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(54) **Title**: AN ELECTROCARDIOGRAPHIC MONITORING SYSTEM AND METHOD

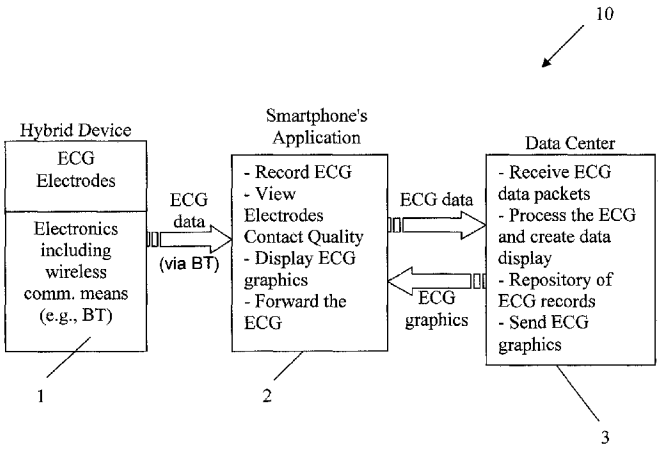

Fig. 1

(57) **Abstract**: The present invention relates to a method for obtaining a 12-lead electrocardiogram and/or rhythm strip, comprising: a) anatomically properly positioning at least 9 monitoring electrodes on a user's body for capturing information related to the electrical activity of the heart of said user, wherein each of said electrodes is electrically connected to a personal ECG device, either directly and/or via an electrode belt; b) generating ECG data from said personal ECG device for a 12-lead electrocardiogram and a Rhythm strip (e.g., 12 seconds strip), wherein said generated ECG data represent the electrical activity of the heart of said user over time (and in real-time) as obtained by said skin electrodes; and c) wirelessly transferring said ECG data to a mobile communication device (e.g., a smartphone) for locally manipulating said ECG data and/or for forwarding said ECG data to a remote data center (e.g., remote medical center).

WO 2012/160550 A1

AN ELECTROCARDIOGRAPHIC MONITORING SYSTEM AND METHOD

Field of the Invention

The present invention relates to the field of telemedicine systems. More particularly, the invention relates to a method and system for capturing 12 lead ECG and rhythm strip data from a patient remotely using a telecommunication mobile device, such as iPhone.

Background of the invention

It is known that chronically ill, people or patients known to suffer from cardiac problems, and patients recovering from a surgical intervention or cardiac episode or a disease use personal ECG devices whether this on regular basis or while they don't feel well. In the prior art there are several ECG devices that can obtain a standard 12 lead ECG, such as clinical ECG machines, personal acoustic devices (e.g., CardioSenC, Cardiobeeper 12L or CardioBeeper 12/12 by SHL Telemedicine). The latter personal devices adapted to be used by a non medical individual to capture a 12 lead ECG and/or Rhythm strip when the user has symptoms, routinely, as part of drug studies, pre/post surgery, etc. Although these devices do allow a user to gather some information and transfer it to remote medical data center, no ECG information is available for the user itself.

Moreover, some of the prior-art personal devices, such as the Cardiosen'C are less comfortable to carry by the user due to their overall dimensions. For example, the Cardiosen'C can communicate with a remote data center directly via its internal cellular modem. However, this takes considerable power thus a large battery and charger is required resulting in a device having relatively large dimensions. Therefore, there is also a need for a smaller device than the Cardiosen'C and the other prior-art units. With a smaller battery the device is easier to carry and therefore it is more desirable.

Although these prior art ECG devices are capable of transmitting data to remote medical data center, there still exists a need for a device that can be quickly and accurately applied to obtain a clinical 12 lead ECG and rhythm strip. There also still exists a need for such a system which is reliable in use and is user-friendly. There further exists a need for a personal ECG device which can be used in combination with existing portable computer based communication devices (e.g., a mobile cellphone or a smartphone) for enhancing the interaction between the remote medical data center the personal ECG device and the user itself.

It is an object of the present invention to overcome the drawbacks of the prior-art devices and to fulfill the aforementioned needs. The present

invention is particularly aimed at ill, people or patients known to suffer from cardiac problems, and patients recovering from a surgical intervention or cardiac episode or a disease.

It is another object of the present invention to provide a system which is capable of remotely communicated with a data center.

It is yet another object of the present invention to provide a system which is capable of locally displaying ECG related activity information to the user including the quality of the electrode contact and other relevant information (e.g., guiding and instructions for the user during and/or after the use).

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention relates to a method for obtaining a 12-lead electrocardiogram and/or rhythm strip, comprising: a) anatomically properly positioning at least 9 monitoring electrodes on a user's body for capturing information related to the electrical activity of the heart of said user, wherein each of said electrodes is electrically connected to a personal ECG device, either directly and/or via an electrode belt; b) generating ECG

data from said personal ECG device for a 12-lead electrocardiogram and a Rhythm strip (e.g., 12 seconds strip), wherein said generated ECG data represent the electrical activity of the heart of said user over time (and in real-time) as obtained by said skin electrodes; and c) wirelessly transferring said ECG data to a mobile communication device (e.g., a smartphone) for locally manipulating said ECG data and/or for forwarding said ECG data to a remote data center (e.g., remote medical center).

According to an embodiment of the present invention, the method further comprises transmitting the ECG data to the remote data center while speaking with a representative of said remote data center.

According to an embodiment of the present invention, the method further comprises displaying a 12 lead ECG and Rhythm strip on the mobile communication device by locally displaying the electrical activity of the heart on the screen of said mobile communication device.

According to an embodiment of the present invention, the method further comprises forwarding the ECG data via one or more error checking communication protocols to a remote terminal unit, thereby, for example, allowing said ECG data to be reviewed at remote site by a medical stuff or other professional user. The mobile communication device can transmit the ECG data to any destination in real-time (or near real-time).

According to an embodiment of the present invention, the personal ECG device transmits 8 sample (e.g., of 2.5 second) views of the heart which commonly defined as lead I, II ,V1, V2, V3, V4, V5, V6, and in addition it transmits the Rhythm strip (lead II). An exemplary set of electrodes for these leads is shown and described with respect to Figs 5 and 6 hereinafter.

According to an embodiment of the present invention, the method further comprises improving electrode contact quality by using the smartphone to display to the user the contact quality of each ECG electrode, thereby providing feedback to the user to evaluate the quality of the electrode contact and permit said user to improve the contact and thus the quality of the resulting ECG. Furthermore, the smartphone's screen permits user device instructions to be displayed and /or spoken (e.g., voicing instructions, questions and/or other relevant data) to the user while operating the personal ECG device.

The present invention further relates to an electrocardiographic monitoring system, which comprises: a) a personal ECG device for providing 12-lead electrocardiogram data that represents the electrical activity of a user's heart, wherein said 12-lead electrocardiogram obtained from a set of at least 9 skin electrodes each of which is electrically

connected to said personal ECG device, either directly or via a chest electrode belt; b) a short range wireless communication module embedded within said personal ECG device for data communicating with a smartphone; and c) a dedicated smartphone application for being executed by said smartphone, for visually displaying information related to said provided 12-lead electrocardiogram and for data communicating with a remote data center.

According to an embodiment of the present invention, the electrode belt includes a chest strap with 6 anatomically positioned precordial ECG electrodes, Right/Left Arm electrodes, an elastic portion to extend around the chest and a unique, convenient closure containing electrical connections. Optionally, the electrode belt can be detached from the personal ECG device and replaced by various belts to personalize belt size to chest size and gender.

According to an embodiment of the present invention, the personal ECG device is configured in such a way that it is capable of storing at least one retractable ECG electrode (i.e., the waist electrode that is placed at the waist or belt line positioned halfway from the naval to the left hip) and its conductive wire within its housing to conserve space. According to some embodiments, the electrode is a spool with an outside electrically conductive electrode surface to allow the winding of the wire into the

housing of the personal ECG device similar to a child's YOYO. Alternatively the retractable ECG electrode is provided with a retracting means to store the wire, such as a spring or alternative device within the housing of the personal ECG device to retract the wire inside for compact storage.

