UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301

CONFIRMATION NO. 2113

21971
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

POWER OF ATTORNEY NOTICE

OC000000111438515

Date Mailed: 09/27/2019

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/23/2019.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hsarwari/

APPLE 1002

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301

CONFIRMATION NO. 2113

151512
WOMBLE BOND DICKINSON (US) LLP/AliveCor
Attn: IP DOCKETING
P.O. BOX 7037
ATLANTA, GA 30357-0037

POA ACCEPTANCE LETTER

OC000000111438554

Date Mailed: 09/27/2019

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/23/2019.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hsarwari/

PTO/AIA/80 (07-17)
Approved for use through 01/31/2018. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

[X] Practitioners associated with Customer Number: 151512

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

[X] The address associated with Customer Number: 151512

OR

[ ]

Firm or individual name		
Address		
City	State	Zip
Country		
Telephone	Email	

Assignee name and address: AliveCor, Inc.
444 Castro Street, Suite 600
Mountain View, CA 94041

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature Brian Clarke	Date 10/18/2017
Name Brian Clarke	Telephone
Title General Counsel	

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/47 (03-09)
Approved for use through 07/31/2018. OMB 0651-0016
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below**: If you have a Customer Number to represent the fee address. **When to check the second box below**: If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☒ Customer Number: 14420

OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
9,572,499	14/730,122

Completed by (check one):

☐ Applicant/Inventor

☒ Attorney or Agent of record 74,758 (Reg. No.)

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☐ Assignee recorded at Reel Frame

/Bill Jacobs/
Signature

William D. Jacobs, Jr.
Typed or printed name

408 341-3091
Requester's telephone number

September 23, 2019
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more that one signature is required, see below*.

☑ * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	37247942
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	William D Jacobs Jr/Aaron Dunn
Filer Authorized By:	William D Jacobs Jr
Attorney Docket Number:	41188-720.301
Receipt Date:	23-SEP-2019
Filing Date:	03-JUN-2015
Time Stamp:	18:10:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Assignee showing of ownership per 37 CFR 3.73	A102992_1170USC1_373_Statement.pdf	129988 0de57ebdbfe8894d1ad966e314d03dc163fb66c2	no	3

Warnings:

Information:					
2	Power of Attorney	Alive_POA.pdf	162218 7d6406dca0fe26f38cd96de77969e2ae320349b3	no	2
Warnings:					
Information:					
3	Maintenance Fee Address Change	A102992_1170USC1_Fee_Address.pdf	144113 956438fef193ea2719b4fc0425c4d28747c4e015	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	436319	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: ALIVECOR, INC.

Application No./Patent No.: 9,572,499 Filed/Issue Date: February 21, 2017

Titled: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

ALIVECOR, INC., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 038690, Frame 0255, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Bill Jacobs/	September 23, 2019
Signature	Date
William D. Jacobs, Jr.	74,758
Printed or Typed Name	Title or Registration Number

[Page 2 of 2]

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,572,499 B2
APPLICATION NO. : 14/730122
DATED : February 21, 2017
INVENTOR(S) : Ravi Gopalakrishnan et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 27, Claim 11, should read as follows:

11. A system for determining the presence of an arrhythmia of a first user, comprising
a heart rate sensor coupled to said first user;
a mobile computing device comprising a processor,
wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
a motion sensor
a non-transitory computer readable medium encoded with
a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user, based on said heart rate of said first user, compare said activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

Signed and Sealed this
Twentieth Day of June, 2017

Joseph Matal

Joseph Matal
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

ATTORNEY DOCKET NO. 41188-720.301
PATENT

In re the Patent Application of: Inventors: Ravi GOPALAKRISHNAN et al. Application Serial No.: 14/730,122 Filed: June 3, 2015 Issued Patent No.: 9,572,499 Issue Date: February 21, 2017 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Confirmation No.: 2113 **Certificate of Electronic Filing** I hereby certify that this Response to Notice to File Corrected Application Papers (Notice of Allowance mailed) and all marked attachments are being deposited by Electronic Filing on May 15, 2017, by using the EFS-Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: /Angela Olivos-Blackburn/ Angela Olivos-Blackburn

REQUEST FOR CERTIFICATE OF CORRECTION OF THE ISSUED PATENT FOR OFFICE MISTAKE UNDER 37 C.F.R. § 1.322

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

It is noted that an error appears in this patent due to mistake on the part of the Office, as more fully described below. The Patentee believes that correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination of the patent. A certificate of correction is therefore requested

Attached hereto is Form PTO/SB/44 which is suitable for printing.

MISTAKES ON THE PART OF OFFICE

In reviewing the issued Patent, Applicant noted the following error which is of a typographical nature and which do not constitute new matter or require reexamination. Deletions are denoted by [~~strikethrough~~] and additions are denoted by underline. These corrections are needed on page 27, at Claim 11, as follows:

11. A system for determining the presence of an arrhythmia of a first user, comprising
a heart rate sensor coupled to said first user;
a mobile computing device comprising a processor,
wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
a motion sensor
a non-transitory computer readable medium encoded with
a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user, based on said heart rate of said first user, compare ~~and~~ said activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

Support for this correction may be found in the records of the Office. Patentee points to the entire record along with the amendment to claim 11 entered by Patentee on December 20, 2016 which recites "***said*** activity level," and not "***and*** activity level" as published. (emphasis added). Therefore, this error is incurred through the fault of the Office, which mistake is clearly disclosed in the records of the Office in accordance with 37 C.F.R. § 1.322.

The above noted correction is needed to correctly reflect the named invention. ***Patentee further requests that the Director correct the above error through a republication of the issued patent as the Director is authorized to do under 37 C.F.R. § 1.322(b).*** Patentee believes that a republication of the corrected claim will add clarity to the correction of mistake on part of the Office.

FEE AUTHORIZATION

Patentee believes that no fee is due for this request. Should Patentee be mistaken, the Commissioner is authorized to charge any additional fees which may be required, including petition fees, or credit any overpayment to Deposit Account No. 23-2415 (Docket No. 41188-720.301).

The Commissioner is encouraged to contact the undersigned attorney at (858) 350-2365 if he or she has any questions.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date: May 15, 2017

By: /Uri Greenwald/
Uri M. Greenwald
Reg. No. 72,686

650 Page Mill Road
Palo Alto, CA 94304
Direct Dial: (858) 350-2365
USPTO Customer No. 21971

PTO/SB/44 (09-07)
Approved for use through 01/31/2020. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,572,499

APPLICATION NO.: 14/730,122

ISSUE DATE : February 21, 2017

INVENTOR(S) : Ravi GOPALAKRISHNAN et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On page 27, Claim 11, should read as follows:

11. A system for determining the presence of an arrhythmia of a first user, comprising
a heart rate sensor coupled to said first user;
a mobile computing device comprising a processor,
wherein said mobile computing device is coupled to
said heart rate sensor, and wherein said mobile computing
device is configured to sense an electrocardiogram of said first user; and
a motion sensor
a non-transitory computer readable medium encoded with
a computer program including instructions executable
by said processor to cause said processor to receive a
heart rate of said first user from said heart rate sensor,
sense an activity level of said first user from said
motion sensor, determine a heart rate variability of said
first user, based on said heart rate of said first user,
compare said activity level of said first user to said heart
rate variability of said first user, and alert said first user
to record an electrocardiogram using said mobile computing
device.

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

650 Page Mill Road, Palo Alto, California 94304

Electronic Patent Application Fee Transmittal

Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald/Angela Olivos-Blackburn
Attorney Docket Number:	41188-720.301

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Certificate of correction	1811	1	100	100

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**100**

Electronic Acknowledgement Receipt	
EFS ID:	29212414
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Angela Olivos-Blackburn
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	15-MAY-2017
Filing Date:	03-JUN-2015
Time Stamp:	16:34:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$100
RAM confirmation Number	051617INTEFSW00003976232415
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	AliveCor_41188-720_301_Request_for_Certificate_of_Correction.pdf	242159 0828a875c897cddf4adee6d04763ee70f4ce9997	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30489 a0a161c3254ffa5a7ee9672816d18b90c4075f0d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	272648		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	02/21/2017	9572499	41188-720.301	2113

21971 7590 02/01/2017

WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Ravi GOPALAKRISHNAN, San Francisco, CA;
AliveCor, Inc., San Francisco, CA;
Lev KORZINOV, San Francisco, CA;
Fei WANG, San Francisco, CA;
Euan THOMSON, San Francisco, CA;
Nupur SRIVASTAVA, San Francisco, CA;
Omar DAWOOD, San Francisco, CA;
Iman ABUZEID, San Francisco, CA;
David E ALBERT, San Francisco, CA;

ATTORNEY DOCKET NO. 41188-720.301
PATENT

In re the Patent Application of: Inventors: Ravi GOPALAKRISHNAN Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Confirmation No.: 2113 Group Art Unit: 3762 Examiner: Johnson, Nicole f. **Certificate of Electronic Filing** I hereby certify that this Response to Notice to File Corrected Application Papers (Notice of Allowance mailed) and all marked attachments are being deposited by Electronic Filing on January 24, 2017, by using the EFS-Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: /Angela Olivos-Blackburn/ Angela Olivos-Blackburn

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS
(NOTICE OF ALLOWANCE MAILED)
IN COMPLIANCE WITH 37 C.F.R. § 1.312

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This Amendment is submitted after payment of the Issue Fee and is in response to a Notice to file Corrected Papers (Notice of Allowance mailed) mailed on January 5, 2017 by the Office of Patent Publication. According to the Notice, this Amendment is entered with a waiver by the Office of Patent Publication of any requirement under 37 CFR 1.312 to withdraw the instant patent from issue.

Amendments to the Drawings begin on page **2** of this paper.

Remarks and **Conclusion** are on page **3** of this paper.

AMENDMENTS TO THE DRAWINGS

Replacement Sheet for Figure 6 is herewith submitted in response to a Notice to file Corrected Papers issued on January 5, 2017 by the Office of Patent Publication. No new matter has been added.

REMARKS

Replacement Sheet for Figure 6 is herewith submitted in response to a Notice to file Corrected Papers issued on January 5, 2017 by the Office of Patent Publication. Figure 6 has been revised in order to remove a stray mark identified by the Office of Patent Publication in the Notice dated January 5, 2017. Removal of the stray mark is an informality that is directly responsive to the Notice dated January 5, 2017.

Applicant respectfully requests that Figure 6 be replaced with the Replacement Sheet filed herewith, and that the instant Application go on to issue.

No new matter has been added to the drawing by these amendments.

CONCLUSION

Applicants respectfully solicit the Examiner to enter the amendments. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney (858) 350-2365.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 41188-720.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date: January 24, 2017

By: /Uri Greenwald/
Uri M. Greenwald
Reg. No. 72,686

650 Page Mill Road
Palo Alto, CA 94304
Direct Dial: (858) 350-2365
USPTO Customer No. 21971

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

21971 7590 01/05/2017
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
JOHNSON, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
01/05/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@wsgr.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 14730122
Applicant : Gopalakrishnan
Filing Date : 06/03/2015
Date Mailed : 01/05/2017

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Vermel Wilson/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 14730122 **Drawings filed: 06/03/2015**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 6 (see below), 14
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [X] COMMENTS:
There is possible missing data under box labeled "616"

Electronic Acknowledgement Receipt	
EFS ID:	28155530
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Angela Olivos-Blackburn
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	24-JAN-2017
Filing Date:	03-JUN-2015
Time Stamp:	17:51:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Drawings-only black and white line drawings	AliveCor_41188-720_301_REPLACEMENT_SHEET_FIG_6.pdf	557690 dba083363b0620ea82a5d9a36d3129851940d74d	no	1
Warnings:					

Information:					
2	Miscellaneous Incoming Letter	AliveCor_41188-720_301_Response_to_Notice_to_File_Corrected_Appl_papers_after_ALLOWANCE.pdf	221232 c63a1263399bd0c54b0829f3aff9b1df5779210c	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	778922	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

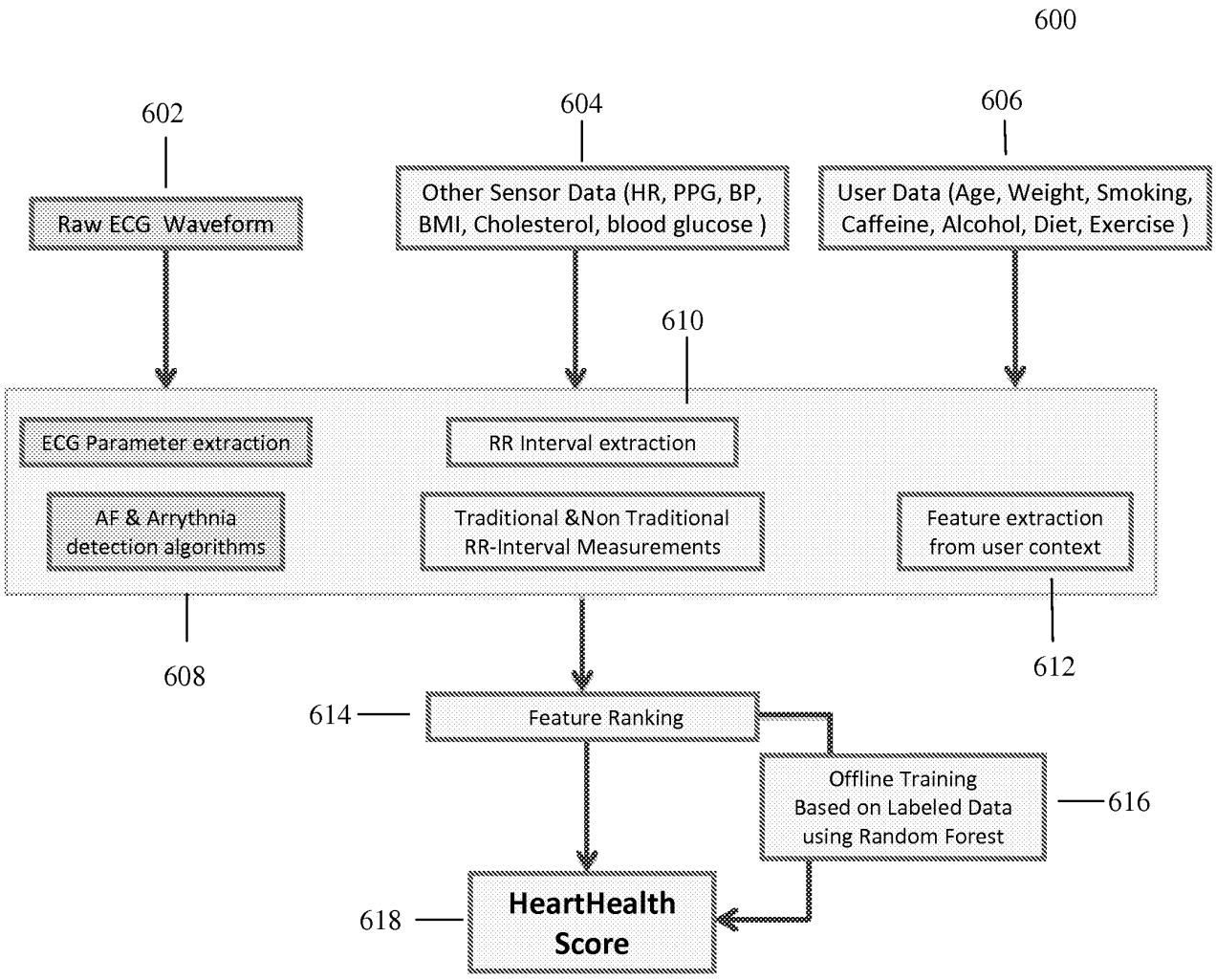

600
602
604
606
Raw ECG Waveform
Other Sensor Data (HR, PPG, BP, BMI, Cholesterol, blood glucose)
User Data (Age, Weight, Smoking, Caffeine, Alcohol, Diet, Exercise)
610
ECG Parameter extraction
RR Interval extraction
AF & Arrythnia detection algorithms
Traditional &Non Traditional RR-Interval Measurements
Feature extraction from user context
608
612
614
Feature Ranking
Offline Training Based on Labeled Data using Random Forest
616
618
HeartHealth Score

FIG. 6

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

21971 7590 01/05/2017
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
JOHNSON, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
01/05/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@wsgr.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 14730122
Applicant : Gopalakrishnan
Filing Date : 06/03/2015
Date Mailed : 01/05/2017

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Vermel Wilson/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 14730122 **Drawings filed: 06/03/2015**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 6 (see below), 14
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as “New” or “Amended” or “Canceled” as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as “Canceled” but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as “Canceled.” See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [X] COMMENTS:
There is possible missing data under box labeled "616"

Response to Rule 312 Communication	Application No.	Applicant(s)
	14/730,122	GOPALAKRISHNAN ET AL.
	Examiner	Art Unit
	NICOLE F. LAVERT	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *20 December 2016* under 37 CFR 1.312 has been considered, and has been:

a) ☒ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

/NICOLE F. JOHNSON/
Primary Examiner, Art Unit 3762

OK TO ENTER: /N.F.L/

12/28/2016

PATENT
Attorney Docket No.: 41188-720.301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Inventor(s): Ravi GOPALAKRISHNAN, et al. Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Group Art Unit: 3762 Examiner: JOHNSON, NICOLE F. Confirmation No.: 2113 Customer No.: 21971

ELECTRONICALLY FILED ON: December 20, 2016

M/S ISSUE FEE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Commissioner:

The present Amendment under 37 C.F.R. § 1.312 is filed after the Notice of Allowance mailed December 6, 2016.

Amendments to the Claims begin on page **2** of this paper.

Remarks and Conclusion are on page **5** of this paper.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6047206	04-04-2000	ALBRECHT; Paul et al.	
	002	US-7162291	01-09-2007	NACHALIEL; Ehud	
	003	US-8725229	05-13-2014	FURUE; Masaaki et al.	
	004	US-9420956	08-23-2016	GOPALAKRISHNAN; Ravi et al.	
	005	US-20050239493	10-27-2005	BATKIN; Izmail et al.	
	006	US-20070073266	03-29-2007	CHMIEL; Alan et al.	
	007	US-20120083705	04-05-2012	YUEN; Shelten Gee Jao et al.	
	008	US-20120289790	11-15-2012	JAIN; Jawahar et al.	
	009	US-20130281816	10-24-2013	STRAUSS; Benjamin Jordan et al.	
	010	US-20140051941	02-20-2014	MESSERSCHMIDT; Robert G.	
	011	US-20140051946	02-20-2014	ARNE; Lawrence et al.	
	012	US-20140073969	03-13-2014	ZOU; Rui et al.	
	013	US-20140114166	04-24-2014	BAXI; Amit	
	014	US-20140163927	06-12-2014	MOLETTIERE; Peter Andrew et al.	
	015	US-20140221859	08-07-2014	ALBERT; David E.	
	016	US-20150182132	07-02-2015	HARRIS; Paul Ronald et al.	
	017	US-20160235319	08-18-2016	ALBERT; David E.	

Examiner Signature	/NICOLE F LAVERT/	Date Considered	12/28/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L/

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	EP-2192526-A2	06-02-2010	FUJITSU LTD [JP]		☐
	002	EP-3079571-A1	10-19-2016	ALIVECOR INC [US]		☐
	003	JP-2006180899-A	07-13-2006	SHARP KK.	Abstract:	☒
	004	JP-2008532587-A	08-31-2006	SOFTWARE SOLUTIONS LTD [GB], et al.	English counterpart is attached: See WO 2006/090371-A2 for English	☒
	005	JP-2010166961-A	08-05-2010	PARAMA TEC KK.	Abstract:	☒
	006	WO-2009112976-A1	09-17-2009	KONINKL PHILIPS ELECTRONICS NV [NL], et al.		☐

Examiner Signature	/NICOLE F LAVERT/	Date Considered	12/28/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L/

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	001	CARPENTER and FRONTERA, Smart-watches: a potential challenger to the implantable loop recorder? Europace, 18:791-793, 2016.	☐
	002	European Patent Application No. 14785223.0 extended European Search Report dated August 23, 2016.	☐
	003	Japanese Patent Application No. 2014-511335 Decision of Rejection dated July 28, 2016.	☒
	004	Japanese Patent Application No. 2014-554916 Office Action dated September 26, 2016.	☒
	005	Notice of Allowance issued June 16, 2016 for U.S. Patent Application No. 14/569,513.	☐
	006	Notice of Allowance issued March 29, 2016 for U.S. Patent Application No. 14/254,310.	☐
	007	PCT Patent Application No. PCT/US2014/070170 International Preliminary Report on Patentability dated June 23, 2016.	☐
	008	PCT/US2016/032524 International Search Report and Written Opinion dated August 19, 2016.	☐
	009	U.S. Patent Application No. 14/479,105 Office Action dated July 22, 2016.	☐
	010	U.S. Patent Application No. 14/494,191 Office Action dated July 20, 2016.	☐

Examiner Signature	/NICOLE F LAVERT/	Date Considered	12/28/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L/

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	011	U.S. Patent Application No. 14/479,105 Office Action dated August 25, 2015	
	012	U.S. Patent Application No. 14/569,513 Office Action dated October 6, 2015	

Examiner Signature	/NICOLE F LAVERT/	Date Considered	12/28/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L/

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21971 7590 12/06/2016
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

TITLE OF INVENTION: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHNSON, NICOLE F	3762	600-508000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Wilson Sonsini Goodrich & Rosati
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: ALIVECOR, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Francisco, CA 94108

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 232415 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature Uri Greenwald Date 12/28/16
Typed or printed name Uri Greenwald, M.D., J.D. Registration No. 72686

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald/diane garcia
Attorney Docket Number:	41188-720.301

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt	
EFS ID:	27919778
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/diane garcia
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	28-DEC-2016
Filing Date:	03-JUN-2015
Time Stamp:	16:21:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$960
RAM confirmation Number	122916INTEFSW00002885232415
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	41188_720_301.pdf	1753161 5660caedc080b991a8806f37ea86b04ff1f1eafa	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30547 d67843114c43362e508e8d8c848b91aaa3bd5ae4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1783708		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Inventor(s): Ravi GOPALAKRISHNAN, et al. Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Group Art Unit: 3762 Examiner: JOHNSON, NICOLE F. Confirmation No.: 2113 Customer No.: 21971

ELECTRONICALLY FILED ON: December 20, 2016

M/S ISSUE FEE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Commissioner:

The present Amendment under 37 C.F.R. § 1.312 is filed after the Notice of Allowance mailed December 6, 2016.

Amendments to the Claims begin on page **2** of this paper.

Remarks and Conclusion are on page **5** of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces any and all prior listings of claims.

1. (Currently amended) A method of determining a presence of an arrhythmia of a first user, said method comprising

sensing a heart rate of said first user with a heart rate sensor coupled to said first user;

transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;

determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;

sensing an activity level of said first user with a motion sensor;

comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and

alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

2. (Original) The method of claim 1, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.
3. (Original) The method of claim 1, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.
4. (Original) The method claim 3, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.
5. (Cancelled).
6. (Previously presented) The method of claim 1, wherein said mobile computing device comprises a smartphone.
7. (Previously presented) The method of claim 1, wherein said mobile computing device comprises a smartwatch.

8. (Currently amended) The method of claim 1, further ~~comprises~~ comprising determining a presence of said arrhythmia using a machine learning algorithm.
9. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
10. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.
11. (Currently amended) A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, ~~compare said activity level to said heart rate variability of said first user, and~~ determine a heart rate variability of said first user based on said heart rate of said first user, compare said activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.
12. (Original) The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.
13. (Original) The system of claim 11, wherein said system further comprises a biometric data sensor, and wherein said computer program including instructions executable by said

processor further causes said processor to sense biometric data of said first user from said biometric data sensor.

14. (Original) The system claim 13, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.
15. (Cancelled)
16. (Previously presented) The system of claim 11, wherein said mobile computing device comprises a smartphone.
17. (Previously presented) The system of claim 11, wherein said mobile computing device comprises a smartwatch.
18. (Currently amended) The system of claim 11, ~~further comprises~~ wherein said computer program further causes said processor to ~~determining~~ determine a presence of said arrhythmia using a machine learning algorithm.
19. (Original) The system of claim 18, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
20. (Original) The system of claim 19, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.
21. (Currently amended) The method of claim 1, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.
22. (Currently amended) The system of claim 11, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.

REMARKS

Claim(s) 1, 8, 11, 18, 21, and 22 have been amended in order to correct certain formal errors not affecting the scope of the claims in accordance with 37 CFR 1.312. No new matter is introduced by these amendments. Applicants respectfully request consideration and entry of these proposed amendments.

CONCLUSION

Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at (858) 350-2365.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 41188-720.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

Date: December 20, 2016

By:/Uri Greenwald/
Uri Greenwald, MD, Esq.
Reg. No. 72686

650 Page Mill Road
Palo Alto, CA 94304
(858) 350-2300
Customer No. 21971

Electronic Acknowledgement Receipt	
EFS ID:	27855480
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Lora Kim
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	20-DEC-2016
Filing Date:	03-JUN-2015
Time Stamp:	19:07:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		41188_720301_312Amendment_DEC202016.pdf	38269 e381d55d8336639a18ad82e6f6691714f56f8940	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	38269	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

21971 7590 12/06/2016

WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER
JOHNSON, NICOLE F

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/06/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

TITLE OF INVENTION: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21971 7590 12/06/2016
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

TITLE OF INVENTION: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/06/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHNSON, NICOLE F	3762	600-508000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

21971 7590 12/06/2016

WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
JOHNSON, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/06/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/730,122	Applicant(s) GOPALAKRISHNAN ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the arguments and/or amendments*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-4, 6-14 & 16-22*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☒ Other *A. NE 11/14/16*.

/NICOLE F. JOHNSON/
Primary Examiner, Art Unit 3762

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

EXAMINER'S STATEMENT OF REASON FOR ALLOWABILITY

2. The following is an examiner's statement of reasons for allowance: The closest prior art, Levitan, fails to disclose, suggest and/or teach the claimed invention having a system and a method of determining a presence of an arrhythmia of a first comprising a means of sensing an activity level of said first user with a motion sensor and comparing a heart rate variability of said first user to said activity level, in combination with the other claimed elements (e.g., see 'Arguments').

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Allowable Subject Matter

3. Claims 1-4, 6-14 & 16-22 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. JOHNSON whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Koharski can be reached on 571-272-7230. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICOLE F. JOHNSON/
Primary Examiner, Art Unit 3762

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14730122	GOPALAKRISHNAN ET AL.
	Examiner	**Art Unit**
	NICOLE F JOHNSON	3762

CPC						
Symbol					**Type**	**Version**
A61B		5	/	02055	F	2013-01-01
A61B		5	/	02405	I	2013-01-01
A61B		5	/	0245	I	2013-01-01
A61B		5	/	02416	I	2013-01-01
A61B		5	/	046	I	2013-01-01
A61B		5	/	7264	I	2013-01-01
A61B		5	/	681	A	2013-01-01
A61B		5	/	0022	I	2013-01-01
A61B		5	/	7275	I	2013-01-01
A61B		5	/	021	A	2013-01-01
A61B		5	/	02438	A	2013-01-01
A61B		5	/	0452	A	2013-01-01
A61B		5	/	1118	A	2013-01-01
A61B		5	/	6898	I	2013-01-01
G06F		19	/	322	A	2013-01-01
G06F		19	/	3418	I	2013-01-01
G06F		19	/	3487	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/NICOLE F JOHNSON/ Primary Examiner.Art Unit 3762	11/28/16	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14730122	GOPALAKRISHNAN ET AL.
	Examiner	**Art Unit**
	NICOLE F JOHNSON	3762

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
600	508	A	6	1	B	5 / 02 (2006.0)						
CROSS REFERENCE(S)		A	6	1	B	5 / 04 (2006.01.01)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											
600	509											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/NICOLE F JOHNSON/ Primary Examiner.Art Unit 3762	11/28/16	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14730122	GOPALAKRISHNAN ET AL.
	Examiner	**Art Unit**
	NICOLE F JOHNSON	3762

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	18	19												
2	2	19	20												
3	3	10	21												
4	4	20	22												
5	6														
6	7														
7	8														
8	9														
9	10														
11	11														
12	12														
13	13														
14	14														
15	16														
16	17														
17	18														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/NICOLE F JOHNSON/ Primary Examiner.Art Unit 3762 (Primary Examiner)	11/28/16 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office

Part of Paper No. 20161127

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2971	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/28 09:45
L2	5119	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/28 09:45
L3	4594	a61b5/02405.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/28 09:45
S1	2755	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:05
S2	4833	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:07
S3	2551	(heart same "HRV")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S4	620	S3 and ((score or value) same 'HRV')	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S5	269	S4 and arrhythmia	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S6	3396	a61b5/02405.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:16
S7	161	S5 and @py<="2012"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:16
S8	2	"20120197148" and external	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 09:47
S9	2	"20120197148" and (display and algorithm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 10:11
S10	2	"20120197148" and screen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 10:13
S11	2846	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/02/17 09:59
S12	3	"20120197148"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/02/18 17:17
S13	2	S12 and motion	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2016/02/18 17:17

			IBM_TDB			
S14	2908	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:09
S15	5031	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:12
S16	4046	a61b5/02405.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:12
S18	3	"20120197148"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:30
S20	2	S18 and alarm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:41
S21	3	"20120197148"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/27 14:22
S22	0	S21 and (motion same (sensor or signal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/27 14:23
S23	2971	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/27 14:23
S24	5119	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/11/27 14:23

11/28/2016 10:44:39 AM
C:\Users\nlavert\Documents\EAST\Workspaces\14730122.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14730122	GOPALAKRISHNAN ET AL.
	Examiner	Art Unit
	NICOLE F LAVERT	3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner
A61B5/02405	2/17/2016	NFL
ABOVE UPDATED	6/7/2016	NFL
ABOVE UPDATED	11/28/2016	NFJ

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	508-509	2/17/2016	NFL
ABOVE	UPDATED	6/7/2016	NFL
ABOVE	UPDATED	11/28/2016	NFJ

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Search (eDAN)	2/17/2016	NFL
EAST Search (see attachment)		
Consulted Search notes from 14/569513		

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
Searched the classes and subclasse from the Searched notes	Searched the USPAT, USOCR, USPGPUB, EPO, JPO, DERWENT, etc. databases	11/28/2016	NFJ

OK TO ENTER: /N.L./

11/28/2016

PATENT
Attorney Docket No.: 41188-720.301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Inventor(s): Ravi GOPALAKRISHNAN, et al. Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Group Art Unit: 3762 Examiner: JOHNSON, NICOLE F. Confirmation No.: 2113 Customer No.: 21971 Certificate of Electronic Filing I hereby certify that the attached Response to Final Office Action is being deposited by Electronic Filing on 11/14/2016, by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: /Lora Kim/ Lora C. Kim

M/S AFTER FINAL
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION DATED JUNE 13, 2016

Dear Commissioner:

Applicants hereby submit a response to the Office Action dated June 13, 2016. Applicants also request a one-month extension of time to allow the timely filing of all required items in the Office Action as mailed. Since November 13, 2016 falls on a Sunday, Applicant believes that this response is being timely filed. The Commissioner is hereby authorized to charge any additional fees due to Deposit Account No. 23-2415, referencing Docket No. 41188-720.301. Consideration of the above-referenced application is respectfully requested in view of the following remarks.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-6047206	04-04-2000	ALBRECHT; Paul et al.	
	002	US-7162291	01-09-2007	NACHALIEL; Ehud	
	003	US-8725229	05-13-2014	FURUE; Masaaki et al.	
	004	US-9420956	08-23-2016	GOPALAKRISHNAN; Ravi et al.	
	005	US-20050239493	10-27-2005	BATKIN; Izmail et al.	
	006	US-20070073266	03-29-2007	CHMIEL; Alan et al.	
	007	US-20120083705	04-05-2012	YUEN; Shelten Gee Jao et al.	
	008	US-20120289790	11-15-2012	JAIN; Jawahar et al.	
	009	US-20130281816	10-24-2013	STRAUSS; Benjamin Jordan et al.	
	010	US-20140051941	02-20-2014	MESSERSCHMIDT; Robert G.	
	011	US-20140051946	02-20-2014	ARNE; Lawrence et al.	
	012	US-20140073969	03-13-2014	ZOU; Rui et al.	
	013	US-20140114166	04-24-2014	BAXI; Amit	
	014	US-20140163927	06-12-2014	MOLETTIERE; Peter Andrew et al.	
	015	US-20140221859	08-07-2014	ALBERT; David E.	
	016	US-20150182132	07-02-2015	HARRIS; Paul Ronald et al.	
	017	US-20160235319	08-18-2016	ALBERT; David E.	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	EP-2192526-A2	06-02-2010	FUJITSU LTD [JP]		☐
	002	EP-3079571-A1	10-19-2016	ALIVECOR INC [US]		☐
	003	JP-2006180899-A	07-13-2006	SHARP KK.	Abstract:	☒
	004	JP-2008532587-A	08-31-2006	SOFTWARE SOLUTIONS LTD [GB], et al.	English counterpart is attached: See WO 2006/090371-A2 for English	☒
	005	JP-2010166961-A	08-05-2010	PARAMA TEC KK.	Abstract:	☒
	006	WO-2009112976-A1	09-17-2009	KONINKL PHILIPS ELECTRONICS NV [NL], et al.		☐

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	001	CARPENTER and FRONTERA, Smart-watches: a potential challenger to the implantable loop recorder? Europace, 18:791-793, 2016.	☐
	002	European Patent Application No. 14785223.0 extended European Search Report dated August 23, 2016.	☐
	003	Japanese Patent Application No. 2014-511335 Decision of Rejection dated July 28, 2016.	☒
	004	Japanese Patent Application No. 2014-554916 Office Action dated September 26, 2016.	☒
	005	Notice of Allowance issued June 16, 2016 for U.S. Patent Application No. 14/569,513.	☐
	006	Notice of Allowance issued March 29, 2016 for U.S. Patent Application No. 14/254,310.	☐
	007	PCT Patent Application No. PCT/US2014/070170 International Preliminary Report on Patentability dated June 23, 2016.	☐
	008	PCT/US2016/032524 International Search Report and Written Opinion dated August 19, 2016.	☐
	009	U.S. Patent Application No. 14/479,105 Office Action dated July 22, 2016.	☐
	010	U.S. Patent Application No. 14/494,191 Office Action dated July 20, 2016.	☐

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	Ravi Gopalakrishnan
Art Unit	3762
Examiner Name	Nicole Johnson
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	011	U.S. Patent Application No. 14/479,105 Office Action dated August 25, 2015	
	012	U.S. Patent Application No. 14/569,513 Office Action dated October 6, 2015	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Electronic Acknowledgement Receipt	
EFS ID:	27580070
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/DG/Maki Howes
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	21-NOV-2016
Filing Date:	03-JUN-2015
Time Stamp:	20:33:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP2192526A2.pdf	8648919 f3dcaac3b25f3a150a267f18915bc7db6d601210	no	58
Warnings:					

Information:					
2	Foreign Reference	EP3079571A1.pdf	15512 181286bd3234535f0e833516b4ed551966e1de45	no	1
Warnings:					
Information:					
3	Foreign Reference	JP2006180899A_EngAbstract.pdf	135066 d84b9b001ae937503340efd7e17d69a9bed44d70	no	1
Warnings:					
Information:					
4	Foreign Reference	WO06090371.pdf	3992254 ccf3ec4bc12d47f0859d36e51d6d81e6a9668fbf	no	79
Warnings:					
Information:					
5	Foreign Reference	JP2010166961A_EngAbstract.pdf	150110 e8745a3079ad9491345f0b149e809ab06354056f	no	2
Warnings:					
Information:					
6	Foreign Reference	WO09112976.pdf	4160542 8e43ac8de91848b323578b1301807d844f7da3ac	no	98
Warnings:					
Information:					
7	Non Patent Literature	Carpenter.pdf	495762 125145cd0f8f873718e388c4c97742175c0e27dc	no	3
Warnings:					
Information:					
8	Non Patent Literature	EP147852230_EESR_23AUG2016.pdf	293663 4e340450b68713e5ee06f5bf2cb8a2c67c3559c7	no	8
Warnings:					
Information:					

9	Non Patent Literature	JP2014511335_OA_Eng_28JUL2016.pdf	141512 f323d722be2366554672fb92da237fad9260bc10	no	2
Warnings:					
Information:					
10	Non Patent Literature	JP2014554916_OA_26SEPT2016.pdf	1610251 242d32447aeb1142520ba546d13ae0c8bc57618a	no	5
Warnings:					
Information:					
11	Non Patent Literature	US14569513_NOA_16JUN2016.pdf	151566 4d9d0cb1cf39e2ab1a9b88226feda654ff616a28	no	4
Warnings:					
Information:					
12	Non Patent Literature	US14254310_NOA_29MAR2016.pdf	414778 2589375a57349003dbeb39b1bd4580934f7d47ba	no	7
Warnings:					
Information:					
13	Non Patent Literature	PCTUS2014070170_IPRP_23JUN2016.pdf	396259 e72ad87b57f883da784da3b414998d44901de355	no	7
Warnings:					
Information:					
14	Non Patent Literature	PCTUS2016032524_ISRWO_19AUG2016.pdf	643558 e6ac8d41c4b666c29121d9fbd50ab42d8d4bc2ec	no	9
Warnings:					
Information:					
15	Non Patent Literature	US14479105_OA_22JUL2016.pdf	998853 41b9968f9e4e9aff45e45595f83d76f26bc8c778	no	20
Warnings:					
Information:					

16	Non Patent Literature	US14494191_OA_20JUL2016.pdf	144345 9c159fc5c0eb46569cdf5bf35b401d9e27108cf2	no	8
Warnings:					
Information:					
17	Non Patent Literature	US14479105_OA_25AUG2015.pdf	257225 1c3d42bf06ee3ea6ba8d5eae614f12d35babb902	no	7
Warnings:					
Information:					
18	Non Patent Literature	US14569513_OA_06OCT2015.pdf	198851 6a01eb04ad812026dc980a68edae7a7b39271510	no	5
Warnings:					
Information:					
19		41188_720_301_sIDS_11212016.pdf	263953 db7ac045fffe53f3acdd415d196d3cd6beb23ca7	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	4
	Information Disclosure Statement (IDS) Form (SB08)	5	8
Warnings:			
Information:			
	Total Files Size (in bytes):	23112979	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 192 526 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
02.06.2010 Bulletin 2010/22

(51) Int Cl.:
G06K 9/00 *(2006.01)*

(21) Application number: **09177317.6**

(22) Date of filing: **27.11.2009**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **27.11.2008 JP 2008303258**

(71) Applicant: **Fujitsu Limited**
Kawasaki-shi, Kanagawa 211-8588 (JP)

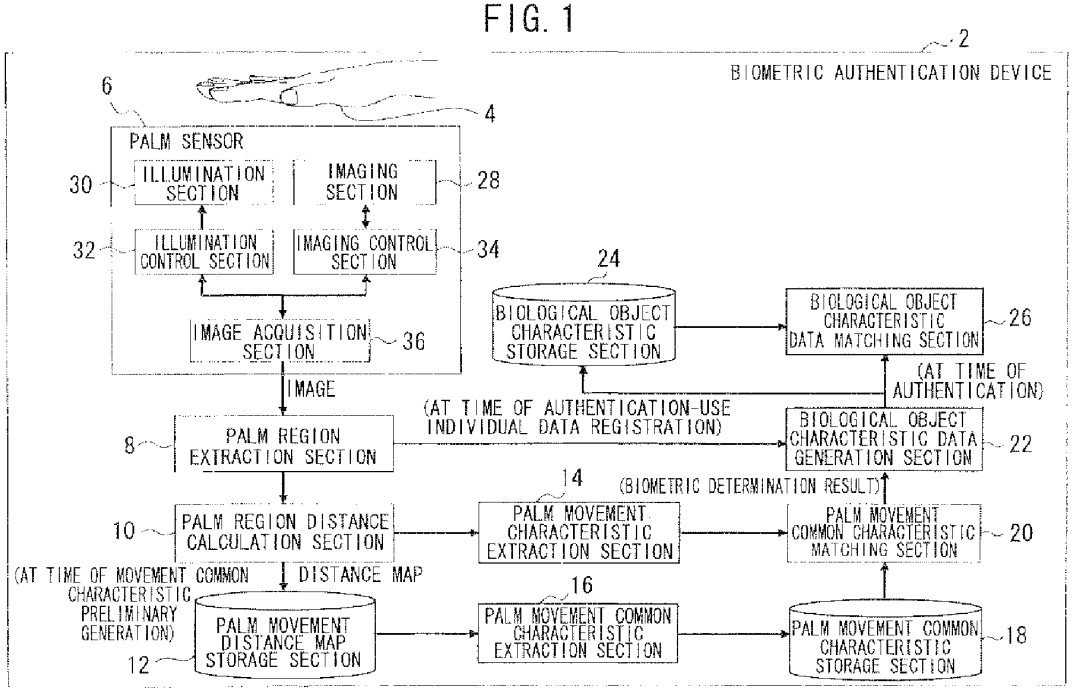
(72) Inventor: **Watanabe, Masaki**
Kanagawa 211-8588 (JP)

(74) Representative: **HOFFMANN EITLE**
Patent- und Rechtsanwälte
Arabellastrasse 4
81925 München (DE)

(54) Biometric authentication device, biometric authentication method, and recording medium

(57) A biometric authentication device and method include extracting movement information representing bending and stretching of an imaging object from a plurality of images obtained, and determining whether or not the imaging object is a biological object, based on the movement information.

FIG. 1



EP 2 192 526 A2

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND

1. Field

[0001] Embodiments described herein relate to a biometric determination using images acquired from a biological object, such as a palm, etc.

2. Description of the Related Art

[0002] For example, there is a biometric authentication which uses a vascular pattern of a palm. This authentication utilizes the fact that reduced hemoglobin in blood vessels absorbs near-infrared light. This reduced hemoglobin is included in veins near the surface of the palm. Reflected light of near-infrared light illuminated onto the palm is imaged. From an image obtained by this means, it is possible to extract a vein pattern of the palm as a black line portion. By using this vein pattern, it is possible to identify a biological object, and it is possible to check an individual who is a biological object.

[0003] In relation to a biometric determination performed as a preliminary to this kind of authentication, Japanese Laid-open Patent Publication No. 2003-111749 discusses one which measures electrical output characteristics of a body and, by comparing them with electrical output characteristics of a human body, determines whether or not the body is a human body.

[0004] Also, Japanese Patent Application Publication No. 2007-524441 discusses a biometric determination which analyzes scattered light of light illuminated onto a body using a multi-spectrum, and confirms whether or not a frequency configuration of the scattered light is the same as one emitted from a human body.

[0005] Also, Japanese Laid-open Patent Publication No. 2002-150296 discusses a dynamic biometric authentication which two-dimensionally treats and matches a matching of people's movements, and images.

SUMMARY

Technical Problem

[0006] However, the kind of electrical output characteristic measurement described in Japanese Laid-open Patent Publication No. 2003-111749 requires bringing one portion of a biological object into contact with a device, so is not suitable for a non-contact type of palm vein recognition. Also, this method requiring a disposition of an antenna as well as a sensor, it is necessary to install a device other than a sensor. Also, the kind of scattered light multi-spectral analysis described in Japanese Patent Application Publication No. 2007-524441 requires a device for checking light frequency characteristics. This kind of device being generally highly-priced, the cost of the sensor increases. Also, the kind of collation which two-dimensionally treats and collates a collation of people's movements, and images, described in Japanese Laid-open Patent Publication No. 2002-150296 gives rise to errors because people's movements are three-dimensional.

[0007] Japanese Laid-open Patent Publication No. 2003-111749, Japanese Patent Application Publication No. 2007-524441, and Japanese Laid-open Patent Publication No. 2002-150296 do not disclose or hint at these kinds of requirement and problem, neither do they disclose or hint at configurations or the like for solving them.

[0008] Therein, an object of a biometric authentication device, biometric authentication method, or recording medium on which is recorded a biometric authentication program of the present disclosure, relating to a biometric determination, is to use a movement of an object being checked to determine whether or not the object is a biological object.

[0009] Also, another object of the biometric authentication device, biometric authentication method, or recording medium on which is recorded the biometric authentication program of the present disclosure, relating to a biometric determination, is to use a movement of the biological object to determine whether or not it is a registered person.

Solution to Problem

[0010] According to an embodiment, a biometric authentication device includes an imaging section, and a determination section which extracts movement information representing bending and stretching of an imaging object from a plurality of images obtained from the imaging section, and determines whether or not the imaging object is a biological object, based on the movement information. According to embodiments described, a biometric authentication method and a computer readable medium storing a program are provided.

[0011] The object and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the claims. It is to be understood that both the foregoing general description and the

following detailed description are exemplary and explanatory and are not restrictive of the invention, as claimed.

[0012] Additional aspects and/or advantages will be set forth in part in the description which follows and, in part, will be apparent from the description, or may be learned by practice of the invention.

Advantageous Effects of Invention

[0013] According to the biometric authentication device, biometric authentication method, or recording medium on which is recorded the biometric authentication program of the present disclosure, the following kinds of advantageous effect are obtained.

[0014] 1. As the configuration of the present disclosure causes bending and stretching of a biological object which is to be an imaging object, images it, and determines using movement information of the biological object from a plurality of images obtained with the imaging, the accuracy of a determination of whether or not the imaging object is a biological object is increased.

[0015] 2. As the configuration of the present disclosure causes bending and stretching of a biological object which is to be an imaging object, images it, and determines whether or not the imaging object is a biological object using movement information of the biological object from a plurality of images obtained with the imaging, there is an increase in the accuracy of a determination of whether or not a person being checked is a registered person which uses a comparison of the obtained movement information of the biological object and registered movement information.

[0016] 3. As the configuration of the present disclosure determines whether or not an imaging object is a biological object by means of a collation using a common model of a movement due to bending and stretching of a biological object, it is possible to determine whether or not the imaging object is a biological object, even in the event that a movement of a biological object at a time of registration and the movement of the biological object at a time of determination differ slightly.

[0017] 4. The configuration of the present disclosure, for a non-contact type of vascular pattern recognition and the like, can realize a determination using images of a biological object of whether or not an object is a biological object with a low-priced sensor.

[0018] 5. As the configuration of the present disclosure, can collate using movements common to humans, and also, can extract and collate three-dimensional information from a plurality of images, the accuracy of a determination of whether or not an object is a biological object is increased.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] These and/or other aspects and advantages will become apparent and more readily appreciated from the following description of the embodiments, taken in conjunction with the accompanying drawings of which:

Fig. 1 depicts a biometric authentication device according to an embodiment;
Fig. 2 depicts one example of an operation of a palm sensor;
Fig. 3 is a flowchart depicting a comprehensive biometric determination process;
Fig. 4 is a flowchart depicting a palm movement common characteristic generation process procedure;
Fig. 5 is a flowchart depicting a determination-use biological object characteristic registration process procedure for a person being checked;
Fig. 6 is a flowchart depicting a determination process procedure;
Figs. 7A, 7B and 7C are diagrams for illustrating an extraction of a palm region;
Fig. 8 is a photograph depicting an image depicting a palm in a condition in which there is illumination;
Fig. 9 is a photograph depicting an image of a palm in a condition in which there is no illumination;
Fig. 10 is a diagram for illustrating a height detection principle;
Fig. 11 is a diagram illustrating calculating of a height;
Fig. 12 is a diagram for illustrating a principle of carrying out a conversion of a distance using a reflection coefficient;
Fig. 13 depicts an image of a calibration surface;
Fig. 14 depicts a distance map;
Fig. 15 depicts a palm sensor used in a distance map generation;
Fig. 16 depicts a distance map generation function section;
Fig. 17 is a flowchart depicting a procedure of a preliminary process for a distance map generation;
Fig. 13 is a flowchart depicting a procedure of an execution process for a distance map generation;
Fig. 19 is a photograph depicting a palm region distance calculation example;
Fig. 20 is a flowchart depicting a palm movement extraction process procedure;
Fig. 21 is a flowchart depicting a palm movement information representation normalization process procedure;
Figs. 22A and 22B depict a condition in which a palm is open and a condition in which the palm is starting to be closed;

Fig. 23 depicts image frames;
Fig. 24 is a diagram depicting a palm region height normalization;
Figs. 25A and 25B are diagrams depicting a palm region size normalization;
Figs. 23A and 26B are diagrams depicting a palm region position normalization;
Figs. 27A and 27B are diagrams depicting a palm region orientation normalization;
Fig. 28 is a diagram depicting a palm movement frame temporal normalization;
Figs. 29A and 29B are diagrams depicting palm movement common characteristics and movement characteristics of a person being checked;
Figs. 30A and 30B are image frame comparison diagrams;
Fig. 31 is a flowchart depicting a process procedure according to an embodiment;
Fig. 32 is a diagram depicting an oval sphere which is fitted into a normalized palm image;
Figs. 33A, 33B, 33C, 33D and 33E are diagrams depicting a fitting in of an oval sphere in an opening and closing of a palm;
Fig. 34 is a flowchart depicting a process procedure according to an embodiment;
Figs. 35A, 35B and 35C are diagrams for illustrating a calculation of shapes of surface of a palm;
Fig. 36 is a flowchart depicting a process procedure according to an embodiment; and
Fig. 37 depicts a hardware configuration of a biometric authentication device according to an embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

[0020] Reference will now be made in detail to the embodiments, examples of which are illustrated in the accompanying drawings, wherein like reference numerals refer to the like elements throughout. The embodiments are described below to explain the present invention by referring to the figures.

[0021] Figs. 1 and 2 will be referred to with regard to an embodiment. Fig. 1 depicts a biometric authentication device. Fig. 2 depicts one example of an operation of a palm sensor. The configurations shown in Figs. 1 and 2 being examples, the invention is not limited to these kinds of configuration.

[0022] This biometric authentication device 2 is one example of an authentication device. The biometric authentication device 2 images (captures) an image including based on an operation of a palm shifting from an open state to a closed state, that is, an operation of shifting from an open state by for example a gripping operation, as bending and stretching of a biological object such as a hand, and acquires a plurality of images. Then, the biometric authentication device 2 obtains palm movement information from the images, and determines whether or not the imaged object is a human hand. In the event that the movement is not that of a human palm, the biometric authentication device 2 determines that the imaged object is not a palm, that is, not a biological object. The biometric authentication device 2 can be used in biometric authentication using vein recognition, and the like. A three-dimensional measuring technique based on brightness using active illumination is used for a measurement of a shape of an object of authentication with the biometric authentication device 2. The determination with the biometric authentication device 2 of whether or not an object is a biological object utilizes movements common to all humans, rather than individual movements of the person being checked. Then, the determination confirms a similarity with movement characteristics extracted from movement information based on a three-dimensional shape, rather than a similarity of operational images.

[0023] The biometric authentication device 2 takes, for example, a palm 4 as an object of determination, as a determination region of a biological object, as shown in Fig. 1. The biometric authentication device 2 includes a palm sensor 6, a palm region extraction section 8, a palm region distance calculation section 10, a palm movement distance map storage section 12, a palm movement characteristic extraction section 14, a palm movement common characteristic extraction section 16, a palm movement common characteristic storage section 18, a palm movement characteristic matching section 20, a biological object characteristic data generation section 22, a biological object characteristic storage section 24, and a biological object characteristic data matching section 26.

[0024] The palm sensor 6, being one non-limiting example of a biometric sensor which acquires an image from a biological object, a specific site of a biological object, or the like, is one example of a detection section which acquires from the palm 4, which is the object of determination, an image used in the determination of whether or not it is the person. The palm sensor 6 captures light reflected from the palm 4, which is illuminated with light, imaging the palm 4, and acquires images thereof. The palm sensor 6 includes an imaging section 28, an illumination section 30, an illumination control section 32, an imaging control section 34, and an image acquisition section 36. The imaging section 28, being one example of an imaging section which images the palm 4, is an imaging instrument such as a digital camera. The imaging section 28 acquires images for reading a vascular pattern of the palm 4. This embodiment acquires images capturing a movement from an open state to a closed state of the palm 4, and images capturing a movement from the closed state to the open state of the palm 4. The imaging control section 34 controls the number of imagings in accordance with the timing of the imaging, and the operational shift of the palm 4.

[0025] The illumination section 30 is one example of a illuminating section which illuminates the palm 4, which is the

object of determination, with light. The illumination section 30 includes two functions. A first function is a function which uniformly illuminates the palm 4 with light in order to read the vascular pattern of the palm 4. A second function is a function which, in order to measure a distance from the palm sensor 6 (imaging section 28) to the palm 4, emits a beam of light in a known direction differing from an optical axis of the imaging section 28. It is sufficient that the light used in the imaging is of a wavelength within the detection range of the imaging section 28. As shown in Fig. 2, the palm 4, which receives the illumination light from the illumination section 30, reflects the light. The imaging section 28, which captures the reflected light, images the palm 4. The illumination control section 32 controls the light of the illumination section 30, and an emission amount thereof.

[0026] The image acquisition section 36 acquires the images obtained by the imaging section 28. Image information output from the image acquisition section 36 is added to the palm region extraction section 8.

[0027] The palm region extraction section 8 is one example of an extraction section which extracts a region of a biological object. In an embodiment, the palm region extraction section 8, being a unit extracting a palm region which is an object of determination information, extracts a palm region using, for example, an image processing.

[0028] The palm region distance calculation section 10 is one example of a calculation section which calculates a distance of a biometric region. In an embodiment, the palm region distance calculation section 10, being a processing section which calculates a distance of an optional portion of the palm 4, which is the object of determination, whose position is known, calculates a distance of the palm region based on the image information. A relative reflection coefficient of the palm 4 with respect to a reference object can be calculated based on an image which images a reference object having a uniform identical reflection coefficient existing at a known distance, and on an optional distance, whose position is known, at which the palm 4 exists. The palm region distance calculation section 10, using this relative reflection coefficient, calculates the distance between the palm sensor 6 and the palm region by using, for example, a principle wherein the strength of the light is inversely proportional to the square of the distance.

[0029] The palm movement distance map storage section 12 is an example of a biological object movement distance map storage section. The palm movement distance map storage section 12, being, for example, a data storage section, stores a distance map generated from the distance calculated with the palm region distance calculation section 10.

[0030] The palm movement characteristic extraction section 14 is one example of a processing section which extracts movement characteristics of a biological object. In an embodiment, the palm movement characteristic extraction section 14 extracts movement characteristics of the palm 4. The palm movement characteristic extraction section 14 extracts the movement characteristics of the palm 4 based on the palm region distance calculated by the palm region distance calculation section 10.

[0031] The palm movement common characteristic extraction section 16 is one example of a processing section which extracts biological object movement common characteristics. In an embodiment, the palm movement common characteristic extraction section 16 is a processing section which extracts characteristics common to movements of the palm 4. The palm movement common characteristic extraction section 16 extracts common characteristics of the movements of the palm 4 based on a distance map, which expresses the movements of the palm 4, stored in the palm movement distance map storage section 12.

[0032] The palm movement common characteristic storage section 18 is one example of a storage section which stores biological object movement common characteristics. For example, the palm movement common characteristic storage section 18, being a data storage section, stores the common characteristics of the movements of the palm 4 extracted with the palm movement common characteristic extraction section 16.

[0033] The palm movement characteristic matching section 20 is one example of a matching section which matches movement characteristics of a biological object. In an embodiment, the palm movement characteristic matching section 20 is one example of a determination section which matches the movement characteristics of the palm 4, and determines whether or not it is a biological object. The palm movement characteristic matching section 20 matches the movement characteristics of the palm 4 at a time of registration or a time of authentication, and outputs a matching result as a result of the determination of whether or not it is a biological object.

[0034] The biological object characteristic data generation section 22 is one example of a processing section which generates biological object characteristic data. The biological object characteristic data generation section 22 generates biological object characteristic data using palm region information from the palm region extraction section 8, and palm movement characteristic information from the palm movement characteristic matching section 20.

[0035] The biological object characteristic storage section 24 is one example of a storage section which stores biological object characteristic data. The biological object characteristic storage section 24 stores, for example, personal authentication data such as vein recognition data.

[0036] The biological object characteristic data matching section 26 is one example of a matching section which matches biological object characteristic data at a time of authentication. The biological object characteristic data matching section 26 matches registration data stored in the biological object characteristic storage section 24, and the biological object characteristic data obtained by the biological object characteristic data generation section 22. Depending on whether or not the biological object characteristic data, which are the object of determination, match the registration

data, the biological object characteristic data matching section 26 determines whether or not the person being checked is a registered person. That is, after the determination that the person being checked is a biological object, an authentication of whether or not he or she is a registered person is carried out.

[0037] Next, Figs. 3 to 6 will be referred to with regard to the determination of whether or not the person being checked is a biological object. Fig. 3 is a flowchart depicting a comprehensive biometric determination process. Fig. 4 is a flowchart depicting a palm movement common characteristic generation process procedure. Fig. 5 is a flowchart depicting a determination-use biological object characteristic registration process procedure. Fig. 6 is a flowchart depicting a procedure of the determination process. The processes shown in Figs. 3 to 6 being examples, the invention is not limited to these processes.

[0038] In this biometric determination, a process procedure (Fig. 3) is used which carries out a determination using characteristic information of a movement, for example, an operation of shifting from an open state to a closed state, of the palm 4 as the biological object. This process procedure is one example of a process carried out using a biometric authentication method or biometric authentication program. As shown in Fig. 3, the process procedure generates palm movement common characteristics (operation S1), registers determination-use biological object characteristics of the person being checked (operation S2), and carries out the determination process using the registered information (operation S3). As sub-routines of the main routine, which is this process procedure, the palm movement common characteristic generation process procedure (Fig. 4), the determination-use biological object characteristic registration process procedure for the person being checked (Fig. 5), and the determination process procedure (Fig. 6) are executed.

[0039] As shown in Fig. 4, the palm movement common characteristic generation process procedure includes stages of a process for all of a plurality of people (F0), an imaging of a movement of the palm 4 of the plurality of people (F1), and a conversion to a distance map of each image obtained by the imaging (F2). By means of this process procedure, palm movement common characteristics are extracted based on the distance maps of the plurality of people.

[0040] As the process F0 for all of the plurality of people, the process procedure starts imaging (operation S11), and prompts the person being checked to open the palm 4 (operation S12). The person being checked, complying with the prompt, opens the palm 4, putting it into the open state. At this point, a motionlessness of the palm 4 is confirmed (operation S13). Next, the process procedure prompts the person being checked to close the palm 4 from the motionless state (operation S14), images the palm 4 during the shift in state from the open state to the closed state, and acquires a plurality of images. Subsequently, the process procedure finishes the imaging (operation S15), carries out a conversion to a distance map as a processing of each imaged frame (operation S16), executes processing for each frame, and generates movement characteristics (operation S17) across data captured for the plurality of people (users). Continuing, the process procedure calculates an average of each person's movement characteristics from the plurality of images acquired (operation S18), stores it in the palm movement common characteristic storage section 18 (operation S19), and finishes the process.

[0041] The determination-use biological object characteristic registration process procedure for the person being checked includes a matching process F3 (Fig. 5) with movement common characteristics executed before the registration. As shown in Fig. 5, the process procedure images the movement of the palm 4 of the person being checked (operation S21), converts the imaged frame into a distance map (operation S22), and extracts movement characteristics of the palm 4 (operation S23). After this process is finished, the previously mentioned matching process F3 is executed.

[0042] The matching process F3 compares the palm movement characteristics of the person being checked with the palm movement common characteristics (operation S24), and carries out a determination of whether or not they match (operation S25). If it is determined that they match (operation S25: Yes) in the matching process F3, the process procedure extracts biological object characteristics from the image frame obtained by the imaging (operation S26), stores the biological object characteristics in the biological object characteristic storage section 24 (operation S27), and finishes the process.

[0043] Also, if there is no match in operation S25 (operation S25: No), the matching process F3 determines that registration is not possible (NG) (operation S28), and finishes the process.

[0044] The determination process procedure, including a matching of the movement extracted from the image and the common characteristics (F4), and a matching of the biological object characteristics extracted from the image frame and the registered biological object characteristics (F5), carries out a determination of whether or not the palm is a biological object based on these matchings. Therein, as shown in Fig. 6, the process procedure images the movement of the palm 4 of the person being checked (operation S31), and converts the imaged frame into a distance map (operation S32). Also, the process procedure extracts movement characteristics of the palm 4 from the imaged frame (operation S33), compares the palm movement characteristics of the person being checked with the palm movement common characteristics (operation S34), and carries out a determination of whether or not they match (operation S38). If it is determined that they match (operation S35: Yes), the pracess-procedure extracts biological object characteristics from the imaged frame (operation S36), retrieves the registered biological object information of the person being checked from the biological object characteristic storage section 24 (operation S37), and compares the biological object characteristics extracted from the imaged frame and the biological object characteristics retrieved from the biological object

characteristic storage section 24 (operation S38), The process procedure, based on the comparison, carries out a determination of whether or not there is a match (operation S39) and, if there is a match (operation S39: Yes), determines that registration is possible (operation S40), while if there is no match (operation S39: No), it determines that registration is not possible (NG) (operation S41), and finishes the process.

[0045] Also, if there is no match in operation S35 (operation S35: No), the process procedure determines that registration is not possible (NG) (operation S41), and finishes the process.

[0046] Next, Figs. 7A, 7B, 7C, 8, and 9 will be referred to with regard to the extraction of the palm region. Figs. 7A to 7C are diagrams for illustrating the extraction of the palm region. Fig. 8 is a photograph illustrating an image illustrating the palm in a condition in which there is illumination. Fig. 9 is a photograph illustrating an image illustrating the palm in a condition in which there is no illumination. Figs. 7A to 7C, 8, and 9 being examples, the invention is not limited to these configurations.

[0047] The strength of the illumination of the palm 4 is adjusted or set in connection with the extraction of the palm region. Taking a range within a certain distance, for example, approximately 10cm., from the illumination section 30 as an illumination limit, the strength is set so as the light does not reach beyond the range. In the case of this kind of setting, the person being checked holds the palm 4 over the palm sensor 6 in such a way that it is at a distance within approximately 10cm. from the palm sensor 6. The imaging section 28 takes an image in which the palm 4 receiving light is imaged (Figs. 7A and 8), and an image in which the palm 4 is imaged with the light extinguished (Figs. 7B and 9). In an image 38 obtained by imaging the palm 4 receiving light, a background image 42 appears together with an image 40 representing the palm 4, as shown in Fig. 7A. In an image 44 obtained by imaging the palm 4 with the light extinguished, the image 40 representing the palm 4, and the background image 42, both appear dimly, as shown in Fig. 7B.

[0048] Therein, by calculating a difference between the images 38 and 44, a portion (the background image 42) other than the image 40 representing the palm 4 is removed from the image 44, as shown in Fig. 7C. As a result, a clear image 40 of the palm 4 is obtained. That is, the palm region can be extracted as a region in the difference image in which a luminance value is not zero, that is, as a region in the difference image which has a luminance value equal to or greater than a certain threshold value. Fig. 8 is an actual image wherein the palm 4 receiving light is imaged. Fig. 9 is an actual image wherein the palm 4 is imaged with the light extinguished.

[0049] To describe in more detail, the following kind of process is carried out in the extraction of the palm region. An image obtained by illuminating the palm 4 with light, and imaging, is taken to be $I_{on}(x,y)\{0<x<w, 0<y<h\}$. This being a two-dimensional array, a luminosity value is stored in each element as an unsigned 8 bit integer. w indicates the width of the image, while h indicates the height of the image.

[0050] An image obtained by extinguishing the illumination section 30, and imaging the palm 4 with no illumination light, is taken to be $I_{off}(x,y)\{0<x<w, 0<y<h\}$.

[0051] The difference between the two images is taken for each element of these arrays, that is, each (i,j) pair of $0<i<w$, $0<j<h$. When the absolute value of the difference is less than a predetermined threshold value t, it is determined that the elements of the arrays (pixels in the image) are not the palm region. This is expressed by the following kind of formula (1).

$$\left| I_{on}(x,y) - I_{off}(x,y) \right| \geq t \qquad \cdots(1)$$

[0052] It is determined that pixels (i,j) which satisfy the formula (1) are the palm region, while pixels which do not satisfy the formula (1) are not the palm region.

[0053] Next, Figs. 10 to 19 will be referred to with regard to calculation of a palm region distance and a distance map. Fig. 10 is a diagram for illustrating a height detection principle. Fig. 11 is a diagram for calculating a height. Fig. 12 is a diagram for illustrating a principle of carrying out a conversion of a distance using a reflection coefficient. Fig. 13 depicts an image of a calibration surface. Fig. 14 depicts a distance map. Fig. 15 depicts a palm sensor used in a distance map generation. Fig. 16 depicts a distance map generation function section. Fig. 17 is a flowchart depicting a procedure of a preliminary process for a distance map generation. Fig. 18 is a flowchart depicting a procedure of an execution process for a distance map generation. Fig. 19 is a photograph depicting a palm region distance calculation example. Figs. 10 to 19 being examples, the invention is not limited to them. In Figs. 12, 15, and 16, portions that are the same as those in Fig. 1 are given the same reference numerals and characters as in Fig. 1.

[0054] In the calculation of the distance to the palm region, a height l is calculated of a position 48 on the palm 4 where a light beam 46 illuminated from a light source 31 hits, as shown in Fig. 10. The light source 31 which emits the light beam 46 is disposed in a position a distance d away from the imaging section 28, within a plane 52 which intersects perpendicularly with an optical axis 50 of the imaging section 28, including a lens focal point. The direction of the light

beam 46 has a tilt of an angle θ with respect to the optical axis 50 of the imaging section 28, in the case of Fig. 10, with respect to the central axis of the light source 31, which is parallel to the optical axis 50, within a plane including the imaging section 28, its optical axis 50, and the light source 31.

[0055] Taking a half of the field angle of the imaging section 28 as α, and the height from the lens focal point to the palm 4 as l, the angle formed by the plane 52, including the imaging section 28 and light source 31, with the horizontal axis of an image 64 is taken as φ (Fig, 11). Then, it is taken that edges of the plane 52 and image 64 intersect, as shown in Fig. 11. As a relative relationship of the position 48 of the light beam 46 and the edge of the image 64 in the image 64, and their relative relationship in the actual world, are identical, the following formula (2) is established.

$$\frac{a}{W} = \frac{d + l\tan\theta}{l\tan\alpha} \qquad \cdots(2)$$

[0056] Note that W=h/sinφ, and a=d+x. By solving the formula (2) based on the height l of the palm 4, the following formula (3) is obtained.

[0057]

$$l = \frac{d}{\frac{a}{W}\tan\alpha - \tan\theta} \qquad \cdots(3)$$

[0058] According to the formula (3), the height l of the palm 4 is obtained based on the position 48 in the image 64 where the light beam 46 hits. The position 48 in the image 64 where the light beam 46 hits is obtained by taking the difference between an image for which the light beam 46 is turned on and an image for which the light beam 46 is extinguished, and calculating the coordinates of the center of a region which appears brightly in the difference image.

[0059] Next, a description will be given, referring to Fig. 12, of the principle of carrying out a conversion of a distance using a reflection coefficient, utilizing a measurement result which acts as a reference. As shown in Fig. 12, it is taken that paper of a uniform color is disposed at a known height Z_C, and an image relating to a brightness on an imaged calibration surface 66 is obtained. Actually, an image 68 shown in Fig. 13 is obtained as the calibration surface 66. As the brightness diminishes in inverse proportion to the square of the distance, the six variables in Fig. 12 are obtained from the following formula (4).

$$Z_F = \sqrt{\frac{r_F E_C}{r_C E_F}} Z_C \qquad \cdots(4)$$

[0060] By this means, when using the light beam 46, a luminosity E_F at a measurement point on the palm 4 and a distance Z_F are known, so a ratio r_F/r_C of the reflection coefficient is obtained. On knowing the reflection coefficient ratio r_F/r_C, as the luminosity E_F at points other than the measurement point are known with the light beam 46, it is possible to calculate the distance Z_F of each point. E_C is the luminosity of the calibration surface 66, Z_C is the distance between the lens focal point and the calibration surface 66, r_C is a diffuse reflection coefficient of the calibration surface 66, E_F is the luminosity of the palm 4 (the object), which is the object of measurement, Z_F is the distance between the lens focal point and the palm 4, and r_F is a diffuse reflection coefficient of the palm 4.

[0061] Next, the distance map of the palm 4 is obtained. A two-dimensional array in which is stored the previously mentioned distance Z_F is defined in each element of a two-dimensional array of the same size as the image of the palm 4. The two-dimensiona! array being an array which has distances as elements, it is called a "distance map". When the distance map is visualized using CG technology so that its contours can be seen, the kind of visualized distance map shown in Fig. 14 is obtained.

[0062] The palm sensor 6 including a distance map generation function includes the imaging section 28 in the center

of a light blocking frame 70, and includes palm illumination devices 302, 304, 306 and 308 as a plurality of illumination sections 30, and a light beam illumination device 310 (the light source 31), on the periphery of the imaging section 28, as shown in Fig. 15. The palm illumination devices 302, 304, 306 and 308 are light sources which illuminate the whole of the palm. The light beam illumination device 310 is a light source which emits the light beam 46.

[0063] In the event that this kind of palm sensor 6 is used, a calibration surface storage section 72 and a light beam position detection section 74 are provided, as shown in Fig. 16, as a configuration for realizing the distance map generation function. The calibration surface storage section 72, being a predetermined storage medium, stores the height, image, and the like of the calibration surface 66 as the previously mentioned information relating to the calibration surface 66. The light beam position detection section 74 detects a position hit by the light beam 46. The palm region distance calculation section 10, based on the information relating to the calibration surface 66, the palm region, and the light beam position, calculates the distance of the palm region, and generates a distance map. Therefore, the palm region distance calculation section 10 is one example of a distance map generation section.

[0064] The generation of the distance map is such that, after the preliminary process (Fig. 17), the execution process (Fig. 18) is carried out. The procedure of the preliminary process is that of the previously mentioned process using the calibration surface 66. As shown in Fig. 17, firstly, the process procedure disposes an object (the calibration surface 66) of a uniform color at a known height (operation S51). Subsequently, the process procedure carries out an imaging of the calibration surface 66 (operation S52), stores the height and image of the calibration surface 66 in the calibration surface storage section 72 (operation S53), and finishes the preliminary process.

[0065] Also, the execution process procedure, as shown in Fig. 18, turns on the light beam illumination device 310 (operation S61), and carries out an imaging of the palm 4 using the light beam 46 (operation S62). The process procedure stores the image obtained by the imaging in the calibration surface storage section 72 as an image B (operation S63).

[0066] Next, the process procedure extinguishes the light beam illumination device 310 (operation S64), and turns on the palm illumination devices 302, 304, 306 and 308 (Fig. 16) (operation S65), illuminating the palm 4 (operation S65). Continuing, the process procedure carries out an imaging of the palm 4 in a condition in which the whole of the palm is illuminated with light (operation S66), and stores the image obtained by the imaging in the calibration surface storage section 72 as an image A (operation S67).

[0067] Subsequently, the process procedure extinguishes the palm illumination devices 302, 304, 306 and 308 (operation S68), images the palm 4 in a condition in which it is not illuminated with light (operation S69), and stores the image obtained by the imaging as an image C (operation S70).

[0068] The process procedure takes a difference between the image B and image C obtained in this way, and makes the difference an image D (operation S71). The process procedure calculates the central coordinates of a bright region in the image D (operation S72), calculates the ratio r_F/r_C of the reflection coefficient of the palm 4 and calibration surface 66 (operation S73), and calculates a palm region S by taking the difference between the image A and image C (operation S74). Finally, the process procedure calculates the distance from the palm sensor 6 of each pixel of the palm region S (operation S75), and obtains distance map data. By so doing, the process procedure finishes the execution process.

[0069] With this kind of process, the kind of image 76 of the palm 4 shown in Fig. 19 is obtained in the imaging section 28. In the case of this image, as a portion surrounded by a border 78 is in a condition in which it droops toward the palm sensor 6, it appears bigger than the other fingers in the image 76. That is, from this kind of image, it is possible to know that the finger is in a drooping condition.

[0070] Next, Figs. 20 and 21 will be referred to with regard to an extraction of a movement of the palm. Fig. 20 is a flowchart depicting a palm movement extraction process procedure. Fig. 21 is a flowchart depicting a palm movement information representation normalization process procedure. The processes shown in Figs. 20 and 21 being examples, the invention is not limited to these processes.

[0071] The palm movement extraction process procedure is a process which acquires images representing the operation of the palm 4 shifting from the open state to the closed state. The process procedure, as shown in Fig. 20, carries out an extraction of an object frame (operation S81), and normalizes the palm 4 movement information representation (operation S82).

[0072] The object frame extraction process (operation S81) prompts the person being checked to open the palm 4, monitors the image obtained, and calculates the palm region distance for each frame of the image (Fig. 18). Then, at a point at which the diffusion of distance values within the palm region becomes equal to or less than a predetermined threshold value, and there ceases to be any fluctuation between consecutive frames, the extraction process determines that the palm 4 is in an opened condition (the open state). Even after it is determined that the palm 4 is opened, the monitoring of the image and the calculation of the palm region distance are continued.

[0073] After it is determined that the palm 4 is in the open state, the extraction process prompts the person being checked to close the palm 4. Then, in the way heretofore described, the extraction process calculates the diffusion of distance values within the palm region and, at a point at which there ceases to be any fluctuation between consecutive frames, determines that the movement of the palm 4 is in a stopped condition (the closed state). The extraction process takes a distance image obtained when the palm is in that condition to be a distance image of when the palm is closed.

[0074] It is possible to take the image frames from the time it is determined that the palm 4 is opened to the time it is determined that the palm 4 is closed to be the movement of the palm 4 from the time the palm 4 is opened to the time the palm 4 is closed recorded as distance values, In the process procedure, as shown in Fig. 21, the distance values are normalized (operation S91). For the sake of the normalization, a minimum value and maximum value of the distances within the palm region are calculated for all of the image frames. Then, the process procedure seeks a frame in which the difference between the minimum value and maximum value is largest, and normalizes all of the frames so that the difference becomes a predetermined K.

[0075] Next, the process procedure normalizes information of the height of the palm region (operation S92). In order to carry out this normalization process, the maximum value of the distances in the palm region is calculated. In order that the palm appears to have been placed at a predetermined height H, the process procedure converts the distance image of the palm 4 in such a way that the maximum value of the distances is equal to the height H. That is, in the event that the maximum value of the distances is the height h, the palm region is enlarged or reduced by a ratio of H/h. Then, the process procedure adds H-h to the pixel value.

[0076] Next, the process procedure normalizes information of the size of the palm region so that the area of the palm region in each frame attains a predetermined pixel number S (operation S93), normalizes the position of the palm region (operation S94), and normalizes the orientation of the palm region (operation S95). In the palm region orientation normalization process, the process procedure calculates a two-dimensional moment of the palm 4 and, based on the result of the calculation, two-dimensionally rotates the image so that the long axis of the palm region follows the vertical direction of the image.

[0077] Then, the process procedure temporally normalizes the palm 4 movement frames (operation S96). That is, the process procedure takes a time t of a frame when the palm 4 is opened to be t=0, and the time t of a frame when the palm 4 is closed to be t=1, and temporally normalizes frames between the palm 4 being in the open condition and its being in the closed condition (image frames of which the time t is between 0 and 1). The temporal normalization process records, for example, eleven frames in 0.1 increments of the time t from t=0 to t=1. In the event that there exists a time from the time t=0. to the time t=0.9 at which no frame exists, the normalization process interpolates for the frame at that time with the image of the frame at the time nearest to that time.

Distance Value Normalization (operation S91)

[0078] Figs. 22A, 22B and 23 will be referred to with regard to a distance value normalization. Fig. 22A depicts a condition in which a palm is opened. Fig. 22B depicts a condition in which a palm is starting to be closed. Fig. 23 depicts image frames. The configurations shown in Figs. 22A, 22B and 23 being examples, the invention is not limited to these kinds of example.

[0079] The distance value normalization uses the image frames (Fig. 23) of the palm 4 from the condition in which the palm 4 is opened (Fig. 22A) to the condition in which it is closed. The normalization process calculates a minimum value d_{min} and a maximum value d_{max} within the palm region in each frame for all of the frames. As shown in Fig. 22B, in the condition in which the palm 4 is starting to be closed, the thumb droops, and the palm comes closest to the palm sensor 6. At this time, the distance between the palm region and the palm sensor 6 is the minimum value d_{min}. The normalization process seeks the frame in which the difference (d_{max}-d_{min}) between the minimum value d_{min} and the maximum value d_{max} is largest, and normalizes all of the frames so that the difference becomes the predetermined K (Fig. 22B). As shown in Fig. 23, when it is taken that an image frame of when the palm 4 is closed is an image frame 80n, the object image frames from an image frame 801 of when the palm 4 is open are configured of an n number of image frames. Putting the time t on the horizontal axis, the image frames shift through 801, 802 and so on to 80n, as shown in Fig. 23.

[0080] The normalization process calculates the maximum value d_{max} and minimum value d_{min} for each of these kinds of image frames 801 to 80n, and converts each image frame so that the difference in an image frame 80k, in which the difference (d_{max}-d_{min}) between the maximum value and minimum value is largest, is K.

[0081] Taking the number of the frame in which the difference (d_{max}-d_{min}) is largest to be k_{max}, a distance map $d'_k(i, j)$ after the normalization of a distance map $d_k(i,J)$ of a k^{th} frame is obtained with the following formula (5).

[0082]

$$d'_k(i,j) = \frac{K}{d_{max}(k_{max}) - d_{min}(k_{min})} \left\{ d_k(i,j) - \frac{d_{max}(k) - d_{min}(k)}{2} \right\} + \frac{d_{max}(k) - d_{min}(k)}{2} \quad \cdots (5)$$

[0083] Note that the d_{max} and d_{min} of the k^{th} frame are d_{max} (k) and d_{min} (k) respectively. Palm region Height Normal-

ization (operation S92)

[0084] This normalization process calculates the maximum value of the distances between the palm region and the palm sensor 6 and, in order that the palm 4 appears to have been placed at the predetermined height H, converts the distance image of the palm 4 in such a way that the maximum value of the distances is equal to the height H. That is, in the event that the maximum value of the distances is h, the palm region is enlarged or reduced by the ratio of H/h. Then, the normalization process adds H-h to the pixel value. A schematic diagram of when the palm 4 is in the opened condition is as in Fig. 24.

[0085] A distance map d"(i,j) after the normalization of a distance map d'(i,j) of each frame is obtained with the following formula (6).

[0086]

$$d''(i,j) = d'\left(\frac{h}{H}i, \frac{h}{H}j\right) + (H-h) \qquad \cdots(6)$$

Palm region Size Normalization (operation S93)

[0087] Next, information of the size of the palm region is normalized so that the area of the palm region in each frame attains the predetermined pixel number S. Fig. 25A illustrates a frame 81 with an area s before normalization. Fig. 25B illustrates a frame 82 with the area S after normalization. By means of this process, the frame 81 with the area s (Fig. 25A) is normalized to the frame 82 with the area S (Fig. 25B).

[0088] Taking the area of the palm region of each frame to be s, a distance map d'''(i,j) after the normalization of the distance map d"(i,j) of each frame is obtained with the following formula (7).

$$d'''(i,j) = d''\left(\sqrt{\frac{s}{S}}i, \sqrt{\frac{s}{S}}j\right) \qquad \cdots(7)$$

Palm region Position Normalization (operation S94)

[0089] This normalization process, in each frame, shifts a center of gravity G of the palm region to the center of the image so that the position of the palm 4 comes into the middle of the image. The position normalization process takes the center of gravity coordinates of the palm region in each frame to be (C_x,C_y), as shown in Fig. 26A, and shifts the center of gravity coordinates (C_x,C_y) into the center of the image, as shown in Fig. 26B. Taking the central coordinates of the image to be (0,0), a distance map d""(i,j) after the normalization of the distance map d'''(i,j) of each frame is obtained with the following formula (8). Each frame 83 is converted to a normalized frame 84, as shown in Fig. 26B.

$$d''''(i,j) = d'''(i + C_x, j + C_y) \qquad \cdots(8)$$

Palm region Orientation Normalization (operation S95)

[0090] This normalization process calculates the two-dimensional moment of the palm 4 and, based on the result of the calculation, two-dimensionally rotates the image so that the long axis of the palm region follows the vertical direction of the image. A principal axis of inertia is used in the orientation normalization. A long axis 86 of the palm region (Fig. 27A) is, in other words, the principal axis of inertia. This normalization process sets coordinate axes (x axis, y axis) in an image 88, and takes the center O of the image 88 as the origin, as shown in Fig. 27A. in the event that the principal axis of inertia 86 is at an angle θ with respect to the y axis, a distance map d""'(ij) after the normalization of the distance map d""(i,j) of each frame 91 is obtained with the following formulas (9) and (10). Fig. 27B illustrates a normalized frame 92.

$$\begin{pmatrix} i' \\ j' \end{pmatrix} = \begin{pmatrix} \cos\theta & -\sin\theta \\ \sin\theta & \cos\theta \end{pmatrix} \begin{pmatrix} i \\ j \end{pmatrix} \quad \cdots(9)$$

$$d''''''(i,j) = d''''(i,j) \quad \cdots(10)$$

[0091] A method of calculating this kind of principal axis of inertia 86 is disclosed in, for example, pages 91 to 94 of "Robot Vision" by Masahiko Yachida.

Palm Movement Frame Temporal Normalization (operation S96)

[0092] As shown in Fig. 28, a time of an image frame 811 when the palm 4 is opened is taken to be t=0, a time of an image frame 81 n when the palm 4 is closed is taken to be t=1, and image frames between the palm being in the open condition and its being in the closed condition (image frames of which the time t is between 0 and 1) are temporally normalized. The normalization process records, for example, eleven frames in 0.1 increments of the time t from t=0 to t=1. In the event that there exists a time from the time 1=0.1 to the time t=0.9 at which no frame exists, the normalization process obtains the frame for that time by interpolating with the image of the frame at the time nearest to that time.

[0093] Then, a distance map $d''''''_{k'}(i,j)$ of a k'th frame ($0 \leq k' \leq 11$, where k' is an integer) after the normalization is obtained from a distance map $d''''_{k}(i,j)$ before the normalization with the following formula, s and e indicate frames depicted in Fig. 28, where $s \leq k \leq e$, and k is an integer.

[0094] Regarding k in formula (11), in the event that k is an integer, formula (12) is established.

$$k = \frac{(10-k')s + k'e}{10} \quad \cdots(11)$$

$$d''''''_{k'}(i,j) = d''''''_{k'}(i,j) \quad \cdots(12)$$

[0095] Regarding k in formula (11), in the event that k is not an integer, [] is taken to be a Gauss symbol, and formula (13) is established.

$$d''''''_{k'}(i,j) = \{1-(k-[k])\}d''''''_{[k]}(i,j) + (k-[k])d''''''_{[k]+}(i,j) \quad \cdots(13)$$

[0096] The palm movement common characteristic extraction process collects the previously mentioned palm movements from a plurality of people, and averages the distance maps of each frame in pixel units. As a result, the previously mentioned eleven frames obtained (Fig. 28) form the palm 4 movement common characteristics. The palm 4 movement common characteristics obtained are stored in the palm movement common characteristic storage section 18.

[0097] The palm movement characteristic matching process registers biological object information for, for example, a palm vein recognition, and checks the palm movement information in order to determine whether or not a palm (the object) held over the palm sensor for a matching is a biological object. The matching process acquires the palm movement characteristics of the person being checked by means of the heretofore mentioned process, and acquires the palm 4 movement common characteristics stored in the palm movement common characteristic storage section 18. As the characteristics are normalized for distance value, area, orientation, and time, the matching process, by comparing the corresponding images of the eleven frames (Figs. 29A and 29B), can carry out a matching of the two. Fig. 29A is a diagram depicting the eleven frames which show the palm movement common characteristics. Fig. 29B is a diagram depicting the eleven frames which show the palm movement characteristics of the person being checked.

[0098] The comparison of the images calculates and accumulates the difference in distance values for each pixel in all eleven frames. Then, in the event that the accumulated value is equal to or less than a predetermined threshold value, the comparison process determines that the object of determination has carried out a movement similar to that of a biological object.

[0099] In the event of comparing a kth frame 84k representing the common characteristics, as shown in Fig. 30A, and a kth frame 85k representing the characteristics of the person being checked, as shown in Fig. 30B, the sum of the differences between corresponding coordinates of the frames 84k and 85k is calculated as the common characteristics $d_{mk}(i,j)$ of the frame 84k, and the characteristics $d_{nk}(i,j)$ of the person being checked of the frame 85k.

[0100] Taking the palm region of the common characteristic frame 84k as R_k, an accumulated value M of the differences can be obtained with the following formula (14).

$$M = \sum_{k=0}^{11} \sum_{(i,j) \in R_k} \left| d_{mk}(i,j) - d_{nk}(i,j) \right| \qquad \cdots (14)$$

[0101] In the event that the accumulated value M is equal to or less than a predetermined threshold value Mth ($M \leq Mth$), the matching process determines that the object of determination has carried out a movement similar to that of a biological object. Also, in the event of a match with the registered information, the matching process can confirm that the person being checked is a registered (authorized) person.

