

Description

Title of Invention : Compact Wearable 12 Lead Wireless ECG System

Technical Field

[1] The invention generally relates to a system and method of monitoring electrical activity (ECG) of human heart, more specifically, the invention relates to a wireless wearable device with the usage of two sets of active capacitance sensors with unique lead placements to measure a 12 lead Electrocardiogram (ECG).

Background Art

- [2] Cardiovascular disease or heart disease is the major issue faced by majority of present day population; The heart diseases may include congenital heart disease heart valve problems, arrhythmia, heart attacks, and diseases of heart muscle. Most of these can be identified by a 12 lead ECG. The easiest way of testing said parameters is by conducting ECG.
- [3] Traditionally, any ECG measuring system involves placing multiple leads, on the limbs and the chests, so only the electronic data collection device could be shrunk. we present a new device where the sensors send wirelessly ECG data to a receiving device and it is carried wirelessly to the cloud
- [4] Further, an ECG can be utilized to measure the regularity and the rate of heartbeats, evaluate the electrical activities of heart, analyse and identify the muscle damages, check level of response and effect of drugs on the heart.
- [5] ECG techniques, make use of different number of ECG leads. These leads are used to record the signals coming out of the heart. The leads used may be one to twelve in numbers. Usage of these leads differs based on their applications. ECG can be used primarily for basic heart monitoring, checking for rhythm and the status of the muscle of the heart by recording electrical pictures of heart from various directions. ECG may also be used for monitoring the heart in association with regular exercise, workout and sports activities.

- [6] Further, the most popular way of performing ECG as in prior art involves patients to be tethered to the ECG machine by a wire, where the ECG machine uses wet electrodes to glue on to patient's skin. The placement of electrodes is dispersed over chest and limbs of the patient. This placing electrodes on the limbs, makes the patient immobile and makes sense only in the case of bedridden patients as said ECG machine is proved to be heavy weighted, vigorous structured and considered as the network of few long cables connected between the patient and the monitor. These machines are also considered costly and cumbersome to use in ambulatory requirements and are bulky and uncomfortable for prolonged and continuous usage. Moreover, the usage of wet electrodes leads to skin irritation and irritable stickiness. Electrolyte gel dehydration and expiry of wet electrodes, generation of environmentally negative waste, high cost of maintenance are all additional tribulations.
- [7] There are many modern methods which are in existence to measure ECG, even though the existing methods are considered feasible to use as compared to conventional ECG, all of the modern methods use 1-2 lead ECGs only and are used as Holter or long term monitoring devices. In the prior arts, no wireless wearable devices have been used to measure 12 lead ECG. Existing ECG systems have continued using wet leads with resultant placements all over the chest and shoulder to obtain clinically equivalent ECGs as shown in the prior art figure. Moreover, no real-time on line ECGs have been available for Holter and 12 lead ECGs with resultant delays in interpretation and action for patients. The device presented here , provides in one embodiment a 6 lead continuous ECG monitoring system , and in another, a 12 lead ECG stat ECG followed by continuous 12 lead monitoring system
- [8] The solution for these problems of big devices , awkward lead placements is to design a wireless, compact ECG machine which will help in eliminating the restrictions caused by long lead wires, excess weight and complex structure. Particularly, there is a need for system which is wearable, wireless, portable and lightweight that provides comfort to patient. Further the system which is described has advantages such as reusable electrodes, easy accessibility, compact design and no consumable like wet electrodes are preferred.

Object of Invention

- [9] The first object of the invention is to provide a compact wearable wireless system with the usage of active capacitance sensors to analyse electrical condition of heart.
- [10] Another object of the invention is to implement reusable active capacitance sensors to achieve 12 lead ECG.
- [11] Yet another object of the invention is to provide wireless communication between the wearable device and a user device, further, from the user to device to server/cloud.
- [12] Yet another object of the invention is to provide a unique lead/sensor placement on the patient's body to record 12 lead ECG, thus making the ECG device compact.
- [13] Additional object of the invention is to provide a machine learning module that is disposed in server/cloud which is configured to continuously monitor the output received from the user device in real time.