Brief Description of the Drawings

In the drawings:

- Fig. 1 schematically illustrates a layout of the personal ECG electrocardiographic monitoring system, according to an embodiment of the present invention;
- Figs. 2 schematically illustrates a front view of a personal ECG device, according to an embodiment of the present invention;
- Figs. 3 schematically illustrates a rear view of the personal ECG device of Fig. 2;
- Fig. 4 schematically illustrates an electronic block diagram of the personal ECG device, according to an embodiment of the present invention;
- Fig. 5 schematically illustrates a front view of a personal ECG device provided with an electrodes belt, according to an embodiment of the present invention;
- Fig. 6 schematically illustrates a rear view of the personal ECG device of Fig. 5; and

- Figs. 7-11 schematically illustrate example Smartphone screen layouts of a dedicated application to be used with the personal ECG device, according to an embodiment of the present invention.

Detailed Description of the Invention

The following description relates to embodiments of an electrocardiographic (ECG) monitoring system and method of the present invention by way of illustration only. It should be noted that from the following discussion, alternative embodiments of the structures and methods disclosed herein will be readily recognized as viable alternatives that may be employed without departing from the principles of the claimed invention.

Reference will now be made to several embodiments of the present invention(s), examples of which are illustrated in the accompanying figures. Wherever practicable similar or like reference numbers may be used in the figures and may indicate similar or like functionality. As aforementioned hereinabove, the figures depict embodiments of the present invention for purposes of illustration only. One skilled in the art will readily recognize from the following description that alternative embodiments of the structures and methods illustrated herein may be employed without departing from the principles of the invention described herein.

Unless otherwise indicated, the functions described herein may be performed by executable code and instructions stored in computer readable medium and running on one or more processor-based systems. However, hardwired electronic circuits can also be utilized. Further, with respect to the example processes described herein, not all the process states need to be reached, nor do the states have to be performed in the illustrated order. Further, certain process states that are illustrated as being serially performed can be performed in parallel.

Similarly, while certain examples may refer to a smartphone, other computer or electronic systems can be used as well, such as, without limitation, a network-enabled personal digital assistant (PDA), computer, communication hub or data device with an operating system and on which a user can install applications and so on.

In addition, while certain user inputs or gestures are described as being provided via phone key presses, data entry via a keyboard, the use of touch screens or by clicking a button, optionally, user inputs can be provided using other techniques, such as by voice or otherwise.

Fig. 1 schematically illustrates a layout of an ECG monitoring system 10, according to an embodiment of the present invention. System 10 enables

an individual to immediately gather and transmit 12-lead ECG and a rhythm strip data to a remote unit or to any required destination. The system 10 provides data which represents the electrical activity of the heart. The 12 Lead ECG defines the graphic representation of the electrical activity of the heart from various anatomical locations of the body. The electrical activity of the heart recorded over time is called a rhythm strip. The system 10 and its components are described in further details herein below.

System 10 comprises three main components: a personal ECG device 1, an application installed on a suitable mobile communication device 2 (e.g., an iPhone application) and a remote data center 3 with a dedicated software (e.g., the SHL medical monitoring center of SHL Telemedicine, remote medical center, or any other data center).

The personal ECG device 1 comprises skin electrodes and electronic components which are used for real-time transmission of the electrical activity of the heart as acquired by the skin electrodes. Device 1 transmits the data representing the electrical activity of the heart via a wireless communication link (e.g., via Bluetooth) to the mobile communication device 2.

According to an embodiment of the present invention, the electrocardiogram is constructed in the remote data center 3. The construction of the ECG and the operation of the remote data center 3 involve the following tasks:

- receiving ECG data packets (from the mobile communication device) and performing error checking (by using any suitable error control technique that enables reliable delivery of digital data over communication channels);
- processing the ECG data and creating a 12 lead ECG and/or Rhythm strip record;
- storing the ECG records; and
- upon request, sending ECG records and/or other related data in a variety of forms to other data devices (e.g., fax, email, printer, mobile phone, smartphone, etc).

In some uses, it is advantageous for the user to be able to capture and visualize their own ECG and then forward it to their doctor or another medical facility. By utilizing a smartphone, the system 10 of the present invention allows the user to acquire the ECG, visualize the ECG (as delivered from the remote data center 3) on a smartphone and further, utilizing the smartphone allows the user to forward the electrocardiogram to a medical expert, his own doctor, or to a remote facility for analysis and/or advice.

According to some embodiments of the invention, ECG related activity can be conveyed to the user via the display unit of the smartphone. These may further include indication regarding the quality of the electrode contact and other relevant information (e.g., guiding and instructions for the user during and/or after the use), to be discussed in greater details below.

Figs. 2 and 3 show a personal ECG device 1 that can be used in conjunction with the invention. The device 1 illustrated in this figures is particularly convenient because it has a relatively small dimension and wherein its housing 11 is configured in such a way that it contains on its front panel a visual indicator 12 (e.g., in form of a glowing heart), which displays the status of the personal ECG device 1.. Device 1 further comprises a "start" button 13 which used for turning "on" (or "off") the personal ECG device 1 (e.g., the "start" button can be located adjacent to the visual indicator 12). Preferably, the visual indicator 12 should be located on the front side of the housing of the personal ECG device 1 or on other location that will be seen easily by the user. This visual indicator 12 displays the status of the personal ECG device 1, whether it is turned on, measuring or has an error.

Device 1 further comprises a set of skin electrodes, wherein some of them are deployed along an electrode belt 16 (such as the exemplary electrodes

indicated by numerals 21, 22 and 23), while other electrodes V1 and V2 are attached to the rear side of the housing 11 (see Fig. 3).

According to an embodiment of the invention, the device 1 also comprises a waist electrode 14 that is electrically connected to device 1 through a novel and unique retractable mechanism (i.e., a yoyo-like mechanism), as will be described in further herein after. The housing 11 of device 1 includes a compartment 20 adapted to store the waist electrode 14 while it is not in use. In this embodiment, the compartment 20 is located at the rear side of the housing 11, as easily seen in Fig. 3. This arrangement provides a compact and comfortable solution to the storage of the waist electrode 14. Another advantage of the present invention over the prior-art devices is that the waist electrode 14 can easily and automatically be returned into its storage compartment 20 after the use, due to the retractable mechanism.

In this embodiment, the rear side of the housing 11 has two electrodes (precordial electrodes V1 and V2). The housing 11 should be placed against the center of the user's chest. The housing's ergonomic design ensures the correct positioning of the electrodes V1 and V2 against the chest, while affording the user maximum comfort with minimal exertion when operating the device.

The device 1 further comprises a belt closure 18 for closing the belt 16, while it surrounds the body of the user. According to an embodiment of the invention, in addition to the mechanical attachment, the buckle of belt 16 and the belt closure are also electrically connected. For example, electrical wirings (not shown) can be used to connect each of the skin electrodes 21-23 (that are deployed along belt 16) to the buckle 19 of belt 16, while the electrical connection between the belt's buckle 19 and the belt closure 18 allows to transfer the electrical activity of the heart as acquired by the skin electrodes 21-23 to the electronic components of device 1.

The personal ECG device 1 is powered by a power source such as one or more batteries. For example, the batteries can be 2 lithium "AAA" batteries. Alternatively, alkaline batteries can also be used.

Referring now to Fig. 4, a schematic layout of the electronic components within the housing 11 of the personal ECG device 1 is shown in accordance with an embodiment of the present invention. The electronic components that are located inside the housing 11 of device 1 are divided to two main electronic modules: an analog module 32 and a digital module 33.

The analog module 32 contains signal conditioning circuitry to acquire the low level electrical signals from the electrodes 31. The signals from the electrodes 31 are acquired in such a manner to obtain the data for the

standard Einthoven limb leads, the Goldberger augmented leads and the Wilson precordial leads which comprise the standard 12 lead electrocardiogram. For example, the signal condition circuitry may include typical electronic components for amplifying the low level electrical signals from the electrodes 31 and to convert them into a digital form, such as input amplifiers, analog to digital converters, filters, and/or other components that can be used to manipulate analog signals.