[0102] Some of the advantages of the disclosure including characteristic particulars of the heretofore described embodiment are, for example, as follows. However, although few advantages are listed herein, these are not the only benefits and advantages of the present invention.

1. Using palm movement information from a plurality of images acquired by an imaging of, for example, a palm as a biological object, can check the palm, and determine via the check whether or not the palm is a biological object. Moreover, an embodiment confirms whether or not a person being checked is a registered person by a comparison with registered movement information.

2. Using a palm as a determination region of a biological object, acquires movement information using an opening and closing of the palm as one example of bending and stretching of the biological object. According to an embodiment, the person being checked can undergo a determination of whether not he or she is a biological object with the simple operation of opening and closing the palm, and without being compelled to carry out any special operation.

3. The embodiment can realize a palm biometric determination method for a non-contact type of palm vein pattern recognition with a low cost sensor.

4. The embodiment, as it matches using a movement of a biological object common to humans, and carries out a matching by extracting three-dimensional information from a plurality of images, can increase determination accuracy.

5. The embodiment carries out a biometric determination based on images imaged (captured) while illuminating a palm with light, and checks an individual based on the determination.

6. A biometric authentication device in an embodiment, having an illumination part and an imaging part, issues an instruction to open and close a hand when carrying out a registration, a matching, or an identification for a biometric determination. As this carries out a check of a biological object based on an existence or otherwise of a movement thereof, it is possible to easily confirm whether or not it is a biological object.

7. The embodiment determines a movement of, for example, a palm as a biological object by collating a movement of a palm of a person being checked and palm movement information collected from a plurality of people, enabling a one to N authentication.

8. As an embodiment uses, in a measurement of a movement of, for example, a palm as a biological object, a light beam illumination position, and images having as values distances to each point on the palm calculated from a luminosity of a reflected light, it can provide a highly accurate determination. The luminosity of the reflected light, being the strength of reflected light entering the imaging section 28 from the palm 4, is the luminosity of each pixel

of the images.

9. An embodiment uses, as images having as values distances which measure a movement of, for example, a palm as a biological object, a plurality of images imaged from a time of an instruction to open the palm to a time of an instruction to close the palm, and acquires movement information from the images.

10. An embodiment utilizes, as movement information of, for example, a palm as a biological object, information which has distance as a value, and in which a palm movement, a palm height, a palm size, a palm orientation, and a time when imaging, are each normalized.

11. An embodiment utilizes, as movement information of, for example, a palm as a biological object, information which has distance as a value, and in which numerals representing contours of an image normalized from a plurality of images with regard to the palm movement are normalized with regard to a time when imaging.

12. An embodiment, when determining whether or not a person being checked is a biological object, gives an instruction for an operation of clenching a palm, confirms whether or not the same kind of transformation is carried out for the object as for a human palm and, in the event that the same kind of transformation as for the palm does not occur, determines that the object is not a hand. As a three-dimensional measuring technique based on brightness using active illumination is used for a measurement of a shape of the object, the determination accuracy is increased.

13. An embodiment can determine that a fake object configured of an object having a reflective property equivalent to that of, for example, a palm as a biological object is not a hand.

[0103] Next, Figs. 31, 32, and 33A to 33E will be referred to with regard to another embodiment. Fig. 31 is a flowchart depicting a process procedure according to an embodiment. Fig. 32 is a diagram depicting an oval sphere which is fitted into a normalized palm image. Figs. 33A to 33E are diagrams depicting a fitting in of an oval sphere in an opening and closing of a palm, The configurations shown in Figs. 31, 32, and 33A to 33E being example, the invention is not limited to these configurations.

[0104] Although a palm movement information representation differs from that of the above-described embodiment in a biometric authentication device, biometric authentication program, or biometric authentication method, this embodiment uses the same kind of device (Fig. 1) as the above-identified embodiment.

[0105] In the process procedure, as a distance value normalization (operation S101), a palm region height normalization (operation S102), and a palm region size normalization (operation S103) are the same as in the above-identified embodiment (Fig. 21), a description thereof will be omitted.

[0106] In an embodiment, after the normalization of the palm region size, simulates an oval sphere as one example of a geometry model, and fits the oval sphere into a palm image (operation S104). That is, an oval sphere 92 (Figs. 32 and 33A to 33E) is fit into an image generated via operations S101 to S103, in which the distance value, palm region height, and palm region size are normalized. An embodiment, based on the fitting in of the oval sphere 92, normalizes the time of movement frames of coefficients of the oval sphere 92 (operation S105).

[0107] A coordinate system when fitting the oval sphere 92 into the palm region sets central coordinates (X_1, Y_1, Z_1) in the oval sphere 92, and takes an origin Q of the imaging section 28 of the palm sensor 6 as a reference. In this case, a, b, and c are distances to portions farthest away from the central coordinates (X_1, Y_1, Z_1) of the oval sphere 92 in an x axis direction, a y axis direction, and a z axis direction respectively.

[0108] In this coordinate system in which the top left of the image is set as the origin, the oval sphere 92 is expressed with the following equation (15). It is sufficient that the coefficients X_1, Y_1, Z_1, a, b, and c in the equation are obtained.

$$\frac{(X-X_1)^2}{a^2}+\frac{(Y-Y_1)^2}{b^2}+\frac{(Z-Z_1)^2}{c^2}=1 \qquad \cdots(15)$$

[0109] These coefficients are obtained using an iterative approximation method based on a least squares method, Newton's method, the Levenberg-Marquardt method, or the like, with a pixel in the palm 4 region in a distance map as a sample point. As a result of fitting the oval sphere 92 into the palm region in each frame, the six coefficients (X_1, Y_1, Z_1, a, b, and c) are obtained.

[0110] In the fitting of the oval sphere 92, which is one example of the previously mentioned geometry model, into the palm region, a condition in which the palm 4 is opened is a condition in which the hollow of the palm 4 is placed on the

oval sphere 92, as shown in Fig. 33A. When the palm 4 is shifted from this condition to a condition in which it is closed, firstly, the oval sphere 92 is placed inside the palm 4, and the fingers assume a condition in which they surround the oval sphere 92, as shown in Fig. 33B. Subsequently, a condition is such that the fingers are moved from this condition in a direction which closes the palm 4, as shown in Fig. 33C. In this case, the oval sphere 92 fitted into the palm 4 becomes elongated. A condition immediately before the palm 4 is closed is a condition wherein the palm 4, which is in a curved condition, is enclosed in the interior of the oval sphere 92, as shown in Fig. 33D. Also, a condition wherein the palm 4 is completely closed, and a fist is formed, is a condition wherein a surface of the oval sphere 92 coincides with a lower surface side of the palm 4, as shown in Fig. 33E. In this way, the condition of the palm corresponds to an outline of the oval sphere 92, and the operation from the condition in which the palm 4 is opened to the condition in which it is closed shifts in the way shown in Fig. 33A, through Figs. 33B to 33D, to Fig. 33E. This operational shift forms information for determining whether or not the palm is a biological object.

[0111] In the operational shift, an embodiment takes a time of a frame when the palm 4 is opened to be t=0, and the time of a frame when the palm 4 is closed to be t=1, and temporally normalizes frames between the palm being in the opened condition and its being in the closed condition (frames of which the time t is between 0 and 1). An embodiment records six coefficients corresponding to each of eleven frames obtained with the time t from t=0 to t=1 in 0.1 increments. In the event that there exists a time from the time t=0.1 to the time t=0.9 at which no frame exists, an embodiment interpolates with the coefficient of the oval sphere 92 of the frame at the time nearest to that time, and obtains a coefficient value for that time for each coefficient. Then, common characteristics of this kind of palm 4 movement are obtained by collecting the previously mentioned palm movements from a plurality of people, and calculating an average value of each coefficient of the oval sphere 92 in corresponding frames for each frame indicating the operational shift.

[0112] An embodiment, when collating the movement of a determination object and the movement common characteristics, firstly, calculates a difference for each frame, and for each coefficient of the oval sphere. Then, an embodiment, using a predetermined weight, calculates the sum of weightings of the differences for one frame and, depending on whether or not an accumulated value of the sums of all the frames is less than a predetermined threshold value, can determine whether or not the movement of the determination object is the same as the movement of a biological object.

[0113] Non-limiting characteristic particulars of an embodiment are, for example, as follows.

1. Palm movement information in an embodiment is information wherein, when fitting a geometry model into an image which has distance as a value, and in which a palm movement, a palm height, and a palm size are normalized, coefficients defining the geometric model are temporally normalized for a time when a shifting palm is imaged.

2. As an embodiment determines whether or not an object of determination is a biological object by means of a matching using a palm movement common model, it is possible to determine whether or not the object of determination is a biological object, even in the event that a palm movement at a time of registration and a palm movement at a time of determination differ slightly. Also, an embodiment, after confirming that the object of determination is a biological object, can confirm whether or not a person being checked is a specific individual.

[0114] Next, Figs. 34 and 33A to 35C will be referred to with regard to another embodiment. Fig. 34 is a flowchart depicting a process procedure according to this embodiment. Figs. 35A to 35C are diagrams for illustrating a calculation of shapes of surface of a palm. The shapes of surface of the palm is represented by a ratio (hereinafter, "convexity and concavity ratio") according to convexity and concavity of surface of the palm. The configurations shown in Figs. 34 and 35A to 35C being examples, the invention is not limited to these kinds of configuration.

[0115] An embodiment including a process which calculates a convexity and concavity ratio of the palm 4 in a palm movement information representation, it differs from the first described embodiment in this respect. As shown in Fig. 34, the process procedure of an embodiment, firstly, carries out a normalization of distance values in the same way as described in the above embodiment (Fig. 21) (operation S111). After the normalization, the process procedure calculates for a distance value image a convexity and concavity ratio indicating a ratio of pixels within a palm region which are of a distance deviating from a reference (operation S112), and temporally normalizes movement frames with this convexity and concavity ratio (operation S113). The reference in the convexity and concavity ratio calculation is the height of the center of the palm region.

[0116] The convexity and concavity ratio calculation (S112) is such that a circumscribed rectangle 94 is simulated in the palm region as one example of a geometry model, the circumscribed rectangle 94 (Fig. 35A) is fitted into the palm region, and a value h of the height of a pixel in a center P of the circumscribed rectangle 94 is calculated. Also, the calculation is such that a pixel number s within the palm region which is $h \pm \Delta h$ is calculated in accordance with a predetermined Δh. That is, the pixel number s is the number of pixels in positions in the palm region which deviate by Δh from the center P of the circumscribed rectangle 94. The pixel number s being an area, taking the area of the whole of the palm region as S, and a ratio of the area s to the area S as r, the ratio r is expressed with an formula (16). The ratio r is calculated as the convexity and concavity ratio.

$$r = \frac{s}{S} \qquad \cdots(16)$$

[0117] As shown in Fig. 35A, taking a palm region in a distance map $d_0(i,j)$ of a zeroth frame when the palm 4 is opened as R_0, the circumscribed rectangle 94 thereof is a border which touches an outline of the fingers farthest away from the center of the opened palm 4.

[0118] On the palm 4 beginning to be closed, the circumscribed rectangle 94 contracts in accordance with a change in the outline of the palm 4, as shown in Fig. 35B. A portion 96 indicated by shading in the diagram is a portion of pixels in positions in the palm region which deviate by Δh from the center P of the circumscribed rectangle 94. The palm 4 is closed and, in a final position in which it is in the closed state, the circumscribed rectangle 94 contracts further in accordance with a change in the outline of the palm 4, as shown in Fig. 35C. Also, the portion of pixels in positions in the palm region which deviate by Δh from the center P of the circumscribed rectangle 94 expands, and the portion of pixels in positions which deviate by Δh spreads to a portion in the vicinity of the wrist. The pixels in positions in the palm region which deviate by Δh from the height of the center of the circumscribed rectangle 94 diffusing as shown by the shading, when the palm 4 shifts from the opened condition to the closed condition, the operational shift can be known by the change in the convexity and concavity ratio.

[0119] Taking the coordinates of the center P of the circumscribed rectangle 94 as (C_x,C_y), the height h of the coordinates is calculated as $d_0(C_x,C_y)$. Because of this, as the pixel number s within the palm region R_0 on the distance map $d_0(i,j)$ which has a value of $h \pm \Delta h$ in accordance with the predetermined Δh is calculated, the ratio r of the pixel number s to the area S of the whole of the palm region R_0 (the number of pixels included in the palm region R_0) is calculated as previously mentioned.

[0120] Then, the temporal normalization of the movement frames with the convexity and concavity ratio (operation S113), as previously mentioned, takes the time of a frame when the palm 4 is opened to be t=0, and the time of a frame when the palm 4 is closed to be t=1, and temporally normalizes frames between the palm being in the open condition and its being in the closed condition (frames of which the time t is between 0 and 1). The normalization process records the convexity and concavity ratio of, for example, eleven frames in 0.1 increments of the time t from t=0 to t=1. In the event that there exists a time from the time t=0.1 to the time t=0.9 at which no frame exists, the normalization process obtains the convexity and concavity ratio for that time by interpolating with the image of the frame at the time nearest to that time.

[0121] An average of a plurality of people for obtaining movement common characteristics is calculated by averaging the convexity and concavity ratio for each frame. Also, when collating the movement of the object of determination and the movement common characteristics, it is sufficient that an embodiment calculates the difference in the convexity and concavity ratio for each frame and, depending on whether or not an accumulated value of the sums of all the frames is less than a predetermined threshold value, determines whether or not the movement of the determination object is the same as the movement of a biological object.

[0122] According to an embodiment, as the palm movement information, having distance as a value, uses a numeral representing a convexity and concavity in an image normalized with respect to palm movement from a plurality of images, it is possible to acquire highly accurate movement information. Also, an embodiment, using this kind of movement information, can increase a determination accuracy of a biometric determination.

[0123] Next, Fig. 36 will be referred to with regard to another embodiment. Fig. 36 is a flowchart depicting a process procedure according to this embodiment. The configuration shown in Fig. 36 being an example, the invention is not limited to this configuration.

[0124] This embodiment is a simplification of the process procedure according to the above-described embodiment (Fig. 34).

[0125] The process procedure, as shown in Fig. 36, normalizes distance values (operation S121), calculates convexity and concavity ratios (operation S122), and calculates a maximum convexity and concavity ratio (operation S123). The processes of normalizing the distance values (operation S121) and calculating the convexity and concavity ratios (operation S122) are the same as those of the above-described embodiment.

[0126] The calculation of the maximum convexity and concavity ratio (operation S123) is such that a maximum value is obtained from among convexity and concavity ratios from a frame of a time when the palm 4 is opened to a frame of a time when the palm 4 is closed. The maximum convexity and concavity ratio is utilized as a movement characteristic. In order to obtain movement common characteristics, an average of information on a plurality of people is calculated based on an average of the maximum convexity and concavity ratios. The previously mentioned convexity and concavity ratio r of each frame from a zeroth frame to a tenth frame being calculated, the maximum convexity and concavity ratio is the maximum value of r amongst them.

[0127] When collating the movement of the object of determination and the movement common characteristics, an embodiment determines whether or not the difference between the maximum convexity and concavity ratios is less than a predetermined threshold value. That is, an embodiment confirms whether or not the determination object changes in the same way as the movement of a biological object.

[0128] Fig. 37 will be referred to with regard to another embodiment. Fig. 37 is a diagram depicting a hardware configuration of a biometric authentication device according to this embodiment. The configuration shown in Fig. 37 being an example, the invention is not limited to this configuration. In Fig. 37, portions identical to those in Fig. 1 are given identical reference numerals.

[0129] The biometric authentication device 2, as shown in Fig. 37, includes a processor 100, a program storage section 102, a data storage section 104, a random access memory (RAM) 106, a display section 108, and the palm sensor 6. These functional sections are mutually connected by a bus 110.

[0130] The processor 100, as well as executing an operating system (OS) 112 in the program storage section 102, executes various kinds of application program besides a biometric authentication program 114.

[0131] The program storage section 102, being a recording medium, stores various kinds of application, sub-routine, and the like, besides the previously mentioned OS 112 and biometric authentication program 114. The data storage section 104, being a recording medium, includes the previously mentioned palm movement distance map storage section 12, palm movement common characteristic storage section 18, biological object characteristic storage section 24, and calibration surface storage section 72. The RAM 106 is primarily a recording medium which forms a work area.

[0132] The display section 108, being one example of an information presentation section, is realized with a liquid crystal display (LCD) indicator, or the like. The display section 108 displays an instruction message during a process of a determination or the like, a determination result, and the like. The instruction message during the process is an instruction to a person being checked to open or close the palm 4. It being acceptable that the instruction message is output by voice, it is acceptable that the display section 108 includes a voice emission section which emits a voice message.

[0133] The palm sensor 6, as previously mentioned, includes the imaging section 28, illumination section 30, illumination control section 32, imaging control section 34, and image acquisition section 36. These functional sections are controlled by the processor 100.

[0134] According to this kind of configuration, the palm region extraction section 8, palm region distance calculation section 10, palm movement characteristic extraction section 14, palm movement common characteristic extraction section 16, palm movement characteristic matching section 20, biological object characteristic data generation section 22, and biological object characteristic data matching section 26 are realized with the processor 100 and RAM 106, based on an execution of the OS 112 and biometric authentication program 114.

[0135] The heretofore described embodiments illustrate an opening and closing of a palm as one example of bending and stretching of a biological object, but it is also acceptable that, besides the palm, the biological object is a biometric region such as a hand, an arm, a foot, etc. In this case, the palm sensor 6 becoming a biological object sensor, the palm region extraction section 8 a biological object region extraction section, the palm region distance calculation section 10 a biological object region distance calculation section, the palm movement distance map storage section 12 a biological object movement distance map storage section, the palm movement characteristic extraction section 14 a biological object movement characteristic extraction section, the palm movement common characteristic extraction section 16 a biological object movement common characteristic extraction section, the palm movement common characteristic storage section 18 a biological object movement common characteristic storage section, and the palm movement characteristic matching section 20 a biological object movement characteristic matching section, another embodiment is configured of those and the biological object characteristic data generation section 22, biological object characteristic storage section 24, and biological object characteristic data matching section 26.

[0136] As opposed to the opening and closing of the palm in the heretofore described embodiments, it is acceptable that another embodiment is configured in such a way as to image bending and stretching of a hand, bending and stretching of a palm, or bending and stretching of a finger and, using a plurality of images representing the bending and stretching of the hand, palm, or finger in the same way as the heretofore described embodiments, determine whether or not the object of determination is a biological object. In the event that a movement of a hand as a biological object is taken as an object of determination, the other embodiment can determine whether or not the object of determination is a biological object easily and with a high accuracy, as a result of which it is possible to increase the accuracy of a biometric authentication.

[0137] Although the heretofore described embodiments image an operation of a palm shifting from an open state to a closed state, it is acceptable that another embodiment is configured in such a way as to take the closed state of the palm 4 as an operation starting point, and image an operation of shifting from the closed state to the open state.

[0138] The heretofore described embodiments, simulating a geometry model in order to identify a movement of a palm, indicate the oval sphere 92 (Fig. 32) and the circumscribed rectangle 94 (Fig. 35) as examples of the model. It is acceptable that another embodiment fits a different polyhedron or spherical object into the movement of the palm, and

calculates the previously mentioned coefficients in order to identify a convexity and concavity, or a distance from a reference position.

[0139] The heretofore described embodiments indicate palm images as one example of a vein recognition, but the invention can also be applied to a biometric determination, other than the vein recognition, which uses palm movement information.

[0140] The heretofore described embodiments exemplify with the palm sensor 6 as a processing section which acquires a palm image, but it is acceptable that the invention uses a different detection section which acquires determination information as a sensor which acquires an image other than one of a palm.

[0141] The heretofore described embodiments carry out a normalization process from a plurality of aspects for a plurality of images, but it is also acceptable to carry out a normalization process from any one aspect, or a selected plurality of aspects, rather than from all of them.

[0142] All examples and conditional language recited herein are intended for pedagogical purposes to aid the reader in understanding the invention and the concepts contributed by the inventor to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions, nor does the organization of such examples in the specification relate to a showing of the superiority and inferiority of the invention. Although the embodiments of the present inventions have been described in detail, it should be understood that the various changes, substitutions, and alterations could be made hereto without departing from the spirit and scope of the invention.

[0143] The embodiments can be implemented in computing hardware (computing apparatus) and/or software, such as (in a non-limiting example) any computer that can store, retrieve, process and/or output data and/or communicate with other computers. The results produced can be displayed on a display of the computing hardware. A pragram/software implementing the embodiments may be recorded on computer-readable media comprising computer-readable recording media. The program/software implementing the embodiments may also be transmitted over transmission communication media. Examples of the computer-readable recording media include a magnetic recording apparatus, an optical disk, a magneto-optical disk, and/or a semiconductor memory (for example, RAM, ROM, etc.). Examples of the magnetic recording apparatus include a hard disk device (HDD), a flexible disk (FD), and a magnetic tape (MT). Examples of the optical disk include a DVD (Digital Versatile Disc), a DVD-RAM, a CD-ROM (Compact Disc - Read Only Memory), and a CD-R (Recordable)/RW. An example of communication media includes a carrier-wave signal,

[0144] Further, according to an aspect of the embodiments, any combinations of the described features, functions and/or operations can be provided.

[0145] Although a few embodiments have been shown and described, it would be appreciated by those skilled in the art that changes may be made in these embodiments without departing from the principles and spirit of the invention, the scope of which is defined in the claims and their equivalents.

Claims

1. A biometric authentication device, comprising:

   an imaging section; and
   a determination section which extracts movement information representing bending and stretching of an imaging object from a plurality of images obtained from the imaging section, and determines whether the imaging object is a biological object, based on the movement information.

2. The biometric authentication device according to claim 1, wherein
   the determination section matches the movement information representing the bending and stretching of the imaging object and movement information collected from a plurality of people, and determines whether the imaging object is a biological object.

3. The biometric authentication device according to claim 1, comprising:

   a illuminating section which illuminates the imaging object with light; and
   a measurement section which measures a movement of the imaging object using images having distance information representing distances of surface of the imaging object calculated from a position of and strengths of reflected light of the imaging object.

4. The biometric authentication device according to claim 3, wherein
   the images having the distance information are a plurality of images having distance information of the imaging object imaged from an open state to a closed state, or from the closed state to the open state.

5. The biometric authentication device according to claim 3, wherein
the movement information used in the determination by the determination section includes the distance information, is normalized with respect to one or all of movement, information of height, size, orientation of the imaging object, and a time of imaging the imaging object.

6. The biometric authentication device according to claim 4, wherein
the movement information used in the determination by the determination section is information where a geometry model is fitted into an image, the distance information and plurality of images are normalized with respect to the movement of the imaging object, information of a height of the imaging object, or information of a size of the imaging object, and coefficients defining the geometry model are normalized with respect to a time of imaging the imaging object.

7. The biometric authentication device according to claim 4, wherein
the movement information used in the determination by the determination section is information having a numeral representing a shape of surface of the imaging object, where the distance information and plurality of images are normalized with respect to the movement of the imaging object that is normalized with respect to a time of imaging the imaging object.

8. The biometric authentication device according to claim 4, wherein
the movement information used in the determination by the determination section is a maximum value of numerals representing an shapes of surface of the imaging object normalized with respect to the movement of the imaging object, among the distance information and plurality of images.

9. A biometric authentication method, comprising:

imaging an imaging object; and
extracting movement information representing bending and stretching of the imaging object from a plurality of images obtained from the imaging, and determining whether the imaging object is a biological object, based on the movement information.

10. The biometric authentication method according to claim 9, wherein
the determining matches the movement information representing the bending and stretching of the imaging object and movement information collected from a plurality of people, and determines whether the imaging object is a biological object.

11. The biometric authentication method according to claim 9, comprising:

acquiring movement information of the imaging object includes using images having distance information representing distances of surface of the imaging object calculated from a position of an illuminating section and strengths of reflected light of the imaging object.

12. The biometric authentication method according to claim 11, wherein
the images having the distance information are a plurality of images having distance information of the imaging object imaged from an open state to a closed state, or from the closed state to the open state.

13. The biometric authentication method according to claim 11, wherein
the movement information used in the determination is information having the distance information, is normalized with respect to one or all of a movement, information of height, size, orientation of the imaging object, and a time of imaging the imaging object.

14. The biometric authentication method according to claim 12, wherein
the movement information used in the determination is information where a geometry model is fitted into an image, the distance information and plurality of images are normalized with respect to the movement of the imaging object, information of the height of the imaging object, or information of the size of the imaging object, and coefficients defining the geometry model are normalized with respect to a time of imaging the imaging object.

15. The biometric authentication method according to claim 12, wherein
the movement information used in the determination is information where a numeral representing a shape of surface

of the imaging object of an image wherein the distance information and plurality of images are normalized with respect to the movement of the imaging object is normalized with respect to a time of imaging the imaging object.

16. The biometric authentication method according to claim 12, wherein
the movement information used in the determination is a maximum value of numerals representing shapes of surface of the imaging object normalized with respect to the movement of the imaging object, among the distance information and the plurality of images.

17. A computer readable recording medium recording a biometric authentication program, the biometric authentication program allowing a computer to execute:

an imaging function of imaging an imaging object; and
a determining function of extracting movement information representing bending and stretching of the imaging object from a plurality of images obtained from the imaging, and determining whether the imaging object is a biological object, based on the movement information.

FIG. 1

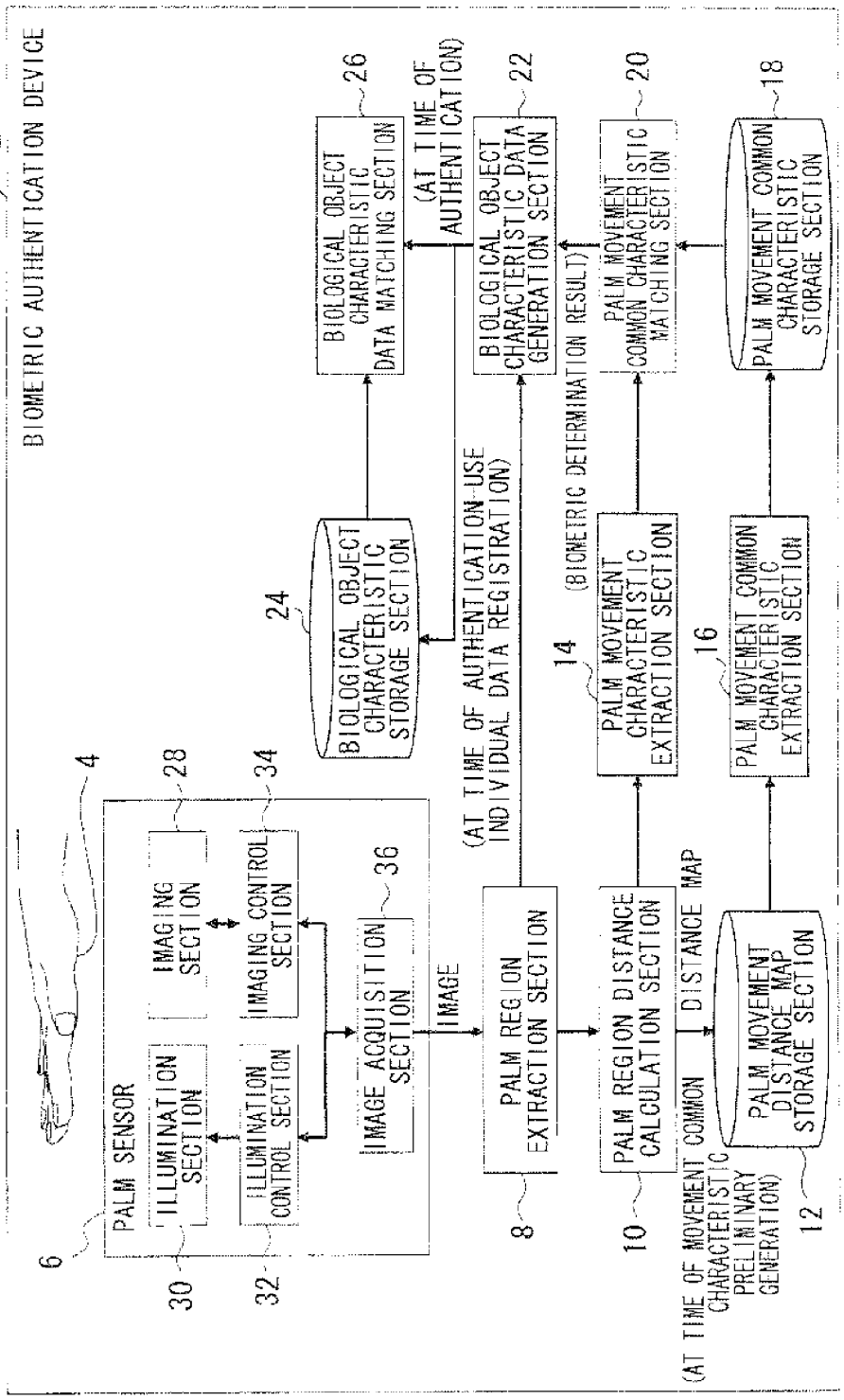

2
BIOMETRIC AUTHENTICATION DEVICE
4
6
PALM SENSOR
ILLUMINATION SECTION
30
ILLUMINATION CONTROL SECTION
32
IMAGING SECTION
28
IMAGING CONTROL SECTION
34
IMAGE ACQUISITION SECTION
36
IMAGE
PALM REGION EXTRACTION SECTION
8
PALM REGION DISTANCE CALCULATION SECTION
10
DISTANCE MAP
(AT TIME OF MOVEMENT COMMON CHARACTERISTIC PRELIMINARY GENERATION)
PALM MOVEMENT DISTANCE MAP STORAGE SECTION
12
(AT TIME OF AUTHENTICATION-USE INDIVIDUAL DATA REGISTRATION)
BIOLOGICAL OBJECT CHARACTERISTIC STORAGE SECTION
24
BIOLOGICAL OBJECT CHARACTERISTIC DATA GENERATION SECTION
22
(BIOMETRIC DETERMINATION RESULT)
PALM MOVEMENT CHARACTERISTIC EXTRACTION SECTION
14
PALM MOVEMENT COMMON CHARACTERISTIC EXTRACTION SECTION
16
BIOLOGICAL OBJECT CHARACTERISTIC DATA MATCHING SECTION
26
(AT TIME OF AUTHENTICATION)
PALM MOVEMENT COMMON CHARACTERISTIC MATCHING SECTION
20
PALM MOVEMENT COMMON CHARACTERISTIC STORAGE SECTION
18

FIG. 2

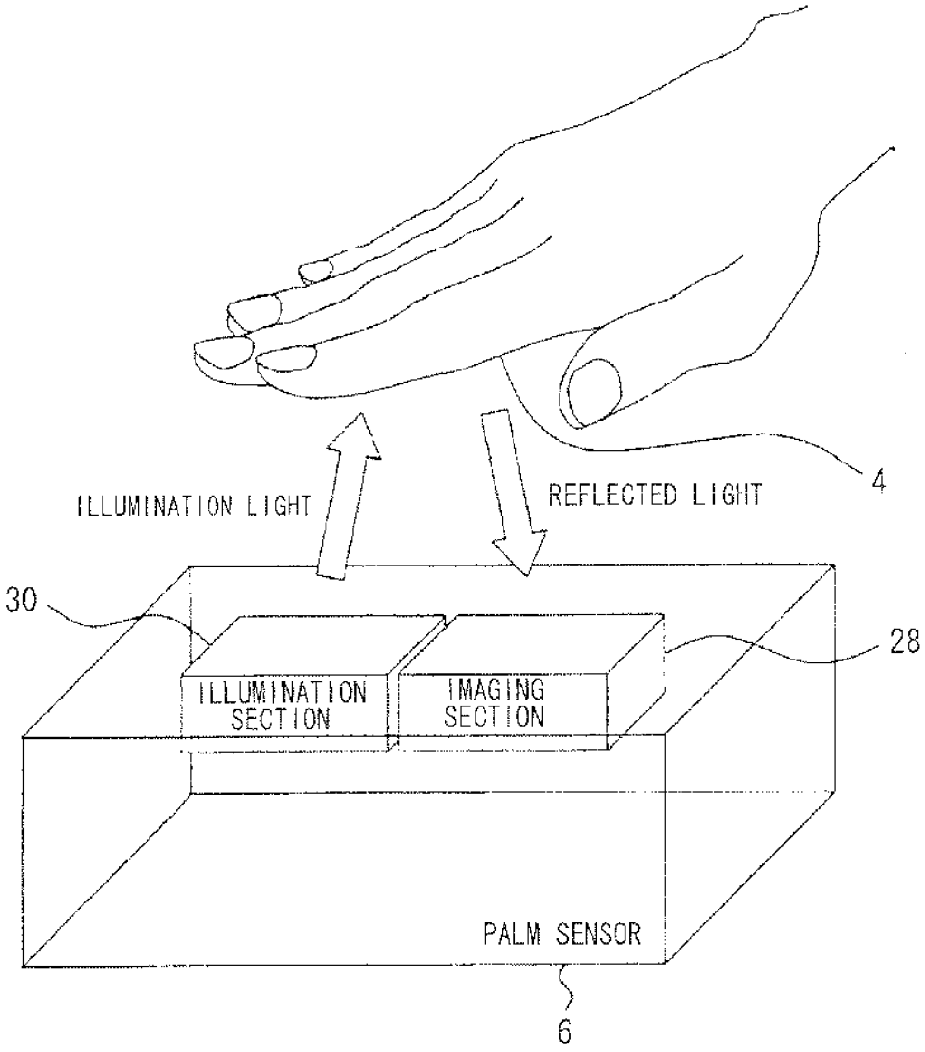

ILLUMINATION LIGHT
REFLECTED LIGHT
4
30
28
ILLUMINATION SECTION
IMAGING SECTION
PALM SENSOR
6

FIG. 3

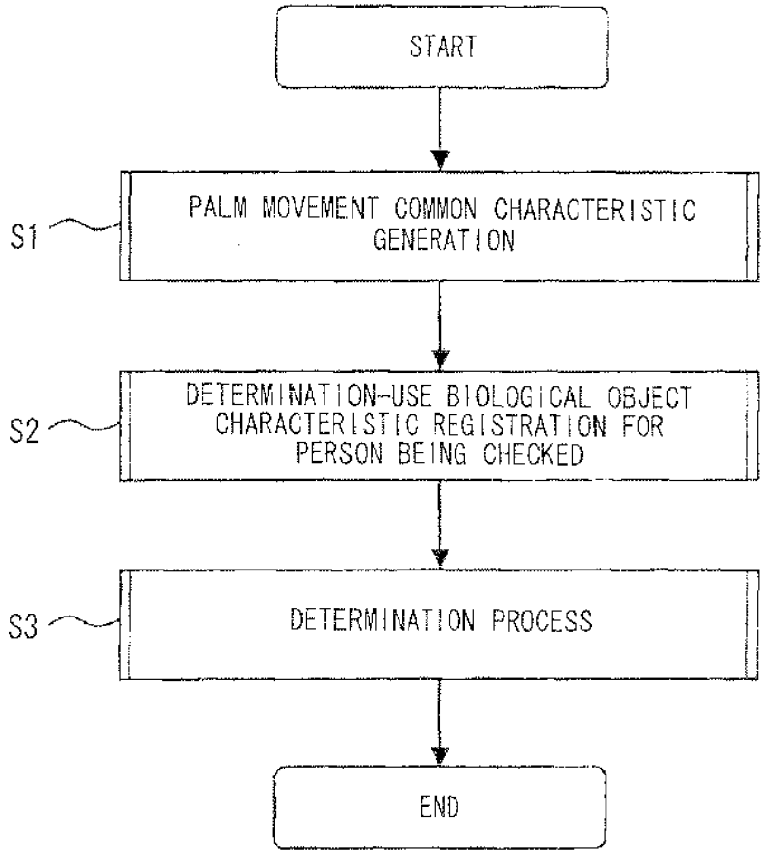

START
S1
PALM MOVEMENT COMMON CHARACTERISTIC GENERATION
S2
DETERMINATION-USE BIOLOGICAL OBJECT CHARACTERISTIC REGISTRATION FOR PERSON BEING CHECKED
S3
DETERMINATION PROCESS
END

FIG. 4

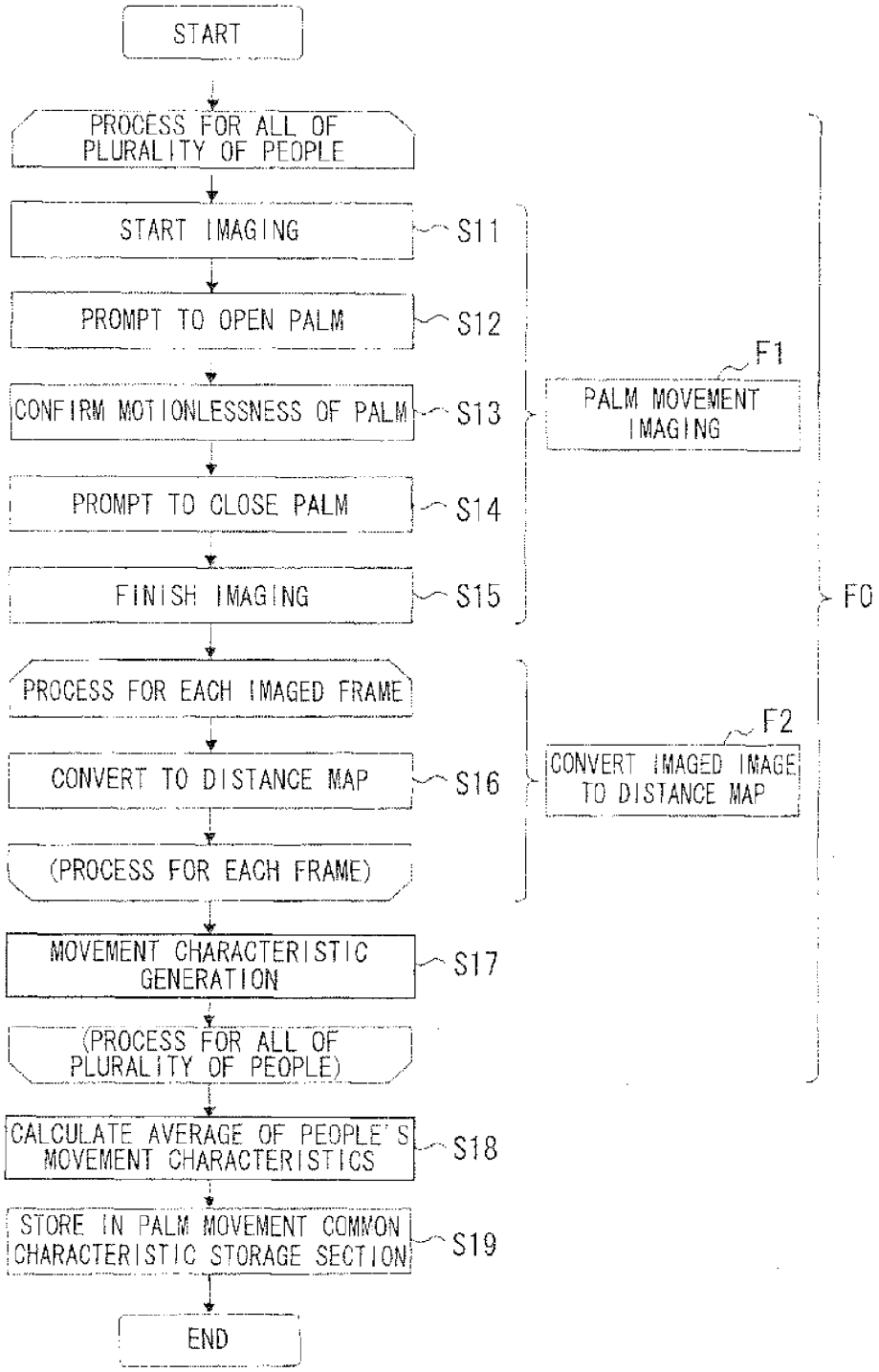

START
PROCESS FOR ALL OF PLURALITY OF PEOPLE
START IMAGING
S11
PROMPT TO OPEN PALM
S12
CONFIRM MOTIONLESSNESS OF PALM
S13
PROMPT TO CLOSE PALM
S14
FINISH IMAGING
S15
F1
PALM MOVEMENT IMAGING
PROCESS FOR EACH IMAGED FRAME
CONVERT TO DISTANCE MAP
S16
(PROCESS FOR EACH FRAME)
F2
CONVERT IMAGED IMAGE TO DISTANCE MAP
MOVEMENT CHARACTERISTIC GENERATION
S17
(PROCESS FOR ALL OF PLURALITY OF PEOPLE)
CALCULATE AVERAGE OF PEOPLE'S MOVEMENT CHARACTERISTICS
S18
STORE IN PALM MOVEMENT COMMON CHARACTERISTIC STORAGE SECTION
S19
END
F0

FIG. 5

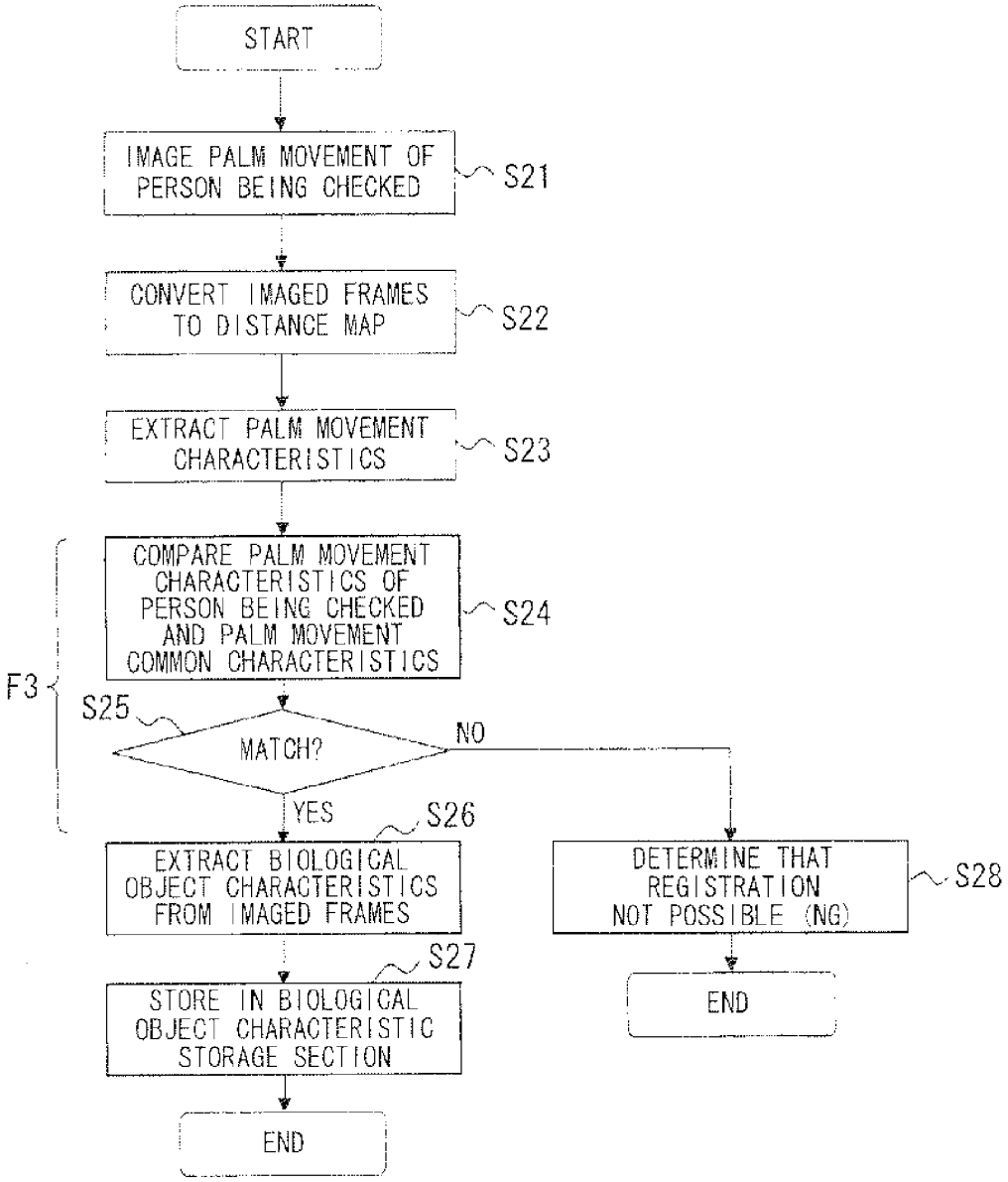

START
IMAGE PALM MOVEMENT OF PERSON BEING CHECKED
S21
CONVERT IMAGED FRAMES TO DISTANCE MAP
S22
EXTRACT PALM MOVEMENT CHARACTERISTICS
S23
COMPARE PALM MOVEMENT CHARACTERISTICS OF PERSON BEING CHECKED AND PALM MOVEMENT COMMON CHARACTERISTICS
S24
F3
S25
MATCH?
NO
YES
S26
EXTRACT BIOLOGICAL OBJECT CHARACTERISTICS FROM IMAGED FRAMES
S27
STORE IN BIOLOGICAL OBJECT CHARACTERISTIC STORAGE SECTION
END
DETERMINE THAT REGISTRATION NOT POSSIBLE (NG)
S28
END

FIG. 6

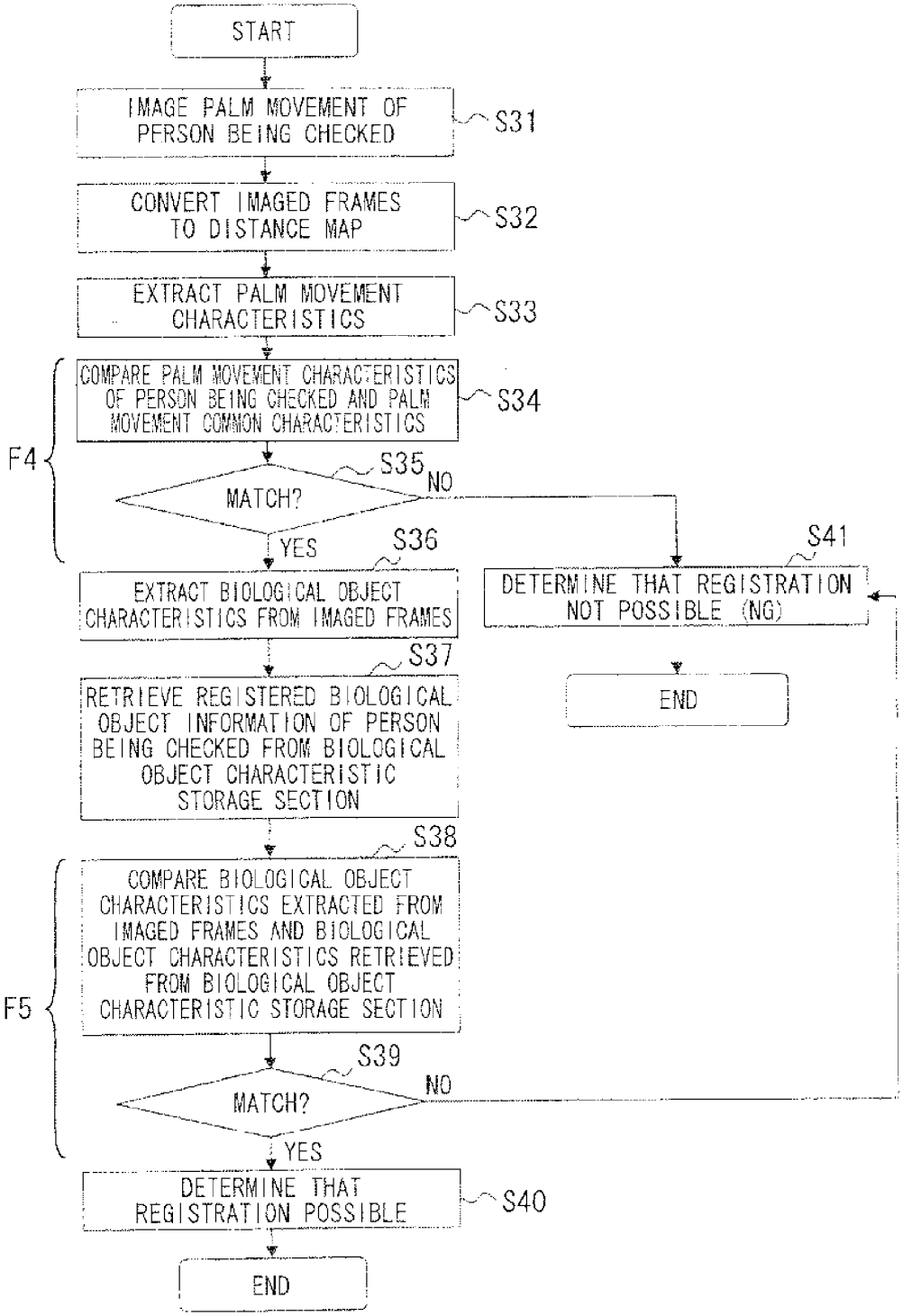

START
IMAGE PALM MOVEMENT OF PERSON BEING CHECKED
S31
CONVERT IMAGED FRAMES TO DISTANCE MAP
S32
EXTRACT PALM MOVEMENT CHARACTERISTICS
S33
COMPARE PALM MOVEMENT CHARACTERISTICS OF PERSON BEING CHECKED AND PALM MOVEMENT COMMON CHARACTERISTICS
S34
F4
S35
MATCH?
NO
YES
S36
EXTRACT BIOLOGICAL OBJECT CHARACTERISTICS FROM IMAGED FRAMES
S37
RETRIEVE REGISTERED BIOLOGICAL OBJECT INFORMATION OF PERSON BEING CHECKED FROM BIOLOGICAL OBJECT CHARACTERISTIC STORAGE SECTION
S38
COMPARE BIOLOGICAL OBJECT CHARACTERISTICS EXTRACTED FROM IMAGED FRAMES AND BIOLOGICAL OBJECT CHARACTERISTICS RETRIEVED FROM BIOLOGICAL OBJECT CHARACTERISTIC STORAGE SECTION
F5
S39
MATCH?
NO
YES
DETERMINE THAT REGISTRATION POSSIBLE
S40
END
S41
DETERMINE THAT REGISTRATION NOT POSSIBLE (NG)
END

FIG. 7A

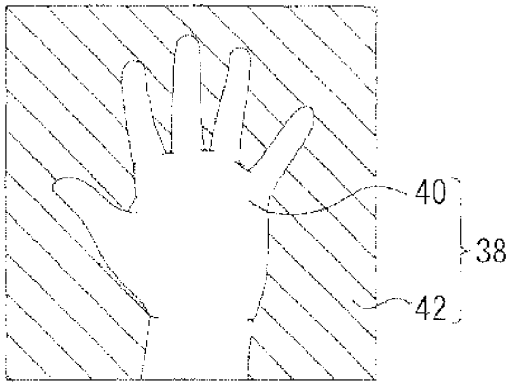


FIG. 7B

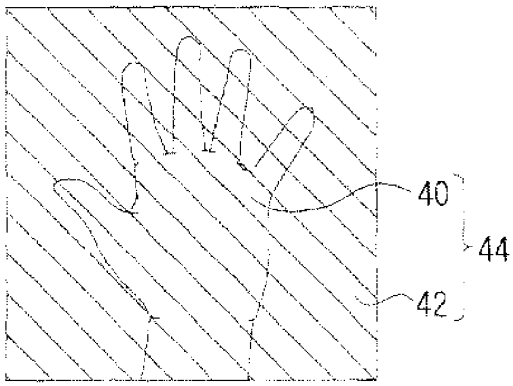


FIG. 7C

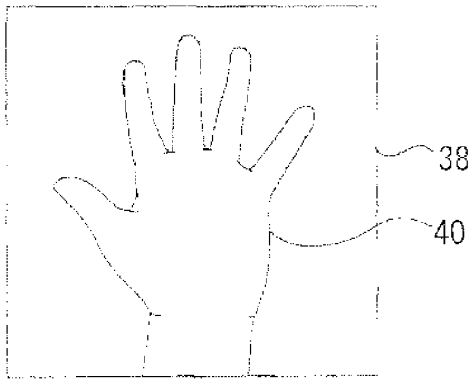
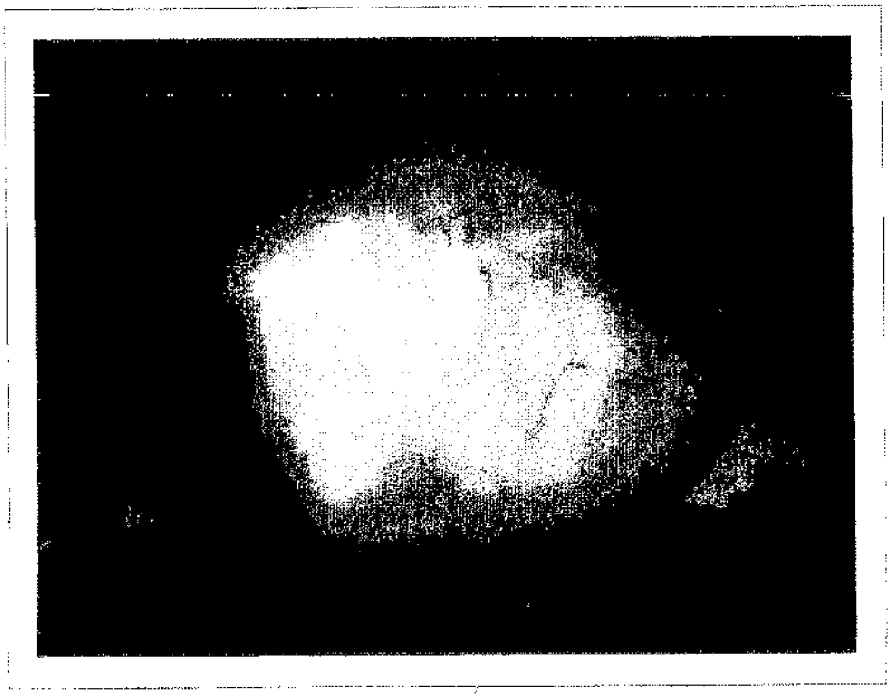
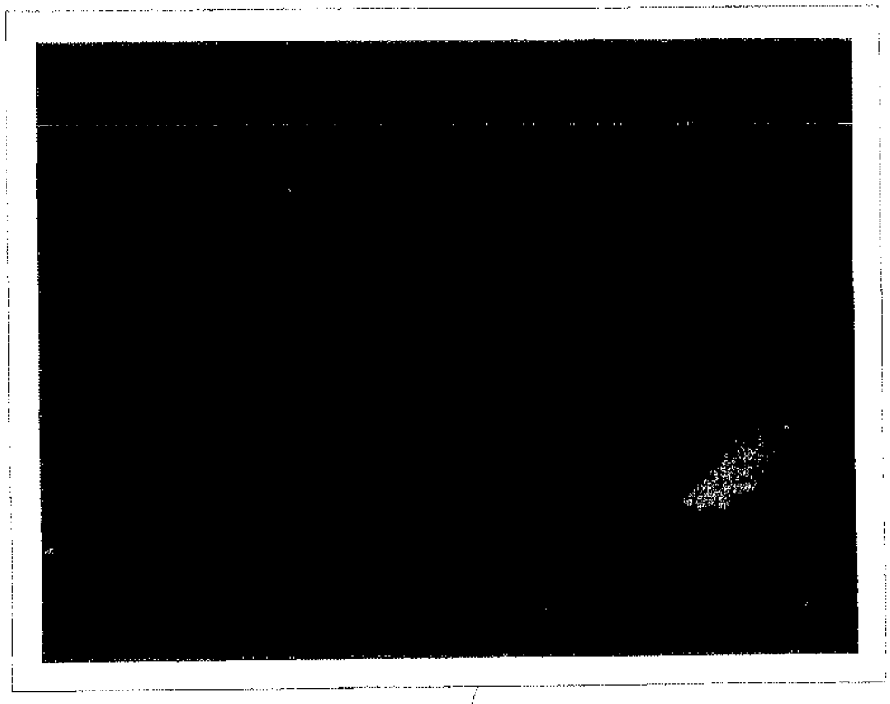


FIG. 8



38 (Fig. 7A)

FIG. 9



44 (Fig. 7B)

FIG. 10

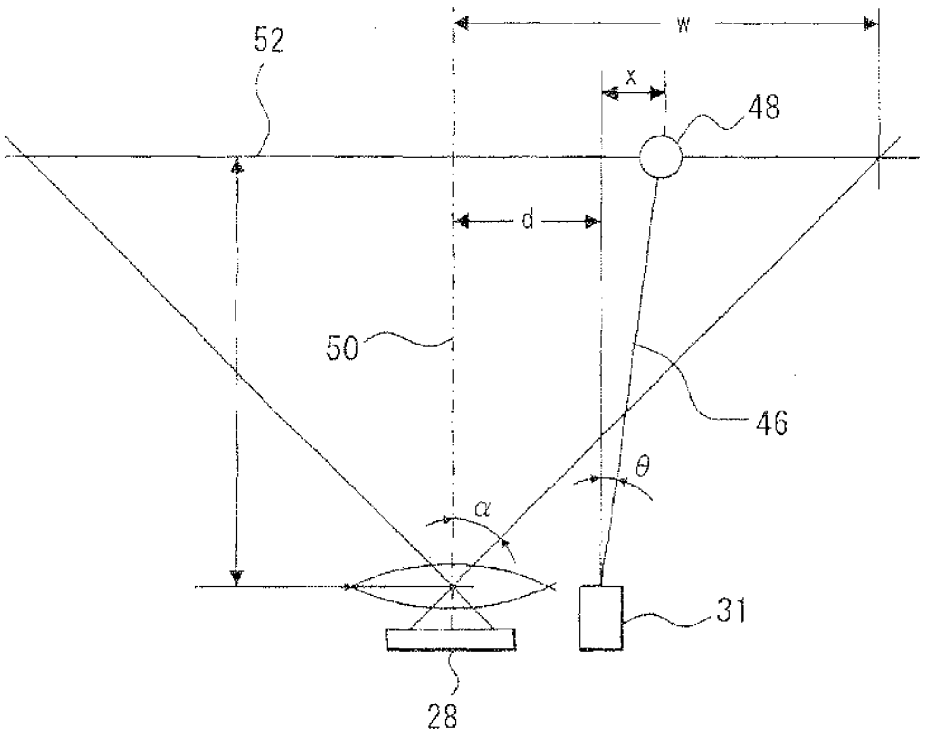


FIG. 11

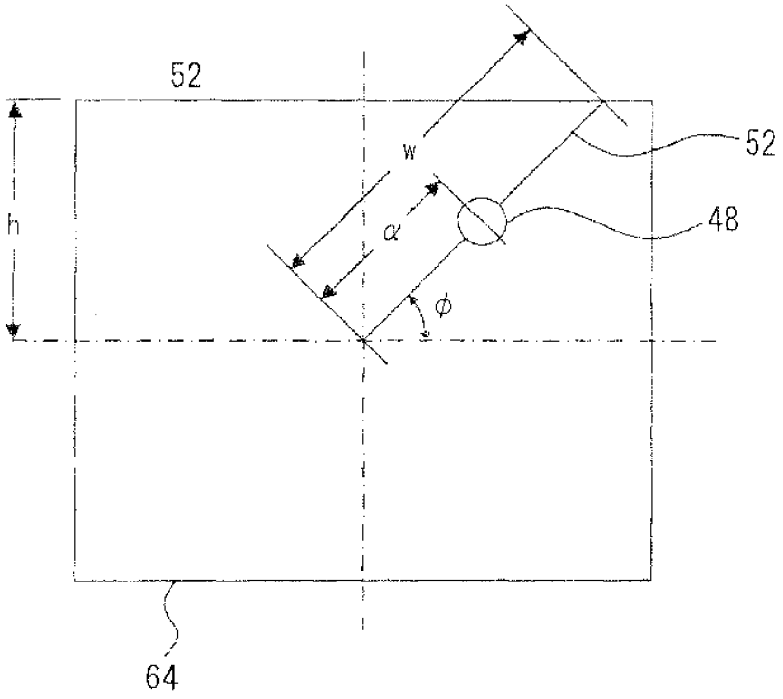


FIG. 12

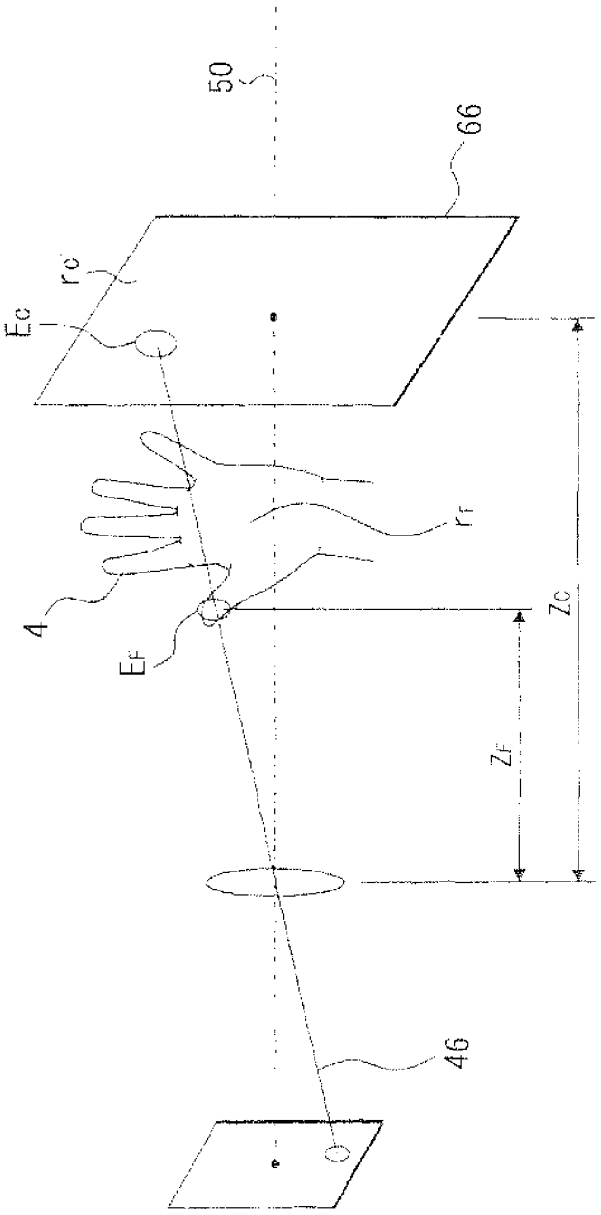


FIG. 13

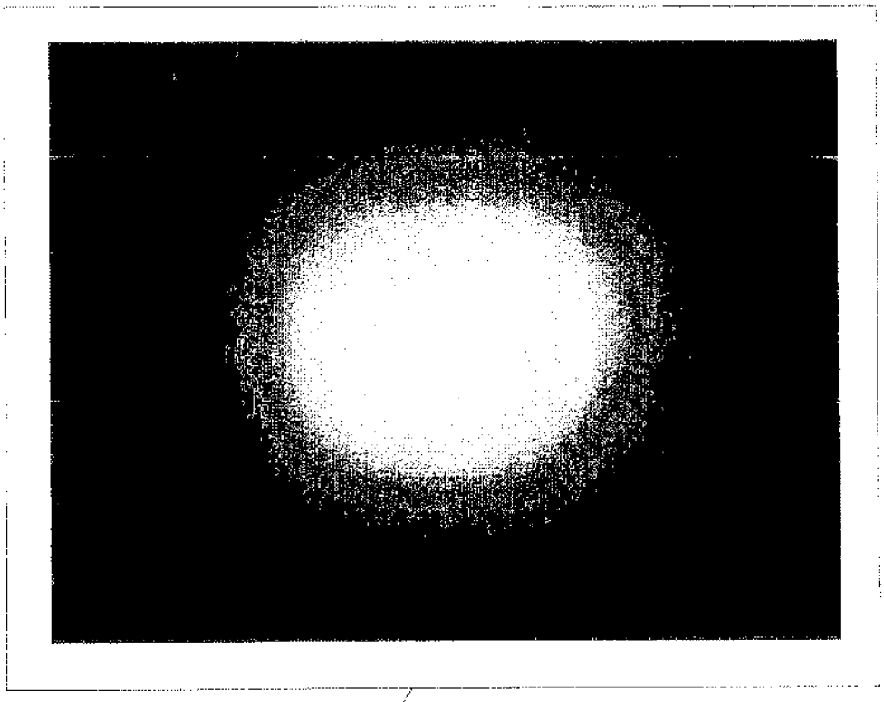


FIG. 14

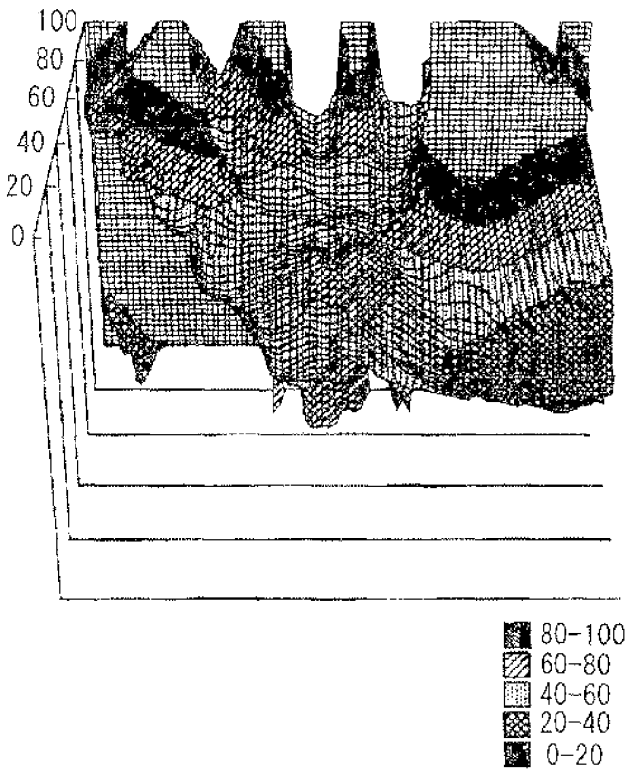


FIG. 15

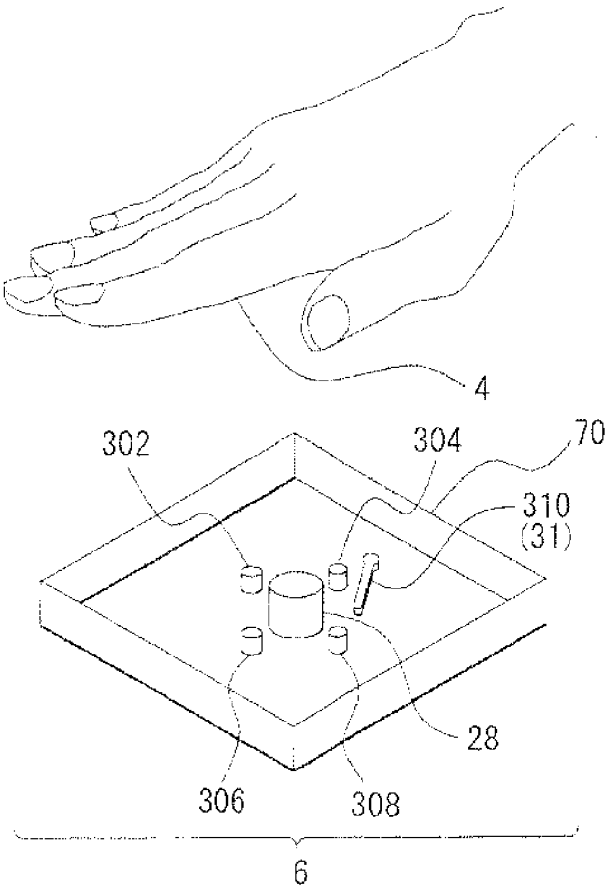


FIG. 16

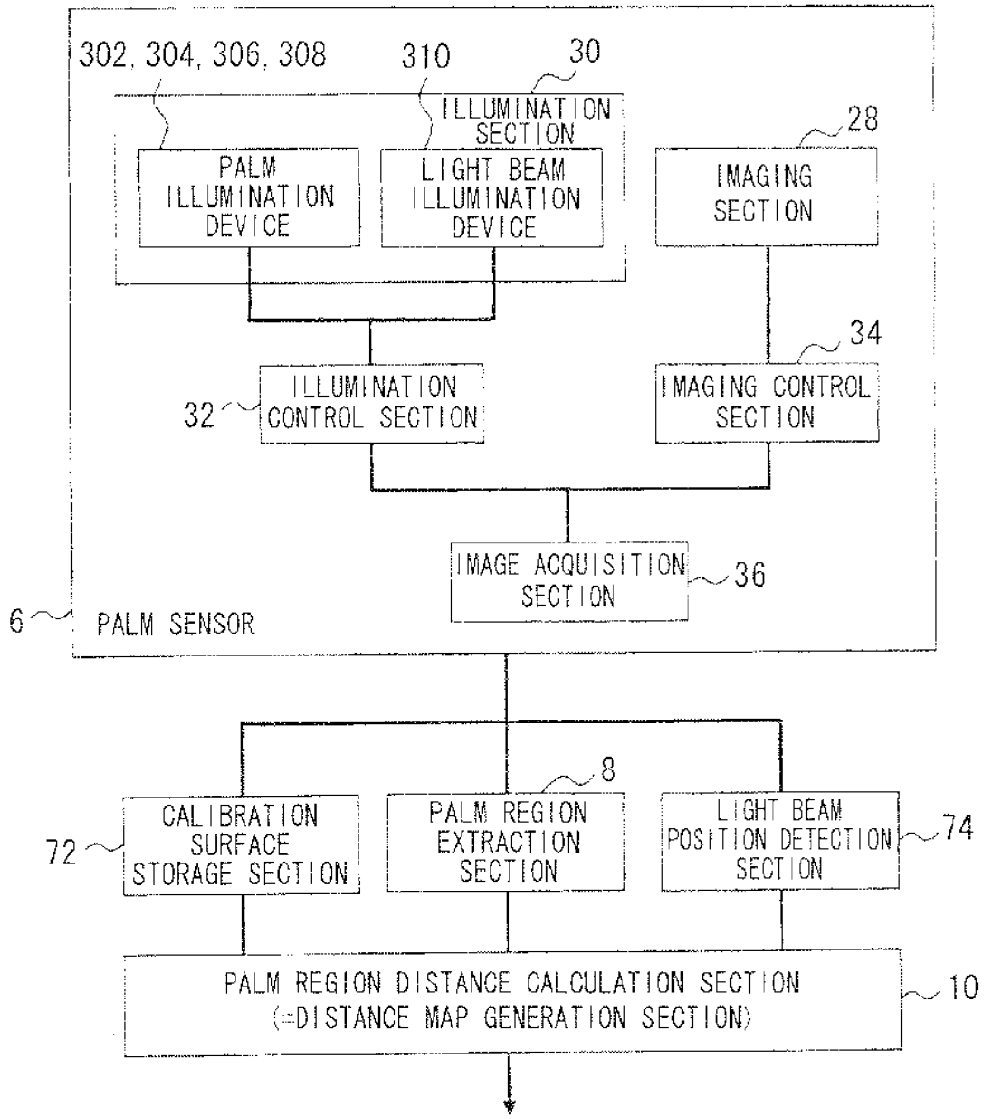

302, 304, 306, 308
310
30
ILLUMINATION SECTION
PALM ILLUMINATION DEVICE
LIGHT BEAM ILLUMINATION DEVICE
28
IMAGING SECTION
34
32
ILLUMINATION CONTROL SECTION
IMAGING CONTROL SECTION
IMAGE ACQUISITION SECTION
36
6
PALM SENSOR
8
72
CALIBRATION SURFACE STORAGE SECTION
PALM REGION EXTRACTION SECTION
LIGHT BEAM POSITION DETECTION SECTION
74
PALM REGION DISTANCE CALCULATION SECTION (=DISTANCE MAP GENERATION SECTION)
10

FIG. 17

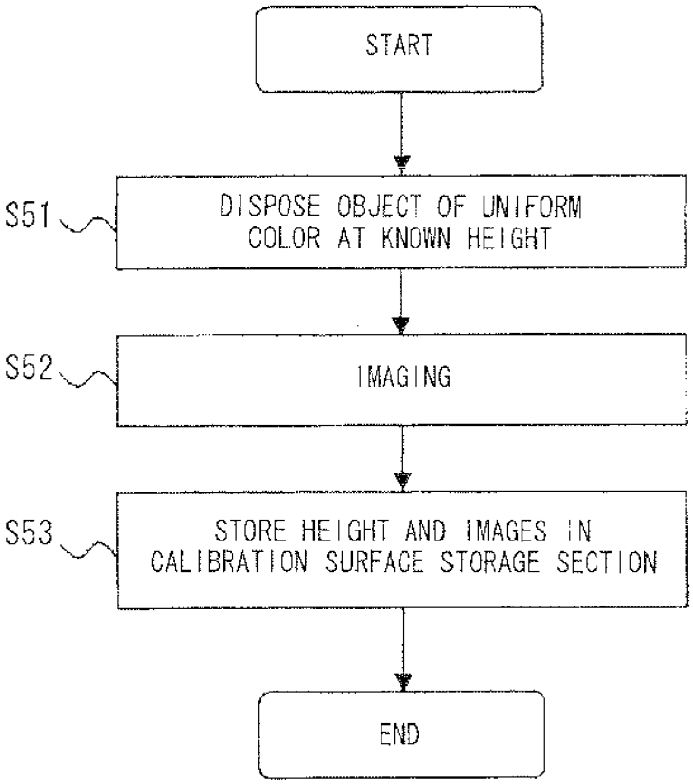

START
S51
DISPOSE OBJECT OF UNIFORM COLOR AT KNOWN HEIGHT
S52
IMAGING
S53
STORE HEIGHT AND IMAGES IN CALIBRATION SURFACE STORAGE SECTION
END

FIG. 18

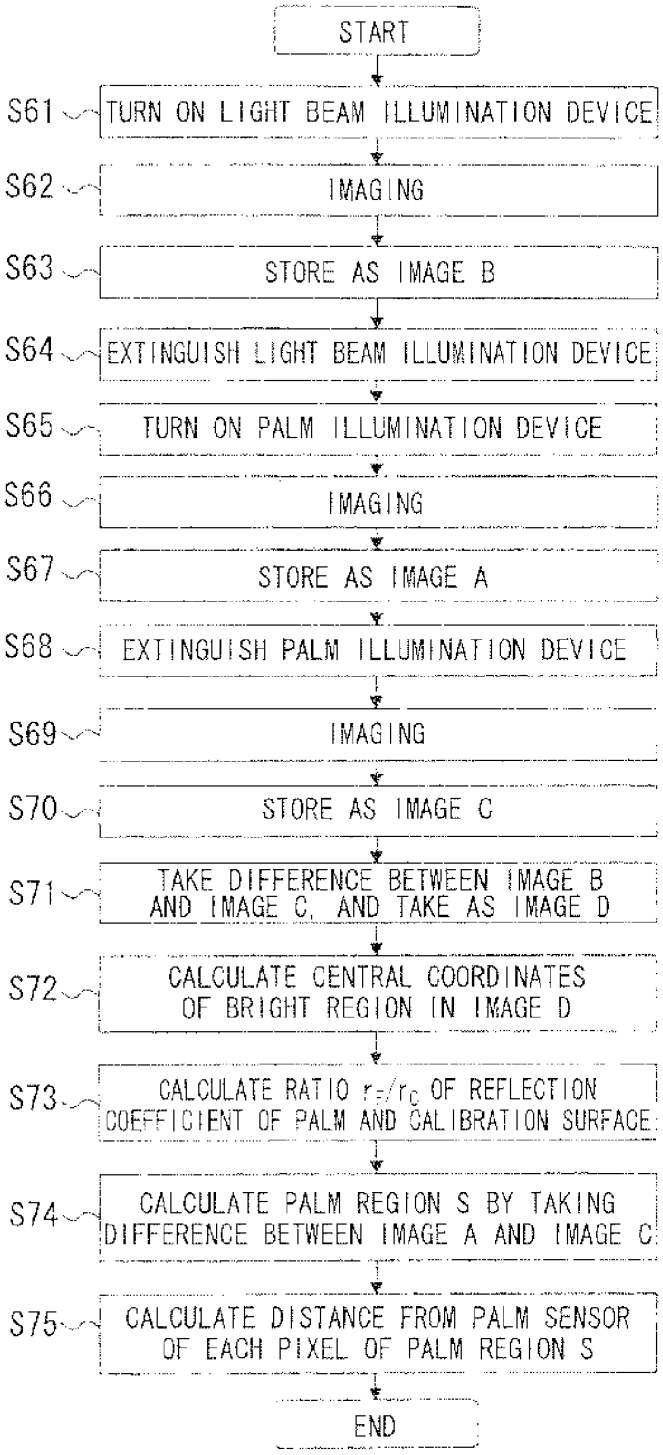

START
S61
TURN ON LIGHT BEAM ILLUMINATION DEVICE
S62
IMAGING
S63
STORE AS IMAGE B
S64
EXTINGUISH LIGHT BEAM ILLUMINATION DEVICE
S65
TURN ON PALM ILLUMINATION DEVICE
S66
IMAGING
S67
STORE AS IMAGE A
S68
EXTINGUISH PALM ILLUMINATION DEVICE
S69
IMAGING
S70
STORE AS IMAGE C
S71
TAKE DIFFERENCE BETWEEN IMAGE B AND IMAGE C, AND TAKE AS IMAGE D
S72
CALCULATE CENTRAL COORDINATES OF BRIGHT REGION IN IMAGE D
S73
CALCULATE RATIO r_s/r_c OF REFLECTION COEFFICIENT OF PALM AND CALIBRATION SURFACE
S74
CALCULATE PALM REGION S BY TAKING DIFFERENCE BETWEEN IMAGE A AND IMAGE C
S75
CALCULATE DISTANCE FROM PALM SENSOR OF EACH PIXEL OF PALM REGION S
END

FIG. 19

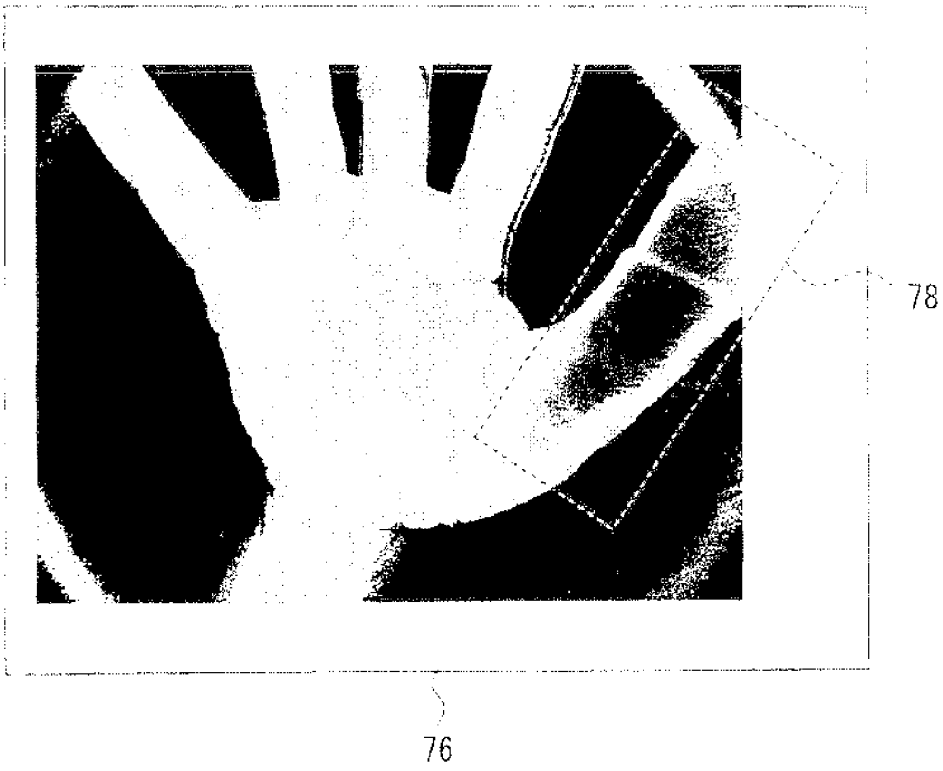


FIG. 20

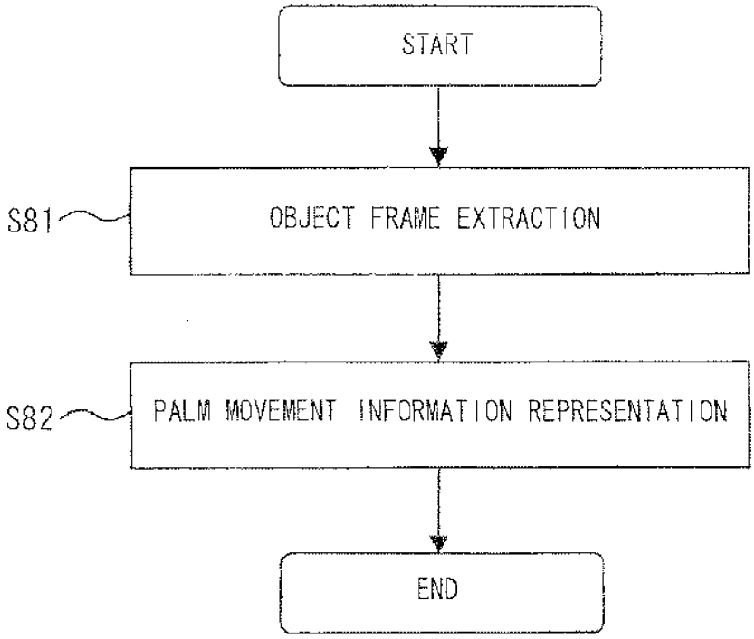

START
S81
OBJECT FRAME EXTRACTION
S82
PALM MOVEMENT INFORMATION REPRESENTATION
END

FIG. 21

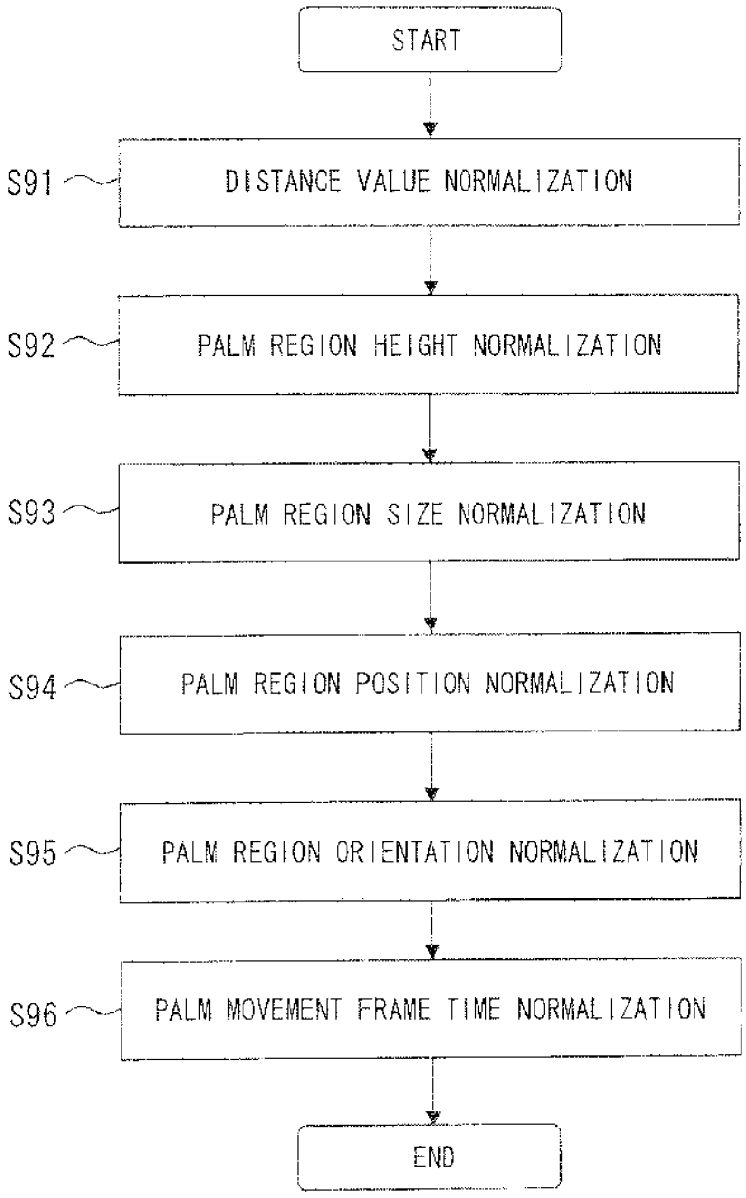

START
S91
DISTANCE VALUE NORMALIZATION
S92
PALM REGION HEIGHT NORMALIZATION
S93
PALM REGION SIZE NORMALIZATION
S94
PALM REGION POSITION NORMALIZATION
S95
PALM REGION ORIENTATION NORMALIZATION
S96
PALM MOVEMENT FRAME TIME NORMALIZATION
END

