reference electrode is also configured to average the capacitance potential noise generated by the anatomy of a subject, e.g., skin, muscle, etc., and the capacitance potential of the first and second ECG electrodes to provide an average capacitance potential value (C'_{Avg}).

[0027] In a preferred embodiment, the average capacitance potential values C_{Avg}, C'_{Avg} represent the ECG signal associated with the subject.

[0028] In some embodiments, the reference electrode provides an electromagnetic shield for the first and second ECG electrodes.

[0029] In some embodiments, the physiological monitoring system further includes an electronics module that preferably includes a processing system, which is programmed and configured to control the ECG sensor system and the function thereof, and the transmission and receipt of signals therefrom.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Further features and advantages will become apparent from the following and more particular description of the preferred embodiments of the invention, as illustrated in the accompanying drawings, and in which like referenced characters generally refer to the same parts or elements throughout the views, and in which:

[0031] FIG. **1** is a schematic illustration of one embodiment of an ECG physiological monitoring system, in accordance with the invention;

[0032] FIG. **2** is a top plane view of one embodiment of an ECG sensor system, in accordance with the invention;

[0033] FIG. **3** is a perspective view of one embodiment of a wearable ECG physiological monitoring system employing the ECG sensor system shown in FIG. **2**, in accordance with the invention;

[0034] FIG. **4** is a perspective view of one embodiment of an external ECG physiological monitoring system, in accordance with the invention;

[0035] FIG. **5**A is a top plane view of another embodiment of an ECG sensor system shown in FIG. **4**, in accordance with the invention;

[0036] FIG. **5**B is a top plane view of another embodiment of an ECG sensor system shown in FIG. **4**, in accordance with the invention; and

[0037] FIG. **6** is a perspective view of another embodiment of an external ECG physiological monitoring system, in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0038] Before describing the present invention in detail, it is to be understood that this invention is not limited to particularly exemplified apparatus, systems, structures or methods as such may, of course, vary. Thus, although a number of apparatus, systems and methods similar or equivalent to those described herein can be used in the practice of the present invention, the preferred apparatus, systems, structures and methods are described herein.

[0039] It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments of the invention only and is not intended to be limiting.

[0040] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one having ordinary skill in the art to which the invention pertains.

[0041] Further, all publications, patents and patent applications cited herein, whether supra or infra, are hereby incorporated by reference in their entirety.

[0042] Finally, as used in this specification and the appended claims, the singular forms "a, "an" and "the" include plural referents unless the content clearly dictates otherwise. Thus, for example, reference to "a sensor signal" includes two or more such signals and the like.

Definitions

[0043] The term "monitor", as used herein, means and includes, without limitation, one-time and continuous detection of ECG signal(s) and, hence, physiological characteristics and parameters of a subject associated therewith over a defined period of time.

[0044] The terms "physiological parameter" and "physiological characteristic", as used herein, mean and include, without limitation, electrical activity of the heart, electrical activity of other muscles, electrical activity of the brain, pulse rate, blood pressure, blood oxygen saturation level, skin temperature, and core temperature.

[0045] The term "electrode", as used herein, means and includes, without limitation, any electrical conductor used to provide physical communication between the metallic and non-metallic materials and/or compositions that comprise a circuit.

[0046] The following disclosure is provided to further explain in an enabling fashion the best modes of performing one or more embodiments of the present invention. The disclosure is further offered to enhance an understanding and appreciation for the inventive principles and advantages thereof, rather than to limit in any manner the invention. The invention is defined solely by the appended claims including any amendments made during the pendency of this application and all equivalents of those claims as issued.

[0047] Although the ECG physiological monitoring systems and associated methods of the invention may be described in connection with monitoring ECG signals rep-

resenting a defined physiological characteristic, e.g. heart rate, it is understood that the ECG physiological monitoring systems and associated methods of the invention can be employed to monitor ECG signals representing various physiological characteristics.

[0048] It is further understood that although the ECG physiological monitoring systems and associated methods of the invention are described herein in connection with a wearable garment, bed and car seat, the invention is not limited to such use/applications. The physiological monitoring systems and associated methods of the invention can also be employed in any other apparatus or system that maintains physical communication with a subject.

[0049] It is also understood that although the physiological monitoring systems and associated methods of the invention are described herein in connection with monitoring signals that are representative of physiological characteristics of a human, the invention is not limited to such use. The physiological monitoring systems and associated methods of the invention can also be employed to monitor signals that are representative of physiological characteristics of a non-human, i.e. animal.