The digital module 33 digitizes the electrocardiographic signals. Further this module also provides the two way wireless communication protocol to convey all the digital data to and from the mobile communication device 2 (e.g., a wireless communication between the device 1 and an iPhone, iPad, iTouch, other smartphones or wireless communication devices via a Bluetooth (BT) module 36 or other wireless protocol). Device 1 further comprises a User Interface (UI) 34 or other Man Machine Interface, which may include one or more visual indicator (e.g., the glowing heart 12) and/or other display unit (e.g., LCD panel), one or more functional button (e.g., such as the start button 13), etc..

One of the advantages of the personal ECG device of the present invention with respect to prior-art devices is that it needs to transmit data to a paired and relatively adjacent portable communication device, such as a smartphone (using short range data communication protocol, e.g.,

Bluetooth). Short range transmissions reduce power consumption. Accordingly, the personal ECG device requires a smaller battery, which leads to its relatively smaller dimensions (e.g., about 8.5cm width, 11cm length and 1.5cm height). A smaller battery also results in a lighter unit (e.g., about 100g). Lower power consumption also allows the practical use of disposable batteries, eliminating the need for a recharger with cable. All these factors further reduce the size and weight of a user's carrying/storage package.

Electrodes

The device housing and belt contain electrodes (i.e., set of skin electrodes) for acquiring electrical signals from the conventional anatomic electrode locations for a 12 lead electrocardiogram from the chest and limbs. For example, the electrodes can be made from PC ABS + 20% glass fiber with a coating of silver/silver chloride (Ag/AgCl).

Usually several electrodes are used and they can be combined into a number of pairs (e.g., left arm and right arm electrodes). The output from each combination is known as a lead. Each lead is said to look at the heart from a different angle. A 12-lead ECG is a recording of the heart's electrical activity from 9 anatomical located electrodes on the body which are combined to produce a conventional clinical 12-lead record.

Referring now to Figs. 5 and 6, a personal ECG device with electrodes belt is shown in accordance with an embodiment of the present invention. In this embodiment, the electrodes Location deployed as follows: two electrodes are located on the housing (indicated by V1 & V2), four precordial electrodes are located on the left electrode belt (indicated by V3 to V6, two limb electrodes consisting of Left Arm (LA), Right Arm (RA) belt mounted electrodes and a flying lead Left Leg (LL) (waist) retractable limb electrode (i.e., the waist electrode 14 with the yoyo-like mechanism (not shown in rear view fig, 4)) attached via a conductive wire.

According to an embodiment of the present invention, the belt can be detached from the housing of the personal ECG device. For example, there can be plurality of belts sizes in order to accommodate variety of chest sizes, wherein each one of them is designed for a specific gender and body size. By replacing the belt, the personal ECG device can fit all users. To accommodate different chest sizes, different belts with strategically positioned electrodes can be used for each gender.

According to an embodiment of the present invention, the electrode belt comprises a dual purpose belt closure: An interlocking fastener is attached to the belt. This permits the user to mechanically attach the end of the chest belt to the housing. Further, this fastener contains electrical contacts to electrically connect some belt monitoring electrodes to the

electronics of the device as will be described in further details herein after in the electrodes belt section.

According to an embodiment of the present invention, the personal ECG device is provided with a dual proposes belt closure (as shown in Figs. 5 and 6). The electrode belt includes electrical wiring for electrically contacting the electrodes via the belt closure to the electronics of the personal ECG device.

In this embodiment, the electrode belt is an elastic chest strap which comprises 6 precordial ECG electrodes, Right/Left Arm electrodes (indicated by RA and LA in Fig. 5) and a unique, convenient belt closure 18 containing electrical connections to electrically connect with buckle 19 (in addition to their mechanical engagement while fastening the belt around the user's chest).

In general, in order to obtain a 12 lead electrocardiogram, at least 9 electrodes are required to be positioned on the user's body. Six of the electrodes are precordial electrodes that a positioned at certain anatomical electrode locations on the chest (as indicated by electrodes V1-V6 in Fig. 6). The remaining 3 electrodes are limb electrodes monitor the electrical signals on the left arm (LA electrode), right arm (RA electrode) and the left leg (i.e., the retractable waist electrode). For simplicity of use, as

aforementioned herein before the personal ECG device has 2 precordial, chest-facing electrodes on the electronic enclosure case (i.e., on the rear side of the housing) and the remaining 4 precordial electrodes are on the belt itself. In addition, two limb electrodes Right Arm (RA) and Left Arm (LA) outward facing electrodes. To easily apply the elastic belt, the electrode belt is permanently attached to the electronic enclosure and the other end is fitted with a novel closure/snap. In this way, when the mechanical belt fastener is engaged with the case, an electrical connection is also achieved to the RA sensing electrodes.

According to an embodiment of the invention, the electrodes belt further includes a body reference electrode as indicated by numeral 27 in Fig. 6. The body reference electrode 27 provides a reference for the input amplifiers of the signal conditioning circuitry, which contributes to reduction of mains noise and better performance.

For example, the electrodes belt can be made from neoprene covered with Nylon fabric which is the same material utilized for wet suits. This is a comfortable and soft material, ideal for repeated flexing applications. Two electrodes belts are connected with stretch belt.

The left part of the electrode belt is permanently attached to the left side of the housing and contains seven electrodes: five electrodes (4 precordial

monitoring electrodes and one amplifier reference electrode) on the inside of the belt and a further two limb electrodes (i.e., a duplication of electrodes to monitor LA (Left Arm)) on the outside. The right part of the electrode belt contain two electrodes on the outside, both are for the RA right arm connection. The right electrode belt has a double contact buckle that insures good electrical connection between the electrodes and the housing. The two parts of the electrode belt are connected with stretch belt between them. To accommodate different chest sizes, there are different size belts. The belts have electrodes positioned in the optimal position for each chest size.

YOYO "flying" electrode

According to an embodiment of the present invention, the personal ECG device further comprises an electrode attached with wire to the bottom of the housing (referred to as “flying” electrode). This "flying" electrode is labeled ‘waist’, referring to where it should be placed. The flying (‘waist’) is positioned at the user’s belt line against the bare skin, halfway from the navel to the left hip. Together with the electrodes on the front of the electrode belts, these make up the three limb electrodes. The limb electrodes and the other electrodes on the belt in combination with those on the housing device permit the acquisition of ECG data for a rhythm strip and 12 lead ECG for remote interpretation by a qualified healthcare professional.

The flying electrode has wire a spool or retractor that collect the entire waist electrode wire to the electrode compartment. Using this retractor enables the compact packing of the waist electrode. When the device is not in use, there is no electrode wire hanging outside the housing as occur in prior art devices.

The outer plastic of the flying electrode may have a conductive coating to reduce electrical noise. The electrode wire connects with a spring to the plastic with good conductivity.

Smartphone Application

The example screen layouts, appearance, and terminology of Smartphone application as depicted and described herein with respect to Figs 7-11, are intended to be illustrative and exemplary, and in no way limit the scope of the invention as claimed.

The application may include the following options or application menus:

Symptoms menus – the application can display menus of predefined selectable symptoms so that the user can select any present symptoms.

Perform an ECG – This permit selecting symptoms and recording an ECG including a screen to display the electrode status and guide the user in

how to position the electrodes. Fig. 7 shows a graphical example screen of a symptom menu of the smartphone application.

Electrodes Contact Quality Display - Fig. 8 shows a graphical example of electrodes contact quality screen of the smartphone application. This screen displays the contact status of the electrodes and will guide the user to correctly position the electrodes in order to improve the contact of the electrodes with the user's body, for example, by displaying visual messages on the displayed image of the human chest (when the personal ECG device is not position correctly), such as "position waist electrode tightly against your skin", "attach device to chest", "tighten strap", etc.

ECG recording progress - Fig. 9 shows a graphical example of the ECG perform starting screen of the smartphone application. This screen shows an indication that all the electrodes are in contact (i.e., which is an essential information before the beginning of the recording progress).

Viewing ECGs - Fig. 10 shows a graphical example of recorded ECGs screen of the smartphone application. This screen permits the viewing of the recorded ECGs.

Sending ECG - Fig. 11 shows a graphical example of Send ECGs screen of the smartphone application. This screen permits the forwarding of ECGs, e.g., via e-mail or fax.

Help Function – This includes training information for using the personal ECG device, using the smartphone application and information about the symptoms.