FIG. 22B

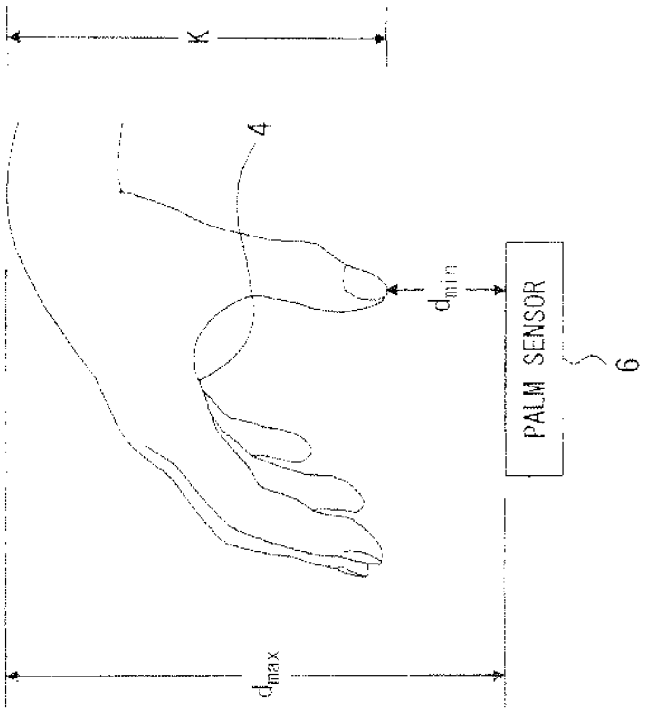


FIG. 22A

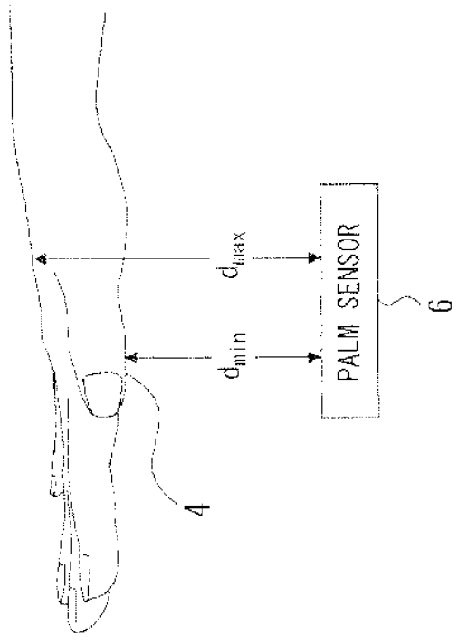


FIG. 23

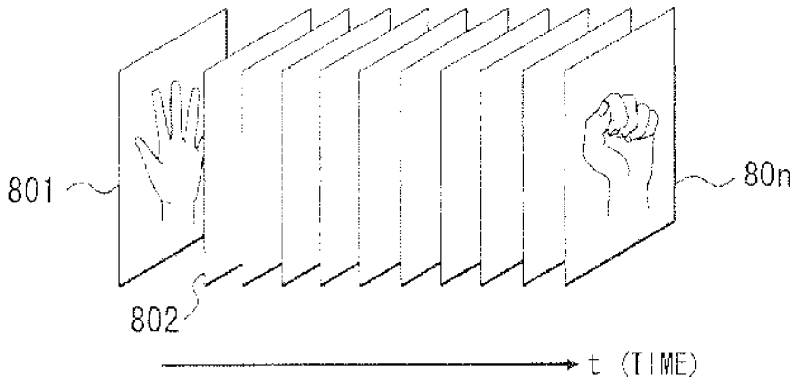


FIG. 24

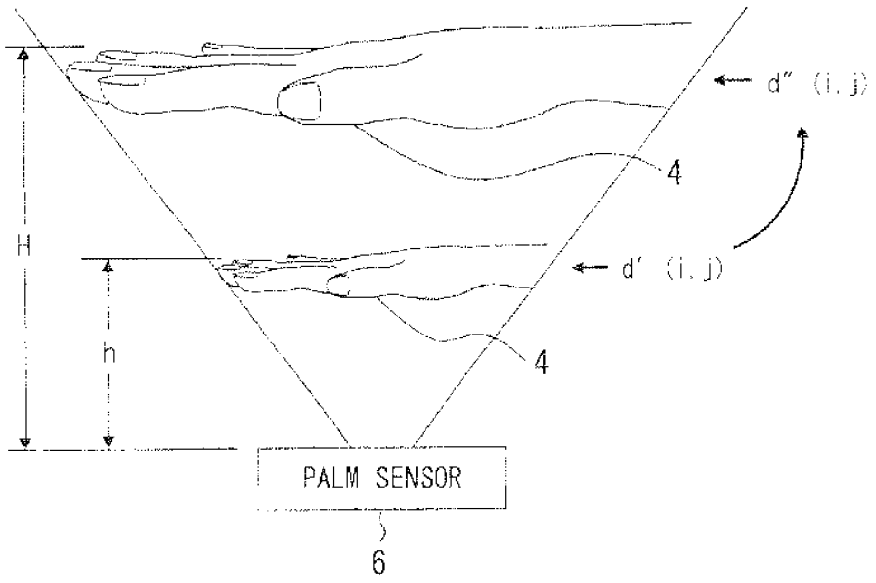


FIG. 25B

(AREA S)

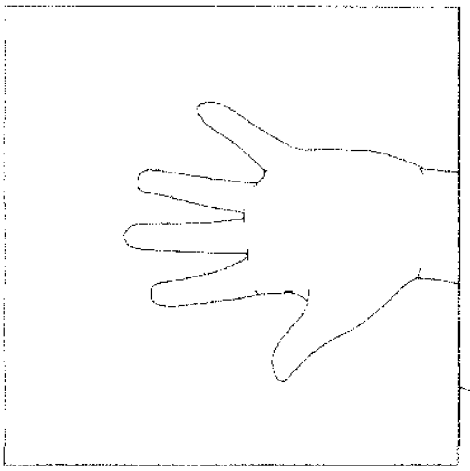


FIG. 25A

(AREA s)

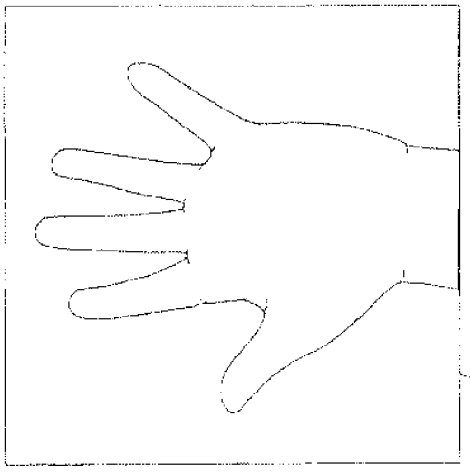


FIG. 26B

(d''')

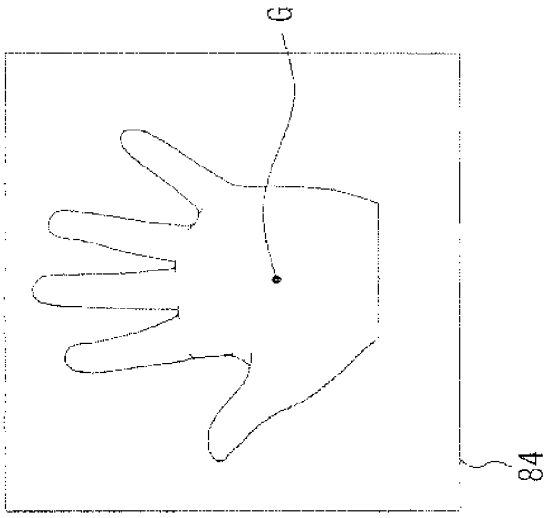


FIG. 26A

(d''')

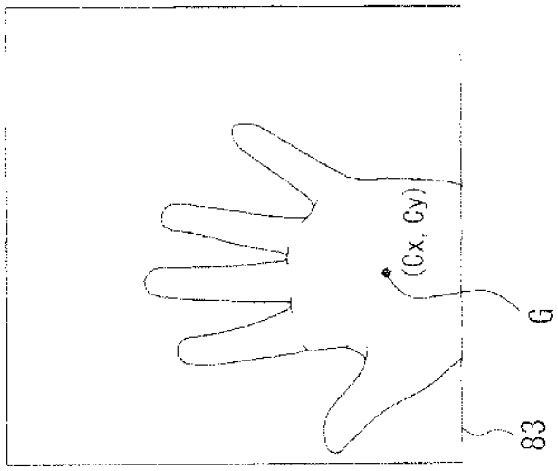


FIG. 27B

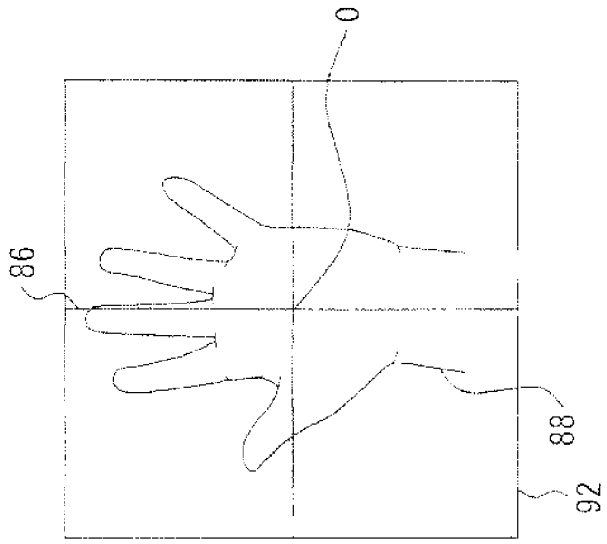


FIG. 27A

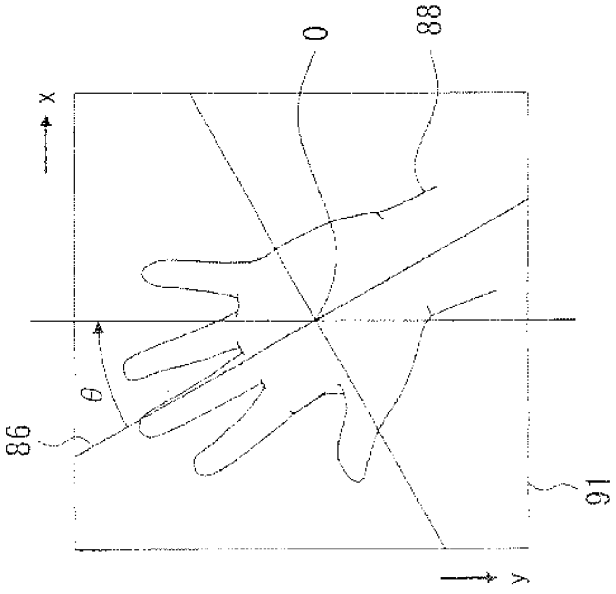


FIG. 28

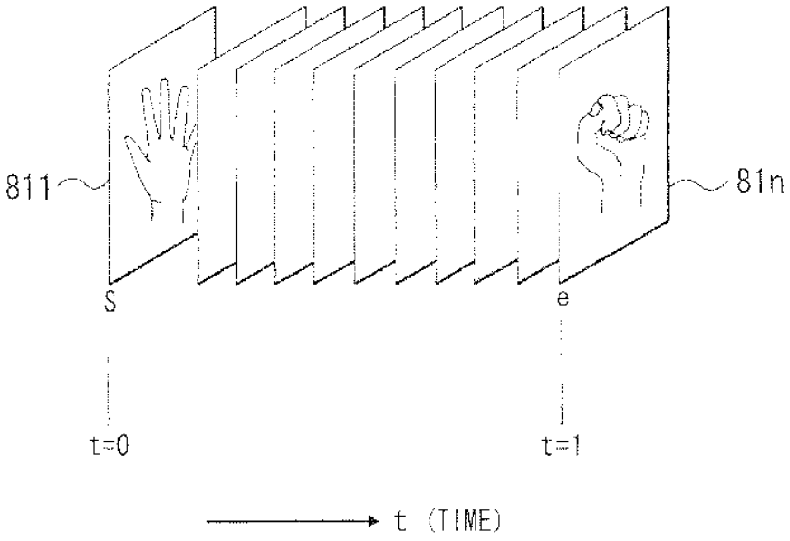


FIG. 29A

(PALM MOVEMENT COMMON CHARACTERISTICS)

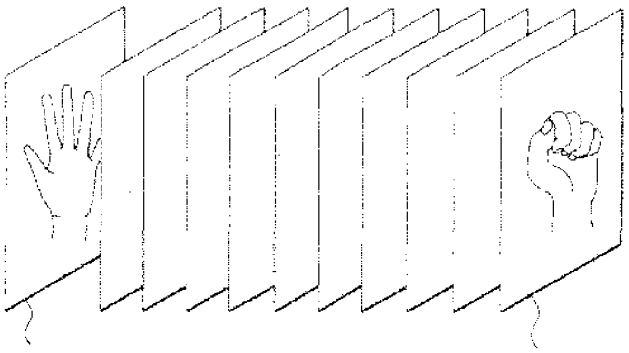


FIG. 29B

(MOVEMENT CHARACTERISTICS OF PERSON BEING CHECKED)

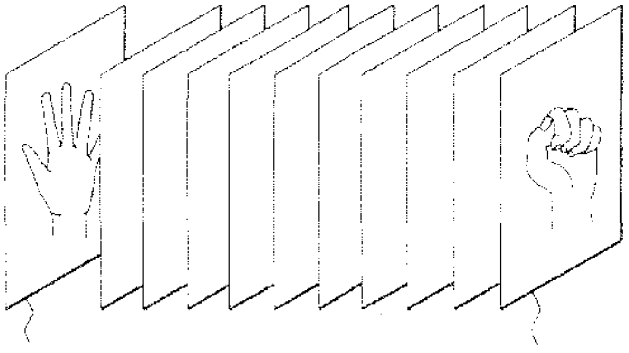
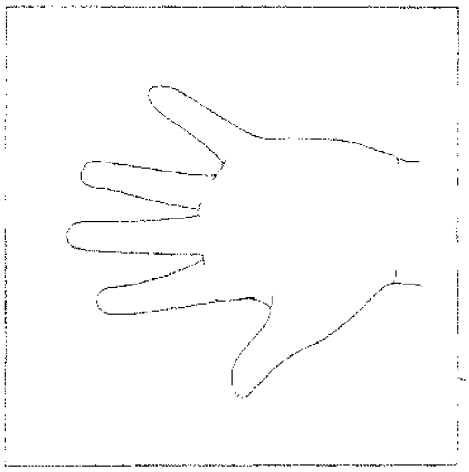


FIG. 30A

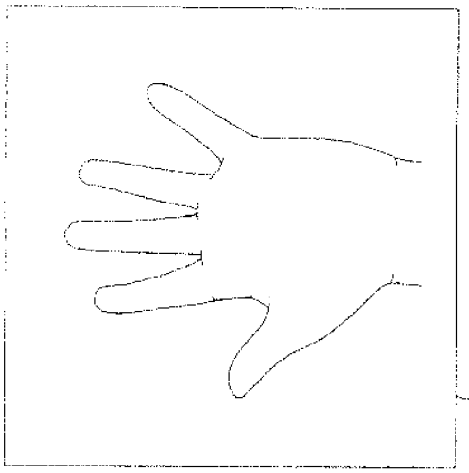
$d_{mk}(i, j)$ COMMON CHARACTERISTICS



84k

FIG. 30B

$d_{rjk}(i, j)$ CHARACTERISTICS OF PERSON BEING CHECKED



85k

FIG. 31

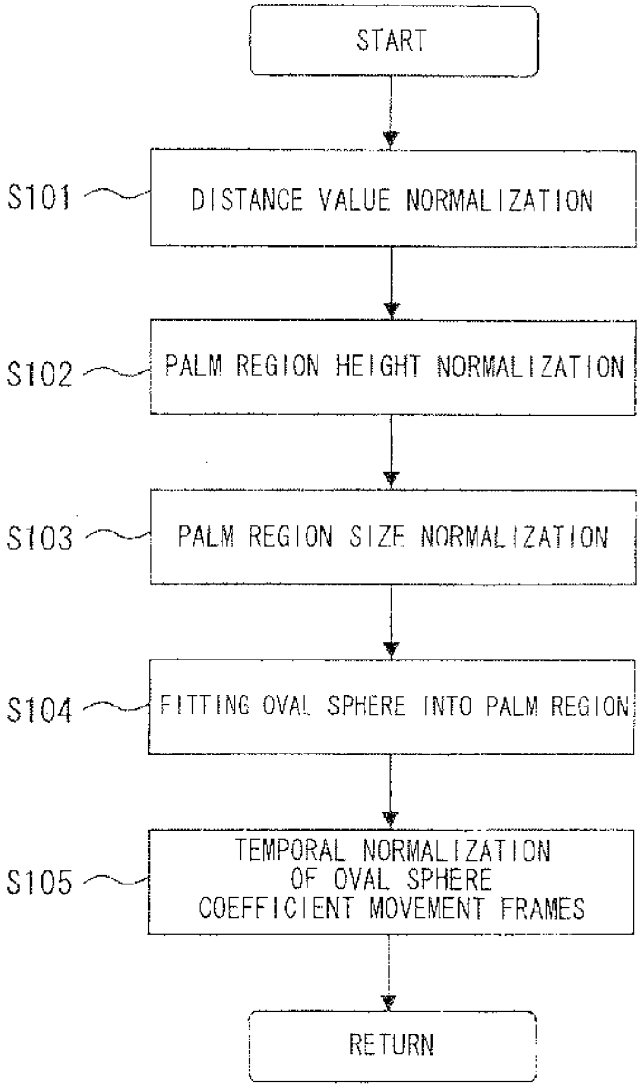

START
S101
DISTANCE VALUE NORMALIZATION
S102
PALM REGION HEIGHT NORMALIZATION
S103
PALM REGION SIZE NORMALIZATION
S104
FITTING OVAL SPHERE INTO PALM REGION
S105
TEMPORAL NORMALIZATION OF OVAL SPHERE COEFFICIENT MOVEMENT FRAMES
RETURN

FIG. 32

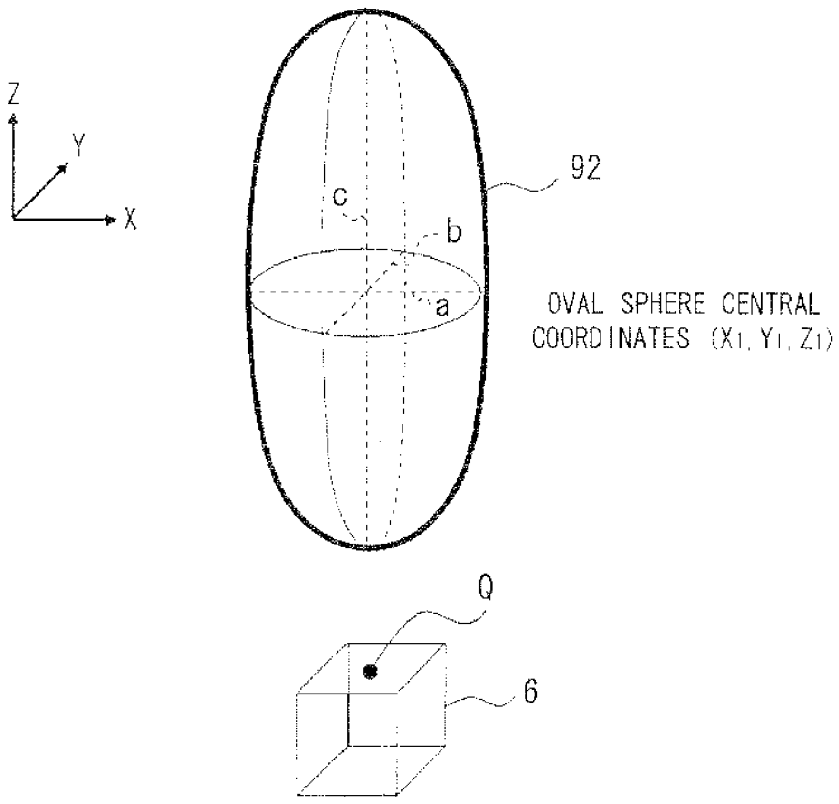


FIG. 33A

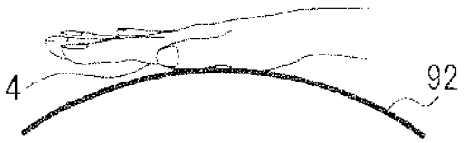


FIG. 33B

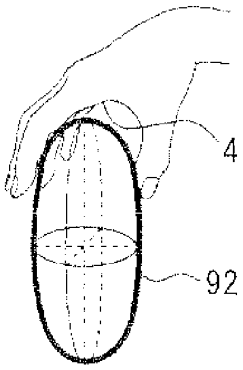


FIG. 33C

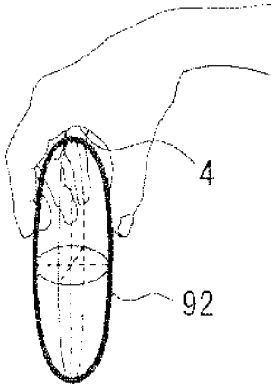


FIG. 33D

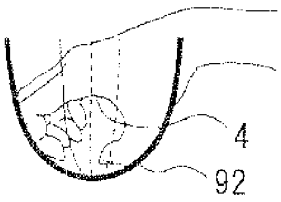


FIG. 33E

FIG. 34

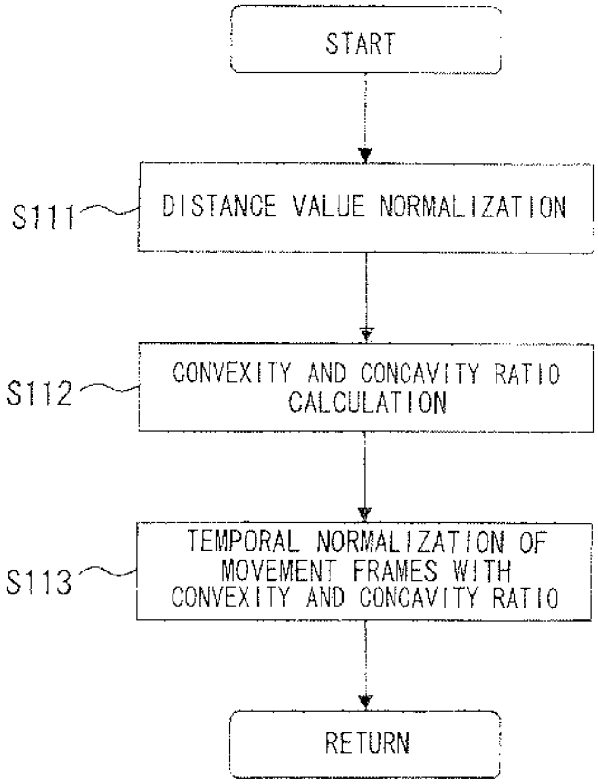

START
S111
DISTANCE VALUE NORMALIZATION
S112
CONVEXITY AND CONCAVITY RATIO CALCULATION
S113
TEMPORAL NORMALIZATION OF MOVEMENT FRAMES WITH CONVEXITY AND CONCAVITY RATIO
RETURN

FIG. 35A

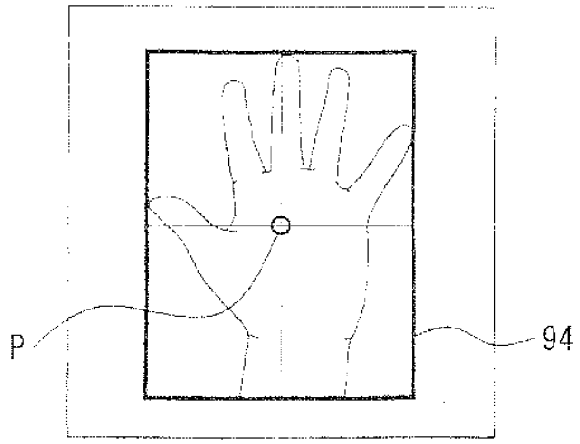


FIG. 35B

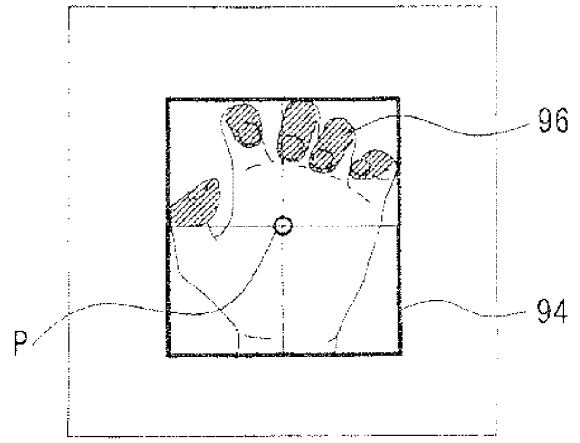


FIG. 35C

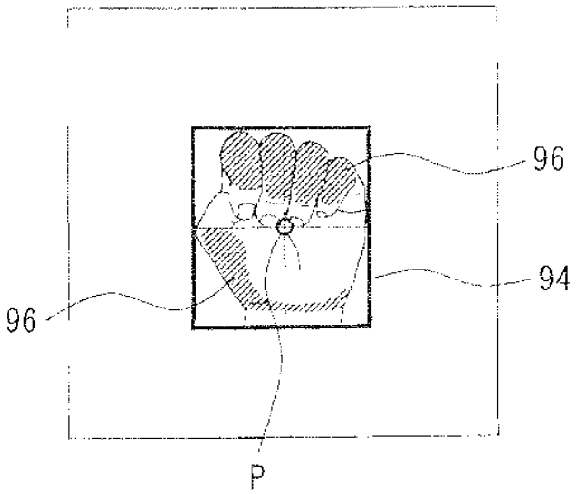


FIG. 36

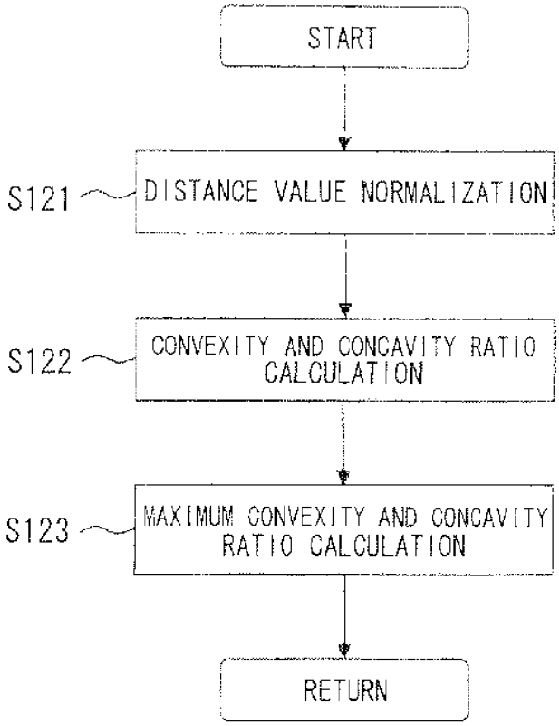
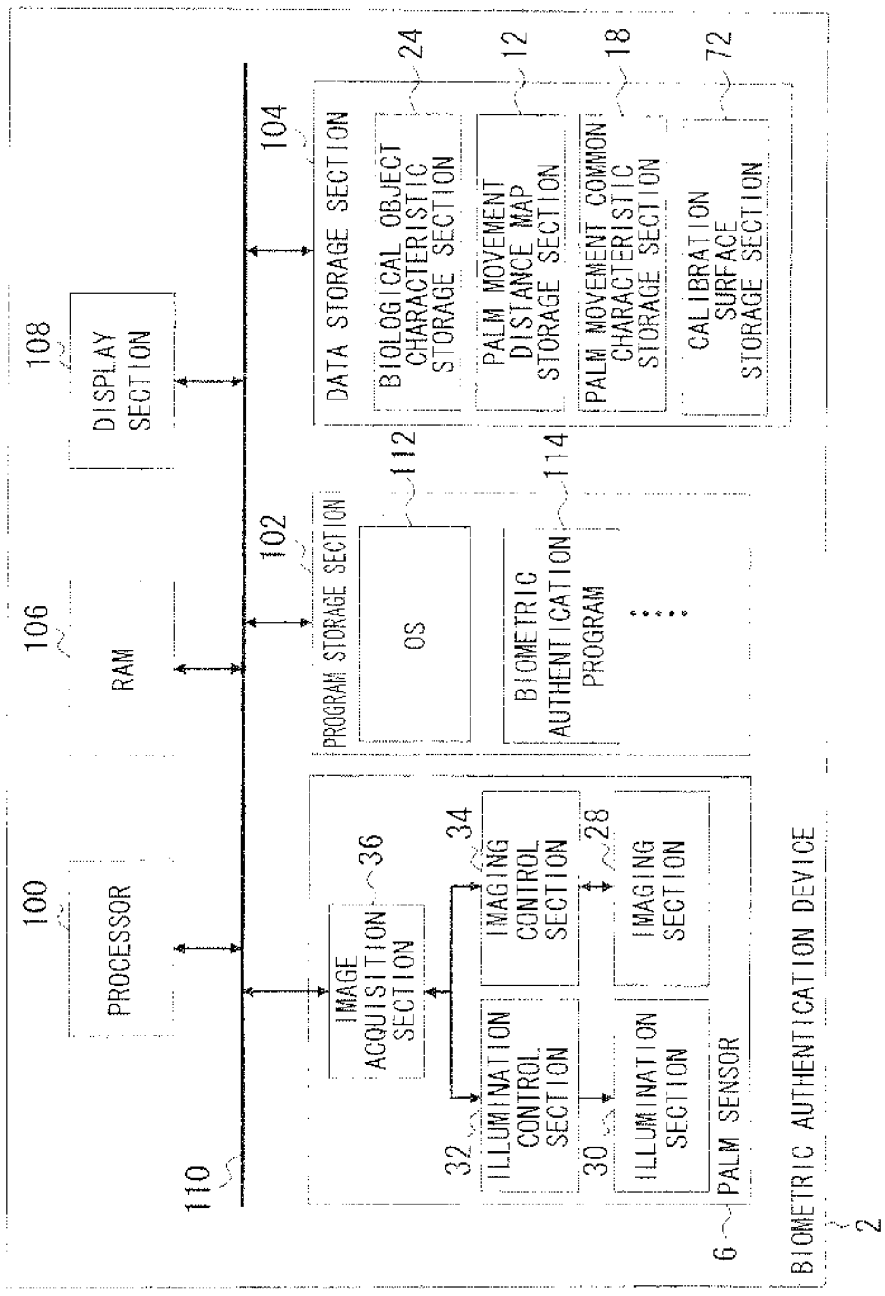

START
S121
DISTANCE VALUE NORMALIZATION
S122
CONVEXITY AND CONCAVITY RATIO CALCULATION
S123
MAXIMUM CONVEXITY AND CONCAVITY RATIO CALCULATION
RETURN

FIG. 37


BIOMETRIC AUTHENTICATION DEVICE
2
PALM SENSOR
6
ILLUMINATION SECTION
ILLUMINATION CONTROL SECTION
IMAGING SECTION
IMAGING CONTROL SECTION
IMAGE ACQUISITION SECTION
PROCESSOR
100
RAM
106
DISPLAY SECTION
108
110
102
PROGRAM STORAGE SECTION
OS
112
BIOMETRIC AUTHENTICATION PROGRAM
114
DATA STORAGE SECTION
104
BIOLOGICAL OBJECT CHARACTERISTIC STORAGE SECTION
24
PALM MOVEMENT DISTANCE MAP STORAGE SECTION
12
PALM MOVEMENT COMMON CHARACTERISTIC STORAGE SECTION
18
CALIBRATION SURFACE STORAGE SECTION
72
32
30
28
34
36

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- JP 2003111749 A **[0003] [0006] [0007]**
- JP 2007524441 A **[0004] [0006] [0007]**
- JP 2002150296 A **[0005] [0006] [0007]**

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer:
(11) Publication number: **EP 3 079 571 A0**
(11) Numéro de publication:

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum unter der Nummer:

WO 2015/089484 (Art. 153(3) EPÜ).

International application published by the World Intellectual Property Organization under number:

WO 2015/089484 (Art. 153(3) EPC).

Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle sous le numéro:

WO 2015/089484 (art. 153(3) CBE).

Espacenet

Bibliographic data: JP2006180899 (A) — 2006-07-13

LIFE ACTIVITY ANALYSIS DEVICE, LIFE ACTIVITY ANALYSIS METHOD, PROGRAM, AND RECORDING MEDIUM

Inventor(s): SONE MOTOKI ± (SONE MOTOKI)

Applicant(s): SHARP KK ± (SHARP CORP)

Classification: **- international:** ***A61B5/22***
- cooperative:

Application number: JP20040374456 20041224 Global Dossier

Priority number(s): JP20040374456 20041224

Also published as: JP4617154 (B2)

Abstract of JP2006180899 (A)

PROBLEM TO BE SOLVED: To determine the posture and behavior of a user and to accurately compute the total consumed calories based on the posture and behavior. ;SOLUTION: The life activity analysis device comprises an information detecting part for detecting the body motion of the user around the thighs and outputting signals, a signal saving part for saving the signals outputted by the information detecting means, and an analysis part for processing the saved signals and determining the posture or behavior of the user. ;COPYRIGHT: (C)2006,JPO&NCIPI

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 August 2006 (31.08.2006)

PCT

(10) International Publication Number
WO 2006/090371 A2

(51) International Patent Classification:
A61B 5/0476 (2006.01)

(21) International Application Number:
PCT/IL2006/000230

(22) International Filing Date:
22 February 2006 (22.02.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/654,460 22 February 2005 (22.02.2005) US

(71) Applicant *(for all designated States except US)*: **SOFTWARE SOLUTIONS LTD.** [GB/GB]; P.o.box 546, 28-30 The Parade, St. Helier, Jersey Je48xy, St. Helier, Jersey Je48xy (VG).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **ORBACH, Tuvi** [IL/GB]; 5 Ravenscroft Avenue, London NW11 0SA (GB).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.o.box 4060, 61040 Tel Aviv (IL).

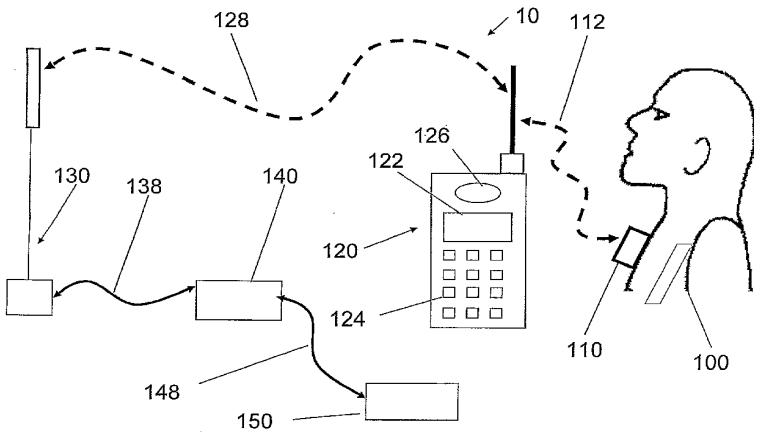
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS AND SYSTEMS FOR PHYSIOLOGICAL AND PSYCHO-PHYSIOLOGICAL MONITORING AND USES THEREOF



(57) Abstract: The invention provides a system and method for monitoring one or more physiological parameters of a user. The system of the invention includes one or more wearable sensor modules sensing the one or more physiological parameters. One or more transmitters wirelessly transmit signals indicative of values of the one or more physiological parameters to a mobile monitor. The mobile monitor includes a processor processing the signals received from the transmitter in real time using expert knowledge. A device provides one or more indications of results of the processing. The invention also provides wearable mobile sensors for use in the system of the invention. The method of the invention includes obtaining values of the physiological parameters of the user from one or more wearable sensor modules. Signals indicative of values of the one or more physiological parameters are wirelessly transmitted to a mobile monitor. The signals are processed in real time using expert knowledge, and one or more indications of results of the processing are provided to the mobile unit.

WO 2006/090371 A2

METHODS AND SYSTEMS FOR PHYSIOLOGICAL AND PSYCHO-PHYSIOLOGICAL MONITORING AND USES THEREOF

FIELD OF THE INVENTION

The present invention is related generally to the field of physiologically monitoring and bio interactive applications.

BACKGROUND OF THE INVENTION

Biofeedback has been in use for many years to alleviate and change an individual's negative behavior patterns but existing systems have a number of significant drawbacks: Most current systems are reliant on powerful computers First of all, they require the user to be trained either by health professionals or complex on-line programmers. Once the user has been trained, they must remember to implement the internal physiological changes in their daily lives. The biofeedback sessions are rarely undertaken on a daily basis and certainly not in real time. This requires the user to remember specific events that occurred days before and recall his exact emotional responses.

US patent 6,026,322; entitled "Biofeedback apparatus for use in therapy"; to Korenman, et al. filed February 6, 1997; discloses an apparatus and a program designed to train the user to control one or more aspects of his or her psycho-physiological state by controlling signals representative of a psycho-physiological parameter of the user, e.g. his galvanic skin resistance, which may be detected by a sensor unit with two contacts on adjacent fingers of a user. The sensor unit can be separate from a receiver unit which is connected to a computer running the program. The disclosed apparatus is described for use in treating patients with a physiological condition, for example, irritable bowel syndrome. In a treatment session, one or more psycho-physiological parameters of the patient are sensed and the sensed parameter

used to alter a display which the patient watches. The display includes a visual or pictorial representation of the physiological condition being treated which changes in appearance in a fashion corresponding to the physiological change desired in the patient.

PCT application WO0047110; discloses a method for obtaining continuously and non-invasively one or more parameters relating to the cardiovascular system of a subject, for example: systolic blood pressure, diastolic blood pressure, young modulus of an artery, cardiac output, relative changes in vascular resistance, and relative changes in vascular compliance.

US patent 6,067,468; to Korenman, discloses a program, designed to train the user to control one or more aspects of his or her psycho-physiological state. The program is controlled by signals representative of a psycho-physiological parameter of the user, e.g., his galvanic skin resistance which may be detected by a sensor unit with two contacts on adjacent fingers of a user. The sensor unit is separate from a receiver unit which is connected to a computer running the program.

SUMMARY OF THE INVENTION

In its first aspect, the present invention provides portable, cordless, and wearable sensors, for monitoring queries emotional and physiological responses to events as they occur. These results, gathered in real time, may be more effective and relevant to the user than those recreated days later after they occurred, under artificial conditions. The new sensors may utilize mobile phones and other technology to display the user's physiology and emotional state, real-time coaching based on expert knowledge, and to train the user to modify negative behavior patterns.

As used herein, the term *"wearable device"* refers to a device that the user can carry with him, for example, under or above his clothing, in his pocket, attached to his clothes, or in his hand.

In its second aspect, the invention provides a system for monitoring a user's emotional and physiological responses to events as they occur.

In another of its aspects, the invention provides methods to analyze the user's state of mind and physiology. In yet another of its aspects, the invention provides applications of the methods and sensors of the invention.

The invention also provides new methods to assess subtle information from this data – such as the user's emotions; new methods of therapy; and new methods of entertainment, based on the interactions with the user's physiology and responses.

Thus, in one of its aspects, the invention provides a system for monitoring one or more physiological parameters of a user comprising:

(a) one or more wearable sensor modules sensing the one or more physiological parameters;

(b) one or more transmitters wirelessly transmitting first signals indicative of values of the one or more physiological parameters to a mobile monitor; and

(c) the mobile monitor, wherein the mobile monitor comprises:

a first processor processing the first signals received from the transmitter in real time using expert knowledge; and

a device providing one or more indications of results of the processing.

The system of the invention may further comprise a remote server capable of communication with said mobile monitor, the remote server receiving second signals from the mobile monitor, the remote server associated with a viewing station having a second processor, the remote server being configured to perform at least one of the following:

(a) transmitting the second signals to a viewing station for analysis, the analysis ;

(b) accessing historical data relating to the subject;

(c) transmitting the historical data to the viewing station;

(d) receiving from the viewing station results of the analysis;

(e) transmitting the results of the analysis to the mobile unit; the analysis being based upon the second signals, and one or more of the historical data, expert knowledge and computerised protocols.

At least one sensor module of the system may comprise at least one sensor selected, for example, from the group comprising:

(a) An electro dermal activity sensor;

(b) An electrocardiogram sensor;

(c) A plethysmograph; and

(d) A piezoelectric sensor.

The system of the invention may comprise at least two sensors selected, for example, from a group comprising:

(a) an electro dermal activity sensor;

(b) an electrocardiogram sensor;

(c) a plethysmograph; and

(d) a respiration sensor.

The first signals may be transmitted from a sensor module to the mobile monitor, for example, by any one or more of the following protocols:

(a) Bluetooth;

(b) WiFi; and

(c) Wireless Lan;

The mobile monitor may be selected, for example, from the group comprising:

(a) a cellular phone;

(b) a personal digital assistant (PDA);

(c) a pocket PC;

(d) a mobile audio digital player;

(e) an iPod,

(f) an electronic note-book;

(g) a personal laptop computer;

(h) a DVD player;

(i) a hand held video game with wireless communication; and

(j) a mobile TV.

The mobile unit may be a cellular telephone and communication between the mobile monitor and the remote server may be over a cellular communication network.

The mobile unit may include any one or more of a visual display, one or more speakers, a headphone, and a virtual reality headset.

In another of its aspects, the invention provides a wearable sensor module for use in the system of the invention.

The wearable sensor module may comprise at least one sensor selected, for example, from the group comprising:

(a) An electro dermal activity sensor;

(b) An electrocardiogram sensor;

(c) A plethysmograph; and

(d) A pizoomagnetic sensor.

The wearable sensor module may comprise at least two sensors selected, for example, from a group comprising:

(a) an electro dermal activity sensor;

(b) an electrocardiogram sensor;

(c) a plethysmograph; and

(d) a respiration sensor.

The wearable sensor module may comprise a transmitter transmitting signals, for example, by any one or more of the following protocols:

(a) Bluetooth;

(b) WiFi; and

(c) Wireless Lan;

The wearable sensor unit may comprise an electro dermal activity sensor adapted to monitor skin conductivities using at least a 16 bit A to D conversion without the need of manual calibration.

The sensor module may comprise an EDA sensor comprising:

(a) at least two electrodes adapted to be applied to a skin surface;

(b) electronic circuitry for measuring a skin resistance across the electrodes and calculating an EDA based upon the resistance using an algorithm in which the EDA does not depend linearly on the resistance.

The sensor module may comprise a blood flow sensor comprising:

(a) a light source adapted to emit light towards a skin surface;

(b) a light detector adapted to detecting light reflected from the skin surface;

(c) electronic circuitry for measuring an intensity of the reflected light and controlling an intensity of said light source based upon the intensity of the reflected light.

Electronic circuitry in the sensor module may be capable of measuring skin resistance across the electrodes over a range of at least from 50 K Ohm to 12 M Ohm.

The first processor of the system of the invention may be configured to calculate from the first signals one or both of a parameter indicative of an arousal state of the user and a parameter indicative of an emotional state of the user.

Calculation of a parameter indicative of an arousal state of the user may include calculating a score of a sympathetic and parasympathetic activity of the user using an algorithm based on any one or more of the user's Electro Dermal activity, Heart Rate, EDA variability, and HR variability.

The the first processor may be configured to calculate a parameter indicative of an arousal state of the user and to display the parameter indicative of an arousal state of the user on a display associated with the mobile unit as a two-dimensional vector.

The first processor may be configured to display on a display associated with the mobile monitor any one or more of the following images: an image indicative of bio-feedback information relating to the user; an image indic

of breathing activity of the user, an image including a graph indicative of an EDA activity of the user, an image including a graph indicative of a heart rate of the user, an image including a graph indicative of a heart rate variability of the user; an image including a graph indicative of an autocorrelation of a heart rate variability of the user; and an image indicative of recommendation to improve the user's psycho-physiological state based on one or both of the user's physiological data and experts' knowledge.

An image indicative of breathing activity may include a bar having a length indicative of the breathing activity. An image indicative of bio-feedback information relating to the user may include one or more parameter target values.

The first processor may be configured to calculate in a calculation based upon the first signals any one or more of the following: a breathing rate of the user; and a heart rate variability of the user. The user's rate of breathing may be calculated and analysis by monitoring changes in the electrical capacitance of the body while the user is breathing.

The system of the invention may further comprise an entertainment system In this case, the first processor may be configured to determine at least one command based on the first signals and to transmit the at least one command based to the entertainment system. The entertainment system may comprise a third processor configured to perform an action based upon the one or more commands. The action may comprises any one or more of generating an SMS massage, controlling a DVD, controlling a computer game, and controlling a "Tamaguchi" animation. The action may comprise processing a user reaction to any one or more of the following: a displayed animated image; a video clip, an audio clip, a multimedia presentation, real-time communication with another human, a question that the user has to answer, and a task that the has to perform.

In another of its aspects, the invention provides a method for monitoring one or more physiological parameters of a user comprising:

(a) obtaining values of the physiological parameters of the user from one or more wearable sensor modules;

(b) wirelessly transmitting first signals indicative of values of the one or more physiological parameters to a mobile monitor; and

(c) processing the first signals received from the transmitter in real time using expert knowledge; and

(d) providing one or more indications of results of the processing to the mobile unit.

The results of the processing may include bio-feedback information of the user.

The method may further comprise transmitting second signals from the mobile monitor to a remote server having an associated viewing station and providing an analysis of the second signals at the viewing station. The viewing station may include one or both of a remote call center and an interactive expert system.

The processing may include calculating one or both of a parameter indicative of an arousal state and a parameter indicative of an emotional state of the user._Calculating a parameter indicative of an emotional state of the user may be based upon one or both of a sympathetic activity and parasympathetic activity of the user. Calculating a parameter indicative of an emotional state of the user may be based upon any one or more of an electro dermal activity, a heart rate, an electro dermal activity variability and a heart rate variability.

The method of the invention may further comprise a step of displaying on a display associated with the mobile unit one or both of an image indicative of a parameter indicative of an arousal state of the user; and an image indicative of a parameter indicative of emotional state of the user. An image may include one or both of a two-dimensional vector and a color indicative of a parameter.

The method of the invention may be used in obtaining respiration information selected from the group comprising duration of the inspiratory phase, and duration of the expiratory phase. The respiratory information m

obtained from audio sounds produced during breathing or speaking. The respiratory information may be obtained by the user indicating the beginning of one or more inspiratory phases and the beginning of one or more expiratory phases of the user's breathing. A breathing rate of the user may be calculated based upon a heart rate variability of the user. The user's rate of breathing may be calculated based upon changes in an electrical skin capacitance of the user while the user is breathing.

The method of the invention may further comprise training the user to increase any one or more of the followings: a duration of the inspiratory phase, a duration of the expiratory phase, and the ratio of the duration of the inspiratory phase to the duration of the expiratory phase.

The method of the invention may further comprise displaying on a display associated with the mobile monitor an image indicative of bio-feedback information, wherein the image includes any one or more of the following: an image indicative of breathing activity, an image including a graph indicative of EDA activity, an image including a graph indicative of heart rate, an image including a graph indicative of heart rate variability and an image including a graph indicative of an autocorrelation of heart rate variability. The analysis of the second signals may include a recommendation for the user to improve a psycho physiological state of the user. The recommendation may be displayed on a display associated with the mobile unit.

The method of the invention may comprise displaying a target value for one or more of the one or more obtained physiological parameters.

The method of the invention may further comprise steps of:

(a) challenging the user with one or more stimuli;

(b) monitoring one or more reactions of the user to said one or more stimuli;

(c) calculating, in a calculation based upon the one or more reactions, at least one parameter selected from the group of: latency time of a

reaction, maximum reaction time, half recovery time, maximum stress, and new baseline stress; and

(d) providing feedback to the user based on one or more of the calculated parameters.

The method of the invention may be used in a method of self behaviour modification comprising any one or more of the methods selected from the group comprising:

(a) cognitive behavioural therapy (CBT);

(b) visualisation;

(c) self hypnosis;

(d) auto suggestion;

(e) mindfulness;

(f) meditation;

(g) emotional intelligence skills;

(h) psychological counselling provided over a communications network.

When the method of the invention is used in a method of self behaviour modification the method may further comprise:

(a) providing the user with an interactive introduction about a specific condition of the user;

(b) providing the user interactive questionnaires for self assessment; and

(c) providing the user with one or more interactive sessions selected from the group comprising:

an interactive session for self training to implement cognitive techniques;

interactive sessions for self training to implement behavioural therapy;

interactive sessions for self hypnosis;

interactive sessions for visualisation;

interactive sessions for auto suggestions;

interactive training to acquire and implement life and interpersonal relational skills;

interactive training to improve emotional intelligence skills;

interactive training to find purposes and goals; and

interactive training to plan steps in life.

The user may be provided with one or more interactive sessions while the user is in a deep relaxation state.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

An exemplary embodiment of the invention is described in the following section with respect to the drawings. The same reference numbers are used to designate the same or related features on different drawings. The drawings are generally not drawn to scale.

The invention is herein described, by way of example only. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

Fig. 1 is a physiology monitoring system, according to an exemplary embodiment of the invention;

Fig. 2 shows a sensor module attached to a user's finger, according to an exemplary embodiment of the invention;

Fig. 3 shows some details of a sensor module, according to an exemplary embodiment of the invention;

Fig. 4 is a schematic representation showing the mental and physiologic states of a person;

Fig. 5a shows a typical electro cardiogram (ECG) of a healthy person;

Fig. 5b shows a typical light reflection optical signal as affected by the blood flow;

Fig. 5c shows frequency analysis of heart monitoring signal;

Fig. 6a shows a graph of typical heart beat rate vs. time and its correlation to breathing cycle;

Fig. 6b shows frequency analysis of Heart Rate Variability (HRV);

Fig. 7a shows an exemplary display showing sensors output, according to an exemplary embodiment of the invention;

Fig. 7b shows an exemplary display showing heart beat rate (HR), according to an exemplary embodiment of the invention;

Fig. 7c shows an exemplary display showing Electro Dermal Activity (EDA), according to an exemplary embodiment of the invention;

Fig. 7d shows an exemplary display showing Heart Rate Variability, demonstrating the breathing cycle, according to an exemplary embodiment of the invention;

Fig. 8 shows an exemplary graph of stimuli induced stress used in a training session, according to an exemplary embodiment of the invention;

Fig. 9 schematically shows an electric circuitry of a reflective Photo-Plethysmograph with automatic continual adjustment of the source light intensity in accordance to an exemplary embodiment of the invention;

Fig. 10 shows an improved electronic circuit for EDA monitoring in accordance to an exemplary embodiment of the invention;

Fig. 11 shows an exemplary graph of the relationship between the user's skin resistively and voltage measured by improved electronic circuit for EDA in accordance to an embodiment of the invention; and

Fig. 12 shows an entertainment system according to an aspect of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENT

The following detailed description is the best presently contemplated modes of carrying out the present invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles in accordance with the present invention. The scope of the present invention is best defined by the appended claims.

With reference to the drawings, in Fig. 1 shows a physiological monitoring system **10**, in accordance with an exemplary embodiment of the invention.

A sensor module **110** is attached to a user **100**. A communication link **112** is used to transfer data from the module **110** to a mobile monitor **120**. Based on the transferred data the mobile monitor **120** provides visual biofeedback to the user by means of a display **122** and optionally an audio biofeedback to the user by means of speaker **126**. Optionally, a keypad **124** is used to control the operation of the mobile monitor **120**, sensor module **110**, or both. Optionally the user can control the operation using voice recognition methods.

Optionally, a communication link **128** is used to connect the mobile monitor **120** to a remote server **140** where in-depth analysis of data obtained by the sensor unit **110** may be done and, optionally, data can be transmitted to an expert or another user. In the exemplary embodiment of Fig. 1, the mobile monitor **130** is a cellular phone, communication link **112** is a Bluetooth link, and communication link **128** is cellular RF link to a cellular base station **130** which is linked to a remote server **140** by a data link **138**.

Optionally, an additional data link **148** such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server **140** to a viewing

station **150** where a human expert may provide interpretation of the data and transmit recommendations to the user.

Sensor module

Fig. 2 depicts a sensor module **210** that may be used in the system **10** instead of the sensor module **110**. The sensor module **210** is in contact with the user's finger **200**. The sensor module **210** may be attached to the finger by a strap **212** as shown in Fig. 1, or the sensor module **210** may be shaped to fit over the finger. Alternatively, the finger **200** may simply be applied to the sensor module **210**.

Fig. 3 shows a block diagram of a sensor module **310** for use in the system **10** according to an exemplary embodiment of the invention.

In the exemplary embodiment of Fig. 3, Electro Dermal Activity (EDA) at a user's skin surface **300** is monitored by applying at least first electrode **332** and second electrode **334** to the skin surface **300**. EDA electronics **330** monitors the skin resistively by applying a very low electric voltage across the first and second electrodes and creating a minute electrical current between the electrodes. EDA electronics **330** generates a digital signal indicative of the skin resistively.

In the exemplary embodiment of Fig 3, blood flow under the skin **300** is monitored by Plethysmograph Electronics **320** which is used for Heart Rate (HR) monitoring. In this exemplary embodiment, a light source **322** illuminates the skin surface **300** with emitted light **324**. The intensity of scattered light **326** reflected from the skin and received by light detector **328** depends on the blood flow in the skin. Phethysmograph **electronics 320** generates a digital signal indicative of the blood flow and thus may be used to monitor heart activity.

Optionally, one or more additional sensors 372 connected to additional sensor electronics **370** is used to monitor one or more additional physiological signals such as temperature, Electrocardiogram (ECG), blood pressure, etc.

The processor **340** receives digital data from EDA electronics **330**, Phjethysmograph electronics **320** and optionally from additional sensor electronics **370** and processes the data according to instructions stored in a memory **342**. The memory **342** may be a Read Only Memory (ROM) storing a pre-installed program. a

Random Access Memory (RAM), a non-volatile memory such as flash memory or combination of these types of memory. The processor **340** may store raw or processed data in memory **342** for later use.

Optionally, the sensor module **310** is equipped with an indicator **380**. Indicator **380** may provide visual or audio indication as to the status of the module such as "on/off", "low battery". Additionally or alternatively, indicator **380** may provide visual or audio indication as to the physiological state of the user based on the data from the sensors.

In the exemplary embodiment of Fig. 9, a communication module **350** is used as an interface between the sensor module **310** and mobile monitor **120** (Fig. 1). In this embodiment, a wireless communication link is used. Preferably, communication module **350** supports "blue-tooth" RF bidirectional wireless communication and is connected to antenna **352.** Alternatively or additionally, Infra-Red (IR) communication, ultrasonic communication, WIFI communication, or wire communication may be used.

Battery **360** provides power for all the electronics within sensor module **310.**

Alternatively or additionally, a wired connection, for example Universal Serial Bus (USB) may be used. In this case, a wired connection may provide power, optionally using electrical isolation such as a transformer which isolates the supplied power for safety, as well as means for data transfer.

The location of the sensor module on the user's body may depend on the type of physiological data to be acquired by the module and the type of sensor used.

For example, for measuring an EDA signal, the sensor's electrodes could be placed where the skin resistively changes depending on the person's stress or arousal level or any minute change in the autonomic nerves system, such as the palm of the hand, fingers wrist or ear lobe.

For measuring blood flow by optical reflectance, the module could be attached to locations where blood vessels are close to the surface such as the wrist, fingertips ear lobe etc, or the forehead to monitor blood flow in the brain.

For measuring cardiac electrical activity (ECG), the sensor may be attached to the user's chest using an adhesive or a strap, alternatively ECG can be monitored by attaching electrodes to two hands.

For temperature sensing, a sensor, which may be external to the sensor module, may be placed in the armpit or ear etc.

Alternatively, sensor may be temporarily touched to the measurement location for the duration of the measurement.

More than one sensor module may be used simultaneously. Two or more sensor modules may acquire the same or different physiological signals and communicate them to the same or different mobile monitors. Optionally, a plurality of sensors may monitor one or plurality of users simultaneously. The sensors may communicate with the same mobile monitor or with different monitors.

The communication link **112** is preferably bidirectional and continues while the sensor module is in operation. In such cases, the sensor module transmits information indicative of the user's physiological state to the mobile monitor for display and processing and receives commands and instructions from said mobile module. Such commands and instruction may control the operation mode of the sensor module. For example, the data sampling rate may be changed by such a command. Additionally or alternatively, data sampling accuracy or range may be changed by such commands. Programs executed by processor **340** may be uploaded and stored in the memory **342**.

Alternatively, the communication link **112** may be unidirectional in which case the sensor module **310** only transmits information to mobile monitor **120**. Optionally, the communication link **112** is intermittent. For example, for saving power and prolong battery life, the communication link may be activated only on demand, or when signals detected by the sensor are in specific ranges, for example: above or below thresholds or satisfy other conditions. For example, if the processor **340** detects an anomaly in the acquired physiological signal, it may initiate a data transfer to the mobile monitor. Alert conditions may be set up that trigger such data transfer to the mobile monitor **120**. For example, heart rate may be monitored by the processor **340** to detect anomalous conditions regarding the rate and its Variability such as:

Rate (HR) too high, HR too low, Heart Rate Variability (HRV) too low. Breathing rate which may be inferred from analysis of HRV as will be demonstrated later, may also be used to trigger data transfer.

Alternatively or additionally, data transfer may be triggered by the mobile monitor.

For example, the mobile monitor **120** may be a laptop computer, The sensor module **310** may acquire and log physiological information, preferably in a compressed form in memory **342**. Such a log may span a duration of several minutes or hours. When the sensor module **310** is in the vicinity of the mobile monitor, the acquired and stored data may be transferred on command initiated automatically or manually.

The data transfer rate may change depending on the operation mode of the sensor module. For example, one or few of HR, EDA ECG and HRV may be relayed to the mobile monitor during normal operation mode, while more or all of the signals are transferred during another mode of operation. Optionally, data is stored in a buffer, for example a cyclic buffer within memory **342** such that data recently acquired is available until over-written. Buffered data may be transferred on demand or initiated by the processor **340** or the mobile monitor.

Instructions and commands may be initiated by the remote server **140** or expert station **150** and relayed to sensor module **110** through mobile monitor **120**. Alternatively, different communication methods may be used for different purposes. For example, data transfer from sensor module **112** to mobile monitor **120** may be achieved by a unidirectional communication such as IR transmission, while reprogramming the sensor module or setting alert parameters may be done while sensor **110** is connected to mobile monitor **120** using a USB cable. It should be apparent that other combinations of communication modes and methods are possible.

Preferably, the sensor module **310** comprises means for monitoring blood flow in the skin **300** using the phethysmograph electronics **320**; light source **322** and light detector **328**. In the preferred embodiment, the light source **322** is a Light Emitting Diode (LED) emitting red or IR light **324**, or a plurality of LEDs transmitting sar

plurality of wavelengths for example both red and IR light. Other light sources may be used such as solid-state diode lasers or Vertical Cavity Surface Emitting Laser (VCSEL). In the preferred embodiment, the light detector **328** is a Silicon photodiode.Optionally, the intensity of the emitted light **324** is not constant. For example, HR electronics **320** may turn off the light to conserve energy or to perform periodic calibration and ambient light subtraction. Additionally or alternatively, the intensity of emitted light **324** may be controlled by plethysmograph electronics **320** to compensate for different skin colors and person to person variations in skin light scattering properties such that reflected light **326** will remain within specific range. This method ensures that the light detector **328** and its associated amplifier and Analog to Digital Converter (ADC) will not be saturated or out of range. Alternatively the light source **322** may be placed on one side of the user's appendage such as finger or ear lobe and the light detector **328** placed on the other side of the appendage. In this case the detector detects the light transmitted through the appendage instead of the reflection light.

Fig. 9 shows some details of exemplary electric circuitry of a reflective photo-plethysmograph **900** with automatic continual adjustment of the source light intensity in accordance to an embodiment of the invention. The circuit is designed to pick up changes in light intensity as blood passes through the capillary bed of a user for example, in the finger. The intensity of reflected light intensity changes in time reflecting the pulsatile action of the heart in the user. The change is converted to a voltage, amplified, filtered and then digitized signal before being passed to a microcontroller **340**

The interface sensor comprises an intensity-controlled Opto-transmitter Tx, preferably a red or Infra-red LED and a light receiver Rx preferably a photodiode or a phototransistor and a trans-impedance (current to voltage) amplifier. In the preferred embodiment, the receiver Rx is an integrated component including both photo-detector and amplifier. The signal S1 from the output of the trans-impedance amplifier is feed to one input of a differential amplifier A1 and is also low-pass filtered and taken to a unity-gain buffer amplifier A2 giving output signal S2. Output signal S2 represents the

average level of light falling on the opto-sensor with any pulsatile component removed due to the low pass action of the filter. S2 is then used as the other input to the differential amplifier A1. The output from A1 is low-pass filtered and then fed along with S2 to the differential inputs of an analogue to digital converter AD1 providing a digitized pulse signal to microcontroller 340. Additionally, S2 is used along with a fixed reference voltage Vref slugged comparator A3 whose output controls the intensity of the opto-transmitter Tx. This allows optimal biased input conditions for the receiver by automatic continual adjustment of the source light intensity. The overall effect of the circuit provides for wide variability in ambient light conditions, skin tone of the subject and minimizes unnecessary current drain due to optimal control of the light source. It is possible to replace the photo-plethysmograph with a piezo-electric sensor, which monitors minute changes in blood vessel pressure instead of changes in reflected light.

Another aspect of the invention is a GSR EDA sensor. GSR and EDA have been used for many years to monitor general arousal levels. However, efficacy has been compromised because the difference between skin resistance / impedance of individuals is very high as is the disparity encountered within the same individual experiencing differing emotional and physiological states.

In order to accommodate a wide spectrum of users, current systems are not sensitive enough to diagnose minute changes. One way, used in the art, to overcome this problem is to have two reading sessions monitored by experts: the first reading creates a base line, the second session is done at higher sensitivity centered around the baseline. In the present invention,

- A 16-bit Analog to Digital Converter (ADC) microchip is preferably used to cover a larger range with high sensitivity.
- The electronic circuit, as depicted in Figure 10, is modified to enhance dynamic range.
- Software is used that can automatically monitor both the user's base line and level of sensitivity, and display it to the user in an understandable way.

In contrast to prior art EDA units which use 8-bit or 12 bit ADC, the EDA electronics **330** of the preferred embodiment uses a 16-bit ADC. It was discovered that small temporal changes in skin resistance provide significant physiological information, while the EDA may change over a wide range. Additionally, the large dynamic range reduces or eliminates the need to manually adjust the ADC range or baseline or sensitivity. Since the EDA signal is low bandwidth, high accuracy ADC such as "sigma delta" type may be used.

Optionally, automatic auto ranging and auto scaling may be used. In this method, a baseline may be subtracted from each measurement. The subtracted value may be stored or transmitted to the mobile monitor so that actual values may be restored. Similarly, automatic scaling may be used to re-define the signal change associated with each bit of the ADC. Optionally or additionally, a Logarithmic or other non-linear scaling of acquired data may be used.

Fig. 10 shows an electronic circuit **1000**, for using non-linear scaling for EDA monitoring. The circuit **1000** is designed to pick up very small changes in sweat gland activity reflecting changes in the emotional arousal of the user. The circuit monitors changes in skin resistance level, which are then amplified, filtered and digitized before being passed to the microcontroller **340**.

In one preferred embodiment, the interface consists of a pair of gold plated finger electrodes **1032** and **1034**, etched onto a PCB. The EDA signal has a large dynamic range and there are also very large variations between subjects of base skin resistance level. The electronics comprise a modified constant current source. Operational amplifier A4 tries to maintain the potential at intersection **1100** at voltage Vref, providing a fixed current through the resistor R3. This current is the current flowing through the combination of resistor R1 and the EDA electrodes **1023** and **1034**. The voltage Vx, required to maintain this constant current is measured with respect to reference voltage Vref and digitized by Analog to Digital Converter AD2 after low-pass filtering. Preferably, AD2 is a 16-bit ADC.

The resistance R2 is preferably high, for example (R2 > 10 times the normal subject base readings) and during normal operation has no significant effect i

circuit. However for subjects with high levels of basal skin resistance, R2 becomes more significant and the voltage output from A4 is reduced to prevent output saturation. This allows subjects with high base resistance to be measured using the same circuitry with the output measured with a non-constant current.

The measured voltage Vx is given by:

$$Vx = \frac{Vref / R3}{1/(R1 + Rx) + 1/R2}$$

where R1, R2 and R3 are the resistor values. Vref is a reference voltage value, and Rx is the changing resistance of the user's skin appearing between the electrodes.

An EDA monitoring device based on the circuitry according to the current invention may be capable of measuring small changes in the skin resistance over a large range, for example from 50 KOhms (50,000 Ohm) to 12 MOhms (12,000,000 Ohm). The exact range may be adjusted by changing the values of the components in said circuitry.

Fig. 11 shows an exemplary graph of the relationship between the measured voltage Vx and the user's skin resistively Rx plotted in arbitrary units on a log-log scale. A linear range is observed near the origin. The plot becomes non-linear for high Rx values.

Optionally, the sensor module **310** is equipped with an indicator **380**. Indicator **380** may provide visual or audio indication as to the status of the module or provide one or few of: visual, vibrational, or audio indication as to the physiological state of the user based on the data from the sensors. For example, indicator **380** may be used to alert the user that a physiological signal is out of the predefined range. The alert may be initiated locally by processor **340** or communicated to the sensor module through communication link **112**. Optionally, indicator **380** may be used as biofeedback in a training session as will be detailed later.

The indicator **380** may comprise an LED or a few LEDs optionally of different colors. Optionally, indicator **380** may comprise a speaker providing audio signal to the user. Optionally, indicator **380** may comprise a means to produce vibration such as

PZT buzzer or miniature electric motor so that the alert may be sensed by the user and no one else.

Mobile monitor

In an embodiment of the current invention the sensor module **110** is connected by communication link **112** to a mobile monitor **120**. In one preferred embodiment, the mobile monitor **120** is a cellular phone or a Personal Digital Assistant (PDA) equipped with a processor to perform data analysis, memory, a display, Audio output, input means such as keypad, and microphone and sketchpad and means to communicate with both sensor module and remote server.

Specific programs necessary for interfacing with the sensor module and for providing feedback to the user may be uploaded by the user. For example, the program may be loaded into a cellular phone wirelessly in the same way a new game or ring tone is loaded.

Alternatively, other personal computing devices may be used as mobile monitors, for example a Laptop Personal Computer LPT or a media player such as Apple iPOD®, pocket PC or an electronic note-book. Alternatively, a standard PC may be used if the user wants to execute a training session without moving around or if the user wants to download data stored in the sensor module periodically or to reprogram the sensor.

The communication range of the sensor module is limited due to its small size and low battery capacity to few meters or up to almost 100 meters using Bluetooth. In contrast, the Mobile monitor is equipped with means to connect to a remote server wirelessly over the cell network, preferably using the Internet. For example, cellular phone may be connected using one of the cellular data exchange protocols such as GPRS. Other standard and proprietary protocols may be used such a wired connection to a phone line using a modem or an Asymmetric Digital Subscriber Line (ADSL), a Local Area Network (LAN) Wireless LAN (WAN), etc.

Remote servers may provide additional processing of the sensor's data, initial and updating of mobile monitor and sensor module programming, feedback and recommendations to the user, issue alerts to the user or summon rescue teams to a

the user in emergency. Some mobile monitors may be equipped with means to establish their physical location such as Global Positioning System (GPS) which may be used to direct the rescue team to a user in distress such as during cardiac mishap or epilepsy episode.

States of mind

Reference is now made to Fig. 4 illustrating schematically examples of possible "states of mind" of a user. The vertical axis is the arousal level of the user while the horizontal axis is his emotional state.

Biofeedback and monitoring systems are not designed to analyze emotions. The GSR or EDA sensor reflects arousal level, but the system cannot differentiate between positive arousal – that is when the user is enthusiastic and negative arousal when the user is stressed and angry. The existing methods also cannot differentiate between positive low arousal - when the user is relaxed and meditating, and negative low arousals – when the user is depressed and despondent.

Reference is now made to Fig. 4 illustrating schematically examples of possible "states of mind" of a user. The vertical axis is the arousal level of the user while the horizontal axis is his emotional state.

By integrating a sensitive EDA sensor (such as disclosed herein according to the current invention), HRV analysis, and optionally a multimedia display (such as a smart phone , PDA or PC), it is possible not only to analyze the state of the emotions of the user as described in Fig. 4 , but also to train the user to improve his state of emotions and physiology.

For example: the system can have several modes of operation:

a) Baseline calibration: The system automatically determines a base line of the specific user. The base line includes vectors of parameters which will be calculated and recorded during the first interval, including: minimum, maximum and average HR, HRV, FFT (Fast Fourier transform), respiration rate (which can be calculated indirectly or monitored directly), and EDA - max, min, average, variance, number of fluctuation and slope.

b) Calibration using induced state of mind: Preferably, a short time after the base line has been stabilized, the system presents prerecorded triggers. Each trigger is designed to elicit specific emotions in the user. The triggers may be prerecorded scenarios which can cause specific emotional reactions. The preferred methods are multimedia methods, which can be a prerecorded audio visual movie on a smart phone or PC. For a professional system, this can be virtual reality goggles with a real 3D scenario. For a less expensive system, the trigger can be only an audio session using a mobile phone. These triggers or scenarios can be general scenarios which have been tested and validated in the past to create a specific emotional reaction, or can be customized for a specific culture, people or person. For example, a scenario might be an audio visual display of a dentist drill in a tooth, or a car accident for negative arousal; winning a game, or a romantic relationship for a positive arousal; a relaxing nature movie for positive relaxation, and a boring and sad scenario for negative low arousal. Before, during and after each trigger, the system monitors, calculates and records the vectors of parameters as described above and calculates the parameters which are described in Fig. 8 when each trigger start and finish.

c) Calibration using user reported state of mind: The system can ask the users to input their subjective feeling, for example, by using the keyboard of their cell phone (e.g.) if you feel very happy press 9, very sad press 1). By calculating the above vectors and correlating them with the specific triggers, the system is able to differentiate between specific states of emotions and to correlate them with the physiological state of the user. The system can keep those vectors and their correlations to specific emotional states for specific users, and/or for each group of users.

d) Learning mode: The system can incorporate neural network and similar methods to continue learning, using the data from a group of users in the past to predict the emotional state of a specific user in a shorter time using his vector of data as describe above. For example, using this algorithm with a group of people, the system can predict that when a user has a low HRV and at the same time a high skin

conductivity, his emotional state is *"negative stress"*, while user with a high HRV and a low skin conductivity is *"relaxed and positive"*.

e) Training mode: The system can also train the users first to be more aware of their physiological and emotional state during their daily activities, and, second to acquire better behavioral, physiological and psycho- physiological habits, such as increasing their respiration cycle, and the ratio of expiration to inspiration, increasing their HRV, and learning to relax. , Third, the system can be used to train users to improve their reaction and responses to negative triggers and events during their daily life, and to improve their reactions and performance under pressure. The system can simulate real events and train the user to improve his reaction, performance and behavior. For example while prior art biofeedback systems can be used only in an artificial setting (e.g. the therapist's office) the wireless sensors of the invention can be used during actual important activities, such as driving, playing music, competing in sports, during exams, work interviews, etc.

The system of the invention may be calibrated or customized to a specific user. Alternatively, statistical parameters acquired by studying the general population or a specific sub-group of the population may be used. In some embodiments, a remote server receives data from a plurality of users, optionally including information about the user, and uses the information to create a data set used for state of mind analysis. Optionally, parameters extracted from the data set are transmitted to the mobile units of at least some of the users to be used for determination of the state of mind of the users. Optionally, a study group or plurality of study groups of users are used by the service provider in order to create the data set. This real time analysis of the state of mind of the users including their emotional reactions to specific triggers can be used to train the users to improve their performance and also to analyze their reactions to specific events, triggers, products and services.

The users can receive feedback in real time directly from the system by audio-visual feedback in real time, and at the same time the system can transmit the information to an expert or coach who can help them improve their reactions. This can be relevant for health issues –e.g. a child with asthma who can get feedback in

time from the system and/or physician, or an athlete receiving feedback to improve his performance. For training and analysis, it is recommended to record the physiological vectors as described above together with the external situation –e.g. a video of the competition, or a musical performance. In this way, it is possible to find the correlation between the best performance and the physiological vectors, and to train the user to optimize his physiological, emotional and mental performance, using simulation of the event by video or visualization together with the real time feedback of the sensors.

Schematically, the upper section of Fig. 4 is characterized by high arousal state, such as physical or emotional stress. This stress may be a result of vigorous physical activity or by emotional state of anger, aggressiveness, fear, or anxiety. Alternatively, high arousal may be a result of excitement caused by constructive thoughts such as concentrating on performing a task, or feelings of enthusiasm or passion. These two different states are separated by their being on the right (negative emotionally) and left (positive emotionally) sides of the figure respectively.

Similarly, low stress states of mind, schematically symbolized by the lower half of the figure, may be a result of depression or boredom, characterized by low arousal or energy level and negative emotions on the lower right of the figure; or relaxation and self contained pleasure on the lower left side of the figure.

In an embodiment of the invention, the combination of sensors and data processing enable automatic determination of the state of mind of the user and may be used to provide feedback and interactive multimedia training to achieve and maintain the positive state of mind and body.

A high stress state is characterized by a high production of adrenalin hormone associated with high HR. However, high HR by itself cannot separate enthusiasm and passion from anger and anxiety. Positive mental states (left two quadrants of Fig. 4) are associated with secretion of growth hormone and dehydroepiandrosterone (DHEA), and characterized by high heart rate variability (HRV) and high skin resistance. In contrast, negative mental states (right two quadrants of figure 4) are associated with secretion of Cortisol hormone and characterized by

HRV.Additionally, a state of relaxation is characterized by slow, steady breathing with slow exhale periods.

In an exemplary embodiment of the invention the state of mind is characterized by a two component vector: Emotional level: Left- more positive emotions, right- more negative emotions – on the horizontal axis; and Stress level on the vertical axis: Up- more stress, down- less stress.

In some embodiments of the invention a marker, for example an icon is displayed in the coordinates representing the state of mind vector and may be viewed by the user to allow monitoring of his state. The location of the marker may be periodically updated as the state of mind changes.

Alternatively or additionally, color codes may be used to symbolize the state of mind. For example, the horizontal axis may be represented by shades of yellow on the left to black on the right; while the vertical axis may be represented by shades of red on the top and blue on the bottom.

The combinations of these colors yields: Orange – representing a passionate mood on the upper left quadrant of the two dimensional scale; Green – representing a relaxed mood on the lower left quadrant; Dark Red - representing an aggressive mood on the upper right quadrant; and Dark Blue - representing depression on the lower left quadrant.

The resulting combination color, representative of the state of mind may be displayed on the display **122** of unit **120**. For example, the resulting combination color may be used as background for one or some of the graphs as depicted in Figs. 7a to 7d. It should be clear that other color schemes may be used within the general embodiment of the current invention. Such a color representation of state of mind is easy to view and may be intuitively understood by the user without the need to carefully observe the monitor or while performing other mental or physical tasks.

Data processing

In an embodiment of the invention, heart pulses are tracked by data analysis performed by processor 340 within the sensor module.

Fig. 5a shows a typical ECG signal of a healthy person. Three heartbeats are clearly seen separated by time intervals T1 and T2.

Fig. 5b shows a typical optical signal. Three heartbeats are clearly seen separated by time intervals T1 and T2.

In an embodiment of the invention, optical signals from detector 328 are analyzed and individual heartbeats are determined.

This can be done by identifying the peaks, minima or zero crossings in the signals, by performing auto correlation or by wavelet analysis.

In one preferred embodiment, local maxima are found in the optical signal. Then, the system checks if this peak is a heartbeat peak or only a local maximum due to noise. This determination may be assisted by performing comparison with signals from previous heartbeats and using, for example, probabilistic, heuristic or fuzzy logic algorithms.

In contrast to standard heart rate monitors which display only an average heart rate, the combination of the electronics and the peak detector – heartbeat recognizer algorithm enables the system to detect, calculate and present more accurately each heartbeat.

A similar analysis may be performed on an ECG signal if available. It is easier to detect accurate peaks in an ECG because the R wave has high amplitude and is sharp. The instantaneous HR is define as $HR(t)=1/_{Ti}$, where T(i) is the duration of heart cycle "*i*" (T is also known as R-R duration as seen in Fig. 5a), HR(t) is tracked over time (t) and optionally stored in the memory 342. Alternatively, the T(i)'s may be stored.

An average HR (AHR) may be calculated by averaging the values of HR over a specific period. A running average may be calculated over a predetermined time window to reduce noise in the signal.

HR Variability (HRV) may be calculated by several methods. One of them is the absolute value of the difference between the AHR and HR(t), and calculating the average of the HR(t) in the specific interval.

Other methods are calculation of the standard deviation or variance of the HR in a specific interval.

Optionally or additionally, spectral analysis of a heart signal may be performed. A computational efficient Fast Fourier Transform (FFT) algorithm is preferably performed to calculate the spectrum.

Fig. 5c shows a typical Fourier spectrum of heart signal. AHR can be inferred from the location of a peak, that is typically located between 0.5 to 3 Hz corresponding to an average heart rate of 30 to 180 beats per minutes. HRV may be inferred from the width of the peak.

A stress level can be inferred from the AHR wherein a high level of stress is characterized by higher than normal AHR. It should be emphasized that "normal" AHR is different for each individual and depends on age and physical stamina. Thus, this level may need to be updated from time to time, for example by measuring and averaging the AHR over an extended duration or by measuring it during a calibration session while the person is in a known state of mind. Similarly, the two ends of each axis may be calibrated during training and calibration sessions, for example: vigorous physical exercises vs. meditation rest or sleep.

Variability in HRV may be assessed from width of the peak in Fig 5c.

It was discovered that heart rate is correlated with the breathing cycle and autonomic nervous system functionality. Fig. 6a shows a typical graph of a healthy person's HR as a function of time during normal breathing cycle. The HR increases during inhalation and decreases during air exhalation.

Breathing monitors known in the art use strain gauge sensors strapped around the chest, or air movement sensors positioned near the person's mouth and nostrils. Using these sensors is cumbersome and uncomfortable. In contrast, an embodiment of the current invention infers the breathing from HR information.

In an embodiment of the invention, values of instantaneous HR(t) determined for example from optical signals or from ECG signals are analyzed and the breathing cycles are determined. This can be done by identifying the peaks, the valleys or zero crossings in the HR sequence, by performing auto correlation or using FFT analy

by wavelet analysis. Each breathing cycle may be analyzed for Breathing Rate (BR), Breathing Depth (BD) and the Ratio of Exhale over Inhale duration (REI). Alternatively or additionally it can be analyzed and presented as two parameters: Inhalation duration and exhalation duration (average duration in seconds).

Where: BR per minute is defined as 60 over the duration of the breathing cycle in seconds;

BD is defined as the Minimum HR subtracted from the maximum HR during the breathing cycle normalized by the AHR, and

REI is defined as exhale duration divided by inhalation duration.

These values may be transmitted to the mobile monitor and optionally stored in the memory **342**. Alternatively, the breathing analysis may be done at the mobile monitor.

The average values of BR, BD and REI (ABR, BD and REI respectively) may be calculated by averaging the values of BR, BD and REI over a specific period. A running average may be calculated over a time window to reduce noise in the signal.

Optionally or additionally, a spectral analysis of HR or HRV sequence, using a computational efficient Fast Fourier Transform (FFT) algorithm, is performed to calculate the spectrum.

In some embodiments of the invention, HR(t) is displayed to the user, for example as shown in Figure 7a. A graph of HR(t) may be useful for assessing the ability of the user to quickly adapt to changing circumstances, for example to regain a calm mood after an exciting stimulus.

An additional method to analyze the data and extract breathing pattern is to perform autocorrelation on the HR(t). Autocorrelation, AC(k) may be defined as the sum over a specific interval j = {t-K to t} of HR(j)*HR(j-k). In some embodiments of the invention, the autocorrelation function is displayed to the user to assist visualization of the breathing cycle as will be seen in Figure 7d. When breathing is steady, the autocorrelation function exhibits a deep wave pattern with a cycle's length equal to the breathing rate. The depth of the waves of the autocorrelation function is indicative to the depth of the berating. In contrast, when the user is in agitated sta[illegible]

mind, the breathing is unsteady and may be shallow, causing the autocorrelation function to flatten. The autocorrelation function may be used for calculating the Breathing Rate (BR), the Average Breathing Rate (ABR) and the Breathing Rate Variability (BRV).

The Exhalation to Inhalation Ratio (EIR) may be calculated from the graph of Figure 6a by measuring the Exhalation Duration (ED), the Inhale Duration (ID) and calculation EIR = ED/ID. Note that the breathing rate BR is given by 1/ BD wherein the Breathing Duration BD = ED + ID. The values of EIR, BD, breathing depth and breathing stability may be assessed from the autocorrelation function, or from an FFT analysis or using other input devices such as a mobile phone or mouse as described below.

Fig. 6b shows a typical FFT spectrum of the HRV. An average breathing rate (ABR) can be inferred from the peak at around 1/10 Hz corresponding to average breathing cycle of 10 seconds. Average breathing depth may be inferred from the height of the peak and Variability in breathing rate from width of the peak.

By analyzing the FFT of the HR and analyzing the EDA over the same period, the balance of the sympathetic and parasympathetic nervous system can be analyzed.

Optionally or additionally, a conventional breathing sensor may be use to provide independent measurement of the breathing cycle. Optionally or additionally, the user may be requested to provide independent measure of the breathing cycle. For example, the user may be asked to use an input device of the mobile monitor, for example an LPT, **[define],** mouse or keypad, cellular phone keypad, scratchpad of a PDA or any other input device. The user may provide an input at each breathing cycle or provide more information, for example by pressing the "up" key during inhalation and the "down" during exhalation, thus providing information needed to calculate REI independently from the values inferred by HB analysis.

Alternatively or additionally, a microphone may be used as an input device to allow the user to speak an indication or the microphone is placed close to the user's airways to pick up noise caused by air currents during breathing. For example, a headset microphone attached to a cellular phone may be used for sensing the user'

breathing. These methods are simple to implement, do not require a special respiration sensor, and provide important information and feedback to the user.

It was found that during relaxation, a breathing pattern is dominated by regular, slow, deep breathing. This pattern manifests itself by increased amplitude of the peak 60 in the curve of Fig 6b. At the same time, due to the increased depth of inhalation, and the stabilization of the breathing rate, the Variability in HR increases, causing the broadening of the peak HRV shown in Fig 6b.

Respiration guide bar

The system may present to the user a respiration guide using any one or more of a graphic bar display, musical cues voice instructions, and/or vibration.. In the graphical bar display, the breathing bar length may vary, for example, in accordance with the user's respiration rate or the duration of the inspiratory or expiratory phase of the respiration cycle. The system can calculate the user's respiration rate and use it as a starting base line, and train him to improve the pace (increase the exhalation period) according to the user's needs, for example, using predetermined instructions that can be overridden by the user or a coach. As another example, the breathing bar length may vary in accordance with the lung volume of the user, increasing in length as the user inhales and decreasing as he exhales. Using an autocorrelation method, the application may anticipate the breathing pattern based on recent berating history. By displaying a delayed image of the breathing pattern, the user may train to slow down his breathing rate. Optionally, the training may be aimed at achieving a predetermined breathing rate goal. Similarly, the breathing depth, as determined by the HRV, may be indicted by the length of the breathing bar. Inspiratory and expiratory phases can easily be followed by the user observing the changing breathing bar. The speaker **126** may be used to give voice indications, encouragement and commands such as: "inhale", "hold breath" or "exhale". Alternatively, the breathing bar may change color according to the phase of the breathing cycle. Alternatively, another type of display, such as an expanding and contracting balloon may be displayed, where the size of the balloon represents the volume of the lungs. Optionally, the user may choose the operation and display mode of the breathing bar.

Display screens

Figs. 7a, 7b, 7c and 7d show exemplary display modes according to different embodiments of the invention.