[0050] Referring now to FIGS. **1** and **2**, in one embodiment of the invention, the ECG physiological monitoring system (denoted "**102**") includes an ECG sensor system (or assembly) **20**, signal transmission conductors **6** and an electronics module **22**. As illustrated in FIGS. **1** and **2**, the ECG sensor system **20** further includes first and second ECG electrodes **2***a*, **2***b* and reference electrode **4**.

[0051] In a preferred embodiment, the first and second ECG electrodes **2***a*, **2***b* comprise capacitive electrodes that are designed and configured to detect ECG signals without direct physical communication with the skin of a subject.

[0052] In a preferred embodiment, the first and second ECG electrodes **2***a*. **2***b*, i.e. capacitive electrodes, comprise a conductive material, including, without limitation, a conductive fabric and flexible conductive polymer, e.g., silver coated polyesters, carbon-impregnated polymers.

[0053] In some embodiments, the first and second ECG electrodes **2***a*, **2***b* preferably comprise an area in the range of 1.0-10 cm^2.

[0054] Preferably, the first and second ECG electrodes **2***a*, **2***b*, i.e. capacitive electrodes, are configured to couple to a subject's skin and accurately detect ECG signals at electrode-to-skin distances in the range of 0.1-1.0 mm.

[0055] In a preferred embodiment, the first and second ECG electrodes **2***a*, **2***b* are configured to electrically couple to a subject's skin and accurately detect ECG signals at electrode-to-skin distances in the range of 0.1-1.0 mm.

[0056] In some embodiments, the reference electrode **4** preferably comprises a conductive material that is incorporated into a garment band **104**, which is configured to wrap around a subject or to be incorporated into a wearable physiological monitoring system. (See FIGS. **2** and **3**)

[0057] According to the invention, the conductive material can comprise, without limitation, silver coated polyesters, carbon-impregnated polymers and conductive rubbers. Preferably, the conductive material comprises a flexible and/or stretchable configuration.

[0058] In a preferred embodiment, the conductive material is configured to move or stretch along at least two axes.

[0059] According to the invention, the reference electrode **4** can comprise any shape or dimension required to shield the first and second ECG electrodes **2***a*, **2***b*.

[0060] In some embodiments, the reference electrode **4** preferably comprises an area in the range of two to twenty times (2-20×) the area of the first and second ECG electrodes **2***a*, **2***b*.

[0061] According to the invention, the reference electrode **4** provides a capacitive reference as a function of the capacitance potential of the first and second ECG electrodes **2***a*, **2***b*. In a preferred embodiment, the capacitive reference comprises the average of the capacitance potential of the first and second ECG electrodes **2***a*, **2***b* (C_{Avg}).

[0062] In some embodiments, the reference electrode **4** is configured to provide an average the capacitance potential (C_{Avg}) of any given quantity of ECG electrodes.

[0063] In some embodiments, the reference electrode **4** is also configured to average the capacitance potential noise generated by the anatomy of a subject, e.g., skin, muscle, etc., and the capacitance potential of the first and second ECG electrodes **2***a*, **2***b* to provide an average capacitance potential value (C'_{Avg}).

[0064] According to the invention, the average capacitance potential values C_{Avg}, C'_{Avg} represent the ECG signals associated with a subject.

[0065] In some embodiments, the reference electrode **4** provides an electromagnetic shield for the first and second ECG electrodes **2***a*, **2***b*.

[0066] According to the invention, the reference electrode **4** reduces external electromagnetic interference, such as interference due to the magnetic fields of power lines, by shielding the first and second ECG electrodes **2***a*, **2***b*. By positioning the first and second ECG electrodes **2***a*, **2***b* between the reference electrode **4** and the skin of a monitored subject, signal interference due to the displacement of the electrode-to-skin distance is also reduced.

[0067] According to the invention, the ECG sensor system **20** can comprise any number of ECG electrodes and reference electrodes. In some embodiments, the ECG sensor system **20** thus comprises a single ECG electrode. In some embodiments, the ECG sensor system **20** comprises a plurality of ECG electrodes.

[0068] In some embodiments, the ECG sensor system **20** comprises a single reference electrode. In some embodiments, the ECG sensor system **20** comprises a plurality of reference electrodes.

