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(71) Applicant: **TESSERACT SENSORS, LLC** [US/US]; 101 Gordon Street, Sanford, FL 32771 (US).

(72) Inventor; and
(71) Applicant : **VOSCH, Michael, J.** [US/US]; 101 Gordon Street, Sanford, FL 32771 (US).

(74) Agent: **OLIVE, Bentley, J.**; Olive Law Group, PLLC, 125 Edinburgh South Drive, Suite 220, Cary, NC 27513 (US).

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WO 2015/009980 A1

(54) Title: MEDICAL DATA ACQUISITION SYSTEMS AND METHODS FOR MONITORING AND DIAGNOSIS

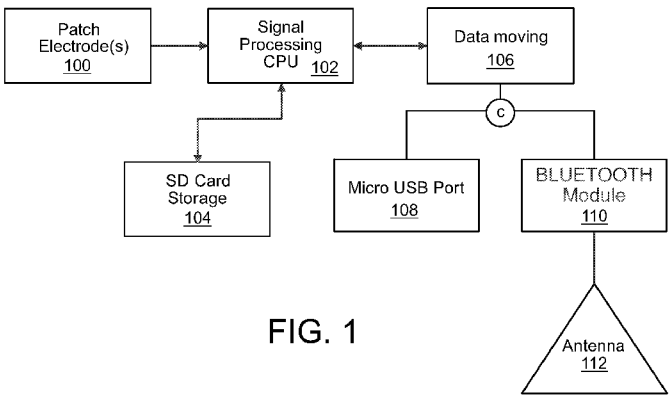


FIG. 1

(57) Abstract: Medical data acquisition systems and methods for monitoring and diagnosis are disclosed. According to an aspect, a system may include one or more electrodes configured to detect biological data and to convert the detected biological data into a signal. The system may also include a monitor recorder configured to receive the signal and store the detected biological data. Further, the system may include a transceiver configured to wirelessly communicate the biological data.

DESCRIPTION

MEDICAL DATA ACQUISITION SYSTEMS AND METHODS FOR MONITORING AND DIAGNOSIS

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claim the benefit of and priority to U.S. Provisional Patent Application No. 61/847,873, filed July 18, 2013 and titled MEDICAL DATA ACQUISITION SYSTEMS AND METHODS FOR MONITORING AND DIAGNOSIS; the content of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present subject matter relates to medical monitoring and diagnosis. Particularly, the present subject matter relates to medical data acquisition systems and methods for monitoring and diagnosis.

BACKGROUND

[0003] Medical data acquisition equipment has been used in many settings including hospitals. In other applications, such equipment can be used for remote monitoring of individuals. Example data that can be collected and remotely communicated for analysis includes electrocardiography data. It is desired to provide improved systems and techniques for medical monitoring and diagnosis. Particularly, it is desired to provide improvements for rapidly collecting large amounts of medical data, wirelessly communicating the data, and remotely analyzing the data.

SUMMARY

[0004] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter.

[0005] Disclosed herein are medical data acquisition systems and methods for monitoring and diagnosis. According to an aspect, a system may include one or more electrodes configured to

detect biological data and to convert the detected biological data into a signal. The system may also include a monitor recorder configured to receive the signal and store the detected biological data. Further, the system may include a transceiver configured to wirelessly communicate the biological data.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The foregoing summary, as well as the following detailed description of various embodiments, is better understood when read in conjunction with the appended drawings. For the purposes of illustration, there is shown in the drawings exemplary embodiments; however, the presently disclosed subject matter is not limited to the specific methods and instrumentalities disclosed. In the drawings:

[0007] FIG. 1 is a block diagram of an example medical data acquisition system for monitoring and diagnosis in accordance with embodiments of the present subject matter;

[0008] FIG. 2 is an exploded view of a medical data diagnostic system;

[0009] FIGs. 3 and 4 are bottom and top perspective views, respectively, of the system shown in FIG. 2;

[0010] FIG. 5 is another top perspective view of the system shown in FIG. 2;

[0011] FIG. 6 is a top view of the electronic circuitry of the system shown in FIG. 2;

[0012] FIG. 7 is a block diagram of another example medical data acquisition system for monitoring and diagnosis in accordance with embodiments of the present subject matter; and

[0013] FIGs. 8 – 11 show different examples of patch electrodes in accordance with embodiments of the present subject matter.

DETAILED DESCRIPTION

[0014] The presently disclosed subject matter is described with specificity to meet statutory requirements. However, the description itself is not intended to limit the scope of this patent. Rather, the inventors have contemplated that the claimed subject matter might also be embodied in other ways, to include different steps or elements similar to the ones described in this document, in conjunction with other present or future technologies. Moreover, although the term "step" may be used herein to

connote different aspects of methods employed, the term should not be interpreted as implying any particular order among or between various steps herein disclosed unless and except when the order of individual steps is explicitly described.

[0015] As an example, a system in accordance with the present disclosure may include a monitoring system card configured to store and transmit data received from multiple manners such as, but not limited to, an EKG strip or full 12 lead EKG. Further, a system may include a 2 – 8 channel circuit card capable of measuring biometrics and transmitting biometric data. The monitoring system card can perform numerous physiological measurements at a very high sampling rate. For example, the sampling rate may be up to 32,000 samples per second per channel. The card may be capable of reading, processing, and transmitting the following information in addition to EKG: microphone/voice recording, accelerometer, respirations, oxygen (O_2) saturation, and/or the like. In an example, the system may include a battery having a 1 week life or longer. Further, the card may include programmable intervals of data recording and/or event or patient activation.