It should be noted that these exemplary display screens are shown for demonstration purposes as adopted to be viewed on a specific cellular phone. Other display means, for example a PDA, etc, and display designs may be created within the general scope of the current invention.

Fig. 7a shows an exemplary display on a screen 122 of a cellular phone used as mobile monitor 120. On the top of the display screen 122 is an icon driven phone menu 72 that allows the user to access other functions of the cellular phone. In this example, the menu comprises: "incoming call" icon 73a, "address book" icon 73b, "message" icon 73c and it may comprise of other icons. At the bottom of the display screen 122 is a phone status line 86 showing status indicators of the cellular phone, such as *"battery level"* 81a, *"speaker on"* 81b, *"RF reception level indicator"* 81c, etc. Generally, these top and bottom lines are part of the cellular phone system and are not involved with the operation of the mobile unit as physiological monitoring and training.

Some or all functions of the mobile unit, for example cellular phone 120, are available to the user during physiological monitoring. For example, the user may accept an incoming call on the cellular unit. Preferably, physiological data continue to be accepted and logged, to be processed and displayed later. Similarly, the user may access an address book or other information stored in memory of the mobile unit without interruption of physiological data logging.

In the case where the mobile unit 120 is a cellular phone, the data analysis and screen display may be created by an application loaded into the cellular phone memory and executed by the processor within the cellular phone.

The data logged on the mobile unit may be transmitted to a remote server for further analysis. For example data may be sent to via the cellular network using a data exchange protocol such as GSM, GPRS or 3G. Alternatively or additionally, data may

be transferred to a PC or a laptop computer using a cable such as USB cable, Bluetooth RF communication or Infrared (IR) communication.

Below the icon driven phone menu 72 is an application menu 85 that allows the user to access other functions and display modes of the current invention. For example, the user can choose specific tutorial or interactive training. The application menu 75 may allow control of the sensor's mode of operation, for example: starting and stopping data acquisition or data transfer, turning on or off a sensor, determining the sampling rate and accuracy, etc.The user may use the application menu 85 to choose the format of the displayed graphs and data.

The display screen 122 may display breathing bar 77. In the examples herein, breathing bar 77 is in the upper left, below the application menu 75. In the embodiment of Fig. 7a, the graph 80 shows the pulse signal 81 plotted vs. time on the horizontal axis, as measured for example by blood flow in the skin which is monitored by Heart Rate (HR) Electronics 320 within sensor module 210. Preferably, the graph is continuously updated and displays the data in real time. Alternatively, the graph is represents previously logged data.

In the embodiment of Fig. 7a, the graph 90 shows the EDA signal 91 plotted vs. time on the horizontal axis, as measured by the EDA electronics 330 within the sensor module 210. Preferably, the graph is continuously updated and displays the data in real time. Alternatively, said graph may display previously logged data.

The large main graph 50 shows instantaneous HR(t) 51 in units of heart-beats per second on the vertical axis plotted vs. time in minutes on the horizontal axis. Optionally the main graph 50 comprises a navigation icon 54 (shown here in "play" state) used to manipulate the display. For example, the user can *"freeze"* the display to closely examine a specific time frame. Similarly, the user can perform any or all of the commands *"fast forward," "shift up", "shift down", "move back", "zoom in", "zoom out", "smooth"* etc. Manipulations performed on the large graph 50 may also effect one or both of the graphs 80 and 90 so as to maintain the synchronization of all the graphs. Alternatively, some of the graphs may show real time data while another graph shows previously logged data.

Target or optimal range zone limits 52a and 52b are marked on the main graph 50 so that the user can easily compare his heart rate to a training goal. The target zone may be colored. For example a central green zone may indicate the goal values, while shades of yellow designate the target zone and shades of red indicate dangerously high or low values. The background color of one or some of the graph may be indicative of the state of mind of the user.

In the embodiment of Fig. 7a, the numerical data on the left 65a shows the instantaneous heart rate HR(t). In this example, the value 61 beats per seconds may also be inferred from the last value of graph 51. Alternatively, numerical data on the left 65a may display the average heart rate over a predetermined time interval.

In the Embodiment of Fig. 7a, the numerical data on the right 65b shows the average heart rate variability as computed from the standard deviation of HR(t) over a time window. Alternatively, numerical data on the right 65b may display data indicative of the difference between the minimum heart rate and maximum heart rate as depicted in Fig. 6a.

Fig. 7b shows another exemplary display on a screen 122 of a cellular phone used as mobile monitor. In this example, graph 90 shows HRV values 93 plotted vs. time on the horizontal axis instead of showing EDA data. The values 93 may be indicative of an autocorrelation function of the HRV.

Fig. 7c shows another exemplary display on a screen of a cellular phone used as mobile monitor. In this embodiment, graph 90 shows HRV values 93 while large graph 50 shows EDA data 91. A navigation icon 54 indicates that the data display is in a *"pause"* mode..

Fig. 7d shows yet another exemplary display on a screen of a cellular phone used as mobile monitor. In this embodiment, graph 80 shows pulse data 81, graph 90 shows data 51 and graph 50 shows HRVdata 93.

The exemplary screens depicted in Figs. 7a to 7d may be used by a user to assess his physiological state and as a biofeedback device to modify his condition and reactions to daily events. The mobile monitor may be used to display *"real-t...."*

parameters calculated from data recently acquired or may be used to replay a sequence of parameters previously acquired and stored. The date and time at which the data were acquired may be stored and associated with the stored data and is optionally displayed too.

The display screens may be flexibly designed to fit the size and type of display of the mobile monitor. Different combinations of signals and parameters may be displayed in various ways such as graphs, colors, pie charts, numerical values, bars, clock-like indicators, alert signals, alphanumerical messages, etc. Static or moving animations may also be displayed according to the interpretation of the physiological data. For example, a happy *"smiley face"* may be displayed when the state of the user is relaxed and sad face when the user is in a state of anxiety. The speed of the motion of the animation may be correlated with vital parameters such as HR or BR.A pulsing heart or breathing lungs may be displayed and animated to follow the cycles of the user. Music and musical tones may also be used as indicators, for example the pitch or intensity may be correlated with HR and BR and the user may train to achieve and maintain low quiet sound.

Training session

Because the EDA sensor as described herein is sensitive to changes in the arousal level of the user, it is possible to calculate several types of scores that reflect changes in the user's responses to different stimuli, including subconscious responses. The stimulus can be, for example, a question, a picture, music, a smell, or multimedia clips such as a short video. The stimulus can be presented/asked by another person or by prerecorded information on the mobile monitor or computer. It can be a message transmitted to the user such as text message or multimedia message on the mobile phone or TV clip or any other stimulus that can affect the user's response consciously or sub-consciously. The system monitors the user's physiology before, during and after the stimulus, and may calculate any one or more of the following parameters: EDA scores, heart scores and state of mind scores.

Fig. 8 shows an EDA graph as an example of a stress response of a user to such a stimulus. From these responses the system can calculate the following

scores:the stimulus (trigger) time, the latency (response time) until the EDA changed, the time to maximum conductivity, the absolute and relative changes in the amplitude before the stimulus (baseline), during the stimulus, and the new base line after a predetermined time following the stimulus, the half recovery time, the full recovery time; the variance and standard deviation of the EDA calculated periodically (such as every one tenth of a second) before during and after the stimulus; calculating a similar parameter based on the variance of the EDA- including the standard deviation and/or variance of the variance of the EDA, and latency, maximum of the variance, half recovery time of the variance, and recovery time of the variance.

Trying these scores with many users, it was found that this system can be effective in finding which number a person has chosen or if he is or is not telling the truth, and detecting other information that the user tried to hide. For example, users were asked to choose a number. The mobile phone presents a randomly chosen number, and calculates the parameters described above. The user is instructed to say no to all the numbers. But the system can detect the number that the user had chosen by finding the number with the maximum standard deviation of the variance of the EDA after presenting the chosen number.

In a similar way the system also calculated changes in the pulse, heart rate and heart rate variability of the user during a specific time interval or as a response to a stimulus (heart scores).

In the exemplary embodiment of the invention, the system can monitor and calculate both EDA scores and pulse scores, and present to at least one user a multimedia audio-visual response on the mobile monitor. Therefore it is possible to present different audiovisual clips which represent different moods. The system can also record the user's subjective responses (degree of fear or joy) and calculate the EDA scores and the heart scores simultaneously. This can be used for research, for therapy, for assessment, and for fun. Using these methods it is possible to map at least two dimensions of a user's state of mind; one dimension is arousal or relaxation, and the second dimension is positive or negative – does the user enjoy this state or dislike

it. Fig. 4 shows a two-dimensional array of states of mind. The present invention can be used to map an individual's state of mind in the two-dimensional array.

An additional aspect of the present invention is integration of Computerized Cognitive Behavioral Therapy (CCBT) together with the system of the invention (the sensors, algorithms as described). Several systems have been developed for computerized psychological methods known as CBT. For example, in a Doctorate thesis in Clinical Psychology August 2002, Kings College London UK Dr. Gili Orbach presented a Computerized Cognitive Behavior Therapy (CCBT) program. This is a method and clinical process to train students using a multimedia interactive program over the internet to reduce anxiety, and improve self confidence and results in exams. The CCBT programs can educate the users, explain to them about their thought mistakes, provide them with behavioral advice, etc. By integrating together CCBT, visualization, self hypnosis, and the present invention, including sensors and methods to monitor responses, and interactive multimedia feedback to train them to change their responses, a method and system are created, that can train users to modify their behavioral responses, know themselves better, help them to overcome habits and change themselves in their preferred direction.

Possible uses

When the system of the present invention may be equipped with programmable data processing power and flexible output means, numerous applications and uses may be adopted and used, optionally simultaneously and in combinations. A few exemplary applications will be described below.

Alerts

The system may be programmed to alert the user or someone else when certain conditions occur. Conditions may be assessed, and an alert initiated by any or few of: processor 340 in the sensor module, in the mobile monitor **120**, in the server **140** or by the human expert **150**.

The system of the invention may generate an alert under predetermined conditions. Heart and breathing alerts may be life saving for patients at risk of heart attack, epilepsy, old or incapacitated people, people with mental disability etc. A

may be indicated by any or few of: indicator **380**, display **120** and speaker **126**.Alternatively or additionally, alerts may be relayed to other locations by any or few of: mobile monitor **120**, server **140** or by the human expert **150**. For example a medical, law enforcement or rescue team may be informed if the system detects possible behavior abnormality. Data supporting the assessment may be relayed in association with the alert. If it exists, data on identity, health condition such as medical records, and location of the user, for example a GPS reading of the mobile monitor, may also be transferred. Conditions for generating an alert may be related to heart rate for example: HR below or above a predetermined value, abnormal HRV for example HRV below or above a predetermined value or rapidly changing, or indication for arrhythmia. Conditions for alerts may be related to breathing for example: any or more of: HR, BR or ERI below or above a predetermined value, abnormal BR for example BR rapidly changing. Conditions for generating an alert may be related to stress for example: EDA below or above a predetermined value or rapidly changing. Conditions for generating an alert may be related to a combination of signals from multiple sensors.

Training for improving quality of life

The system of the invention may be used for training aimed at modifying his condition. For example, the user may observe his physiological signs and optionally or alternatively the interpretation of these signs to modify his behavior to avoid negative emotions depicted on the right side of Fig. 4. Additionally, the user may train to achieve, strengthen or maintain concentration and enthusiasm depicted in the upper-left quadrant of Fig. 4 by modifying his behavior. Or, the user may train to achieve, strengthen or maintain a state of relaxation as depicted in the lower -left quadrant of Fig. 4.

It has been shown that people are able to achieve these goals by using biofeedback, even though they are not fully aware how they control their emotional and physical states, and thus gain control over involuntarily body activities such as blood pressure, hormone secretion etc. The system of the invention may also be used for training voluntary activity. , For example a user may train to breath at a steady

slow rate optionally achieving deep breathing with low ERI. This type of breathing is known to promote relaxation.

According to another embodiment of the invention, a user known to suffer from episodes of anger or anxiety may use the system in his daily routine. The system may be used to detect early signs of an approaching attack and prompt the user to take measures to mitigate the situation ether by taking medication or by mental or physical exercises such as taking deep breaths or by stopping his current activity. A silent alert such as vibration or a concealed alert such as Short Message Service SMS or a *"fake"* call to a cellular phone may serve to distract the user from the harmful path that may lead to aggressive or an anxiety attack. People suffering from various phobias may also benefit from an alert generated when a stimulus eliciting the phobia is approaching.

When the breathing cycle is followed by both HRV analysis and another means such as breathing sensor or user input, the correlation between HRV and actual breathing cycle may be monitored and the user may train to achieve better synchronization between the two. Generally, inhaling induces sympathetic system response causing arousal and increase of HR while exhaling induces the parasympathetic system response causing relaxation and decrease of HR. Thus, learning to control breathing, an art that currently requires years of studying, meditation or Yoga, may be achieved using the present invention.

According to another embodiment of the invention, the system may be used to record the physical and mental state of the user during his daily routine and correlate its readings to the type of activities performed. For example, times of high stress, high concentration, best performance, or high pleasure may be timed and displayed. The user may compare these times with the activities performed that date, for example, by referring to his diary records. Sensor readings may be integrated with diary records automatically, for example by integrating the software with commercial applications such as Microsoft Outlook®, and displayed on a mobile monitor such as a PDA or LPC.

Additionally or alternatively, the user may use input means on the mobile monitor to input memorandums such as voice or written messages indicating the type of activity he is performing, and his subjective feelings which will be integrated into the log of daily activity and sensor readings. In this way, the user may compare his activities and his subjective feelings to the objective sensor reading. Knowing the activities that induce stress, the user may prepare himself for future repetitions of the same or similar activities, or attempt to avoid them.

According to another embodiment of the invention, the system may be used to record physiological readings during sports training. In contrast to available devices that display only moving AHR, the system of the invention is capable of recording and storing virtually a record of each individual heartbeat and breath. Data compression, large memory capacity in the mobile monitor and mass storage in the remote server enable acquiring and storing these records over long periods of use. Because the sensors are small and transmit the data wirelessly –either using the Bluetooth protocol or the mobile network communication services- an expert coach can view and monitor the physiological parameters, the emotional- arousal states and the performance of the athlete , and coach him in real time to improve his reactions and performance. The data can be also saved for analysis later on. An athlete can also rehearse at his home or office using the invention, with either a multimedia mobile phone or PC or PDA (personal digital device) while he is viewing his performance, and simulating his emotional and physiological conditions, as in a real competition. By using several of the sensors simultaneously (e.g. heart rate, HRV, breathing, EDA EMG), the user learns to tune not only his physiology but also his attitude, arousal level etc, and to achieve his best performance.

According to another embodiment of the invention, the system may be used to record physiological reading while the user is sleeping in order to help identify and possibly correct sleep disorders.

Wearable Biofeedback Tools:

Biofeedback has been in use for many years to alleviate and change an individual's negative behavior patterns but existing systems have a number of significant drawbacks:

1. Hardware, software and information gathering:

- Most current systems are reliant upon powerful computers
- They require users to be trained either by health professionals or complex on-line programmers;
- Once users have been trained they must remember to implement the internal physiological changes in their daily lives;
- The biofeedback sessions are rarely undertaken on a daily basis and not in real time. This requires the user to remember specific events that occurred days before and recall his exact emotional responses.

This invention utilizes portable,, cordless wearable sensors, which enable users to monitor their emotional and physiological responses to events as they occur. These results, gathered in real time, may be more effective and relevant to the user than those recreated days later under completely different conditions. The sensors of the invention utilize mobile phones to display the user's physiology and emotional state.

2. Methodology:

The current method is to train users to modify the underlying physiology related to negative behavior patterns for example,. to reduce muscular tension (EMG), GSR, or electro-dermal activity (EDA) –the main purpose of which is to train users to relax. However, although it is important to train users to relax, two other aspects must also be taken into account for successful treatment:

- Enhancment of emotional health and training to be more positive, enthusiastic and motivated. These states are not reflected in relaxation levels as measured by GSR, EDA or EMG which can give false impressions. For example, a user may display increased physical tension when experiencing positive emotions such as excitement or enthusiasm. Similarly, low levels of physical tension may not necessarily be a positive thing and could represent negative states such as depression or boredom. One example was use of EDA for people suffering

IBS (irritable bowel syndrome). EDA was found to be very useful for people with high anxiety suffering from diarrhea, but not for depressed people suffered from constipation.

By utilizing two sensors simultaneously, a sensitive EDA sensor and a heart rate monitor for HRV, and by analyzing the changes in specific situations, the system of the invention may beused to monitor and train users not only to relax but also to develop a positive state of mind.

Objective Emotional Monitor:

Another application of the present invention is to monitor emotional reactions by using an objective scale. Although EDA is very sensitive there are disadvantages in monitoring and analyzing emotional reactions using this method:

- EDA levels change between sessions and individuals because of many variables unrelated to a user's emotional state. Therefore EDA levels can only be interpreted as a trend. That is, the user is becoming more relaxed if his skin resistance is increasing above the level when the session began. But the user cannot learn in an objective way how to control his reactions and improve his physiology and performance. The sensor of the invention allows monitoring and real time presentation of changes related to thought and emotion and calculation of parameters that reflect how the user is responding to specific trigger events. By integrating the analysis of the change in the EDA and the Heart Rate and heart rate variability in real-time a scale can be created to enable the user to learn how to improve and monitor his reactions.

Figure 8 shows response to a stimulus (such as PTSD, bulling , phobia). The parameters relating to the response include the amount of time it takes for the user to return to the base line after the stimulus, the amount of time it takes to return to baseline plus half arousal jump, the level of the arousal jump related to specific triggers. By using a mobile sensor, the user can continually monitor and improve his reactions and performance. By adding multimedia instructions the system can be a real

time coach for the user. By transmitting the data in real time using a mobile phone user will be able:

- To get feedback from a sophisticated expert system on a server almost in real time.
- to record their reactions to specific situations during the day
- To receive advice from an expert who can monitor their reaction almost in real time.
- to modify their reaction and implement this new knowledge in their daily behavior while an expert (system or professional caregiver) monitors them.

Integrating CBT and a wearable bio interactive sensor

Existing biofeedback systems use behavioral methods but do not include CBT (Cognitive Behavioral Therapy) training. The system of the invention may integrate computerized CBT, visualization with interactive sensors allowing users to learn not only how to change their physiology but also modify their way of thinking and address negative thought patterns.

New Methods of integrated CEBIT (Cognitive Emotional Behavioral Interactive Therapy). Training utilizing an integrated sensor of the invention allows a user to examine his belief system, his behavior, his unconscious thought processes, emotional and cognitive reactions, and his physiology. It also trains the user to monitor himself, to be aware, listen to his body, his emotions, and his external reactions.

Performance improvement- by using the methods and systems of the invention, and by monitoring their progress, users can learn not only how to modify their health and feel better but also to improve their performance: e.g. exam anxiety, trading, music and singing, sports, relationships, creativity, public speaking etc. The interactive physiology monitoring of the invention can be combined with CBT, and with realtime feedback from the user's performance, to train the user to achieve a predetermined state. This can be applied also to relationships and to happiness lev

Survey and poles

According to another application of the invention, the system may be used to record reactions of viewers to commercials in order to conduct viewer surveys.

Training session

Yet another aspect of the invention is to train a user by conducting a training session involving exposing the user to stress inducing stimuli.

Fig. 8 shows a schematic chart of the stress level of a user following a stimulus The stimulus may be, for example, a phobia caused by an image, for example a picture of a spider to a user suffers from arachnophobia, a disturbing voice message or written phrase. Stress induced by the stimuli may be measured by EDA reading, HR, or a combination of few sensors readings.

In Fig. 8,, the stimulus is given at time ST. At time LT, stress level starts to rise from the Initial Baseline Stress (IBS) after a short latency period in which the user's brain interprets the stimulus. Usually the stress climbs and reaches its Maximum Stress (MS) level at Maximum Reaction Time (MRT), then recovers slowly to the IBS or to a New Baseline Stress (NBS).

Recovery Time (RT) may be defined as the time it takes for the stress level to decrease from MS level to the Half maximum Stress (HS) at the Half Recovery Time (HRT), i.e. RT = HRT – MRT,where HS is defined as: HS = (IBS+ MS)/2. In a training session, the user observes his reactions and learns to minimize one or more of MS, RT and NBS.

A training session may consist of analyzing HR, HRV and changes in EDA using several methods such as neural network software and or wavelet analysis, while presenting to the user specific positive and negative triggers. For example images, video or audio clips. Scenes such as of an accident may be used as negative triggers; while relaxing triggers may be nature scenes. Training may be in a form of interactive games in which the user can win and feel positive; frustrating games or challenges in which the user looses and feels stressed; sexual clips etc;

A *"User psycho-physiological responses profile"* (UPPP) may be created and stored. Using this UPPP, the system can monitor and analyze the user response and state of mind to both real life events (e.g. a meeting with someone, preparing for an exam, receiving a phone call, etc), and or interactive questionnaires, simulation of specific scenarios, etc. These methods can be used for several purposes: to assess the user responses and/or to train the user to improve his responses to specific triggers (such as overcoming a phobia). The system can use the UPPP to drive games and multimedia using the sensors and the user's emotional reaction to drive and navigate the games.

The term *"user"* should be interpreted as encompassing both a male and a female individual, and also to a group of individuals. When there are several users, each one can be monitored with his sensors, or some of them can share sensors, they can either use the same display (for example connected with Bluetooth to the same PC or mobile phone) or each one can have a separate device with their devices configured to communicate with each other. It can also include a plurality users connected through mobile phones or Internet to a center or TV station, watching and sharing one or more images which are transmitted either as broadcast or internet etc to all the users or some of them. In this mode the invention can be used as a new real-time TV show game, or emotional poll, etc.

Entertainment system: Mind Activated Games for Interactive Communication

According to another aspect of the invention, the system may be used for entertainment by providing games and other forms of entertainment.

For example, a person may use the sensor module during a phone conversation or Internet chat with peers. The sensor readings may automatically send SMS or pictorial symbols indicating the user's state of mind and his reactions to the conversation. This can be a basis for emotional based games and communication between a group of users of mobile phones and/or internet and or TV games.

In another example, sensor readings may be used to control devices and appliances such as a DVD or compute, for example, during computer games.

sensor can be added to a remote control, and the content presented to the users can be changed and unfold according to the state of mind of the users who are monitored by the sensors. This can be a basis for a new interactive DVD (or any alternative direct access digital media), for interactive movies, interactive sport, or interactive games, or psychological profiling.

Fig. 12 depicts an entertainment system **1200** according to one embodiment of this aspect of the invention. In the system 1200, a sensor **1210** is in contact with a user **1201** and is used for monitoring the user's physiological parameters. The Sensor **1210** is in communication with an entertainment system controller **1220**, such as a remote control of a DVD or video game device, through communication link **1212**. Communication link **1212** may be unidirectional or bi-directional. The entertainment system controller **1220** comprises a transmitter **1226** for transmitting commands to the entertainment system **1240** using communication link **1228**. Link **1228** may be unidirectional, for example, IR communication. Optionally, the system controller **1220** comprises of an input means such as keypad **1224**. The sensor **1210** may directly communicate with the entertainment system, and a cable may be used for communicating physiological information or commands.

In accordance with this aspect of the invention, at least one parameter reflecting a state of mind and or body of the players/users is obtained by monitoring one or more parameters indicative of their physiological or psycho-physiological reactions/conditions. The one or more parameters are transmitted to a system that analyses the parameters and calculates one or more scores and uses the calculated scores as input for a process in which audiovisual material (audio and/or visual) is displayed on a screen and/or a physical object (such as remote controlled car) is moved. The content of the audiovisual material, and/or some of the parameters of the movement (e.g. the speed or direction of movement of the remote controlled car) depend on the scores reflecting the state of the user's mind and or body.

The scores, or some information which reflect results of changes in the state of mind and or body of the user or users may be presented directly or indirectly either to the same user / player that is being monitored by the sensor or to another user / pl

or to both of them. The users may use information relating to either their own scores / results or the other players' scores / results in order to win or change their reactions / decisions or to guess the other user's feelings or thoughts, or to influence the other user's reactions, or the results of the games / interactive story/ remote controlled toy.

Examples of games:

Battleship (submarines). In this a familiar game, two players try to guess and find the location of the opponent player's submarines/ships and *"destroy"* them, (for example in a 10 by ten array of positions). The present invention may be used to add a new aspect to the game. Before user A *"shoots"*a torpedo to a specific location (the location "b-4", for example) he can ask the other player 3 questions (e.g. by words or by moving a mouse to specific locations but not clicking it). The questions may be, for example "Do you have submarine in location b-2 or b-4 or c-4?". The user A can see the reaction of the other player as reflected in one of his scores. The other user can respond yes or not and can even lie (high arousal- high bar).User A can use this information to assess where there is a submarine. Thus, a psychological and *"mind reading"* dimension is added to a game.

a) A group of users, such as teenagers, with mobile phones can send multimedia messages to each other and view pictures and/or a short video of each other. Using this invention we add an emotional dimension to the communication as follows. The scores of the emotional and/or state of mind reaction are also transmitted to the other users, and these scores are used as a basis for games and interactive communication, such as a truth or dare game. The reaction (emotional scores) of a user is transmitted to one or more other users. For example, the scores may be sent to a first user that was the most "aroused" when he or she saw the picture and/or read an MMS message from a particular second user. The first user then has to send a text message to the second user revealing what the first user feels about the second user. While the first user does this, the first user's arousal level can be watched by the second user and/or other users. Thus, either the *"system"*

and or other users and/or the first user can see if the first user "loves" the second user. In a simple version of this game, a user can see 10 pictures on the screen of his mobile phone or PC or game console and the system can tell him, for example, who he loves, which number he has chosen, or which card he has chosen.

b) Interactive "Tamaguchi" (an electronic pet or animation of a person which the user has to *"love"* and take care). By incorporating the features of the present invention to this toy, each time that the user is angry and/or anxious, as indicated by the scores obtained from the results monitored by the sensors, the Tamaguchi can feel it and react, be sad, angry, or ill, etc. When the user is calm, relaxed and happy, the Tamaguchi reacts in a positive way, e.g. by smiling, singing, playing, eating etc.

c) In a more advanced version, a user can create a symbolic animated version of himself (a *"virtual me"* or *"Vime"*) in a mobile phone, ,PC or game consol. The user and/or other individuals (that have received permission/authority to interact with the user's virtual personality), can interact with this *"Virtual me"* using a mobile communication device or Internet. An individual may play with the user's virtual personality, for example, by sending the Vime positive and/or negative messages such as that the individual loves the Vime. The "conscious" message is transmitted together with the individual's State of Mind/emotional score and influences the *"virtual me"*. This can be used as games and entertainment but also as adding an emotional dimension and new way of communication and playing, and even virtual *"dating"*.

d) Behavioral skills may be added to the version of the game presented in c) such as how to react and with whom. This can create a psychological/emotional/communication game/community creation. For example, real or imaginary qualities can be added to the Vime and descriptions (physical dimensions, hobbies, area of interest etc); behavioral

rules *("if a girl with predetermined characteristics and predetermined scores contacts me then send a predetermined response")*. The Vime can have several modes such as a *"live"* mode in which the user is connected, an *"offline"* mode in which the Vime can communicate without the user, a *"receive only"* mode, or a *"sleep"* mode.

e) In another application, the sensors are used as amplifiers of subconscious intuition responses, for example to provide real or fun decision advice. While the user is connected to the sensors, he asks questions and/or is asked questions by the phone, PC or DVD. By watching his scores when he thinks and answers a specific question he can see what his *"intuition"* advises him to do. The system may train the user to tune himself to make a better decision by integration of his or her physiological and psychological states, together with other methods such as logical analysis, systematic planning, scoring etc. (i.e. *"to use his heart and his brain"* together, or to use his analytical mind with his intuition, to combine his *"gut feelings"* with *"objective information"*).

While the invention has been described with reference to certain exemplary embodiments, various modifications will be readily apparent to and may be readily accomplished by persons skilled in the art without departing from the spirit and scope of the above teachings.

It should be understood that features and/or steps described with respect to one embodiment may be used with other embodiments and that not all embodiments of the invention have all of the features and/or steps shown in a particular figure or described with respect to one of the embodiments. Variations of embodiments described will occur to persons of the art.

It is noted that some of the above described embodiments may describe the best mode contemplated by the inventors and therefore include structure, acts or details of structures and acts that may not be essential to the invention and which are described as examples. Structure and acts described herein are replaceable by equivalents which perform the same function, even if the structure or acts are different, as known ir

art. Therefore, the scope of the invention is limited only by the elements and limitations as used in the claims. The terms *"comprise"*, *"include"* and their conjugates as used herein mean *"include but are not necessarily limited to"*.

CLAIMS:

1. A system for monitoring one or more physiological parameters of a user comprising:
   (a) one or more wearable sensor modules sensing the one or more physiological parameters;
   (b) one or more transmitters wirelessly transmitting first signals indicative of values of the one or more physiological parameters to a mobile monitor; and
   (c) the mobile monitor, wherein the mobile monitor comprises:
   a first processor processing the first signals received from the transmitter in real time using expert knowledge; and
   a device providing one or more indications of results of the processing.
2. The system according to Claim 1 further comprising a remote server capable of communication with said mobile monitor, the remote server receiving second signals from the mobile monitor, the remote server associated with a viewing station having a second processor, the remote server being configured to perform at least one of the following:
   (a) transmitting the second signals to a viewing station for analysis, the analysis ;
   (b) accessing historical data relating to the subject;
   (c) transmitting the historical data to the viewing station;
   (d) receiving from the viewing station results of the analysis;
   (e) transmitting the results of the analysis to the mobile unit; the analysis being based upon the second signals, and one or more of the historical data, expert knowledge and computerised protocols.
3. The system according to Claim 1 wherein at least one sensor module comprises at least one sensor selected from the group comprising:
   (a) An electro dermal activity sensor;
   (b) An electrocardiogram sensor;

(c) A plethysmograph; and

(d) A piezoelectric sensor.

4. The system according to Claim 1 comprising at least two sensors selected from a group comprising:

(a) an electro dermal activity sensor;

(b) an electrocardiogram sensor;

(c) a plethysmograph; and

(d) a respiration sensor.

5. The system according to Claim 1wherein the first signals are transmitted from a sensor module to the mobile monitor by any one or more of the following protocols:

(a) Bluetooth;

(b) WiFi; and

(c) Wireless Lan;

6. The system according to Claim 1 wherein said mobile monitor is selected from the group comprising:

(a) a cellular phone;

(b) a personal digital assistant (PDA);

(c) a pocket PC;

(d) a mobile audio digital player;

(e) an iPod,

(f) an electronic note-book;

(g) a personal laptop computer;

(h) a DVD player;

(i) a hand held video game with wireless communication; and

(j) mobile TV.

7. The system according to Claim 6 wherein the mobile unit is a cellular telephone and communication between the mobile monitor and the remote server is over a cellular communication network.

8. The system according to Claim 1 wherein the mobile unit includes any one or more of a visual display, one or more speakers, a headphone, and a virtual reality headset.

9. A wearable sensor module for use in the system according to Claim 1.

10. The wearable sensor mosule according to Claim 9 comprising at least one sensor selected from the group comprising:

(a) An electro dermal activity sensor;

(b) An electrocardiogram sensor;

(c) A plethysmograph; and

(d) A pizoomagnetic sensor.

11. The wearable sensor module according to Claim 10 comprising at least two sensors selected from a group comprising:

(a) an electro dermal activity sensor;

(b) an electrocardiogram sensor;

(c) a plethysmograph; and

(d) a respiration sensor.

12. The wearable sensor module according to Claim 10 comprising a transmitter transmitting signals by any one or more of the following protocols:

(a) Bluetooth;

(b) WiFi; and

(c) Wireless Lan;

13. The wearable sensor unit according to Claim 10 or 11 comprising an electro dermal activity sensor adapted to monitor skin conductivities using at least a 16 bit A to D conversion without the need of manual calibration.

14. The sensor module according to Claim 10 or 11 comprising an EDA sensor comprising:

(a) at least two electrodes adapted to be applied to a skin surface;

(b) electronic circuitry for measuring a skin resistance across the electrodes and calculating an EDA based upon the resistance using

an algorithm in which the EDA does not depend linearly on the resistance.

15. The sensor module according to Claim 10 or 11 comprising a blood flow sensor comprising:

(a) a light source adapted to emit light towards a skin surface;

(b) a light detector adapted to detecting light reflected from the skin surface;

(c) electronic circuitry for measuring an intensity of the reflected light and controlling an intensity of said light source based upon the intensity of the reflected light.

16. The sensor module according to Claim 14, wherein the electronic circuitry capable of measuring skin resistance across the electrodes over a range of at least from 50 K Ohm to 12 M Ohm.

17. The system according to Claim 1 wherein the first processor is configured to calculated from the first signals one or both of a parameter indicative of an arousal state of the user and a parameter indicative of an emotional state of the user.

18. The system according to Claim 14 wherein calculation of the parameter indicative of an arousal state of the user includes calculating a score of a sympathetic and parasympathetic activity of the user using an algorithm based on any one or more of the user's Electro Dermal activity, Heart Rate, EDA variability, and HR variability.

19. The system according to Claim 14 wherein the first processor is configured to calculate a parameter indicative of an arousal state of the user to display the parameter indicative of an arousal state of the user on a display associated with the mobile unit as a two -dimensional vector.

20. The system according to Claim 1 wherein the first processor is configured to display on a display associated with the mobile monitor any one or more of the following images: an image indicative of bio-feedback information relating to the user; an image indicative of breathing activity of the user, an ir

including a graph indicative of an EDA activity of the user, an image including a graph indicative of a heart rate of the user, an image including a graph indicative of a heart rate variability of the user; an image including a graph indicative of an autocorrelation of a heart rate variability of the user; and an image indicative of recommendation to improve the user's psycho-physiological state based on one or both of the user's physiological data and experts' knowledge.

21. The system according to Claim 17 wherein an image indicative of breathing activity includes a bar having a length indicative of the breathing activity.

22. The system according to Claim 17 wherein an image indicative of bio-feedback information relating to the user includes one or more parameter target values.

23. The system according to Claim 1 wherein the first processor is configured to calculate in a calculation based upon the first signals any one or more of the following: a breathing rate of the user; and a heart rate variability of the user.

24. A system according to Claims 23 wherein the user's rate of breathing is calculated and analysis by monitoring changes in the electrical capacitance of the body while the user is breathing.

25. A method for monitoring one or more physiological parameters of a user comprising:

(a) obtaining values of the physiological parameters of the user from one or more wearable sensor modules;

(b) wirelessly transmitting first signals indicative of values of the one or more physiological parameters to a mobile monitor; and

(c) processing the first signals received from the transmitter in real time using expert knowledge; and

(d) providing one or more indications of results of the processing to the mobile unit.

26. The method according to Claim 25 wherein the results of the processing includes bio-feedback information of the user.

27. The method according to Claim 25 further comprising transmitting second signals from the mobile monitor to a remote server having an associated viewing station and providing an analysis of the second signals at the viewing station.

28. The method according to Claim 27 wherein the viewing station includes one or both of a remote call center and an interactive expert system.

29. The method according to Claim 25 wherein the processing includes calculating one or both of a parameter indicative of an arousal state and a parameter indicative of an emotional state of the user.

30. The method according to Claim 29 wherein calculating a parameter indicative of an emotional state of the user is based upon one or both of a sympathetic activity and parasympathetic activity of the user.

31. The method according to claim 30 wherein calculating a parameter indicative of an emotional state of the user is based upon any one or more of an electro dermal activity, a heart rate, an electro dermal activity variability and a heart rate variability.

32. The method according to Claim 29 further comprising the step of displaying on a display associated with the mobile unit one or both of an image indicative of a parameter indicative of an arousal state of the user; and an image indicative of a parameter indicative of emotional state of the user.

33. The method according to Claims 32 wherein an image includes one or both of a two-dimensional vector and a color indicative of a parameter.

34. The method according to Claim 25 for use in obtaining respiration information selected from the group comprising duration of the inspiratory phase, and duration of the expiratory phase.

35. A method according to Claim 34 wherein respiratory information is obtained from audio sounds produced during breathing or speaking.

36. The method according to Claim 34 wherein respiratory information is obtained by the user indicating the beginning of one or more inspiratory phases and the beginning of one or more expiratory phases of the user's breathing.

37. The method according to Claim 34 wherein_a breathing rate of the user is calculated based upon a heart rate variability of the user.

38. The method according to Claim 34 wherein the user's rate of breathing is calculated based upon changes in an electrical skin capacitance of the user while the user is breathing.

39. The method according to Claim 34 further comprising training the user to increase any one or more of the followings: a duration of the inspiratory phase, a duration of the expiratory phase, and the ratio of the duration of the inspiratory phase to the duration of the expiratory phase.

40. The method according to Claim 26, further comprising displaying on a display associated with the mobile monitor an image indicative of bio-feedback information, wherein the image includes any one or more of the following: an image indicative of breathing activity, an image including a graph indicative of EDA activity, an image including a graph indicative of heart rate, an image including a graph indicative of heart rate variability and an image including a graph indicative of an autocorrelation of heart rate variability.

41. The method according to Claim 27 wherein the analysis of the second signals includes a recommendation for the user to improve a psycho physiological state of the user.

42. The method according to Claim 41 further comprising displaying the recommendation on a display associated with the mobile unit.

43. The method according to Claim 26 comprising displaying a target value for one or more of the one or more obtained physiological parameters.

44. The method according to Claim 26 comprising displaying on a display associated with the mobile unit a target value for one or more of the one or more obtained physiological parameters.

45. The method according to Claim 26 comprising steps of:

(a) challenging the user with one or more stimuli;

(b) monitoring one or more reactions of the user to said one or more stimuli;

(c) calculating, in a calculation based upon the one or more reactions, at least one parameter selected from the group of: latency time of a reaction, maximum reaction time, half recovery time, maximum stress, and new baseline stress; and

(d) providing feedback to the user based on one or more of the calculated parameters.

46. The method according to Claim 25 for use in a method of self behaviour modification comprising any one or more of the methods selected from the group comprising:

(a) cognitive behavioural therapy (CBT);

(b) visualisation;

(c) self hypnosis;

(d) auto suggestion;

(e) mindfulness;

(f) meditation;

(g) emotional intelligence skills;

(h) psychological counselling provided over a communications network.

47. The method according to Claim 46 further comprising:

(a) providing the user with an interactive introduction about a specific condition of the user;

(b) providing the user interactive questionnaires for self assessment; and

(c) providingng the user with one or more interactive sessions selected from the group comprising:

an interactive session for self training to implement cognitive techniques;

interactive sessions for self training to implement behavioural therapy;

interactive sessions for self hypnosis;

interactive sessions for visualisation;

interactive sessions for auto suggestions;

interactive training to acquire and implement life and interpersonal relational skills;

interactive training to improve emotional intelligence skills;

interactive training to find purposes and goals; and

interactive training to plan steps in life.

48. The method according to Claim 47 wherein the user is provided with one or more interactive sessions while the user is in a deep relaxation state.

49. The system according to Claim 1 further comprising an entertainment system and wherein the first processor is configured to determine at least one command based on the first signals and transmitting the at least one command based to the entertainment system; and wherein the entertainment system comprises a third processor configured to perform an action based upon the one or more commands.

50. The system according to Claim 49 wherein the action comprises any one or more of generating an SMS massage, controlling a DVD, controlling a computer game, and controlling a "Tamaguchi" animation.

51. The system according to Claim 49 wherein the action comprises processing a user reaction to any one or more of the following: a displayed animated image; a video clip, an audio clip, a multimedia presentation, real-time communication with another human, a question that the user has to answer, and a task that the has to perform.

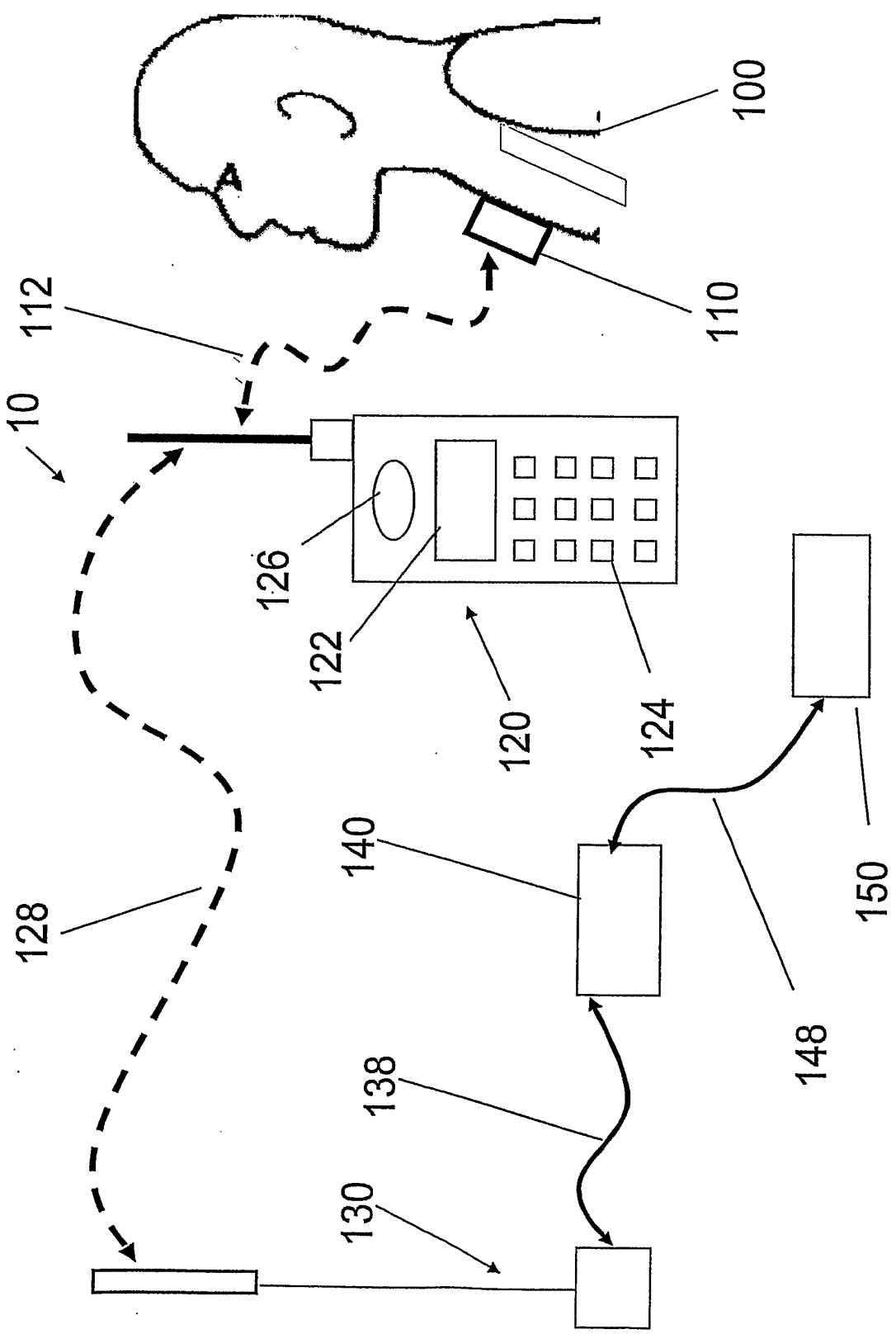


Fig. 1

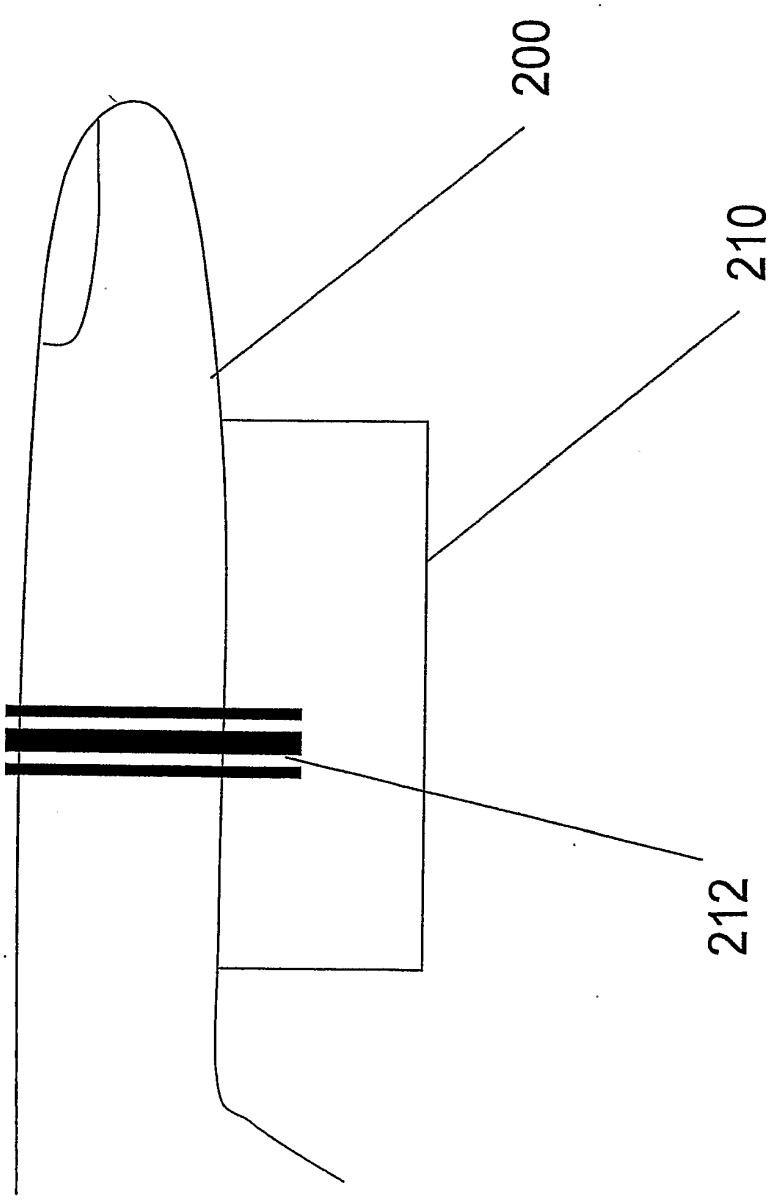


Fig. 2

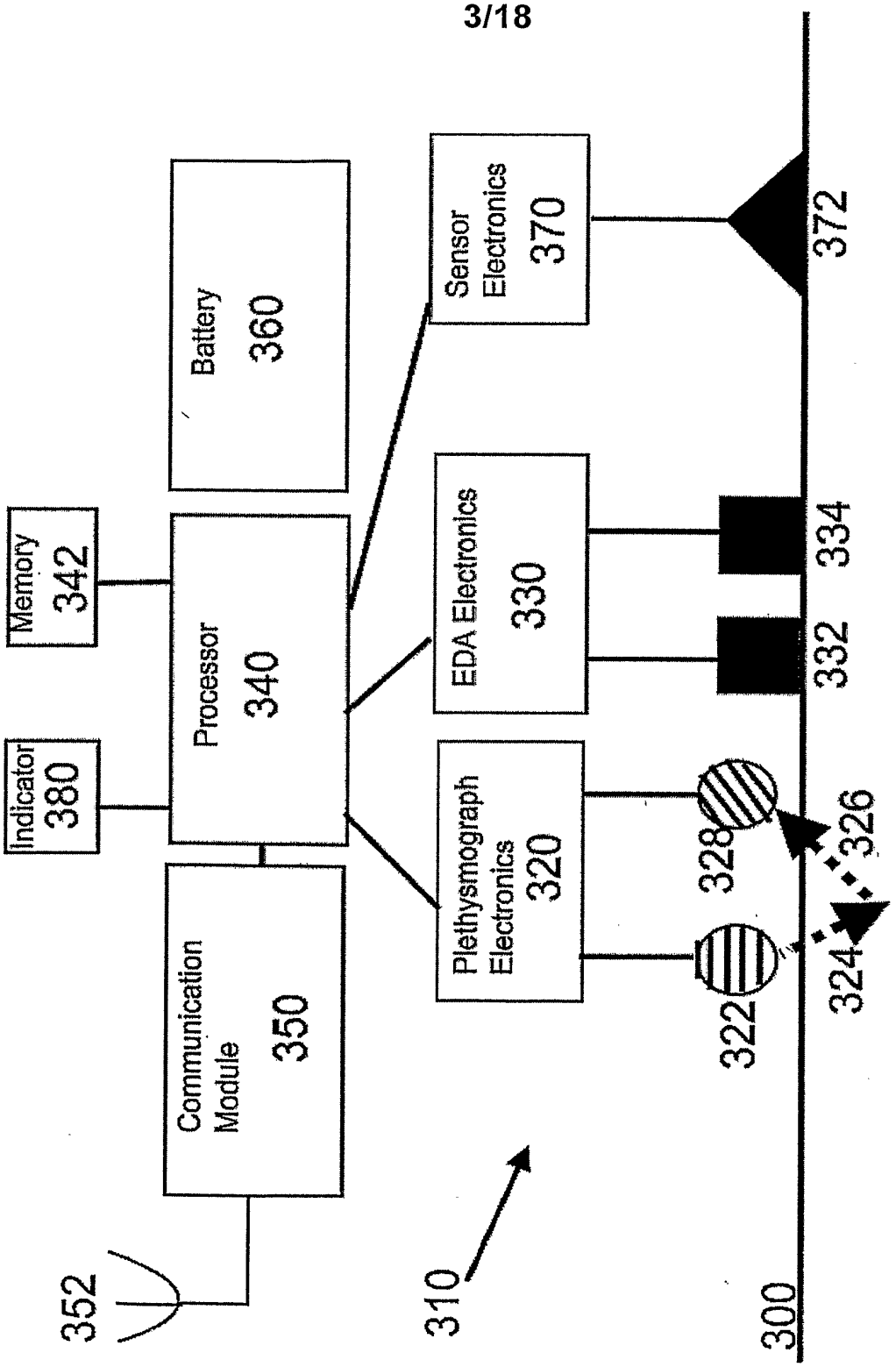

Battery
360
Sensor
Electronics
370
372
Memory
342
Processor
340
EDA Electronics
330
334
332
Indicator
380
Communication
Module
350
Plethysmograph
Electronics
320
328
326
324
322
352
310
300

FIG 3

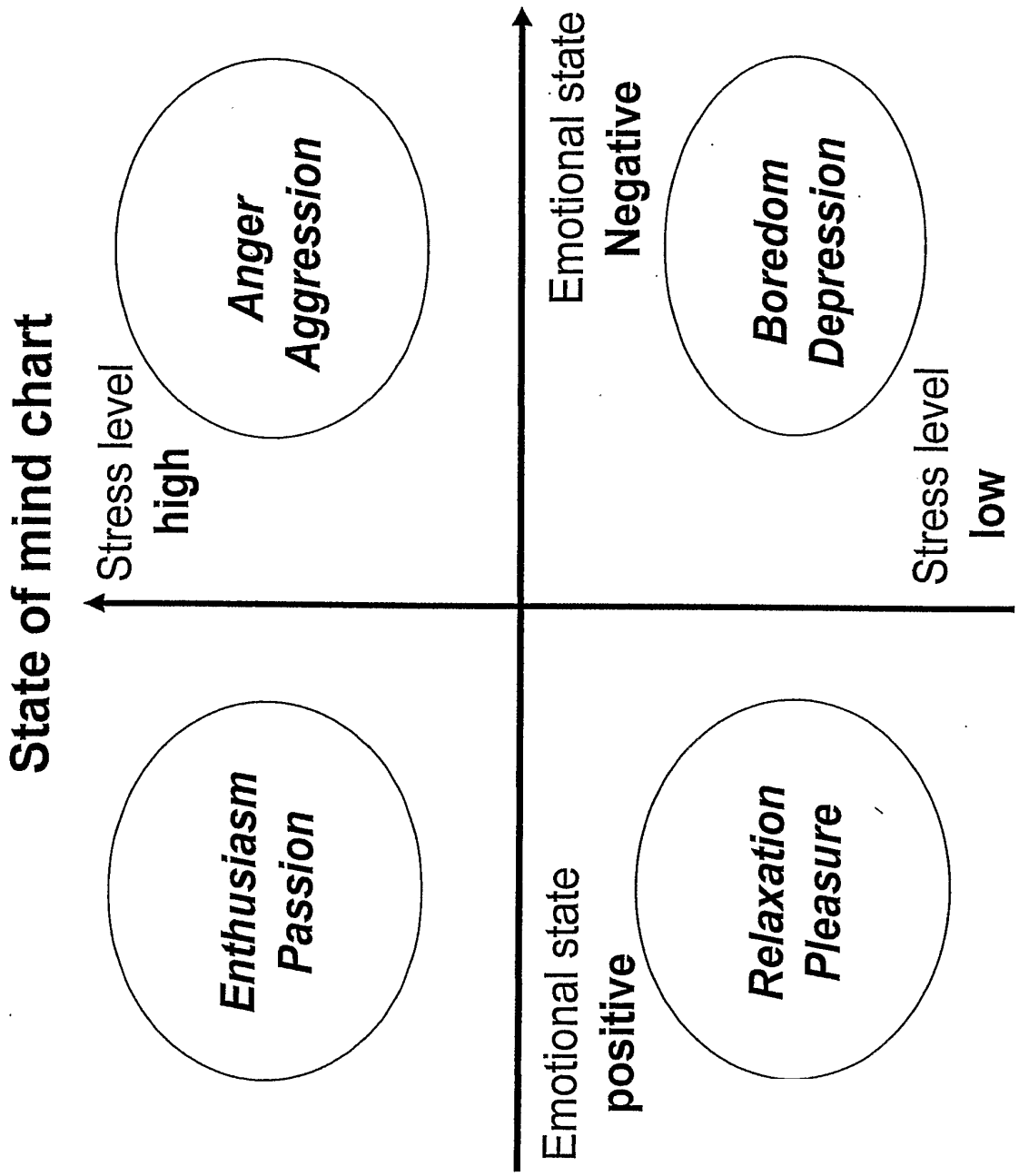

State of mind chart
Stress level high
Stress level low
Emotional state Negative
Emotional state positive
Anger Aggression
Boredom Depression
Enthusiasm Passion
Relaxation Pleasure

Fig. 4

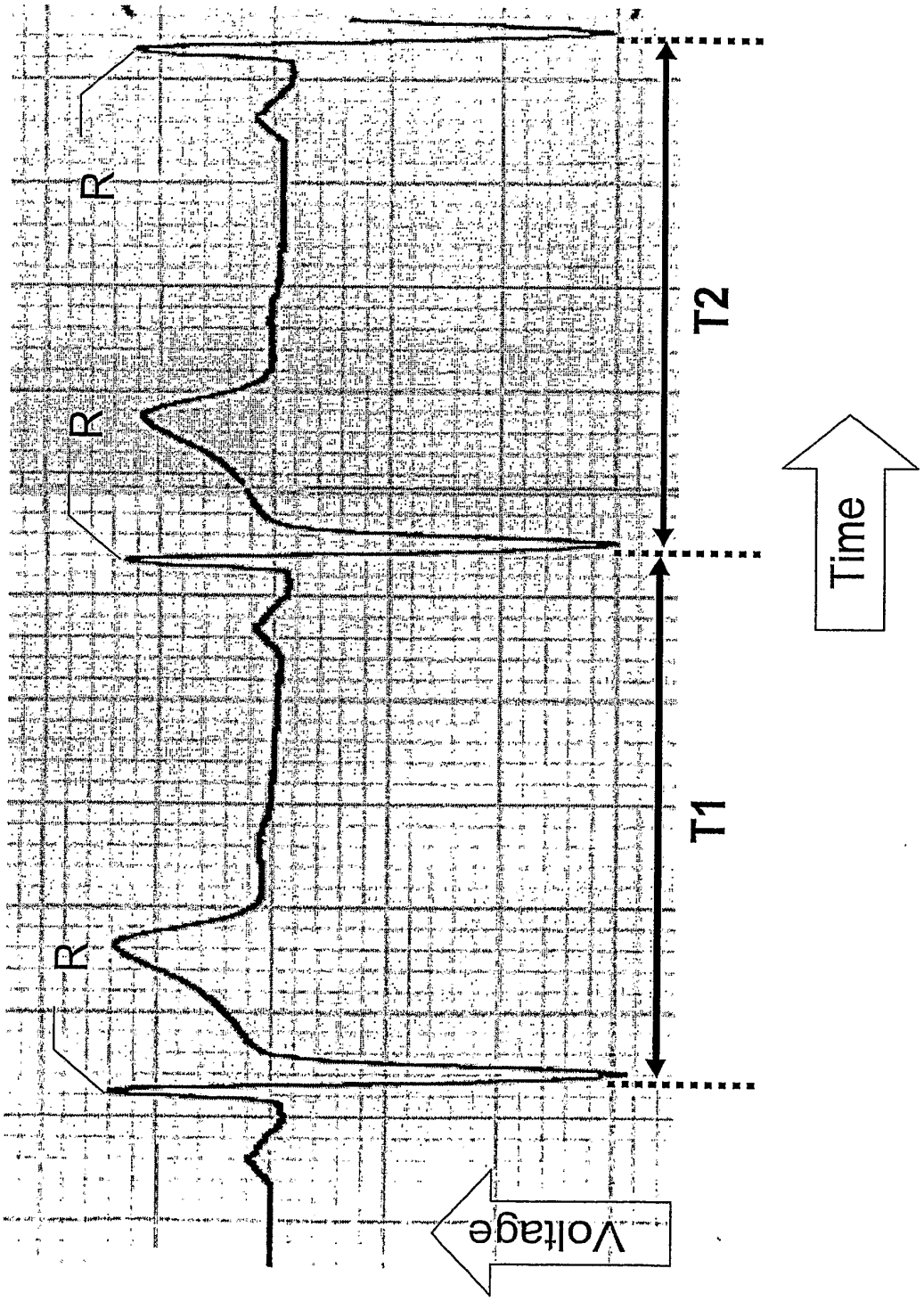


Fig. 5a

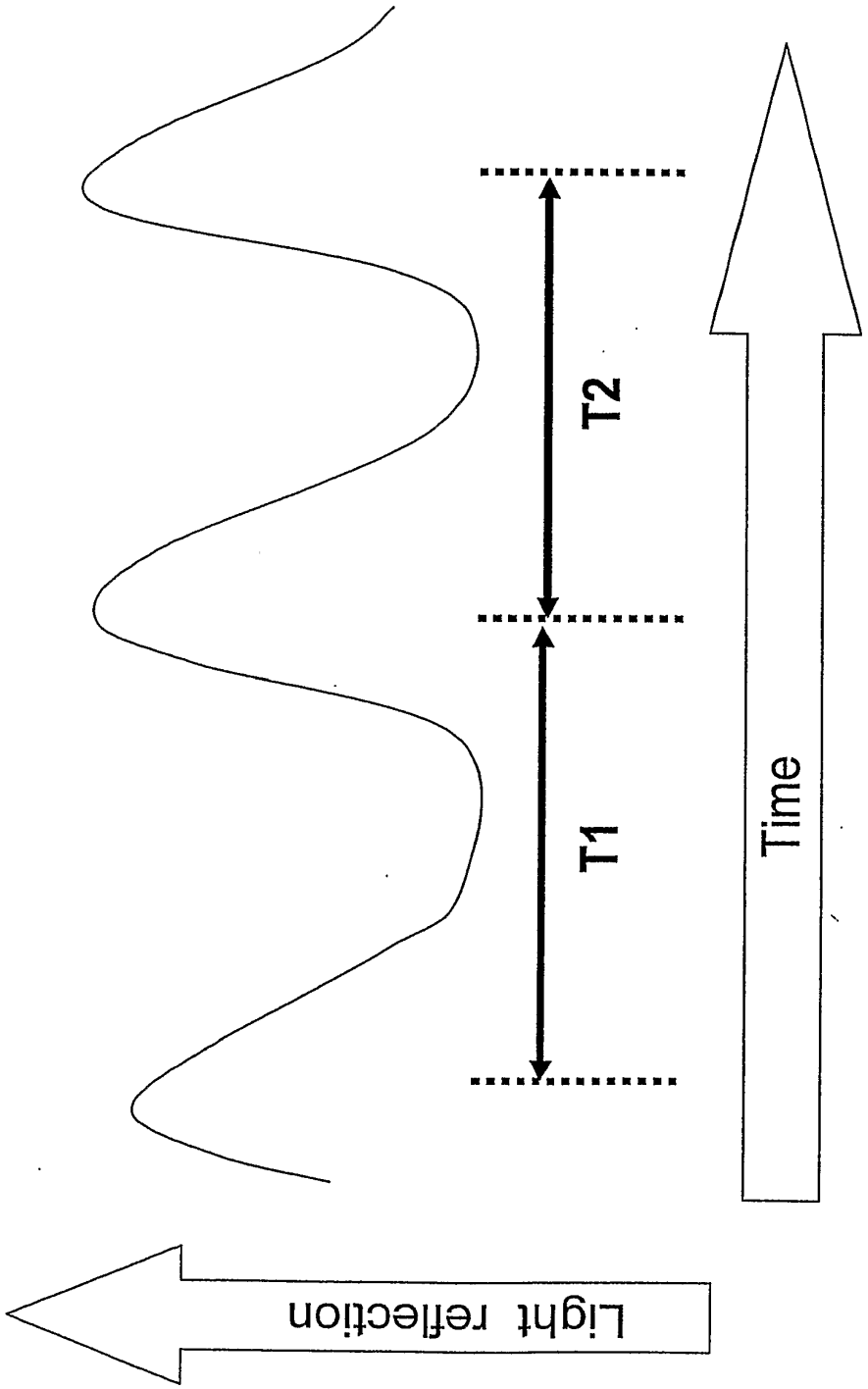


Fig. 5b

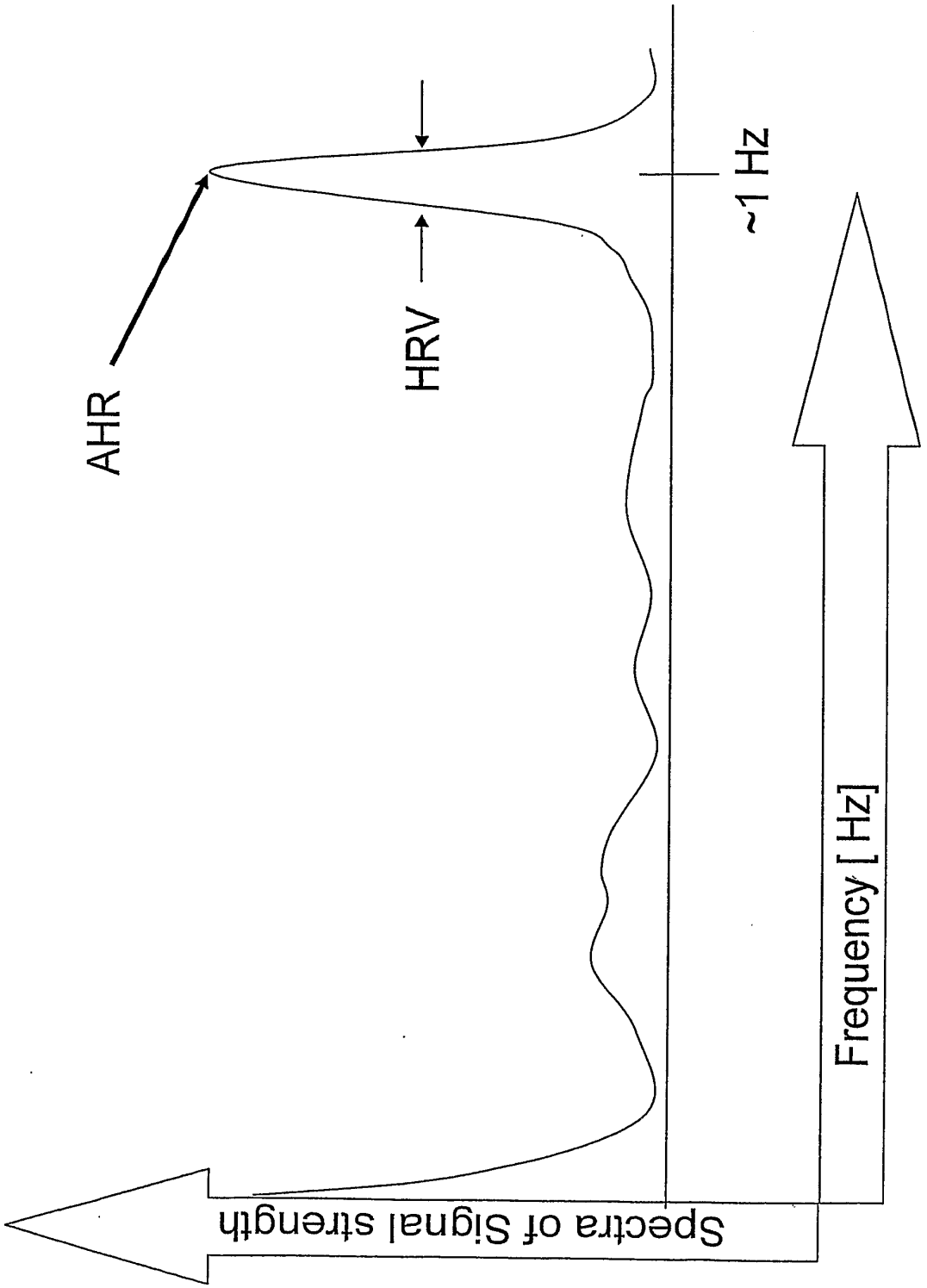


Fig. 5c

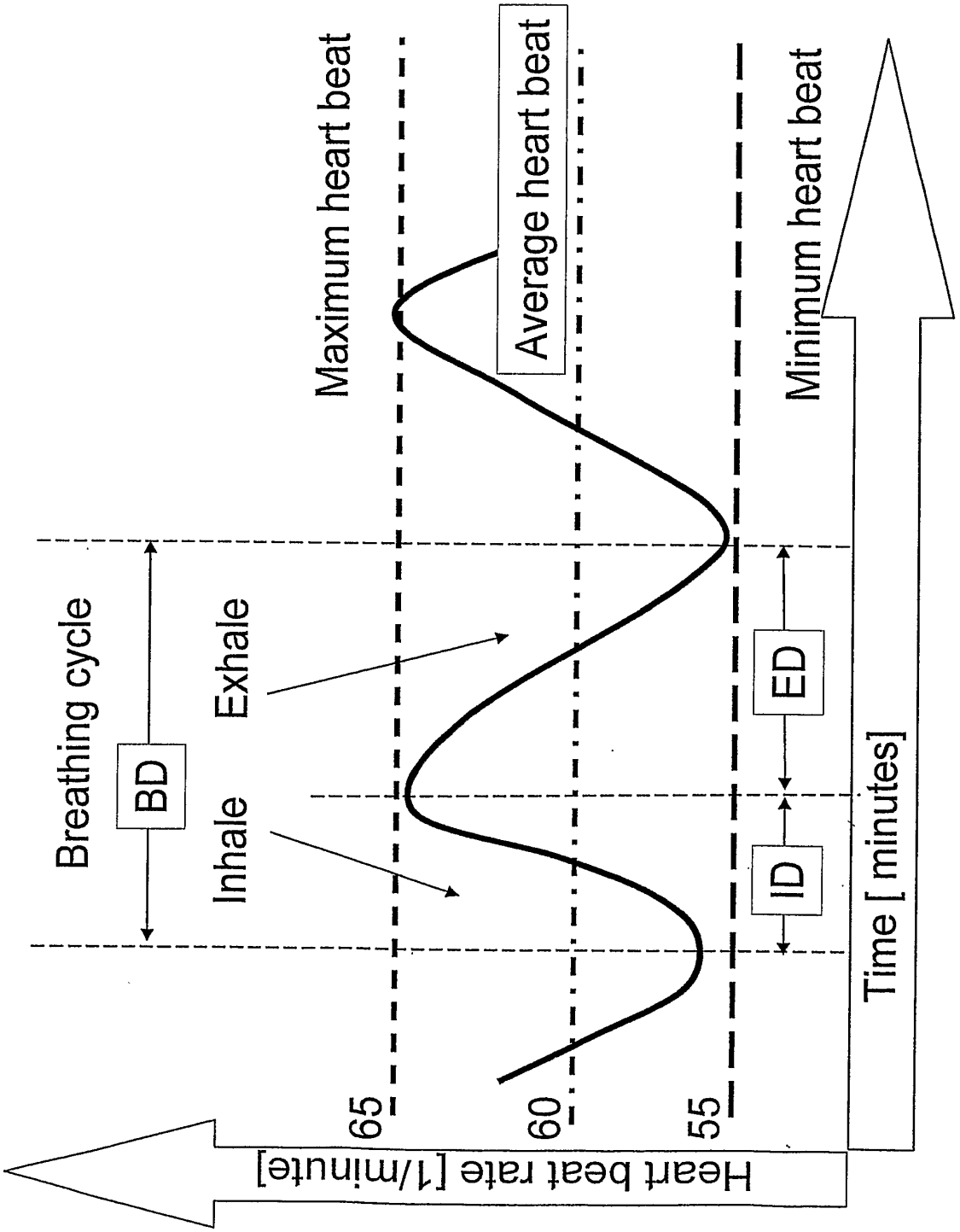

Maximum heart beat
Average heart beat
Minimum heart beat
Breathing cycle
BD
Exhale
Inhale
ED
ID
65
60
55
Heart beat rate [1/minute]
Time [minutes]

Fig. 6a

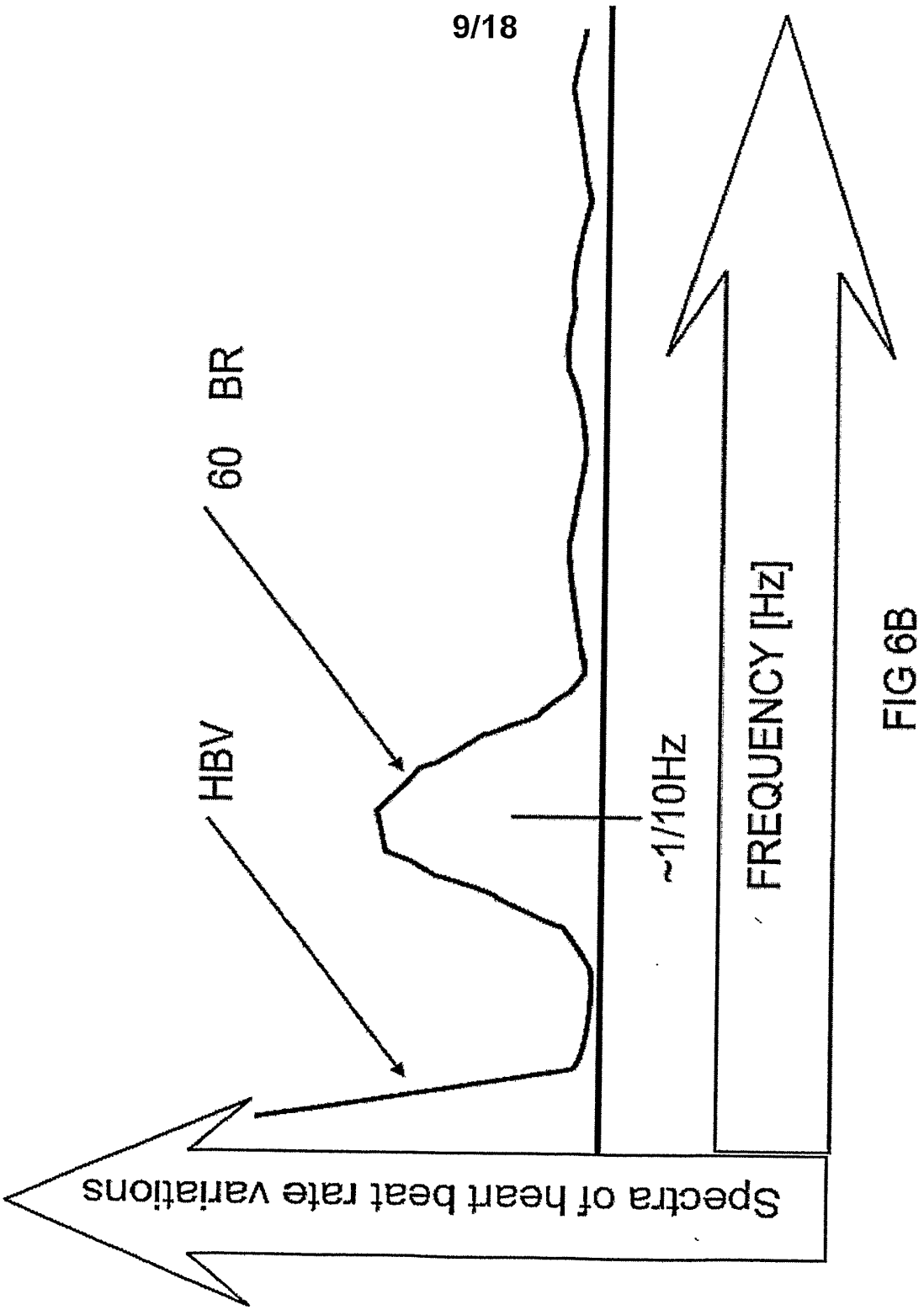

Spectra of heart beat rate variations
FREQUENCY [Hz]
~1/10Hz
HBV
60 BR

FIG 6B

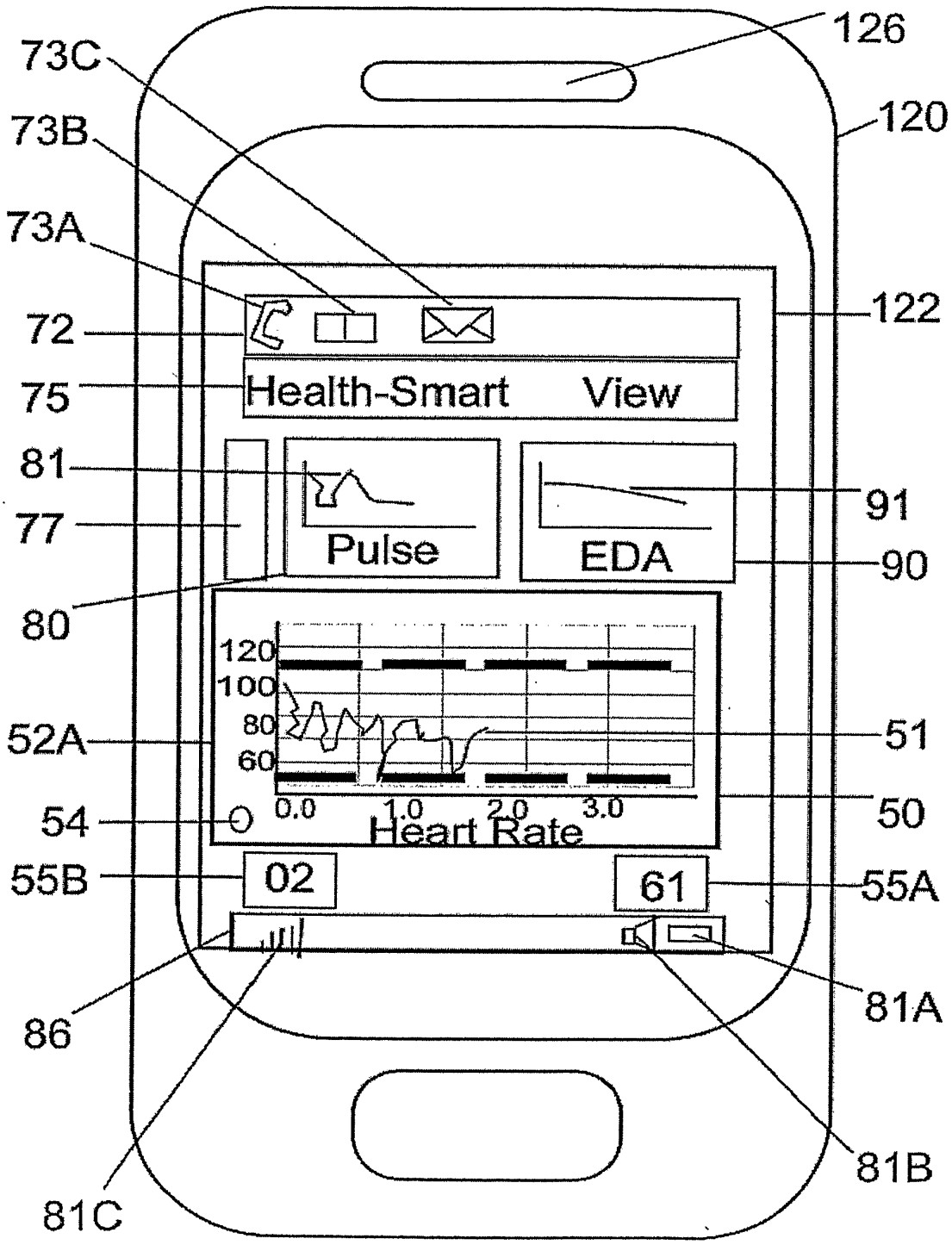

73C
73B
73A
72
75
81
77
80
52A
54
55B
86
81C
126
120
122
91
90
51
50
55A
81A
81B
Health-Smart View
Pulse
EDA
120
100
80
60
0.0
1.0
2.0
3.0
Heart Rate
02
61

FIG 7A

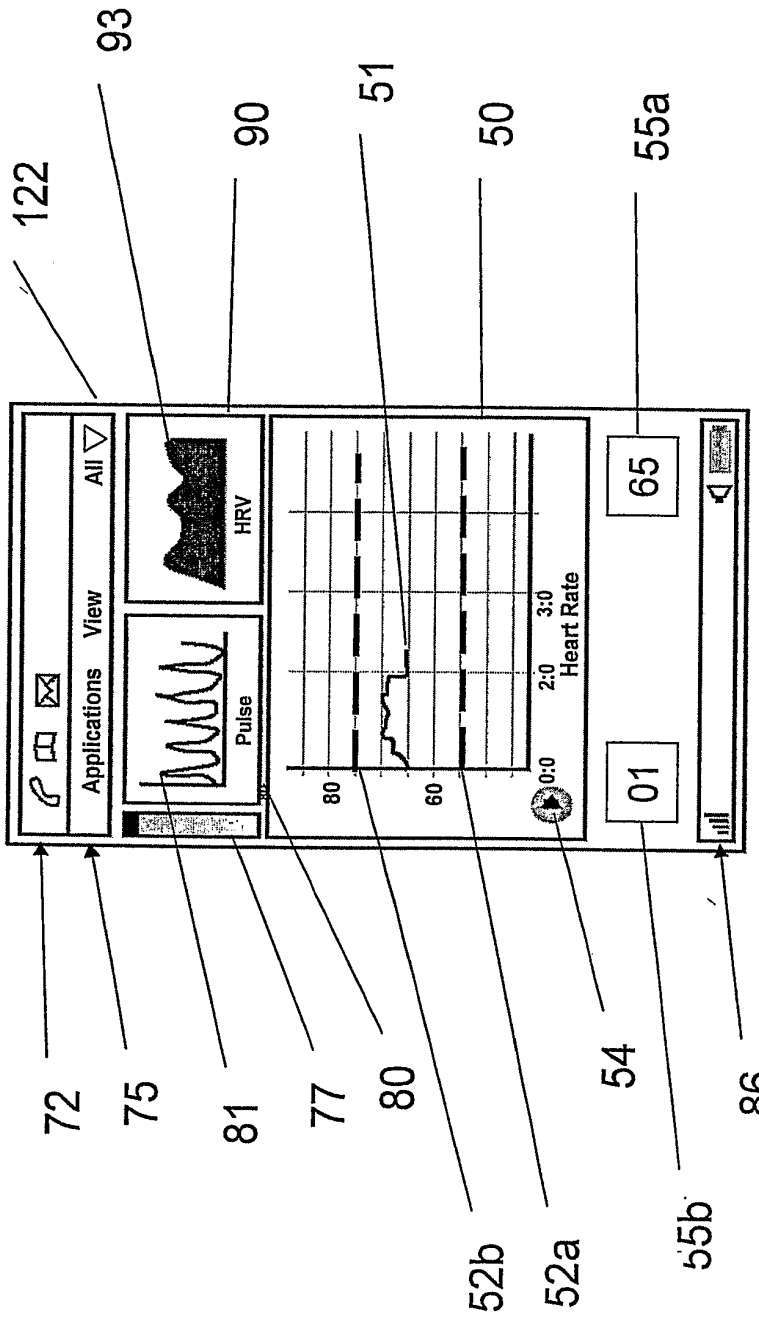

93
122
90
51
50
55a
Applications
View
All
HRV
Pulse
Heart Rate
80
60
0:0
2:0
3:0
65
01
72
75
81
77
80
52b
52a
54
55b
86

Fig. 7b

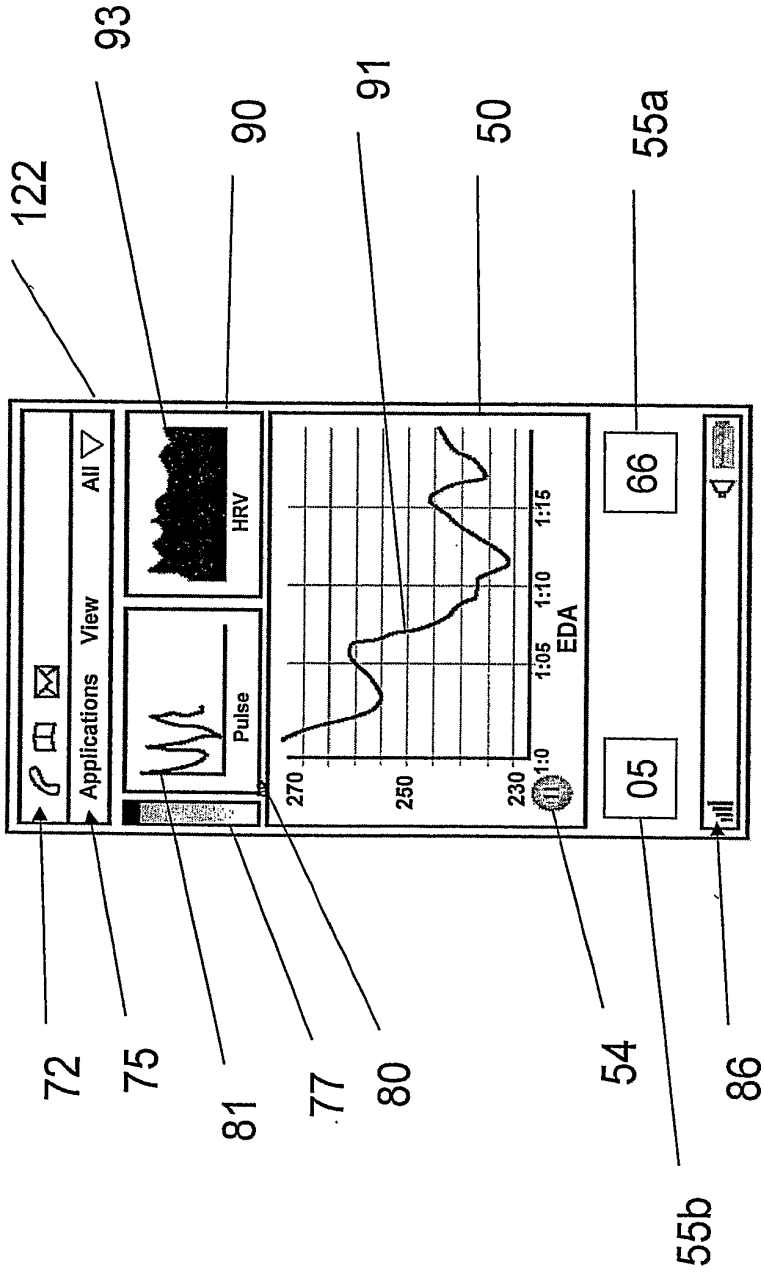

93
90
91
50
55a
122
HRV
Pulse
EDA
Applications
View
All
66
05
270
250
230
1:0
1:05
1:10
1:15
72
75
81
77
80
54
86
55b