[0069] As illustrated in FIG. **1**, in a preferred embodiment of the invention, the ECG sensor system **20** comprises two ECG electrodes and one reference electrode.

[0070] Referring back to FIG. **1**, in a preferred embodiment, the physiological monitoring system **102** further includes an electronics module **22**. The electronics module **22** preferably includes processing system **8**, which is programmed and configured to control the ECG sensor system **20** and the function thereof, and the transmission and receipt of signals therefrom.

[0071] The processing system **8** is also preferably programmed and configured to receive and process transmissions or signals from the ECG sensor system **20**, and determine physiological information associated with a monitored subject (as a function of the signals), including at least one physiological characteristic, e.g. heart rate.

[0072] In some embodiments of the invention, the electronics module **22** comprises a power source **10**. According to the invention, the power source **10** can comprise any system configured to provide electrical energy to a device, such as a battery.

[0073] In some embodiments of the invention, the electronics module **22** further includes a data transmission system **14**. Preferably, the data transmission system **14** comprises a transmitter that is programmed and configured to wirelessly transmit processed signals representing physiological characteristics to a remote signal receiving device (not shown), e.g., a base module or a hand-held electronic device, such as a smart phone, tablet, computer, wearable electronic, etc.

[0074] In some embodiments of the invention, the physiological monitoring system **102** is further configured to monitor one or more additional physiological characteristics associated with a monitored subject. Thus, in some embodiments, the physiological monitoring system **102** further includes one or more additional physiological sensors, such as a pulse oximeter (S_pO_2) or core body temperature sensor (not shown), which are in communication with the signal transmission conductors **6**.

[0075] Referring now to FIGS. **2-6**, several embodiments of ECG physiological monitoring systems of the invention will be described in detail.

[0076] Referring first to FIGS. **2-4**, there is shown one embodiment of a wearable ECG physiological monitoring system **200**. As illustrated in FIG. **3**, the wearable ECG physiological monitoring system **200** includes garment **101**, and the ECG sensor system **20** and electronics module **22** shown in FIG. **1**.

[0077] According to the invention, the wearable ECG physiological monitoring system **200** can comprise any wearable garment, such as the garments disclosed in U.S. application Ser. No. 13/854,230, which is expressly incorporated by reference herein in its entirety.

[0078] As also illustrated in FIG. **3**, in the noted embodiment, the wearable garment **101** is preferably configured to cover at least the chest region and upper back of a subject **50**. According to the invention, the wearable garment **101** can, however, also be configured to cover other regions of the subject **50**, including, without limitation, the lower abdominal region.

[0079] As illustrated in FIGS. **2** and **3**, in some embodiments, the wearable garment **101** includes band **104**, which, as discussed below, is preferably incorporated in the wearable garment **101**.

[0080] According to the invention, the band **104** can comprise various conventional fabrics having fibers of variable loft and thickness. In some embodiments of the invention, the garment **101** comprises a form fitting garment constructed of Lycra® or like material.

[0081] In a preferred embodiment, the band **104** is attached to an interior portion of the wearable garment **101**. According to the invention, the band **104** can be permanently attached to the garment **101** or removeably secured to the garment **101**, e.g. via a zipper or Velcro® system.

[0082] In some embodiments of the invention, at least one of the shoulder portions **106** of the garment **101** comprises a two-piece portion, i.e. an over-lapping strap configuration, to facilitate easy placement of the garment **101** on a wearer, e.g., elderly user. In the noted embodiments, the two-piece portion includes a conventional Velcro® system or hooks or snaps to secure the ends of the over-lapping strap after the garment **101** is positioned on the wearer's body.

[0083] As indicated above and shown in FIG. **2**, the band **104** includes ECG sensor system **20**. In a preferred embodiment, the band **104** is positioned on the garment **101** such that the ECG sensor system **20** is disposed proximate the thoracic region of the subject **50** when the garment is worn by the subject **50**.

[0084] In some embodiments, the band **104** further comprises integral signal transmission conductors **6**. In a preferred embodiment, the signal transmission conductors **6** are disposed in a flexible configuration thereon.

[0085] In some embodiments, the signal transmission conductors **6** comprise a conventional insulated conductive wire. such as a copper wire insulated by a rubber coating.

[0086] In some embodiments of the invention, the signal transmission conductors **6** comprise conductive fabric.