While some embodiments of the invention have been described by way of illustration, it will be apparent that the invention can be carried into practice with many modifications, variations and adaptations, and with the use of numerous equivalents or alternative solutions that are within the scope of persons skilled in the art, without departing from the spirit of the invention or exceeding the scope of the claims.

Moreover, the terms, "for example", "e.g.", "optionally", as used herein, are intended to be used to introduce non-limiting examples. While certain references are made to certain example system components or services, other components and services can be used as well and/or the example components can be combined into fewer components and/or divided into further components.

CLAIMS

1. A method for obtaining a 12-lead electrocardiogram and/or with a rhythm strip, comprising:
    a. positioning at least 9 skin electrodes on a user's body for capturing information related to the electrical activity of the heart of said user, wherein each of said electrodes is electrically connected to a personal ECG device, either directly and/or via an electrode belt;
    b. generating ECG data from said personal ECG device for a 12-lead electrocardiogram and a Rhythm strip, wherein said generated ECG data represent the electrical activity of the heart of said user as obtained by said skin electrodes; and
    c. wirelessly transferring said ECG data to a mobile communication device (e.g., a smartphone) for locally manipulating said ECG data and/or for transmitting said ECG data to a remote data center (e.g., remote medical center).

2. A method according to claim 1, wherein the smartphone establishes data communication with the remote data center for transmitting the ECG data while in voice contact with a representative of said remote data center.

3. A method according to claim 1, further comprises enabling the user to observe a representation of the ECG data on the smartphone by locally displaying the electrical activity of the heart on the mobile communication device.

4. A method according to claim 3, further comprises forwarding the ECG data via one or more communication protocols to a remote terminal unit, thereby allowing said ECG data to be reviewed by a medical professional.

5. A method according to claim 1, wherein the mobile communication device transmits the ECG data in real-time.

6. A method according to claim 1, wherein the personal ECG device transmits at least 8 sample (e.g., of 2.5 second) views of the heart which commonly defined as lead I, II ,V1, V2, V3, V4, V5, V6, and in addition it transmits the Rhythm strip.

7. A method according to claim 1, further comprising improving electrode contact quality by using the smartphone to display to the user the quality of each ECG electrode contact, thereby providing feedback to the user to evaluate the quality of the electrode contact

and permit said user to improve the contact and thus the quality of the resulting ECG.

8. A method according to claim 1, further comprising utilizing the smartphone for displaying or voicing instructions, questions, or other relevant data to the user while operating the personal ECG device.

9. An electrocardiographic monitoring system, comprising:
   a. a personal ECG device for providing 12-lead electrocardiogram that represents the electrical activity of a user's heart, wherein said 12-lead electrocardiogram obtained from a set of at least two or more skin electrodes each of which is electrically connected to said personal ECG device, either directly or via a chest electrode belt;
   b. a short range wireless communication module embedded within said personal ECG device for data communicating with a smartphone; and
   c. a dedicated smartphone application for being executed by said smartphone, for visually displaying information related to said provided 12-lead electrocardiogram and for data communicating with a remote data center.

10. A system according to claim 9, in which the electrode belt is an elastic chest strap with 6 anatomically positioned precordial ECG electrodes, right/left arm limb electrodes and a unique, convenient closure containing electrical connections.

11. A system according to claim 9, in which the personal ECG device and the electrode belt comprise corresponding mechanisms which allows the replacing of the electrode belt, therefore said electrode belt can be detached and replaced by various belts to personalize belt size to chest size and gender.

12. A system according to claim 9, in which the personal ECG device configured in such a way that it is capable of storing an ECG electrode and its conductive wire within its housing to conserve space.

13. A system according to claim 12, in which the electrode's wire is a spool with an outside electrically conductive electrode surface to allow the winding of the wire into the housing of the personal ECG device similar to a child's YOYO.

14. A system according to claim 12, in which the ECG electrode is provided with a retracting means to store the wire, such as a spring

or alternative device within the housing of the personal ECG device to retract the wire inside for compact storage.

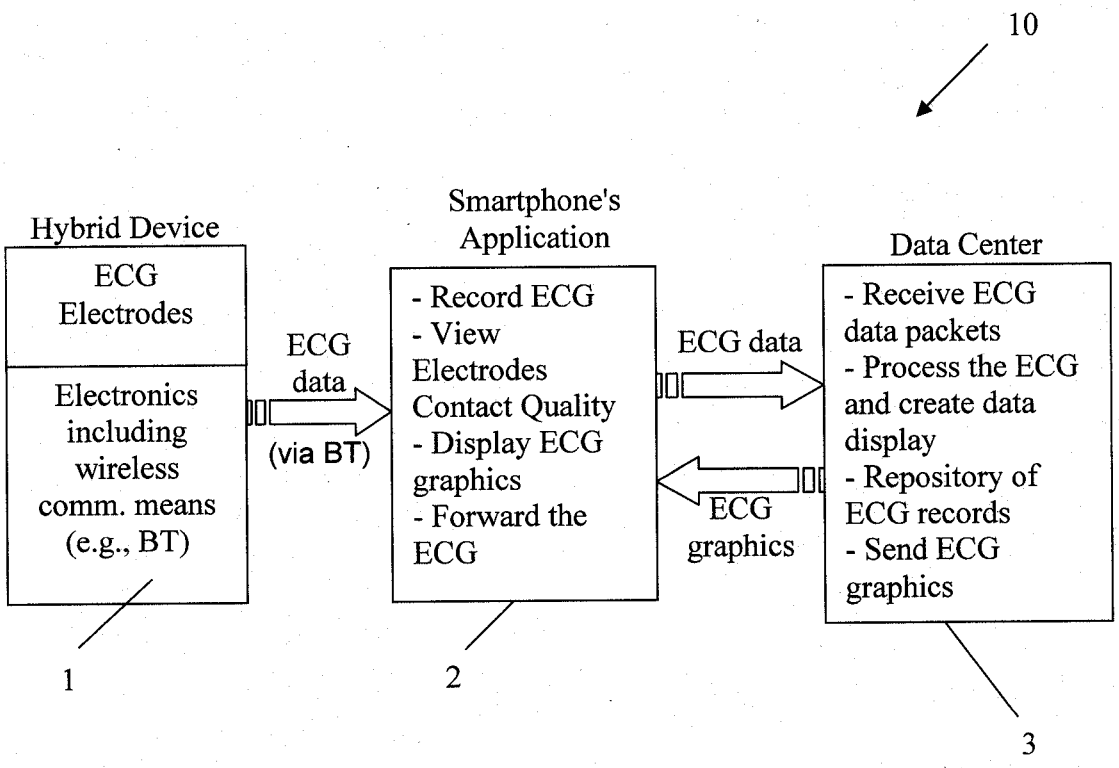
10
Hybrid Device
ECG Electrodes
Electronics including wireless comm. means (e.g., BT)
1
ECG data
(via BT)
Smartphone's Application
- Record ECG
- View Electrodes Contact Quality
- Display ECG graphics
- Forward the ECG
2
ECG data
ECG graphics
Data Center
- Receive ECG data packets
- Process the ECG and create data display
- Repository of ECG records
- Send ECG graphics
3

Fig. 1

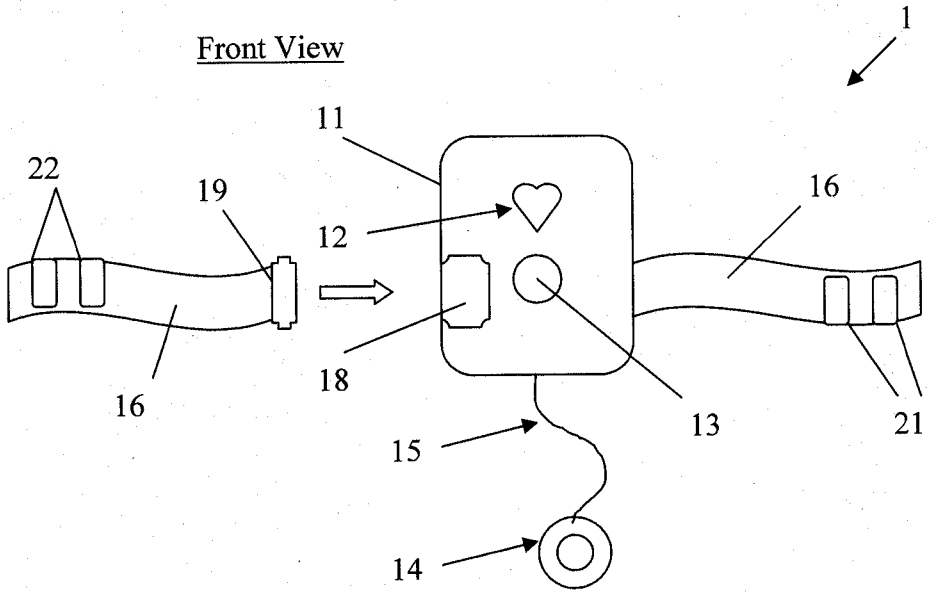
Front View
1
11
22
19
12
16
18
16
13
21
15
14