Fig. 7c

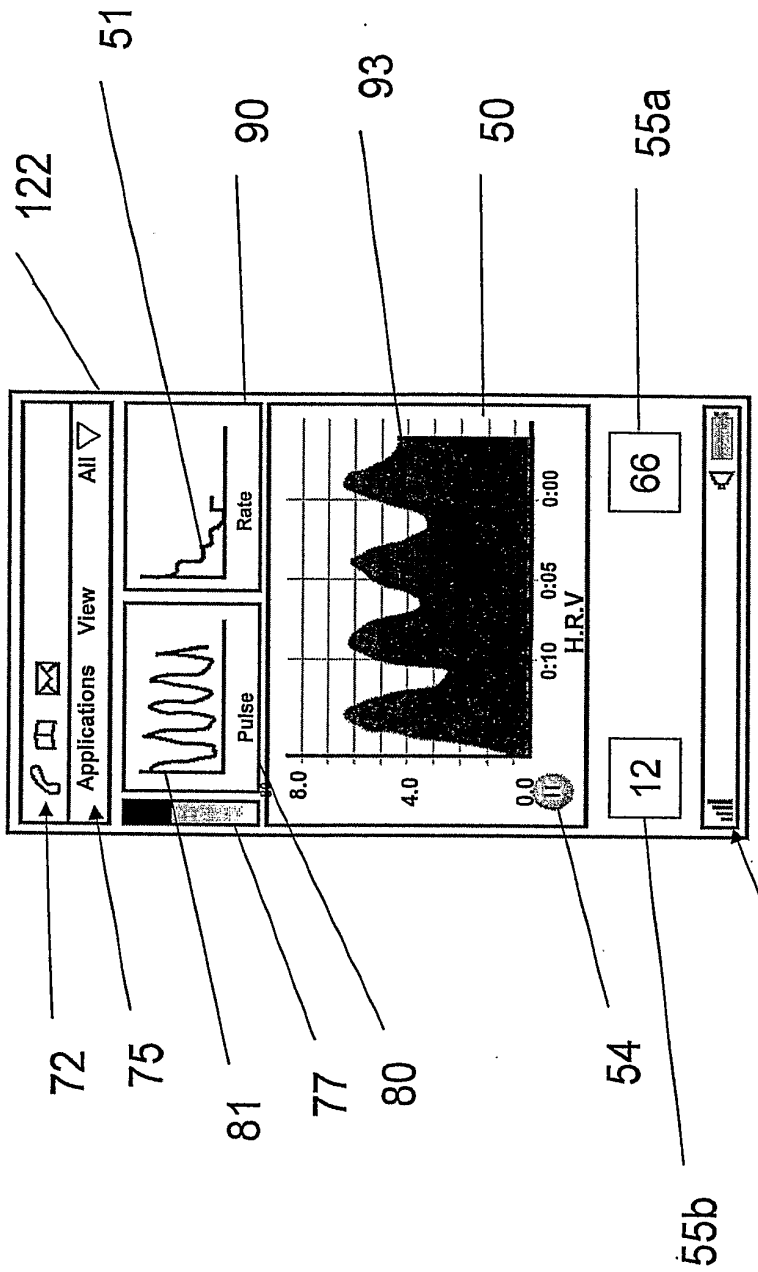

122
51
90
93
50
55a
Applications
View
All
Rate
Pulse
H.R.V
0:00
0:05
0:10
8.0
4.0
0.0
66
12
72
75
81
77
80
54
86
55b

Fig. 7d

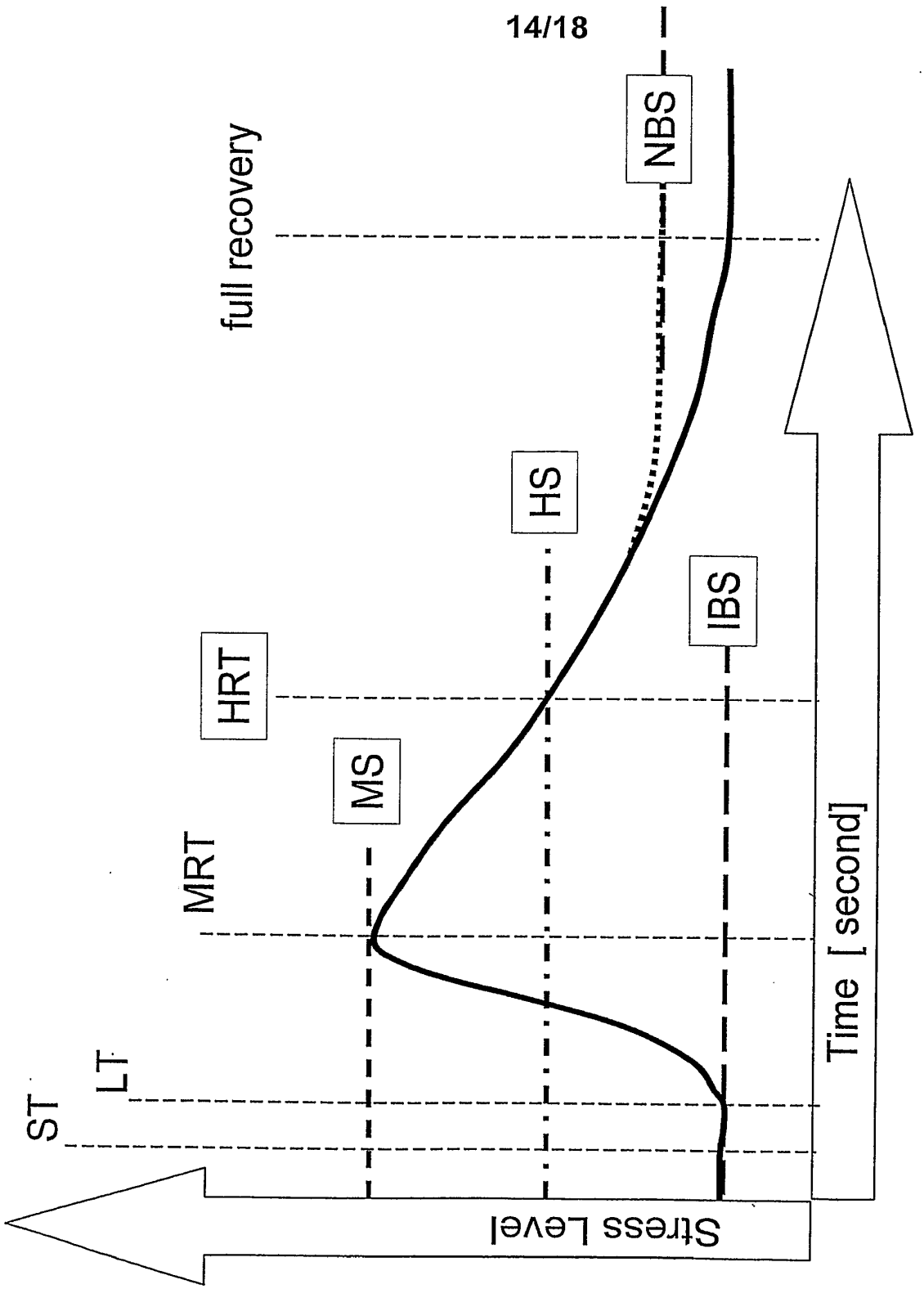

full recovery
NBS
HS
IBS
HRT
MS
MRT
LT
ST
Stress Level
Time [second]

Fig. 8

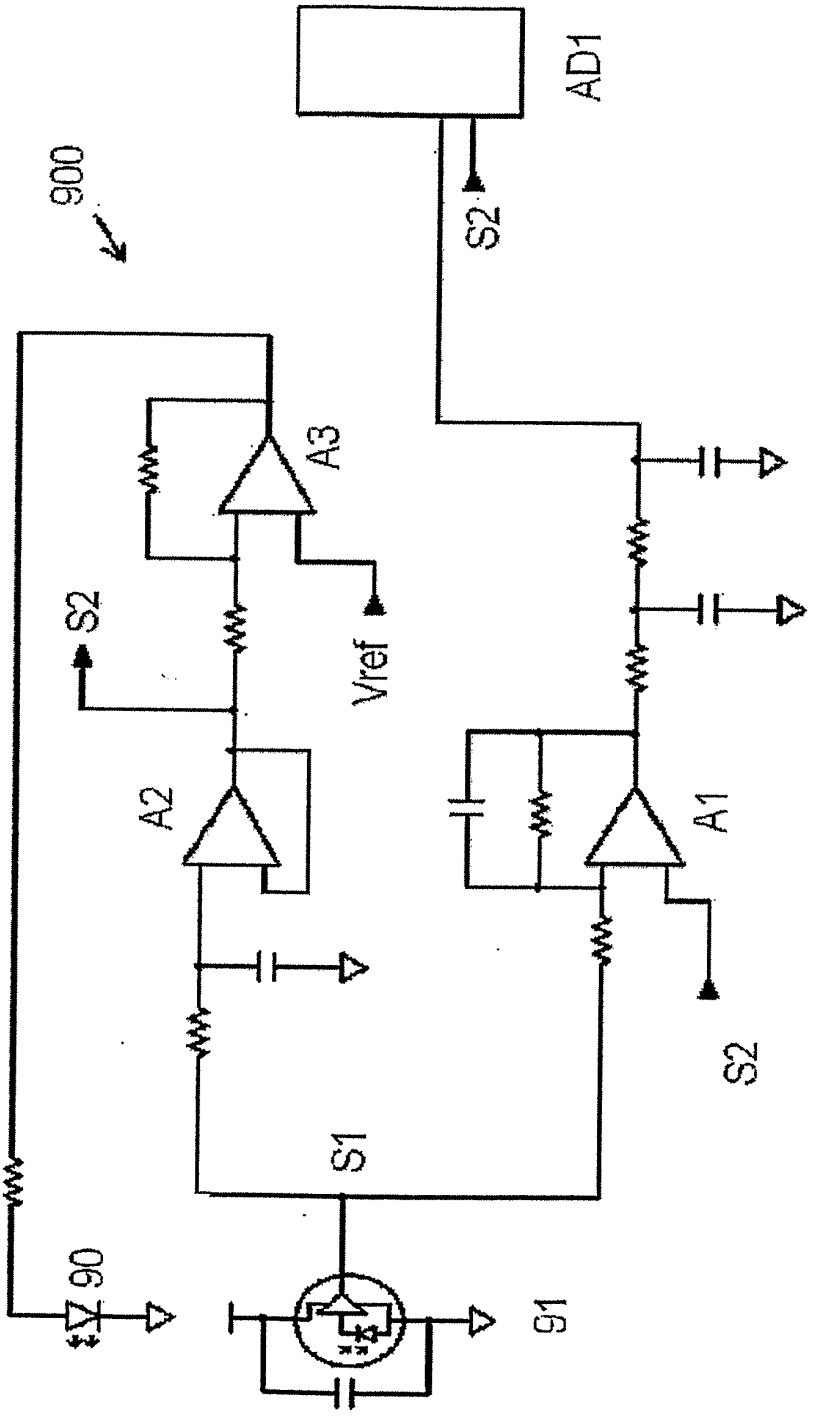


Fig 9

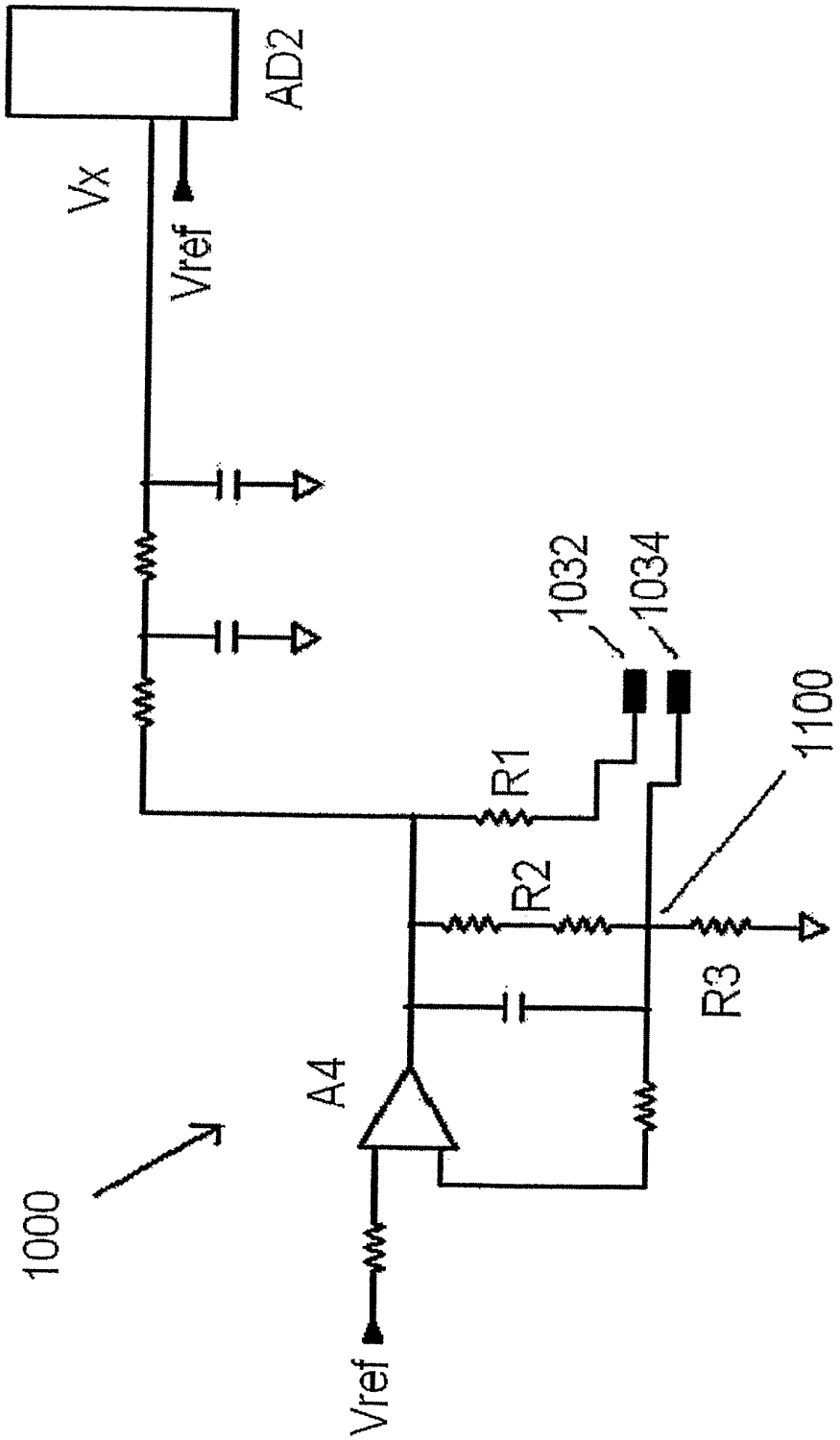


Fig 10

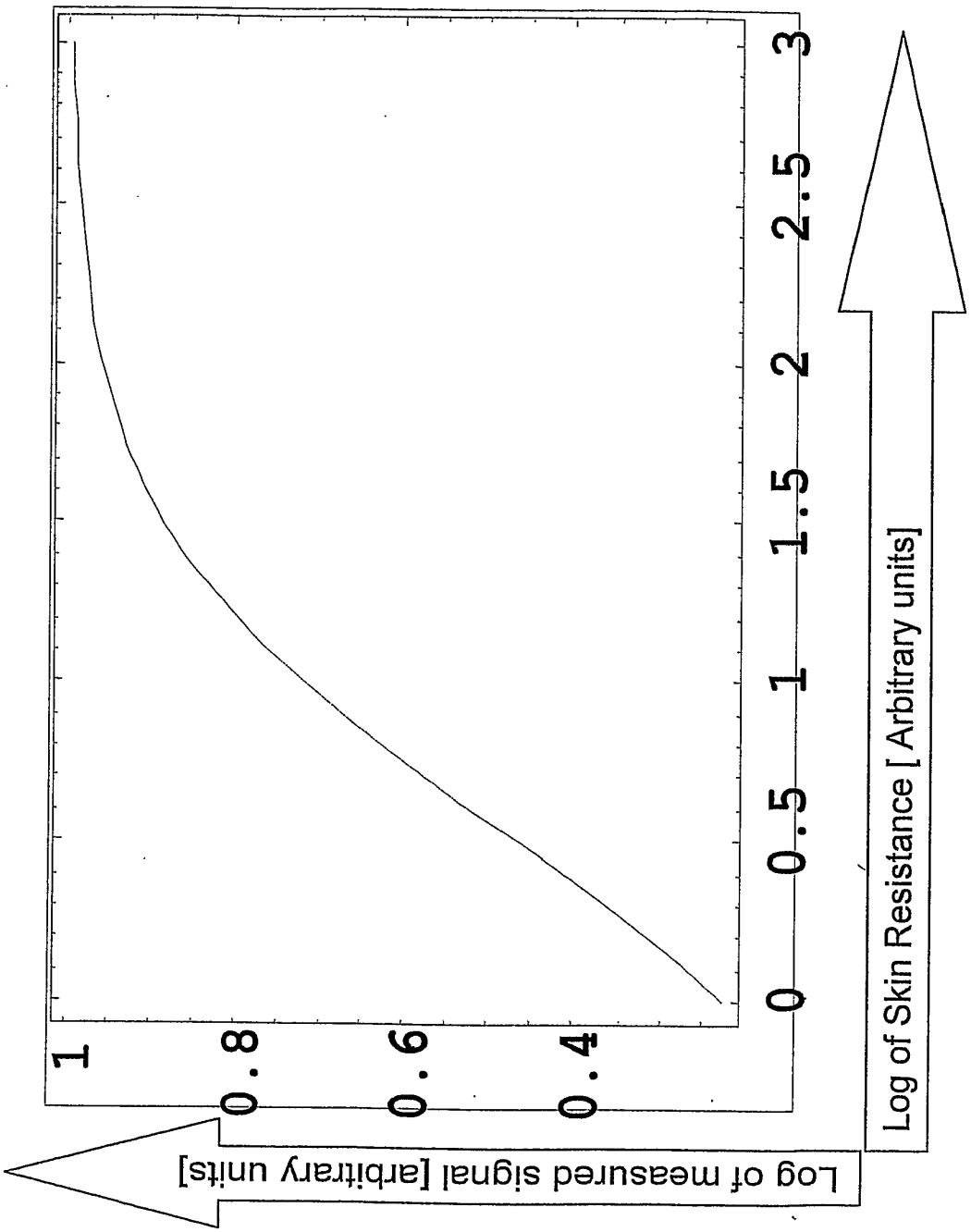

Log of measured signal [arbitrary units]
1
0.8
0.6
0.4
0
0.5
1
1.5
2
2.5
3
Log of Skin Resistance [Arbitrary units]

Fig. 11

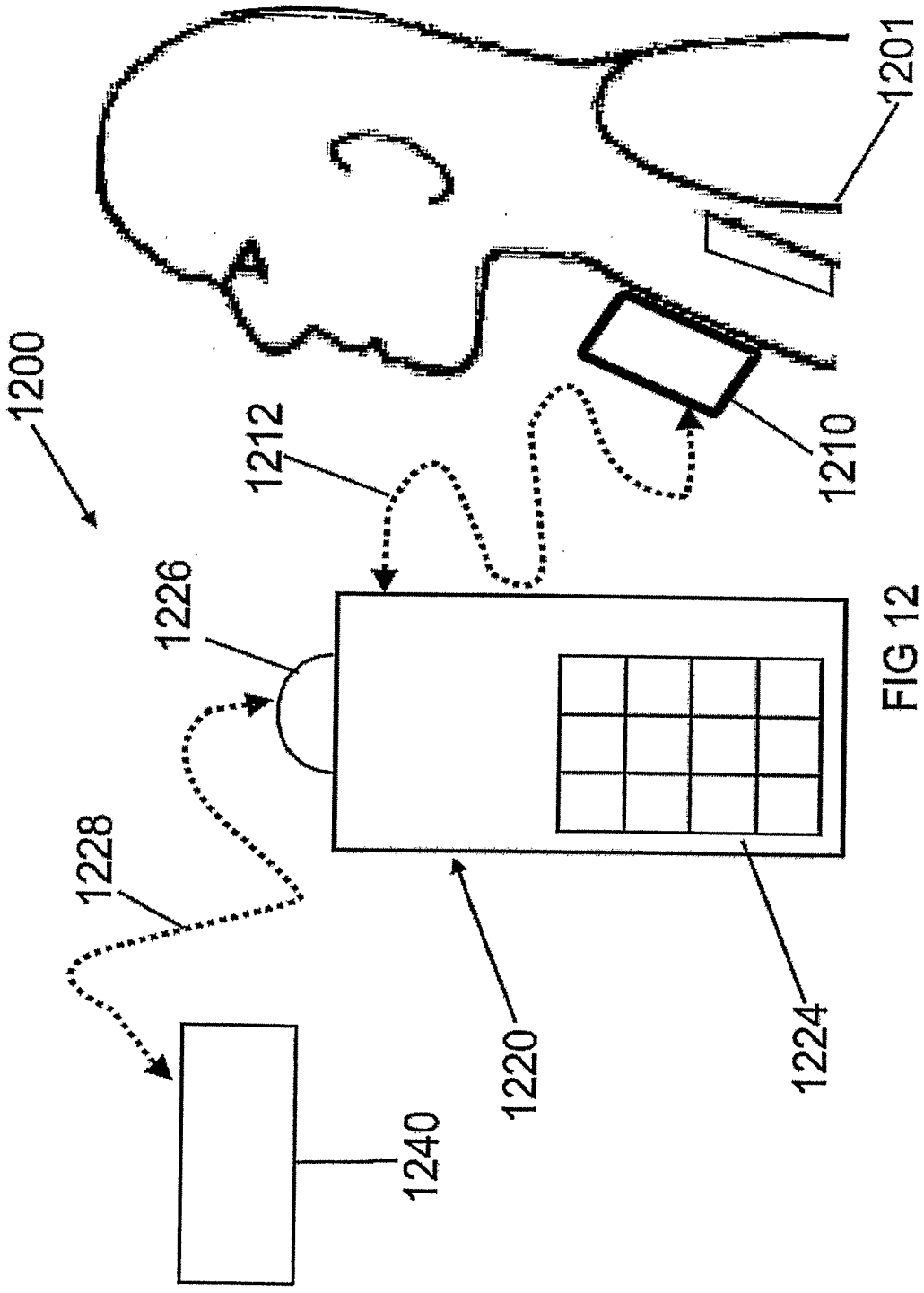


FIG 12

Espacenet

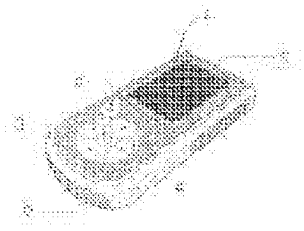
Bibliographic data: JP2010166961 (A) — 2010-08-05

ELECTROCARDIOGRAPH

Inventor(s):	FUKAMIZU TETSUJI; MAEDA TATSUO + (FUKAMIZU TETSUJI, ; MAEDA TATSUO)
Applicant(s):	PARAMA TEC KK + (PARAMA TEC:KK)
Classification:	**- international:*A61B5/0404; A61B5/0408; A61B5/0478; A61B5/0492*** **- cooperative:**
Application number:	JP20090009998 20090120 Global Dossier
Priority number (s):	JP20090009998 20090120
Also published as:	JP5560400 (B2)

Abstract of JP2010166961 (A)

PROBLEM TO BE SOLVED: To solve a problem wherein it depends on memory to determine the method by which the acquired electrocardiographic waveform is measured because the electrocardiographic waveform is measured by using electrodes in a body of an electrocardiograph or measured by using disposable electrodes in an induction electrode cord without using the electrodes in the body of the electrocardiograph. ;SOLUTION: A first mode to output the electrocardiographic waveform of a subject by using the electrodes in the body of the electrocardiograph or a second mode to output the electrocardiographic waveform by using the induction electrode cord connected to an internal circuit of the electrocardiograph without using the electrodes in the body of the electrocardiograph can be selected in the electrocardiograph. Since both the selected mode and the information on the electrocardiographic waveform, etc. measured in the mode are recorded, the information can be stored in the elapse of time after the measurement. ;COPYRIGHT: (C)2010,JPO&INPIT



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 September 2009 (17.09.2009)

PCT

(10) International Publication Number
WO 2009/112976 A1

(51) International Patent Classification:
H04M 1/725 (2006.01) *A61B 5/0432* (2006.01)
H04M 1/02 (2006.01) *A61B 5/0205* (2006.01)
H04M 11/00 (2006.01) *G06F 19/00* (2006.01)

(21) International Application Number:
PCT/IB2009/050885

(22) International Filing Date:
4 March 2009 (04.03.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/035,074 10 March 2008 (10.03.2008) US

(71) Applicant *(for all designated States except US)*: **KONINKLIJKE PHILIPS ELECTRONICS N.V.** [NL/NL]; Groenewoudseweg 1, NL-5621 BA Eindhoven (NL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **FONG, Shannon** [US/US]; PO Box 3003, Bothell, Washington 98041-3003 (US). **CROSS, Brett** [US/US]; P.O. Box 3003, Bothell, Washington 98041-3003 (US). **SOLOSKO, Thomas** [US/US]; P.O. Box 3003, Bothell, Washington 98041-3003 (US). **BISHAY, Jon** [US/US]; P.O. Box 3003, Bothell, Washington 98041-3003 (US). **MAUSER, Corinne** [US/US]; PO Box 3003, Bothell, Washington 98041-3003 (US).

(74) Agent: **SCHOUTEN, Marcus, M.**; Philips Intellectual Property & Standards, High Tech Campus 44 PO Box 220, NL-5600 AE Eindhoven (NL).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) **Title**: CELLPHONE HANDSET WITH COVER FOR AN ECG MONITORING SYSTEM

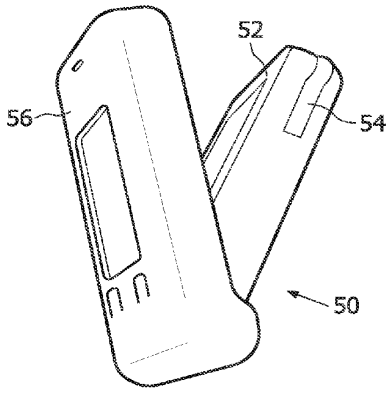


FIG. 5

(57) **Abstract**: An ECG monitoring system for ambulatory patients includes a small multi-electrode patch that adhesively attaches to the chest of a patient. A reusable battery-powered ECG monitor clips onto the patch and receives patient electrical signals from the electrodes of the patch. A processor continuously processes received ECG signals and a wireless transceiver in the ECG monitor transmits the event information and an ECG strip to a cellphone handset. The cellphone handset automatically relays the event information and ECG strip to a monitoring center. The cellphone handset has a cover which adapts the user interface of a standard commercial cellphone to the ECG monitoring application and includes a custom control program that displays ECG monitoring messages on the cellphone display and controls the automatic relay of ECG and event information to the monitoring center.

WO 2009/112976 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

CELLPHONE HANDSET WITH COVER FOR AN ECG MONITORING SYSTEM

This application is a continuation in part application of pending international application no. PCT/IB2006/054019, filed October 30, 2006, which claims the benefit of U.S. provisional application serial number 60/741,492, filed November 30, 2005.

This invention relates to ECG monitoring systems and, in particular, to the continuous ECG monitoring of patients in an outpatient setting.

Numerous patients have a demonstrated need for continuous cardiac monitoring over an extended period of time. This patient population includes those who may have arrhythmias such as atrial fibrillation, atrial flutter, and other supraventricular tachycardias, and atrial or ventricular ectopy, brady arrhythmias, intermittent bundle branch block, and arrhythmias associated with conditions such as hyperthyroidism or chronic lung disease. Other patients may exhibit symptoms that may be due to cardiac arrhythmias such as dizziness or lightheadedness, syncope, or dyspnea. Other patients may experience palpitations for which it is desirable to correlate patient rhythm with symptoms. Other patient conditions may need to be monitored for cardiac effects of drugs, in situations where the arrhythmic effects of drugs or the effects of drugs to suppress arrhythmias should be monitored. For drugs with known arrhythmic effects, possible lengthening of the QT interval should be monitored. Patients who have diagnosed sleep disordered breathing such as sleep apnea, have suffered a stroke or transient ischemia, or are recovering from cardiac surgery may often benefit from continuous cardiac monitoring.

Several monitoring devices are presently used for some of these conditions. Holter monitors are used to continuously record a patient's ECG waveform over a period of time such as a 24-hour period. However, the data recorded by a Holter monitor is only known and can be analyzed after the recording period is over. Immediate analysis of the ECG is not possible when the ECG data is only recorded and not immediately reported. Also, many patients feel constrained from engaging in normal activities when wearing a Holter monitor and its many lead wires and electrodes, and often object to the discomfort and inconvenience of these monitors.

Another monitoring device in present use is the loop or event monitor. A loop monitor records data in a continuous loop recording. When the loop is full, the loop monitor will overwrite previously recorded data. A loop monitor is therefore ineffective as a full disclosure recorder for an extended period of time since data can be lost. With an event monitor the patient is attached to numerous electrodes and wires so that the monitor can be activated by the patient whenever the patient feels symptomatic. When the patient feels pain or discomfort the patient activates the monitor to record the ECG at the time of the symptom. Some monitoring systems also enable the ECG data to be transmitted to a local base station which relays the ECG data by phone to a diagnostic center where it can be promptly scrutinized for arrhythmias. However this constrains the normal daily activities of the patient, as the patient must continually stay within range of the local base station.

Still other monitors have a recorder which is auto-triggered by a cardiac event to record the ECG

at the time of the event. The patient will then connect the monitor to a telephone line modem to transfer the ECG data to a monitoring center for review. These systems pose numerous problems. One is that a patient mistake in connecting the monitor to the telephone equipment or operating the equipment can result in a loss of uploaded data. Another problem is that a cardiac event such as syncope can leave the patient unconscious or disoriented and unable to conduct the upload process correctly or, in some cases, at all. Moreover, if the cardiac event occurs while the patient is traveling in a car, considerable time may pass before the patient returns to the location of the uploading equipment and is able to perform the data upload process.

Accordingly it would be desirable for a cardiac monitoring system to overcome the shortcomings of these devices. Such a monitoring system would continuously record the patient's ECG waveforms, analyze the ECG for arrhythmias in real time, and send ECG data to a diagnosing clinician whenever a possibly significant arrhythmia is detected. The system would also be operable by the patient to record a symptomatic event, preferably with an oral description of the event, and would then automatically send the description of the symptom and the associated ECG data to a clinician or monitoring center for review. The monitoring system would desirably be very comfortable and convenient for the patient to use without disrupting the patient's normal daily activities.

In accordance with the principles of the present invention, an ECG monitoring system is provided which is completely wireless for patient comfort and convenience. A small monitor adhesively attaches to

the chest of a patient. The monitor continuously records and analyzes the patient's ECG. If a suspected arrhythmia is detected, a strip of ECG data is immediately sent to a cellphone and forwarded on to a monitoring center for clinical review. The patient can also make a voice record of a symptomatic event with the cellphone, which promptly send the voice record and a concurrent ECG strip to the monitoring center. The cellphone has a cover which fits over a standard commercially available cellphone to adapt the cellphone to the monitoring function, the cover permitting the patient to see the cellphone display and to use only those cellphone controls adapted to the monitoring function.

In the drawings:

FIGURE 1 illustrates a patient wearing an ECG monitoring system of the present invention.

FIGURE 2 illustrates an electrode patch which adhesively attaches to the chest of a patient and holds an ECG monitor.

FIGURES 3a and 3b illustrate front and back views of ECG monitors of the present invention which clip into the patch of FIGURE 2.

FIGURE 4 illustrates how an ECG monitor of FIGURE 3 snaps into the electrode patch of FIGURE 2.

FIGURE 5 illustrates the cellphone handset of an ECG monitoring system of the present invention with its cover.

FIGURE 6 illustrates the cellphone handset of FIGURE 5 with the cover snapped onto the cellphone.

FIGURE 7 is a plan view of the front of the cellphone handset of FIGURES 5 and 6 when the handset is in communication with a monitor.

FIGURES 8a-8i illustrate some of the screen displays of a typical cellphone handset of an ECG

monitoring system of the present invention.

FIGURE 9 illustrates a monitor charging dock and cord for recharging a cellphone handset.

FIGURE 10 illustrates a monitor inside the charging dock of FIGURE 9 prior to closure of the lid of the charging dock.

FIGURE 11 illustrates a charging dock of an ECG monitoring system kit of the present invention while being used to recharge a monitor and a cellphone handset.

FIGURE 12a is a functional block diagram of an ECG monitor constructed in accordance with the principles of the present invention.

FIGURE 12b is a block diagram of the function of the ECG monitor of FIGURE 12a from a hardware perspective.

FIGURE 13 is a functional block diagram of a cellphone handset in communication with a monitoring center.

FIGURE 14 is an illustration of the communication between an ECG monitor and a monitoring center and its functions for an ECG monitoring system of the present invention.

FIGURE 15 illustrates a screen display of a setup template for the configuration and alert limits of an ECG monitor of the present invention.

FIGURE 16 illustrates a screen display to set up procedure configuration and alarm limits for an ECG monitor of the present invention, showing a custom alarm.

FIGURE 17 illustrates a screen display used to associate the components of an ECG monitoring kit of the present invention.

FIGURE 18 illustrates a screen display used to track the disposition of ECG monitoring kits of the

present invention.

FIGURE 19 illustrates a screen display used to track ECG monitors and their Bluetooth addresses in accordance with the present invention.

FIGURE 20 illustrates a screen display used to track ECG monitor usage in accordance with the principles of the present invention.

FIGURE 21 illustrates a screen display used to track cellphone handsets, their phone numbers and Bluetooth addresses in accordance with the present invention.

FIGURE 22 illustrates a screen display used to track ECG handset usage in accordance with the present invention.

FIGURE 23 illustrates a computerized template used to record suitable electrode patch placement locations and patch orientations for a patient.

FIGURE 24 illustrates a setup screen used to program the generation of reminders for a patient to recharge a monitor and cellphone handset of an ECG monitoring system of the present invention.

FIGURE 25 illustrates a screen display used by a monitoring center to record a physician's requirements for reports during use of an ECG monitoring system of the present invention.

FIGURE 26 illustrates a screen display to track account activity during use of an ECG monitoring system of the present invention.

FIGURE 27 illustrates a screen display of the patient communication log for an ECG monitoring procedure conducted in accordance with the principles of the present invention.

FIGURE 28 illustrates a screen display of an ECG viewer used to display the data produced by a four channel ECG monitor constructed in accordance with

the principles of the present invention.

FIGURE 29 illustrates a screen display of an ECG viewer for an ECG monitor of the present invention with the notification and event windows expanded.

FIGURE 30 illustrates a screen display of status notifications received from an ECG monitor of the present invention.

FIGURE 31 illustrates a screen display of an ECG viewer with a magnification window for detailed examination of an ECG waveform in accordance with the principles of the present invention.

FIGURE 32 is a flow diagram of a method for setting up an ECG monitoring procedure in accordance with the present invention.

FIGURE 33 is a flow diagram of a method for initially outfitting a patient with an ECG monitor in accordance with the present invention.

FIGURE 34 is a flow diagram of a method for daily replacement and charging of an ECG monitor in accordance with the present invention.

FIGURE 35 is a flow diagram of a method for using the "Call for Help" button of a cellphone handset of an ECG monitoring system of the present invention.

FIGURE 36 is a flow diagram of a method for using the "Record Voice" button of a cellphone handset of an ECG monitoring system of the present invention.

FIGURE 37 is a flow diagram of a method for voice contact with a patient to resolve a difficulty reported by an ECG monitoring system of the present invention.

FIGURE 38 is a flow diagram of activities performed by a refurbishment center in preparing an ECG monitoring system of the present invention for

use by another patient.

FIGURE 1 illustrates the significant patient comfort and ease of use of a wireless ECG monitoring system constructed in accordance with the principles of the present invention. The man in the drawing of FIGURE 1 is going about his normal daily activities, unbothered and unhindered by the continuous ECG monitoring system he is wearing. This is because the ECG monitoring system he is wearing is thin, lightweight, and comfortable to wear. In the main, it is because the ECG monitoring system has no wires draped about the man's body. There are no wires from the monitor to electrodes on other areas of the body, no wires connecting the monitor to a communicator, and no wires connecting a communicator to a communication network. The ECG monitoring system is completely wireless. To a casual observer it would only appear that the man is wearing a cellphone in a carrying case 10 which is circled on the hip of the man. Shown on the chest of the man is a wireless ECG monitor 12 of the present invention. Although the location of the ECG monitor 12 is shown in Fig. 1, in fact the monitor would be unseen by an observer because it would be under the man's shirt. With a diameter of less than 2.5", a thickness of 0.5", and a weight of less than an ounce, the monitor would be virtually invisible under the man's clothing. As the man goes about his daily activities, the ECG monitor 12 continuously monitors, analyzes, and records the ECG of each heartbeat. If an arrhythmia is detected by the monitor, an alert and an ECG strip are wirelessly sent to the cellphone handset in the carrying case 10. The cellphone handset silently calls a monitoring center which may be hundreds or thousands of miles away and relays the alert and ECG

strip to the monitoring center. At the monitoring center this cardiac information is promptly reviewed by a medical specialist and any necessary action taken or report made to the patient's physician. The patient's cardiac function is monitored in this way for 24 hours a day for typically several weeks (*e.g.*, 10-30 days), providing an archive of ECG information and a level of arrhythmia protection not otherwise available on an outpatient basis.

FIGURE 2 illustrates an electrode patch 20 suitable for use with a wireless ECG monitor of the present invention. This patch and variations thereof are described in detail in the parent application which is published as international publication number WO2007/063436, the contents of which are incorporated herein by reference. FIGURE 2 is a view of the outward-facing side of the patch 20. The patch is formed of a flexible substrate 22. On the back (patient-facing side) of the patch are four hydrogel electrode pads s1, s2 and s3 and a central electrode pad not visible in this drawing. The central electrode pad is a reference or RLD electrode, so named for its correspondence to the "right leg drive" reference electrode of a standard ECG set. The rest of the patient-facing side of the patch 20 is covered by a biocompatible adhesive which securely attaches the patch to the chest of a patient. Electrical signals received at the three electrode pads s1, s2 and s3 are coupled to electrical contacts on the outward-facing side of the patch by a flex circuit layer as described in the parent application and the signals so provided are used to form three ECG lead vectors as described below. In the center of the patch on the outward-facing side is a plastic clip 24 with curved lips at

the top and bottom into which an ECG monitor may be snapped and retained as shown in FIGURE 4. In the center of the clip 24 is a row of elastomeric contacts 26 by which the electrical signals received by the electrode pads s1, s2 and s3 are coupled to the ECG monitor, and a reference signal produced by the ECG monitor is coupled to the RLD electrode for the sensing of loose electrodes and reduction of common mode noise.

FIGURE 3a is a plan view of the outward-facing front side of an ECG monitor 30 constructed in accordance with the principles of the present invention. The ECG monitor 30 is enclosed in a plastic clamshell case which is ultrasonically welded closed or sealed closed with an adhesive or solvent. On the back 38 of the case as shown in the example of FIGURE 3b is a row of electrical contacts 36 which are inserted in and thermally sealed flush with the case surface. In a constructed embodiment there are three rows of electrical contacts 36. One of these rows makes connection with the elastomeric contacts 26 of the clip 24 and couples the ECG signals into the monitor and applies a small signal to the reference electrode. The other two rows engage matching rows of contacts in a charging dock when the monitor 30 is being recharged as described below. The monitor in this example has no external controls or displays and no on/off switch, only electrical contacts 36 on the back of the case. In a constructed embodiment the ECG monitor measures 2.4" wide by 1.9" high by 0.5" thick, and weighs 0.9 ounces. Since the case is sealed closed around its periphery and the contacts on the back are fully sealed, the monitor can be worn in the shower while posing no hazard to either the patient or the

monitor. As the case is closed permanently in this embodiment, replacement of the internal battery or components is not possible in this design. If the monitor fails to operate properly or the battery is no longer capable of holding a sufficient charge, it is disposed of properly.

The plastic case is keyed on the bottom with an indentation 32 that matches the shape of the bottom of the clip 24 of the electrode patch 20. A notch 34 is also formed in the bottom of the case, which matches a projection inside the bottom of the clip. The example of FIGURE 3b has two indentations 34a and 34b for keying to matching projections of a patch clip 24. This keying mandates that the ECG monitor 30 can only be snapped into the clip 24 in one orientation. FIGURE 4 is a side view showing the monitor 30 being snapped into the clip 24. The bottom of the monitor of FIGURE 3a is inserted into the clip first with the keying 32,34 of the bottom of the monitor engaging the matching shape of the bottom of the clip. The top of the monitor is then tilted back to the top of the clip as indicated by the arrow in FIGURE 4, and the top of the monitor snaps under the top 28 of the clip 24. As the monitor snaps into place, providing a tactile indication to the patient that the monitor is in place, the contacts 36 on the back of the monitor are aligned with and engage the row of contacts 26 of the clip. The monitor is now in position to monitor the ECG signals of the patient, which commences at once as the monitor senses this engagement, terminates its "sleep" mode, and powers up to full operational capability.

FIGURES 5-7 illustrate a cellphone handset 50 suitable for use with the ECG monitor 30 of FIGURE 3. The cellphone handset 50 includes a standard

commercially available "smart phone" cellphone 52 over which is placed a plastic cover 56, which snaps into place. The cover 56 functions to cover up most of the keys of a standard cellphone and restricts the patient to use of only a few buttons necessary for the ECG monitoring procedure. The cover thereby turns an often complex commercial cellphone into a communicator which is simple for the patient to understand and use. FIGURE 5 shows the cellphone 52 being placed in the cover 56. The on/off button 54 is shown located on the side of the cellphone 52 and the cellphone 52 is turned on before the cover is snapped on. As FIGURE 6, shows, the cover 56 has a hole on the front the size of the cellphone screen so that the screen 58 of the cellphone 52 can be observed through the hole in the cover. The cover also has two partial cutouts 62 and 64 on the front. These cutouts 62,64 can be depressed by the patient as buttons to operate the two underlying keys of the cellphone keypad. In other implementations the cover may cover most of the keys of the cellphone and leave only a few keys uncovered and available for use. The cutouts or uncovered keys are operated as "soft keys", with the functions affected by key depression at any moment shown on the cellphone screen 58 at the bottom of the screen and just above each cutout. Depending on the operation of the monitoring system and the actions of the patient, these functions will change as described below. FIGURE 7 is a front view of the covered cellphone handset showing the screen 58, the buttons below the screen, a small hole 72 at the top of the cover through which the patient can listen to the earphone of the cellphone, and three small holes 74 at the bottom of the cover 56, into which the patient can speak when recording a message

or conversing with the monitoring center as discussed below. When the cellphone 52 is turned on and the cover 56 is in place, there are only two buttons, 62 and 64, which can be operated by the patient in this embodiment.

A significant advantage of this commercial cellphone with cover implementation is that the monitoring system can be quickly and inexpensively adapted to new cellphone technology. As new cellphone models are introduced and older ones become obsolete, a new cellphone model can be used by redesigning the cover to fit the new model and producing the new cover in inexpensive high volumes as an injection molded part, for instance. The effort and cost to do so is far less than that required to design and produce a custom cellphone communicator, which would not keep up with technological changes and would be expensive in low volumes. The inventive approach of adapting a new cover to new commercial cellphone models enables the monitoring system designer to take advantage of the low cost of high volume commercial cellphones and avoid the need for an expensive and technically limiting custom communicator.

In other embodiments it may desirable to provide additional buttons or button functions for the patient to use. For instance, an information button labeled "i" can be provided for use by a patient when he has a question about the current state of the monitor or a message. If a message appears on the screen which the patient does not understand, the patient presses the "i" button, and the cellphone handset will provide information about the current state of the monitor or message on the display 58. Such information is context driven as determined by

the current state or status of the system. The information can be provided as text on the display 58 of the handset, or as a voice prompt which is played and articulates the information audibly. Another button which may be desirable is a "911" button which calls the 911 emergency response service when pressed. Another button which may be useful in a particular embodiment is a "Physician" button which automatically dials the phone number of the patient's physician when pressed.

FIGURES 8a-8i are examples of displays shown on the screen of the cellphone handset during use of the ECG monitoring system of the present invention. FIGURE 8a shows the screen display when the monitor and handset are in the "ECG streaming" mode. This is a mode which can be initiated by the physician when the patient is first set up with the monitor. During setup, the physician will place the electrode patch and monitor at various locations on the patient's chest, looking for a number of locations where a good ECG signal can be received. In a constructed embodiment this is done by peeling a portion of the release liner to uncover the electrode gel without uncovering the patch adhesive as explained in international patent application number IB2007/054879 (Cross et al.) In order to gauge the effectiveness of a given location, the physician will type in a certain key combination on the cellphone keypad when the cover 56 is removed from the cellphone. The key combination switches the cellphone operation to the ECG streaming mode. If the ECG monitor and electrode patch are not both attached to the patient at the time this mode is entered, the screen display of FIGURE 8a is shown, with the instruction to connect the monitor to the patient. When the monitor 30 is

in place on the patient, the patient's ECG waveform is streamed to the display and shown in real time as a function of time and amplitude as it is received from the patient, as shown in FIGURE 8b. The ECG monitor sends four channels of data to the monitoring center, three channels of ECG lead data identified in FIGURE 8b as c1, c2, and c3, and a channel M of motion information. In other embodiments other channels of data may be provided such as a reference signal channel. By depressing the right button 64 the physician can toggle through the display of all four channels of information. After the physician has found the desired number of electrode patch locations and has verified operation of the ECG monitor 30 and cellphone handset 50 in the ECG streaming mode, the left button 62 is depressed to exit the ECG streaming mode. The "System OK" display of FIGURE 8c should then appear on the screen. This screen appears when the following conditions are met: the ECG monitor 30 is communicating with the cellphone handset 50; the ECG monitor and handset system software are both functioning properly; the contact quality of the electrode patch 20 to the skin of the patient is acceptable; and the most recently conducted monitor self-test was successful. Thus, the display of FIGURE 8c indicates that the ECG monitor 30 and patch 20 are properly applied to the patient and that the ECG monitor and the cellphone handset 50 are operating properly. In other implementations it may be desirable to display a message or graphic indicating that communication with the ECG monitor is satisfactory. Another alternative is for the cellphone handset to selectively produce a tone when communication with the monitor is satisfactory, such as a beep in synchronism with

received R-wave information. At the bottom of the display of FIGURE 8c are the button labels seen on the screen above buttons 62 and 64 when the system is in its normal monitoring operation. The left button 62 is used to "Record Voice", and the right button 64 is used to "Call For Help."

FIGURE 8d shows a reminder display, reminding a patient at the end of the day that the monitor and handset need to be charged. As described below, this reminder screen will appear at a pre-programmed time each day if the patient has not begun to recharge the monitor and handset. FIGURE 8e is a display which appears when the battery charge of the cellphone handset is detected to be low. FIGURE 8f is a display that notifies the patient that the battery charge of the monitor 30 is low. FIGURE 8g is a display that appears on the handset screen when the cellphone handset 50 loses communication with the ECG monitor 30. In the constructed embodiment the ECG monitor 30 and the cellphone handset 50 communicate with each other via wireless Bluetooth radio. The patient is advised to keep the cellphone handset and ECG monitor within six feet of each other to maintain the Bluetooth wireless link. If the patient sets the handset down and walks away from it, the display of FIGURE 8g will appear when Bluetooth communication is broken. It is for this reason that the patient is advised to wear the cellphone handset in a carrying case on the waist, which maintains the Bluetooth link continuously. FIGURE 8h is the display shown on the screen when the ECG monitor 30 detects poor contact with the skin of the patient. The patient is advised to press down on the edges of the electrode patch 20 to more securely adhere it to the skin.

For all of these alert conditions, the patient

can depress the left button 62 to dismiss the alert from the screen (FIGURE 8d). Depressing the right button 64 will cause the reminder to reappear in an hour. Alerts which have been dismissed will remain displayed on the screen as small icons as shown in FIGURE 8i, until the patient takes the requested action or addresses the notified condition.

Whenever an alert appears on the screen, the cellphone handset concurrently sounds a tone to audibly inform the patient that a notification has appeared. The attention of the patient is thereby directed to the notification. Simultaneously with or instead of the display notifications, voice prompts stored on the cellphone handset can be played through the speakerphone of the handset. For example, instead of or in addition to a display showing "Poor Contact" and "Press down on edges of patch," the patient can hear a voice saying that the contact between the patch and the body has become poor and the patient should press down in the center of the patch and around its edges to reattach the patch to the body properly.

A kit of the present invention also comes with a charging dock 90 as shown in FIGURE 9 to recharge the ECG monitor 30 and the cellphone handset 50. FIGURE 9 shows a charging dock of a constructed embodiment of the present invention, which includes a base unit 100 as shown in FIGURE 10 with a hinged cover 102 for charging the monitor 30 and a cable 92 with a plug 94 for charging the handset 50. The a.c. power cord is not visible in these drawings. The monitor 30 is placed in its form-fitting space inside the base unit 100 as shown in FIGURE 10 with its electrical contacts 36 facing downward. The space is keyed so that the monitor will only fit in the space when an

LED 104 is positioned in the notch 34 of the monitor. With the lid 102 open as shown in the drawing, the monitor rests lightly on elastomeric charging contacts underneath the monitor. In other embodiments the contacts may be spring-loaded pins. The lid 102 must be closed for charging to begin; charging will not take place with the lid open. When the lid is closed the inside of the lid presses the monitor firmly against the charging contacts. This engagement is measured by the charging dock, which measures the impedance of the contact engagement. With the lid closed as indicated by the arrow in FIGURE 10, the circuitry and software program inside the base unit 100 start to initialize and the LED begins to blink with an orange color. After initialization is complete, the charging circuitry begins to charge the lithium-ion battery inside the monitor 30 and the LED 104 emits a steady green light. As the monitor is being charged, the monitor begins wirelessly transmitting its archive of ECG data to the cellphone handset 50. The cellphone handset immediately relays the ECG data on to the monitoring center for analysis, reporting and storage. After successful receipt of the archive data has been acknowledged by the monitoring center, the ECG data in the monitor is erased or cleared from memory for receipt of new ECG data when the monitor is reattached to the patient.

While the monitor 30 is being charged the cellphone handset 50 can be charged at the same time as shown in FIGURE 11. The plug 94 of cable 92 is connected to the cellphone handset and the charging dock charges the cellphone handset at the same time as the monitor is being charged. In other embodiments the cellphone handset is recharged using

a standard cellphone charger supplied by the cellphone manufacturer. As the cellphone handset is being charged a light 96 is illuminated on the handset to indicate that charging is taking place.

After the monitor 30 has been recharged and its archive data transferred to the cellphone handset from the charging dock, the circuitry and software of the monitor run a self-test of the monitor 30. Among the elements of the monitor which are tested are the random access memory of the monitor, reading and writing to the monitor flash card is tested, the motion channel of the monitor is tested, the wireless radio of the monitor is tested, and the analog and digital power supplies of the monitor are tested. A charging dock can also produce test signals which are applied to the electrode contacts of the monitor for testing the ECG circuitry of the monitor. If charging is not successful, the transmission of the archive data is not successful, or any of the self-tests is not successful, the illuminated LED begins to alternately flash orange and green to indicate that an error condition is present, and to inform the patient that a service call should be made to the monitoring center.

FIGURES 12a and 12b illustrate the functions and components of an ECG monitor constructed in accordance with the principles of the present invention, FIGURE 12a from a functional perspective and FIGURE 12b from a hardware perspective. The ECG electrodes s1, s2, s3 and RLD of the patch 20 are coupled to ECG front end circuitry 202. The ECG circuitry 202 amplifies and filters the ECG signals received from the body of the patient and injects a small signal to the RLD electrode to detect loose electrodes. Suitable ECG front end circuitry is

described in international application number IB2007/054461 (Herleikson), filed November 2, 2007, which is incorporated herein. A small 75 Hz signal is injected into the body from the RLD electrode and can be sensed at each of the s1, s2, and s3 electrodes. The signal received at each of the s1, s2, and s3 electrodes is applied to an input of a respective differential amplifier, along with a reference voltage formed by combining signals from the s1, s2, and s3 electrodes. If an electrode becomes loose on the body, the 75 Hz signal will be detectable at the output of the differential amplifier of that electrode. When the electrodes are properly in contact with the patient the signal will disappear as a common mode signal. A signal from the combination of the electrode signals is fed back to the RLD electrode as a feedback signal to balance common mode voltage and noise. The analog signals from the s1, s2, and s3 electrodes are converted to digital signals by A/D converters 204 by sampling at a 300 Hz rate. This sampling frequency is a multiple of the 75 Hz loose lead signal, enabling the 75 Hz signal to be easily filtered out. The digitized electrode signals are coupled to a lead signal formatter 206 which forms multi-vector lead signals s1-s2 and s1-s3. These two signals can be combined to compute a third vector, s2-s3. The three lead signals are formed in a manner equivalent to the manner in which the I, II, and III leads of a conventional ECG lead set are formed. The lead signals are coupled to an ECG characteristic analyzer 208 which defines characteristics of an ECG signal such as the QRS complex, the average beat, R-R interval and pulse rate. A suitable lead signal formatter and ECG characteristic analyzer are

described in U.S. provisional patent application no. 60/954,367 (Zhou et al.), filed August 7, 2007. The ECG characteristics are coupled to an arrhythmia detector 210 which analyzes the ECG for certain signal characteristics and threshold levels determined by the patient's physician and coupled to the arrhythmia detector, as described in detail below. If a sought-after arrhythmia is detected, that event is coupled to the transmit/receive controller 218, along with a 90-second ECG strip from 60 seconds prior to the occurrence of the event to 30 seconds after. The time of the event is marked in either the event information, the ECG strip, or both, and can be indicated as the time the event first appears in the ECG data, the time the event ends, the time the event was detected, or some other clinically significant time mark. The ECG strip and event information, which may be sent separately or merged together, are packetized and transmitted to the cellphone handset by a Bluetooth radio 220. This information and all of the ECG data received by the monitor are downsampled to a 200 Hz reporting rate and stored on a 2 GB flash card memory 216. A 2 GB memory can hold approximately 36 hours of ECG data at this reporting rate.

Located inside the monitor 30 is a motion detector M such as an accelerometer or a piezoelectric strip. The motion detector senses motion of the monitor while attached to the patient and hence motional activity of the patient. The motion signal from the detector is amplified, digitized by an A/D converter 214, and stored on the memory 216. The motion signal is a fourth data channel sent to the monitoring center along with the s1, s2, and RLD ECG signals and can be correlated

with the ECG information to interpret possible patient conditions as described in international patent application publication no. WO2007/066270 (Solosko et al.) For instance, a pause in the ECG signal accompanied by a large motion signal could indicate that a patient with syncope has fainted.

The monitor also includes power management circuitry 232 which monitors the condition of the lithium-ion battery 230 and controls charging of the battery. A fuel gauge 235 monitors charge into and out of the battery and continually assesses the state of the battery, its charge level, and its capacity for recharging.

Since the monitor 30 is permanently sealed in this example with no external controls, there is no ability or need to turn the monitor on and off manually. As soon as the monitor is fully assembled in the factory, it begins operating immediately. However, if the monitor does not sense after a predetermined period of time that its contacts are engaged with contacts of a charging dock or a patch, the power management system of the monitor switches the monitor into a "sleep" mode. In the sleep mode the only circuitry kept operating is that which senses engagement with the contacts of a charging dock or patch, which consumes only a small amount of current. When the power management system senses this engagement, the monitor is turned on to its fully operational state. Thus, the monitor can remain idle in inventory for weeks or months and awake virtually fully charged when placed into service.

In a constructed embodiment the core of the monitor is a microcontroller 240 which receives the digitized ECG and motion signals and performs the

lead signal formatting, analysis, and arrhythmia detection described above, as well as the transmission and receipt of data by the Bluetooth radio 220. The microcontroller also has a USB port which is coupled to the row of contacts on the back of the monitor case, enabling data and programs to be coupled to the microcontroller and its data storage devices 216 and 244.

FIGURE 13 shows the balance of a monitoring system of the present invention, including a block diagram of the cellphone handset 50 and a communication link to a monitoring center 400. The cellphone handset 50 is a commercially available cellphone with a Windows Mobile operating system for a smart phone. The cellphone includes cellphone electronics which receives inputs from a keypad 302 and displays graphical information on a display 58. The cellphone handset 50 includes a Bluetooth radio 310 which communicates with one or more monitors 30. A 2 GB memory 304 stores programs and data such as ECG data transferred to the handset from an ECG monitor. The cellphone handset is powered by a battery 314 controlled and charged by power management circuitry 312. The Windows Mobile operating system enables the cellphone directory structure to be viewed by a personal computer when the cellphone is connected to the p.c. by the same (USB) cord 92 used to charge the battery 314. An executable program which controls the cellphone to operate as described herein is loaded into a memory of the cellphone, either memory 304 or the cellphone's built-in memory, along with graphics for the cellphone display as an installer routine. The startup directory of the operating system is modified with a link to the executable program so that, when

the cellphone is turned on and boots up, it will automatically begin running the executable program and displaying the graphics designed for the monitoring application. The cellphone handset 50 communicates over a cellular network and then land lines to a monitoring center 400 which receives ECG data and status notifications from the ECG monitor and sends commands and configuration information to the monitor.

The interaction of monitoring components of the present invention which are with the patient and those that are at the monitoring center is shown in FIGURE 14. The monitor communicates by Bluetooth (BT) with the cellphone handset 50. The ECG information is sent in an HTTP protocol to a server 402 at the monitoring center 400. If the transmission is at the time of an event, the accompanying ECG strip is viewed by an ECG technician on an ECG viewer 404. If the transmission is a daily archive of ECG data, it is sent to a Holter 2010 system 406 for triage and reporting. Reports from an event diagnosed by an ECG technician or daily reporting of an archive are forwarded to an onsite patient administrator or the administrator in charge of the patient and study. Overall coordination of the monitoring center is directed by one or more monitoring center administrators.

The transfer each day of a complete recording archive of full disclosure data, every heartbeat of the patient, enables subtle cardiac conditions to be diagnosed which may not be found with typical ECG strip reporting. For instance, a high heart rate alarm limit may be set to a level considerably above the patient's normal heart rhythm. Thus, a slight increase in the patient's heart rate may not be

detected as a reportable event by the patient's arrhythmia detector. However, the slight increase in heart rate may recur numerous times in a short period of time, or may extend continuously over a long period of time. These more subtle behaviors of cardiac rhythm can be recognized by more sophisticated analysis systems operating on full disclosure data such as the Holter 2010 system mentioned above. The Holter 2010 system can be used to analyze each daily archive of data and produce a daily report which identifies such symptomatic patterns of heart rhythm. The identification of such subtleties in the daily archive by sophisticated analysis programs at the monitoring center can lead to a prompt diagnosis of the patient's condition or to the resetting of alarms and alarm limits to more effectively reveal characteristics of a cardiac condition.

A patient administrator such as the patient's physician may decide during a study to change the parameters of an arrhythmia which is to be detected. For example, the threshold for a detected tachycardia may be reset to 160 bpm. Such a change may be instituted by an ECG technician at the monitoring center, and the new setup sent to the patient's monitor as a configuration change. The new configuration information is dispatched by the server 402, received over the cellphone network by the cellphone handset, then forwarded over the Bluetooth link to the monitor 30, where it is installed in the arrhythmia detector.

FIGURE 15 illustrates a setup screen which may be used to set up or reset thresholds for arrhythmia detection by the ECG monitor 30. In this example limits can be set from pulldown boxes for ventricular

fibrillation, high heart rate, low heart rate, very low heart rate, asystole, pause in the heartbeat, and atrial fibrillation. In addition to detection limits, the user can also set a priority for an alert, such as urgent, medium, or low priority. When the ECG technician has set the desired thresholds and priorities, the configuration is saved with the "Save" button at the bottom of the screen. If the study has not yet started, the configuration information is stored on the server 402 at the monitoring center and uploaded to the monitor when the monitor is initially attached to the patient and its communication links are established. On the monitor's first communication with the monitoring center the monitor checks for configuration information, which is then uploaded and installed in the arrhythmia detector. If the study is already underway, the new configuration is immediately uploaded for installation on the monitor.

In addition to the seven standard arrhythmia alarms shown in FIGURE 15, the user also has the opportunity to set a custom alarm for a particular patient. The box 160 at the bottom of the configuration screen of FIGURE 16 contains a custom alarm which has been enabled for the illustrated configuration. The box 160 gives an example of some of the parameters which may be configured for a custom alarm setting.

A monitoring system of the present invention is typically supplied as a kit of all of the components needed for a monitoring procedure. FIGURE 17 illustrates a screen by which a monitoring or refurbishment center may assemble an ECG monitoring kit of the present invention from an inventory of ECG monitors 30 and cellphone handsets 50. A box 172 at

the top of the screen displays a list of monitors 30 in inventory. An operator clicks on a monitor to highlight it, then clicks on the "Add Selected Monitor" button to add the selected monitor to the kit. Similarly, the operator can highlight a cellphone handset communicator in box 174 and click the "Add Selected Communicator" button to add a particular cellphone handset to the kit. The serial number of the kit being assembled appears in box 176 with the serial numbers of the monitors and cellphone handset shown below. When the operator is satisfied with the assembled kit, the "Create Kit" button at the bottom of the screen is clicked to assign the selected components to a particular monitoring kit.

FIGURE 18 shows a screen by which an operator can track monitoring kits as they are sent to and received back from physicians, hospitals, and clinics. At the top of the screen are boxes by which an operator can search for a particular kit by entering the serial number for the kit in box 182, then clicking the "Search" button. Similarly the operator can pick another parameter against which to search for a particular kit. For instance, the operator can select a location to which a kit has been shipped in box 184, then search for all kits shipped to that location. The large box 186 at the bottom of the screen shows shipping information concerning a number of kits, including the date the kit was shipped to a user, the location of the user, and the serial numbers of the monitor and handset components of the kit. When a kit has been received by the refurbishment center as discussed below, the "Received Date" can be entered for the kit. The tabs at the top of the box 186 are used to mark particular kits as shipped or received.

FIGURE 19 shows a screen by which an operator can track serial numbers and Bluetooth addresses for monitors and can pair a selected monitor with a Bluetooth address of a cellphone handset. Using the boxes at the top of the screen, the operator can enter a serial number to search for a particular monitor. The large box 196 at the bottom of the screen lists all of the monitors in inventory and their serial numbers and Bluetooth addresses. New monitors can be added to the inventory by entering their characteristic information in the small boxes at the bottom of the screen. FIGURE 20 is a screen by which an operator can search for individual monitors by serial number, shipping dates, and by the locations to and from which they have been shipped. This screen also enables a search of monitors which have been received back from a user after a study is complete. The large box 250 at the bottom of the screen lists the search results of monitors by their kit serial numbers, dates they were shipped to a location, and the dates the monitors were received back from those locations.

FIGURE 21 shows a screen by which an operator can search for cellphone handsets by serial number, Bluetooth address, or phone number. The large box 252 at the bottom of the screen lists the search results for cellphone handsets and their identifying numbers, and enables new handsets to be added from the small boxes at the bottom of the screen.

The screen of FIGURE 22 is similar to the monitor screen of FIGURE 20 and allows cellphone handsets to be searched and listed by shipping location and kit serial number. This screen also enables tracking of cellphone handsets as they are returned from a user.

When a physician or nurse is outfitting a patient with a monitoring kit for a study, one of the first tasks is to find locations on the patient's chest where the patch can be applied so that the attached monitor will receive a strong ECG signal. Furthermore, it is desirable to find a number of acceptable locations so that one location on the chest is not used repeatedly, potentially causing skin irritation from repeated use. FIGURE 23 shows an interactive screen by which the nurse or physician can record information concerning patch placement. At the top of the screen is data concerning the procedure or study, such as start date and end date of the procedure. The screen can also record the dates on which the patch positions were updated and who updated the information. The body template of figurine 260 at the bottom of the screen shows three patches over the left side of the chest. These patch graphics can be dragged to different positions on the torso template, rotated if required, and then dropped to record an acceptable chest location for attachment. A suitable location on the patient's chest may be found by clipping a monitor into a patch and peeling away the portion of the release liner of the patch which covers the electrode locations, as described in U.S. provisional patent application no. 60/869,009 (Cross et al.), filed December 7, 2006. The patch can then be placed and repositioned to multiple chest locations with the hydrogel of the electrodes conducting ECG signals to the monitor. Alternatively as described in the Cross et al. patent application, if the release liner has conductive coverings over the electrode locations, the patch and monitor can be maneuvered to find suitable locations without peeling away the release liner. Each time a

suitable location is found, a patch graphic 264 is repositioned over the body template 260 to mark the identified location. The screen of FIGURE 23 can be saved and referred to each time a new patch is to be applied by the nurse or physician during the study, or a printed copy taken home by the patient and referred to each time it is necessary to replace a patch. Alternatively or additionally an electronic copy of the body template can be displayed on the cellphone handset display 58 to guide the patient when replacing a patch. Patches can normally be worn for about three days before they need to be replaced.

FIGURE 24 shows a screen which is used to record information about a procedure including the time each day when a patient is to be reminded to recharge the monitor and the cellphone handset. This screen is normally filled in when the monitoring kit is first given to the patient and the patient decides when he or she is going to recharge the monitor and handset. In a typical procedure the patient will wear the monitor and the handset all day as the patient goes about his or her normal daily activities. At the end of the day when the patient retires for the night is a convenient time to recharge the monitor and the cellphone. The patient will take a recharged monitor from the charging dock 90, remove the monitor in use from the patch and place it in the charging dock, and snap the freshly charged monitor into the patch. Just before getting into bed the patient will attach the cellphone handset to the cord 92 of the charging dock. The used monitor and the cellphone can then recharge during the night. The cellphone is left on at all times, and the charging dock is preferably left on a bedside table so that the charging cellphone handset will remain in range for Bluetooth

communication with the monitor on the patch as the patient sleeps. While the patient sleeps the used monitor is recharged, its archive data sent to the cellphone and on to the monitoring center, the monitor self-tests performed, and the previous day's archive data cleared from memory in preparation for the next daily use of the monitor. It is preferable for the kit to include two monitors so that one can be worn for monitoring while the other is being recharged and its archive data transmitted to the monitoring center. Typically, the patient will retire for the night wearing the freshly charged monitor while the used monitor is in the charging dock being recharged during the night and transmitting its archive of ECG data to the cellphone handset and on to the monitoring center. If the patient experiences a detected arrhythmia during the night, the event notification and ECG strip are sent to the cellphone handset by the Bluetooth link and immediately sent on to the monitoring center by the handset. Both monitors, the one being worn by the patient and the one in the charging dock, are in Bluetooth communication with the cellphone handset at this time and events detected by the monitor being worn by the patient are immediately sent to the monitoring center without waiting for completion of the archive data transfer, either on a priority interrupt or time-interleaved basis.

If the patient forgets to place the monitor in the charging dock so that its archive data can be uploaded to the monitoring center or is otherwise unable to do so, the patient will be prompted by the cellphone handset to do so, as shown in FIGURE 8d. If the patient dismisses the prompt or ignores the prompt and continues to wear the monitor, there may

come a time when the memory of the monitor has been completely filled with recorded ECG data. In this situation the monitor will begin to operate as a loop recorder. Newly acquired ECG signal data will be stored in the memory and the oldest stored ECG data in the memory will be overwritten and lost.

When the patient gives the physician or nurse a schedule of the time each day when the patient expects to start the recharging procedure, the time for each day is recorded on the screen of FIGURE 24. A printed copy of the screen may then be given to the patient to take home. In addition, the screen is forwarded to the monitoring center and the charging reminder times sent as configuration information to the patient's monitor or handset. At the appointed time each day, a recharge reminder message will appear on the screen 58 of the handset (see FIGURE 8d), accompanied by a tone or voice prompt to draw the attention of the patient to the reminder. The schedule can be easily changed by sending different reminder configuration information to the monitor or handset.

FIGURE 25 shows a screen by which the reporting requirements of the physician can be recorded by the monitoring center. This screen shows the procedure start and end dates at the top of the screen. On the "Reports deliver" section of the screen are listed the time when a daily report will be sent to the physician and the mode by which it will be sent. Generally, the physician will receive a report each day of the previous day's events and an analysis of the previous day's 24 hours of ECG information from the daily ECG archive of data. This example also shows the time and date when the reports delivery section was updated.

Reports and patient information may be posted on the server 402 at the monitoring center for access by particular accounts. An account may be an individual physician, hospital, or clinic. Patient information must be password-protected for the security of individual patient data. FIGURE 26 illustrates a screen by which the monitoring center may track activity of a particular account. The top of the screen gives status information and information about the account's password and its use. A high number of failed attempts to gain password access may be an indicator of someone seeking unauthorized access to the account information, which needs to be investigated. Login activity for the account is also tracked on this screen. The list in box 262 at the bottom of the screen shows individual sessions when the account logged onto and out of the server including the time of the session.

FIGURE 27 is a screen showing a patient communication log with the monitoring center. The search boxes at the top enable an operator to search for patient information by site, physician, or patient. The search results, showing patients, their physicians, their procedures, and the procedure dates are returned in box 272. Detail for a selected patient is shown in box 274. The most recent communication between the patient and the monitoring center is recorded at the top of the box, and earlier communications are listed at the bottom of the box.

FIGURE 28 illustrates an ECG viewer screen suitable for receiving and analyzing event information received at the monitoring center from an ECG monitor of the present invention. In this embodiment the ECG viewer screen has three major sections: a Notification window 282 which shows

information about a particular procedure or study and lists the notifications received from that patient; an Events window 284 which displays the information received at the time of an event; and an ECG viewing window 286 in which the data received over the channels transmitted by the monitor may be analyzed in detail. In FIGURE 28 the Notification and Events windows are unexpanded and the ECG viewing window is expanded. In this embodiment the ECG monitor 30 transmits five channels of data and the cellphone handset transmits a voice channel recorded with the handset. The data channels are three ECG signals, s1, s2, and s3 in this example, the RLD signal ("rld"), and the motion channel ("vp"). Differential lead signals s1-s2, s2-s3, and s1-s3 may be derived from the ECG signals of this example. The RLD signal may be used to further process and refine the lead signals and identify noise conditions. The controls at the left of each display strip allow an operator to adjust the scaling and other parameters of the strip display. In the display strips of this example it is seen that a significant motion signal has occurred at the time of the sizeable ECG signals of the s1-s2 and s1-s3 channels. The audio controls 288 at the bottom of the display enable a transmitted voice recording from a patient to be replayed by the ECG viewer operator.

FIGURE 29 illustrates the ECG viewer screen of FIGURE 28 with the Notification window 282 and the Events window 284 expanded. In a constructed embodiment the monitor 30 sends a notification every time the status of the monitor changes and these notifications, as well as those originating from status changes of the cellphone handset, are forwarded on to the monitoring center by the

cellphone handset. For example, when the monitor senses that it is attached to a patient and receiving ECG signals from the patient, a status message is sent to the monitoring center. When the monitor detects a loose lead, a status message is sent to the monitoring center. When the loose lead is reattached a status message is sent to the monitoring center. When the monitor is removed from the patch a status message is sent to the monitoring center. Thus, the continual flow of status messages enables the monitoring center to evaluate the patient's use of the monitor and the technician at the monitoring center can intervene with a call to the patient's cellphone handset if the flow of messages indicates that the patient is having a problem or overlooking something. Table 1 below lists some of the typical messages which may be sent during use of a monitoring system.

Table 1

Notification	Type
Monitor on patient, operating properly	Status
Loose lead	Status
Loose lead corrected	Status
Monitor removed from patient	Status
Monitor powered down	Status
Low battery (monitor)	Status
Low battery (handset)	Status
ECG streaming mode	Status
Bluetooth communication lost	Status
Bluetooth communication restored	Status
Cellphone communication lost	Status
Cellphone communication restored	Status
Self-test successful	Status
Self-test unsuccessful	Alert
Monitor placed in charging dock	Status
Monitor removed from charging dock	Status
Monitor charging started	Status
Monitor charging completed	Status
Monitor charging unsuccessful	Alert
Cellphone charging started	Status
Cellphone charging completed	Status
Cellphone charging unsuccessful	Alert
Charging dock error	Alert
ECG archive transmission start	Status
ECG archive transmission complete	Status
Event information + ECG strip transmitted	Alert: priority = hi, med, low
Voice message + ECG strip transmitted	Alert: priority = hi, med, low

Different notifications can be handled in different ways. For example, interruption of Bluetooth communication may be a common occurrence. A patient may set the cellphone handset down and walk away to perform some task, resulting in a loss of Bluetooth communication when the monitor is out of range with the cellphone handset. A few minutes later the patient returns to the cellphone handset and picks it up and puts it back in the carrying case, a purse or pocket, which re-establishes the Bluetooth

communication when the monitor and cellphone handset are back within Bluetooth signal range of each other. In such circumstances it may be desirable to delay notification of Bluetooth communication loss for five or ten minutes to allow a period of time for communication to be restored before sending a notification. Alternately, the communication loss notification may be sent immediately as a status message, and if a notification that communication has been restored is received shortly thereafter, the notification canceled or automatically marked as resolved. If the resolution notification is not received within five or ten minutes or some other predetermined period of time, the priority of the notification is raised at the monitoring center to bring it to the attention of a technician. Loose lead notifications may similarly be delayed or subject to priority escalation to allow the patient to recognize and correct the situation without a notification being sent or responded to by the monitoring center.

It will be appreciated that different status notifications can originate from different sources. A notification that Bluetooth communication has been lost must originate from the cellphone handset since the monitor is out of communication with the handset at this time and cannot originate the message. Similarly a notification that cellphone communication has been lost will originate at the monitoring center, generally when the monitoring center tries to send a message to the cellphone and finds that it is unable to do so.

In the example of FIGURE 29 all notifications received from the patient are listed in the Notifications box 282. Routine status notifications

appear in normal text and in chronological order of receipt. Higher priority alerts are displayed at the top of the list of notifications and are color-coded to indicate urgency, for example, yellow highlighting for medium priority alerts and red highlighting for high priority alerts. In a preferred embodiment, ventricular fibrillation and asystole events are of the highest priority, heartbeat pauses and heart rate notifications are next in priority, loose lead and poor electrode contact notifications are lower in priority, and other status changes and technical alerts such as low battery and loss of communication are of the lowest priority. As the notifications are reviewed by an ECG technician at the monitoring center they may be processed appropriately then deleted from the displayed list. The second box 283 in the Notification window 282 has entry spaces where the technician can enter a disposition for the notification and provide appropriate comments with the disposition. The Notification window thereby provides a task list which the technician can use to review and handle notifications from a patient's monitor in a priority order and efficient manner. In a constructed embodiment multiple technicians may view the notifications from the same patient at the same time, but when a technician has selected a particular notification to analyze and disposition, the other ECG viewers are locked out from selection of the notification so that only one technician can work on disposition of a notification at any given time. This prevents redundant processing of a single notification and enables flexibility in the operation of multiple ECG viewers at a large monitoring center.

The status notifications can also be displayed on a separate screen as shown by the screen display

of FIGURE 30. As this example illustrates, low priority mode change status notifications are listed below the higher priority event "alarm HRLo" at the top of the list. Notifications which have been dispositioned by a technician are marked by a check mark in the box at the left side of a notification. The boxes at the top of the screen are used to search for notifications of certain characteristics, such as Event notifications or notifications received during a selected time period.

When an Event notification is received, including a patient voice recording, the Event notification is accompanied by a 90-second ECG strip which was recorded starting sixty seconds prior to the event time and continuing for thirty seconds thereafter. Event notifications will appear in the Event window 284. The identity of the event is displayed in the first box 285 and the ECG strip transmitted with the event notification appears in box 287. The ECG technician can thereby quickly review the ECG signal from the time of the event. If more detailed analysis is desired, the ECG strip can be reviewed in the larger ECG viewing window at the bottom of the viewer screen as shown in FIGURE 29.

FIGURE 31 illustrates a feature of a constructed embodiment of the present invention, which is an ECG magnifier window 290. The ECG technician can right-click on an ECG strip window 292 when it is desired to view an ECG waveform in greater detail. A list of option will appear and the technician selects "magnifier", causing the circular magnifier window 290 to appear. A central area of the ECG strip where the magnifier window 290 is located is then shown in an enlarged view in the window 290. A setup option allows the user to determine the degree of

magnification (*e.g.*, 2x, 5x, 10x) to be provided within the magnifier window 290. The user can drag the magnifier window across the ECG strip window 292 to enlarge any section of the displayed ECG strip.

FIGURES 32-37 illustrate steps by which certain activities attendant to the use of an ECG monitoring system of the present invention may be conducted. FIGURE 32 is a sequence of steps performed when a patient is registered for an ECG monitoring procedure. At 321 the patient's physician enrolls the patient with a monitoring center. Patient information is given to the monitoring center and the monitoring center begins to prepare to receive notifications from the kit to be used by the patient. The physician may already have a kit on hand which can be used by the patient. If not, the monitoring center dispatches a kit to the physician for use by the patient. The monitoring center associates the kit to be used by the patient with the patient being enrolled by the physician. At 322 the monitoring center sets up the reporting requirements desired by the physician using a screen such as that shown in FIGURE 25. At 323 the types of arrhythmia alerts to be monitored are set up using a screen such as those shown in FIGURES 15 and 16, and alarm limits are set as illustrated on those screens. At 324 the monitoring center sets up the reminder schedule for the times at which the patient will be reminded to recharge the handset and monitor as illustrated in FIGURE 24. If the physician has completed a patch position chart such as that illustrated in FIGURE 23, the chart is sent at 325 to the monitoring center for use by monitoring center technicians in assisting the patient with patch application if necessary. In other instances the patch position chart may be sent

to the monitoring center at a later time. It will be appreciated that most or all of the information provided in the steps of FIGURE 32 may be provided by the physician completing the enrollment and setup screens remotely in the physician's office without person-to-person contact with the monitoring center. That is, the setup screens can be made available to an account of the monitoring center as a Web accessible application. Once the information has been entered at a remote terminal it is available at the monitoring center, which can process and enroll the patient without personal contact with the physician.

FIGURE 33 illustrates a sequence of steps performed when the patient is initially introduced to a monitoring system of the present invention. At 331 a physician or nurse turns on the cellphone handset 50 and keys the handset to the ECG streaming mode. The monitor 30 is snapped into a patch 20 at 332 and the perforated center of the release liner is removed from the patch to uncover the gel electrodes. If locations for patch attachment have not previously been located on the chest of the patient, the clinician slides and/or rotates the patch and monitor over the patient's chest as described above to locate one or more suitable locations and orientations for patch attachment at which a clear ECG signal is be received, as indicated by the streaming ECG display. As suitable chest locations are found the patch position chart is filled in at 333 to record the locations, the chart is sent to the monitoring center and a copy given to the patient, step 325 of FIGURE 32. The release liner is fully removed from the patch 20 to expose the adhesive and the patch and monitor attached to one of the ascertained locations

on the patient's chest at 334. Channels of the ECG data should now stream to and appear on the handset display 58, verifying operation of the Bluetooth communication link between the monitor 30 and the cellphone handset 50 at 335. The clinician can reset the cellphone handset to normal operation by depressing the left "Exit" button shown in FIGURE 8b and call the monitoring center at 336 to verify the second connection link, that between the cellphone handset and the monitoring center. Alternatively the control software of the cellphone handset can be programmed to make this connection automatically. A technician at the monitoring center can verify the complete communication path by, for instance, sending a command to the monitor to transmit an ECG strip to the monitoring center and verifying its receipt on an ECG viewer at the monitoring center. Communication with the monitoring center may indicate the need to further reposition the monitor and patch. When the cellphone handset 50 relays the first message from the monitor 30 to the monitoring center, the monitoring center responds by transmitting the configuration data for the procedure to the monitor 30. The configuration data and its arrhythmia alert limits are installed in the monitor at 337 and the monitor is then ready to proceed with the study.

When it is time to exchange monitors and recharge the used monitor, the sequence of steps shown in FIGURE 34 can be followed. At 341 the patient removes the monitor 30 from the patch 20. If the patch needs to be replaced, the patch 20 is removed from the chest and a new patch attached to a new area of the skin to avoid irritation, using the patch position chart of FIGURE 23. The monitor which was recharged the previous day and is still in the

charging dock 90 is removed from the dock and snapped into the patch at 342. The used monitor is placed into the charging dock and the lid 102 closed at 343, and the cellphone handset is attached to the charging cord 92 at 344. Preferably this procedure is carried out at bedtime with the charging dock located next to the patient's bed so that the patient can go to bed and remain within Bluetooth communication range of the charging handset 50. When the patient gets out of bed in the morning, the charged handset is removed from its charging cord and put into the carrying case on the patient's waist at 345.

It will be appreciated that the wireless communication links of the system, the Bluetooth link between the monitor 30 and the handset 50, and the link between the cellphone handset and a cell tower, can be disrupted due to a variety of causes. Bluetooth communication range is usually a matter of feet, and it is generally recommended that the patient keep the cellphone handset within six feet of the patient to maintain this communication. If a patient puts the cellphone handset down and walks away for a period of time, this line of communication will be broken. Likewise, a patient with monitor and handset can travel out of range of a cellphone transceiver and cellphone communication will be lost. As another example, if a patient is going to travel by airplane, aviation regulations require that the cellphone handset be turned off before the plane departs and kept off until the plane lands. Thus, cellphone communication can be intentionally unavailable for a period of many hours.

Disruption of the Bluetooth link does not disrupt operation of the monitor 30. The monitor will continue to receive ECG signals from the patient

and continue to analyze the heart information and store the data in the memory 216 of the monitor, even if the Bluetooth link is not operating. If an arrhythmia event is detected it will not be possible to transmit the event data or other status message to the cellphone handset 50 until the Bluetooth link is restored, however. Generally an out-of-range timeout will be allowed to expire before a loss of Bluetooth communication status message is sent to the monitoring center by the cellphone handset to allow the activity of the patient to restore the link before reporting the status change. When the Bluetooth link is restored the event data and its ECG strip and all other pending notifications are immediately sent to the cellphone handset for relay on to the monitoring center. Preferably the Bluetooth radio is operated in the "sniff" mode, a low power mode in which synchronization between a Bluetooth transmitter and receiver can be maintained for short intervals and quickly re-established. When the monitor has a message to send, the Bluetooth transmitter is returned to full power for transmission of the message. The Bluetooth link is operated in full duplex so that either the monitor or the cellphone handset can initiate transmission of data to the other component. The monitor will continue to "sniff" for the cellphone handset while communication is disrupted so that, when the handset is back in range, pending messages such as event and status data can be sent to the handset and monitoring center immediately at that time.

If the Bluetooth link is operational but cellphone service is disrupted, communication will continue between the monitor 30 and the cellphone handset 50 so long as the cellphone handset is turned

on. Event and status messages from the monitor will continue to be sent over the Bluetooth link and received by the cellphone. However, the messages will not be sent to the monitoring center, but will be stored in memory on the cellphone until cellphone service is restored. When service is restored, the messages stored on the cellphone will be immediately sent to the monitoring center at that time. It is for this reason that the flash card memory of the cellphone is of the same or greater capacity as the memory in the monitor, 2GB in the above example. This means that if cellphone service is disrupted at nighttime when the day's archive data is being downloaded from the monitor, Bluetooth transmission of the archive to the cellphone can continue even if cellphone service is down. The archive will continue to be transferred from the monitor to the cellphone handset even if cellphone service is down, since the flash card memory 304 of the cellphone has the capacity to store the entire archive and, in a constructed embodiment, up to several days of complete archived data. When cellphone service is restored, the cellphone will automatically resume sending the archive data to the monitoring center.

In analyzing ECG and event data, it is important to record the times of events and waveforms so that all of this patient information can be correlated to make an accurate assessment of the patient's condition. This means that the information must be time-stamped with the time of occurrence of the information and that the information be related to a common time base. The patient data could be time-stamped at the time of its receipt at the monitoring center and related to a common time base there, however, as just mentioned, the wireless

communication links can be interrupted, thereby delaying the receipt of data at the monitoring center and resulting in erroneous time stamps. Each monitor has its own time base and on-board clock, and this clock could be used to time-stamp data before it is stored in the monitor's memory or sent to the monitoring center. The monitoring center would thereby have a common time base for data received from a monitor. However, the kit of the preferred embodiment uses two monitors which are exchanged each day, each monitor with its own clock. Accordingly, the clocks of the two monitors could be synchronized prior to delivery of the kit to the patient. But clocks can drift over time, and the two clocks of the two monitors could drift at different rates over time, causing a time base disparity between the two clocks. In the preferred embodiment these problems are addressed, not by adjusting the monitor clocks, but by relating the patient data to the time base of the cellphone network. The cellphone handset periodically sends its cellular network-based time to the monitor(s). When the cellphone time is received by a monitor, the monitor stores the cellphone time and the current monitor time as part of the patient data. When the monitoring center receives the data with this timestamp information, it can correlate the patient data to the cellphone network-based time. The monitoring center, having access to the cellphone network and its time base, can relate the patient data and its cellphone network-based time stamps to its own time base if desired. In this way the data produced by multiple monitors used by a patient is related to a common and reliable time base.

