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WO 2012/163733 A1

(54) **Title**: DETECTION OF ANOMALIES IN ELECTROCARDIOGRAPHY

(57) **Abstract**: The invention provides an apparatus to receive electrocardiography data from a mobile communication device. The apparatus generates an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data. The alert may be sent to the patient or to a third party, such as a doctor or a relative.

DETECTION OF ANOMALIES IN ELECTROCARDIOGRAPHY DATA

The present invention is related to the collection and use of electrocardiography (ECG) data.

Cardiovascular disease (CVD) is the number one cause of death globally. By 2030, 40.5% of the US population is projected to have some form of CVD. Between 2010 and 2030, real total direct medical costs of CVD are projected to triple, from $273 billion to $818 billion. Real indirect costs (due to lost productivity) for all CVD are estimated to increase from $172 billion in 2010 to $276 billion in 2030, an increase of 61%.

CVD incidents are usually associated with cardiac arrhythmias. On the other hand, issues related to cardiac arrhythmia risk do not only apply to persons with known cardiac disease or after a heart attack, but there are many other risk factors for cardiovascular diseases and sudden cardiac death.

The number of out-of-hospital sudden cardiac arrests (SCA) is significant. According to a study made in UK, 74% of all fatal events occurred outside hospital. Fewer than eight percent of people who suffer cardiac arrest outside the hospital survive.

In case of suspected heart issues, patients usually need to remain in hospital for ECG monitoring, or have to use an expensive home monitoring unit (event recorder).

As is well known in the art, electrocardiograph (ECG) techniques monitor the electrical activity of the heart. A typical ECG tracing of the cardiac cycle (heartbeat) consists of a P wave, a QRS complex and a T wave.

For ECG interpretation, the P, QRS and T waves are analyzed in terms of amplitude, duration, intervals between peaks and valleys and changes over time. Very often, rhythm events do not occur

continuously, but require long observation time (perhaps one or more days).

A complete ECG analysis requires measurement of 12 voltages between different locations on the human body (12-lead ECG). In one embodiment of the invention, in order to meet the target of low cost and easy usability, a known single-lead ECG sensor is used. Single-lead ECG sensors detect many, but not all, heart anomalies. Clearly, any suitable ECG sensor, such as known 3-lead, 5-lead and 12-lead sensors could be used in embodiments of the present invention.

In addition to electrical measurement, acceleration measurement is performed in order to detect physical movement of the patient. This information is used to adjust thresholds for feedback notifications dynamically.

Doctor resources today are stretched with unnecessary visits from patients. It is also clear that an aging population is placing further burden on health care resources. On the other hand, there is a growing trend with consumers wanting to independently control and manage their own healthcare. No market solution is currently available to provide mobility to patients with real time feedback such as warning of critical events or issues.

The present invention seeks to address at least some of the problems outlined above.

The present invention provides an apparatus (e.g. a server) comprising: a first input configured to receive electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device; a processor for processing said electrocardiography data; and a first output configured to provide an alert in the event that one

of a number of defined anomalies are detected in said electrocardiography data.

The present invention also provides a method comprising: receiving electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device; processing said electrocardiography data; and providing an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data.

The alert may be provided to the said user (typically via the mobile communications link). Alternatively, or in addition, the alert may be provided to a second user (different to said first). The second user might, for example, be a doctor, a caregiver, a relative, a paramedic etc.

The alert may include location data for said user (e.g. obtained by determining the location of the mobile communication device).

The present invention further provides a computer program comprising: code (or some other means) for receiving electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device; code (or some other means) for processing said electrocardiography data; and code (or some other means) for providing an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data. The computer program may be a computer program product comprising a computer-readable medium bearing computer program code embodied therein for use with a computer.

Exemplary embodiments of the invention are described below, by way of example only, with reference to the following numbered drawings.