[0016] A monitoring system card in accordance with the present subject matter may obtain patient data for software analysis as described in examples herein and in any suitable technique. Example techniques for obtaining and communicating patient data include, but are not limited to: via a BLUETOOTH® transmitter to an analysis station; data transmission via a BLUETOOTH® transmitter to a cloud network or to a cell phone (which in turn can transmit data over a data network) to an analysis station; and writing data to a micro SD card or data transmission via micro USB. Post processing can be defined by an end user.

[0017] FIG. 1 illustrates a block diagram of an example medical data acquisition system for monitoring and diagnosis in accordance with embodiments of the present subject matter. Referring to FIG. 1, the system includes one or more patch electrodes **100** configured to detect physiological data and to convert the detected physiological data into a signal. For example, the patch electrodes **100** may be attached to a person for collecting electrocardiography (ECG) data. A patch electrode may be any suitable type of electrode or sensor configured to detect current or voltage. The patch electrode may include an adhesive for attachment to a patient. The detected current or voltage may indicate physiological information about the patient as will be understood to those of skill in the art.

[0018] The patch electrodes **100** may be communicatively connected to a signal processing central processing unit (CPU) **102** such that the ECG data and/or other physiological data can be

communicated to the CPU **102**. For example, the patch electrodes **100** may be suitably connected to the CPU **102** by one or more lead wires and conditioning circuitry. The data may be converted to a signal for communication to the CPU **102**. The CPU **102** may process, organize, and store the ECG data in secure digital (SD) card storage **104**.

[0019] A data moving module **106** may receive ECG data from the CPU **102** and pass the data to either a micro USB port **108** or a BLUETOOTH® module **110**. The data communicated to the USB port **108** may be suitably downloaded by a computing device, such as a laptop computer. The module **110** may wirelessly communicate the data by use of an antenna **112** or transceiver.

[0020] Data downloaded via the USB port **108** or received from the antenna **112** via wireless communication may be evaluated by a software analysis system. The software analysis system may import the data in one of various file formats including, but not limited to: SIFOR file format (SDF), simple control protocol (SCP), medical diagnostic workstation (MDW) (for use with Cardio Perfect ECG Diagnostic System), MIT format, and 2-10 cubed (Phillips format).

[0021] In accordance with embodiments of the present disclosure, the system may utilize software for receiving and processing data collected from an individual as described herein. For example, the software residing on a system shown in FIG. 1 may be implemented by the CPU **102**. The software that receives the obtained data can be any suitable ECG diagnostic system software. The data produced by the card can be formatted with the CPU **102** so that the receiving software can read the data in, in accordance with that software's particular requirements. This allows the card to be developed to meet a myriad of systems while maintaining the same configuration, thereby reducing overall cost to manufacture different models for different external software systems.

[0022] FIG. 2 illustrates an exploded, perspective view of a medical data diagnostic system in accordance with embodiments of the present disclosure. Referring to FIG. 2, the system may include a plastic protective shell or casing **200** for containing electronics such as the components shown in FIG. 1. For example, the casing **200** may contain the CPU **102**, the SD card storage **104**, the data moving module **106**, the USB port **108**, the module **110**, and the antenna **112** shown in FIG. 1. The casing **200** may be made of any suitably rigid material such as plastic or metal. This material can be various forms of ABS, carbon fiber, or metal composites that can allow for the ease of manufacture at a low cost with a high reliability for the end-user.

[0023] The system may include patch electrodes, generally designated **102**. The patch

electrodes **102** may include multiple electrodes **202** that are connected to conductive lines or leads **204** for electrical communication with an interface **206**. The interface **206** may connect, for example, the patch electrodes **102** with the CPU **102** shown in FIG. 1 and operate in accordance with examples disclosed herein.

[0024] Further, the system include an adhesive component **208** for attachment to a patient. The adhesive component **208** may define holes **209** for containing or holding the electrodes **202**. The adhesive component **208** may attach on a top side to a layer **210** that holds the leads **204**. The system may also include another layer **212** for interfacing the casing **200** and the layer **210**.

[0025] FIGs. 3 and 4 illustrate bottom and top perspective views, respectively, of the system shown in FIG. 2.

[0026] In accordance with embodiments, a monitoring system does not have the capability to generate ECG tracings, nor does the device perform any ECG analytical functions. The monitoring system may transmit the data via a communication system to the analysis station in formats that conform to the Institute of Electrical and Electronics Engineers (IEEE) 801.11a & b & g specifications. The communication system can be determined by the end user.

[0027] FIG. 7 illustrates a block diagram of another example medical data acquisition system for monitoring and diagnosis in accordance with embodiments of the present subject matter. Referring to FIG. 7, the system is a 4 channel system in which channels A, B, C, and D are electrically connected to 4 electrodes of a patch (not shown). Although 4 channels are shown in this example, it should be understood that the system may include any number of channels connected to a corresponding number of electrodes on one or more suitable electrode patches. The patch may be one of the patches as shown and described by the examples herein, or any other suitable electrode patch.