As mentioned above, in a constructed embodiment of the present invention there are only two buttons

for the patient to operate on the cellphone handset, 62 and 64 as shown in FIGURE 6. As previously mentioned, the default functions of these buttons are "Call for Help" and "Record Voice," as indicated by the softkey legends on the screen 58 above the buttons. FIGURE 35 provides an example of how the "Call for Help" button can be used in an embodiment of the present invention. The patient will generally be instructed to use the Call for Help button whenever the patient has a problem or question about the monitoring system or has a medical emergency. In either of those situations the patient will depress the Call for Help button 64 on the handset 50, and the cellphone handset will call the monitoring center at 352, the only number it can call in this embodiment. As the call is placed, the monitor 30 is prompted at 354 to begin transmission of an ECG strip to the monitoring center for a 90-second period commencing before the time of the call and continuing for a period of time thereafter. A medical technician at the monitoring center will answer the voice call at 356 and begin talking to the patient. While the technician is talking to the patient he can view the concurrent ECG strip so that the ECG data can be viewed if the patient is calling with a medical problem. In a constructed embodiment of the present invention the technician and the patient can engage in a voice communication at the same time as the ECG strip data is being sent to the monitoring center; it is not necessary to end the voice call so that the ECG data can be sent. If the patient has a question about the monitoring system the question will be asked of the technician as indicated at 358. The technician will provide the requested information or guidance so that the patient can continue to

effectively use the monitoring system. If the call is being made in a medical emergency, the technician may call the 911 emergency response system for aid or if appropriate under the conditions, call the patient's physician about the situation. This call-for-help service from the monitoring center should be available to the patient 24 hours a day and seven days a week.

FIGURE 36 gives an example of the use of the "Record Voice" button 62 of the handset 50. When the patient feels a cardiac symptom as directed by his physician, the patient will use the monitoring system as an event recorder by depressing the Record Voice button at 362. When the button is depressed the patient will listen to instructions from the handset and be told to record a message when the cellphone handset is programmed with these functions. In other embodiments the recording instructions may be provided in a printed user guide supplied with the monitoring kit. If the message has a predetermined maximum length, the patient will be told not to exceed this length or to record a second message if greater recording time is needed. This information may be provided visually or audibly. As the patient speaks into the cellphone microphone the patient's voice is recorded by the cellphone at 366. The depression of the Record Voice button will also cause a command to be issued to the monitor 30 to send a 90-second ECG strip encompassing the time of the voice message at 364. The recorded voice message and the concurrent ECG strip are sent to the monitoring center by the cellphone handset, where an ECG technician can listen to the recorded message from the patient and simultaneously analyze the data of the ECG strip with the ECG viewer.

FIGURE 37 provides an example of how the monitoring center may respond to a problem reported by the monitoring system. At 372 the monitoring center receives a status notification from the patient's monitor. As mentioned above, in a preferred embodiment the monitor sends a status message to the monitoring center whenever the status of the monitor changes. The status notification may be that an electrode has come loose from the patient's skin or that the monitor has been placed in the charging dock, for example. In the case of these two examples, the cellphone handset alerts the patient that an error condition needs attention and the patient can resolve the problem without intervention by the monitoring center. When a loose electrode is detected by the monitor 30, a message is sent to the cellphone handset 50 and a graphic appears on the cellphone display 58 as illustrated by FIGURE 8h, informing the patient of the problem and illustrating how to resolve the problem. The display is accompanied by a tone or beep from the handset, drawing the patient's attention to the displayed message, and may also be accompanied by a voice prompt instructing the patient to take the necessary action. If the patient is unsure what to do, the patient may press an information button "i" on the handset in embodiments having this button, and a context-based voice message is played with a description of the problem shown in the graphic and its resolution. However it is possible that the patient may not notice these messages and the situation continues unresolved; the patient may be asleep, for instance. In such instances the monitoring center may wait a period of time after receipt of the status notification for the patient to

resolve the problem. If a period of time has passed without resolution, the ECG viewer may escalate the notification to a higher priority, at which point the monitoring center takes action. The technician at the monitoring center places a call to the patient over the cellphone handset at 374. When the patient answers the cellphone, the technician and the patient discuss the problem and the technician can guide the patient in the resolution of the issue at 376. In this example the resolution may entail replacement of the patch 20 with a new patch, for instance.

In the second example, the patient may have placed the monitor 30 in the charging dock 90 for recharging but forgotten to close the lid 102, which is necessary for recharging to commence in this example. By impedance measurement of the contact engagement the charging dock or monitor will detect that the lid has not been closed to press the monitor into firm engagement with the elastomeric contacts of the charging dock. In other embodiments a switch in the charging dock can detect that the lid has not been closed and a message sent to the monitor of the condition for relay on to the monitoring center. A status notification sent from the monitor is received by the monitoring center at 372, notifying the monitoring center that the monitor has been removed from the patch and/or placed in the charging dock but that recharging has not commenced. The patient is informed locally of this problem, either by the absence of the green charging light in the charging dock or by display or flashing of the LED light 104 of the charging dock in a warning color such as alternate orange and green flashing. A graphic and tone or voice prompt can also be displayed and issued from the cellphone handset 50, alerting the patient

to the problem. But if the patient does not tend to the problem after a period of time, the notification received by the monitoring center is escalated to a higher priority on the ECG viewer, at which point the monitoring center can take action. A technician at the monitoring center calls the patient on the cellphone handset 50 and discusses the situation with the patient at 374. The patient and the monitoring center will then resolve the situation by the voice call at 376 when the patient closes the lid 102 of the charging dock and charging of the monitor begins.

For other notifications received by the monitoring center, no patient involvement is needed or appropriate. For instance, if at the end of recharging and archive transmission the self-tests performed by the monitor reveal an error condition in the monitor, the LED light 104 on the charging dock 90 will begin to flash alternately green and orange, informing the patient to contact the monitoring center by using the "Call for Help" button 64 on the cellphone handset. The result of the self-test will also cause the monitor 30 to send a notification of the self-test result to the monitoring center, and if the error condition does not prevent the transmission of the notification, the monitoring center is informed of the problem when the notification is received. A technician at the monitoring center will see the notification and, if the reported condition requires attention, the technician can subsequently call the patient's cellphone handset 50 and instruct the patient to take appropriate action. A replacement monitor may be dispatched to the patient by express courier to replace the monitor with the error condition, for instance. In this case the patient will be instructed to begin using the

replacement monitor and to send the monitor with the error condition back to the monitoring center. In other embodiments the patient is provided with both a new monitor and a new cellphone handset which have been Bluetooth-paired. Another alternative is to download the Bluetooth pairing data to the monitor and handset from the monitoring center.

A procedure or study conducted with a monitoring system of the present invention will generally continue for twenty-one to thirty days, on average. At the end of the study the patient will return the kit components for reuse by other patients. The patient can take the kit back to the patient's physician at the next office visit, but preferably the kit is supplied with a pre-addressed, postage-paid shipping container or envelope for return of the kit as soon as the study is concluded. The kit can be returned to the monitoring center where it is prepared for the next patient, but preferably the kit is returned to a refurbishment center which specializes in inspecting and preparing kits for subsequent patients. FIGURE 38 illustrates some of the procedures performed by such a refurbishment center in preparing a kit for reuse. At 380 the kit is received at a refurbishment center from a postal carrier or transport service. The kit components are unpacked, disinfected at 382 to safeguard against possible exposure to infectious disease, and inventoried to determine that all of the kit components have been returned. A database with screens such as those shown in FIGURES 18, 20 and 22 may be used to log the receipt of the returned kit and its monitors and cellphone handset. If a component is missing the patient or physician is contacted so that the missing component can be

returned to the refurbishment center. At 384 the monitor and cell phone batteries are charged, and the batteries of the monitors and cellphone handset are checked at 386 to ensure that they can continue to be recharged to necessary levels during the next study. At 388 any patient data still resident in the memories 216 and 304 of the monitors and cellphone handset is cleared for protection of patient privacy. At 390 the components are self-tested and the self-test results verified. At 392 the kit components are inspected and tested to verify their operability according to specifications. At 394 the software of the charging dock 90, the cellphone handset 50 and the monitors 30 is upgraded if upgrades have become available. As previously mentioned in conjunction with FIGURE 12b, in a preferred embodiment the monitors 30 have a USB port accessible through the contacts on the back of the monitor case. New software can be loaded into the monitor by this USB connection. It may also be desirable to re-image the data storage of these devices each time to ensure a fresh software start for each patient. The kit components can be reassembled into a kit at 396 and the kit put back into inventory for subsequent delivery to a new patient. In a preferred embodiment a kit includes two monitors 30, a cellphone handset 50 with cover 56, a charging dock 90 with cellphone charging cord 92 and a power cord, a carrying case for the cellphone handset, a number of patches 20, and a user guide with instructions for the patient. Preferably the kit is delivered to the patient in a box or case which is suitable for shipping the kit back to the refurbishment center, monitoring center, or physician in the same box or case in which the kit was supplied to the patient. Alternatively as

indicated at 398, the individual kit components can be put back into inventory for subsequent assembly into a kit as described in conjunction with FIGURE 17.

Other variations and features for the present invention will readily occur to those skilled in the art. For instance, cellphones are commercially available with built-in GPS receivers which identify the geographical location of the cellphones. The use of such a cellphone in an implementation of the present invention would enable the location of the cellphone handset to be communicated to the monitoring center, enabling the monitoring center to direct medical assistance to the exact location of the patient if a life-threatening arrhythmia or other medical emergency occurred. Alternatively, cellular triangulation techniques could be used to ascertain the patient's location. For example, if the monitoring center receives an Event notification and ECG strip indicating the occurrence of a serious cardiac event, the technician at the monitoring center will immediately call the patient's cellphone handset to see if the patient needs medical aid. However, the cardiac event may have rendered the patient unconscious and incapable of answering the call from the monitoring center. The control software of the cellphone handset is programmed to answer a call from the monitoring center after a predetermined number of rings, so the connection between the monitoring center and the patient's cellphone will be established even if the patient does not answer the cellphone. In the United States the technician at the monitoring center can then call the local 911 emergency response service, which is able to pinpoint the patient's location from the

connection between the monitoring center and the patient's cellphone handset. Medical assistance can be immediately dispatched to the identified location of the stricken patient.

WHAT IS CLAIMED IS:

1. In an ECG monitoring system for cardiac monitoring of an ambulatory patient which includes an ECG monitor which receives and processes patient ECG signals for wireless transmission to a receiver, a cellphone handset comprising:

a commercially available cellphone having a keypad which communicates over a cellular network with a monitoring center and including a display and a wireless receiver adapted to receive ECG signals from the ECG monitor; and

a cellphone cover which fits onto the commercially available cellphone, the cellphone cover permitting the display to be viewed, permitting the cellphone to be used for voice communication by a patient, and making only a reduced number of keys of the cellphone keypad available for use by the patient.

2. The cellphone handset of Claim 1, wherein the reduced number of keys is two.

3. The cellphone handset of Claim 1, wherein one of the two keys may be used by a patient to call the monitoring center and the other of the two keys is actuated to make a voice recording.

4. The cellphone handset of Claim 1, wherein the functions of the reduced number of keys are shown on the display in proximity to the keys.

5. The cellphone handset of Claim 4, wherein the cellphone handset further comprises a control program which controls the display,

wherein the control program causes the displayed functions of the keys to change in accordance with the current mode of operation of the handset.

6. The cellphone handset of Claim 1, wherein the ECG monitor is further operable to transmit status messages concerning the operating condition of the monitor to the cellphone handset,

wherein the cellphone handset is responsive to a monitor status message for displaying status information on the cellphone display.

7. The cellphone handset of Claim 6, wherein a key further comprises means by which a user may respond to displayed status information.

8. The cellphone handset of Claim 1, wherein the ECG monitor is further operable to transmit status messages concerning the operating condition of the monitor to the cellphone handset,

wherein the cellphone handset responds to a monitor status message by producing an audible signal.

9. The cellphone handset of Claim 8, wherein the audible signal further comprises a tone or voice prompt.

10. The cellphone handset of Claim 1, wherein the reduced number of keys includes an information key which may be used by a patient to provide information about the status of the monitoring system.

11. The cellphone handset of Claim 10, wherein

the information key provides information related to the context of the current operating state of the monitoring system.

12. The cellphone handset of Claim 11, wherein the information is provided at least one of visually on the cellphone display or audibly.

13. The cellphone handset of Claim 1, wherein the reduced number of keys includes a key which may be used by a patient to call an emergency response service.

14. The cellphone handset of Claim 13, wherein the key which may be used to call an emergency response service calls 911 in the United States.

15. The cellphone handset of Claim 1, wherein the reduced number of keys includes a key which may be used by a patient to call the patient's physician.

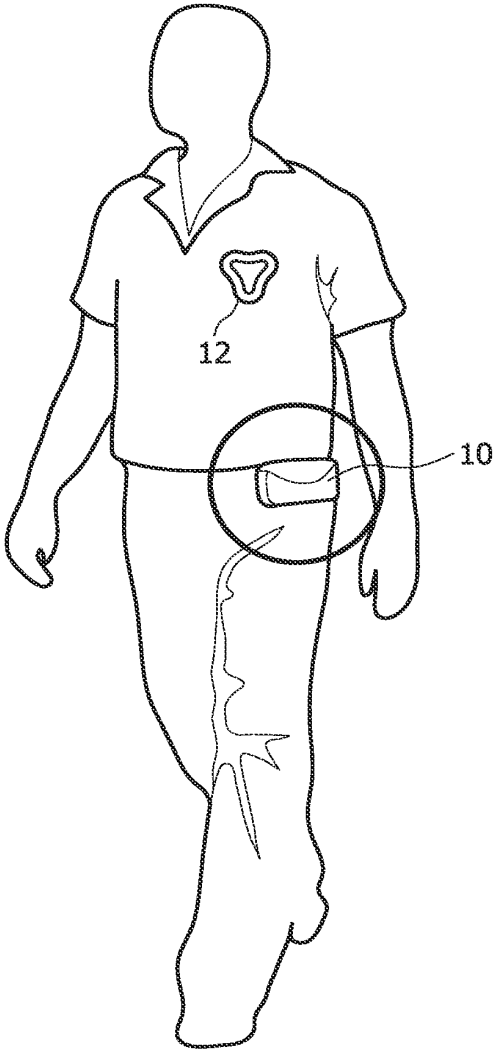


FIG. 1

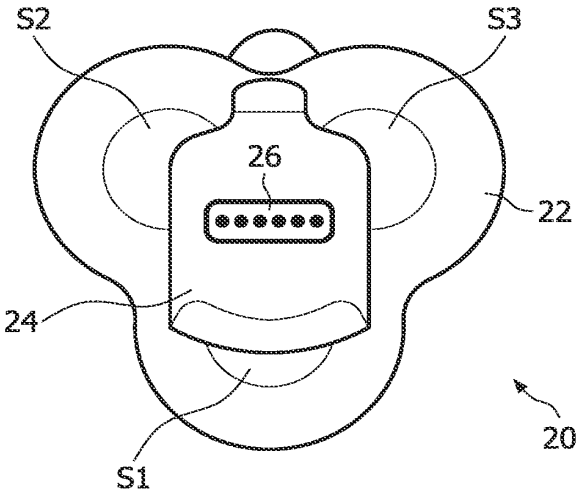


FIG. 2

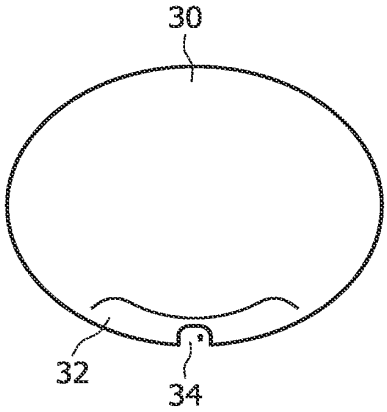


FIG. 3a

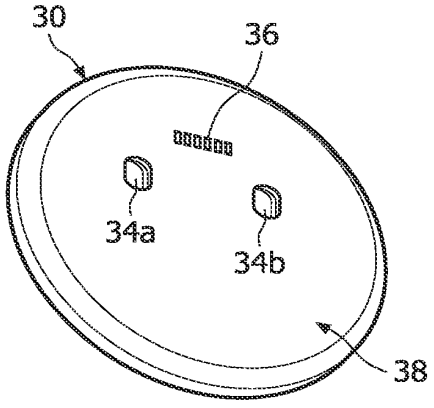


FIG. 3b

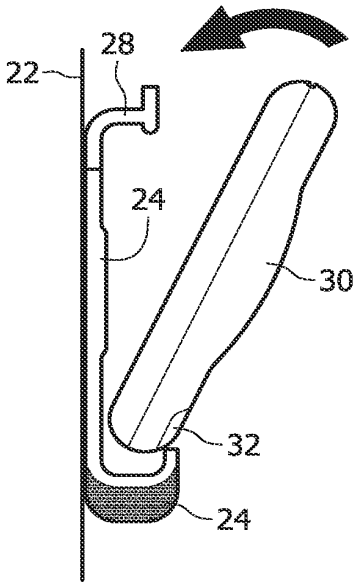


FIG. 4

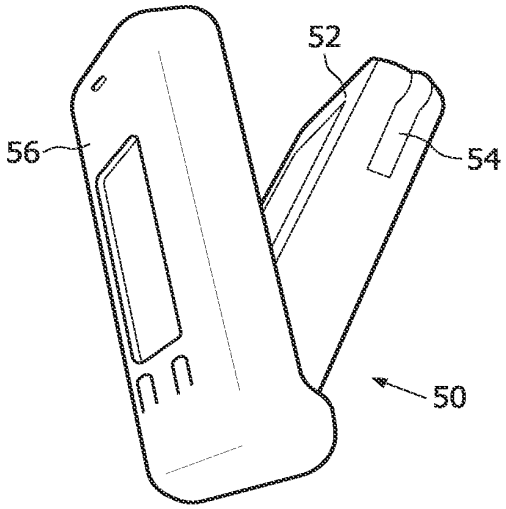


FIG. 5

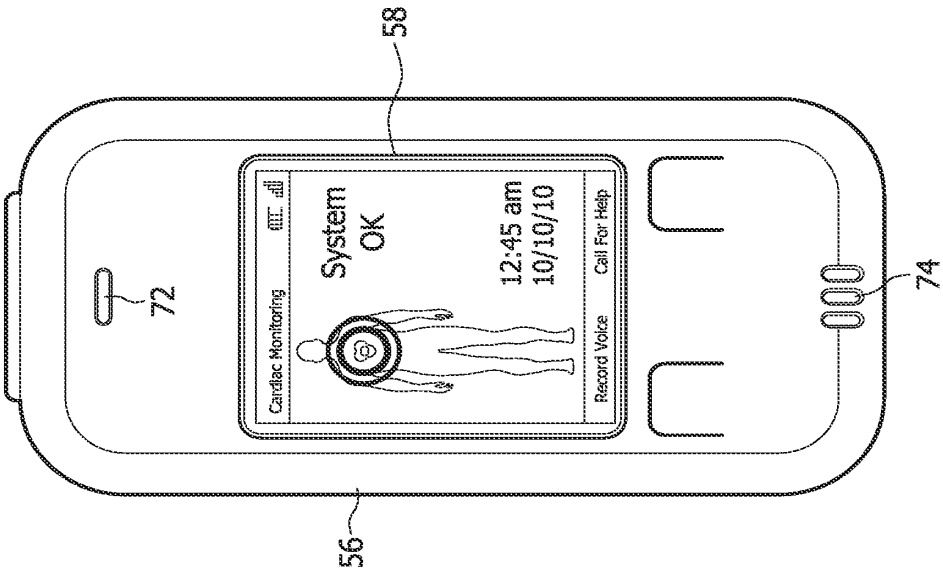

58
72
Cardiac Monitoring
System
OK
12:45 am
10/10/10
Call For Help
Record Voice
74
56

FIG. 7

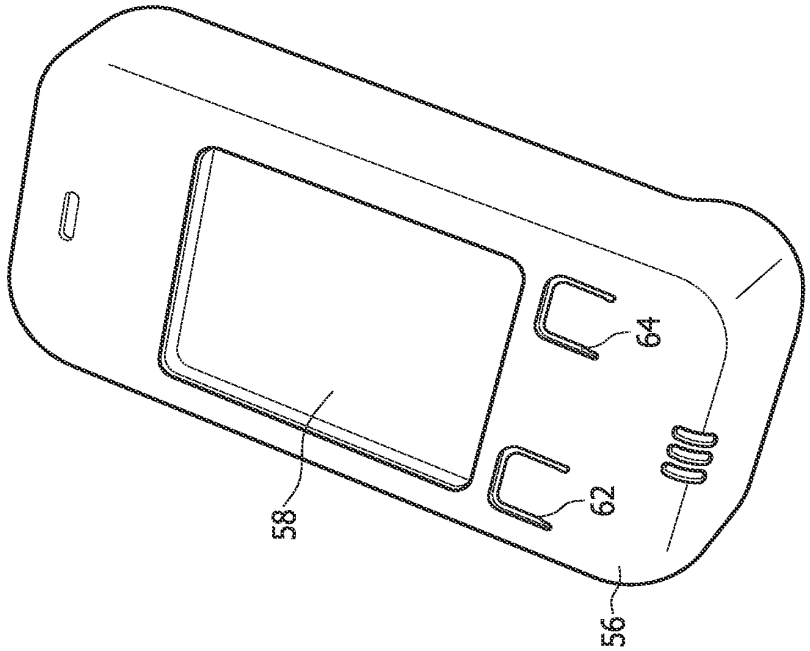

64
58
62
56

FIG. 6

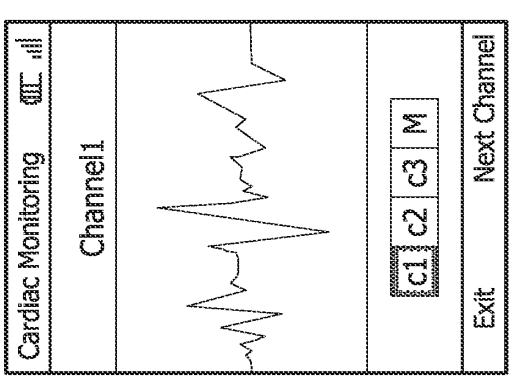


FIG. 8b

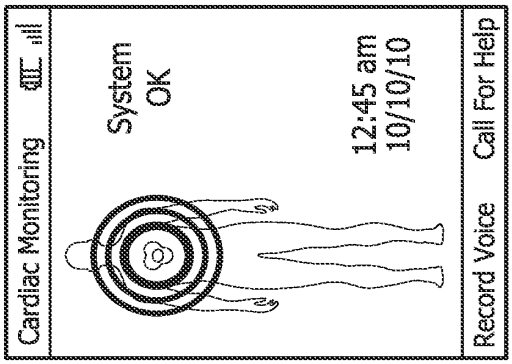


FIG. 8c

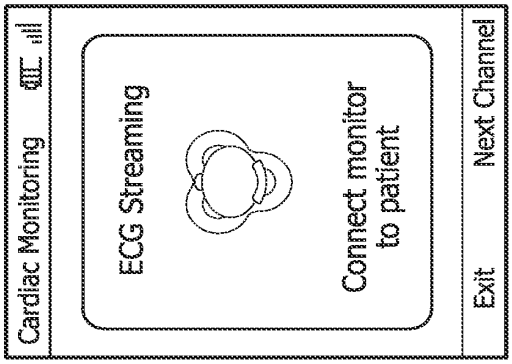


FIG. 8a

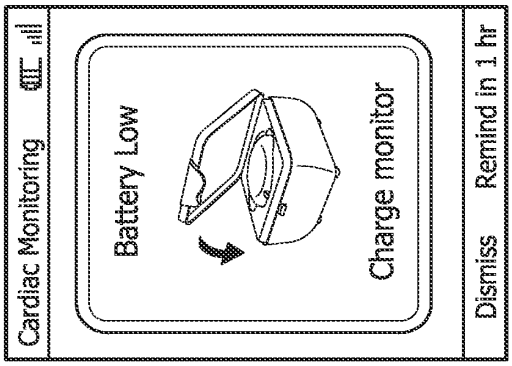


FIG. 8f

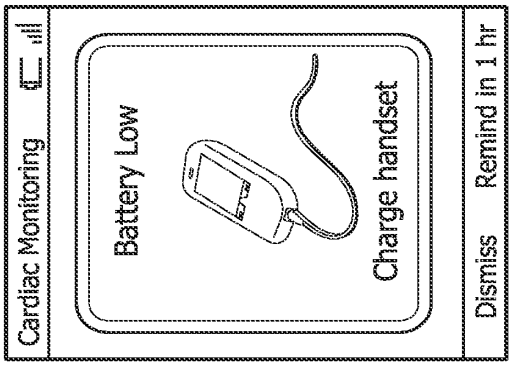


FIG. 8e

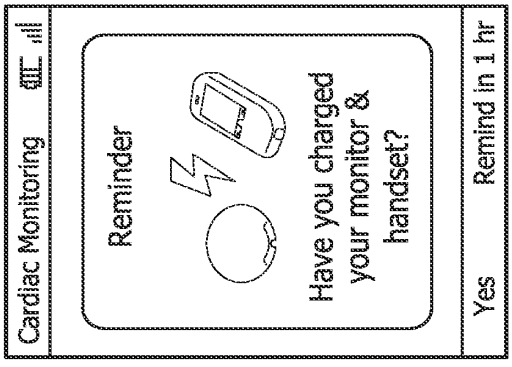


FIG. 8d

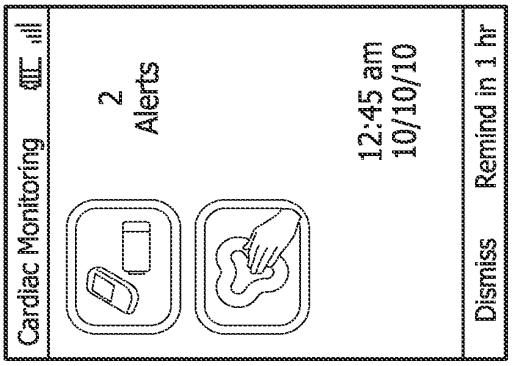


FIG. 8i

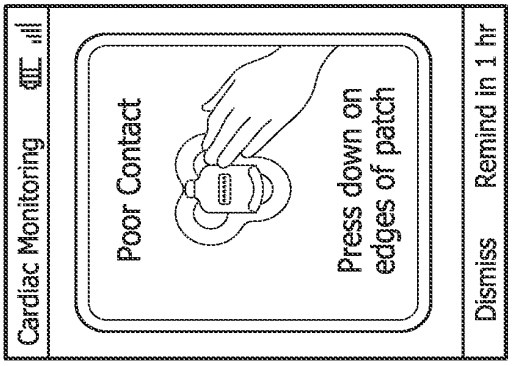


FIG. 8h

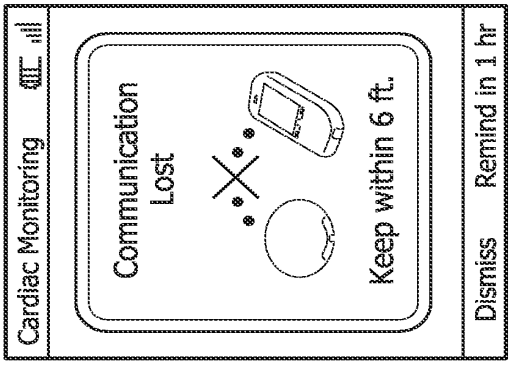


FIG. 8g

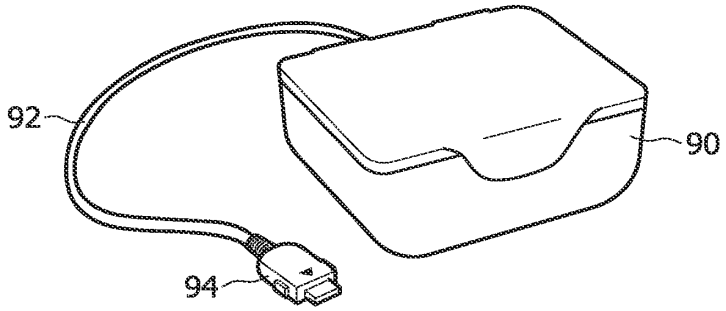


FIG. 9

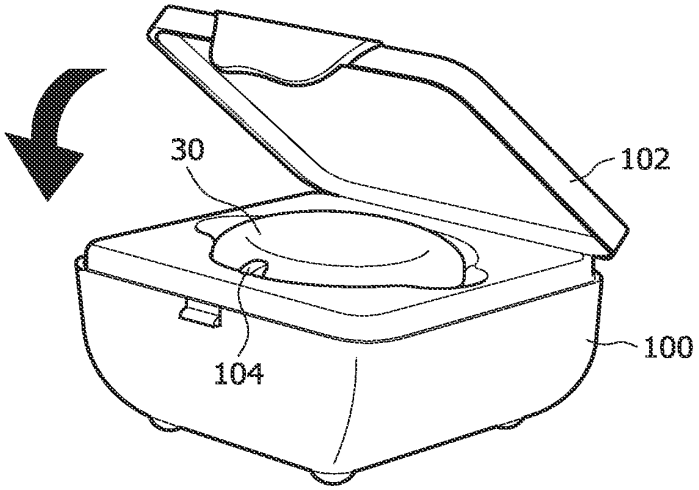


FIG. 10

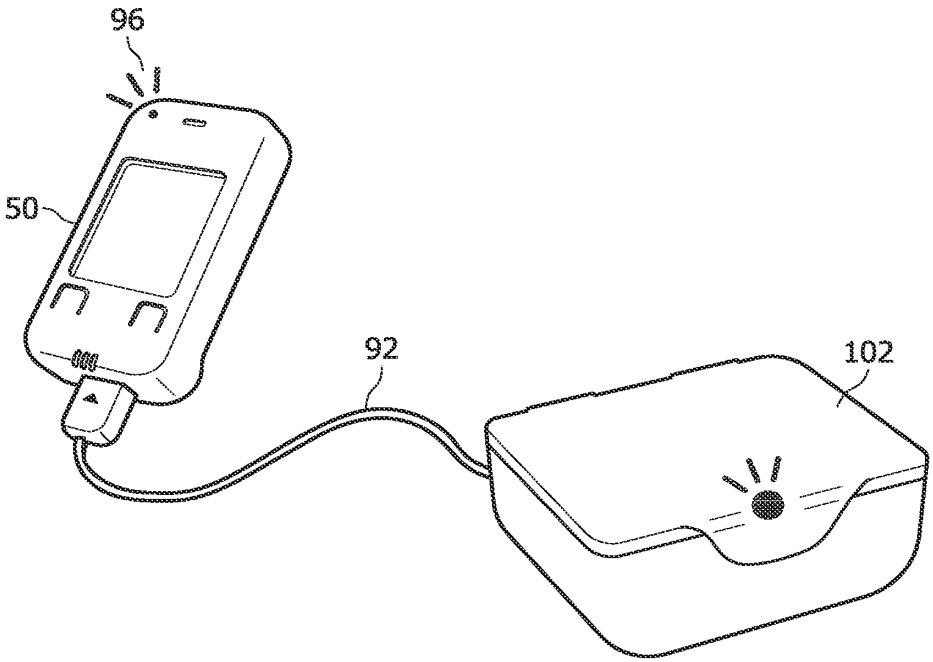


FIG. 11

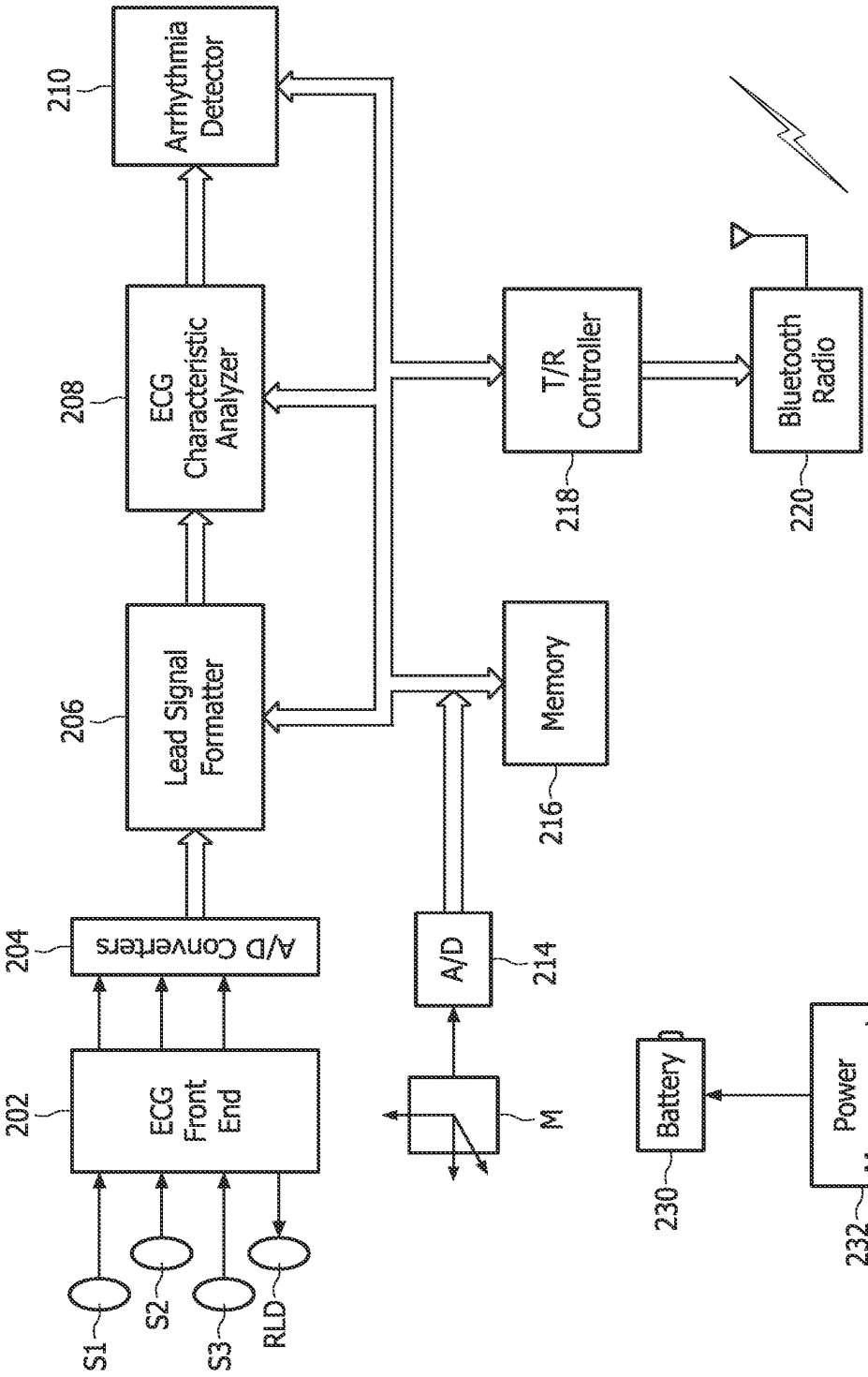

Arrhythmia Detector
210
ECG Characteristic Analyzer
208
Lead Signal Formatter
206
A/D Converters
204
ECG Front End
202
S1
S2
S3
RLD
M
A/D
214
Memory
216
T/R Controller
218
Bluetooth Radio
220
Battery
230
Power Management
232

FIG. 12a

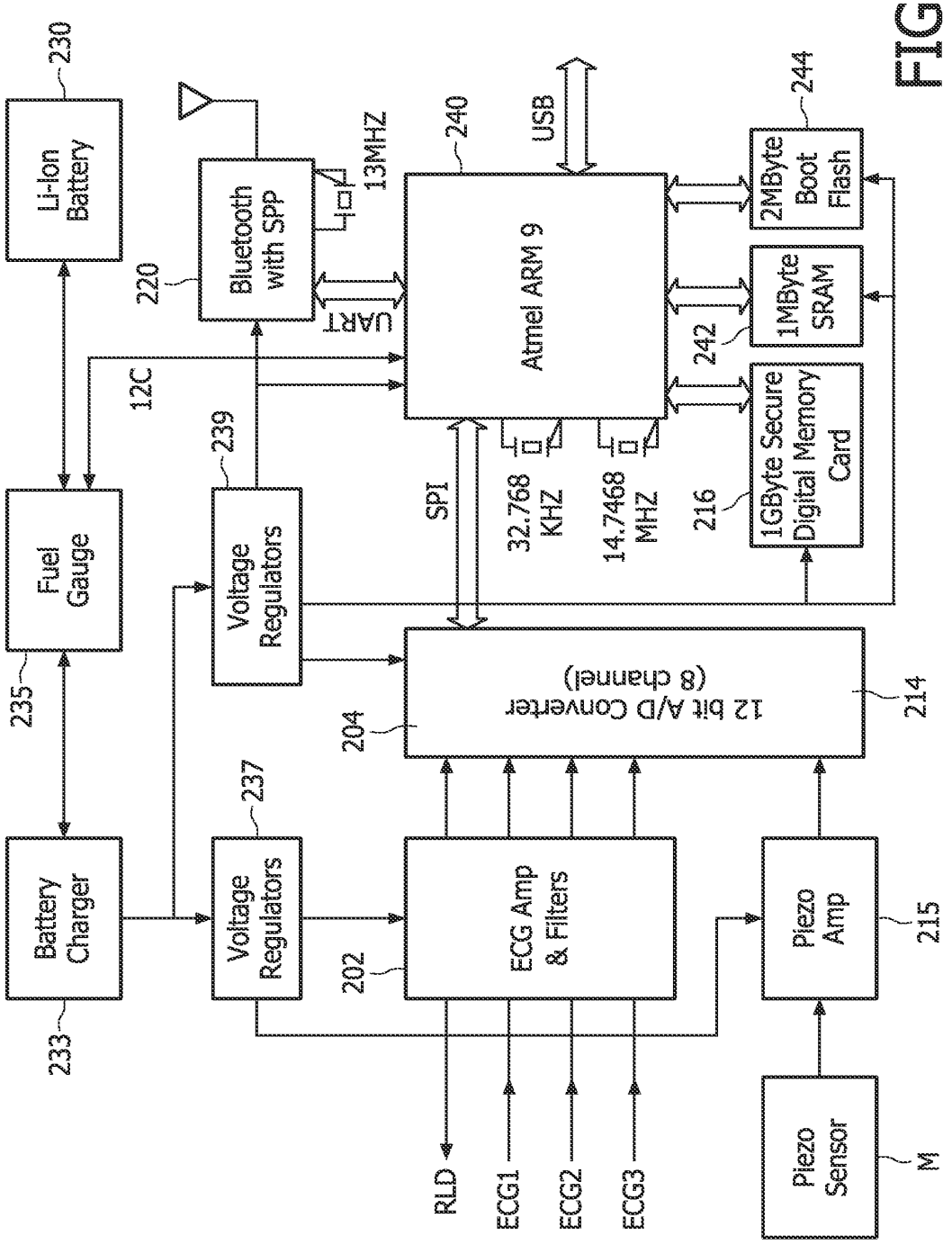

Li-Ion Battery
230
Bluetooth with SPP
220
13MHZ
USART
240
Atmel ARM 9
USB
2MByte Boot Flash
244
1MByte SRAM
242
1GByte Secure Digital Memory Card
216
12C
239
Fuel Gauge
235
Voltage Regulators
SPI
32.768 KHZ
14.7468 MHZ
12 bit A/D Converter (8 channel)
214
204
Battery Charger
233
Voltage Regulators
237
ECG Amp & Filters
202
Piezo Amp
215
RLD
ECG1
ECG2
ECG3
Piezo Sensor
M

FIG. 12b

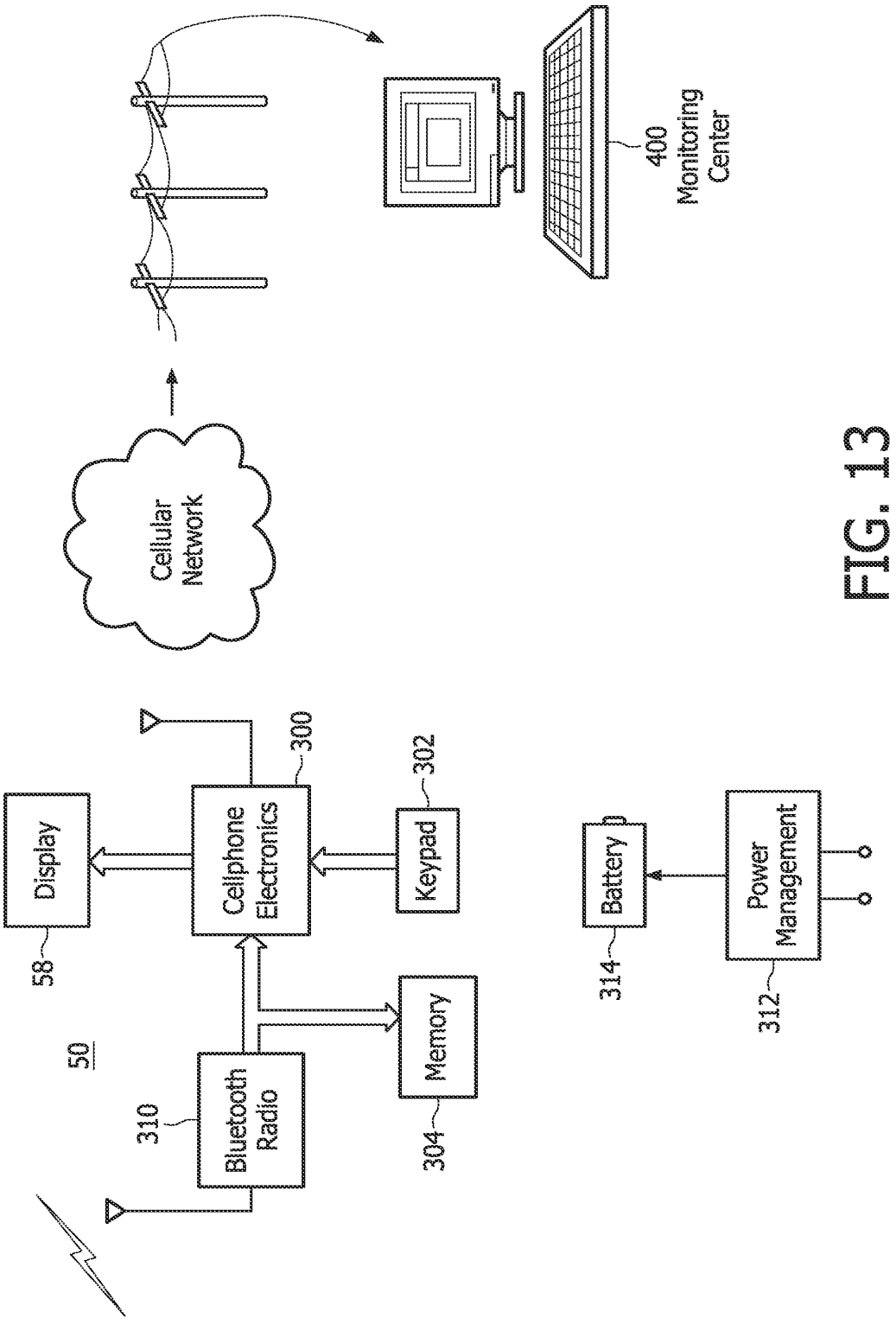

400
Monitoring
Center
Cellular
Network
50
Display
58
Cellphone
Electronics
300
Keypad
302
Memory
304
Bluetooth
Radio
310
Battery
314
Power
Management
312

FIG. 13

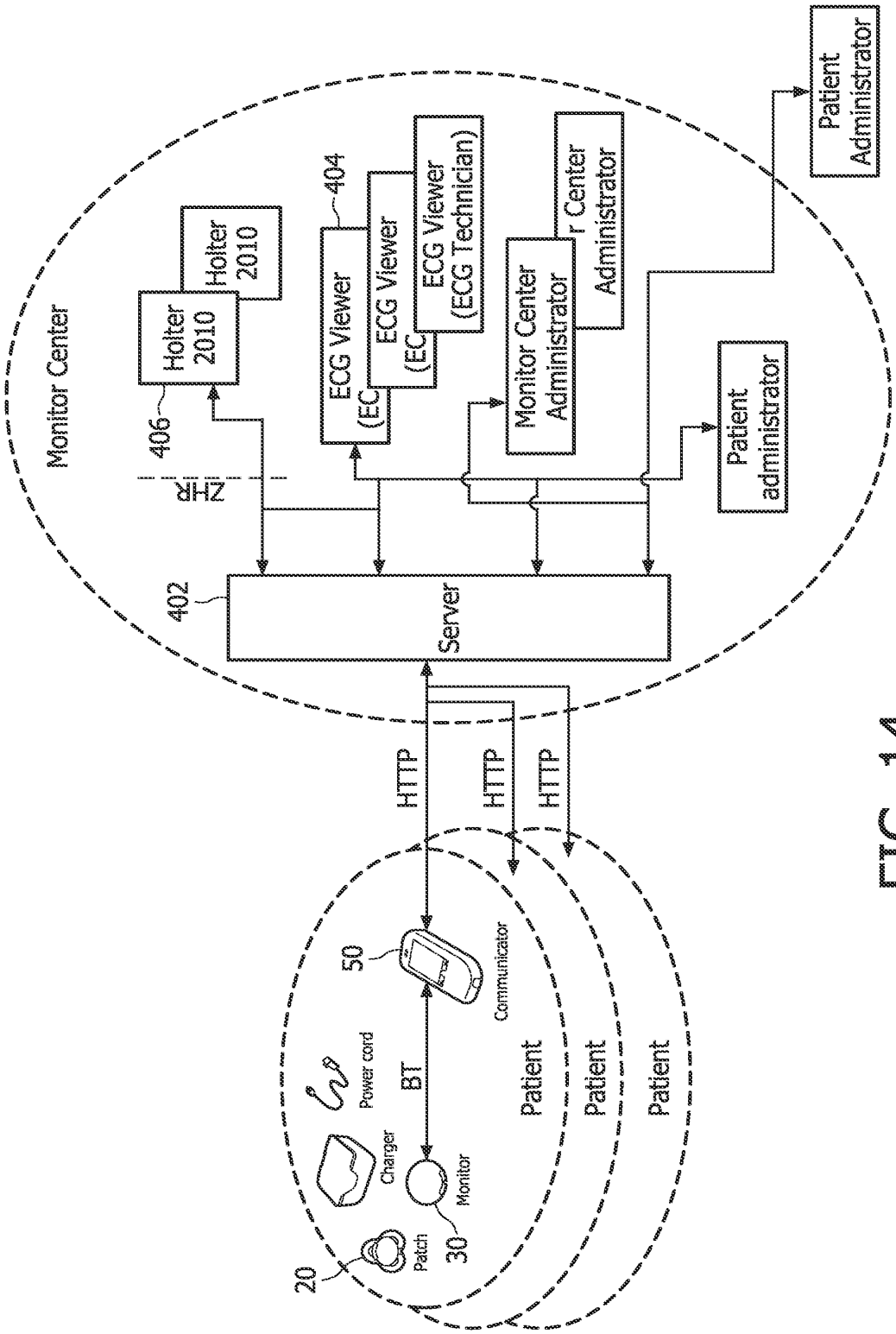

Monitor Center
Holter 2010
Holter 2010
406
ZHR
404
ECG Viewer
ECG Viewer
ECG Viewer (ECG Technician)
Monitor Center Administrator
r Center Administrator
Patient Administrator
Patient administrator
402
Server
HTTP
HTTP
HTTP
50
Communicator
Power cord
BT
Charger
Monitor
Patch
30
20
Patient
Patient
Patient

FIG. 14

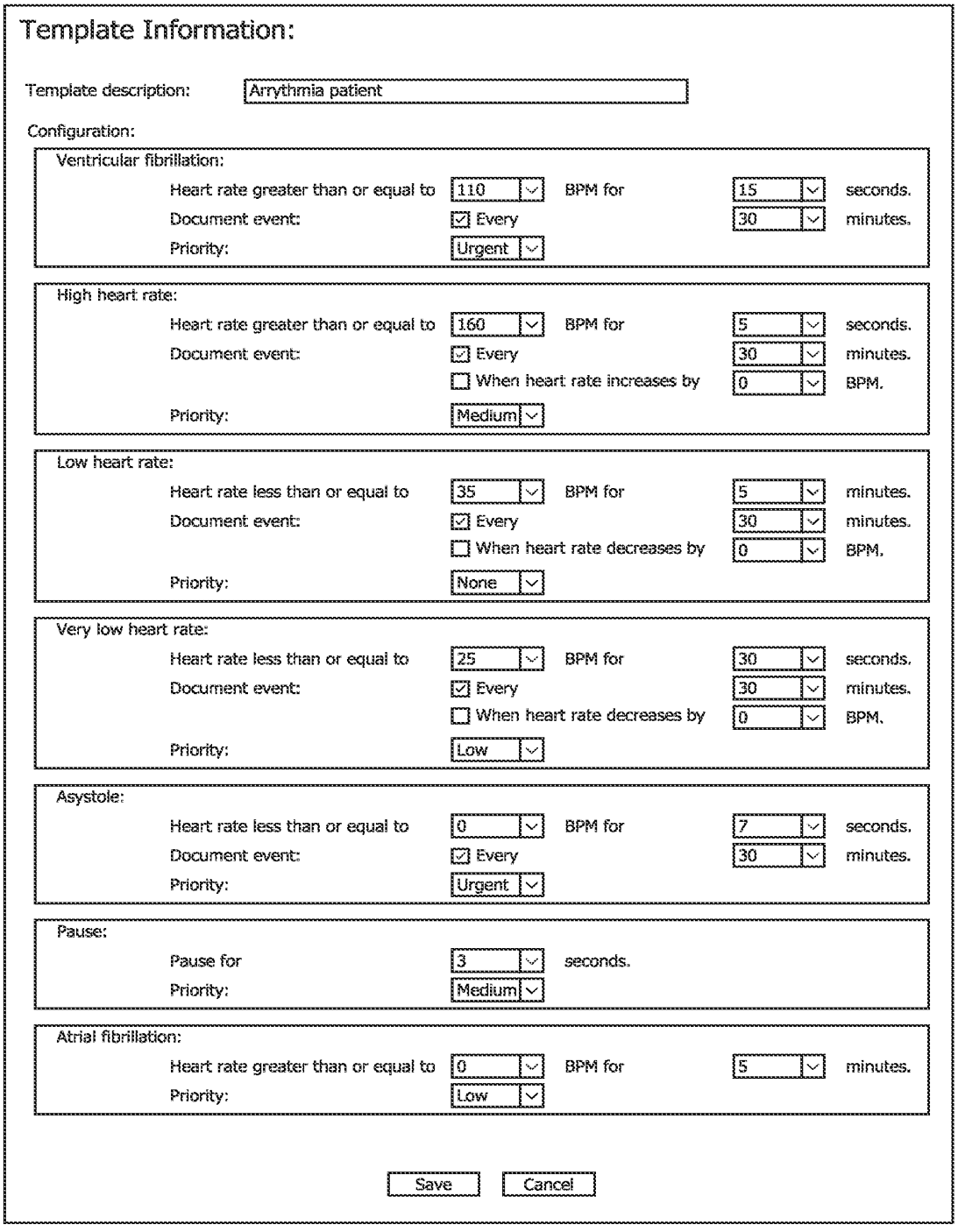

Template Information:
Template description: Arrythmia patient
Configuration:
Ventricular fibrillation:
Heart rate greater than or equal to 110 BPM for 15 seconds.
Document event: Every 30 minutes.
Priority: Urgent
High heart rate:
Heart rate greater than or equal to 160 BPM for 5 seconds.
Document event: Every 30 minutes.
When heart rate increases by 0 BPM.
Priority: Medium
Low heart rate:
Heart rate less than or equal to 35 BPM for 5 minutes.
Document event: Every 30 minutes.
When heart rate decreases by 0 BPM.
Priority: None
Very low heart rate:
Heart rate less than or equal to 25 BPM for 30 seconds.
Document event: Every 30 minutes.
When heart rate decreases by 0 BPM.
Priority: Low
Asystole:
Heart rate less than or equal to 0 BPM for 7 seconds.
Document event: Every 30 minutes.
Priority: Urgent
Pause:
Pause for 3 seconds.
Priority: Medium
Atrial fibrillation:
Heart rate greater than or equal to 0 BPM for 5 minutes.
Priority: Low
Save
Cancel

FIG. 15

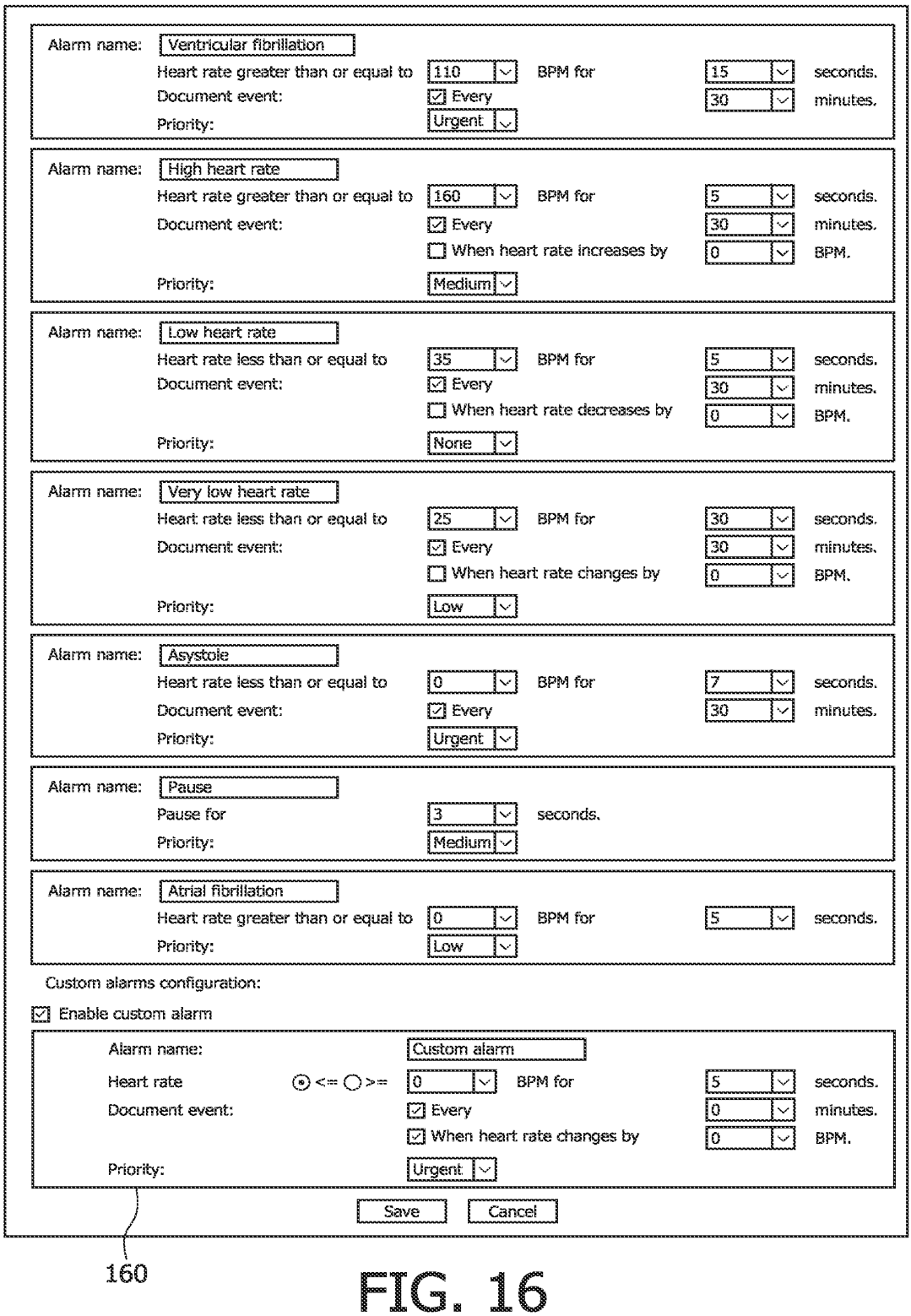

Alarm name: Ventricular fibrillation
Heart rate greater than or equal to 110 BPM for 15 seconds.
Document event: Every 30 minutes.
Priority: Urgent
Alarm name: High heart rate
Heart rate greater than or equal to 160 BPM for 5 seconds.
Document event: Every 30 minutes.
When heart rate increases by 0 BPM.
Priority: Medium
Alarm name: Low heart rate
Heart rate less than or equal to 35 BPM for 5 seconds.
Document event: Every 30 minutes.
When heart rate decreases by 0 BPM.
Priority: None
Alarm name: Very low heart rate
Heart rate less than or equal to 25 BPM for 30 seconds.
Document event: Every 30 minutes.
When heart rate changes by 0 BPM.
Priority: Low
Alarm name: Asystole
Heart rate less than or equal to 0 BPM for 7 seconds.
Document event: Every 30 minutes.
Priority: Urgent
Alarm name: Pause
Pause for 3 seconds.
Priority: Medium
Alarm name: Atrial fibrillation
Heart rate greater than or equal to 0 BPM for 5 seconds.
Priority: Low
Custom alarms configuration:
Enable custom alarm
Alarm name: Custom alarm
Heart rate <= >= 0 BPM for 5 seconds.
Document event: Every 0 minutes.
When heart rate changes by 0 BPM.
Priority: Urgent
Save
Cancel
160

FIG. 16

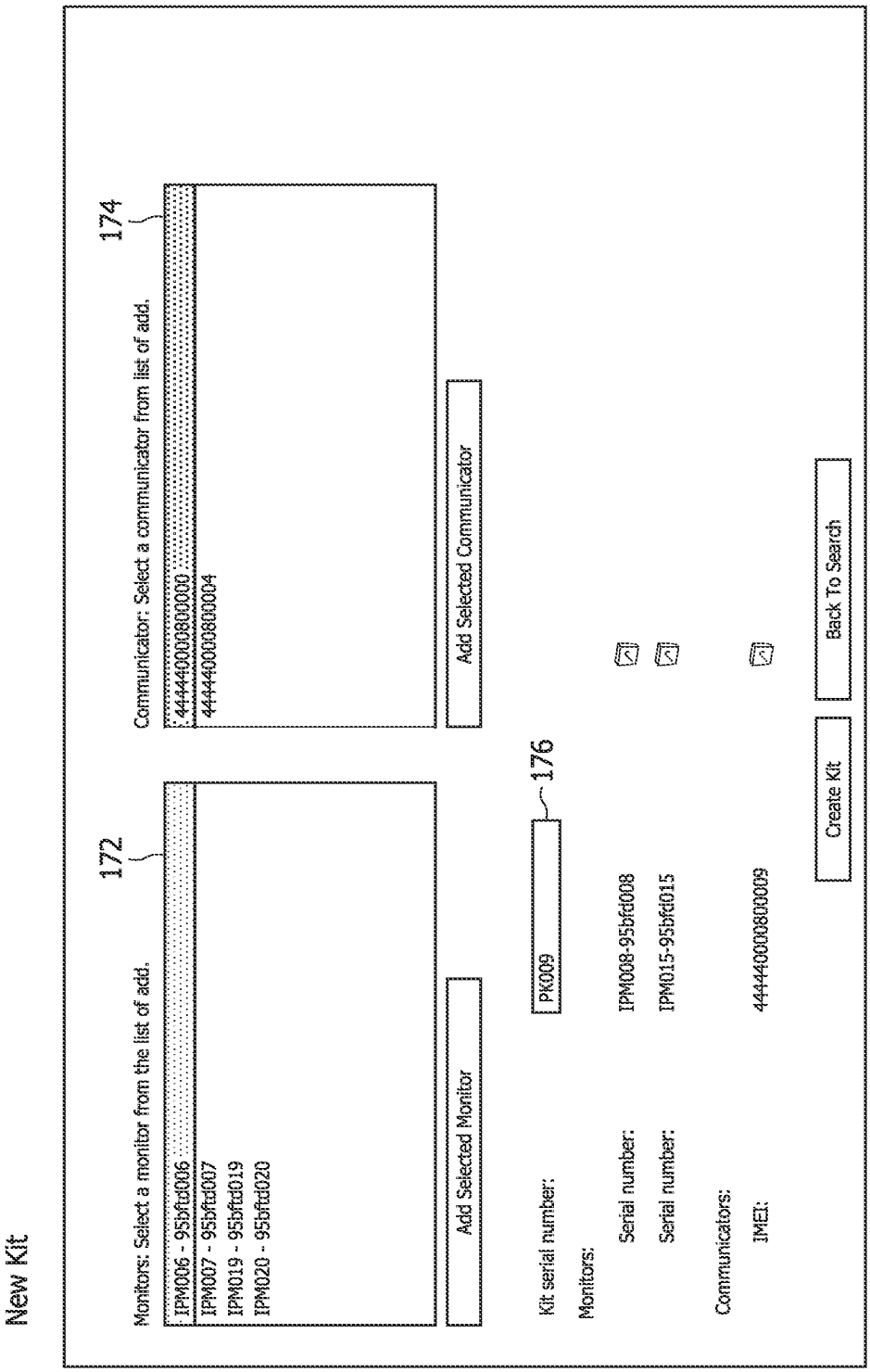

New Kit
Monitors: Select a monitor from the list of add.
172
IPM006 - 95bfd006
IPM007 - 95bfd007
IPM019 - 95bfd019
IPM020 - 95bfd020
Add Selected Monitor
Kit serial number:
PK009
176
Monitors:
Serial number:
IPM008-95bfd008
Serial number:
IPM015-95bfd015
Communicators:
IMEI:
444440000800009
Communicator: Select a communicator from list of add.
174
444440000800000
444440000800004
Add Selected Communicator
Create Kit
Back To Search

FIG. 17

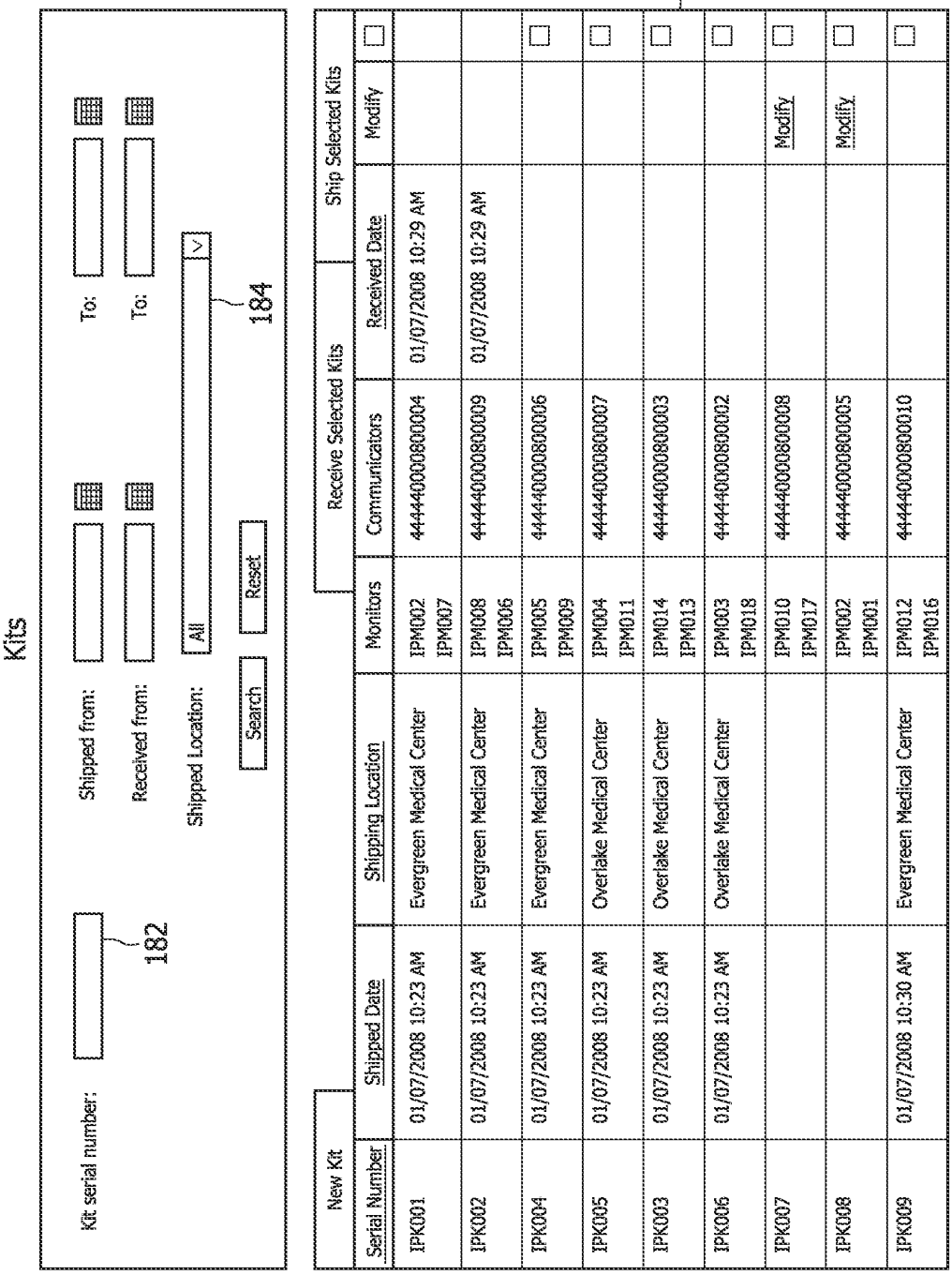

Kits
Kit serial number:
182
Shipped from:
To:
Received from:
To:
Shipped Location:
All
184
Search
Reset
New Kit
Receive Selected Kits
Ship Selected Kits
186
Serial Number
Shipped Date
Shipping Location
Monitors
Communicators
Received Date
Modify
IPK001 01/07/2008 10:23 AM Evergreen Medical Center IPM002 IPM007 444440008000004 01/07/2008 10:29 AM
IPK002 01/07/2008 10:23 AM Evergreen Medical Center IPM008 IPM006 444440008000009 01/07/2008 10:29 AM
IPK004 01/07/2008 10:23 AM Evergreen Medical Center IPM005 IPM009 444440008000006
IPK005 01/07/2008 10:23 AM Overlake Medical Center IPM004 IPM011 444440008000007
IPK003 01/07/2008 10:23 AM Overlake Medical Center IPM014 IPM013 444440008000003
IPK006 01/07/2008 10:23 AM Overlake Medical Center IPM003 IPM018 444440008000002
IPK007 IPM010 IPM017 444440008000008 Modify
IPK008 IPM002 IPM001 444440008000005 Modify
IPK009 01/07/2008 10:30 AM Evergreen Medical Center IPM012 IPM016 444440008000010

FIG. 18

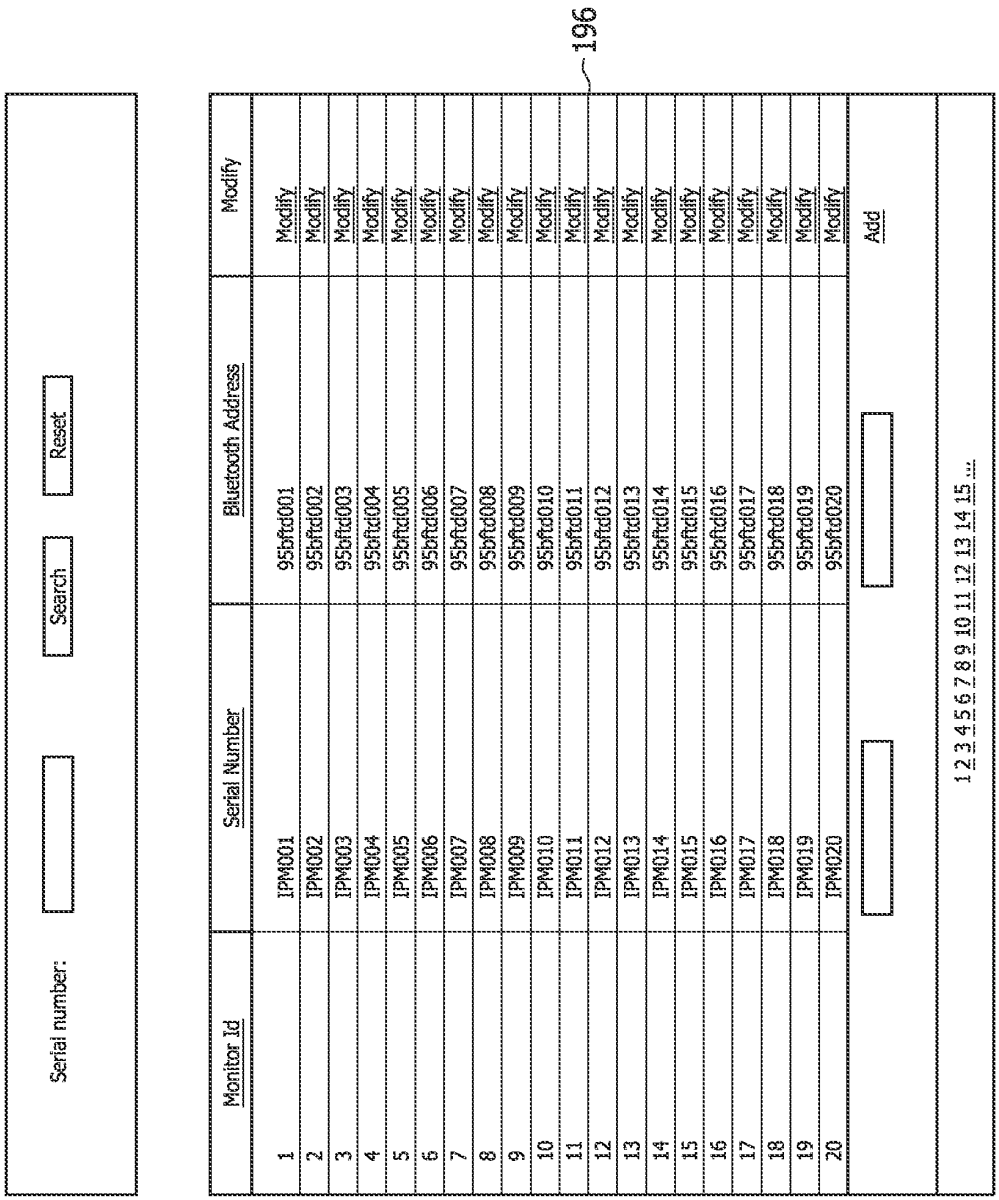

Monitors
Serial number:
Search
Reset
196
Monitor Id
Serial Number
Bluetooth Address
Modify
1 IPM001 95bfcd001 Modify
2 IPM002 95bfcd002 Modify
3 IPM003 95bfcd003 Modify
4 IPM004 95bfcd004 Modify
5 IPM005 95bfcd005 Modify
6 IPM006 95bfcd006 Modify
7 IPM007 95bfcd007 Modify
8 IPM008 95bfcd008 Modify
9 IPM009 95bfcd009 Modify
10 IPM010 95bfcd010 Modify
11 IPM011 95bfcd011 Modify
12 IPM012 95bfcd012 Modify
13 IPM013 95bfcd013 Modify
14 IPM014 95bfcd014 Modify
15 IPM015 95bfcd015 Modify
16 IPM016 95bfcd016 Modify
17 IPM017 95bfcd017 Modify
18 IPM018 95bfcd018 Modify
19 IPM019 95bfcd019 Modify
20 IPM020 95bfcd020 Modify
Add
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ...

FIG. 19

Monitor Usage

Monitor serial number: [ ] Shipped from: [ ] [ ] To: [ ] [ ]

Received from: [ ] [ ] To: [ ] [ ]

Shipped Location: [All ▽]

[Search] [Reset]

Monitor Serial Number	Kit Serial Number	Shipped Date	Shipping Location	Received Date
IPM001	IPK001	02/26/2008 02:53 PM	Eastside Heart Hospital	
IPM002	IPK001	02/26/2008 02:53 PM	Eastside Heart Hospital	
IPM003	IPK002	10/14/2007 12:00 PM	American Cardiac care	
IPM004	IPK002	10/14/2007 12:00 PM	American Cardiac care	
IPM005	IPK003	10/14/2007 12:00 PM	American Cardiac care	
IPM006	IPK003	10/14/2007 12:00 PM	American Cardiac care	
IPM007	IPK004	10/14/2007 12:00 PM	American Cardiac care	
IPM008	IPK004	10/14/2007 12:00 PM	American Cardiac care	
IPM009	IPK005	10/14/2007 12:00 PM	American Cardiac care	
IPM010	IPK005	10/14/2007 12:00 PM	American Cardiac care	
IPM011	IPK006	10/14/2007 12:00 PM	American Cardiac care	
IPM012	IPK006	10/14/2007 12:00 PM	American Cardiac care	
IPM013	IPK007	10/14/2007 12:00 PM	American Cardiac care	
IPM014	IPK007	10/14/2007 12:00 PM	American Cardiac care	
IPM015	IPK008	10/14/2007 12:00 PM	American Cardiac care	
IPM016	IPK008	10/14/2007 12:00 PM	American Cardiac care	
IPM017	IPK009	10/14/2007 12:00 PM	American Cardiac care	
IPM018	IPK009	10/14/2007 12:00 PM	American Cardiac care	
IPM019	IPK010	10/14/2007 12:00 PM	American Cardiac care	
IPM020	IPK010	10/14/2007 12:00 PM	American Cardiac care	

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ...

250

FIG. 20

Communicators

IMEI: [ ] Phone number 1: [ ]

Search Reset

Id	IMEI	Bluetooth Address	Phone Number 1	Phone Number 2	Activation Code	Modify
1	444440000800000	95ead00001	4940080000	NULL	NULL	Modify
2	444440000800001	95ead00002	4940080001	NULL	NULL	Modify
3	444440000800002	95ead00003	4940080002	NULL	NULL	Modify
4	444440000800003	95ead00004	4940080003	NULL	NULL	Modify
5	444440000800004	95ead00005	4940080004	NULL	NULL	Modify
6	444440000800005	95ead00006	4940080005	NULL	NULL	Modify
7	444440000800006	95ead00007	4940080006	NULL	NULL	Modify
8	444440000800007	95ead00008	4940080007	NULL	NULL	Modify
9	444440000800008	95ead00009	4940080008	NULL	NULL	Modify
10	444440000800009	95ead00010	4940080009	NULL	NULL	Modify
11	444440000800010	95ead00011	4940080010	NULL	NULL	Modify
12	444440000800011	95ead00012	4940080011	NULL	NULL	Modify
13	444440000800012	95ead00013	4940080012	NULL	NULL	Modify
14	444440000800013	95ead00014	4940080013	NULL	NULL	Modify
15	444440000800014	95ead00015	4940080014	NULL	NULL	Modify
16	444440000800015	95ead00016	4940080015	NULL	NULL	Modify
17	444440000800016	95ead00017	4940080016	NULL	NULL	Modify
18	444440000800017	95ead00018	4940080017	NULL	NULL	Modify
19	444440000800018	95ead00019	4940080018	NULL	NULL	Modify
20	444440000800019	95ead00020	4940080019	NULL	NULL	Modify

Add

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ...

252

FIG. 21

Communicator Usage

Communicator IMEI: Shipped from: To:

Received from: To:

Shipped Location: All

Search Reset

IMEI	Phone Number 1	Kit Serial Number	Shipped Date	Shipping Location	Returned Date
444440000800000	4940080000	IPK001	02/26/2008 02:53 PM	Eastside Heart Hospital	
444440000800001	4940080001	IPK002	10/14/2007 12:00 PM	American Cardiac care	
444440000800002	4940080002	IPK003	10/14/2007 12:00 PM	American Cardiac care	
444440000800003	4940080003	IPK004	10/14/2007 12:00 PM	American Cardiac care	
444440000800004	4940080004	IPK005	10/14/2007 12:00 PM	American Cardiac care	
444440000800005	4940080005	IPK006	10/14/2007 12:00 PM	American Cardiac care	
444440000800006	4940080006	IPK007	10/14/2007 12:00 PM	American Cardiac care	
444440000800007	4940080007	IPK008	10/14/2007 12:00 PM	American Cardiac care	
444440000800008	4940080008	IPK009	10/14/2007 12:00 PM	American Cardiac care	
444440000800009	4940080009	IPK010	10/14/2007 12:00 PM	American Cardiac care	
444440000800010	4940080010	IPK011	10/14/2007 12:00 PM	American Cardiac care	
444440000800011	4940080011	IPK012	10/14/2007 12:00 PM	American Cardiac care	
444440000800012	4940080012	IPK013	10/14/2007 12:00 PM	American Cardiac care	
444440000800013	4940080013	IPK014	10/14/2007 12:00 PM	American Cardiac care	
444440000800014	4940080014	IPK015	10/14/2007 12:00 PM	American Cardiac care	
444440000800015	4940080015	IPK016	10/14/2007 12:00 PM	American Cardiac care	
444440000800016	4940080016	IPK017	10/14/2007 12:00 PM	American Cardiac care	
444440000800017	4940080017	IPK018	10/14/2007 12:00 PM	American Cardiac care	
444440000800018	4940080018	IPK019	10/14/2007 12:00 PM	American Cardiac care	
444440000800019	4940080019	IPK020	10/14/2007 12:00 PM	American Cardiac care	

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ...

FIG. 22

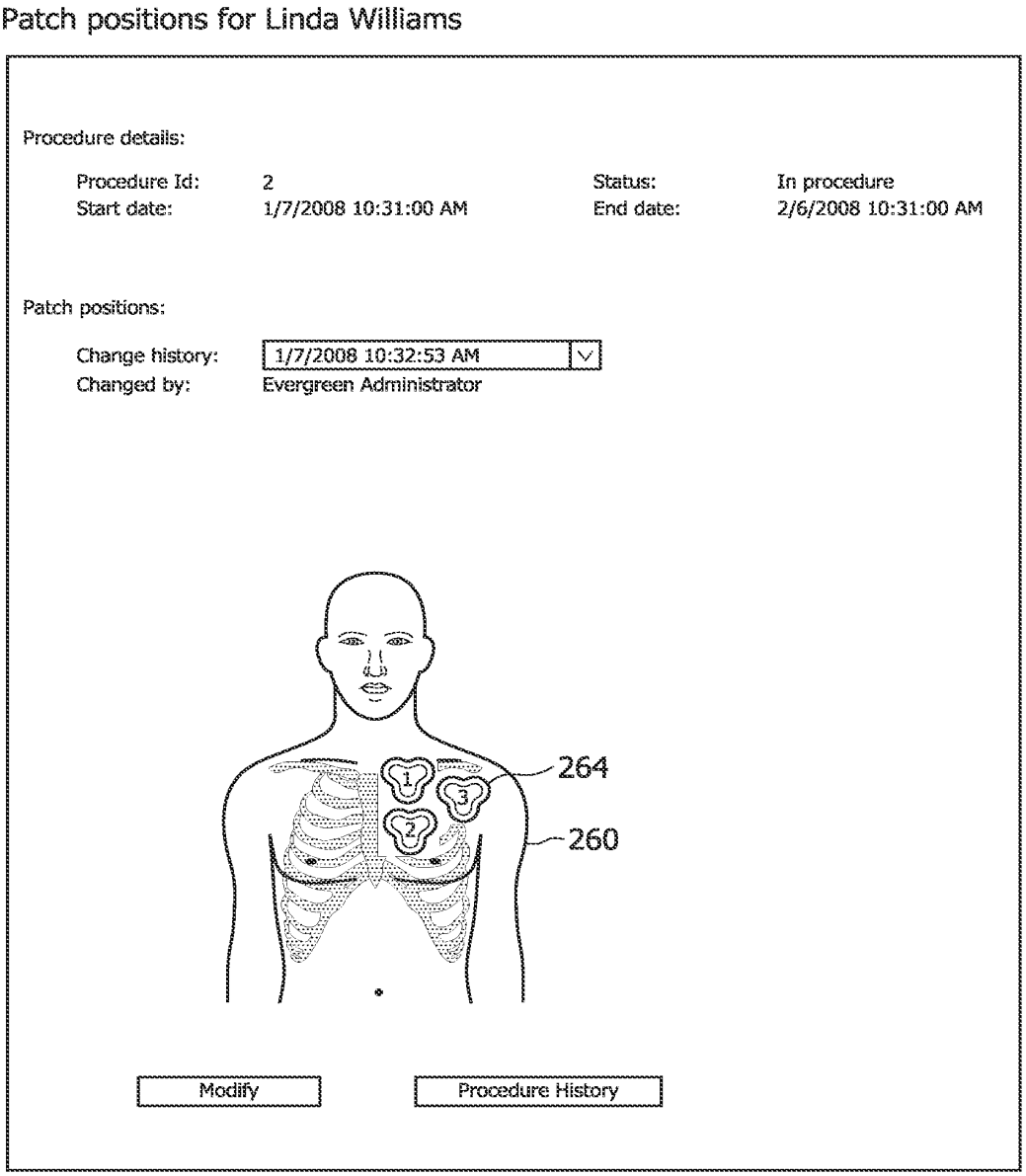

Patch positions for Linda Williams
Procedure details:
Procedure Id: 2
Status: In procedure
Start date: 1/7/2008 10:31:00 AM
End date: 2/6/2008 10:31:00 AM
Patch positions:
Change history: 1/7/2008 10:32:53 AM
Changed by: Evergreen Administrator
264
260
Modify
Procedure History

FIG. 23

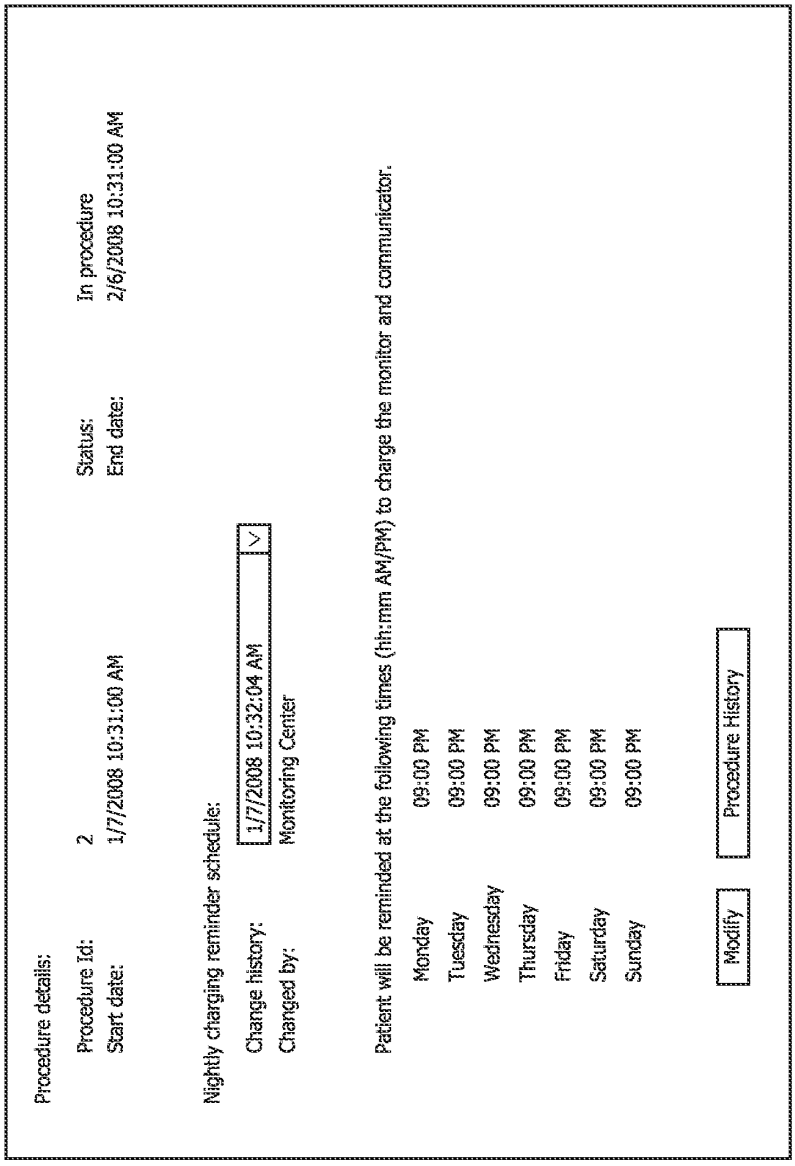

Patient Nightly Reminder Setup for Linda Williams
Procedure details:
Procedure Id: 2
Start date: 1/7/2008 10:31:00 AM
Status: In procedure
End date: 2/6/2008 10:31:00 AM
Nightly charging reminder schedule:
Change history: 1/7/2008 10:32:04 AM
Changed by: Monitoring Center
Patient will be reminded at the following times (hh:mm AM/PM) to charge the monitor and communicator.
Monday 09:00 PM
Tuesday 09:00 PM
Wednesday 09:00 PM
Thursday 09:00 PM
Friday 09:00 PM
Saturday 09:00 PM
Sunday 09:00 PM
Modify
Procedure History

FIG. 24

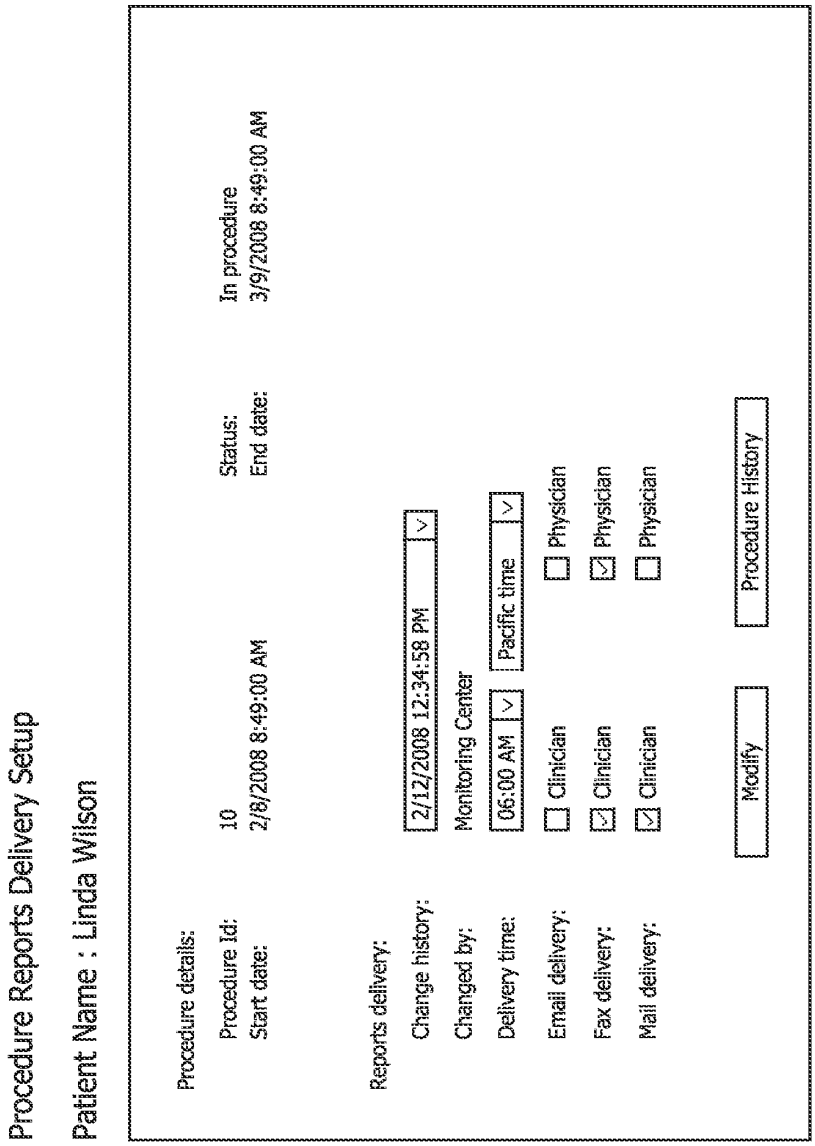

Procedure Reports Delivery Setup
Patient Name : Linda Wilson
Procedure details:
Procedure Id:
10
Status:
In procedure
Start date:
2/8/2008 8:49:00 AM
End date:
3/9/2008 8:49:00 AM
Reports delivery:
Change history:
2/12/2008 12:34:58 PM
Changed by:
Monitoring Center
Delivery time:
06:00 AM
Pacific time
Email delivery:
Clinician
Physician
Fax delivery:
Clinician
Physician
Mail delivery:
Clinician
Physician
Modify
Procedure History

FIG. 25

User Activity Details - Monitoring Center

Active Details:

Account status:	Active	Last login date:	01/07/2008 11:09:46 AM
Lockout:	Unlocked	Last lockout date:	
Last password change date:	01/07/2008 10:08:29 AM		
Failed password attempts:	0	Failed password attempts start date:	
Failed password answer attempts:	0	Failed password answer attempt start:	

Activity Log - Number of Logins:

In Past 24 hours:	7
In Past 7 days:	9
In Past 30 days:	9
Total Logins:	9

262

Clear Activity History

IP Address	Login Date	Logout Date
127.0.0.1	01/07/2008 11:09:46 AM	
127.0.0.1	01/07/2008 10:44:43 AM	
127.0.0.1	01/07/2008 10:31:17 AM	01/07/2008 10:32:28 AM
127.0.0.1	01/07/2008 10:25:53 AM	
127.0.0.1	01/07/2008 10:10:54 AM	01/07/2008 10:11:09 AM
127.0.0.1	01/07/2008 09:39:50 AM	01/07/2008 10:09:45 AM
127.0.0.1	01/07/2008 09:31:07 AM	
127.0.0.1	01/07/2008 03:49:32 PM	
127.0.0.1	01/07/2008 03:36:13 PM	

Back to Search

FIG. 26

Monitoring Center Originated Logs
Site:
Select site
First Name:
Last Name:
Physician:
Select physician
Patient Id:
Procedure Id:
Search
Reset
Physician
Patient
Patient Id
Procedure Id
Procedure Start Date
Procedure End Date
Logs
Matt Kimmons
James V Smith
1
1
01/07/2008 10:24 AM
01/07/2008 10:28 AM
View
Abigail Arthur
Linda I Williams
3
2
01/07/2008 10:31 AM
02/06/2008 10:31 AM
View
272
Log for James V Smith - Procedure started on 1/7/2008 10:24:00 AM
Entry time:
01/07/2008 11:23:07 AM
Notes:
Event time:
01/07/2008 11:23 AM
1000 characters left
Event Category:
Device issue
Alert Notification Id:
274
Create Log
Cancel
New Log
Entry Time
Event Time
Event Category
Notification Id
Notes
01/07/2008 10:45 AM
01/07/2008 10:45 AM
Other symptoms
Experienced mild palpitations and dizziness.
01/07/2008 10:45 AM
01/07/2008 10:45 AM
Device issue
Phone got run over by car.