[0087] In some embodiments, the signal transmission conductors **6** comprise a thin linear member, e.g. thread or chord, which is wrapped with a conductive wire. Preferably, the linear member comprises a stretchable member, i.e. is at least partially constructed of a stretchable material, and the wire is spirally wrapped around the stretchable member.

[0088] In a preferred embodiment, the wearable ECG physiological monitoring system **200** further includes electronics module **22**, which is in direct communication with the ECG sensor system **20** via the signal transmission conductors **6**.

[0089] In some embodiments, the electronics module **22** is incorporated into and/or disposed on the wearable garment **101**. In some embodiments, the electronics module **22** is incorporated into band **104**.

[0090] As indicated above, in one embodiment of the invention, the electronics module **22** preferably includes at least processing system **8** and data transmission system **14**.

[0091] As also indicated above, the processing system **8** preferably includes programs, instructions and associated algorithms and parameters to control the ECG sensor system **20** and, hence, the first and second ECG electrodes **2***a*, **2***b* and the function thereof, and the transmission and receipt of signals therefrom, as well as the data transmission system **14**.

[0092] The processing system **8** is also preferably programmed and configured to process signals from the ECG sensor system **20**, and determine physiological information associated with the monitored subject (as a function of the signals).

[0093] In a preferred embodiment, the processing system is further configured to generate the average capacitance potential values C_{Avg}, C'_{Avg} discussed in detail above.

[0094] In some embodiments of the invention, the processing system **8** also includes a "rules set" that includes a rule in which an alert signal is transmitted if the signals from the ECG sensor system **20** indicate that an ECG parameter or other physiological parameter that is being monitored is outside a predetermined range.

[0095] In some embodiments, the processing system **8** further comprises at least one signal interference and/or noise reducing algorithm, including, without limitation wavelet neural network algorithms, adaptive filtering algorithms, least mean squared algorithms, normalized least mean squared algorithms, sign error least mean squared algorithms, sign data least mean squared algorithms, sign least mean squared algorithms and recursive least mean squared algorithms.

[0096] In some embodiments, the electronics module **22** further comprises a signal filtering means, such as a band-pass filter.

[0097] Referring back to FIG. **1**, in a preferred embodiment, the electronic module **22** further comprises an amplifier system **9** that is designed and configured to amplify ECG signals, i.e. capacitance signals, provided by the ECG sensor system and transmit the amplified ECG signals to the processing system **8**.

[0098] In some embodiments, the amplifier system **9** comprises an input impedance in the range of 10^7 Ω to 10^9 Ω (100 MΩ−10 GΩ).

[0099] In some embodiments, the data transmission system **14** includes a transmitter that is programmed and configured to wirelessly transmit processed signals representing physiological characteristics to a remote signal receiving device, e.g., a base module or a hand-held electronic device, such as a smart phone, tablet, computer, electronic wearable, etc.

[0100] In some embodiments, the electronics module **22** further comprises display means **12** and is programmed and configured to display received and/or processed signals.

[0101] In some embodiments, the wearable ECG physiological monitoring system **200** further includes one or more additional physiological sensors, such as a temperature or SpO_2 sensor. In at least one embodiment, the system includes a temperature sensor.

[0102] According to the invention, the wearable ECG physiological monitoring system **200** can further include a portal, such as a website accessible over a network, to display and store the processed ECG signals.

[0103] According to the invention, when the wearable ECG physiological monitoring system **200** is positioned on a subject, the system **200** accurately monitors ECG signals and characteristics, i.e. electrical activity associated with the subject, determines at least one physiological characteristic represented by the ECG signals, and, in some embodiments, wirelessly transmits signals representing the physiological characteristic to a remote receiving and/or display device.

[0104] As indicated above, in some embodiments, the garment band **104** illustrated in FIG. **2** and discussed in detail above is configured to wrap around a subject. Thus, a further embodiment of a wearable ECG physiological monitoring system of the invention comprises the garment band **104** and an external or remote electronics module **22**. The noted system would similarly accurately monitor ECG signals and characteristics, determine at least one physiological characteristic represented by the ECG signals, and transmit signals representing the physiological characteristic to a remote receiving and/or display device.