Figure 1 is a block diagram of a system in accordance with an aspect of the present invention;

Figure 2 is a block diagram showing further details of the system of Figure 1;

Figure 3 is a block diagram showing further details of the system of Figure 1; and

Figure 4 is a flow chart showing an exemplary use of the system of Figure 1; and

Figure 5 is a block diagram of a system in accordance with an aspect of the present invention.

Figure 1 is a block diagram of a system, indicated generally by the reference numeral 1, in accordance with an aspect of the present invention.

The system 1 comprises one or more sensors 2, a mobile communication device 4, and a server 6 and may additionally include a doctor 8. The sensor(s) 2 provide data to the mobile communication device 4. The device 4 is in two-way communication with the server 6 and so is able to upload data received from the sensor 2 to the server 6. The doctor 8 (when present in the system 1) is in two-way communication with the server 6 and can therefore access data uploaded to the server 6 by the mobile communication device 4.

The sensor 2 is an electrocardiography (ECG) sensor; however, the ECG sensor 2 may take many different forms. Indeed, one of the advantages of the present invention is that the system is sufficiently flexible to allow any suitable sensor to be used. Exemplary sensors 2 may, however, be chosen to meet at least some of the following criteria:

- Single-lead ECG measurement

- Acceleration measurement
- Lead-off detection (whether the sensor is properly attached)
- Battery supervision
- Wireless connectivity to the mobile communication device 4
- Low cost
- Easy to handle by the user
- Long battery lifetime (several days continuous operation)

Due to long-term usage, a sealed package is ideal.

Figure 2 is a further block diagram showing the sensor 2, mobile communication device 4 and server 6 of the system 1 and additionally showing further details of the mobile communication device 4. As shown in Figure 2, the mobile communication device includes a controller 32 that receives data from the sensor 2 and is in two-way communication with the server 6. The device 4 also includes a graphical user interface (GUI) 34 and a buffer 36 that are each in two-way communication with the controller 32. The GUI 34 enables the user (i.e. the subject of the monitoring by the sensor 2) to interact with the mobile communication device 4.

The device 4 typically supports at least some of the following functionality: pairing with the sensor 2; reception of ECG, impedance and acceleration measurement data from the sensor 2; display of ECG measurement data in a sliding window of the GUI 34; buffering (using the buffer 36) of measurement data with respect to the configurable data upload frequency; uploading of measurement data to the server 6; notifying the user if network connectivity is interrupted (WAN supervision), sensor connectivity is interrupted, in particular if the phone is not in proximity of the patient (PAN supervision), if the sensor

device is not properly attached (lead-off detection) or if the sensor battery needs to be replaced or recharged; and notification to the user of ECG interpretation results (via the GUI 34). Many of these features are discussed further below.

Figure 3 is a further block diagram showing the sensor 2, the mobile communication device 4 and the server 6 of the system 1 and additionally showing further details of the server 6. As shown in Figure 3, the server 6 includes a controller 42, an ECG interpreter 44, a notification engine 46, a data store 48 and a graphical user interface (GUI) 50 for the doctor. The controller 42 is in two-way communication with the mobile communication device 4, the ECG interpreter 44, the notification engine 46, the data store 48 and the GUI 50. The doctor 8 interfaces with the server 6 via a two-way connection with the GUI 50.

In use, the mobile communication device 4 receives data from the sensor 2 and forwards that data (in a format discussed further below) to the controller 42 of the server 6. The controller 42 communicates with the data store 48 to store the data.

Data is sent from the controller 42 to the ECG interpreter 44 for analysis and results are returned to the controller 42. The results obtained from the ECG interpreter 42 are typically also stored in the data store 48. The doctor 8 uses the GUI 50 to access the data stored in the data store 48. Thus, the doctor can gain access to both the raw data received at the server 6 from the mobile communication device 2 and the results obtained from the ECG interpreter 44.

In some cases, the controller 42 may determine that a user (e.g. the subject of the monitoring by the sensor 2 of the doctor 8) should be informed of an event (such as an arrhythmia detected by the ECG interpreter 44 or a problem noted by the doctor 8). In this case, the controller 42 communications with a

notification engine 46 and the engine provides a message for sending to the user (typically to the mobile communication device 4).