FIG. 27

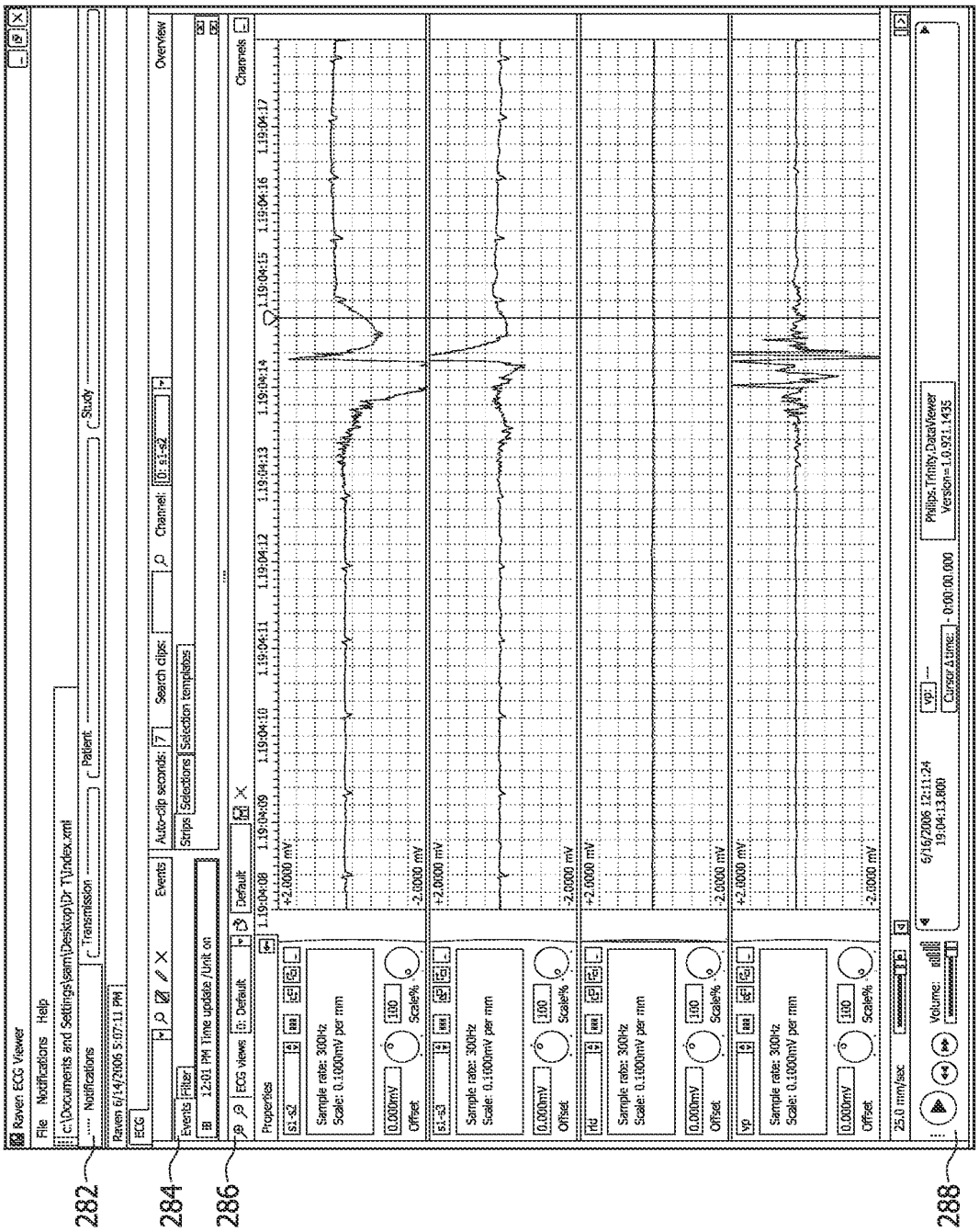

Raven ECG Viewer
File Notifications Help
Notifications
Transmission
Patient
Study
Events
Auto-clip seconds: 7
Search clips:
Channel:
Overview
Strips Selections Selection templates
Channels
Properties
ECG views
Default
Sample rate: 300Hz
Scale: 0.1000mV per mm
Offset
Scale%
+2.0000 mV
-2.0000 mV
1.19:04:08
1.19:04:09
1.19:04:10
1.19:04:11
1.19:04:12
1.19:04:13
1.19:04:14
1.19:04:15
1.19:04:16
1.19:04:17
6/16/2006 12:11:24
19:04:13.800
Cursor & time:
0:00:00.000
Philips.Trinity.DataViewer
Version=1.0.921.1435
25.0 mm/sec
Volume:
282
284
286
288

FIG. 28

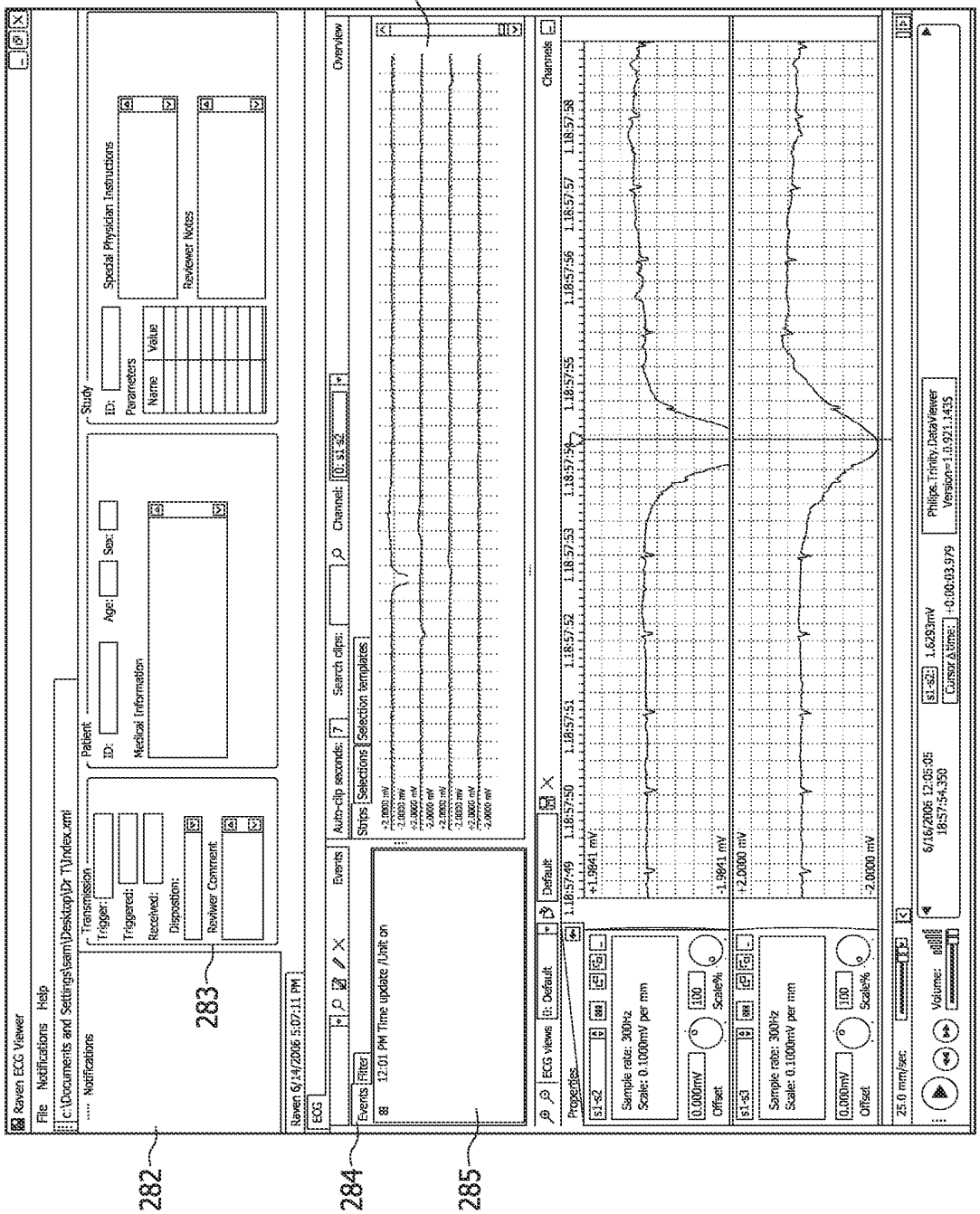

Raven ECG Viewer
File Notifications Help
c:\Documents and Settings\sam\Desktop\Dr T\index.xml
Notifications
Transmission
Trigger:
Triggered:
Received:
Disposition:
Reviewer Comment
Patient
ID:
Age:
Sex:
Medical Information
Study
ID:
Parameters
Name
Value
Special Physician Instructions
Reviewer Notes
Raven 6/14/2006 5:07:11 PM
ECG
Events
Auto-clip seconds:
Search clips:
Channel:
Overview
Strips
Selections
Selection templates
Events
Filter
88 12:01 PM Time update /Unit on
ECG views
Default
Properties
Channels
Sample rate: 300Hz
Scale: 0.1000mV per mm
Offset
Scale%
Philips.Trinity.DataViewer
Version=1.0.9211.1435
Volume:
6/16/2006 12:05:05
16:57:54.350
Cursor Atime:
25.0 mm/sec
282
283
284
285
287

FIG. 29

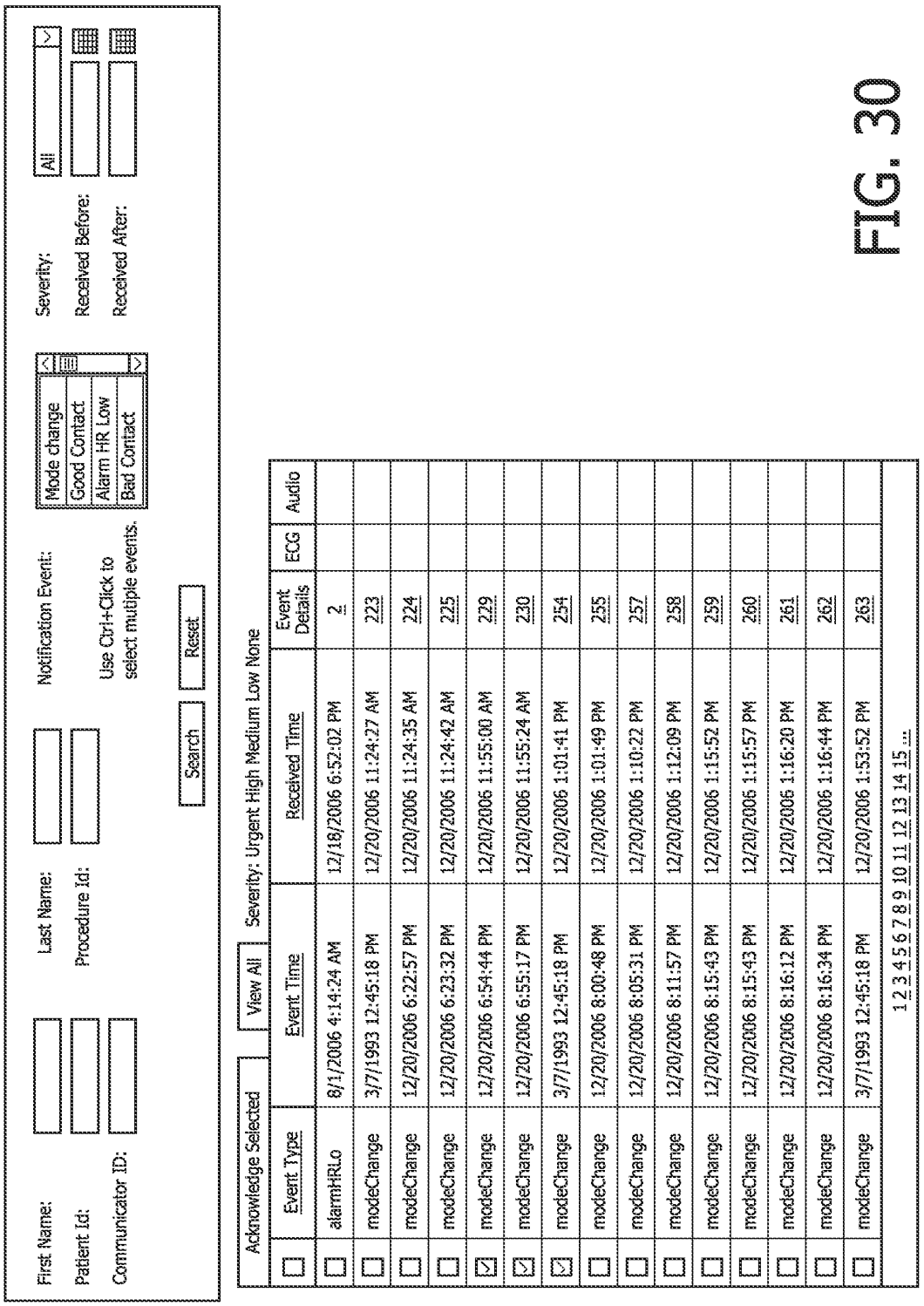

Status Notifications
First Name:
Patient Id:
Communicator ID:
Last Name:
Procedure Id:
Notification Event:
Use Ctrl+Click to select multiple events.
Mode change
Good Contact
Alarm HR Low
Bad Contact
Severity:
All
Received Before:
Received After:
Search
Reset
Acknowledge Selected
View All
Severity: Urgent High Medium Low None
Event Type
Event Time
Received Time
Event Details
ECG
Audio
alarmHRLo 8/1/2006 4:14:24 AM 12/18/2006 6:52:02 PM 2
modeChange 3/7/1993 12:45:18 PM 12/20/2006 11:24:27 AM 223
modeChange 12/20/2006 6:22:57 PM 12/20/2006 11:24:35 AM 224
modeChange 12/20/2006 6:23:32 PM 12/20/2006 11:24:42 AM 225
modeChange 12/20/2006 6:54:44 PM 12/20/2006 11:55:00 AM 229
modeChange 12/20/2006 6:55:17 PM 12/20/2006 11:55:24 AM 230
modeChange 3/7/1993 12:45:18 PM 12/20/2006 1:01:41 PM 254
modeChange 12/20/2006 8:00:48 PM 12/20/2006 1:01:49 PM 255
modeChange 12/20/2006 8:05:31 PM 12/20/2006 1:10:22 PM 257
modeChange 12/20/2006 8:11:57 PM 12/20/2006 1:12:09 PM 258
modeChange 12/20/2006 8:15:43 PM 12/20/2006 1:15:52 PM 259
modeChange 12/20/2006 8:15:43 PM 12/20/2006 1:15:57 PM 260
modeChange 12/20/2006 8:16:12 PM 12/20/2006 1:16:20 PM 261
modeChange 12/20/2006 8:16:34 PM 12/20/2006 1:16:44 PM 262
modeChange 3/7/1993 12:45:18 PM 12/20/2006 1:53:52 PM 263
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ...

FIG. 30

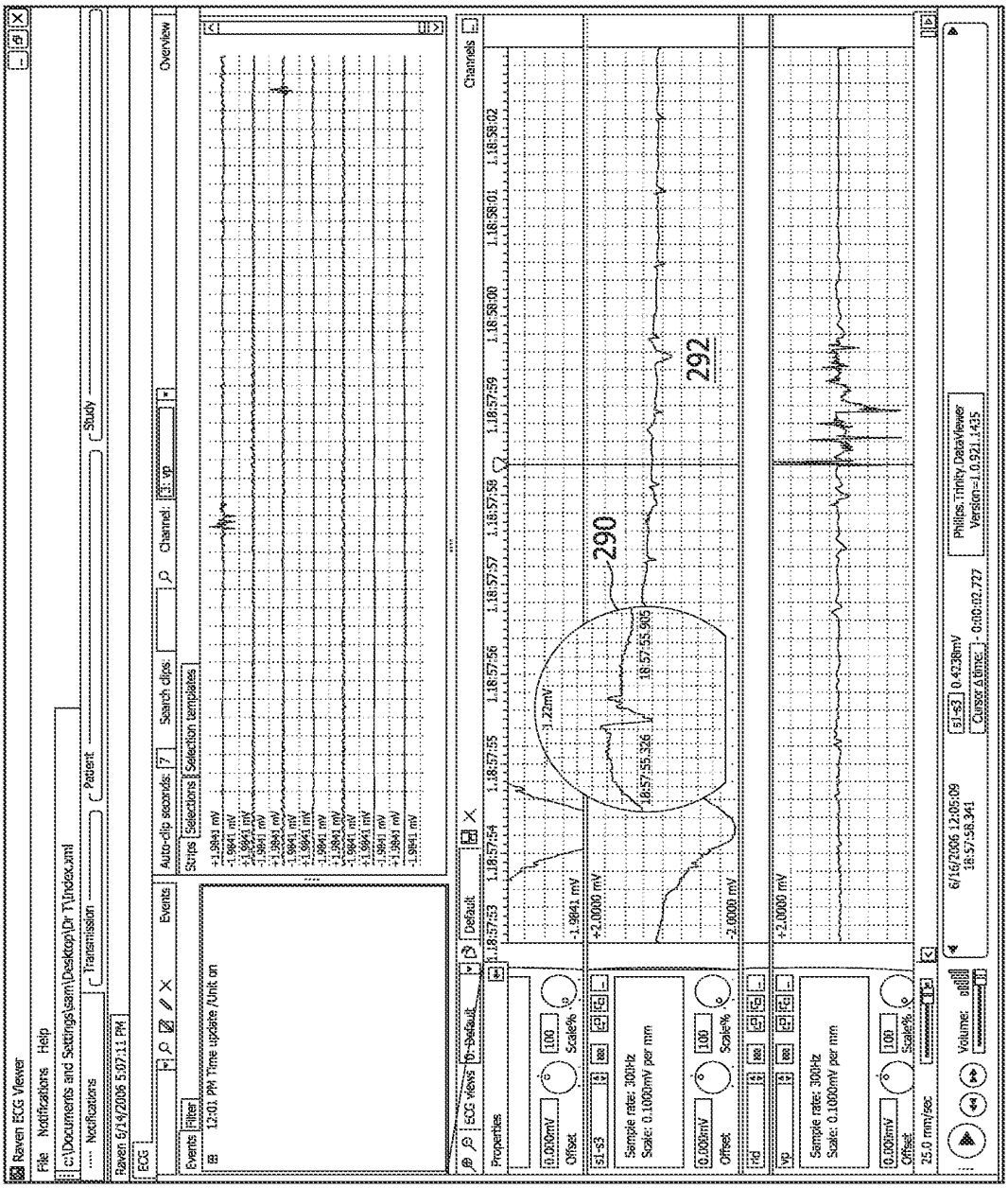

Raven ECG Viewer
File Notifications Help
c:\Documents and Settings\sam\Desktop\Dr T\index.xml
Notifications
Transmission
Patient
Study
Raven 6/14/2006 5:07:11 PM
ECG
Events
Filter
12:01 PM Time update /Unit on
Auto-clip seconds: 7
Search clips:
Channel: 51: vp
Overview
Strips
Selections
Selection templates
ECG views
16-Default
Default
Channels
Properties
Sample rate: 300Hz
Scale: 0.1000mV per mm
Offset
Scale%
Volume:
6/16/2006 12:05:09
18:57:58.941
Cursor Δtime: 0:00:02.727
Philips.Tinnity.DataViewer
Version=1.0.521.1435
290
292
3.22mV

FIG. 31

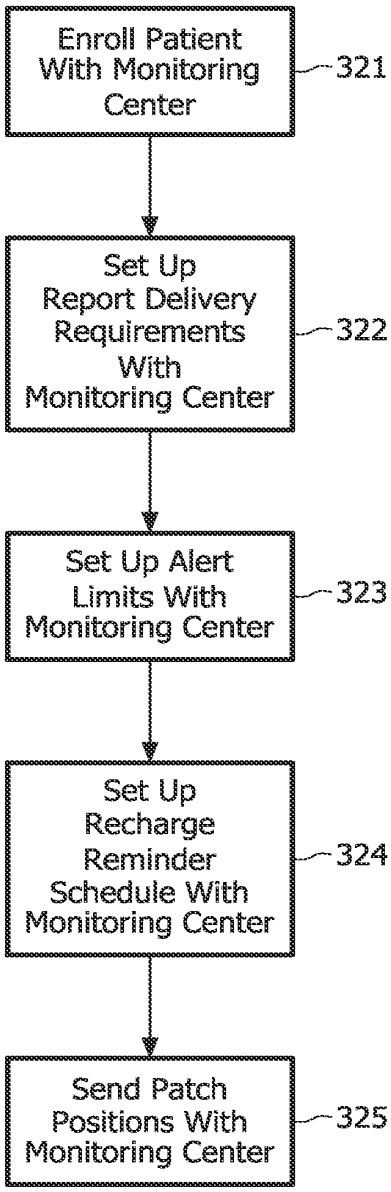

Enroll Patient With Monitoring Center
321
Set Up Report Delivery Requirements With Monitoring Center
322
Set Up Alert Limits With Monitoring Center
323
Set Up Recharge Reminder Schedule With Monitoring Center
324
Send Patch Positions With Monitoring Center
325

FIG. 32

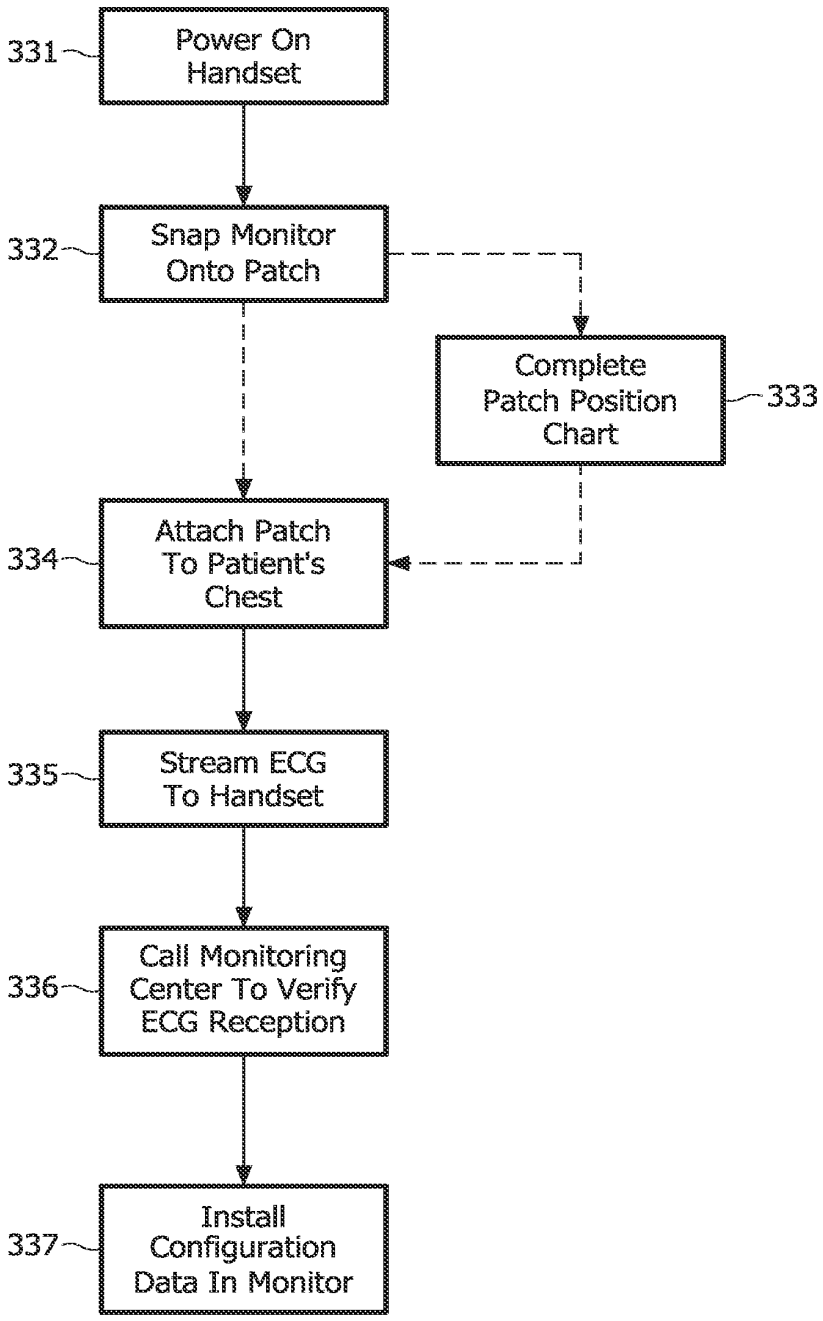

331
Power On Handset
332
Snap Monitor Onto Patch
Complete Patch Position Chart
333
334
Attach Patch To Patient's Chest
335
Stream ECG To Handset
336
Call Monitoring Center To Verify ECG Reception
337
Install Configuration Data In Monitor

FIG. 33

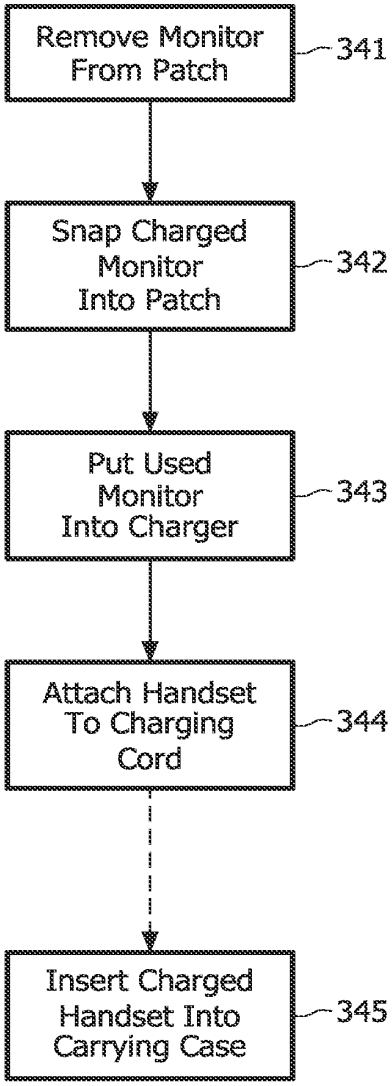

Remove Monitor From Patch
341
Snap Charged Monitor Into Patch
342
Put Used Monitor Into Charger
343
Attach Handset To Charging Cord
344
Insert Charged Handset Into Carrying Case
345

FIG. 34

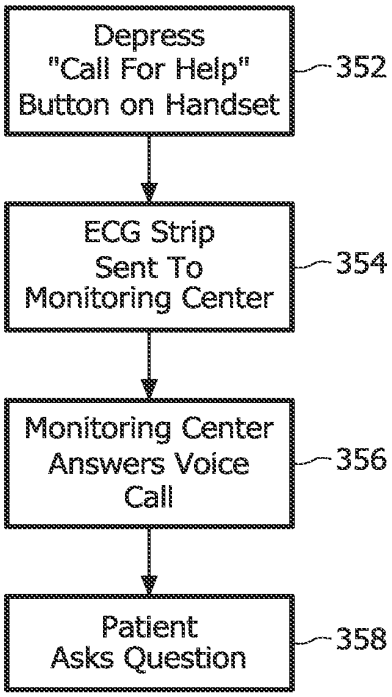

Depress "Call For Help" Button on Handset
352
ECG Strip Sent To Monitoring Center
354
Monitoring Center Answers Voice Call
356
Patient Asks Question
358

FIG. 35

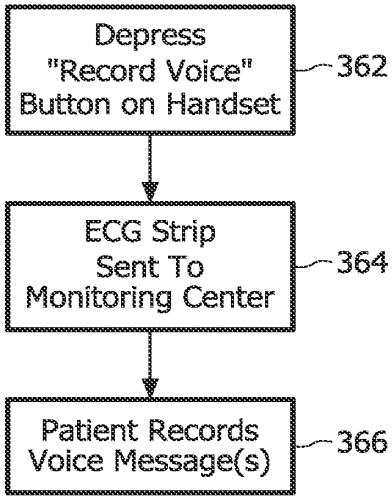

Depress "Record Voice" Button on Handset
362
ECG Strip Sent To Monitoring Center
364
Patient Records Voice Message(s)
366

FIG. 36

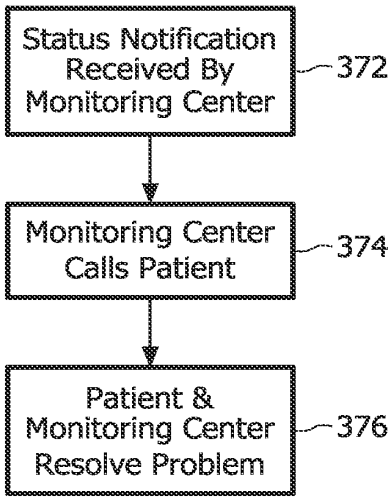

Status Notification Received By Monitoring Center
372
Monitoring Center Calls Patient
374
Patient & Monitoring Center Resolve Problem
376

FIG. 37

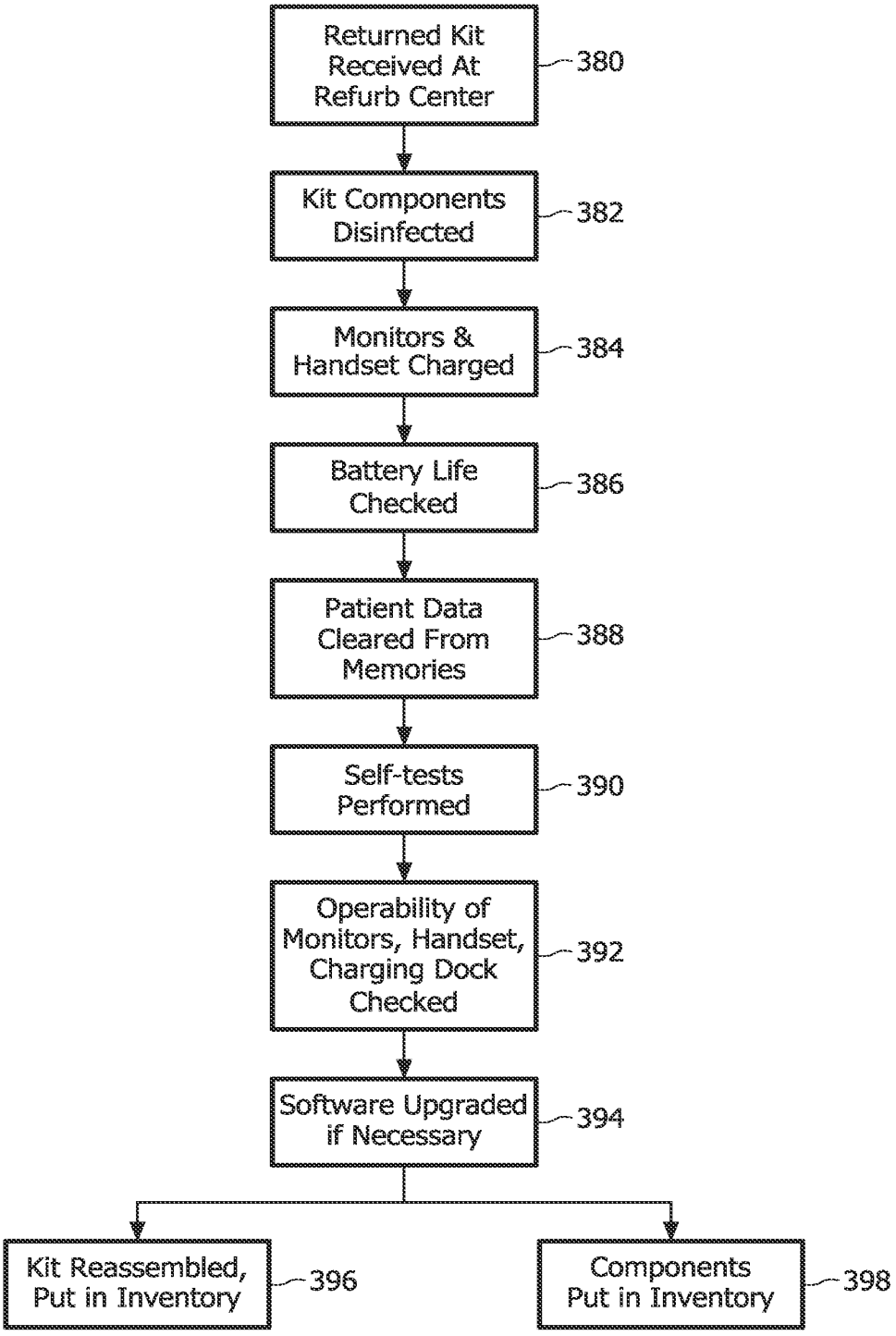

Returned Kit Received At Refurb Center
380
Kit Components Disinfected
382
Monitors & Handset Charged
384
Battery Life Checked
386
Patient Data Cleared From Memories
388
Self-tests Performed
390
Operability of Monitors, Handset, Charging Dock Checked
392
Software Upgraded if Necessary
394
Kit Reassembled, Put in Inventory
396
Components Put in Inventory
398

FIG. 38

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/050885

A. CLASSIFICATION OF SUBJECT MATTER
INV. H04M1/725 H04M1/02 H04M11/00 A61B5/0432 A61B5/0205
G06F19/00

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)
H04M A61B A61N G06F G08B A45F H04B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/058614 A1 (BANET MATTHEW J [US] ET AL) 6 March 2008 (2008-03-06) abstract; figures 1,2,5 paragraphs [0029], [0051]	1-3,14
Y	DE 202 19 001 U1 (KARCHER KURT [DE]) 20 February 2003 (2003-02-20) abstract; claim 1; figures 2,5	1,2
Y	WO 2004/093517 A (MODELABS LTD [CN]; ASSEO PIERRE [CN]) 4 November 2004 (2004-11-04) page 2, lines 4-26 page 5, lines 4-26 abstract; figure 1	3

-/--

[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 document 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
9 July 2009	16/07/2009

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	Jonsson, P.O.

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/050885

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 365 570 A (BOUBELIK MARK J [US]) 15 November 1994 (1994-11-15) abstract; figures 1-4 column 2, lines 37-56 column 3, lines 42-64	14
A	US 5 720 770 A (NAPPHOLZ TIBOR A [US] ET AL) 24 February 1998 (1998-02-24) abstract; figures 1-6 column 2, line 35 - column 3, line 19 column 9, line 53 - column 10, line 32	1
A	US 5 544 661 A (DAVIS CHARLES L [US] ET AL) 13 August 1996 (1996-08-13) abstract; figures 1-4 column 1, lines 43-60	1
A	US 2007/061361 A1 (TANAKA TOSHIYUKI [JP] ET AL) 15 March 2007 (2007-03-15) paragraphs [0079], [0090], [0105] - [0107]	3

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2009/050885

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008058614 A1	06-03-2008	NONE	
DE 20219001 U1	20-02-2003	NONE	
WO 2004093517 A	04-11-2004	EP 1623562 A2	08-02-2006
		FR 2853799 A1	15-10-2004
US 5365570 A	15-11-1994	NONE	
US 5720770 A	24-02-1998	NONE	
US 5544661 A	13-08-1996	NONE	
US 2007061361 A1	15-03-2007	CN 1867291 A	22-11-2006
		EP 1698274 A1	06-09-2006
		WO 2005048833 A1	02-06-2005

Form PCT/ISA/210 (patent family annex) (April 2005)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 41188-720601	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2014/070170	International filing date *(day/month/year)* 12 December 2014 (12.12.2014)	Priority date *(day/month/year)* 12 December 2013 (12.12.2013)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ALIVECOR, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 14 June 2016 (14.06.2016)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: URI GREENWALD
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	30 APR 2015
Applicant's or agent's file reference 41188-720601	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2014/070170	12 December 2014	12 December 2013

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 5/02, 5/0402 (2015.01)
CPC - A61B 5/02, 5/0402 (2015.04)

Applicant ALIVECOR, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 *bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	16 April 2015	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2011)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2014/070170

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

   ☐ on paper

   ☐ in electronic form

   b. (time)

   ☐ in the international application as filed

   ☐ together with the international application in electronic form

   ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.: PCT/US2014/070170

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☐ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

see supplemental box

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-20

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2014/070170

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	None	YES
	Claims	1-20	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by Orbach.

Referring to Claim 1, Orbach discloses a computer implemented method for managing cardiac health (Abstract, Fig. 7A), said computer implemented method comprising: receiving by a computer biometric data of a user (Fig. 5A); generating by said computer a cardiac health score in response to said received biometric data (Para. [0273] explains determining cardiac score); and displaying to said user by said computer one or more of a recommendation (Para. [0092]) for improving said generated cardiac health score and a goal for improving said generated cardiac health score (Fig. 7B shows the line 52b acting as a goal for the user).

Referring to Claim 2, the method of claim 1 as disclosed by Orbach, Orbach discloses wherein said biometric data comprises one or more of an electrocardiogram (ECG) (Fig. 5A), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, and genotype data.

Referring to Claim 3, the method of claim 1 as disclosed by Orbach, Orbach discloses further comprising updating (Para. [0195] explains updating said one or more of said recommendations) for improving said generated cardiac health score and said goal for improving said generated cardiac health score in response to said user meeting said one or more of said recommendation for improving said generated cardiac health score and said goal for improving said generated cardiac health score (Para. [0316] explains tracking real-time user performance to train user to achieve a predetermined state, thereby explaining the providing user with realtime feedback based on user reaching particular target).

Referring to Claim 4, the method of claim 1 as disclosed by Orbach, Orbach discloses wherein displaying to said user said one or more of said recommendation (Para. [0195] explains updating said one or more of said recommendations) for improving said generated cardiac health score and said goal for improving said generated cardiac health score comprises alerting said user if said one or more of said recommendation for improving said generated cardiac health score and said goal for improving said generated cardiac health score has not been completed by said user (Fig. 7B shows the display showing a goal line 52b, thereby alerting the user about the goal he needs to achieve).

Referring to Claim 5, the method of claim 1 as disclosed by Orbach, Orbach discloses further comprising downloading from the Internet a set of instructions configured for managing cardiac health, wherein said set of instructions causes said computer to receive said biometric data (Para. [0170]).

Referring to Claim 6, the method of claim 5 as disclosed by Orbach, Orbach discloses wherein said set of instructions causes said computer to automatically generate one or more of said cardiac health score (Para. [0273]), said recommendation (Para. [0092]) for improving said generated cardiac health score, and said goal (Fig. 7B shows the line 52b acting as a goal for the user) for improving said generated cardiac health score.

Referring to Claim 7, the method of claim 5 as disclosed by Orbach, Orbach discloses wherein said cardiac health score is generated using a machine learning algorithm (Para. [0205] explains the use of neural networks).

Referring to Claim 8, the method of claim 7 as disclosed by Orbach, Orbach discloses wherein said machine learning algorithm (Para. [0205] explains the use of neural networks) generates said cardiac health score of said user in response to biometric data from a plurality of users (Para. [0273]).

Referring to Claim 9, the method of claim 5 as disclosed by Orbach, Orbach discloses wherein said set of instructions causes said computer to allow a medical professional to access said received biometric data (Para. [0170] explains instructions that are relayed from the remote computer to the monitor, Fig. 7A-C shows the ability to access biometric data).

Referring to Claim 10, the method of claim 9 as disclosed by Orbach, Orbach discloses wherein said one or more of said recommendation for improving said generated cardiac health score and said goal for improving said generated cardiac health score is generated by said medical professional (Para. [0311] explains the ability to receive advice from an expert in real time).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.: PCT/US2014/070170

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:

Box IV Lack of Unity:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees need to be paid.

Group I, claims 1-20 are drawn to generating a cardiac health score in response to received biometric data.

Group II, claims 21-37 are drawn to determining heart rate variability.

Group III, claims 38-41 are drawn to determining whether a physiological parameter has met a first threshold.

Group IV, claims 42-57 are drawn to a method of building an ECG database.

Group V, claims 58-68 are drawn to determining when to record an electrocardiogram.

The inventions listed in Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, displaying to a user one or more of a recommendation for improve said generated health score and a goal for improving a generated cardiac health score are not present in Groups II-V; the special technical features of Group II; determining a heart rate variability value in response to received heart rate information, and generating a heart health score in response to said determined heart rate variability value are not present in Groups I, III-V; the special technical features of Group III; receiving a plurality of physiological parameters of said user; determining whether a first physiological parameter of said plurality of physiological parameters has met a first threshold; determining whether a second physiological parameter of said plurality of physiological parameters has met a second threshold; and providing an instruction to said user when said first physiological parameter has met said first threshold and said second physiological parameter has met said second threshold are not present in Groups I, II and IV, V; the special technical features of Group IV; a method of building an ECG database, said method comprising: recording a first ECG data at a first time using an ECG recording device having electrodes placed on a first patient; associating a first metadata with said first ECG data, said first metadata including a first patient identifier, said first time, information about the ECG recording device, about electrode placement on said first patient at said first time, and information about a condition of said first patient at said first time; transmitting said first ECG data and said first metadata to a database; storing said first ECG data and said first metadata in said database; recording a second ECG data at a second time using said ECG recording device; associating a second metadata with said second ECG data, said second metadata including said first patient identifier, said second time, information about said ECG recording device, information about said electrode placement on said first patient at said second time, and information about said condition of said first patient at said second time; storing said second ECG data and said second metadata in said database; and retrieving one or more ECG data based on a customizable set of criteria, said customizable set of criteria corresponding at least to said metadata are not present in Groups I-III and V; the special technical feature of Group V, continuously monitoring said subject's hear rate using a wearable heart rate monitor to provide heart rate information; processing said subject's heart rate information in a processor to determine if said subject's heart rate displays one or more predetermined characteristics; alerting said subject to perform an electrocardiogram when said subject's heart rate displays said predetermined characteristics; and recording said subject's ECG using a personal ECG recording device operated by the subject are not present in Groups I-IV.

Groups I-V share the technical feature of receiving physiological features of a user and monitoring health of a user. However, this shared technical feature does not represent a contribution over the prior art. Specifically US 2012/0108916 A1 to Riftine discloses receiving physiological features of a user and monitoring health of a user (Fig. 1; para 0002; para 0017).

Groups I and II share the technical feature of receiving biometric data from a body-worn sensor and generating a cardiac health score in response to the received biometric data. However, this shared technical feature does not represent a contribution over the prior art. Specifically US 2012/0108916 A1 to Riftine discloses receiving biometric data from a body worn sensor (Fig. 1; para 0002) and generating a cardiac health score in response to the received biometric data (Figs. 1 and 6 fitness score; para 0017; para 0099).

Groups II and IV share the technical feature of receiving heart rate information from a heart rate sensor coupled to a user. However, this shared technical feature does not represent a contribution over the prior art. Specifically US 2012/0108916 A1 to Riftine discloses receiving heart rate information from a heart rate sensor coupled to a user (as shown in Fig. 1; para 0002 regarding heart rate monitor)

Groups IV and V share the technical feature of recording ECG data. However, this shared technical feature does not represent a contribution over the prior art. Specifically US 4,977,899 A to Digby et al disclose recording ECG data (abstract regarding continuous ECG monitoring...and selecting recording of arrhythmic events).

Since none of the special technical features of the Groups I-V inventions are found in more than one of the inventions, unity is lacking.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2014/070170

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Referring to Claim 11, Orbach discloses a non-transitory computer readable storage medium (Para. [0191]) of one or more of a body-worn computer, a tablet computer, or a smartphone storing a set of instructions capable of being executed by one or more of the body-worn computer, the tablet computer, or the smartphone (Fig. 1), that when executed by the one or more the body-worn computer, the tablet computer, or the smartphone causes the one or more of the body-worn computer, the tablet computer, or the smartphone to receive biometric data of a user (Fig. 5A), generate a cardiac health score (Para. [0273] explains determining cardiac score) in response to said received biometric data; and display to said user one or more of a recommendation (Para. [0092]) for improving said generated cardiac health score and a goal (Fig. 7B shows the line 52b acting as a goal for the user) for improving said generated cardiac health score.

Referring to Claim 12, Orbach discloses a system for managing cardiac health (Abstract, Fig. 7A), said system comprising: a sensor (Para. [0030]) for recording biometric data of a user (Fig. 5A); and a local computing device (Para. [0037]- [0047]) receiving said biometric data (Fig. 5A) from said sensor, wherein said local computing device is configured to display a cardiac health score (Para. [0273] explains determining cardiac score) and one or more of a recommendation (Para. [0092]) for improving said generated cardiac health score and a goal (Fig. 7B shows the line 52b acting as a goal for the user) for improving said generated cardiac health score in response to the received biometric data.

Referring to Claim 13, the system of claim 12 as disclosed by Orbach, Orbach discloses further comprising a remote server (Para. [0017]) receiving said biometric data from said local computing device.

Referring to Claim 14, the system of claim 13 as disclosed by Orbach, Orbach discloses wherein one or more of said local computing device or said remote server comprises a machine learning algorithm (Para. [0205] explains the use of neural networks) generating one or more of said recommendation for improving said generated cardiac health score and said goal for improving said generated cardiac health score (Para. [0273]).

Referring to Claim 15, the system of claim 13 as disclosed by Orbach, Orbach discloses wherein the remote server is configured for access by a medical professional (Para. [0087] explains a viewing station).

Referring to Claim 16, the system of claim 15 as disclosed by Orbach, Orbach discloses wherein one or more of said recommendation (Para. [0092]) for improving said generated cardiac health score and said goal for improving said generated cardiac health score is generated by said medical professional and provided to said local computing device through said remote server (Para. [0311] explains the ability to receive advice from an expert in real time).

Referring to Claim 17, the system of claim 12 as disclosed by Orbach, Orbach discloses wherein said sensor comprises one or more of a hand-held electrocardiogram (ECG) sensor, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer (Para. [0162]), or a pulse oximeter.

Referring to Claim 18, the system of claim 12 as disclosed by Orbach, Orbach discloses wherein said sensor is configured to be in wireless communication with said local computing device (Para. [0061] - [0064]).

Referring to Claim 19, the system of claim 12 as disclosed by Orbach, Orbach discloses wherein said local computing device comprises one or more of a personal computer, a laptop computer, a palmtop computer, a tablet computer, a smartphone; or a body-worn computer (Para. [0037] - [0047]).

Referring to Claim 20, the system of claim 12 as disclosed by Orbach, Orbach discloses wherein said biometric data comprises one or more of an electrocardiogram (ECG) (Fig. 5A), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, or genotype data.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: URI M. GREENWALD
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 19 AUG 2016
Applicant's or agent's file reference 41188-720602	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 16/32524	International filing date *(day/month/year)* 13 May 2016 (13.05.2016)
Applicant ALIVECOR, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau of WIPO preferably through ePCT or on paper to, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **19 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee W. Young PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2014)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 41188-720602	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 16/32524	International filing date *(day/month/year)* 13 May 2016 (13.05.2016)	(Earliest) Priority Date *(day/month/year)* 13 May 2015 (13.05.2015)
Applicant ALIVECOR, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/32524

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/02 (2016.01)
CPC - A61B 5/02
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 (2016.01)
CPC: A61B 5/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC: A61B 5/00, A61B 5/021, A61B 5/0215, A61B 5/0452, A61B 5/0402 (keyword limited search below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Scholar, Google Patents; Search Terms: discordance, heart rate, Tachycardia, Bradycardia, cardiac rate, activity tracker, activity monitor, heart rate variability, ALIVECOR, ALBERT, correlat*, accelerometer, gyroscope, photosensor, atrial fibrillation

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 2012/0289790 A1 (Jain et al.) 15 November 2012 (15.11.2012) entire document especially Abstract, para [0138]-[0140], para [0158], para [0246], para [0403]-[0404]	24 ---------- 1-23
Y	US 2013/0281816 A1 (Strauss et al.) 24 October 2013 (24.10.2013) entire document especially Abstract, para [0058]-[0062]	1-23
A	US 2012/0083705 A1 (Yuen et al.) 05 April 2012 (05.04.2012) entire document	1-24
A	US 2014/0163927 A1 (Molettiere et al.) 12 June 2014 (12.06.2014) entire document	1-24

☐ 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
08 July 2016	19 AUG 2016
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. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: URI M. GREENWALD
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	19 AUG 2016
Applicant's or agent's file reference 41188-720602	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 16/32524	13 May 2016 (13.05.2016)	13 May 2015 (13.05.2015)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 5/02 (2016.01)
CPC - A61B 5/02

Applicant ALIVECOR, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule *43bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 *bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	08 July 2016	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/32524

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

a. ☐ forming part of the international application as filed:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Form PCT/ISA/237 (Box No. I) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/32524

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-23	YES
	Claims	24	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	None	NO

2. Citations and explanations:

Claim 24 lacks novelty under PCT Article 33(2) as being anticipated by US 2012/0289790 A1 to Jain et al. (hereinafter 'Jain').

As to claim 24, Jain discloses a method for cardiac monitoring ('heart-rate monitor' Abstract), comprising:

sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual ('a user may be wearing a heart-rate monitor and an accelerometer, which transmit a heart-rate data stream and an accelerometer data stream, respectively. A data set in the heart-rate data stream may show the user had an elevated heart-rate during a certain time period. Analysis system 180 may contextualize the heart-rate data by mapping the heart-rate data against data from an accelerometer data stream that shows that the user had an elevated activity during the same time period. A data set may be contextualized using data from a data stream from a sensor 112 or from fixed data accessed by analysis system 180' para [0138]);

sensing a heart rate value of said individual with a second sensor of said wearable device ('heart-rate monitor' para [0138]);

determining if a discordance is present between two or more of said activity level value and said heart rate value by using an activity level threshold and a heart rate threshold with a processor of said wearable device ('there is a positive correlation activity level in a person and the heart rate of the person. Analysis system 180 may analyze heart-rate data and accelerometer data and establish that when a user increases his activity beyond a certain level, it will cause an increase in his heart-rate and that activity level and heart-rate will increase proportionally until the user's heart-rate reaches a certain rate ... an elevated heart-rate that coincides with increased activity is typically a normal response. However, a spike in heart-rate that coincides with a marginal elevated physical activity may not be a normal response. Analysis system 180 could then determine, based on the comparison, whether certain levels of activity produce abnormal heart-rate spikes in the user' para [0139]-[0140]);

and adjusting said activity level threshold and said heart rate level threshold using a machine learning algorithm executed by said processor ('Analysis system 180 may analyze one or more of these data streams to determine the stress index of the user. Any combination of two or more sensors may be used to generate a stress index value. These stress index values may be improved and calibrated by monitoring a person over time to determine when a change in physiological state is due to stress or due to a non-stress related event (such as, for example, exercise, dehydration). The stress-induced physiological changes may be used to establish a baseline physiological state for a person and a range of physiological variation associated with stress. A person may also engage in a training or control period during which the person's input or feedback may be used to engage machine-learning algorithms to develop a stress model that allows the person's stress index to be calculated. Similarly, machine learning may be used to correlate physiological stress responses with changes in psychological, behavioral, or environmental state' para [0158], para [0403]-[0404]).

--(Continued in Supplemental Box)--

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/32524

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V, 2. Citations and explanations:

Claims 1-23 lack an inventive step under PCT Article 33(3) as being obvious over Jain in view of US 2013/0281816 A1 to Strauss et al. (hereinafter 'Strauss').

As to claim 1, Jain discloses a method for cardiac monitoring ('heart-rate monitor' Abstract), comprising:

sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual ('a user may be wearing a heart-rate monitor and an accelerometer, which transmit a heart-rate data stream and an accelerometer data stream, respectively. A data set in the heart-rate data stream may show the user had an elevated heart-rate during a certain time period. Analysis system 180 may contextualize the heart-rate data by mapping the heart-rate data against data from an accelerometer data stream that shows that the user had an elevated activity during the same time period. A data set may be contextualized using data from a data stream from a sensor 112 or from fixed data accessed by analysis system 180' para [0138]);

sensing a heart rate value of said individual with a second sensor of said wearable device ('heart-rate monitor' para [0138]);

determining a heart rate variability value with a processor of said wearable device ('heart-rate variability' para [0246]);

determining if a discordance is present between two or more of said activity level value, said heart rate value, and said heart rate variability value with said processor ('there is a positive correlation activity level in a person and the heart rate of the person. Analysis system 180 may analyze heart-rate data and accelerometer data and establish that when a user increases his activity beyond a certain level, it will cause an increase in his heart-rate and that activity level and heart-rate will increase proportionally until the user's heart-rate reaches a certain rate ... an elevated heart-rate that coincides with increased activity is typically a normal response. However, a spike in heart-rate that coincides with a marginal elevated physical activity may not be a normal response. Analysis system 180 could then determine, based on the comparison, whether certain levels of activity produce abnormal heart-rate spikes in the user' para [0139]-[0140]);

and indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present ('the data aggregation system may analyze one or more data streams from one or more sensors 112 and generate one or more derivative data streams that may be synchronized, stored, and transmitted. ... sensor array 110 may include an electrocardiogram and a pulse oximeter. The data aggregation system may use a meta-sensor to measure the time difference between the registered heartbeat spikes on the data stream from the electrocardiogram and on the data stream from the pulse oximeter to generate a derivative data stream comprising blood pressure data' para [0097]-[0108]) but fails to specifically disclose indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present.

However, Strauss in analogous art discloses indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present in Abstract (In response to the detection of an abnormal detected cardiac function, at least one person is automatically alerted of the detected abnormal cardiac function of the patient) and in para [0058]-[0062] (smartphone 2500 can instruct device 2000 to administer the appropriate amount of medication to the patient if required (e.g., because of a detected abnormality in cardiac activity, instructions pushed by the healthcare practitioner, preset time-dependent dosing, etc.). Also, if a serious cardiac event is detected, a message can be sent to harness 2000 from smartphone 2500 to stream the sensor data immediately and continuously as opposed to periodically for discrete amounts of time ... Server 2600 makes the recorded ECG and its analysis available to the healthcare practitioner via the healthcare practitioner's device 2700).

It would have been obvious to one of ordinary skill in the art to add Strauss's method of recording ECG in response to abnormal cardiac event to Jain's method so that if the comparison of detected cardiac activity to baseline/normal activity an abnormality is discovered, an alert can be sent to the patient. The alert can be a request for information concerning a possible innocent explanation for the detected abnormality (e.g., elevated heart rate caused by exercise). In addition or in the alternative, it can take the form of instructions to take medicine or to seek medical assistance immediately, or the like. The system is configurable so that an alert can be sent automatically from the remote computer to the patient/user, or the alert can be sent after the healthcare practitioner approves the alert, or an alert can be sent solely manually by the healthcare practitioner (see para [0057]: Strauss).

As to claim 12, Jain discloses a wearable device for cardiac monitoring ('heart-rate monitor' Abstract), comprising: a processor;

a first sensor configured to sense an activity level value of an individual, wherein said first sensor is coupled to said processor ('a user may be wearing a heart-rate monitor and an accelerometer, which transmit a heart-rate data stream and an accelerometer data stream, respectively. A data set in the heart-rate data stream may show the user had an elevated heart-rate during a certain time period. Analysis system 180 may contextualize the heart-rate data by mapping the heart-rate data against data from an accelerometer data stream that shows that the user had an elevated activity during the same time period. A data set may be contextualized using data from a data stream from a sensor 112 or from fixed data accessed by analysis system 180' para [0138]);

a second sensor configured to sense a heart rate value of an individual, wherein said second sensor is coupled to said processor ('heart-rate monitor' para [0138]);

a first electrode and a second electrode configured to sense an electrocardiogram ('the data aggregation system may analyze one or more data streams from one or more sensors 112 and generate one or more derivative data streams that may be synchronized, stored, and transmitted ... sensor array 110 may include an electrocardiogram and a pulse oximeter. The data aggregation system may use a meta-sensor to measure the time difference between the registered heartbeat spikes on the data stream from the electrocardiogram and on the data stream from the pulse oximeter to generate a derivative data stream comprising blood pressure data' para [0097]);

--(Continued in Supplemental Box)--

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/32524

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V, 2. Citations and explanations:

a non-transitory computer readable storage medium encoded with a computer program including instructions executable by said processor to cause said processor to:

determine if a discordance is present between said activity level value of said individual and said heart rate value of said individual ('there is a positive correlation activity level in a person and the heart rate of the person. Analysis system 180 may analyze heart-rate data and accelerometer data and establish that when a user increases his activity beyond a certain level, it will cause an increase in his heart-rate and that activity level and heart-rate will increase proportionally until the user's heart-rate reaches a certain rate . an elevated heart-rate that coincides with increased activity is typically a normal response. However, a spike in heart-rate that coincides with a marginal elevated physical activity may not be a normal response. Analysis system 180 could then determine, based on the comparison, whether certain levels of activity produce abnormal heart-rate spikes in the user' para [0139]-[0140]);

and indicate that said electrocardiogram be recorded when said discordance is determined to be present ('the data aggregation system may analyze one or more data streams from one or more sensors 112 and generate one or more derivative data streams that may be synchronized, stored, and transmitted. ... sensor array 110 may include an electrocardiogram and a pulse oximeter. The data aggregation system may use a meta-sensor to measure the time difference between the registered heartbeat spikes on the data stream from the electrocardiogram and on the data stream from the pulse oximeter to generate a derivative data stream comprising blood pressure data' para [0097]-[0108]) but fails to specifically disclose indicating that said electrocardiogram be recorded when said discordance is determined to be present.

However, Strauss in analogous art discloses indicating that said electrocardiogram be recorded when said discordance is determined to be present in Abstract (In response to the detection of an abnormal detected cardiac function, at least one person is automatically alerted of the detected abnormal cardiac function of the patient) and in para [0058]-[0062] (smartphone 2500 can instruct device 2000 to administer the appropriate amount of medication to the patient if required (e.g., because of a detected abnormality in cardiac activity, instructions pushed by the healthcare practitioner, preset time-dependent dosing, etc.). Also, if a serious cardiac event is detected, a message can be sent to harness 2000 from smartphone 2500 to stream the sensor data immediately and continuously as opposed to periodically for discrete amounts of time . Server 2600 makes the recorded ECG and its analysis available to the healthcare practitioner via the healthcare practitioner's device 2700).

It would have been obvious to one of ordinary skill in the art to add Strauss's method of recording ECG in response to abnormal cardiac event to Jain's method so that if the comparison of detected cardiac activity to baseline/normal activity an abnormality is discovered, an alert can be sent to the patient. The alert can be a request for information concerning a possible innocent explanation for the detected abnormality (e.g., elevated heart rate caused by exercise). In addition or in the alternative, it can take the form of instructions to take medicine or to seek medical assistance immediately, or the like. The system is configurable so that an alert can be sent automatically from the remote computer to the patient/user, or the alert can be sent after the healthcare practitioner approves the alert, or an alert can be sent solely manually by the healthcare practitioner (see para [0057]: Strauss).

As to claims 2 and 13, Jain discloses a method/device wherein said first sensor comprises an accelerometer (para [0138]).

As to claims 3 and 14, Jain discloses a method/device wherein said first sensor comprises a gyroscope (para [0044]).

As to claims 4 and 15, Jain discloses a method/device wherein said second sensor comprises a photosensor ('Photoplethysmograph; Photodetector; Photodiode; Photoelectric sensor; Photoionization detector; Photomultiplier; Photoresistor; Photoswitch; Phototransistor; Phototube' para [0044]).

As to claims 5 and 16, Jain discloses a method/device wherein said discordance is determined to be present when said activity level value is normal and said heart rate value is elevated ('an elevated heart-rate that coincides with increased activity is typically a normal response. However, a spike in heart-rate that coincides with a marginal elevated physical activity may not be a normal response. Analysis system 180 could then determine, based on the comparison, whether certain levels of activity produce abnormal heart-rate spikes in the user' para [0139]-[0140]).

As to claims 6 and 18, Jain discloses a method/device wherein said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is increased (para [0139]-[0140], 'Physical exertion changes heart rate, blood pressure, heart rate variability, respiratory rate, oxygen saturation, sweat and galvanic skin response, as well as blood glucose level . For example, when using heart-rate variability to measure stress, the results may be confounded if physical movement and exertion is not taken into account during the stress measurement. Furthermore, many sensors provide erroneous data when accelerated, for example, because the physical connection between the sensor and the subject moves, causing the sensor to generate an inaccurate or false reading. By using an accelerometer (or another suitable movement sensor, such as, for example, a kinesthetic sensor), analysis system 180 may monitor the physical movement and exertion of a person. By contextualizing physiological sensor data with accelerometer data, analysis system 180 may be able to eliminate changes in physiological data or erroneous sensor measurements caused by physical movement and thereby more accurately measure and monitor stress in a person' para [0246]).

As to claims 7 and 19, Strauss discloses a method/device comprising indicating a presence of atrial fibrillation (para [0094]).

--(Continued in Supplemental Box)--

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 16/32524

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V, 2. Citations and explanations:

As to claim 8, Strauss discloses a method wherein said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is decreased ('physical activities that may explain abnormal cardiac activity, symptoms being experienced by the user/patient, etc' para [0016], 'To detect atrial fibrillation a few separate variables are used. First and simplest, the heart rate is used. However, there are many possibilities for supraventricular tachycardia, so it cannot be used alone. The system also uses heart rate variability, defined as the 1st and 2nd derivative of the heart rate. Lack of a P wave presence is hard to prove, since it could be that the system simply missed the detection. Therefore, the system uses variation in height and locale of P wave, as inconsistencies indicate an unstable system ... To train the classifier, standard data from the MIT arrhythmia database is preferably used, as patient presentation of these variables in the case of Atrial fibrillation is very similar' para [0095]).

As to claims 9 and 21, Strauss discloses a method/device comprising indicating a presence of a supraventricular tachycardia (para [0094]).

As to claims 10 and 22, Strauss discloses a method comprising setting one or more threshold values based on said activity level value, said heart rate value, and said heart rate variability value ('if a small event is actually detected that would fall under the preset threshold for automatic dosing and the patient experiences pain, self-dosing will be enabled ... the invention provides a device and method for monitoring and analyzing bioelectric (more specific, ECG) signals, and delivering automated therapy based on the analysis. The algorithm customized for patient by treating party. The invention includes a device for detecting, treating, and terminating ischemic episodes of the myocardium' para [0054]-[0055]).

As to claims 11 and 23, Strauss discloses a method wherein said one or more threshold values is determined using a machine learning algorithm ('the invention provides a device and method for monitoring and analyzing bioelectric (more specific, ECG) signals, and delivering automated therapy based on the analysis. The algorithm customized for patient by treating party. The invention includes a device for detecting, treating, and terminating ischemic episodes of the myocardium' para [0054]-[0055]).

As to claim 17, Jain discloses a method wherein said computer program includes instructions that cause said processor to determine a heart rate variability value (para [0168]).

As to claim 20, Jain discloses a device wherein said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is elevated ('Physical exertion changes heart rate, blood pressure, heart rate variability, respiratory rate, oxygen saturation, sweat and galvanic skin response, as well as blood glucose level ... when using heart-rate variability to measure stress, the results may be confounded if physical movement and exertion is not taken into account during the stress measurement. Furthermore, many sensors provide erroneous data when accelerated, for example, because the physical connection between the sensor and the subject moves, causing the sensor to generate an inaccurate or false reading. By using an accelerometer (or another suitable movement sensor, such as, for example, a kinesthetic sensor), analysis system 180 may monitor the physical movement and exertion of a person. By contextualizing physiological sensor data with accelerometer data, analysis system 180 may be able to eliminate changes in physiological data or erroneous sensor measurements caused by physical movement' para [0246]).

Claims 1-24 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Ravi GOPALAKRISHNAN et al.	Group Art Unit:	3762
Serial Number:	14/730,122	Examiner:	Nicole JOHNSON
Filing or 371 (c) Date:	2015-06-03	**CONFIRMATION NO:**	**2113**
Title:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING		

FILED ELECTRONICALLY ON: November 21, 2016

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

A. ☒ *37 CFR § 1.97 (b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☒ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

B. ☐ *37 CFR § 1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97 (e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR § 1.97 (d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in § 1.97 (e);

-- AND --

ii. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97 (e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 is NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 41188-720.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: November 16, 2016

By: /Uri Greenwald/
Uri Greenwald, M.D., J.D.
Reg. No. 72686

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 21971

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	14730122	Filing Date	2015-06-03	Docket Number (if applicable)	41188-720.301	Art Unit	3762
First Named Inventor	Ravi GOPALAKRISHNAN			Examiner Name	JOHNSON, NICOLE F.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☐ Enclosed

- ☐ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 232415

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Uri Greenwald/	Date (YYYY-MM-DD)	2015-06-04
Name	Uri Greenwald, MD, Esq.	Registration Number	72686

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal	
Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald/Lora Kim
Attorney Docket Number:	41188-720.301
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE- 1st Request	1801	1	1200	1200
		Total in USD ($)		**1200**

Electronic Acknowledgement Receipt	
EFS ID:	27580432
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Lora Kim
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	21-NOV-2016
Filing Date:	03-JUN-2015
Time Stamp:	21:21:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1200
RAM confirmation Number	112216INTEFSW00007920232415
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	41188_720301_RCE.pdf	81221 43d0493d48148d18004d3e0f4494442ae84a3ae3	no	3
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30330 639e0e766bba026b00e6a2d5753f734bad8d70c6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	111551		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Inventor(s): Ravi GOPALAKRISHNAN, et al. Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Group Art Unit: 3762 Examiner: JOHNSON, NICOLE F. Confirmation No.: 2113 Customer No.: 21971 Certificate of Electronic Filing I hereby certify that the attached Response to Final Office Action is being deposited by Electronic Filing on 11/14/2016, by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: /Lora Kim/ Lora C. Kim

M/S AFTER FINAL
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION DATED JUNE 13, 2016

Dear Commissioner:

Applicants hereby submit a response to the Office Action dated June 13, 2016. Applicants also request a one-month extension of time to allow the timely filing of all required items in the Office Action as mailed. Since November 13, 2016 falls on a Sunday, Applicant believes that this response is being timely filed. The Commissioner is hereby authorized to charge any additional fees due to Deposit Account No. 23-2415, referencing Docket No. 41188-720.301. Consideration of the above-referenced application is respectfully requested in view of the following remarks.

AMENDMENTS TO THE CLAIMS

Listing of the Claims:

1. (Currently amended) A method of determining a presence of an arrhythmia of a first user, said method comprising

sensing a heart rate of said first user with a heart rate sensor coupled to said first user;

transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;

determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user; [[and]]

sensing an activity level of said first user with a motion sensor;

comparing, using said mobile computing device, said heart rate variability of said first user to said activity level; and

alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability.

2. (Original) The method of claim 1, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.
3. (Original) The method of claim 1, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.
4. (Original) The method claim 3, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.
5. (Cancelled).
6. (Currently amended) The method of claim [[5]] 1, wherein said mobile computing device comprises a smartphone.
7. (Currently amended) The method of claim [[5]] 1, wherein said mobile computing device comprises a smartwatch.

8. (Original) The method of claim 1, further comprises determining a presence of said arrhythmia using a machine learning algorithm.
9. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
10. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.
11. (Currently amended) A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, compare said activity level to said heart rate variability of said first user, and determine a heart rate variability of said first user based on said heart rate of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.
12. (Original) The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.
13. (Original) The system of claim 11, wherein said system further comprises a biometric data sensor, and wherein said computer program including instructions executable by said processor further causes said processor to sense biometric data of said first user from said biometric data sensor.

14. (Original) The system claim 13, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.
15. (Cancelled)
16. (Currently amended) The system of claim [[15]] 11, wherein said mobile computing device comprises a smartphone.
17. (Currently amended) The system of claim [[15]] 11, wherein said mobile computing device comprises a smartwatch.
18. (Original) The system of claim 11, further comprises determining a presence of said arrhythmia using a machine learning algorithm.
19. (Original) The system of claim 18, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
20. (Original) The system of claim 19, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.
21. (New) The method of claim 1, wherein an irregularity comprises an increase in said heart rate variability without a corresponding increase in said activity level.
22. (New) The system of claim 11, wherein an irregularity comprises an increase in said heart rate variability without a corresponding increase in said activity level.

REMARKS

Amendments to the Claims

The listing of the claims provided herein replaces all prior versions and listings of claims in the above-referenced patent application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Amendments to the claims were made for purposes of more clearly stating the claimed subject matter and do not add new matter or alter the scope of the claims.

Applicants have herein amended claims 1, 6-7, 11, and 16-17 and added new claims 21 and 22. In addition, claims 5 and 15 have been cancelled herein. Support for the claim amendments to claims 1 and 11 comprise the inclusion respectively of originally filed claims 5 and 15, and further support for which can be found throughout the specification. Claims 6-7 and 16-17 are amended to depend respectively from claims 1 and 11, because originally filed claims 5 and 15, from which claims 6-7 and 16-17 originally respectively depended, were cancelled. Support for new claims 21 and 22 can be found in, for example, paragraphs [00116]-[00118] of the application as filed. No new matter has been added. Applicants respectfully request reconsideration of the claims as amended in view of the following arguments.

Claim Rejections – 35 U.S.C. § 102

Claims 1-20 are rejected under 35 U.S.C. § 102(a)(2) as being allegedly anticipated by Levitan et al. (US 2012/0197148) ("Levitan"). Applicants overcome this rejection due to at least the following:

In order to expedite prosecution, Applicants have amended claims 1 and 11 herein to respectively include the recited features of originally filed and previously examined claims 5 and 15. As such, claims 1 and 11 now recite "*sensing an activity level of said first user*" with a "*motion sensor*" and "*comparing said activity level to said heart rate variability of said first user.*" Levitan does not teach or suggest this feature. Levitan does not, for example, describe use of a ***motion sensor*** nor does Levitan describe either ***sensing an activity level of a user*** or ***comparing an activity level of a user to an HRV value of the user*** as recited by amended claims 1 and 11.

While the Office rejected originally filed claims 1-20 as allegedly being anticipated by Levitan in the Final Office Action dated June 13, 2016 (the "Action), Applicants respectfully point out that no support for the rejections of originally filed claims 5 and 15 was provided in the Action. In order for a cited reference to anticipate a claim under 35 U.S.C. § 102, the reference must teach each and every element of the claim, and the Office has not specifically addressed originally filed claims 5 and 15 by showing how the Office believes Levitan teaches the recited elements of these claims. As stated above, Levitan fails to teach or suggest a ***motion sensor***, ***sensing an activity level of a user***, and ***comparing an activity level of the user to an HRV value of the user*** as recited by original claims 1 and 11.

Because Levitan does not teach each and every element of claims 1 and 11 as amended, the rejection under 35 U.S.C. § 102 should not be maintained. Applicants therefore, respectfully request withdrawal of the rejections of claims 1 and 11 with allowance of claims 1 and 11 along with dependent claims 2-4, 6-10, 12-14, and 16-23 that respectively depend therefrom.

In addition, while Applicants make the above described amendments to claims 1 and 11 in order to expedite prosecution, Applicants further wish to respectfully point out that the Office's remarks provided on pages 3 and 4 of the Action fail to rebut the Applicants' arguments presented in the response filed by Applicants on May 23, 2016.

The Office first argues on page 3-4 of the Action that a "data collection subsystem" described by Levitan teaches a heart rate sensor as recited by claims 1 and 11, because "the present claims do not explicit claim any structure and composition that would render the examiner from said interpretation, i.e. nothing within the present claims excludes the examiner from interpreting the disclosed data collection subsystem as being the claimed heart rate sensor {e.g., [0013]-[0019] & [0056]-[0059])." Applicants respectfully disagree. Claims 1 and 11 recite a ***specific*** rather than a generic sensor type. Namely, claims 1 and 11 recite a "heart rate sensor." Levitan describes a "data collection subsystem" for collecting ECG data ***only***. *See* e.g. para [0058]. That is, Levitan describes a method for determining HRV from peak to peak interval data taken from a sensed ECG (i.e. using a data collection system), and does not describe use of ***a heart rate sensor*** in determining an HRV as recited by claims 1 and 11. Therefore, it is

neither explicit nor inherent that a "data collection subsystem" as described by Levitan teaches use of a ***specific*** type of sensor for measuring a heart rate to determine an HRV as recited by claims 1 and 11.

The Office then argues on page 4 of the Action that Levitan teaches that a user "is alerted to sense an electrocardiogram in response to a determined heart rate variability value." The Office points to paragraph [0099] of Levitan as allegedly teaching this feature as recited by claims 1 and 11. Applicants respectfully disagree and point out that Levitan does not teach sensing an electrocardiogram in response to an ECG as alleged by the Office. Paragraph [0099] of Levitan describes an alarm that is sounded to alert medical care providers from a patient when a patient is "hooked up to an ECG programmed to apply the ***continuous monitoring*** embodiment of the present invention." *See* para. [0099]. Applicants respectfully point out that a patient whose ECG is being ***continuously monitored*** would not then have an additional ECG recorded ***in response to*** an HRV value as recited by claims 1 and 11, because as described by Levitan his or her ECG is being continuously monitored regardless of his or her HRV. Rather, as described in paragraph [0099] of Levitan, the continuously monitored ECG results in an alarm that would lead a medical care provider to "quickly attend to the patient to administer a drug or other treatment." Levitan does not teach that an ECG is sensed in response to an HRV value and therefore Levitan does not teach that a user is alerted to sense an ECG ***in response to*** an HRV value as recited by claims 1 and 11.

CONCLUSION

Applicants respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned at (858) 350-2300. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 41188-720.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

Date: November 14, 2016

By:/Uri Greenwald/
Uri Greenwald, MD, Esq.
Reg. No. 72686

650 Page Mill Road
Palo Alto, CA 94304
(858) 350-2300
Customer No. 21971

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
41188-720.301	14/730,122	June 3, 2015
First Named Inventor:	**Title:**	
Ravi GOPALAKRISHNAN	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Uri Greenwald/	November 14, 2016
Name (Print/Typed) Uri Greenwald	Practitioner Registration No. 72686

***Note**: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal	
Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald/Lora Kim
Attorney Docket Number:	41188-720.301
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt	
EFS ID:	27508643
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Lora Kim
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	14-NOV-2016
Filing Date:	03-JUN-2015
Time Stamp:	20:27:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$200
RAM confirmation Number	111516INTEFSW00007805232415
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		41188_720301_Response_FOA_NOV142016.pdf	58419 6aa283a1f302b0461b16c77511f754a20f75ac2a	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Response After Final Action		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	8	
Warnings:					
Information:					
2	After Final Consideration Program Request	41188_720301_Certification_PilotProgram.pdf	157488 482cd1b443ce8149b63934e905a60f1c608d0b93	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30662 0dd7b1e508fe9c91ea552e3fd39e3f023de7231f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	246569		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/730,122	Filing Date 06/03/2015	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/14/2016	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
THUY TA

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 11/22/2016

TTA111 SALE #00000001 Mailroom Dt: 11/14/2016 232415 14730122
01 FC : 1252 400.00 DA

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301	2113

21971 7590 06/13/2016

WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
06/13/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@wsgr.com

Office Action Summary	Application No. 14/730,122	Applicant(s) GOPALAKRISHNAN ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/23/16*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *6/3/15* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

3. **Claims 1-20** are rejected under 35 U.S.C. 102(a)(2) as being anticipated by Levitan et al. (US 2012/0197148).

Levitan et al. discloses a method and a system of determining a presence of an arrhythmia of a first user, said method comprising (e.g., [0013]-[0019]) sensing a heart rate of said first user with a heart rate sensor, (e.g., via the disclosed means of 'data collection' 24); coupled to said first user; transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram; determining, using said mobile computing device (e.g., via the disclosed external device), a heart rate variability of

said first user based on said heart rate of said first user; and alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability [e.g., via the disclosed means of calculating/generating a HRV relative density parameter (RD)] in response to said determined HRV value {e.g., [0056]-[0059] & (Figs 2-3)}.

Further comprising receiving biometric data of said first user from a biometric sensor coupled to said first user (e.g., via the disclosed 'data collection 24').

Further comprising determining a presence of said arrhythmia using a machine learning algorithm [e.g., 0067].

Wherein said heart rate sensor is in communication with a portable computing device (e.g., via the disclosed external device), i.e., a smartphone, smartwatch, and/or wearable computing device, further comprising a processor and display [e.g., 0091].

Response to Arguments

2. Applicant's arguments filed March 23, 2016 have been fully considered but they are not persuasive. The applicant argues the following points in which the examiner provides a reason(s) as to why the arguments are not persuasive:

- The applicant argues that the primary reference, Levitan, fails to disclose receiving heart rate information from a heart rate sensor and determining a heart rate variability based on the user's heart rate.

Based on the broadest interpretation of the claims the examiner disagrees and further points out that Levitan discloses a method of measuring heart rate variability via recording ECG measurements from a series of heartbeats and utilizing specific parameters obtained from said

ECG the HRV is calculated, wherein said measurements are collected via a data collection subsystem (e.g., element 24). The examiner notes that the data collection system is interpreted as being the claimed heart rate sensor and that the present claims do not explicit claim any structure and composition that would render the examiner from said interpretation, i.e. nothing within the present claims excludes the examiner from interpreting the disclosed data collection subsystem as being the claimed heart rate sensor {e.g., [0013]-[0019] & [0056]-[0059]).

- The applicant argues that Levitan fails to describe that the user is alerted to sense an electrocardiogram in response to a determined heart rate variability value.

The examiner disagrees and further points out that Levitan discloses a means of utilizing a data collection system to obtain raw ECG data, wherein said data is then sent to a data analysis subsystem that outputs the data, i.e. the HRV value, via a display device, which said data may trigger an alarm, i.e. patients at risk for specific cardiac disorders can be hooked up to a device that provides continuous monitoring and upon detection of cardiac issues, derived from a HRV value parameter said alarm can be used in order to alert nearby medical personal based on said data and ECG data can thus be continuously [e.g., 0099] provided therefore providing the claimed means of a user being alerted to sense an electrocardiogram in response to a determined heart rate variability value {e.g., [0013]-[0019], [0056]-[0059]).