Summary of Invention

- [14] The invention provides a wearable compact wireless twelve lead ECG system that comprises of two sets of active capacitance sensors, the first set of active capacitance sensors is configured to collect six limb leads whereas the second set of active capacitance sensors, in communication with said first set of active capacitance sensors, is configured to collect six chest leads. The system further contains a set of grounding sensors surrounding sets of active capacitance sensors and a set of surface noise sensors (auxiliary plate) configured to reduce noise generated while collecting said leads. There is a communication module disposed within said system configured to communicate said collected leads in the form of twelve lead ECG to one or multiple devices.
- [15] Further, the invention provides a method to generate the twelve lead ECG by collecting six limbs leads using a first set of active capacitance sensors and six

chest leads using a second set of active capacitance sensors which are uniquely placed on a patient's body. To aid in reduction of noise associated said collected leads, a set of grounding sensors and noise reduction sensors are implemented. The collected leads are transmitted to one or more devices.

Brief Description of Drawings

- [16] This invention is illustrated in the accompanying drawings, throughout which, like reference letters indicate corresponding parts in the various figures.
- [17] The embodiments herein will be better understood from the following description with reference to the drawings, in which:
- [18] Fig. 1 shows/illustrates the wearable device with 12 leads for conducting ECG process, in accordance with an embodiment of the invention.
- [19] Fig.2 shows/illustrates the placements of active capacitance sensors on a human body to get chest leads and limb leads, in accordance with an embodiment of the invention.
- [20] Fig. 3 shows/illustrates the details of a system to carry out ECG using wireless apparatus, in accordance with an embodiment of the invention.
- [21] Fig. 4 shows/illustrates the internal architecture of the system to carry out ECG, in accordance with an embodiment of the invention.
- [22] Fig. 5 shows/illustrates a method of carrying out wireless ECG test, in accordance with an embodiment of the invention.

Description of Embodiments

- [1] The embodiments herein, the various features, and advantageous details thereof are explained more fully with reference to the non-limiting embodiments that are illustrated in the accompanying drawings and / or detailed in the following description. Descriptions of well -known components and processing techniques are omitted thereto obscure the embodiments herein. The examples used herein are intended merely to facilitate an understanding of ways in which the embodiments herein may be practised and to further enable those of skill in the

art to practice the embodiments herein. Accordingly, the examples should not be construed as limiting the scope of the embodiments herein.

- [2] In a conventional method of conducting a 12-lead ECG, 10 electrodes are placed on the patient's chest and limbs, providing 9 leads of direct measurement and 3 leads are derived from calculation. 12-lead ECG refer to 12 different angle magnitude measurement of the heart's electrical potential, thus overall magnitude and directions of heart's electrical potential is captured at 250-500 samples each second throughout the cardiac cycle.
- [3] In comparison, the present invention provides a wireless wearable digital ECG system sampled at 1000-2000 samples per second that may be paired with the computers or smartphones to address the problems faced by existing 12-lead Electrocardiogram process and to enable high quality digital acquisition of 12-lead ECG. The leads placed are precise and are the sources of measurement of a vector formed by heart's pulses. This allows clinically equivalent ECG, comparable to conventional machines.
- [4] Accordingly, the invention provides a wearable device configured to monitor electrical activity (ECG) of a heart, where the device comprises of two sets of active capacitance sensors along with surface noise sensors (auxiliary plates), wherein these capacitance sensors are configured to detect the electrical activity of the heart and in turn provide 12 lead ECG analysis. There is grounding sensors configured in the apparatus to provide return path to faulty or abnormal electric conditions.
- [5] The device further comprises of a battery, configured to power the device. Also, a wireless communication module is on the device, where the wireless communication module is configured to transmit processed signal data from the ECG device to one or more devices such as a user device, a server, a cloud storage and the like, which are configured to further process received data and represent in a readable manner.
- [6] The system described here collects heart signals, wirelessly transmits the signals to a computing device or a smart-phone and stores 12-lead ECG data in a storage (server/cloud/user device). The system is in the form of wearable device,

which is made of rigid/flexible or stretchable material. The system interfaces with the human skin via active capacitance sensors as described above. The active capacitance sensors that have been enclosed in a custom designed harness supports a diagnostic quality 12-lead ECG. To achieve said quality, placement of the active capacitance sensors on human body plays a very important role.

[7] In a conventional ECG system, misplacement of ECG electrodes may result in unrecognised signal changes, electrical axis change that can create artefacts and improper ECG signal interpretations. In the process of measuring 12 lead ECG, placement of electrodes/leads are crucial, misplacement of electrodes may happen at any level, for example Limb electrode misplacement, Right/Left reversal, Arm/Leg reversal, Left arm/Left leg reversal or Precordial electrode misplacement. Misplacement of these electrodes will affect the waveforms in some of the standard and augmented leads that may represent a wrong disease and sometimes even the device fails to read the potential difference between the leads placed in left and the right arm. Precordial electrode misplacements may lead to morphological changes on ECG signals ,enough to falsely diagnose myocardial infarction. Considering above mentioned disadvantages, the necessity of right placement of sensors to get 12 lead ECG is very important. The present invention through disclosed device, provides an unique lead placement in a specific form where wrong placements are virtually eliminated. The device can be applied to the patient without any formal training.