At least some of the elements of the server 6 may be provided remotely from the server. For example, the ECG interpreter 44 may be provided by a third party, with the server 6 sending data to the ECG interpreter and the ECG interpreter returning results to the controller 42 of the server 6. Similarly, data storage, such as the data store 48 may be provided remotely.

Figure 4 is a flow chart, indicated generally by the reference numeral 10, showing an exemplary use of the system 1.

The algorithm 10 starts at step 12, where the patient installs the relevant application on his mobile communication device 4. Next, at step 14, the patient attaches the sensor 2 to his chest.

The newly-attached sensor 2 needs to be paired with the mobile communication device 4 that the patient will use to upload data to the server 6. This is done in step 16 and need be done only once. Subsequently, the connection between the sensor 2 and the mobile communication device 4 is established automatically.

Next, at step 18, the patient logs into the server 6 using the application installed on his mobile communication device in step 12 above using credentials (username, password) as provided, for example, by the doctor 8.

At this stage, the sensor 2 is paired with the mobile communication device 4. Accordingly, at step 20, ECG measurement data is wirelessly transmitted from the sensor 2 to the mobile communication device 4. Next, at step 22, the data received at the mobile communication device 4 from the sensor 2 is transmitted to the server 6. Steps 20 and 22 are repeated for the duration of the measurement period.

Depending on the risk position of the patient and the actual medical need, the following sub-use cases (applications) are supported: very-long-term ECG (non-real-time); fast response (near real-time); and on demand (real-time).

On-demand ECG sends data continuously from the device 4 to the server 6 and supports remote diagnosis without a visit to the doctor.

The fast response ECG is further enhanced by a high upload frequency (e.g. once per minute). Continuous automatic ECG interpretation allows for fast response in case of a potentially dangerous situation for the user/patient. This application requires more resources, in particular battery power from the mobile phone and a consistent network connection. During phases of network unavailability, the data will be stored on the mobile phone.

Very-long-term ECG is a conventional long-term ECG application, enhanced by virtually infinite observation time and characterized by significantly lower costs. For optimum usage of mobile phone resources, data is uploaded with low frequency (e.g. once per day). This use case is applicable to the family doctor as well as the clinician.

The server application software correlates the measured ECG data with the acceleration data and identifies heart rhythm anomalies (arrhythmia). This function is known as ECG interpretation.

If a visit to the doctor is needed, a warning (feedback notification) will be sent to the user's phone (the mobile communication device 4) while in critical or severe circumstances, alerts will be sent additionally to the paramedics as well as to caregivers named by the user (relatives, neighbors, etc.).

The server 6 provides a Web GUI for the doctor 8. It supports the following functions: secure login (by the doctor 8); management of patient data (Patient List Page); browsing through stored and interpreted ECG data (ECG Page); filtering and grouping of arrhythmia events; and annotations to the ECG data.

Anomalies (ECG events) will be logged in the Event List and highlighted in the Overview Timeline and ECG Plot. Forward notifications are also logged in the Event List, so they can be easily correlated with ECG events. Browsing is possible in the Event List and the ECG Plot. Events can be grouped and filtered according to a set of pre-defined rules.

Figure 5 is a block diagram of a system, indicated generally by the reference numeral 60, in accordance with an aspect of the present invention. The system 60 comprises a sensor 62, a mobile communication device 64 and a server 66 that are similar to the sensor 2, mobile communication device 4 and server 6 described above with reference to Figure 1.

The system 60 optionally includes a doctor 68 and, as in the system 1, the doctor may be informed of problems identified in the ECG data and may be able to provides inputs to the system 60.

The system 60 additionally includes a third party 70. As described above, the controller 42 of the server 6 (which corresponds to the server 66) may use the notification engine 46 to send alerts to the patient. The system 60 differs from the system 1 by additionally enabling the controller 42 to use the notification engine to provide alerts to the third party 70.