Fig. 2

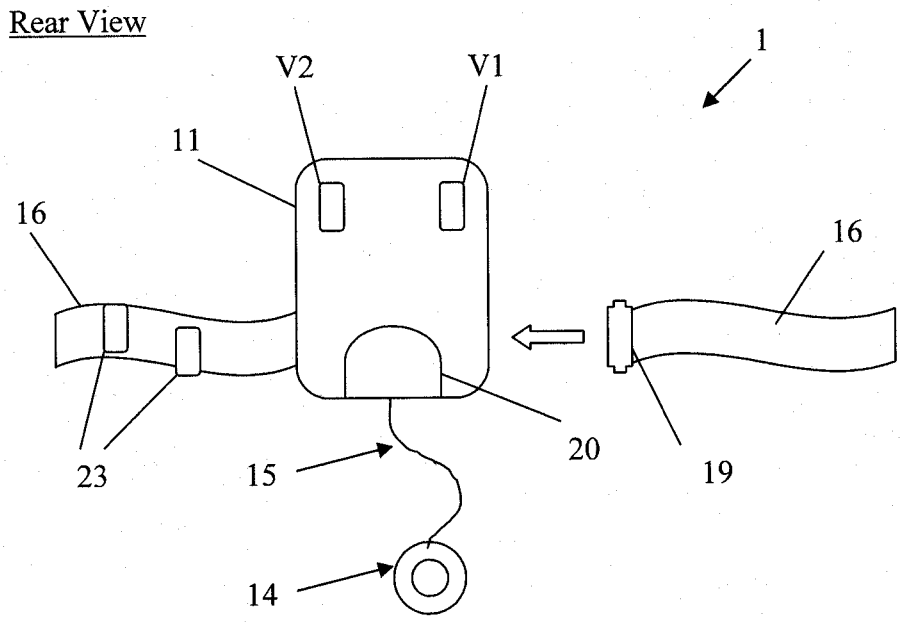
Rear View
1
V2
V1
11
16
16
20
23
15
19
14

Fig. 3

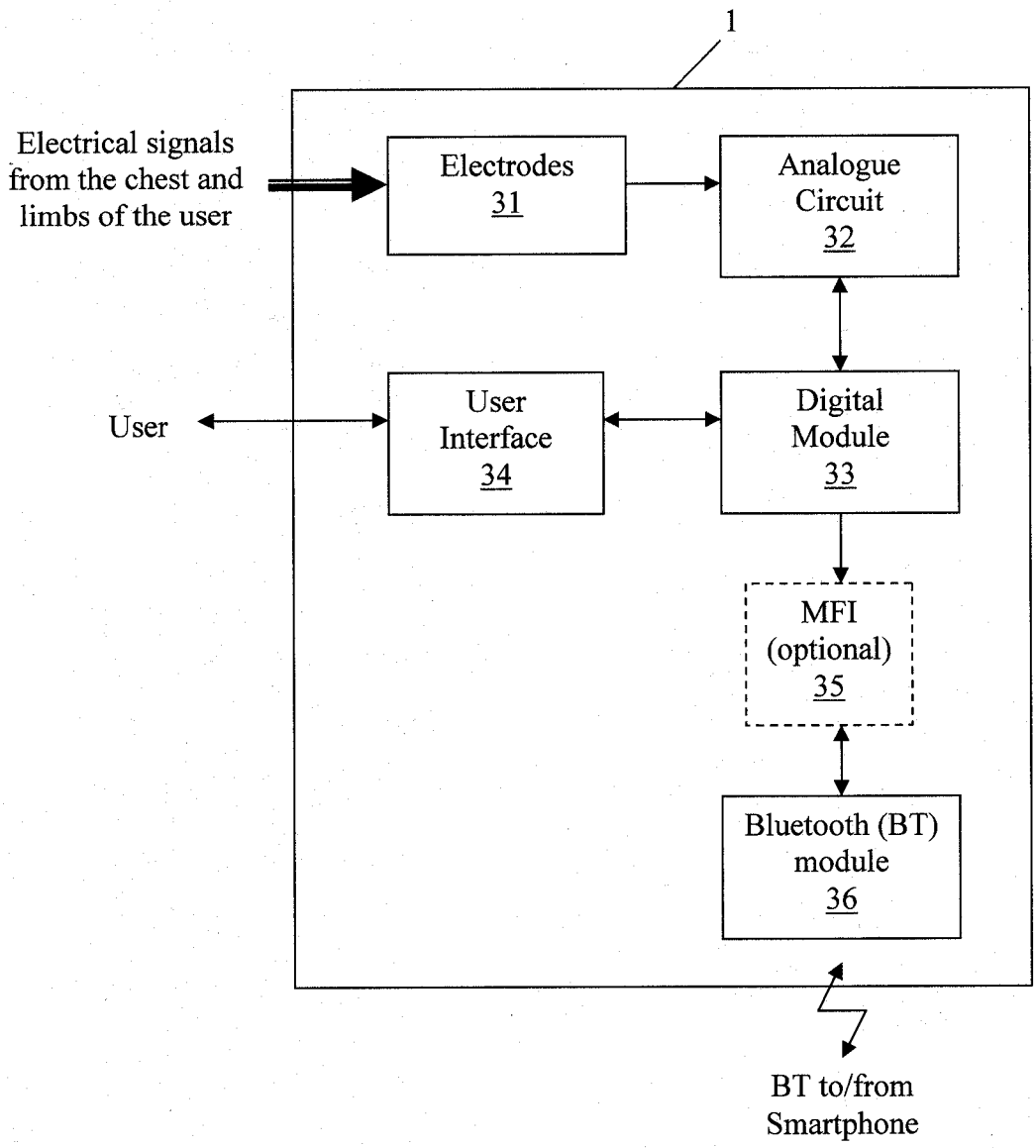
1
Electrical signals from the chest and limbs of the user
Electrodes 31
Analogue Circuit 32
User
User Interface 34
Digital Module 33
MFI (optional) 35
Bluetooth (BT) module 36
BT to/from Smartphone