[0028] The monitoring system may include a suitable 2 to 8 channel ECG processing board and recorder **500**. The monitoring recorder stores and transmits data received from the processing board via a communication system to a remotely located ECG analysis station for evaluation by a medical professional. Particularly, the board and recorder **500** may include an amplifier **502** having inputs that connect to the channels A, B, C, and D for suitable conditioning. The output of the amplifier **502** may be connected to an input of an analog-to-digital (A/D) converter **504**, which is in turn connected to a multiplexer (MUX) **506**. As an example, the A/D converter **504** may have a sampling rate greater than 1,200 s/s or any other suitable rate. The monitoring system is capable of

performing various types of test such as, but not limited to, Holter monitoring, 24 hour continuous monitoring for event monitoring, vector cardiograms, arrhythmia monitoring, signal averaged ECG's, O_2 saturation, respirations and other patient physiological data depending on the type of analytical software used to interrogate and evaluate the processing board. The ways the signals are processed from the human body are both unique and advanced. The use of various amplifier and filtering techniques are used to increase the overall signal-to-noise ratio (SNR). The data set from the human body that the device is capable of processing may also be varied depending on the external software. Some of the examples of the type of data that can be acquired and processed by the card are: EKG, EEG, temperature, respirations, oxygen saturation, and the galvanic skin resistance. The processing board and monitoring recorder **500** can use various techniques to increase the SNR and thereby remove most muscle noise and outside environmental noise to produce a cleaner and over all better signal for the post processing software to use.

[0029] A clock/timing control module **508** may control timing of the MUX **506**. A transceiver **510** may receive the output of the MUX **704** and wirelessly communicate physiological data or other data via an antenna filter **512** and an antenna **514**. A battery **516** may power the system components.

[0030] FIGs. 6 – 9 illustrate different examples of patch electrodes **600** in accordance with embodiments of the present subject matter. The patch electrodes **600** may be used with any of the systems and methods disclosed herein. Referring to FIGs. 6 – 9, the patch electrodes **600** may each be a multi-layer patch including embedded ECG electrodes **202**, leads (not shown), and a battery (not shown) on a Mylar substrate. The patch electrode **600** can be affixed to a patient's chest for monitoring ECG activity or other physiological activity. The patch electrode **600** can have various designs depending on analysis software. For Phillips, it includes four precordial ECG electrodes that are positioned orthogonally so that, when the patch is applied in accordance with the present subject matter, the leads correspond to positions of EASI & G. The patch electrode may be used with modified Frank algorithms or any other suitable algorithms and techniques. Other suitable patch designs may be set up to various software configurations including the MEANS algorithm or other suitable algorithms and techniques. The patch component, though varying in configurations, can be divided into layers, which includes a top layer of polyester biocompatible foam with a lower adhesive layer. The middle layer can be a mylar-based conductive layer with adhesive covering both sides. The

bottom layer is the same as the top layer with the use of a polyester-based reticulated foam to allow for a conductive gel to be utilized which can provide a medium between the human body and the middle layer conductive surface.

[0031] The ECG leads in all models of the patch electrode are connected to the processing board. The processing board receives the ECG data from the leads and transmits or stores this information to the monitor recorder.

[0032] The various techniques described herein may be implemented with hardware or software or, where appropriate, with a combination of both. Thus, the methods and apparatus of the disclosed embodiments, or certain aspects or portions thereof, may take the form of program code (i.e., instructions) embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or any other machine-readable storage medium, wherein, when the program code is loaded into and executed by a machine, such as a computer, the machine becomes an apparatus for practicing the presently disclosed subject matter. In the case of program code execution on programmable computers, the computer will generally include a processor, a storage medium readable by the processor (including volatile and non-volatile memory and/or storage elements), at least one input device and at least one output device. One or more programs may be implemented in a high level procedural or object oriented programming language to communicate with a computer system. However, the program(s) can be implemented in assembly or machine language, if desired. In any case, the language may be a compiled or interpreted language, and combined with hardware implementations.

[0033] The described methods and apparatus may also be embodied in the form of program code that is transmitted over some transmission medium, such as over electrical wiring or cabling, through fiber optics, or via any other form of transmission, wherein, when the program code is received and loaded into and executed by a machine, such as an EPROM, a gate array, a programmable logic device (PLD), a client computer, a video recorder or the like, the machine becomes an apparatus for practicing the presently disclosed subject matter. When implemented on a general-purpose processor, the program code combines with the processor to provide a unique apparatus that operates to perform the processing of the presently disclosed subject matter.

[0034] Features from one embodiment or aspect may be combined with features from any other embodiment or aspect in any appropriate combination. For example, any individual or collective features of method aspects or embodiments may be applied to apparatus, system, product, or

component aspects of embodiments and vice versa.

[0035] While the embodiments have been described in connection with the various embodiments of the various figures, it is to be understood that other similar embodiments may be used or modifications and additions may be made to the described embodiment for performing the same function without deviating therefrom. Therefore, the disclosed embodiments should not be limited to any single embodiment, but rather should be construed in breadth and scope in accordance with the appended claims.

CLAIMS

What is claimed:

1. A system comprising:

one or more electrodes configured to detect physiological data and to convert the detected physiological data into a signal;

a monitor recorder configured to receive the signal and store the detected physiological data; and

a transceiver configured to wirelessly communicate the physiological data.

2. The system of claim 1, wherein the physiological data includes one of respiration data, oxygen data, and saturation data.

3. The system of claim 1, wherein the monitor recorder is configured to receive a plurality of signals from the one or more electrodes via a plurality of channels.