[0105] By virtue of the dry capacitive ECG electrodes, i.e. first and second ECG electrodes **2***a*, **2***b*, the reference electrode **4** material and configuration, the defined spacing by and between the first and second ECG electrodes **2***a*. **2***b* and reference electrode **4**, and positioning of the monitored subject, the wearable ECG physiological monitoring systems described above provide several unexpected superior results and advantages:

The provision of wearable ECG physiological monitoring systems and methods that are suitable for long term, highly accurate monitoring of physiological characteristics. As discussed above, in a preferred embodiment, accurate monitoring of physiological characteristics is achieved by averaging the capacitive potential of ECG electrode(s) over time.

The provision of wearable ECG physiological monitoring systems and methods that substantially reduce or abate external electromagnetic interference, e.g. electromagnetic radiation from any powered device, power lines and interstellar sources. As discussed above, in a preferred embodiment, the external electromagnetic interference reduction/abatement is achieved by utilizing a reference electrode as an electromagnetic shield for the ECG electrodes.

The provision of wearable ECG physiological monitoring systems and methods that substantially reduce or abate internal interference, e.g. interference due to changes in displacement of the electrode-to-skin distance and friction between the electrodes and the medium that the electrodes are attached to.

The provision of wearable ECG physiological monitoring systems and methods that provide a substantially greater (or enhanced) signal-to-noise (SNR) ratio compared to conventional ECG physiological monitoring systems.

[0106] As indicated above, according to the invention, the ECG physiological monitoring systems of the invention can also be employed in other apparatuses and/or systems that maintain direct physical contact with a subject.

[0107] Referring now to FIG. **4**, there is shown another embodiment of an ECG physiological monitoring system of the invention. As illustrated in FIG. **4**, the system **202** comprises a seat **210** having an integrated ECG sensor system **201***a*, which is disposed on a seat surface **206**, and an external or remote electronics module **22**.

[0108] According to the invention, the electronics module **22** can also integrated into the vehicle seat **210**.

[0109] As further illustrated in FIG. **4**, the integrated ECG sensor system **201***a* comprises first and second ECG electrode strips **3***a*, **3***b* that are positioned on a reference electrode surface **204**.

[0110] In a preferred embodiment, the first and second ECG electrode strips **3***a*, **3***b* comprise one of the aforementioned ECG electrodes. In some embodiments, the reference electrode surface **204** comprises one of the aforementioned reference electrodes.

[0111] According to the invention, the ECG electrode strips can comprise any width and any length, thus, in some embodiments the ECG electrode strips comprise a width in the range of 1.0-5.0 cm and a length in the range of 1.0-100 cm.

[0112] According to the invention, the first and second ECG electrode strips **3***a*, **3***b* and reference electrode surface **204** are preferably in direct communication with a subject, wherein the reference electrode surface **204** provides a capacitive reference based on the first and second ECG electrode strips **3***a*, **3***b*. In a preferred embodiment, the capacitive reference similarly comprises the average of the capacitance potential of the first and second ECG electrodes **3***a*, **3***b* (C_{Avg}).

[0113] As discussed in detail below, in some embodiments, the reference electrode surface **204** is configured to average the capacitance potential of multiple ECG electrode strips.

[0114] In some embodiments, the reference electrode surface **204** is also configured to similarly average the capacitance potential noise generated by the anatomy of a subject, e.g., skin, muscle, etc., and the capacitance potential of the first and second ECG electrode strips **3***a*. **3***b* to provide an average capacitance potential value (C'_{Avg}).

[0115] As indicated above, the average capacitance potential values C_{Avg}, C'_{Avg} represent ECG signals associated with a subject.

[0116] According to the invention, when a subject is seated in seat **210**, the ECG physiological monitoring system **202** similarly accurately monitors ECG signals and characteristics associated with the subject, determines at least one physiological characteristic represented by the ECG signals, and transmits signals representing the physiological characteristic to a remote receiving and/or display device.

[0117] As will be readily appreciated by one having skill in the art, the ECG physiological monitoring system **202** can be employed with any conventional seating means, e.g. chairs, sofas, airline seats, etc.

[0118] Again, by virtue of the use of the dry capacitive ECG electrodes, i.e. first and second ECG electrode strips **3***a*, **3***b*, the reference electrode surface **204** material and configuration, the defined spacing by and between the first and second ECG electrode strips **3***a*, **3***b* and reference electrode **204**, and positioning of the monitored subject, the ECG physiological monitoring system **202** described above similarly provides the superior results and advantages provided by the wearable ECG physiological monitoring system **200**.