The third party 70 may, for example, be a caregiver, a paramedic or a relative as identified by the patient. The third party contacted may be selected by the server 66 on the basis of the location of the patient. This location data can be readily obtained by determining the location of the mobile communication

device 64 in a manner well known in the art. By way of example, if the patient is deemed by the server 66 to be at home, then the server may contact a neighbour with alert data. If the patient is deemed to be at work, then the server may contact a work colleague. In any event, if an alert is sufficiently serious to warrant contacting a paramedic, then the paramedic can be provided with location data based on the location of the mobile communication device 64 that is providing data to the server 66. Of course, any other third party to whom an alert is sent could be provided with location data.

The systems 1 and 60 provide solutions for both individuals and doctors, built upon low-cost ECG monitoring devices that are connected to the network via the mobile phone of the user and a Cloud based server architecture. Users have full mobility and heart rhythms are continually monitored with near "real time" feedback from an analytical engine being provided, if required. The solution supports continual recording, storage and processing of information for doctors. It automatically alerts the patient, first responders, doctors or caregivers of any major rhythm event.

Two exemplary use cases of the systems 1 and 60 are described below.

The first use case is intended largely for use by doctors. ECG data is recorded by the system and the doctor can access the recorded data using the GUI 50 described above. In addition, the ECG interpreter 44 can alert the doctor in the event that potential problems (such as arrhythmia events) are detected.

The second use case is intended largely for use by individuals. The system 1 supports self-monitoring by the user (preventive care). This is facilitated by the ECG interpreter 44 running autonomously on the server 6. The server 6 notifies the user

instantly if anomalies exceed a certain threshold and the user should visit the doctor. In case of the system 60, the system may also alert the emergency services and other caregivers (e.g. relatives or neighbours) nominated by the user. The user may provide his doctor access to his data.

As described above, the invention provides a simple low-cost ECG monitoring device connected to a server (typically cloud based) via a mobile network with a mobile phone acting as a gateway.

The remote software can analyse the data. Raw data, and analysed results, are stored in bulk remote from the sensor (e.g. in the cloud). The doctor has access to this data without requiring the patient to be present (and has access to data generated after the patient's last visit to the doctor).

The basic system architecture involves a sensor device, a mobile phone and a server. The sensor device is typically an "off-the-shelf" device, such as a digital plaster. The sensor communicates with a paired mobile phone in a very simple and well-established manner. The mobile phone has the relevant software installed. Data is received from the sensor and sent to the server; data buffering may be required (e.g. if connection to the server is lost). A data display (to the user) may be provided, but this is not essential. User notification (e.g. of alerts) may be provided. The server may require secure login and may have the bulk data storage and the main data processing capability of the system. The server typically provides the ECG interpretation, performs data plotting and issues alerts (if such a feature is provided by the system). The server may need to interface with multiple users (e.g. the patient, doctors, paramedics, relatives, emergency contacts).

Advantages of the invention include the following. Each part of the system can be optimized. The sensor can be as simple as

possible (just provides data - no need for data processing); thus the sensor can be cheap and battery usage minimized. The communication system is optimized by allowing mobile phone operators to do all the work (e.g. redundancy by providing multiple communication methods). The storage in the cloud is cheap. The centralized software (rather than providing software to the phones) is cheaper, simpler and easier to update. The system enables long observations times that provide a clear medical advantage. The system is universal and scalable. The system is also flexible, allowing new applications/modified applications to be provided (e.g. by others) as required. Doctors have access to bulk data stored at the server regardless of whether the patient is present. Paramedics can also potentially access bulk data (e.g. via a similar GUI to that available to a doctor).

The main benefit for the individual is higher quality of life, a patient who is post operative or has post event condition (e.g. heart attack) is able to experience a quick, easy and safe reintegration into their home environment. A patient with the concern of a heart related disease can continue their private and professional routine as a result of being able to monitor their situation. Since the patient can stay at home, the so-called "white coat syndrome" is eliminated and occupational rehabilitation costs will be reduced.