4. The system of claim 1, wherein the monitor recorder comprises an amplifier configured to amplify the signal.

5. The system of claim 1, further comprising a battery configured to power the monitor recorder and the transceiver.

6. The system of claim 1, wherein the physiological data includes electrocardiography (ECG) data.

7. The system of claim 1, wherein the monitor recorder is configured to receive one of sound data and accelerometer data, and

wherein the transceiver is configured to wirelessly communicate the one of the sound data and accelerometer data.

8. A method comprising:

detecting physiological data and converting the detected physiological data into a signal;
receiving the signal and storing the detected physiological data; and
wirelessly communicating the physiological data.

9. The method of claim 8, wherein the physiological data includes one of respiration data, oxygen data, and saturation data.

10. The method of claim 8, wherein detecting and converting comprises using one or more electrodes to detect the physiological data and to convert the detected physiological data into the signal.

11. The method of claim 8, wherein receiving the signal comprises receiving a plurality of signals from the one or more electrodes via a plurality of channels.

12. The method of claim 8, further comprising amplifying the signal.

13. The method of claim 8, further comprising powering the monitor recorder and the transceiver.

14. The method of claim 8, wherein the physiological data includes electrocardiography (ECG) data.

15. The method of claim 8, further comprising:
receiving one of sound data and accelerometer data; and
wirelessly communicating the one of the sound data and accelerometer data.

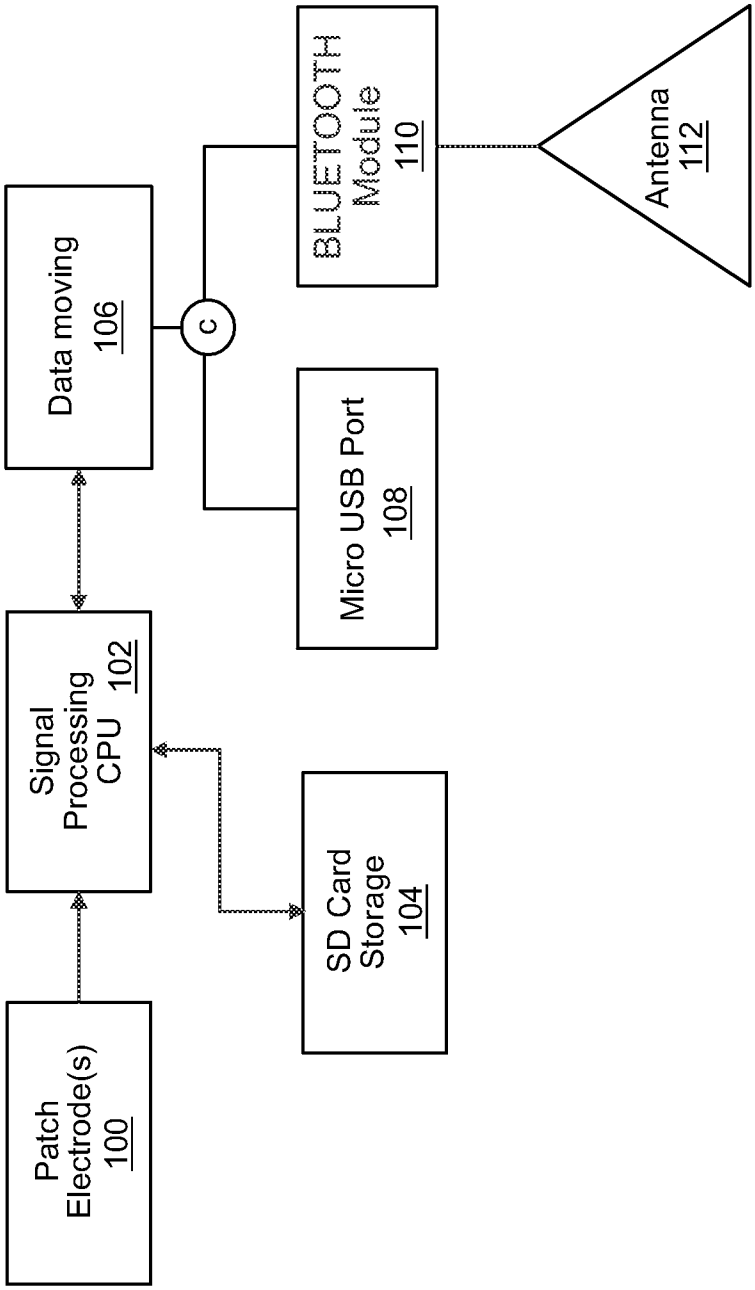

Patch Electrode(s) 100
Signal Processing CPU 102
SD Card Storage 104
Data moving 106
C
Micro USB Port 108
BLUETOOTH Module 110
Antenna 112