[0119] According to the invention, the integrated ECG sensor system **201***a* described above can comprise more than two ECG electrode strips. Illustrative are the ECG sensor systems **201***b* and **201***c* shown in FIGS. **5**A and **5**B.

[0120] Referring now to FIG. **5**A, there is shown one embodiment of an integrated ECG sensor system **201***b* comprising first, second, third and fourth ECG electrode strips **3***a*, **3***b*, **3***c*, **3***d* and reference electrode surface **204**. As illustrated in FIG. **5**A, ECG electrode strips **3***a*, **3***b*, **3***c*, **3***d* are in direct communication with amplifier system **16** via signal transmission conductors **6**.

[0121] Referring now to FIG. **5**B, there is shown another embodiment of an integrated ECG sensor system **201***c* similarly comprising first, second, third, fourth, fifth and sixth ECG electrode strips **3***a*, **3***b*, **3***c*, **3***d*, **3***e*, **3***f* and reference electrode surface **204**. As illustrated in FIG. **5**B, ECG electrode strips **3***a*, **3***b*, **3***c*, **3***d*, **3***e*, **3***f* are in direct communication with amplifier system **16** via signal transmission conductors **6**.

[0122] Referring back to FIG. **4**, according to the invention, the first and second ECG electrode strips **3***a*, **3***b* and reference electrode surface **204** are preferably in direct communication with a subject, wherein the reference electrode surface **204** provides a capacitive reference based on the first and second ECG electrode strips **3***a*, **3***b*. In a preferred embodiment, the capacitive reference similarly comprises the average of the capacitance potential of the first and second ECG electrodes **3***a*, **3***b* (C_{Avg}).

[0123] In some embodiments, the reference electrode surface **204** is similarly configured to average the capacitance potential noise generated by the anatomy of a subject, e.g., skin, muscle, etc., and the capacitance potential of the first and second ECG electrodes **3***a*, **3***b* to provide an average capacitance potential value (C'_{Avg}).

[0124] Referring now to FIG. **6**, there is shown another embodiment of an ECG physiological monitoring system of the invention. As illustrated in FIG. **6**, the physiological monitoring system **302** comprises a bed **310** having two ECG sensor systems **304***a* and electronics module **22**.

[0125] According to the invention, the ECG sensor systems can be placed in any position on the bed surface **312**. In a preferred embodiment, one ECG sensor system **304***a* is positioned at one end of the bed **310** and one ECG sensor system **304***a* is disposed on the other end of bed **310**.

[0126] According to the invention, the electronics module **22** can also be integrated into the bed **310**.

[0127] As illustrated in FIG. **6**, in the illustrated embodiment, ECG sensor system **304***a* comprises first, second, third and fourth ECG electrode strips **5***a*, **5***b*, **5***c*, **5***d* and reference electrode layer **306***a*.

[0128] Although, in the illustrated embodiment, the ECG sensor systems **304***a* comprise similar systems, according to the invention, dissimilar ECG systems can also be employed, e.g., one ECG sensor system comprising four ECG electrode strips and one ECG sensor system comprising six ECG electrode strips.

[0129] Preferably, the ECG electrode strips **5***a*, **5***b*, **5***c*, **5***d* comprise one of the aforementioned ECG electrodes. In some embodiments, the reference electrode layer **306***a* comprises one of the aforementioned reference electrodes.

[0130] According to the invention, when a subject is in a supine or prone position on the bed **310** such that the ECG sensor systems **304***a* and, hence, ECG electrode strips **5***a*, **5***b*, **5***c*, **5***d* and the reference electrode **306***a* are covered by the subject's body, the ECG physiological monitoring system **302** similarly accurately monitors ECG signals and characteristics associated with the subject, determines at least one physiological characteristic represented by the ECG signals, and transmits signals representing the physiological characteristic to a remote receiving and/or display device.

[0131] By virtue of the use of the dry capacitive ECG electrodes, i.e. ECG electrode strips **5***a*, **5***b*, **5***c*, **5***d* and the reference electrode **306***a* material and configuration, the defined spacing by and between the ECG electrode strips **5***a*, **5***b*, **5***c*, **5***d* and reference electrode **306***a*, and positioning of the monitored subject, the ECG physiological monitoring system **302** described above similarly provides the superior results and advantages provided by the wearable ECG physiological monitoring system **200**.