3. The examiner notes that an executed oath and declaration was submitted on March 30, 2016.

4. Applicant's arguments, filed May 23, 2016, with respect to double patenting rejection have been fully considered and are persuasive and have been withdrawn in lieu of the terminal disclaimer submitted on May 23, 2016.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Koharski can be reached on 571-272-7230. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICOLE F. LAVERT/
Primary Examiner, Art Unit 3762

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	GOPALAKRISHNAN
Art Unit	3762
Examiner Name	Lavert
Attorney Docket Number	41188-720.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-20150297134	10-22-2015	ALBERT; David E. et al.	
	002	US-20160071392	03-10-2016	HANKEY; Martha E. et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-105338892-A	02-17-2016	ALIVECOR INC		☒
	002	EP-2986204-A1	02-24-2016	ALIVECOR INC [US]		☐
	003	WO-2014172451-A1	10-23-2014	ALIVECOR INC [US]		☐

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

Examiner Signature	/Nicole Lavert/	Date Considered	06/07/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.L./

Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	GOPALAKRISHNAN
Art Unit	3762
Examiner Name	Lavert
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	001	Chinese Patent Application No. 2013800135500 First Office Action dated October 20, 2015.	☒
	002	International preliminary report on patentability dated 07/29/2014 for PCT/US2013/023370.	☐
	003	International search report dated 12/10/2013 for PCT/US2013/057576.	☐
	004	PCT/US2014/054414 International Preliminary Report on Patentability mailed March 17, 2016.	☐
	005	U.S. Patent Application No. 13/964,490 Office Action dated December 21, 2015	☐

Examiner Signature	/Nicole Lavert/	Date Considered	06/07/2016

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.L./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14730122	GOPALAKRISHNAN ET AL.
	Examiner	Art Unit
	NICOLE F LAVERT	3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner
A61B5/02405	2/17/2016	NFL
ABOVE UPDATED	6/7/2016	NFL

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	508-509	2/17/2016	NFL
ABOVE	UPDATED	6/7/2016	NFL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Search (eDAN)	2/17/2016	NFL
EAST Search (see attachment)		
Consulted Search notes from 14/569513		

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2908	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:09
L6	5031	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:12
L7	4046	a61b5/02405.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:12
L9	3	"20120197148"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/06/07 21:30
S1	2755	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:05
S2	4833	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:07
S3	2551	(heart same "HRV")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S4	620	S3 and ((score or value) same 'HRV')	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S5	269	S4 and arrhythmia	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:14
S6	3396	a61b5/02405.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:16
S7	161	S5 and @py<="2012"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 02:16
S8	2	"20120197148" and external	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 09:47
S9	2	"20120197148" and (display and algorithm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 10:11
S10	2	"20120197148" and screen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/09/30 10:13
S11	2846	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/02/17 09:59
S12	3	"20120197148"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2016/02/18 17:17

			IBM_TDB			
S13	2	S12 and motion	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/02/18 17:17

6/7/2016 9:39:19 PM
C:\Users\nlavert\Documents\EAST\Workspaces\14730122.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/730,122	06/03/2015	Ravi GOPALAKRISHNAN	41188-720.301

CONFIRMATION NO. 2113

21971
WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

POA ACCEPTANCE LETTER

OC000000083366867

Date Mailed: 06/03/2016

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/23/2016.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/zabraha/

PATENT
Attorney Docket No.: 41188-720.301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Inventor(s): Ravi GOPALAKRISHNAN, et al. Serial No.: 14/730,122 Filed: June 3, 2015 Title: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	Group Art Unit: 3762 Examiner: LAVERT, NICOLE F. Confirmation No.: 2113 Customer No.: 21971 Certificate of Electronic Filing I hereby certify that the attached Response to Non-Final Office Action is being deposited by Electronic Filing on 5/23/2016, by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: /Lora Kim/ Lora Kim

M/S AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION DATED FEBRUARY 24, 2016

Dear Commissioner:

Applicants hereby submit a response to the Office Action dated February 24, 2016. This Response is being filed within the three-month statutory period for reply. Therefore, this response is timely filed and no fee should be due. The Commissioner is hereby authorized to charge any additional fees due to Deposit Account No. 23-2415, referencing Docket No. 41188-720.301. Consideration of the above-referenced application is respectfully requested in view of the following remarks.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings in the above-referenced patent application. The foregoing amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not so be construed. No new matter is added with the amendments made herein. Applicant reserves the right to pursue the subject matter of the canceled subject matter in this or any other appropriate patent application. Deletions are denoted by ~~strikethrough~~ and additions are denoted by underline.

Listing of the Claims:

1. (Currently amended) A method of determining a presence of an arrhythmia of a first user, said method comprising

   sensing a heart rate of said first user with a heart rate sensor coupled to said first user;

   transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;

   determining, using said mobile computing device, a heart rate variability of said first user based on said ~~transmitted~~ heart rate of said first user; and

   alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability.
2. (Original) The method of claim 1, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.
3. (Original) The method of claim 1, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.
4. (Original) The method claim 3, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.

5. (Original) The method of claim 1, further comprising sensing an activity level of said first user with a motion sensor and comparing, using said mobile computing device, said heart rate variability of said first user to said activity level.
6. (Original) The method of claim 5, wherein said mobile computing device comprises a smartphone.
7. (Original) The method of claim 5, wherein said mobile computing device comprises a smartwatch.
8. (Original) The method of claim 1, further comprises determining a presence of said arrhythmia using a machine learning algorithm.
9. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
10. (Original) The method of claim 8, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.
11. (Original) A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user;

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, determine a heart rate variability of said first user based on said heart rate of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

12. (Original) The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

13. (Original) The system of claim 11, wherein said system further comprises a biometric data sensor, and wherein said computer program including instructions executable by said processor further causes said processor to sense biometric data of said first user from said biometric data sensor.
14. (Original) The system claim 13, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.
15. (Original) The system of claim 11, wherein said system further comprises a motion sensor, and wherein said computer program including instructions executable by said processor further causes said processor to sense an activity level of said first user from said motion sensor and compare said activity level to said heart rate variability of said first user.
16. (Original) The system of claim 15, wherein said mobile computing device comprises a smartphone.
17. (Original) The system of claim 15, wherein said mobile computing device comprises a smartwatch.
18. (Original) The system of claim 11, further comprises determining a presence of said arrhythmia using a machine learning algorithm.
19. (Original) The system of claim 18, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.
20. (Original) The system of claim 19, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.

REMARKS

Claims 1-20 were previously pending. Claim 1 is amended herein and support for which is found in the originally filed claims as well as through the specification as filed. Thus, no matter is added. Applicants respectfully request reconsideration of the claims as amended in view of the following arguments.

Claim Rejections – 35 U.S.C. § 102

Claims 1-20 were rejected under 35 U.S.C. § 102(a)(2) as being allegedly anticipated by Levitan, et al. (US 2012/0197148). Applicants traverse this rejection due to at least the following.

Levitan describes a method for determining an HRV value from an electrocardiogram waveform. *See* Levitan, para. [0055]-[0056]. However, Applicants respectfully argue point out that Levitan ***does not*** describe all of the recited features of independent claims 1 and 11.

First, Levitan does not describe receiving heart rate information from a heart rate sensor ***and*** determining a heart rate variability value ***based on the user's heart rate*** as recited by claims 1 and 11. Rather, to the extent that Levitan determines an HRV value at all, it is in response to the recording of an electrocardiogram rather than based on heart rate information. *See* Levitan, Figs. 1-5, and para. [0058]-[0059]. Specifically, Levitan utilizes mathematical models in combination with statistical analysis to determine an HRV value from a two dimensional electrocardiogram waveform. *See* Levitan, para. [0059]. Nowhere does Levitan reference determining ***heart rate information*** from an electrocardiogram, and thus Levitan does not describe determining a heart rate variability value based heart rate information. In contrast, claims 1 and 11 of the instant application recite that a heart rate variability value ***is determined, using said mobile computing device, based on said heart rate of said user***.

Second, Levitan does not describe that ***the user is alerted to sense an electrocardiogram in response to a determined heart rate variability value*** as recited by claims 1 and 11. Rather, to the extent that Levitan describes determining an HRV value, Levitan describes the ***opposite*** of the recited features of claims 1 and 11. Namely, Levitan describes the determination ***of an heart***

rate variability value in response to a sensed electrocardiogram. *See* Levitan, para. [0055]-[0056], [0058]-[0059]. Levitan describes determining an HRV value based on an electrocardiogram, rather than sensing an electrocardiogram in response to an HRV value, as is recited by claims 1 and 11.

Because Levitan does not describe each and every feature of amended claims 1 and 11, a rejection under 35 U.S.C. § 102(a)(2) cannot be maintained. Applicants, therefore, respectfully request withdrawal of this rejection with allowance of claims 1 and 11 along with claims 2-10 and 12-20 that respectively depend therefrom.

Double Patenting Rejections

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over Claims 21-37 and 69-72 of co-pending U.S. Application No. 14/569,513 (Attorney Docket No. 41188-720.201). Without agreeing to or acquiescing in this ground of rejection, Applicants respectfully submit a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321 with respect to U.S. 14/569,513. This Terminal Disclaimer obviates the present rejection. Accordingly, Applicants request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned attorney at (858) 350-2365.

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 23-2415, referencing Attorney Docket No. 41188-720.301.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
A Professional Corporation

Date: May 23, 2016 By: /Uri Greenwald/
Uri Greenwald, MD, Esq.
Reg. No. 72686

650 Page Mill Road
Palo Alto, CA 94304
(858) 350-2300
Customer No. 21971

PTO/AIA/80 (07-12)
Approved for use through 11/30/2014. OMB 0651-0035
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

☒ Practitioners associated with Customer Number: 021971

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☒ The address associated with Customer Number: 021971

OR

☐

Firm or Individual Name		
Address		
City		
Country		
Telephone		Email

Assignee
AliveCor, Inc.
30 Maiden Lane, Suite 600
San Francisco, CA 94108

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record
The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date
Name	Ravi Gopalakrishnan	Telephone
Title	Chief Technical Officer	

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

6517981_1.doc

Electronic Patent Application Fee Transmittal	
Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald/Lora kim
Attorney Docket Number:	41188-720.301
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt	
EFS ID:	25861994
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald/Lora kim
Filer Authorized By:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Receipt Date:	23-MAY-2016
Filing Date:	03-JUN-2015
Time Stamp:	21:33:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$160
RAM confirmation Number	6801
Deposit Account	232415
Authorized User	KIM, LORA
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		41188_720301_Response_NFOA_MAY232016.pdf	49270 32309e0805e702dbc28ad5c0c078d763accf6247	yes	7
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	4	
	Applicant Arguments/Remarks Made in an Amendment		5	7	
Warnings:					
Information:					
2	Terminal Disclaimer Filed	41188_720301_TD_US14569513_MAY232016.pdf	290799 79bfff9fa3e005cd4040eda9aa809bf792587592	no	2
Warnings:					
Information:					
3	Assignee showing of ownership per 37 CFR 3.73	41188_720301_Statement373c_CopyOfAssignmentFrom720201.pdf	7526148 31552a0c1ca54f8549509e2d5d9f350a9d31e3f8	no	21
Warnings:					
Information:					
4	Power of Attorney	AliveCor41188_POA.pdf	90185 8ae00b878f304eec7c226fe9fd09a519b21f18fe	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30518 ea5d8f1ace8257d0aaf3b1aa84ed823eed9b65b1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7986920		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/25 (04-13)
Approved for use through 04/30/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) 41188-720.301

In re Application of: Ravi GOPALAKRISHNAN, et al.

Application No.: 14/730,122

Filed: June 3, 2015

For: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

The applicant, AliveCor, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 14/569,513, filed, December 12, 2014, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent granted on the pending **reference** application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 72686

/Uri Greenwald/	May 23, 2016
Signature	Date
Uri Greenwald, MD, Esq.	
Typed or printed name	
Attorney of Record	(858) 350-2300
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Ravi GOPALAKRISHNAN, et al.

Application No./Patent No.: 14/730,122 Filed/Issue Date: June 3, 2015

Titled: METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

AliveCor, Inc., a Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. [✓] The assignee of the entire right, title, and interest.

2. [ ] An assignee of less than the entire right, title, and interest (check applicable box):

   [ ] The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   [ ] There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. [ ] The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. [ ] The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. [✓] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Uri Greenwald/	May 23, 2016
Signature	Date
Uri Greenwald, MD, Esq.	72686
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s))," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____
Ravi GOPALAKRISHNAN

Date: _____
Lev KORZINOV

Date: _____
Lei WANG

Date: _____
Euan THOMSON

Date: _____
Nupur SRIVASTAVA

Date: _____
Omar DAWOOD

Date: _____
Iman ARUZHD

Date: 6-8-15
David E. Albert
David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s))," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below

Date: 7/28/15	Ravi GOPALAKRISHNAN	Date:	Lev KORZINOV
Date:	Fei WANG	Date:	Euan THOMSON
Date:	Nupur SRIVASTAVA	Date:	Omar DAWOOD
Date:	Imad ABUZEID	Date:	David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s)," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____	_____ Ravi GOPALAKRISHNAN	Date: _____	_____ Lev KORZINOV
Date: _____	_____ Fei WANG	Date: 8/4/15	_____ Euan THOMSON
Date: _____	_____ Nupur SRIVASTAVA	Date: _____	_____ Omar DAWOOD
Date: _____	_____ Iman ABUZEID	Date: _____	_____ David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s)," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____ _____
Ravi GOPALAKRISHNAN

Date: _____ _____
Lev KORZINOV

Date: August 6, 2015 _____
Fei WANG

Date: _____ _____
Euan THOMSON

Date: _____ _____
Nupur SRIVASTAVA

Date: _____ _____
Omar DAWOOD

Date: _____ _____
Iman ABUZEID

Date: _____ _____
David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s)," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____	_____ Ravi GOPALAKRISHNAN	Date: _____	_____ Lev KORZINOV
Date: _____	_____ Fei WANG	Date: _____	_____ Euan THOMSON
Date: _____	_____ Nupur SRIVASTAVA	Date: _____	_____ Omar DAWOOD
Date: August 11, 2015	_____ Iman ABUZEID	Date: _____	_____ David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Pei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s)," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____	_____ Ravi GOPALAKRISHNAN	Date: _____	_____ Lev KORZINOV
Date: _____	_____ Fei WANG	Date: _____	_____ Euan THOMSON
Date: 9/11/2013	_____ Nupur SRIVASTAVA	Date: _____	_____ Omar DAWOOD
Date: _____	_____ Iman ABUZEID	Date: _____	_____ David E. ALBERT

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

WHEREAS, the undersigned:

1. Ravi **GOPALAKRISHNAN**
   San Jose, CA, USA
2. Lev **KORZINOV**
   San Francisco, CA, USA
3. Fei **WANG**
   Fremont, CA, USA
4. Euan **THOMSON**
   San Francisco, CA, USA
5. Nupur **SRIVASTAVA**
   San Francisco, CA, USA
6. Omar **DAWOOD**
   San Francisco, CA, USA
7. Iman **ABUZEID**
   San Francisco, CA, USA
8. David E. **ALBERT**
   San Francisco, CA, USA

(hereinafter "Inventor(s)," have invented certain new and useful improvements in

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

☐ for which a United States patent application is executed on even date herewith;
☒ for which Application No. 14/569,513 was filed on December 12, 2014 in the United States Patent Office;
☒ for which Application No. PCT/US2014/070170 was filed on December 12, 2014 in the U.S. Receiving Office of the Patent Cooperation Treaty;
☐ for which Application No. _____ was filed on _____ in the _____ Patent Office; and/or
☐ for which an application was filed upon which a United States Patent issued on _____, as U.S. Patent No. _____
(hereinafter "Application(s)").

WHEREAS, AliveCor, Inc., a Delaware corporation, having a place of business at 30 Maiden Ln., San Francisco, CA 94108 U.S.A., (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said Application(s) and the inventions disclosed therein, and in and to all embodiments of the inventions, heretofore conceived, made or discovered, whether jointly or severally, by said Inventor(s) (hereinafter collectively referred to as "Inventions"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter "Patent(s)") thereon granted in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventor(s) to have been received in full from said Assignee:

1. Said Inventor(s) do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said Inventions and Applications, including the right to claim priority to said Inventions and said Applications; (b) in and to all rights to all United States and corresponding non-United States patent applications and Patent(s), including those filed under the Paris Convention for the Protection of Industrial Property, The Patent Cooperation Treaty or otherwise; (c) in and to any and all applications filed and any and all Patent(s) granted on said Inventions in the United States, in any foreign country, or under any international convention, agreement, protocol, or treaty, including each and every application filed and any and all Patent(s) granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said Application(s); (d) in and to each and every reissue, reexamination, or extensions of any of said Patent(s); and (e) in and to all claims for past, present and future infringement of the Patent(s), including all rights to sue for and to receive and recover for Assignee's own use all past, present, and future lost profits, royalties, and damages of whatever nature recoverable from an infringement of the Patent(s).

2. Said Inventor(s) hereby covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty. Such cooperation by said Inventor(s) shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any applications covering said Inventions; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said Inventions; (d) for filing and prosecuting applications for reissuance of any said Patent(s); (e) for interference or other priority proceedings involving said Inventions; and (f) for legal proceedings involving said Inventions and any applications therefor and any Patent(s) granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventor(s) in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventor(s), their respective heirs, legal representatives and assigns.

4. Said Inventor(s) hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

5. Said Inventor(s) hereby request that any Patent(s) issuing in the United States, foreign countries, or under any international convention, agreement, protocol, or treaty, be issued in the name of the Assignee, or its successors and assigns, for the sole use of said

PATENT ASSIGNMENT	Docket Number 41188-720.201 41188-720.601

Assignee, its successors, legal representatives and assigns.

6. This instrument will be interpreted and construed in accordance with the laws of the State of California, without regard to conflict of law principles. If any provision of this instrument is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law. This instrument may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement.

IN WITNESS WHEREOF, said Inventor(s) have executed and delivered this instrument to said Assignee as of the dates written below:

Date: _____
Ravi GOPALAKRISHNAN

Date: 12/31/2015
Lev KORZINOV

Date: _____
Fei WANG

Date: _____
Euan THOMSON

Date: _____
Nupur SRIVASTAVA

Date: _____
Omar DAWOOD

Date: _____
Iman ABUZEID

Date: _____
David E. ALBERT

ALIVECOR, INC.

INDEPENDENT CONTRACTOR AGREEMENT

This Independent Contractor Agreement is made and entered into as of August 19th, 2013 ("**Effective Date**") between AliveCor, Inc., a Delaware corporation ("**Company**"), and Omar Dawood ("**Contractor**"). In consideration of the mutual promises contained in this Agreement, the parties agree as follows:

1. SERVICES AND COMPENSATION

1.1 Services. Subject to the terms and conditions of this Agreement and at Company's request and direction, Contractor will perform for Company the services ("**Services**") described in **Exhibit A** during the term of this Agreement.

1.2 Compensation. As consideration for Contractor's proper performance of the Services, Company will pay Contractor the compensation set forth in **Exhibit A**.

2. TERM AND TERMINATION

2.1 Term. This Agreement commences on the Effective Date and will continue until the earlier of (a) December 20th, 2013 or (b) termination as provided below.

2.2 Termination. Company may terminate this Agreement by giving two weeks prior written notice to Contractor. Company may terminate this Agreement immediately and without prior notice if Contractor refuses to or is unable to perform the Services, is in breach of any material provision of this Agreement, or Company is dissatisfied with the quality of Contractor's work.

2.3 Survival. Upon termination, all rights and duties of the parties toward each other cease except that:

(a) Within 30 days of the effective date of termination, Company will pay all amounts owing to Contractor for Services or Contractor will return to Company any amount paid to Contractor as a retainer that is not owed against Services; and

(b) Sections 2, 3, 4, 5, 6, 7, 8, and 10 survive termination of this Agreement.

2.4 Return of Materials. Upon the termination of this Agreement, or upon Company's earlier request, Contractor will deliver to Company all of Company's property and Confidential Information (as defined in Section 3.1) that is in Contractor's possession or control.

3. CONFIDENTIALITY

3.1 Definition. "**Confidential Information**" means any non-public information that relates to the actual or anticipated business, research, or development of Company and any proprietary information, trade secrets, and know-how of Company that is disclosed to Contractor by Company, directly or indirectly, in writing, orally, or by inspection or observation of tangible items. Confidential Information includes, but is not limited to, research, product plans, products, services, customer lists, development plans, inventions, processes, formulas, technology, designs, drawings, marketing, finances, and other business information. Confidential Information is the sole property of Company.

3.2 Exceptions. Confidential Information does not include any information that: (a) was publicly known and made generally available in the public domain prior to the time Company disclosed the information to Contractor, (b) became publicly known and made generally available, after disclosure to Contractor by Company, through no wrongful action or inaction of Contractor or others who were under confidentiality obligations, or (c) was in Contractor's possession, without confidentiality restrictions, at the time of disclosure by Company, as shown by Contractor's files and records.

3.3 Nondisclosure and Nonuse. Contractor will not, during and after the term of this Agreement, disclose the Confidential Information to any third party or use the Confidential Information for any purpose other than the performance of the Services on behalf of Company. Contractor will take all reasonable precautions to prevent any unauthorized disclosure of the Confidential Information including, but not limited to, having each employee of Contractor, if any, with access to any Confidential Information, execute a nondisclosure agreement containing terms that are substantially similar to the terms contained in this Agreement.

3.4 Former Client Confidential Information. Contractor will not improperly use or disclose any proprietary information or trade secrets of any former or concurrent client of Contractor or other person or entity. Furthermore, Contractor will not bring onto the premises of the Company any unpublished document or proprietary information belonging to any client, person, or entity unless consented to in writing by the client, person, or entity.

3.5 Third Party Confidential Information. Company has received, and in the future will receive, from third parties confidential or proprietary information subject to a duty on Company's part to maintain the confidentiality of the information and to use it only for certain limited purposes. Contractor owes Company and these third parties, during and after the term of this Agreement, a duty to hold this confidential and proprietary information in the strictest confidence and not to disclose it to any person or entity, or to use it except as necessary in carrying out the Services for Company consistent with Company's agreements with these third parties.

4. OWNERSHIP

4.1 Assignment. All works of authorship, designs, inventions, improvements, technology, developments, discoveries, and trade secrets conceived, made, or discovered by Contractor during the period of this Agreement, solely or in collaboration with others, that relate in any manner to the business of Company (collectively, "**Inventions**") will be the sole property of Company. In addition, Inventions that constitute copyrightable subject matter will be considered "works made for hire" as that term is defined in the United States Copyright Act. To the extent that ownership of the Inventions does not by operation of law vest in Company, Contractor will assign (or cause to be assigned) and does hereby assign fully to Company all right, title, and interest in and to the Inventions, including all related intellectual property rights.

4.2 Further Assurances. Contractor will assist Company and its designees in every proper way to secure Company's rights in the Inventions and related intellectual property rights in all countries. Contractor will disclose to Company all pertinent information and data with respect to Inventions and related intellectual property rights. Contractor will execute all applications, specifications, oaths, assignments, and other instruments that Company deems necessary in order to apply for and obtain these rights and in order to assign and convey to Company, its successors, assigns, and nominees the sole and exclusive right, title, and interest in and to these Inventions, and any related intellectual property rights. Contractor's obligation to provide assistance will continue after the termination or expiration of this Agreement.

4.3 Pre-Existing Materials. If in the course of performing the Services, Contractor incorporates into any Invention any other work of authorship, invention, improvement, or proprietary information, or other materials owned by Contractor or in which Contractor has an interest, Contractor will grant and does now grant to Company a nonexclusive, royalty-free, perpetual, irrevocable, worldwide license to reproduce, manufacture, modify, distribute, use, import, and otherwise exploit the material as part of or in connection with the Invention.

4.4 Attorney-in-Fact. If Contractor's unavailability or any other factor prevents Company from pursuing or applying for any application for any United States or foreign registrations or applications covering the Inventions and related intellectual property rights assigned to Company, then Contractor irrevocably designates

and appoints Company as Contractor's agent and attorney in fact. Accordingly, Company may act for and in Contractor's behalf and stead to execute and file any applications and to do all other lawfully permitted acts to further the prosecution and issuance of the registrations and applications with the same legal force and effect as if executed by Contractor.

5. CONTRACTOR'S WARRANTIES

As an inducement to Company entering into and consummating this Agreement, Contractor represents, warrants, and covenants as follows:

5.1 Organization Representations; Enforceability. If Contractor is a company, (a) Contractor is duly organized, validly existing, and in good standing in the jurisdiction stated in the preamble to this Agreement, (b) the execution and delivery of this Agreement by Contractor and the transactions contemplated hereby have been duly and validly authorized by all necessary action on the part of Contractor, and (c) this Agreement constitutes a valid and binding obligation of Contractor that is enforceable in accordance with its terms.

5.2 Compliance with Company Policies. Contractor will perform the Services in accordance with all policies and procedures provided by Company, including any third party policies and procedures that Company is required to comply with.

5.3 No Conflict. The entering into and performance of this Agreement by Contractor does not and will not: (a) violate, conflict with, or result in a material default under any other contract, agreement, indenture, decree, judgment, undertaking, conveyance, lien, or encumbrance to which Contractor is a party or by which it or any of Contractor's property is or may become subject or bound, or (b) violate any applicable law or government regulation. Contractor will not grant any rights under any future agreement, nor will it permit or suffer any lien, obligation, or encumbrances that will conflict with the full enjoyment by Company of its rights under this Agreement.

5.4 Right to Make Full Grant. Contractor has and will have all requisite ownership, rights, and licenses to fully perform its obligations under this Agreement and to grant to Company all rights with respect to the Inventions and related intellectual property rights to be granted under this Agreement, free and clear of any and all agreements, liens, adverse claims, encumbrances, and interests of any person or entity, including, without limitation, Contractor's employees, agents, artists, and contractors and their contractors' employees, agents, and artists, who have provided, are providing, or will provide services with respect to the development of the Inventions.

5.5 Pre-existing Works and Third Party Materials. Contractor will not, without Company's prior written consent, incorporate any pre-existing works or third party materials into the Inventions. Additionally, Contractor has the right to assign and transfer rights to pre-existing works and third party materials as specified in this Agreement.

5.6 Noninfringement. Nothing contained in the Inventions or required in order for Contractor to create and deliver the Inventions under this Agreement does or will infringe, violate, or misappropriate any intellectual property rights of any third party. Further, no characteristic of any Invention does or will cause manufacturing, using, maintaining, or selling the Invention to infringe, violate, or misappropriate the intellectual property rights of any third party.

5.7 No Pending or Current Litigation. Contractor is not involved in litigation, arbitration, or any other claim and knows of no pending litigation, arbitration, other claim, or fact that may be the basis of any claim regarding any of the materials Contractor has used or will use to develop or has incorporated or will incorporate into the Inventions to be delivered under this Agreement.

5.8 No Harmful Content. The Inventions as delivered by Contractor to Company will not contain matter that is injurious to end-users or their property, or which is scandalous, libelous, obscene, an invasion of privacy, or otherwise unlawful or tortious.

5.9 Inspection and Testing of Inventions. Prior to delivery to Company, Contractor will inspect and test each Invention and the media upon which it is to be delivered, if applicable, to ensure that the Invention and media contain no computer viruses, booby traps, time bombs, or other programming designed to interfere with the normal functioning of the Invention or Company's or an end-user's equipment, programs, or data.

5.10 Services. The Services will be performed in a timely, competent, professional, and workmanlike manner by qualified personnel.

6. INDEMNIFICATION

6.1 Indemnification. Contractor will indemnify, defend, and hold harmless Company and its directors, officers, and employees from and against all taxes, losses, damages, liabilities, costs, and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with: (a) any negligent, reckless, or intentionally wrongful act of Contractor or Contractor's assistants, employees, or agents, (b) any breach by Contractor or Contractor's assistants, employees, or agents of any of the covenants, warranties, or representations contained in this Agreement, (c) any failure of Contractor to perform the Services in accordance with all applicable laws, rules, and regulations, or (d) any violation or claimed violation of a third party's rights resulting in whole or in part from Company's use of the work product of Contractor under this Agreement.

6.2 Intellectual Property Infringement. In the event of any claim concerning the intellectual property rights of a third party that would prevent or limit Company's use of the Inventions, Contractor will, in addition to its obligations under Section 6.1, take one of the following actions at its sole expense:

(a) procure for Company the right to continue use of the Invention or infringing part thereof; or

(b) modify or amend the Invention or infringing part thereof, or replace the Invention or infringing part thereof with another Invention having substantially the same or better capabilities.

7. NONSOLICITATION

To the fullest extent permitted under applicable law, from the date of this Agreement until 12 months after the termination of this Agreement for any reason Contractor will not, without Company's prior written consent, directly or indirectly, solicit any of Company's employees to leave their employment, or attempt to solicit employees of Company, either for Contractor or for any other person or entity. Contractor agrees that nothing in this Article 7 shall affect Contractor's continuing obligations under this Agreement during and after this 12 month period, including, without limitation, Contractor's obligations under Section 3.

8. ARBITRATION AND EQUITABLE RELIEF

8.1 Arbitration. Except as provided in Section 8.3 below, any dispute or controversy arising out of, relating to, or concerning any interpretation, construction, performance, or breach of this Agreement, will be settled by arbitration to be held in San Francisco, California, in accordance with the rules then in effect of the American Arbitration Association. The arbitrator may grant injunctions or other relief in the dispute or controversy. The decision of the arbitrator will be final, conclusive, and binding on the parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court having jurisdiction. Company and Contractor will each pay one-half of the costs and expenses of the arbitration, and each will separately pay their own counsel fees and expenses.

8.2 Waiver or Right to Jury Trial. This arbitration clause **constitutes a waiver of Contractor's right to a jury trial** for all disputes relating to all aspects of the independent contractor relationship (except as provided in Section 8.3 below), including, but not limited to, the following claims:

(a) claims, both express and implied, for breach of contract, breach of the covenant of good faith and fair dealing, negligent or intentional infliction of emotional distress, negligent or intentional misrepresentation, negligent or intentional interference with contract or prospective economic advantage, and defamation;

(b) any and all claims for violation of any federal, state, or municipal statute.

8.3 Equitable Remedies. The parties may apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other interim or conservatory relief, as necessary, without breach of this Agreement and without abridgement of the powers of the arbitrator.

8.4 Consideration. Each party's promise to resolve claims by arbitration in accordance with the provisions of this Agreement, rather than through the courts, is consideration for the other party's like promise.

9. INDEPENDENT CONTRACTOR; BENEFITS

9.1 Independent Contractor. It is the express intention of the parties that Contractor perform the Services as an independent contractor. Nothing in this Agreement will in any way be construed to constitute Contractor as an agent, employee, or representative of Company. Without limiting the generality of the foregoing, Contractor is not authorized to bind Company to any liability or obligation or to represent that Contractor has any authority. Contractor must furnish (or reimburse Company for) all tools and materials necessary to accomplish this contract, and will incur all expenses associated with performance, except as expressly provided for in **Exhibit A**. Contractor is obligated to report as income all compensation received by Contractor under this Agreement, and to pay all self-employment and other taxes thereon. Contractor will indemnify and hold Company harmless to the extent of any obligation imposed on Company (a) to pay in withholding taxes or similar items or (b) resulting from a determination that Contractor is not an independent contractor.

9.2 Benefits. Contractor acknowledges that Contractor's employees will not receive benefits from Company either as a Contractor or employee, including without limitation paid vacation, sick leave, medical insurance, and 401(k) participation. If a Contractor employee is reclassified by a state or federal agency or court as an employee of Company, Contractor's employee will become a reclassified employee and will receive no benefits except those mandated by state or federal law, even if by the terms of Company's benefit plans in effect at the time of the reclassification Contractor's employee would otherwise be eligible for benefits.

10. MISCELLANEOUS

10.1 Services and Information Prior to Effective Date. All services performed by Contractor and all information and other materials disclosed between the parties prior to the Effective Date will be governed by the terms of this Agreement, except where the services are covered by a separate agreement between Contractor and Company.

10.2 Nonassignment and No Subcontractors. Neither this Agreement nor any rights under this Agreement may be assigned or otherwise transferred by Contractor, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of Company. Contractor may not utilize a subcontractor or other third party to perform its duties under this Agreement without the prior written consent of Company. Subject to the foregoing, this Agreement will be binding upon and will inure to the benefit of the parties and their respective successors and assigns. Any assignment in violation of the foregoing will be null and void.

10.3 Notices. Any notice required or permitted under the terms of this Agreement or required by law must be in writing and must be: (a) delivered in person, (b) sent by first class registered mail, or air mail, as appropriate, or (c) sent by overnight air courier, in each case properly posted and fully prepaid to the appropriate address as set forth below. Either party may change its address for notices by notice to the other party given in accordance with this Section. Notices will be deemed given at the time of actual delivery in person, three business days after deposit in the mail as set forth above, or one day after delivery to an overnight air courier service.

10.4 Waiver. Any waiver of the provisions of this Agreement or of a party's rights or remedies under this Agreement must be in writing to be effective. Failure, neglect, or delay by a party to enforce the provisions of this Agreement or its rights or remedies at any time, will not be construed as a waiver of the party's rights under this Agreement and will not in any way affect the validity of the whole or any part of this Agreement or prejudice the party's right to take subsequent action. Exercise or enforcement by either party of any right or remedy under this Agreement will not preclude the enforcement by the party of any other right or remedy under this Agreement or that the party is entitled by law to enforce.

10.5 Severability. If any term, condition, or provision in this Agreement is found to be invalid, unlawful, or unenforceable to any extent, the parties will endeavor in good faith to agree to amendments that will preserve, as far as possible, the intentions expressed in this Agreement. If the parties fail to agree on an amendment, the invalid term, condition, or provision will be severed from the remaining terms, conditions, and provisions of this Agreement, which will continue to be valid and enforceable to the fullest extent permitted by law.

10.6 Confidentiality of Agreement. Contractor will not disclose any terms of this Agreement to any third party without the consent of Company, except as required by applicable laws.

10.7 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed to be an original and together will constitute one and the same agreement.

10.8 Governing Law. The internal laws of California, but not the choice of law rules, govern this Agreement.

10.9 Headings. Headings are used in this Agreement for reference only and will not be considered when interpreting this Agreement.

10.10 Integration. This Agreement and all exhibits contain the entire agreement of the parties with respect to the subject matter of this Agreement and supersede all previous communications, representations, understandings, and agreements, either oral or written, between the parties with respect to said subject matter. No terms, provisions, or conditions of any purchase order, acknowledgement, or other business form that either party may use in connection with the transactions contemplated by this Agreement will have any effect on the rights, duties, or obligations of the parties under, or otherwise modify, this Agreement, regardless of any failure of a receiving party to object to these terms, provisions, or conditions. This Agreement may not be amended, except by a writing signed by both parties.

"Company"

AliveCor, Inc.

Name: _____

Title: _____

Signature: _____

Address for Notice: _____

"Contractor"

Omar Dawood

Name: OMAR DAWOOD, M.D., M.P.H.

Title: Consultant

Signature: _____

Address for Notice: 425 1st St., Apt. 3801
San Francisco, CA 94105

EXHIBIT A

Services and Compensation

1. Contact. Contractor's principal contact with Company:

   Name: Euan Thomson

   Title: CEO

2. Services. Services include, but are not limited to, the following:

   To assist AliveCor with development of clinical programs with a specific focus on accelerating deployment of 10,000 devices, free of charge, to patients, physicians and other consumers

   To assist AliveCor with development of a clinical strategy for current and future products

   To identify current and future market opportunities and advise the management team on how best to optimize R&D to capitalize on those opportunities

   To assist the AliveCor team with development of educational materials for patients, physicians and other consumers

3. Compensation

(a) Company will pay Contractor $10,000 per month of services, and such amount shall be pro-rated for any partial month of services. Consultant agrees to devote at least ten full days per month to the Company for the rate provided, and any days worked less than ten full days, will result in an adjustment to the rate based upon ten full days as a month of services.

(b) Company will reimburse Contractor for all reasonable expenses incurred by Contractor in performing Services pursuant to this Agreement, if Contractor receives written consent from an authorized agent of Company prior to incurring the expenses and submits receipts for the expenses to Company in accordance with Company policy.

(c) As an additional incentive, upon Contractor achievement of the following objectives (i) Before December 15th, 2013 Contractor to have procured non-cancellable executed agreements for the deployment of 10,000 AliveCor devices and (ii) to have fully deployed 5,000 of the units in the field, Company will recommend at the first meeting of the Company's Board of Directors following December 15th, 2013 that the Company grant Contractor a nonqualified stock grant of 5,000 shares of the Company's Common Stock at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Company's Board of Directors. This stock grant shall be subject to the terms and conditions of the Company's Stock Option Plan and Stock Option Agreement.

(d) Every two weeks, Contractor will submit to Company a written invoice for Services and expenses. The statement will be subject to approval of the contact person listed above or other designated agent of Company.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/730,122	Filing Date 06/03/2015	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **05/23/2016**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	=	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/KATRINA . TURNER/

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/730,122	GOPALAKRISHNAN ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 23 May, 2016	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/PAMELA YOUNG/

Technology Center: PLRC

Telephone: _____

U.S. Patent and Trademark Office

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	GOPALAKRISHNAN
Art Unit	3762
Examiner Name	Lavert
Attorney Docket Number	41188-720.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	US-20150297134	10-22-2015	ALBERT; David E. et al.	
	002	US-20160071392	03-10-2016	HANKEY; Martha E. et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	001	CN-105338892-A	02-17-2016	ALIVECOR INC		☒
	002	EP-2986204-A1	02-24-2016	ALIVECOR INC [US]		☐
	003	WO-2014172451-A1	10-23-2014	ALIVECOR INC [US]		☐

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	14730122
Filing Date	06-03-2015
First Named Inventor	GOPALAKRISHNAN
Art Unit	3762
Examiner Name	Lavert
Attorney Docket Number	41188-720.301

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	001	Chinese Patent Application No. 2013800135500 First Office Action dated October 20, 2015.	☒
	002	International preliminary report on patentability dated 07/29/2014 for PCT/US2013/023370.	☐
	003	International search report dated 12/10/2013 for PCT/US2013/057576.	☐
	004	PCT/US2014/054414 International Preliminary Report on Patentability mailed March 17, 2016.	☐
	005	U.S. Patent Application No. 13/964,490 Office Action dated December 21, 2015	☐

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Electronic Patent Application Fee Transmittal	
Application Number:	14730122
Filing Date:	03-Jun-2015
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Filer:	Uri M. Greenwald
Attorney Docket Number:	41188-720.301
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt	
EFS ID:	25672138
Application Number:	14730122
International Application Number:	
Confirmation Number:	2113
Title of Invention:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING
First Named Inventor/Applicant Name:	Ravi GOPALAKRISHNAN
Customer Number:	21971
Filer:	Uri M. Greenwald
Filer Authorized By:	
Attorney Docket Number:	41188-720.301
Receipt Date:	03-MAY-2016
Filing Date:	03-JUN-2015
Time Stamp:	16:11:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	3018
Deposit Account	232415
Authorized User	GREENWALD, URI
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	CN105338892A_Trans.pdf	129881 eee227dcb31bb246668f3c26a938d7e63e895084	no	1
Warnings:					
Information:					
2	Foreign Reference	EP2986204A1.pdf	19546 1c514038f17c36cec8d529dcc59a11310ce19f42	no	1
Warnings:					
Information:					
3	Foreign Reference	WO14172451.pdf	1690614 55de86f47ebec3164f93981edab80517201ab553	no	36
Warnings:					
Information:					
4	Non Patent Literature	CN2015101501333680_OA_ENG_20OCT2015.pdf	67729 a95ef1b31961f02ed6e58884e17833750a1b8f40	no	3
Warnings:					
Information:					
5	Non Patent Literature	PCTUS2013023370_IPRP_29JUL2013.pdf	508465 56b2897907927c7ccc32170d57afdc19c2c5c8a8	no	11
Warnings:					
Information:					
6	Non Patent Literature	PCTUS2013057576_ISR_10DEC2013.pdf	149573 8faa93f96565d11b3fbc676d699213073a9d9905	no	3
Warnings:					
Information:					
7	Non Patent Literature	PCTUS2014054414_IPRP_17MAR2016.pdf	371502 ef383a969a1f653d5ee43e0601709695c75bb78b	no	7
Warnings:					
Information:					

8	Non Patent Literature	US13964490_OA_21DEC2015.pdf	446926 b619b6389be50518031f12edc7be3cdcd8f93fe8	no	12
Warnings:					
Information:					
9		41188_720_301.pdf	241806 62bf4dd41d612ae6b7125d055182ba4760d17dba	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	4	
	Information Disclosure Statement (IDS) Form (SB08)		5	6	
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	30630 9a3619b14b8628979d5981639aa98cc453d04511	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3656672		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer:
(11) Publication number: **EP 2 986 204 A0**
(11) Numéro de publication:

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum unter der Nummer:

WO 2014/172451 (Art. 153(3) EPÜ).

International application published by the World Intellectual Property Organization under number:

WO 2014/172451 (Art. 153(3) EPC).

Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle sous le numéro:

WO 2014/172451 (art. 153(3) CBE).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 October 2014 (23.10.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/172451 A1

(51) International Patent Classification:
A61B 5/0402 (2006.01) *A61B 5/0432* (2006.01)
A61B 5/0408 (2006.01) *A61B 5/044* (2006.01)

(21) International Application Number:
PCT/US2014/034350

(22) International Filing Date:
16 April 2014 (16.04.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/812,655 16 April 2013 (16.04.2013) US

(71) Applicant: **ALIVECOR, INC.** [US/US]; 30 Maiden Lane, Suite 600, San Francisco, CA 94108 (US).

(72) Inventor: **ALBERT, David, E.**; 800 Research Parkway, Suite 339, Oklahoma City, OK 73104 (US).

(74) Agent: **YUILL, Barbara, K.**; Dunlap Codding, PC, P.O. Box 16370, Oklahoma City, OK 73113-2370 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: TWO ELECTRODE APPARATUS AND METHODS FOR TWELVE LEAD ECG

(57) Abstract: Described herein are methods, apparatuses, and systems for heart monitoring of a patient. The heart monitoring system can be used to take an electrocardiogram (ECG) using only two electrodes. A handheld device can be used to sequentially measure the electrical signal between different positions on a patient's body. The electrical signals can be processed and analyzed to prepare an ECG for the patient, including a 12-lead ECG.

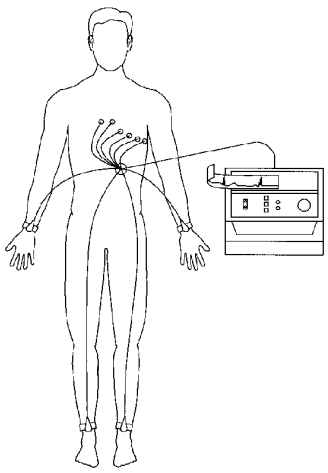


FIG. 1

WO 2014/172451 A1

TWO ELECTRODE APPARATUS AND METHODS FOR TWELVE LEAD ECG

CROSS REFERENCE TO RELATED APPLICATIONS/INCORPORATION BY REFERENCE STATEMENT

[0001] This application is a continuation-in-part of U.S. Ser. No. 13/108,738, filed May 16, 2011, which is a continuation-in-part of U.S. Ser. No 12/796,188, filed June 8, 2010, now U.S. Patent No. 8,509,882, each of which is hereby expressly incorporated herein by reference in its entirety. This application also claims priority to U.S. Provisional Application No. 61/812,655 filed on April 16, 2013 which is hereby expressly incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTIVE CONCEPTS

1. Field of the Inventive Concepts

[0002] The presently claimed and disclosed inventive concept(s) relates generally to heart monitoring devices and methods and, more particularly, but not by way of limitation, to devices, systems and software for generating and providing one or more 12-lead electrocardiograms utilizing only two electrodes.

2. Brief Description of Related Art

[0003] Electrocardiography has been used to study the electrical activity of the heart. Electrocardiograms (ECG) can be recorded or taken using electrodes placed on the skin of a patient. The electrical signals recorded between any two electrodes placed on the skin of the patient are referred to as "leads." Varying numbers of electrodes and leads can be used to take the ECG. Exemplary numbers of leads used conventionally for taking ECGs are 3, 5, and 12 leads. For a standard 12-lead ECG, ten electrodes are used with six electrodes positioned on the chest and one electrode on each of the patient's arms and legs.

[0004] FIG. 1 is a pictorial representation of the 10 electrodes of a conventional electrocardiograph being placed on the patient for obtaining a standard 12-lead ECG. The electrode placed on the right arm is commonly referred to as RA. The electrode placed on the left arm is referred to as LA. The RA and LA electrodes are placed at the same location on the left and right arms, preferably but not necessarily near the wrist. The leg electrodes can be referred to as RL for the right leg and LL for the left leg. The RL and LL electrodes are placed on the same location for the left and right legs, preferably but not necessarily near the ankle.

[0005] FIG. 2 illustrates the placement of the six electrodes on the chest in the prior art arrangement with such electrodes being labeled V_1, V_2, V_3, V_4, V_5, and V_6. V_1 is placed in the fourth intercostal space, for example between ribs 4 and 5, just to the right of the

sternum. V_2 is placed in the fourth intercostal space, for example between ribs 4 and 5, just to the left of the sternum. V_3 is placed in the fifth intercostal space midway between electrodes V_2 and V_4. V_4 is placed in the fifth intercostal space between ribs 5 and 6 on the left mid-clavicular line. V_5 is placed horizontally even with V_4 on the left anterior axillary line. V_6 is placed horizontally even with V_4 and V_5 on the left mid-axillary line.

[0006] The electrocardiograph then calculates and outputs three limb lead waveforms. Limb leads I, II, and III are bipolar leads having one positive and one negative pole. Lead I is the voltage between the left arm (LA) and right arm (RA), e.g. I = LA – RA. Lead II is the voltage between the left leg (LL) and right arm (RA), e.g. II = LL – RA. Lead III is the voltage between the left leg (LL) and left arm (LA), e.g. III = LL – LA. Leads I, II and III are commonly referred to as "limb leads."

[0007] Unipolar leads also have two poles; however, the negative pole is a composite pole made up of signals from multiple other electrodes. In a conventional cardiograph for obtaining a 12-lead ECG, all leads except the limb leads are unipolar (aVR, aVL, aVF, V_1, V_2, V_3, V_4, V_5, and V_6). Augmented limb leads (aVR, aVL, and aVF) view the heart from different angles (or vectors) and are determined from RA, RL, LL, and LA. For example, the augmented vector right (aVR) positions the positive electrode on the right arm, while the negative electrode is a combination of the left arm electrode and the left leg electrode, which "augments" the signal strength of the positive electrode on the right arm. Thus the augmented vector right (aVR) is equal to RA–(LA+LL)/2 or – (I+II)/2. The augmented vector left (aVL) is equal to LA–(RA+LL)/2 or (I–II)/2. The augmented vector foot (aVF) is equal to LL–(RA+LA)/2 or (II – I)/2.

[0008] The six electrodes on the chest of the patient are close enough to the heart that they do not require augmentation. A composite pole called Wilson's central terminal (often symbolized as CT_W, V_W, or WCT) is used as the negative terminal. Wilson's central terminal is produced by connecting the electrodes RA, LA, and LL together, via a simple resistive network, to give an average potential across the body, which approximates the potential at an infinite distance (i.e. zero). Wilson's central terminal, WCT, is calculated as (RA + LA + LL) / 3.

[0009] FIG. 3 illustrates an example Lead I annotated to show PQRST waves generated by a 12-lead electrocardiograph. The identification and measurement of the PQRST waves based on the electrocardiogram is known in the art. FIG. 4 illustrates an example of a 12-lead electrocardiogram in a conventional format.

[0010] While a conventional 12-lead electrocardiogram gives very useful information concerning the health and condition of an individual's heart, the conventional electrocardiograph equipment is expensive and the procedure is not normally available in

areas other than hospitals and medical doctors' offices. Therefore monitoring is not done frequently even in wealthy countries, and in poorer areas of the world an electrocardiograph may not even be available. To significantly reduce costs of obtaining an electrocardiogram, a 2-electrode electrocardiograph device as described in U.S. Patent No. 8,301,232 was marketed. The 2-electrode electrocardiograph device utilizes a smart phone connected to and at least partially surrounded by a phone protective case incorporating and supporting the two electrodes. Such devices significantly simplify and reduce the cost of obtaining an electrocardiogram, although such an electrocardiogram does not include as much information as a 12-lead electrocardiogram produced by an electrocardiograph having 10 electrodes. The 12-lead electrocardiogram produced by the 10-electrode electrocardiograph offers additional and important heart-related information to the cardiologist, allowing the diagnosis of conditions like heart attacks (myocardial infarctions) that a single-lead ECG cannot do. It would be advantageous if a readily available and inexpensive device could generate and produce an electrocardiogram that substantially replicates the 12-lead electrocardiogram produced by a 10-electrode electrocardiograph.

SUMMARY OF THE DISCLOSURE

[0011] In general, described herein are apparatuses, methods and systems for producing an electrocardiogram that substantially replicates the electrocardiogram produced by a 10-electrode electrocardiograph but using an electrocardiograph device having only two electrodes. In one embodiment, the electrocardiograph device has a first electrode assembly with a first electrode adapted to measure an electrical signal on a patient's body, and a second electrode assembly with a second electrode adapted to measure an electrical signal at another location on the patient's body. The electrocardiograph device also includes control circuitry configured to measure electrocardiogram signals between the first and second electrodes, and a data transmission module configured to transmit the measured electrocardiogram signals to a portable computing device by a wired or wireless transmission system and protocol such as, for example, those known in the art as USB, WI-FI®, BLUETOOTH®, NFC, or as audible or ultrasonic sound signals.

[0012] The electrocardiograph device can be used in combination with a portable computing device to form an electrocardiograph. The portable computing device is provided with computer hardware including a processor in communication with a non-transitory computer readable medium. The non-transitory computer readable medium stores software that includes instructions that when executed by the processor causes the processor to record the electrocardiogram signals between the first electrode and the second electrode while the first and second electrodes are sequentially placed in predetermined paired positions on a patient's body that are known by the processor. In one embodiment the

processor is caused to (a) calculate an average PQRST beat from the measured electrocardiogram signals as the first and second electrodes are sequentially placed in Limb Lead I, II, and III positions on a patient's body for a time required to measure at least one heartbeat in each Limb Lead position, the Limb Lead positions known by the processor; (b) use the relationship (Lead III = Lead II – Lead I) to time-align and display Limb Leads I, II, and III; and (c) calculate and display augmented Leads aVR, aVL, and aVF from the time-aligned Limb Leads I, II, and III.

[0013] The software can further include instructions that when executed by the processor causes the processor to calculate and display average time-aligned Leads V1, V2, and V3 from the measured electrocardiogram signals obtained from sequentially placing one of the first and second electrodes in a V1, V2, and V3 position while contacting the other of the first and second electrodes with a left arm of the patient for a time required to measure at least one heart beat (or more if an average beat is to be calculated). The processor is further caused to calculate and display average Leads V4, V5, and V6 from the measured electrocardiogram signals obtained from sequentially placing one of the first and second electrodes in a V4, V5, and V6 position while contacting the other of the first and second electrodes with a right arm of the patient for a time required to measure at least one heartbeat. The resulting 12-lead display and report replicated the 12-lead electrocardiogram produced by a 10-electrode electrocardiograph.

[0014] Methods are provided for generating a 12-lead electrocardiogram using an electrocardiograph comprising an electrocardiograph device and a portable computing device. The electrocardiograph device has a first electrode, a second electrode, control circuitry, and a data transmission module, the control circuitry configured to measure electrocardiogram signals between the first and second electrodes. In one embodiment, such a method includes directing, by the portable computing device, a user to place the first electrode and the second electrode at predetermined locations on a patient's body. The portable computing device receives and records location data indicative of the predetermined location on which the first electrode and the second electrode are placed. The control circuitry of the electrocardiograph device receives electrocardiogram signals from the first electrode and the second electrode, and the data transmission module of the electrocardiograph device transmits the electrocardiogram signals to the portable computing device. The portable computing device generates a 12-lead electrocardiogram from the sequentially measured electrocardiogram signals between the first and second electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a pictorial representation of a prior art electrocardiograph having 10 electrodes positioned on a patient's body for taking a prior art 12-lead electrocardiogram.

[0016] FIG. 2 is a pictorial representation of a chest showing an example of electrode placement on the chest for taking a prior art 12-lead electrocardiogram.

[0017] FIG. 3 illustrates an example Lead I annotated to show PQRST waves generated by a 12-lead electrocardiograph.

[0018] FIG. 4 shows an example 12-lead electrocardiogram in a conventional format.

[0019] FIG. 5A illustrates a front elevational view of one embodiment of an electrocardiograph constructed in accordance with the presently disclosed and claimed inventive concepts in which the electrocardiograph includes a two-electrode electrocardiograph device and a portable computing device.

[0020] FIG. 5B illustrates a rear elevational view of the electrocardiograph depicted in FIG. 5A.

[0021] FIG. 5C is a front elevational view of the electrocardiograph device depicted in FIG. 5A in which the electrocardiograph device has been removed from the portable computing device.

[0022] FIG. 5D is a cross-sectional view of the electrocardiograph device depicted in FIG. 5C and taken along the lines 5-5.

[0023] FIG. 6 another embodiment of a two-electrode electrocardiograph device configured in a pen-shape and constructed in accordance with the inventive concepts disclosed herein.

[0024] FIG. 7A-FIG. 7E illustrates an example sequential electrode placement used by the electrocardiograph to generate a 12-lead electrocardiogram in accordance with the presently disclosed inventive concepts.

[0025] FIG. 8 shows a correlation of V1 leads for Subject 35 of the Example Clinical Trials.

[0026] FIG. 9 shows an excellent correlation of leads 1-8 for Subject 35 in the Example Clinical Trials.

DETAILED DESCRIPTION

[0027] Before explaining at least one embodiment of the inventive concepts disclosed herein in detail, it is to be understood that the inventive concepts are not limited in their application to the details of construction, experiments, exemplary data, and/or the arrangement of the components set forth in the following description, or illustrated in the drawings. The presently disclosed and claimed inventive concepts are capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for purpose of description only and should not be regarded as limiting in any way.

[0028] In the following detailed description of embodiments of the inventive concepts, numerous specific details are set forth in order to provide a more thorough understanding of the inventive concepts. However, it will be apparent to one of ordinary skill in the art that the inventive concepts within the disclosure may be practiced without these specific details. In other instances, well-known features have not been described in detail to avoid unnecessarily complicating the instant disclosure.

[0029] Further, unless expressly stated to the contrary, "or" refers to an inclusive or and not to an exclusive or. For example, a condition A or B is satisfied by any one of the following: A is true (or present) and B is false (or not present), A is false (or not present) and B is true (or present), and both A and B are true (or present).

[0030] In addition, use of the "a" or "an" are employed to describe elements and components of the embodiments herein. This is done merely for convenience and to give a general sense of the inventive concepts. This description should be read to include one or at least one and the singular also includes the plural unless it is obvious that it is meant otherwise.

[0031] Finally, as used herein, any reference to "one embodiment" or "an embodiment" means that a particular element, feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. The appearances of the phrase "in one embodiment" in various places in the specification are not necessarily all referring to the same embodiment.

[0032] The term "lead" in electrocardiography causes much confusion because it can be used to refer to two different things. In accordance with common usage, the word "lead" may be used to refer to the electrical cable attaching the electrodes to the electrocardiograph. Alternatively, and as used herein, the word "lead" refers to the tracing of the voltage difference between at least two electrodes. Conventionally, 10 electrodes are used to produce twelve of this type of lead, thereby forming a "12-lead" electrocardiogram as exemplified in FIG. 4.

[0033] A "12-lead electrocardiogram format" is used herein and in the appending claims to refer to presentation of electrocardiogram signals from at least Lead I, Lead II, and V_1 through V_6 leads, and optionally Lead III, aVR, aVL and aVF, displayed over the span of at least one heartbeat using a uniform time scale.

[0034] The term "patient" as used herein includes humans and other warm-blooded animals, such as mammals, for example, dogs, cats, horses, and cattle or cold-blooded animals such as reptiles, and refers to the person or animal whose heart-related signals are being measured. The term "user" refers to the one applying the electrodes to the body to

measure the ECG. The user can be the same as the patient, or the user can be another such as, for example, a nurse, doctor, or veterinarian.

[0035] In general methods, devices, and systems are provided for measuring electrical signals on the body of a patient. Referring now to FIGS. 5A and 5B, shown therein is an exemplary embodiment of an electrocardiograph 8 constructed in accordance with the inventive concepts disclosed and claimed herein. The electrocardiograph 8 includes an electrocardiograph device 10 and a portable computing device 11. The electrocardiograph device 10 as discussed below is a two-electrode device; however, it should be understood that the electrocardiograph device 10 may include more than two electrodes. The electrocardiograph device 10 includes a first electrode assembly 12 having a first electrode 14, a second electrode assembly 16 having a second electrode 18, and a housing 20 containing control circuitry 22 and a data transmission module 24. The first electrode 14 and the second electrode 18 are adapted to measure an electrical signal on a patient's body. The control circuitry 22, can communicate with the first and second electrodes 14 and 18 via ports 23-1 and 23-2, respectively, and is configured to measure electrocardiogram signals between the first and second electrodes 14 and 18, respectively. The electrocardiogram signals can be analog signals indicative of the electrical potentials on a body surface of the patient that are associated with heart muscle activity. The ports 23-1 and 23-2 may be designed to receive analog signals, and may include two, three or four contacts. In some embodiments, the ports 23-1 and 23-2 are standard female connectors in which a three-contact version is known in the art as a TRS connector, where T stands for "tip", R stands for "ring" and S stands for "sleeve". Similarly, two- and four-contact versions are known in the art as TS and TRRS connectors respectively.

[0036] The data transmission module 24 is configured to receive the measured electrocardiogram signals and transmit the measured electrocardiogram signals to the portable computing device 11. The data transmission module 24 may transmit the measured electrocardiogram signals to the portable computing device 11 using a wired or wireless transmission system and protocol such as those known in the art as USB, WI-FI®, BLUETOOTH®, NFC, or as audible or ultrasonic sound signals.

[0037] While there can be multiple electrodes, in one embodiment there are only two. The first electrode assembly 12 can be configured in any way consistent with its function, i.e., it should include the first electrode 14 in a manner available to make contact with a patient's body on the hands, chest or other parts of the body, to measure an electrical signal for obtaining the patient's electrocardiogram. The first electrode assembly 12 can include a non-conductive hand-held portion 26 as well as the first electrode 14. By using only two electrodes, and sequentially measuring electrocardiogram signals at separate and distinct

instants of time as discussed below, a patient can easily measure his or her own electrocardiogram signals and produce a 12-lead electrocardiogram without the need to apply 10 electrodes and adhesives to the body as would be the case using a conventional electrocardiograph.

[0038] The second electrode assembly 16 can likewise be configured in any way consistent with its function. In one embodiment, the second electrode assembly 16 is configured to removably attach to an upper limb of the patient. For example, the electrocardiograph device 10 shown in FIGS. 5A and 5B includes a second electrode assembly 16 configured as a spring-hinged cuff. By allowing the second electrode assembly 16 to "grasp" the patient rather than the patient grasping an electrode, little or no electrical "noise" is created by the nerves and adjacent muscles holding the second electrode 18.

[0039] Other nonlimiting examples of suitable electrodes include suction cup electrodes, disposable snap electrodes, alligator clip electrode connectors with disposable electrodes, and any combination thereof.

[0040] The portable computing device 11 can be implemented as a personal computer, a smart phone, network-capable TV set, TV set-top box, a tablet, an e-book reader, a laptop computer, a desktop computer, a network-capable handheld device, a video game console, a server, and combinations thereof, for example. Preferably, the portable computing device 11 comprises an input device 30, an output device 32, and computer hardware 34 (which is shown in Phantom). The computer hardware 34 may be a system or systems that are able to embody and/or execute the logic of the processes described herein. Logic embodied in the form of software instructions and/or firmware may be executed on any appropriate hardware. For example, logic embodied in the form of software instructions or firmware may be executed on a dedicated system or systems, or on a personal computer system, or on a distributed processing computer system, and/or the like. In some embodiments, logic may be implemented in a stand-alone environment operating on a single computer system and/or logic may be implemented in a networked environment, such as a distributed system using multiple computers and/or processors. The computer hardware 34 of the portable computing device 11 may have a processor and a non-transitory computer readable medium. The term "processor" as used herein may include a single processor or multiple processors working independently and/or together to execute the logic described herein. Exemplary non-transitory computer readable medium may include random access memory, read only memory, flash memory, and combinations thereof. The term non-transitory computer readable medium, as used herein, may be implemented as a single physical device or multiple physical devices of a distributed system that may or may not be logically related.

[0041] The input device 30 is capable of receiving information input from a user, and transmitting such information to the computer hardware 34. The input device 30 can be implemented as a keyboard, a touchscreen, a mouse, a trackball, a microphone, a fingerprint reader, an infrared port, a slide-out keyboard, a flip-out keyboard, a cell phone, a PDA, a video game controller, a remote control, a fax machine, and combinations thereof, for example.

[0042] The output device 32 outputs information in a form perceivable by a user. For example, the output device 32 can be a computer monitor, a screen, a touchscreen, a speaker, a website, a TV set, a smart phone, a PDA, a cell phone, a fax machine, a printer, a laptop computer, and combinations thereof. It is to be understood that the input device 30 and the output device 32 may be implemented as a single device, such as for example a touchscreen of a smartphone or a tablet.

[0043] In one embodiment, the housing 20 is configured as a protective cover for the portable computing device 11. As shown in FIG. 5C and FIG. 5D, the housing 20 may be provided with a base 35 having a perimeter 36. The base 35 has an interior surface 38 and an opposing exterior surface 40. The housing 20 may also be provided with a rim 42 extending from the interior surface 38 and generally following the perimeter 36 of the base 35. The rim 42 and the interior surface 38 define a space 44 that is sized and adapted to receive the portable computing device 11. The ports 23A and 23B may be proximate to the exterior surface 40 so as to be available when the portable computing device 11 is positioned within the space 44. The base 35, in some embodiments, surrounds and supports the control circuitry 22 and the data transmission module 24. In this embodiment, the base 35 may include a pocket for receiving a power source 45, such as a battery, for powering the control circuitry 22 and the data transmission module 24 and may also include a door 46 proximate to the interior surface 38 for providing access to the pocket such that a user can install and/or replace the power source 45. In other embodiments, the power source 45 maybe a solar cell supported by the base 35 proximate to the exterior surface 40.

[0044] The housing 20 may be constructed as a single unit, or multiple units connected together. Exemplary materials forming the housing 20 include plastic, and/or a combination of plastic and elastomers.

[0045] In another embodiment that is shown in FIG. 6 and labeled by way of example with reference numeral 10-1, the electrocardiograph device combines the first and second electrodes 14 and 18 on opposing ends of a unit 50 shaped like a flash light or pen. For example, the electrocardiograph device 10-1 that is shown in FIG. 6 by way of example has a second electrode 18 on a cylindrical surface of one end of the "pen" touching a holder's hand in use. The first electrode 14 is located on an opposing end and is used to contact the

holder's chest, hand or other body part when in use. The electrocardiograph device 10-1 can thus be used to measure the electrical signals between the opposing first and second electrodes 14 and 18, respectively.

[0046] The devices and apparatuses disclosed herein can also be configured to use one or more disposable first and second electrodes 14 and 18, respectively, or first and second electrode assemblies 12 and 16, respectively. Use of disposable electrodes or disposable electrode assemblies allows the electrocardiograph device 10 or 10-1 to be used by multiple patients with reduced chance spreading disease by transfer of microbes and bodily fluids from one patient to another.

[0047] The first and second electrodes 14 and 18, respectively, can be connected to the control circuitry 22 in a wired or wireless manner. In one embodiment, and as shown in FIGS. 5A and 5B, the first and second electrodes 14 and 18, respectively, are electrically connected to the control circuitry 22 by the ports 23-1 and 23-2, and wires or cables.

[0048] The control circuitry 22 measures the small voltage between the first and second electrodes 14 and 18, respectively. In one embodiment, the data transmission module 24 converts the voltage measurements to a frequency modulated electrocardiogram audio signal and transmits the signal to a receiver of the computer hardware 34 of the portable computing device 11 via cable, a wired audio jack connection, wirelessly (using, for example, a BLUETOOTH® connection) or acoustically. The receiver of the portable computing device 11 can thus be a cable connection, audio jack, BLUETOOTH® or similar wireless receiver, or a microphone. In order to provide enhanced privacy, in one embodiment, the data transmission module 24 encrypts the signals prior to transmitting to the portable computing device 11. Numerous encryption techniques are known to those skilled in the art.

[0049] Nonlimiting examples of portable computing device 11 having, or adaptable to have, such receivers include smartphones, personal digital assistants (PDAs), tablet personal computers, pocket personal computers, notebook computers, desktop computers, and server computers. The receiver may include an antenna and/or a microphone depending upon the types of signals to be transmitted from the data transmission module 24.

[0050] In one embodiment, the electrocardiogram signals are converted to a frequency modulated audio or sound signal having a carrier frequency in a range of from about 1 kHz to about 24 kHz or greater and in this case the receiver of the computer hardware 34 will include a microphone. In another embodiment, the data transmission module 24 converts the electrocardiogram signals to a frequency modulated sound signal having a carrier frequency in a range of from about 18 kHz to about 24 kHz or greater. Nonlimiting examples of suitable ultrasonic transmitters include, but are not limited to, miniature speakers,

piezoelectric buzzers, and the like. The ultrasonic signals can be received by, for example, a microphone of the computer hardware 34 of the portable computing device 11.

[0051] Referring now to FIG. 7, a non-transitory computer readable medium of the computer hardware 34 stores a set of instructions, wherein the set of instructions are capable of being executed by the processor of the portable computing device 11. When the set of instructions are executed, the one or more portable computing device 11 is caused to receive and record electrocardiogram signals between the first electrode 14 and the second electrode 18, while the first and second electrodes 14 and 18, respectively, are sequentially placed in predetermined paired positions on a patient's body at separate and distinct instants of time, and held in each predetermined paired position for multiple heartbeats. The computing device essentially steps the user through the positioning each lead and can, for example, show a picture of a body on a computer screen with the desired electrode positioning indicated by a flashing point. The set of instructions further cause the portable computing device 11 to calculate the electrocardiogram signals into signal sets representing a heartbeat for each paired position, and from the signal sets representing a heartbeat, to calculate average heartbeat representations for each paired position. The set of instructions can then cause the portable computing device 11 to align the average heartbeat representations, and to store and output electrocardiogram data indicative of the average heartbeat representations in a standard 12-lead electrocardiogram format.

[0052] For example, ten seconds of each lead can be recorded and an average PQRST computed for each lead from each recording. The limb lead average beats (I, II, and III) can then be time-aligned. Augmented lead average beats are calculated from aligned average limb leads. The V1-V6 beats are averaged and aligned to create a 12-lead report from averaged beats.

[0053] The 12-lead electrocardiogram format output can display on the output device 32, such as a display screen of the portable computing device 11 or can be output through a printer. The set of instructions can cause the 12-lead electrocardiogram format output to be retained in a storage memory of the portable computing device 11, or to be transmitted to a computer external to the portable computing device 11, such as a web server via an internet connection on the portable computing device 11.

[0054] In one embodiment, the set of instructions can further cause the portable computing device 11 to digitize and demodulate the electrocardiogram signals using technology known to those skilled in the art or technology yet to be developed.

[0055] In another embodiment, when the set of instructions are executed, the portable computing device 11 is caused to interact with a user (e.g. via the output device 32) to provide audio and/or textual instructions to direct the placement of the first and second

electrodes 14 and 18, respectively, and/or to request the user to confirm placement of the first and second electrodes 14 and 18, respectfully via the input device 30. For example, the portable computing device 11 can be made to provide textual instructions to a user for contacting the first electrode 14 to the patient's left arm and the second electrode 18 to the patient's right arm on a display screen, after which the electrocardiograph device 10 or the electrocardiograph device 10-1 and the portable computing device 11 measures and records the electrical signal between the left arm and right arm for a suitable time interval to correspond to Lead I in a 12-lead ECG. The instructions can further cause the portable computing device 11 to calculate and store an average heartbeat representation for Lead I. A suitable time interval for obtaining heartbeat data for Lead I, and all leads generally, can be between 5 seconds and 30 seconds. Longer times are possible but not necessary.

[0056] The set of instructions can further cause the portable computing device 11 to provide instructions to a user, or request placement confirmation from a user, to collect the electrocardiogram data. For example, after the portable computing device 11 has stored the data for Lead I, the portable computing device 11 may provide instructions to the user, or request placement confirmation from the user regarding contacting the first electrode 14 to the patient's left leg and the second electrode 18 to the patient's right arm, wherein the electrical signal measured between the left leg and right arm corresponds to Lead II, and to calculate and store an average heartbeat representation for Lead II.

[0057] Similarly, the set of instructions can further cause the portable computing device 11 to provide instructions to a user, or request placement confirmation from a user, regarding contacting the first electrode 14 to the patient's left leg and the second electrode 18 to the patient's left arm, wherein the electrical signal measured between the left leg and the left arm corresponds to Lead III in a 12-lead electrocardiogram and then to analyze the electrical signal corresponding to Lead III to calculate and store an average heartbeat representation for Lead III.

[0058] Using the average heartbeat representations Lead I and Lead II, the set of instructions can cause the computing device to calculate aVR, aVL, and aVF. The augmented vector right (aVR) is equal to RA–(LA+LL)/2 or –(I+II)/2. The augmented vector left (aVL) is equal to LA–(RA+LL)/2 or (I–II)/2. The augmented vector foot (aVF) is equal to LL–(RA+LA)/2 or (II – I)/2.

[0059] The set of instructions can further cause the portable computing device 11 to provide instructions to a user, or request placement confirmation from the user, for contacting the first electrode 14 with each of the V1, V2, V3, V4, V5, and V6 chest locations while contacting the second electrode 18 to one of the patient's left arm and the patients right arm. The electrical signals measured between each of the V1, V2, V3, V4, V5, and V6

chest locations and the left arm or the right arm correspond to Leads V1, V2, V3, V4, V5, and V6 in a 12-lead electrocardiogram. The set of instructions can then further cause the portable computing device 11 to analyze the electrical signals corresponding to Leads V1, V2, V3, V4, V5, and V6 to calculate average heartbeat representations for Leads V1, V2, V3, V4, V5, and V6.

[0060] While not being bound by any particular theory, it has been discovered that use of multiple electrodes to achieve a composite pole such as Wilson's central terminal is not necessary. In one embodiment, the patient's right arm can be used as a negative terminal for each of Leads V1, V2, V3, V4, V5, and V6 captured with conventional placement of electrodes on the chest. In some individuals, however, V1, V2 and V3 measurements do not correlate well. In such individuals, the electrodes must be placed on either side of the heart to achieve duplication of conventional V1, V2 and V3 measurements. It has been definitively demonstrated that in such individuals, the left arm can be used for Leads V1, V2, and V3, while the right arm is used for Leads V4, V5, and V6, and excellent correlation to conventional measurements is achieved.

[0061] Once average heartbeat representations are calculated and stored for Leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6, the set of instructions can cause the portable computing device 11 to align each of the heartbeat representations based on corresponding characteristics of the heartbeat representations. The averaged and aligned signals can be stored and output in a 12-lead electrocardiogram format.

[0062] While it is customary for the voltage measurements to be made in one direction, the software can be made to recognize when the first and second electrodes 14 and 18 are reversed and invert the average heartbeat representation. For example, it is customary for Lead I to measure the left arm (LA) minus the right arm (RA), e.g. I = LA – RA. However, if the first and second electrodes 14 and 18 were reversed such that RA-LA was measured instead, the software would recognize that the first and second electrodes 14 and 18 were reversed and would invert the average heartbeat representation for Lead I to obtain the traditional Lead one output.

[0063] Methods for generating a traditional 12-lead electrocardiogram using only two electrodes, e.g. the first and second electrodes 14 and 18, are provided by operating the portable computing device 11 and the above-described electrocardiograph device 10 or 10-1. A 12-lead electrocardiogram can be generated by sequentially measuring electrical signals between the first and second electrodes 14 and 18 at separate and distinct instants of time after the first and second electrodes 14 and 18 are positioned at predetermined locations on a patient's body. Average heartbeat representations for each of the leads can

be calculated as described above, and aligned to produce an electrocardiogram having a 12-lead electrocardiogram format.

[0064] There are several commonly used 12-lead electrocardiogram formats. The most common format is a 4X3 format; four columns of three leads. The first column includes Limb Leads I, II and III. The second column includes Leads aVR, aVL and aVF. The third column includes Leads V1, V2 and V3, while the fourth column includes Leads V4, V5 and V6.

[0065] In some embodiments, the portable computing device 11 is a commercially available smart phone having a standard operating system such as the operating systems identified in the art as "iOS" or "Android." In this embodiment, the electrocardiograph 8 for generating a 12-lead electrocardiogram using only two electrodes can be provided using the above-described electrocardiograph device 10 and software downloadable to the portable computing device 11, wherein the software provides instructions to the portable computing device 11 as described above. In these embodiments, the control circuitry 22 and data transmission module 24 are configured to function and interact with the portable computing device 11 when the portable computing device 11 is executing an application downloadable to the portable computing device 11.

[0066] In one embodiment, the systems and methods described above include sending the 12-lead electrocardiogram to a remote server or to a medical professional. In another embodiment, the systems and methods described above include a display and displaying the 12-lead electrocardiogram a on a display screen. Similarly, the systems and methods described above can include a printer and printing the 12-lead electrocardiogram. In yet another embodiment, the methods and systems described above include saving the 12-lead electrocardiogram to a storage memory of the portable computing device 11.

[0067] In order to further illustrate the present invention, the following examples are given. However, it is to be understood that the examples are for illustrative purposes only and are not to be construed as limiting the scope of the invention.

EXAMPLE 1

[0068] The above-described system was tested on 121 patients in a clinical trial. Each patient was monitored using the conventional 10 electrodes, i.e., placing 6 electrodes on the patient's chest and one electrode on each of the patient's arms and legs. A conventional 12-lead electrocardiogram report was then prepared for each patient using a traditional stationary electrocardiograph sold under the trademark GE® MAC3500.

[0069] The electrocardiograph device 10-1 having the first and second electrodes 14 and 18 in a pen-type configuration was tested on each patient and a conventional format 8-lead report was prepared from the sequential measurements. The 2-electrode electrocardiograph calculated the V1-V6 leads using the right hand (RA) for the negative

terminal and then the left hand (LA) for the negative terminal. A statistical analysis was made comparing the 2-electrode electrocardiograph results with the traditional 10-electrode electrocardiograph results.

[0070] FIG. 8 compares V1 for Subject 35 having the highest correlation between the 10-electrode and the 2-electrode measurements. A correlation coefficient of 0.99 was achieved.

[0071] FIG. 9 shows each of the 8 leads for Subject 35, comparing the 10-electrode results with the 2-electrode results. The correlation coefficient averaged over all of the leads was 0.988.

[0072] From the above descriptions, it is clear that the presently disclosed and claimed inventive concepts are well-adapted to carry out the objects and to attain the advantages mentioned herein, as well as those inherent in the presently disclosed and claimed inventive concept. While the presented embodiments have been described for purposes of this disclosure, it will be understood that numerous changes may be made which will readily suggest themselves to those skilled in the art and which are accomplished within the spirit of the presently disclosed and claimed inventive concepts.

What is claimed is:

1. An electrocardiograph comprising:

an electrocardiograph device having (a) a first electrode assembly with a first electrode adapted to measure an electrical signal on a patient's body; (b) a second electrode assembly with a second electrode adapted to measure an electrical signal on the patient's body; (c) control circuitry configured to measure electrocardiogram signals between the first and second electrodes; and (d) a data transmission module configured to transmit the measured electrocardiogram signals to a computing device; and

a computing device having a non-transitory computer-readable storage medium storing software that includes instructions that when executed by a processor causes the processor to (a) calculate an average PQRST beat from the measured electrocardiogram signals as the first and second electrodes are sequentially placed in Limb Lead I, II, and III positions on a patient's body for a time required to measure at least one heartbeat in each Limb Lead position, the Limb Lead positions known by the processor; (b) use the relationship (Lead III = Lead II – Lead I) to time- align and display Limb Leads I, II, and III; and (c) calculate and display augmented Leads aVR, aVL, and aVF from the time-aligned Limb Leads.

2. The electrocardiograph of claim 1, wherein software further includes instructions that when executed by the processor causes the processor to (d) calculate and display average Leads V1, V2, and V3 from the measured electrocardiogram signals obtained from sequentially placing one of the first and second electrodes in a V1, V2, and V3 position while contacting the other of the first and second electrodes with a left arm of the patient for a time required to measure at least one heart beat; and (e) calculate and display average Leads V4, V5, and V6 from the measured electrocardiogram signals obtained from sequentially placing one of the first and second electrodes in a V4, V5, and V6 position while contacting the other of the first and second electrodes with a right arm of the patient for a time required to measure at least one heartbeat.

3. The electrocardiograph of claim 1 or 2, wherein the data transmission module is configured to transmit the measured electrocardiogram signals to the computing device by wire.

4. The electrocardiograph of claim 1 or 2, wherein the data transmission module is configured to transmit the measured electrocardiogram signals to the computing device wirelessly.

5. The electrocardiograph of claim 1 or 2, wherein at least one of the first and second electrode assemblies comprises a spring-hinged cuff.

6. The electrocardiograph of claim 1 or 2, wherein at least one of the first and second electrode assemblies comprises a disposable electrode.

7. The electrocardiograph device of claim 1 or 2, wherein the portable computing device is a smartphone and the electrocardiograph device further comprises a housing for the control circuitry and the data transmission module, the housing adapted to fit onto or within a protective case for the smartphone.

8. The electrocardiograph device of claim 1 or 2, wherein the data transmission module is further configured to transmit the measured ECG signals as ultrasonic, frequency modulated (FM) sound signals.

9. The electrocardiograph device of claim 1 or 2, wherein the data transmission module is further configured to encrypt and transmit encrypted signals.

10. A non-transitory computer-readable storage medium storing software that includes instructions that when executed by a processor causes the processor to:

receive and record electrocardiogram signals between a first electrode and a second electrode, the first and second electrodes sequentially placed in predetermined paired positions on a patient's body for a time required to measure at least one heartbeat, the paired positions known by the processor and corresponding to Limb Leads I, II and III, and V1, V2, V3, V4, V5, and V6;

for each Limb Lead paired position, determine electrocardiogram signal sets representing a heartbeat and calculate average time-aligned heartbeat representations for Limb Leads I, II and III; and

calculate augmented leads aVR, aVL, and aVF from the average time-aligned heartbeat representations for Limb Leads I, II, and III and output the electrocardiogram signals in a 12-lead electrocardiogram format.

11. The non-transitory computer-readable storage medium of claim 10, wherein the electrocardiogram signals analyzed comprise at least one of wired electrical signals, wireless electromagnetic signals, and acoustic sound signals.

12. The non-transitory computer-readable storage medium of claim 10, wherein the set of instructions, when executed by the processor, further causes the processor to digitize and demodulate frequency modulated electrocardiogram acoustic signals.

13. The non-transitory computer-readable storage medium of claim 10, wherein the set of instructions, when executed by the processor, further causes the processor to interact with a user to identify first and second electrode paired positions corresponding to a lead.

14. The non-transitory computer-readable storage medium of claim 10, wherein the set of instructions, when executed by the processor, further causes the processor to (a) provide instructions to a user or request placement confirmation from the user regarding contacting the first electrode to the patient's left arm and the second electrode to the patient's right arm, wherein the electrical signal measured between the left arm and right arm corresponds to Lead I in a 12-lead electrocardiogram, and (b) analyze the electrical signal corresponding to Lead I to calculate an average heartbeat representation for Lead I.

15. The non-transitory computer-readable storage medium of claim 14, wherein the set of instructions, when executed by the processor, further causes the processor to (c) provide instructions to a user or request placement confirmation from the user regarding contacting the first electrode to the patient's left leg and the second electrode to the patient's right arm, wherein the electrical signal measured between the left leg and right arm corresponds to Lead II in a 12-lead electrocardiogram, and (d) analyze the electrical signal corresponding to Lead II to calculate an average heartbeat representation for Lead II.

16. The non-transitory computer-readable storage medium of claim 15, wherein the set of instructions, when executed by the processor, further causes the processor to (e) provide instructions to a user or request placement confirmation from the user regarding contacting the first electrode to the patient's left leg and the second electrode to the patient's left arm, wherein the electrical signal measured between the left leg and left arm corresponds to Lead III in a 12-lead electrocardiogram, and (f) analyze the electrical signal corresponding to Lead III to calculate an average heartbeat representation for Lead III.

17. The non-transitory computer-readable storage medium of claim 16, wherein the set of instructions, when executed by the processor, further causes the processor to time-align the average heartbeat representations for Lead I and Lead II and calculate aVR, aVL, and aVF average heartbeat representations from the time-aligned average heartbeat representations for Lead I and Lead II.

18. The non-transitory computer-readable storage medium of claim 17, wherein the set of instructions, when executed by the processor, further causes the processor to (g) provide instructions to a user or request placement confirmation from the user regarding contacting the first electrode with each of the V1, V2, V3, V4, V5, and V6 chest locations while contacting the second electrode to one of the patient's left arm and the patients right arm, wherein the electrical signals measured between each of the V1, V2, V3, V4, V5, and V6 chest locations and the left arm or the right arm correspond to Leads V1, V2, V3, V4, V5, and V6 in a 12-lead electrocardiogram, and (h) analyze the electrical signals corresponding to Leads V1, V2, V3, V4, V5, and V6 to calculate average heartbeat representations for Leads V1, V2, V3, V4, V5, and V6.

19. The non-transitory computer-readable storage medium of claim 18, wherein the left arm is used for Leads V1, V2, and V3 and the right arm is used for Leads V4, V5, and V6.

20. The non-transitory computer-readable storage medium of claim 18, wherein the right arm is used for each of Leads V1, V2, V3, V4, V5, and V6.

21. The non-transitory computer-readable storage medium of claim 18, wherein the set of instructions, when executed by the processor, further causes the processor to (i) output the average heartbeat representations for Leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6.

22. A method for generating a 12-lead electrocardiogram using an electrocardiograph comprising an electrocardiograph device and a portable computing device, the method comprising:

operating a portable computing device and an ECG device having a first electrode, a second electrode, control circuitry, and a data transmission module, the control circuitry configured to measure ECG signals between the first and second electrodes, the data transmission module configured to transmit the measured ECG signals to the portable computing device;

sequentially measuring ECG signals between the first and second electrodes positioned at predetermined locations on a patient's body; and

using the portable computing device to generate a 12-lead ECG from the sequentially measured ECG signals between the first and second electrodes.

23. The method of claim 22, wherein the step of sequentially measuring ECG signals comprises:

contacting one of the first and second electrodes with a left arm of a patient while contacting the other of the first and second electrodes with a right arm of the patient to measure an electrical signal corresponding to a Lead I;

contacting one of the first and second electrodes with a left leg of the patient while contacting the other of the first and second electrodes with the right arm of the patient to measure an electrical signal corresponding to a Lead II;

contacting one of the first and second electrodes with the left leg of the patient while contacting the other of the first and second electrodes with the left arm of the patient to measure an electrical signal corresponding to a Lead III;

sequentially contacting one of the first and second electrodes with a V1, V2, V3, V4, V5, and V6 chest location on the patient while contacting the other of the first and second electrodes with the patient's left arm or the patient's right arm to measure electrical signals corresponding to a Leads V1, V2, V3, V4, V5, and V6, respectively.

24. The method of claim 22, wherein the step of sequentially measuring ECG signals comprises:

contacting one the first and second electrodes with a left arm of a patient while contacting the other of the first and second electrodes with a right arm of the patient to measure an electrical signal corresponding to a Lead I;

contacting one of the first and second electrodes with a left leg of the patient while contacting the other of the first and second electrodes with the right arm of the patient to measure an electrical signal corresponding to a Lead II;

contacting one of the first and second electrodes with the left leg of the patient while contacting the other of the first and second electrodes with the left arm of the patient to measure an electrical signal corresponding to a Lead III;

sequentially contacting one of the first and second electrodes with a V1, V2, and V3 chest location on the patient while contacting the other of the first and second electrodes with the left arm of the patient to measure electrical signals corresponding to Leads V1, V2, and V3, respectively; and

sequentially contacting one of the first and second electrodes with a V4, V5 and V6 chest location on the patient while contacting the other of the first and second electrodes with the right arm of the patient to measure electrical signals corresponding to Leads V4, V5, and V6, respectively.

25. The method of claim 24, further comprising using the portable computing device to time-align the average heartbeat representations for Lead I and Lead II, and

calculate aVR, aVL, and aVF from the time-aligned average heartbeat representations for Lead I and Lead II.

26. The method of claim 25, further comprising using the portable computing device to output the ECG signals in a 12-lead ECG format.

27. A system for generating a 12-lead ECG using two electrodes comprising:

a first electrode assembly having a first electrode adapted to measure an electrical signal on a patient's body;

a second electrode assembly configured to removably attach to an upper limb of the patient, the second electrode assembly having a second electrode adapted to measure an electrical signal on the patient's body;

control circuitry configured to measure ECG signals between the first and second electrodes;

a data transmission module configured to transmit the measured ECG signals to a portable computing device; and

a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by one or more computing devices, that when executed by the one or more computing devices causes the one or more computing devices to: (a) analyze ECG signals between a first electrode and a second electrode, the first and second electrodes sequentially placed in predetermined paired positions on a patient's body; (b) average the ECG signals for each paired position to calculate average heartbeat representations for each paired position; and (c) time-align the average heartbeat representations to output in a 12-lead ECG format.

28. The system of claim 27, wherein the first electrode assembly is configured to be hand held.

29. The system of claim 27, wherein the second electrode assembly comprises a spring-hinged cuff.

30. The system of claim 27, wherein the set of instructions, when executed by the one or more computing devices, further causes the one or more computing devices to interact with a user to identify first and second electrode paired positions corresponding to a lead.

31. The system of claim 27, wherein the set of instructions, when executed by the one or more computing devices, further causes the one or more computing devices to (a)