FIG. 1

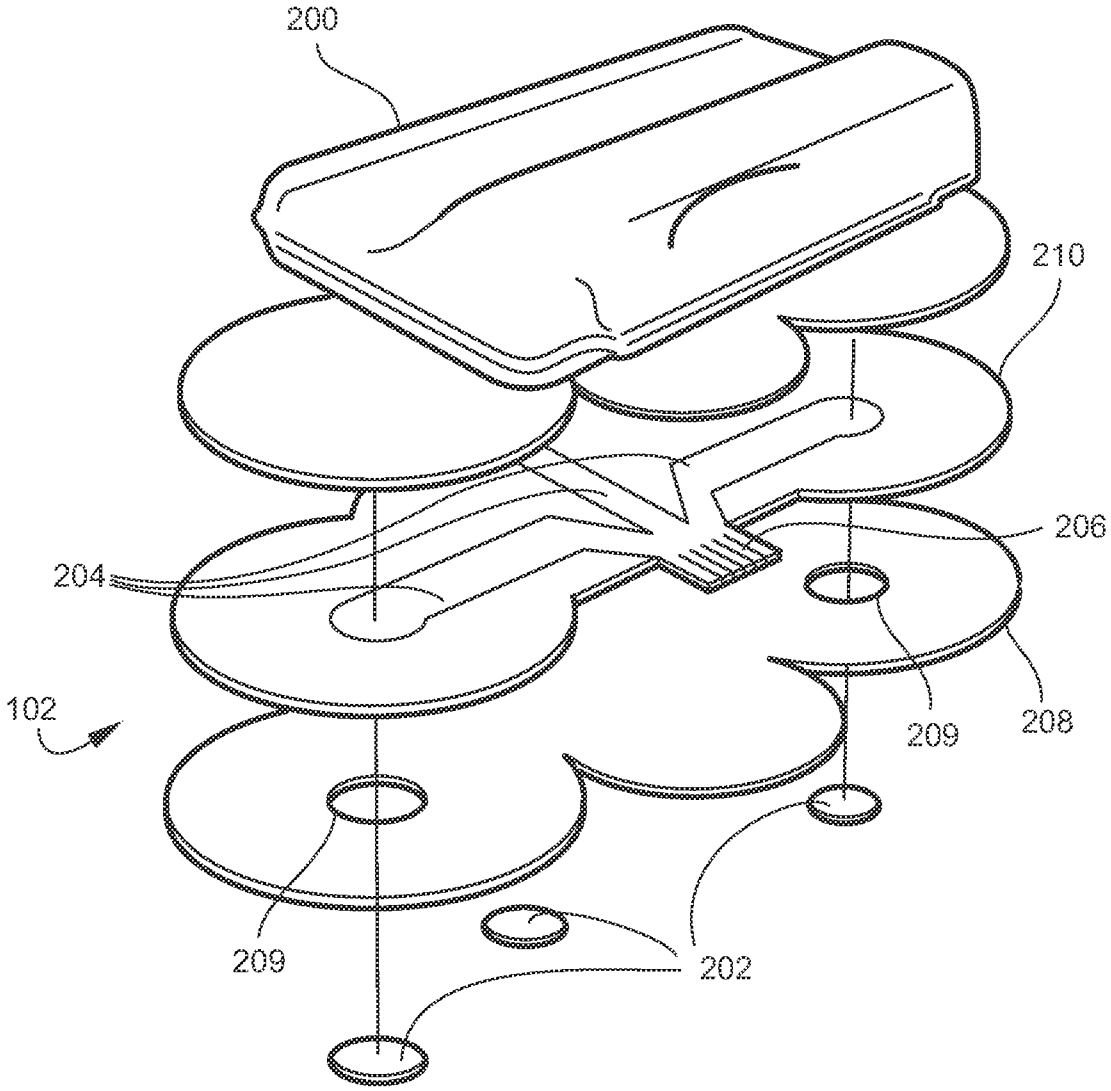


FIG. 2

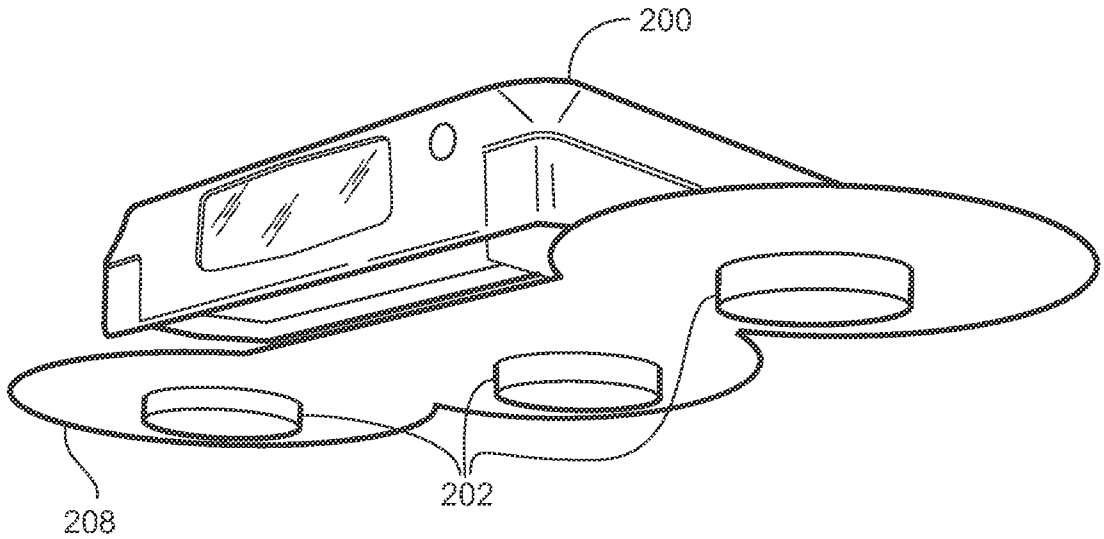


FIG. 3

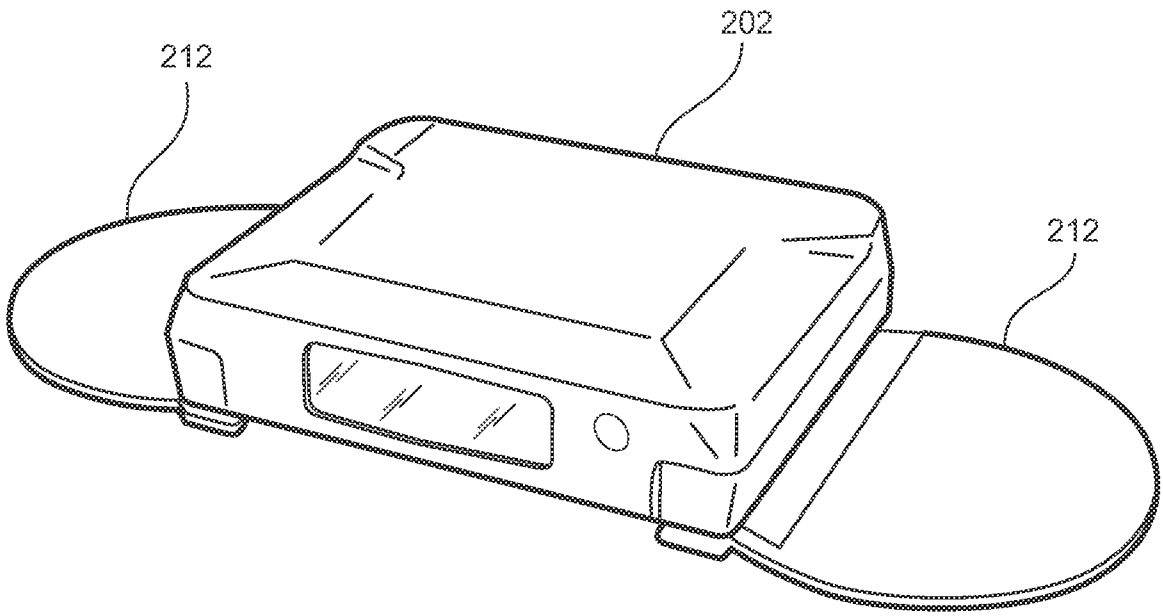


FIG. 4

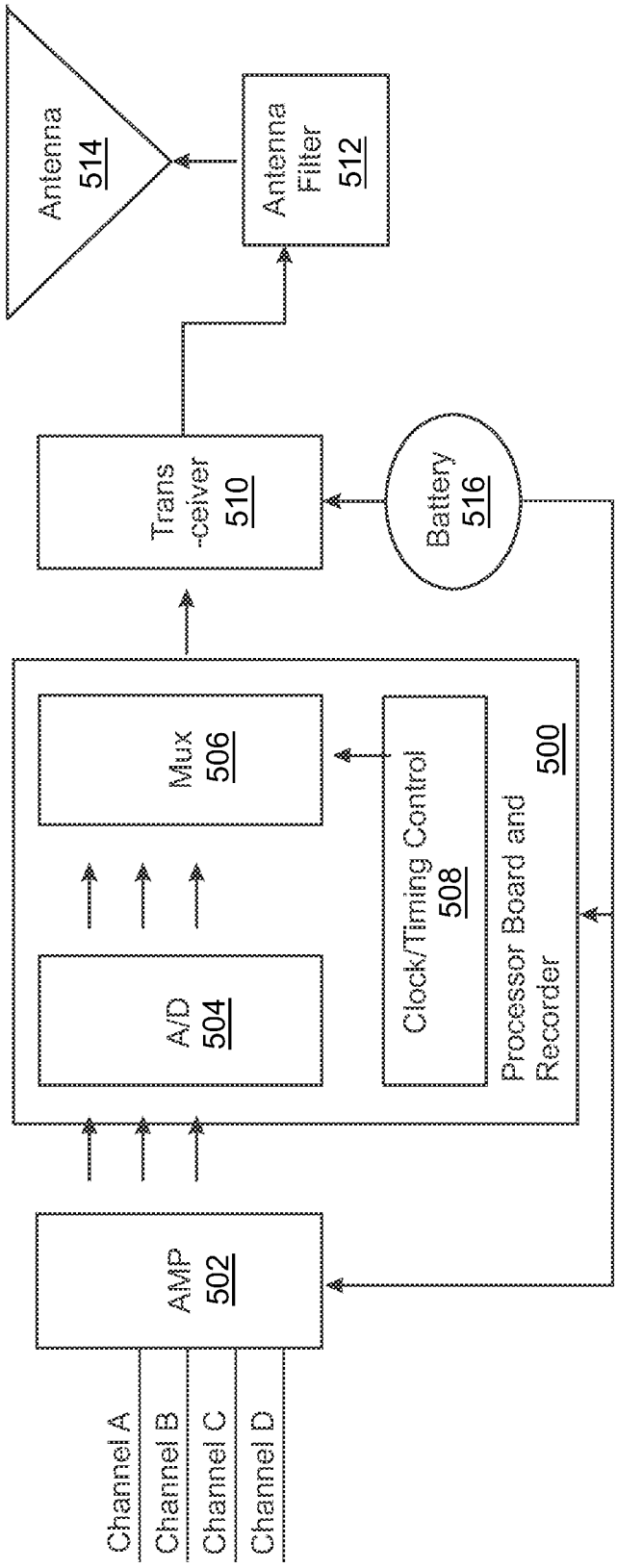

Antenna
514
Antenna
Filter
512
Trans
-ceiver
510
Battery
516
Mux
506
A/D
504
Clock/Timing Control
508
Processor Board and
Recorder
500
AMP
502
Channel A
Channel B
Channel C
Channel D