[0132] As will readily be appreciated by one having ordinary skill in the art, the present invention provides numerous advantages compared to prior art methods and systems for monitoring and/or detecting physiological characteristics. Among the advantages are the following:

The provision of ECG physiological monitoring systems and methods that accurately monitor ECG signals representing one or more physiological characteristics associated with a user or wearer.

The provision of ECG physiological monitoring systems and methods that accurately measure one or more additional physiological characteristics associated with a user or wearer, e.g. body temperature.

The provision of ECG physiological monitoring systems and methods that do not require the use of conductive gels.

The provision of ECG physiological monitoring systems that are suitable for long term monitoring of physiological characteristics.

The provision of ECG physiological monitoring systems and methods that substantially reduce or abates external electromagnetic interference.

The provision of ECG physiological monitoring systems and methods that substantially reduce or abate internal interference.

The provision of ECG physiological monitoring systems and methods that provide a substantially greater (or

enhanced) signal-to-noise (SNR) ratio compared to conventional ECG physiological monitoring systems.

[0133] Without departing from the spirit and scope of this invention, one of ordinary skill can make various changes and modifications to the invention to adapt it to various usages and conditions. As such, these changes and modifications are properly, equitably, and intended to be, within the full range of equivalence of the following claims.

What is claimed is:

1. An electrocardiography (ECG) physiological monitoring system, comprising:

an ECG sensor assembly that is configured to be positioned proximate to a subject's skin;

said ECG sensor assembly comprising at least first and second capacitive electrodes configured to electrically couple to said subject's skin and detect ECG signals, said ECG sensor assembly comprising at least a first reference electrode that is configured to average the capacitance potential of said first and second electrodes;

an electronics module comprising a processing system and a data transmission system, said electronics module being in direct communication with said ECG sensor assembly, said processing system including programs, instructions and associated algorithms and parameters to control said ECG sensor assembly, retrieve and process ECG signals transmitted by said ECG sensor assembly, determine physiological information associated with said subject as a function of said ECG signals, said data transmission system including a transmitter that is configured to wirelessly transmit said processed ECG signals; and

signal transmission conductors that are configured to provide a signal communication path between said electronics module and said ECG sensor assembly.

2. The ECG physiological monitoring system of claim **1**, wherein said first and second capacitive electrodes are positioned between said subject's skin and said first reference electrode, wherein said first reference electrode is configured to shield said first and second capacitive electrodes from electromagnetic interference.

3. The ECG physiological monitoring system of claim **1**, wherein said electronics module comprises an amplifier system that is configured to amplify said ECG signals.

4. The ECG physiological monitoring system of claim **1**, wherein said system includes a remote display device that is configured to receive and display said processed ECG signals from said electronics module.

5. The ECG physiological monitoring system of claim **1**, wherein said system includes at least one additional physiological sensor that is in communication with said signal transmission conductors.

* * * * *

专利名称(译)	电容式心电图（ECG）生理监测系统		
公开(公告)号	US20170303810A1	公开(公告)日	2017-10-26
申请号	US15/491775	申请日	2017-04-19
[标]申请(专利权)人(译)	医疗设计解决方案		
申请(专利权)人(译)	医疗设计SOLUTIONS，INC.		
当前申请(专利权)人(译)	医疗设计SOLUTIONS，INC.		
[标]发明人	STONE ROBERT T		
发明人	STONE, ROBERT T.		
IPC分类号	A61B5/0408 A61B5/0205 A61B5/04 A61B5/00 A61B5/0404 A61B5/044		
CPC分类号	A61B5/04085 A61B5/0006 A61B5/04012 A61B5/0404 A61B2562/182 A61B5/0205 A61B5/6893 A61B5/6804 A61B2562/0214 A61B5/044 A61B5/0245 A61B5/6892		
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摘要(译)

一种心电图（ECG）生理监测系统，其包括ECG传感器组件，所述ECG传感器组件具有第一和第二电容电极，所述第一和第二电容电极被配置为电耦合到受试者的皮肤并检测ECG信号，参考电极被配置为平均所述第一和第二电容电位。第二电极，电子模块，其与ECG传感器组件直接通信并被编程以控制ECG传感器组件，从其处理ECG信号，以及无线传输处理的ECG信号，以及被配置为提供信号通信路径的传输导体在电子模块和ECG传感器组件之间。