There are benefits for the doctor as well. ECG monitoring costs can be significantly reduced through low-cost devices and simpler handling. Longer observation time supports a high quality of diagnosis. Cloud based computing with secure web access keeps infrastructure costs low.

The embodiments of the invention described above are illustrative rather than restrictive. It will be apparent to those skilled in the art that the above devices and methods may incorporate a

number of modifications without departing from the general scope of the invention. It is intended to include all such modifications within the scope of the invention insofar as they fall within the scope of the appended claims.

CLAIMS:

1. An apparatus comprising:

a first input configured to receive electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device;

a processor for processing said electrocardiography data; and

a first output configured to provide an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data.

2. An apparatus as claimed in claim 1, wherein the alert is provided to the said user.

3. An apparatus as claimed in claim 1 or claim 2, wherein the alert is provided to a second user.

4. An apparatus as claimed in any one of claims 1 to 3, wherein the alert includes data relating to the location of the mobile communication device.

5. A method comprising:

receiving electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device;

processing said electrocardiography data; and

providing an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data.

6. A method as claimed in claim 5, wherein the alert is provided to the said user.

7. A method as claimed in claim 5 or claim 6, wherein the alert is provided to a second user.

8. A method as claimed in any one of claims 5 to 7, wherein the alert includes data relating to the location of the mobile communication device.

9. A computer program product comprising:

means for receiving electrocardiography data from a mobile communication device via a mobile communication link, wherein the electrocardiography data relates to a user of said mobile communication device;

means for processing said electrocardiography data; and

means for providing an alert in the event that one of a number of defined anomalies are detected in said electrocardiography data.