[8] Referring now to the drawings, where similar reference characters denote corresponding features consistently throughout the figures, there are shown preferred embodiments.

[9] Fig. 1 depicts/illustrates details of a wearable device 100 with two sets of active capacitance sensor combination to get a 12 leads ECG wirelessly, in accordance with the present invention. Device 100 shall consist two sets of active capacitance sensors 110 connected with each other as shown in fig. 1 where, first set is responsible for collecting six limb leads and second set collects six chest leads and thus contributes in fetching 12 lead ECG. The 2 patches may be connected to each other by a wire or wirelessly

- [10] In one embodiment, said wearable device 100 may consists of two patches where the first patch has first set of active capacitance sensors and the second patch has second set of active capacitance sensors.
- [11] In detail, the device 100 includes active capacitance sensors 110 enclosed within an electronic layer (shown in fig.4) along with surface noise sensors (auxiliary plates) 140. There are grounding sensors 150 configured in device 100 surrounding the active capacitive sensors 110, which aids in reducing the noise recorded in the process of ECG recording . Surface noise sensors (auxiliary plates) provides the return path to remove the surface noise (acts as Right Leg Driver Circuits) It should be noted that the active capacitive sensors 110 and the surface noise sensors 140 can be considered disabled in absence of the grounding sensors 150 as the output signal will not be in readable due to excessive noise in absence of grounding sensors 150. . There is a device cover 130 for the protection of the sensors 110, 140 and 150 and other electronic modules of the device 100. The sensors 110, 140 and 150 are reusable.
- [12] In one embodiment, the active capacitance sensors 110 may be any sensors known in the art or developed in the future, which is capable of picking up the electrical or pulse signals from human heart such as electro potential, inductive sensors, etc.
- [13] Active capacitive sensors work by measuring changes in an electrical property called capacitance. Capacitance describes how two conductive objects with a space between them respond to a voltage difference applied to them. This change is picked up and processed in the electronics of the patch .Capacitance sensors work with anything that holds an electrical charge – including human skin hence helping the system pick up ECG signals.
- [14] Further, the surface noise sensors (auxiliary plates) 140 are used in the device 100 majorly to address noise reduction. The device 100 is compact and because of the nature of the sensors there is excess noise pick up from muscle contractions, power line radiations etc. As the raw ECG signals are low in amplitude, high noise level will result in masking and overlapping of actual ECG signals.. This problem can be resolved by noise subtraction and elimination. Noise subtraction is achieved by the usage of surface noise sensors and

(auxiliary plate) 140, proprietary noise reduction hard ware and soft ware filters all of which helps in getting accurate heart signals inspire of the sensors 140 predominantly picking-up the noise and. Additionally, digital software filters may be used in the cloud to remove the excess of noise present during ECG data capture from the patient body.

[15] In one embodiment, according to Fig .1, device 100 is further provided with a battery 120 to power the device 100. Device 100 also consists of wireless module (not shown in the figure), which will be used for signal and data transmission from the device 100 to a respective server and/or hand held device (not shown in Fig.1) via network. One skilled in the art may recognize that the network can be various types of networks such as Internet, Local area network (LAN), Wide area network (WAN), internet, etc.

[16] In one embodiment, the lead placement of the device 100 on human body plays a major role in getting accurate 12 lead ECG signals, as the right lead placement results in less noise and accurate electrical axis. Theoretically speaking, sensors 110 are to be placed in such way that the leads form an Einthoven triangle (shown in the fig.2). This triangle is an imaginary formation of limb leads formed by shoulders and left leg , which will assist in more accurate diagnosis. The imaginary lines connecting the three points (two points on shoulders and left leg) forms a shape of an inverted equilateral triangle with heart at the centre producing the constant potential during the summation of voltages.

[17] In details, Fig.2 represents two sets of active capacitance sensors and can be used in recording of 12 Lead ECG. ECG is measured by placing all the 10 electrodes on the patient chest. Both the first 201 and second sets 202 are electrically connected (connected with a wire or by wireless communication) where the first set of active capacitance sensors 201 contains three active capacitance sensors which represents electrodes RA, LA, LL1 and second set of active capacitance sensors 202 contains 7 active capacitance sensors which represents electrodes V1 - V6, LL2. LL1 in first set is used in the embodiment wherein patch 1 is used independently to monitor 6 leads continuously , as in a

Holter . LL1 is disabled and LL2 is electrically activated in second patch to in get 12 lead ECG.