Fig. 4

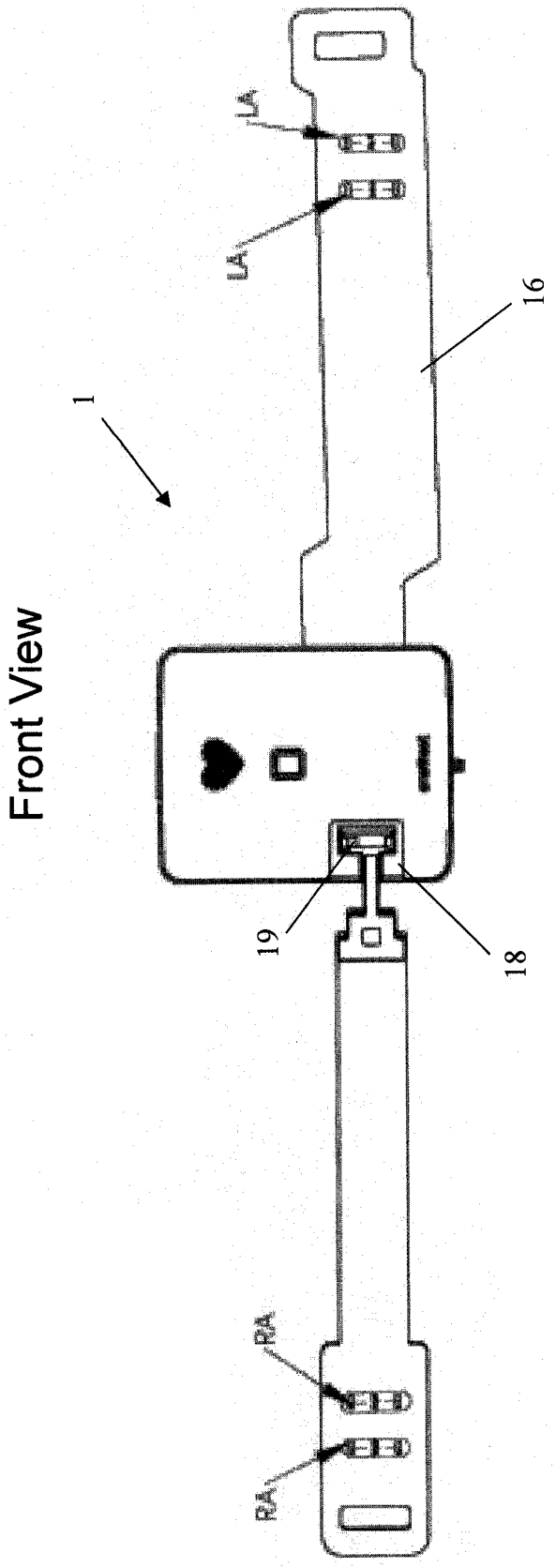

Fig. 5

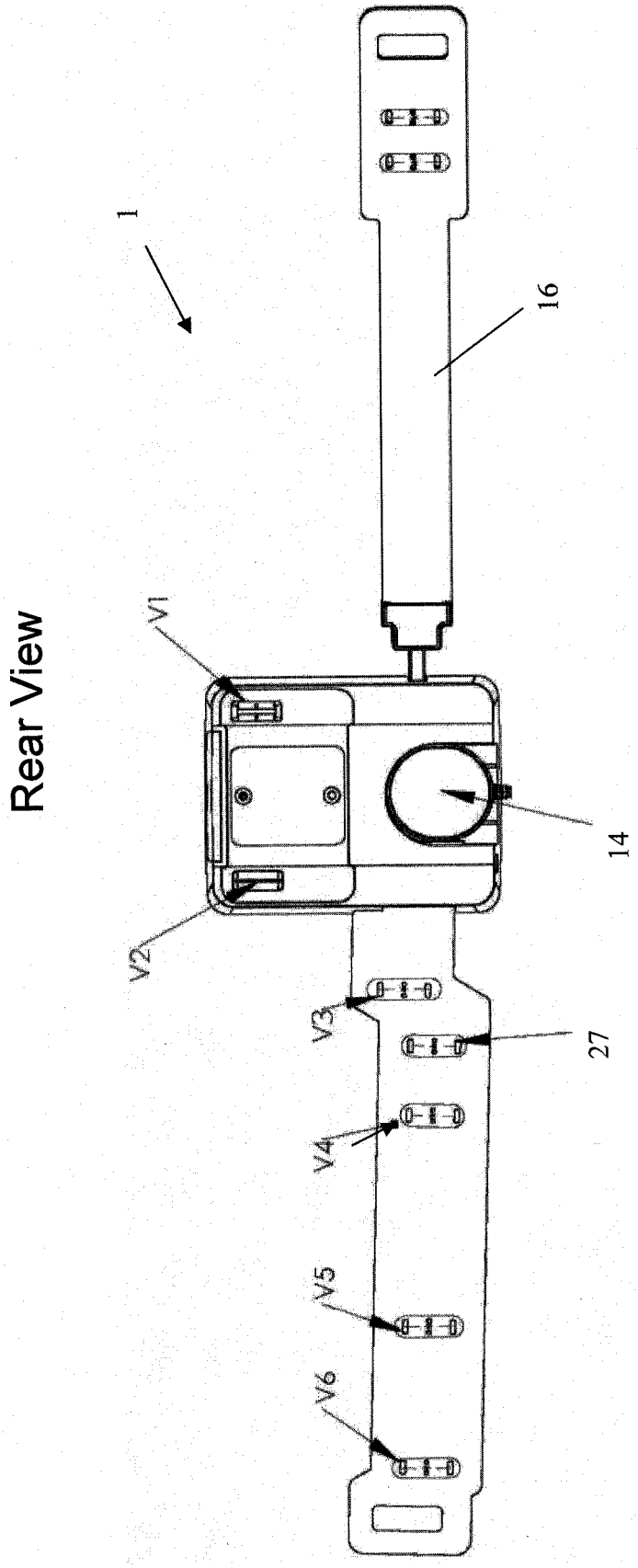

Fig. 6

Symptoms

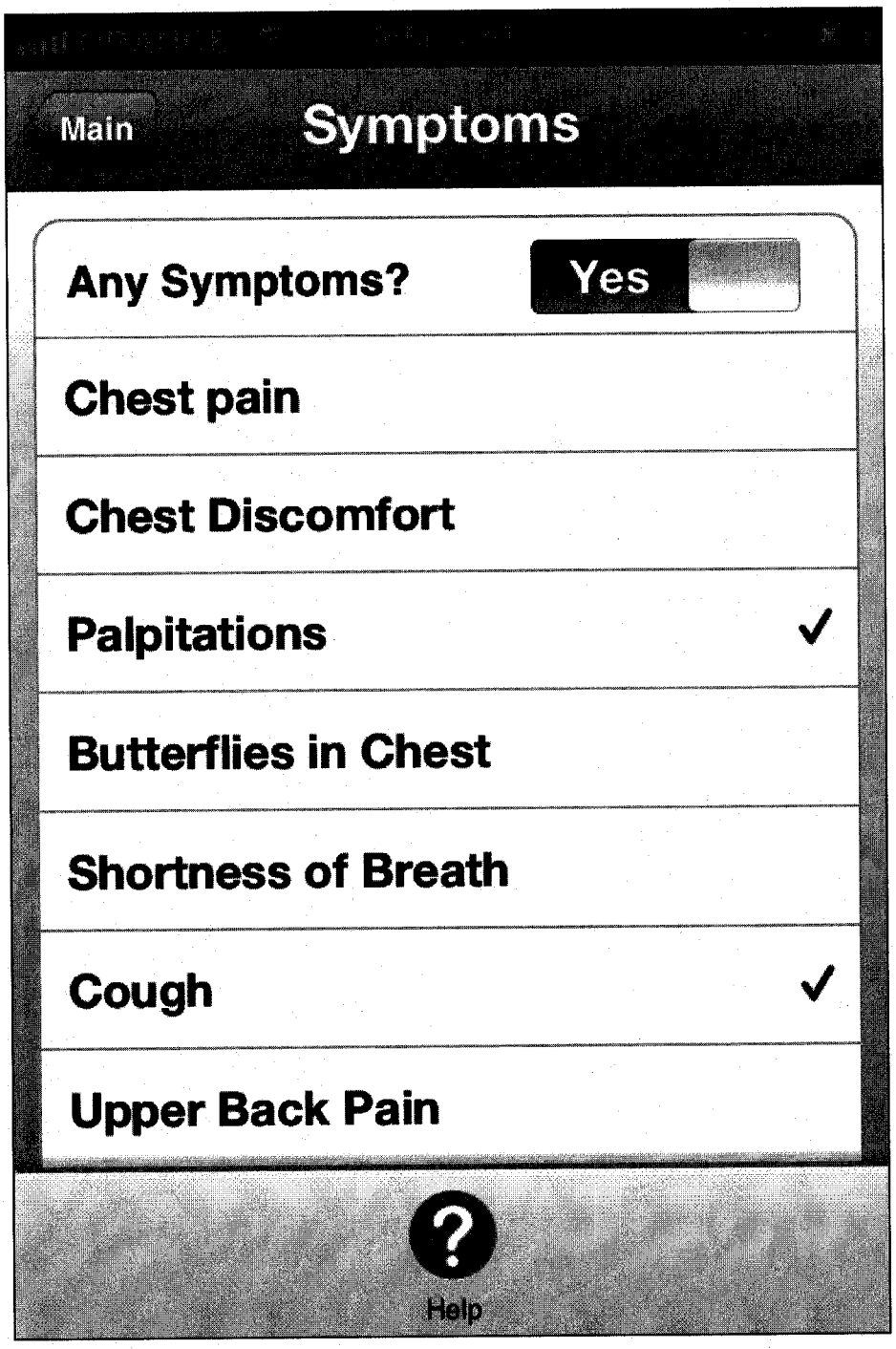

Fig. 7

Electrodes Positioning