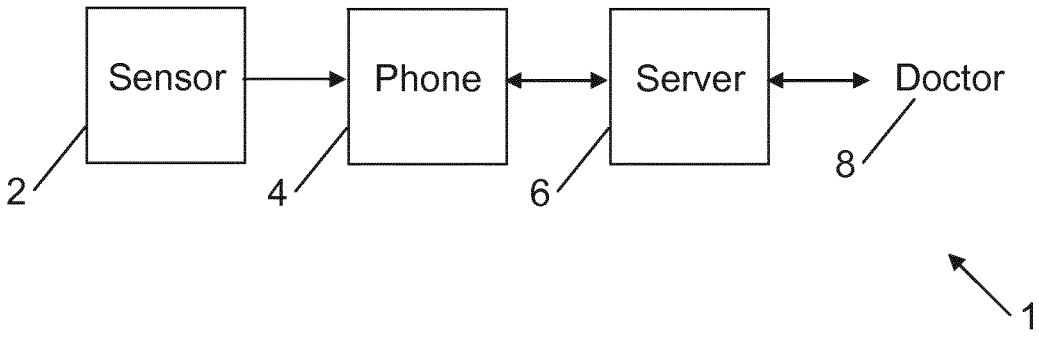
Sensor
Phone
Server
Doctor
2
4
6
8
1

Fig. 1

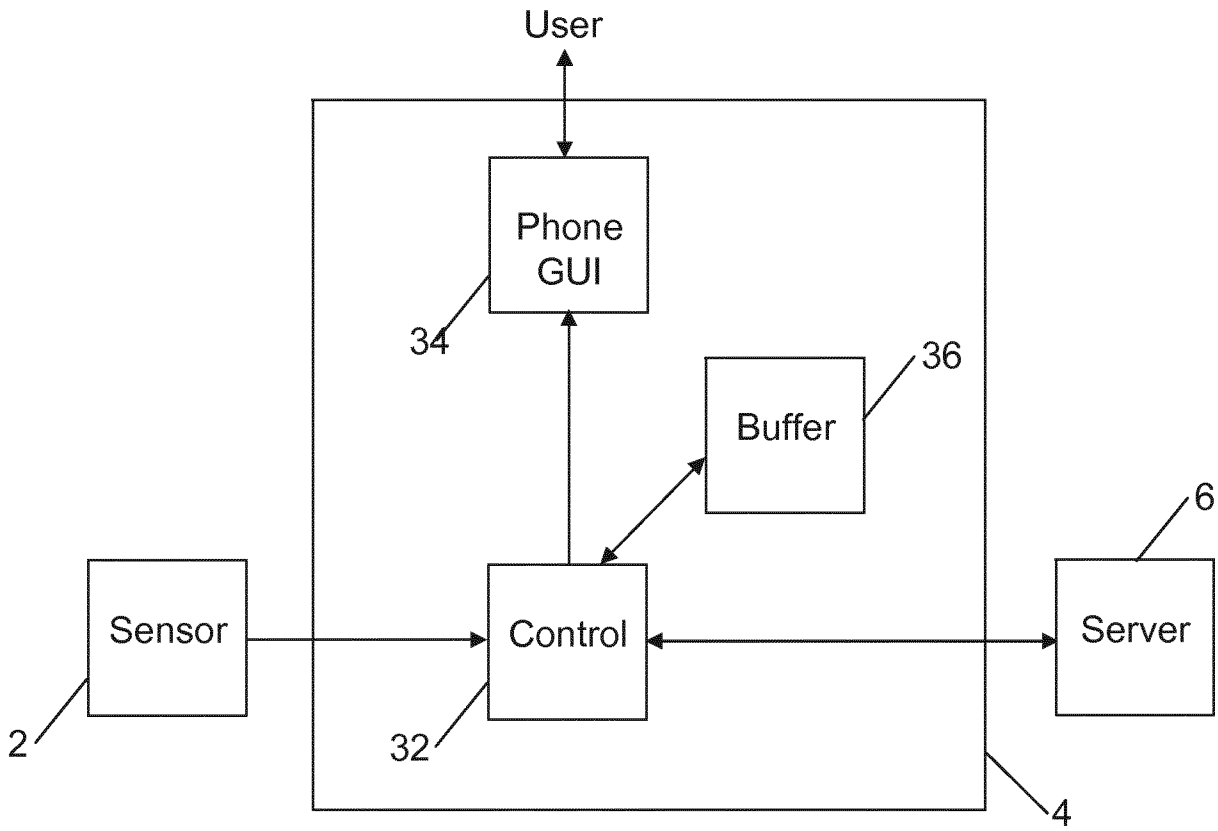
User
Phone GUI
34
Buffer
36
6
Sensor
Control
Server
2
32
4