[18] In one embodiment, to record 12 Lead ECG, both sets 201 and 202 will be applied on the patient body with the help of biocompatible double sided custom-made adhesive.

[19] Further, the position of both set of sensors 201 and 202 together has been decided in such a way that it records clinical grade ECG without any false infarct, distinct axis and amplitude change, even though Einthoven triangle is minimized compared to that of conventional method. In our device, Patch 1, 201 is placed in left chest . 2 sensors from the first patch 201 is utilised and LL1 inactivated .The positions of second set of sensors 202 containing sensors V1 to V6 and LL2 .these have been decided based on clinical trials the chest leads are placed conventionally and the LL2 becomes part of the Einthoven triangle. In one embodiment, the system explained in the Fig.1 may be appropriately modified by adding/removing active capacitance sensors and get 1, 2 and/or 6 lead ECG.

[20] Further Fig.3 depicts/illustrates system details 300, in accordance with an embodiment of the invention. The sensor module or wearable sensing device 310 represented here consists of dual combination of active capacitance sensors and surface noise sensors (auxiliary plates) as explained in illustration of Fig. 1 device 100. The data collected from the device 310 will be sent to the user device 340 through communication module. From the user device 340 said data may be communicated to a main server 330 through a communication network 320. From the server 330, stored ECG data may be retrieved by multiple users including medical professionals to common people.

[21] In one embodiment, communication module may be any wireless communication protocols such as BLE, Bluetooth, Wifi, Zigbee and the like.

[22] In another embodiment, the data from the device 310 will be directly sent to the server 330, which may be a cloud server, through communication networks 320, from the server 330 the data is sent to the user device 340.

[23] One skilled in the art may recognize that the signal transmission network is a wireless communication network. The wireless communication can be done

through internet connection provided by an Internet Service Provider, 2G/3G/4G/5G internet connection provided by the mobile service provider etc. Such wireless communication is not possible without the standard protocols as known in the art, where the standard protocols can be Bluetooth, TCP/IP, HTTP, FTP, UDP, IPV4, IPV6 etc. The user device 340 may be a Personal Digital Assistant (PDA), laptop, hand-held device, mobile phone, smart phone, smart tablets and computer system.

[24] Fig. 4 shows/illustrates the internal architecture 400 of the device 100 used to carry out ECG, in accordance with an embodiment of the invention. The components contributing in the architecture 400 are battery 403, lids 402 and 403, PCB layer 405, surface noise sensors (auxiliary plates) 406, active capacitance sensors 407, grounding sensors (not shown in fig) and adhesive 408. The battery 403 that powers up the device 100 is covered by two lids 402 and 404 to separate it from the PCB layer 405. In the layered architecture, surface noise sensors (auxiliary plates) 406 and active capacitance sensors 407 sit below the PCB layer 405 with adhesive 408 forming the bottom layer of the architecture.

[25] Fig. 5 shows a flowchart depicting/illustrating a method for providing ECG with active capacitance sensors, in accordance with the present invention. First and foremost, the device will be worn by the user and hence it gives the indication of initiating the check for the wearable device connection conditions 510. As soon as device is worn by the user, active capacitance sensors start collecting the Electrical or pulse signals coming from the Heart. The sensors are also effectively protected and insulated to ensure that pick-up of signals from any unwanted direction is minimized. These sensors, may be placed and positioned using light weight and highly flexible material to ensure minimal discomfort and easy to wear intention with minimal skin surface preparation.

[26] In an embodiment, wireless module in the device will receive the Electrical signals or data collected by all the sensors and sends it to the user device and/or main server 530. Data or signals received by the main server/user device may store the data and sends it to the multiple wireless signal receiving user devices 540. The Electrical signals collected by the sensors may be transferred to a hand

held mobile computing device such as mobile phone or a tablet or even a pc, through wireless channel band. These sensors can be battery operated.

[27] In one embodiment, the wireless device is embedded on a wearable piece, where wearable piece is made of flexible and stretchable material. Few more additional advantages of current invention are as follows;

a. 12 lead ECG helps in rapid identification of infarction/injury, since the diagnosis process will happen sooner without the skin preparation and full undressing for chest access.

b. It facilitates Decreased time to reperfusion treatment because of speed of deployment .

c. Increases chance of diagnosis as it, can be done by any doctor/staff without training and can be speedily reported elsewhere by a specialist

d. Easy modification in method of therapy with immediate access to reports and peer reviewed ECGs, accurate instructions on remote management of patients in out of hospital, rural ambulance type locations and like.

e. Helps to obtain strong signals without wasting time for skin preparation.