FIG. 5

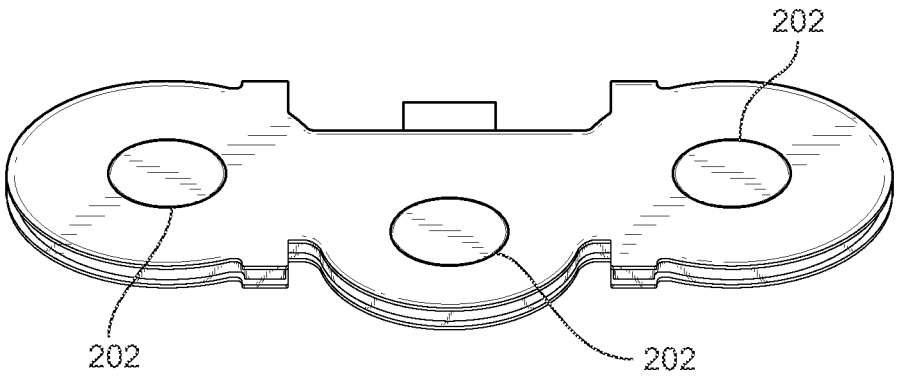


FIG. 6

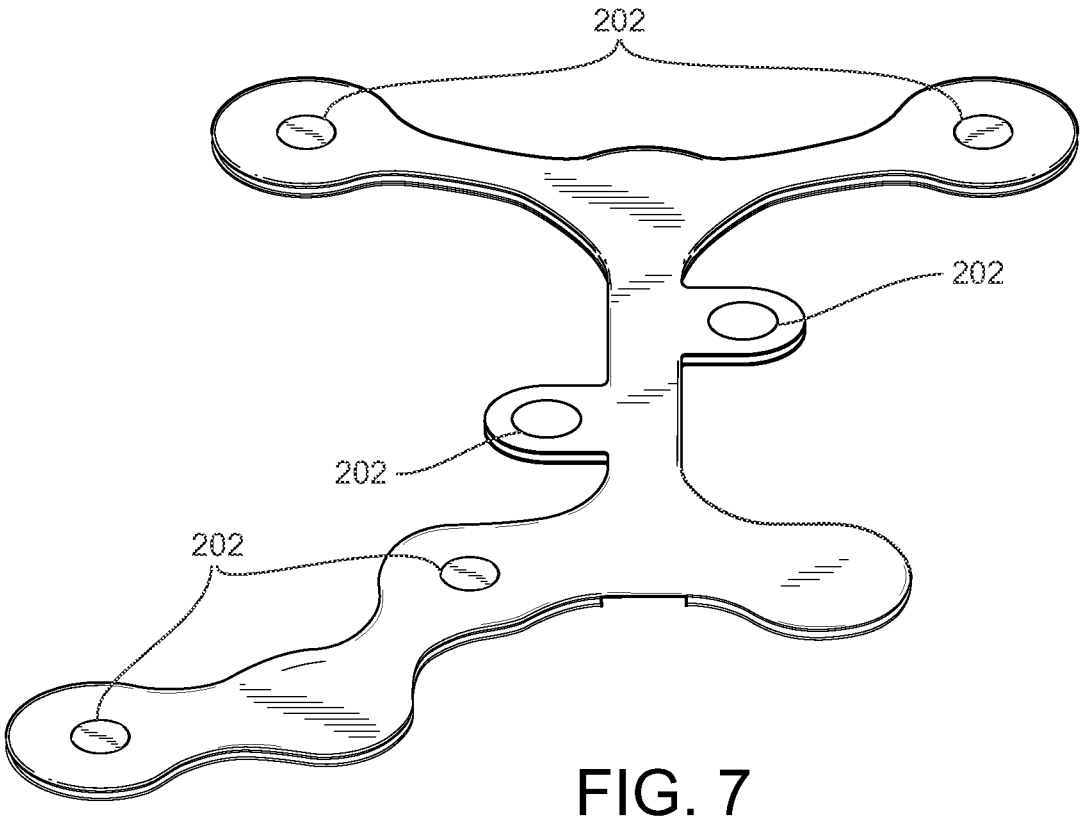


FIG. 7

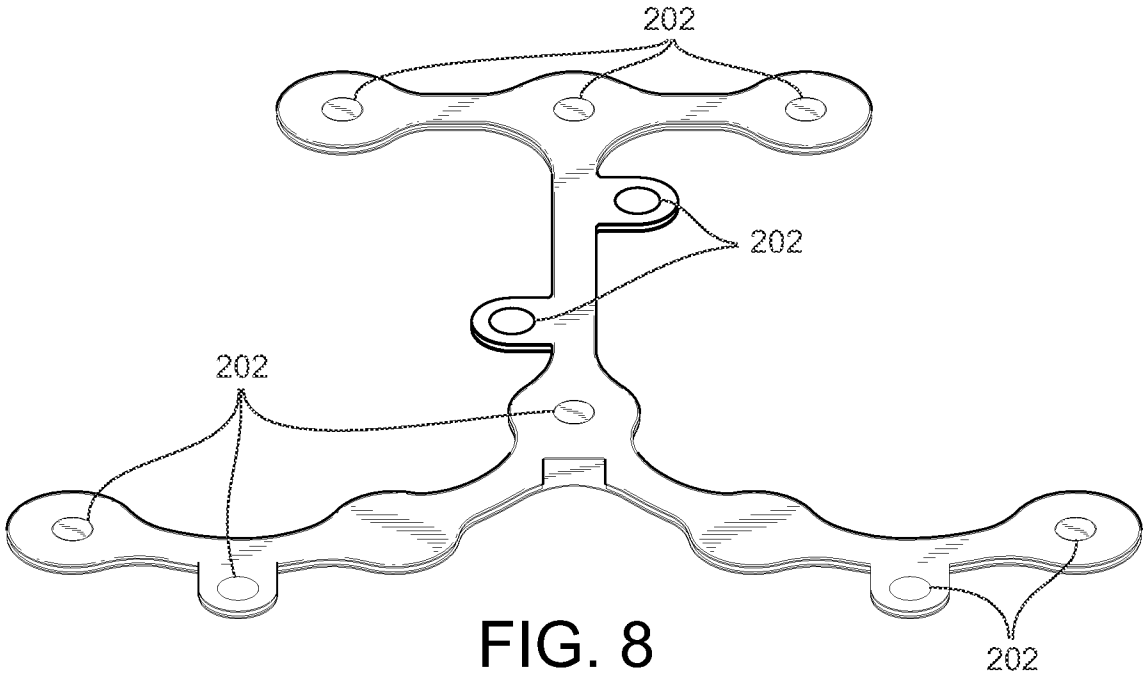


FIG. 8

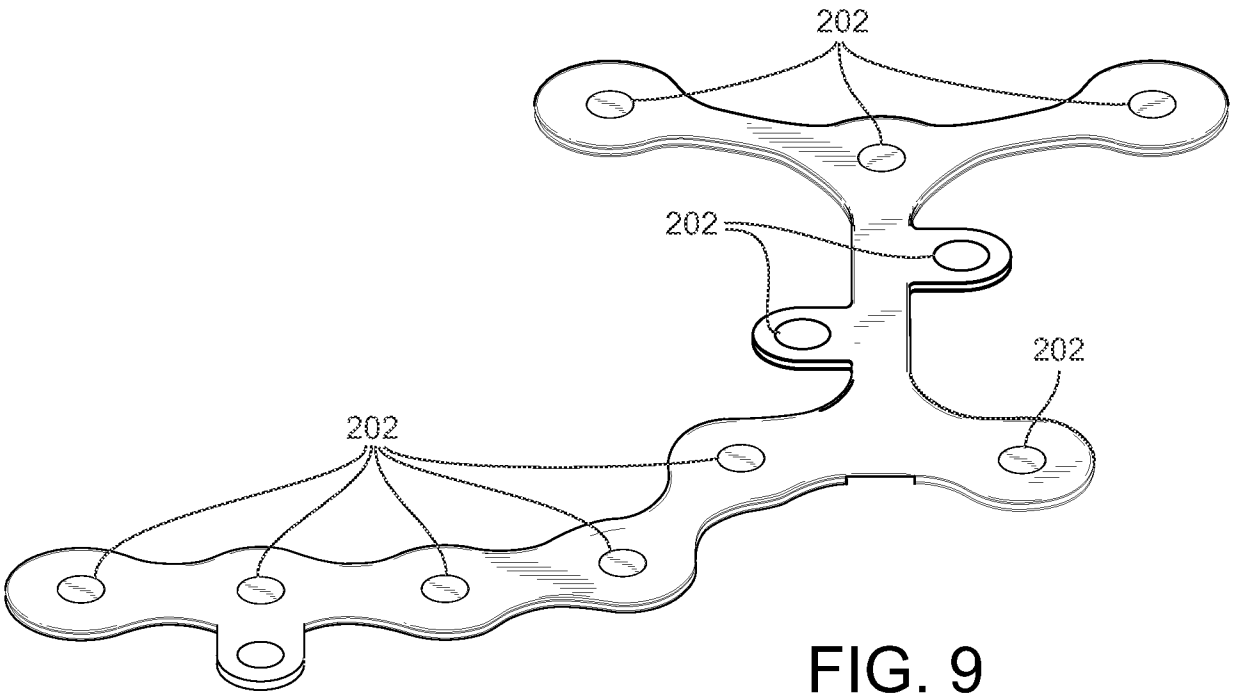


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/047109

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/04(2006.01)i, A61B 5/0402(2006.01)i, A61B 5/08(2006.01)i, A61B 5/1455(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/04; A61B 5/021; A61B 5/11; A61N 1/00; A61B 5/103; A61B 5/0402; A61B 5/08; A61B 5/1455

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: electrode, transceiver, wirelessly, accelerometer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0224557 A1 (MATT BANET et al.) 15 September 2011 See abstract, paragraphs [0069]-[0088],[0126],[0142], claim 1 and figure 4.	1-15
A	US 2006-0111640 A1 (CHIEN-LUNG SHEN et al.) 25 May 2006 See abstract, paragraph [0020] and figure 1.	1-15
A	US 2012-0053491 A1 (VAIDHI NATHAN et al.) 01 March 2012 See abstract, paragraphs [0021]-[0054] and figures 1A-3B.	1-15
A	US 2007-0073132 A1 (MICHAEL VOSCH) 29 March 2007 See abstract, paragraphs [0013]-[0017], claims 1-8 and figures 1,2.	1-15
A	US 2008-0281381 A1 (MARTIN T. GERBER et al.) 13 November 2008 See abstract, paragraphs [0016]-[0029], claims 1,2 and figures 1,2.	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 November 2014 (18.11.2014)	**18 November 2014 (18.11.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
KIM, Tae Hoon
Telephone No. +82-42-481-8407

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
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