Fig. 2

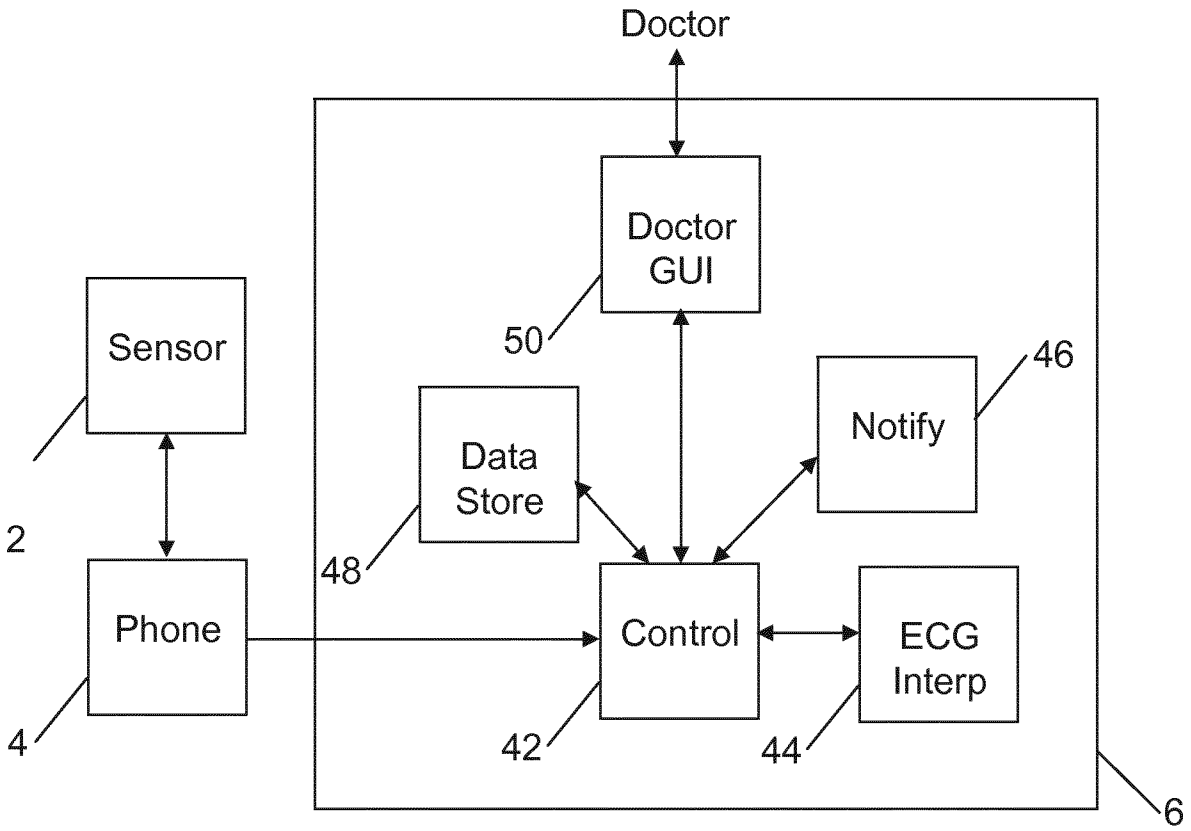
Doctor
Doctor GUI
50
Sensor
2
Data Store
48
Notify
46
Phone
4
Control
42
ECG Interp
44
6

Fig. 3

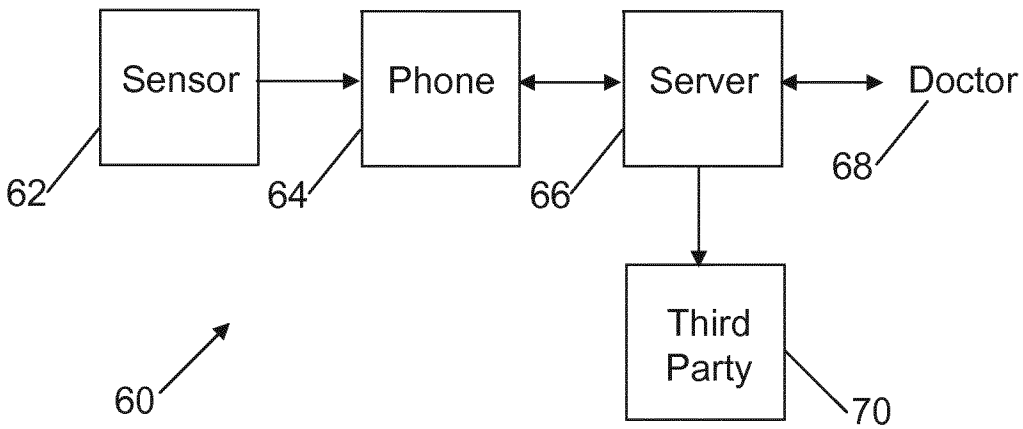
Sensor
Phone
Server
Doctor
62
64
66
68
Third Party
60
70