[28] The foregoing description of the specific embodiments will so fully reveal the general nature of the embodiments herein that others can, by applying current knowledge, readily modify and/or adapt for various applications such specific embodiments without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation. Therefore, while the embodiments herein have been described in terms of preferred embodiments, those skilled in the art will recognize that the embodiments herein can be practised with modification within the scope of the embodiments as described herein. iments herein.

Claims

[Claim 1] A wearable compact wireless twelve lead ECG system, said system comprising:

 wherein said first set of active capacitance sensors configured to collect six limb leads;

a second set of active capacitance sensors disposed within said system wherein said second set of active capacitance sensor further configured to collect six chest leads;

a set of grounding sensors disposed with said first and/or second set of active capacitance sensors wherein said surface noise sensors configured to reduce noise generated while collecting said leads; and

a communication module disposed within said system wherein said communication module configured to communicate said collected leads in the form of twelve lead ECG to multiple devices. The system of claim 1 wherein said first user device and said second said user device may be a single user device.

[Claim 2] The system of claim 1 wherein said wearable device comprising of two patches wherein first patch is disposed with said first set of active sensors and second patch is disposed with said second set of active sensors.

[Claim 3] The system of claim 2 wherein said first patch is in communication with said second patch.

[Claim 4] The system of claim 1 wherein said first set of active capacitance sensors comprising of at least three capacitance sensors.

[Claim 5] The system of claim 1 wherein said second set of active capacitance sensors comprising of at least six capacitance sensors.

[Claim 6] The system of claim 1 wherein said communication between said first set of active capacitance sensors and said second set of active capacitance sensors is carried out through wired and/or wireless means.

[Claim 7] The system of claim 1 wherein two sensors of said first set of active capacitance sensors are placed on left upper part of the chest 5 cm apart

from each other and the third sensor is placed in posterior auxiliary line at the same horizontal plane as second set of active capacitance sensors.

[Claim 8] The system of claim 1 wherein the position of said second set of active capacitance sensors has been decided based on a predefined rule. The rule is that difference of the position of each sensor in said second set of sensors from the centre of the Einthoven triangle formed is predefined to meet all conditions in order to get a twelve lead ECG.

[Claim 9] The system of claim 1 wherein said first and second set of active capacitance sensors are enclosed within an electronic layer along with surface noise sensors.

[Claim 10] The system of claim 1 wherein said system further comprising of surface noise sensor configured to provide return path to faulty or abnormal electric conditions.

[Claim 11] The system of claim 1 wherein said system further comprising of a battery to power up said system.

[Claim 12] The system of claim 1 wherein said communication module is a wireless communication protocol such as BLE, Bluetooth, Wifi, Zigbee and the like.

[Claim 13] The system of claim 1 wherein said multiple devices may be a user device, a server, a cloud storage and the like.

[Claim 14] The system of claim 1 wherein said multiple devices further configured to process received data and represent in a readable manner.

[Claim 15] A compact wireless twelve lead ECG generation method, said method comprising:

collecting six limbs leads using a second set of active capacitance sensors;

collecting six chest leads using a first set of active capacitance sensors;

reducing noise associated with said collected leads using a set of grounding sensors; and

transmitting said collected leads to multiple devices.

[Claim 16] The method of claim 15 wherein said first set of active capacitance sensors comprising of at least three capacitance sensors.

[Claim 17] The method of claim 15 wherein said second set of active capacitance sensors comprising of at least six capacitance sensors.

[Claim 18] The method of claim 15 wherein two sensors of said first set of active capacitance sensors are placed on left upper part of the chest 5 cm apart from each other and the third sensor is placed in posterior auxiliary line at the same horizontal plane as second set of active capacitance sensors.

[Claim 19] The method of claim 15 wherein the position of said second set of active capacitance sensors has been decided based on a predefined rule. The rule is that difference of the position of each sensor in said second set of sensors from the centre of the Einthoven triangle formed is predefined to meet all conditions in order to get a twelve lead ECG.

[Claim 20] The method of claim 15 wherein said transmission of collected leads is carried out by a communication module, wherein said communication module is a wireless communication protocol such as Bluetooth, Wifi, Zigbee and the like.

[Claim 21] The method of claim 15 wherein said multiple devices may be a user device, a server, a cloud storage and the like.

[Claim 22] The method of claim 21 wherein said multiple devices further configured to process received data and represent in a readable manner.