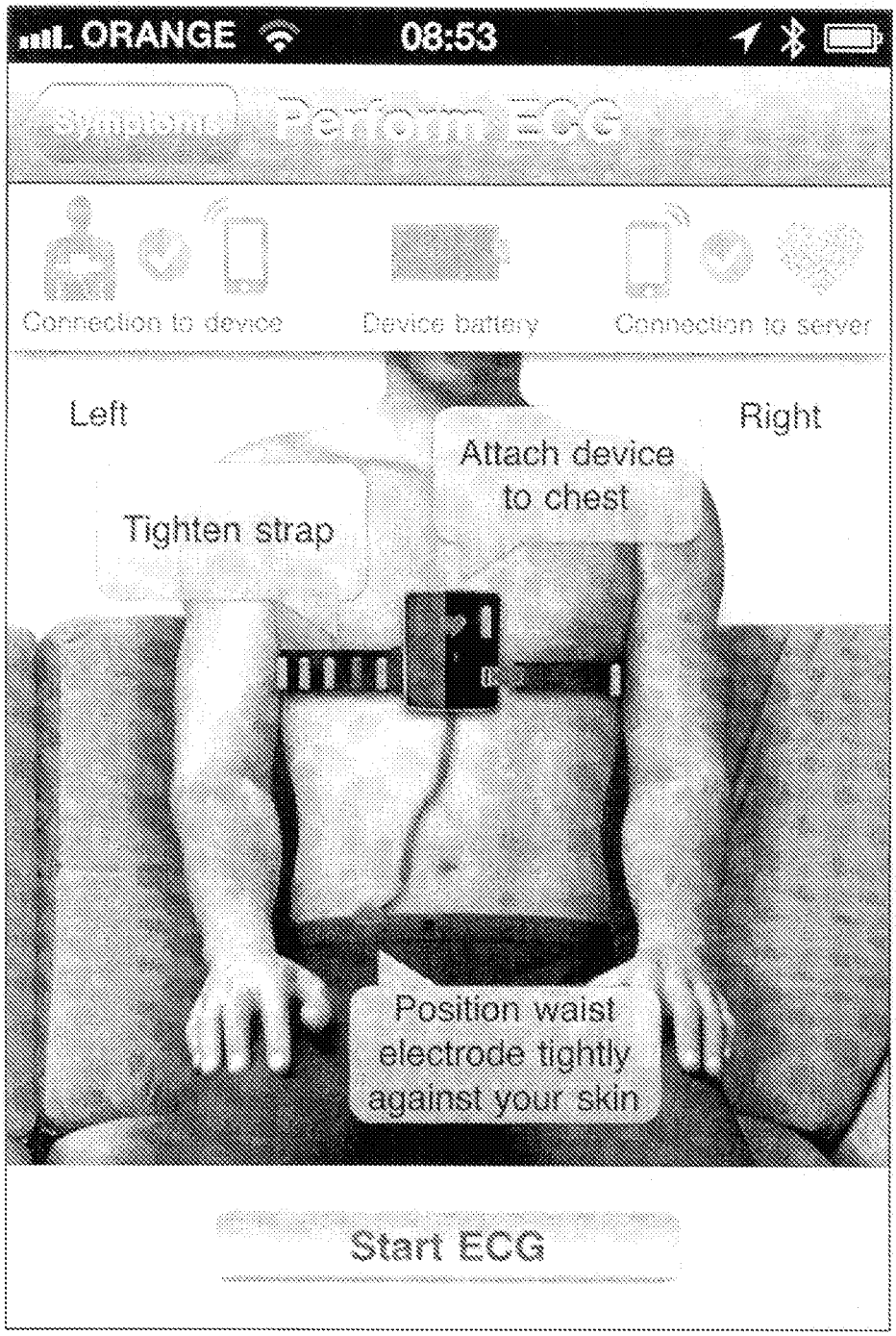

Fig. 8

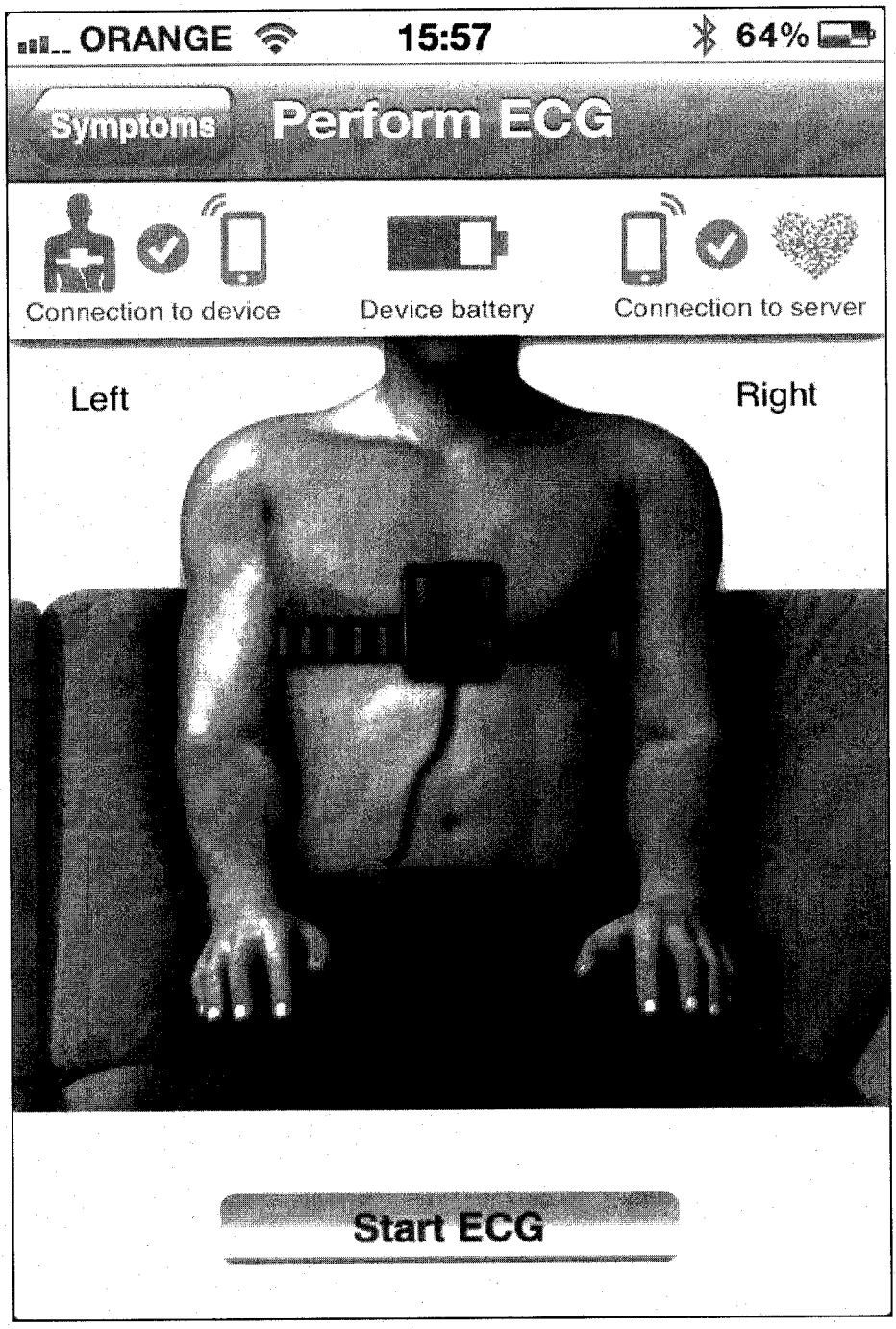
ORANGE
15:57
64%
Symptoms
Perform ECG
Connection to device
Device battery
Connection to server
Left
Right
Start ECG