Fig. 5

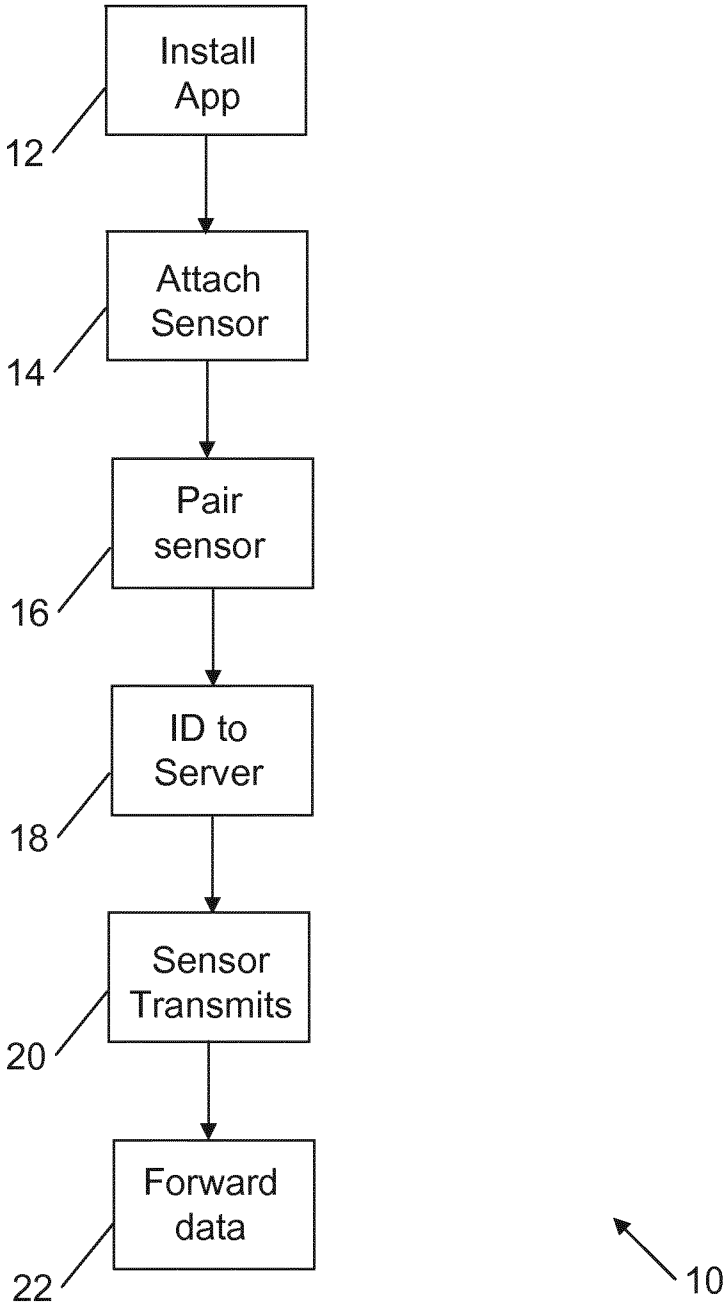
Install App
12
Attach Sensor
14
Pair sensor
16
ID to Server
18
Sensor Transmits
20
Forward data
22
10

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/059504

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00
ADD.

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)
G06F

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)
EPO-Internal, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KALA JOHN KAPPIARUKUDIL ET AL: "Real-Time Monitoring and Detection of Heart Attack Using Wireless Sensor Networks", SENSOR TECHNOLOGIES AND APPLICATIONS (SENSORCOMM), 2010 FOURTH INTERNATIONAL CONFERENCE ON, IEEE, PISCATAWAY, NJ, USA, 18 July 2010 (2010-07-18), pages 632-636, XP031739541, ISBN: 978-1-4244-7538-4 the whole document	1-4,9
X	US 2005/075542 A1 (GOLDREICH RAMI [IS]) 7 April 2005 (2005-04-07) the whole document	1-4,9
X	EP 1 867 274 A1 (HEALTHPIA CO LTD [KR]) 19 December 2007 (2007-12-19) the whole document	1-4,9

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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

"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
25 September 2012	08/10/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sanandrés Ledesma, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/059504

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/253301 A1 (SIMMS HOWARD D [US] ET AL) 9 November 2006 (2006-11-09) the whole document -----	1-4,9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/059504

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 5-8
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-mater of claims 5-8 is directed towards a method for diagnosing cardiac anomalies based on electrocardiography data and therefore falls under the exception defined in Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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