Fig. 9

View of recorded ECGs

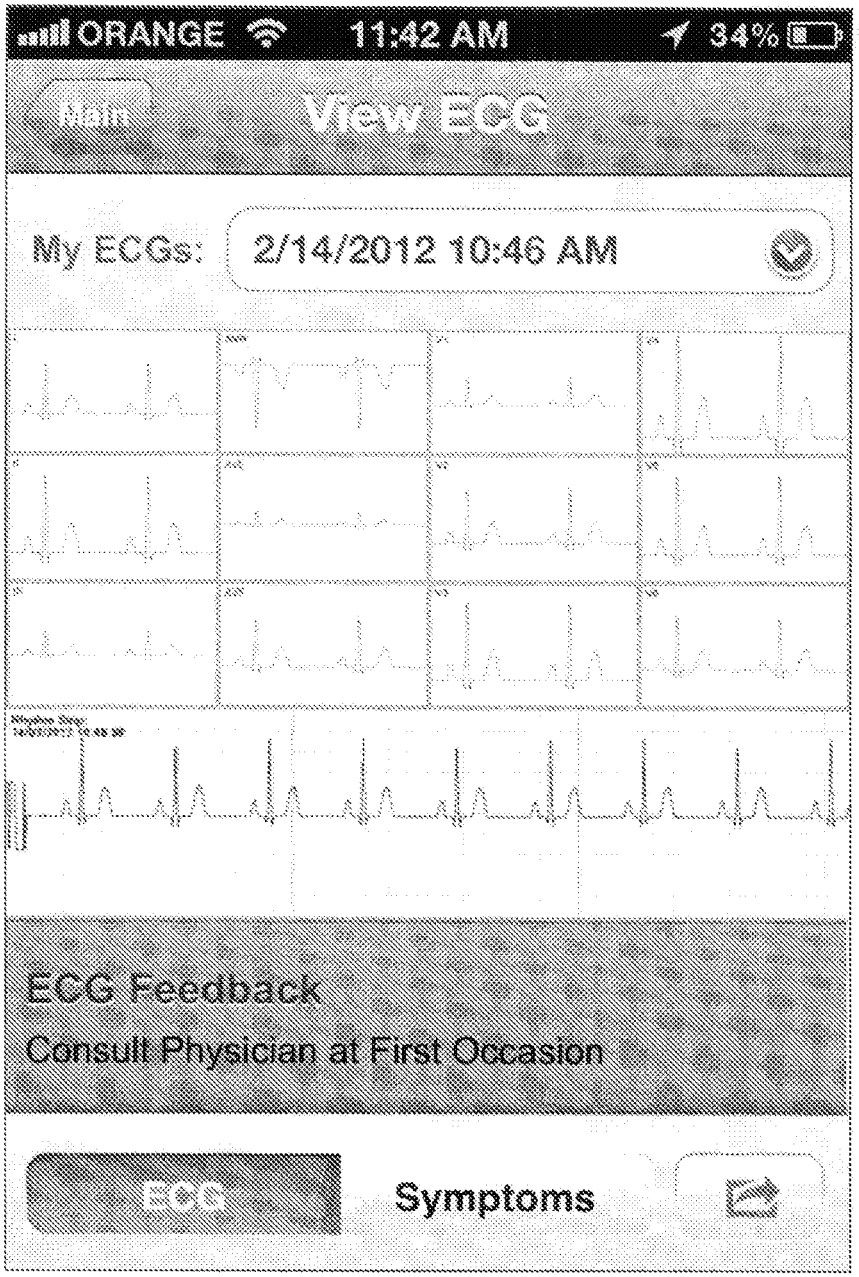

Fig. 10

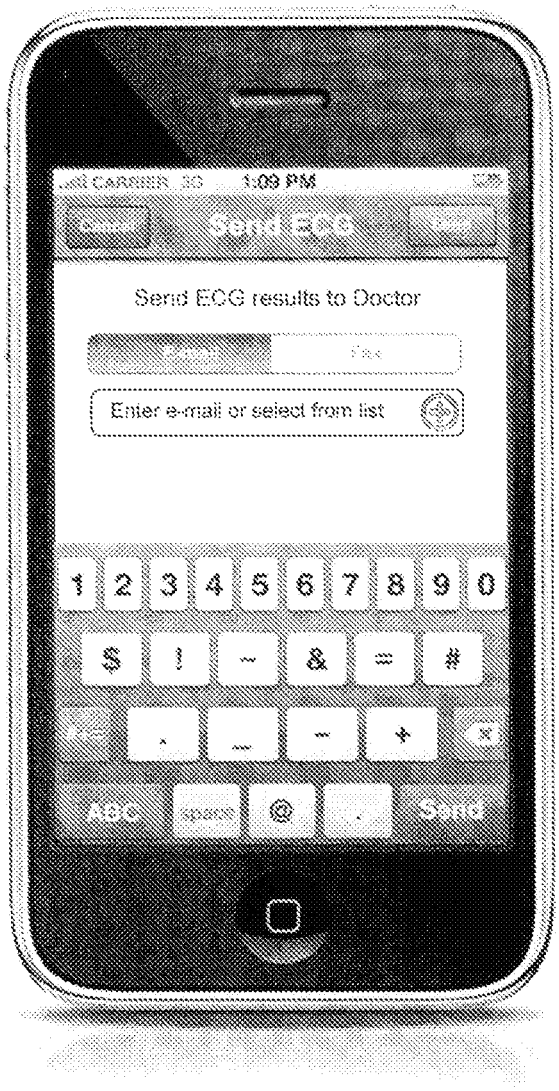
1:09 PM
Send ECG
Send ECG results to Doctor
Enter e-mail or select from list
1 2 3 4 5 6 7 8 9 0
$! ~ & = #
ABC
Send

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2012/000200

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/0404 (2012.01)
USPC - 600/509
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)
IPC(8) - A61B 5/02, 5/04, 5/0402, 5/0404; A61N 1/00, 1/04; G08B 23/00 (2012.01)
USPC - 128/903, 904; 340/573.1; 600/386, 393, 500, 508, 509, 523; 607/152

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 2011/0105928 A1 (BOJOVIC et al) 05 May 2011 (05.05.2011) entire document	1, 3-9 --- 2, 10-14
Y	US 2005/0165319 A1 (BRODNICK et al) 28 July 2005 (28.07.2005) entire document	2
Y	US 2008/0234592 A1 (LIM et al) 25 September 2008 (25.09.2008) entire document	10, 12-14
Y	US 7,266,405 B1 (ALROY et al) 04 September 2007 (04.09.2007) entire document	11

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"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
21 September 2012	01 OCT 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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申请号	EP2012788738	申请日	2012-05-21
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当前申请(专利权)人(译)	SHL远程医疗INTERNATIONAL LTD.		
[标]发明人	REINHOLD JR HERBERT E LEIBOVITZ SHAY KAZAZ RONI		
发明人	REINHOLD JR., HERBERT E. LEIBOVITZ, SHAY KAZAZ, RONI		
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CPC分类号	A61B5/6898 A61B5/0006 A61B5/0022 A61B5/0404 A61B5/04085 A61B5/044 A61B5/486 A61B5/6823 A61B5/6824 A61B5/6828 A61B5/6831 A61B5/7221 A61B5/7465 A61B5/7475		
优先权	61/488913 2011-05-23 US		
其他公开文献	EP2713865A4 EP2713865B1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于获得12导联心电图和/或节律带的方法，包括：a）在解剖学上适当地将至少9个监测电极定位在用户身体上，用于捕获与所述用户的心脏的电活动有关的信息。 ，其中每个所述电极直接和/或通过电极带电连接到个人ECG装置; b）从所述个人ECG装置产生用于12导联心电图和节律带（例如，12秒带）的ECG数据，其中所述生成的ECG数据表示所述用户的心脏随时间的电活动（并且在实际中）时间）由所述皮肤电极获得; c）将所述ECG数据无线传输到移动通信设备（例如，智能手机），用于本地操纵所述ECG数据和/或用于将所述ECG数据转发到远程数据中心（例如，远程医疗中心）。